eHAction
Joint Action supporting the eHealth Network

D5.1 - Report for the information of the eHN on policy level actions

WP 5 – Innovative Use of Health data

02-03-2020

Version 0.3

17th eHealth Network meeting, June 2020

Adopted

To ease the uptake of innovative usage of data across the healthcare sector for the benefits of society, individuals and performance of Member State health systems, this report proposes recommendations for

- strengthening the awareness of the possibilities and potentially beneficial impact of big data in health by identifying best practices

- developing frameworks and common principles for realising the added value of big data in health

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

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D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Table of Contents

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Acronyms

Acronym	Description
AC	Action Coordinator
AI	Artificial Intelligence
AP	Associated Partner
AV	Added Value
BDTI	Big Data Test Infrastructure
CA	Consortium Agreement
CBeHIS	Cross-Border eHealth Information Services
CEF	Connecting Europe Facility
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
CSR	Corporate social responsibility
D5.1	Deliverable of Task 5.1 in Work Package 5 of eHealth Action
DSM	Digital Single Market
EBSI	European Blockchain Services Infrastructure
EEA	European Economic Area
eHAction	eHealth Action – 3rd Joint Action supporting the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHDSI Member States Expert Group
eHN	eHealth Network
eHOMB	eHealth Operational Management Board
eHPS-EC	eHealth Policy Secretariat - European Commission, DG SANTE Unit B3
EU	European Union
FAIR data	Findable, Accessible, Interoperable and Reusable data
GDPR	General Data Protection Regulation
HP	Health Professional
ML	Machine learning
MWP	Multi-annual Work Programme
OECD	Organisation for Economic Co-operation and Development
PA	Priority area
PLA	Policy-level action
RDI	Research, development and innovation

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

T5.n	Task 5.n
TL	Task Leader
WHO	World Health Organization
WP	Work Package
WPCo-L	Work Package Co-Leader
WPL	Work Package Leader

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

List of Tables

List of Figures

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Executive Summary

One of the eHAction's main objectives is to improve the knowledge base for health and healthcare policy, envisioning development of new ways in the usage of data across the healthcare sector. Tasks related to this objective are included in Work Package 5 (WP5): 'Innovative use of health data'.

This report provides information about Deliverable 5.1 (D5.1) of Task 5.1 'Mapping, awareness raising and policy relevant actions on innovative use of big data in health' described in WP5.

D5.1 provides information about compiling policy-relevant documentation, obstacles to replicate recommendations and good practices, and the added value of big data. In our work we focused on the expectations, needs and interests of the key stakeholders, and compared them to the identified obstacles and barriers to transfer good/best practices and make use of existing recommendations. We took into consideration the effects of GDPR and also the implications of FAIR data principles.

WP5, to achieve its objectives, was identifying and understanding obstacles and barriers to transfer good/best practices and make use of existing recommendations on the innovative use of health data, especially big data. Therefore, WP5 organised a kick-off meeting in Brussels in October 2018, met stakeholders at the DIBSS Conference in Dubrovnik in May 2019 and held a workshop in Prague in September 2019, where experts tested and validated a framework intended to capture the rationale behind the lack of use of already-collected health data for better health outcomes. This framework has been developed to analyse challenges in implementing policy recommendations or replicating good practices. The workshop contributed to finalising a mapping tool to identify key stakeholders, their needs, goals, offers/evaluation, behaviour and attitude, as well as interdependencies, obstacles and possible interventions and expected results. This tool helped to collect detailed information for the stakeholder value chain analysis framework. Member States/countries were asked to provide information first, then key stakeholders were requested to provide their views and contribution. T5.1 experts compared and assessed the information which was gained by the questionnaire and imported from the approved Deliverable 5.2, in order to provide a full picture in the final D5.1 report.

In this final version we deliver operationalised recommendations containing information for the eHealth Network (eHN) on policy-level actions (PLAs), including an initial set of enabling actions based on the recommendations of the Study on Big Data in Public Health, Telemedicine and Healthcare (hereinafter referred as 'EU Study')[1]. D5.1 final version also builds on findings and recommendations of approved deliverables of eHAction.

The aim of elaborating PLAs was to support not only awareness raising and communication of the added value of big data to different stakeholder groups, especially at the governance level in Member States/countries via the eHN, but also to provide an initial set of recommendations for enabling actions to mitigate challenges in implementing available good practices, opportunities, recommendations and guidance to foster the growth of innovative use of health data and big data for primary and secondary purposes as well.

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[1] https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Accordingly, the method we chose, policy relevant documentation, including the EU Study, the implications of FAIR data principles and the effects of GDPR, as well as the review of Member State/country policy level efforts on governing big data in health, was compiled through the identification and assessment of stakeholders' goals, needs, drivers, challenges and opportunities.

Considering that T5.1 has been delivering information on the obstacles (and reasons) preventing Member States/countries to implement (more) effective actions in (more) efficient ways to foster successful transformation of data into innovation, we have begun matching this information with the plans or results and experiences of national strategies which could contribute to making the value we want to deliver in T5.3 as a next step.

In order to make a smooth transition from T5.1 and T5.2 to T5.3, WP5 joined the workshop on health data governance for secondary use, named 'Towards the European Health Data Space - National Strategies for Secondary Use of Data in the Context of National and EU Digital Health Networks', organised by the co-leader of WP8 in Lisbon in January 2020.

Main findings and initial recommendations

The use of health data is considered 'innovative' if this use results in better patient outcomes and/or higher quality of healthcare delivery and/or higher productivity and performance.

Innovative use of health data, regardless of whether the use is primary or secondary, fosters innovation in the field of public health interventions, prevention strategies and health system management, as well as in the organisation and provision of health services and medical care, including health promotion and disease prevention interventions. It has the potential to improve public health outcomes, enhance the quality of care to patients and respond to unmet needs, and also to foster the competitiveness of stakeholders and to improve the cost-efficiency and sustainability of health services and medical care.

Use cases for the prioritised fields of the enabling actions can be selected by identifying innovations delivering gains in the varying areas listed above. Higher priority can be awarded to those cases which deliver gains in more areas while using less resources at minimum risk.

The result of the mapping showed that **three general obstacles** appeared as reasons slowing down or hampering translation of policy-level recommendations into actions: **lack of trust, legal uncertainties, and lack of funding and financial resources**. Detailed guidance reflecting on the three major findings will be delivered by T5.3.

The creation of a European Health Data Space (EHDS) may help to foster innovative use of health data, however it needs to be defined first. EHDS may be neither a tool, nor a final goal, but it is likely that it could be an important, fundamental part of the digitalised healthcare ecosystem, therefore it requires EU level co-ordination.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

1   Background

This report is a deliverable of eHAction Work Package 5 (WP5) – Innovative use of health data, led by Hungary (NHSC) and Finland (THL).

WP5 builds on priority areas B.1, B.2 and B.3 of the 2018-2021 Multiannual Work Programme (MWP) of the eHealth Network. Secondary use of data and big data can provide value for research, teaching, managing and planning healthcare systems. It can also be a great opportunity for the development of personalised medicine, the improvement of the effectiveness and safety of medicine, efficiency of health systems, and continuity of care. WP5 faces the problem of lack of awareness of these potential benefits and the need for sharing expertise.

The proposal also builds upon Deliverable 5.2 – 'Report on identified cross-border use cases, including assessment of pros & cons of stakeholders, and practical solutions with potential for European scale benefits', which was delivered and adopted during the 16th eHealth Network meeting in November 2019.

1.1 Purpose

WP5 builds on priority areas B.1, B.2 and B.3 of the 2018-2021 Multiannual Work Programme (MWP) of the eHealth Network. Secondary use of data and big data can provide value for research, teaching, managing and planning healthcare systems. It can also be a great opportunity for the development of personalised medicine, the improvement of the effectiveness of medicine, efficiency of health systems, and continuity of care. WP5 faces the problem of lack of awareness of these potential benefits and the need to share expertise.

The concept and use of big data in health institutions and systems are still new and there is much uncertainty on how to go forward on benefitting from big data on the practical level. On the policy level, it is important to strengthen the awareness of the possibilities and to highlight the potentially beneficial impacts of big data in health.

The healthcare sector is a data-intensive industry generating large volumes of data. There has been tremendous growth in the range of information that is being collected, such as clinical, genetic, behavioural and environmental data from an array of devices including electronic health records, genome sequencing machines, patient registries, social networks and smartphone applications monitoring patient health.

The combined use of large volumes of fragmented health data could unlock great potential in the healthcare sector. Powerful data analytics can discover patterns that will lead to new prevention, diagnostic and therapeutic avenues (approaches, treatments or alternatives); can help remove inefficiencies in care processes and reduce waste; and help make better management and clinical decisions that will improve the performance of health systems (e.g. in terms of procedures, quality of care, patient safety and patient outcomes).

Available new technologies offer the opportunity to integrate big data sets and could enable exact, rapid and personalised diagnosis, treatment, detection, tracking, prevention and control, such as system or policy development. However, developing, testing, providing, maintaining and improving data provenance management, trusted big data solutions and cybersecurity are

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

key challenges in exploiting opportunities, advantages and potentials offered by any innovation in the use of health and care data.

The overall objective of WP5 is to support the application of good practices in Member States and provide guidance at European Union (EU) level on handling big data in health within the existing EU regulatory framework, on secondary use of personal health data, and consequently to ease the uptake of innovative usage of data across the healthcare sector for the benefits of society, individuals and performance of Member State health systems. One of the aims of the WP is to enable the communication of the value of big data to different stakeholder groups and to provide a way for public health promotion, preventive measures and care from the analysis of big data across the healthcare sector and following FAIR data (i.e. Findable, Accessible, Interoperable, Reusable) and patient-curated data principles.

To implement this aim, T5.1 – '*Mapping, awareness raising, and policy relevant actions on innovative use of big data in health'* foresees to deliver '***D5.1 – 'Report for the information of the eHN on policy level actions'*** (by Month 24 of eHAction) on:

1. Compiled policy-relevant documentation, including the Study on Big Data in Public Health, Telemedicine and Healthcare; this covers topics of big data applications in health and innovations before 2016[2] (hereinafter referred as 'EU Study') and the effects of GDPR, and review of Member State/country policy-level efforts on governing big data in health, and also assesses the implications of FAIR data principles[3]. This document will also provide information for the eHealth Network (eHN) about expectations on big data, definitions, scope of work, terms, conditions, obstacles, importance to people, as well as the possible re-use of reports on Big Data and Health Analytics;

2. Identified obstacles preventing Member State/country policies from being replicable either in other Member States/countries or on EU level, and proposals on how to overcome these;

3. The outlining of the added value (AV) of big data on the eHN governance level with the EU Study recommendations operationalised; and

4. Information for the eHN on policy-level actions (PLAs), including an initial set of enabling actions based on the recommendations of the EU Study to support awareness raising and communication of the added value of big data to different stakeholder groups, especially at the governance level in Member States/countries via the eHN.

1.2 Working definitions

Working definitions were elaborated by WP5 members at the kick-off meeting in order to lay down statements of the meaning of certain phrases which have been explained in various ways in the literature. The kick-off meeting of Work Package 5 was held on 16 October 2018 in Brussels. The meeting included a workshop to review available definitions and to propose for

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[2] https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

[3] FAIR data principles: A set of guiding principles in order to make data findable, accessible, interoperable and reusable (Wilkinson et al., 2016). These principles provide guidance for scientific data management and stewardship and are relevant to all stakeholders in the current digital ecosystem. https://www.nature.com/articles/sdata201618

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

adoption those that are important to empower patients, policy makers and professionals about the innovative use of health data. Experts agreed on defining health data, big data in health, big data analytics in health and innovative use of health data. These working definitions were introduced to the eHealth Network in November 2018, and are considered as continuously evolving definitions based on the evolutionary and constantly changing nature of the field. Definitions reflect the value-based approach followed in WP5, where value refers to satisfaction of a specific need and replicability at an economical cost.

- *Health data*: Patient data in health records (records kept by health professionals and care providers, as well as self-reported health data), data from apps and wearables, any background data that will give insights on the social determinants of health.

- *Big data in health*: Consolidated data from existing fragmented data sources for the purpose of understanding, forecasting and improving health and health system status, needs and performance.[4]

- *Big data analytics in health*: Statistical learning methods and algorithms applied to big data in health, which include descriptive analytics, mining/predictive analytics to support evidence-based decision making, analytical techniques that are ideal for analysing a large proportion of text-based health documents and other unstructured clinical data (e.g. physicians' written notes and prescriptions and medical imaging).

- *Artificial intelligence*: Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems), or can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications). Many AI technologies require data to improve their performance. Once they perform well, they can help improve and automate decision making in the same domain.[5]

- **Primary and secondary use of health data**: In many cases the term 'innovative use of health data' is defined as secondary use of health data and big health data. However, it is worth considering whether there was a tangible border between primary and secondary use, or there are other data usable for primary and/or secondary use.

   In our interpretation, **primary use of health data** is related to the care or treatment of a person (owner[6] of the data), while **secondary use** covers every other case related to any goals regarding policy making, system governance or planning, regulation, authorisation, control, monitoring, governance, management, research, innovation, development, etc.

   The pellucid border between primary and secondary use is well reflected in the introductory description of the UK NHS Innovative Uses of Data Team: 'Our Innovative Uses of Data (IUoD) team aims to improve our information analysis and reporting, by using novel data science techniques. This will enable new insights from data that work to improve

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[6] One shall be very careful to use the notion of 'owner' or 'ownership' in relation to any personal data without deeper legal elaboration. There is an ongoing professional debate about the concept of ownership in this regard. In this context ownership refers to the origin and the beneficiary of data.

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

health and social care. Products will be focused on the needs of patients, clinicians and organisations within the health and social care sector, to increase the likelihood of delivering real benefits that will improve patient outcomes.'[7]

- **_Innovative use of health data_**: Innovation is the process of translating an idea or invention into goods or services that create value, or for which customers will pay. To be called an innovation, an idea must be replicable at an economical cost and must satisfy a specific need. Innovation involves deliberate application of information, imagination and initiative in deriving greater or different values from resources, and includes all processes by which new ideas are generated and converted into useful products[8].

  The use of health data is considered 'innovative' if this use results in better patient outcomes and/or higher quality of healthcare delivery and/or higher productivity and performance (see Figure 1 – Definition of innovation and innovative use of health data). Our approach in defining innovative use of health data is also based on the definition of innovation of the World Health Organization (WHO): 'Health innovation identifies new or improved health policies, systems, products and technologies, and services and delivery methods that improve people's health and wellbeing. Health innovation responds to unmet public health needs by creating new ways of thinking and working with a focus on the needs of vulnerable populations. It aims to add value in the form of improved efficiency, effectiveness, quality, sustainability, safety and/or affordability. Health innovation can be preventive, promotive, curative and rehabilitative and/or assistive care. The WHO engages in health innovation to achieve universal health coverage within the context of the Sustainable Development Goals.'[9] Innovative use of health data is determined by the ways of converting unstructured, separated datasets into new or renewed things, services, solutions, organisations or systems (See: Figure 2 – Innovative use of health data (framework) and Figure 3 – Transforming separated health data into Big Data and innovation).

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020
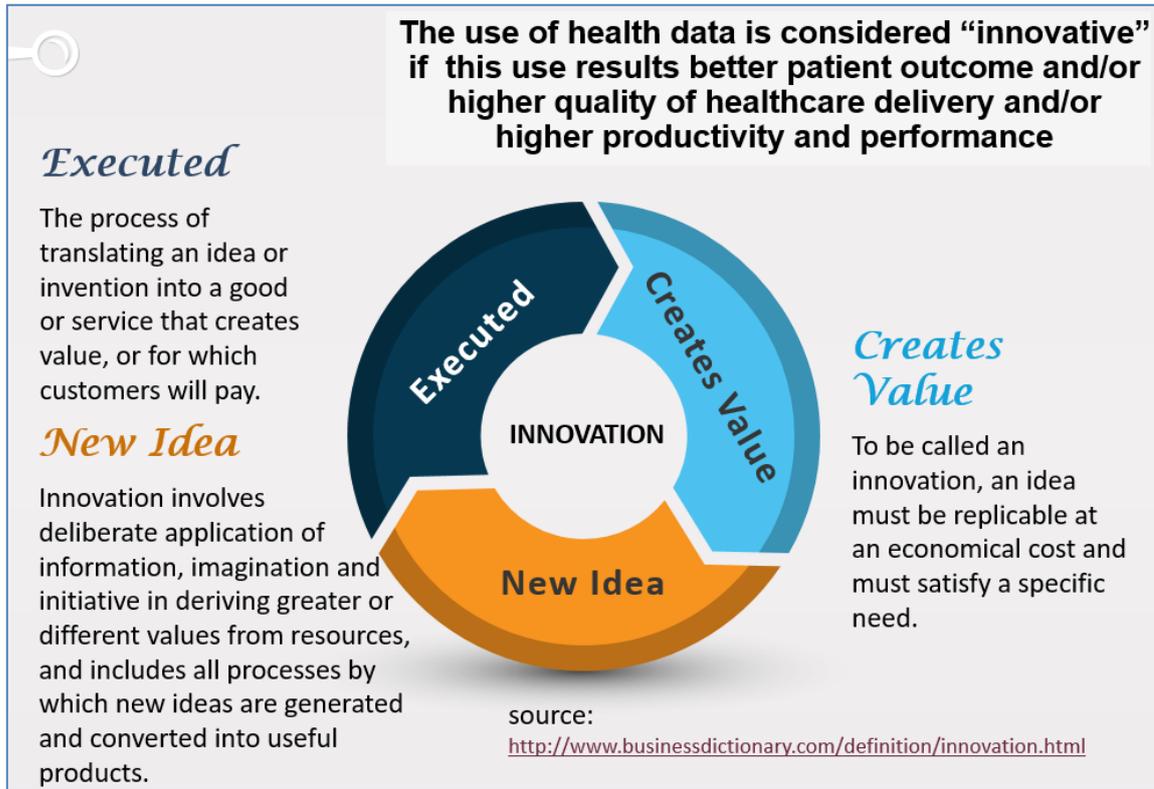
Figure 1 – Definition of innovation and innovative use of health data
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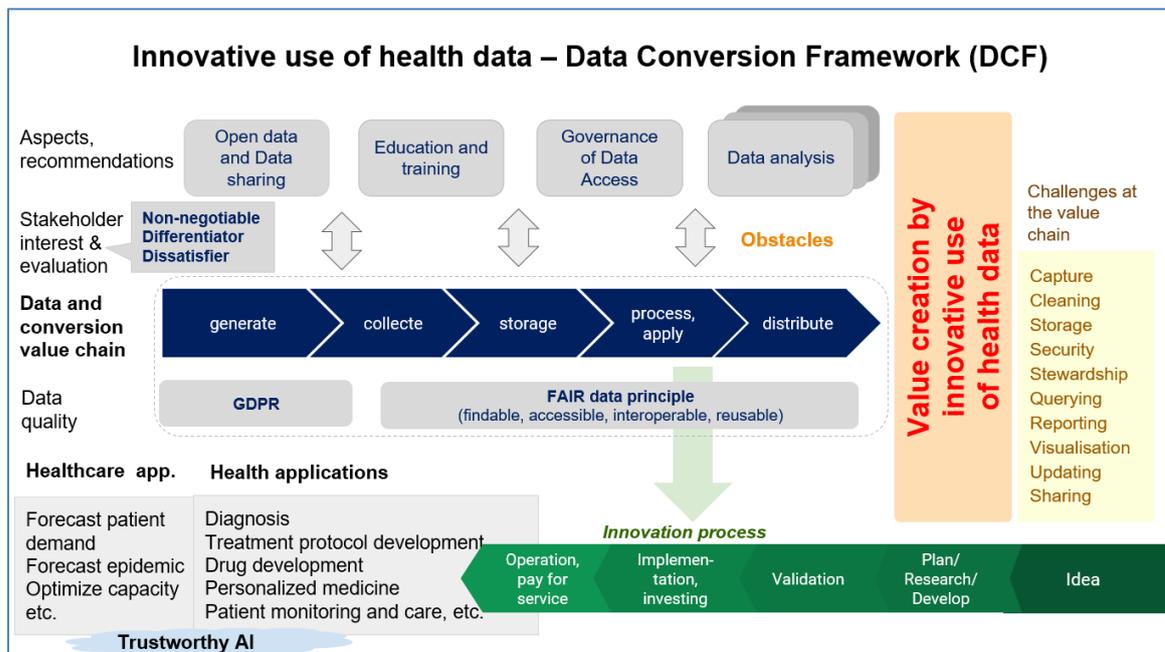
Figure 2 – Innovative use of health data (framework)

