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The new European interoperability framework as a facilitator of digital transformation for citizen empowerment

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ABSTRACT

Healthcare is a highly regulated domain. Seamless, online access to integrated electronic health records for citizens is still far from becoming a reality. The implementation of personally managed health data systems still needs to overcome several interoperability, usability, ethics, security, and regulatory issues to deliver the envisioned benefits. This paper offers a policy viewpoint on how the new European Interoperability Framework (EIF) may benefit the implementation of eHealth systems for the management of personal health information for citizens. Interoperability facilitates sharing of health and illness experiences, coordinated care and research for citizen empowerment and improved health outcomes. The adoption of principles relevant to core interoperability and generic user needs and expectations, as described in the new EIF, in line with European and national regulations are quite essential for the development of safe and secure patient access services to support mobility. An interoperability framework facilitates the creation of the appropriate context in which personal health record applications can be designed and implemented in support of disease specific solutions, such as chronic non-malignant pain, diabetes and cancer. It is evident that no solution will fit all circumstances. However, the new EIF, when adapted for personally managed health data, provides a useful and relevant framework to facilitate implementation and adoption of personal health record systems within a coordinated care environment. Practical implications of this work relate to the need of multi-disciplinary cooperation and European level compatibility and sustainability of the underlying infrastructures required to support reliable and secure access to and sharing of medical data, as well as the readiness to address continuously evolving functional and non-functional requirements for regional, national, and cross-border settings.

1. Introduction

It is widely accepted that secure sharing of health information will enable citizens to become more active in managing their personal health data, improve their health and illness experiences, and at the same time support coordinated care and research [1]. The demand for electronic health record (EHR) systems that collect and manage personal health data for individuals and the need for flexible access to eHealth systems has increased [2]. The existence of comparable and high-quality administrative and clinical data form the basis for effective and efficient management of public and clinical health. However, citizens, healthcare administrators, governing bodies, and healthcare practitioners face several barriers when trying to collaborate and exchange information electronically. Interoperability within healthcare systems is a wider concept and encompasses the ability of organizations to work together towards mutually beneficial and commonly agreed goals. Eliminating data silos and automating data integration, recognizing unseen patterns, as well as providing new intelligence to service patients and care-givers is expected to offer value across the care continuum [3]. Healthcare is a highly complex environment. Subsequently all programs and projects aiming to change a healthcare system are similarly complex [4].

It is important to distinguish the meaning of simple, complicated, and complex problems to obtain a deeper insight about healthcare systems. Simple problems are easy to understand and have easy solutions. Solutions can be replicated without the need for any particular expertise. Such an example is following a protocol. It encompasses issues of technique and terminology but once mastered, offers high

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assurance of success. Complicated problems are harder to understand and require high levels of expertise in order to have a successful outcome. An example of a complicated problem is a surgical procedure. It requires issues of coordination and expertise. Outcomes of complicated problems have a relatively high degree of certainty. Complex problems are not fully knowable in advance, are characterized by complexity of processes, high uncertainty in outcomes but with a certain degree of predictability [4]. Interoperability implementation falls within the boundaries of a complex problem as it requires an understanding of unique local conditions and their historical pathways. Clinical practice, healthcare organization, management and sharing of information, research, education, and professional development are interdependent and built around multiple self-adjusting and interacting systems. Frameworks that can incorporate a dynamic, emergent, creative, and intuitive view of the world are fundamental in understanding the healthcare ecosystem and are essential to facilitate the analysis of clinical care and service organizations [5].

Interoperability is complex in its various aspects including all its layers and its governance. It involves various actors, dissimilar perspectives, norms and values. Solutions to complex problems require a more explorative, experimental, and reflexive approach. From a personal health data perspective, interoperability in healthcare is also a complex societal issue, because it is directly relevant to the individual members of society, i.e. its citizens. Without interoperability in eHealth, continuity of care cannot be delivered and citizens cannot have an overall view of their health information.

