The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Implementing a 'user-friendly' European Health Data Space

Guiding the integration of an intuitive electronic health record

Main messages:

- The primary function of the electronic health record (EHR) is to support clinical practice and the requirements of the European Health Data Space (EHDS) must not compromise this purpose;
- Usability measures must be adopted to evaluate effectiveness, efficiency and healthcare professional satisfaction when using an EHR system;
- Only 'user-friendly', fully functional systems should be allowed on the market and essential 'user-friendly' features should be included in EHR systems without additional costs;
- The right balance between structured and unstructured data must be found, based on the needs of practicing clinicians;
- EHR systems should avoid multiple entry of the same data and support that data are used for multiple purposes in primary and secondary use;
- Support the implementation of information standards in the EHR based on clinicians' needs;
- Improve the usability of EHR systems in Europe with auto-population (pre-filled data) and automated solutions;
- EHR use and identification and authentication processes must be secure and practical;
- Realtime practical solutions to report and resolve EHDS implementation bottlenecks must be in place;
- Member States must finance the implementation of the EHDS and 'user-friendly' functionalities in the EHR without additional costs for healthcare professionals and healthcare providers.

Introduction

European doctors welcome the provisions in the European Health Data Space (EHDS) Regulation[1] which intend to create a 'user-friendly' and intuitive electronic health record (EHR) to reduce administrative burdens for doctors and other healthcare professionals. CPME is concerned with the workload and economic burden that cumbersome digital tools place on healthcare professionals and on healthcare systems.[2] Time spent with administrative and statistical data means less time spent with patients.[3] Initiatives should be taken to measure documentation burden, for example using the NASA Task Load Index method (NASA-TLX). More 'user-friendly' and efficient documentation can improve communication with patients, reduce multitasking and frequent interruptions during clinical practice, increasing satisfaction and acceptance by healthcare professionals. [4]

European doctors fear that additional data management obligations for research, innovation and policy-making under the EHDS Regulation, may further decrease time spent with patients, and increase the economic and administrative burden of the digital transformation in healthcare. The primary reason for healthcare services is to help the patient. Free text in clinical notes is fast, efficient and flexible, and the need for structured data must be weighed against the increased workload and lower efficiency when entering data. The right balance between structured and unstructured data must be found, based on the needs of practicing clinicians.

This policy intends to explore the legal concept of a 'user-friendly' system foreseen in Article 12 of the EHDS Regulation,[5] and Annex II, point 2.5 of the EHDS Regulation which forbids features in the EHR system which places an undue burden on authorised access, and on personal electronic health data sharing.[6]

---

[1] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

[2] Baumann, Lisa Ann, Jannah Baker, and Adam G. Elshaug. "The impact of electronic health record systems on clinical documentation times: A systematic review." *Health policy* 122, no. 8 (2018): 827-836, p. 834. The authors conclude that delegating documentation burden to non-specialist administrative staff, where appropriate, alleviates healthcare professionals multitasking and reduce hospital costs. The authors also note that documentation time with EHR increased from 16% to 28%, and that "user-friendliness and reliability of the system", along with testing features prior implementation, are factors which increase healthcare professionals satisfaction and acceptance of clinical decision support systems in clinical practice (p.828); Wang Z, West CP, Vaa Stelling BE, Hasan B, Simha S, Saadi S, Firwana M, Nayfeh T, Viola KE, Prokop LJ, Murad MH. Measuring Documentation Burden in Healthcare. Technical Brief No. 47. (Prepared by the Mayo Clinic Evidence-based Practice Center under Contract No. 75Q80120D00005.) AHRQ Publication No. 24-EHC023. Rockville, MD: Agency for Healthcare Research and Quality; May 2024. DOI: https://doi.org/10.23970/AHRQEPCTB47;

[3] Wenger, Nathalie, Marie Méan, Julien Castioni, Pedro Marques-Vidal, Gérard Waeber, and Antoine Garnier. "Allocation of internal medicine resident time in a Swiss hospital: a time and motion study of day and evening shifts." *Annals of internal medicine* 166, no. 8 (2017): 579-586;

[4] Moy, Amanda J., Jessica M. Schwartz, RuiJun Chen, Shirin Sadri, Eugene Lucas, Kenrick D. Cato, and Sarah Collins Rossetti. "Measurement of clinical documentation burden among physicians and nurses using electronic health records: a scoping review." *Journal of the American Medical Informatics Association* 28, no. 5 (2021): 998-1008.

