A Framework for eHealth Interoperability Management

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Reliable and secure access to and sharing of medical data can help patients practice self-care, promote patient engagement and improve their communication with healthcare professionals. This requires overcoming several interoperability, usability, ethics, security, and regulatory issues. The existence of a common interoperability framework can accelerate digital transformation in support of disease specific solutions. This paper presents a useful and relevant interoperability management framework with the potential to improve the quality of life and better control costs for the development and provision of electronic health services to individuals, within a coordinated care environment, under a local, regional, national, or cross-border setting.

Keywords: Coordinated Care, Electronic Health Record, Enterprise Architecture Adoption and Governance, Interoperability Management, Public Health

EXECUTIVE SUMMARY

This work presents an approach for the organized development of a countrywide framework to address the ever-growing demand for acquiring, exchanging and exploiting patient information to support high quality and cost-effective healthcare delivery. The authors examine the national electronic health (eHealth) landscape in Greece, within the context of the recent recommendation on a European electronic health record (EHR) exchange format. Improving quality of life and well-being, in a secure and safe manner that respects the patients' privacy, is the key challenge. Interoperability of information and communication technology (ICT) systems is central for reliable and efficient collaboration between the involved stakeholders, including the patient and associated caretakers. In order to accelerate transformation towards citizen empowerment and a more sustainable health system, national authorities need to address issues relevant to mutually beneficial goals in a coherent manner. Practical implications have to deal with the sustainability of the underlying national infrastructure required to support reliable and secure exchange of meaningful EHR data, for both primary and secondary use, and by defining technical specifications for well-defined use cases, in a legitimate and standardized manner, under a highly regulated environment.

INTRODUCTION

Electronic health records (EHRs) have the potential to improve significantly the quality of healthcare outcomes and as such, they are an important tool for coordinated care. They aim at improving health outcomes through the delivery of healthcare services from multiple providers by ensuring that care is not delivered in silos (McDonald, et al., 2007). As stated in (Katehakis, et al., 2018), prerequisites for enabling data reuse and workflow automation include well-defined use cases, agreed terminology, and reliable clinical content. Effective coordination of care requires collaboration, goal oriented care planning, tracking care activities and interventions, as well as continuous assessment and review.

Increased healthcare needs will require a more resilient healthcare system. This is due to population ageing, the rising occurrence of chronic conditions, and an increase in demand for long-term care (OECD/ EU, 2018). In order to use and interpret EHR information in a clinical relevant context, certain requirements are considered to be of great priority, including contextual information related to medical encounters and decisions, privacy and confidentiality of information, and disclosure law (Katehakis & Tsiknakis, 2006).

The widespread adoption of mobile technologies facilitates the introduction of new and innovative ways to improve healthcare delivery. Citizens, healthcare professionals and patients included, can now use these technologies to manage their own health and promote healthy living and active ageing by accessing useful information and linking to useful resources when needed (Kouroubali, et al., 2019). Mobile devices are becoming an integral part of the healthcare industry, changing how care is delivered and received. The use of electronic medical records (EMRs) and electronic prescription is growing across the European Union (EU) countries, and growing numbers of EU residents use the Internet to obtain health information and access health services. Despite the fact that citizens have the right to access their personal data, including their health data, as provided for by (European Union, 2016) most citizens cannot yet access (nor securely share) their health data seamlessly across the units of their national healthcare system.

In spite of the fact that large amounts of health data are generated and stored electronically, during and between citizen encounters with national and regional health systems across Europe, they continue to reside in data silos. Opportunities to reuse data for better healthcare are often missed, due to the limited interoperability among digital health solutions (Beerenwinkel, et al., 2018). A framework to provide for the specific set of standards, protocols, procedures, best practices and policies to help professionals and patients improve the cost-effectiveness of the eHealth solutions they design, implement, and use is considered to be essential (Barbarella, et al., 2017; Lamine, et al., 2017).

A recent study by the Healthcare Information and Management Systems Society (HIMSS) in Europe points out the fact that eHealth professionals should pay more attention to the patient over the next years (HIMMS, 2018). This is mainly due to the patient-generated data (through wearables or other tools and gadgets made for "consumers") as well as health records citizens/ patients own and manage. Once a country has reached a certain level of Electronic Medical Record (EMR) maturity - the priorities shift towards patient empowerment. Successful digital transformation requires an effective and efficient team play.

