

## **NORDeHEALTH - Learning from the Nordic Experiences of Patient Online Record Access**

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## Abstract

The Nordic countries are forerunners in online record access (ORA) which has now become widespread. The importance of accessible and structured health data has also been highlighted by policymakers internationally. To ensure the full realization of ORA's potential in the short and long term, there is a pressing need to study ORA from a cross-disciplinary, technical, clinical, humanistic, and social sciences perspective that looks beyond strictly technical aspects. In this viewpoint paper, we explore the policy changes in the European Health Data Space (EHDS) proposal to advance ORA across the European Union, and introduce a Nordic-led research project that carries out the first of its kind, large-scale international investigation of patients' ORA; NORDeHEALTH. We argue that the EHDS proposal will pave the way for patients to access and control third-party access to their electronic health records (EHRs). This will have implications within Europe and globally as it will further extend the boundaries for accessing and using EHRs for primary and secondary data use. Research such as that led by the NORDeHEALTH project is essential in guiding the design and implementation of solutions to meet the requirements of the EHDS proposal. Further international collaboration and research are needed to ensure that socio-technical and contextual factors are considered to ensure successful and secure implementation.

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## Original Manuscript



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## Abstract

The Nordic countries are forerunners in online record access (ORA) which has now become widespread. The importance of accessible and structured health data has also been highlighted by policymakers internationally. To ensure the full realization of ORA's potential in the short and long term, there is a pressing need to study ORA from a cross-disciplinary, technical, clinical, humanistic, and social sciences perspective that looks beyond strictly technical aspects. In this viewpoint paper, we explore the policy changes in the European Health Data Space (EHDS) proposal to advance ORA across the European Union, and introduce a Nordic-led research project that carries out the first of its kind, large-scale international investigation of patients' ORA; NORDeHEALTH. We argue that the EHDS proposal will pave the way for patients to access and control third-party access to their electronic health records (EHRs). This will have implications within Europe and globally as it will further extend the boundaries for accessing and using EHRs for primary and secondary data use. Research such as that led by the NORDeHEALTH project is essential in guiding the design and implementation of solutions to meet the requirements of the EHDS proposal. Further international

collaboration and research are needed to ensure that socio-technical and contextual factors are considered to ensure successful and secure implementation.

**Keywords:** Patients' Online Record Access; Open Notes; Electronic Health Records; Patient Portals; European Health Data Space

## Introduction

Digitalization of healthcare is increasing rapidly, changing the way patients communicate and collaborate with healthcare providers. The importance of access to and use of digital health data became even more evident during the Covid-19 pandemic (1), including the use of online patient portals, and patients' online record access (ORA) (2). The Nordic countries are forerunners in providing their residents with online tools that enable interaction not only with healthcare but also with the patient's own health data (3). ORA has become a key means to these ends (4–6). National patient portals have been implemented in all Nordic countries, enabling residents to access different health-related e-services, e.g. patient-accessible electronic health records (PAEHRs). Table 1 provides an overview of key concepts related to patients' ORA that will be used in this paper.

In many countries, ORA is considered a logical extension of patients' already existing legal rights to request copies of their health records. ORA provides a rapid and convenient method of accessing the information held by clinicians that increases the total number of patients who read their records. Considering the growing body of evidence presenting the benefits of ORA for the individual (in terms of improved health outcomes and self-management) (4–8), we argue that health organisations in other countries can learn from the Nordic experience, and should also consider striving to provide patients' ORA (9).

### Textbox 1. Key terminology

**Electronic health record (EHR)**

The WHO defines EHRs as *"shared patient records that contain historical data about a patient that are compiled from all local Electronic Medical Records"* (10).

**Patient-accessible EHR (PAEHR)**

PAEHRs are online services providing patients secure access to view and sometimes edit or comment on their Electronic Health Records (EHRs) made available by their health care providers (5), i.e. ORA.

