Towards individual centric support services during pandemics

MyData-4-Pandemics response to HERA Impact Assessment
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We congratulate the European Commission teams who have been working on the *European Health Emergency Preparedness and Response Authority (HERA) – Inception Impact Assessment*[1]. It is not an easy task to bring forward a common European approach to manage cross border outbreaks like the COVID19 pandemic, in respect of the diverse legislations, health systems, procurement systems and economic challenges across EU countries. We welcome the initiative as a well needed common approach for more effective management of pandemics and cross border outbreaks, to protect and support all EU citizens equally. More specifically we hope that this will help EU authorities and decision-makers to define and deploy appropriate measures for the common goods while ensuring that EU citizens' data privacy rights are respected whenever their personal data are being used.

MyData-4-Pandemics is a thematic group within MyData Global[2] an award-winning international nonprofit, based in Helsinki, Finland whose purpose is to empower individuals by improving their right to self-determination regarding their personal data; the MyData Declaration[3] outlines the paradigm shifts and the principles that are needed to make this a reality.
The European Data Strategy[4] recognises MyData as one of the movements that 'promise significant benefits to individuals, including to their health and wellness, better personal finances, reduced environmental footprint, hassle-free access to public and private services and greater oversight and transparency over their personal data'. MyData Global operates a self-regulatory process for data intermediary services focusing on human-centric personal data. In 2020, 27

[1] HERA – Inception Impact assessment paper
[2] MyData Global
[3] MyData Declaration
[4] A European Strategy for Data

organisations providing intermediary services from 15 countries were awarded the status of MyData operator[5]. These MyData operators are potential candidates to provide the type of platform needed to support citizens and authorities during pandemics, as further described in the document.

The mission of the MyData-4-Pandemic Thematic Group is to enable responsible and secure freedom of movement of individuals during pandemics like COVID-19, while minimizing the impact on health, the economy and education. We comment on *HERA – Inception Impact Assessment* from the perspective of the MyData-4-Pandemics Thematic group. Several members participated to draft this commentary. Still, it should not be considered comprehensively representative of the complete MyData community.

Our top picks for potential improvements are:

1. **Need for a coordinated multifactorial approach.** While we understand that HERA is focusing on Medical CounterMeasures (MCM)s, we believe that the management of pandemics requires coordinated definition and deployment MCMs and non-pharmaceutical interventions (NPI). We specifically encourage bringing HERA and ECDC under a single authority.
2. **Need to empower individuals as responsible citizens, through ICT;** we think that EU citizens are forgotten in the HERA proposal, while it is clearly acknowledged by WHO[6] that citizens are key stakeholders in endemics/pandemics. Citizens need to adapt their behaviour, and for this, they need to understand what they need to do and why; this can be done most effectively through appropriate and cross EU consistent communication messages, coordinated through a single organisation, adapted to different levels of education and delivered through virtual assistants.
3. **Need to preserve EU citizen data privacy rights during pandemics.** Citizen's data are critically important to support the definition and deployment of MCMs and NPIs during cross border outbreaks. Sharing and reusing personal data must be compliant with GDPR; new approaches aligned with the emerging EU Data Governance Act[7] should be supported proactively, to ensure that authorities have access to the needed data without infringing on

[5] Understanding MyData Operators white paper
[6] WHO – Managing epidemics
[7] EU Data Governance Act – Draft regulation

EU citizens data privacy rights. In case of emergency, reuse of personal data without citizen consent must be strictly controlled and limited; any breach must be quickly notified.

4. **Need to provide user-friendly and sustainable technology solutions supporting a Personal Public and Private Partnership (4P).** Management of pandemics does not only require personal data but also non-personal data from the private sector. In addition, it is important that authorities regularly communicate findings and guidelines to keep citizens empowered. Effective and rapid exchange of data and information within a 4P require technology solutions; more specifically we suggest developing and deploying new individual centric pandemic related services on top of emerging EU Data Intermediaries and Data Altruism Organisations[5].
5. **Opportunity to increase the impact of HERA by taking a citizen centric approach.** While HERA will bring much value on different fronts, we believe that the impact can be significantly increased if individual centric solutions as described before are deployed.

