
# LOST* and found:
# Report on interoperability landscape in Europe

**Deliverable D10.1**

**Work package 10: Assessing and piloting interoperability for public health policy**

* Acronym for Legal, Organisational, Semantic and Technical, the interoperability layers used in this work.

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# Executive summary

This report is the first deliverable of the InfAct Joint Action's Work Package 10 (WP10) and presents rationale, methodology, results and recommendations of our 2-year work on *"assessing and piloting interoperability for public health policy"*. This report deals mainly with the *"assessing" part* and WP10's first three tasks (T10.1, T10.2 and T10.3). We assessed how different projects and initiatives, dealing with cross-border health data exchange in Europe (and beyond), perceive and work with interoperability - through its four main levels: legal, organisational, semantic and technical. Hence, the acronym "LOST" in the title: "LOST and found".

To start with, we collected and mapped over one-hundred examples of cross-border health data work (projects and initiatives) through online stakeholder surveying, supplemented by desk research. Using the conceptual and analytical framework we developed and validated, 59 of these satisfied the inclusion criteria. We called these projects and initiatives "inspirational experiences" and researched them in more detail by conducting 17 semi-structured interviews with 20 health information experts involved in 17 inspirational experiences. Our goals were to get more specific insights into the everyday concerns and practices of data coders, custodians and managers in relation to data sharing, linkage and management, and to learn about the enablers and barriers in achieving project goals. The interviews were qualitatively analysed by using framework analysis methodology.

Our work showed that the European landscape of projects and initiatives linking, sharing and managing health data among countries is vibrant and diverse. We learned that there is dispersion and limited duration of projects and initiatives. The analysed inspirational experiences did show a rather comprehensive approach to dealing with all domains of data exchange. Also, we noticed that as the complexity of data "manipulation" activities increases, the rate of initiatives dealing with these "methods" decreases. Even though the benefits of interoperability, when working with health data, are plentiful, one of the most important interoperability capabilities – receiving, providing and exchanging large amounts of patient data – is often difficult to perform among European cross-border health data exchange initiatives due to diverse data infrastructures (and governance) within the same country and – even more – across national boundaries. European health data infrastructures differ greatly in their characteristics such as content, semantics, quality, update frequency and completeness, legislative and governance rules and obligations. Further investigation into the specifics of day-to-day operation of cross-border health data exchange, for research or clinical purposes, could certainly be useful in gaining a better understanding of the practical challenges faced by these professionals.

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# LOST and found: Report on interoperability landscape in Europe

## Introduction

### Work Package 10 of the InfAct project

Through Work Package 10 (WP10), of the InfAct (Information for Action!) Joint Action on Health Information, we are set to thoroughly describe methods and techniques used to get sound knowledge of (public) health data linkage, sharing and management, as well as reporting. We are doing so by using concepts, frameworks and practices of interoperability. As the title of the package itself suggests, goal of the WP10 is to *"assess and pilot interoperability for public health policy"*. We structured the WP10 work into four tasks focused on two streams of

1. assessing (tasks 10.1, 10.2 and 10.3) and
2. piloting (task 10.4)

best practices in data linkage, sharing and management. During the course of the InfAct project, WP10 results were reported through a number of milestone reports and are finally presented in two major WP deliverables (this being the first one) and a series of case studies to be piloted in parallel.

### Interoperability

Interoperability, in the broadest sense, stands for "ability to operate with others", thus can be applied to any situation where two or more entities work to achieve their goals or purpose by successfully interchanging services.[1] Institute of Electrical and Electronics Engineers (IEEE) defines interoperability as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged".[2]

The European Interoperability Framework (EIF), in which we anchor our InfAct WP10 work, defines interoperability as "the ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their information and communication technology (ICT) systems".[3]

An essential starting point in InfAct Joint Action WP10 work are the interoperability layers described in the EIF:

1. Legal,
2. Organisational,
3. Semantic and
4. Technical;

a cross-cutting component of the four layers which is integrated public service governance, and a background layer of interoperability governance. This model is depicted below in Figure 1.

[1] Cross-border Patient Registries Initiative PARENT: Methodological guidelines and recommendations for efficient and rational governance of patient registries. 2015 https://ec.europa.eu/health/sites/health/files/ehealth/docs/patient_registries_guidelines_en.pdf

[2] Institute of Electrical and Electronics Engineers, *IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries*, New York, 1990

[3] European Commission: The New Interoperability Framework: Promoting seamless services and data flows for European public administrations. https://ec.europa.eu/isa2/sites/isa/files/eif_brochure_final.pdf

Using the first letter of the four main interoperability layers, we developed an acronym *"LOST"* to use for the title of this report. We added *"and found"* to describe the exploratory ambition of this work.

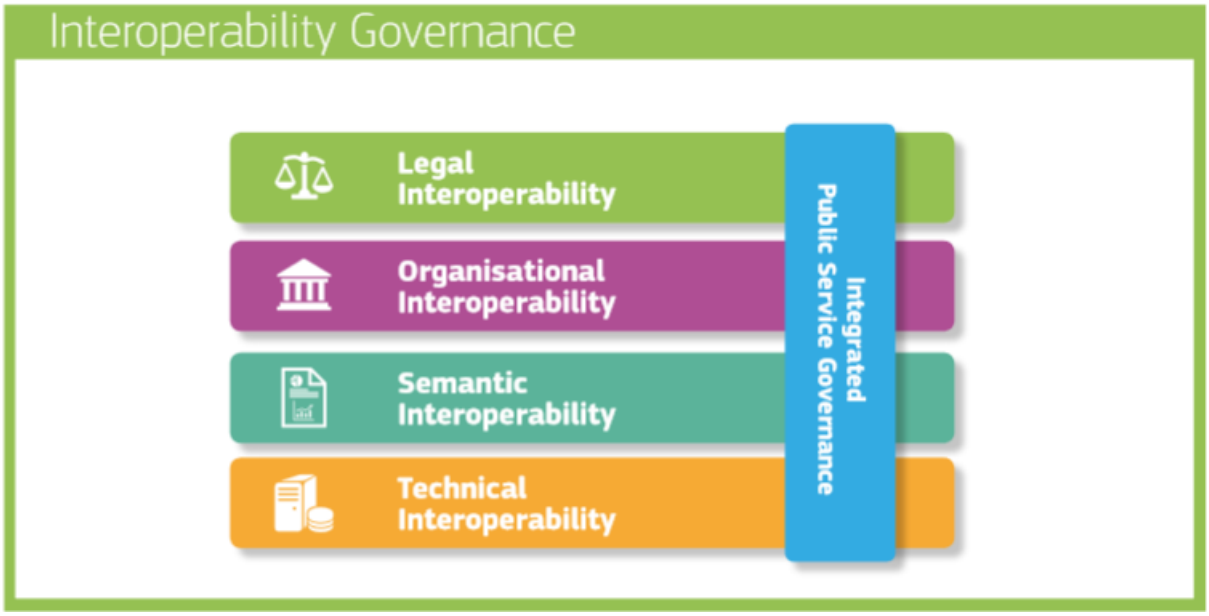



*Figure 1: Interoperability model and layers*[4]

## Interoperability and the European projects working with health data (infrastructure)

BRIDGE-Health, a network of public health research networks and a predecessor to the InfAct project, posed the need of developing a European data infrastructure that can translate data, information and knowledge into support for policy making, using services based on data linkage, sharing and management, and knowledge development.

Establishing such infrastructure with data management, conceptualised and dealt with only on technical and semantic levels, is insufficient for achieving full interoperability. Our experience, working with patient registries in the scope of the PARENT (cross-border PAtient REgistries INiTiative) Joint Action project, shows that interoperability is largely understood as primarily technical, with a certain consideration given to the semantic level as well. However, these two elements are only a part of a bigger picture as described by the EIF. While the majority of registries explicitly stated that they mostly dealt with technical and semantic levels of interoperability, our research showed that some other aspects were considered as well: albeit less visible to the registry holders, they were no less important. For example, this was made clear in a study done within the scope of the PARENT project: a registry data structure was not provided by several of our respondents because their data structure was being revised to conform to new legal frameworks, which indicated that the political, legal and organizational issues were also crucial for their daily operation and data sharing practices.[5]

Our aim is to support efforts on establishing a research network that facilitates policy making, using services based on data linkage, sharing and management, and knowledge development. We are doing so through a number of sensible case studies, by piloting methods and techniques required to make this possible. For that purpose, WP10 is

[4] *New European Interoperability Framework, EC, 2017*
https://ec.europa.eu/isa2/sites/isa/files/eif_brochure_final.pdf
[5] Valentic M., Plese B, Pristas I,Ivankovic D. Addressing the Data Linking Challenges: Interviewing for Best Practices in Patient Registry Interoperability. Methods of Information in Medicine. 2017; 56: 407-13. 10.3414/ME16-02-0029.

developing upon the building blocks defined in the EIF, while also getting inspiration from the EIF for e-Health[6].

### Work package 10 goals

Based on this concept and the perceived and recognized need, WP10 is specifically:

1. 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; in tasks 10.1, 10.2 and 10.3; and
2. Developing empirical work on interoperability, data linkage, data sharing and data management, for a number of case studies, using a variety of data sources from different countries; in task 10.4.

This deliverable reports on the work of the first three tasks of the WP10 through three methodological steps used: the mapping exercise, interview instrument design and testing and, finally, conducting the interviews and the thematic analysis of their content.

## Mapping exercise

We started with a mapping exercise and the ambition to identify inspirational experiences in data linkage, sharing and management among European cross-border health data exchange projects. This was a starting point for a more detailed analysis and results to be used in future sustainable European infrastructures working with health information.

In order to achieve this, we have started by defining the inspirational experiences criteria including details on which system domains these projects and initiatives studied but also which performance areas they provided insights on, which data sources were used and whether they produced policy recommendations as an end-result. The criteria framework was tested and agreed upon among WP10 partner during the work package kick-off meeting in Zagreb, Croatia in May 2018.

Applying the criteria framework, we collected a number of inspirational experiences through a structured questionnaire distributed among InfAct and WP10 partners, but also among the broader health information community in Europe. We supplemented the results of the survey with desk research. Following the need to select a finite subset of initiatives fulfilling the established criteria for further analysis on how they approached interoperability issues, we did not aim for an exhaustive approach. However, we do foresee that this task could remain open as a continuous iterative effort to map interoperability standards arising from projects tackling data sharing and management across countries. Following the collection of inspirational experiences, we analysed them using the same criteria framework that was used as a set of inclusion criteria.

## Interview instrument design and testing

After conducting a mapping exercise, we proceeded with developing an interview instrument to be used for a series of semi-structured in-depth interviews with representatives of the identified inspirational experiences.

Work on tasks two and three of the WP10 work was based on the results of task one work and the milestone report produced but also on feedback received, immediately after presenting the report, from the project partners and a wider group of stakeholders. The work on designing and testing the interview instrument acted as a preparatory activity for conducting a series of in-depth surveys and interviews. The goal was to identify and present,

[6] https://ec.europa.eu/digital-single-market/news/ehealth-interoperability-framework-study-0

in a case-study and "cookbook" format, a series of enabling and disabling factors and recommendations that make some data linking, sharing and managing efforts work better than others.

## Interviews and the thematic analysis

Following the mapping exercise, WP10 team of researchers conducted a series of in-depth interviews using the interview instrument piloted in the previous phase of this work. Interview format was chosen because of its potential to gather a large amount of data/information in a relatively short time period as well as the ability to use a semi-structure approach suitable for the kind of data we were keen on collecting. We did so by steering the discussion through the four interoperability layers, as described above.

The goal of the interviewing stage was to:

1. Learn more about these projects from people that actively participate(d) in their own words;
2. Make an in-depth analysis of how inspirational experience projects tackled issues related to data sharing, linkage and management.
3. Compare projects / initiatives with other projects that deal(t) with cross-border health data work
4. Learn what were / are the enablers and barriers in achieving the goals of your project.

Interviews were transcribed and the transcripts of the interviews were analysed by framework analysis and grouped into four layers of interoperability (legal, semantic, organisational and technical). These were further grouped into enablers and barriers for each layer of interoperability based on the interpretation of the codes.

A note on the temporal component and sustainability

Although, throughout this deliverable report, we refer to the inspirational examples work in past tense, as if they were all finalised, this is not always the case. Some of the examples are indeed still active today as we research and produce this report.

We believe that the issue of sustainability of projects and initiatives, like the ones analysed here, is an important one. The future European research infrastructure on health information should make sure to actively work on this topic, perhaps even including interoperability as a permanent work-area of the infrastructure. Nevertheless, we felt that this topic is mostly out of the scope of the WP10 work and have decided to semantically refer to all the work in the inspirational examples analysed, in past tense.

## Methods

Using the three-stage approach, as described in the previous section, we have identified a number of European initiatives, projects and organisations (all embedded under our umbrella term "inspirational experience") that have dealt with cross-border health data sharing, linkage and management. Once we made sure that we have mapped a(n opportunistic and non-exhaustive but a relevant) set of these experiences, we proceed with designing and testing a semi-structured approach to interviewing people that were involved on different levels. Having refined the interview tool and process, we proceeded with a number of in-depth interviews. Finally, we conducted a thematic analysis of all interview transcripts, identifying main enablers and barriers that were discussed through each of the four interoperability layers.

Methodological steps are described below in more detail through each of the three stages.

## Mapping exercise

The specific objective of the Task 10.1 "Mapping exercise: identification of inspirational experiences" was to identify a number of "best (or inspirational) practices" in the European Union Member States (EU MS) participant countries. In order to be accepted as "inspirational", the experience had to fulfil five inclusion criteria presented in Figure 2 and the following paragraph.

### Inclusion criteria

1. The example addresses the study of health status, health determinants, and/or health systems performance;
2. The example provides insight on surveillance and/or impact or effectiveness research;
3. The example includes a variety of data sources (e.g., patient registries, population-based registries, surveys, electronic health or medical records, administrative data, etc.) from different countries;
4. The example addresses data linkage, sharing, and management (quality assurance) activities;
5. The example produces outcomes reported to public health stakeholders, particularly policy-makers.

| Inspirational example: | EuroPeriStat | | | | | | |
|---|---|---|---|---|---|---|---|
| Studies: | Health status | | | Health determinants | | Health system performance | |
| Provides insight on: | Surveilance | | | Impact | | Effectiveness | |
| Includes data sources: | Disease-based registries | Population-based registries | Surveys | EHRs | Administrative data | Other: N/A | |
| Addresses: | Data linkage | | | Data sharing | | Data management | |
| Produces: | Policy recommendations | | | | | | |
| Link: | http://www.europeristat.com/ | | | | | | |

*Figure 2: Inclusion criteria mapping; example of EuroPeriStat - "Better Statistics for Better Health for Mothers and their Newborns in Europe"; kindly provided by Jennifer Zeitlin; InfAct green cells represent completely fulfilling the criteria, while the orange ones represent partially doing so*

### Collecting data

A list of inspirational experiences was collected via two streams of work. Firstly, by conducting a survey among the WP10 and InfAct project partners and the wider European health information community. The wider community represents health informaticians,

public health professionals, statisticians, health data stewards and health information systems governance bodies for which we knew or assumed might provide insights on inspirational experience tackling data interoperability issues in cross-country data sharing projects.