**European Health Data Space (EHDS)**

The European Health Data Space is a health-specific ecosystem comprising rules, common standards and practices, infrastructures, and a governance framework (11).

**Open notes**

Online access to the visit note summaries, or the narrative, free-text entries, written by clinicians about patient health.

**Online record access (ORA)**

ORA has been used as a *"solution-neutral"* concept to describe the phenomenon of patients' online record access (12). ORA can be implemented through a PAEHR or any other technical system that gives patients access to their health records online.

**Patient portal**

Patient portals are online portals that can be provided locally by a specific healthcare provider, or nationally as is the case in the Nordic countries. Patient portals are increasingly used to provide patients with ORA. In some patient portals, a PAEHR is provided as a specific service (13), whereas others may have more seamlessly integrated ORA through different patient portal functions. In a local patient portal, patients often have ORA to only one specific EHR system, whereas national patient portals can provide ORA to several EHR systems.

In parallel with the increased use of digital health services, the importance of accessible and structured health data has also been highlighted by policymakers internationally. In the US, a federal rule in the 21st Century Cures Act mandated US healthcare providers offer patients access, with few exceptions, to all the health information in their electronic medical records without charge (14). The 21st Century Cures Act is also motivated by the idea of a health app economy, and it is mandated that patients' health information should be available in a form that is downloadable to third-party apps. In Europe, the proposal for an EHDS aims to both empower people to control and utilise their health data in their home country or other member states, as well as offer "a consistent, trustworthy and efficient framework to use health data for research, innovation, policy-making, and regulatory activities, while ensuring full compliance with the EU's high data protection standards" (11). Furthermore, the EU has adopted the NIS directive (EU 2022/255), which sets requirements for security in networks and information systems. The rules cover providers of socially important services and certain digital services where healthcare is a designated sector (15).

Despite growing international evidence that ORA has the potential to empower patients and yield many health benefits, its implementation has not always been straightforward (16,17). Not all patients use online portals (4,5,7,18), and ORA remains controversial among providers (12,19). Healthcare professionals have raised concerns regarding patient ORA in several contexts where it has been implemented (12,20–23); The concerns include that patients might misunderstand what they read, become worried, and that clinicians' workload will increase as patients ask more questions, both during and between appointments. Within mental health care, such concerns have been especially prominent (19,22,24).

Despite clinicians' concerns and the need for a more fine-grained policy concerning e.g. proxy access (25) and psychiatric care (26), and ethical exemptions from ORA (27), mounting international experience challenges clinicians' scepticism and evinces the benefits to patients of this practice innovation (28). Nonetheless, as the shift towards giving patients more autonomy over their health data is under way, there is an urgent need to address more contested aspects of ORA. Doing so may simultaneously offer guidance to other countries as well where implementation is currently lagging behind. We argue that to ensure the full realisation of its potential in the short and long term, there is a pressing need to study patients' ORA from a cross-disciplinary, technical, clinical, humanistic, and social science perspective that looks beyond narrow technical aspects of implementation (29). In this Viewpoint, we explore the policy changes in the EHDS proposal to enable ORA and introduce a Nordic research project that carries out the first large-scale international investigation of ORA.

## **The European Health Data Space (EHDS) and patient online record access**

The EHDS proposal aims to "*improve access to, and control by, natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalized medicine, official statistics or regulatory activities (secondary use of health data)*" (11). 'Natural person' is a legal term used to signify an individual human being,



distinguishing them from a ‘juridical person’, which can encompass other entities too. We will use ‘person’ in our text to signify a ‘natural person’, unless in a direct quote from the EHDS proposal. Primary use of electronic health data is the main focus of patients’ ORA, and is further defined as the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products, and medical devices, as well as for relevant social security, administrative, or reimbursement services.

Embedded within the EHDS Chapter 2, Primary use of electronic health data, section 1, article 3 describes the “rights of natural persons in relation to the primary use of their personal electronic health data” (11). Through our work, we have identified five key principles in the EHDS of high relevance for patient ORA, where ongoing research in the NORDeHEALTH project may contribute to important input to the design and implementation of the EHDS across Europe. The five principles we highlight here are: i) the right to access, ii) proxy access, iii) patient input of their own data, iv) error and omission rectification, and v) access control.