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020
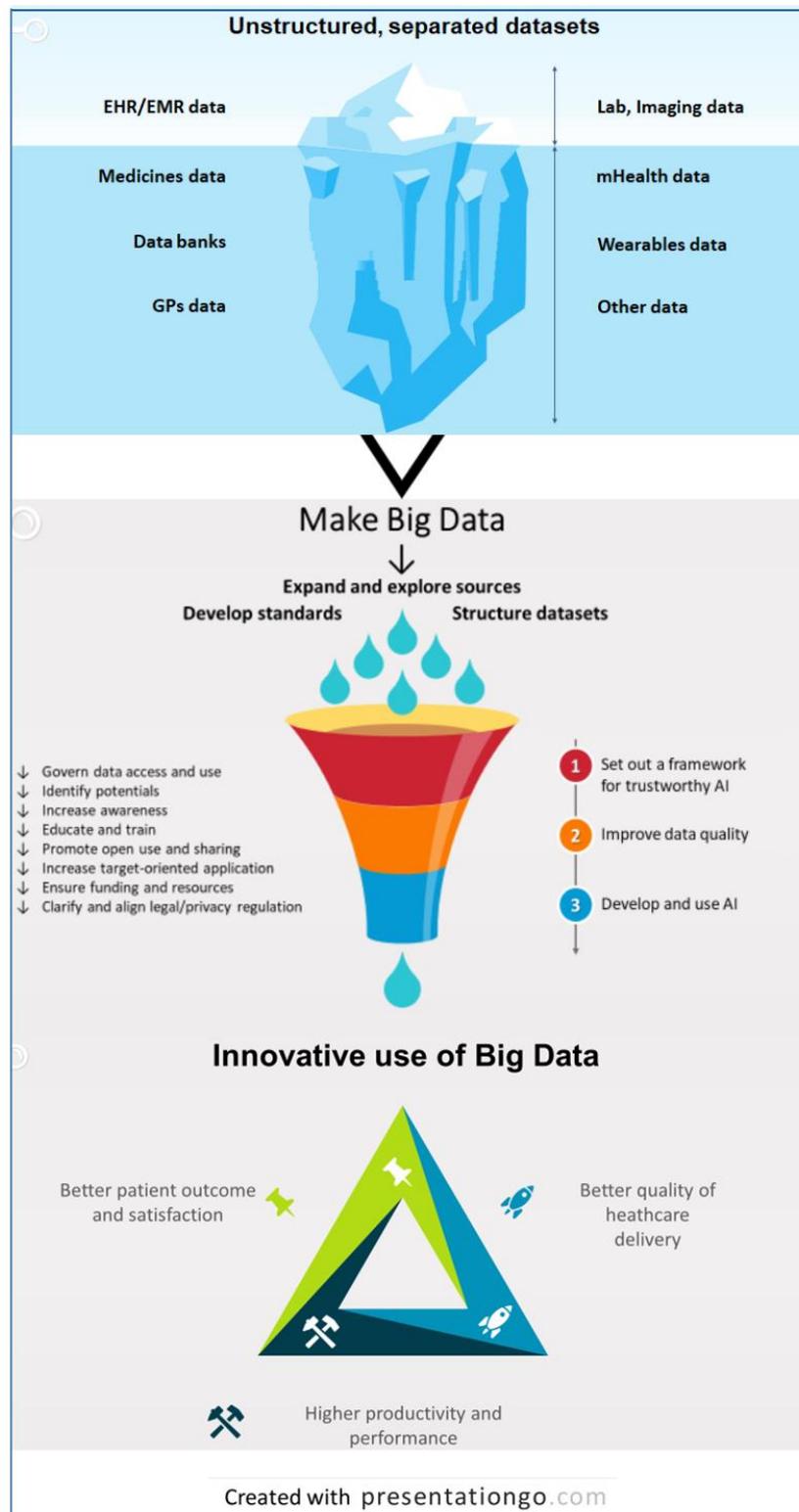
Figure 3 – Transforming separated health data into Big Data and innovation[10]


[10] Not all the mentioned attributes necessarily belong "under the surface" in the Iceberg picture. E.g. medicines can be already part of EHR or ePrescription or Insurance claims and their usability has improved along medical records.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

1.3 Scope

The aim of the task is to provide a way forward for public health promotion, preventive measures and care from the analysis of big data across the healthcare sector.

Identifying obstacles that prevent Member State/country policies from being replicable either in other Member States/countries or on an EU level, as well as proposing how to overcome them, has been in the scope of the task in order to enable the communication of the value of big data to different stakeholder groups. Initiatives and results of the 'My Health My Data' project[11] as well as FAIR data principles are also in the focus of the work. The added value of big data for the eHN and governance level with the EU Study recommendations will be outlined and operationalised by the methods introduced below. We also intend to acknowledge the growing importance of artificial intelligence in the healthcare sector and its implications in secondary data use governance and implementation processes, in accordance with European Commission policy recommendations.

In this report, for the information of the eHN on policy-level actions, an initial set of enabling actions will be introduced to support awareness raising and communication of the added value of big data to different stakeholder groups, especially at the governance level in Member States/countries via the eHN.

The 'effective implementation of digital technologies in health is widely recognised as being crucial in establishing efficient, well-functioning health systems, and empowering patients as part of a transition to integrated person-centred care and ensuring that the vital health information which underpins the future of clinical care and decisions is made available when and where it is most needed.'[12] Therefore, D5.1 recommendations will also be focused on transferring the lessons learnt in order to help Member States/countries to overcome obstacles, as well as avoid the usual case that the use of digital technologies in the current healthcare system and services will surely result only in more expensive solutions and treatments.

D5.1 '*Report on policy-level actions*' has compiled policy-relevant documentation, including the EU Study and the effects of GDPR, and a review on Member State/country policy-level efforts on governing big data in health.

The work at task level within WP5 followed the logic of 'expectations - obstacles - relevant actions'. Based on this logical order the main scope of D5.1 is to:

- assess the current state of the play and identify the main obstacles, barriers that prevent the satisfaction of those expectations;

- examine the expectation-obstacle-recommendations-action relation with respect to a) policy-relevant documentation; b) EU study and OECD Ministerial Statement; c) effects of GDPR; and d) review of Member State/country policy-level efforts on governing big data in health;

- further refine the identified expectations with D5.2 from literature review and analysis;

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- prepare the background information for relevant policy-level recommendations in D5.3.

Considering that T5.1 has been delivering information on the obstacles (and reasons) preventing Member States/countries to implement (more) effective actions in (more) efficient ways to foster successful transformation of data into innovation, we have begun matching this information with the plans or results and experiences of national strategies which could contribute to making the value we want to deliver in eHAction T5.3 as a next step.

1.4 Methods

In order to prepare mapping, awareness raising and policy-relevant actions, WP5 analysed the state of play (needs, barriers, opportunities and goals) and the (future) use cases of innovative use of health data.

One of the key components of the working methods selected to produce D5.1 builds on the analysis of reports on big data and health analytics.

As another key component of the working methods, we assessed whether there are underperforming functions in the value chain of converting data into innovation in health (Data Conversion Value Chain).

This chain consists of: 1) generating, capturing, collecting and cleaning data (in order to scout the value); 2) storing, securing, protecting and processing data (in order to create, determine and engineer the value); 3) the motivation and interests of stakeholders (influenced or defined by non-negotiables, differentiators and dissatisfiers), comparing satisfaction of specific needs with the replicability at economical cost (in order to engineer the value); and 4) the stewardship, querying, analysis, reporting, visualisation, updating, sharing or distribution of the relevant data (in order to foster the uptake of the value) (see Figure 4 – Data Conversion Value Chain).

Challenges were traced and assessed at every link in the Data Conversion Value Chain.

WP5 has been working on identifying possible underperformances in these functions and drivers to cope with the challenges. In order to collect information about these obstacles and barriers, we prepared an online survey (hereinafter called 'WP5-survey'). The online WP5-survey was completed by 9 Member States/countries so far taking part in the work of Task 5.1.

Findings derived from the results of the WP5-survey are introduced in section 2.2.2.

A further key component of the working methods was to focus on detecting obstacles preventing Member States/countries from implementing available recommendations and guidance for increasing innovative use of health data and big data.

Task 5.1 prepared a tool to identify key stakeholders, their needs, goals, offers/evaluation, behaviour and attitude, as well as interdependencies, obstacles and possible interventions and results to be expected. The form of the tool was a questionnaire designed to collect and provide information for further assessment through a canvas which allows for rendering of 2D shapes and mapping.

Using this canvas tool, named 'the stakeholder value chain analysis framework for data conversion' (in short: 'Data Conversion Framework' or 'DCF'), WP5 mapped privacy aspects, as well as identified obstacles that prevent Member State/country policies from being replicable either in other Member States/countries or at the EU level (see Figure 5 – Stakeholder value chain analysis framework for data conversion).

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

The framework has outlined interdependencies with the dysfunctions challenging the strength of the Data Conversion Value Chain. Further interdependencies were outlined among innovative use of health data, patient empowerment, digital health skills of professionals and other use cases of interoperability.

The purpose of the analysis is to look for obstacles preventing the growth of innovative use of health data in Member States/countries.

WP5 focused the tool on detecting obstacles preventing Member States/countries to implement available recommendations and guidance for increasing innovative use of health data and big data. Thus, it helped to elaborate compiled policy-relevant documentation on governing big data in health (results of the mapping are detailed in sections 2.2.3 and 2.2.3.2).

Additional key components of the working methods:

- WP5 also had a look at on the trends of the global ecosystem affecting the innovative use of health data;

- Interdependencies with other tasks and activities in eHAction and deliverables of JAseHN were taken into consideration;

- The European Health Data Space was investigated, as one potential data sharing structure.

The countries participating in the survey were asked to fill in and submit the canvas pointing out the main goals, needs, obstacles, possible interventions and results in connection with four recommendations of the EU study. We experienced that Member States/countries achieved some progress and faced challenges on most of the 10 recommendations. The highest level of challenges or concerns particularly appeared at implementing recommendations on:

- 'Open Data and Data Sharing',

- 'Education and Training',

- 'Governance of Data Access', and

- 'Data Analysis'.

Using the framework tool (canvas) we intended to obtain information about the reasons and the root causes why these challenges occur.

Inspired by an OECD publication in 2013[13] and the Ministerial Statement on 'The Next Generation of Health Reforms' of the OECD Health Ministerial Meeting, 17 January 2017, Paris (hereinafter referred as 'OECD Ministerial Statement')[14], as well as other relevant articles,[15, 16] this assessment analysed whether the links in the Data Conversion Value Chain were challenged.

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13 Exploring data-driven innovation as a new source of growth: Mapping the policy issues raised by "big data". OECD Publishing, 2013.

14 http://www.oecd.org/newsroom/oecd-health-ministerial-statement-the-next-generation-of-health-reforms.htm

15 Top 10 Challenges of Big Data Analytics in Healthcare. Jennifer Bresnick, healthitanalytics.com, June 12, 2017

16 "How to Get Ecosystem Buy-In" by Martin Ihrig and Ian MacMillan, HBR MARCH–APRIL 2017 (https://hbr.org/2017/03/how-to-get-ecosystem-buy-in)

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Challenges were traced and assessed at every link in the Data Conversion Value Chain. These challenges are related to the way of solving potential problems caused by underperforming functions working at the links in the chain.

WP5 was working on identifying possible underperformances in these functions and drivers to cope with the challenges by:

- The work at task level within WP5 follows the logic of 'objectives & needs & expectations - obstacles - relevant actions', and thus we have been identifying main obstacles, barriers that prevent the fulfilment of expectations derived from existing recommendations of the EU Study, the OECD Ministerial Statement and recent European Commission communications and guidelines on AI.

  In order to collect information about these obstacles and barriers, we prepared an online survey (hereinafter called: WP5-survey). The online WP5-survey has been completed by nine Member States/countries so far taking part in the work of Task 5.1.

- WP5 joined WP7 to organise a workshop to overcome implementation challenges by discussing the results of data protection in healthcare and approaches on data protection at national level, as well as the effects of GDPR and the implications of FAIR data principles. The event took place from 11th to 13th September 2019 in Prague, Czech Republic. In addition, the workshop contributed to finalising DCF. The framework has outlined interdependencies with the dysfunctions challenging the strength of the Data Conversion Value Chain. Further interdependencies have been outlined among innovative use of health data, patient empowerment, digital health skills of professionals and other use cases of interoperability. Thus, it has helped in elaborating compiled policy-relevant documentation on governing big data in health.

- Task 5.1 prepared a questionnaire to collect detailed information for the stakeholder value chain analysis framework. Member States/countries were asked to provide information first. Task 5.1 experts compared and assessed the information that was gained in this way. Key stakeholders will also be requested to provide their views and contribution during the implementation of Task 5.3.
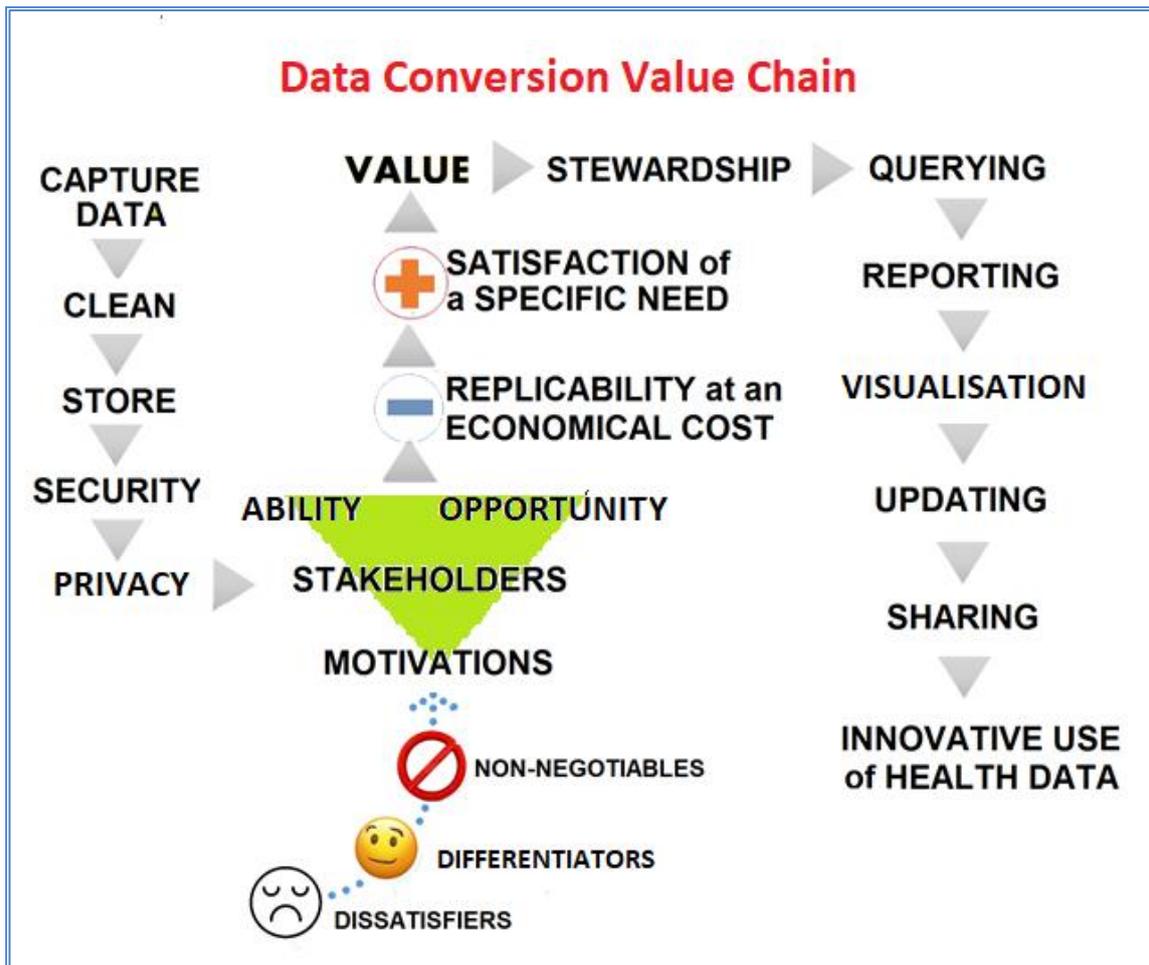
D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

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

Figure 4 – Data Conversion Value Chain

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020
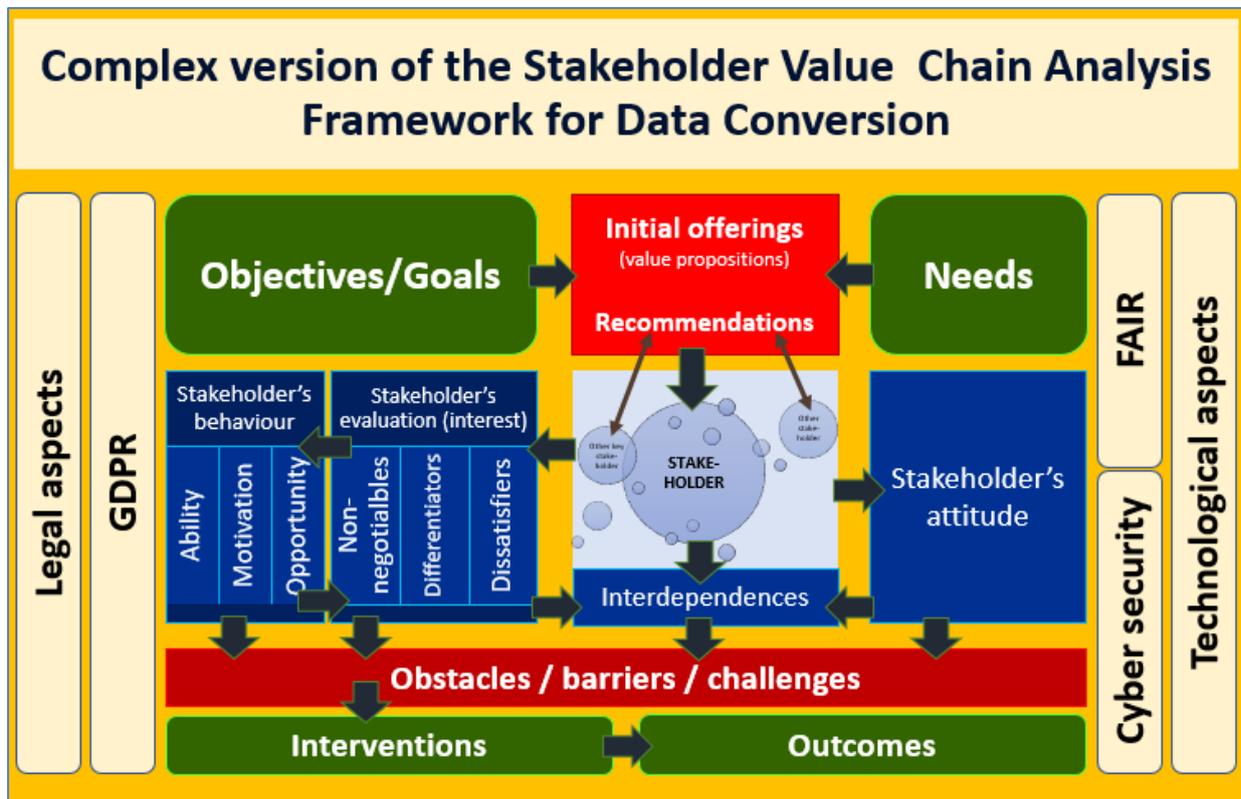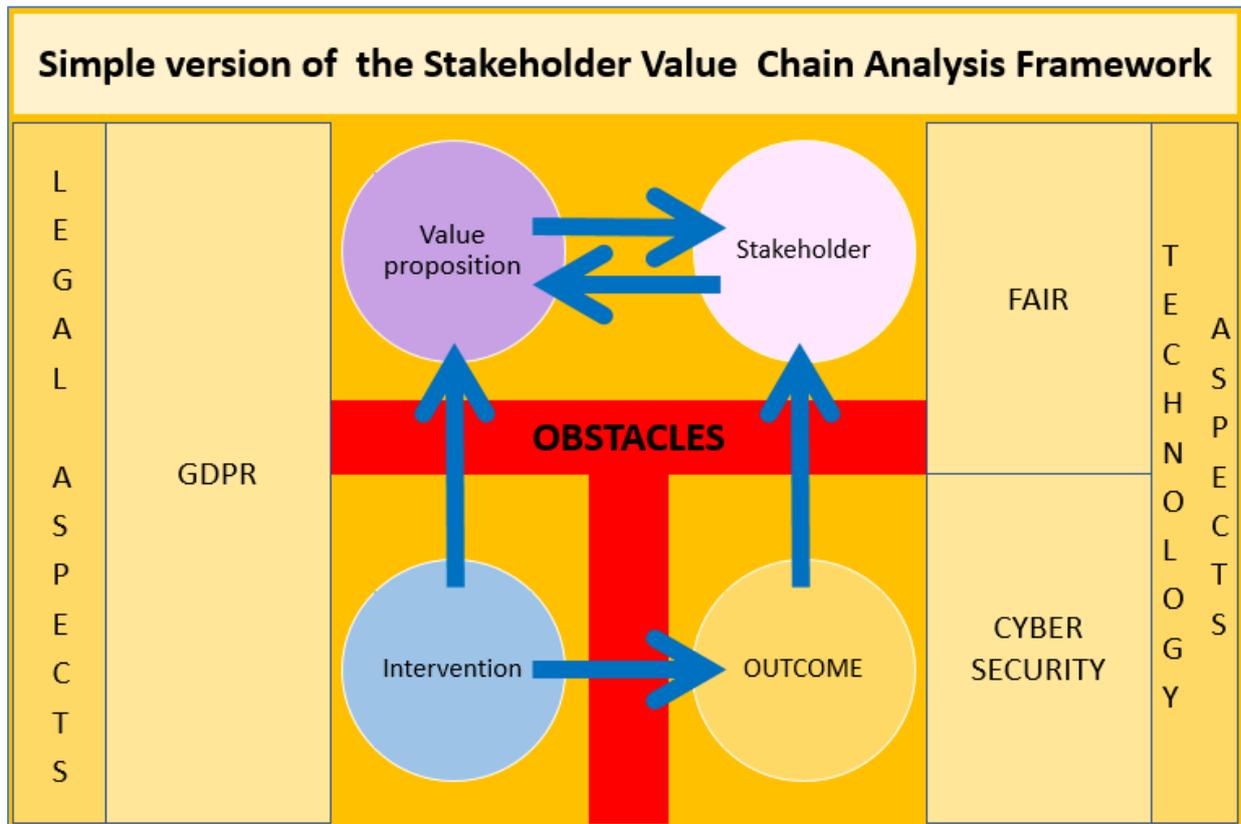
Figure 5 – Stakeholder value chain analysis framework for data conversion
(Simple and complex versions)

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

2   The state of play in innovative use of health data

D5.1 took into consideration existing recommendations of policy documents such as the EU Study; the OECD Ministerial Statement of 17 January 2017, and the guidelines and communications of the European Commission on Artificial Intelligence.