Secondly, the data was collected through desk research of projects that potentially fulfilled the inclusion criteria. For this, we mostly used publicly available information on the Health Data Navigator (HDN) site[7] and European Commission's Community Research and Development Information Service (CORDIS) database.[8]

Results obtained via the online questionnaire and desk research were in no way meant to be exhaustive. Rather, they intended to give an overview of the state-of-art in projects linking, sharing and managing health data in Europe and beyond.

### Online questionnaire

Survey, in a form of an online questionnaire, was conducted in order to collect a representative sample of inspirational experience from EU MS for the selection of a subset and further analysis. The questionnaire was sent out to a convenient sample of 890 e-mail addresses with a request to also further share the questionnaire to professionals that might be able to contribute. Due to the quasi-snowball sampling method, the response rate cannot be calculated nor discussed. The questionnaire was first sent out on January 14th 2019, and a subsequent reminder was sent on January 24th. Data collection was finalised on January 31st 2019. LimeSurvey online surveying tool, licenced with the Croatian Institute of Public Health (CIPH), was used as a questionnaire platform, and the collected data was stored on CIPH's data servers.

The survey was titled "Collecting inspirational examples in health information interoperability". It consisted of 2 pages. On the 1st page, and in the whole questionnaire, only one question was mandatory: "What is the name of the inspirational example?"; three questions were non-mandatory: contact person for the inspirational example, project website link, and short description of the project. Questions on the 2nd page covered topics listed in the framework for inspirational experiences identification and analysis:

- If inspirational examples studied health status, health determinants, or health system performance;
- If they provided insight on available data and indicators, measurement issues, concept, data and indicators;
- Which data sources they included;
- If they addressed topics of data linkage, sharing and data management;
- If they produced any policy recommendations.

Each of these page-2 questions could be answered with "Yes", "Partially / Somewhat", "No", "I don't know" or "No answer".

The questionnaire is presented in the Appendix 1 of this report. A complete list of inspirational experiences, acquired through the questionnaire and desk research, that satisfied the inclusion criteria, are available in a table in the Appendix 2. This list also includes a short description of each experience and information on whether the example was retrieved through the survey or desk research.

[7] http://hdn.euhs-i.eu/international-home/eu-and-international-projects/103-share (The hyperlink is not accessible in November 2020)
[8] https://cordis.europa.eu

### Desk research

Desk research was conducted using publicly available information on different websites, mostly the Health Data Navigator (HDN) site and European Commission's CORDIS database. The HDN is an interactive platform for researchers, policy makers, and healthcare professionals to easily access health data and enhance cross-country analysis of European health systems o Austria, Estonia, Finland, France, Germany, Israel, Luxembourg and United Kingdom developed within the scope of the EuroREACH project[9]. CORDIS database is the European Commission's primary source of results from the projects funded by the EU's framework programmes for research and innovation (FP1 to Horizon 2020). CORDIS has a public repository with all project information held by the European Commission. It is managed by the Publications Office of the European Union on behalf of the European Commission's research and innovation Directorates-General, Executive Agencies and Joint Undertakings.

The desk research search was conducted on January 30th and January 31st 2019. CORDIS website was searched with the following filters[10] "Collection: Projects" and "Domain of Application: Health". The search retrieved 1348 results.

The projects were deemed as inspirational if they fulfilled the aforementioned inclusion criteria. The inspirational examples retrieved through this research are available in Appendix 2 of this report.

### Analysis of inspirational examples

The exploratory purpose of this analysis was to:

1. get an overview of the European health data sharing, linking and managing landscape in the last decade; and to
2. facilitate the choice of approximately 10 to 15 experiences to be examined in more detail in the continuation of the WP10 work through tasks 10.2 and 10.3.

Inspirational experiences, identified either through questionnaire or desk research, were analysed against the aforementioned criteria. This was done in order to get a better understanding of the profile of data linkage, sharing and management initiatives.

The answers received via the questionnaire were not further checked nor changed by the authors of this report. Information about the inspirational examples were retrieved from the projects' websites where available. If project website was not available, information available on HDN or CORDIS site were used.

## Interview instrument design and testing

### Developing the interview instrument

Interview instrument presented here, and used for piloting, was developed by researchers from WP10 at the Croatian Institute of Public Health. The instrument was developed with a specific aim of being used for semi-structured interviewing technique involving InfAct

[9] http://www.euroreach.net/compendium

[10] https://cordis.europa.eu/search/en?q=contenttype%3D%27project%27%20AND%20exploitationDomain%2Fcode%3D%27health%27&p=1&num=10&srt=contentUpdateDate:decreasing

researchers, as interviewers, and representatives of cross-country health data exchange projects in scope, as interviewees.

Previously mentioned, EIF interoperability layers have been used as a starting point for the development and structuring of the interview instrument. Meant as a list of questions for a semi-structured interview, the instrument consisted of a number of sections. Is started by asking interviewees general questions about the project / initiative and continued with questions related to four interoperability layers (legal, organisational, semantic and technical). Having in mind the mandate of WP10 as well as the "fifth layer" of "public service governance", an additional set of questions was introduced - on policy implications and use of the work stemming from the initiatives and projects.

Face validity of the interview instrument was confirmed by researchers and reviewed by Spanish WP10 Co-Leads.

### Testing the interview instrument

Aim of the interview instrument testing exercise, presented here, was to pilot the instrument with respondents which are representative of interview subjects that we plan to contact in the continuation of our work. Respondents were opportunistically selected among representatives of projects included in the mapping exercise within task one work of WP10. Interview setting and structure replicated the planned interviewing methodology for the next stage of work. Piloting interviews were conducted either using online teleconferencing software (Skype) or through in-person meetings. Two piloting interviews were conducted in English and one in Croatian. With participants' consent, interviews were recorded. Researchers transcribed the recordings and qualitatively analysed respondents' answers.

For the testing phase, we chose piloting subject that participated in beforementioned projects on different levels (project leaders, national project coordinators, national project researchers) in order to gauge which level of involvement with projects should we aim for in the interviewing work in the next phase. Piloting interviews were conducted by three InfAct researchers from the Croatian Institute of Public Health that will also proceed with conducting interviews at later stages of task two and three work between September 2019 and August 2020.

Additionally, testing the interview instrument also included questions about the method, structure and questions in the interview – in order to improve on them.

For the qualitative thematic analysis, we used NVivo 12 Pro software. After multiple readings of interviews, we constructed the coding scheme that largely resembles structure of our questionnaire.

## Interviews and thematic analysis

### Conducting interviews

For the final data collection step, in the period between February 5$^{th}$ and March 18$^{th}$ 2020, we conducted a series of 14 additional interviews (to a total of 17) with 17 (to a total of 20) representatives of 14 inspirational case projects (to a total of 17) based in a number of different European countries. Through these semi-structured interviews our main goal was to discuss in-depth how these projects and initiatives tackled issues related to data sharing, linkage and management as well as to learn about the enablers and barriers in achieving project goals. We did so by steering the discussion through the four interoperability layers, as described above, leaving ample time and space for discussions on specifics of day-to-day operation of cross-border health data exchange in the discussed projects.

We have to note that the initial plan to reach a number of 20 interviews (between 59 identified inspirational experience), was cut short due to the onset of the COVID-19 pandemic.

### Thematic analysis

Following the finalisation of all interviews, recordings were transcribed and the transcripts of all interviews, including the three pilot ones, were analysed by framework analysis using NVivo software. Transcripts were coded using line by line coding and the codes were grouped into four layers of interoperability (legal, semantic, organisational and technical). These were further grouped into enablers and barriers for each layer of interoperability based on the interpretation of the codes.

## Results

Following section present results of the three stages of our work. The mapping exercise resulted in a list of recognised and preliminarily analysed inspirational experiences. Interview instrument design and testing resulted in a finalised interview instrument and a developed approach to discussing interoperability with representatives of these experiences. The interviews themselves as well as the subsequent thematic analysis resulted in a list of reported topics, including enablers and barriers, through each of the four interoperability layers.

## Mapping exercise

### Questionnaire

During the two-and-a-half-week data collection period, total of 48 completed questionnaires were received. Some of the responses provided more than one inspirational experience. Finally, once accounting for those, the questionnaire resulted in 60 project and initiative examples deemed inspirational by the respondents.

Out of these 60 experiences received, 32 were analysed to be unsuitable according to the inclusion criteria by the questionnaire analysts. 22 out of 32 did not deal with cross-border data work but were rather confined within a single country. Ten out of 32 experiences did address cross-border data activities, but did not deal with data linkage, management nor data sharing.

Using the analysis framework and inclusion criteria, the questionnaire resulted in 28 inspirational examples to be taken forward.

### Desk research

Desk research resulted in collecting 42 examples. One example was rejected because it did not deal with neither health determinants, status, nor health system performance. Ten examples did not address data linkage, sharing nor management. This means 31 examples were accepted as inspirational through desk research.

In total, we analysed 59 inspirational experiences collected through an online questionnaire (n=28) and desk research (n=31); Figure 3.

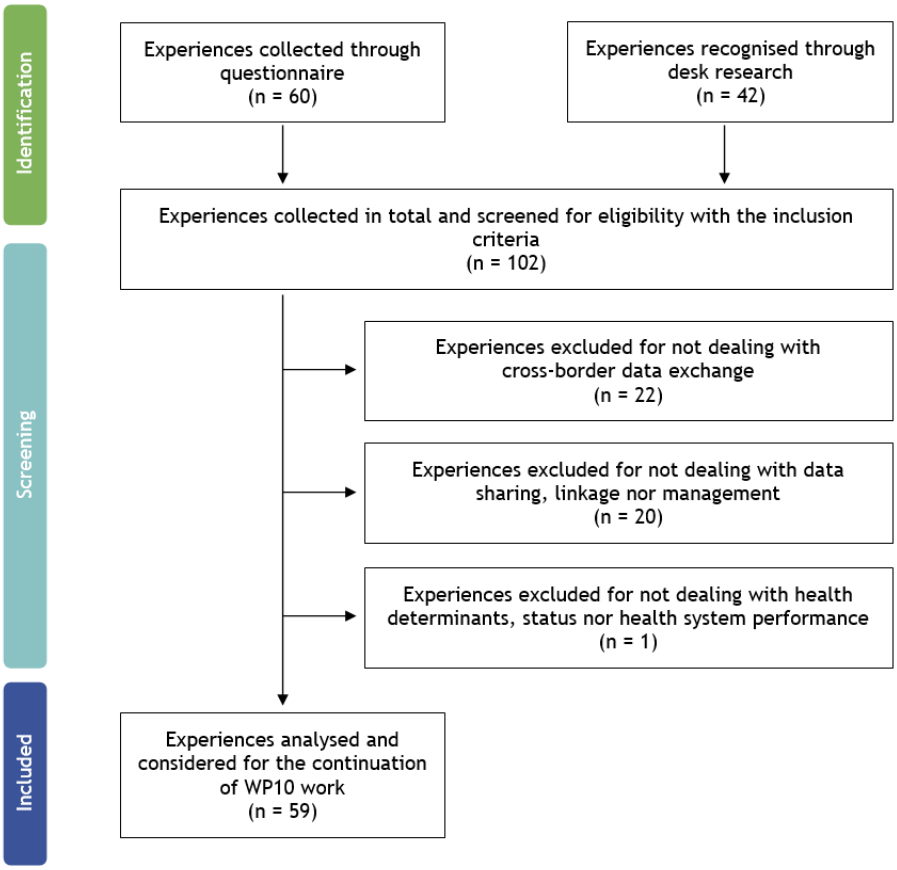
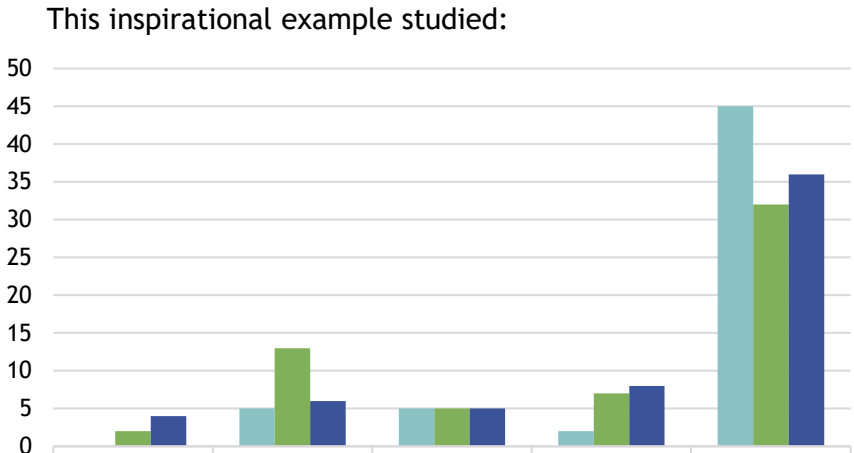



*Figure 3: A flow diagram of data collection and screening*

## Inspirational experiences analysis

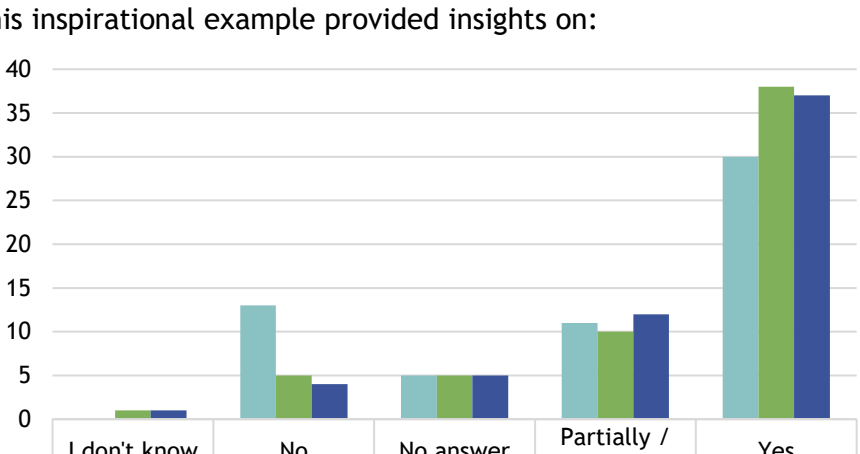
Thematically, inspirational experiences dealt with a range of topics and areas related to health information. A short description of each inspirational experience is provided in the Appendix 2 at the end of this report. In terms of domains, majority of inspirational examples did study at least one, and more often two or all three, of the domains recognised as being relevant for international data management: health status (45/59; 76%), health determinants (32/59; 54%) and health system performance (36/59; 61%). Details in Figure 4.




| | I don't know | No | No answer | Partially / Somewhat | Yes |
|---|---|---|---|---|---|
| Health Status | 0 | 5 | 5 | 2 | 45 |
| Health Determinants | 2 | 13 | 5 | 7 | 32 |
| Health System Performance | 4 | 6 | 5 | 8 | 36 |