The European Union (EU), having recognized the need for interoperability among member states, has created the 'interoperability solutions for European public administrations' (ISA) funding program to enable the creation and interoperability of eGovernment services to European public administrations, businesses and citizens [4]. In 2016, the EU launched the ISA^2 program to support the development of digital solutions for interoperable cross-border and cross-sector public services [6]. Within this context, one of the EU priorities is to create a digital single market that aims, amongst others, to unlock the potential of a European data economy, helping citizens, public authorities, companies and researchers to make the most of new technologies by funding EU research in health and high performance computing [7]. The new European Interoperability Framework (new EIF) was adopted in 2017, in the context of the digital single market strategy in Europe, to support interoperability within the public sector. The public sector plays a key role in the digital single market as a regulator, services provider and employer [6]. The new EIF offers recommendations, models and guidance that have the potential to improve the quality of European public services.

This paper proposes a new methodological approach for overcoming barriers to the adoption of digital tools for citizen empowerment and other forms of patient-centered eHealth. It proposes the new EIF as a framework that can be tailored to support interoperability for citizen-centered care. It presents the main principles and models of the new EIF, and enriches them with interoperability experiences from the healthcare domain, offering a holistic framework that promotes exploration, experimentation and reflexivity upon the complex issue under consideration. An extensive presentation of interoperability governance is also provided as it is considered an essential aspect for successful implementation initiatives. The proposed methodological approach offers general guidelines to help stakeholders within the healthcare ecosystem improve the interoperability of the eHealth solutions they design, implement, and use.

2. Interoperability in healthcare and citizen engagement

National and regional health systems generate and store large amounts of EHR data for every citizen encounter. The majority of these data continue to be confined in data silos [8]. The limited interoperability among digital health solutions diminish the opportunities to reuse data for better healthcare. Disparate data repositories and departmental systems store health data using different information models, in different syntaxes, semantics, or formats. Data capture is often inconsistent or follows incompatible formats. Further uses of data for specific purposes are not formalized or readily available. Often, data are of variable quality and unstructured, as free text, posing greater challenges for automatic processing [9]. The role of terminologies is instrumental in enabling interoperability, however, there are issues related to fragmented, inconsistent and complex terminologies, often rendering terminologies difficult to use and implement.

EHealth systems are not always designed with a vision of collectively using health data for innovative purposes such as data exchange, aggregation, analysis, decision support and research. Modern systems are still being built focusing on local, proprietary data models, propagating the difficulty of accurate and safe health data integration. Standardization in message and document exchange has made a significant contribution to sharing health data, however, quality and integrity of data requires collaboration and negotiations among stakeholders [10]. Existing eHealth systems collect and exploit only limited, fragmented information without unveiling their real potential. Software vendors and buyers are eager to solve short term problems, while the capacity of systems to truly interoperate and deliver the right data to the right person at the right time require long term strategic investments.

Despite the fact that patients are consumers of healthcare, they do not yet have the power to act as drivers for accessing and exchanging their own health information. Their role is not the same as that of consumers that act as drivers in a competitive market. Policy and laws across Europe and the world, already place the citizen as the central actor of the healthcare process [8,11,12]. In Europe, patient inclusion is fundamental in order to receive subsidies for eHealth projects. However, true implementation of these policies and laws has not yet occurred [13]. The citizen as patient remains "*an underestimated force within the inherently conservative healthcare systems*" [13]. The balance of power has not shifted towards citizens, even if they are the fundamental stakeholder within the healthcare ecosystem. The majority of citizens still do not have access to their own personal health information. Even in cases were digital tools could be available for citizens, the underlying cultural issue of provider to provider and provider to patient information sharing, needs to be addressed [14]. Interoperability in the healthcare domain has tangible benefits such as saving time, reducing costs, increasing transparency and improving the quality of services offered to citizens and businesses. However, there is a lack of incentives to motivate health systems and providers to share health information with patients and with each other, as the benefits are often not directly visible.

The majority of eHealth system implementations have traditionally focused on professionals. The citizen has had very limited access to these systems, and hence to the personal information stored within. There are however examples, towards creating digital health environments for the citizen. In the Netherlands, applications exist that connect mobile devices, with the hospital, the pharmacy, and the general practitioner giving an overview to the citizen of their information in the different systems. Decisions for sharing these data rely with the citizen [13]. Another success story occurs in Australia, where approximately 26% of the country's population has registered for My Health Record [15], an online summary of the citizen's key health information that can be viewed securely online, from anywhere, at any time from any computer or device that is connected to the internet.