We comment on these in more detail and suggest specific improvements in the sections below.

1. Need for a coordinated multifactorial approach

Comments

The HERA-Inception Impact Assessment focuses on medical countermeasures (MCM); we recognize the importance and complexity of this and congratulate the team who developed the approach. We understand that European Centre for Disease Control (ECDC) is responsible for the coordination of non-pharmaceutical interventions (NPI): they developed and published guidelines[8] for implementation of NPIs related to COVID-19, and they maintain a list of NPIs within the EU RMD Database[9].

In agreement with the independent expert panel[10] on pandemic preparedness, we believe that management of pandemics is multifactorial and cross-sectoral; it requires definition, deployment and enforcement of MCMs and NPIs in a cohesive way to ensure complementarity and reinforcement. Indeed, they both rely heavily on personal data sources, and therefore need to respect GDPR; they both need input from multiple actors in a Person, Public, Private Partnership (4P); they both require harmonization across the EU; they both need to be communicated properly to the EU citizens for effective deployment.

While the HERA document describes harmonization and consolidation of MCMs across EU, there is no indication on the need and intent to harmonize NPIs across EU – through HERA or through the ECDC - while (1) NPIs is the first instrument used in case of major pandemics and therefore should be quickly scalable in case of outbreaks, (2) it is well documented that restrictions of mobility and confinement have an important impact on health[11] - as well as on the economy and education, (3) it is clear that interoperability of contact tracing applications[12] alone is not sufficient, and (4) the current lack of harmonization of MCMs and NPIs across the different EU countries is creating confusions.

[8] Guidelines for the implementation of non-pharmaceutical interventions against COVID-19, Sep 2020
[9] Response Measures Database (RMD) of ECDC and JRC
[10] Independent Expert Report. Improving pandemic preparedness and management. Nov 2020
[11] Calling for benefit-risk evaluations of COVID-19 control measures
[12] Technical specifications for interoperability of contact tracing applications

There is an acknowledgement in the HERA paper that synergies should be built with the European Centre for Disease Control (ECDC) - and the European Medicine Agency (EMA) – but there is no clarity on the objective, scope and approach of this collaboration and no reference to ECDC and EMA in the implementation scenarios. It is noteworthy also that there is no mention in the document on the role of - and impact to – citizens and the private sector, outside of medical companies.

In section "B. Objectives and Policy options", the HERA paper mentions: "*The Authority will take a whole value chain approach, from threat assessment to conceptualisation to deployment in case of need. It will support Member States' response capacities and access and ensuing availability and deployment of countermeasures to prepare for and address human cross-border health threats."*. To reach this objective, there is a need to have a well-defined multifactorial approach in a 4P across all stakeholders.

Our Proposal

We urge the European Commission to consider a holistic approach to manage ALL aspects of pandemics[13], not just MCMs but also NPIs, in a coordinated way across all EU stakeholders in a 4P approach. We believe it is particularly important to foresee an active role for EU citizens.

If the objective of HERA is to define an End-to-End solution for pandemics, we believe that options 1 or 3, described in *Section B. Objectives and Policy options* would be the most appropriate ones, assuming they cover the complete scope of MCM and NPIs AND under the condition that collaboration and synergies with ECDC and EMA are clarified. We strongly suggest however to consider a **fourth scenario** that would bring HERA and ECDC as two operational units within a single authority, or to expand the existing ECDC organisation with HERA. This would simplify decision making for EU staff, decrease administrative burden for national authorities, private sector and EU citizens and generally ensure a more effective, less costly approach to cross-border outbreaks that will inevitably be generated if two separate organisations with the same final goal (prevent and manage cross-borders outbreaks) were to co-exist.

In addition, there is a need for further clarification on how citizens and the private sector – outside of medical actors – should be involved, building on the suggestions included in this document.