## Lessons from the NORDeHEALTH research project

The NORDeHEALTH (Nordic eHealth for Patients: Benchmarking and Developing for the Future) research project was launched in 2021, with the aim to identify challenges and opportunities in the digitalization of health services, especially after the implementation of national portals which offer to give ORA (see Textbox 2). The project, funded by NordForsk [grant nr 100477], has research partners in Sweden, Norway, Finland, Estonia, and the US. The goal is to enable further digitalization of the public health sector by providing concrete feedback to the national authorities in the respective countries, providing guidelines and frameworks for the design, implementation, and evaluation of patients' ORA as well as other eHealth services.

### Textbox 2. NORDeHEALTH project aims.

**Aim 1.** Study the current implementation and adoption of patients’ online records access (ORA) in the Nordic countries to create new knowledge and an in-depth understanding of challenges and opportunities.

**Aim 2.** Develop evidence-based evaluation frameworks and guidelines to help researchers and practitioners within and beyond the Nordic countries evaluate ORA and its acceptability, and support successful implementation and adoption.

**Aim 3.** Explore factors around the co-design of ORA and patient portals through innovation projects focusing on patient-generated data and tools for patients’ co-creation of the electronic health record.

The foundation for the NORDeHEALTH research project is a socio-technical analysis of the context in the respective country using a model proposed by Sittig and Singh (29,30). Key focus areas have included policy and regulations for patients’ ORA in mental healthcare (31–33), ORA for adolescents and parents (25,34), and ORA within oncology specifically focusing on multi-disciplinary team conferences. The project also investigates benchmarking for the usability and acceptance of national patient portals and patients’ ORA, which iteratively feeds into the co-design of novel ORA and patient portal functionality.

Empirical data in the project is gathered by exploring the needs of specific patient and demographic groups using the current implementations of PAEHRs as a case; mental health patients, cancer

patients, and adolescents and their caregivers. Most research into patient ORA to date collects data from one country or region (4–7), making it difficult to compare results across contexts. In the NORDeHEALTH project, we have therefore designed an international cross-sectional survey study, and in 2022 data was collected simultaneously in Sweden, Norway, Finland, and Estonia (35). The aim of the survey is to study patients' experiences with the PAEHR provided through the national patient portals in the respective country. In parallel with the international patient survey, qualitative interviews with healthcare professionals working in psychiatric care are performed in Sweden, Norway, and Finland, and a survey of healthcare professionals' experiences of patient ORA in oncology is also being performed. Patients' and family carers' views, knowledge, and stewarding of their own health data are also analyzed from privacy and information security perspectives.

The NORDeHEALTH research provides essential knowledge for successfully implementing the EHDS proposal regarding patient ORA. Table 1 provides an overview of how the NORDeHEALTH research contributes to the identified patient ORA principles of the EHDS; i) the right to access, ii) proxy access, iii) patient input of their own data, iv) rectifying errors and omissions, and v) access control. In the next sections, we further deepen the analysis of the five principles.

**Table 1.** Alignment of the NORDeHEALTH project with the EHDS principles

<b>EHDS principle</b>	<b>NORDeHEALTH research</b>
The right to access	<ul style="list-style-type: none"> <li>- Socio-technical analysis of current implementations of ORA</li> <li>- Usability and acceptance</li> </ul>
Proxy access	<ul style="list-style-type: none"> <li>- Current regulations for proxy access</li> <li>- Experiences of parental proxy access and adolescent access</li> </ul>
Patient input of their own data	<ul style="list-style-type: none"> <li>- Current functionalities for patient-generated health data</li> <li>- Patient needs and co-design of new functionalities</li> </ul>
Error and omission rectification	<ul style="list-style-type: none"> <li>- Extent of patient-identified errors and omissions</li> <li>- Patients' needs and current strategies for rectification</li> </ul>
Access control	<ul style="list-style-type: none"> <li>- Current implementation of patients' access control</li> <li>- Patients' experiences of unwanted access</li> </ul>

