



eHAction

Joint Action supporting
the eHealth Network

D7.2 Report on best practices and approaches on data protection at national level

Draft

WP 7 Overcoming implementation challenges

Revision 0.3.1, 27-03-2019

15th eHN meeting, June 2019

For Information

Grant Agreement n° 801558



Co-funded by the European
Union's Health Programme
(2014-2020)

Abstract:

Work package 7 is intended to provide the eHealth Network with valuable practical recommendations, guidelines and priorities on three of the most critical issues concerning the eHealth European ecosystem: interoperability, data protection and data and systems security. Also, WP7 will employ stakeholders in order to collect information through questionnaires and organize – under the supervision of WP2 - workshops disseminating its results.

CONTROL PAGE OF DOCUMENT	
Document name	D7.2 Report on best practices and approaches on data protection at national level
Work Package	WP 7 Overcoming implementation challenges
Dissemination level	CO
Status	Draft
Author(s)	Jiri Borej Milan Cabrnoc Jakub Tomas Tomas Bezouska
Beneficiary(ies)	Ministry of Health of the Czech Republic

Dissemination level:

PU = Public, for wide dissemination (public deliverables shall be of a professional standard in a form suitable for print or electronic publication) or CO = Confidential, limited to project participants and European Commission.

REVISION HISTORY				
Revision	Date	Author	Organisation	Description
0.1	21-09-2018	Tomas Bezouska	MZCR	Outline of the document
0.1.1	23-09-2018	Milan Cabrnoc	MZCR	Revision of the first draft of the document
0.1.2	24-09-2018	Tomas Bezouska	MZCR	Revision of the first draft of the document
0.2	04-03-2019	Tomas Bezouska	MZCR	Update of the document based on current progress of the project
0.3	21-03-2019	Vivian Brincat, Hugo Agius Muscat	MFH	QM review
0.3.1	27-03-2019	Tomas Bezouska	MZCR	QM revisions settlement

Ref. n.	Document
	eHAction Grant Agreement n. 801558
	Annex I – eHealth Action Proposal
	eHAction Consortium Agreement
	MWP 2018-2021

Table of Contents

Table of Contents	3
Acronyms.....	4
List of Figures.....	5
1. Executive Summary.....	6
2. Introduction	8
2.1. Cooperation with Public Interest Groups.....	8
3. Methods and Means.....	9
3.1. Short overview of Personal Data Protection	9
3.2. Guiding Principles and Methods Used	9
3.3. Survey – Best Practice data collection.....	10
3.3.1. Areas of interest	10
3.3.2. The Questionnaire version A	10
3.3.3. The Questionnaire version B	17
3.3.4. Survey Respondents.....	23
3.3.5. Analysis of Survey Data	23
4. Best practices and approaches on data protection.....	24
5. References	25
6. Conclusions	27
7. Bibliography.....	28
8. Appendix I	29

Acronyms

Acronym	Description
EC	European Commission
eHN	eHealth Network
EIF	European Interoperability Framework
eP	ePrescription
GDPR	General Data Protection Regulation
ICT	Information and Communication Technology
JAsEHN	Joint Action to support the eHealth Network
MS	Member State
MWP	Multiannual Work Programme
NIS Directive	Network and Information Security Directive
PS	Patient Summary
ReEIF	Refined eHealth European Interoperability Framework
WP	Work Package

List of Figures

No table of figures entries found.

1. Executive Summary

Work Package 7 is about providing the eHealth Network, national and European health authorities, eHealth professionals and IT staff in large healthcare organisations with guidelines and recommendations for implementing interoperable and secure eHealth services at national and cross-border level. Even though too many initiatives have already been raised, there are issues that need to be addressed; this work package aims at tackling challenges on three of the most critical issues concerning the eHealth European ecosystem: interoperability, data protection (General Data Protection Regulation or GDPR) and data and systems security (Network and Information Security Directive, or NIS Directive). This document, as it is a part of Task 7.2, focuses solely on the issues related to personal data protection as covered by the GDPR.

This document aims at introducing the vision, objectives/outputs, operational plan, work methodology, findings, broad context and possible legal issues related to GDPR in the healthcare environment.