The results of the WP-5 survey, summarised in section 2.2.2, show that most statements about challenging issues, as well as recommendations to mitigate them, are still relevant.

However, before going into detail about the survey findings, we are bound to pay some attention to the relationships between innovative use, primary use and secondary use of health data. While this issue has been relevant for quite some time, its importance is rapidly growing, due to the dramatic changes induced by digitalisation of healthcare delivery and the exponentially growing quantity of available health data.

2.1   Innovative use of (health) data

One of the objectives of WP5 is to 'provide a way for public health promotion, preventive measures and care from the analysis of big data across healthcare sector and following FAIR data (i.e. Findable, Accessible, Interoperable, Reusable) and patient-curated data principles'[17]. In many cases the term 'innovative use of health data' is defined as secondary use of health data and big health data. However, it is worth considering if there is a tangible border between primary and secondary use, or there are other data usable for primary and/or secondary use.

We use the working definitions in accordance with the provisions of Regulation (EU) No 282/2014 establishing the third Programme for the Union's action in the field of health (2014-2020)[18]. The regulation underlines that innovation in health should be understood as a public health strategy which is not limited to technological advances in terms of products and services.

Therefore, innovative use of health data, regardless of whether the use is primary or secondary, fosters innovation in the field of public health interventions, prevention strategies, health system management and in the organisation and provision of health services and medical care, including health promotion and disease prevention interventions. It has the potential to improve public health outcomes, enhance the quality of care to patients and respond to unmet needs, and also to foster the competitiveness of stakeholders and to improve the cost-efficiency and sustainability of health services and medical care.

Following this approach and definition, we can define priorities for selecting enabling actions to increase awareness and commitment to foster Member States/countries to exploit advantages offered by data analytics techniques.

Use cases for the prioritised fields of the enabling actions can be selected by identifying innovations delivering gains at the varying areas listed above. Higher priority can be awarded to those cases which deliver gains in more areas while using less resources at minimum risk.

2.2 Needs, barriers, drivers, challenges, opportunities and goals

Accordingly the method we chose, policy relevant documentation, including the EU Study and the effects of GDPR, as well as the review of Member State/country policy level efforts on

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[17] Application form - Part B, pp 33.
[18] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0282

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

governing big data in health, was compiled through the identification and assessment of stakeholders' goals, needs, drivers, challenges and opportunities.

2.2.1 Challenged recommendations and objectives

Guided by the intention to fill the gap between existing strengths or opportunities and weaknesses or threats, most available policy recommendations reflect primary expectations from big data and from the use of health data.

We detected challenges faced by Member States/countries in implementing existing recommendations, guides and guidelines on the better/wider/innovative use of data, big data, artificial intelligence (AI), and machine learning (ML) in health.

Mapping barriers and obstacles preventing Member States/countries replicating available good practices and policy recommendations on improving innovative use of big data in health and healthcare is the initial step to prepare practical guidance to foster innovative use of health data.

As barriers and obstacles are related to use cases, value creation (or engineering) and meeting expectations or utilising recommendations and following regulation or guidelines, the following issues were examined and assessed by using the methods introduced above:

- Use cases and the added value of big data and AI, effects of GDPR, and implications of the FAIR data principles (as key conditions derived from special rules and guidance);

- Expectations and existing recommendations.

Major challenges facing GDPR, FAIR data and patient-curated data principles are detailed in 'Appendix A - Mapping practical barriers and obstacles'.

The task of mapping, awareness raising, and policy relevant actions on innovative use of big data in health was based on identifying obstacles and barriers that prevent the satisfaction of the expectations related to the recommendations of the following documents:

- Study on Big Data in Public Health, Telemedicine and Healthcare - 2016 (EU Study);
- Ministerial Statement on 'The Next Generation of Health Reforms' of the OECD Health Ministerial Meeting, 2017;
- Relevant guidelines and communications of the European Commission on Artificial Intelligence.

A summary of these documents is available in 'Appendix B - Expectations and existing recommendations'. The findings about the challenges are introduced in the following sections.

2.2.2 WP5 online survey

The work on a task level within WP5 followed the logic of 'expectations - obstacles - relevant actions', and thus identifying the main obstacles and barriers that prevent the fulfilment of those expectations.

The work took into consideration the following recommendations which reflect the most important expectations on big data and AI set out by:

- EU Study recommendations 1-10

- OECD Ministerial Statement

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

• Recent European Commission communications and guidelines on AI.

2.2.2.1 Study on Big Data in Public Health, Telemedicine and Healthcare (EU Study)

The aim of the EU Study was to identify applicable examples of the use of Big Data in Health and develop recommendations for their implementation in the European Union.

The recommendations aim to benefit European citizens and patients in terms of strengthening their health and improving the performance of Member State health systems. They should be seen as suggestions for the European Union and its Member States on how to utilise the strengths and exploit the opportunities of Big Data for Public Health without threatening privacy or the safety of citizens.

Recommendations were developed for 10 relevant fields (see appendix B.1 - Study on Big Data in Public Health, Telemedicine and Healthcare for the detailed list of recommendations):

- awareness raising,

- education and training,

- data sources,

- open data and data sharing,

- applications and purposes,

- data analysis,

- governance of data access and use,

- standards,

- funding and financial resources,

- legal aspects,

- privacy regulation.

The EU Study covers the topics of big data applications in public health and innovations before 2016. These topics overarch technical, legal, awareness, scientific issues, etc. Effects of GDPR and implications of the FAIR data principles are partly assessed or touched upon by the recommendations of the study.

The authors suggested to also consider the following general notions regarding their policy recommendations:

- The scope was to give suggestions for the EU and its Member States on how to utilise the strengths and exploit the opportunities of Big Data for Public Health without compromising privacy or safety of citizens.

- Big Data in Health should not be seen as a goal in itself, but as a tool to reach certain purposes that benefit the patient and the public.

- Current ethical standards must not be weakened or compromised for potential benefits of Big Data.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- Stakeholders need to be included in the implementation of any recommendations in the field. This is especially true for patients (represented by their advocacy groups), who ultimately have to give support to the use of Big Data in Health.

The result of the mapping showed that three general obstacles appeared as reasons slowing down or hampering translation of policy-level recommendations into actions: lack of trust, legal uncertainties, and lack of funding and financial resources.

Based on the first findings of the WP5-survey and the results of the workshop in Prague, the implementation of 9 out of 10 recommendations of the EU Study is still a challenge (less challenge was experienced for Recommendation 8 on Standards).

Assessing WP5-survey responses about the progress in implementing recommendations, it can be highlighted that the highest level of challenges appeared for 'Open Data and Data Sharing' and 'Education and Training'. Less, but still considerable challenge appears for 'Governance of Data Access' and 'Data Analysis'.

The workshop in Prague added to this picture that a new interrelated chain of obstacles (consisting of funding-legal-trust) seems to dominate the scene; this phenomenon needs further elaboration with Member State/country representatives as well as the main players in the concerned stakeholder sector.

Trust in data provision (FAIR) and data privacy, integrity, security and protection (GDPR) seems to be the main barrier – which can be eliminated by setting a clear legal framework (both on Member State and EU level), clearly defining things, especially like data ownership and sharing, access, value and utilisation rights as well as all financial and economic implications.

Generally, we experienced that Member States have achieved some progress on most of the recommendations, but results are mainly fragmented and are not part of an adeptly implemented large scale strategy. In several fields, the Member States are just facing the challenge and endeavouring to depart on the road of execution (See: Figure 6 – Challenges and progress in implementing recommendations of the EU Study).
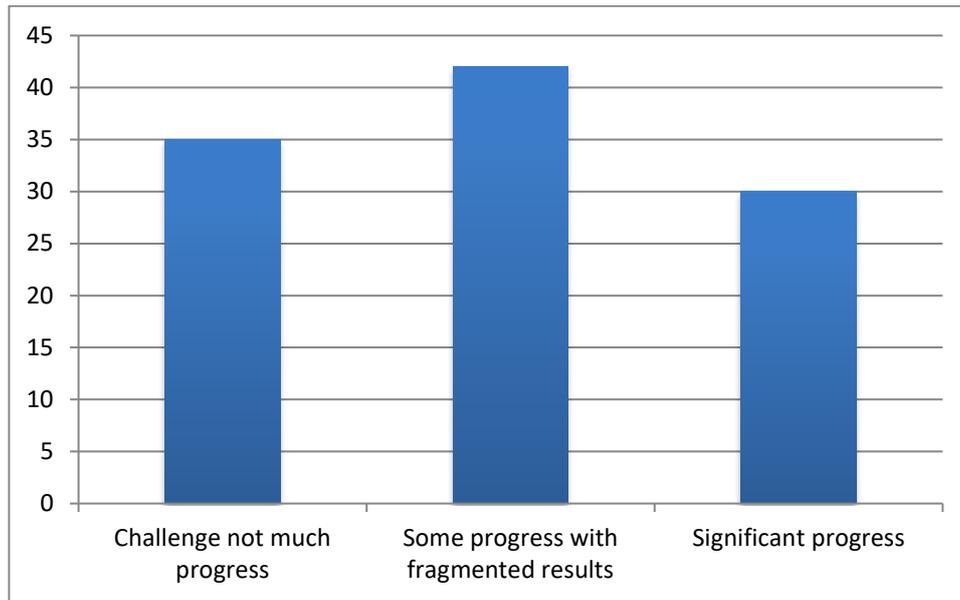
Figure 6 – Challenges and progress in implementing recommendations of the EU Study

Answers, such as 'not important in my country', 'lack of stakeholders' support' and 'lack of financial resources' appeared with almost equal weights. After eliminating redundancies caused by multiple responses from one country, 'unconcern' (disinterest) is the most dominant cause of impeding progress. (See: Figure 7 – Barriers in implementing recommendations of the EU Study)
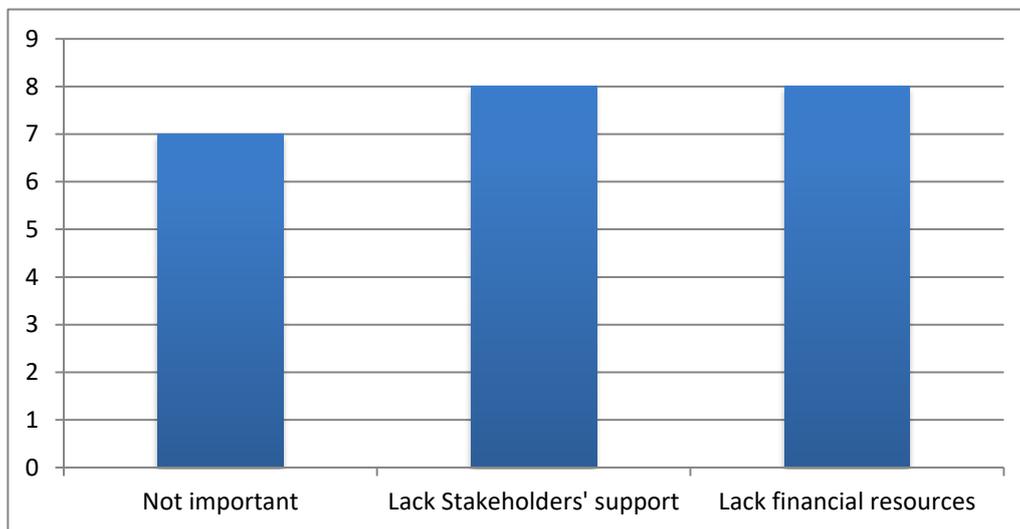
Figure 7 – Barriers in implementing recommendations of the EU Study

Going into a little more detail of the 10 recommendations, Member States in the sample are mainly at an infancy phase of 'Open Data and Data Sharing', 'Education and Training' and 'Governance of Data Access and Use'.

We received most 'moderately positive' responses for 'Data Analysis', 'Legal Aspects and Privacy Regulation' (due to the implemented GDPR); also 'Education and Training', 'Data Sources' and 'Standards'. Results of the survey show that 'significant progress' responses were

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

distributed almost evenly (see Table 1 – Progress and challenges in implementing recommendations of the EU Study and **Error! Reference source not found.**).

Progress weight		1	2	4			
Challenge Weight		4	2	1			
		Progress					
No.	Recommendation	Not much progress	Some and fragmented progress	Significant progress	scores	Level of Progress (LoP)	Level of Challenge (LoC)
04.	Open Data and Data Sharing	7	3	3	13	1,92	2,85
02.	Education and Training	6	5	2	13	1,85	2,77
07.	Governance of Data Access	5	1	4	10	2,30	2,60
03.	Data Sources	3	5	2	10	2,10	2,40
06.	Data Analysis	3	7	2	12	2,08	2,33
01.	Awareness Raising	3	3	4	10	2,50	2,20
05.	Applications and Purposes	3	3	4	10	2,50	2,20
09.	Funding and Financial Resources	3	4	4	11	2,45	2,18
10.	Legal Aspects and Privacy Regulations	2	6	4	12	2,50	2,00
08.	Standards	0	5	2	7	2,57	1,71
Av.	Average	3,5	4,2	3,1	10,8	2,25	2,36

Table 1 – Progress and challenges in implementing recommendations of the EU Study

Looking at the fields with a micro view, 'standards' were mentioned most, despite the fact that some Member States have also achieved some progress.

Assessing responses about the progress in implementing recommendations, it can be highlighted that the highest level of challenges appeared for 'Open Data and Data Sharing' and 'Education and Training'. Less, but still a considerable challenge appears for 'Governance of Data Access' and 'Data Analysis' (see**Error! Reference source not found.**).

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Chart legend:
- Level of Challenge (LoC)
- Level of Progress (LoP)
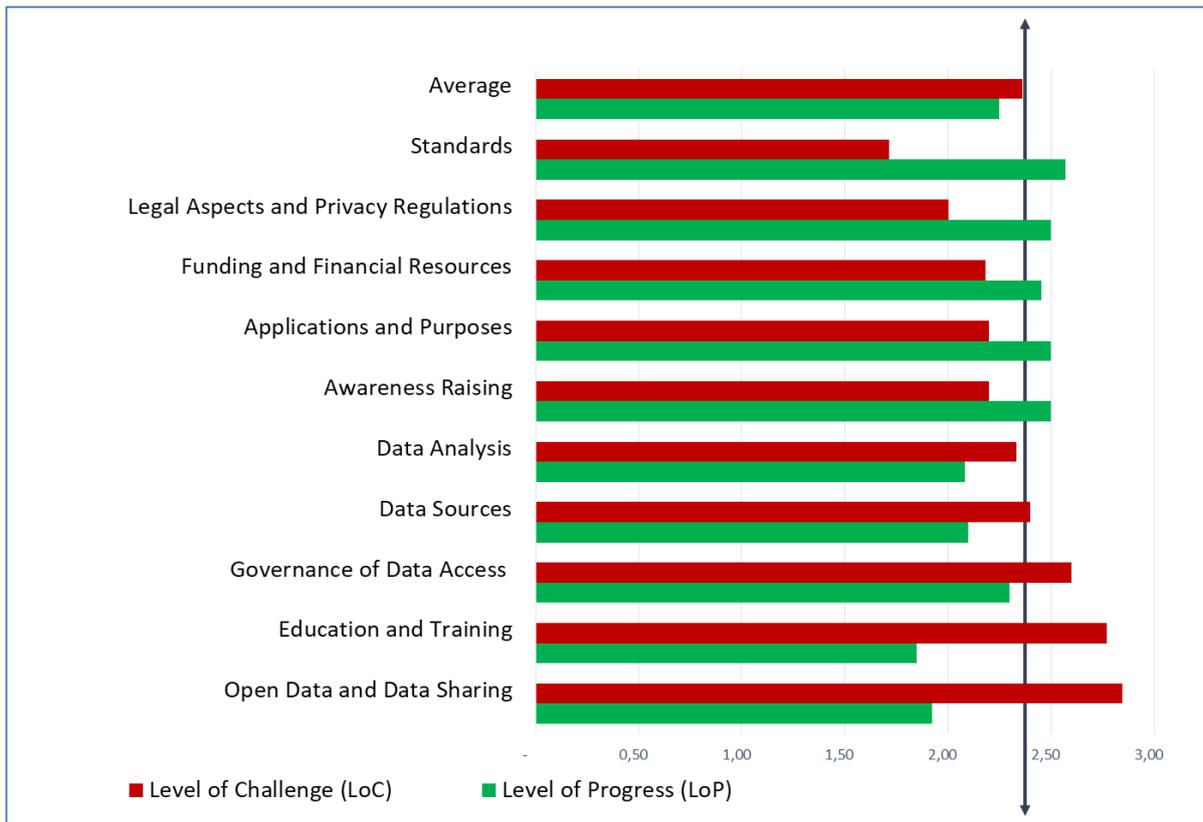
2.2.2.2   OECD Ministerial Statement, 17 January 2017

Relevance and challenges concerning following recommendations were asked in the WP5 online survey:

- *OECD health ministers' recommendation 1 on 'Establishing national health data governance frameworks':* Governments establish and implement a national health data governance framework to encourage the availability and use of personal health data to serve health-related public interest purposes while promoting the protection of privacy, personal health data and data security.

- *OECD health ministers' recommendation 2 on 'Harmonising frameworks between countries':* Governments support trans-border co-operation in the processing of personal health data for health system management, research, statistics and other health-related purposes that serve the public interest subject to safeguards consistent with this Recommendation.

In this section, surveyed Member States were either at the starting line or reported significant progress. Based on detailed answers, progress is much more on the 'theoretical' level with shared ideas and not in implementation. The most important barrier is the lack of stakeholder support, which emphasises the importance/significance of more frequent joint discussions and aligning interests and arguments.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

2.2.2.3 Guidelines and communications of the European Commission on Artificial Intelligence

The European Council of October 2017 stated that the EU needs a sense of urgency to address emerging trends such as AI 'while at the same time ensuring a high level of data protection, digital rights and ethical standards' and invited the Commission 'to put forward a European approach to artificial intelligence' that was set out in the Communication from the European Commission 'Artificial Intelligence for Europe' that urged European leaders to put AI at the top of their agendas.

Results of our survey show that Member States started using AI at almost all fields listed in our survey, which conveys a good message. The most prominent achievements are for the diagnosis and treatment protocol development. Meaningful areas are patient monitoring and health. At the same time there are huge opportunities and significant fields to develop (see Figure 8 – Achievements in implementing recommendations of the EU Study).
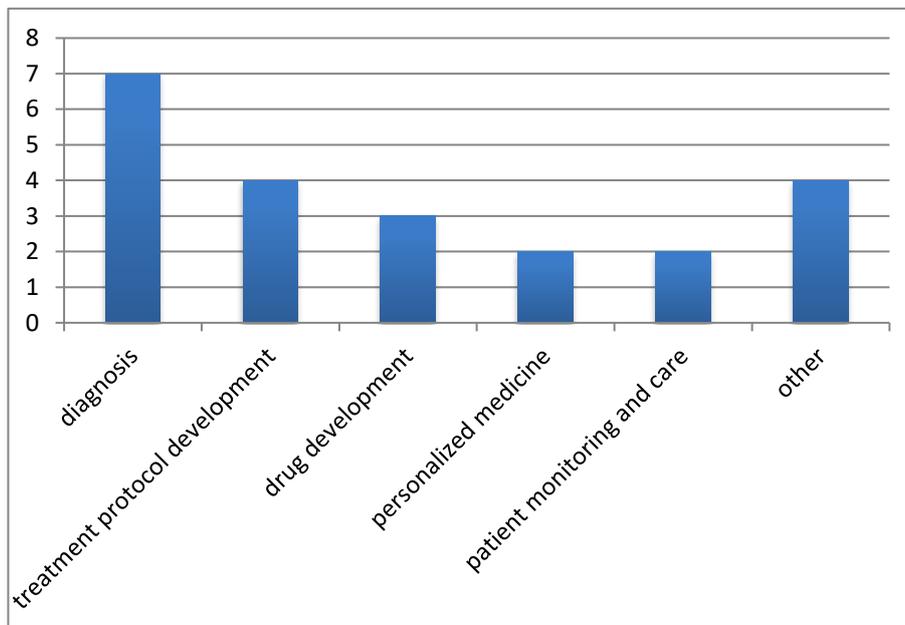
Figure 8 – Achievements in implementing recommendations of the EU Study

AI is seen as a tool operating in the service of humanity and the public good, aiming to increase individual and collective human well-being. Since people will only be able to confidently and fully reap the benefits of a technology that they can trust, AI's trustworthiness must be ensured.