[13] The Swiss Cheese Strategy to pandemics – Tomas Puyeo

More precisely, i the objective of HERA is to focus only on MCMs, building on the model of the US BARDA, then we strongly suggest identifying an EU wide mechanism - with or within ECDC - with all the different stakeholders in a 4P, to harmonize the definition, deployment, communication and enforcement of NPIs across all EU countries, while respecting the principle of subsidiarity. NPIs should be managed in alignment with MCMs to complement and reinforce each other.

2. Need to empower individuals as responsible citizens, through ICT

Comments

The HERA - Inception Impact Assessment is proposing solutions that are designed to solve problems (e.g., monitoring on needs; development, manufacturing, procurement, distribution of key medical countermeasures...) **FOR the individuals**. In this approach, EU citizens are passive - and often confused and frustrated - while WHO[10] stresses the importance to change citizens' behaviour during a pandemic. In addition, social media used by non-informed passive citizens is the source of infodemics, spreading disinformation and increasing confusion and frustration. This happened for vaccines described as non-safe because it was developed too rapidly.

With MyData, an international non-profit organization whose mission is to improve the right of individuals to self-determination for their personal data, we believe we need to move toward active participation **BY the individuals**, toward individual agency If citizens are informed on what they can and cannot do and why, and if they are in control of their data, they feel empowered and in trust, and they are incentivized to adapt their behaviour and become responsible, pro-active stakeholders; in addition, they are more comfortable to share personal data for the common goods.

The need for communication and the need for coordination of knowledge across different stakeholders and sectors is mentioned in Section B, though there are no details on how this will take place and how communication will be harmonized and regularly updated – potentially daily - across stakeholders at national and international level in an efficient way. In addition, there is no specification on how communication with citizens will take place. During major outbreaks, with constantly changing situations and measures, communication needs to go beyond regular communications provided by ECDC and EMA if it wants to have an impact: it must be up to date, adapted to different contexts and education levels, and targeted to potentially each EU citizen.

Our Proposal

Taking into account the importance to engage EU citizens and ensure they are able and encouraged to become responsible and become proactive / positive actors in pandemic management, we believe that HERA – with or within ECDC - should build a coordinated approach

to communication across EU stakeholders, WITH citizens representative in a 4P, and with the view to build not only consistent messages across EU but also messages that are adapted to the context of each individual. With emerging virtual assistant technologies, building on chatbot like SIRI, ALEXA, Google Home or bot applications on smartphones, the messages can easily be spread with the latest information. To be really impactful with targeted messages adapted to the context of each individual, the bot would need to have access to citizen specific data as proposed in Section 4.

3. Need to preserve EU citizen data privacy rights during pandemics.

Comments

Section A. Context, problem definition emphasizes the need for data to support analysis, monitoring and definition of coordinated approaches across the EU. Clinical data are also needed to support clinical research and development of new therapies and vaccines. This is all personal data, subject to GDPR.

Following the principle of data minimisation, described in article 5 of GDPR, processing of data shall be ".... *(c) adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (‘data minimisation’)*". As the same personal data are needed to support different aspects (MCMs and NPIs) of the same goal (manage cross border outbreaks), compliance with GDPR mandates the establishment of a common infrastructure to reuse personal data for both MCMs and NPIs, unless specifically demonstrated it is not feasible.

In the current model – if data privacy rights are to be preserved – personal data coming from different sources are typically aggregated and anonymized at the population level. When integrating multiple anonymized data sources, it is impossible to know if a record in one data source belongs to the same individual in another data source. As a result, authorities have a good view at the population level but do not have a view at the individual level. This has a specifically negative impact for NPI where social distancing and lockdown can only be defined at the population level (regional or even national level), while more granular approaches (at the neighbourhood, county or city level) would be more appropriate with less negative impact. In order to have a more precise understanding of the situation, it is important to combine data from different data sources at the individual level. For instance, data on residence, employment, transport and travel, contact tracing, self-assessment and COVID-19 testing/vaccination should all be combined at the individual level and then aggregated at the population level to allow for more acceptable, individualized measures. This requires however full consent from the individuals per GDPR.

