Ethical and legal requirements for biomedical research involving health data in the context of the Covid-19 pandemic: is informed consent still playing the leading role?

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ABSTRACT: The current pandemic could have accelerated a change of the traditional paradigm about the secondary use of health data. The traditional one has been based on the faculty of the individuals about accepting or not that use of their health data through the main role of informed consent. The new paradigm considers the current value of that secondary use for the improvement of the health of community and its individuals, through the possibilities offered by Big Data and AI. Therefore, the need of a balance between individual rights and the common good is indispensable. Pseudonymization could be the way to find this balance.

KEYWORDS: Data protection; health data; informed consent; privacy; pseudonymization

SUMMARY: 1. Big Data and the opportunities of secondary use of health data for improvement of medicine and health – 2. Is my health data mine anymore? – 3. Is there a clear legal solution at the EU regulatory framework? – 4. Has informed consent a main role in this new context of secondary use of health data? – 5. Conclusion.

1. Big Data and the opportunities of secondary use of health data for improvement of medicine and health

Big Data offer new opportunities for the development of our societies and for solving many of our current economic and social problems in general, but most specifically in the field of health research. The extensive use of conventional health data and even their interlinking with non-traditional data shall help to fight against many diseases and to develop new treatments which is a new hope for patients and for all the community. The results extracted from data use took decades to obtain only a few years ago. Currently, because Big Data and AI, it can be revealed within months, even days, and, above all, at a very affordable cost. Algorithms enable the comparison of a large number of healthcare processes, thus offering accurate conclusions, in terms of volume, on the most acute diagnosis and the best treatment for many diseases.

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The context is, therefore, unique from an historical perspective and not taking advantage of it could be seem as a not very ethical option, above all, if we consider the opportunities offered for the prediction, prevention or healing of many diseases. Furthermore, this unprecedented scenario unfolds at a time when new uncertainties grow about the evolution of several diseases, which although very well known, such as cancer, offer new paradigms of cell and protein development, as well as of new diseases, many of which are untreatable yet (i.e. orphan diseases). The interactions among the determinants of countless diseases are highly complex. Big Data enable researchers to integrate and aggregate information from across multiple sources. The opportunity is therefore undeniable from the perspective of the protection of life: this requires that we discard an *a priori* approach that conceives health-related data processing negatively.

As the German Ethics Council (*Deutscher Ethikrat*) pointed out, in biomedical research, the analysis of large volumes of health data should provide a better understanding of important scientific processes and their connections. Among the most data-intensive applications are modern imaging and molecular biological procedures, such as those employed in what we call 'omics' (e.g. genomics or proteomics[1]).

Also, this idea is explicitly recognized in the EU Regulation 2016/679, April 27, 2016, on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereinafter referred to as the EU Regulation). In fact, Recital 157 of the Regulation explicitly notes, "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".

Thanks to the massive use of data, results analysed collectively have a different value than results analysed individually. As Professor Vanesa Morente highlighted very clearly, the use of Big Data brings a deeper, and more significant insight, that goes beyond the obvious. Professor Morente uses a paradigmatic metaphor to explains the phenomenon: it is like an onlooker who may spot a human face in Giuseppe Arcimboldo's still lives only contemplating them as a whole, when the painting is a mere conglomerate of separate and assorted fruits and vegetables. The primary purpose of Big Data entails therefore a look that not only sees, but also discovers: it is a transformative look that sees value in raw, unprocessed information[2]. In the medical and health contexts in general, this has an

[1] GERMAN ETHICS COUNCIL, *Big Data and health. Data sovereignty as the shaping informational freedom*, Opinion, Executive Summary and Recommendations, Berlin, 2018, p. 9.

[2] V. MORENTE PARRA, *Big data o el arte de analizar datos masivos. Una reflexión crítica desde los derechos fundamentales*, in *Revista Derechos y Libertades,* 41 (época II), 2019, p. 2.

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unquestioned value, because unlike other research fields, this sector attaches a particularly relevant value to the quantitative method, even though, as they say, there are no illnesses, but rather patients. In any case, in order to improve medical treatments further, the opportunity to correlate millions of healthcare processes is fundamental, in that these results shall later be contextualized and personalised.

This opportunity has even more value and projection for the future in those States, such many of the EU Member States, which have implemented a public healthcare system where there is a correlation among millions of medical records and health data.

