INFACT
Joint Action on Health Information

Interim report on a mapping exercise: legal, organisational, semantic and technical interoperability

Interview instrument development and testing

Work package 10: Assessing and piloting interoperability for public health policy
Tasks 10.2 and T10.3: Interim milestone reports; MS36 / MS37

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Executive summary

This milestone interim report is the second output of the InfAct Joint Action's Work Package 10 (WP10) research on "assessing and piloting interoperability for public health policy".

First report was delivered in February 2019 and presented results of work on task one (T10.1) mapping exercise in identifying inspirational experiences, initiatives and project in cross-border sharing, linkage and management of health data. We developed and validated a conceptual and analytical framework of cross-border health data sharing, linkage and management initiatives to be used both as an inclusion criteria checklist, as well as an analytical tool. Through online stakeholder surveying, supplemented by desk research, we collected over a hundred inspirational experiences in health data use and included a total of 59 in further analysis.

This milestone document is an interim report on the progress of work within tasks two and three (T10.2 and T10.3) of the WP10. In order to proceed with an in-depth analysis of the recognised inspirational experiences, **we developed and tested a tool to be used for interviewing public health data professionals** involved with these projects and initiatives. This exercise will be conducted in the following 12 months, between September 2019 and August 2020.

Respondents found the interview instrument, as well as the interviewing methodology, appropriate and the interview questions very relevant. Additionally, despite this not being our primary goal in this stage of work, patterns regarding the enablers and barriers in exchanging health data across (European) borders started to emerge. Important topics, such as data quality and project funding, were suggested as potential additional discussion topics for the next interviewing stage. Testing the interview instrument also made us aware of the importance of having to capture experiences of professionals involved in these projects on different levels - from national "data providers" to "top level" project coordinators - in order to get a complete picture of issues tackled and the impact of these initiatives on national public health policies.

We are convinced that InfAct's and WP10's work is an important step towards understanding and promoting the importance of a comprehensive approach to the concept of interoperability, which has to be an integral, sustainable and well-represented topic in the future research infrastructure dealing with health information at a European level.

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

CROATIAN INSTITUTE
OF PUBLIC HEALTH

and the
Aragon Health Sciences Institute

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Interview instrument – design and testing

I. Introduction

InfAct and the Work of the Package Ten (WP10)

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 into four tasks focused on two streams of 1) mapping (tasks 10.1, 10.2 and 10.3) and 2) piloting (task 10.4) best practices in data linkage, sharing and management.

WP10 results are (and will be) reported through a number of milestone reports (MS35 and MS36/37), two major WP deliverables (D10.1 and D10.2) and a series of case studies to be piloted (MS38).

Interoperability: frameworks, layers and our previous work related to it

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. We also included 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.

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[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

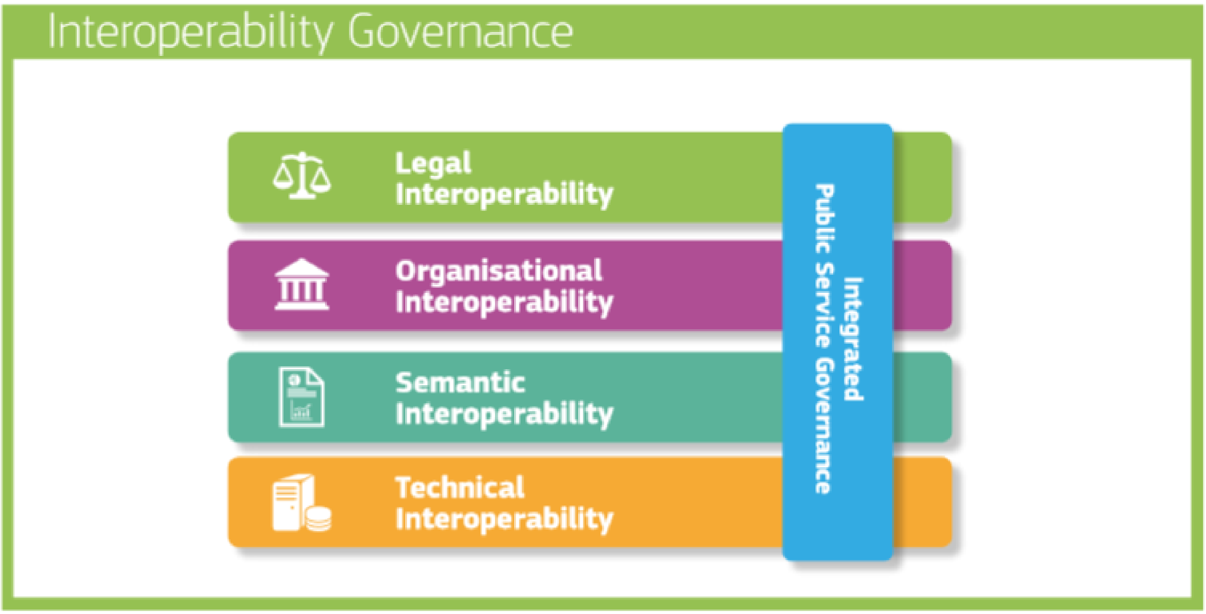

Figure 1: Interoperability model and layers[4]

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. Idea of integrating this work package within the InfAct Joint Action, which will conceptualise the model and the business case for such an infrastructure, is to prevent this focus on solely technical and semantic aspects from happening.