Based on fundamental rights, ethical principles as well as the used Guidelines, seven key requirements that AI systems should meet in order to be trustworthy were listed[19] (see Figure 9 – Key requirements or prerequisites for using AI):

- Human agency and oversight,
- Technical robustness and safety,
- Privacy and data governance,
- Transparency,

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[19] https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines/1#Human%20agency

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- Diversity, non-discrimination and fairness,

- Societal and environmental well-being,

- Accountability.

Member States mentioned privacy and data governance as the most important requirements or prerequisites for using AI. Technical robustness and safety are also important, pointing out the significance of cybersecurity issues.
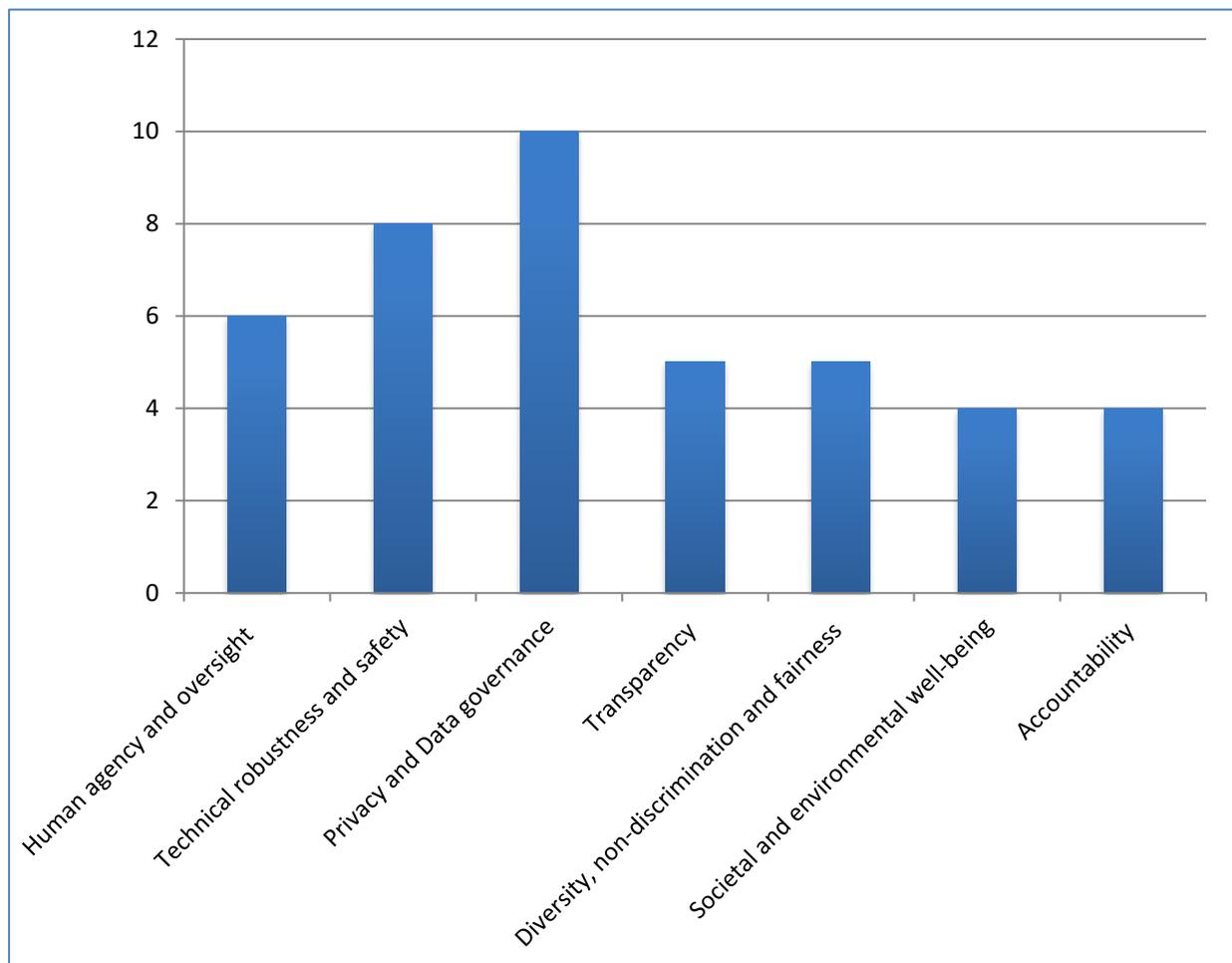
Figure 9 – Key requirements or prerequisites for using AI

We also tried to identify the most important barriers to adopting AI (see Figure 10 – Key barriers to adopting AI).

We experienced that in most Member States stakeholders are concerned about the effects on the job market, and business models are still not clear. Moreover, another very important issue is trust, which re-justifies the conclusions made in the previous part above that Privacy and Data governance and Technical robustness and safety have utmost significance.

Member States also mentioned 'other cases' which mainly refer to lack of information and knowledge (e.g. 'in my country AI is still not well known, citizens are not informed and have no opinion').

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020
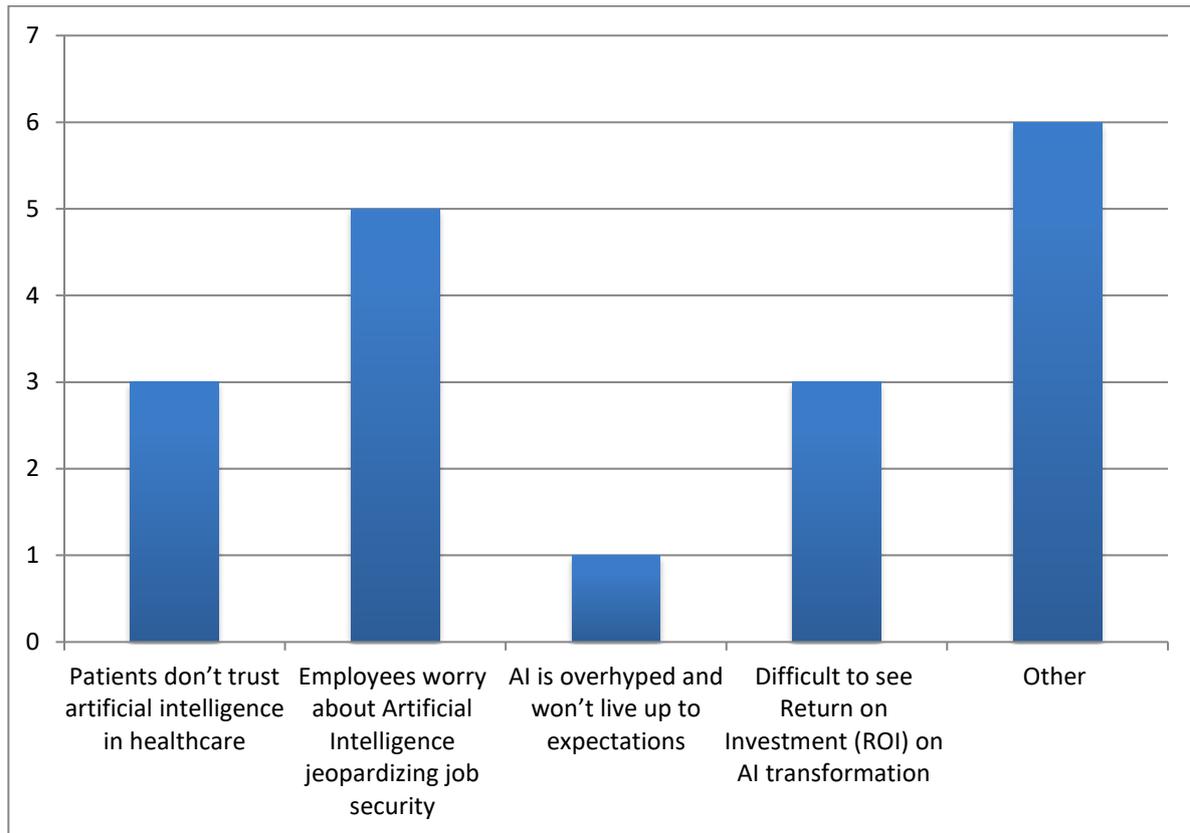
Figure 10 – Key barriers to adopting AI

2.2.3 Challenges identified

During the preparation for the workshop, as well as the common work at the event, participants identified what the most challenged recommendations, guides and guidelines on the better/wider/innovative use of data, big data, AI, ML in health were.

Challenges have been traced and assessed at every link in the Data Conversion Value Chain. These challenges are related to the way of solving potential problems caused by underperforming functions working at the links in the chain. It has been essential to explore the effects, root causes and required resources of the biggest challenges appearing at the implementation of recommendations on 'Open Data and Data Sharing', 'Education and Training', 'Governance of Data Access' and 'Data Analysis'. Challenges in these four fields, one-by-one, do not affect all the links. However, together they have an impact on the whole chain. One challenge related to the utilisation of open data is that it in order to be open it has to be aggregated and anonymous, which does not enable deeper analysis. This will be tackled later in the report.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

2.2.3.1 First findings delivered by WP5 workshop in Prague (September 2019)

Challenged recommendations

Challenges faced in 'Open Data and Data Sharing' can significantly affect capturing, cleaning, storing, updating and sharing data for innovative purposes. Underperformances in these links have a negative impact on all use cases by making reliable data less available.

Challenges to 'Education and Training' can have the strongest effect on stakeholder empowerment, stewardship, value creation and visualisation. Most affected use cases are client-to-provider and provider-to-provider telemedicine and targeted client communication. However, optimisation and decision-making focused use cases are also affected.

Uncompleted measures aiming at improvement of 'Governance of Data Access' affect security, privacy and sharing issues. Unaddressed challenges do harm not only to research but increase costs and reduce efficiency of prediction or decision systems as well.

Querying and reporting can be seriously affected by the troubles and lag in fostering 'Data Analysis'. Delay or lack in improving the use of analytical tools and methods leads to less effective and efficient performance at individual, organisational and system level.

Effects

The effects of the European General Data Protection Regulation (GDPR) and implications of the FAIR data principles were partly assessed or touched by the recommendations of the EU Study. Expectations and recommendations on privacy and data ownership or the purpose of data collection, as special cases, are worth being examined prior to other cases, since they determine the possibility and opportunity to use data at all.

One of the most interesting areas of GDPR is consent, as it is one of the legal bases for data processing but it is restricted under the GDPR, and must be 'freely given, specific, granular, informed, explicit and unambiguous.' This set of requirements raised the question whether GDPR was an obstacle to data sharing and use, or whether it was a promoter and might have positive effects. This question was also raised in a blog by the Office of Science Policy (NIH, US)[20] in March 2019. The blog ends with a complex response: 'GDPR presents us with great opportunities as well as challenges: 'If we can harmonise consent and data sharing between U.S. and EEA researchers, we will be able to pool analysis of genomic and other health data and tissue samples, powering new and innovative trials and advancing the science of the future.' This response matched one of the conclusions of the workshop, where experts agreed that legal uncertainties created delays in the implementation of recommendations or even increased them.

WP5 agrees that meeting GDPR requirements means a lot of work, time, cost and risk, however, there are opportunities too. Preparing specific, granular and unambiguous consent supports

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[20] https://osp.od.nih.gov/about-us/

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

primary and secondary use of data, artificial intelligence and analytics projects. Success, however, also depends on managing a data science team[21] by:

- Building trust and being candid

- Creating a specialised team of best experts

- Developing a culture that will support a steady process of learning and experimentation

- Connecting the work to the goals the project owner has

- Positioning data science as its own entity

- Equipping the data scientists with all the technical resources they need

- Ensuring proper funding for the above actions.

What does it mean? There is big potential in the Guidelines on Consent under Regulation 2016/679 (wp259rev.01)[22]. Preparing proper consent and making use of the above advice on managing a data science team have several common features.

Differences between legal systems may narrow the space for designing and implementing successful innovative use of health data. Policy measures provide assistance for innovators to prepare a proper offer for consent by adopting a data analytics strategy based on the above recommendations, originally developed for business and science, can give significant help to all stakeholders.

Initiatives and results of the 'My Health My Data' (MHMD) project,[23] together with FAIR data principles, are additional potential drivers for facilitating innovative use of health data.

MHMD – as well as any familiar national, regional or transregional and cross-border eHealth digital service infrastructure – can be a good practice for satisfying multiple needs of:

- building and maintaining the 'storage of care provider datasets in their original, identifiable form in local repositories, while securely exchanging them with third parties, in de-identified form' (e.g. through blockchain);

- complying with the right of data portability and consent set out in the GDPR;

- allowing patients to keep and access a digital copy of their medical records;

- making it possible to aggregate any Internet of Things (IoT)- and mobile app-data related to health, fitness and well-being (and switching this aggregated data to their copied personal data account);

- providing availability, from anywhere and at any time, for receiving medical care or other personal use, as well as research or innovation, or ensuring possibility to share it in exchange for services or reward through dynamic consent;

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[21] https://hbr.org/2018/10/managing-a-data-science-team

[22] https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051

[23] https://mydata.org/ and http://www.myhealthmydata.eu/

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- facilitating researchers 'in the identification and lawful access to highly curated and harmonised big data resources for their everyday work, avoiding expensive and time-consuming intermediation' through appropriate technology (e.g. blockchain) and access protocols.

In 2016, an article in Nature titled 'The FAIR Guiding Principles for scientific data management and stewardship' launched the FAIR concept[24]. Since 2016, the principles of this concept have been used as an international guideline for high quality data stewardship. However, implementing FAIR Data has impacts and implications for people and machines. The concept is highly recommended for anyone interested in effective data sharing in any sector. It is also worth mentioning that the launch of the FAIR concept can be linked to the activities of Research Data Alliance (RDA) too. RDA builds the social and technical bridges to enable the open sharing and re-use of data. Quoting the RDA website[25]: 'The Research Data Alliance (RDA) was launched as a community-driven initiative in 2013 by the European Commission, the United States Government's National Science Foundation and National Institute of Standards and Technology, and the Australian Government's Department of Innovation with the goal of building the social and technical infrastructure to enable open sharing and re-use of data.' RDA's Health Data Interest Group (HDIG), for example, has been dealing with topics such as 'Artificial Intelligence (AI) in Hospitals and research: towards a large-scale health data sharing ecosystem' (24 June 2019) or 'Health Data Privacy & Security issues', 'Health data mapping and diverging trends in health data protection' and 'Meaningful health data for research and for industry'[26]. HDIG also dealt with identifying barriers to share research data (26 April 2019)[27].

Taking part in the FAIR4HEALTH project[28], HDIG members contributed to delivering 'Guidelines for implementing a FAIR data policy in health research'[29]. Based on the findings of FAIR4HEALTH's guidelines, we can collect and assess challenges in the 'FAIRification workflow' context (see Figure 11 – FAIRification workflow).

We should make a difference between open data and FAIR data. The key difference is that open data should be available to everyone to access, use, and share, without licences, copyright, or patents. It is expected that open data at most should be subject to attribution/share-alike licences. FAIR data, however, uses the term 'Accessible' to mean accessible by appropriate people, at an appropriate time, in an appropriate way. This means that data can be FAIR when it is confidential, when it is accessible by a defined group of people, or when it is accessible by everyone (open data). It depends completely on the purpose of the data, where the data currently is in its lifecycle, and the end-usage of the data.[30]

Both initiatives can help with building the missing trust towards data utilisation. The question is how to govern the standardisation and elevation of these efforts to EU level. Patient empowerment is tackled in WP4 of eHAction, while reliability and interoperability is dealt with

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[24] https://www.nature.com/articles/sdata201618

[25] https://www.rd-alliance.org/about-rda

[26] https://www.rd-alliance.org/artificial-intelligence-ai-hospitals-and-research-towards-large-scale-health-data-sharing-ecosystem

[27] https://www.rd-alliance.org/group/health-data-interest-group/post/identifying-barriers-share-research-data

[28] https://www.fair4health.eu/

[29] https://www.fair4health.eu/storage/files/Resource/18/FAIR4Health%20ICIMTH2019_Final.pdf

[30] https://www.go-fair.org

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

in WP7. Further analysis of the evergrowing potential use of health data is needed to be sure the ethical approach is applied by design.

Reasons, root causes and barriers

Participants of the joint WP7-WP5 workshop in Prague (September 2019) finalised and tested the stakeholder value chain analysis framework designed to find and analyse barriers, reasons and root causes, which led to the identified challenges in implementing policy recommendations or replicating good practices. The first findings were that 'lack of trust', 'legal uncertainties' and 'lack of funding and financial resources' had the biggest influence on slowing down or hampering translation of policy-level recommendations into actions. The workshop was followed by a full WP5 teleconference, where further input was gathered on the framework.

Root causes of 'lack of trust', 'legal uncertainties' and 'lack of funding and financial resources' were assessed in two steps. First, experts attending the workshop in Prague matched objectives and needs of stakeholders with imbalances among drivers of their evaluation. Second, Member States/countries were asked to complete a questionnaire after the workshop.In several cases the above-mentioned three reasons hide imbalances in health systems (e.g. lack of professionals is treated by recruiting the same persons in two or more organisations). This can lead to loss and duplication of data occurring at the same time if professionals cannot enter data in all the IT systems they should because of identification problems. In other cases, legal uncertainties concern both sharing and accessing data.

2.2.3.2   Additional analysis and findings – the WP5 canvas tool

The stakeholder value chain analysis framework for data conversion

The information for the analysis was collected by a tool identifying key stakeholders, their needs, goals, offers/evaluation, behaviour and attitude, as well as interdependencies, obstacles and possible interventions and results to be expected. The form of the tool was a questionnaire designed to collect and provide information for further assessment through a canvas which allows for rendering of 2D shapes and mapping.

Using this canvas tool, named 'the stakeholder value chain analysis framework for data conversion' (in short: Data Conversion Framework or DCF tool) WP5 mapped privacy aspects, as well as by identified obstacles that prevent Member State/country policies from being replicable either in other Member States/countries or on an EU level. (Figure 5 – Stakeholder value chain analysis framework for data conversion).

Further explanations of the DCF tool, such as descriptions of the stakeholder groups and the different factors, can be found in appendix Appendix C - DCF-canvas tool (questionnaire).

The framework has outlined interdependencies with the dysfunctions challenging the strength of the Data Conversion Value Chain. Further interdependencies were outlined among innovative use of health data, patient empowerment, digital health skills of professionals and other use cases of interoperability. Focus was put on the tool on detecting obstacles preventing Member States/countries to implement available recommendations and guidance for increasing innovative use of health data and big data. Thus, it helped in elaborating compiled policy-relevant documentation on governing big data in health.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

The countries participating in the survey (see appendix C.3 - Countries participating in the survey) were asked to fill in and submit the canvas pointing out to the main goals, needs, obstacles possible interventions and result in connection with four recommendations of the EU study. We experienced that Member States/countries achieved some progress and faced challenges on most of the 10 recommendations. The highest level of challenges or concerns particularly appeared at implementing recommendations on

- 'Open Data and Data Sharing',

- 'Education and Training',

- 'Governance of Data Access' and

- 'Data Analysis'.

Using the framework tool (canvas), the intention was to obtain information about the reasons and the root causes why these challenges occur.

We asked Member States/countries to examine the causes from the perspective of three key stakeholder groups:

- patient/citizen,

- care provider,

- payer.

The framework was built up based on following logic: Objectives/use cases – Needs – Value propositions – Objectives – Interventions – Results.

Main findings of the WP5 canvas tool (DCF)

It was possible to identify the key drivers on how 'initial offerings' (as a specific value propositions, e.g. policy recommendations) were valued by the stakeholder who gets them. The result of this assessment was the first step to find reasons behind obstacles (see Table 2 – Drivers how 'initial offerings' are valued by stakeholders).

Findings of the canvas supported the presumption that stakeholders, while they could well define advantageous features (differentiators) that positively distinguish an offering from the competition, had difficulties to identify a trade-off. Of course, it is not easy to find and sacrifice things as a dissatisfier that can be interesting or valuable for other stakeholders. Generally, such a situation leads to imbalance among the drivers. According to our results, it was the case for the use of health data and recommendations for fostering innovative use.