*Figure 4: Domains of inspirational experiences' work*

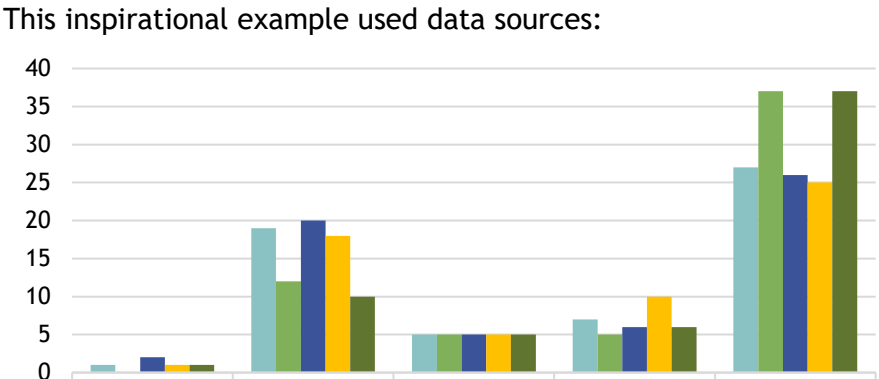
Inspirational examples were also comprehensive in covering topics related to health system performance domains with almost two-thirds of projects dealing with data related to quality of care and patient experience (38/59; 64%) and effectiveness (37/59; 63%). Half of them also worked with surveillance data (30/59; 51%). Details in Figure 5.




| | I don't know | No | No answer | Partially / Somewhat | Yes |
|---|---|---|---|---|---|
| Surveillance | 0 | 13 | 5 | 11 | 30 |
| Quality of care and patient experience | 1 | 5 | 5 | 10 | 38 |
| Effectiveness | 1 | 4 | 5 | 12 | 37 |

*Figure 5: Health system domains tackled by inspirational experiences*

Data sharing, linking and management efforts in the inspirational examples collected used a variety of data sources. Almost two-thirds of the initiatives used population-based registry (37/59; 63%) and administrative data (37/63; 63%) while half (also) used disease-based registry (27/59; 46%), survey (26/59; 44%) and Electronic Health Record (EHR) (25/59; 42%) data. Details in Figure 6.



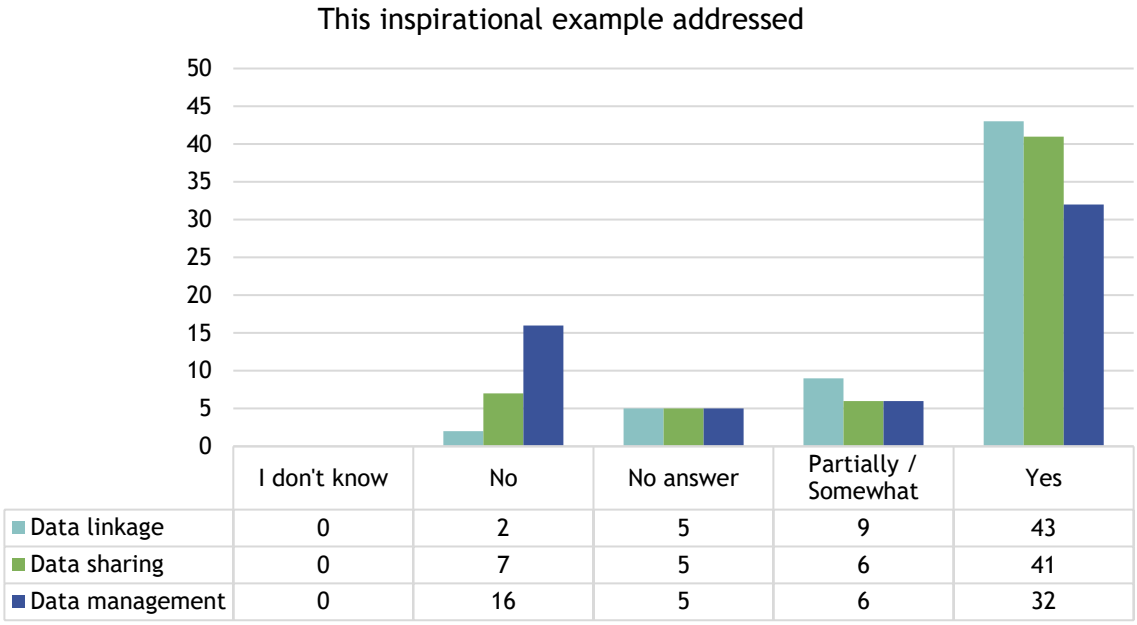

| | I don't know | No | No answer | Partially / Somewhat | Yes |
|---|---|---|---|---|---|
| Disease-based registries | 1 | 19 | 5 | 7 | 27 |
| Population-based registries | 0 | 12 | 5 | 5 | 37 |
| Surveys | 2 | 20 | 5 | 6 | 26 |
| EHRs | 1 | 18 | 5 | 10 | 25 |
| Administrative data | 1 | 10 | 5 | 6 | 37 |

*Figure 6: Data sources used by inspirational experience examples*

Other data sources reported to have been used include: “biobank data”, “data on patients' satisfaction and patients' complaints (healthcare quality of experience and doctor-patient relationship)”, “data on health care coordination and transitions”, “geographical information (GIS) regarding the statistical and administrative area units (NUTS - nomenclature of territorial units for statistics - and organisational healthcare areas)”; “environmental data”, “cities' resource allocation information”, and “qualitative: interviews and focus groups with health care providers and organisational representatives”.

Due to heterogeneous efforts and implementation methods of collecting patient reported outcome (PROM) and experience (PREM) data, these could have been listed under more than one category (i.e. survey or EHR data) and some respondents also listed these separately under “other data sources used”.

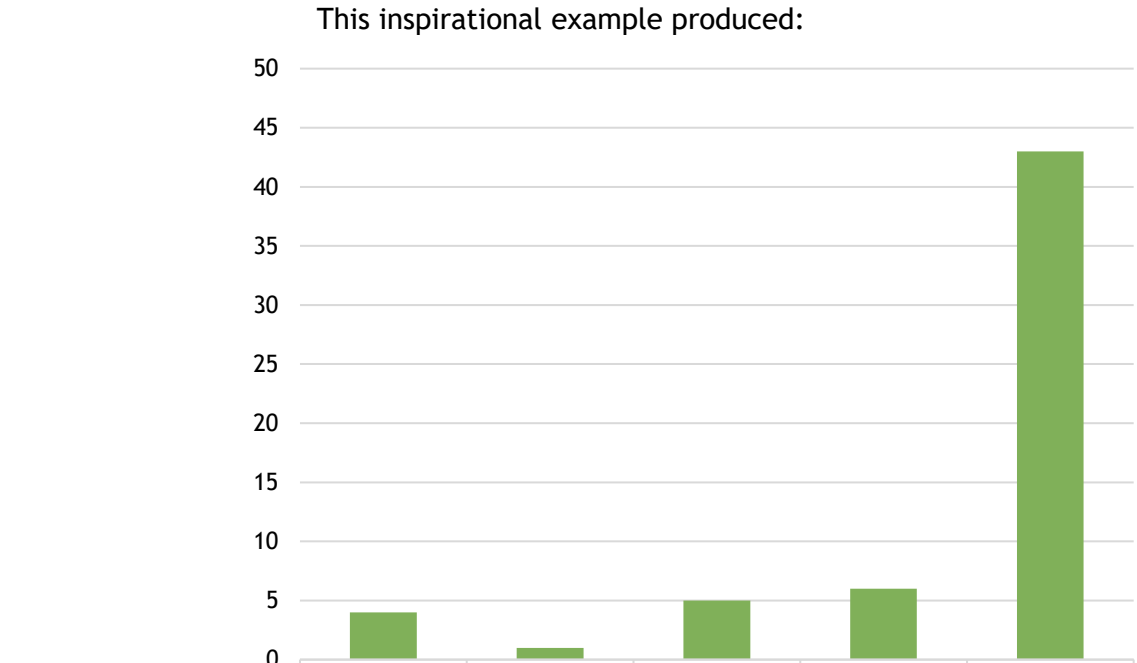
Three quarter of initiative dealt with data linkage (43/59; 73%), two-thirds with data sharing (41/59; 69%) and a bit more over a half with data management (32/59; 54%). It seems that, in the linkage, sharing and managing cascade, as the complexity of activities increases the rate of dealing with these "methods" goes down, as seen in Figure 7.




| | I don't know | No | No answer | Partially / Somewhat | Yes |
|---|---|---|---|---|---|
| Data linkage | 0 | 2 | 5 | 9 | 43 |
| Data sharing | 0 | 7 | 5 | 6 | 41 |
| Data management | 0 | 16 | 5 | 6 | 32 |

*Figure 7: Data manipulation activities by inspirational examples*

Almost three-quarter of examples (43/59; 73%) produced policy recommendations based on the data linkage, sharing and management work, while additional 10% (6/59) did that "partially / somewhat", as shown in Figure 8. Based on the short descriptions of the project, also available in the Appendix 2, it is clear that a lot of projects and initiatives had policy-involved work as part of their mandate, even in the "definition" of the project.




| | I don't know | No | No answer | Partially / Somewhat | Yes |
|---|---|---|---|---|---|
| Policy recommendations | 4 | 1 | 5 | 6 | 43 |

*Figure 8: Whether inspirational experiences produced policy recommendations?*

## Interview instrument design and testing

### Interview instrument development

Interview instrument, developed and tested, is available in Appendix 3 of this report. Interview questions are also presented in the same Appendix with the accompanying invitation letter sent to interviewees via email.

### Interview instrument testing

Interview instrument was tested in three separate testing sessions with three respondents during July 2019.

Piloting subjects were chosen conveniently from the partners with which WP10 researchers had personal contact and that participated in projects mapped in the first task of WP10.

*Table 1 presents details on piloting subjects and piloting sessions.*

*Table 1: Piloting subjects and details*

| Piloting session | Piloting subject name and country of work | Project | Role in the project | Date of the interview | Piloting modality |
|---|---|---|---|---|---|
| 1 | Jennifer Zeitlin, France | EuroPeristat | Project leader, France | 16.07.2019 | Teleconference |
| 2 | Håkon Haaheim, Norway | Nordic Welfare dataBASE | Data expert (NOMESCO), Norway | 23.07.2019 | Teleconference |
| 3 | Mario Šekerija, Croatia | EUROCARE, RARECASE, ECIS, CONCORD and ENCR | National coordinator, ENCR Steering Committee Member | 26.07.2019 | In-person |

Piloting subjects were provided with the interview questions beforehand and informed that the piloting interview sessions will last around 45 minutes. Indeed, the interviews lasted between 40 and 50 minutes each.

We conducted the interviews in two stages. First one was completely simulating the interview process, as it will take place in the continuation of our WP10 work. Second stage was the discussion on the experience of the interview itself. With respondents, we discussed the clarity and relevance of questions posed as well as possible changes to the interviewing questions and methodology needed.

All piloting subjects prepared themselves for the interview, by having read the questions and drafting their replies. Respondents introduced their projects, including the aim, scope, history and their involvement. Afterwards, and without being asked explicitly, all piloting subjects provided their answers to the majority of questions from the invitation letter. We further clarified some statements and asked questions that the participants have not answered previously or that needed further clarifications.

Within the results of testing the interview instrument, we present preliminary interview content analysis results, as we plan to use it in the later stage of this work, but with the focus on presenting participants' comments and suggestions on how to improve the interview instrument and method itself.

## Interview content analysis

This section of the results presents participants' replies to specific questions, as this is the scope of the next phases of our task two and three WP10 work. Despite conducting only three interviews, whose primary goal was not to analyse the content of replies itself, but rather the interview instrument and process, certain reply patterns started emerging.

Figure 9 shows a hierarchy chart representing number of references per code / category. As we can see, most references were made to semantic and technical interoperability.


*Figure 9: Hierarchy chart representation of topic references per code / category*

Figure 10 presents coverage, measured in number of words, that resembles general number of references, with the exception of respondents providing shorter replies when referring to technical interoperability. Substantial part of replies was related to semantic interoperability as our respondents considered it the most time-consuming part of their projects and provided an abundance of examples.

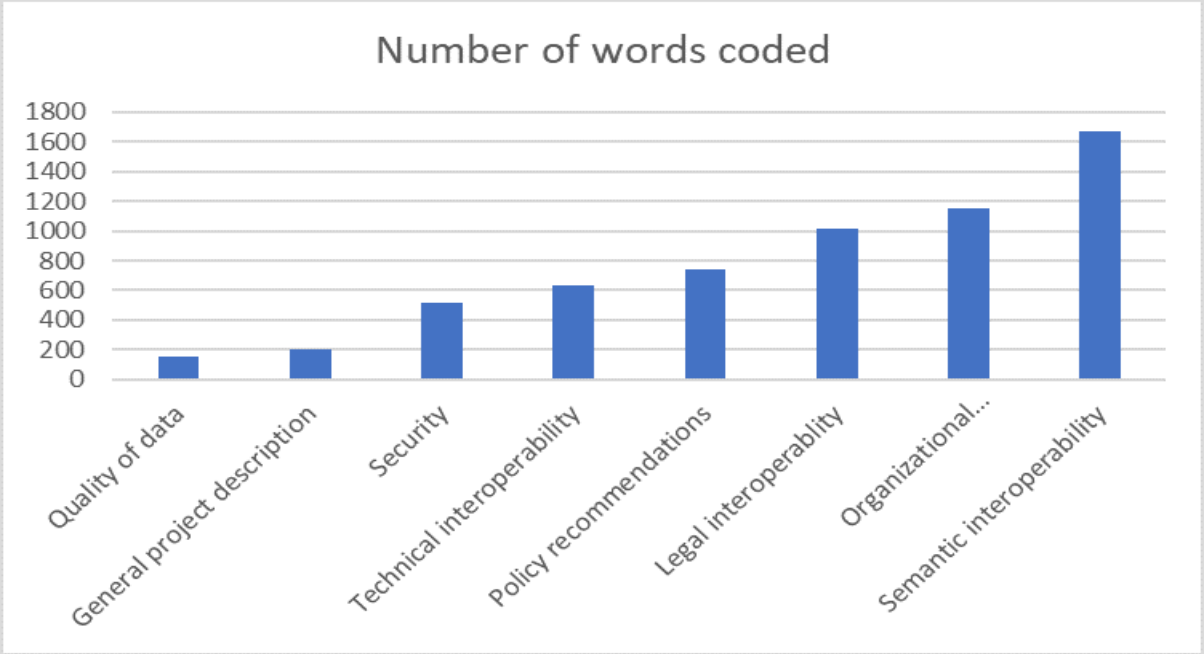



*Figure 10: Number of words per category*

To assess respondents' replies on enablers or barriers, we analysed and coded transcripts through *sentiments*, with "very positive" and "moderately positive" representing enablers and "very negative" and "moderately negative" representing barriers. Figure 11 shows share of references made to enablers and barriers, coded in this manner. This graphic representation shows that there were more comments and examples of what respondents perceived as enablers than barriers, which they have / had to overcome.

