ScanBalt Digital Forum 2020
Joint Declaration

ScanBalt Forum 2020

Towards a European Common Dataspace in Health in the Time of COVID 19

Preamble: Health is a key to Europe's social and economic sustainability. The socio-demographic change and the enormous progress in Information Technology (IT) and data driven health and care related sciences and technologies increase the need and demand for fundamentally more effective and efficient health and care systems. At the same time, the healthcare industry is developing into one of the largest and most important economic sectors of the future - in Europe and worldwide.

An international comparison reveals that Europe, the European Union (EU) and especially the countries in the ScanBalt region have a well-developed modern health infrastructure. In addition, they profit from agile and powerful health research infrastructure. These are good prerequisites for Europe to be able to play a leading role globally in the mega-future sector of health – to the benefit of people and to the advantage of Europe's economic competitiveness.

Digitization creates a variety of new opportunities for fundamental health innovations. and it also offers excellent prospects for making existing products and services better and more cost-effective. This became and is particularly evident in the Corona COVID-19 crisis. Digitization is becoming a key for significant improvements in the health economy, including technologies for collection and application of health-relevant data in high dimensions and quantity from many individuals and different sources, with substantial impact on the healthiness and prosperity of the population.

However, the prerequisite for future-oriented and sustainable development of the health economy in Europe is that the European Union and its member states use and can apply the potential of digitization for more health and better care proactively and with emphasis. The following joint declaration outlines valuable perspectives, opportunities, and construction sites for this. Additionally, it names bottlenecks and outlines ways in which they can be overcome.

1. Digital solutions for European cross-border collaboration in healthcare

The European Commission states: "Creating a single market for data will allow it to flow freely within the EU and across sectors for the benefit of businesses, researchers and public administrations." To create such a single data market, Europe needs a definition of consistent communication and data standards for intersectoral data exchange (e.g., Fast Healthcare Interoperability Resources) and Member States need to promote their implementation. As demonstrated during the Covid-19 pandemic crisis, cross-border coordination of treatment capacities, the distribution of medical goods and sharing of medically relevant information can save lives and economic power. It puts the citizens at the centre of the data-driven economy.

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Description of the situation

- During the last two decades, a lot of attention has been paid to the digitization and interoperability of health, health care and medical data in EU member states separately and at the EU level in general. Still the goal to achieve seamless exchange of health care data of European citizens throughout the EU is not achieved. Also, the level of digitization and interoperability varies remarkably between the EU member states because of different approaches to the level of patient engagement, health care organization, standardization, legal issues, accession rights to medical data and other related issues.
- The EU Commission has provided funding for various national and international projects at an early stage. These projects aim to create the basis for a secure, reliable, and standardized exchange of information between the stakeholders in the health care system.
- The major EU project epSOS[1] initiated in 2008, ran until 2014. With participants from 25 European countries and a budget of 36.5 million euros it was co-financed by the EU Commission. Within the framework of that project and other partner projects, proposals for organizational, technical, and legal framework conditions were developed and successfully piloted.
- The results were taken up at EU level and taken into account, for example, in the Directive on the Application of Patients' Rights in Cross-Border Health Care (2011/24/EU). On this basis, the European "eHealth[2] Network" was established, which is responsible for political steering in the EU.
- Nevertheless, the statements of the EU Commission are sceptical when it comes to the level of digital healthcare:
  - “Market fragmentation and lack of interoperability of health systems stand in the way of an integrated approach to the prevention, treatment, and cure of diseases, tailored to people's needs." (COM[3](2018) 233 final)

Bottlenecks

- Current efforts to exchange patient data across borders in the EU are based on voluntary cooperation between health authorities through the eHealth Digital Service Infrastructure ("eHDSI")30, supported by the Connecting Europe facility (broadband and ICT[4]). They follow the eHealth network guidelines for the management, deployment, and operation of the digital eHealth service infrastructure. This exchange is currently limited to patient summary records and electronic prescriptions and e.g. does not extend to electronic health records, let alone biological or genomic data.
- At present, many citizens in Europe have still limited access to their own digital health data. Often their data are untraceable and scattered in different locations. Data on diagnosis, treatment and aftercare, for example, if a patient is abroad and his or her medical information is not accessible, were needed. Besides, incompatible formats and

[1] European Patient Smart Open Services
[2] Electronic Health
[3] European Commission
[4] Information and communications technology

standards in electronic health record systems continue to be used in the EU. Also, there is a lack of common terminology, information and standardization methods/codes for data collection and data presentation in national health information systems, and in mortality and morbidity projects.

