Deliverable 6

Report on legal issues on inter-professional consultation of complex cases

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1-Background and rationale

1.1 eHealth

eHealth tools and services have demonstrated their effectiveness to provide better care and to contribute to more effective use of resources. eHealth tools or services include tools for both health authorities and professionals as well as personalised health systems for patients and citizens. Examples include health information networks, electronic health records, telemedicine, health portals and many other information and communication technology (ICT) based tools assisting prevention, diagnosis, treatment, health monitoring and lifestyle management, as well as new means for linking citizens with medical research. (1)

E-health solutions are providing health authorities with novel means to organise their health delivery systems. The corollary is bringing 'health' outside of the traditional clinical care context and into people's homes and workplaces, integrating the concern for bodily wellbeing into individual's everyday lives. (2)

1.1.1 Telemedicine

According with the "Commission Communication on telemedicine for the benefit of patients, healthcare systems and society", Telemedicine is defined as "the provision of healthcare services, through the use of ICT (Information and Communication Technology), in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients". (3)

Telemedicine could involve medical actions as diagnosis (including a medical second opinion), treatment or follow up of patients.

The European Commission has adopted a favourable vision concerning telemedicine as a tool to improve healthcare and quality of life, to short waiting times, and to optimise the use of available resources. (3)

The gathering of data is conditioned to the objectives of the platform, and thus to the aims of the processing of such data. If the aim is to provide remote diagnosis/treatment orientation on complex cases, traceability of the cases introduced is required, therefore personal data (including also codes and pseudonyms) would be necessary to achieve the purposes and thus,

specific legal measures shall be adopted taking into consideration the General Data Protection Regulation. On the contrary, if the aim is research purposes including patients' registries, implementation of appropriate safeguards could lead to derogation of some patients' rights in specific situations.

1.1.2 Electronic health records

E-health refers to the application of ICT-based tools and services for prevention, diagnosis, treatment, monitoring and management of health. In its broadest definition, e-health covers a range of functions in the health sector, including mHealth and telemedicine. However, e-health also serves as a common shorthand for a narrower set of tools aimed at data sharing between healthcare providers and between providers and their patients, in particular electronic health records. (1)

An electronic health record (EHR), is the systematized collection of patient and population electronically-stored health information in a digital format. EHRs may include a range of data, including demographics, medical history, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.

While the implementation of ICT in healthcare is a competence of EU Member States, the European Commission has since 2004 been developing targeted policy actions aimed at fostering e-health throughout the EU, citing the economic, efficiency and health benefits of tools such as electronic health records.

Although all the EU Member States make use of electronic health records, variations exist in the formats and standards applied, security, quality controls, etc. Directive 2011/24/EU on patients' rights in cross-border healthcare calls for Member States to provide, on a voluntary basis, compatible database systems that would allow patients to facilitate the transfer of patient data between Member States. (2)

As previously seen with the telemedicine platforms, the gathering of data within the EHR is conditioned to the objectives of the platform, and thus to the aims of the processing of such data. For example, if the aim of the registry is to provide a picture of the disease/s in a very specific moment, data can be kept without any personal information. However if the aim is to perform a longitudinal study for the analysis of the trends of the disease/s, personal data has to be included in the platform in order to avoid duplications and update the records, re-contact the patient for research purposes (if consented)... In this case, legal measures shall be adopted as described in the General Data Protection Regulation.

1.2 Relevance of eHealth in Rare Diseases

For most of Rare Diseases (RDs), expertise is scarce and heterogeneously distributed across the EU, especially in the case of ultra-rare diseases, many healthcare professionals, face problems for diagnosis and/or choosing among therapy options in some complex cases and a significant number of patients remain undiagnosed or misdiagnosed. This makes impossible offering a proper prognosis, treatment and genetic counselling, increasing patient and patient's family anxiety.

On the other hand, while high level research is conducted in many centers and excellent care is routinely delivered, very few data report outcomes of health care delivery and utilization across Europe. No up-to date data on the burden of most of RDs across the European Union is available, due to the absence of organized data system collection and to the lack of widespread newborn screening in many countries.

As a result, the lack of high-quality epidemiological data, the high variation of disease prevalence in different ethnic groups and in different regions within the same country as well as general underestimates of disease incidence are serious impediments to appropriate policy making for lifelong disorders, requiring many resources in order to achieve the desired outcomes in prevention and patient care. In particular, patient numbers are known in few locations since no registries exist and, thus, location of services and budgetary allocations cannot be accurately estimated.