In Europe, according to a recent EU survey [16], citizens expect to be able to:

- Access their own data given that these are available, interoperable, and of good quality;
- Share their health data if privacy and security are ensured;
- Provide feedback on the quality of treatments.

As citizens, with the role of patient and consumer of healthcare, become more empowered, they begin to have an increasing influence on how healthcare services are being delivered. They are becoming more sophisticated [17], with a better understanding of their conditions, and a greater need to play a role in their treatment. Availability of healthcare information on the Internet has widened the knowledge and understanding of disease for the non-professional and has changed the communication model between physicians and patients [18]. Social media and groups such as "Patients like me" have the power to influence the healthcare system [19]. There are several commercial digital tools that enable citizens to access their data as well as contribute to their health data through mobile apps that allow the collection of health information. Data collected and analyzed in real time can offer opportunities for response and feedback. The citizen needs to at least have access to his or her own information, laboratory results, diagnostic images, medical history and medications, as a personal copy of his or her EHR. A first step would be a view only of the information that is currently within clinical settings. An interoperable personal health record provides the opportunity to become the active link between citizens and their health information that resides in different places within the healthcare ecosystem.

2.1. Personal health record

A personal health record, or PHR, is an electronic application through which citizens can maintain and manage their health information in a private, secure, and confidential environment. A PHR can have several modules [20] that are summarized in Table 1.

The PHR has the potential to combine data from multiple sources and assist individuals with the organization and interpretation of their own health and illness experiences. However, this is only possible if these systems are connected with a larger network of eHealth systems that contain the citizen's health information generated upon his or her encounters with the healthcare system. Health information can be found, for example, in the electronic medical record at the primary care office, the hospital, and in diagnostic centers. Personal information also exists in applications for physical activity management, devices such as glucometer, electronic scales, and others. These applications allow patients to provide daily life-status information, to maintain their own records of medical exams, and to define the access rights to their personal data, leveraging that access to improve their personal health and to manage any diseases that may affect them. Citizens have the opportunity to become more active in the management of their own care, through personally managed digital tools that support interoperability and citizen-centered eHealth applications.

2.2. Continuity of care

Interoperability supports continuity of care as information can be shared across the different actors towards a common goal, which is healthcare and well-being delivery. Healthcare is provided to citizens in a coordinated way even when the information resides in different eHealth systems and healthcare providers from different settings are involved. Through continuity of care, it is possible to coordinate health provision and communication among all stakeholders involved, including health professionals, citizens who receive care, carers, and family members. EHealth systems can greatly support this process [21]. However, inadequate interoperability creates coordination gaps that render continuity of care difficult to achieve [22]. Interoperability enables capturing, sharing, and understanding of data that leads to taking appropriate actions for better medical care and better patient outcomes, while at the same time enables knowledge discovery and research in the direction of evidence based medicine.

2.3. Healthcare as an ecosystem

The increased frequency of chronic illness and the continuous aging of the global population requires a reorganization of healthcare systems based on exchange of information to address citizen needs towards facilitating digital transformation. Implementing the vision of healthcare professionals adopting digital tools that would allow them to interoperate with those of other clinicians and the health system at large is an enormous task that requires behavioral and organizational changes. EHealth implementations do not usually take into consideration the change management that is required as well as the amount of communication and collaboration among stakeholders in order to achieve adequate interoperability [23].

Policies and interoperability roadmaps in Europe and abroad place the citizen at the core of the healthcare ecosystem. These will eventually change the interdependencies and collaborations among stakeholders [24]. Setting the appropriate guidelines at all levels of the healthcare ecosystem, helps to drive all actors towards actions that are in line with the holistic vision of citizen-centered healthcare.

3. The new European interoperability framework

The new European Interoperability Framework (new EIF) defines interoperability, within the context of European public service delivery, as "*the ability of organizations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organizations, through the business processes they support, by means of the exchange of data between their ICT systems*" [25]. It offers basic interoperability guidelines in the form of common principles, models and recommendations for the delivery of European public services [25]. It 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;

Table 1
High-level description of PHR modules in support of patient empowerment and research.

