EHDS Proposal: the perspective of the cardiovascular community

The European Society of Cardiology (ESC) welcomes the European Commission's proposal to encourage the primary access to and secondary use of health data for clinical care, research, evidence-based policymaking and regulation, with a trusted governance framework through the realisation of a European Health Data Space.

We share the belief that health data is an invaluable resource for the improvement of healthcare delivery and the conduct of scientific research, and that common standards are essential to this scope. It is with this vision that the ESC collects cardiovascular data from across its 57 members countries through its Atlas of Cardiology. This unique compendium underlines major healthcare gaps and inequalities and provides robust data for budget owners and decision-makers who can advance population health at a European level. Additionally, ESC launched the EuroHeart Project, a European unified registries project on heart care, providing standardised datasets and an optional IT infrastructure for continuous online registration of harmonised patient data and supporting continuous improvement of care and outcomes and collaborative research in patients with common cardiovascular diseases.

Healthcare professionals will be considerably affected by the new digital framework in relation to both primary and secondary use of electronic health data, in quality of physicians and researchers, and they will play a key role in its implementation. For this reason, we call the European Commission to consider the following recommendations:

Primary use of health data

- The European Health Data Space should avoid any additional bureaucratic workload on healthcare professionals. The data should be available in an automated fashion from electronic health records in compliance with the defined characteristics and technical specifications and with data protection regulations.
- The ESC urges the European Commission to consult medical societies in the definition of implementing acts determining the requirements for the registration of electronic health data by healthcare providers, in relation to:
    - Categories of health data required by different health professions.
    - Categories of healthcare providers that are to register health data electronically.
    - Categories of health data for primary use referred to in art. 5.
    - Data quality requirements.
- ESC, uniting National Cardiac Societies from across Europe can contribute to build capacity for implementing interoperability and security of the primary use of electronic health data and participate in capacity building activities at Union level.
- Medical societies can play a key role in supporting the harmonization of data with reference to the priority categories defined in art. 5. We ask for medical societies to be involved upfront in the definition of technical specifications and, again, the ESC is fully available to share the results achieved by EuroHeart in terms of standardisation and homogenisation.

Secondary use of health data

- The ESC fully supports the intention to establish a consistent framework for the re-use of electronic health data to advance health research and inform policymaking and regulatory activities, provided that adequate safeguards of the privacy of patients are adopted.
- It is important to take into account that codes and formats can differ among countries. This could lead to interoperability issues and potentially hinder the effective reuse of data. Structured data based on clinical characteristics is fundamental to ensure interoperability and allow for analyses across large datasets. For this reason, we suggest the creation of standardised minimal sets of predefined structure for each different diseases in collaboration with medical societies, leveraging on the significant work in terms of standardisation and harmonisation already achieved by medical registries like EuroHeart.
- One of the recitals of the Regulation (#61) reports that cooperation is ongoing between professional organisations and institutions to set up minimum data fields and other characteristics of different datasets, such as registries, and mentions cancer and rare diseases as areas where this work is more advanced. The ESC reiterates that the same activities are ongoing in the area of cardiovascular diseases and the role of cardiovascular diseases (CVD) and EuroHeart as valuable use case and hopes to be consulted in the definition of standards through implementing acts, to ensure a harmonized provision, coding and registration of electronic heath data relevant to CVD pathologies.
- More clarity is needed concerning the delegated acts to amend the duties of the data holders. ESC is fully available to provide expert advice based on activities of academic institutions and learned societies in this respect. In relation to the duties of data holders, among others, we call for:
    - clear statements/recommendations to include predefined structured harmonized data as part of the electronic patient record.
    - more detailed specifications around IP protection.
    - clarification of the role of data holders/providers as joint controllers.
    - better clarify the fees proportionate for (to) the efforts to gather data and to its quality.
    - adequate financial and technical support for non-profit organisations, researchers, and medical societies, also in relation to the design, implementation, and governance of internal systems and procedures for the collection and sharing of data with health data access bodies.
    - the consultation of clinical experts in the definition of:
        - minimum information elements data holders have to provide for the datasets and their characteristics.
        - characteristics and technical specifications of data quality and utility label.
- Article 34.2. limits access to electronic health data only to public sector bodies. ESC believes that many of these activities can be undertaken by the medical community, including learned societies, academic and research institutions, that do not fulfill the definition of public sector bodies nevertheless may serve public interests.

Capacity building and raising awareness

Effective capacity building actions should be put in place at the national level, with adequate and specific financial resources allocated to this scope as follows:

- In line with article 10.2 and with the aim of building national capacity for implementing interoperability and security of the primary use of electronical health data, scientific communities representing national societies can facilitate towards this goal.
- Healthcare professionals, who need to receive training on the rules, standards and obligations deriving from the Regulation.
- Healthcare institutions, which will face challenges and incur in significant costs to implement the new system.
- The general population, improving individuals' digital literacy and raising awareness on their additional rights in relation to the access and exchange of their data - but also on their responsibilities such as the restriction of health data to health professionals – and on the re-use of electronic health data.
- The needs for data collection (e.g. in EHR) must be clearly defined and as easy as possible. The manufacturers of such software have an obligation that data exchange is possible, source data registration is easy and does not require much capacity and future adaptation possible and easy.

ESC, together with National Cardiac Societies from across Europe can contribute to capacity building by cooperation with health data access bodies.

Avoiding fragmentation & regulatory complexity

Significant experts' involvement in the development of common specifications referred to in par 23. especially a) 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

Although the Regulation will be directly applicable in all Member States, there are significant concerns around the risk of different interpretation and implementation at national, regional and local level, as has occurred for the General Data Protection Regulation. The Regulation should avoid the risk of fragmentation, which would jeopardize efforts and hinder the effective use and exchange of health data for both primary and secondary uses.

More clarity is needed concerning the interplays of the Regulation with other EU legislation, especially the General Data Protection Regulation, the Medical Devices Regulation the Artificial Intelligence Act.

Last but not least, ESC strongly recommends to the Commission to ensure a close and regular involvement of clinical experts within the European Health Data Space Board which will be established at the EU level and to further clarify article 66 on the role of experts/stakeholders and their involvement. Following the adoption of the proposal, ESC is fully available to contribute to the expert group, in order to advise and assist it in the preparation of delegated acts, as well as on issues related to implementation of the Regulation.