

The EHR as an Instrument for Effective Digital Transformation in the Post COVID-19 Era*

Dimitrios G. Katchakis¹[0000-0002-3763-191X] and Angelina Kouroubali¹[0000-0002-3023-8242]

¹ Institute of Computer Science, Foundation for Research and Technology – Hellas,
Heraklion, Greece
{katehaki, kouroub}@ics.forth.gr

Abstract. The coronavirus pandemic of 2019 has accelerated the shifting of attitudes of health and social care professionals towards digital technology use, mainly through online consultations and telemedicine services, aiming at the decongestion of health units. While the improvement of patient experience becomes a higher priority for healthcare professionals, the need for online access to one's electronic health record (EHR) remains within the top policy priorities in Europe. This is due to the anticipated benefits from the use of the EHR that include better support of medical decisions, patient empowerment via online access to clinically significant information, enhancement of vendor potential to introduce innovative tools, and acceleration of evidence-based research. The authors of this paper highlight quality EHR characteristics, within the wider context of the European digital single market, towards supporting continuity of care. Key challenges addressed include the linking of electronic medical records with the medical practice workflow, building trust and acceptance, and the assurance of appropriate resources needed to support digital transformation sustainability in a coordinated manner. These topics are examined in conjunction with digital transformation initiatives that continue to accelerate in the post-pandemic era, such as artificial intelligence, cloud computing, blockchain, enterprise resource planning software, and 5G.

Keywords: Continuity of Care, Patient Safety, Health Information Exchange.

1 Introduction

Over the past two years, the coronavirus pandemic (COVID-19) accelerated the adoption of digital solutions [1, 2] in an effort to mitigate its impact. As a result, many mobile and other apps have been developed to support education, the exchange of information, risk assessment, self-management of symptoms, contact monitoring and decision making, offering easy to use and effective pandemic support digital tools [3]. The pandemic has amplified the need for care provision outside the traditional healthcare settings, facilitating patient self-monitoring using various connected devices, and

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digital therapeutics that can deliver interventions via apps. Under this context, improving the patient experience is becoming a higher priority for healthcare professionals.

Typically, providers (i.e. physician offices, clinics, and hospitals) use the electronic medical record (EMR) for keeping notes and information such as medical history, diagnoses, medications, allergies, and immunizations for diagnosis and for treatment purposes. Even though EMRs enable providers to track data over time, identify patients for preventive visits and screenings, monitor patients, and improve healthcare quality [4, 5], they were not designed to be shared outside the individual practice [6, 7]. Furthermore, market fragmentation and lack of interoperability across health systems hinder the potential of EMRs to contribute towards an integrated approach to disease prevention, care and cure.

The use of the electronic health record (EHR) requires specific user and system attributes and numerous organizational and environmental facilitators. Healthcare providers play a critical role in adopting and utilizing health information technology (IT), including EMRs in hospitals. However, many healthcare professionals, from nurses to ambulatory care physicians, are still reluctant to use the available technologies, leading to limited system use and, eventually, system failure [8, 9].

As EHRs evolved, they became a digital tool containing the information collected from all the clinicians involved in a patient's care and could be potentially accessed by all authorized clinicians to provide care to that patient, going beyond standard clinical data collected in clinical settings [10]. Secure access to a comprehensive EHR anywhere in the European Union (EU) will enable citizens to share their health data for medical treatment, preventive services, and research, irrespective of where the data is located and in line with data protection legislation. EHRs can follow patients – to the specialist, the hospital, the nursing home, across or even beyond the country borders [11, 12], while at the same time they can assist in promoting legible documentation and improved productivity.

The growth of mobile computing leads to the need for an integrated method of storing health-related data that can be used by healthcare providers and patients [13]. The increased demand by patients to access their healthcare data has led to more personal use of the EHR. The personal health record (PHR) is now interfaced with EHR applications and facilitating care continuity. The PHR, on the contrary to the EMR and the EHR, is not a legal record. PHR enables integrating main information components in the EMR and EHR systems [14]. Connecting to the EMR requires establishing interfaces to link islands of information based on specific workflows and semantically homogenizing the produced information [15]. The new medical devices regulation (MDR) in Europe is expected to increase the evidence required to receive conformity, which is a prerequisite for use and reimbursement in Europe. Developers of innovative solutions will need to invest heavily in generating clinical (i.e. EHR) data if they want to market digital therapeutics after 2020.

