Towards European Health Data Space

COUNTRY VISIT
Sweden

Country visit – Sweden

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 Sweden took place face to face in Stockholm between **24 and 28 October 2022.**

Who was involved?

26 stakeholder organisations were interviewed: Analytic Imaging Diagnostics Arena (AIDA); Astra Zeneca; Biobank Sweden; Dental and Pharmaceutical Benefits Agency (TLV); Genomic Medicine Sweden (GMS); Karolinska University Hospital; Medtech4Health; Ministry of Health and Social Affairs; National Board of Health and Welfare (NBHW); National Life Sciences Coordinator; Public Health Agency of Sweden; Regional Cancer Centres (RCC); Research-based Pharmaceutical Industry (Lif); Roche; Statistics Sweden; SciLifelab; Stockholm Center for Health Data; Swedish Association of Local Authorities and Regions (SALAR); Swedish Authority for Privacy Protection (IMY); Swedish e-Health Agency; Swedish Ethical Review Authority; Swedish Medical Products Agency; Swedish MedTech; Swedish Research Council; Swelife;

Any questions?

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

Sweden in brief

Sweden has a tax funded healthcare system. It has fully digitalised health care systems, with complete coverage of the population. It is characterised by a rich health data landscape with a long tradition of national registries, and quality registries. However, data sources are currently existing in silos, limiting full use of the richness of data. All residents have a personal identification number, which is used for linking individual level health data. Healthcare and health data management in Sweden is decentralised due to the division into several responsible agencies, 21 regions and 290 municipalities with high level of autonomy. eHealth has long been a priority in Sweden. With a newly elected government at the time of the country visit, there were still some uncertainties regarding preparations for a future implementation of EHDS. However, development of a common infrastructure for the Swedish health care sector has been indicated as a priority.

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Data collections/sources

- EHR systems are fragmented across the regions. Each region can choose the EHR system to be used.
- The National Board of Health and Welfare (NBHW) maintains six national health registries with individual level health data.
- There are about 100 national quality registries (NQRs), which contain individual level data on different diseases, medical interventions, and treatment outcomes. The NQRs are under the responsibility of the regions, and is coordinated by the Swedish Association Of Local Authorities And Regions (SALAR).
- The Public Health Agency of Sweden (PHAS) collects and analyses data for public health monitoring and surveillance for health threats and communicable diseases, performs microbiological analysis, carries out several national health surveys and maintains national health register for vaccinations.
- Information Network Cancer (INCA) is a registry platform owned by Regional Cancer Centres (RCC) organisations, and brings together all cancer related quality registries.
- Statistics Sweden is the main source of sociodemographic data.
- The eHealth Agency collects data on prescription drugs and medical products.
- The Medical Products Agency has data on manufacturing and sale of pharmaceuticals.
- There are about 200 biobanks across six regional biobank centres. The national infrastructure Biobanks Sweden is set up to allow easier collaboration among the different biobanks.
- There are multiple genomic data collections fragmented across Sweden. There is a national genomics platform (NGP) which is being set up by Genomics Medicines Sweden (GMS).

Data quality

- Quality controls are generally implemented at point of data collection. Errors are fed back to HCPs.
- The Swedish eHealth Agency ensures quality of their data by producing statistics based on the international standard “Generic Statistical Business Process Model” (GSBPM).
- The PHAS uses automated quality checks, quality protocol for the national registry, and mandatory reporting of a specific set of variables.
- The NBHW uses various quality protocols for each registry.
- The NQRs are certified based on the quality of the register. However, stakeholders noted that the quality of data in the different quality registries varies greatly.
- The cancer registries at INCA use integrations and set forms for data validation. The RCCs follow up with the clinics regarding missing cancer cases.

Data infrastructure

- There is no centralised national repository for EHRs. They are stored at regional and municipal levels.
- Similarly, biobanks and genomic data are currently not stored centrally.
- Data for monitoring and secondary use are collected into national registries by different data holders.
- The Register Utiliser Tool (RUT) provides metadata from national registers, biobank sample collections, and other major research databases.
- NBHW also provides some metadata for the national health registries they maintain
- In general, both national and international researchers can get access to aggregated data.
- Access to individual-level health data for the purpose of research requires approval from Swedish Ethical Review Authority.
- Access application forms are available from the stakeholders: NBHW, NQRs, eHealth Agency. A digital application for PHAS is under development.
- Most data holders request an hourly fee to cover the processing and delivery of the data, which depends on the size and complexity of the data set. Time to access varies.
- The main SPE in use is MONA (Microdata Online Access) owned by Statistics Sweden. Researchers may upload data they have been granted access to for further analysis.
- ICD-10-SE is widely used ensuring statistical comparability. Additionally, there is a general aim to also promote SNOMED CT for semantic interoperability in relevant use cases.
- The agency for digital governance (DIGG) is leading the work, together with several other agencies, to establish a joint administrative digital infrastructure called ENA.