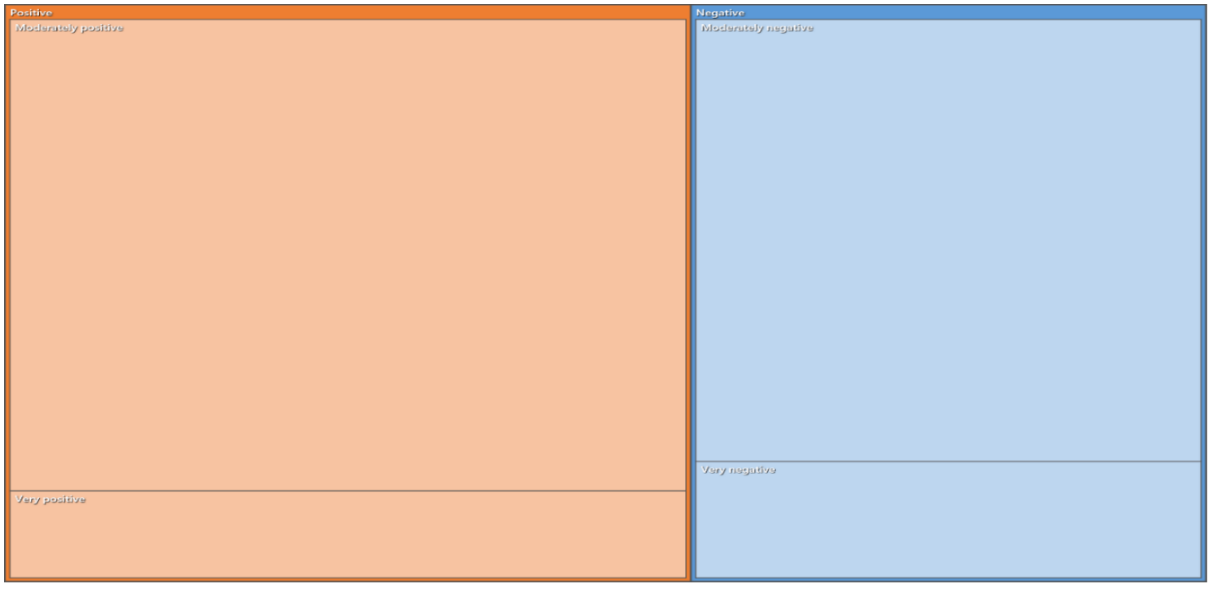



*Figure 11: Share of references made to enablers and barriers*

Table 2 presents the preliminary results, based on the three piloting interviews, classified within the four (plus one) categories of interoperability layers tackled within this WP.

| **Legal interoperability** |
|---|

| | |
|---|---|
| Enablers:<br>• some projects collect what already exists, aggregated data and do not have legal issues<br>• having legal requirements for reporting because it forces countries to adjust their systems | Barriers:<br>• no clear distinction between pseudonymized and anonymized data<br>• vague definition of anonymized data<br>• some countries are not able to share internationally data that are not aggregated even though they are not re-identifiable<br>• perceived impossibility of working with anything resembling patient level data because of GDPR<br>• legal obligations can be constraint to accept second best solution because people don't want to promise to give certain types of data<br>• Brexit<br>• laws on certain procedures are not harmonized |
| **Organisational interoperability** | |
| Enablers:<br>• giving flexibility to each country to organise their own team<br>• not being legally binding to participate, having a network of people interested in the subject<br>• doing research, publishing results, and allowing people to participate on those levels motivates them to push things in their own countries<br>• each member chooses the best source of information that they have in their county | Barriers:<br>• legislation does not always equal practice, so some countries may have very different legislation but have practices which are very the same, and some countries may have the same legislation, but completely different practices.<br>• some services are provided in different area of specialized and primary care in different countries |
| **Technical interoperability** | |
| Enablers:<br>• federated database system<br>• existence of unique identifier<br>• dataset templates<br>• standards<br>• protocols | Barriers:<br>• lack of unique identifier<br>• lack of resources |
| **Semantic interoperability** | |
| Enablers:<br>• international standards and recommendations<br>• existence of specialised code books<br>• using existing definitions for each indicator<br>• having data calls with clearly defined dataset, coding scheme and inclusion criteria<br>• having limited number of indicators | Barriers:<br>• lack of recommendations and standards in certain areas, "grey zones"<br>• clash of different recommendations |

| Policy recommendations | |
|---|---|
| **Enablers:** | **Barriers** |
| • having platform for result dissemination<br>• publishing in scientific journals | • no way of measuring impact<br>• depends on the advocacy of people in certain country |

*Table 2: Preliminary list of recognised enablers and barriers based on the three piloting interviews*

Further, we present the results of the analysis of the interview methodology as well as the interview instrument used.

### Invitation letter and the introduction to InfAct project and interoperability

Briefly introducing the InfAct project and the role of our work on interoperability (including the layers) within it, was perceived as a very good introduction to the interview. Although most participants in this testing phase were already familiar, or even involved, with InfAct and working on the topic of interoperability on a daily basis, most have not really encountered the classification of layers into legal, organisational, semantic and technical ones. This brief explanatory text was perceived as being very useful in understanding the structure of the interview questions following.

Participants strongly suggested to keep the format and content of the introduction in the final version of the interview instrument. Additionally, two participants commented on the need to further elaborate on the "organisational" level of interoperability.

### Structure of the interview instrument

Participants were positive about structuring the interview questions according to the EIF interoperability layers. At the same time, an issue of interconnectedness between layers was flagged as an important topic during testing interviews.

In line with that, pilot testing subjects recognised the advantage of having an interview which is not strictly adhering to levels but is allowing us to discuss also the links and interconnectedness between levels and how this possibly acts as an enabler and/or a barrier in working with health data across borders.

### Profile of interviewees

Two out of three piloting subjects commented that, from their position of a national contact point, researcher or "data provider", they were unable to provide all the replies on the questions in the interview. In order to be able to answer all the questions, covering all the interoperability layers, we were referred to contacts working on these projects on the top, coordination level. On the other hand, project coordinators, not working on the national level and use of data, are rarely able to provide insights into the impact of projects on the national policy making.

### Additional questions suggested

Respondents suggested talking about two additional topics, as part of these interviews. These were 1/ funding and 2/ data quality issues, which they felt related to the scope of the interview and helped contextualise some of the discussions and replies.

## Interviews and thematic analysis

### Interviews

Between July 2019 and March 2020, a total of 17 interviews with 20 representatives of 23 inspirational cases were conducted. Table 3 shows an overview of the interviewees, their roles in projects and projects presented.

*Table 3: Full list of interview participants*

| Session | Subject name and country of work | Project | Role in the project | Date of the interview | Modality |
|---|---|---|---|---|---|
| **1*** | Jennifer Zeitlin, France | EuroPeristat | Project leader, France | 16.07.2019 | TC |
| **2*** | Håkon Haaheim, Norway | Nordic Welfare dataBASE | Data expert (NOMESCO), Norway | 23.07.2019 | TC |
| **3*** | Mario Šekerija, Croatia | EUROCARE, RARECASE, ECIS, CONCORD and ENCR | National coordinator, ENCR Steering Committee Member | 26.07.2019 | In-person |
| **4** | Arpo Aromaa, Finland | ECHIM | Project leader, Finland | 06.02.2020 | TC |
| **5** | Nigel Hughes, United Kingdom | EMIF, EHDEN | Project leader, United Kingdom | 18.02.2020 | TC |
| **6** | Liesbet M. Peeters, Belgium | MSDA | Project coordinator, Belgium | 26.02.2020 | TC |
| **7** | Peija Haaramo, Finland | CEPHOS LINK | Project participant, Finland | 26.02.2020 | TC |
| **8** | Rosa Suñol, Spain | DUQuE | Project leader, Spain | 03.03.2020 | TC |
| **9** | Roberta de Angelis, Italy | EuroCare | Project leader, Italy | 04.03.2020 | TC |
| **10** | Rupert Kisser, Austria | EU-IDB | Project leader, Austria | 04.03.2020 | TC |
| **11** | Karima Bourquard, France | EUROCAS | Project leader, France | 09.03.2020 | TC |
| **12** | Laura Pucci, Tino Marti, Francesco Torelli, Stefano Dalmiani, Italy | InteropEHRate | Project leader/participant, Italy | 10.03.2020 | TC |
| **13** | David Morgan, France | OECD | Head of Health Accounts, OECD | 12.03.2020 | TC |
| **14** | Andre Dekker, Netherlands | GoFair | Project leader, Netherlands | 16.03.2020 | TC |
| **15** | Tamara Poljičanin, Croatia | EUBIROD | Project participant, Croatia | 17.03.2020 | In-person |

| | | | | | |
|---|---|---|---|---|---|
| **16** | Karl A. Stroetmann, Germany | OPEN MEDICINE | Project leader, Germany | 18.03.2020 | TC |
| **17** | Kari Kuulasmaa, Finland | MORGAM | Project leader, Finland | 19.03.2020 | TC |

* These interviews were conducted in the piloting stage and were transcribed and thematically analysed together with other interviews.
TC - Teleconference

## Thematic analysis

Following the finalisation of all interviews, recordings were transcribed and the transcripts of the interviews were analysed by framework analysis using NVivo software. Transcripts were coded using line by line coding and the codes were grouped into four layers of interoperability (legal, semantic, organisational and technical). These were further grouped into enablers and barriers for each layer of interoperability based on the interpretation of the codes.

## Legal level

Discussions on the legal level made up 20% of the themes covered during the interviews. GDPR discussion made 44.6% of the discussion on legal layer with GDPR enables making up 10.3% and GDPR barriers making up 26% of the discussion on legal layer. General legal enablers making up 4.6% and barriers 10.7% of the discussion on legal layer as shown in Figure 12.


*Figure 12: Legal interoperability*

Table 4 presents a summarised version of discussion topics divided into recognised enablers and barriers coming from the legal level of interoperability. Given its importance, this level, or layer, of interoperability also contains relevant information elicited from the interviewees on their perceived enablers and barriers related to the General Data Protection Regulation (GDPR) where 35% of the participants perceived GDPR as a barrier, 18% as an enabler, 18% both as an enabler and a barrier, and 29% did not see it as a barrier nor as an enabler. Hence, these have been separately presented.

*Table 4: Legal interoperability enablers and barriers – a thematic analysis of interview transcripts*

| **Legal interoperability** | |
|---|---|
| **Enabler themes** | **Examples** |
| Mandatory data collection | When data collection is mandatory, a more uniform level of coverage of variables between countries is observed, as opposed to when the data collection is voluntary and the coverage can be very variable between countries.<br><br>When certain type of data collection is legally obligatory, countries adapt their systems to what is being requested of them. Having a legal requirement to collect, analyse and share the data is an enabler for health data exchange between countries. |
| EU-wide harmonization and regulation | Having a European coordinating legal centre which would replace the need for bilateral agreements between countries, contributing to the speed and cost of such arrangements.<br><br>Also, Europe-wide regulations for health data collection, processing and exchange are an enabler for international organizations which collect the data from European countries. |
| **Subsection: GDPR-related enablers** | |
| User rights over their data | GDPR helps with defining the user ownership and right over the data and specific purposes for which the data can be used.<br><br>It also facilitates development of tools which give control over the data to data owners (patients) and data custodians (organisations). |
| Pre-existing laws regarding data privacy and data sharing | GDPR is easier to implement in countries with previously existing and implemented laws regarding data privacy and data sharing. |
| Anonymised statistics | GDPR defines and enables sharing of anonymised statistics. |
| New data analysis approaches | GDPR is a facilitator for the introduction of new data analysis approaches which do not require full data sets to be shared as it minimizes data privacy risk. |

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

| **Barrier themes** | **Examples** |
|---|---|
| Obtaining ethics committees' permission | In some countries, getting an ethics board permission takes a lot of time and paperwork and slows down the project work substantially.<br><br>A single member of an ethics board can slow down the process if he/she is not in an agreement with the rest of the board with giving the permission needed for the project.<br><br>Time to get an ethical permission in some countries delays the collection and processing of the data. Obtaining an ethics board permission is more difficult in some countries than in others. |
| Lack of health data understanding by the ethics boards | Ethical boards sometimes cannot distinguish between different types of data collections, which requires additional explanation both at the country level as well as at the institutional level. |
| Population level data | There are legal issues and setbacks when projects use the data for whole population in certain countries. |
| Legislation as an excuse | People often say that they do not have legal or ethical approval for sharing the data when they actually do not want to share the data.<br><br>Data protection legislation is sometimes used as an excuse not to share the data. |
| Collaboration outside EU | Often, there is a stricter legal process in EU countries for collecting, analysing and sharing data than in other non-EU countries, which constrains data sharing on international level. |
| Time | Legal issues rarely not stop anything, but they often slow down the process considerably. |
| Complicated landscape of legal requirements | Researchers are sometimes not aware of all the legal requirements when dealing with health data. |

| | |
|---|---|
| Non-harmonised legislation between countries – an example of consent for already collected data | Some countries require additional consents when using historical data while other countries recognize the consents from the time when the data collection occurred as valid. |
| 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. |
| **Subsection: GDPR-related barriers** | |
| Identifiable and patient-level data | GDPR is an issue with health data narrowly defined by region, sex, age group and International Classification of Disease (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.<br><br>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.<br><br>GDPR makes it complicated to work with anything resembling patient level data as everything is potentially confidential and identifiable. |
| Data sharing | There are much more concerns about data protection which makes it more difficult to share data for scientific purposes.<br><br>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 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. |
| 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. |
| Workload (and resources) involved in GDPR compliance | 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.<br><br>There is a lack of funding to set up data and information exchange systems, which would be compliant with the GDPR. |
| Local legal legislation | There are differences in local regulations between countries and sometimes the local regulations are opposite to the GDPR. |
| Different (and stricter) interpretations | 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.<br><br>There are interpretations of the GDPR, which are stricter than it was intended with the GDPR. A lot of people over interpret the GDPR and make it stricter 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. |
| Access to data | Access to individual data is restricted to 3rd parties, only aggregated results are shared. GDPR and privacy concerns are sometimes used as an excuse to stop sharing the data. Data providers are concerned about eventual violation of the data protection laws, which leads some countries to stop sharing their data. |
| GDPR interpretation | There is a contradiction in the interpretation of the GDPR between reading it word by word and the spirit ant the purpose of the GDPR. Lawyers are not sure how to interpret GDPR, which, in the end, makes the interpretation of the GDPR stricter 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. |

## Organisational level

Discussions on the organisational level made up 10% of the themes covered during the interviews. Organisational enables making up 17% and organisational barriers 18.5% of the discussion on the organisational layer of interoperability as shown in Figure 13.