## The right to access

The EHDS proposal clearly states that “natural persons shall have the right to access their personal electronic health data” immediately, free of charge, and in an easily readable, consolidated, and accessible form (11). This is not limited to EHR data, but considering the EHRs core role for documentation in healthcare, patients' ORA must be considered essential for EHDS. Article 3, paragraph 2 continues to declare that:

*“natural persons shall have the right to receive an electronic copy, in the European*

*electronic health record exchange format [...] of at least their electronic health data in the priority categories referred to in Article 5” (11).*

These include patient summaries, electronic prescriptions, electronic dispensations, medical images and image reports, laboratory results, and discharge reports.

Many European countries already have legislation stipulating that patients should have ORA (16). In Norway, the patient is both the object and the owner of the health record. The Norwegian Patient Right Act of 2001 states that patients have the right by law to access their health records (36) and, in 2013, a White Paper stated that patients should have digital access (37). Similar legislations are in place in all the Nordic countries (16).

In Germany, the Patient’s Rights Act of 2013 stipulates that healthcare professionals must document diagnosis and treatment promptly and comprehensively. It grants patients the right to fully view their records and attain an electronic copy (38), yet progress in implementing patients’ ORA has been slow. In the Netherlands, patients have had the right to a digital copy of all the information in their EHRs since 2020 (17), and different types of incentive programs have been implemented to encourage healthcare providers to provide such access.

Given the current challenges in implementing patients' full ORA across Europe, the EHDS proposal is ambitious. Mandating patients’ ORA is to be broadly encouraged, considering the positive experiences reported by patients with full ORA, but experiences show that regulations are often not enough to ensure implementation.

The NORDeHEALTH project has designed and tested a socio-technical framework for studying and comparing factors that affect the implementation and adoption of patient ORA. The framework was designed based on the existing Sittig and Singh socio-technical framework (30). ORA-specific factors are explored related to e.g. what information patients have access to and when they can access it (immediately or with a delay), what functionality is provided (e.g. being able to upload or edit information, proxy access), rules and regulations for ORA (on national or local levels), the usability of the PAEHR, technical infrastructure, and population characteristics (e.g. educational levels, digital literacy, and diversity). An in-depth understanding of the local socio-technical context is essential for comprehending the impact of ORA, and to be able to design successful interventions for implementing ORA.

We argue that simply providing ORA may not be enough to ensure that all patients can use it. Usability is a key factor for the adoption of ORA (39). Therefore, the NORDeHEALTH project strives to benchmark PAEHR usability (6) and investigating how it affects the acceptance and adoption of PAEHRs among different patient groups.

## **Proxy access**

In the EHDS proposal, proxy access is described in Article 3, paragraph 5. Member States shall:

*“establish one or more proxy services enabling a natural person to authorize other natural persons of their choice to access the electronic health data on their behalf.” (11)*

This includes guardians and other representatives, either automatically or upon request. With a growing population of older people (>60 years) seeking health care services, many of which are likely to have (multiple) chronic conditions, the demands on health and social care services are increasing (40). However, the time that individuals with chronic conditions seek health and social care represents only a fragment of their 24/7 lived experience of coping with a chronic disease. As we grow older, we often become increasingly dependent on psychosocial and/or physical support outside of formal health care services, but this is far from only an issue for the old. Parents, especially of children with chronic or life-threatening conditions, have an instrumental role in their children’s care and report great benefits from ORA (34) when it is available. Having a (strong) social network and informal caregivers (e.g. family and friends), especially in times of life-changing illness

could mean the difference between survival and death (41).