Modules	Functions
Data acquisition	Medications, scheduled appointments, vital signs, medical history (problems list), laboratory information, immunizations, scanned documents, progress notes about changes in the patient's health
Interoperable and adaptable	Home care services, connection to wellness applications to automate input of data, e.g. steps/day, water/day, sleep patterns and others, links to the electronic health record of the citizen, national eGovernment services, other connections to third party apps for accessing data from clinical/hospital information systems
Personalized medicine	Genetic information, medical advice and recommendations, and prevention information
Condition specific	Specific chronic conditions modules to support patient empowerment and self-management
Analytics	Tools for cohort analysis on all patient data, graphic visualization of the psycho-emotional profile of patients using various graphical paradigms, advanced search engine tools to perform searches in specialized databases using natural language, tools for researchers to generate requests for specific cohorts
Clinical decision support	Advanced decision support functionalities exploiting computer-based clinical guidelines

- Privacy-by-design and security-by-design to secure infrastructure and building blocks compliant with the legal requirements and obligations regarding data protection and privacy;
- Interoperability-by-design 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 it is stated within the official document of the new EIF "*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 organisations or domains*" [25].

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 [25]. Expected benefits include time-savings, increased transparency, cost savings, better data availability, better data quality, higher satisfaction levels, improved compliance and better decision-making [26]. In addition, interoperability allows digital cooperation and is crucial for the development of cost effective, quality solutions. It benefits research through the facilitation of innovation and promotes business initiatives through competitiveness.

The new EIF provides a framework that maps most of the processes that are necessary for establishing interoperable systems. When applied bottom-up, it helps national administrations to create the interoperability conditions so that national services can also be used across borders. When applied top-down it increases the interoperability potential of the follow-up national actions. It contributes to the development of a European public services ecosystem. All involved stakeholders, including owners, designers and users of systems and services become aware of interoperability requirements, and develop a culture towards collaboration and seamless information flow within national and across national borders to support a digital single market in Europe. The new EIF addresses public administrations in Europe across domains. It does not focus particularly on healthcare but rather on the entirety of public government. However, its comprehensive framework, principles, guidelines and models offer a valuable insight that can be adopted to support interoperability in healthcare. Its propositions become applicable in understanding and setting the foundations for healthcare ecosystems at any level of the healthcare process: personal, within organizations, within healthcare systems, at national levels or cross-border to support diverse use cases.

EHealth in Europe already has its domain specific interoperability framework, the Refined eHealth EIF (ReEIF), which describes six layers of interoperability with actors and activities on each layer. It can be used in combination with the new EIF to support interoperability activities in healthcare [27]. The new EIF offers a more comprehensive overview of interoperability and has been used as the main focus for the remaining paper. The next sections present the new EIF principles and layers adapted for application in the healthcare domain.

3.1. Interoperability principles

The ***interoperability principles*** (Fig. 1) are fundamental behavioural aspects to drive interoperability actions. Principle 1 sets the context for EU actions on interoperability; Principles 2 to 5 are core to interoperability; Principles 6 to 9 relate to generic user needs and expectations; and Principles 10 to 12 are the foundation principles for cooperation among public administrations within but also across national borders.

Principle 1 (*Subsidiarity and proportionality***).** The subsidiarity principle requires EU decisions to be taken as closely as possible to the citizen, while the proportionality principle limits EU actions to what is necessary.

Principle 2 (*Openness***).** The concept of openness mainly relates to data, specifications and software. It refers to the idea that all public data should be freely available 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. Users of health data will often combine open data with data that is only available to them as the holder (closed data), or data that they are able to access because they meet certain criteria (shared data). Open source software technologies and products are encouraged to minimize cost, and avoid a lock-in effect. Open source software has the potential to give healthcare organizations flexibility and scalability, however open source vulnerability is a serious security issue and should be taken into consideration. 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, to contribute to service improvement and to give feedback about the quality of the existing public services.

