



The impact of GDPR on secondary use of health data

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InfAct (Information for Action!)



WP 10 : Assessing and piloting interoperability for public health policy

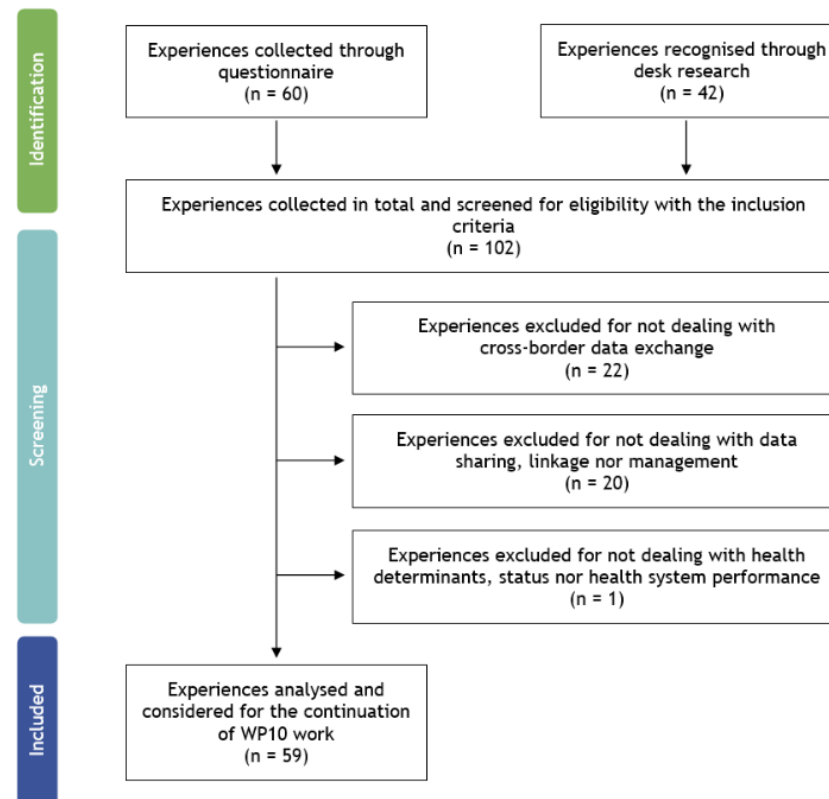


Mapping and analysing cross-national inspirational case studies on public health surveillance or research, where interoperability, data linkage, data sharing and data management are present

Identification of inspirational experiences where interoperability, data linkage, data sharing and data management, data security and privacy issues play an important role.