As there are no readily available solutions in place to combine data at the individual level with individual's consent, authorities have no other choice than to infringe on data privacy rights in the

name of the common good: in April 2020[14], 34 countries - including 9 European countries - were identified as potentially infringing on Data Privacy rights.

The European Data Protection Board[15] confirms that breach of GDPR for emergency reasons should be voted by national law, exceptionally, explained to citizens and limited in time. The WHO-ACT Data governance[16] section 4.3.2 mentions conditions under which personal data can be accessed WITHOUT individual's consent, though with the approval from an independent accredited ethical committee. Unfortunately, countries - like Belgium[17] - are still not following these recommendations and infringe on GDPR without control by an ethical committee or a limitation in time. Other non-European countries have similar tendency, linking different personal data sources without individual consent and infringing on data privacy[18].

Our proposal

We understand - and encourage - to need to access personal data to support researchers and authorities to define, adapt and enforce MCMs and NPIs throughout a major cross border outbreak. **There is no need however to trade data privacy for human health**: emerging solutions can be used. Data Intermediaries and/or Data Altruism organisations – as described in the draft EU Data Governance Act regulation[5] - lays the legal foundations of data sharing and reuse in Europe. Building on the MyData operator[3] type solutions, it is possible today for EU citizens to share their data in trust and in compliance with GDPR. This would also support the GDPR requirement for data minimisation.

We suggest that HERA - with or within ECDC, the WHO and national authorities – encourages the deployment of Data Intermediaries and/or Data Altruism organisations, supporting regulated and trustworthy data sharing of personal data to avoid the need to infringe on GDPR.

[14] We mapped how the Coronavirus is driving new surveillance programs around the world - April 2020
[15] EPD Statement on restrictions on data subject rights in connection to the state of emergency in Member States Guidelines - June 2020
[16] WHO-ACT Framework for the governance of personal data - January 2010
[17] Moniteur Belge – January 2021. Article 8 says: "*The office of National Social Security can .....collect, combine and process - including via datamining and datamatching - health-related data for the coronavirus COVID-19, contact, identification, work and residence data for employed persons and self-employed, to support the tracking and review of clusters and communities.*"
[18] COVID-19 vaccinations in Japan linked with SSN

As such action may not be effective on time, we understand that under SPECIFIC conditions, HERA/ECDC should have access to personal data. This should however be strictly controlled and specified within the HERA operating model, in alignment with the ECDC

1. HERA/ECDC should specify the conditions under which personal data can legally be used without individual consents; this should be in compliance with Article 23 of GDPR and aligned with the European Data Protection Board and the WHO-ACT data governance framework[10].
2. HERA/ECDC should set up an ethical committee of independent experts assessing if the decision to use personal data without consent is proportionate to the need to protect the common good.
3. HERA/ECDC - or the relevant EU authority - shall monitor EU authorities during cross-border outbreaks and apply article 33 of GDPR in case of breach.

4. Need to provide user friendly and sustainable technology solutions supporting a Personal Public and Private Partnership (4P)

Comments

The COVID-19 pandemic is not yet controlled; it is responsible for more than 2,4 Millions deaths[19] with an economical cost in excess of $10 Trillions[20]. Experts expect COVID-19 to become endemic (though with less danger)[21], and more, more deadly outbreaks can be foreseen[22]. While the focus should remain on prevention, European authorities should make sure the right measures - MCMs and NPIs - can be ***rapidly scaled up*** and adapted should an outbreak occur.

