

Stakeholders 'interviews - citizen engagement in health data
secondary use and sharing
Summary report

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1 Executive Summary

Within the framework of their participation in the Joint Action "Towards a European Health Data Space", the Health Data Hub, Sciensano and the NHS Confederation conducted 53 semi-structured interviews with stakeholders from their national health data ecosystem. The interviewees were asked about two main topics: their experiences, perceptions, and needs and expectations regarding data, particularly from a European perspective; their knowledge and projection of the perceptions and role that citizens could play in the governance of a European health data space. The results will feed into the citizens' e-consultation that will be organised at the end of 2021 until the beginning of 2022 in Belgium, France and the United Kingdom and more generally in the work conducted by the three institutions on citizen engagement for the Joint Action.

With regards to health data secondary use and sharing, among British and Belgian stakeholders secondary use of health data was usually defined as any use of health data beyond the primary purpose it was collected for. The lack of clear definition was raised in both countries and perceived as having a negative impact in data sharing in Belgium. Stakeholders from the three countries made general remarks related to the benefits that could result from reusing and sharing health data. However, some interviewees from France and Belgium raised that the current valorisation model surrounding health data could be a barrier to health data sharing practices. While French and Belgian interviewees insisted either on the increasing sensitivity of the topic or on the intimate link between health data and people, stakeholders from the UK and France seem to perceive an impact on public trust of the purpose and nature of the data user, especially when commercial interests are at play. On the contrary, French and British stakeholders perceived healthcare professionals as benefiting from public trust. Concerning the implication of private actors, their suggestions varied from increasing public funding, not allowing use from commercial actors to supporting it and fostering partnership relationships.

Furthermore, they all reported issues related to legal and technical aspects of data reuse, such as the lack of clarity and/or harmonisation of the legal framework, notably concerning data access procedures, the difficulty to pool data or the length of the timeframes to access it. In all three countries this could have resulted in a reluctance from some actors to proceed to data reuse or sharing for fear of being sanctioned. Consent was also sometimes perceived as a potential barrier in France and Belgium. The sanctions framework was either seen as absent or overly repressive, depending on the regulations in Belgium. The UK stakeholders insisted more on the difficulty to engage healthcare professionals, due in part to the lack of technical infrastructure for them. Another issue raised in France and Belgium related to anonymization and the need to re-contact people. Visions to improve the current situations were focused on easing access procedures while fostering privacy protection and security safeguards, as well as increasing some key actors' role, such as healthcare professionals. A final point raised only in the UK was related to improving representation in data sets to not worsen health inequalities.

Stakeholders developed less on the situation at the European level. Interviewees from the three countries mostly talked about the barriers impeding on health data use and sharing across borders. Obstacles included the lack of a common legislative and technical framework across European countries and the differences in healthcare systems and practices.

Despite the fact that the creation of the European Health Data Space (EHDS) was associated with multiple benefits by French and Belgian stakeholders for patients' care, public health, the private sector and political decision-making, they also expressed their doubts about the feasibility of the project due to the lack of legal, technical and cultural harmonization across and even within countries. Interviewees from the 3 countries emitted several suggestions to build the future European Health Data Space. UK's stakeholders advocated for a fair repartition of the benefits among the states participating to the initiative, Belgian interviewees focused on the need to harmonize technical standards and to ensure the protection of health data, and French actors suggested different starting points and governance formats for the future EHDS to ensure its viability.

With regards to citizen engagement, stakeholders across all three nations shared that the public have had a historically low understanding of the use of their health data for secondary purposes, but that knowledge of health data has been increasing recently, which could be according to UK stakeholders in part due to the

greater use of data during the pandemic. This low knowledge was characterised by British interviewees as being the result of historically poor engagement of citizens by data controllers and users relating to the secondary sharing, use, and governance of their health data. Engagement was also described by UK interviewees as being poorly funded, and by French patients' associations as a component of the research life-cycle that is often added on only at the end of the projects.

It was described by British interviewees across all sectors that it is this low and inconsistent engagement that has allowed common perception on data sharing to be shaped by negative media coverage and the spreading of misinformation. However, stakeholders from all three countries also underlined that secondary use and sharing was perceived as a positive when the projects had a public good purpose.