Member States are currently facing implementation challenges brought about by new critical EU frameworks and legislation affecting health data and services on the national and cross-border services levels (GDPR, NIS, Patient Summary); Task 7.2 aims at aligning all the above to facilitate implementation and fix any relevant issues, with a specific focus on the GDPR.

Task 7.2 will also serve as a link to all current European Commission (EC) policies, project calls and other initiatives on eHealth, such as “The Rolling Plan on ICT Standardisation” (EC, 2018), the European Electronic Health Record exchange format and the new European Interoperability Framework (EIF).

Task 7.2's findings can be disseminated to national health policy makers and other interested bodies and stakeholders to aid in tackling challenges on implementing data protection principles.

Regarding possible risks, this work package can suffer from a lack of participation in the work done by experts from all MS and affiliated entities. Another challenging factor is the dissemination of the outcomes of this WP7.2.

The next steps are:

- Sharing the outcomes (deliverables) of this work package to all interested parties.
- Evaluation of the implementation of the knowledge gained in this WP.

As part of WP7, Task 7.2 is focused on GDPR implementation and its implications for (not only) cross-border healthcare. The aim of this task is to share best practices and approaches on data protection at national level and to monitor the situation regarding data protection and the new requirements that the GDPR brings to eHealth.

The task is motivated by both the urgent need for correct GDPR adoption in the healthcare sector and the utilisation of GDPR potential for comprehensive respect for human rights in healthcare provision practice in the long term.

In Section 2 the general objectives, vision, scope and objectives of WP7 and its deliverables are presented, stressing the purpose of WP7, its importance and its contribution to the project, as well as the operational plans of each work package task.

Section 3 describes the work methodology, giving emphasis to the cooperation procedures that will be followed between partners. Also, this section will outline the work package outcome evaluation

approaches, as well as the work package results exploitation, impact and outreach.

Section 4 presents the references to the topic of data protection in healthcare. Also, this section briefly presents the relationships between Task 7.2 and the internal and external eHAction environment. Section 4 will focus on the relationship of Task 7.2 with other eHAction tasks and with the external eHAction environment, namely external stakeholders, giving special attention to the potential impact of Task 7.2 results on them.

Finally, section 5 outlines legal issues that might arise which may produce risks on Task 7.2 activities, while section 7 summarises the document conclusions, listing the next steps of Task 7.2.

2. Introduction

As defined in the project documents, Task 7.2 is focused on GDPR implementation and its implications for cross-border healthcare. This document represents the main deliverable of the task. The aim of this document is to share best practices and approaches on data protection at national level, the situation regarding data protection, and the new requirements that GDPR brings to eHealth.

The topic is implemented in 5 steps:

1. Review of the GDPR topic in general and review of its impact on healthcare stakeholders.
2. Characteristics of main points and requirements of GDPR adoption in the healthcare sector.
3. Proposal of the set of relevant recommendations/policies for successful completion of GDPR adoption in the healthcare sector.
4. Sketches of collaborative instruments for related information and education at present and in future dealing with the GDPR topic in healthcare settings.
5. Foresight – vision and mission – of the future fulfilment and development of the GDPR.

The task is motivated by both the urgent need for correct GDPR adoption in the healthcare sector, and the utilisation of GDPR potential for comprehensive respect for human rights for healthcare provision practice in the long term.

2.1. Cooperation with Public Interest Groups

In topics no. 2, 3 and 5, the cooperation with public interest groups (patient and health professionals' organisations) will be actively sought and utilised. The following groups are planned to be contacted:

To be completed in next version of the document.

3. Methods and Means

3.1. Short overview of Personal Data Protection

The area of personal data protection has been regulated on the EU level since October 1995 by the Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data. This Directive drew up some basic rules on personal data protection but most of the regulation was delegated to the national level and left to be solved by national legislation. This resulted in varying approaches towards personal data protection and problems have arisen especially in cross-border data sharing and processing of data in multiple countries.

With growing exchange and transfer of personal data related to the expansion of the digital economy, and increased mobility of both people and services, it became necessary to synchronise the approach to personal data protection among member states and to define a new level of personal data protection in reaction to growing risks of personal data being misused or mishandled.

As a reaction, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (known as General Data Protection Regulation or GDPR) was created and came into effect on 25 May 2018.