Solutions

- In its mid-term review of the implementation of the strategy for the digital single market, the Commission set out its intention to take further action in three areas:
  - secure access for citizens to health data and secure cross-border exchange of these data;
  - better data for the promotion of research, disease prevention, and personalised health care and nursing;
  - digital tools for informed citizen participation and patient-centred care.
- Necessary next steps for pan-European alliances:
  - Establishing EU-wide minimum set of health care taxonomies and standards for data quality, data reliability and cyber-security, permitting technological evolution;
  - Establishing EU-wide minimum data sets for health data exchange;
  - EU-wide standardization of electronic health records;
  - Better interoperability through open exchange formats, as a means to promote quality and reliability through data integration in uniform database structures.
  - Extending harmonization and interoperability efforts to an increasingly diverse range of data relevant to promote research, prevention and personalized care such as data related to biological samples stored in EU biobanks, -omics data, behavioural and environmental data, PROMs5, PREMs6, etc
- In essence, citizens should have access to a complete electronic file containing their health data anywhere in the EU. They should retain control over their health data according to GDPR[7] and be able to share them in a secure way with authorised partners (e.g. Health Providers, Data-Cooperatives, regional Health Organisations, Diagnostic-, Biotech-, Medtech and Pharma- Companies, Disease Management Partners) for medical treatment, prevention services, research and solution/product development or any other purpose they deem appropriate).
- To make data usable for research and development across Europe, we need uniform, data protection-compliant, and cross-border consent systems coordinated with the data protection officers of the member states.
- Another critical success factor is the use of international standards with regard to medical terminology. (e.g. SNOMED CT[8] International)
- The EU needs to agree on uniform, internationally recognised and tested standards/codes throughout Europe to ensure procedural interoperability (e.g. IHE[9]),

[5] Patient-reported outcome measures
[6] Patient-reported experience measures
[7] General Data Protection Regulation
[8] Systematized Nomenclature of Medicine Clinical Terms
[9] Integrating the Healthcare Enterprise

syntactic interoperability (e.g. HL7[10] FHIR[11]) and semantic interoperability (e.g. LOINC[12]). Semantic interoperability is particularly relevant for research and development. The standard used influences the quality of data acquisition considerably, and thereby meaningful use of health data.

- Other health data, also relevant, including a) non-terminological data, b) data groups, c) numerous layers of context like: situational, protocol, order workflow, episode of care, care pathway, care plan, guidelines, have a lack of standardization. The use of other standards like openEHR[13] in conjunction with the above terminologies should be promoted.
- Also, an effort should be done to use an Information Architecture Model that promotes the storage of clinical data cross multiple vendors using common clinical concepts and formats (e.g. openEHR)
- The software systems of hospitals and physicians must comply with uniform international standards concerning semantic and syntactic interoperability. Provide a consistent import/export interface so that data acquisition or data transfer between the primary systems of the service providers and the Electronic Patient File (ePA) receiver will be possible.
- Harmonization in data at all the layers described above is key for any positive development in building new ventures in (digital) health and gaining speed in the global competitiveness.
- Creating a European server infrastructure

2. Digital solutions for European health research and development

Especially in the COVID-19 era, the importance of conducting medical research and development in the EU becomes apparent. Collection and analysis of data is one of the driving forces for innovation. It should increase effectiveness and efficiency and lead to economic and social benefits for the population. To provide the industry with access to anonymous, pseudonymous, aggregated or synthetic patient-related health and treatment data is one of the keys to a cultural change in healthcare service and product delivery. The consent for data usage agreements has to be revised, and data donation or secure access must be possible for all European citizens. For both, academia and industry, it is not always possible to fully specify the precise purpose of scientific research in advance. With big data and AI[14] approaches, this becomes much more evident. That freedom must be perceived, however, with full transparency towards the data owner when the focus is changed, through opt-out possibilities at any time.

Additionally, top-level research and long-term observations can take more than 10 years, so the data is required for a more extended period than possible under current legislation. Enabling the citizens to give a "broad consent" thus better allows for scientific research and

[10] Health Level Seven
[11] Fast Healthcare Interoperability Resources
[12] Logical Observation Identifiers Names and Codes
[13] Open industry specifications, models and software for e-health
[14] Artificial Intelligence

development. This demands implementation of universal data consent engine and legal regulation for European citizens. Europe also needs to establish a reliable infrastructure for secure and efficient data flow between patients, medical care, and research. A centralized coordination support institution could help in achieving this (see for example the United States: "Office of the National Coordinator for Health Information Technology").