Stakeholders across the UK, France and Belgium all described varying methods for engaging the public and patients further in the governance of their health data. Interviewees in the UK and Belgium advocated for deliberative engagement mechanisms, such as citizen juries and lay advisory committees that provide an active role to citizens in the governance of their data. By contrast, French interviewees mostly talked about citizen engagement through the greater involvement of patient's associations. Furthermore, interviewees in France and the UK highlighted the value that informative material such as case studies, videos and vignettes can play in raising awareness, and improving the understanding of secondary use among the public, patients and healthcare professionals.

Central to all this engagement is a need for transparency with the public about who is accessing their data, why it is being accessed, the security mechanisms in place to protect their data and the individual and societal benefits of this data being used. Interviewees stressed the need for this information to be presented in a way that is easy for a lay audience to understand.

Stakeholders in the UK and Belgium also raised the issue of equality and equal representation when engaging with citizens. UK interviewees described the need for any engagement to include the active engagement of left behind communities that ensures those from minority populations are provided with an equal opportunity to express their views. Additionally, interviewees in Belgium and the UK described the need to overcome digital inequalities that risk being exacerbated as engagement mechanisms take an ever-greater online approach.

Stakeholders developed less on citizens' engagement when talking about the European level. Only a few of them did mention this topic in all three countries. While the heart of the conversation in Belgium was the acceptability of the EHDS project by citizens and the need to ensure the protection of the citizens through consent of anonymisation, in France stakeholders highlighted the barriers to the involvement of patients' associations at the European level. In the UK, the focus was made on the lack of a common public participation, engagement and Inclusion culture across countries.

Introduction

Responding to the European Council's call for the creation of a European Health Data Space (EHDS), the Joint Action "Towards a European Health Data Space" (TEHDaS) was launched on February 1, 2021. Co-financed by the European Commission in partnership with 25 countries, this initiative is part of the third programme of the European Health Action. The aim is to develop the future policy, legal and technical framework for the sharing and secondary use of health data in the EU.

The Joint Action has set up the Work Package iCitizen (WP8) to formulate recommendations on the involvement of patients, citizens, and their representatives in the governance of the EHDS. A public e-consultation will be organised in late 2021-early 2022 in three pilot countries - Belgium, France and the United Kingdom - in order to better understand citizens' perceptions and expectations regarding the use of their data and their role in this governance.

In order to prepare this e-consultation and, more generally to feed WP8's reflections on the EHDS, the Health Data Hub, the Belgian public health institute Sciensano and the British NHS Confederation conducted a series of stakeholders' interviews between June and August 2021 with actors from their respective health data ecosystem, i.e., health professionals, patient representatives, institutions, researchers and industrialists.

These interviews had two goals. The first was to understand their experiences, perceptions as well as their needs and expectations with regards to health data secondary use and sharing, at the national and European level. This enabled us to obtain the contextual framework that was necessary to reach our second goal, which was to get a better understanding of their knowledge of citizens' involvement in health initiatives and projects, citizens' perceptions, but also on their expectations and projections with regards to citizens' role in the governance of a European health data space. The collected answers will feed the WP8 reflection on citizen involvement in the future European Health Data Space.

This summary report presents the key insights of these discussions. The Health Data Hub, the NHS Confederation and Sciensano conducted 53 interviews in total. The stakeholders were selected so that actors from the public, private, academic, healthcare and patients' associations sectors would be represented in the study. Two journalists were also included in the sample due to their expertise on the topic. The interviews were based on a semi-structured interview guide composed of two main sections: the first one was dedicated to asking to the stakeholders their experiences and perceptions regarding the sharing of health data and their secondary use, including from a European perspective; the second focused on their knowledge, needs and expectations regarding the place of citizens in the governance of health data.

Each interview lasted about one hour and led to the redaction of an anonymised report, either in a Word written format or on a Miro whiteboard. A participant information sheet presenting the project and the framework of the discussion was also sent to the stakeholders participating in the interviews.