This new regulation defines, among other things:

- key principles of personal data protection,
- rights of the data subject,
- controller and processor of personal data and their obligations,
- transfers of personal data to third countries or international organisations,
- independent supervisory authorities.

A two-year period was set for adaptation of national legislation to the new regulation, as well as for its implementation in personal data processing methods and tools of every subject acting as controller or processor.

Since the healthcare industry is one of the most personal-data-heavy industries and personal data processing lies at the core of most tasks handled by all the subjects operating in this field, the implementation of the GDPR's principles and requirements in specific regulations, standards and procedures of the industry was paramount to its successful adoption.

On national level there are huge differences in approach to providing universal healthcare services, both in terms of the financial and organisational levels and in terms of extent and methods of regulation of the industry, which has a tremendous impact on the implementation of the GDPR both in national legislation and in the general practice of personal data processing.

3.2. Guiding Principles and Methods Used

To be completed in next version of the document.

3.3. Survey – Best Practice data collection

3.3.1. Areas of interest

There are several areas of interest covered by the survey; each area is tackled by a series of questions. All areas were defined to cover some key aspects of the GDPR and its implementation at the national level, especially in general legislation and with special focus on healthcare services and its providers.

The following areas of interest were defined:

- Legislation
 - National legislation on personal data protection
 - Legislation implementing GDPR on national level
 - Other relevant Regulations
 - Enforcing GDPR
 - National Legislation on Health Records
- Key impacts of GDPR implementation on Healthcare
 - Lawfulness of Personal Data processing in Healthcare
 - Patient Data, Healthcare Documentation, Electronic Health Records in practical use
 - Access to Patient Data
 - Execution of Rights of the Data Subject
 - Practical impacts of GDPR on Health Records
- Known challenges for implementing GDPR in the Health Sector

3.3.2. The Questionnaire version A

The complete list of questions comprises a body that is to be asked to survey respondents 1 to 4 (see chapter 3.3.4 Survey Respondents).

Survey Question	Comment
Identification and contact details	Basic identification of the survey respondent for the possibility of further clarification of provided responses or follow-up questions if necessary.
E-mail address	Contact information
Full Name	Contact information
Institution / Organisation	Contact information
Type of Institution / Organisation	Some of the questions are specific in relation to the type of the institution for which the answers are collected, identification of the

Survey Question	Comment
	institution/organisation type aims to help with the interpretation of such answers.
Work Phone	Contact information
National Legislation on Personal Data Protection	This section focuses on information regarding national legislation on personal data protection
Was there (in your country) any legislation regarding personal data protection in place prior to GDPR? If so, please provide a short description (up to 1000 characters) and an English translation where possible.	According to Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data, each EU member state was required to have personal data protection law in place, the legislation was of varying nature and extent, the question aims to gather information on the state of personal data protection regulation before GDPR was introduced.
Legislation implementing GDPR on national level	This section focuses on information regarding national legislation on personal data protection
Is there any legislation implementing GDPR in place as of today? If so, when was it passed? Please provide a short description (up to 1000 characters) and an English translation where possible.	GDPR expects member states to implement country-specific legislation addressing particular areas defined within GDPR as well as any other areas national legislation would consider relevant. The question aims to gather information on such legislation.
If not, is it planned to pass such legislation and in what time frame? What is the key reason for the delay?	National legislation is expected to be passed by GDPR itself to adjust particular areas according to the needs of individual member states. The question aims to find out what the time frame is for such legislation to be passed and what the main reasons are if it was not passed during the implementation period of GDPR.
What does / will the legislation regulate within the framework for national regulations defined by GDPR? (which particular areas of personal data protection prescribed for national	This question aims to find out the specific areas regulated by the national legislation.