Healthcare in Greece is provided by the national health system (NHS). It consists of a universal healthcare provision through national health insurance, and private healthcare. During the past few years, the introduction of a multitude of eHealth services, in line with EU priorities, aimed to control costs and improve services in a secure manner. These include electronic prescription (ePrescription), electronic dispensation (eDispensation) and electronic referral (eReferral) for primary care, electronic confirmation (eConfirmation) for insurance status verification, electronic reimbursement (eReimbursement), electronic appointment (eAppointment) for booking doctors' appointments for primary care, and a business intelligence system (Bi-Health) that automates online retrieval of operational data for the Hellenic Ministry of Health (MoH) (Katehakis, et al., 2018).

Despite the fact that significant progress has been made to effectively link hospitals, regional health systems, and primary care (Katehakis, et al., 2012), still no uniform access to EHR is available

nationwide (Katehakis, 2018). Relevant challenges for the Greek NHS have to do with the non-optimal use of available data due to the lack of an interoperability framework and base registries (i.e. a trusted and authoritative source of information which can and should be digitally reused by others), for the exchange and use of data across different organizations. For example, a number of organizations process information regarding drugs administered to patients. However, the lack of a consistent, good quality, complete, centralized drug registry creates a number of problems for doctors, nurses and pharmacists across the country that eventually affect patients.

The lack of a well-defined interoperability framework also affects other important patient care scenarios such as the management of available beds in public hospitals as well as providing medication for the chronically ill. The development of services built upon international standards and best practices, under the provisions of national and EU legislation, turns out to be very important. The appropriate legal framework and governance, independently of the maturity of the technologies used, are key ingredients for establishing a successful framework for accessing and sharing EHR data at a national level, in line with the recently introduced recommendation on a European EHR exchange format (European Commission, 2019). The aim of interoperability with regard to EHR exchanges is to allow for the processing of information consistently in a way that the recipient can meaningfully interpret communicated information.

In the following section, CONCEPTUAL MODEL, the authors present the EU framework of cooperation towards the digital single market, together with interoperability guidelines and standards, including security and policy considerations. The road towards developing a national EHR, addressing relevant challenges for the Greek NHS, is subsequently described in section PROPOSITION DEVELOPMENT. Authors pay emphasis on governance and sustainability towards the development of a national domain interoperability framework (DIF) for eHealth, highlighting critical research and practical issues. The paper concludes in DISCUSSION AND CONCLUSION with some key recommendations.

CONCEPTUAL MODEL

EU Framework

EU member states have to make their eHealth systems more interoperable to support citizens in gaining greater control over their health data, to improve clinical outcomes, and to manage the economic and social aspects of healthcare. Technical challenges for the implementation and adoption of EHRs and personal health records have mostly to do with issues relevant to interoperability, device connectivity, security, compliance with national and international legislation, as well as with local policies, usability and accessibility from different devices by users with different profiles (Katehakis, et al., 2017).

Data generated within an organization can be used in a different manner by another organization, while information exchange can occur within a small network or it can expand to regions, nations and cross-national initiatives (Sheikh, et al., 2017). For example, in order to provide effective care, clinicians need comprehensive longitudinal data sets, while researchers and policy makers need quality data, in order to conduct research and support health planning. Deeper understanding and effective clinical interventions, as in the case of bioinformatics and personalized medicine, require innovative use of existing data. Standardization in medical informatics enables the interconnection and the interoperability between both care and research systems. Local clinical systems can be better aligned for easier data integration by preserving the meaning across information systems. Both transmitter and recipient interpret the shared information identically in different geographical locations, with possibly different local languages.

Interoperability is not possible without formal standards and specifications. Organizations such as Health Level Seven International (HL7) and Personal Connected Health Alliance (PCHAlliance) help towards the delivery of standards-based, open specifications that can support the flow of data from the point of capture into EHRs in the same format and coded content. Consensus on systems requirements is also important. Integrating the Healthcare Enterprise (IHE) describes how standards may be used effectively. Standard can be used with third party terminologies such as the Current Procedures

Terminology (CPT) code set, the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), the Logical Observation Identifiers Names & Codes (LOINC), and the International Classification of Diseases (ICD) codes.

In an effort to guarantee the secure and free flow of data within the EU, the new European Interoperability Framework (EIF) was announced in 2017 (European Commission, 2017). The new EIF provides guidance to public administrations, through a set of recommendations, on how to improve governance of their interoperability activities, streamline processes supporting end-to-end digital services, establish cross-organizational relationships, and ensure that existing and new legislation do not compromise interoperability efforts.