Epidemiological data of high quality are also important for clinical trials because they can direct researchers to the available and suitable patient groups. Many unmet needs are present in RDs. Numbers of patients are rarely adequate in one centre or one country and, hence, pooling of patients in many countries is necessary, as proven by recently conducted trials. The standardised collection of data regarding the main clinical complications of RDs is fundamental to establish the need and the priorities in the development of clinical trials.

All in all, high-quality epidemiological data are critical to persuade ministries of health, policy makers, funders and the pharmaceutical industry to devote appropriate resources for the adequate tackling of RDs.

Taking into consideration the specifities of RDs and for all the above mention, by means of Telemedicine and EHR platforms, eHealth tools provide solutions to the heterogeneous distribution of expertise and to the lack of epidemiological data.

1.3 Clinical Patient Management System in the framework of the European Reference Networks

Set-up under the 2011 Directive on Patient Rights in Cross-Border Healthcare, European Reference Networks (ERNs) are virtual networks bringing together medical specialists across Europe to tackle rare or complex diseases and conditions that require highly specialized healthcare and a concentration of knowledge and resources. For the first time, a formal structure of voluntary collaboration between healthcare providers across the EU has been created for the direct benefit of the patient.

The first 24 thematic networks include over 900 highly specialized healthcare units located in more than 300 hospitals of 25 EU countries plus Norway, and cover a wide range of disease groups that became operational in March 2017.

Healthcare providers who are members of ERNs are connected through a dedicated IT platform and, using a variety of telemedicine tools, offer access to expertize and knowledge of multidisciplinary teams, enabling patients suffering from such conditions to receive the best advice for treatment and diagnosis. A fundamental principle of the ERNs is the stipulation that knowledge should travel rather than patients (with the exception of few cases where patients may be referred for treatment in another country). [(4)]

Research is another key element of the ERNs providing a structured framework for joining research efforts across countries, thereby creating a knowledge hub, facilitating translational research and the development of good practice guidelines for diagnosis and care, and supporting cross-border registries. By gathering and analyzing a large pool of patient cases, ERNs should contribute to observational studies and clinical trials, leading to new insights into RD and new drug therapies with potentially far-reaching benefits for patients. [(4)]

In this context, the European Commission DG SANTÉ has provided ERNs with the Clinical Patient Management System (CPMS), a secure web-based application to support the networks in two core tasks:

1. Bringing expert specialised care to all patients in Europe the diagnosis and treatment of rare or low prevalence complex diseases or conditions across national borders: The system allow for virtual consultation across national borders, ensuring that the needed expertise can travel to the patient, instead of the other way around.

2. Keeping de-identified information on clinical data in a registry: to improve future knowledge on RDs, a database will be created with de-identified data of the cases introduced in the system.

In order to be included in the software application, the patient has to give explicit and unambiguous consent to his healthcare provider. This consent form has three boxes: the first concerns consent for sharing data, the second is about consent on the inclusion in the database and the third is about the possibility to be contacted for research purposes. Patients have to sign directly either in the box providing 'I consent' or in the box entitled 'I do not consent'.

First version of the CPMS was released on November 20th 2017 and a pilot phase is foreseen until March 2018. During this first phase all ERNs will familiarise themselves with the system in order to assure optimal functionality. At a later stage the CPMS will become available for healthcare providers outside ERNs to consult the highly specialised experts within ERNs.

1.4 Legal frame

The Directive 2011/24/EU on the application of patients' rights in crossborder healthcare [5], was approved in early 2011 and Member States (MS) had to bring into force the national regulations to comply with the Directive by 25 October 2013. The Directive seeks to facilitate access to healthcare for EU citizens and encourage cooperation between EU MS in the field of health.

An important issue that should be taken into consideration for the implementation of an Electronic Health Record and Telemedicine systems is to protect the rights and fundamental freedom of patients. In addition, consideration of the protection of personal data and ensuring a high level of protection against cross-border trafficking is an obligation. Electronic health records and Telemedicine systems can include some of the most sensitive data of an individual. Therefore, they deserve the highest degree of protection against all kinds of abuse, requiring special handling to protect the data. The privacy protection of an individual is regulated by the law, medical confidentiality and any other rules.