Principle 3. *Transparency* refers to enabling visibility to help stakeholders understand administrative rules, processes, data, services and decision-making. Transparency ensures availability of interfaces so that systems within an organization are interoperable and able to exchange data. Internal interoperability creates the conditions to integrate data exchange within larger systems. Transparency also focuses on securing the right to the protection of personal data, by respecting the applicable legal framework for the large volumes of personal data of citizens, held and managed by public administrations and healthcare institutions.

Principle 4. *Reusability* requires organizations to be open to sharing its interoperability solutions, concepts, frameworks, specifications, tools and components with others. Reusability of IT solutions, information and data, is an enabler of interoperability and improves quality because it extends operational use, as well as saving money and time [1].

Principle 5. *Technological neutrality and data portability* enables organizations to adapt to the rapidly evolving technological environment. This principle is especially important for healthcare interoperability as there is a great need to have the ability to move and reuse data easily among different applications and systems, which becomes even more challenging in cross-border scenarios.

Principle 6. *User-centricity* refers to services that consider all user needs and are designed to address them. Underlying principles of user centered services offer the possibility to users to provide feedback about the service. An interface that hides internal complexity offers to users a single point of contact where they can provide data once only. 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 absolutely necessary at any given point of time and at any interaction with the healthcare sector.

Principle 7 (*Inclusion and accessibility***).** Inclusion is about enabling everyone to take full advantage of the opportunities offered by new technologies. Accessibility ensures that people with disabilities, the elderly and other disadvantaged groups can use healthcare services comparable to those provided to other citizens.

Principle 8 (*Security and privacy***).** Healthcare systems and interoperability efforts need to ensure that citizens' privacy, and the confidentiality, authenticity, integrity and non-repudiation of information provided by citizens and other users is guaranteed. All

Fig. 1. Interoperability principles [25].

services need to follow the regulations and directives on data protection, and on electronic identification and trust services.

Principle 9 (*Multilingualism***).** The multilingual aspect of interoperability 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***).** Healthcare processes and services need to be streamlined, simplified or eliminated based on whether they offer public value.

Principle 11 (*Preservation of information***).** To guarantee the long-term preservation of electronic records and information, formats should be chosen to ensure long-term accessibility, including preservation of associated electronic signatures or seals.

Principle 12 (*Assessment of effectiveness and efficiency***).** Interoperability solutions need to be evaluated for their effectiveness and efficiency considering user needs, proportionality and balance between costs and benefits.

These principles provide an overall guide for building interoperable eHealth solutions to accommodate end user needs and expectations.

3.2. Interoperability layers

The interoperability framework defines four layers in which interoperability needs to occur. These layers are legal, organizational, semantic and technical.

Legal interoperability occurs when organizations that operate under different legal frameworks, policies and strategies are able to work together. New legislations are often needed to establish a public service. When this occurs, it is important to take into consideration existing legislations and the corresponding data protection requirements.

Organizational interoperability occurs when public administrations align their business processes, responsibilities and expectations to achieve commonly agreed and mutually beneficial goals. Business processes need to be thoroughly documented and the relevant re-engineering needs to take place in order to achieve integration and alignment to enable relevant information exchange. Organizational interoperability also aims to meet the requirements of the user community by making services available, easily identifiable, accessible and user-focused.

Semantic interoperability refers to both the semantic and syntactic aspects of data. Semantic interoperability focuses on the meaning of data, and involves the development and use of standardized vocabularies and formats so that the meaning of exchanged data and information is well understood by the different parties, resolving any possible ambiguities regarding the notions in the domain of interest. Syntactic interoperability requires describing the exact format of the information to be exchanged.

Technical interoperability covers the applications and infrastructures linking systems and services. Aspects include interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols. Technical interoperability should be ensured, whenever possible, via the use of formal technical specifications and widely accepted and used standards.

The principles and layers of the new EIF can be used to facilitate interoperability initiatives within the complex system of healthcare.

4. Governance

Interoperability governance "*refers to decisions on interoperability frameworks, institutional arrangements, organisational structures, roles and responsibilities, policies, agreements and other aspects of ensuring and monitoring interoperability at national and EU levels*" [25]. A holistic approach on interoperability can only be achieved through appropriate governance. Governance indicates fundamental guidelines in establishing the application of interoperability rules. Sustainability of interoperability across the care continuum can establish true coordinated care systems rather than one-off targets or project [28].