Survey Question	Comment
regulation by GDPR are addressed, what other areas not defined by GDPR are covered)	
Is there any relevant legislation other than GDPR and its implementing legislation or any generally implemented standards relevant for personal data protection in the healthcare sector in place? If so, please provide a short description (up to 1000 characters) and an English translation where possible.	This question aims to find out the specific areas regulated by other local regulatory frameworks.
Enforcing GDPR	National supervisory authority according to Article 51 of GDPR
Which is the supervisory authority responsible for monitoring the application of personal data protection legislation on the national level?	This question aims at identifying the national supervisory authority as described in Article 51 and the following articles of the GDPR.
Are there so far any experiences or other outcomes of problems / issues / incidents / infringements / penalties regarding the Personal Data Protection legislation and its implementation? If so, please provide a short description (up to 1000 characters) and an English translation where possible.	This question aims to find out whether there are so far any results of the regulatory oversight by the National Supervisory Authority in terms of identified breaches of personal data protection and what were the consequences of the identified misconduct.
National Legislation on Health Records	This section is focused on legislative regulation of health records and patient data
Is there any specific legislation regarding patient data, healthcare documentation, electronic health records, etc.? If so, please provide a short description (up to 1000 characters) and an English translation where possible.	This question aims to find out what legislation applies to handling of patient data.
What are the key provisions of the above-mentioned legislation in terms of data formats and standards of patient data, healthcare documentation, electronic health records, etc.? Please provide a short description (up to 1000 characters)	This question aims to find out specific impacts of legislation related to handling of patient data on formats and standards applicable to this data.

Survey Question	Comment
What are the key provisions of the above-mentioned legislation in terms of handling and use of patient data, healthcare documentation, electronic health records, etc.? Please provide a short description (up to 1000 characters)	This question aims to find out specific impacts of legislation related to handling of patient data.
What are the key provisions of the above-mentioned legislation in terms of exchange and sharing of patient data, healthcare documentation, electronic health records, etc.? Please provide a short description (up to 1000 characters)	This question aims to find out specific impacts of legislation related to sharing and exchange of patient data.
What are the key provisions of the above-mentioned legislation in terms of storage and disposal of patient data, healthcare documentation, electronic health records, etc.? Please provide a short description (up to 1000 characters)	This question aims to find out specific impacts of legislation related to storage and disposal of patient data.
Key impacts of GDPR implementation on Healthcare Please provide a short description (up to 1000 characters) of impacts on rights, obligations and/or other aspects of GDPR implementation on particular groups listed in questions below regarding their work with patient data, healthcare documentation, electronic health records, etc. in connection with providing healthcare services.	This section is focused on key impacts GDPR has on particular groups of professionals or organisations in healthcare.
What are the key impacts of GDPR implementation on health professionals (doctors, other health professionals, etc.)? (Should this question be irrelevant to your organisation, please indicate so)	This question relates to health professionals.
What are the key impacts of GDPR implementation on emergency healthcare providers? (Should this question be irrelevant to your organisation, please indicate so)	This question relates to emergency healthcare providers.
What are the key impacts of GDPR implementation on healthcare providers (hospitals, clinics, medical practice owners,	This question relates to healthcare providers.

Survey Question	Comment
pharmacies, etc.)? (Should this question be irrelevant to your organisation, please indicate so)	
What are the key impacts of GDPR implementation on healthcare insurance providers? (Should this question be irrelevant to your organisation, please indicate so)	This question relates to healthcare insurance providers.
What are the key impacts of GDPR implementation on national authorities and organisations collecting patient data, healthcare documentation, electronic health records, etc.? (Should this question be irrelevant to your organisation, please indicate so)	This question relates to national authorities and organisations.
<p>Lawfulness of personal data processing in healthcare. Please provide a short comment (up to 1000 characters)</p> <ul style="list-style-type: none"> • Consent • Performance of a contract • Compliance with a legal obligation • Protection of a vital interest • Public interest or exercise of an official authority • Legitimate interest 	<p>What is a key legal basis for personal data processing in healthcare according to GDPR in case of particular types of providers (tick all that apply as major legal reasons for personal data processing in healthcare)?</p> <ul style="list-style-type: none"> • Health professionals • Emergency healthcare providers • National authorities and organisations
Patient Data, Healthcare Documentation, Electronic Health Records in practical use	This section is focused on the use of patient data in each phase of its lifecycle.
<p>What is the prevailing form for patient data, healthcare documentation, health records? (paper/digital/combined)</p> <ul style="list-style-type: none"> • in major hospitals • in specialised practices and clinics • in primary care 	This question aims to find out the extent of patient data digitisation.
What regulatory obligations (other than GDPR related) are in place related to the use / handling / exchange / sharing / storage of patient data, healthcare documentation,	This question aims to identify key legislation and other regulations applicable to patient data.