In the European Union, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 concerns the protection of individuals with regard to the processing of personal data and on the free movement of such data is the most important directive relating to the protection of personal data, which establishes a regulatory framework in order to establish a balance that will ensure a high level of protection of personal privacy and free movement of

personal data within the European Union (EU). The Directive sets limits on the collection and use of personal data and requires the establishment in each MS, of an independent national agency charged with protecting these data.

The data covered by this Directive relate to data which can be used to identify a specific person and data which will be processed by one person. This Directive shall apply even if the test results are stored in coded identifiers, such as the identification number of a patient. The basic idea is that if a piece of information which can describe a person, whether through the use of simple techniques or by using a third person, then these data are considered as data that can characterize any person and therefore fall the level of implementation of the Directive. [7]

If the information relates to a group of people or if the information is comprehensive or unique so that it can be applied to a very small group of people, for example, for a specific disease, age, ZIP code, then the data can be categorized, whether or not actual identification data. The Directive applies to the processing of data which is made by a natural person in the course of a purely personal or household activity or if the treatment is for activities outside Community law, such as public safety.

This legal frame was transposed in every MS according to national regulations specifications, however the entry into force in 2018 with direct implementation to all MS of the new "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)" [6] will provide EU MS with a common frame for cross-border data sharing. [7]

Therefore, a legal analysis and impact of this regulation on the development of European registries and telemedicine platforms is needed in the context of the new ERNs.

2-Objectives

The CPMS platform developed by the EC can be understood as a two-in-one eHealth systems fulfilling two different needs of the ERNs:

- CPMS as a Telemedicine platform for facilitating interprofesional consultation on RDs complex cases.
- CPMS as an electronic health record for keeping clinical data to increase the evidence-based knowledge of RDs and thus, improving research on the field.

e-Health systems arise new legal and ethical considerations regarding the use and protection of personal data. An important issue when implementing a new e-Health tool is the system's compliance with the law on the rights of patients.

Taking into consideration the legal analysis undertaken for the ENERCA Telemedicine and e-Registry platforms, the present deliverable will review the legal framework for the sharing of data within the CPMS in the light of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) that will entry into force next May 2018.

3-Analysis of the Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

A core objective of the Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) [(6)] is to create the legal framework for the seamless cross-border delivery of all kinds of data services essential to a digital single market. The coordination and harmonisation of national regulatory regimes are indispensable in achieving this goal. However, since the organisation of health systems is competence of each MS, the General Data Protection Regulation provides for several derogations that may mean that there are still variations across EU. [(8)]

Since ERNs are designed to be an information forum for healthcare providers, rather than a care provision mechanism, many of the issues related to variations between MS interpretations of the GDPR will not present any problem for ERN Members [(8)], nevertheless some issues need to be taken into consideration:

3.1 General Data Protection Regulation scope

The General Data Protection Regulation applies to all data that are considered as personal data, noting that anonymous data are out of the scope of this Regulation.

According to article 4 (1) of the Regulation, 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Therefore, the data containing any identifiers that make possible to find out who the subjects are, are considered personal data. This includes data that are handled in a coded or pseudonymized form.

Coding or pseudonymization is a relevant process when establishing the conditions for data processing, as will be seen below, but it does not represent the exclusion of this legal regime.

The pseudonymisation process is also defined in article 4 (5) of the Regulation as “the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data is not attributed to an identified or identifiable natural person”.

On the other hand, the registration data fall into a specific category that deserves enhanced protection by the General Data Protection Regulation. They are data related to health or genetic data. According to Article 4:

(13) ‘genetic data’ means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.

(15) ‘data concerning health’ means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.

In contrast, the data from which a subject cannot be identified are considered anonymous and do not fall within the scope of the Regulation (for example if it is aggregated data that does not allow, due to its characteristics, to know who are the referred subjects).

When the term "processing" is mentioned in this document, it means any work performed on personal data such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

We call attention to processing that includes obtaining data and also transfer to third parties.

3.2. Purposes legitimated for Health data processing

According to article 9 of the General Data Protection Regulation, the processing data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

However, this prohibition will not be applicable in certain cases. Some of these assumptions are the following:

"The **data subject has given explicit consent** to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject "

Or

"Processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, **medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems** and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3". In paragraph 3 it is defined that personal shall be processed in this case when those data are processed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies.

