Towards European Health Data Space

COUNTRY VISIT
Czech Republic

Country visit – Czech Republic

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
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Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to the Czech Republic took place virtually between **11 and 14 July 2022.**

Who was involved?

14 stakeholder organisations were interviewed: General Health Insurance Company (VZP); Institute of Health Information and Statistics (UZIS); Masaryk Memorial Cancer Institute; Masaryk University; Masaryk University – Computer Centre; Ministry of Education, Youth and Sports; National Institute of Mental Health (NUDZ); OAKS Consulting; Olomouc University Hospital (FNOL); Representative of EHDS Rapporteur (Chamber of Deputies, Parliament of the Czech Republic); State Institute of Drug Control (SUKL); St. Anne's University Hospital Brno (FNUSA); Czech Technical University in Prague (CVUT CIIRC); University Hospital Hradec Králové (FNHK). The selection of interviewers, support and contextual information was provided by the Ministry of Health of the Czech Republic.

Czech Republic in brief

The Czech Republic is in the process of digitalisation of the healthcare system. Digitalisation is one of the key specific objectives of the Strategic Framework for the development of healthcare until 2030 (Health 2030). The provision of healthcare services in the Czech health system is financed through mandatory health insurance, provided by seven health insurances. The main health insurance provider is the General Health Insurance Company of the Czech Republic (VZP), covering around 6 million people. The birth number is currently used as the unique personal identifier in healthcare. However, there are plans to move towards sector-specific unique identifiers (e.g., for healthcare, employment) due to the sensitivity of the birth number. This may affect the future ability to perform cross-sectoral linkage. It is currently not possible to link health data with data from other sectors because the linkage needs to be defined in law.

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Data collections/sources

- Some health data are digitalised. Electronic information systems are used by healthcare providers (HCPs) on all levels. However, most medical records are also paper-based due to a legal barrier to e-signature of health documentation. The Act on Health Services requires special e-identity of HCPs for e-signature of health documentation but no law has been enacted yet to create this e-identity.
- Hospitals have different software for processing, storing and archiving health data, produced by at least five suppliers. Several hospitals were updating their information systems in 2022. There is no central data repository; an infrastructure for exchange of health data is currently being built. Currently, patients' health data is generally not shared electronically between HCPs. No centralised electronic health record (EHR) exists. A concept of a national EHR is under examination.
- The Institute of Health Information and Statistics (UZIS) maintains the National Health Information System (NHIS), including national registries (system oriented and medical). Reporting from HCPs is mandatory. UZIS is responsible for health surveys in cooperation with the Czech Statistical Office.
- Health insurance data is mainly digitalised and centralised in the Registry of Reimbursed Services.
- There is no national biobank; biobanks are decentralised at the healthcare providers.
- The National Institute of Mental Health (NUDZ) generates data on mental health.
- Some disease-specific registries have been set up by private sector players through voluntary agreements with HCPs, to overcome barriers to linking individual-level data with national registries.

Data quality

- In general, data quality was noted as an important area for development.
- The national registries have basic built-in automatic controls. Manual checks are also performed.
- At the hospital level, quality departments regularly perform audits and accreditations, and generally manual quality checks are performed.
- Administrative quality checks are performed on health insurance data (e.g., for coding errors).
- NUDZ performs manual quality checks.

Data infrastructure

- Data storage in healthcare is generally decentralised. Medical records and biobanks are stored within individual healthcare providers. Registry data is stored centrally in the NHIS.
- There is no national metadata catalogue. There is an initiative to develop a national 'directory' for research data. A catalogue for biobank data is also under development, using different vocabularies.
- For data access, no distinction is made between national/foreign, or private/public researchers.
- There is no centralised infrastructure for access to data; data users apply to each data holder. Access is generally provided by sending data files electronically or physically. There is a secure processing environment (SPE) for academic research at the Czech Technical University in Prague (CVUT CIIRC), however its use appears limited with respect to health data.
- For the national registries, the Act on Health Services (2011) states that external users cannot access identifiable data. In practice, researchers receive pseudonymised data.
- Hospital data can be accessed by applying to the individual hospitals. Access to medical records for research requires consent from patients, a barrier to retrospective studies in particular.
- Access to biobank data is coordinated through the Czech node of BBMRI (BBMRI.cz).
- Timelines for access to data vary. Reimbursement of costs for the effort associated with data preparation can be requested, but is usually not requested in practice.
- Hospital information systems are not interoperable. It is generally not possible to link health data with data from other sectors.
- The Ministry of Health is responsible for developing national standards. The DASTA national standard describes healthcare related information. It is used for data transfer between information systems of healthcare facilities. It is also used for data exchange between hospitals since the first version in 1994. Challenges were noted to achieve interoperability with other European countries.
- ICD-10 is generally used, as well as other national and international standards (e.g., ATC for drug classification). ICD-11 is in the pre-implementation phase.