Survey Question	Comment
health records (e.g. compulsory exchange, storage or use in certain situations)?	
How are the above-mentioned obligations related to the use / handling / exchange / sharing / storage of patient data, healthcare documentation, health records fulfilled in practice?	This question aims to identify how key legislation and other regulations are applied to patient data.
If there is no particular regulation besides GDPR in place, how are obligations related to the use / handling / exchange / sharing / storage of patient data, healthcare documentation, health records fulfilled in practice?	This question aims to identify what key principles are applied to patient data in situations where there is no applicable legislation.
How has the GDPR and related legislation affected the use / handling / exchange / sharing / storage of Health Records? (e.g. were there any processes or tools that had to be modified significantly or are no longer available due to GDPR implementation?)	This question aims to identify what the key impact of GDPR on the above-described legislation and its implementation was.
Are there any challenges in implementation of GDPR and relevant national legislation in terms of patient data, healthcare documentation, health records and its use / handling / exchange / sharing / storage?	This question aims to identify what problems are met during the implementation of GDPR and related national legislation.
Access to Patient Data	This section is related to the access of patient data in various circumstances
What are the implications of GDPR and related legislation on patients' access to their own patient data, healthcare documentation, electronic health records?	This question aims to find out how patients' access to their own data is granted.
How is the access to patient data, healthcare documentation, health records without the consent of the patient implemented in the legislation?	There are certain situations when it is not possible to obtain patients' consent to access their medical history and other personal data. This question aims to find out what tools, procedures or other measures are implemented to circumvent patient consent in such situations and what protective measures are in place to prevent misuse of such tools and procedures.

Survey Question	Comment
<p>On what level is a unique Patient ID implemented?</p> <ul style="list-style-type: none"> • Patient ID unique on a national level • Patient ID unique on a regional level • Patient ID unique on a level of a healthcare provider • Patient ID unique for every case of a healthcare service • Other 	<p>This question aims to find out whether there is some form of unique Patient ID implemented and on what level is it unified / shared.</p>
<p>Execution of Rights of the Data Subject</p>	<p>This section is related to personal data other than data on the course and outcomes of provided health care services.</p>
<p>What defines rules for execution of a right to rectification (please describe how the right is implemented by healthcare providers)?</p>	<p>Question related to the right to rectification according to Article 16 of the GDPR.</p>
<p>What defines rules for execution of a right to erasure (please describe how the right is implemented by healthcare providers)?</p>	<p>Question related to the right to erasure according to Article 17 of the GDPR.</p>
<p>What defines rules for execution of a right of access (please describe how the right is implemented by healthcare providers)?</p>	<p>Question related to the right of access by the data subject according to Article 15 of the GDPR.</p>
<p>Practical impacts of GDPR on Health Records</p>	<p>This section is related to implications and impacts of implementing GDPR in the healthcare environment</p>
<p>What are challenges that prevent any group of stakeholders in healthcare from fully implementing GDPR?</p>	<p>This question aims to find out whether there are any problems preventing the full implementation of GDPR.</p>
<p>Are there any excessive costs or other types of induced resource consumption due to implementing GDPR that seem to be inadequate in the context of healthcare services? (either in context of your organisation or in healthcare sector in general)</p>	<p>This question aims to find out if the full implementation of GDPR is prevented by lack of available resources.</p>
<p>What is the estimated cost of GDPR implementation? (Please state cost relevant to</p>	<p>This question aims to quantify the overall cost of GDPR implementation (analysis, change of processes, information systems, etc.) and the</p>

Survey Question	Comment
your institution, or nationwide if you are a ministry or a government agency)	increase of operational expenditure related to GDPR adoption.
Are there any other obstacles to GDPR implementation (e.g. personnel capacity, cybersecurity issues, etc.)?	This question aims to find out if there are any obstacles preventing full GDPR implementation and compliance other than direct financial costs.
What are the expected benefits to be derived from the general adoption of GDPR and related national legislation?	This question aims to find out what benefits may arise from GDPR implementation.
Known challenges for implementing GDPR in the Healthcare Sector	This section aims to identify key problems related to implementing GDPR (obstacles, challenges and problems addressed during the implementation) and key problems related to GDPR being implemented (complications and problems in day to day operations resulting from GDPR implementation).
What are the key issues and challenges related to implementing GDPR in the healthcare sector?	This question aims to identify main challenges in the healthcare sector.
How are these issues addressed at the healthcare providers level?	This question focuses on issues at the level of particular organisations and their perception of GDPR.
How are these issues addressed on national level and in national legislation?	This question focuses on issues at the national level in terms of policy and legislation and the challenges faced.