In the view of the definition given by the World Health Organization a few years ago, whereby health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", a holistic approach to health should blur the line between health seen from the medical perspective and lifestyle. Big Data provide the technical opportunity to support such a holistic vision, as they do not confine data use to strictly or traditionally health-related data, such as clinical records, but also integrate data on a person's lifestyle, habits and even environment.

On the other hand, these new opportunities of the development of new technologies, Big Data or AI pose some ethical and legal conflicts and dilemmas. Health data is one with a strict regulation and legal protection considering the impact of their revelation in individuals' privacy.

There are risks to personal rights, as there are opportunities. This is why the German Ethics Council specified that Big Data represent a major challenge to the legal system and, in particular, to constitutional law. Nonetheless, personal information goes hand in hand with these risks, even more so in areas such as healthcare, where highly sensitive data are at stake. However, Big Data will potentially multiply these risks[3]. In fact, they are not only limited to the right to privacy, since information on a person's health status can affect other rights and interests, such as access to employment, credit or insurance[4].

In any case, the balance between the individual rights and the common good or general interest is, sometimes, not very easy to fulfil. In any case, principle of proportionality always offers an ethical and legal pathway to do so, above all, from the perspective of the subprinciple of proportionality *stricto sensu* or balancing[5].

2. Is my health data mine anymore?

This question could be seen as a strong one or, at least, a tricky one. In any case, as we explained before, new technologies and mainly Big Data offers a great number of new opportunities in the area

[3] GERMAN ETHICS COUNCIL, *Big Data and health. Data sovereignty as the shaping informational freedom*, Opinion, Executive Summary and Recommendations, Berlin, 2018, p. 10.

[4] R. MARTÍNEZ, *Big data, investigación en salud y protección de datos personales ¿Un falso debate?,* in Revista Valenciana d'Estudis Autonòmics, 62, 2017, p. 236.

[5] The point of the balancing stage is to determine which of the two (or more) values at stake takes priority in the concrete circumstances of the case. In other words, the question is whether the interference with the right is justified in light of the gain in the protection for the competing right or interest. To this end, the two values have to be "balanced" against each other. Vid. K. MÖLLER, *Proportionality: challenging the critics*, in *I.Con*., 10 (3), 2012, p. 715.

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of health where we have a huge amount of data coming from medical records, clinical trials protocols, internet consultations, etc.

Consequently, it can be stated that clinical data are no longer a mere reminder of the healthcare process, but rather the main source of knowledge and progress in Medicine and Biology. Health data can already be considered as the true treasure of biomedical research, as many said that biological samples were the treasure of the previous decade.

In any case, considering risks and conflicts for individual rights, health data and biological samples are not the same, above all, if we consider the possibilities of anonymization or pseudoanynomization of data which are not identical for samples. Protection of individual identity from whom biological sample comes is not an easy task, because samples carry the genetic identity of the individual. But when we are talking about data, the possibilities of protecting his or her identity is not an unsolvable problem anymore.

In the healthcare field or in a specific clinical trial, data are not strictly of interest as documentary evidence of the most relevant facts concerning the treatment provided, treatment-related decisions or the diagnoses and conclusions reached, but for their secondary use. It is independent from the main purposes for which those data were initially provided. Patients contribute their data for a specific purpose and such data can be useful for a secondary purpose, or use, enabled by the tools offered by Big Data.

Moreover, the opportunities offered by the extensive use of health data become even more relevant in healthcare systems characterized by both essentially public management and care provision schemes (the Beveridge formula) and the recent process of digitalization of documents and clinical records, that helped introduce millions of data in a single or, at least, in easily comparable databases. Consequently, we are not exclusively referring to data extracted from research projects on humans or clinical trials, but to the secondary use of health data, which is more significant in terms of numbers and, possibly, value.

From an ethical perspective, as the Spanish Bioethics Committee said on its Report on the ethical-legal requirements in research with health data and biological samples in the framework of the Covid-19 pandemic, 2020[6], maintaining the postulate that the disease and the data generated by its treatment only belong to those who suffer it is not only to ignore reality, but also to ignore the existence of conflicting values and rights and the correct way in which they should be reconciled. Data protection is not, nor has it ever been, an end in itself, but rather serves to protect the person in their privacy, both in their private sphere and in the public sphere. However, it is also important to remember that this right to privacy, like other rights, plays in a social environment of interrelations, in which it is as relevant to recognize the autonomy of the individual as the solidarity of the citizen.