This study presents some limitations. A general limitation faced by all three countries was related to the limited number of interviews which were conducted. Indeed, it should be highlighted that **this qualitative study was a preliminary, exploratory work. It was not aiming at making any recommendation** and had the sole purpose to get a better understanding of the relationship between stakeholders of the health data ecosystem and citizens. **Its results are thus not exhaustive** and will be complemented by future work on the topic, including a citizen e-consultation and workshops with stakeholders from Belgium, France, the UK and the European Union. Moreover, the interviews only offer a snapshot of the current situation and may have been influenced by current data events, such as the recent challenges surrounding the 'General Practice Data for Planning and Research' event in the UK, for more than a million of citizens opted out¹. It should also be pointed out here that while the European Health Data Space is not an EU project and involved 4 non-EU member states, most of the

¹ Jayaneti C., 'NHS data grab on hold as millions opt out', *the Guardian website*, released on August 22, 2021 accessed on October 19, 2021, available at [NHS data grab on hold as millions opt out | NHS | The Guardian](#)

interviewed stakeholders did refer or think about EU institutions and about the current situation within the Single Market when talking about this topic. This can be partly explained by the fact that the qualitative study was presented by the interviewers as part of the Joint Action "Towards a European Health Data Space" co-organized by the European Commission and European Member-States, and could thus have been perceived as a pure EU initiative by the stakeholders. Finally, with regards to France more specifically, the fact that the interviewers themselves came from a public structure aiming at facilitating an easy, unified, transparent and secure access to health data did in fact constitute a bias during the exchanges. Indeed, the interviewees focused on their experiences, needs and expectations with regards to the datasets to which the Health Data Hub (HDG) facilitates access, but talked less about their own experiences of using the data from their own databases or with databases from other actors than the HDH.

Table 1: Repartition of the interviews conducted per stakeholder type

Stakeholder type	Number of interviews conducted
Patients' associations	7
Healthcare professionals and researchers	8
Academics	10
Public sector	15
Private sector	10
Additional stakeholders	2
Insurance	1
Total	53

2 Health data secondary use and sharing

2.1 General and national-level experiences, perceptions and expectations towards health data secondary use

A lack of common definition of health data secondary use and sharing

For the majority of British and Belgian stakeholders, the secondary use of health data was defined as any use of health data beyond the purposes that the data was originally collected for. Therefore, data linkage or data use for audit, service improvement, public health and research are all falling under the definition of secondary use. A minority saw a distinction in practice between primary and secondary use depending on uses that were realized in the context of care or not. A third distinction was made depending on whether health data use was impacting health directly, thus including in primary use any use made in the organisation of healthcare systems (such as reimbursement). Furthermore, many interviewees from the UK raised that it wasn't always easy to make a clear distinction between primary and secondary uses, with some examples of secondary uses having a direct impact upon the treatment of patients providing health data. Belgian stakeholders also perceived the lack of clear definition as an issue which could result in discrepancies among data holders and users.

The benefits induced by health data secondary use and sharing

A first general aspect brought by interviewees from the UK, Belgium and France covers the **interest of reusing and sharing health data**. Indeed, respondents emphasized that it could increase the quality of data, improve health care, avoid duplication of medical acts, while being cost-saving. Participants from the United Kingdom gave the example of COVID-19, where using data in real time has enabled decision making and the production of products without the need to go through a long process to access data. Other UK-based actors referenced the possibility offered by increasing methods of data collection, such as data providing from wearables and application – even though it presents a regulatory challenge as this method of data collection isn't currently provided for.

Health data's economic valorisation

In both France and Belgium, stakeholders mentioned the economic value of data. Several French stakeholders highlighted that the current valorisation model surrounding health data was constituting a barrier to health data sharing practices. According to French and Belgian stakeholders, the generation of economic profits from holding and accessing health data would provide several disincentives to share such as losing opportunities to obtain fundings, using data or producing publications. French interviewees thus suggested to operate a paradigm shift in order to provide more incentives to share data. One proposed suggestion was to increase foster public funding.

Stakeholders' views on the perceptions of health data by citizens

Another common topic covered by stakeholders from France and Belgium is related to the perception **of health data by citizens**. In France, the analysis shows the mention of the growing sensitiveness of the topic among the population, while in Belgium stakeholders described the link between people and health data as being part of their intimate, their being and their lives.

Furthermore, stakeholders from the three countries seem to perceive that the **purpose and the nature of the user involved in data reuse** can influence public trust, especially in the case of commercial actors of for-profit goals, which have a negative impact on people's perception of data reuse. One reason for this is that the public does not perceive the public benefit and societal interest that is at stake even when involving commercial actors. Once this is the case though, for British respondents, the negative perception decreases. Conversely to the instinctive distrust resulting from the involvement of commercial actors, Belgian and British stakeholders perceive that healthcare professionals usually benefit from the public trust.