Online questionnaire

Desk research



2 in person interviews

15 interviews conducted via GoToMeeting software

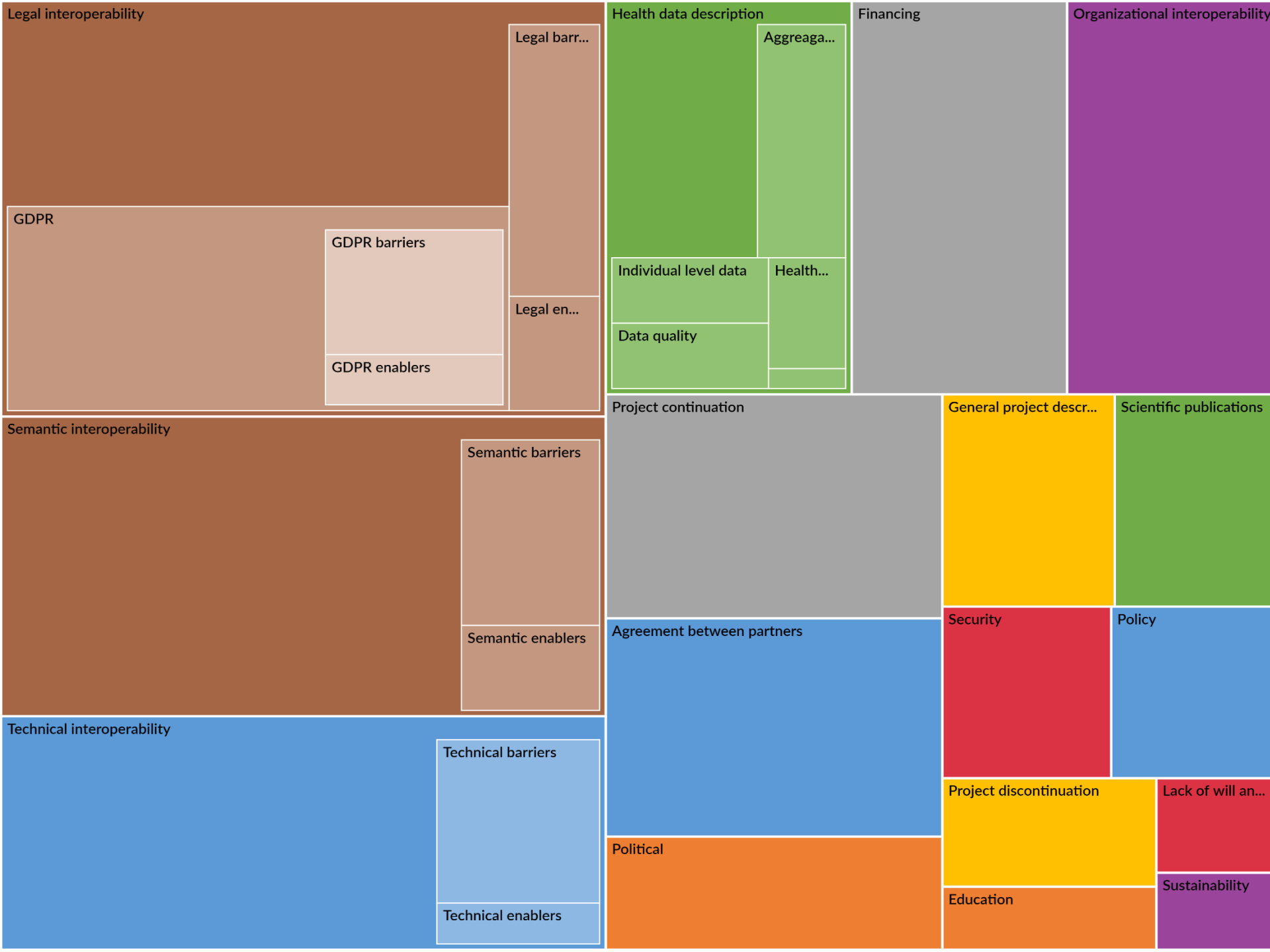
Mean duration of the interviews was 50 minutes

Interviews were recorded and transcribed

Interviews were conducted from July 2019 to April 2020

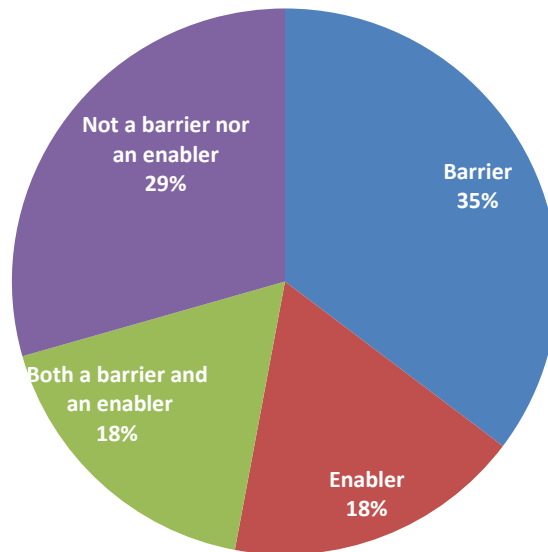
17 semi-structured in-depth interviews were conducted with key opinion leaders from different European cross-border projects that dealt with sharing, linking and managing health data

Research goal: to understand enablers and barriers to the cross-border linkage and sharing of health data through four interoperability layers (legal, organisational, semantic and technical)



SENTIMENT TOWARDS THE GDPR AND ITS EFFECT ON THE CROSS-BORDER HEALTH DATA SHARING, LINKING AND MANAGING

■ Barrier ■ Enabler ■ Both a barrier and an enabler ■ Not a barrier nor an enabler



GDPR as an enabler



User rights over their data	GDPR helps with defining the user rights over the data and specific purpose for which the data can be used. GDPR facilitates development of tools which give control over the data to patients.
Pre-existing laws regarding data privacy and data sharing	GDPR is easier to implement in countries with a previously existing laws regarding data privacy and data sharing.
Anonymous statistics	GDPR is an enabler when sharing anonymous statistics
New data analysis approaches	GDPR is a facilitator for new data analysis approaches which do not require the data to be shared as it minimizes data privacy risk.