The objective of this work is to describe the means for effective use of the EHR as an instrument to support digital transformation in the post-COVID-19 era. The authors propose specific directions for implementing quality EMRs in line with international developments, the need for improved care for major chronic conditions, and equal access to high quality health services for all citizens.

2 Quality Electronic Health Record Characteristics

The EHR is considered an essential tool for improving both the safety and quality of healthcare. The gains from EHR systems depend on meaningful sharing, access to information regardless of place and time, and reuse of information for multiple purposes [16]. These result in less time searching for information and more quality time with patients. Improved organizational efficiency and secondary data uses are typically amongst the most commonly expected benefits [17]. However, physicians must actively use these systems to accrue the benefits [18].

Patient-centered and patient owned medical records are known as PHRs. They were introduced as an enabler for the self-management of medical records and can serve as a lifelong record of health. They support the shift from institution-centered care to citizen-centered care, emphasizing continuity of care, prevention and management of chronic conditions [19]. PHR information is expected to be sent, received, or exchanged from multiple systems, including EHR, insurer, payer, public health, clinical trials, and collaborative care systems. The EHR consists of components implemented according to measurable and realistic benefits, including PHR information. It includes wellness information and nontraditional links to external knowledge, like guidelines, protocols, and genetic information. It extends beyond the boundaries set by a single healthcare organization and is primarily created and managed by healthcare professionals.

In recent years, several countries move towards developing national infrastructures to support the development of legitimate, state-controlled EMR and EHR adoption using standardized access protocols. Some prominent initiatives include My Health Record in Australia, Elektronische Gesundheitsakte in Austria, E-health records in Estonia, Kanta digital services in Finland, The Electronic Patient Record in Switzerland, the Sequoia Project in the United States, as well as the eHealth Digital Service Infrastructure run by the European Commission Connecting Europe Facility.

National implementations of the EHRs offer the ability to electronically exchange health information across healthcare structures of the national health sector. Expected benefits can be characterized as clinical (e.g. quality of care, reduced errors, more patient safety and continuity of care), organizational (e.g. improvements in the efficiency of service delivery, including financial and operational performance), and societal (e.g. research and public health) [20]. To achieve these benefits, the systems that feed information to the EHR should be responsive to the complexity of the environment, tailored to user needs, and have the capacity to communicate with each other in the context of the automation of operational processes.

3 The European Digital Single Market

The European digital single market strategy is built on three main objectives: (i) to provide better access to digital goods and services across Europe; (ii) to create the necessary conditions for digital networks and innovative services; and (iii) to maximize the growth potential of the digital economy. In line with this strategy, the European Commission has created policy guidelines towards the digital transformation of health and

care to empower citizens and build a healthier society. Building upon precedent initiatives, the digital transition aims towards benefiting everyone, putting people first and opening new opportunities for business. Health is one of the sectors included in this agenda, given the potential benefits that digital services have to offer citizens and enterprises in this area. Within this context a target to have 100% of European citizens have access to medical records (e-records) has been set by the Commission. Towards that direction it is expected that the ability for European citizens to access, and control access to, their EHR across the EU should be greatly improved by 2030. This is expected to require systems to follow certain principles throughout their lifecycle, from conception, to design, to implementation:

- digital-by-default, to provide services and data via digital channels;
- cross-border-by-default, to be accessible by all citizens in the EU;
- open-by-default, to enable reuse, participation, access and transparency;
- secure-by-design in compliance with the legal requirements and obligations; and
- interoperable-by-design as a standard approach for the design and operation of European public services.

Relevant interoperability principles and a clear implementation roadmap act as facilitators for the development and implementation of EMRs, to enable healthcare providers to share health data outside their organization [21]. Interoperability governance proposes and guides the change management practices that need to be implemented and establishes foundations for sustainability of interoperability.

3.1 The European Electronic Health Record Exchange Format

The interoperability of EHR systems of member states can be supported with the development and adoption of the European EHR exchange format (EEHRxF), which is based on open standards, taking into consideration the potential use of data for research and other purposes [22]. The framework includes: (i) a set of principles that should govern access to and exchange of EHRs across borders in the EU; (ii) a set of standard technical specifications for the cross-border exchange of data in particular health information domains, which should constitute the baseline for an EEHRxF; and (iii) a process to take forward the further elaboration of an EEHRxF. The European EEHRxF has the potential to facilitate the cross-border interoperability of EHR systems and provide European citizens secure access to and exchange of health data across the EU. Incentives for its wider adoption and other measures to tackle the lack of interoperability will help promote the strategic priorities of the single digital market in this area.