Implication of private actors

On the opportunity to commercially exploit health data Belgium respondents were more divided between not allowing it as a rule or supporting it for the economic welfare of the community. Some British respondents

supported the idea to foster collaboration/ partnership relationships for access to data rather than through a financial transaction from commercial companies.

The legal and technical barriers to secondary use and sharing

Subsequently, in all three countries, stakeholders made remarks about **the legal and technical aspects of data reuse**. A point on which they all agree is related to **the lack of clarity or harmonisation of the legal framework** on data reuse in their respective countries. In Belgium and the United Kingdom, respondents indicated the existence of barriers due to the **lack of harmonisation of data access procedures** among the various data holders and controllers. In both cases, this can result in a range of difficulties for some potential data users to access certain information, such as higher costs or stricter requirements, due to their being external to the institution that owns the data they are interested in. In the UK this is the case for some actors external to the NHS, such as doctoral students or small businesses with limited resources. In Belgium the problem is between institutions, where the procedures are more complicated for those seeking access to data from another institution than for those interested within the same organisation. To this can be added the problems mentioned in the three analyses relating to interoperability between databases, either because of the fragmentation of internal systems as in the case of the NHS or between databases of several institutions.

A specific problem due to the Belgian constitutional system is the lack of a legal framework for **gathering regional data at federal level**, which sometimes slowed down the taking of rapid initiatives, such as during the COVID-19 crisis. Conversely, regional actors were quite satisfied with the regional centralization of health policy and operational oversight existing in their area.

Another particular issue encountered in France and in the United Kingdom is related to the length of the **timeframes** to access data, which can brake development and innovation sometimes, due to unclear and long regulatory procedures.

The uncertainty caused by this lack of legal clarity may have led to a **reluctance** on the part of some actors, in all three countries, **to proceed to data reuse or sharing** for fear of being sanctioned on the basis of data protection regulations. In Belgium this reluctance was defined as triggered by the perception that people fear a misuse of their data, while in France it was caused by the fear from users to make mistakes and lack of understanding of the regulatory framework. Belgium stakeholders also focused on the **sanctions framework** and were divided between perceiving that it was lacking in some regulation and overly repressive in others (notably the GDPR).

Furthermore, a point mentioned in both French and Belgium analysis was linked to **consent**. Even though on the French side the topic was barely raised as an important concern for data users, in both cases consent could be identified as a barrier to health data sharing and reuse. In the Belgium case, they specifically raised the difficulty to define in advance the purpose of the reuse, and to ensure that patients access their data and are properly informed.

Concerning more technical aspects, on one side the British respondents highlighted that while there is a willingness to conduct population level projects, healthcare professionals are still lacking **basic infrastructure**, such as quality computers, and it can be hard to engage these professionals when basic infrastructure isn't provided. Moreover, **anonymization** was raised as an issue in both Belgian and French interviews. Concerns raised were related either to the technical difficulty to ensure absolute anonymization, or to the impossibility to re-contact people when needed (to inform about secondary effects of treatment for example).

When talking about the future of health data secondary use and sharing, stakeholders underlined several issues:

- On the Belgian side, the need to create a framework for pooling data at federal level was raised, while French stakeholders were more likely to mention the need to set up database cross-referencing practices and to accelerate data access procedures. For UK-based respondents, data should be collected more comprehensively across the healthcare system.
- Concerning privacy protection, Belgium stakeholders advised to set up privacy by design regulation, and French respondents emphasized the need for security safeguards. Both Belgium actors and French

patients' associations' members insisted on ensuring that citizens could not be re-identified, even though some Belgium stakeholders also proposed to involve a third party as an intermediary in case re-contacting patients was necessary. Some Belgian actors also highlighted that giving more control to citizens could be a solution.

- In all three analyses, respondents mentioned the important role some key actors should play, notably healthcare professionals, who should be more engaged and educated on the topic in both cases.

Finally, a last aspect related to **health inequalities** was raised only by British actors. According to them, ethnicity is poorly coded. Therefore, the results deriving from data use and sharing could worsen inequalities if the data is not sufficiently statistically representative.

