The International Classification of Diseases Included in the European Health Data Space

Background

The COVID-19 pandemic demonstrated the importance of digital services in the health area. The uptake of digital tools increased significantly during this time. However, the complexity of rules, structures and processes across Member States made it difficult to access and share health data, especially cross-border.

Therefore, the European Commission presented the European Health Data Space (EHDS), which built on the GDPR, the Data Governance Act, the Data Act and the Network and Information System (NIS) Directive. The legal bases for the EHDS are Treaty on the Functioning of the EU TFEU 114; the Rules of Procedure EP 58; the Treaty on the Functioning of the EU TFEU 016-p2; and the Rules of Procedure EP 57.

A public consultation on the EHDS ran between May-July 2021. SIP provided a response here and noted, amongst others, the following:

SIP calls for the EU framework on the access and exchange of personal health data to:

1) *Permit EU institutions and national governments to develop, share, and implement instruments to assess the societal impact of pain, namely, instruments to assess pain as a quality indicator within European health systems,*

2) *Allow European health systems to exchange cross border data on pain measurement (via standardised EHRs and/or common tools) and,*

3) *Ensure healthcare professionals and patients receive education and training on digital technologies as part of the educational curricula and training (via promoting access to education).*

Further, the International Classification of Diseases (ICD), developed by the World Health Organization (WHO), is the international standard diagnostic tool for epidemiology, health management, research, and clinical purposes, as well as the international standard for reporting diseases and health conditions. The ICD allows for:

- Recording individual health conditions at the desired level of detail. This is why it is used in many health systems to diagnose conditions and determine which treatment is received,
- Generating healthcare statistics and reimbursement information,
- Sharing and comparing health information between hospitals, regions, settings, and countries,
- Comparing data in the same country across different time periods.

The International Classification of Diseases 11th Revision (ICD-11), is a key development and milestone that came into effect in 2022. Its implementation is of the utmost importance:

- To facilitate record and report diagnosis,
- To improve the quality of life of individuals living with pain,
- To support data collection for global epidemiological research,
- To support health services in developing effective interventions,
- To support the digitalisation of healthcare services which, in turn, will ensure the needs and rights of individuals living with pain are rightly covered and,
- To facilitate the access to precise information on costs, treatments and the societal impact of pain for shaping public health policies and campaigns.

The European Health Data Space (EHDS)

The EHDS will:

- Support individuals to take control of their own health data,
- Support the use of health data for better healthcare delivery, better research, innovation and policy making and,
- Enable the EU to make full use of the potential offered by a safe and secure exchange, use and reuse of health data.

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at:

- Empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support to their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high risk AI systems (primary use of data) and,
- Providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data).

As such, the EHDS is a pillar of the European Health Union and it is the first common EU data space in a specific area to emerge from the European Strategy for Data.

Between June-December 2022, discussions were held between different Institutional Stakeholders, such as the Employment, Social Policy, Health and Consumer Affairs Council or the European Economic and Social Committee, amongst others.

On the other hand, the European Parliament decided to refer the proposal to the ENVI and LIBE Committees, and ITRE and IMCO adopted their opinions. The Rapporteurs for the file were MEP Sokol (EPP – ENVI) and MEP Tardino (ID – LIBE).

SIP held a first meeting with MEP Sokol on November 2022, where the potential transformative effect of the International Classification of Diseases (ICD) 11th Revision (ICD-11) on healthcare systems was discussed. A second meeting was held in early 2023, where the possible ways in which a reference to ICD could be included was discussed. The main outcome of such meeting was that a reference to ICD-11 was not possible as it would get outdated in years to come, however, a reference to ICD and therefore, the latest version of the classification, was indeed possible.

The Draft Report of the European Parliament on the EHDS, which was published in February 2023, included a clear ICD reference in Article 5, which refers to the scope of electronic health data, which encompasses six priority categories (i.e. patient summaries, e-prescriptions, e-dispensations, medical images/image reports, laboratory results and discharge reports). The references included the following:

1. ***Article 5 – Paragraph 1 – Subparagraph 1 – Introductory Part:***
    - *Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories making use of the* ***International Classification of Diseases (ICD)*** *codes, where applicable.*

Once the Draft Report was published, SIP worked with multiple MEPs and prepared Amendments Recommendations, which resulted in a series of tabled Amendments, and Voting Recommendations. From those, several Amendments were included in the European Parliament final Report. Including a further reference to ICD in Annex 1, references to the need of harmonisation, interoperability, and the need to use the latest version of the coding system. Please find below the second ICD reference included in the European Parliament final Report:

2. ***Annex 1, Table A,***

    Main Characteristics of Electronic Health Data Categories,

    1. Patient Summary

    Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The patient summary shall be harmonised across Member States and include a minimum data set that can be expanded to include disease-specific data. The following information is part of a patient summary:

    - *Personal details*
    - *Contact information*
    - *Information on insurance*
    - *Allergies*
    - *Medical alerts*

- *Vaccination/prohylaxis information, possibly in the form of a vaccination card*
- *Current, resolved, closed or inactive problems in an **international classification coding system***
- *Textual information related to medical history*
- *Medical devices and implants*
- *Medical procedures*
- *Functional Status*
- *Current and relevant past medicines*
- *Social history observations related to health*
- *Pregnancy history*
- *Patient provided data*
- *Observation results pertaining to the health condition*
- *Plan of care*
- *Information on rare disease such as details about the impact or characteristics of the disease*

The Report was ratified at the Plenary Session on 11th December 2023. The Trialogues between the European Parliament and the Council of the European Union, started on 30th January 2024 and finalised on 15th March 2024. Throughout the negotiation process, SIP continued its collaboration with key MEPs.

