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## **Digital health data and services – the European health data space European Commission Public Consultation on the proposal for a Regulation on the European Health Data Space**

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The EFN welcomes the EHDS legislative proposal and its key objectives as a logical next step in the digital transformation of health and care ecosystems.

The EFN is part of Smart4Health<sup>1</sup> and Interopérate<sup>2</sup>, both EU projects empowering citizens to use and donate their health data. The deliverable of both EU projects should be more connected to the legislative developments so that EU funds are used to develop fit-for-purpose solutions. The formulation of the end-user requirement will therefore need to be addressed in the legislative proposal:

- Understand users, their needs and the context;
- Define the outcome and how the technology will contribute to it;
- Use health data for the purposes it is being used;
- Be fair, transparent and accountable about what health data is being used;
- Make use of open standards;
- Be transparent about the limitations of the health data being used;
- Generate evidence of effectiveness for the use and value of the tools;
- Make security integral to design.

Tangible benefits can only be achieved when the end-users will use the EHDS infrastructure to lower down the workload and deliver better healthcare outcomes.

Therefore, the EFN welcomes that the EHDS proposal links electronic health records with ePrescribing systems, thus allowing nurses providing direct patient care to access necessary patient information from the electronic health records to provide better care and boosting access to care. Many nurses in several EU Member States prescribe the full range of medication and medical devices (ENS4Care, 2015: evidence-based guideline on e-prescribing<sup>3</sup>).

Nurse prescribing is an area of professional development which has made huge steps forward in the past few years and that is being fully implemented in several Member States (UK, Ireland, Finland, Sweden, Spain, etc.). Evidence suggests that this implementation is safe and clinically appropriate (West, 2011; University of Southampton, 2011; Latter et al, 2011, An Bord Altranais, 2008), and shows that nurse prescribing improves patient care by ensuring timely access to medicines and treatment, and increasing flexibility for patients (Carey N, Stenner K 2011; Drennan J et al 2009; National Prescribing Centre 2010).

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<sup>1</sup> [https://efn.eu/?page\\_id=10687](https://efn.eu/?page_id=10687)

<sup>2</sup> [https://efn.eu/?page\\_id=10684](https://efn.eu/?page_id=10684)

<sup>3</sup> <http://www.efn.eu/wp-content/uploads/Final-ENS4Care-Guideline-5-Nurse-ePrescribing-pv.pdf>

The EHDS proposal includes electronic prescriptions among priority categories of personal electronic health data for primary use, which implies that Member States shall implement access to and exchange to this category of data. Therefore, it is important to set out measures to enhance recognition of electronic prescriptions across different Member States and ensure full applicability of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border health care.

Furthermore, the International Classification for Nursing Practice (ICNP)<sup>4</sup> is designed to facilitate the expression of nursing diagnoses, interventions and outcomes. Nursing terminologies and classifications represent relevant tools for making the practice of nursing visible in complex, evolving healthcare settings. They allow nurses to rigorously document nursing clinical data with standardized language and to make measurable nursing diagnoses, outcomes, and interventions, as key elements in the description of nursing care. The ICNP has been defined as a unified language for nursing. It is a compositional terminology for nursing practice that facilitates developing and cross-mapping of local terms and existing terminologies. The ICNP has been accepted in 2009 by the World Health Organization (WHO) as part of the WHO Family of International Classifications (WHO-FIC).

The ICNP provides an agreed set of terms that can be used to record the observations and interventions of nurses across the world. ICNP also provides a framework for sharing data about nursing and for comparing nursing practice across settings. There are a number of benefits associated with the use of ICNP, which of course can determine the end-user requirement:

- ICNP is helping to increase nursing visibility, ensure safety and enhance quality<sup>5</sup>;
- ICNP is helping to ensure that nursing is adequately represented in multidisciplinary health information systems<sup>6</sup>;
- ICNP is helping to ensure that nurses have the information tools they need to meet the changing health and care needs of citizens<sup>7</sup>;
- ICNP is helping to enhance practice and support policymaking through national information standards<sup>8</sup>;
- ICNP is helping to support both general, specialist and advanced nursing practice across settings<sup>9</sup>;
- ICNP is helping to ensure that the contribution of nursing is accurately captured in resource management systems<sup>10</sup>;
- ICNP is helping to support evidence-based practice<sup>11</sup> (Data for Health Research);
- ICNP is helping to bring different nursing terminologies together<sup>12</sup>.

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<sup>4</sup> <https://www.who.int/standards/classifications/other-classifications/international-classification-for-nursing-practice>

<sup>5</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20Values.pdf>

<sup>6</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20SNOMED%20CT.pdf>

<sup>7</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20Norway.pdf>

<sup>8</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20Portugal.pdf>

<sup>9</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20Paediatric%20Pain%20Management.pdf>

<sup>10</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20ICHI.pdf>

<sup>11</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20ICNP%20and%20RNAO%20-%20Transforming%20Nursing%20Practice.pdf>

<sup>12</sup> <https://www.icn.ch/sites/default/files/inline-files/Benefits%20of%20ICNP%20-%20Harmonising%20Nursing%20Terminologies%20Using%20ICNP.pdf>

Nurses need to be able to access and share patient information in a standard way, to ensure safety, improve quality of care across the health care delivery system, and communicate with the citizen/patient and other health professions.