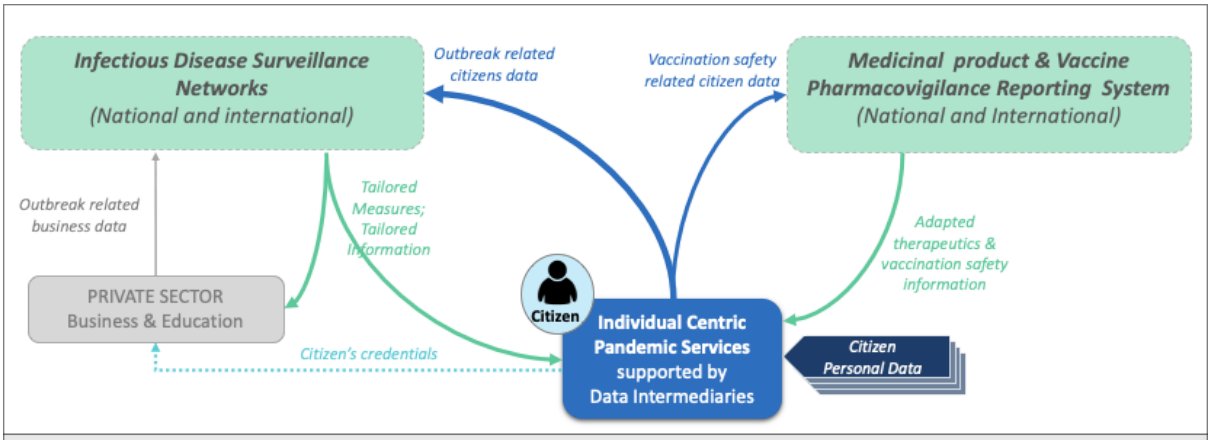
As well identified in the HERA paper, to be successful in defining and deploying MCMs - and NPIs - during cross border health threats, the EU needs to ensure collaboration and harmonized decisions across all EU relevant authorities. There is also a need for harmonized communications and messaging across all stakeholders, with the inclusion of citizens and the private sector (medical and other sectors). This requires personal data from citizens (e.g., health status, self-assessment, test and vaccination status...) and non-personal data from the private sector. In addition, findings and measures from authorities should be regularly communicated to citizens, as soon as they are updated, to ensure they can be followed.

Existing infectious disease surveillance and support systems include epidemiological surveillance, early warning systems and infectious disease modelling; they are all based on anonymized data. HERA mentions the need to add simulation and modelling for the procurement and distribution of medical goods (materials, medicinal products, vaccines). ***There is no mention of solutions to support citizens and to manage personal data, and non-personal data***.

On the other hand, the EU Commission is defining an ambitious Data Strategy[23] that builds on 4 pillars – including sector specific data spaces and data governance. More specifically, the EU recently issued a Draft version of Data Governance Act[5] regulating sharing and reuse of personal and non-personal data. We believe that HERA – with or within ECDC - should leverage the EU

[19] WHO - COVID dashboard - February 2021
[20] What is the economic cost of COVID019 - The Economist - January 2021
[21] The Coronavirus is here to stay - Nature, February 2021.
[22] IPBES Workshop Report on Biodiversity and Pandemics.
[23] European Strategy for Data – February 2020

Data Strategy, and more specifically we believe that HERA/ECDC should identify individual centric pandemic related services to be deployed on top of these emerging Data Intermediaries/Data Altruism Organisations for the benefit of the citizens, the authorities and the private sector, during cross border outbreaks. As displayed in the figure below, this would enable citizens to share their data – in trust – with infectious disease surveillance networks and with drug regulatory authorities, and in return to receive tailored information that can be integrated within a virtual assistant described in Section 2. In addition, such solution could make use of emerging technologies such as verified credentials[24] allowing to implement more granular measures around confinement and mobility. For instance, vaccinated or immune or negative citizens (for less than 2 days) could have more freedom to move than other citizens.



A Person Public Private (4P) pan-european approach for cross-border outbreaks, enabling data privacy compliant reuse of personal data and empowering EU citizens as responsible stakeholders

Our proposal

We suggest that the EU - as well as the WHO and national authorities - support the research and development of scalable individual centric pandemic specific services on top of Data intermediaries / Data altruism organisations, to meet authorities and researchers needs during cross border outbreaks, while preserving EU citizens data privacy rights. We propose to use existing instruments such as Horizon Europe to identify and prototype such services, in a way that ensures rapid scalability when outbreak occurs and sustainability outside of outbreaks.

[24] Verified Credentials are digital credentials; it is classically represented by a QR code contained in a digital wallet of the citizen. The QR code is issued by one organization – for instance a vaccination lab – and can then be verified by any relevant 3party – for instance an airport or an airline company.