Using the DCF canvas tool, WP5 managed to identify root causes of obstacles preventing the growth of innovative use of health data in Member States/countries, reinforcing the results of our first survey and our research based on contemporary literature. Root causes were found by detecting and assessing imbalance among non-negotiables, differentiators and dissatisfiers challenging the implementation of recommendations. The result of the assessment is summarised in Table 3 – Root causes of obstacles.

Assessing the information collected by the DCF tool let us detect opportunities, recommendable interventions and desired solution as well (see Table 4 – Opportunities for interventions). Possible interventions recommended in this table served as basis for our final conclusions and recommendations introduced in D5.1 section 3.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

The following three tables summarise the process through which WP5 arrived to potential interventions (Table 4 – Opportunities for interventions) from drivers (Table 2 – Drivers how 'initial offerings' are valued by stakeholders) through obstacles (Table 3 – Root causes of obstacles). Further information about DCF and the collected answers are available in 'Appendix C - DCF-canvas tool (questionnaire)'.

	Non-negotiables	Differentiators	Dissatisfiers
Patients /citizens	- Availability of healthcare services - Data security, safety and privacy assured by clear regulation - Right to access data, consent, disposal and ownership - Receiving education on data sharing and access	- Efficiency gains (i.e. shorter waiting times) - Data representation (easier to comprehend) - Availability of better treatment or services - Getting user friendly and ergonomic devices, apps - Get benefits from RDI (intellectual property, fee, knowledge, better care conditions)	- Sacrifice intimacy - Spend time to learn about rights, usage of information and digital services, solutions, apps and improved systems - Higher expenses for better (advanced) treatment or services - Participating in RDI projects
Care providers	- Availability of resources (financially and physically) - Availability of data relevant, accessible and useful for a specific purpose (via metadata, user profiles...) - Availability of relevant, comprehensible and useful education (for the given audience) - Transparent, well defined governance (unambiguous power and responsibilities)	- Efficiency gains (saving time in providing and accessing data) - Enhance working processes to save time, resources and money - Availability of better (evidence based, approved) treatment protocols, equipment and (skilled) staff - Access to data collected by other care and RDI institutions or professionals	- Legal and administrative burdens (patients' information requests on data processing cases) - Invest time & money (for capturing FAIR data, using data, interpretation of analytical deliverables, education and training - Share collected data by other care and RDI institutions or professionals - Spending time to provide information to patients to increase

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

	Non-negotiables	Differentiators	Dissatisfiers
		- Get benefits from RDI (intellectual property, wages, knowledge, better working conditions)	trust, adherence, (digital and/or health) literature and empowerment
Payers	- Have public trust in the funding and data exchange system in general - Availability and accessibility of quality data (health, healthcare and general) - Effective and efficient spending of resources, including funds and data - Transparent, well defined regulation	- Customised analytical algorithms and tools - specific for payers - Access to data collected by care and RDI institutions or professionals and other payers - Possibility to use personal data for secondary use - Long term benefits of time & cost saving - Get benefits from RDI (intellectual property, fees, knowledge)	- Invest time & money to capture, use and analyse FAIR data, interpret analytical deliverables, education and training - Hire/pay qualified staff (data analysts etc.) - Spend time to provide information to stakeholders to increase trust, adherence, (digital and/or health) literature and empowerment - Spend time and money on approving and implementing new processes and protocols

Table 2 – Drivers how 'initial offerings' are valued by stakeholders

	Trust	Regulation	Funding
Open data and data sharing	▪ Lack of willingness ▪ Comprehensive data is not available ▪ Fear of abuse	▪ Misunderstanding needs of stakeholders ▪ Lack of knowledge about technology at policy making and regulatory levels	▪ Uncertain total costs of meeting GDPR and FAIR data requirements ▪ Lack of political support

	Trust	Regulation	Funding
Education and training	▪ Resistance to learn ▪ Lack of motivation for further education ▪ Lack of resources (not only financial, but trained personnel as well) ▪ Lack of expertise	▪ Unclear interpretation of legal framework ▪ Lack of commonly understood and accepted success factors for health system transformation	▪ Uncertain total costs of meeting the need for skilled personnel (uncertainties about the level of digital health literacy of key stakeholders)
Governance of data	▪ There is a significant amount of data still kept somewhere in paper format. ▪ Unmet need about transparency in capturing, cleaning, storing, sharing or using data	▪ Lack of commonly accepted standards ▪ Unclear impacts of data availability, sharing, storage and accessibility (uncertainties in liability control) ▪ Lack of support (due to lack of awareness) of key stakeholders	▪ Uncertain efficiency of standards ▪ Unclear impacts of data availability, sharing, storage and accessibility (efficiency)
Data analysis	▪ Misunderstanding the difference between analysis and reporting ▪ 'Transparency paradox'[31] (transparency makes methods vulnerable while it can help mitigate issues of fairness, trust and discrimination,)	▪ Uncertainties about implications and unclear impacts on: - intellectual property issues - fairness - safety - security - trust - liability - algorithmic transparency - social inclusion.	▪ Uncertain costs of protecting transparent methods against attacks ▪ Unclear impacts of methods (efficiency)

Table 3 – Root causes of obstacles

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[31] Andrew Burt: The AI Transparency Paradox, published on hbr.org, December 13, 2019

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

	Opportunities	Interventions recommended	Desired solutions
Open data and data sharing	▪ Existing international standards, building blocks and technical capacities for exchange data for primary use (care level)	▪ Launch specific funding programmes to reuse and further develop existing and technical capacities for exchange data	▪ Quicker and cheaper breakthrough in use cases offering optimal set of gains ▪ Delivering backbone for further development
Education and training	▪ There are more and more good (even best) practices of varying use cases at different levels ▪ Available funds and programmes ▪ Tangible interest of the industry (corporate social responsibility – CSR)	▪ Launch specific funding programmes to: - foster empowerment, adherence and grit to increase level of knowledge, skills and competences related to sharing and accessing data for analysis and innovation purposes - find use cases that provide optimal set of gains at different levels - process good/best practices for optimised use cases - develop and implement new curriculum and training programmes - prepare and run communication, and dissemination and CSR programmes.	▪ Understand difference between analysis and reporting ▪ Increase knowledge, willingness to learn and understanding needs of stakeholders ▪ Clear positive impacts of methods, procedures, standards, services and products ▪ Higher efficiency in utilising funds ▪ Contribution to successful change management
Governance of data	▪ Scientific evidence, recommendations by international organisations (WHO,	▪ Launch dedicated regulatory programmes to help: - accelerate product, procedure and	▪ Mitigated liability and intellectual property issues, treated trust questions, fear of

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

	Opportunities	Interventions recommended	Desired solutions
	OECD, European Commission, HIMSS)	service development and bring new innovations and advances to patients - mitigate uncertainties about implications and unclear impacts on intellectual property issues, fairness, safety, security, trust, liability, algorithmic transparency, social inclusion.	abuse and 'transparency paradox' ▪ Higher efficiency in utilising funds ▪ Find link that connects secondary use of data to innovative primary use
Data analysis	▪ EU Member States/countries and overseas examples*	▪ Launch dedicated regulatory programmes to offer clarity about the roles of varying agencies in the Member States/countries and the EU.	▪ Clear functions for committed agencies ▪ Higher efficiency in utilising funds

Table 4 – Opportunities for interventions

(*:) Among overseas examples, one should take into consideration that the U.S. Food and Drug Administration (FDA) has been taking incremental steps to update its regulatory framework to keep up with the rapidly advancing digital health market. In 2017, the FDA released its Digital Health Innovation Action Plan to offer clarity about the agency's role in advancing safe and effective digital health technologies and addressing key provisions of the 21st Century Cures Act.[32, 33, 34]

2.2.3.3   Main conclusions on barriers, obstacles and challenges

The answers of the Member States gave us the opportunity to go deeper and have a better understanding about the factors and their interdependencies from the perspective of the selected stakeholders (patients, care providers, payers).

Summarising the results of our analysis, the following conclusions can be considered:

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[32] Roger Kuan: Adopting AI in Health Care Will Be Slow and Difficult, HBR.ORG October 18, 2019, https://hbr.org/2019/10/adopting-ai-in-health-care-will-be-slow-and-difficult

[33] FDA Digital Health Innovation Action Plan: https://www.fda.gov/media/106331/download

[34] The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, USA: https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- Lack of trust and legal uncertainties are highly interdependent. Without adequate regulation patients are more reluctant to give consent to share their data (e.g. FAIR data and patient-curated data principles).

- Lack of trust can be traced back to lack of normative regulation at the state level (over GDPR).

- GDPR in many cases did not accelerate, but rather impeded, the processes at data sharing and processing, and caused confusion in governance of data access (unclear implementation).

- Safety of healthcare data is a major concern in establishing trust over privacy; cybersecurity threat is imminent at several sections of the healthcare data value chain.

- Much data exist in paper format, and databases are not interoperable even on national level; governments also must recognise it and provide funds to enhance digitisation, but there are a limited number of valid use cases.

- Policy makers and market regulators together with stakeholders in the data value chain should set up and understand the business models of healthcare data management to provide enough financial resources in subsidies or in other formats (public-private partnership, etc.); without sustainable business models, results and the inclination to provide broader funding could be constrained.

- Standardisation of data and fulfilment of the criteria of FAIR data principles is in the interest of all stakeholder groups, but it needs time, money and proper design thinking with the right staff; all these are scarce resources.

- There is considerable reluctance to learn at care giver and payer level, due to no clear vision about the short-term benefits of using healthcare data and lack of enough financial resources.

- In most Member States/countries, the level of digital health literacy at patient and care giver level is low, which damages both awareness and trust.

- There is lack of data for scientists participating in big horizontal healthcare projects contributing to successful scientific results and valid business cases which could function as proof to enhance state and EU funding.

- A solid legal environment is a prerequisite to setting up suitable data infrastructure and education/training plans.

- There are unsolved issues of sharing benefits among stakeholders in accordance with consent and ownership and invested time and resources in data capture, store, development, processing, analysis and use (e.g. intellectual property, wages, fees, knowledge, better working or care conditions).

2.3 What is the impact of a broader context?

In the end of the previous section of this report, we managed to draw some fundamental conclusions which are used as the basis for our initial set of recommendations in Section 3.

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

However, in order to prepare our current final conclusions and further work in T5.3, it is worth considering some additional aspects in a broader context as well.

Widening our scope is inevitable, as health digitalisation is not a separate effort; it should be aligned with other changes induced by the Digital Single Market efforts, and also Member State level changes in digitalisation of public administration, as well as developments and interdependencies with other industries (IT, cybersecurity, energy, environment, transport, logistics, etc.). New possibilities and challenges are arising from the continuous upgrading of underlying infrastructure (eIDAS, eHDSI, etc.) and their legal framework.

2.3.1 EU strategies, policies, regulations, directives, communications and guidelines

Do general EU regulations, directives and communications and guides or policies and strategies effect innovative use of health data? To answer this question we have to assess if some existing measures (e.g. Digital Single Market and Open Science Policy, or building blocks) could serve as 'low hanging fruits' for the implementation of our objectives. In addition we had a look at relevant WHO guidelines and communications as well.

2.3.1.1   Digital Single Market (DSM) and Open Science Policy

One of the broadest contexts in which to effect the innovative use of health data is the Digital Single Market concept. Under that initiative, through the use of big data, researchers can help health professionals and health policy makers to identify, simulate, select and monitor the effectiveness of current and new treatments. The most important expectations set by DSM are all relevant for the healthcare industry and advanced health data management:

- Free flow of data

- Data access and transfer

- Liability

- Portability, interoperability and standards

- Experimenting and testing.

Open science policy[35] has developed progressively in the EU. It concerns all aspects of the research cycle, from scientific discovery and scientific review to research assessment, publishing and outreach; its cornerstone is open access to publications and research data. Since 2016, the Commission organises its open science policy according to eight 'ambitions'.

A prerequisite, and also part of the implementation to ensure data access and transfer, portability, interoperability and standards, is the application of the FAIR data model. FAIR is also part of the eight 'ambitions' of open science.

The FAIR data principles detailed in Section 2.2.3 also create a European context. At the implementation on national and international levels it is necessary to determine which funding and business models can make FAIR data sustainable. In December 2018, FAIR4Health, a three-year EU-funded (Horizon 2020), pan-European project, was launched. The overall objective of FAIR4Health is stated as 'to facilitate and encourage the European Union (EU) Health Research

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[35] https://ec.europa.eu/research/openscience/index.cfm

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

community to FAIRify, share and reuse their datasets' using publicly available datasets and show the benefits this will have on this community. The EU could save €10.2 billion per year overall by using FAIR data.[36]

The 'Cost-benefit analysis for FAIR research data' publication[37] provided evidence to decision makers for setting up short- and long-term actions pertinent to the practical implementation of FAIR principles. This report formulates 36 policy recommendations for cost-effective funding and business models to make the FAIR data model sustainable useful in healthcare as well, especially:

- Think beyond organisations and disciplines. Cross-disciplinary fair data use cases have the potential to create positive externalities, spill-over effects and innovation.

- Use emerging technology, such as artificial intelligence and robotic process automation for automating and industrialising repetitive, standardised and time-consuming activities, such as data transformation, data classification or assignment of identifiers, to reduce operational costs linked to FAIR implementation.

- Define templates for service-level agreements with trusted FAIR research data infrastructures will need to comply, for establishing a European baseline for service quality.

- Provide paid data analytics services targeting different customer segments.

- Charge big industry players for access to data.

- Provide a FAIR data certification.

- FAIR research data infrastructure must be encouraged and supported via fiscal incentives and policy interventions to explore mixed models (public funding plus revenues).

European Research Infrastructures are facilities that provide resources and services for research communities to conduct research and foster innovation. The Commission does this while cooperating closely with EU countries and countries associated to Horizon 2020.[38] These funds can be used in healthcare also, in the innovative use of datasets. An example for Research Infrastructure project in healthcare is SHARE, which is a survey on health, ageing and retirement in Europe.[39]

In the EU, the public sector is one of the most data-intensive sectors. The re-use of open data can contribute to the development of artificial intelligence and to overcoming societal challenges. The EU open data market is a key building block of the overall EU data economy. On 25 April 2018, the European Commission adopted a proposal for a revision of the PSI Directive (Directive 2013/37/EU)[40], which was presented as part of a package of measures aiming to

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[36] https://www.fair4health.eu/

[37] https://publications.europa.eu/en/publication-detail/-/publication/d3766478-1a09-11e9-8d04-01aa75ed71a1/language-en

[38] https://ec.europa.eu/info/research-and-innovation/strategy/european-research-infrastructures_en

[39] http://www.share-project.org/

[40] https://ec.europa.eu/digital-single-market/en/public-sector-information-psi-directive-open-data-directive

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

facilitate the creation of a common data space in the EU. Public healthcare data could be part of that common data space.

The Directive introduces the concept of high value datasets, defined as documents the re-use of which is associated with important benefits for the society and economy. They are subject to a separate set of rules ensuring their availability free of charge, in machine-readable formats, provided via Application Programming Interfaces (APIs) and, where relevant, as bulk download. Healthcare data is not part of the thematic categories of high-value datasets but it would be an aim to be part of it.

According to the European Commission, health data and data management are crucial when it comes to empowering citizens and building a healthier society. To facilitate the achievement of these goals, the Commission adopted a Communication and a Staff Working Document on Digital transformation of health and care in the Digital Single Market (DSM)[41]. The DSM initiative can be interpreted as a broader framework and context of facilitating the successful transformation of data into innovation in healthcare.

DSM builds on the concept of the common market, intended to eliminate trade barriers between Member States with the aim of increasing economic prosperity and contributing to 'an ever closer union among the peoples of Europe'. Unjustified restrictions on the free movement of data are likely to constrain the development of the EU data economy of which healthcare data is a very important part. A well-functioning and dynamic data economy requires the flow of data in the internal market to be enabled and protected which is true for healthcare data as well.

The first priority of the Communication on Digital Transformation of Health and Care[42] in the Digital Single Market (mentioned above) focuses on citizens' secure access to their health data, also when they are abroad. The goal is to make it possible for citizens to exercise their right to access their health data across the EU, including, inter alia, the interoperability of electronic health record (EHR) systems.

The second priority of the Communication stresses the importance of personalised medicine through shared European data infrastructure. Researchers and other professionals should pool resources (data, expertise, computing processing and storage capacities) across the EU, for better health prevention, faster and more personalised diagnosis and treatment.

The third priority targets the empowerment of citizens with digital tools for user feedback and person-centred care.

Access to healthcare data helps researchers to produce more accurate, faster tests on medicines to be launched on the market.

Examples of projects are:

- Evotion project - on hearing loss;[43]

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- BigO project - on child obesity;[44]

- i-PROGNOSIS - on Parkinson's Disease;[45]

- SOMA - on work-related stress;[46]

- m-Resist project – on treatment-resistant schizophrenia;[47]

- CrowdHEALTH[48], InnoHealth DataLake[49] projects – on integrating multiple sources of data to support treatment and care or policy making decisions;

- VeroCity platform[50] - Vienna, the 'number one smart city in the world', uses CEF Context Broker to effectively manage Big Data[51] (a cross-sector good practice for utilising CEF building blocks);

- The 'Towards access to at least 1 million sequenced genomes in the EU by 2022' initiative has the potential to improve disease prevention, allow for more personalised treatments and provide a sufficient scale for new clinically impactful research.[52]

In October 2019, during the European Research and Innovation (R&I) Days[53], a session addressed the challenges and success factors in the transition from science-based research to innovation. The key recommendations derived from the session are the following; these issues are also relevant for health and healthcare data management:

- Ensure the flow of disruptive technology propositions in the (European Innovation Council) EIC value chain

- Assess the potential of disruptive business models and build execution capacity

- Select and nurture Pathfinder projects with an open-ended business perspective

- Stimulate customer and market interaction

- Strengthen conditions to move from prototype to product

- Build strong and motivated entrepreneur-lead teams with competence in technology and business development, and with strong innovation ecosystem connections

These recommendations must be considered when drafting and planning nurturing conditions for innovative solutions in healthcare data management and innovative use of those data; however, these principles have to be adapted to EU policy context.

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[44] https://bigoprogram.eu/
[45] http://www.i-prognosis.eu/
[46] https://www.soma-analytics.com/
[47] https://www.mresist.eu/
[48] https://www.crowdhealth.eu/

[49] https://innohealth.eu/en/datalake/
[50] https://smartdata.wien
[51] https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/Context+Broker (see success stories)
[52] https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative
[53] https://ec.europa.eu/digital-single-market/en/news/closing-gap-between-research-and-innovation

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

2.3.1.2   CEF Building Blocks

The European digital infrastructure is continuously developing. The Connecting Europe Facility (CEF) Building Blocks are available to help anyone who wants to build great European digital services for the public good. The industry-independent building blocks can serve as back office for the digital health transition, and they can speed up the process, if Member States/countries and EU level players coordinate their inclusion in health-specific services systematically.

Currently the following building blocks are readily available for utilisation:

- eArchiving provides sample specifications, software and support services for describing, transmitting and preserving data based on international standards.

- Big Data Test Infrastructure (BDTI) is a virtual sandbox where public administrations can experiment with different big data tools and techniques to innovate new digital services and solutions.

- Context Broker centralises and consolidates data from different IoT data sources, enabling comprehensive analyses and real-time reports for more informed decision making.

- eDelivery offers specifications, sample software and support services for setting up a registered delivery service infrastructure for exchanging data and documents.

- eID helps to set up the technical infrastructure needed to electronically identify citizens businesses and public authorities from other European Member States, as defined in the eIDAS Regulation.

- eInvoicing supports the seamless generation, sending, receiving and processing of electronic invoices across borders in line with the European Directive and standard on electronic invoicing.

- eSignature helps to create and verify electronic signatures in line with the eIDAS Regulation.

- eTranslation provides machine translation services that can be used on demand for translating text snippets and documents (web service) or integrated directly into a digital service platform.

- European Blockchain Services Infrastructure (EBSI) to enhance trust between parties and improve the efficiency of operations.

- Once Only Principle (OOP) reduces administrative burden for individuals and businesses. The OOP is currently a CEF preparatory action.[54]

It is easy to realise that BDTI, eID and EBSI are directly related to any secondary use of health data on European level, but eArchiving, Context Broker, eDelivery and eTranslation also can be really useful when building cross-border data sharing services.

Big Data Test Infrastructure (BDTI) helps public administrations improve the experience of the citizen, make government more efficient and boost business and the wider economy through big data. BDTI is a big data platform that offers virtual environments, allowing public organisations to experiment with big data sources, methods and tools. Users can launch pilot projects on big data and data analytics, through a selection of software tools. BDTI allows

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[54] https://en.wikipedia.org/wiki/Connecting_Europe_Facility

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

sharing data sources across policy domains and organisations and having access to best practices and methodologies on big data. Further information about BDTI is available at CEF Digital website[55].