The new EIF was designed to promote the secure and free flow of data within the EU through advanced interoperability structures for public services across member states. Expected benefits include time savings, increased transparency, cost savings, better data availability, better data quality, higher satisfaction levels, improved compliance and better decision-making. The interoperability guidelines of the new EIF encourages public administrations to design and deliver services that are:

- digital-by-default, providing services and data preferably via digital channels;
- cross-border-by-default, accessible for all citizens in the EU;
- open-by-default, enabling reuse, participation, access and transparency;
- trustworthy-by-design to secure compliance with the legal requirements in respect to data protection and privacy;
- interoperable-by-default as a standard approach for the design and operation of European public services.

The new EIF provides guidance on the design and update of national interoperability frameworks, and on national policies, strategies and guidelines promoting interoperability. It contributes to the establishment of the digital single market by fostering cross-border and cross-sectoral interoperability for the delivery of European public services. As stated within (European Commission, 2017): "*The lack of interoperability is a major obstacle to progress on the digital single market. Using the EIF to steer European interoperability initiatives contributes to a coherent European interoperable environment, and facilitates the delivery of services that work together, within and across organizations or domains*".

The eHealth domain in Europe uses the refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2015) as the common framework for managing interoperability in the context of the eHealth Digital Services Infrastructure supported under the Connecting Europe Facility Programme. Member States have taken important steps to foster interoperability with the support of the Commission, through the activities of the eHealth Network established under Article 14 of Directive 2011/ 24/ EU of the European Parliament and of the Council (also known as the cross-border healthcare directive).

The ReEIF and the new EIF provide the tools to support the creation of a national DIF for eHealth. According to (European Commission, 2017) four layers of interoperability form the basis for the interoperability framework:

- Legal interoperability to ensure that organizations operating under different policies, legal frameworks and strategies are able to work together.
- Organizational interoperability for the alignment of public administrations responsibilities, business processes and expectations to achieve mutually beneficial goals.
- Semantic interoperability to ensure that when parties exchange data and information they preserve and understand their precise format and meaning.
- Technical interoperability covers the applications and infrastructures linking systems and services, including interface specifications, data presentation and secure communication protocols.

Citizens across Europe want to access and share their health data (European Commission, 2018). They also want to be able to provide feedback on quality of treatments. The slow deployment of

interoperable digital health solutions across European countries remains a barrier for scaling-up integrated care (COCIR & IHE-Europe, 2017).

In order to secure the citizen's access to and sharing of health data the EU is moving towards the development of specifications for a European EHR exchange format, based on open standards, taking into consideration the potential use of data for research and other purposes. The recommendation on a European EHR exchange format sets out a framework (European Commission, 2019) to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the EU. The framework includes:
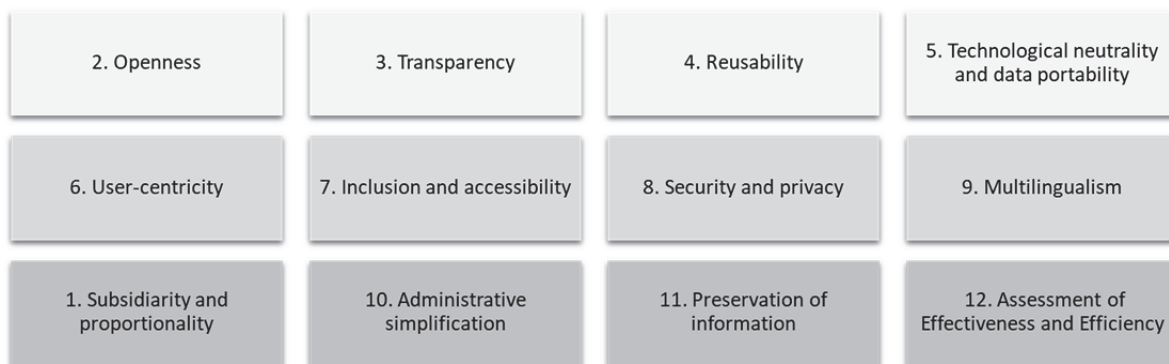
- a set of principles that should govern access to and exchange of EHRs across borders in the EU;
- a set of common technical specifications for the cross-border exchange of data in certain health information domains;
- a process to take forward the further elaboration of a European EHR exchange format.

The aim is to deliver the right data, at the right time, for citizens and healthcare providers, and allow for the secure access, sharing and exchange of EHRs. The baseline includes patient summaries, ePrescription/ eDispensations, laboratory reports, medical images and reports, and hospital discharge reports, in alignment with established priorities at a European level.