Interoperability increases the value of data. In the long term, medical images, lab results and hospital discharge reports are expected to be available across the EU, with the entire health record to follow later on. Data-driven applications will benefit citizens and businesses in many ways, including improving health care, generating new products and services, and reducing the costs of public services. In that respect, the Commission has proposed a regulation on European data governance as part of its data strategy. The new rules will allow this data to be harnessed and pave the way for sectoral European data spaces to benefit society, citizens and companies. A European health

data space is expected to improve safe and secure accessibility of health data allowing for targeted and faster research, diagnosis and treatment. The EU is already expanding EEHRxF to supply quality data, facilitating access to public services.

3.2 Privacy & Security Considerations

Due to the fact that health data are considered to be particularly sensitive, privacy and security concerns present the largest and most important barrier to EHR adoption. Security safeguard measures are centered around physical, technical, and administrative methods [23, 24] that could be implemented to prevent unauthorized access to EHRs. Due to the fast introduction of technology advancements, vulnerabilities are constantly being identified, and new threats are emerging. According to [25], ransomware remains at the center of concern. Effective cybersecurity controls have to be applied to protect the availability, authenticity, integrity, and confidentiality of data.

Typical cloud security challenges that need to be addressed include the lack of trust, lack of security and technology expertise, lack of investments, as well as difficulties related to the integration of cloud with legacy systems [26-28]. The report on cloud security for health services by the EU agency for cybersecurity [29] helps healthcare organizations securely adopt cloud services and prepare for cybersecurity challenges. To this direction, specific legal requirements in respect to privacy & data protection, including the general data protection regulation (GDPR), the network and information systems (NIS) directive, the European cybersecurity act, MDR and the electronic cross-border health services directive, need to be established, aligned and enforced.

Data encryption protects against data breaches, whether the data is in transit or at rest. Password protection is necessary for maintaining data privacy. Use of audit trails to review the data at regular intervals and flag access to information that seem suspicious. This way patients can report breaches as soon as they happen.

The development of a national EHR to support the needs of an NHS requires the existence of an integrated vision for the provision of health care, which includes the creation of criteria and specifications for the selection of EHR systems, but also the provision of protection of personal data (consent management). This inevitably requires standardization of quality for all EHR products available in the market based on international practices (e.g. certification for functionality, but also for interoperability).

3.3 Artificial Intelligence

Global efforts to manage COVID-19 have shown that the use of healthcare data is increasing exponentially when it can be interconnected, combined and communicated. A future eHealth system is expected to support organized and complete data recording, care anytime anywhere, and use of advanced analysis, to support the transition from digital to smart systems [30]. This cannot be achieved without interoperability.

The recent pandemic crises forced several hospitals, in response, to shift their investments and priorities towards enhancing their interoperability capabilities, and the development of virtual health and digital solutions to provide offerings that enable the shift of patients out of the hospital by improving consumer experience.

Smart hospitals adopt an integrated vision focusing on digital transformation from digital health services to smart health services, by supporting technologies such as artificial intelligence (AI), virtual reality (VR), connected devices, blockchain, robotics, etc. This vision includes creating mutually interconnected and harmoniously co-functioning EMRs, which would connect industry and service providers. Further, for a truly integrated digital health service, this vision includes EMR systems connected to a national EHR, to digital health services such as remote patient monitoring and health apps, and the possibility to capture information for data analysis towards the generation of patient and population health insights.

AI technologies can support socially and environmentally beneficial outcomes and provide critical competitive advantages to companies and the European economy. Such action is especially needed in high-impact sectors, such as health. However, the same elements and techniques that power the socio-economic benefits of AI can also bring about new risks or negative consequences for individuals or society. The recently introduced AI act presents a balanced and proportionate horizontal regulatory approach to AI that is limited to the minimum requirements to address the risks and problems linked to AI without unduly constraining or hindering technological development or otherwise disproportionately increasing the cost of placing AI solutions on the market.

4 Solutions and Recommendations

Large amounts of health data of every citizen are stored in national and regional digital health systems. The majority of these data continue to be confined in data silos [31]. Key challenges for implementing quality EMRs, relate to (i) linking information systems with the clinical and operational workflow through open and secure interfaces; (ii) engaging champions and key stakeholders; and (iii) securing the financial means for the digital transformation and sustainability (Fig. 1).