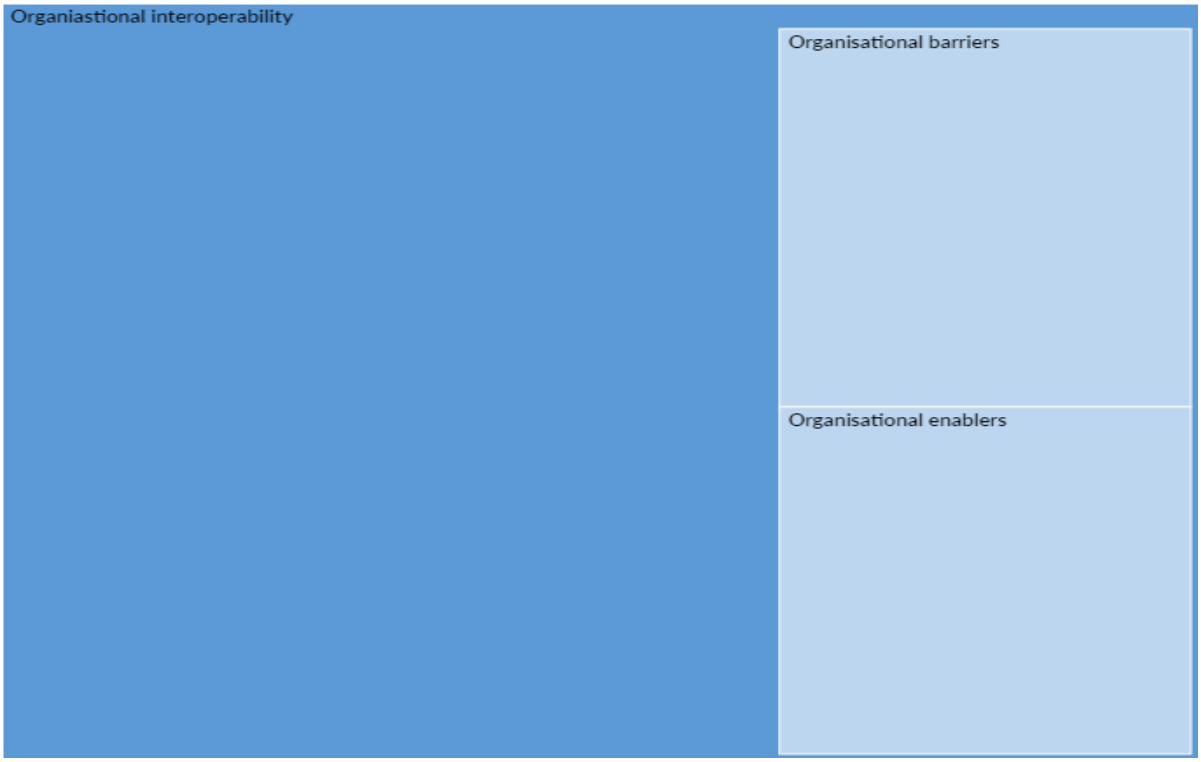



*Figure 13: Organisational interoperability*

Table 5 presents a summarised version of discussion topics divided into recognised enablers and barriers coming from the organisational level of interoperability.

*Table 5: Organisational interoperability enablers and barriers – a thematic analysis of interview transcripts*

| **Organisational interoperability** | |
|---|---|
| **Enabler themes** | **Examples** |
| Well organized national health information systems | Some countries have a strong national governance on hospitals, they have excellent health statistics and for them extracting the needed information from an already existing databases for all the hospitals is not a challenge because the hospitals are already involved in the national health information system. In other countries, the responsibility is not centralized at the national level but on the federal states where the provinces have the main competence. |
| Network of people who are interested in a certain topic | A network of people who are interested in the scientific background of the project is able to put together the data which is needed. |
| Organized structure | For the long run, organized structure would be better for international health data collection rather than a voluntary network. |
| Political pressure | Countries which do not collect data which other countries collect are under political pressure to improve their systems. |

| | |
|---|---|
| Partner assessment | Project consortium works better when project partners are being selected based on an assessment, rather than project partners being predetermined. |
| Presence of a central(ised) national health data / information body | Presence of a central(ised) national body dealing with health data and information is recognised as an important enabler. Not only for work within the country but also in approaching cross-border health data exchange and management, including the issues of interoperability. |
| High level support | Having a support for project from a high level (ministry, board of directors) makes conducting the research easier. |
| Development of "data economy"[11] | Developing data economy enables interoperability as data holders are motived to share their data if they benefit from the research as well, not just the researcher who is conducting the research. |
| Clear instructions | Clear instructions (e.g. for software installation and use) are a facilitator of work since it leaves no place for confusion and individual interpretations. |
| Technical support | Existence of and effective communication with the technical support facilitates work. |
| Resources | Data centres which have more resources and better-trained staff are in a better position to do the data harmonization than the centres with less resources and less trained staff. |
| **Barrier themes** | **Examples** |
| Process complexity | Complexity of retrieving the data in a country makes projects less likely to use that data. Data collection can be postponed and cancelled in a country where it is complex to retrieve the data. |
| Lack of understanding of organisational interoperability | Organizational interoperability is often understood as a different layer of interoperability, if at all. A lot of people do not appreciate or understand the benefits of cross-border health data exchange which poses a barrier towards achieving interoperability, while the ones who understand it and are interested in it are academics. |
| Motivation and time | No one has enough time or will to collect extensive datasets with a large number of variables. There is a lack of will to do something when it comes to implementing novel solutions.<br><br>It is challenging to motivate medical staff to collect all the information that is needed. |

[11] Communication on Building a European Data Economy, Digital Single Market, COM(2017) 9 final. European Commssion. Retrieved 20 August 2018.

| | |
|---|---|
| | In some countries, it is possible to involve almost all hospitals for data collection while in some countries there are only few hospitals willing to be involved in data collection which represents a challenge when creating a representative sample of hospitals in a certain country. |
| Harmonizing national data collecting system(s) | It is challenging when you have data from hospitals, primary care, registries, cohorts, all together in a single project.<br><br>Harmonizing the national data collecting system is a big challenge as there are different styles, different cultures, different environments, different understandings, the hospitals in various countries function in different ways and there is a need for finding different organisational solutions at national level. |
| Different national opinions towards different types of data | National data collection, for instance on suicide, is impossible in some countries because suicide is considered a taboo and you do not get proper data on suicide in these countries, while in other countries data collection for suicide is not a problem. |
| Convincing people | Convincing people and building the community to allow the cross-border health data exchange takes a lot of time because there is a lack of the understanding. |
| Time needed for getting the owner's approval for data usage | Approval for usage of the data varies from one data source to another and some data sources take a long time to give the approval for usage, which prolongs the project. |
| Human resources and reluctance towards change | People are used to send the data and it is hard to educate them that the data can be analysed at the data holder and only the results are shared.<br><br>Statistics people who are used to working in SPSS are reluctant towards implementing new approaches to data analysis, as it requires them to adapt to a new system.<br><br>Sometimes it is not possible to involve all hospitals in data collection because specially trained interviewers are needed which means a significant burden to the hospitals. |
| Variable interest for participation in projects | Response rates for institutions willing to participate in certain project varies from country to country. |
| Lack of central funding | Harmonization of various national data collection systems and creation of European health database is not achievable without proper central funding. |

| | |
|---|---|
| Control over data | There is a cultural change in a sense that people are hesitant to send their data outside of their source because they lose control over the data.<br><br>People are sometimes reluctant to share the data because they are afraid what will be learned from the data. They are afraid of the possibility that the data shows that they are doing a bad job, they do not have time or will to send the data, that they do not have the resources to send the data or because of the ethical and legal issues. |
| Different priorities | Various countries set their own priorities. Even though there is political support, Europe-wide agreement and understanding for cross-border benefits, some countries are more active when implementing solutions while others are sitting on the fence and watching the outcome prior to implementing solution as implementing solutions costs money. |

## Semantic level

Discussions on the semantic level made up 14.5% of the themes covered during the interviews. Semantic enables making up 7.5% and semantic barriers 16% of the discussion on semantic layer of interoperability as shown in Figure 14.

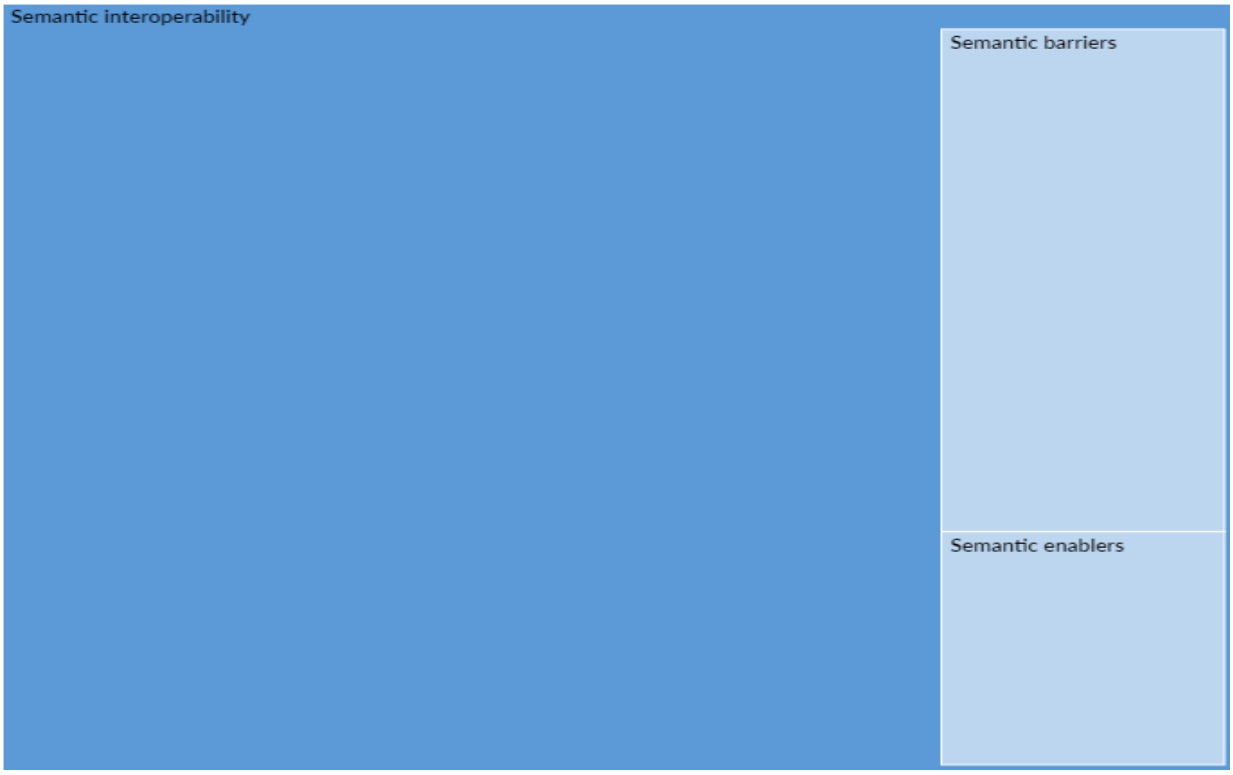



*Figure 14: Semantic interoperability*

Table 6 presents a summarised version of discussion topics divided into recognised enablers and barriers coming from the semantic level of interoperability.

*Table 6: Semantic interoperability enablers and barriers – a thematic analysis of interview transcripts*

| **Semantic interoperability** | |
|---|---|
| **Enabler themes** | **Examples** |
| International organizations taking the lead | Countries expect from international organizations to have a lead in promoting certain international standards. |
| First-adopters as role models | Some countries are fast in setting up new indicators and set up an example for "slower" countries. |
| Working with both minimum and full datasets | Working with minimum datasets makes it easier to collect and standardise but often does not give that much information.<br><br>Full dataset gives more detail information and is can be used for more purposes but are usually harder to implement and populate.<br><br>It is better to have a limited set of core indicators which would help to follow up at the population and European level sufficiently well so that all the country can collect the limited indicators than to have large set of indicators which all the countries could not collect. |
| Standardization of definitions | Standardization of definitions is a facilitator for users, but burden for countries to comply to. Getting people to think about using common definitions when they compare data across European countries is of a key importance. |
| One national database | One national database for health data collection instead of more databases is a facilitator. |
| Health data standards | Existence of the health data standards is a facilitator for the deployment of the digital health, as well as the training of the workforce. ICD is and obvious example. |
| Compromise | When comparing variables, it is important to realize that it is not possible for the two always be the same and to accept that they are close enough to each other so they can be compared. It is good to be careful when comparing the variables, but also willing to compromise when the variables are not the same but are close enough to be compare because otherwise there are fewer variables to compare. |
| FAIR data | Using the FAIR data catalogue is a facilitator for semantic interoperability. |

| | |
|---|---|
| Multilanguage information | When information or data are available in multiple languages, this facilitates semantic interoperability. |
| **Barrier themes** | **Examples** |
| Specific national classifications | Cross-border harmonization and comparison is hard when there are national classifications, which differ from country to country. |
| Access to comparable information (e.g. indicators) | Different countries collect different indicators and getting comparable indicators is hard. |
| Lack of resources | Resources are needed for collecting full dataset and to educate the coders and often insufficient. |
| Different terminologies | Different hospitals sometimes use different terminologies, different value sets for different kinds of information so the project has to specify a set of standard international terminologies that must be used by all the organizations that want to exchange the data using a protocol. |
| Clinicians and patients | Clinicians and patients often change their mind about the list of variables that they need as well as the domains that they feel are relevant. |
| Time constraints | Less variables are being included in the projects due to the time constrains of the project and the lack of funding which makes project partners being very careful and selecting quite narrow number of variables that they are sure that can be comparable. Project lifetime is not sufficient for implementing the core indicator set. |
| Time needed to harmonize | People do not realize how big work is to harmonize the data and they are not prepared for that. |
| Complicated coding | Complicated coding represents a problem in both centralized settings as well as in the distributed settings. |
| Time consuming mapping | Limited number of variables is being mapped because it is time consuming which limits the variables to a minimal list. |
| Low data quality | There are differences in information, which makes databases not usable for cross border exchange as the quality of the data is low. |

## Technical level

Discussions on the technical level made up 11.2% of the themes covered during the interviews. Technical enables making up 5.4% and technical barriers 22% of the discussion on technical layer of interoperability as shown in Figure 15.