The twelve underlying EIF principles are fundamental behavioral aspects to drive interoperability actions. As depicted in Figure 1, they belong into four categories:

- core interoperability principles (Nos 2 to 5);
- principles related to generic user needs and expectations (Nos 6 to 9);
- one principle setting the context for EU actions on interoperability (No 1);
- foundation principles for cooperation among public administrations (Nos 10 to 12).

FIGURE 1
INTEROPERABILITY PRINCIPLES

2. Openness	3. Transparency	4. Reusability	5. Technological neutrality and data portability
6. User-centricity	7. Inclusion and accessibility	8. Security and privacy	9. Multilingualism
1. Subsidiarity and proportionality	10. Administrative simplification	11. Preservation of information	12. Assessment of Effectiveness and Efficiency

Interoperability principles offer a guide for building interoperable eHealth solutions to accommodate end user needs and expectations.

- Principle 1: Subsidiarity and proportionality require EU decisions to be taken closely to the needs of citizen.
- Principle 2: Openness refers to the idea freely available public data for use and reuse by others, unless restrictions apply. In the case of healthcare, much health data is not published as open data, as is sensitive and personal information. Open source technologies and products are encouraged to minimize cost, and avoid a lock-in effect. This principle also refers to the level of openness of a specification/ standard so that software components implementing that specification can be reused. Openness also supports empowerment of stakeholders, especially citizens to be involved in the design of new services.

- Principle 3: Transparency refers to enabling visibility to help stakeholders understand administrative rules, processes, data, services and decision-making. It focuses on securing the right to the protection of personal data in respect of legal frameworks.
- Principle 4: Reusability requires the sharing of interoperability solutions, concepts, frameworks, specifications, tools and components with others.
- Principle 5: Technological neutrality and data portability enables healthcare interoperability among different applications and systems.
- Principle 6: User-centricity refers to services that consider all user needs and are designed to address them. This is particularly relevant for the healthcare domain as data resides in silos and multiple organizations repeat actions in order to obtain the same data, from patient demographics, to repeated examinations, laboratory tests and others. Another user-centered characteristic of interoperable services is that the user provides only the information that is necessary at any given point of time and at any interaction with the healthcare sector.
- Principle 7: Inclusion and accessibility enables people with disabilities, the elderly and other disadvantaged groups to use healthcare services comparable to those provided to other citizens.
- Principle 8: Security and privacy ensures that privacy, confidentiality, authenticity, integrity and non-repudiation of information provided by citizens and other users is guaranteed.
- Principle 9: Multilingualism becomes relevant when information systems exchanges need to occur across language boundaries, as the meaning of the information exchanged must be preserved.
- Principle 10: Administrative simplification addresses the need for simplification of healthcare processes and services.
- Principle 11: Preservation of information ensures long-term accessibility, including preservation of associated electronic signatures or seals.
- Principle 12: Assessment of effectiveness and efficiency focuses on evaluation of effectiveness and efficiency and balance between costs and benefits.

Systems and technologies designed based on these principles give the opportunity to citizens to increase the benefits they receive using technologies and tools either directly or indirectly.

The General Data Protection Regulation (GDPR) (European Union, 2016) requires protected and properly secured patient data so that confidentiality, integrity and availability are ensured. In addition, citizens and their healthcare professionals must have online access to their EHRs using secure electronic identification means (eIDAS Regulation) (European Union, 2014), while EHR systems rely on secure networks and information systems in order to avoid data breaches and minimize the risk of security incidents (Directive on security of network and information systems - NIS Directive) (European Union, 2016b). In addition, the EU Agency for Cybersecurity has published several documents on strategies and ways of implementing privacy by design (European Union Agency for Network and Information Security, 2018).