Description of the situation

- Digitization will revolutionize healthcare and research in Europe and make cross-border healthcare a reality.
- Digitization enables automatic intelligent data acquisition and exchange systems/sensors or processes that help to link different data sets together. As a result, care can be more focused on the prevention of illness instead of curing diseases.
- Sharing of digital data between attending physician, researchers, and patients will result in more effective diagnoses, treatment and prevention. It also increases patient safety, as it helps to avoid unnecessary duplication of examinations, adverse drug reactions and prescription of ineffective drugs and/or suboptimal dosage. Finally, it triggers the identification and application of the best suitable prevention and treatment options for the individual in a patient-centred (borderless) team approach.

Solution

- Patients should be able to consent to the Europe-wide use of their health data for research and development purposes and thus help researchers in academia and industry to develop more effective early stage prevention strategies, more precise diagnosis options and more individualised therapies.
- The more data is available in digital form, the more researchers and the life sciences industry can support efficient prevention, prediction and treatment. This is made possible by linking clinical data, socio-economic data, biomedical research, and patient's own collected data. Basic IT developments and new analytical and communication approaches, largely based on AI technologies, will continue to expedite these achievements.
- One way to achieve faster digitization of the hospital sector is through the incentive systems promoted by EU member states governments like the one modelled on the US[15] government's "meaningful use" program. Hospitals that follow the FAIR[16]-principles for their data collection, data management, data exchange could receive additional funds for this during a transitional phase.
- Data protection is a valuable asset and must not be put at risk. European policy of the legal situation and the interpretation of the law in data protection law should be agreed on in appropriate detail between the member states based on the General Data Protection Regulation of the EU.
- The foundations must be laid for patients and healthy citizens to be able to declare (and also revoke) their consent to Europe-wide data use (research & care) at the lowest possible threshold. This includes educational and promotional efforts.

[15] United States (of America)
[16] Findable, Accessible, Interoperable, and Re-usable

- In a digitalised healthcare system, the protection of patient data must meet the highest security standards. Patient confidence in the healthcare system depends on this. An open and transparent, secure IT infrastructure with involved parties trusted by the citizens is a prerequisite for delivering that confidence.
- To make rapid progress in the exchange and use of patient data within a European eHealth infrastructure, procedural simplification and the adaptation of the legal framework agreements is necessary.
- Create and implement a European metadata catalog that is machine-readable and follows the FAIR - principles. Where aggregated metadata from the member state can be found (One stop shop).
- Creation of a right of participation for European patient organisations in decisions on data protection.

3. Digital solutions for a resilient population protection

Promotion of integrated and patient centred care, beyond but also in the context of COVID-19 underlines the importance of international cooperation and collaboration to global health. Digital applications concerning civil protection, including for example pandemic wave warning and social distancing apps, as well as exchange of data of research and health system management need to work on a cross-national level.

Description of the situation

- Lacking a digitally based infrastructure to trace infections, many EU countries had to impose a partial or total lockdown to stop the virus. With dramatic consequences for their economies, for the freedom, the supply and and economic wealth of their citizens, for education and for social peace.
- Pricing, reimbursement, application of procurement rules, primarily dealt with at the national level of EU member states → no coherent strategy possible as per today.
- The ECDC17 lacks power: national authorities decide whether or not to implement its' technical advice.
- Lack of clarity concerning data protection and lack of awareness among citizens makes it extremely difficult to track the spread of the virus via apps also at the national level, with a broad majority of citizens opting-out from existing programmes.

Bottlenecks

- National tracing apps are mostly not compatible with each other, so cross-border tracing is difficult. In consequence national borders in the EU were closed to considerable extend, with manifold negative impact. National digital strategies solidified borders instead of bridging them.
- Fragmentation of data collection and sharing rules and data formats across Europe does not allow harnessing the benefit of data, such as EU-wide optimized and dynamic management of medical key resources, diagnosis and treatment improvements as well

[17] European Centre for Disease Prevention and Control

as development of preventive, diagnostic and curative approaches. A harmonized framework in EU is a crucial factor for success of digitalization of health systems with largely increased resilience against pandemia.