3.3.3. The Questionnaire version B

The reduced list of questions comprises a body that is to be asked to survey respondents 5 to 7 (see chapter 3.3.4 Survey Respondents).

Survey Question	Comment
Identification and contact details	Basic identification of the survey respondent for the possibility of further clarification of provided responses or follow-up questions if necessary.
E-mail address	Contact information
Full Name	Contact information

Survey Question	Comment
Institution / Organisation	Contact information
Type of Institution / Organisation	Some of the questions are specific in relation to the type of the institution for which the answers are collected, identification of the institution/organisation type aims to help with the interpretation of such answers.
Work Phone	Contact information
Enforcing GDPR	National supervisory authority according to Article 51 of GDPR.
Are there so far any experiences or other outcomes of problems / issues / incidents / infringements / penalties regarding personal data protection legislation and its implementation? If so, please provide a short description (up to 1000 characters) and an English translation where possible.	This question aims to find out whether there are so far any results of the regulatory oversight by the national supervisory authority in terms of identified breaches of personal data protection and what were the consequences of the identified misconduct.
National Legislation on Health Records	This section is focused on legislative regulation of health records and patient data
Is there any specific legislation regarding patient data, healthcare documentation, electronic health records, etc.? If so, please provide a short description (up to 1000 characters) and an English translation where possible.	This question aims to find out what legislation applies to handling of patient data.
What are the key provisions of the above-mentioned legislation in terms of data formats and standards of patient data, healthcare documentation, electronic health records, etc.? Please provide a short description (up to 1000 characters)	This question aims to find out specific impacts of legislation related to handling of patient data on formats and standards applicable to this data.
What are the key provisions of the above-mentioned legislation in terms of handling and use of patient data, healthcare documentation, electronic health records, etc.? Please provide a short description (up to 1000 characters)	This question aims to find out specific impacts of legislation related to handling of patient data.

Survey Question	Comment
<p>Key impacts of GDPR implementation on Healthcare</p> <p>Please provide a short description (up to 1000 characters) of impacts on rights, obligation and/or other aspects of GDPR implementation on particular groups listed in questions below regarding their work with patient data, healthcare documentation, electronic health records, etc. in connection with providing healthcare services.</p>	<p>This section is focused on key impacts GDPR has on particular group of professionals or organisations in healthcare.</p>
<p>What are the key impacts of GDPR implementation on health professionals (doctors, other health professionals, etc.)? (Should this question be irrelevant to your organisation, please indicate so)</p>	<p>This question relates to health professionals.</p>
<p>What are the key impacts of GDPR implementation on emergency healthcare providers? (Should this question be irrelevant to your organisation, please indicate so)</p>	<p>This question relates to emergency healthcare providers</p>
<p>What are the key impacts of GDPR implementation on healthcare providers (hospitals, clinics, medical practice owners, pharmacies, etc.)? (Should this question be irrelevant to your organisation, please indicate so)</p>	<p>This question relates to healthcare providers.</p>
<p>What are the key impacts of GDPR implementation on healthcare insurance providers? (Should this question be irrelevant to your organisation, please indicate so)</p>	<p>This question relates to healthcare insurance providers.</p>
<p>What are the key impacts of GDPR implementation on national authorities and organisations collecting patient data, healthcare documentation, electronic health records, etc.? (Should this question be irrelevant to your organisation, please indicate so)</p>	<p>This question relates to national authorities and organisations.</p>
<p>Lawfulness of personal data processing in healthcare. Please provide a short comment (up to 1000 characters)</p>	<p>What is a key legal basis for personal data processing in healthcare according to GDPR in case of particular types of providers (tick all</p>