Coordination and governance are necessary when multiple organisations are involved. In healthcare, different organizations need to work together to meet end-user needs and provide services within integrated eHealth systems. Planning, implementing and operating the services should focus on integration, seamless execution, reuse of services and data, and development of new services and building blocks. Whithin this framework, there needs to be analysis of the following aspects:

- Organisational structures;
- Roles & responsibilities;
- Decision-making processes for the stakeholders involved;
- Interoperability essentials such as
  - o Quality, scalability and availability of reusable building blocks;
  - o Information sources such as base registries, open data portals, and others;
  - o Interconnected services.

Services across organizations need to be governed by clear service level agreements. Also, a change management plan needs to be in place to support redesign of processes. Plans for business continuity and disaster recovery also need to be established to ensure that digital public services and their building blocks continue to work in a range of situations such as cyberattacks or the failure of building blocks.

The new EIF incorporates governance as a concept that spans across the different interoperability layers: legal, organizational, semantic and technical. Governance refers to the set of processes, policies and customs affecting the management of an organization, the relationships among stakeholders the structures and functions that support organizational objectives and the monitoring of whether objectives have been achieved. Governance includes decisions for effective management and establishes who takes these decisions [28,29].

Interoperability governance establishes enablers to ensure alignment with the overall interoperability objectives at policy level. Interoperability governance proposes and guides the change management practices that need to be implemented, and establishes the foundations for the sustainability of interoperability initiatives at present and future times. Development and diffusion of knowledge about interoperability in each given sector to all involved stakeholders is an important enabler for sustainability of change.

Interoperability governance needs to be integrated in strategic and policy decision making to align strategic objectives with the actual implementation of interoperability initiatives and solutions. Interoperability governance incorporates the concepts of an interoperability framework, an interoperability architecture and appropriate and effective project management [28–30].

The multi-level approach to transition management defines the levels at which actors may perform governance functions [28,29]. In the public sector, legislative power of political actors and administrative power of public institutions are important drivers for interoperability initiatives. Governance functions may occur at the political level, the strategic level, the tactical level and the operational level. Actors performing political and legislative actions apply governance at the political level. Actions that determine how the legislation and political decisions are transferred into practice, are performed at the strategic level. Implementation oriented activities are performed as part of the tactical level governance. Actors and activities at this level guide the operational layer, defining the necessary tools and knowledge to support operations (Table 2). All actions depend on the strategic decisions and governance that occurred in the previous level. The operational level, covers governance of the provision of public services and interoperability of building blocks. Project execution occurs at this level. Governance is guided by various artefacts such as strategic policy documents, legal frameworks, funding programs, interoperability frameworks and other guiding documents [28].

The complexity perspective on healthcare makes it clear that uncertainties, nonlinear processes of change and innovation, and emergence of change coexist with specific patterns, dynamics, and mechanisms that drive change [30]. Taking a complex system approach to interoperability in healthcare, offers a basis for looking into specific patterns and mechanisms allowing for an improved insight into the feasibility of directing and influencing them. Actors and governance processes co-evolve within the broader societal dynamics. They are interrelated and act towards shared objectives [30]. These objectives can often be better achieved jointly than individually. Networks facilitate the development of decisions and strategies that lead to changes [31]. Governance depends on its surrounding environment, political, societal, organization. Drivers such as the European digital single market, and citizen empowerment, cost reduction imperatives, and alignment with European directives ensure the effective production and implementation of policies within a democratic state. Governance is embedded within the wider societal network. Practices of interactive policy and network approaches are becoming more widespread.

Table 2
Governance functions.

