Virtual High-Level Conference
"Digital Health 2020 – EU on the Move"
11 November 2020

Presidency Summary

On 11 November 2020, the virtual High-level Conference "Digital Health 2020 – EU on the Move" was held in the framework of Germany's Presidency of the Council of the European Union (EU). The conference brought together virtually representatives and experts from all areas involved in the continued development of digital health.

Prof. Effy Vayena (ETH Zurich) provided a summary as an essential part of the conference. With her wrap-up of the sessions – "AI and me", "AI and my doctor" and "AI in my hospital" – Prof. Vayena identified the challenges and the actions needed for application of AI in healthcare and framed the way forward. This Presidency Summary is based on this wrap-up:

Debates and discussions throughout the conference highlighted that artificial intelligence offers immense opportunities in all different settings looked at during the conference: the individual, outpatient healthcare providers, as well as inpatient health care institutions. At the same time, its development and deployment pose equally immense challenges. What's more, AI shifts roles and responsibilities of the actors in these three settings allowing them to enter more complex and multi-faceted relationships.

The underlying promise throughout the conference was that AI offers the unprecedented chance of breaking the iron triangle of health care. Namely, that access, quality and cost can be improved at the same time. That's a promise that everyone must take seriously and help realise.

Key learnings:

- Data is needed to make AI work.
- Building trustworthy systems and earning public trust is paramount.
- Attention is needed on interoperability, evidence of effectiveness, governance that ensures transparency, fairness and accountability.
- Future thinking should focus on "AI and WE".

What are the challenges?

The lifeblood of AI is DATA. Data is needed to train algorithms, to improve evidence, to improve care. But we continue to struggle with:

- access to data within institutions, nations, and internationally;
- technical and semantic interoperability issues, organisational interoperability and maturity of federated data systems,
- regulatory confusion and informed consent deficits – one size does not fit all;
- lacking sector specific codes of conduct for data uses that are foreseen by the GDPR and therefore offer an opportunity for the necessary granularity and specificity;
- misaligned incentives – be it in AI research or in adoption;
- agreement on metrics and processes for demonstrating meaningful benefits;
- insufficient digital literacy of both health care providers and lay people.

During the conference, many mentioned the challenge of accessing data and training AI models while at the same time respecting our individual and collective dignity. For example, collecting and reusing data without the risk of these uses having adverse effects on the very people whose data are accessed by their communities. The issue of trust and trustworthiness came up frequently as a sine qua non for the future of AI in health. Building trustworthy systems and earning public trust is probably the biggest challenge that we are facing in AI.

In the most recent and pan European experiment of a digital application in health, the COVID-19 contact proximity tracing, the magnitude of the challenge became evident. Several observations from this large scale experiment are worth noting: the debate was quickly reduced to the binary health or privacy; efficacy and effectiveness of the apps was chained into a catch 22, if people did not use it, we could not ascertain effectives, but people needed to know it works in order to use it. At the same time, it became clear, that digital health and AI do not have to come at the cost of privacy, that big tech can sit at the table with regulators. The tireless efforts of the European Data Protection Supervisor is a case in point. The famous challenge of interoperability can be overcome with political will and decisive action, for example the EU interoperability gateway for contact tracing and warning apps was available in the course of a few months. We also saw that putting a product like this on the market, even if in a privacy preserving manner, even if with the stamp and blessing of national health authorities, has not been enough to guarantee wide public adoption. And this is a lesson that needs to be studied carefully when rolling out the Electronic Health Record (EHR) systems, data spaces and integration of AI into health care systems.

Where should we focus our attention?

There still is need for action on technical and semantic standards that allows uniformity that can make data usable and useful. Interoperability is long overdue and a concrete and comprehensive strategy for overcoming it is neccessary. Achieving interoperability will help improve data quality, data completion and their access.

Clarity is also needed on what constitutes evidence of effectiveness in health AI. Such clarity will allow developers to know what standards they should be meeting, and authorities what they must be evaluating. The European Medicines Agency (EMA) is working on these standards of evidence; progress is being made also in expanding the data sources used for generation of evidence as well as in the use of real-world data (RWD). But there is an urgent need for standards for the many AI products (often labelled as health and wellness apps) that are in everyone's hands and mobile phones claiming efficacy but having no basis of this. Not only will AI of this type erode trust and confidence in health care systems, but it will also discourage than promote innovation.

Finally and very importantly, especially in creating the European Health Data Space (EHDS) we need to focus on good governance. Governance that ensures, transparency, fairness and accountability. We do not have to re-invent the wheel of governance. There is an extensive body of conceptual work available in academic scholariship and in policy guidelines. What is needed is to translate this into a concrete governance process that will allow data access to happen, privacy to be preserved and society to trust health authorities and tech companies. This governance process will set the conditions of data collection and access as well as the conditions for fair and equitable distribution of benefits that will come out of the uses of these data. Federal Minister Jens Spahn used the metaphor of a house when speaking about the EHDS. By the end of the last session of the conference, the house turned into a town, a city with public transportation. Whether we are building a house or a city, we do need clarity of vision and clarity on the conditions that apply when the house or the city is filled with data. The European Commission informed that this work on governance is already underway. For governance of such a complex initiative like the EHDS to be successful it needs to be adaptive, reflexive and responsive.

Moving Forward

The conference broke down the big and complex question of AI to AI and me, AI and my doctor and AI and my institution. This was very helpful for analysis and reflection. But to see the whole picture, we need to stitch the pieces back together. In doing that we clearly see that future thinking should focus on **"AI and WE"**:

- It is **WE – all of us** who are **making AI possible** because **our** data train it and validate it. Without these data, most AI will be of little if any value. We should

therefore have a saying on what happens with these data and whether their use serves the common good.

- It is **WE, the humans behind the algorithms or at their mercy,** the humans who hopefully still interact with **empathy and respect for one another**. We should therefore ensure that our common values and ethical principles are infused in the technology we use, even if the technology companies that provide them are not European.
- Finally, and importantly it is **WE the people of these European countries** expecting from our political representatives to make sure that our AI enabled health care will be accountable, equitable and trustworthy.