PROPOSITION DEVELOPMENT

Towards a National EHR

The development of national EHR in Greece implies a vision for the provision of healthcare in the country and significant technical knowledge. It has to follow best international practices and be combined with the existence of a national strategy. It is a long term, evolutionary process that requires the gradual integration and deployment of EHR information domains over time. Already the majority of EHR system components, within the information and communication technology (ICT) infrastructure of healthcare organizations, are operational in the country (Katehakis, 2018). Key EHR information exchange providers in Greece include:

- IDIKA (e-Government Center for Social Security Services) for eConfirmation (for insurance status verification), ePrescription/ eDispensation, eRDV (for appointment booking – directly accessible to citizens), AHFY (citizen EHR focused on primary care – aiming to become the backbone of the national EHR system, under development), and NCPeH (cross border services for ePrescription and patient summary)
- EOPYY (National Organization for Health Care Services) for eReimbursement (e-ΔΑΠΥ) and also registries for Hepatitis C and Chronic Myelogenous Leukemia
- Hospitals
- Healthcare Professionals

The eHealth and telemedicine landscape in the country is filled by several EHR systems, including clinical and non-clinical ones (e.g. for clinical trials), communicating mostly application to application. Despite the wide availability of EHR systems, there exists large fragmentation of information, limited out of the box interoperability capabilities among them, and questionable data quality. An outstanding example is the fact that many organizations are directly involved in the management of pharmaceutical products without the existence of a common registry of medicinal products to serve as a common point of reference (Katehakis, et al., 2018). Synthesis of information required about medicinal products is fragmented within the above-mentioned entities. Communication between them, in the context of handling their business processes related to drug administration, is done by means of email exchanges and spreadsheet files. Data used by each entity is incomplete and not always up to date. Safety rules do not usually apply on the roles and responsibilities of data controllers involved in data management.

The Bi-Health system of the MoH supports the automated extraction of certain data sets from public hospitals, related to patients, the cost of care per hospital, the use of consumables, and others. Bi-Health aims towards supporting documented decisions for the improvement of public health by extracting hidden knowledge through big data analytics. Initial data sets, collected online, included inpatient and outpatient data (admission, discharge and transfer notes, charging, etc.), materials, human resource and financial management data, as well as appointment booking data. Still not all points of care in the country have established a link with Bi-Health.

Digitizing health records and creating systems so that citizens can access and securely share them within and between the different actors in the health system is an important step towards integrating digital technologies into healthcare. That integration requires EHRs, to be interoperable across the NHS whereas currently many of the formats and standards in EHR systems used across the country are incompatible. This is because

- Solution providers propose implementations without consulting each other.
- Interoperability agreements are too generic or non-existent.
- A national semantic authority, responsible and accountable for the provision of national terminology services, is not in place.
- Interoperability standards, such as HL7, are not used in a consistent manner.

The key issue is that no national framework is in place to manage consistently interoperability in the country. Since the use case-driven approach is the foundational methodology for documenting user needs, the practical approach for achieving interoperability can be summarized in the following steps:

- identify use cases from an end-user perspective;
- select profiles and standards that support the use case;
- refine data content, including master files, and terminology;
- prepare implementation guides;
- organize component interoperability and cross-implementer connectivity testing;
- educate end-users;
- support communities of practice to promote sustainable standards-based implementation.

For each of the proposed use cases, rules need to apply in order to determine how to accomplish interoperability at each of the following levels:

- Legal: in order to provide a thorough check of how public services will be established in regards to consistency with relevant legislation and corresponding data protection requirements, when drafting legislation.
- Organizational: for documenting and integrating, or aligning, business processes and relevant information exchanged, while at the same time aiming to meet the requirements of the user community by making services available, easily identifiable, accessible and user-focused.
- Semantic: to make sure, through the development and use of standardized vocabularies and formats, that the meaning of exchanged data and information is well understood by the different parties, resolving any possible ambiguities regarding the notions in the healthcare domain.
- Technical: in order to ensure the use of formal technical specifications and widely accepted and used standards.

A national EHR will only become available when the EMRs generated and maintained by physicians and healthcare providers apply internationally recognized interoperability standards (Aanestad, et al., 2017) in a regulated manner. Interoperability should be guaranteed in a sustainable way and not as a one-off target or project.

In order to achieve this vision within the Greek NHS, the following need to be in place:
- a roadmap for the development and maintenance of national specifications, re-usable services and other assets;
- national, reusable interoperability specifications, compatible with the corresponding European ones, developed through open and transparent processes;
- mechanism and tools for compliance control, testing and certification;
- a national semantic authority.

The introduction of a conformity assessment scheme, considering ISO, IHE CAS and other successfully deployed in member states is expected to promote the adoption and take-up of interoperability testing of eHealth solutions and products against identified eHealth standards and profiles. This will require the establishment of a test and compliance control centre in the country.