Levels	Actions
Political	Political and legislative
Strategic	Determination of how the legislation and political decisions are transferred into practice
Tactical	Implementation oriented activities
Operational	Necessary tools and knowledge to support operations
	Provision of public services and interoperability of building blocks

5. Discussion

Establishing interoperability in healthcare has the potential to accelerate digital transformation and bring about a social change. All societal actors may exert influence towards this direction. Top down planning, government directives and market dynamics are part of this dynamic change, which also includes network dynamics and processes of searching, learning and experimenting. Transition towards the new paradigm requires multilevel, multiphase processes of structural changes within all layers of the healthcare complex system. Governance of complexity needs to take into consideration both process and content. Effective management may only occur with a deep understanding of how the system works. Long term thinking is required to establish short term policy. Short term goals need to be based on long term goals and reflection on future developments through the use of scenarios. Structure and order of the system are changing, therefore, objectives need to be flexible and adjustable. Timing of intervention is very important for effective change. Support of innovation requires creating space for agents to invest time, energy and resources. Change supported from within is most effective as structures, actors and practices adapt to the new when it is cultivated from real and established problems. Importance need to be given to all actor perspectives. Actors need to be presented with a variety of options as a precondition for sustainable and effective change. Interaction and participation of stakeholders forms the basis for policy support, problem solving and the establishment of solutions.

Appropriate interoperability governance, together with principles from the new EIF offer tools to facilitate interoperability initiatives in healthcare. An interoperability framework helps to raise awareness among stakeholders and project managers in order to help them identify the key factors for implementation success. It helps them look into what interoperability aspects need to be established or are too difficult to tackle. Converging factors that need to be in place for successful implementation of large scale integrated and interoperable eHealth systems include: (i) a thorough understanding of the environment in which the systems operate, (ii) the identification of interrelationships and needs of stakeholders, (iii) recommendations for redesign of services and processes, (iv) supporting policies, (v) incentives towards

reaching certain performance targets, (vi) availability of adequate resources including finances and time [10].

When Interoperability policies and implementations are in place, digital tools for citizen empowerment can be developed and used to provide information that would otherwise be unavailable to the citizen. In addition, they push the market towards building systems of higher quality and features. Healthcare providers also benefit, as they are now able to get access to information that is very critical for them.

Interoperability assessment is important to identify what is the current state of information exchange and what new systems or interventions to existing systems need to be implemented to reach the desired interoperability for effective and efficient healthcare processes. Setting clear objectives and reaching consensus among stakeholders are fundamental facilitators to ensure alignment with individual, organizational and governmental objectives.

A broader view of interoperability in eHealth is essential in order to support research, development and innovation in the fields of eHealth, citizen empowerment and citizen-centered care. The amount of data now available for decision making far exceed the ability of a human to make those informed decisions. The volume of data, the variety of data types, the increasing wealth of knowledge, and the ability to track disease and co-morbidities from start to finish will overpower the ability of humans to make informed decision about health and healthcare. Computer based decision-making tools will facilitate the exploration and use of such varied and large data sets. Interoperability of eHealth systems at all layers: legal, organizational, semantic and technical will play a key role in helping the establishment of information channels that are transparent, direct, open and standardized. It is important to make explicitly known that individual data need to be connected to aggregated knowledge in order to contribute to the “big data” management in healthcare.

6. Conclusions

Interoperability of eHealth systems to support the flow of information will greatly contribute to appropriate decision-making that will in turn improve individual health, community health, and population health. All public and private stakeholders acting together may lead the innovation and transformation needed towards a healthcare system that we, as citizens, want for our families and ourselves. An interoperability framework is necessary to provide the conditions so that digital tools are adopted and used in a trustworthy manner. Strong political will, governance, and an educated community can support interoperability efforts and contribute to their success. The new EIF can serve as an appropriate and effective guide for interoperability in the healthcare domain and can serve as a tool for building trust among all relevant stakeholders. Establishing clear interoperability policies, guidelines and governance at legal, organizational, semantic and technical levels, introduces an interoperability culture for all stakeholders involved in the eHealth and healthcare ecosystems. New ways of working and thinking about collaboration and information exchange with the citizen as the central provider and user of services and information will help the paradigm shift from a medical centered healthcare system to a citizen-centered one.

Building flexibility and insight into business processes through digital transformation are essential to respond rapidly to change, pivot towards the right outcomes, and ensure sustainability. Intelligent, integration-ready applications and platforms that are easily extensible and offer a consistent and intuitive user experience are fundamental parts of the digital transformation towards citizen-centered care. Transparent, open, efficient and inclusive, interoperable, personalised, user-friendly, end-to-end digital public services to all citizens and businesses will provide the foundations for a citizen centered society.

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