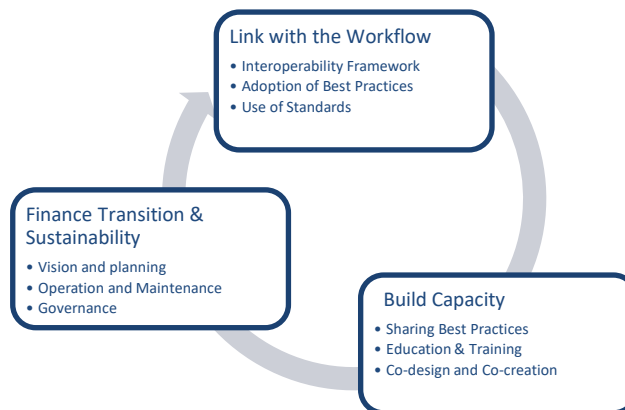


Fig. 1. Key EMR adoption challenges towards using the EHR as an instrument for effective digital transformation in the post COVID-19 era.

4.1 Link with the Workflow

Designing systems that are poorly integrated into workflow may promote workarounds that bypass safety features [32]. Linking information systems with the clinical and operational workflows, requires adopting an interoperability framework tailored to national needs, exploiting available best practices and open standards based on planning.

Due to COVID-19, it has become increasingly clear that data exchange can raise the quality of care. Besides having established appropriate national infrastructure, such as a national EMR, all relevant legal and regulatory enablers need to be in place. This is a strategic approach that needs to be further supported at all levels, technical, semantic, organizational, and legal [33]. According to [34], countries have already prepared to have established in the next five years interoperating EHRs, through national digital health networks allowing total coverage for their populations. Modern patient care depends on a number of different medical devices (such as such as monitors, ventilators, and infusion pumps interfaced to EHRs through custom interface applications) in order to monitor a patient's vital signs, infuse medications, and maintain life support. The vision is to have a country with all hospitals connected to real-time EHR platforms where all patients have their own and secure cyber portal, achieving full interoperability, supported by sustainable and scalable platforms for digital health.

Digital technologies such as 5G mobile communication, artificial intelligence and supercomputing offer new opportunities to transform the way health and care services are delivered. They enable innovative approaches to independent living and integrated health and social care.

4.2 Build Capacity

The health interoperability ecosystem comprises individuals, systems and processes that want to share, exchange and access all forms of EHR information and as such the EHRs should be seen as an inseparable part of the healthcare process. Innovative technologies alone cannot lead to revolutionary changes. Topics to be addressed towards building capacity for the widespread utilization of EHRs include promotion of best practices, skills development through education and training, and designing user-centric services using co-design and co-creation.

Qualified human resources are a vital ingredient for success. Education, training, and continuous professional development for all, including those citizens and patients who are capable and motivated to become engaged in their care, should be strongly promoted [35]. An important factor influencing user adoption is user confidence. Professionals should be encouraged with a transparent motivation system and a detailed presentation of realistically envisioned benefits [36]. The production of communication guidelines and learning objectives that can reach different audiences is essential for the assimilation of innovation [37]. A culture of sharing, trust and collaboration with other healthcare professionals and patients still needs further building.

Resistance to the changes inflicted by digitization is common in many countries [38]. Physicians, in particular, often act as veto players. Therefore, a clear framework that fosters acceptance drives developments towards better patient treatment generates

benefits for the patients themselves and those engaging in secondary use. Therefore, continuous training and education in the logic of the constant improvement of available standards and processes are considered to be essential. Clear strategic objectives need to include emphasizing and adopting best practices, providing support to users, improving the quality of available solutions and establishing co-creation processes with all stakeholders involved.

Patients are the ones who are expected to benefit most from the use of EHRs. For this to happen, EMRs must be in a position to interoperate with each other and encompass intelligence. Social networking tools already enable patients to find each other, support each other, learn from each other and help each other make decisions. From the perspective of patients, it is evident that solutions for sharing medical information electronically are needed. Widespread adoption will require to provide with clear benefits to clinical activities. At the same time, they need to make the professionals' lives easier, not more complex.