GDPR as an enabler

Patients` trust towards dealing with their health data

GDPR is a big asset for Europe as it makes the system safer and helps with keeping the trust of patients when it comes to dealing with their health data.

Transparency

GDPR enables transparency and facilitates the relationships between the stakeholders.

GDPR is an enabler as having more transparent agreements can only be beneficial for research and for relationships of all the stakeholders.

Data oriented

Lawyers are more careful and more data oriented since the implementation of the GDPR.

GDPR as a barrier

Identifiable data

GDPR is an issue with health data narrowly defined by region, sex, age group and ICD code where the size of the sample is very small (1, 2 or 3 persons) as it could be a way of identifying individuals.

When it comes to rare diseases, data is potentially identifiable. There is a great concern when dealing with individual level data as everything is potentially confidential and re-identifiable.

Data sharing

There are much more concerns about data protection which makes it more difficult to share data for scientific purposes.

GDPR limits some projects to only share the aggregated data as a way to avoid sharing patient level data and the GDPR challenges that come with that.

GDPR as a barrier

Local legal legislation	There are differences in local regulations between countries and sometimes the local regulations are opposite to the GDPR.
Cross-border patient level data storage	Amount of the time that the cross-border patient level data can be stored and maintained at hospitals differs by countries and has to be configured locally for each hospital which is a barrier for implementation of novel cross-border patient data exchange solutions, and there is a tendency for restrictive solutions.
GDPR implementation	GDPR is a unique and interesting regulation but the interpretation and implementation of the GDPR has caused problems and represents a challenge in Europe which needs to be addressed.

GDPR as a barrier

Time

GDPR slows down the process.
The idea behind GDPR is not to make research more difficult, the same research can still be conducted but the process is just slower and more complicated.

Work burden

Implementing GDPR is a major work burden and represents a problem in projects which work with limited budgets from research funding and limited personnel as the legal issues take much more time and work than it is available which restricts carrying out the project simultaneously.

The workload to be GDPR compliant is a barrier for projects.

GDPR slows things down and causes harm to the project because the lawyers are overloaded with work.

GDPR as a barrier

Local laws	Locally there are differences between countries as to how strict they are about the interpretation of the GDPR and specific laws which represent a barrier. There are differences between GDPR and local regulation which is a barrier.
Strict interpretations	There are interpretations of the GDPR which are more strict than it was intended with the GDPR. A lot of people over interpret the GDPR and make it more strict that it was intended.
GDPR implementation in countries without pre-existing laws concerning data privacy	GDPR did not make a big difference in countries with an already strict legislation, while it did have an impact on countries where a strict legislation did not exist prior to the implementation of the GDPR.

GDPR as a barrier

Patient level data	GDPR makes it complicated to work with anything resembling patient level data as everything is potentially confidential and identifiable.
Lack of funding	There is a lack of funding to set up data and information exchange systems which would be compliant with the GDPR.
Access to data	<p>Access to individual data is restricted to 3rd parties, only aggregated results are shared.</p> <p>GDPR and privacy concerns are sometimes used as an excuse to stop sharing the data.</p> <p>Data providers are concerned about eventual violation of the data protection laws which leads some countries to stop sharing their data.</p>

GDPR as a barrier

GDPR interpretation

There is a contradiction in the interpretation of the GDPR between reading it word by word and the spirit and the purpose of the GDPR. Lawyers are not sure how to interpret GDPR which, in the end, makes the interpretation of the GDPR more strict to ensure compliance with it. There are different interpretations of the GDPR which represents a barrier.

Novel approaches towards health data

When developing novel approaches to dealing with health data, solutions tend to be restrictive to ensure compliance in all the countries.