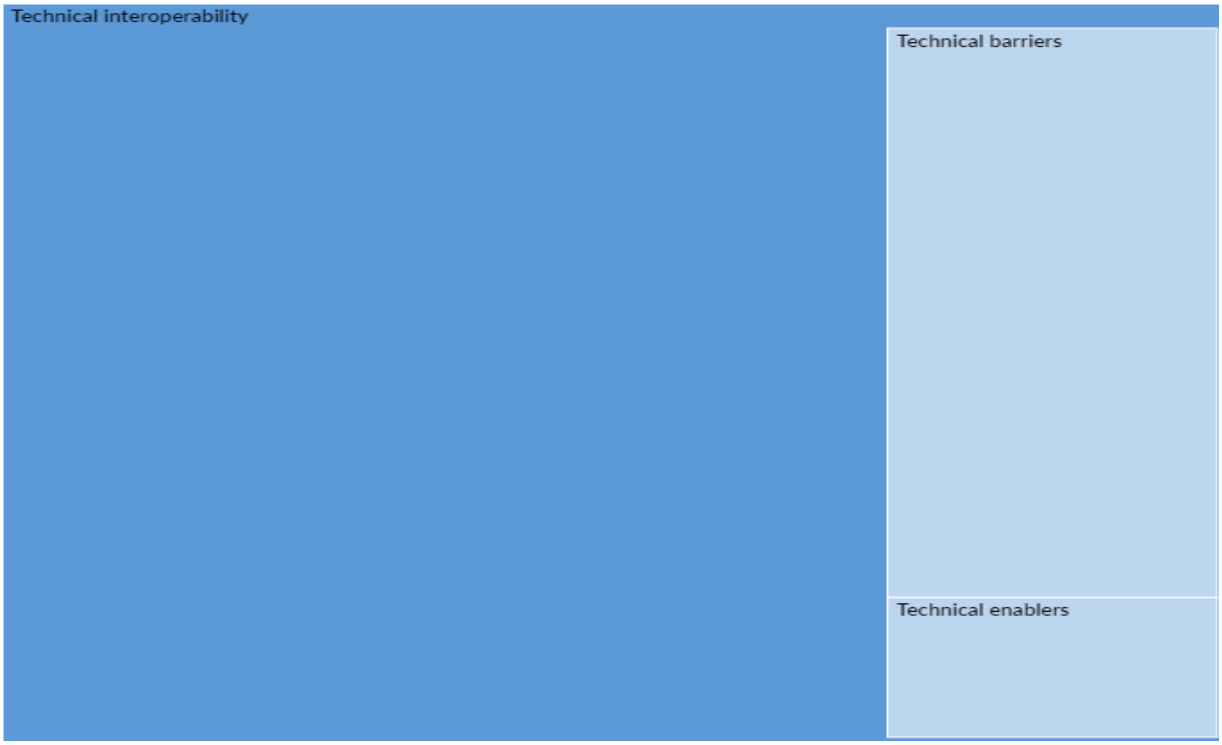



*Figure 15: Technical interoperability*

Table 7 presents a summarised version of discussion topics divided into recognised enablers and barriers coming from the technical level of interoperability.

*Table 7: Technical interoperability enablers and barriers – a thematic analysis of interview transcripts*

| **Technical interoperability** | |
|---|---|
| **Enabler themes** | **Examples** |
| Data format | Using the same data format when exchanging documents as it facilitates compatibility and eases reading the data. |
| New technical solutions | Data holders, as well as management and privacy officers are easily convinced to implement new technical solutions, if they prove to solve a lot of their concerns.<br><br>Federated data model is being developed and used. The idea is that the data stays local and researchers send the query to where the data is and the analysis is conducted locally. The results are then sent back and navigated on the population level which allows for cross border data exchange without actually moving any data or creating any central database or central architecture.<br><br>Developments of IT systems during the lifetime of the projects make work easier. |
| Data harmonization | Data harmonization process increases data quality and removes misprints in the data which |

| | |
|---|---|
| | were not seen by data holders prior to the data harmonization so the end result is better data. |
| Open source code | Open source codes can be used when developing novel solutions since open source code means that someone before you already did part of the job and made it publicly available. You then make your upgrades and changes as necessary. |
| Same software | When using the same software across countries with the same terminologies and coding, data can be easily identified across countries by using key identifier. Using existing tools and existing common data models facilitates scaling of projects. |
| Pre-existing technical infrastructure and knowledge | Pre-existing infrastructure and knowledgeable operators are an enabler for technical interoperability. |
| Electronic submission systems | Development of electronic submission systems, in comparison to paper submission, (e.g. submission of the Common Technical Document in pharmaceutical industry) is an enabler for technical interoperability. |
| **Barrier themes** | **Examples** |
| Security measures | Data sharing is becoming more and more difficult because of the technical security measures, which each organization has to implement.<br><br>On the other hand, a lot of cross-border data exchange is still done via e-mail. |
| Different level of technical sophistication | Countries and institutions are at different levels of sophistication in terms of data handling but also privacy and security of data transfer.<br><br>Older systems are not configurable to add the necessary additional data and features. |
| Data mapping | Mapping of data (searching for the data you need among large quantity of data) is very time consuming. Limited number of variables is being mapped because it is time consuming which limits the variables to a minimal list. |
| Data format | There is a variety of variables in the registries which have different formats and different software are used and it takes a lot of time and motivations for data custodians to harmonize the data. |
| Data quality | During the harmonization process, misprints in the data are often found which the data holders were not aware of before the data harmonization. |
| Unintuitive and non-user-friendly interface | If user interface is complicated and non-user-friendly, it takes lot of time to get the job done. |

| | |
|---|---|
| Lack of technical understanding | Some data owners (e.g. members of patient's associations) do not have the necessary technical knowledge to e.g. use a cloud-based service or any other technical novelty. |
| Combining multiple data sources and multiple datasets | Vertical partitions are hard to accomplish because it is needed to combine data from various data sources and match individual patients across datasets. |
| Different tools | Different organizations use different tools in operations which tends to put constrain on cross border health data exchange. Differences in data collection, different software used and large number of out layers are an issue. |

# Discussion

## Assessing interoperability

This report presents the outputs of the first three tasks (T10.1, T10.2 and T10.3) of the InfAct Joint Action WP10 in assessing the role and position of interoperability in cross-border sharing, linkage and management of health data. This was achieved by identifying inspirational experiences among EU-wide projects that tackled interoperability issues to characterise the panoply of solutions applied to overcome legal, organisational, technical and semantic barriers while addressing comparisons across countries.

In parallel to this work, the task four (T10.4) of the WP10 is benefiting from insights gained from this analysis to propose facilitators and best approaches to set up several pilots on the proposed case studies for a future sustainable infrastructure dealing with health information in Europe, enabling health data analysis across EU countries for informing health policy and conducting public health research.

A summarised schematic representation of the double-stream WP10 work is visible below in the Figure 16.

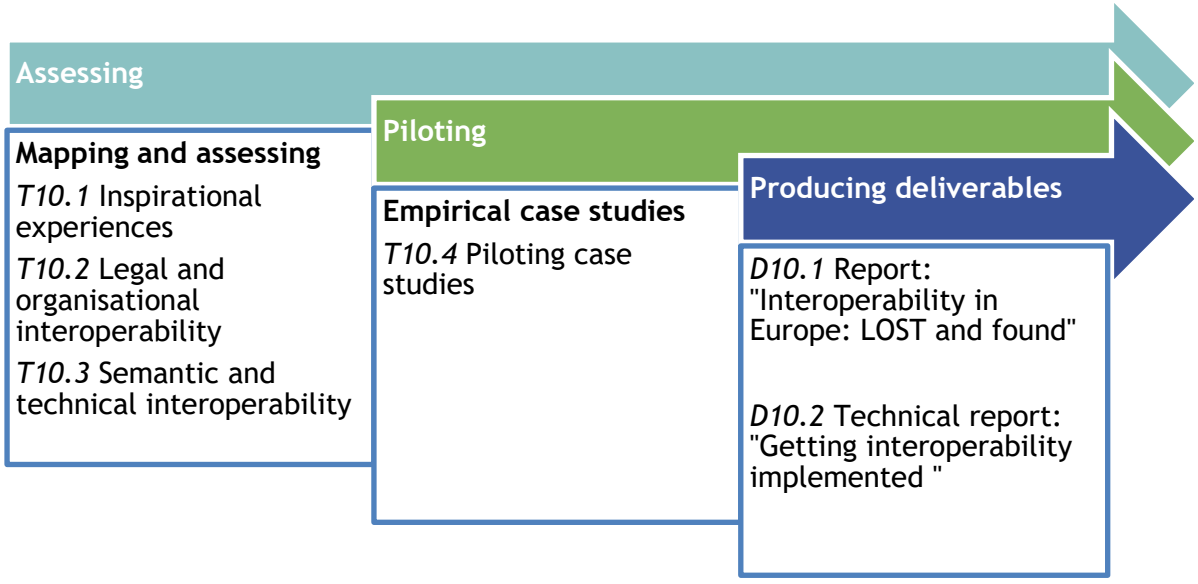



*Figure 16: Work Package 10 work summarised*

## European landscape – different faces of cross-border health data work in Europe

Our simple scoping exercise, through both surveying and desk research, showed that the European landscape of projects and initiatives linking, sharing and managing health data among countries is vibrant and diverse. Despite the non-exhaustive approach, we did manage to list a significant number of inspirational experiences and get an overview of geographic, funding, thematic and governance-style "spread" of these efforts.

Another result of our review, which will not feed directly into the future WP10 work but is of great significance to potential future European infrastructure dealing with health

information, is the dispersion and limited duration of these efforts. Evidence of projects communicating and collaborating among themselves, despite dealing with similar topics and data, is scarce. Also, a minority of the efforts analysed here operate as on-going projects with sustainable governance structures.

The analysed inspirational experiences did show a rather comprehensive approach to dealing with all domains of data exchange - sharing, linking and management of data. Health system domains-wise projects also did holistically address health status, determinants and system performance measures. Experiences also looked at both quality and effectiveness data and, to a bit lesser extent, at surveillance data.

Another interesting finding, which we will look into more detail, is that, in the linkage, sharing and managing cascade, as the complexity of data "manipulation" activities increases, the rate of initiatives dealing with these "methods" decreases.

## Awareness of interoperability

Conducting interviews via teleconferencing proved convenient and successful, as did the 45-minute format of interviews. Generally, we found the "casual" and less structured discussion about the interoperability layers with the participants optimal and insightful. This provided us with a lot of contextual information and revealed topics that we were unable to recognise in our desk research on these projects. This also allowed us to prompt interview questions, if they were not already answered on respondent's own accord, and emphasised the discussion that went back and forth between interoperability layers, discussing issues that cut across them. The core categorisation remained on the main themes that represent the four layers of interoperability and policy recommendations with special attention paid to legal and organisational aspects of working with GDPR.

An important consideration, for the interviewing tasks, was to keep a "mixed profile" of invitees, both top-level project coordinators as well as national-level partners in order to capture a wide range of issues presented as both enablers and barriers on all levels of dealing with projects. Also, by not excluding national-level participants, we are able to get more information on the national implications and use, for policy- and decision-making, of the results from these projects.

## Enablers and barriers

Even though the benefits of interoperability, when working with health data, are plentiful, one of the most important interoperability capabilities – receiving, providing and exchanging large amounts of patient data – is often difficult to perform among European cross-border health data exchange initiatives due to diverse data infrastructures (and governance) within the same country and – even more – across national boundaries. European health data infrastructures differ greatly in their characteristics such as content, semantics, quality, update frequency and completeness, legislative and governance rules and obligations.

Our previous work, on the interoperability of patient registries across European countries, prepared us for a situation in which interoperability is largely understood as a technical first and foremost, with certain consideration given to the semantic level as well.[12]

Despite these expectations, the interviewees' comprehension of the concept of interoperability, its components and its importance were quite developed. All levels were almost equally represented in our conversations, with a slight preference toward the legal one, which might have to do with the introduction and implementation efforts around GDPR in recent years. Also, the notion of interconnectedness between levels and layers of interoperability was a common talking point during interviews. Issues of (i) combining multiple data sources and multiple datasets and (i) using minimum data sets were mentioned as two notable examples. It was evident that most respondents understood, how an example of issues with (i) combining multiple data sources and datasets could be due to

- legal obstacles, such as the existence of lack of legislation, on a national or international level allowing such data merger,
- organisational issues, such as lack of human resources or not wanting to "surrender control" of someone's data "silo",
- different semantic standards employed,
- incompatibility of technical solutions used or

a mix of all these reasons in different amounts.
Similarly, an example of (ii) using a minimum data set, rather than a more comprehensive one, could be due to

- legal issues with collecting more detailed data, on an individual patient level for instance,
- organisational issue of organisation prioritising additional data collections in other areas of work,
- semantic issue of not having the common data model for an extended set,
- a technical issue of outdated infrastructure, which cannot accept additional data collection or

a mix of all these reasons in different amounts.

The interviews, presented here, complemented previous quantitative assessments, and served their primary purpose of providing more specific insights into the everyday concerns and practices of data coders, custodians and managers by providing them a chance to articulate their needs and challenges. Further investigation into the specifics of day-to-day operation of cross-border health data exchange, for research or clinical purposes, could certainly be useful in gaining a better understanding of the practical challenges faced by these professionals.

## Limitations and strengths of this work

Our work, based partly on the methodological principles of action research[13], proceeded with asking questions but also raising awareness of the topic of interoperability, its layers and their interconnectedness, at the same time. Also, to our knowledge, this is the first

[12] Valentic M., Plese B, Pristas I,Ivankovic D. Addressing the Data Linking Challenges: Interviewing for Best Practices in Patient Registry Interoperability. Methods of Information in Medicine. 2017; 56: 407-13. 10.3414/ME16-02-0029.
[13] Brian Morrison, Richard Lilford. How can Action Research Apply to Health Services? https://journals.sagepub.com/doi/abs/10.1177/104973201129119235

study of its kind, researching interoperability layers and levels among projects that dealt with health data sharing, linkage and management.

Due to the COVID-19 pandemic, our work on interviewing representatives of the mapped inspirational experiences was cut short of reaching the goal of 20 interviews. Due to the same reason, we have not proceeded with validating and contextualising our finding through a Nominal Group Technique or a Delphi process with experts from the InfAct project, as planned.

## Implications for the future sustainable European (infra)structure on health data and information

Interoperability has to be an integral, sustainable and well-represented topic in any future European Research Infrastructure dealing with health information. Such an infrastructure should not only use the products and frameworks of other sectors' work on the topic, but should also aim to be a relevant player in future European work on exploring, defining, advancing and implementing interoperability.

WP10 work is an important step towards understanding and promoting the importance of a comprehensive approach to considering and applying the concept of interoperability as well as its four indivisible levels: legal, organisational, semantic and technical. Besides the personal and institutional capacity building role, by the end of its mandate, WP10 plans to produce a series of assessment and piloting deliverables that will be used as a practical tool for professionals in Europe and beyond working with data sharing, linking and management across borders.

## Acknowledgements

This work would not have been possible without the valuable collaboration and inputs from colleagues and friends around Europe responding to our survey and interview requests. End of our interviewing work overlapped with the beginning of the COVID-19 pandemic in Europe and we are especially grateful to everyone that took the time and effort to help with this work. Thank you and stay safe!

We would also like to thank our Spanish colleagues from the Instituto de Salud Carlos III and InfAct's Work Package 4 for their valuable internal review of this deliverable during the times of an unprecedented health and societal crisis. Gracias!