Some British interviewees thus advocated that healthcare professionals should be engaged on the importance of accurate data collection.

2.2 European-level health data secondary use and sharing

When questioned on health data secondary use and sharing at the European level, **stakeholders talked less on health data secondary use and sharing at the European level**. This was more especially the case for the British and, to a lesser extent, for Belgian stakeholders. This could be related to a lack of experience with the European level and/or a difficulty for the interviewees to project themselves at this level, two issues which were highlighted by French stakeholders but which could potentially also apply to Belgian and British actors.

Barriers preventing health data secondary use and sharing in Europe

When talking about the current state of the situation in Europe, stakeholders from the three countries raised several barriers impeding on health data use and sharing across countries. One important challenge raised by interviewees was related to **the lack of a common legislative framework across European countries**, which prevents health data users an easy access to datasets from different member states. Another related barrier pointed out by Belgian and French stakeholders from the private and academic sector was the existence of different administrative requirements for the evaluation of drug and medical devices within Europe. One specific challenge identified by several French stakeholders from the private sector was **the negative impact that the current European legislation had on the competitiveness of European companies** in comparison to other actors - particularly from China and the USA - due to the overarching principle of free competition within the Single Market – which would prevent the public support of European actors – and the more permissive data protection regime in other countries.

Multiple benefits associated with the creation of a European Health Data Space

The creation of a European Health Data Space was thus associated with multiple benefits by French and Belgian stakeholders. Provided that the legislative, administrative and technical framework would be harmonized across countries, the positive effect that was the most quoted was **an eased access to a larger volume of information and data** for a number of purposes, including the conduct of large comparative studies on the effect of medical treatments, on specific and rare diseases and for epidemiological and health policy purposes. This greater access to a larger amount of health data would also bring a number of benefits for citizens and private companies: while one stakeholder from the private sector highlighted the credibility that it would bring to their products ("*countries tend to prefer when studies are carried out with data from their patients*"), members of associations underlined the visibility that it would bring for patients' requests and needs. The cross-referencing and pooling of data on a European scale would make sense because patients' preferences and care pathways are pretty similar across countries. An actor from the pharmaceutical industry also highlighted the minimization of re-identification risks. Echoing the aforementioned competitiveness challenges, one French private stakeholder underlined the opportunity that the creation of the EHDS would represent for the emergence of European champions able to compete with American and Chinese players.

Expectations towards the European Health Data Space

Interviewees from the 3 countries emitted several suggestions to build the future European Health Data Space, highlighting that **the priorities were differing across the three countries**.

- **UK's stakeholders underlined the need for the future EHDS to take into account the resource imbalances across European participating countries** to avoid an unequal repartition of the benefits among the member states to the detriment of non-wealthy western member states
- **Belgian interviewees focused on the administrative and legal aspects of the project**. They highlighted the need to ensure a harmonization of standards and datasets, to avoid adding administrative barriers and to ensure the protection of health data, including the systemic specification of the goal of data processing. The development of open data within the EHDS was also circumspectly perceived by several Belgian stakeholders: while two of them shared their reluctance to fostering this practice, one interviewee highlighted the need to ensure that researchers would be respected in case of the development of open data was also underlined by one Belgian stakeholder.
- French actors suggested different **starting points and governance formats** for the future EHDS, including initiating the project by sharing epidemiological and clinical data – medico-administrative data being difficult to harmonise due to the lack of harmonized reimbursement rules; focusing on the use of synthetic data to avoid risks of re-identification or setting-up a European consortium endowed with structures similar to the Health Data Hub to carry out pilot projects.

Doubts with regards to the feasibility of the project

Despite the aforementioned expected benefits, several Belgian and French stakeholders **expressed their doubts about the feasibility of the project due to the lack of legal, technical and cultural harmonization across and even within countries**, including: the lack of common definitions, standards and interoperability across member states, the differences in European healthcare systems and in drug and medical device evaluation practices.

3 Citizen engagement

3.1 General/national remarks

State of the Situation - Citizens Understanding & Perceptions of Data Use

Interviewees in the UK, France and Belgium all expressed that there is **limited understanding among the general public about how their data is used for secondary purposes**; however, it was also stated that there is a growing understanding of health data use among the populations of France and the UK. UK interviewees made reference to the greater use of data during the response to the COVID-19 pandemic, and the recent challenges surrounding the 'GP Data for Planning and Research' (GPDPR) programme as contributory factors to this.