A similar position is supported by Barbara J Evans: those who invoke their right not to share their data in any circumstance, even when the health of third parties may depend on them, may be blurring the line between individual autonomy and narcissism[7]. A position that ignores the common

[6] http://assets.comitedebioetica.es/files/documentacion/Informe%20CBE%20investigacion%20COVID-19.pdf. (last visited 31/05/2021)

[7] B.J. EVANS, *Big Data and individual responsibility*, in GLENN COHEN et al (ed.), *Big Data, Health Law and Bioethics*, Cambridge University Press, Cambridge, 2018, p. 21.

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good and prioritizes not only autonomy but even selfishness and narcissism does not seem acceptable from an ethical-legal perspective. Also, for Ricard Martínez, there is a change of paradigm towards a new one based on efficient control by the authorities of the use of data from an initial consent[8].

In this regard, UNESCO's International Declaration on Human Genetic Data says in its Art. 14 that human genetic data, human proteomic data and biological samples associated with an identifiable person should not be disclosed or available to third parties, such as employers, insurance companies or relatives of the person in question, except for an important reason of public interest. And when we are talking about the value of secondary use of health data for the health of others, the public interest could be seen as a clear one.

The International Bioethics Committee, IBC-UNESCO, pointed out in its 2017 Report on Big Data in health, that Big Data can already be considered a common good of humanity (literally, "Big Data can be framed as a common good of humankind"). Science and technology in the field of Big Data can help reduce the inequalities that prevent many human beings from enjoying the highest possible level of health, both nationally and internationally. Therefore, it can be said that health data, in the Big Data stage, is a true heritage of humanity, even if it is in merely metaphorical terms. However, the provision of this Big Data cannot be carried out at the cost of violating the right that each individual has.

3. Is there a clear legal solution at the EU regulatory framework?

Despite the above-mentioned relevance of Big Data in general and in healthcare in particular, the European legal framework has not issued any specific regulation. It is true that there is a very complete regulation on personal data protection by the European Union and several parts of this regulation may apply to Big Data. However this is a new reality that may require more specific solutions. Therefore, the problem is not a dearth of general regulations, since several legal conflicts and dilemmas are legally covered by the data protection regulation, but rather of specific provisions and perhaps new principles apt to govern the innovative characteristics of Big Data.

In any case, the new EU regulation, while not specifically addressing the particular dilemmas and conflicts of Big Data, does contain specific references to health data and, more specifically, to the requirements for their secondary use for research purposes. We may say that the Regulation opens up a new era or even a new paradigm in this field. In fact, it replaces the model based on the alternative between informed consent and anonymization, with one based on informed consent or pseudonymization that would enable a more flexible use of health data in the interest of the community and everyone's good health.

From an ethical-legal standpoint, we do not believe that we can apply the ethical-legal principles and values developed for Big Data-driven research to traditional research projects on humans, because the rights involved in research projects not focused on individuals, but on their data differ. It is no longer a matter of affecting an individual's integrity, but rather intruding in his or her private sphere.

[8] R. MARTÍNEZ, *El alcance e interactuación del régimen jurídico de los datos personales y big data relacionado con salud y la investigación biomédica*, in Rev Der Gen H, 52, 2020, p. 59.

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Furthermore, one might ask whether a regulatory model, based essentially on an individual's interest, still responds to citizens' desires. In this respect, some works have already shown that citizens do not oppose data sharing; on the contrary, as Haug stated, patients want their data to be shared quickly, especially to ensure that other patients may learn of any possible treatment-related adverse events. At the same time, they also want to retain some control on how the data are shared, particularly when the research purposes are essentially commercial and not so much when public health systems seek to use data to improve medical treatment or care for other patients. In fact, receiving medical care invariably involves a loss of privacy. Patients must disclose their personal information to obtain help, and that help generally derives from knowledge gained from the experiences of previous patients who disclosed their personal information. The problem is not so much in the use, but in the demand for responsible use[9].

Obviously, this cannot mean prioritizing collective interest at the expense of individual interest, but rather seeking a balanced formula to integrate the two. This formula can be worked out when we safeguard the rights of the individuals involved by adapting one of the two requirements that the new legal model of data protection seeks to accomplish, i.e. anonymization through the new mechanism of pseudonymisation.