Survey Question	Comment
<ul style="list-style-type: none"> • Consent • Performance of a contract • Compliance with a legal obligation • Protection of a vital interest • Public interest or exercise of an official authority • Legitimate interest 	<p>that apply as major legal reasons for Personal Data processing in Healthcare)?</p> <ul style="list-style-type: none"> • Health professionals • Emergency healthcare providers • National authorities and organisations
<p>Patient Data, Healthcare Documentation, Electronic Health Records in practical use</p>	<p>This section is focused on the use of patient data in each phase of its lifecycle.</p>
<p>What is the prevailing form for patient data, healthcare documentation, health records? (paper/digital/combined)</p> <ul style="list-style-type: none"> • in major hospitals • in specialised practices and clinics • in primary care 	<p>This question aims to find out the extent of patient data digitisation.</p>
<p>What regulatory obligations (other than GDPR related) are in place related to the use / handling / exchange / sharing / storage of patient data, healthcare documentation, health records (e.g. compulsory exchange, storage or use in certain situations)?</p>	<p>This question aims to identify key legislation and other regulations applicable to patient data.</p>
<p>How are the above-mentioned obligations related to the use / handling / exchange / sharing / storage of patient data, healthcare documentation, health records fulfilled in practice?</p>	<p>This question aims to identify how key legislation and other regulations are applied to patient data.</p>
<p>If there is no particular regulation besides GDPR in place, how are obligations related to the use / handling / exchange / sharing / storage of patient data, healthcare documentation, health records fulfilled in practice?</p>	<p>This question aims to identify what key principles are applied to patient data in situations where there is no applicable legislation.</p>
<p>How has the GDPR and related legislation affected the use / handling / exchange / sharing / storage of health records? (e.g. were there any processes or tools that had to</p>	<p>This question aims to identify what the key impact of GDPR on above described legislation and its implementation was.</p>

Survey Question	Comment
modified significantly or are no longer available due to GDPR implementation)	
Are there any challenges in the implementation of GDPR and relevant national legislation in terms of patient data, healthcare documentation, health records and its use / handling / exchange / sharing / storage?	This question aims to identify what problems are met during the implementation of GDPR and related national legislation.
Access to Patient Data	This section is related to the access of patient data in various circumstances
What are the implications of GDPR and related legislation on patients' access to their own patient data, healthcare documentation, electronic health records?	This question aims to find out how patients' access to their own data is granted.
How is access to patient data, healthcare documentation, health records without the consent of the patient implemented in the legislation?	There are certain situations when it is not possible to obtain patients' consent to access their medical history and other personal data. This question aims to find out what tools, procedures or other measures are implemented to circumvent patient consent in such situations and what protective measures are in place to prevent misuse of such tools and procedures.
<p>On what level is a unique Patient ID implemented?</p> <ul style="list-style-type: none"> • Patient ID unique on a national level • Patient ID unique on a regional level • Patient ID unique on a level of a healthcare provider • Patient ID unique for every case of a healthcare service • Other 	This question aims to find out whether there is some form of unique Patient ID implemented and on what level is it unified / shared.

Survey Question	Comment
Execution of Rights of the Data Subject	This section is related to personal data other than data on the course and outcomes of provided health care services. The questions are focused on particular ways of implementation of the rights granted by the GDPR in your organisation.
What defines rules for execution of a right to rectification (please describe how the right is implemented by healthcare providers)?	Question related to the right to rectification according to Article 16 of the GDPR.
What defines rules for execution of a right to erasure (please describe how the right is implemented by healthcare providers)?	Question related to the right to erasure according to Article 17 of the GDPR.
What defines rules for execution of a right of access (please describe how the right is implemented by healthcare providers)?	Question related to the right of access by the data subject according to Article 15 of the GDPR.
Practical impacts of GDPR on Health Records	This section is related to implications and impacts of implementing GDPR in the healthcare environment
What are challenges that prevent any group of stakeholders in healthcare from fully implementing GDPR?	This question aims to find out whether there are any problems preventing the full implementation of GDPR.
Are there any excessive costs or other types of induced resource consumption due to implementing GDPR that seem to be inadequate in the context of healthcare services? (either in context of your organisation or in healthcare sector in general)	This question aims to find out if the full implementation of GDPR is prevented by lack of available resources.
What is the estimated cost of GDPR implementation? (Please state cost relevant to your institution, or nationwide if you are a ministry or a government agency)	This question aims to quantify the overall cost of GDPR implementation (analysis, change of processes, information systems, etc.) and the increase of operational expenditure related to GDPR adoption.
Are there any other obstacles to GDPR implementation (e.g. personnel capacity, cybersecurity issues, etc.)?	This question aims to find out if there are any obstacles preventing full GDPR implementation and compliance other than direct financial costs.