The term 'Digital Service Infrastructure' (DSI) describes solutions that support the implementation of EU-wide projects. They provide trans-European interoperable services, composed of core service platforms and generic services. Building Block (BB) DSIs are basic digital service infrastructures, which are key enablers to be reused in more complex digital services. A Building Block is a package of technical specifications, services and sample software that can be reused in different policy domains. Sector Specific DSIs provide trans-European interoperable services for specific domains (e.g. eHealth, cybersecurity, eJustice, eProcurement), with the help of BB DSI.

The CEF eHealth DSI (eHDSI) uses eID, eSignature and eDelivery. It also reuses Trans-European Services for Telematics between Administrations (TESTA), a private, highly-secured network, a special Internet for public administrations in Europe. Current use cases of eHDSI are Patient Summary (PS) and ePrescription (eP).

Objectives to transfer good/best practices and make use of existing recommendations on the innovative use of health data, especially big data, can be built on exploiting opportunities of reusing or building on existing DSIs, including BBs. These opportunities, arising as 'low hanging fruits', may not shorten the way and time to prepare technical background for safe, secure and interoperable data exchange, but can help focusing on priority areas – use cases – for the first round of innovative use of health data partnership. For example, utilising existing eHDSI use cases may make medication clinical support by innovative use of health data more efficient.

2.3.1.3 European Health Data Space (EHDS)

The fight against lacking resource (e.g. blood products) or efficacy of treatment (e.g. antimicrobial resistance) and forecast of highly infectious diseases and epidemics could be more efficient if the value of data usage is engineered and fostered. Absolute and relative shortage of health professionals or funding might be also mitigated by predicting analytical tools. Considering that those organisations which strongly base their production on the use of artificial intelligence and machine learning solutions, can easily remove limits to scale, scope, and learning and become more competitive[56]; new possibilities occur to develop personalised medicine or improve clinical decision making. Furthermore, removing limits to scale, scope, and learning opens the door to a fairly unlimited set of use cases for innovative use of health data and big data too. These issues and trends have overshadowed the question. This trend has been highlighting the importance of innovative use of health data, since the 2018-2021 Multiannual Work Programme (MWP) of the eHealth Network was adopted.

The European Commission has identified the need and importance of data spaces, initially mentioned in the 2018 Communication 'Towards a common European data space'.[57] More

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[55] https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL

[56] Competing in the Age of AI - How machine intelligence changes the rules of business by Marco Iansiti and Karim R. Lakhani: https://hbr.org/2020/01/competing-in-the-age-of-ai

[57] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Towards a common European data space": https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2018:0232:FIN

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

recently, Commissioner Ursula von der Leyen (as President-elect of the European Commission) emphasised the importance of this objective for the healthcare sector in her Mission letter to Stella Kyriakides (who was Commissioner-designate for Health at that time):

> 'We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.'[58]

The vision of a European Health Data Space to promote health-data exchange and usage for innovative purposes by taking the opportunity enabled by the emergence of new technologies and enhanced connectivity is, unfortunately, threatened by keeping data hidden in private or proprietary and project-specific registries.

The most challenging recommendations on fostering the use of big data or health data are, on the one hand, still valid in the context of the EHDS, and, on the other hand, can be turned into reality if improvement of 'Open Data and Data Sharing', 'Education and Training', 'Governance of Data Access' and 'Data Analysis' are backed by solving issues such as lack of trust, legal uncertainties and lack of funding and financial resources.

Creation of a European Health Data Space may help to foster innovative use of health data; however, it needs to be defined first, both in conceptual and operational terms. EHDS may be neither a tool, nor a final goal, but likely could be an important, fundamental part of the digitalised healthcare ecosystem, therefore it will require EU level coordination and support.

The eHAction promoted a workshop in Lisbon, Portugal on 21-22 January 2020: 'Towards a European Health Data Space: National Strategies for secondary use of data in the context of National and EU Digital Health Networks'. As mentioned earlier in this report, secondary use of data has become one of the major cornerstones of digital transformation for health systems improvement. Realising the promise of eHealth, the 'safe use of information to support health and health related factors' will require robust governance and leadership at national and international levels, multisectoral collaborations to establish the technical-scientific base and definition of shared models to improve quality, while ensuring respect for the principles of data protection, privacy and fairness. Robust governance frameworks will also enable an adequate data ecosystem of high quality data for the anticipated AI-backed operation of health information systems, to support improved quality of care, management of resources and sustainability of health systems.

During this workshop, a preliminary/working definition of a Health Data Space was used. A Health Data Space was conceived as an 'aggregate of systems and data that are relevant for health policy, planning, research and patient care, that can be used by information systems in a holistic manner for any secondary use of health data purposes'.

During the work, Member States addressed national data governance models and national strategies for secondary use of data and implications on policy, technical and legal/regulatory

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[58] Mission letter to Stella Kyriakides, Commissioner-designate for Health, 10 September 2019: https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

frameworks of data collection and sharing. National and EU initiatives on secondary use of data, either for personalised medicine or public health were also presented by Member States, EU agencies and research partners. The workshop final report will be available at the end of April 2020 and it will provide further insight on Member State vision and next steps 'towards a European Health Data Space'.

2.3.2 Interdependencies

WP5 also took into consideration results achieved in other work packages of the eHAction and the previous joint action (JAseHN).

2.3.2.1   eHAction topics

D5.2 delivered information on use cases and good/best practices. On the European scale there are already existing projects and initiatives using innovative ways to use and utilise health data in the cross-border context, and in accordance with EU regulatory framework(s). The purpose of D5.2 was to identify implementable and scalable real-life eHealth and big data applications in public health in the EU. This was achieved by collecting, reviewing, analysing and synthesising cases from academia, businesses and service providers.

The analyses made by T5.2 confirmed that many of the stakeholders are facing similar challenges when it comes to developing and implementing eHealth solutions in the cross-border framework. In particular, issues of privacy protection, ethics, data security, health assessments, data quality, interoperability of health data systems, and ability to demonstrate added value to the key actors (such as citizens, patients and professionals) were brought up in the literature and in the interviews. Regarding many recent 'technology hypes' (regarding technologies or ideas such as artificial intelligence, big data or blockchain technology) it would be advisable to wait for more robust results in order to make informed policy decisions. The analyses of the conducted interview results show that there exist already a plethora of experiences and project results that are accessible and available from different EU funded projects. The EU funded projects could be consulted to develop a knowledge base and a framework for continuous exchange of best practices on the EU level. This pool of best practices could serve future projects and policy formation, giving information on real life obstacles and practical ways to overcome them. Enhancing FAIR data principles and interoperability between data systems are important infrastructure elements already today and their value, in instrumental and strategic sense, is of utmost importance in the near future. These may be the corner stones for big data and other applications, such as AI. Common requirements, definitions, data structures and classifications, such as produced by the epSOS project, demonstrate that EU wide interoperability, standardisation and harmonisation efforts do not take place overnight. For these kinds of policies, one has to consider different intersections of the scale and pace of change.

Owners of good practices interviewed by T5.2 suggested useful recommendations for making projects more effective:

- Concentrate on patient empowerment, involving family members and teamwork of clinicians, nurses, psychologists, social workers.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- Strengthen cooperation among IT developers, clinicians and patients to make systems user friendly, as well as build on patients' (and other key stakeholders') capacities, e.g. IT skills.
- Lay down and communicate clear rules of sharing and accessing data, as well as the intellectual property of the results of the innovative use of data.
- Map potential financial and/or funding resources, as well as ensure that all partners understand the conditions of making use of them.

Additional suggestions were drawn up for policy making:

- Predictive analytics require big data: patient data, sensor data, GPS data or telephone usage to measure physical activity, communication, social relations. Efficient utilisation of available technical results, development of IT applications and digitally enabled innovative care services can be fostered and assisted by regulated and promoted access to health data through the institutional, inter-institutional, national and cross-border digital eHealth infrastructure. These measures can be even more effective if involvement and empowerment of the key stakeholders in the co-creation activities are fostered too.
- Feeling of personal care and attention is important for patients, positive approach instead of privacy and data protection concerns (no Big Brother fears).
- National patient pathway coordination and a self-help system would promote screening and individual stress management.
- Health insurance funding measures: take into account the costs reduced by pre-screenings.

eHAction deliverables prepared by WP4, WP6 and WP7 also help in identifying recommendable policy level actions on innovative use of (big) data in health.

Utilising future eHDSI use cases may make clinical support by innovative use of health data more efficient in imaging or laboratory services, patient pathway planning and management or workforce management, etc.

Patient empowerment and development of eSkills, as well as digital health literacy (including legal knowledge too), are deeply interlinked with providing and using data.

2.3.2.2   JAseHN deliverables

As the previous Joint Action supporting the eHealth Network, JAseHN worked on the four priority areas (establishing the baseline for eHAction activities):

1. interoperability and standardisation
2. monitoring and assessment of implementation
3. exchange of knowledge
4. global cooperation and positioning

- Data use related results – key policy documents:
  o General Guideline on the electronic exchange of health data

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- o Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services

- o Organisational Framework for National Contact Points

- o Refined eHealth European Interoperability Framework

The results achieved and the deliverables elaborated are a good basis for further work at both national and EU level. These deliverables are listed in Table 6 below, where the highlighted deliverables have direct effect on secondary data usage.

JAseHN Deliverable	WP.5 Innovative use of health data
D5.3.3 Report on elements to be taken into consideration for uptaking the PARENT joint action guidelines for PR	For information
D5.4.3x Report on standardisation developments in eHealth incl. recommendations for the rolling plan	For information
D5.4.4 Refined eHealth European Interoperability Framework (ReEIF)	For information
D6.1.3 Report on the implementation of PR Guideline	For information
D6.2 Proposal for a sustainable legal basis for cross-border exchange of personal health data	For information
D7.1.2 Report on EU state of play on telemedicine services and uptake recommendations	For information
D7.1.3 Recommendations on Common Framework for Mapping Health Professionals' eHealth competences	For information
D7.2.1 Report on the use of cloud computing in health	For analysis
D7.2.2 How to handle health data for purposes other than patient care	For Further work
D7.3 Report on studies concerning added value of eHealth/mHealth services	For information
D7.5.1 Report on EU state of play on patient access on eHealth data	For information
D7.5.2 Recommendations for patient access to electronic health records	For information
D8.2.1 Inventory of eHealth specifications	For information
D8.2.2 Evaluation and good practice guide for eHealth specifications	For analysis

Table 5 – JAseHN deliverables relevant for eHAction WP5[59]

D7.2.2 Report – How to Handle Health Data (2018)

This JAseHN document gathers practical advice based on previous projects' deliverables (e.g. EHR4CR, eTRIKS) and recommendations (e.g. ENISA), as well as regulations (e.g. eIDAS, GDPR).

Naturally, recommendations and regulations for handling and use of health data will also be implemented in this project; furthermore, in fact, gathering data method and storage security component have since grown in focus.

It is important that patients consciously agree to the use of their data and that they know what their data is used for and for how long. This requires a good trust model: the patients know that

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[59] https://jasehn.eu/index.php/downloads/

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

their health data stored in a safe infrastructure (data protection) and handled properly, so it is in good hands.

According to the referred document, it is advisable to improve the trust model, data handling and data protection (and its principles) in eHAction, task 5.3, by preparing D5.3.

D7.2.1 – Report on the use of cloud computing (2015)

The document introduces the definition of cloud and related services as well as each implementation model (private, community, public, hybrid cloud), and also discusses the security principles of the cloud. The EU policy and strategies part just mentions the growth of cloud-based technology and the usefulness of its adaptation at Member State level, but does not elaborate on its design recommendations (e.g. centralised or decentralised model). The document proposes a policy change in the area of legal fragmentation to regulate data protection, but this should be regulated not only at EU level but also at Member State level.

In the conclusions there are two main recommendations in the field of cloud and secondary use of data: *'that there should be dedicated solutions (private or community cloud) for hosting sensitive data and that there should be negotiation and drafting of specifications that address risk management in data security'*, nevertheless it would also be useful to make recommendations (in eHAction, T5.3, by preparing D5.3) on:

- what cloud model should be useful for the gathering and storage of basic health data at Member State level (centralised/decentralised; public/private/community/hybrid);

- how to store and share health data for secondary use also at EU and Member State level (e.g. in cloud infrastructure that is separated from the basic database);

- how to interlink EU central and Member State cloud infrastructure;

- what functions should be performed by each cloud infrastructure level;

- where to do data depersonalisation (while filtering the main database/there's a depersonalised – for secondary use – database);

- what kind of risks could be mitigated by establishing clear standards and requirements for cloud solutions at the EU level.

D8.2.2 Report – Evaluation and Good Practice Specifications (2017)

The guide discusses processes for development and types of artefact and evaluation criteria for the subsequent use of 'good' requirements and standards are of general application to both healthcare providers and to companies supplying health information systems.

The document provides a good practice guide for eHealth specifications, including quality criteria and a proposed scoring scheme (quality management, assessment in development, assessment in selection and application to the inventory) which are basic requirements (e.g. ISO), and it is already implemented in eHAction.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

3 Recommended solutions

Before talking about recommendations, it is necessary to define possible use cases of innovative use of big data and artificial intelligence in health and healthcare first and to reflect on its added value.

3.1 Use cases

Identifying use cases of innovative use of big data and artificial intelligence in health and healthcare requires the outlining of the added value (AV) of big data. In addition, it is essential to have a clear picture about its importance to people, as well as needs, goals, offers/evaluation, behaviour and attitude.

The EU Study also discovered ten important areas of big data applications in public health and innovations before 2016. These topics overarched technical, legal, awareness, scientific issues, etc. Effects of GDPR and implications of the FAIR data principles are partly assessed or touched by the recommendations of the study. Are they relevant? According to the findings delivered by the T5.1 survey, one of the most relevant items of the compiled policy-relevant documentation is the EU Study.

Possible use cases of innovative use of health and healthcare data, big data, artificial intelligence, machine learning and high-tech (e.g. 3D printing) in public health, institution management and system governance:

- Improve patient care by assisted decision making, diagnostic analytics, robots (software and equipment), smart devices, teleHealth, mHealth and remote care

- Forecast patient demand, attitude, behaviour and need

- Forecast outbreaks and spread of the epidemics

- Optimise staffing and infrastructural capacities

- Optimise administration, finance, procurement, inventory and investment

- Reduce (hospital) re-admission rate

- Find hidden patient/citizen behaviour patterns using big data

- Provide tools and evidence

- Research: academic research and sponsored research

- Provide insight and evidence for policy-making and investments

- Further digital health interventions, accessible at a minimum via mobile devices recommended by WHO[60].

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60 WHO Guideline: recommendations on digital interventions for health system strengthening - https://www.who.int/reproductivehealth/publications/digital-interventions-health-system-strengthening/en/

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

3.1.1 Added value

The added value of innovative use of health data appears in the way and the extent to which it satisfies the needs of the stakeholders. The value can be engineered by increasing the level of need satisfaction and/or decreasing the consumed resources and diminishing side effects (causing new problems to satisfy the original need). Successful value engineering also depends on the content of the minimal level of satisfaction and the number of advantages the stakeholders can get against the trade-offs they have to make.

The use of health data is considered innovative if this use results in better patient outcomes and/or higher quality of healthcare delivery and/or higher productivity and performance.

There is a new use case of innovative use of health data if a certain data-driven solution creates value or contributes to increase the level of value. Use cases for the prioritised fields of the enabling actions can be selected by identifying innovations delivering gains at the varying areas, e.g. personalised care, management of care organisations, national or cross-border health systems, or even the wider ecosystem. Higher priority can be awarded to those cases which deliver gains in more areas while using less resources at minimum risk.

3.1.2 Importance to people and findings of D5.2 delivered by Task 5.2 of eHAction

Comparing the findings and learnings of the interviews carried out in Task 5.2 with preliminary considerations, we found interesting cases where people (patients and relatives) did not concern themselves too much about privacy, but were looking for prompt, reliable, personal contact with health professionals and service or remote care and monitoring if they felt trust in the professionals and the solutions, protocol, equipment, software or app used. People (including care receivers and providers) showed interest to reorient health systems to be more patient-centred, regardless of the level of their digital, health or innovation literacy. However, going into details, we experienced that creation and increase of trust depended on sharing information and knowledge with them and involving them in the innovation processes. People were open to develop their literacy (any kind of it) if clear personal gains were shown, and they could compare these gains with other outcomes (advantages and disadvantages). General or social gains, however, had to be translated into tangible ones which could be understood at a personal level.

However, the translation from the general level to something concrete, faced difficulties and challenges due to lack of information about stakeholders and their objectives, needs, drivers of evaluation, behaviour and attitude. The piloting of the stakeholder value chain analysis framework in Prague, 11-13 September 2019, highlighted that it applied for the Data Conversion Value Chain too. Capturing, cleaning and storing or sharing and processing data for innovation could deliver value if all this yields satisfying specific needs of key stakeholders at a replicable level and economic cost.

3.1.3 Uses cases with special interest for policy making

Providing an initial set of enabling actions for the information of the eHN by translating recommendations of the EU Study into operationalised solutions can be communicated for increased awareness.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

The needs and efforts to increase citizens' digital health literacy offer a unique opportunity to combine it with the communication and dissemination of other public health issues, such as vaccination. Objectives to improve home care and chronic care (e.g. cancer) have been addressed so far by several trials, pilots and other projects. Many of them are acknowledged for good or best practices of digitally enabled integrated care solutions.

Plans and intentions to ensure that the European pharmaceutical industry remains an innovator and world leader can be implemented by innovative use of health, healthcare and other data. Effective implementation of the new regulatory framework on medical devices requires data driven development connecting health and healthcare records.

3.2 Overall recommendations

Results from the tools applied, namely the online survey, the DCF tool, the consolidation of documentation already delivered (D5.2 and the respective deliverables from JAseHN), showed that the main obstacles in translating available policy-level recommendations into actions are legal uncertainties, lack of trust, and lack of funding and financial resources. To overcome those obstacles T5.1 presents its recommendations in the following chapters.

The result of the mapping showed that three general obstacles appeared as reasons slowing down or hampering translation of policy-level recommendations into actions: lack of trust, legal uncertainties, and lack of funding and financial resources. Detailed guidance reflecting on the three major findings will be delivered by Task 5.3. Recommendations stated in section D7.2.1 'Report on the use of cloud computing (2015)' will be further developed in T5.3 too. Key stakeholders will also be requested to provide their views and contribution during the implementation of T5.3.

It must be emphasised that the lack of trust, as the deepest root cause, can hide behind other obstacles. Therefore, it is important that patients consciously agree to the use of their data and that they know what their data is used for and for how long. This requires a good trust model: the patients know that their health data stored in a safe infrastructure (data protection) and handled properly, so it is in good hands. According to the referred document, it is advisable to improve the trust model, data handling and data protection (and its principles) in eHAction, T5.3, by preparing D5.3.

The issue of 'lack of funding and financial resources' is reflected in the document. It is important, however, to further assess, in T5.3, in which sense this lack is a problem. KPMG estimated that the overall health care analytics markets were going to reach 50 billion USD in 2025 (information from KPMG Finland in 2018). Therefore, it might be conceived counterintuitive that the lack of funding and financial resources is a problem and mechanisms should be further elaborated. The difference[61] between 'funding' and 'financing' should be considered too.

In T5.3 further issues will be taken into consideration:

3.2.1 Overcome legal uncertainties

A clear legal framework is necessary to overcome legal uncertainties and to further foster the innovative use of big data in health which can contribute to improve the healthcare systems of

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[61] http://www.differencebetween.net/business/difference-between-funding-and-financing/

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Member States/countries. As already stated in the EU Study on Big Data in Public Health, Telemedicine and Healthcare, legal frameworks at EU as well as on national level need to be: 1) identified; 2) assessed regarding legal loopholes and / or grey areas which need to be closed; and 3) adapted in order to facilitate secure generation, sharing and access to health data. Existing legislation should be as clear as possible. In the drafting of new EU legislation, emphasis should be given to clearness and preciseness [62]. Those results presented in the EU study are still relevant and valid and should be taken into account when drafting or reviewing legal frameworks at EU level.

3.2.2 Launch specific funding programmes, investment in education and training

Specific funding programmes should be launched to:

1. Foster empowerment, adherence and grit to increase level of knowledge, skills and competences related to sharing and accessing data for analysis and innovation purposes in

   o Marketing (communication and sales) of innovative use of health data and big data: 'Boosting institutional and personal ambition in scientific/academic area: sell the innovative use of data as a key to ground-breaking achievements';

   o Education and training programmes on EU level;

   o Cultural change and mainstream best practices, success stories and learnings;

   o Campaigns to increase determination of key stakeholders.

2. Find use cases that provide optimal set of gains at different levels by:

   o Increasing efficacy at micro and macro levels in the same time in:

     - personalised care and treatment (medical and medication decision support),

     - managing organisations,

     - prevention and prediction of diseases,

     - patient pathway management,

     - workforce and capacity management at system governance;

   o Increasing efficiency by consuming less resources by:

     - common public FAIR data standards and platforms on EU level,

     - reuse of existing data assets, building blocks, technical infrastructure and framework for primary use of data,

     - mapping regulatory barriers, reuse of existing legal framework of primary use of data.