What is relevant in this new model is not so much an individual's prior consent to the new purpose for which data are intended or strict data anonymization. In fact, what matters is the legitimate origin of the data, the great importance of their secondary use for community health and the adoption of sufficient measures to prevent non-authorised third parties from gaining access to an individual's identity through the data, without necessarily demanding any strict anonymization. This seems to be legally achievable through what is commonly named pseudonymisation, defined by the EU Regulation as the processing of personal data in such a way that they can no longer be attributed to a specific individual without the use of additional information, as long as that such additional information is kept separately and subject to technical and organisational measures of non-attribution to an identified or identifiable individual.

The advantages of pseudonymization over traditional, strict anonymization are clear from the standpoint of community health. In fact, interlinking the data to the person, even when it is extraordinarily difficult for a third party to decode them, means not only to broaden the data used in a research to include other initially insignificant data (data enhancement), but also to corroborate the results of data use with the patients' real progress (results verification), for example. And this is very relevant in today's Big Data science. Pseudonymisation is, in the end, the only guarantee against the previously mentioned misleading causalities that are one of the main risks of Big Data.

In short, against this backdrop of great opportunities in the fight against disease and in the improvement of people's health, it is important to promote new paradigms that do not present technology only as something essentially good that totally excludes human intuition and wisdom. In fact, such models should not neglect that the context has deeply evolved over the years and the enormous advantages of massive data processing must go beyond a vision exclusively based on

[9] C.J. HAUG, *Whose Data Are They Anyway? Can a Patient Perspective Advance the Data-Sharing Debate*?, in NEJM, 26th April 2016, pp. 1-2.

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individual interest at the expense of the common good. As it is in many other areas, true virtue seems to assert itself as the centre of gravity between the two approaches.
Furthermore, the debate must be addressed so as not to lose sight of the context. In the health protection models developed in Western Europe after the Second World War and, above all, in those based on a social-democratic formula such as the Beveridge model, it would be contradictory to maintain a position only taking into account the individual or the subjective dimension, in that those models feature essential traits of communitarianism. Going to a hospital and having a serious health problem solved thanks to public spending demands that citizens exercise their responsibility that is manifested, in the current context of technological progress, in the moral duty to share their data so that others who have not been so easily and readily treated can benefit from medical care.

4. Has informed consent a main role in this new context of secondary use of health data?

If the secondary use of health data offers the opportunity to know what is the best chance of overcoming the disease for those who are suffering from it or who may unfortunately suffer from it in the future, can we sustain a presumed paradigm of the absolute sovereignty of the individual about her or his personal data? It seems that Big Data has not only substantially altered the form and method of research in Medicine, but also the nature of conflicting rights and interests. And all this makes more sense if possible, in a context such as the current one, of a pandemic as serious as the one we are suffering.
The general interest never justifies the sacrifice of individual rights. If there are situations in which Bioethics must inform decision-making in an unavoidable way, they are precisely those in which all our values are put in tension, and when the error of giving priority almost exclusively to the collective interest in detriment to the dignity and rights of the individual. Bioethics was born in the context of a crisis and it is precisely in moments of greatest difficulty that it reveals its fundamental role, providing the framework for reflection and deliberation that allows the most appropriate ethical decisions to be taken. Seeking the right balance between the common good and the rights of the individual must be the main target.
Thus, in the new framework offered by the advancement of science and technology through the secondary use of health data, when projects are of obvious common or general interest, the requirement of a new informed consent for a different use of data can be not attended for three fundamental reasons, following again the opinion of the Spanish Bioethics Committee (Report on the ethical-legal requirements in research with health data and biological samples in the framework of the Covid-19 pandemic, 2020)[10]:
Firstly, because obtaining a new consent to the secondary use of the data means allocating a large part of the personal and material resources of the projects to a different purpose than that of health research itself. Furthermore, obtaining such authorization in the current context can be very difficult, if not impossible when we are talking about a huge amount of data as Big Data usually implies. Certainly, this reason is relevant, but it may not be considered sufficient.

[10] http://assets.comitedebioetica.es/files/documentacion/Informe%20CBE%20investigacion%20COVID-19.pdf. (last visited 31/05/2021)

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Therefore, the second and most important reason that informs in favour of dispensing with the requirement of a new consent to carry out research with a great interest for public health or for the protection of the health of third parties, has to do with the scope of the right from the individual to his privacy within the framework of the society in which he develops his life. If certain conditions do not meet in a society, people's rights are nothing more than empty expressions. The Universal Declaration of Human Rights recognizes this when it states that "everyone has the right to establish a social and international order in which the rights and freedoms proclaimed in this Declaration are fully effective" (art. 28).