Foreseen benefits include less effort in the introduction of new services, lower cost for the application of new solutions, a solid ground to support better research, less red tape, and more empowered patients in control of their diseases.
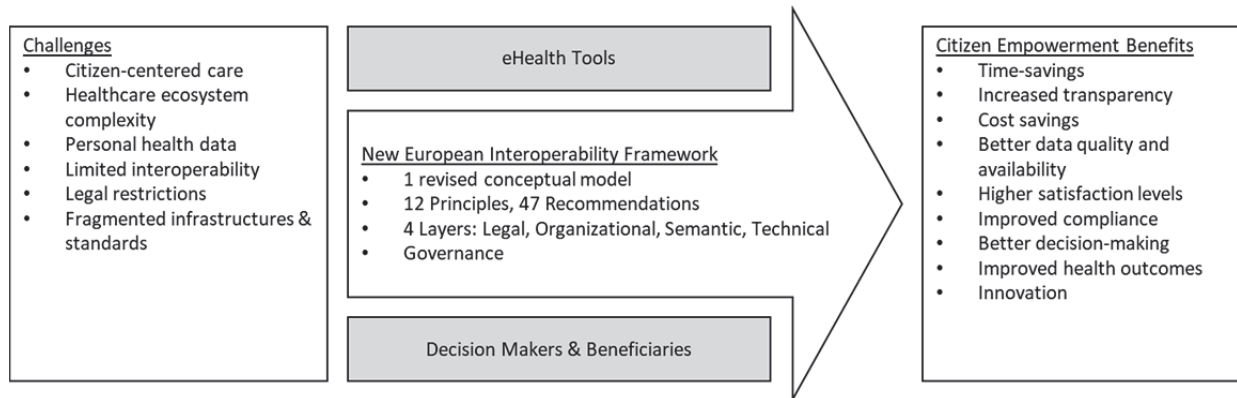
DISCUSSION AND CONCLUSION

Interoperability in healthcare is a complex societal issue because it involves various actors, dissimilar perspectives, norms and values. Existing systems, policies and governance structures are interrelated and in a continuous co-evolution within the broader societal dynamics. Solutions to complex problems require a more explorative, experimental and reflexive approach. Addressing the complexity of interoperability in healthcare makes it clear that innovation and change is an ongoing process that coexists with specific structures and dynamics. Within complex ecosystems, shared objectives can often be better achieved jointly than individually. Addressing the existing structures and focusing on the emergent vision of citizen empowerment allows for an improved insight into the feasibility of change.

A key and essential pillar to establish a National EHR in Greece is the design and implementation of an interoperability framework that, with the appropriate open governance, will enable the systematic implementation of the necessary use cases that will populate the EHR with valid and quality elements. In order to accelerate transformation towards citizen empowerment and a more sustainable health system, national authorities need to address issues relevant to mutually beneficial goals in a coherent manner. Transparency will allow other public administrations, citizens and businesses to view and understand administrative rules, processes, data, services and decision-making. Appropriate governance and legislation can guarantee the consistent management of sustainable eHealth interoperability in the country and that all involved parties, including health organizations and ICT solution providers comply with it.

Establishing interoperability in healthcare is a key enabler of digital transformation and social change, as presented in Figure 2 (Kouroubali & Katehakis, 2019). Effective management and governance requires taking into consideration all aspects of healthcare system complexity. As structures are changing, objectives need to be flexible and adjustable, timed appropriately for effective action. Support of innovation requires creating space for agents to invest time, energy and resources. Interaction and participation of stakeholders form the basis for policy support, problem solving and the establishment of solutions.

FIGURE 2
THE NEW EIF AS A FACILITATOR FOR CITIZEN EMPOWERMENT

The rising of chronic illness and the continuous aging of the global population requires a re-organization of healthcare systems based on relations and exchange of information to address citizen needs. Policies and interoperability roadmaps, as presented in the new EIF for Europe, place the citizen at the core of the healthcare ecosystem. As citizens, with the role of patient and consumer of healthcare services, become more empowered, they begin to have an increasing influence on how healthcare services are being delivered. Digitizing health records and enabling their exchange in a secure, transparent manner, could support the creation of large health data structures, which combined with the use of new technologies, such as big data analytics and artificial intelligence can support the search for new scientific discoveries.

Future Research

Further research is required to establish insights into flexibility building and digital transformation business processes. Societal changes require adaptability and prompt response to change, pivoting towards the right outcomes, and ensuring sustainability. The development and implementation of intelligent, integration-ready, extensible EHR platforms and applications are essential in order to achieve end-to-end digital public services to all citizens and businesses for the transition to sustainable patient empowerment projects for a citizen centered society.

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