Further, SIP held meetings and engaged with the Spanish Presidency of the European Council in Q3-Q4 2023, where amongst other topics, ICD-11 was discussed. Further, SIP engaged with the Health Permanent Representation of Spain, Belgium, Hungary, France, Portugal, Italy, and Germany, to convey our position on ICD whilst the negotiations took place, with some very positive responses, such as the Germany Representation confirming the SIP Position Paper on ICD-11 had been sent to the German Ministry of Health.

SIP is delighted to announce that ICD is included within the Joint Text of the European Parliament and the Council of the European Union in the following way:

Recital 61:

*Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is more advanced in areas such as cancer, rare diseases, cardiovascular and metabolic diseases, risk factor assessment, and statistics and should be taken into account when defining new standards and **disease-specific harmonised templates for structured data elements**. **However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised coding and registration of electronic health data to enable its supply for secondary use in a consistent way.** Such datasets may include data from registries of rare diseases, orphan drugs databases, cancer registries*

and registries of highly relevant infectious diseases. Member States should work towards delivering sustainable economic and social benefits of European electronic health systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of healthcare and ensuring access to safe and high-quality healthcare. ***Existing health data infrastructures and registries can provide models useful for defining and implementing data standards and interoperability and should be leveraged to enable continuity and to build on existing expertise.***

Article 5:

Priority categories of personal electronic health data for primary use.

1. For the purposes of this Chapter, where data is processed in electronic format, the priority categories of personal electronic health data shall be the following:

(a) ***patient summaries****;*

(b) electronic prescriptions;

(c) electronic dispensations;

(d) medical imaging studies and related imaging reports;

(e) medical test results, including laboratory and other diagnostic results and related reports;

(f) discharge reports.

The main characteristics of the priority categories of personal electronic health data shall be as set out in Annex I.

Member States may provide by virtue of national law that additional categories of personal electronic health data shall be accessed and exchanged for primary use pursuant to this Chapter. ***The Commission may, by means of implementing acts, lay down cross-border specifications for these data categories pursuant to Article 6(1A) and Article 12(8).***

2. *The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend Annex I by adding, modifying or removing the main characteristics of the priority categories of personal electronic health data as referred to in paragraph 1. The amendments shall satisfy the following cumulative criteria:*

(a) the characteristic is relevant for healthcare provided to natural persons;

(b) category the characteristic as modified is used in the majority of Member States according to the most recent information;

(c) ***changes are aimed to adapt the priority categories to the technical evolution and international standards.***

Article 6:

European electronic health record exchange format.

1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 55(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. The format should support transmission of structured and unstructured health data. The format shall include the following elements:

(a) ***harmonised*** *datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;*

(b) coding systems and values to be used in datasets containing electronic health data;

(c) technical ***interoperability*** *specifications for the exchange of electronic health data, including its content representation, standards and profiles.*

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).

(1a.) The Commission shall provide regular updates of the European electronic health record exchange format through implementing acts to integrate relevant revisions of the healthcare coding systems and nomenclatures.

(-1a.) The Commission may, by means of implementing acts, lay down technical specifications that extend the European electronic health record exchange format to additional categories of electronic health data referred to in Article 5(1A). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).

3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the European electronic health record exchange format referred to in paragraph 1. Where such data are transmitted by automatic means for primary use the receiving provider shall accept the format of the data and be able to read it.

Annex 1:

Main characteristics of priority categories of personal electronic health data for primary use.

1. ***Patient Summary***

Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healhcare to that person. The following information is part of a patient summary:

- *Personal details*
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Finally, the final result goes as far as the technical experts would consider possible, as EU legislation usually delegates these responsibilities and updates technical points periodically, via the input of expert committees. A reference to ICD-11 was always deemed unlikely. Further, it seems plausible that the ICD system is the only relevant system aligning with what is set out in Annex 1 and therefore it should point towards its uptake in the future. Historically, the issue has been the varying timelines for national implementation, with certain countries still in the process of adopting ICD-10. As a result, it remains unclear to what extent this will compel a harmonised adoption of ICD-11. Nonetheless, this situation underscores the urgency of addressing the issue.

This is a step in the right direction and will hopefully be interpreted in a way in which ICD is the main point of reference with regards to disease coding systems. The World Health Organization (WHO) International Classification of Diseases is the primary classification system for such a purpose and SIP looks forward to technical implementation confirming this will be used. ICD-11, can help capture and code chronic pain diagnoses, paving the way to better recognition, management, education and research in the field. Until now, many pain patients have not received an adequate explanation for their pain symptoms and those living with chronic pain have often suffered from stigma. ICD-11 has new diagnoses for chronic pain that should give many

pain patients confidence and validate the cause of their pain for their families, employers, and national authorities.

On behalf of the Societal Impact of Pain (SIP) thank you to all policymakers involved in the EHDS for the continued support and collaboration throughout the last couple of years in advocating for improved pain care in Europe. Thank you for persevering. We hope to continue the close collaboration in the future and we remain open for further discussions on the topic.