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[62] Study on Big Data in Public Health, Telemedicine and Healthcare (December 2016), Gesundheit Österreich Forschungs- und Planungs GmbH, page 95.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

3. Process good/best practices for optimised use cases.

4. Develop and implement new curriculum and training programmes.

5. Prepare and run communication, dissemination and CSR programmes.

3.2.3 The role of a European Health Data Space (EHDS)

Creation of a European Health Data Space (EHDS) may help to foster innovative use of health data; however, it needs to be defined first. EHDS may be neither a tool, nor a final goal, but likely could be an important, fundamental part of the digitalised healthcare ecosystem, therefore it requires EU level coordination.

EU level coordination is needed to Identify priority domains (governance, regulation, infrastructure and cybersecurity) and areas of work for a 'Health Data Space' shared agenda both at policy and operational levels. This coordination may create added value by assisting stakeholders in:

- Raising awareness and building trust around the secondary use of data added value for health systems improvement, and supporting research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes;

- Ensuring alignment with relevant EU level eHealth initiatives and coordinated actions to provide high-quality healthcare and reduce inequalities;

- Developing proper channels for managing freely given, specific, granular, informed, explicit and unambiguous consent to ensure citizens have control over their own personal data;

- Building an adequate data governance framework for trustworthy AI development and deployment in the healthcare sector;

- Building trust and being transparent to promote health-data exchange ;

- Developing and maintaining infrastructure for FAIR capture, management, exchange and use of health-data for innovative purposes by taking the opportunity enabled by the emergence of new technologies and enhanced connectivity;

- Creating a specialised teams of best experts;

- Developing a culture that will support a steady process of learning, experimentation, change management and regulation;

- Connecting micro level business cases to macro level (policy) goals;

- Positioning data science as its own entity;

- Equipping the data scientists with all the technical resources they need;

- Ensuring compliance and common understanding of GDPR, privacy and security for secondary use of data;

- Ensuring proper funding for the above actions (at micro and macro level).

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Appendices

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Appendix A - Mapping practical barriers and obstacles

Mapping barriers and obstacles preventing Member States/countries replicating available good practices and policy recommendations on improving innovative use of big data in health and healthcare is the initial step to prepare practical guidance to foster innovative use of health data.

Challenges have been traced and assessed at every link in the Data Conversion Value Chain. These challenges are related to the way of solving potential problems caused by underperforming functions working at the links in the chain. It has been essential to explore the effects, root causes and required resources of the biggest challenges appearing at the implementation of recommendations on 'Open Data and Data Sharing', 'Education and Training', 'Governance of Data Access' and 'Data Analysis'. Challenges in these four fields, one-by-one, do not affect all the links. However, together they have an impact on the whole chain:

- Challenges faced in 'Open Data and Data Sharing' can significantly affect capturing, cleaning, storing, updating and sharing data for innovative purposes. Underperformances in these links have a negative impact on all use cases by making reliable data less available.

- Challenges to 'Education and Training' can have the strongest effect on stakeholder empowerment, stewardship, value creation and visualisation. Most affected use cases are client-to-provider and provider-to-provider telemedicine and targeted client communication. However, optimisation and decision making focused use cases are also affected.

- Uncompleted measures aiming improvement of 'Governance of Data Access' affect security, privacy and sharing issues. Unaddressed challenges do harm not only to research but make use cases of prediction more difficult as well.

- Querying and reporting can be seriously affected by the troubles and lag in fostering 'Data Analysis'. Delay or lack in improving the use of analytical tools and methods leads to less effective and efficient performance at individual, organisational and system level.

The first result of the mapping of reasons for challenges by the stakeholder value chain analysis framework showed that lack of trust, legal uncertainties, and lack of funding and financial resources, have been slowing down or hampering translation of policy-level recommendations into actions. The impact can be direct (or more direct) or indirect (or less direct). In an indirect case, an obstacle results in the impact through one or more intermediate reasons. Lack of trust, for example, is a direct reason why development of 'Open Data and Data Sharing' suffers delay, while implementation of a 'Data Analysis' programme depends on recruiting experts or knowing that an analytical tool exists and being aware of the evidence that it works. Trust has its importance in recruiting experts. (Of course, lack of funding and financial resources has a direct impact in this case too.)

Root causes of lack of trust, legal uncertainties, and lack of funding and financial resources, have been assessed by matching objectives and needs of stakeholders with imbalances among drivers of their evaluation, behaviour and attitude.

In several cases, the above-mentioned three reasons hide imbalances in health systems (e.g. lack of professionals is treated by recruiting the same persons in two or more organisations).

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

This can lead to loss of data if professionals cannot enter all the IT systems they should. In other cases, legal uncertainties concern both sharing and accessing data.

In this section we are going to introduce and assess key findings regarding the resources required to overcome or mitigate dysfunctions challenging the strength of the Data Conversion Value Chain, or the obstacles and barriers to transfer good/best practices and recommendations. Further interdependencies have been outlined among innovative use of health data, patient empowerment, digital health skills of professionals and other use cases of interoperability.

As barriers and obstacles are related to use cases, value creation (or engineering) and meeting expectations or utilising recommendations and following regulation or guidelines, the following issues were examined and assessed by using the methods introduced above:

- Use cases and the added value of big data and AI, effects of GDPR, and implications of the FAIR data principles (as key conditions derived from special rules and guidance);

- Expectations and existing recommendations.

A.1 - Effects of GDPR

The effects of the European General Data Protection Regulation (GDPR) and implications of the FAIR data principles are partly assessed or touched by the recommendations of the EU Study. Expectations and recommendations on privacy and data ownership or the purpose of data collection, as special cases, are worth being examined prior to other cases, since they determine the possibility and opportunity to use data at all.

A.1.1 - The role of consent

One of the most interesting areas of GDPR is consent, as it is the legal basis for data processing but it is restricted under the GDPR and must be 'freely given, specific, informed and unambiguous.'

By default, any time personal data of an EU citizen is collected, it will need explicit and informed consent from that person. Citizens can revoke that consent, and they can request all the data an entity has on them so as to verify that consent. Guidelines on Consent under Regulation 2016/679 (wp259rev.01)[63] adopted on 28 November 2017 by the Article 29 Working Party[64] provides useful up-to-date knowledge for sharing and using personal data.

Key effects of GDPR on innovative use of health data, following this guideline, can be assessed by the next principles:

- **Freely given consent, not forced by imbalance of power or not conditioned by contract:**

    The controller needs to prove that withdrawing consent does not lead to any disadvantage. The consent must not be built on deception, intimidation, coercion or any significant negative consequences.

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[63] As last Revised and Adopted on 10 April 2018: https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051

[64] https://ec.europa.eu/newsroom/article29/news.cfm?item_type=1358

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

For instance, the situation of 'bundling' consent with acceptance of terms or conditions, or 'tying' the provision of a contract or a service to a request for consent to process personal data that is not necessary for the performance of that contract or service, is considered highly undesirable. If consent is given in this situation, it is presumed to be not freely given.

- **Specific consent, given for processing for a specific purpose:**

The following is an example of a special case: if a controller seeks to process personal data that is in fact necessary for the performance of a contract, then consent is not the appropriate lawful basis. The appropriate lawful basis could then be GDPR Article 6(1)(b) (contract).

✓ **Granularity of consent given for partial processing for a specific purpose:**

A service may involve multiple processing operations for more than one purpose. In such cases, the data subjects should be free to choose which purpose they accept, rather than having to consent to a bundle of processing purposes. In a given case, several consents may be warranted to start offering a service, pursuant to the GDPR.

✓ **Informed consent - to be fully informed before consent is given:**

- the identity of the data controller;

- the purpose of each of the processing operations for which consent is sought,

- the personal data that will be collected based on consent;

- the existence of the right to withdraw consent;

- information about the use of the personal data for decisions based solely on automated processing, including profiling;

- if the consent relates to transfers of personal data outside the European Economic Area (EEA), information about the possible risks of personal data transfers to third-party countries in the absence of an adequacy decision and appropriate safeguards.

✓ **Unambiguous indication of wishes:**

The GDPR is clear that consent requires a statement from the data subject or a clear affirmative act which means that it must always be given through an active motion or declaration. It must be obvious that the data subject has consented to the particular processing.

✓ **Obtaining explicit consent**

Explicit consent is required in certain situations where a serious data protection risk emerges, hence, where a high level of individual control over personal data is deemed appropriate. Under the GDPR, explicit consent plays a role in Article 9 on the processing of special categories of data, the provisions on data transfers to third countries or international organisations in the absence of adequate safeguards in Article 49, and in Article 22 on automated individual decision-making, including profiling.

(Recitals 50, 42, 54 and 159 must be taken into consideration too.)

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

A.1.2 - GDPR: obstacle or promoter? Opportunities and challenges

The question of whether GDPR is an obstacle to data sharing or it may have positive effects, was also raised in a blog[65] by the Office of Science Policy (NIH, US[66]) in March 2019:

'GDPR defines personal data broadly — from name and email address to special categories such as health and genetic data — and provides people in the EEA with control over when and how their personal data is collected, retained, passed along, and used. So, given that GDPR was written to protect people in the EEA from data and privacy breaches, and not intended to target biomedical research — where significant protections for individual privacy and the concept of explicit consent already exist — why has the onset of GDPR created barriers for critical research collaborations between NIH grantees and their European research partners?'

The blog ends with a hopeful positive response: 'GDPR presents us with great opportunities as well as challenges. If we can harmonise consent and data sharing between U.S. and EEA researchers, we will be able to pool analysis of genomic and other health data and tissue samples, powering new and innovative trials and advancing the science of the future.' The Office of Science Policy also declared that they 'are interested in hearing from you about any GDPR-related problems or resolved issues and will certainly keep you updated on our experiences.' Unfortunately, no comments have been written so far[67].

WP5 agrees that meeting GDPR requirements means a lot of work, time, cost and risk, however, there are opportunities. Preparing specific, granular and unambiguous consent supports big data, artificial intelligence and analytics projects. Success, however, also depends on managing a data science team by [68]:

- Building trust and being candid,

- Creating a specialised team of best experts,

- Developing a culture that will support a steady process of learning and experimentation,

- Connecting the work to the goals the project owner has,

- Positioning data science as its own entity,

- Equipping the data scientists with all the technical resources they need,

- Ensuring proper funding for the above actions.

There is a big potential in the Guidelines on Consent under Regulation 2016/679 (wp259rev.01). Preparing specific, granular and unambiguous consent and making use of the above advice on managing a data science team have several common features. Differences between legal systems may narrow the space for designing and implementing successful innovative use of health data, but policy measures providing assistance for innovators to prepare a proper offer

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[65] https://osp.od.nih.gov/2019/03/15/gdpr-crossing-data-sharing-bridge-one-regulation-time/

[66] https://osp.od.nih.gov/about-us/

[67] As of 21 September 2019

[68] https://hbr.org/2018/10/managing-a-data-science-team

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

for consent by adopting a data analytics strategy based on the above recommendations originally developed for business and science, can give significant help to all stakeholders.

A.2. - Implications of FAIR data principles

In 2016, an article in Nature titled 'The FAIR Guiding Principles for scientific data management and stewardship'[69] launched the FAIR concept.

Since 2016, the principles of this concept have been used as an international guideline for high quality data stewardship. However, implementing FAIR Data has impacts and implications for people and machines

The concept is highly recommended for anyone interested in effective data sharing in any sector. It is worth mentioning that the AIMS community[70], 'made up of individuals involved in (agricultural) information and data management from around the world', found it important to examine and follow the findings of Research Data Alliance (RDA)[71] which 'for example, keeps identifying different parameters of FAIRness helpful to establish nodes (e.g. ELIXIR nodes: the national implementation of a harmonised FAIR Data Management programmes) for FAIRifying data, important in maximising the discovery and reusability of digital resources in long term goal.'[72] We found the activities of AIM community interesting, since there are several interlinks between agricultural and health information and data management, standards, technology and methodologies (e.g. nutrition). Further attention shall be paid to the activities of RDA too, as it builds the social and technical bridges to enable the open sharing and re-use of data. 'The Research Data Alliance (RDA) was launched as a community-driven initiative in 2013 by the European Commission, the United States Government's National Science Foundation and National Institute of Standards and Technology, and the Australian Government's Department of Innovation with the goal of building the social and technical infrastructure to enable open sharing and re-use of data.'[23] RDA's Health Data Interest Group (HDIG), for example, has been dealing with topics such as 'Artificial Intelligence (AI) in Hospitals and research: towards a large-scale health data sharing ecosystem' (24-06-2019) or 'Health Data Privacy & Security issues', 'Health data mapping and diverging trends in health data protection' and 'Meaningful health data for research and for industry'.[73] HDIG also dealt with identifying barriers to share research data (26-04-2019)[74]. Taking part in FAIR4HEALTH project[75], HDIG members contributed to delivering 'Guidelines for implementing a FAIR data policy in health research'[76].

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[69] https://www.nature.com/articles/sdata201618

[70] http://aims.fao.org/community

[71] https://www.rd-alliance.org/about-rda

[72] http://aims.fao.org/activity/blog/fair-data-what-and-why-easier-said-implemented

[73] https://www.rd-alliance.org/artificial-intelligence-ai-hospitals-and-research-towards-large-scale-health-data-sharing-ecosystem

[74] https://www.rd-alliance.org/group/health-data-interest-group/post/identifying-barriers-share-research-data

[75] https://www.fair4health.eu/

[76] https://www.fair4health.eu/storage/files/Resource/18/FAIR4Health%20ICIMTH2019_Final.pdf

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

A.2.1 - Difference between open data and FAIR data

The key difference is that open data should be available to everyone to access, use, and share, without licences, copyright, or patents. It is expected that open data at most should be subject to attribution/share-alike licences.

FAIR data, however, uses the term 'Accessible' to mean accessible by appropriate people, at an appropriate time, in an appropriate way. This means that data can be FAIR when it is confidential / under privacy protection, when it is accessible by a defined group of people, or when it is accessible by everyone (open data). It depends completely on the purpose of the data, where the data currently is in its lifecycle, and the end-usage of the data. [77]

The FAIR principles were first published in 2016. FAIR Data Principles apply not only to data but also to metadata, and are supporting infrastructures (e.g. search engines). Most of the requirements for findability and accessibility can be achieved at the metadata level, but interoperability and reuse require more efforts at the data level. This scheme depicts the FAIRification process adopted by GO FAIR. Throughout the FAIR principles, the phrase '(meta)data' has been used in cases where the Principles should be applied to both metadata and data.

They contain guidelines for good data management practice aiming at making data FAIR: Findable, Accessible, Interoperable and Reusable.

Each letter refers to a list of principles with a total of 15 principles altogether:

To be Findable:

F1. (meta)data are assigned a globally unique and persistent identifier

F2. data are described with rich metadata (defined by R1 below)

F3. metadata clearly and explicitly include the identifier of the data it describes

F4. (meta)data are registered or indexed in a searchable resource

To be Accessible:

A1. (meta)data are retrievable by their identifier using a standardised communications protocol

A1.1 the protocol is open, free, and universally implementable

A1.2 the protocol allows for an authentication and authorisation procedure, where necessary

A2. metadata are accessible, even when the data are no longer available

To be Interoperable:

I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.

I2. (meta)data use vocabularies that follow FAIR principles

I3. (meta)data include qualified references to other (meta)data

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[77] https://www.go-fair.org

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

To be Reusable:

R1. meta(data) are richly described with a plurality of accurate and relevant attributes

R1.1. (meta)data are released with a clear and accessible data usage license

R1.2. (meta)data are associated with detailed provenance

R1.3. (meta)data meet domain-relevant community standards

A.2.2 - What about the implications of FAIR data principles?

Based on the findings of FAIR4HEALTH's 'Guidelines for implementing a FAIR data policy in health research' we can collect and assess the following challenges in the 'FAIRification workflow' context (see Figure 11 – FAIRification workflow):

- the personalised health challenge;

- the challenge of distributed grid of certified communities of care providers;

- the challenge of trustworthiness (certification, security by design and transparency);

- the challenge of health data management lifecycle (certification, security by design and transparency);

- the challenge of interoperability (technical, semantic and organisational) including standards (e.g. FHIR for FAIR data);

- the cultural change to share data (promotion, data publications)

- the challenge of powerful tools that make sharing easy

- the challenge of permanent, recognised and cost-effective repositories for data and data artefacts

- the challenge of standardised templates and mandatory data management plans as part of grant applications

- the challenge of incentives for successful cases of data sharing (not only the willingness in principle)

- the challenge of stable central services for data enrichment/refinement (e.g. terminology server, annotation services)

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020
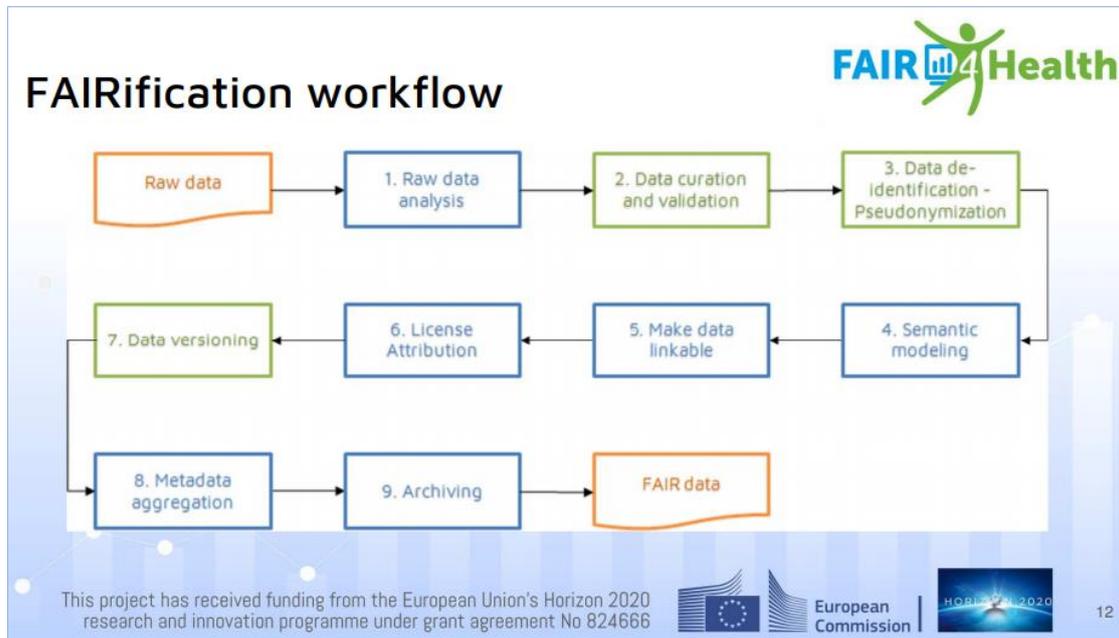
Figure 11 – FAIRification workflow

A.2.3 - Recommendations in FAIR4HEALTH project

The FAIR4HEALTH project offered 12 ways to mitigate challenges concerning 'FAIRification' through Guidelines for implementing a FAIR data policy in health research:

1. To encourage public institutions to deploy FAIR demonstrators with health data

2. To reach a harmonisation of FAIR metrics

3. To implement sound data provenance methods

4. To boost the availability of trusted data repositories

5. To develop a FAIR code of conduct

6. To encourage the development of a sustainability plan beyond the research project

7. To engage software providers to make data FAIR

8. To raise awareness and provide training on the use and management of metadata

9. To emphasise the use of community-based standards and ontologies

10. To set up a best practice guide for the use of health information exchange standards

11. Address alignment and harmonisation of metadata in FHIR IGs.

12. To democratise tools for mapping data with related standards and ontologies.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Appendix B - Expectations and existing recommendations

Guided by the intention to fill the gap between existing strengths or opportunities and weaknesses or threats, most available policy recommendations reflect primary expectations from big data and from the use of health data.

B.1 - Study on Big Data in Public Health, Telemedicine and Healthcare

The Study on Big Data in Public Health, Telemedicine and Healthcare (EU Study) covers the topics of big data applications in public health and innovations before 2016. These topics overarch technical, legal, awareness, scientific issues, etc. Effects of GDPR and implications of the FAIR data principles are partly assessed or touched upon by the recommendations of the study. The study developed 10 recommendations for their implementation in the European Union:

- EU Study recommendation 1 on Awareness Raising: Develop and implement a communication strategy to increase the awareness of the added value of Big Data in Health and encourage a positive public mind set towards Big Data in Health

- EU Study recommendation 2 on Education and Training: Strengthen human capital with respect to the increasing need for a workforce that can utilise the potential of Big Data in Health

- EU Study recommendation 3 on Data Sources: Expand existing and explore new sources of Big Data in Health and secure their quality and safety

- EU Study recommendation 4 on Open Data and Data Sharing: Promote open use and sharing of Big Data in Health without compromising patients' rights to privacy and confidentiality

- EU Study recommendation 5 on Applications and Purposes: Increase target-oriented application of Big Data analysis in health based on the needs and interests of stakeholders including patients

- EU Study recommendation 6 on Data Analysis: Identify the potentials of Big Data analysis, improve analytical methods and facilitate the use of new and innovative analytical methods

- EU Study recommendation 7 on Governance of Data Access and Use: Implement governance mechanisms to ensure secure and fair access and use of Big Data for research in health

- EU Study recommendation 8 on Standards: Develop standards for Big Data in Health to enhance and simplify its application and improve interoperability

- EU Study recommendation 9 on Funding and Financial Resources: Ensure purposeful investment steered by the European Commission to warrant cost-effectiveness and sustainability

- EU Study recommendation 10 on Legal Aspects and Privacy Regulations: Clarify and align existing legal and privacy regulation of Big Data in Health

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

B.2 - OECD Ministerial Statement, 17 January 2017

The success of adapting health systems to new technologies and innovation, however, depends on the way that the enormous potential that health data offers for improving people's health and health system performance is designed and used. According to the OECD Ministerial Statement, 'due consideration of potential benefits and risks involved is needed to make the most of the vast amount of clinical, administrative, and other types of data being generated in health systems'. The OECD Health Ministers welcomed the new Recommendation of the Council on Health Data Governance (see below), which identified core elements to strengthen health data governance and thereby maximise the potential of using health data while protecting individual privacy.