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# Appendix 1: Mapping exercise questionnaire

**Invitation letter (e-mail)**

Subject: *InfAct Joint Action – Work Package 10 short questionnaire*

*Dear Madam or Sir,*
*we are contacting you on behalf of InfAct (Information for Action!) Joint Action Work Package 10.*

*You are receiving this invitation because we have recognised you as an important and an insightful member of the European public health information community.*
*We kindly ask you to help us identify inspirational examples (projects, initiatives and networks) that have linked, shared and managed public health surveillance or research data across countries.*

*Information collected here will help us get an overview of the European health information interoperability landscape and incorporate these findings into the future sustainable European research infrastructure on health information.*

*Filling out this questionnaire is anonymous and will take no more than 2-3 minutes of your time.*

*Survey link: http://survey.hzjz.hr/limesurvey/index.php?r=survey/index&sid=825811*

*Please, feel free to share this email or the survey link to other colleagues that you think might be able to contribute.*

*We thank you in advance!*

*Best regards,*
*Croatian Institute of Public Health InfAct Work Package 10 Research Team*

**Online questionnaire (browser based)**

*Introduction page*

*InfAct Joint Action work package 10 task 10.1 short survey*

*What is InfAct?*

*InfAct (Information for Action!), the Joint Action on Health Information, is a 3-year project funded by the European Commission involving 40 partners in 28 European countries. It builds on the BRIDGE Health project and other initiatives in the area of health information.*

*By country collaboration through 10 work packages, InfAct aims to streamline health information activities across Europe. It builds towards a sustainable and solid infrastructure on EU health information and strengthens its core elements based on capacity building, health information tools and political support.*

*Read more about InfAct at https://www.inf-act.eu*

*What is this very short survey about?*

*There is a need for a holistic European model and data infrastructure to translate data, information and knowledge into support for policy making. Based on the building blocks of the European Interoperability Framework (EIF) and inspired by the EIF for e-Health, InfAct WP10 aims to map, structure and pilot interoperability levels as a support for policy making using services based on data linkage, sharing and management, and knowledge development.*

*We are looking for your insights on (the existence of) inspirational examples (projects, initiatives and networks) around Europe (and beyond) that have linked, shared and managed public health surveillance or research data across countries.*

*Filling out this survey will take no more than 2-3 minutes, per inspirational example.*

*Of course, we will appreciate if you decide to share more than one example with us.*

*Basic information page*

*Think about, but don't be limited to, best examples that you know of, according to (some of) the following criteria:*

- *addresses the study of health status, health determinants, and/or health systems performance;*
- *provides insight on surveillance and/or impact or effectiveness research;*
- *includes a variety of data sources (e.g., patient registries, population-based registries, surveys, electronic health or medical records, administrative data, etc.) from different countries;*
- *addresses data linkage, sharing, and management (quality assurance) activities and*
- *produces outcomes reported to public health stakeholders, particularly policy-makers*

*Q1*
*What is the name of the inspirational example?*

*Q2*
*Can you provide us with an email / phone contact of person we could ask more about this inspirational experience? This can, of course, also be you.*

*Q3*
*A website link, if available, would also be nice.*

*Q4*
*What did the project / initiative do (or is still doing) in one or two sentences?*

*Additional information page*

*Q5*

| **The inspirational experience studies or studied:** | Yes | Partially / somewhat | No | I don't know | No answer |
|---|---|---|---|---|---|
| Health status | | | | | |
| Health determinants | | | | | |
| Health system performance | | | | | |

*Q6*

| **This inspirational example provides or provided insights on:** | Yes | Partially / somewhat | No | I don't know | No answer |
|---|---|---|---|---|---|
| Surveillance | | | | | |
| Quality of care and patient experience | | | | | |
| Effectiveness | | | | | |

*Q7*

| **This inspirational example uses or used data sources:** | Yes | Partially / somewhat | No | I don't know | No answer |
|---|---|---|---|---|---|
| Disease-based registries | | | | | |
| Patient-based registries | | | | | |
| Surveys | | | | | |
| EHRs | | | | | |
| Administrative data | | | | | |
| Does this inspirational example use (or used) any other data sources? | If yes, please specify: | | | | |

*Q8*

| **This inspirational example addresses or addressed:** | Yes | Partially / somewhat | No | I don't know | No answer |
|---|---|---|---|---|---|
| Data linkage | | | | | |
| Data sharing | | | | | |
| Data management | | | | | |

*Q9*

| **This inspirational example produces or produced:** | Yes | Partially / somewhat | No | I don't know | No answer |
|---|---|---|---|---|---|
| Policy recommendations | | | | | |

# Appendix 2: Complete list of inspirational experiences

| Inspirational experience | Short description<br>Provided by the respondents or acquired through desk research | |
|---|---|---|
| **B.I.R.O.** | Best Information through Regional Outcomes (2005-8) developed a shared European Diabetes Information System (SEDIS) that produces diabetes health reports generated automatically from a common dataset used by participating regions (Italy, Austria, Scotland, Norway, Romania, Malta and Cyprus). | (2) |
| **BRIDGE** | BRIDGE Health stands for BRidging Information and Data Generation for Evidence-based Health policy and research.<br>The BRIDGE Health project aims to prepare the transition towards a sustainable and integrated EU health information system for both public health and research purposes. | (2) |
| **CCPRB** | Cancer Control using Population-based Registries and Biobanks (2004-2009) facilitating research linking biobanks and cancer registries. | (2) |
| **CEPHOS-LINK** | Making comparisons of re-hospitalisation rates using routine data began in the 1960's, revealing large differences observed between countries. However, the actual reasons behind these differences are not entirely clear. It is important to distinguish how much of the variation in re-hospitalisation rates can be explained by methodological artefacts, and how much is "real" representing actual differences in patient population, health system dynamics and so on.<br>The CEPHOS-LINK project aimed to clarify these discrepancies striving to identify factors related to re-hospitalisations by comparing psychiatric re-hospitalisation rates and identifying their predictors in unselected patient populations from six European countries (Austria, Finland, Italy, Norway, Romania and Slovenia), all with differently organised health care systems. | (1) |
| **COFI** | Comparing policy framework, structure, effectiveness and cost-effectiveness of functional and integrated systems of mental health care assessing mental health policies on organisation of mental health care and evaluate outcomes, costs and patient experience of care in 5 European countries: Belgium, Germany, Italy, Poland and United Kingdom. | (2) |
| **The Commonwealth Fund Multinational Comparisons of Health Systems Data** | In this project, they use data collected by the Organization for Economic Cooperation and Development (OECD) to compare health care systems and performance on a range of topics, including spending, hospitals, physicians, pharmaceuticals, prevention, mortality, quality and safety, and prices. We present data across eleven industrialized countries: Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States. | (1) |
| **CoNARTaS** | The Committee of Nordic Assisted Reproductive Technology and Safety. The Committee of Nordic ART and Safety (CoNARTaS) was established in 2008 by initiative from members of the European IVF Monitoring group in the European Society of Human Reproduction and Embryology (ESHRE). The collaboration includes researchers from the University of Copenhagen (Denmark), University of Helsinki and THL National Institute for Health and Welfare (Finland), Norwegian University of Science and Technology (Norway), Centre for Fertility and Health, Norwegian Institute of Public Health and University of Gothenburg (Sweden). Initially, the main aim is to study the neonatal and infant health of children born after ART as well as the health of the treated women. | (1) |
| **DUQuE** | Deepening our understanding of quality improvement in Europe (2009-2014) was a cross-sectional study, goal: to study the effectiveness of quality improvement systems in European hospitals. | (2) |
| **EARS-Net** | EARS-Net is based on routine clinical antimicrobial susceptibility data from local and clinical laboratories reported to ECDC by appointed representatives from the Member States. | (1) |
| **ECHIM** | European Community Health Indicators and Monitoring (2009-2012) Goal: to develop and implement health indicators and health monitoring in the EU and all EU Member States. Not enough info. | (2) |
| **ECHO** | European Collaboration for Healthcare Optimization - ECHO aimed at building a common knowledge infrastructure, based on existing datasets, which ultimately allowed international healthcare performance | (1) |

| | | |
|---|---|---|
| | comparisons. ECHO set about the task of bringing together patient-level data from Denmark, England, Portugal, Slovenia and Spain, as well as, contextual information -demographic, socioeconomic, and healthcare supply data. This knowledge infrastructure allows the evaluation of more than 40 performance indicators, carefully developed to avoid inappropriate cross-country comparisons. The ECHO knowledge infrastructure allows the study of several performance dimensions (equity, effectiveness, safety and efficiency) at international, national, regional, and even provider level. | |
| **European Health Data and Evidence Network** | Federated data ecosystem in Europe using OMOP common data model. | (1) |
| **European Health Information Gateway - WHO Europe** | The European Health Information Initiative is a WHO network, which develops the European Health Information Gateway, works in six strategic areas, one of which is improving access to and disseminating health information. Other strategic work areas are a) gathering and analysing data that deepen the understanding of health and well-being, with a focus on indicators; b) building capacity; c) strengthening health information networks; d) supporting the development of health information strategies; and e) communication and advocacy. | (1) |
| **JA EHLEIS** | 2011-2014 Goal: contribute to the first partnership of Innovation Union, which focuses on active and healthy ageing and with the target of increasing by 2 years the average number of healthy life years by 2020. It aims to provide a central facility for the coordinated analysis and synthesis of life and health expectancies to add the quality dimension to the quantity of life lived by the European populations | (2) |
| **Extracorporeal life support association** | An international register; developed a specific dataset in order to help NICE in its assessment of ECMO https://www.nice.org.uk/guidance/ipg391/documents/extracorporeal-membrane-oxygenation-for-severe-acute-respiratory-failure-in-adults-overview2 | (1) |
| **European Medical Information Framework** | Tackle technical challenges when scaling up real-world health data research. | (1) |
| **EPIC CVD** | Investigate the interplay of genetic, biochemical and lifestyle factors on the risk of coronary heart disease. Use data from an existing large-scale multi-cohort observational study to compare existing risk scores across diverse European populations and develop new scores. | (2) |
| **EPIS System** | The Epidemic Intelligence Information System (EPIS) is a web-based communication platform that allows nominated public health experts to exchange technical information to assess whether current and emerging public health threats have a potential impact in the European Union (EU). | (1) |
| **EUBIROD** | European Best Information through Regional Outcomes in Diabetes (2008-2011), implemented European Diabetes Register through the coordination of existing national/regional frameworks and the systematic use of the BIRO technology. Main product: Diabetes Report (each EUBIROD Diabetes Report is entirely comparable across the whole collaboration). | (2) |
| **The European Injury Data Base (IDB)** | The IDB is an injury surveillance system containing publicly available, standardised, cross-national information on the external causes of injuries treated in emergency departments (EDs) across Europe. The database provides information on non-fatal unintentional injuries such as home injuries, sports and leisure, workplace and road injuries; in addition to intentional injuries resulting from violence and self-harm. It is an invaluable surveillance system, serving as a basis for benchmarking and designing appropriate prevention policies across Europe. | (1) |
| **EUNICE** | European Network for Indicators on Cancer 2006-2009, GOAL: to establish and operate a network, comprising primary data providers (European Cancer registries) and organizations with experience in coordination, collection, quality control, standardization, processing and dissemination of data, to provide with updated and standardized indicators of cancer. | (2) |
| **EUPHORIC** | EU Public Health Outcome Research and Indicators Collection (2004-2008) oriented to policy authorities and policy makers and aimed at building a consortium of participating countries to cooperate on benchmarking the outcomes of selected health performances and exchange information on quality standards, best practice and effectiveness in public health by developing and maintaining EU networks. | (2) |

| | | |
|---|---|---|
| **EUPrimeCare** | 2010-2012, aimed to develop a framework to analyse Primary Care across Europe, to assess and compare Primary Care models in terms of quality and identifying costs and to provide recommendations. | (2) |
| **EuroCARE** | EUROpean Cancer Registry-based study (1978 to 2007) on survival and care of cancer patients aimed to provide an updated description of cancer survival time trends and differences across European countries, to measure cancer prevalence, and to study patterns of care of cancer patients. | (2) |
| **EUROCAT** | EUROCAT is the registry of Congenital Anomalies at JRC ISPRA. Gathers, validates, analyses and disseminates data on Congenital Anomalies and its determinants at country level and regional level in EU Countries. Promotes data use in collaborative research projects. | (1) |
| **EUROCISS** | European Cardiovascular Indicators Surveillance Set (2000-2007). Goal was to develop health indicators and recommendations for monitoring the burden and distribution of cardiovascular disease (CVD). Manual of Operations for the implementation of population-based registers of acute myocardial infarction/acute coronary syndrome, stroke and of CVD surveys was the main result. | (2) |
| **EuroDRG** | EuroDRG (Diagnosis-Related Groups in Europe - Towards Efficiency and Quality) analysed the national DRG-based hospital payment systems by using qualitative and quantitative research methods. Beyond the project, the EuroDRG team still collaborates in ongoing research and upcoming publications. In addition to the countries mentioned above, Denmark, Hungary and Italy were analysed within the HealthBASKET project which was the forerunner of the EuroDRG collaboration. | (2) |
| **EurHOBOP** | EurHOBOP, the European Hospital Benchmarking by Outcomes in Acute Coronary Syndrome Processes, was a three-year study initiated in 2009 with the aim to provide European hospitals with a validated set of statistical functions - including determinants of in-hospital case fatality outcome indicator - to benchmark themselves about the quality of management of myocardial infarction (MI) or unstable angina (UA) patients and treatments aimed at removing coronary artery occlusion. | (2) |
| **EuroHOPE** | European Health Care Outcomes, Performance and Efficiency.<br>EuroHOPE - European Health Care Outcomes, Performance and Efficiency - evaluates the performance of European health care systems in terms of outcomes, quality, use of resources and costs. The project focuses on five important disease groups: acute myocardial infarction (AMI), ischemic stroke, hip fracture, breast cancer and very low birth weight and very preterm infants (VLBWI). | (1) |
| **Euro-Peristat** | Better Statistics for Better Health for Mothers and their Newborns in Europe.<br>We use routine data to evaluate maternal and newborn health in Europe. We have just published a report on births in 2015 which is available on our website. We also use these data to produce peer reviewed scientific articles and make our data available to other researchers who also have used it for scientific publications. >60 publication have been based on Euro-Peristat data. | (1) |
| **EuroREACH** | Improved access to health care data through cross-country comparisons.<br>Health Data Navigator EuroREACH aims to ensure comparability and harmonization of health data for cross-country research.<br>The project will also provide a toolbox of guidance to researchers, policymakers and other stakeholders interested in cross-country research by: Identifying information sources of patient-level, disease-based data; b) Offering guidance on key data challenges such as data access, linkage and comparability; c) Highlighting gaps in existing data to encourage data collection in underrepresented areas. | (1) |
| **EUROTHINE** | Tackling Health Inequalities in Europe (2004-2007) aimed to improve the description of health inequalities in Europe and to enhance the evidence-base for policies to reduce inequalities in health. | (2) |
| **EURO-URHIS 2** | European Urban Health Indicators System Part 2 (2006-2008) looking at health issues for people living in urban areas to allow for the better planning of health services and initiatives, goal to develop, test and validate a set of comparable urban health indicators | (2) |
| **EWRS (Early warning and response surveillance)** | The Early Warning and Response System of the European Union is a tool with restricted access for monitoring public health threats in the EU. Access and posting are confidential and only accessed by ECDC, the Member States and the Directorate General Health and Food Safety (SANTE). | (1) |