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Data governance

- eHealth is a priority. Multiple strategies for eHealth and innovation in life science have been published since 2005. A common joint vision for eHealth was developed by the government and SALAR focusing on legislation, standards, semantics.
- The Life Science Strategy for innovation and life sciences includes a focus on secondary use of data and unlocking the potential of data (e.g., through interoperability).
- In 2021, the government launched the national data strategy to promote the use of data and strengthen the digital competence and innovation capacity in Sweden.
- There is a plan for implementing a national strategy for information and cyber security in the society in 2023.
- A new government was elected in October 2022. It was reported that priority would be given to the development of a common infrastructure for the Swedish health care sector.
- The legal framework for data use and re-use is based on five main principles: proportionality, transparency, trust, rights of natural persons, and protection.
- The main laws governing health data use include: Act on Official Statistics (2001); Ethics Review Act (2003); Data Protection Act (2008); Patient Data Act (2008); Regulation for National Registries on Health; and the updated Biobanks Act (2022).
- Ethical approval is required for accessing almost all types of health data according to Article 9.1 GDPR in Sweden, submitted to the Swedish Ethical Review Authority.
- The central application for ethical approval costs 5000SEK per project or 16,000SEK for multi-center project.
- Citizens can in some cases read some of their health data through the 1177.se portal, and are able to access a free transcript on all their information at NBHW once per year, and from the national health register for vaccinations at PHAS.
- In genomics, citizens are involved through activities with patient organisations.

Resources (human, technical, financial)

- Overall, there is a need for skilled staff such as experts on the interplay between health and technology, data stewards, informatics specialists, and lawyers.
- Most stakeholders indicated need for additional funding to further develop the infrastructure for secondary use of health data. A co-funding model (national and international) was suggested to invest in digital health and genomics.
- Stakeholders expressed the need for more hardware for data analysis and cybersecurity.
- Some examples were provided on AI projects in healthcare (for example in medical imaging).

Capacity building

- Swedish organisations offer many training opportunities. Some examples are:
    - NBHW: provides training on application procedure for students, researchers and analysts
    - NQRs: offer technical support and statistical help
    - eHealth Agency: organises workshops to business intelligence system users and researchers
    - Swedish Authority for Privacy Protection: offers guidance on all aspects surrounding ethical application
    - Statistics Sweden: offers training on how to use MONA and statistical analysis
    - SciLifeLab: training on bioinformatics, data management courses, AI courses

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Best practices

- Sweden has set up a National Life Sciences Coordinator, an inter-ministerial office, to bring together views of multiple ministries in all aspects regarding health and life science. This office consists of several officials from the Ministry of Enterprise and Innovation, the Ministry of Education and Research, and the Ministry of Health and Social Affairs.
- The Swedish government launches public inquiries and commissions its agencies with governmental assignments that normally include assessments and piloting of any upcoming issues.

European Health Data Space (EHDS)

- There is strong political will and agreement in Sweden with the overall legislation on the EHDS.
- There is a positive view on the ambition to increase use of health data for primary and secondary use.
- The EHDS was reported to be an important part of the Swedish Presidency of the Council of the EU, starting January 2023.
- Work is already ongoing for implementing future federated analysis. The Medical Products Agency published a report describing the foundation for federated analysis.
- Sweden already implemented a mapping of the RUT metadata catalogue and registry descriptions to DCAT-AP metadata standards.
- The eHealth Agency is the national contact point for the primary use of health data (MyHealth@EU). For secondary use it is not decided yet who will take on the role. Currently, the eHealth Agency is acting as the competent authority for the direct grants to MSs.
- No political decision has been made with regards to the Health Data Access Bodies (HDABs).
- Some stakeholders suggested considering regional HDABs as moving the processing and management of data requests and permits away from the actual holder of data registries and expertise to a central HDAB may be problematic.

- Some needs and concerns were expressed regarding the future EHDS.
- With the current proposed structure of EHDS, Sweden might need to re-assess the national legal framework and governance structures.
- Some stakeholders expressed the need for clearer definitions within the current EHDS proposal, and noted that they perceive some legal uncertainties in parts of the current proposal.

- Expectations from the EHDS:
  - Ensure data protection, patient safety, cybersecurity
  - Provide clarification of the involvement of private companies in the EHDS
  - Improve interoperability and the use of internationally recognised standards
  - Define clear standards that should be set and approved by the EU (e.g., openEHR)
  - Avoid increasing existing workload
  - Ensure adequate privacy protection (avoidance of re-identification)
  - Provide clearer distinction between EHDS and GDPR
  - Maintain the public trust that has been built nationally through strong security and privacy protection processes
  - Define minimum set of datasets that need to be structured
  - Avoid duplication with existing data collection and sharing system at EU level, such as Eurostat and ECDC
  - Provide clearer definitions (e.g. data holder)
  - Ensure balanced administrative burden on Member States

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