Interviewees in the UK, France and Belgium described how citizens' initial viewpoint towards health data sharing is also linked to who is accessing their data for secondary purposes. Interviewees in all three countries pointed to concerns among citizens about the commercialisation of their data and the potential sharing of data outside of their country/Europe. Though this was also matched with an ambivalence from citizens towards the recording of other health data by private companies when using certain health related apps. In Both the UK and France, when citizens are actively engaged, given the opportunity to learn more about secondary data sharing and use, and ultimately come to a more informed position on the merits of data sharing there is, according to the stakeholders, a common trend to support greater data sharing for secondary purposes. For those in the UK, it was also noted by some interviewees that this positive change extended to data sharing with commercial companies. Despite this, interviewees in the UK highlighted that there will always be those that retain, or potentially even develop a negative position towards the secondary use of their health data as a result of engagement.

The need for continuous engagement

Stakeholders from the UK shared the view that the major contributory factor to historically poor engagement with the public on the issues of data sharing and re-use has been the ad-hoc nature of engagement. Attempts to engage citizens on issues of data sharing have typically been an add-on at the end of projects, with little thought given to planning or resourcing. Interviewees described how this lack of quality, consistent engagement has provided opportunities for negative news stories and misinformation to shape public opinion. It is referenced by stakeholders across all sectors interviewed (Commercial, Academic, Public Bodies & Patient/Professional representatives) in the UK as an area contributing to distrust in data sharing and an area requiring improvement.

Stakeholders from the UK thus suggested that:

- Engagement with the public should never be on a one-off basis. The most effective public engagement is conducted in an ongoing way that makes use of a diverse range of engagement techniques.
- greater funding, planning and human resources should be allocated to engagement activities.

Engagement Mechanisms

Stakeholders across the UK, France and Belgium all described, to varying degrees, the need for the views of citizens to constitute a greater voice in the decisions made about data sharing, governance and use. However, they differed in the level of direct activity individual citizens should take, perhaps due to the variation of pre-existing preferences towards citizen engagement.

In the UK this was advocated as taking a deliberative approach that actively engages individual citizens in the decision-making process. This can take many forms including, ranging from the large-scale deliberate process of Citizens Assemblies – which provide deliberative engagement on a specific programme, product, or issue over a concentrated period of time (typically days to weeks) that allow citizens the time to develop an understanding of a topic, critique components of interest and form an ultimate view, through to the use of permanent organisational structure like lay advisory committees and access committees - which provide a mechanism by which members of the public can be engaged on an ongoing basis to inform decisions about projects in development. UK and French stakeholders underlined the need to avoid any participation methods

from becoming tokenistic. UK stakeholders thus advocated for identifying a predefined scope of influence that enables participants to know how far they are able to influence topics. Ideally, this scope will be determined in collaboration with the citizens and will not be predetermined.

Whilst several Belgian interviewees also advocated for deliberative engagement mechanisms, there was less consensus than amongst UK interviewees, with several also expressing a reluctance to hand too much control to citizens as they view this as potentially overburdening citizens with responsibility and requiring input into subjects that are too technical for citizens.

In all but one French interviewee, this active engagement of lay citizens in health data governance was never mentioned. A majority advocated for the greater inclusion of patient representative organisations in research projects from the very beginning, as the preferred method for providing the patient perspective to research. A few French and Belgian stakeholders also advocated for a greater involvement of patients' associations in governance organs such as ethics committees. The involvement of "lay citizens" in the governance of health data secondary use and sharing was however almost never mentioned, which could highlight that citizens per se are rather perceived as passive actors in the health data ecosystem.

The views expressed in France on the role of patients' representatives were not dissimilar to the views of some UK stakeholders who have advocated for the greater engagement of medical charities in order to better engage specific patient groups on the issue of data sharing and better understand their views towards secondary use related to their conditions.

Transparency of data use

Interviewees in all three countries highlighted that central to overcoming negativity, developing trust from the public and effectively engaging citizens is a transparency in communication about how data is used for secondary purposes. When describing what this greater transparency would look like, Belgian interviewees included information about who is accessing data and why, the legal grounds for the sharing of data, and the security mechanisms in place to protect citizens data.