In the Statement, ministers invited the OECD, in collaboration with other relevant bodies, to carry out work in the following areas, subject to resources and in line with the usual budgetary and approval processes of the Organisation:

- Reorient health systems to be more knowledge-based (new health statistics to measure and compare patient-reported experiences and outcomes in healthcare; highlighting best practice: key indicators of health and health system performance which identify relative strengths for all countries to share, and learn from);

- Enhance the people-centred focus of health systems and policies and promote high-value care;

- Provide new approaches to public health surveillance of diseases, risk factors and preventive care;

- Modernise delivery models (artificial intelligence; new technologies; the future of the health workforce);

- Better self-control of patients through data utilisation;

- Decrease the information asymmetry of patients;

- Provide better health outcomes and more personalised therapy for patients;

- Secure better-quality health delivery based on data analysis;

- Provide free flow of data and better access to care provision;

- Improve data security and data protection level for patients;

- Explain why innovative use of health data is important to our citizens;

- Show how people would really benefit from innovation and innovative use of health data.

B.3 - Guidelines and communications of European Commission on Artificial Intelligence

One of the rapidly growing areas of healthcare innovation lies in the advanced use of data science and artificial intelligence, especially machine learning, computerised vision and natural language processing. The European Council of October 2017 stated that the EU needed a sense of urgency to address emerging trends such as AI 'while at the same time ensuring a high level of data protection, digital rights and ethical standards'. The Council invited 'the Commission to put forward a European approach to artificial intelligence' that was set out in the

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

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Communication from the European Commission 'Artificial Intelligence for Europe' that urged European leaders to put AI at the top of their agendas. The public and private sectors must seize the opportunities that come both from developing innovative AI solutions and applying them to a range of fields, including the healthcare sector where AI has disruptive potential.

Following documents contain relevant recommendations or expectations:

- European Commission communication on Artificial Intelligence for Europe: develop and use AI for good and for all building on EU values and strengths. Capitalise on research and public sector data which can be unlocked to feed AI systems, to make data sharing easier and to open up more data – the raw material for AI – for re-use. This includes data from the public sector in particular as well as research and health data.

- European Commission High-Level Expert Group on Artificial Intelligence on Ethics Guidelines for Trustworthy AI: set out a framework for trustworthy AI, a trustworthy approach is key to enabling 'responsible competitiveness', by providing the foundation upon which all those affected by AI systems can trust that their design, development and use are lawful, ethical and robust. These Guidelines are intended to foster responsible and sustainable AI innovation on the assumption that all legal rights and obligations that apply to the processes and activities involved in developing, deploying and using AI systems remain mandatory and must be duly observed which is especially relevant in the healthcare sector and personal health data.

- European Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society: data is a key enabler for digital transformation. EU should support action of Member States to improve data quality to promote research, disease prevention and personalised health and care to enable better health interventions and more effective health and social care systems.

B.4 - WHO guidelines and communications

In the past five years WHO paid more and more attention to monitoring the uptake of eHealth and digital solutions, studying the possible barriers of development in data driven health systems and recommending measures to handle the obstacles.

The following two documents represent both the policy and the practical implementation levels addressed by WHO recommendations:

1. 'From Innovation to Implementation: eHealth in the WHO European Region'

A report on the status of eHealth in the WHO European Region (2016). This document examined the major areas of development, perceived barriers to adoption and potential areas of eHealth. The report stated that health analytics, in a public health context, was the transformation of data for the purpose of providing insight and evidence for decision and policy-making.

The report highlighted that 'The top three most important barriers (rated as very or extremely important) are a lack of data privacy and security laws, limited integration between different health services and other systems collecting data and a lack of support for new analytical methods. These top three barriers are all related to a lack of data governance.' Figure 12 - Barriers to implementing big data for health (Fig. 32 of the cited report) below illustrates the

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

barriers to implementing big data for health by the number of Member States/countries reporting barriers:
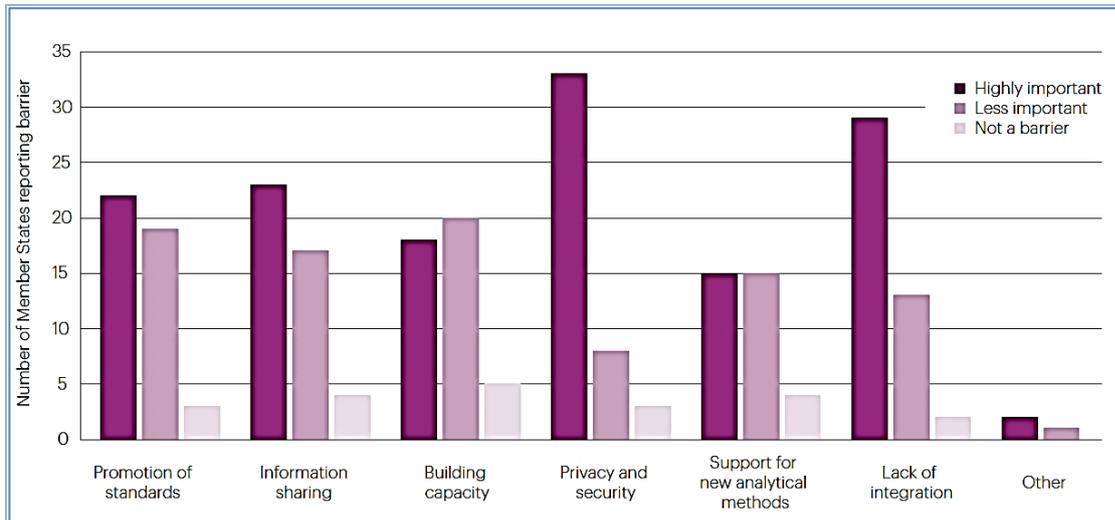

Figure 12 - Barriers to implementing big data for health

27 out of 38 Member States/countries have a national open data portal and 71% of the countries have an open data policy, frequently under digital strategies or eGovernance programmes. Six countries (13%) report having a national policy or strategy regulating the use of big data in the health sector. Four countries (9%) have a national policy or strategy regulating the use of big data by private companies.

Further challenges concerning use of big data in health were also highlighted by the report:
- The existing use of big data did not name 'health' explicitly;
- Lack of integration into analytical framework (EHR and non-health data);
- Feasibility of integrating information was not demonstrated;
- Lack of disparate data sources to better understand specific cohorts or patient conditions;
- Single approach to the adoption of information technology has been limiting;
- Missing local engagement and sensitivity to local circumstances;
- The great potential of health analytics and big data in health is missed when countries cannot yet see applicable uses of big data in health (and they are engaged to care daily problems instead of eliminating root causes).

Since 2016 WHO has fostered creation and implementation of policies regulating the use of big data in the health sector and by private entities as well as increasing guidance on social media use in health and big data:
- According to the findings of WHO, national policies and strategies on regulating the use of big data in the health sector:
  ~ need to be addressed by national health and information and communication technology entities;
  ~ should include a clear position on the use of big data by private companies;
  ~ Member States are recommended to develop national policies governing the use of social media in health professions.

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- Member States should address data governance at the national level, particularly on privacy and data protection, through leadership and collaboration with health ministries, justice ministries and data privacy regulators.
- Public health organisations and health service providers should increase education and training for staff on how to use public data and health data analytics.
- Member States and funders of health research should support research and development into new analytical methods.

2. 'WHO guideline: recommendations on digital interventions for health system strengthening'

The key aim of this guideline is to present recommendations based on a critical evaluation of the evidence on emerging digital health interventions that are contributing to health system improvements, based on an assessment of the benefits, harms, acceptability, feasibility, resource use and equity considerations.

The recommendations in this guideline represent a subset of prioritised digital health interventions accessible at a minimum via mobile devices, and this guideline will gradually include a broader set of emerging digital health interventions over subsequent versions. This includes recommendations on the following digital health interventions, accessible at a minimum via mobile devices:

- birth notification

- death notification

- stock notification and commodity management

- client-to-provider telemedicine

- provider-to-provider telemedicine

- targeted client communication

- tracking of patients'/clients' health status and services

- health worker decision support

- provision of training and educational content to health workers

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Appendix C - DCF-canvas tool (questionnaire)

C.1 - The purpose of the analysis

During the WP5 face-to-face workshop in Prague in September 2019, we tested and validated a framework intending to capture the rationale behind the lack of use of already collected health data for better health outcomes. Our framework has been developed to analyse challenges in implementing policy recommendations or replicating good practices. The face-to-face workshop was followed by a full WP5 teleconference, where we received further input on the framework.

The purpose of the analysis is to look for obstacles preventing the growth of innovative use of health data in Member States/countries.

Task 5.1 prepared a tool to identify key stakeholders, their needs, goals, offers/evaluation, behaviour and attitude, as well as interdependencies, obstacles and possible interventions and results to be expected. The form of the tool was a questionnaire designed to collect and provide information for further assessment through a canvas which allows for rendering of 2D shapes and mapping.

Using this canvas tool, named 'the stakeholder value chain analysis framework for data conversion' (in short: 'Data Conversion Framework' or 'DCF') we mapped privacy aspects, as well as by identified obstacles that prevent Member State/country policies from being replicable either in other Member States/countries or on an EU level (see Figure 5 – Stakeholder value chain analysis framework for data conversion).

The framework has outlined interdependencies with the dysfunctions challenging the strength of the Data Conversion Value Chain. Further interdependencies were outlined among innovative use of health data, patient empowerment, digital health skills of professionals and other use cases of interoperability.

We focused the tool on detecting obstacles preventing Member States/countries to implement available recommendations and guidance for increasing innovative use of health data and big data.

Thus, it helped in elaborating compiled policy-relevant documentation on governing big data in health.

The countries participating in the survey were asked to fill in and submit the canvas pointing out the main goals, needs, obstacles possible interventions and result in connection with four recommendations of the EU study. We experienced that Member States/countries achieved some progress and faced challenges on most of the 10 recommendations. The highest level of challenges or concerns particularly appeared at implementing recommendations on

- 'Open Data and Data Sharing',
- 'Education and Training',
- 'Governance of Data Access', and
- 'Data Analysis'.

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Using the framework tool (canvas) we intended to obtain information about the reasons and the root causes why these challenges occur.

We asked Member States/countries to examine the causes from the perspective of three key stakeholder groups:

- patient/citizen

- care provider

- payer.

The framework was built up based on following logic:

Objectives/use cases – Needs - Value propositions – Objectives – Interventions – Results.

C.2 - Glossary

Key stakeholder

We chose three main key stakeholder groups: citizens (who can be patients, relatives, etc.); care providers (who can be professionals or other persons and organisations or other entities); and payers (who can be social/public or private insurance organisations). Of course, there are other influencing stakeholders as well (for instance commercial trade channels, such as pharmacy chains or manufacturers, researchers or authorities), but we have not involved them into the assessment yet.

Objectives

We are looking for their specific objectives related to implementing the recommendations fostering the use of health data for research, innovation or other secondary purposes. In practice, these objectives can be also related to use cases of exploiting data to create or engineer value in healthcare.

The main or utmost goals implementing the chosen recommendations from the perspective of a certain stakeholder. The objectives were related to use cases of exploiting data (secondary use for various purposes) to create and engineer value in healthcare.

Needs

Needs are articulated by the stakeholder and incorporate the preconditions, means and assets as supporting factors to reach the objectives.

We were looking for their specific objectives related to implementing the recommendations fostering the use of health data for research, innovation or other secondary purposes. In practice, these objectives can be also related to use cases of exploiting data to create or engineer value in healthcare.

Initial offering

An 'initial offering' corresponds to the four selected recommendations (or any of them) of the EU study[78]:

- open data and data sharing

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[78] Study on Big Data in Public Health, Telemedicine and Healthcare - https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

- education and training

- governance of data access

- data analysis

Initial offerings are, in general, value propositions offered to one stakeholder by the others to satisfy needs and reach goals. In our case, the four recommendations were the initial offerings.

We were looking for obstacles preventing the growth of innovative use of health data through keeping us (Member States/countries) from making use of existing recommendations and replicating good/best practices. According to the results of WP5-survey, we experienced that Member States/countries achieved some progress on most of the recommendations. However, assessing responses about the progress, it can be highlighted that the highest level of challenges appeared for implementing recommendations on 'Open Data and Data Sharing' and 'Education and Training'. Less, but still a considerable challenge appeared for 'Governance of Data Access' and 'Data Analysis.

Using the DCF tool, we obtained information about the reasons and the root causes why these challenges occur.

Drivers of stakeholders' evaluation

(Factors determining how an offering, e.g. a recommendation, is valued by stakeholders)

We were looking for information about how an 'initial offering' (as a specific value proposition) could be valued by the stakeholder who received it. Key features (as drivers of this evaluation) are:

- Non-negotiables: performance features that make an offer minimally acceptable;

- Differentiators: features that positively distinguish an offering from the competition;

- Dissatisfiers: attributes that stakeholders are not happy about but may be willing to endure them for a time if compensating differentiators exist.

Since value propositions were related to the four selected recommendations, we were considering the key features characterising stakeholders' interests regarding them.

Obstacles

Obstacles are the factors impeding the manifestation of the interests and materialisation of the goals drafted earlier.

Interventions

Actions intended to eliminate the obstacles obstructing the reaching of the goals.

Solutions

Results of successful interventions.

C.3 - Countries participating in the survey

- ✓ Austria,
- ✓ Croatia,
- ✓ Finland,
- ✓ Hungary,
- ✓ Latvia,
- ✓ Lithuania,
- ✓ Portugal
- ✓ Slovenia

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

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C.4 - Insights (summary of answers)

This part summarise the answers from the perspective of the selected three key stakeholders.

C.4.1 - Citizen/patient

Goals

New innovative services and medicines for patients

Improve patient care (decision support, genomic data for decision making), find hidden patient behaviour patterns

Strengthen patient empowerment through citizens' ownership and control of their data

Healthy aging

Needs

Give consent to share personal health data

Be informed on how personal data is used (what is stored where how long, etc.)

Information about available services

Information about risks

Receive access to all personal health information available

Interests of the patients/citizens

Non-negotiables

Data security and safety

Privacy of data

Right to consent

Differentiators

Availability of services

Efficiency gains (i.e. shorter waiting times)

Data representation (easier to comprehend)

Dissatisfiers

Sacrifice intimacy

Spend time to learn about rights, usage of information, new systems and solutions

More expensive treatment or services

Obstacles

Open data and data sharing

Lack of trust -> lack of willingness

Fear of abuse

Education and training

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Resistance to learn

Lack of resources (financial and also trained personnel to inform patient adequately)

Governance of data

Lack of interoperability of data, electronic data is accumulated using different formats and there is no unified database

There is a significant amount of data still kept in paper format

Data analysis

Data availability (storage, accessibility, etc.)

Understating the difference between 'analysis' and 'reporting'

Interventions

Normative regulations at state level

Population information on health data processing and gains

Education

Standardised and simplified interfaces

Solutions

Unified data formats and interoperability of databases

Acceptance and denial procedures simplification and accessibility

Safe and convenient system presenting data and audit records understandable to patients

More accessible healthcare services

Higher willingness of patients to participate in health research

Better digital health literacy – foster autonomy

Health-conscious patients – reduced costs

Empowered patients

C.4.2 - Care providers (organisation and/or medical staff)

Goals

Offer improved patient care (through use of digital health: big data, assisted decision making, robots, smart devices, teleHealth, mHealth and remote care)

Improve diagnostics quality analysing big data of health sector, epidemiological outbreak forecasting

Evaluation of therapy effectiveness

Make services more attractive for patients/citizens

Share (data) responsibility with patient

D5.1 - Report for the information of the eHN on policy level
actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Needs

Gain information on technologies ready for implementation and receive training

Investigate possible funding opportunities

Good data quality

Interests of the care providers

<u>Non-negotiables</u>

Good data quality and availability

Clear and precisely defined data processing

Ensure resources (financially and physically)

Receive patient consent and access tools

<u>Differentiators</u>

Enhance working processes to save time & money

Interoperability of medical institution information systems with other information systems

FAIR data

<u>Dissatisfiers</u>

High effort and low output (e.g. data available)

Administrative burden (patients' information requests on data processing cases)

High financial investments in IS and reducing resources for other purposes

Obstacles

<u>Open data and data sharing</u>

Lack of trust

Understanding of patient needs

Comprehensive data is not available

<u>Education and training</u>

Lack of expertise

Lack of motivation for further education

<u>Governance of data</u>

Lack of interoperability of data

Unclear interpretation of legal framework

There is a significant amount of data still kept in paper format.

<u>Data analysis</u>

Limited data availability

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Interventions

Offer new services/working methods and research opportunities (e.g. through big data) to improve patient care

Normative regulations at state level. Information system safety, security and employees training on personal data protection

Increase employee motivation on data quality assurance

Build modern data warehouses and data lakes

Build timely and effective reporting system for clinicians and all healthcare professionals

Engaging clinicians and other professionals to participate to data content modelling and planning of reporting

Constant validation cycle of data

Create and communicate organisational rules; organise training and education solutions

Unified data formats and interoperability of databases

Common political view at EU level on necessity of single digital information on patients' rights for medical services

Engagement and trust to building forecasts among the professionals who work for the care provider

tools, competences and dedicated time available

Organisational rules comprehended, topic understood, confidence gained

C.4.3 - Payer

Goals

Optimisation of expenses and resource planning

Optimise administration

Provide insight and evidence for policymaking and investments

Provide optimal treatment to the patient – thus saving insurance money

Prevent unnecessary treatment – saving money

Define/redefine/continuously evaluate medical services eligible for payment

Identify risky ('expensive') patients in advance; adjust insurance rates, offer preventive care

Early disease/risk detection

Reduce (hospital) re-admission rate

Create new financing schemes for health services

Needs

Get proper skills and knowledge to search for information

Be informed about negative impacts of lacking/losing outcomes

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

Clear rules (legal framework)

Evidence-based evaluation of existing/new healthcare services eligible for payment (e.g. new service must be proven to be efficient, choosing between alternative therapies; e.g. does a certain cancer screening really improve the outcome and decrease the overall costs of treatment)

Data for medical evidence-based model of payment

Automatically detect fraudulent activity (false claims)

Predictive analysis to define business model - insurance pricelist; e.g. automated identification of potentially 'expensive' patients who should be offered preventive services

Interests of the payer

Non-negotiables

Availability of resources

Acceptance of stakeholders

Data quality and availability/accessibility

Reliable data

Differentiators

Interoperability of medical institution information systems with other information systems

Customised analytical algorithms and tools - specific for payers

Possibility to receive patient's acceptance to use personal data electronically

Long-term benefits of time & cost saving

Financially rewarding solutions for use of data

Dissatisfiers

Invest financial resources to customise

Need to hire & pay qualified staff (data analysts etc.).

Obstacles

Open data and data sharing

Lack of resources (staff, competences)

Incompetent payers are not able to recognise business opportunities related to FAIR data

Lack of political support

Education and training

Lack of trust / confidence due to doubts and uncertainties about regulatory framework, data governance

Lack of resources

Resistance to learning

D5.1 - Report for the information of the eHN on policy level actions
WP5 – Innovative Use of Health data
Version 0.3, 02-03-2020

<u>Governance of data</u>

Lack of support (due to lack of awareness) of key stakeholders (policy makers, market regulators)

Most relevant for public health insurance, private payers are less dependent and more proactive - if anticipating financial benefits

Lack of interoperability of data, unclear interpretation of legal framework

Difficult to develop complete, accurate, and up-to-date metadata

<u>Data analysis</u>

Limited data availability

Limited data accessibility

Interventions

Gain data-specific competences

Raise the awareness and competences of policy makers, regulators so that they will take stimulating measures and create a trustworthy legal framework

Offer technology and legal framework for up-take of health technologies

Solutions

Competences gained, payers ready to invest staff and money

More awareness, trust and confidence; payers comfortable about FAIR data matters

Market diversity

Enhanced standardisation

Clear strategies and raised awareness

Governmental support to take actions