Or

"Processing is necessary for archiving purposes in the public interest, **scientific** or historical **research purposes or statistical purposes in accordance with Article 89(1)** based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject"

On the other hand, Member States (MS) may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. This means that the national legislation of each MS is relevant to check if there are other limitations. However, it is pointed out in Recital 53 that "this should not hamper the free flow of personal data within the Union when those conditions apply to cross-border processing of such data".

In relation with the legitimacy of the processing, it is important to highlight that the scientific purpose is specifically mentioned as a legitimate purpose allowing the use of data initially

collected for another purpose. This notion is reflected both in the articles of the Regulation and in its articles and recitals:

Article 5. Principles relating to processing of personal data: 1. Personal data shall be: (a) processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency'); (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')".

Recital 157: "By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. **Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law".**

In conclusion, the General Data Protection Regulation describes scientific research and medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems, as an aim that legitimizes the processing of health data, as opposed to the general prohibition.

3.3. Actors involved and legal roles

For any data file it is necessary to determine who is the person responsible for it, namely the controller, to whom is attributed a series of obligations. "Controller" means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

It is the responsibility of the data controller for any given data processing activity to ensure that the standards are met. In the context of ERNs, there are several data controllers. The data collected and stored by an ERN member, who is physically providing care to the patient, will be held according to the rules and processes for collecting and storing patient data in the ERN member's institution. This storage falls outside the legal ambit of the ERN and is covered by the internal rules of the organization and the national legislation of the country in which it is established. (8)

The European Commission has contracted with an external provider for this system, and accordingly has accepted the role of data co-controller for the de-identified data held on that system. The responsibility is shared with the provider of the CPMS who is also a data co-controller for the CPMS. This means that they share the responsibility for ensuring that data sharing facilitated by the CPMS is covered by adequate standards of security. (8)

It is also important to highlight that the concept of healthcare providers does not only cover doctors but also 'any natural or legal person or any other entity legally providing healthcare on the territory of a Member State. (8)

On the other hand, the General Data Protection Regulation provides that there may be other person/s or institution/s ("Processor") that process the data on behalf of the controller (article 4.8).

Obligations of controller and processor are described within the General Data Protection Regulation (Chapter IV. Section 1). In addition, an agreement intended to establish the conditions for regulating the contractual relation between both subjects is foreseen and described within the Regulation (Article 28.3).

Controller, processor and authorized users can access the data stored in the files. Other subjects will be considered as a third party, without legitimacy for such access, except under certain conditions: "third party" means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorized to process personal data (article 4.10).

3.4. Subjects' rights

Several subject's rights must be respected in accordance with the General Data Protection Regulation, including: Right to information (articles 13, 14, 15), right to inhibit processing (articles 17, 18, 19, 21), right to rectification (article 16), right to data portability (article 20). In the present analysis we will focussed on the right to be informed before giving consent and the right to be forgotten:

3.4.1. Right to be informed before giving consent

This concerns the information to be provided to the subject when consent is required for the processing of data.

As mentioned previously, health data shall be processed as first option only if the data subject has given their explicit consent. "Consent" of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her (article 4.11).

It is a subject's right to receive information about the processing of the data before making a decision about it. The controller shall provide the data subject with the following information (articles 13 and 14):

- The identity and the contact details of the controller and, where applicable, of the controller's representative;
- The contact details of the data protection officer, where applicable;
- The purposes of the processing for which the personal data is intended as well as the legal basis for the processing;
- The recipients or categories of recipients of the personal data, if any;
- Where applicable, the fact that the controller intends to transfer personal data to a third country or international organization and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available.
- The period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;

- The existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;
- The existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal.
- The right to lodge a complaint with a supervisory authority;
- From which source the personal data originate, and if applicable, whether it came from publicly accessible sources;

Regarding the specificity of the consent, Recital 33 appoints the following: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose." This consideration is relevant for the CPMS, since information will be provided in a broad manner concerning the future processing of data for scientific research purposes in relation to RDs as a whole, which can be considered as an area of research sufficiently specified.

However, as laid out in article 14.5, information to be provided to a data subject may be not required when: a) the data subject already has the information; b) the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available: and c) obtaining or disclosure is expressly laid down by Union or Member State law to which the controller is subject and which provides appropriate measures to protect the data subject's legitimate interests".