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]

InfAct, WP10 and interoperability

Our aim, within InfAct and WP10, 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

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[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.

purpose, WP10 is developing upon the building blocks defined in the EIF, while also getting inspiration from the EIF for e-Health[6].

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.

<u>Second (interim) report, work so far and work to come</u>

This interim report presents a short recapitulation on the work done in the first task of WP10 (T10.1) and an update on the work done within tasks two and three (T10.2 and T10.3). Progress on this work mostly consisted of the development and testing of the interview instrument to be used for the continuation of T10.2 and T10.3 work.

After conducting a mapping exercise, as part of the WP10's first task (T10.1), with the ambition to identify inspirational experience in data linkage, sharing and management, we proceeded with developing an interview instrument to be used for a series of semi-structured in-depth interviews. In the following 12 months, tested and finalised interview instrument will be used to conduct a series of interviews with representatives of a selected sample of project and initiatives mapped within task one of this WP. This effort will result with WP10's deliverable D10.1: "Interoperability in Europe: LOST and found".

In task one, we 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 also 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.

Work on tasks two and three of the WP10 work is now 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 update presented here acts as a preparatory activity for conducting a series of in-depth surveys, interviews and focus groups in the next 12 months. The goal is to identify and present, 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.

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

The specific objective of the work within tasks two (T10.2) "Mapping exercise: legal and organisational interoperability" and task three (T10.3) "Mapping exercise: semantic and technical interoperability", presented in this interim report, was to develop and test an interview instrument that will be used in the continuation of the work on these two tasks in the following 12 months (September 2019 – August 2020).

II. Methods

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

III. Results

Interview instrument development

Interview instrument, developed and tested, is available in Annex 1 of this report. Interview questions are also presented in the Annex 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.

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

Table 1: Piloting subjects and details

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 2 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 2: Hierarchy chart representation of topic references per code / category

Figure 3 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.

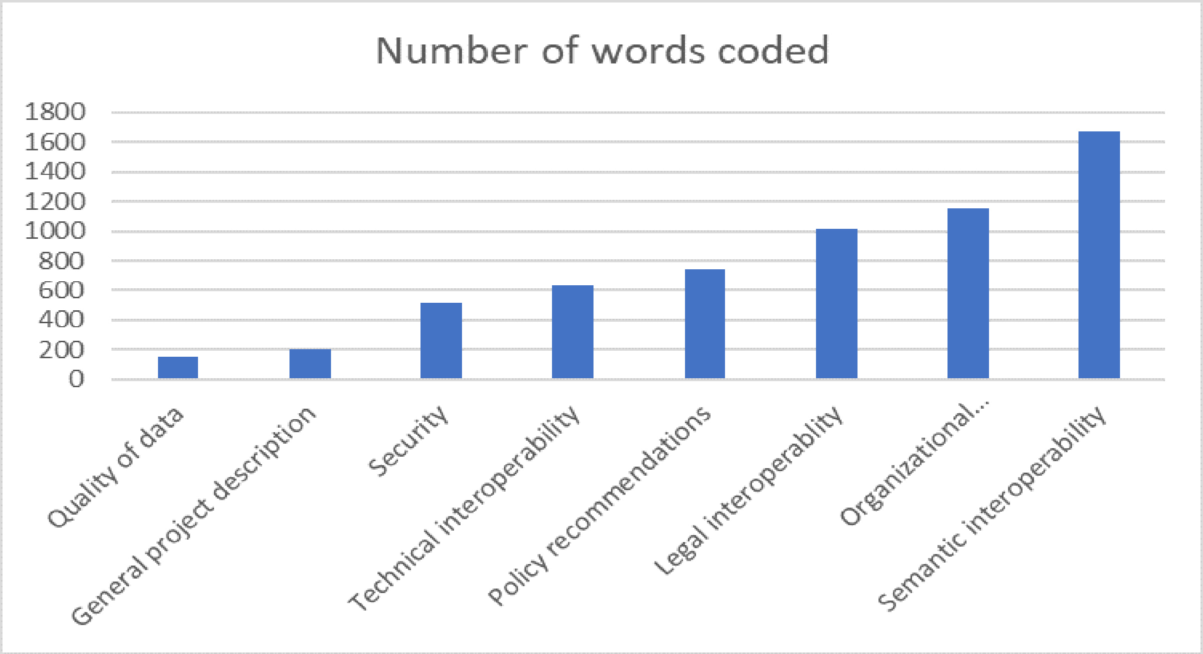

Figure 3: Number of words per category

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 4 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.