Unfortunately, the Horizon Europe draft work programme from January 2021 does not account for this. More specifically the topic *HORIZON-HLTH-2021-DISEASE-04-06: Building a European Research and Innovation Partnership for Pandemic Preparedness* focuses on better coordination funding for R&I at EU, national (and regional) level towards jointly agreed objectives and an agreed strategic R&I agenda for a total budget of € 2 Million. There is strictly no mention of managing EU Citizen data, there is no mention of Data Intermediaries and Data Altruism organisations. And mostly, ***there is a major disproportion between the economic impact of pandemics and the associated budget in instruments such as Horizon Europe to support EU citizens and the private sector during - likely - cross border outbreaks, with innovative technologies***.

We suggest that the final Horizon Europe work programme include topics related to the development of scalable cross-border outbreak services on top of Data intermediaries / Data altruism organisations in a true 4P. These services would include aspects such

- support for clinical research and monitoring of EU citizen needs,
- adapted, up to date and targeted information to EU citizens during outbreaks supported by virtual assistants to increase adoption
- responsible freedom of movement for citizens, while minimizing the risk of contagion; this could include hospital sector, education, local and international travel, employment...
- support mass vaccination program, from identification of citizens at risks to monitoring of safety even
- .....

Such services would need to show benefits for all parties.

- People should be in control of their data, ensured their privacy is preserved when sharing data, and empowered thanks to tailored information and context dependent Verified Credentials
- Private sector should be able to optimize business continuity while limiting contagion & health risks; privacy of their information is preserved.
- Public sector/Authorities should be able to define & adapt appropriate MCMs and NPIs– in respect of citizens – while decreasing the burden on health care systems, the economy and the society
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5. Opportunity to increase the HERA impact through a citizen centric approach

While HERA will bring much value on different fronts, we believe that the impact can be significantly increased if individual centric solutions as described before are deployed.

Current Proposal	Opportunity with citizen centric approach
ECONOMIC IMPACT - strengthen the competitiveness of Europe's health tech industry by bringing in new business models and lowering the risk of investing in the development of new products and services.	Individual centric ICT based services as described in Section 4 can make a major difference in the management of pandemics; they can/should be built on top of emerging data intermediaries, considered as one channel of the EU digital economy. By encouraging development of such services, HERA will contribute to the wider EU data strategy and economic agenda.
SOCIAL IMPACT - contribute to improved health outcomes for European citizens, expressed as more life-years in good health, a lower burden of disease, improved patient experience of care, better diagnoses and more efficient therapies.	HERA is not considering the negative impact on Health of crisis/pandemics like COVID19 – as referenced in Section 1. By having an individual centric approach, increasing citizens empowerment and supporting new services such as AI based personal assistants, the negative health impact would be decreased, with positive social impact.
FUNDAMENTAL RIGHTS - contributes to achieving a high level of human, gender-sensitive, health protection, as well as to upholding the highest standards in the protection of human rights and civil liberties, as enshrined in the Charter of Fundamental Rights of the European Union and in the European Pillar of Social Rights, during health crisis	As specified in Section 3, we respectfully disagree that HERA as shaped currently contributes to support highest standards in the protection of human rights and civil liberties. To be successful HERA requires personal data, and without a clear strategy on how to access these data HERA implicitly supports infringement on GDPR. By supporting an individual centric approach, HERA would truly respect data privacy rights AND have access to high quality data.
SIMPLIFICATION AND/OR ADMINISTRATIVE BURDEN - will likely complement and reduce the administrative burden for Member States.	We also respectfully disagree on this. As specified in Section 1, cross borders outbreaks require implementation of NPIs as well as MCMs. NPIs are today not properly coordinated across the EU - and within each country - with confusion and frustration of EU citizens. Deploying solutions as described in this

	document would truly decrease administrative burden across ALL parties, not just authorities. In addition, creating a new organisation will increase the complexity of bringing coordinated information on MCM and NPIs to the EU citizens; the administrative burden for citizens will be decreased if both aspects are coordinated under a single responsible authority.