3.4.2 Right to erasure ('right to be forgotten')

Article 17 recognizes the right to erasure data prior request from the subject. However, this right presents some exceptions. Article 17.3 states that it shall not apply to the extent that processing is necessary for "(d) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing; or (e) for the establishment, exercise or defense of legal claims."

3.5. Specific legal regime for data gathered for scientific research purposes or statistical purposes

As established in the previous section of this legal framework, processing of data with scientific purposes is legitimate with prior consent from the participant and an assurance of their rights.

It has been mentioned that some exceptions can exist to such premises when conditions foreseen in article 89 of the General Data Protection Regulation are met. This article is the core of the regulation for the processing of health data with scientific purposes, and states the following:

"Article 89. Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes:

1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, **shall be subject to appropriate safeguards**, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of **data minimisation**. Those measures may include **pseudonymisation** provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.

2. Where personal data is processed for scientific or historical research purposes or statistical purposes**, Union or Member State law may provide for derogations** from the rights referred to in Articles 15, 16, 18 and 21, subject to the conditions and **safeguards referred to in paragraph**

1 of this Article in so far as such rights are likely to **render impossible or seriously impair the achievement of the specific purposes**, and such derogations are necessary for the fulfilment of those purposes.

3. Where personal data is processed for archiving purposes in the public interest, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18, 19, 20 and 21, subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

4. Where processing referred to in paragraphs 2 and 3 serves at the same time another purpose, the derogations shall apply only to processing for the purposes referred to in those paragraphs."

However, it is important to highlight that although in article 89, articles 9 (processing health data) and 14 (information that must be given to data subject) are not mentioned, in these articles, exemptions to the right recognized are provided taking into account the safeguards in article 89.1.

3.6. Conclusion

In summary, **as a general rule, explicit and specific informed consent is required for processing of personal data**. In addition, subjects' rights have to be guaranteed and respected in all cases, including the right of erasure of data. **However, processing of data without informed consent from the subject may be allowed in the two following situations**:

First - the **data subject had already consented before**; e.g. National registries including in their informed consent the sharing of data with European registries.

Second - **when the following three conditions are met:**

1. Processing is necessary for archiving **scientific research purposes based on Union or Member State law**

2. Processing **shall be subjected to appropriate safeguards**, ensuring that technical and organisational measures are in place in particular in order to ensure respect for the principle of **data minimisation**. Those measures may include **pseudonymisation** provided that those purposes can be fulfilled in that manner.

3. Request of **informed consent from the data subject is likely to render impossible** or seriously impair the achievement of the objectives of that processing.

4- CPMS analysis in the context of the General Data Protection Regulation

4.1 Informed consent

Informed consent is an ethical and legal requirement for research involving human participants. It is the process where a participant is informed about all aspects that may be important for the subject to make a decision whether to participate or not in a given study or trial. The informed consent provides the participant the possibility to analyze all aspects, in order to then voluntarily confirm or deny his or her willingness to participate in such study. [9]

As mentioned in the introduction, the nature of data stored in an eHealth platform and as a consequence, the legal frame for the processing of such data, is devoted to the final objectives pursued, where in summary:

- If anonynomus data is introduced into the platform (e.g. for generating a picture of the epidemiological situation of a disease) processing of this data comes out of the scope of the General Data Protection Regulation and informed consent is not needed.
- If personal data is introduced into the platform, also including coded data, pseudnomysed data… (e.g. in order to assure traceability for provision of diagnosis/treatment advice or to analyse the trends of the disease), then the General Data Protection Regulation applies for the processing of such data.

The CPMS has been developed in order to fulfill two main objectives: 1) allow for virtual consultation across national borders and 2) improve future knowledge on RDs through the creation of a registry of the cases introduced.

Before introducing a patient into the platform, the signatory of the informed consent is mandatory needed, including three different specifications: 1) sharing data, 2) inclusion in the database and 3) possibility to be contacted for research purposes.

The informed consent form only addresses the consent to share health data within the ERNs, it is not a consent form for treatment. However, it has been crafted with the General Data Protection Regulation in mind and has been considered a best-practice by the European Data Protection Supervisor (EDPS)[10]. It complies with the general data protection requirements in EU data protection law for consent.