A third reason, closely related to the previous one, to justify not requiring a new specific informed consent in certain investigations, has to do with the duty of solidarity that we all have as members of a community. That duty is the condition of possibility of individual realization. Once again, the Universal Declaration of Human Rights summarizes it: "Every person has duties with respect to the community, since only in it can he freely and fully develop his personality" (art. 29.1).

When the preservation of a good of enormous importance for all, such as public health, requires carrying out research with personal data collected in the context of health care, its use may be justified without the need to request specific consent, provided that the guarantees for the safeguarding of the essential content of the right to privacy concur. The traditional paradigm of informed consent poses important problems from an ethical perspective.

As Barbara J Evans points out again, our legal model for medical and biomedical research has been based on the main role of informed consent as a guarantee of the privacy of the individual. However, this model responds to a different reality from the one now offered to us because current research, unlike that which gave rise to the great bioethical documents linked to research such as the Nuremberg Code or the Declaration of Helsinki, does not aims to act on the integrity of people, but on their data. It does not touch the person but their data. We are not facing physical integrity of the individual and collective interest, which would hardly pass the proportionality test, and, above all, the limit of dignity as the essential core of the right, but privacy. It is a new informational research that, neither ethically nor legally, can be equated with clinical trials that can put the integrity of the subject at risk. In Big Data environments, traditional individual informed consent standards can no longer fulfill the primary purpose for which they were designed[11]. And in a similar way, the Institute of Medicine of United States distinguishes between interventional research and research that is exclusively information based[12].

Therefore, we are talking about a different paradigm to the one traditionally called Helsinki paradigm. The so-called Helsinki paradigm refers to the bioethical and legal postulates promoted after the events that occurred in the field of research with human beings at the end of the first half of the 20th century and even a few years later. Bioethics and Biolaw were inaugurated as specific areas of knowledge on the occasion of the those execrable attacks on the dignity and human rights (see Willowbrook State School, Jewish Chronic Disease Hospital Of New York, or Tuskegge Syphilis Study, as sadly paradigmatic examples). Bioethical and bio-legal reflection arise as walls of

[11] B.J. EVANS, Op. Cit., pp. 26-27.

[12] Institute of Medicine, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research*, The National Academies Press, Washington DC, 2009, p. 3.

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containment or prevention against the abuses that can be committed in the field of research, expressing with the counterphrase erroneously attributed to Machiavelli, or, at least, with the pejorative meaning with which it habitually is used, that the ends do not justify the means or the collective interest the sacrifice of the dignity of the individual.

Both Bioethics and Biolaw were born as areas of knowledge with a foundational purpose: the development of guarantees for human dignity in the field of research with human beings. And these guarantees were included in the Nuremberg Code and later in the Declaration of Helsinki, approved by the World Medical Association in 1964. In both the new model inaugurated is based on the strict protection of individual interest, as a reaction to the abuses that occurred a few years before.

And this, precisely, is one of the problems we address. Informed consent, born essentially as a guarantee against atrocities committed at the end of the first half of the 20th century, has ended up postulating the principle of autonomy as the prevailing one, ignoring the context in which it is intended to operate. The problems that the doctrine of informed consent has presented in its evolution are substantially motivated because it arises under the protection of medical research with human beings, intending to implant with the same extension and effects in other areas such as healthcare medicine or of research with data. Although an extraordinarily rigorous compliance with the informed consent makes full sense in a relationship between researcher and subject in which the former is going to act on the life or physical integrity of the latter and in which the individual has to adopt a decision such as participating or not in a clinical trial, whose individual benefit is uncertain. In the research with data, such demands do not seem so necessary.

Furthermore, one might wonder if this legal model, based essentially on the interest of the individual, also responds to the wishes of citizens. In this regard, there are already works that show that citizens do not hold a position against sharing data. As Haug points out, patients want their data to be shared quickly, especially to ensure that other patients are aware of potential treatment side effects. And although it is true that they also want to maintain some control over how they are shared, this occurs especially when the aims pursued by the studies are essentially commercial and not so much when it is the public health systems themselves that intend to use them to improve medical treatment or care for other patients. Patients usually accept to expose their personal information for help, and that help is generally based on knowledge gained from the experiences of previous patients who have disclosed personal information. The problem is not so much in the use, but in the demand for responsible use[13].