Despite informal caregiving being an essential part of healthcare, it is rarely given a lot of credit. In fact, the vast majority of caregiving is informal, and it is undertaken by family members free of charge and with no support provided for them, often at great burden (42,43). Thus, healthcare outcomes highly depend on the competence and ability of the informal caregivers. Still, informal caregivers are often left out of the conversation (44), not the least when digitalization is introduced, and informal communication needs to be formalised.

In the NORDeHEALTH project, ongoing research into proxy access focuses on how parental ORA differs between the participating countries (25) and what this could mean for streamlining proxy access across Europe. Further studies on parental proxy access and adolescents' ability to deny access in certain situations are in process. For general proxy access, there is even greater diversity across countries and even less research available. Internationally, when patients are given online access to their records they are often given the option to share their records with a proxy if needed, usually a close family member such as a spouse or adult son/daughter (45). In a US study, 2 out of 3 surveyed hospitals offered adult patients the option of granting portal access to an informal caregiver, but among hospitals that did, the process for obtaining proxy credentials was often difficult and time-consuming (46). In the original Swedish implementation of ORA, patients could assign a proxy to be able to access their records. This function was available after secure login to the record, and the patient could assign access to any person in Sweden by adding the social security number of the person, and choosing what parts of the PAEHR to share (47). Despite this flexibility of the solution, the Swedish Authority for Privacy Protection requested the function be shut down, and after several appeals from Region Uppsala the Supreme Administrative Court in Sweden finally decided to prohibit the function where patients can share their information with others, finding it to be in conflict with the Patient Data Act (A part of Swedish Data Protection Act (2018:218) and Swedish Data Protection Regulation (2018:219) that entered into force on 25 May 2018 (48)), which refers to allowing only patients themselves direct access to their medical records – not someone else (47).

## Patient input of own data

Article 3, §6 of the EHDS proposal states that:

*“natural persons may insert their electronic health data into their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be marked as inserted by the natural person or by his or her representative.”* (11)

Although the Nordic countries are advanced in providing ORA, entering health data into the EHR is not widely implemented. Swedish patients could previously comment in their electronic health records (49), but this function was removed in 2022 due to technical problems related to initial implementation of the feature. In Finland, patients can save health data to their personal health record via wellbeing applications, but the function is in limited use, only certain applications are accepted, and the data are not yet available to healthcare professionals (50). Furthermore, patients in both Finland and Sweden have asked for more interactivity to their health records, such as the possibility to comment on the notes or request corrections (4,6).

In the NORDeHEALTH project, we explore how patient input to the EHR might become better designed to adequately meet this function. The EHR has traditionally been available to healthcare professionals only. Patients report many positive effects from accessing their records, yet to fully achieve the potential benefits of digitalization we need to further explore how EHRs can shift from being solely a documentation tool for health professionals to a tool for secure collaboration and communication with patients and family caregivers. Here, national patient portals and additional digital services will complement the future development of the EHRs into collaborative, person-

centred tools.

NORDeHEALTH focuses on studying novel digital services and innovation, exploring different ways to make the national patient portals and patients' ORA more useful to both patients and healthcare professionals, supporting person-centred care, patient self-management, and empowerment as well as collaboration. As digitalization is about more than making electronic versions of analog work, and we investigate different ways to use the power of digitalization, including

- patient input to the EHR in narrative form, e.g. patients commenting on notes or contributing with descriptions of their symptoms,
- patient-created structured data, e.g. patient-reported outcome or experience measures - PROMs and PREMs and,
- integration of data and services from third-party applications, e.g. self-tracking data, and decision support.

### Rectifying errors and omissions

The EHDS proposal, Article 3 §7, stresses that Member States shall ensure that:

*“natural persons can easily request rectification online” (11).*

In a U.S study of 22,000 patients who read their notes, one in five reported finding an error, and 40% of those perceived the error to be serious (51). The most common errors were related to diagnoses, medical histories, medications, test results, notes on the wrong patient, and notes pertaining to the wrong side of the patient's body (left vs right). Erroneous records may contribute to diagnostic errors that are common in healthcare (52), between one in twenty to one in every six medical consultations results in missed, wrong, or delayed diagnoses (53). Most diagnostic errors relate to common conditions such as congenital heart failure, pneumonia, and urinary tract infections (54). Research also shows repeated, missed opportunities to detect cancer (55,56).

