Summary page:
TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

This consultation has 4 pages and 26 questions. The first and the second pages are common to all TEHDAS2 public consultations and cover demography of the responder and overall quality of the document. Pages 3 and 4 consist of questions specific to this document.

Demography

1. Country *

Belgium

2. Type of responder *

Other
European Doctors

3. Are you responding on behalf of several organisations? *

If yes: On behalf of how many organisations?

No

4. Sector *

Health care provider

5. Organisation size *

Not applicable / Individual citizen

6. Professional role / function

Senior Policy Advisor

Quality

7. Is the document easy to understand? *

3

8. How well does the document address the key issues related to its subject matter? *

3

9. How feasible do you find the guidelines or technical specifications to implement, as outlined in the document? *

3

10. Generic feedback

Do you have any suggestions for improving the document? Are there any additional topics or areas that should be covered? Max. 5000 characters.

This statement aims to delineate the obligations imposed on doctors and to assess how such obligations translate into practical consequences in everyday clinical practice. Furthermore, the statement will take into account the patients' need for protection in relation to the processing of health data.

As healthcare professionals play a central role in communicating health-related information to patients, the proposed guideline could have an impact our activities.

Since in Q21, Q23 and Q25 it was not possible to justify our answer, please note the following comments:
- Q21 - Medical confidentiality could be emphasised.
- Q23 - It could be useful within the limit of EU level responsibility.
- Q25 - Scenarios involved in the case of data users from outside the EU could for example be provided (but probably out of scope).

The following questions are specific for TEHDAS2 draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

11. Do you expect the proposed guideline on the obligation of notifying natural persons on significant findings from the secondary use of their health data to impact your organisation or activities?

Yes

12. Do you find the scope and objective of the guideline (as outlined in the introductory part) clearly described?

Unclear — please specify
We had chosen 'other' in the word form which is not available as a response in the online form, noting that the scope of this specific guideline is clearly restricted

13. Do you find the explanation of significant findings (Chapter 1) sufficiently clear and appropriate?

If no: Please explain

No
In the context of secondary processing of health data, significant findings are defined as the identification of new, previously unknown, clinically relevant information. The determination of clinical relevance depends on whether the information may potentially influence decisions related to diagnosis, treatment, prevention, or follow-up. Such findings presuppose that the data being processed are not anonymised and can therefore be traced back to an individual. Pseudonymised data may thus constitute a basis for relevant findings, insofar as the individual can be identified through supplementary information. As the EHDS Regulation does not provide a formal legal definition of “significant findings”, this concept needs to be explained more clearly to avoid multiple approaches.

14. Do you find it clear which actors (HDABs, data holders, data users) are involved and what their roles are (Chapters 2 and 3)?

If no: Please explain

No
- In Member States where responsibility for the tasks is shared by several HDABs, their respective roles, coordination mechanisms and place in the communication chain should be clarified. - Situations in which the duties of certain data holders are fulfilled by health data intermediation entities should also be addressed. - Data users are mentioned mostly as researchers.

15. Do you consider the responsibilities of HDABs presented in the document (Chapter 4) appropriate to support the implementation of the provisions of the EHDS Regulation on significant findings?

Yes

16. Do you find the level of detail provided in the recommendations for process and the communication between actors (Chapter 3) appropriate?

No answers

17. Do you see any technical or organisational challenges in implementing the notification of significant findings under the EHDS Regulation as described in the document?

Max. 5000 characters.

Obligation to Notify Regarding Information of Clinical Significance
4.1 Preliminary Remarks on Communication Channels
EHDS entails that the obligation to notify is initially imposed on the user of secondary data. The information shall be provided to the body administering access to health data. This body shall subsequently transmit the information to the health data holder. The health data holder is, in turn, the entity responsible for communicating the finding to the patient. In most countries, typical health data holders may include public hospitals, general practitioners' offices, and contracted specialists.