The current model where the informed consent should play a main role for research with health data seems more based on the opinion of legislators and the doctrine of some academics than on the true will of the citizens.

Therefore, we can affirm that what is relevant in this new model will not be that the individual has given their prior consent for the new purpose to which the data is intended to be used, but a) the legitimate origin of data, b) the relevance for the general interest of the secondary use, c) and the implementation of enough guarantees to protect the individual's identity from whose data come from. And it seems that, legally, it can be achieved through what is now called pseudonymization, understood, in the words of the EU Regulation, as the processing of personal data in such a way that

[13] C.J. HAUG, Op. Cit., p. 1.

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they can no longer be attributed to an interested party without using information additional information, provided that such additional information appears separately and is subject to technical and organizational measures designed to ensure that personal data is not attributed to an identified or identifiable natural person.

The virtues offered by pseudonymization compared to the traditional strict anonymization are evident from the perspective of the interest of the health of the community, since, by maintaining the link between the data and the person, when it is extraordinarily difficult for a third party to decode it, it is allowed not only to expand the data used in the research to others that initially could not be considered transcendent (data expansion) but, which is very important in the current state of Big Data science, to contrast the results of the exploitation of data with, for example, the true evolution of the patients (verification of results)[14]. Pseudonymization is, in the end, the only guarantee against the spurious causalities which is one of the main risks of Big Data at its current stage of evolution.

This is the position of the International Bioethics Committee, IBC-UNESCO, which in the Report on Big Data and Health, 2017, stated (par. 59): "In case research is intended that falls outside the range of the broad consent that was obtained for the use of this data, specific consent is necessary for secondary data processing. This is an essential principle to guarantee confidentiality and data privacy. However, secondary analysis of data could be ethically admissible without a new informed consent for such secondary use provided that all the following requirements are met: 1) appropriate legal foundation; 2) evaluation by the Research Ethics Committee (REC); 3) adequate technical procedures in order to prevent researchers and third parties from accessing personal data, such as pseudo-anonymisation; 4) overriding public interest in this health research; 5) infeasible to obtain a new consent; and 6) data must have been collected according to ethical and legal requirements".

And also the Council of Europe in its Recommendation on Protection of health-related data, CM/Rec(2019)2 (par. 15.9): "Where scientific research purposes allow, data should be anonymised; where research purposes do not allow this, pseudonymisation of the data – with intervention of a trusted third party at the separation stage of the identification – is among the measures that should be implemented to safeguard the rights and fundamental freedoms of the data subject. These measures must be carried out where the purposes of the scientific research can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects".

5. Conclusion

In this new framework of great opportunities to fight against diseases and improve people's health, it is important to promote new paradigms which do not forget that there is a very different context from the existing one a few years ago. The great advantages offered by massive data processing should determine a vision not only based on individual interest with a clear detriment of the

[14] Using the words of The Nuffield Council: "to feed back information to an individual within a cohort who is discovered to be at particular risk, or to validate an analytical procedure, or to enable further data about individuals to be added over time". Vid. NUFFIELD COUNCIL ON BIOETHICS, *The collection, linking and use of data in biomedical research and health care: ethical issues*, The Nuffield Council Publication, London, 2015, p. 68.

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common good. A balance between both positions seems to show itself, as it happens in many other areas, as true virtue.

Furthermore, the debate must be framed in terms where the context is also considered. In the models of healthcare developed in Western Europe after the Second World War and, above all, in those based on the more social democratic formula such as Beveridge model, it is a contradiction to maintain a position that only addresses the individual dimension, when the model has essential features of communitarianism.

Between the two main options offered for a real development of the opportunities of secondary use of health data, a new form of informed consent such as dynamic one, taking advantage of the proper technology to give it for new uses of data, or pseudonymization as a flexibilization of strict anonymization, we consider that the second one should prevail for the reasons explained before.

In any case, this new paradigm also needs the development of a real governance of health data to support correctly it. So, accepting a new model based on pseudonymization means to put all our efforts in that target, a new model of co-governance where all the benefits from the massive exploitation of millions of health data should redound to the benefit not of the industry nor the specific individuals from which these data come from, but to all the community.

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