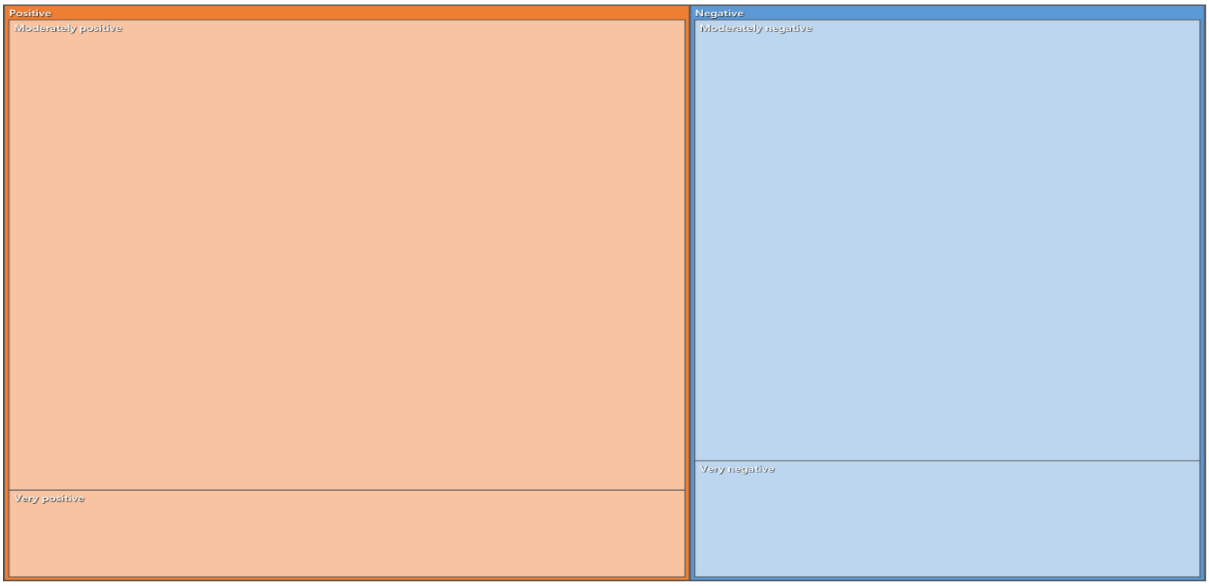

Figure 4: Share of references made to enablers and barriers

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:	Barriers:
• some projects collect what already exists, aggregated data and do not have legal issues • having legal requirements for reporting because it forces countries to adjust their systems	• no clear distinction between pseudonymized and anonymized data • vague definition of anonymized data • some countries are not able to share internationally data that are not aggregated even though they are not re-identifiable • perceived impossibility of working with anything resembling patient level data because of GDPR • legal obligations can be constraint to accept second best solution because people don’t want to promise to give certain types of data • Brexit • laws on certain procedures are not harmonized
Organizational interoperability	
Enablers:	Barriers:
• giving flexibility to each country to organise their own team • not being legally binding to participate, having a network of people interested in the subject • doing research, publishing results, and allowing people to participate on those levels motivates them to push things in their own countries • each member chooses the best source of information that they have in their county	• 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. • some services are provided in different area of specialized and primary care in different countries
Technical interoperability	
Enablers:	Barriers:
• federated database system • existence of unique identifier • dataset templates • standards • protocols	• lack of unique identifier • lack of resources
Semantic interoperability	
Enablers:	Barriers:

international standards and recommendations existence of specialised code books using existing definitions for each indicator having data calls with clearly defined dataset, coding scheme and inclusion criteria having limited number of indicators	lack of recommendations and standards in certain areas, “grey zones” clash of different recommendations
Policy recommendations	
Enablers:	Barriers
having platform for result dissemination publishing in scientific journals	no way of measuring impact depends on the advocacy of people in certain country

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

Interview instrument analysis

Here 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, operational, 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 “operational” 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.

Discussion on implications for further WP10 work, future sustainable structure on health information and EU Member States

This interim report presents the progress of our work on tasks two (T10.2) and three (T10.3) of the InfAct Joint Action WP10 in assessing and piloting interoperability for public health policy, which includes in-depth analysis of inspirational experiences in cross-border sharing, linkage and management of health data.