4.2 Implications for the Secondary User
The secondary user is required to maintain technical and organisational systems enabling the identification of relevant findings during the processing of health data. The regulatory framework also appears to presuppose sufficient competence to determine which findings are of significance. The secondary user is further subject to a duty to report to the body administering access to health data. Compliance with the relevant provisions of the GDPR and EHDS must be ensured throughout the processing and reporting activities.

4.3 Implications for the Body Administering Access to Health Data
This body plays a pivotal role in transmitting information on relevant findings to the health data holder. It bears responsibility for ensuring that such sharing occurs in conformity with the GDPR and EHDS. Moreover, the body could be obliged to identify the patient where it possesses information essential for re-identification.

4.4 Implications for Health Data Holders
Health data holders are responsible for informing the patient of significant findings. This entails that the entity must ascertain whether the patient exercises the right to opt-out. Accordingly, the entity must implement systems ensuring that patients receive adequate information regarding the implications of the right to opt-out, while also registering such opt-out in a manner that guarantees compliance.
Health data holders are further responsible for determining whether the information is clinically relevant and thus subject to the obligation to inform. They will also be required to contribute to re-identification where the entity possesses information necessary to identify the correct patient.

The practical consequences of the regulatory framework for stakeholders will depend on several factors. It is reasonable to assume that the regulation will impose a particular burden on smaller healthcare entities, such as general practitioners' offices and contracted specialists. These entities operate with relatively limited resources and rely on revenue-generating, patient-oriented activities. Additional administrative obligations may therefore have a significant impact. Such entities will be required to undertake

additional tasks related to re-identification and clinical assessments without any clear indication that these efforts will generate increased income. They must also ensure that adequate measures are implemented to guarantee effective compliance with the right of reservation. Furthermore, these entities will incur additional administrative work in the form of further processing of patient data in accordance with the GDPR and EHDS. This also entails that compliance must be demonstrable. Finally, all health data holders will be subject to requirements to maintain technical record-keeping systems enabling communication in accordance with EHDS. This may potentially entail costs associated with ensuring that record systems incorporate compatible solutions.

18. Do you see any legal or data protection challenges in implementing the notification of significant findings under the EHDS Regulation as described in the document?

Max. 5000 characters.

On the Protection of the Patient
Patients may exercise a right to opt out of receiving information regarding findings of clinical significance. However, exceptions to this right of reservation may be permitted. The scope of this right does not appear fully aligned with national law in some countries. For example, corresponding provisions under Section 3-2 of the Norwegian Patients' and Users' Rights Act, where the right of reservation is restricted when necessary to prevent adverse consequences of healthcare provision. CPME alerts that the right of reservation may, in certain circumstances, conflict with the duty of professional diligence and the requirement of informed consent in the provision of healthcare in certain countries (e.g. the regulation under EHDS appears to be in a tension with fundamental principles of Norwegian health legislation).

How the patient will be informed of his right to opt-out of significant findings?

In case of intermediation entities, what their role will be?

19. Is the level of flexibility foreseen for national implementation sufficient while ensuring compliance with the EHDS Regulation?

If no: Please explain

No answers

20. Is the level of legal and technical interoperability foreseen for national implementation sufficient to ensure harmonised implementation of the EHDS Regulation?

If no: Please explain

No answers

21. Do you consider the data protection aspects of notifying significant findings clearly explained and appropriate in the document?

No

22. Do you consider the recommendations on the issues to be addressed at national level are appropriate to support the implementation of the obligations concerning significant findings under the EHDS Regulation (Chapter 4)?

No answers

23. Do you think the guideline should include recommendations on the communication format (e.g., plain language, layered information, patient portals) for notifying individuals?

If no: Please explain

Yes

24. What kind of capacity-building, funding, or infrastructure would HDABs need to operationalise this notification obligation in a sustainable way?

Max. 5000 characters.

No answers

25. Should the guideline provide more guidance on cross-border scenarios (e.g., how findings are notified when data users and data subjects are in different Member States)?

If no: Please explain

Yes

26. Do you believe that this obligation, if not uniformly applied across Member States, could affect citizen trust in the EHDS framework?

If no: Please explain

No answers