Stakeholders from the three countries also underlined that when citizens are easily able to find out how, why and by whom their data is being used, trust in data sharing increases. Further to this, interviewees in all three countries highlighted the need to present the benefits of data sharing to the public at the individual, organisational and societal (local, regional, and national) levels. It was commonly understood amongst interviewees that when citizens are able to materially see the positive impacts that sharing their data is having for them and their communities, they are more likely to support the sharing of health data.

Interviewees in the UK and Belgium also described challenges to this level of sharing both from a technical and communication perspective. At the technical level, the processing requirements for sharing this amount of data would lead to a high administrative burden on organisations, whilst at the communication level it was noted that it is important to provide information to citizens in a way that is able to be understood by a lay audience and there was a concern that providing this volume of data may prove challenging to do in an accessible way, and as a result effect transparency.

Communication Methods

In addition to the need for active engagement methods described above, interviewees in the UK and France both advocated for a range of informative material that could be used to provide citizens and healthcare professionals with more information about data use and sharing, and thus aid in developing transparency.

It has been advocated that these should take a range of mediums including case studies, videos and theoretical scenarios and vignettes. One interviewee in France highlighted that these resources could be used to raise awareness of health data-related issues, to highlight the public utility of research, and to increase transparency in the use of data including within schools and amongst healthcare professionals.

Information should thus, according to several French and UK stakeholders, be provided to citizens in language that they can be understood, highlights the benefits to citizens of sharing data, but does not require a level of administration that would be burdensome to data controllers/users.

Ensuring equal representation

In addition to this, UK stakeholders highlighted the need for any informative materials to be developed in a way that enables utilisation by all citizens including groups traditionally excluded from engagement methods. This would include, but is not limited to, those with learning disabilities, the prisoner population, and those for whom the dominant language is not their first/spoken language.

Interviewees from the UK described the need to ensure that there are appropriate steps to guarantee a fair representation of the population from a minority background in engagement activities, as they are often underrepresented in research more broadly. Several stakeholders described steps being taken to improve representation, including making use of pre-existing forums, community organisations, and faith groups, and working with specialist organisations to recruit participants to their engagement activities.

Further to this, stakeholders in Belgium and the UK also referred to digital inequality/digital divide that prevents full participation in engagement by a high proportion of the population. Up to 20% of the population in the UK do not have ready access to the internet and are thus limited in their ability to participate as online engagement methods continue to play an ever more central role in public participation, engagement and inclusion.

Interviewees in the UK emphasised that

- There must be a process of actively reaching out to 'left behind groups' who have historically been excluded from participation in discussions about data.
- Those organisations utilising online methods for their engagement should provide means for ensure participation for all citizens that does result in additional burden to them

3.2 Citizen engagement at the European level

Stakeholders developed less what citizen engagement could look like at the European institutional level. Only a few of them did mention this aspect during the interviews conducted in Belgium, France and the UK.

In Belgium, the only media expert who talked about the topic **focused on the acceptability of the project by citizens**. They underlined that a European Health Data Space project would likely be a project in which citizens would want to be involved and to understand its beneficial consequences on their personal life, but that its creation would bring fear due to a lack of trust in foreign governments. **In France, stakeholders mostly focused on the barriers to the involvement of patients' associations at the European level**, highlighting that this would be difficult due to a lack of associations' knowledge on EU institutions and to the fact that English was the usual working language. **In the UK, interviewees underlined the lack of common public participation, engagement and inclusion culture** across countries, which could constitute a barrier to introduce a common, harmonized European engagement framework.

As for the insights provided on health data secondary use and sharing practices, **stakeholders' expectations towards engagement in the European Health Data Space slightly differed depending on the country**.

- Echoing the remarks raised about the legal framework surrounding health data reuse and sharing at the European level, **a few Belgian stakeholders highlighted the need to ensure the protection of citizens**: one of them advocated for the use of a systemic application of an informed and specific consent system or a full anonymisation of health data before granting access to them.
- Reflecting their remarks on the current situation, **French stakeholders emitted several ideas to increase the involvement of patients' associations**, including the creation of a committee dedicated to them and an increase in the efforts being made to raise awareness on the functioning of European institutions across stakeholders