[5] Article 12 of EHDS, third paragraph, provides that: *"(…) Personal electronic health data shall be presented in a user-friendly manner in the electronic health records to allow for easy use by health professionals"*.

[6] Annex II, point 2.5 of the EHDS Regulation prescribes that: *"2.5 The harmonised software components of an EHR system shall not include features that prohibit, restrict or place an undue burden on authorised access, personal electronic health data sharing or use of personal electronic health data for permitted purposes."*

CPME calls on the healthcare software industry to accept the challenge of only placing on the market or putting into service EHR systems that are verifiably 'user-friendly' and functional. CPME further calls on policy-makers and co-legislators in Europe to strive for an EHR for the patient and the healthcare professional, removing unnecessary administrative and statistical information obligations from the EHR. A better EHR is a better way of helping patients.

How to build a 'user-friendly' EHR system?

European doctors are committed to provide solutions for an EHR system that is intuitive and user-centric. As the European Commission and Member States prepare for the implementation of the EHDS, CPME highlights non-exhaustive key aspects to reduce administrative burdens for healthcare professionals, limit disruption and facilitate adaptation to the EHR system:

A. Usability measures must be adopted to evaluate efficiency, effectiveness and healthcare professional satisfaction when using an EHR system

1. Standards metrics such as the System Usability Scale (SUS), the National usability focused health information system scale (NuHISS) or the Nasa Task Load Index (NASA-TLX) should be used to measure the usability of EHR systems.[7] Most EHR systems were created with billing and statistical objectives in mind, neglecting users. Studies show that EHR systems are not performing well in comparison with other product technologies, yet by improving EHR usability healthcare professional burnout and job frustration can be reduced.[8]

2. Evaluation of EHR systems for a particular setting should be done as early as possible, before implementation and preferably before procurement, and a high usability rate among clinical users should be a priority.[9]

[7] Brooke, John. "SUS-A quick and dirty usability scale." *Usability evaluation in industry* 189, no. 194 (1996): 4-7; Hyppönen, Hannele, Johanna Kaipio, Tarja Heponiemi, Tinja Lääveri, Anna-Mari Aalto, Jukka Vänskä, and Marko Elovainio. "Developing the national usability-focused health information system scale for physicians: validation study." *Journal of medical Internet research* 21, no. 5 (2019): e12875.
[8] Melnick, Edward R., Liselotte N. Dyrbye, Christine A. Sinsky, Mickey Trockel, Colin P. West, Laurence Nedelec, Michael A. Tutty, and Tait Shanafelt. "The association between perceived electronic health record usability and professional burnout among US physicians." In *Mayo Clinic Proceedings*, vol. 95, no. 3, pp. 476-487. Elsevier, 2020, doi.org/10.1016/j.mayocp.2019.09.024 p 485; Melnick, Edward R., Elizabeth Harry, Christine A. Sinsky, Liselotte N. Dyrbye, Hanhan Wang, Mickey Todd Trockel, Colin P. West, and Tait Shanafelt. "Perceived electronic health record usability as a predictor of task load and burnout among US physicians: mediation analysis." *Journal of medical Internet research* 22, no. 12 (2020): e23382; Persson J, Rydenfält C. Why Are Digital Health Care Systems Still Poorly Designed, and Why Is Health Care Practice Not Asking for More? Three Paths Toward a Sustainable Digital Work Environment. J Med Internet Res. 2021 Jun 22;23(6):e26694. doi: 10.2196/26694. PMID: 34156336; PMCID: PMC8277335.
[9] Kaipio J, Kuusisto A, Hyppönen H, Heponiemi T, Lääveri T. Physicians' and nurses' experiences on EHR usability: Comparison between the professional groups by employment sector and system brand. Int J Med Inform. 2020 Feb;134:104018. doi: 10.1016/j.ijmedinf.2019.104018. Epub 2019 Oct 24. PMID: 31835158.