- The informed consent form is an EU level model consent form for the use of data exchange within the CPMS; it can be combined with a local consent form if necessary.
- The informed consent form complies with current EU level data protection legislation and General Data Protection Regulation so we have a reasonable level of assurance that it is comprehensive; the consent form and the CPMS have undergone a prior-check by the EDPS and adequate safeguards have been implemented based on their Opinion and recommendations.
- The informed consent form must be checked with each hospital or treatment centre legal service because:
    - Each hospital is responsible for their data protection practice by their legal service or Data Protection Officer
    - If further checking is needed at national data protection authority level the hospital legal service will handle this as they are in a position to already clarify any contact requirements foreseen at national level, besides any additional requirements to ensure the processing of personal data;
    - National obligations may contain specificities not covered by the model EU consent form (e.g. obligation to communicate treatment of sensitive data to national data protection authority, ids cannot be collected in some countries, etc.);

4.2 Concept of personal and anonymous data in the context of CPMS and Commission Delegated Decision (2014/286/EU)

An important remark of the new General Data Protection Regulation is the consideration of personal data also as any information relating to an identified or identifiable natural person who can be defined directly or indirectly by reference to an identifier: name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Thus, two important remarks are extracted from this definition:

First, data containing any identifiers that make possible to find out who the subjects are, including data that are handled in a coded or pseudonymized form are considered as personal data. The General Data Protection Regulation considers data to be anonymous only when it cannot be identified by any means “reasonably likely to be used (...) either by the controller or

by any other person" (Recital 23). Thus, even if a given healthcare professional or researcher does not have access to the tools to re-identify data, such data may still be regulated under the General Data Protection Regulation, if it could be re-identified with reasonable effort.

Second, data and/or factors that in tandem allow the re-identification of data subject, although by indirect means, is also considered personal data. This is particularly important for the processing of data in patients affected by rare diseases, where the concept of anonymous data is relative in this sense since the risk of identification of subjects is high due to their low prevalence.

If data are truly anonymous, as defined by the General Data Protection Regulation, they fall outside the ambit of the Regulation and accordingly no consent is needed to sharing such data. However, and given the particularities of the RDs, the concept of anonymous is not so clear as for the rest of diseases and special extra safeguards shall be taken into consideration for avoiding re-identification of patients.

Data shared in the CPMS is de-identified. It is important to note that de-identification (or pseudonymisation) is not the same as making data anonymous. [8] De-identification implies that is the immediately identifying markers which make it possible to directly identify a patient such as name, full date of birth, address and national ID number will be removed. However, in the particular case of RDs, due to the extent of the detail of medical history recorded and the rarity of the condition will make it relatively easy to identify a patient from the de-identified data. Thus, even if a given healthcare professional or researcher does not have access to the tools to re-identify data, such data, unlike anonymous data, remains subject to the remit of the regulation. Accordingly, even though data will be de-identified, it is still important for patient to give consent to the data to be shared for care or registry purposes. [11]

A solution for this would be the establishment of a set of criteria defined by experts in each field for the definition of the borders in the set of parameters gathered that would allow the re-identification of the patient. E.g. data including information about a person with a disease X older than 90 years old may lead to the identification of the person if the disease is very rare, or a person with a disease Y living in a small population, etc.

Furthermore, according to the *Good Practices in Informed Consent and Data Management in European Reference Networks for Rare Diseases* [8] "even if it could be argued that the data shared in the ERN are sufficiently well de-identified to be legally classified as anonymous, it is

important to note that the Commission Delegated Decision on the operation of ERNs states that informed consent is provided for the sharing of data in ERNs."

The Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (2014/286/EU) [12] (hereinafter Commission Delegated Decision) established through Annex I the conditions to be fulfilled by the ERNs, including:

4(a) **exchange, gather and disseminate knowledge, evidence and expertise** within and outside the Network, in particular on the different alternatives, **therapeutic options** and best practices with regard to the **provision of services and the treatments** available for each particular disease or condition;

4(b) **promote expertise and support healthcare providers in order to bring local, regional and national provision of healthcare closer to patients**;

5(c) **reinforce research and epidemiological surveillance**, through setting up of shared registries.

