Towards European Health Data Space

COUNTRY VISIT
Portugal

Country visit – Portugal

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.

Any questions?

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

When did it take place?

The visit to Portugal took place face-to-face in Lisbon between **23 and 26 May 2022.**

Who was involved?

11 stakeholder organisations were interviewed: SPMS International Projects and Affairs Unit; SPMS Advanced Analytics and Intelligence Unit; SPMS Planning, Architecture, Compliance and Engineering Unit; SPMS Data Protection and Cybersecurity Unit; Directorate-General for Health (DGS) Department for Quality in Health and the Information and Analysis Service; Hospital Professor Doutor Fernando Fonseca; Statistics Portugal (INE); Central Administration of the Health System (ACSS); National Institute of Health Doctor Ricardo Jorge (INSA) ; Center Regional Health Administration

Portugal in brief

The Portuguese Health Information System is rich and digitalised with a centralised management of the EHRs. The Ministry of Health is composed of a direct administration comprising the Public Health Agencies, an indirect administration composed of laboratories and national institutes, and a public business sector composed of public enterprises, national hospitals and shared services (SPMS). SPMS is the ICT provider of the National Health Service (NHS). The NHS is financed through taxation, covering all citizens. Most health data is stored in a structured manner at the source. Citizens have access to their health data through a web portal and can opt-out from the use of their data for primary use but not for secondary use. All citizens have a unique health identification number that is given to them at birth allowing individual level data linkage across data sources. Currently, there is no common metadata catalogue available. SPMS guides researchers where to find the data and there is a national template on how to request access to the data. Remote secure processing environments are in discussion but not in place currently. Although the infrastructure for use and re-use of health data is already established, there is a lack of governance and of the legal framework to be ready to join the EHDS for secondary use.

Co-funded by
The Health Programme
of the European Union

sciensano

Data collections/sources

- Electronic health records (EHRs) are digitalised and centralised in the SClinico National Clinical Registry. A copy of structured data from all public hospitals that use the SPMS EHR software and fragmented data from public hospitals using a different EHR software.
- The National Health Service (NHS) is financed through taxation, covering all citizens. Private healthcare activity exists and around 20% of the population opts for it.
- Web portal is available allowing citizens to access a copy of their data from all their healthcare providers, ability to see who uses their data and to opt-out from the use of their health data.
- Transparency portal with at least 150 structured, open data from anonymised datasets, aggregated data and data received from different sources (e.g., INSA, ACSS, DGS). Possibility for the user to create graphs in an interactive dashboard.
- Private hospitals do not have the legal obligation to share their data with the NHS.
- In Portugal apart from the SClinico there are around 80 data registries, or systems, as they are called.
- The National Institute of Statistics (INE) performs the SILC survey on income and living conditions, the European health interview survey and health examination survey. INE also receives administrative data from private hospitals and do the health reporting to Eurostat, the OECD and the WHO.
- The Central Administration of the Health System (ACSS) collects data on hospital mortality, financial data from every hospital and primary healthcare contracting data of every hospital and healthcare provider.
- The National Institute of Health Doctor Ricardo Jorge (INSA) is the national institute of health and the national laboratory of health. It has the only population-based sample biobank.

Data quality

- Quality assessment scheme in place. Several quality checks are implemented with automated tools. At the DGS there is a manual analysis as well as business intelligence tools used to identify duplicates and missing values.
- For every information system/registry there is a quality check locally at the collection and storage point. Then for the analysis step there is also a quality check. Institutes also perform quality checks before they store and share the data.
- The Transparency Portal has a feedback mechanism to maintain its quality by providing an area where users can give feedback about missing indicators of interest to them.

Data infrastructure

- Centralised storage of a copy of digitalised and structured health data at SPMS.
- Currently, no centralised metadata catalogue providing a general overview of health-related data collections and access procedures. The Transparency Portal has a metadata catalogue based on the DCAT-AP standard but only for the open data it gives access to.
- For patient summaries and sematic interoperability ICD-10 is mostly used in hospitals. Portuguese catalogues for laboratory analysis use LOINC and SNOMED CT. For health data exchange they use HL7 V2.5 and will move to HL7 FHIR.
- Data access procedure:
    - Obtain necessary (ethical) approvals from the hosting institution
    - Completion of the SPMS common access request form/template including the approved project protocol
    - Researcher must be part of a recognised institution
    - SPMS performs the legal and feasibility analysis → provides a joint statement
    - DPO of SPMS contacts data controllers of the data sets and they decide on the access terms
- Time to access data is 3-4 months and there are no fees for accessing data.
- Same access procedure and fees apply for foreign researchers.
- Pseudonymisation and linkage of individual level data is done mostly by SPMS using the unique health identification number.
- No remote secure processing environment in place, only physical at the Statistical office.