4.3 Finance Transition and Sustainability

Sustainability requires governance, operation and maintenance under certain service level agreements, planning, and vision. Quality and secure EHR deployment do not come without cost and achieving interoperability requires government involvement, guidance and regulation. Funding should be provided and assured, while responsibilities for sustainability should be clearly defined [39].

As mentioned in [38] most funding schemes for digital healthcare solutions and services are made for an analogue age. Caregivers are paid based on the patients' visit and the care they provide, without considering the value of preventing damage, reducing costs, and making better utilization of doctor's time through the provision of remote care and mobile tools and apps.

Countries that succeed in digitalizing their healthcare systems feature an effective strategy, strong political leadership and a coordinating institution with a clear national mandate. Any new legislation and guidance would need to be developed to govern and enable distributed and decentralized data models [40] that support the use, management, and sharing of data and information while at the same time they address the issues of access, privacy, ethics, interoperability, and ownership. This will require multidisciplinary and intergovernmental governance structures and formal agreements to exchange data and information and new flexible laws to introduce innovations in digital health. Data governance is fundamental in this effort.

The development of quality EMRs, PHRs, and EHRs is not an issue to be resolved by technology on its own. It requires institutional interventions and legislation to properly manage a governance model that will facilitate co-responsible ministries (such as those for health, digital governance, development, social security, economics, etc.) for a coordinated approach towards electronic health interoperability and quality EHRs.

5 Discussion

COVID-19 was a driver and accelerator of digital healthcare innovation during the pandemic. In order to better support innovation, regulators are in the process of breaking down data silos in digital medicine and AI. The EU is integrating data across member states to enable the exchange of EHRs cross-border and the US recently passed rules to enable more seamless data to flow. EMRs are considered to be a core building block of electronic data collection, processing and sharing and data quality seems to be a great concern for automatic processing, especially when they are unstructured. Despite the great potential of EHR data, patient phenotyping from EHRs is still challenging because the phenotype information is distributed in many EHR locations having different structures across sites.

Digital transformation is a change management process aiming to close the gap between demand and supply and as such its progress focuses first on individual, well-prioritized, meaningful services rather than large-scale, all-encompassing programs. Health data and advanced data analytics can help accelerate scientific research, personalize medicine, and provide early diagnosis of diseases.

By having the entire EHR available, it will be by far more possible to tailor medical care to each individual's clinical needs and empower healthcare professionals and citizens to make informed decisions. A significant challenge for interoperability is to transfer patient information from one care setting to a different one, translate it, and simultaneously conserve the clinical meaning of the information. Health data and advanced data analytics can help accelerate scientific research, personalize medicine, and provide early diagnosis of diseases. At the same time, they can facilitate access to better and safer healthcare contributing this way to more efficient, accessible and resilient health systems in the EU by promoting health, preventing diseases and fostering supportive environments for healthy lifestyles.

The EHR can be used as an instrument to support effective digital transformation in the post COVID-19 era. This can be supported by the following strategic actions towards developing quality EHRs:

- Define data quality and interoperability standards. Establish a national interoperability framework and let EMRs interoperate with each other and with EHRs and PHRs. Meet expectations. Support interoperability by design.
- Raise awareness. Expose best practices. Promote the use of open APIs. Use incentives for motivating EMR adoption and use. Learn from best practices and create a positive environment that builds a sustainable ecosystem of health data utilization. Build a coherent dissemination and communication strategy.
- Invest on human resources and digital skills. Provide appropriate education and training to facilitate the best use of digital solutions. Provide resources to upskill both data consumers and data producers with appropriate competencies to understand their data and manage it appropriately.
- Create robust national infrastructure services. Monitor and control progress. Invest on quality assurance. Focus on open API development that will allow the healthcare industry and individuals to access structured electronic health information securely.

- Establish health interoperability governance, as a critical enabler to a holistic approach towards linking EMRs in line with national digital policy governance. Interoperability should be guaranteed sustainably and not as a one-off target or project.

Digital health care transformation has to benefit people, health care systems and the economy. The magnitude of the investment needed should not be underestimated if the EHR implementation is to be successful.

6 Conclusion

The global practice has shown that the proliferation of public EHR services is reinforced when the public maintains the role of a central regulator rather than when it attempts to operate them competitively to the private sector. EHR services are public goods, and as such, they should have the maximum development momentum at the end-user level. Subsequent efforts should be paid towards establishing an integrated EHR backbone, emphasizing issues relevant to protecting sensitive information and cultivating trust among all relevant stakeholders.

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