In Annex II the Commission Delegated Decision establishes the criteria that applicants to ERNs must fulfill, in this concern:

1 (a) (iv) **apply personal data protection rules and ensure access to medical records and clinical information in compliance with EU data protection provisions** and national implementing measures and in particular with Directive 95/46/EC;

1 (a) (v) ensure that the informed consent of the data subject complies with the requirements set out in Article 2(e) of this Delegated Decision, in particular informed consent given freely, unambiguously and explicitly by the subject or his/her legal representative after being informed of the purpose, nature, significance and implications of the use of his/her personal and health data, if personal health data is exchanged under this Delegated Decision, and being informed of his/her rights under the applicable data protection rules. The given consent should be duly documented;

1 (d) with regard to the exchange of expertise, information systems and e-health tools, applicant providers must:

(i) **be able to exchange expertise with other healthcare providers and to support them**;

(ii) have established procedures and a framework for ensuring the management, **safeguarding and exchange of medical data**, including established outcomes, process indicators and patient registers for the specific area of expertise **in accordance with the EU data protection legislation, in particular with Directive 95/46/EC**, and with Article 2(e) of this Delegated Decision;

(iii) be able to **foster the use of telemedicine and other e-health tools** within and outside their facilities, by fulfilling the minimum interoperability requirements and when possible, using agreed standards and recommendations;

In addition, the importance of data sharing is reinforced through its recital 8 "Further horizontal and structural criteria and conditions related to the **exchange of expertise, information systems and eHealth tools** should help developing, sharing and spreading information and knowledge and **fostering improvements in the diagnosis and treatment of diseases within and outside the Networks and to collaborate closely with other centres of expertise and networks at national and international level**. Interoperable and semantically compatible information and communication technology (ICT) systems would facilitate the **exchange of health data and patients' information, and the establishment and maintenance of shared databases and registries**."

Secure sharing of data respecting subject's right and Directive 95/46/EC (to be replaced by the General Data Protection Regulation in May 2018) is also mentioned through its recital 9 "The ability to have an efficient and secure exchange of health data and other patient information as well personal data of the healthcare professionals in charge of the patient is a crucial aspect for the successful functioning of the Networks. **The exchange of data should in particular take place in accordance with the specified purposes, necessity and legal grounds for the processing of data and be accompanied by appropriate safeguards and rights of the data subject. Personal data should be processed in compliance with Directive 95/46/EC** of the European Parliament and of the Council". While in recital 12 is stated "**In order to ensure the exchange of personal data in the context of the Networks, procedures concerning informed consent for processing this data could be simplified by using one single common consent model** that needs to be subject to the requirements set out in Directive 95/46/EC with regard to the consent of the data subject."

In conclusion, the Commission Delegated Decision certainly promotes the initiatives concerning data sharing in the frame of telemedicine and epidemiological surveillance for RDs,

while fully respecting the Directive 95/46/EC (now replaced by the General Data Protection Regulation from May 2018) in terms of data protection and specially informed consent for the patient. Thus, the CPMS offers to ERNs a robust platform for the inter-professional consultation of complex cases based on a systematic gathering of patients' data through a friendly platform and appropriate safeguards for processing of data.

4.3 Analysis of the derogations for the need of informed consent in the CPMS

As previously seen, the processing of health data is legitimate in the General Data Protection Regulation for both purposes of the CPMS, as cited in Article 9 are: "medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems" and "scientific or historical research purposes or statistical purposes", which are in essence, telemedicine and registry. However, it is important to emphasize that derogations related to processing or personal data contemplated in Article 89 are only related to scientific or historical research purposes, in result, to the registry side of the platform.

According to Article 89, provided Member States achieve an appropriate balance between the right of each data subject and the specific interest of research for rare diseases, and provided they adopt the needed safeguards, they will be able to adopt derogations from the data subjects' rights referred to in Articles 15, 16, 18 and 21 (right of access, right to be forgotten, right to restrict processing and right to object processing), for research purposes in ERNs. [(8)] **However, it is important to highlight that although in article 89, articles 9 (processing health data) and 14 (information that must be given to data subject) are not mentioned, exemptions to the right recognized are provided in these articles taking into account the safeguards in article 89.1 (Article 9 2(j) and Article 14 5(b)).**

Accordingly, processing of data without informed consent from the subject may be allowed when the following situations are met: a) processing of data with scientific research purposes b) processing is subjected to appropriate safeguards, and c) informed consent from data subject is likely to render impossible.