Building on the approaches demonstrated by the inspirational examples tackling interoperability issues, we aim to characterise the panoply of solutions applied to overcome legal, organizational, technical and semantic barriers while addressing comparisons across countries. A summarised schematic representation of the double-stream WP10 work is visible below in the Figure 5.

In parallel, the task four (T10.4) will benefit 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.

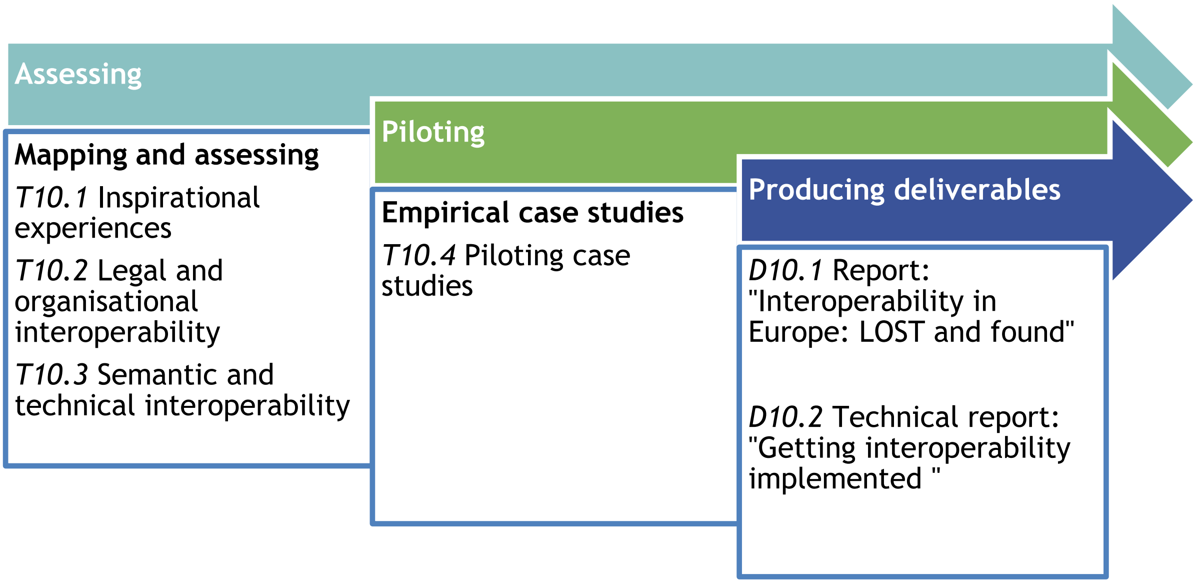

Figure 5: Work Package 10 tasks and deliverables summarised

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.

Piloting the interview instrument, also allowed us to test methods of qualitative analysis of the interview content itself and approach preliminary coding. We do expect that codes will change somewhat as we conduct more interviews, but the core categorisation will remain the same as our main focus are categories (main themes) that represent the four layers of interoperability and policy recommendations with some attention paid to security and quality of data.

A very important take away, for further work on these tasks, is to keep a "mixed profile" of invitees, both top-level project coordinators as well as national-level partners in order to be able to get a good idea of the 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.

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, operational, 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 cooperation and inputs from colleagues participating in the piloting the interview instrument. Thank you, Jennifer, Hakon and Mario. ✱

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Appendix 1: 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 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

Appendix

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.

<u>“Project profile” framework</u>

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.

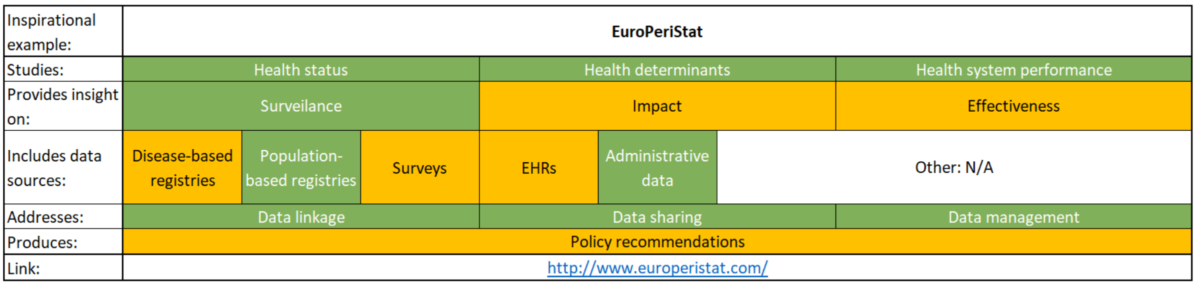
1. The project addresses the study of health status, health determinants, and/or health systems performance;

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.



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 organizational 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 organizational relationships?

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