Solutions

- Strengthening the ECDC to improve its coordination capacities and its mandate to respond to the crisis
  - Expansion of the networking of the ECDC with national competence centers and health care regions
  - Developing a clearing agency for digital health applications in the fields of infection diseases and control
  - Developing a European, publicly accessible medical database
  - Starting a Europe-wide campaign in order to increase the public awareness about the ECDC and its role in disease prevention and control
- Strengthening the European initiatives to ensure it can effectively coordinate the EU's actions in preventing medicines shortages → digital registers of medical supply allow for coordination at EU level
- Interoperability & standardization of eHealth services (developing common standards to enhance interoperable healthcare systems among member states)
- Apps that enable the automatic detection of contacts and trace infection chains ("tracing apps") must be interoperable with systems from other countries to allow the exchange of information beyond national borders
- The EU Commission should create Europe-wide transparency for public reporting on the structures and quality data of the health care system

4. Digital solutions for a protective health care and elderly care system

Ideas long in place were forced towards realisation in times of COVID-19: telemedicine and virtual diagnostics can provide patients with professional help while at the same time minimizing the risk of infections. In all phases of medical care from prevention to aftercare, digital solutions can significantly improve the situation of doctors and patients as well as of healthy people.

Description of the situation

- In many countries of the European Union, patients are reluctant to make appointments for non-urgent consultations in hospitals and at doctors because they fear contracting the virus.
- Hospitals postpone non-emergency and elective procedures to create capacities for COVID-19-patients.
- With no efficient digital tracing of COVID-19-infections, especially elderly people (who are the most vulnerable population about the virus) have to be isolated and thus lack social contacts.

- Cross-border healthcare cooperation in hospitals could ensure better treatment and transfer of patients: some regions and hospitals in Europe have large capacities, while others are short of medical personnel and supplies.
- Local COVID-19-outbreaks are especially dangerous in hospitals and elderly care institutions.
- EU and its member states have a wide variety and an archipelago-like landscape of (very) promising (often evidence-based) pilot-projects on telecare and telemedicine e.g., remote monitoring of health failure or remote support of stroke rehabilitation. Such schemes enable for a significant improvement of treatment and care of older, disabled or chronically ill people and can even become part of prevention programs for specific risk groups. The standard schemes currently in place across Europe are a very high cost burden for the health budgets and result in high suffering and effort burden for the patients. In times of Corona/COVID-19 telemedicine and telecare may also contribute to reduce risks of infections.

Bottlenecks

- Exchange of information between hospitals and primary care networks across borders and even across countries and regions lack coordination.
- Pricing, reimbursement and application of procurement rules dealt primarily with at the national – if not at the regional – level.
- In some member states of the EU: lack of communication and coordination between inpatient and outpatient health sector.
- Treatment of individual patients in different EU countries is complicated → legal and bureaucratic difficulties, lack of patient health data exchange mechanisms, lack of coordination (example: patients who are treated in another EU country officially need prior authorization from the competent social security institution of their home country)
- Concerning telemedicine and telecare there is a significant, broad, and very bitter deployment and interoperability gap to exploit promising pilot projects for broader use and for making them an asset for better treatment, care, and prevention (and fewer infections!)

Solutions (for COVID-19 but also beyond)

- Sharing of COVID-19-patients digital data allows better ways to handle them in hospitals in secure manner, elderly care at institutions or even at home in a controlled and supported manner to prevent infections within the respective institution.
- Developing a platform for healthcare workers to report real-time data on volumes of patients with COVID-19, personal protective equipment, staffing, ventilator usage and other resource information accessible for national and/or European healthcare authorities → status of healthcare facilities can be monitored, capacities (for example hospital beds) can be used efficiently and increased where needed.
- Coordinating cross-border healthcare with the help of data → saving lives especially of intensive care patients by taking them to hospitals in other EU countries with free capacities.

- New prediction models using AI, machine learning and new computational methods such as network analysis can guide clinical decision-making, and resource allocation → regions and hospitals in need of medical supplies and resources can automatically be supported.
- To overcome the deployment gap in telemedicine and telecare, it might be helpful to establish both a biennial research-based EU-wide monitoring-report on pilot sites and well working solutions as well as some kind of obligation for national stakeholders and decision makers to make statements on the pros and cons of innovations. This probably will create pressure in the EU member states to go for a sustainable use and financing basis for evidence-based and digitally supported disease prevention, disease management and telecare schemes.
- Creation of a Europe-wide support program to strengthen digital health literacy to empower citizens.

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