B. Essential 'user-friendly' features should be included in EHR systems without additional costs

3. To be considered 'user-friendly', European doctors consider certain features of EHR systems essential to keep up with the new *modus operandi* of the EHDS Regulation, without placing an undue burden on access and sharing of electronic health data.

4. Essential 'user-friendly' features cannot be charged extra by manufacturers. Cost is a reason why hospitals, healthcare providers and healthcare professionals do not introduce novel features into their systems.

5. For CPME, the **essential features** in all EHR systems are:

    a. **Seamless integration with clinical software.** EHR systems should be designed to gather documentation only once, followed by seamless exchange and reuse of information between systems with minimal effort from the healthcare professional. European doctors can no longer continue to input the same information manually across different EHR systems (re-typing/duplication of data entry). It is an inefficient allocation of time, increases the administrative workload and it is vulnerable to errors.

    Such interoperability should be assessed and evaluated by the end-user, who is in the best position to ascertain whether the digital tool is usable and integrates well with other healthcare information systems.

    b. **Automated clinical coding**. EHR systems should be able to generate automated coding as required for data aggregation, allowing doctors to focus on using the medical language of their professional training. Coding and classifications tasks should be performed by background systems, preferably automatically and possibly aided by AI tools, to reduce the burden of coding and classifications for healthcare professionals.

6. CPME further calls for **automatic transcription and accurate translation for reporting.** This can facilitate the reporting tasks of healthcare professionals in each encounter with a patient, while at the same time improving data quality and standardised reporting, in view of using health data for clinical decision-support systems or for secondary use purposes foreseen in the EHDS Regulation. However, current systems for transcription are not mature, and **this feature should be optional until it becomes fully functional**. The original language version should always be accessible for the healthcare professional.

7. Efforts should be made to develop large language models, specific for clinical documentation at European level to improve transcription, coding and translation. The EU funds for innovation on AI could be a motor for this purpose, supporting European AI development and reducing reliance on China and USA.

C. Code data once but enable multiple uses of the same data

8. Documenting patient's care plan and progress should be simple and straightforward. Doctors should be required to code only once for the continuity of care and the EHR system should provide for multiple primary and secondary uses, including billing and statistical reporting, to reduce data entry requirements. Any translation from one coding system to another must be automated.

9. Doctors should not be data harvesters for other users and interests. Secondary use data should be generated from structured primary data.

10. CPME welcomes current international initiatives which aim to explore seamless data conversion and linkages of different coding terminologies for users. European doctors call for further engagement from coding organisations to enable a common language worldwide.

D. Support the implementation of information standards in the EHR based on clinicians' needs

11. Information standards must be developed by healthcare professionals based on clinical needs, and, if possible, aligned with international standards. When a recognised multidisciplinary team of specialists comes to a consensus on which classifications should be used, which items must be mandatorily structured and which health data must be exchanged between healthcare information systems, manufacturers should be required to implement and exchange such health data correctly and in a user-friendly manner.

12. Medical doctors with informatics knowledge should be assigned the role of advancing the information standard of the medical specialty in question, enabling dialogue with practicing colleagues via formal communication networks, as well as on testing the EHR systems (e.g. implementing a plan-do-check-act cycle – 'PDCA'). The time spent on this activity should be remunerated.

E. Improve the usability of EHR systems in Europe with auto-population (pre-filled data) and automated solutions

13. The EHR should include both structured and unstructured data, to allow healthcare professional to add the necessary nuances to the medical record. Improving the quality of data in primary use will benefit secondary use data, including for example possible training of AI tools on recorded text descriptions. The use of auto-population properties to automatically retrieve data from existing systems and fill in fields in the EHR should be implemented where possible. The patient summary should be based on existing EHR system data.