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| **FAMHEALTH** | Family life courses, intergenerational exchanges and later life health. The overall aim of this research programme is to uncover how family life courses influence health and well-being in later adulthood, whether family related strengths or disadvantages relevant to health offset or compound socio-economic sources of disadvantage, and the extent to which these associations are influenced by societal factors. | (2) |
| **GA2LEN** | the Global Allergy and Asthma European Network (2004-2010) most widespread international network in allergy and asthma research. Project meetings still going on. | (2) |
| **HAEMACARE** | Cancer Registry Based project on Haematologic Malignancies (2005-2008). Goal was to reach a consensus for classifying the existing morphology codes (of haematological tumours) into disease groups that were as similar as possible to those used in clinical studies, and compatible with WHO classifications. | (2) |
| **HCAI** | Antimicrobial resistance and healthcare-associated infections (AMR/HCAI); ECDC. | (1) |
| **HealthBASKET** | Health Benefits and Service costs in Europe. The project developed and tested an innovative approach of cost analysis at the micro-level that allow for international comparisons. | (2) |
| **I2SARE** | Health Inequalities Indicators in the Regions of Europe. Goal: to produce a health profile for each region of the European Union, to create a typology of those regions of Europe and a typology of sub regional territories in a selection of countries and regions. It uses 37 selected indicators covering different aspects of health (mortality, morbidity, socio-economic determinants, health risk factors, health care resources, etc). Health profiles enable both the assessment of population health within an area and comparison with others. | (2) |
| **International Cancer Benchmarking Partnership** | ICBP research is trying to unpick the reasons for existing international cancer survival variation. The project has demonstrated differences in survival between countries and has suggested some possible causes of these differences, as well as ruling out some possible causes. | (1) |
| **GBD** | The Global Burden of Disease (2007-2010) complete systematic assessment of global data on all diseases and injuries. | (2) |
| **INEQ-CITIES** | Socio-economic inequalities in health and mortality in 16 European cities at the beginning of the 21st century. The central aim of INEQ-CITIES was to identify socio-economic inequalities in health and mortality in Europe and to examine urban health policies developed to tackle such inequalities in health. To achieve these aims, a methodological approach was applied to study cross-sectional ecological mortality data from 16 European cities. | (1) |
| **INTEGRIS Integration of European Injury Statistics** | The overall goal is to develop and evaluate a data model for the integration of routine and more detailed hospital data on injuries, namely thru linking the official HDR with the EUIDB. | (2) |
| **InterQuality** | International Research Project on Financing Quality in Healthcare (2010-2013) established to investigate the effect of different financing methods and incentives on quality, effectiveness and equity of access to health care in four patient groups affected by: pharmaceutical care, hospital care, outpatient care and integrated care. | (2) |
| **MANAGED OUTCOMES** | Operations management and demand-based approaches to healthcare outcomes and cost-benefits research (2010-2012) Goal: development and dissemination of theoretically rich but practical conceptual models and a toolkit of the healthcare service production system. | (2) |
| **MasterMind** | Summative evaluation of large-scale implementation and upscaling of Internet interventions for common mental disorders in 15 regions in Europe using a standardised evaluation framework based on the MAST model. | (1) |
| **MONICA** | Multinational MONItoring of Trends and Determinants in CArdiovascular Disease. established in the early 1980s in many Centres around the world to monitor trends in cardiovascular diseases and to relate these to risk factor changes in the population over a ten year period. It was set up to explain the diverse trends in cardiovascular disease mortality which were observed from the 1970s onwards. | (2) |
| **Multiple Sclerosis Data Alliance** | Tackle sociological as well as technical challenges when scaling up real-world health data research in the field of multiple sclerosis. | (1) |
| **Nordic Welfare dataBASE (NOWBASE) - NOMESCO** | NOWBASE is tasked with: working to ensure that health and social statistics in the Nordic Countries is comparable between countries; gathering statistics | (1) |

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| | within this field (health and welfare) and presenting these statistics and making them widely available. | |
| **OECD work on health care quality through the Working party on Health Care Quality and Outcomes.** | Collects data from OECD member countries related to quality of health care. Data collection methodologies are aligned as much as possible in order to get internationally comparable data. It compiles and develops country-level statistics on many health care quality and outcomes indicators. Additionally, it compiles statistics on various other dimensions related to Health expenditure and financing, Health Status, Non-Medical Determinants of Health, Health Care Resources, Health Workforce Migration, Health Care Utilisation, Health Care Quality Indicators, Pharmaceutical Market Long-Term Care Resources and Utilisation, and Social Protection. | (1) |
| **Observational Health Data Sciences and Informatics (OHDSI)** | This project aims at improving health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care. Promoting observational research to produce a comprehensive understanding of health and disease and configuring and supporting a comprehensive international multipurpose common data model enabling the design and implementation of multinational observational studies based on EHRs and administrative health data at a broader scale; also, by facilitating software tools materialising new methodological approaches on observational research. This project is responsible for the development and support of the OMOP Common Data Model and a multipurpose Common Evidence Model for Health and Healthcare Science. | (1) |
| **ONCOPOOL** | Pooling of European Data to Harmonize Translational Research in Breast Cancer (2002-2005) retrospectively compiled database of primary operable invasive breast cancers treated in the 1990s in 10 European breast cancer units. Scarce info. | (2) |
| **PRECeDI** | Personalized PREvention of Chronic DIseases consortium. The aim of the PRECeDI consortium is to promote knowledge transfer between academic and non-academic entities that can lead to a proper integration of -omics information into public health interventions. The main goal of this platform is to cover an existing gap in the evidence-base use of the -omics approach in the prevention of chronic diseases, by sharing knowledge, building synergies and expertise and encouraging an exchange of best practice among top level institutions. In the long run, the results of the consortium activities will enhance the scientific basis for an appropriate implementation of the -omics applications into true benefits for population health. | (1) |
| **QUALICOPC** | Quality and Costs of Primary Care in Europe (2010-2013) evaluated primary care systems in Europe against criteria of quality, equity and costs, aimed to answer which elements of structure and organization of primary care are associated with access to high quality services against affordable costs and also by what mechanisms primary care structure and organisation are related to overall health care system goals. | (2) |
| **RARECARE** | RARECARE, Surveillance of rare cancers in Europe (2007-2010), was intended to help define indicators, collect and analyse data on rare cancers on a sustainable, long-term basis. | (2) |
| **RECAP** | Research on Children and Adults Born Preterm. Attempt to combine data from 1) follow-up studies of children and adults born very preterm (<32 weeks) or at very low birth weight (<1500 g); 2) Nordic registry data on studies following up the health and well-being in children and adults born preterm in Nordic populations. | (1) |
| **The Study of Health, Ageing and Retirement in Europe** | Both studies gather data about ageing and various socio-demographic, economic and health related variables. | (1) |
| **TESSY** | The European Surveillance System (TESSy) is a highly flexible metadata-driven system for collection, validation, cleaning, analysis and dissemination of data. Its key aims are data analysis and production of outputs for public health action. All European Union Member States (28) and EEA countries (3) report their available data on communicable diseases (49) as described in Decision No 2119/98/EC to the system. | (1) |

- Source: (1) InfAct T10.1 Survey; (2) Desk research

# Appendix 3: Invitation letter and a draft interview instrument

***Invitation letter***

Dear [Piloting subject name],

we are contacting you on behalf of InfAct Joint Action project and its work package 10 (hereinafter referred to as WP10).

We believe that your previous work on the [Project name] project links to our current work on cross-border health data sharing, linking and management, as well as interoperability within WP10.

Before explaining why, we decided to get in touch and how we propose to collaborate, we will briefly introduce the InfAct Joint Action and WP10 work.

What is InfAct?

InfAct (Information for Action!), the Joint Action on Health Information, is a 3-year project funded by the European Commission involving 40 partners in 28 European countries. It builds on the BRIDGE Health project and other initiatives in the area of health information.

By country collaboration through 10 work packages, InfAct aims to streamline health information activities across Europe. It builds towards a sustainable and solid infrastructure on EU health information and strengthens its core elements based on capacity building, health information tools and political support.

Read more about InfAct at https://www.inf-act.eu

What does WP10 do?

Title of this work package is: "Assessing and piloting interoperability for public health policy". WP10 work is motivated by the need to establish a holistic European model and data infrastructure able to translate data, information and knowledge into support for policymaking using services based on data linkage, data sharing, data management and knowledge development.

This might sound complicated but we are basically set to:

1/ Understand enablers and barriers to the cross-border linkage and sharing of health data using four interoperability layers (legal, organisational, semantic and technical). We plan to do so by conducting an in-depth analysis of a number of projects that worked with cross-border data sharing, linkage and management in Europe (and beyond).

2/ Empirically test novel approaches to link, share and manage health data between countries in Europe (and beyond). We plan to do so by conducting a series of pilot studies within the InfAct project.

You can read more details on the WP10 work on InfAct's website: https://www.inf-act.eu/wp10

What is interoperability?

Interoperability is the ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their information and communication technology (ICT) systems.

An essential starting point in InfAct Joint Action WP10 work are the interoperability layers: legal, organisational, semantic and technical; a cross-cutting component of the four layers which is integrated public service governance, and a background layer of interoperability governance.

Why did we decide to contact you and how can we work together?

We recognized the [Project name] project as an inspirational example satisfying the criteria of our InfAct WP10 work.

In the next step, we would like to:

1/ Learn more about the [Project name] project from people that actively participate(d) in project's work.

2/ Make an in-depth analysis of how [Project name] project tackled issues related to data sharing, linkage and management.

3/ Compare your project / initiative with other projects that deal(t) with cross-border health data work.

4/ Learn what were / are the enablers and barriers in achieving the goals of your project.

Practically, this means that we would like to hear back from you and organise a 45-minute semi-structured interview session to discuss some of these issues.

For more details on the structure of your reply and interview questions, please have a look at the Appendix / Reply form of this invitation letter. The attached interview questions are just for your information at this moment. We will go through the questions together during the interview.

We sincerely hope that you will find our work interesting and relevant, and decide to get back to us.

Looking forward to your reply.

Kind regards,

Work Package 10 Research Teams from the Croatian Institute of Public Health and the Aragon Health Sciences Institute

***Anex***

We wholeheartedly hope you will agree to participate in our research.

First, we would ask you to fill out the "project profile" table attached below.

"Project profile" framework

In order to get a basic understanding of the [Project name] project, we would like to discuss with you the "project profile" table with information on project's scope, data sources used and products.

1. The project addresses the study of health status, health determinants, and/or health systems performance;

2. The project provides insight on surveillance and/or impact or effectiveness research;

3. The project includes a variety of data sources (e.g., patient registries, population-based registries, surveys, electronic health or medical records, administrative data, etc.) from different countries;

4. The project addresses data linkage, sharing, and management (quality assurance) activities;

5. The project produces outcomes reported to public health stakeholders, particularly policy-makers.

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| Inspirational example: | **EuroPeriStat** | | | | | | |
| Studies: | Health status | | | Health determinants | | Health system performance | |
| Provides insight on: | Surveilance | | | Impact | | Effectiveness | |
| Includes data sources: | Disease-based registries | Population-based registries | Surveys | EHRs | Administrative data | Other: N/A | |
| Addresses: | Data linkage | | | Data sharing | | Data management | |
| Produces: | Policy recommendations | | | | | | |
| Link: | http://www.europeristat.com/ | | | | | | |

Figure: "Project profile" mapping; example of EuroPeriStat - "Better Statistics for Better Health for Mothers and their Newborns in Europe"; kindly provided by Jennifer Zeitlin; InfAct green cells represent completely fulfilling the criteria, while the orange ones represent partially doing so.

Secondly, we would like to set up a 45-minute semi-structured interview to discuss how [Project name] project tackled issues related to cross-border data sharing, linkage and management. The interview will be recorded and transcript will be made.

The transcript will be analysed and general ideas you provide will be included in the final work package report. The pre-final report can be sent to you for review. Please note the report will be publicly disseminated.

Semi-structured interview; *examples of questions*

1/ Please introduce your project in your own words (history, topic, scope, partners, outcomes…).

2/ Is your project still ongoing?

3/ Did your project evolve from JA to a permanent structure? If it did, please describe how this happened?

4/ What kind of health data did the [Project name] project work with?

5/ Was this a one-time (ad hoc?) data exchange effort or it continued? Please, elaborate.

The following set of questions will be about cross-border data exchange and interoperability.

6/ Questions on legal interoperability

Did you have to obtain (legal) approval for data collection, sharing and/or linkage? What about data request protocols?

Did you have to follow any specific laws or rules in order to use obtained data?

Would you say that current laws and rules (or at the time) obstructed or facilitated your work with data exchange? Can you provide an example?

Considering the trends in data privacy and management legal frameworks, do you feel it is now easier or more challenging than before to exchange share, link and manage health data across borders in Europe?

Any other comments or experiences that you would like to share on the topic of legal interoperability?

7/ Questions on organisational interoperability

In order to share, connect and manipulate data, did you have to create new business processes or adjust the old processes related to data?

Were there any agreements or memorandums (such as Memorandum of Understanding or Service Level Agreement) which defined organisational relationships?

Any other comments or experiences that you would like to share on the topic of organisational interoperability?

8/ Questions on semantical interoperability

How did you decide / agree on the definitions you will use (e.g. how did you decide how you define myocardial infarction or cardiovascular incidents)?

Did you use International Statistical Classification of Diseases and Related Health Problems (ICD) or some other disease classification, if applicable?

Was the existence of health data standards a barrier or a facilitator of data exchange?

Any other comments or experiences that you would like to share on the topic of semantical interoperability?

9/ Questions on technical interoperability

Was the technical part of linking / sharing data hard or easy? (Some examples of technical layer of interoperability: reports specification, use of specific databases…)

Any other comments or experiences that you would like to share on the topic of technical interoperability?

Was the technical part enabler or barrier for your project?

Please shortly describe how do you perform data exchange, and which protocols / technical solutions were you using?

Do you, in your knowledge, use any internationally recognized data exchange standards? If yes, please indicate which.

Additional questions

10/ Please describe which procedure/protocol for submitting data sharing requests, access to data was needed. If you have any legal, technical documents or procedures, please send us (the names of the respective legislations and perhaps a concise description of pertinent content).

11/ Talking of legal, organisational, semantic and technical issues of data exchange / sharing, what was the hardest part of the project? Were there any surprises, things you had thought would be easy, but in the end were hard?

12/ Talking of legal, organisational, semantic and technical issues of data exchange / sharing, what was the easiest part of the project? Were there any surprises, things you had thought would be hard, but in the end were easy?

13/ How did you deal with data security and integrity?

14/ Any other comments you would like to make or topics you would like to address?