Survey Question	Comment
What are the expected benefits to be derived from the general adoption of GDPR and related national legislation?	This question aims to find out what benefits may arise from GDPR implementation.
Known challenges for implementing GDPR in the Health Care Sector	This section aims to identify key problems related to implementing GDPR (obstacles, challenges and problems addressed during the implementation) and key problems related to GDPR being implemented (complications and problems in day to day operations resulting from GDPR implementation).
What are the key issues and challenges related to implementing GDPR in the healthcare sector?	This question aims to identify main challenges in the healthcare sector.
How are these issues addressed at the Health Care providers level?	This question focuses on issues at the level of particular organisations and their perception of GDPR.

3.3.4. Survey Respondents

To obtain representative results covering all key aspects of the healthcare industry and the impact of the GDPR, the following key respondent groups to be surveyed were defined in every member state:

1. Member participating in Task 7.2
2. National Ministry of Health
3. National Authority for eHealth (where applicable)
4. National Supervisory Authority according to GDPR Article 51
5. Hospitals / Clinics / Primary Healthcare providers (5)
6. Emergency Healthcare provider (1)
7. Healthcare Insurance Provider (1)

3.3.5. Analysis of Survey Data

To be completed in next version of the document.

4. Best practices and approaches on data protection

To be completed in next version of the document.

5. References

Multiannual Work Programme of the eHealth Network 2018-2021 adopted by the eHN in November 2018

https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co01_en.pdf

JAsEHN T5.1 Trusted eHealth National Contact Points

- D5.1.2_Country_Guide_for_NCPeH_Implementation.pdf

JAsEHN T5.2 Electronic Identification for eHealth

- D5.2.1 eID specific Framework for eHealth
- D5.2.2 Guidelines on the interoperability of electronic professional registries
- D5.2.3 Report on notification of national eID under the scope of the eIDAS Regulation

JAsEHN T5.3 Update & revision of EU eHealth Guidelines

- D5.3.0 General Guideline
- D5.3.1 Update Guideline on PS
- D5.3.2 Update Guideline on eP
- D5.3.3 Report on elements to be taken into consideration for updating the PARENT Joint Action guidelines for Patient Registries

JAsEHN T5.4 Alignment of standardisation activities in eHealth

- D5.4.1 Proposal for a platform consisting of the relevant standards developing organisations
- D5.4.2 Policy paper proposing actions to promote the use of common standards or technical specifications in eHealth within the EU
- D5.4.3x Report on standardisation developments in eHealth incl. recommendations for the rolling plan
- D5.4.4 Refined eHealth European Interoperability Framework (ReEIF)

JAsEHN T5.5 Semantic Interoperability

- D5.5 Report on European semantic interoperability in eHealth

JAsEHN T6.1 Implementation of eHealth guidelines

- D6.1.1 Report on the implementation of PS Guideline
- D6.1.2 Report on the implementation of eP Guideline
- D6.1.3 Report on the implementation of PR Guideline

JAsEHN T7.5 Patient access to Electronic Health Records and health data portability

- D7.5.1 Report on EU state of play on patient access on eHealth data
- D7.5.2 Recommendations for patient access to electronic health records

To be completed in next version of the document.

6. Conclusions

Section 7 summarises the document conclusions listing the next steps of WP7.2.

To be completed in next version of the document.

7. Bibliography

European Commission. (2018). *Rolling plan on ICT standardisation*. Ανάκτηση 08 02, 2018, από eHealth, Healthy Living and Aging, Policy: <https://joinup.ec.europa.eu/collection/rolling-plan-ict-standardisation/ehealth-healthy-living-and-aging>

To be completed in next version of the document.

8. Appendix I

Use the appendix for detailed data points and supporting evidence