14. The Once Only Principle (OOP) should be supported, in respect of data protection rules and the patient's right to opt-out, to avoid duplication and unnecessary burdens stemming from the secondary use regime obligations in the EHDS Regulation,[10] such as the communication of dataset descriptions or making electronic health data available for health data access bodies.

15. Healthcare software manufacturers need to support healthcare professionals and healthcare providers by automating the creation and provision of dataset descriptions for health data access bodies.

16. The duties for healthcare professionals and healthcare providers related to dataset descriptions and data transfers under the secondary use regime of the EHDS Regulation are seen as an administrative burden to their primary task of diagnosing and treating a patient.

17. Considering the current health workforce crisis, healthcare professionals' precious time cannot be exhausted in preparing data for third parties including those which pursue private and commercial interest.

[10] Article 2(1)(e) of EHDS Regulation.

F. Identification and authentication processes must be secure and practical

18. Methods for identification and authentication of health professionals, and patients in online EHR systems[11] need to be robust, easy, fast and with appropriate levels of security for protecting personal data relevant for clinical activities in compliance with eIDAS Regulations.

19. Professional access to online EHR systems needs to be separate from personal access as a patient. A clear separation of roles must be ensured.

20. Identification and authentication of doctors in online EHR systems should balance the need for integrity in a certain setting and the security of the digital tool with the administrative burden for this procedure. The protective equipment healthcare professionals use while practicing needs to be considered. The multi-factor authentication method, such as fingerprinting and face identification, can be cumbersome when wearing gloves, aprons, masks, goggles and/or hoods.

21. The online EHR system should give access to all functionalities in the EHDS without further logins and without compromising the security and confidentiality requirements inherent to software handling of sensitive personal data, such as health data. **CPME supports single sign-on (SSO) authentication and identity management federation concepts. 'One day, one-time login'** to the online EHR system back-end should be the common practice, providing for automatic authentication of national components, such as electronic prescriptions, patient summaries, etc. This means that the session should remain active until the healthcare professional signs out, which **does not invalidate the authentication procedure of locking and unlocking the system** when a healthcare professional is required to use another terminal on the same day.

[11] For the purposes of this policy section, an 'online EHR systems' is a patient-centred overarching EHR system while regular 'EHR systems' refers to while regular 'EHR systems' refers to internal systems in hospitals and doctors' offices (either on-premises or in a private cloud.

G. Realtime practical solutions to report and resolve implementation bottlenecks must be in place

The EDHS Regulation is a special framework which requires planning, preparation and strong collaboration from healthcare professionals at national, European and international level.

CPME calls on Member States to **involve national medical associations (NMAs)** in a meaningful and transparent way, throughout the implementation process of the EHDS Regulation at national level. A formal communication network, composed by medical doctors using current EHR systems with IT (information technology) academic competence, per medical specialty, who can be consulted when developing and implementing the EHR nationally,[12] should be part of the implementation strategy or roadmap of the EHDS Regulation. Close collaboration of the network with the chief medical/clinical information officers, where they exist, is recommended.

CPME further calls on the European Commission to ensure that the implementation guidance on the EHDS Regulation for Member States includes as a **key performance indicator** the meaningful involvement of NMAs during the implementation process.

European doctors also propose the **creation of a reporting point** for healthcare professionals to voluntary and directly report technical errors related to the implementation and updating of EHR systems, of the European electronic health record exchange format (EEHRxF), and of the EHDS Regulation. The implementation process should find ways to address end-users' frustration in a structured and useful way.

The **right to report** should be related to the usability of the system, the non-compliance of the EHDS requirements on interoperability including among healthcare professionals (the so-called 'seamless integration with clinical software'), and the incorrect functioning of the EHR system. Such right to report should be done by healthcare professionals who are knowledgeable about the EHDS requirements on interoperability, such as the chief medical/clinical information officers, where applicable.

***

[12] See 'CPME Statement on Electronic Health Record Systems - Feasible, Functional, Findable', March 2024, point 6, <https://www.cpme.eu/api/documents/adopted/2024/03/cpme.2024-004.statement-on-electronic-health-record-systems.pdf>.