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Data governance

- There is currently no clear and sufficient legal framework for secondary use of health data.
- There are strict laws on privacy in data sharing and processing. A strong emphasis is placed on checking compliance with data handling rules, with systematic supervision by the National Cyber and Information Security Agency (NÚKIB).
- Some experts consider that prior to making legislative changes in the Czech Republic, a final legislative text on the EHDS adopted at EU level is needed.
- Stakeholders report that there is legal uncertainty on electronic signatures (the nature and level of security of electronic signatures and applications).
- Stakeholders highlight the urgent need for clear legal definitions on data processing and secondary use of data in Czech law, and for a code of conduct for health data exchange.
- The main laws governing health data use and re-use of certain data (NHIS) include: Act on Health Services (2011); Czech Personal Data Processing Act (2019); Act on Cybersecurity (2014). A new eHealth Act, valid from January 2022, includes the establishment of an infrastructure for eHealth and health data exchange using certain central electronic healthcare services.
- The Czech Strategic Framework for Health 2030 identifies digitalisation of healthcare as one of the key objectives.
- The birth number is currently used as a unique personal identifier in health. There are plans to move towards sector-specific identifiers (e.g., for health, employment), which may affect cross-sectoral linkage.
- Ethical committee approval is legally required for interventional research only. For research on medical records, it is at the discretion of the data holder whether to request it.
- Access to medical records for research requires consent from patients.
- There is no citizen portal providing access to their health documentation. If citizens want to access their health documentation (as is their right); they must apply to the hospitals directly and receive a physical copy. Some hospitals are implementing digital patient portals for access to certain data.

Resources (human, technical, financial)

- Human resource needs:
  - IT personnel
  - Data analysts and biostatisticians in hospitals, data stewards
  - Lawyers
  - Trained staff for the implementation of standards
  - Specialised human resources for cybersecurity in hospitals
  - Multidisciplinary experts (IT, security, medical, system-oriented aspects)
- Technical resource needs: development of the IT infrastructure in hospitals
- Financial resource needs:
  - UZIS will require more resources to meet increases in requests with the EHDS
  - Financial investment in national infrastructures and research infrastructures are needed
  - Financial resources are required to attract skilled personnel

Capacity building

- Training needs:
  - Education on standards, interoperability and how to input data in a structured format
  - Training on cyber-security and data protection
  - Training on ethical aspects and legal requirements
- Training opportunities:
  - Several data holders provide services to researchers (e.g., in writing research proposals)
  - Education to biobanks and IT staff on use of HL7 FHIR and added value of using standards
  - Training to students to become data stewards
  - Training on using hospital information system, GDPR, data protection

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Best practices

- The OAKS consultancy aims to provide an example of a private sector company supporting public health. They have overcome the barrier to accessing registry data for research by gaining access to medical records through agreements with healthcare providers.
- There is high involvement in EU projects and Research Infrastructures in the Czech Republic (e.g., TEHDAS, JADECARE, X-eHealth, ECRIN, PHIRI, BBMRI, B1MG and others). A national introductory project dedicated to secondary use of health data is under preparation in the EU Recovery and Resilience Facility framework for the Czech Republic.
- The collection and processing of data (NHIS) in UZIS is based on the law and public interest.
- In general, access to certain data in the Czech Republic appears to occur in a timely manner. For UZIS, internal timelines to access are defined in law as 15 days, or 30-60 days for analyses. For biobanks, it generally takes 2-3 months to receive the sample.

European Health Data Space (EHDS)

- In general, there is a positive attitude towards the EHDS and the EHDS legislative proposal from the European Commission, and a recognition of the potential benefits.
- At the time of the country visit, it was not yet clear what entity would take on the role of national contact point or health data access body/bodies for the EHDS for secondary use.
- A hybrid funding model is generally preferred for implementation of the EHDS. Stakeholders expressed concern that fee policies could be a barrier to research.
- Many stakeholders welcome an opt-out mechanism for secondary use of health data.
- The DASTA national data exchange standard may prove to be a challenge regarding interoperability.

- Needs to join the EHDS:
  - Structured EHR data
  - Clear legislative framework for secondary use of data and the legal basis for data sharing
  - Funding for healthcare providers to make their data available
  - Harmonised rules on how to anonymise and pseudonymise data

- Expectations for the EHDS:
  - Guidelines for safe sharing and accessing health data
  - Clear definitions of responsibility and liability in the EHDS
  - Federated analysis should be introduced, as well as the use of synthetic data
  - Harmonisation of data, interoperability and setting standards for structured data storage
  - Reduce administrative burden on healthcare providers by creating an interoperable system that avoids duplication of reporting
  - Provide a legal framework for sharing and linking data between health and non-health institutes (e.g., research)
  - Incentives for data holders to share their data for research: e.g., financial, citations
  - Clear definitions of terms (e.g., pseudonymisation, anonymisation)
  - Clarity on the use of consent
  - Inclusion of data from everyday life of patients to predict and develop decision-support systems
  - The EHDS should take account of differences in countries' health information systems as well as citizens' values

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