DIGITAL HEALTH REGULATION LANDSCAPE AND DATA CHALLENGES

Policy Brief
Center for the Governance of Change
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EXECUTIVE SUMMARY

AI and digital technologies hold promise for a more efficient and effective care delivery. In order to maximise the potential of these emerging technologies and enable their effective integration into European healthcare systems, a concerted, multi-stakeholder effort in data is necessary, with a particular focus on:

Top-down strategic approach for structures, standards & infrastructure by identifying key areas of systemic need where a certain structure and set of standards are key for primary and secondary uses.

Bottom-up approach for solution finding and development, by enabling local actors to identify key local characteristics that will shape the kinds of solutions that are needed, with subsequent co-creation.

Integration of the top-down and the bottom-up approaches by defining a set of standards for data capture and data exchange, and socialising best practices.

DISCUSSION

A diverse group of European stakeholders representing the fields of clinical practice, regulatory affairs, innovative health tech businesses, and academia met on 18th November 2020 to discuss *"Digital Health regulation landscape and data challenges"* for AI in healthcare. Having considered the entirety of the care pathway, the discussants elucidated priority high-impact areas for short- to mid-term improvement and proposed the following actions:

1. UNIFIED DATA CAPTURE & INTEROPERABILITY

The growing number of AI-based solutions offers the opportunity to optimize healthcare systems and create innovative solutions for diagnosis, treatment and hospital management. However, the multitude of solutions from different private-sector developers present a challenge for consistent data capture and interoperability across systems on a national and international level. The introduction of individual initiatives in particular countries challenges legal certainty, presents a potential danger to citizen's rights and leads to fragmentation in healthcare systems which limits the potential for long-term impact of AI solutions on health outcomes.

This introduces one question:

HOW TO ENSURE THERE IS FULL COMPATIBILITY BETWEEN AND WITHIN HEALTHCARE SYSTEMS?

Solution: A top-down strategic approach for structures, standards & infrastructure

There is a need for a strong leadership framework and a unified strategy to initiate the establishment of reliable digital structures and incentivize their acceptance and execution on a national and sub-national level. The concept of a data lake which offers the opportunity for deposition and access of a wide range of unstructured but labelled datasets from different AI providers could be a worthwhile solution to increase interoperability and compatibility across systems and to overcome the silo mindset. Such solutions are commonly used in the finance sector and begin to be established by private sector companies to store health-related data.[1]

The establishment of a unified data repository would require clear guidance on the scope and format of the data that should be made available by individual AI providers and the rules for access by different stakeholders to ensure the consideration all human and ethical implications of AI (as proposed in the European Commission President Political Guidelines[2]).

Actions to take:

— Provide concrete contact-points under the same leadership framework and strengthen the relationships between private and public sector stakeholders to create enabling environment for technology implementation.

— Harmonize governance rules and guidelines on data capture, entry, normalisation, storage, access and exchange and integrate security information and event management systems to ensure the safe and reliable usage of common repositories.

1 www.businesswire.com/news/home/20201208005491/en/AWS-Announces-Amazon-HealthLake
2 ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

2. CONTEXT-SPECIFIC SOLUTION BUILDING AND EVALUATION

The introduction of AI solutions for health that can lead to improved health outcomes on a national level requires a high degree of adaptability and sensitivity to the local context. There are a number of critical needs, related to the frameworks taken to find and develop solutions and to the role that local actors take. Therefore, it is key to acknowledge the heterogeneity in local needs and contexts, the digital maturity of the underlying infrastructure and the local skill sets in order to ensure the adoption and scale-up of solutions.

This introduces two questions:

HOW TO DEVELOP SOLUTIONS THAT WILL BE FULLY EXPLOITED?

Solution: Co-creation and co-design / Empowerment of local actors

Being able to deliver context-specific solutions that also ensure interoperability, requires the involvement of local stakeholders from the design phase of solution development as well as the creation of systematic feedback loops to allow for timely reporting of optimisation needs based on user experience with the ultimate goal to maximise impact for end-user.

Actions to take:

— Communicate clearly the value-added of new solutions compared to the current standard.

— Cultivate acceptance/trust by having mature conversations about risks and benefits.

— Establish relevant structures for systematic follow-up and feedback on the implemented solutions to continuously monitor their feasibility and impact.

HOW TO FIND SOLUTIONS THAT FULLY MATCH LOCAL NEEDS?

Solution: Bottom-up approach for solution finding

The introduction of AI solutions in local contexts needs to ensure that the key needs of the local area are addressed. Given the high degree of flexibility and adaptability of software nowadays, it becomes possible to use a bottom-up approach for solution finding and development. A good example is seen in the banking sector where there is a common strategic framework on an EU level but combined with a diverse range of services and products that are offered to the different types of consumers according to their needs, geographical areas and existing infrastructures.

Actions to take:

— Identify local gaps in healthcare services that can be addressed by digital health solutions and engage with local stakeholders in a bottom-up manner to Identify the degree of digital maturity of the available infrastructure.

— Build a modular approach for integration of new tools and technologies that allow for their flexible adoption in a context-specific manner and incentivise developers to integrate these principles from the point of design

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— Develop evaluation methodologies for technical, impact and feasibility assessment for digital solutions that take into account local legislative and infrastructure barriers and can be delivered in line with the timelines of development of new technologies.

3. INTEGRATION OF THE TOP-DOWN AND THE BOTTOM-UP APPROACHES

It is key that while interoperability and compatibility is directed in a top-down fashion, solution building occurs in a bottom-up approach. This means that there needs to be a connector to ensure that both approaches answer the same aims. Data needs to be of a high enough quality to allow for uses by different systems and for different goals. Best practices need to be identified, recognised and shared.

This introduces two questions:

HOW TO ENSURE DATA HAS THE RIGHT QUALITY TO BE USED IN ALL DESIRED CONTEXTS?

Solution: Incentivisation (of all actors) for harmonized/high-quality data capture

A crucial component of building an integrated approach for implementation of AI in healthcare is the identification of a harmonized system for bridging the topdown leadership framework with the bottom-up solution building. This requires a continuous dialogue between policy-makers, solution developers and end users from clinical and biomedical sectors to ensure the quality and the representativeness of the developed solutions and to avoid the misinterpretation or misuse of data.

Actions to take:

— Communicate more clearly the secondary benefits and potential use cases (of each data point) (i.e., research databases or national registries).

— Create a financing model (grants, consultancy fees) to incentivize participation of key experts in solution building or testing gather all relevant perspectives and generate sufficient number of use cases.

HOW CAN BEST PRACTICES BE IDENTIFIED AND EXTENDED?

Solution: Platforms for harmonization of resources and collection of best practices

Achieving high degree of interoperability of AI-based solutions in healthcare, requires the identification and open sharing of all challenges associated with implementation of solutions in different contexts. In conjunction with this, there is also a need for creation of a unified certification system for both hardware and software aspects of digital solutions in the broad category of internet of medical things (IoMT) to ensure that all basic requirements are met irrespective of the context of implementation and key learnings from the implementation process can be attributed to the context itself rather than major differences in the digital solutions.

Actions to take:

— Create a system for mutual recognition agreements for equivalent local tools and practices to enable sharing of best practices and key solutions across countries.

— Implement a framework for harmonization and certification of the exchange, integration, and sharing of electronic health information that is applied to all digital health solutions (efforts in this direction have already been initiated by HL7.[3]

3 www.hl7.org/about/index.cfm?ref=nav

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REFERENCES

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