Condition a) is fulfilled, while the CPMS provides several safeguards that ensures condition b). Coding or pseudonymization is a relevant process when establishing the conditions for data processing. The pseudonymisation process is defined in article 4 (5) of the Regulation as "the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such

additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data is not attributed to an identified or identifiable natural person". Specifically, the pseudonymisation in the CPMS includes [13]:

- CPMS ID: When enrolling a patient into the CPMS, the system generates automatically a unique ID for each patient known as CPMS ID. This ID is only visible for health professionals within a particular centre/hospital.
- Record label: Within a particular centre, the CPMS proposes by default a structured Record Label for each patient to complete the enrolment. This record label is composed of the patient identifying data entered in the enrolment form (e.g. first, last name, etc.). However, authorised medical professionals can edit the record label if they wish. Similarly to the CPMS ID, the record label is only visible to authorised users in a particular centre/hospital.
- Panel ID: When initiating a panel in an ERN, OpenApp emphasise that none of the invited experts from different centres/hospitals from same/different ERN, can see any patient identifiers (i.e. CPMS ID, Record Label, enrolment data). That means all Panel members from outside the centre to which the patient belongs, cannot see the real patient identity when participating in a Panel or a Meeting. Panels are identified uniquely by a unique Panel ID number, shown always in the Panel Header.
- Nickname: The CPMS allows users to give Nicknames to their patients per each individual consultation request. Clinicians will be always requested not to reveal any real patient identifiers. When a user initiates a panel, he/she will be requested to fill in the consultation request as the minimum amount of data required to invite other health professionals to consult the submitted request. In the consultation request section, users will need to provide a "Nickname" for every individual consultation request for the same patient.
- ERN Database/Registry ID: In the ERN Database/Registry known as low accessibility database, all data are made available for research once the Panel lead decides to push anonymized data to the research database when the panel has been closed. A new patient ID is given to the Panel and nickname is removed; These database contains only clinical data collected as part of the panel, small amount of panel admin data, decision column as the outcome of the consultation interaction. Data in the ERN database can be exported by authorized researchers in several formats with no identifiable data. Clinical data in the low accessibility database are made available conditionally the second consent has been given by the patient (i.e. ERN Databases/Registries). ERN authorized users will have an access to the research environment in the CPMS to conduct research activities and export data.

Accordingly, the only condition remaining to be fulfilled for the avoidance of the need of informed consent would be condition c) “informed consent from data subject is likely to render impossible”. This condition represents itself a hot point of the Regulation due to its subjectivity in the practical use. Without any additional explanation it is difficult to establish the limit for define the cases that fall into this scope and how to prove it.

In conclusion, the General Data Protection Regulation contemplates some derogation for the need of informed consent for the processing of personal data for scientific or research purposes that may apply in the context of the CPMS. However, this exception is not contemplated in the legal frame of the CPMS since entry of cases is only observed when medical advice is required.

4.4 Conclusions

In conclusion, the CPMS has established a policy in accordance with the General Data Protection Regulation that ensures the appropriate safeguards for the processing of personal data at both sides of the platform, either telemedicine or registry, by the configuration of a European legal frame common to all Member States.

Thus, the CPMS offers to ERNs a robust platform for the inter-professional consultation of complex cases based on a systematic gathering of patients' data through a friendly platform and appropriate safeguards for processing of data.

However, its use in the daily clinical routine by health professionals represents itself a challenge. Health professionals, especially those dealing with rare diseases, are used to share, mainly by e-mail, their patients' clinical data with colleagues in another MS to obtain expert advice on diagnosis or treatment without obtaining patients' informed consent or institutional approval.

The mandatory need of informed consent may hamper the use of the CPMS given not only the potential difficulties that getting the informed consent from the patients represents, but also the time efforts for assuring the legal compliance with the national rules and getting the approval from the Healthcare Providers legal departments, which may occasionally take months until approval.

Thus, from our point of view, especial efforts need to be done for implementing actions aiming at increase the awareness of the CPMS and the entry into force of the new Regulation not only among ERNs members but also at the level of medical centres administrations and the public level.

In addition, medical administrations should contemplate this activity as a remunerate activity to avoid putting more workload on experts' shoulders and facilitate the integration of eHealth solutions in the daily care of the patients affected by rare diseases as required by the Commission Delegated Decision.

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