Data governance

- Legislative framework for primary use of health data is more defined but there is no legislation yet on the secondary use of health data.
- SPMS already has a legal governance in place.
- Some scattered laws on genomics and clinical research exist but the regulation on the EHDS will drive the development of a national legislation for the secondary use of health data.
- Privacy control and safeguards to avoid data privacy breaches, each data requestor needs to sign a data confidentiality and data processing agreement.
- The roles and coordinating bodies are being currently defined by the roadmap for secondary use by the Ministry of Health. SPMS and ACSS inform policy makers through the DGS.
- SPMS also supervises compliance with the GDPR, receives complaints from citizens in case of data breaches and gives guidance to data controllers on the interpretation of the GDPR.
- Citizens have access to their health data using the Web portal where they can access their e-prescriptions, vaccination card, allergies, previous consultations, telemedicine services and can perform administrative actions. They can opt out from the use of their data and can see who is accessing their data. However, they cannot opt-out for the secondary use of their data.
- 24 hours phone contact (NHS24/SNS 24 Balcão) providing support to citizens on the use of the platform, the application and how to schedule a consultation.

Resources (human, technical, financial)

- Human resources needs:
  - Data analysts, scientists etc.
  - ICT experts
  - Legal personnel at the hospitals
  - Difficulty responding to all data access requests due to a lack of human resources was reported
  - Difficulty retaining skilled data analysts in the public sector due to lack of financial incentives
- Technical resources needs:
  - Need to develop the IT infrastructure at ACSS.
  - In INSA there is a need for more technical resources, for instance a virtual machine, an upgraded IT infrastructure and resources to maintain it.
- Financial resources needs and status quo:
  - Need for financial resources at several institutes, such as INSA, to support with the fees for the services provided by their technical provider, SPMS.
  - The recovery and resilience fund has helped the developments but there is a need for more funding.

Capacity building

- Training needs:
  - Need for more training on data literacy, programming and big data analysis.

- Training opportunities:
  - Hospitals provide training to new staff on how to use the local EHR software.
  - SPMS offers public training sessions on SNOMED-CT and other standards. These training sessions are followed by healthcare providers among others. They also provide implementation guidelines for the HL7 FHIR data exchange standard.
  - The Transparency Portal provides special courses on the GDPR for implementers in the Public Administration and more courses.
  - INSA offers training on epidemiology.
  - The central regional health administration there is already an ongoing programme on data protection issues at the level of the healthcare providers. They also provide training to university students in statistics and big data analysis.

Co-funded by
The Health Programme
of the European Union

Best practices

- It is important to highlight the well-developed infrastructure, the fact that most health data is digitalised and that citizens have control over their health data (e.g., web portal).
- The short time to access data and the fact that there are no fees requested is a best practice. This likely results from the fact that health data is centralised in Portugal within SPMS.
- The pilot study conducted by INSA on linking individual level data and doing a multi-country assessment for the COVID-19 vaccine effectiveness, financed by the ECDC.

European Health Data Space (EHDS)

- General will to participate in the EHDS for secondary use. Ongoing work on setting up the roadmap for the legislation on the secondary use of health data and building the National Health Data Space.
- The National Health Data Space might be under the responsibility of SPMS.
- It is likely that the Portuguese health data access body and national contact point within the EHDS network will be one of the existing entities rather than creating a new one. SPMS has been working on the EHDS so it is possible it will take on this role. The national decision had not been made at the time of the country visit.
- Cross-border sharing of health data is very important and is happening, EHDS is expected to scale it up.
- Portugal is participating in multiple European projects and research infrastructures, such as ELIXIR and TEHDAS.
- Portugal participates actively in MyHealth@EU and they are the coordinators of the X-eHealth project (designing the business specification of MyHealth@EU).

- Needs to join the EHDS:
  - Need for a governance and legal framework to establish the roles of every stakeholder in the HIS.
  - Strong need for resources at the hospitals. Currently they have to outsource the digitalisation and structuring of health data, which is very costly.
  - Need to have a common descriptive metadata catalogue for Portugal.

- Stakeholders stressed the importance to ensure coherence between the EHDS and Eurostat. The EHDS should align with the standards already in use and requested by Eurostat.
- Stakeholders noted that the European Commission could work on providing a European cloud solution.
- Stakeholders highlighted the need to have a reference document at EU level, giving an overview of the methodology used in different EU member states when it comes to indicators for public health monitoring for example.

Co-funded by
The Health Programme
of the European Union