Patients have so far had a marginal role in diagnostic processes, as acknowledged in the U.S. National Academy of Medicine's (NAM) report “Improving Diagnosis in Health Care”. The report prompts a deeper discussion about the role of patients in closing feedback loops on care and helping to avoid mistakes that can lead to diagnostic errors, and ultimately patient harm (57). Patient ORA is cited as a mechanism for improving diagnostic accuracy (57) and has been described by medical safety experts as a “transforming concept” in patient safety (58). Emerging research supports these conclusions (8,59,60). Patient ORA may help patients avoid delays and missed diagnoses by encouraging timely follow-up of recommended tests, results, and referrals (51). Patients with ORA who identify and report errors could prevent clinicians from relying on incorrect data that may lead to poor diagnostic or treatment decisions, or even legal liability (61). A meta-analysis of 20 ORA-related randomised clinical trials (involving 17 387 patients) supports the conclusion that ORA could improve patient safety (8). Most research to date on patients' ORA and documentation errors has been performed in the US with a remarkably different medico-legal system from the European one. In this respect, the NORDeHEALTH research complements the existing research and provides important evidence for the usefulness of patient ORA in patient safety work in contexts dominated by public healthcare provision.

In the NORDeHEALTH patient survey (35), we explore the extent to which patients in Sweden, Norway, Finland, and Estonia find errors or missing information in their PAEHR, and the action they have taken in these situations. The results from these studies will help guide the further implementation of the EHDS with respect to the management of errors and missing information.

## Access control

Finally, EHDS proposes increased access control for patients, to be able to request that electronic health data be made accessible to actors in the health or social security sector, and also to have the right to restrict access.

*“Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their choice from the health or social security sector, immediately, free of charge, and without hindrance from the data holder or from the manufacturers of the system used by that holder”*  
Article 3, §8 (11)

*“[...] natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data.”* Article 3, §9 (11)

The Swedish Agency for Health and Care Services Analysis (62) also reports that the majority of the population accepts and wants digital data about their own care and health to be used so that it is useful, including for safer care and research. At the same time, it is important that the data is handled securely and protected from unauthorized access.

In the NORDeHEALTH 2022 patient survey (35), questions related to sharing of the respondents' records were asked, as well as unwanted record access, or requests for unwanted record access. Among the Swedish respondents, 4% of respondents (501/12334) answered that they had experienced that someone had seen their health records without their consent (63), a finding that requires further analysis. Although 4% can be considered a low number, it stands in stark contrast to the clear message from policymakers that unauthorized access should not occur (10, 11). Unauthorized access can reduce both patient safety and trust in healthcare, but also erode opportunities for secondary use of health data. Existing controls for information security and privacy, therefore, need to be improved. Further results regarding the management of information security and privacy in healthcare will therefore be presented from the NORDeHEALTH project.

## Conclusions

We argue that with the realisation of the European Health Data Space, patients' opportunities to access and control third-party access to their EHRs are likely to change dramatically. The EHDS policy change has implications not only within Europe but also globally as it will likely serve as an example to further push the boundaries for accessing and using EHRs for primary and secondary use. Research such as that performed in the NORDeHEALTH project offers important firsthand insights and will be essential to inform the design and implementation of ORA to meet the requirements of the EHDS. However, further international collaboration and research, and dedicated funding, is needed to achieve a comprehensive understanding of socio-technical and contextual factors necessary to consider for ensuring its successful, secure, and ethical implementation.

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## Conflicts of Interest

None declared.

## Abbreviations

EHR: Electronic Health Record

ORA: Online Record Access

PAEHR: Patient Accessible Electronic Health Record

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