Therefore, it is necessary to clarify in article 4 that the provider or health professional shall be informed of the existence and nature of the restricted electronic health data in order to provide adequate healthcare when data cannot be taken into consideration when providing health services.

Furthermore, to attain a high level of trust and uptake by the end-user, the EHDS should support frontline to deliver higher quality and safe services and improved health outcomes for citizens/patients, provide support for healthcare professionals, enhance different administrative processes and boost continuity of care as part of healthcare ecosystems strengthening.

Under ongoing COVID-19 pandemic conditions<sup>13</sup>, healthcare systems, including community care, are operating under significant resource limitations affecting the recruitment and retention of healthcare professionals and workers with the digitalisation coming now on top of already an exhausted frontline.

EHDS implementation should be done with the frontline staff and not above the end-user. End-user engagement should get a specific reference in the EHDS legislation, if not, the EU developments will stay theoretical, leading to a waste of EU funds. Targeted EU funding will need to support the human resources needed to make the transition a reality.

The main challenge, as indicated in the eHealth Stakeholder Policy Paper (EFN, 2021<sup>14</sup>), will be the setting up of IT infrastructures with semantic and technical interoperability, lowering down the workload of frontline healthcare professionals. The realisation of the EHDS ambition will depend on a high level of interoperability and standardisation to facilitate the meaningful use of personal health data in healthcare and in research. Developers and vendors are still too much operating in silos with the end-user disconnected from the co-creation. This will only lead to patchwork with no significant impact.

Importantly, the ownership of the EHDS must be in the hands of citizen and not the IT industry, to make sure that the actual needs of citizens/patients are met. The EFN welcomes that the proposal gives citizens' rights to have more control over their health data. In many Member States some of these rights already exist. Clarification is needed whether the regulation of the European Commission proposes a system that implicitly assumes the consent of citizens and in which they must explicitly object to the making available of their health data or a system in which the citizen/patient has to explicitly express her/his consent. It is essential that Member States ensure that patients are aware of the system and its consequences.

Furthermore, any misuse of individual citizens data or any breach of data security constitutes a great risk, given the huge amount of very sensitive health data in the EHDS. Appropriate sanctions for breaches of confidentiality and data security needs to be part of the EHDS legislative proposal. There should also proportionate fines for unwanted use and sharing of citizens data. Otherwise, it would be difficult to build trust, which would ultimately impact the acceptance of the EHDS.

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<sup>13</sup> EFN Report on Lessons Learned with Ebola and COVID-19 (2020). <https://bit.ly/3e76mZn>

<sup>14</sup> eHealth Stakeholder Policy Paper on Interoperability (2021). <http://efn.eu/wp-content/uploads/2022/07/EFN-lead-eHSG-WG1-Policy-Paper-on-Interoperability-Nov-2021.pdf>

Finally, it is important the EHDS proposal increases the digital health literacy of patients, citizens and healthcare professionals. Digital literacy is not part of the EHDS proposal, although it is the condition to be successful. Developing and maintaining a coherent collaboration with all relevant stakeholders to map common digital competencies for the appropriate use of eHealth services will be key (Pact for Skills) as up-scaling and effectively integrating digital competencies into the nurses' education and training programmes at both undergraduate and postgraduate level as well as through Lifelong Learning (LLL) will be an important KPI for success.

### **To conclude:**

The COVID-19 pandemic has demonstrated the importance of digital solutions in the healthcare sector but also highlighted the need to build fit-for-purpose interoperable infrastructures that support frontline nurses, instead of adding more administrative burden on the already overloaded frontline. Nurses experience daily the complexity of rules, structures and processes that hinder adequate access and use of health data, within facilities, countries and cross-border settings. Deploying digital tools and systems will need to reduce the workload of nurses and safeguard the quality of care.

Within the context of the digitalisation of the EU health systems<sup>15</sup>, nurses require fast and full access to Electronic Health Records (EHR) in order to be able to diagnosis, plan and care for patient in an effective and efficient way. Therefore, any implementation of the EHDS implies the pro-active engagement in the co-design process formulating end-user requirements that guide digital development and innovation, ensuring fit-for-purpose solutions. Nurses therefore advocate for digitalisation practices and processes to mainly focus on patient safety and empowerment, improving the quality of cross-border care and interoperability through a common terminology (for nurses ICNP).

The EHDS should allow easy access to the citizens health data, supporting the nurses' workflow when data are used, and use the EHDS for more citizens/patient engagement and co-creation. From a research perspective, and putting priorities into the requirements, better measurable health outcomes are key to support policy design.

European nurses remain committed to finding workable solutions that lower down the workload of frontline to achieve a EHDS which will benefit citizens/patients. The success of the European Health Data Space (EHDS) lies in its ability to reach out to frontline healthcare professionals, in particular 6 million nurses in Europe, to be shaped with them, to be accepted by them and to respond to their unmet needs.

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<sup>15</sup> EFN Policy Statement on End-user co-designing EU digital health systems (2019). <http://www.efn.eu/wp-content/uploads/EFN-Policy-Statement-on-end-user-co-designing-EU-digital-health-systems-22-10-2019.pdf>