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BRIEF WORDS FROM THE GUEST EDITOR

The last months of 2022 delivered me a very pleasant – and yet a heavy burden – task: put together a group of authors and organize a theme issue for the Medicine & Law Journal, to be released during the first quarter of 2023.

Once the main theme was defined – the importance of information in healthcare services – the idea that was put into practice was to invite scholars, professors, and specialists to share their view, and to offer a broad perspective on the subject, considering patient´s rights, physician´s duties, ethical commands, new technologies, and bioethics.

The result of this mission is what we see in the following pages: fifteen papers offering a broad overview from different angles and countries, discussing the role of information and its relation to autonomy and consent, demonstrating that Medical Law is constantly evolving, and our role as researchers is, more than answering to problems, to pose new questions that will help understand health sciences from a legal point of view, establishing a fruitful dialogue that will benefit society as a whole.

Patient autonomy refers to the right of individuals to make decisions about their own medical treatment and healthcare, free from coercion or undue influence. Adequate information is a key component of patient autonomy, as it enables individuals to make informed decisions about their own health and medical treatment. In modern jurisdictions, patient autonomy is protected by both legislation and ethical principles, which aim to ensure that individuals receive the information they need to make informed decisions and to participate fully in decisions about their own health and medical treatment.

The research developed by the authors to deliver these works demonstrates and reinforces what I have been defending for several years: Medical Law, in addition to its constant evolution, is necessarily intertwined with other sources of Law, and has a wide intersection with reality, interacting directly with the spectrum of contemporary changes in the social fabric, uniting tradition, innovation and technologies in a very harmonious and original way.

Without any further delay, I wish you a positive and thought-provoking reading experience.

With my warmest regards,

Eduardo Dantas

Recife, January 2023

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PERSONAL HEALTH DATA IN THE BRAZILIAN GENERAL PERSONAL DATA PROTECTION LAW: PECULIARITIES AND PROTECTIVE SCOPE

José Luiz de Moura Faleiros Júnior[1]

Abstract: Personal health data is regarded as sensitive data in the Brazilian General Personal Data Protection Law (Law No. 13.709, of August 14, 2018). As there is no need for the prioritization of consent or any other hypothesis for the processing of personal data, it is important to know the limits for which the figure designated in the law as "to protect health" has greater value. It is from this that the theme-problem and the hypothesis of this article are extracted, aiming to clarify the ballast situations for the processing of personal data in terms of what is meant by health protection. To this end, concepts and clarifications on important aspects of the law and its incidence will be presented. In methodological terms, the paper will be based on the deductive method, starting from introductory and conceptual aspects of the law to advance towards more in-depth outlines on the chosen hypothesis of processing personal data. At the end, a conclusion will be presented.

Keywords: Personal Health Data; Brazilian General Personal Data Protection Law; Health Protection; Data Processing; Sensitive Personal Data

Introduction

Personal health data is regarded as sensitive data in the Brazilian General Personal Data Protection Law—Law No. 13.709, of August 14, 2018—and its processing is only permitted in specific hypotheses listed in Chapter II of the

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law, titled "Requirements for the processing of data". The regime structured according to the conceptual dichotomy between personal data and sensitive personal data is the preponderant factor for seeking greater clarity in defining the scope of each regime and in the contexts of application of each data processing hypothesis.

Thus, as there is no need for the prioritization of consent or any other hypothesis for the processing of personal data, it is important to know the limits for which the figure designated in the law as "to protect health" has greater value. It is from this that the theme-problem and the hypothesis of this article are extracted, aiming to clarify the ballast situations for the processing of personal data in terms of what is meant by health protection. To this end, concepts and clarifications on important aspects of the law and its incidence will be presented.

In methodological terms, the paper will be based on the deductive method, starting from introductory and conceptual aspects of the law to advance towards more in-depth outlines on the chosen hypothesis of processing personal data. At the end, a conclusion will be presented.

1 Introductory Notes on the Brazilian General Personal Data Protection Law and its Scope

The Brazilian General Personal Data Protection Law—Law No. 13.709, of August 14, 2018 (the "LGPD")—defines, in its Article 5, two conceptual types of personal data: (i) personal data, which is all information regarding an identified or identifiable natural person (item I); (ii) sensitive personal data: personal data concerning racial or ethnic origin, religious belief, political opinion, trade union or religious, philosophical or political organization membership, data concerning health or sex life, genetic or biometric data, when related to a natural person (item II).

Long before the LGPD, the Law on Access to Information (Law No. 12.527 of November 18, 2011, or "LAI") already provided, in its Article 4, item I, a very similar concept, but with an inversion between the words "information" and "data": "I - information: data, processed or not, that can be used for the production and transmission of knowledge, contained in any medium, support or format". Still, there is, in the LAI, the concept of "personal information" in Article 4, item IV, which defines it as "that related to an identified or identifiable natural person"—and this is a definition closer to the one that inspired the edition of the two initial items of Article 5 of the LGPD.

What cannot be denied is that the repertoire of Article 5, item II (sensitive personal data) is quite broad and, due to the well-known influence of the European experience in the construction of the Brazilian law, it is noteworthy that the legislator structured the dichotomous model between personal data and sensitive personal data, when, on the other hand, there is a broader category of personal data and only three categories are highlighted and conceptualized in a more detailed way so that they are given greater protection, in the European Union's General Data Protection Regulation (Regulation 2016/679(EU), the "GDPR"). The three categories are as follows: genetic data, biometric data, and data concerning health.

Here are the concepts of the European GDPR:

Article 4
EU GDPR
"Definitions"

For the purposes of this Regulation:

(1) '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;

(...)

(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;

(14) 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data;

(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;[2]

2 European Union. *General Data Protection Regulation (2016/679(UE))*. Available at https://gdpr-text.com/pt/read/article-4/ Accessed on Dec. 30, 2022.

It is undeniable that legal doctrine has always faced the controversial conceptual distinction between "data" and "information"[3]. Despite this, the technological evolution that has marked recent years, especially since the 1990s—when the Internet became popular—has raised the importance of understanding the most peculiar aspects of information, challenging the reframing of the fundamental right to privacy. For this reason, the legislator opted to grant greater legal protection to personal data classified as "sensitive", identifying it in line with the protective set housed by the Brazilian legal system that is based on the recognition of the prominence of personality rights and the important amalgamation contained in the repertoire of fundamentals of Article 2 of the LGPD and in the conceptualization of Article 17 of the law, which enunciates the ownership attributed to the natural person over their data based on three very important fundamental rights: privacy, freedom and intimacy.

The doctrine is not pacific in relation to the nature of the list of item II of Article 5 of the LGPD—whether exhaustive or exemplary—, which reveals the correlation of the hypotheses listed with the projections of the individual's personality, conjecturing the desired protection of the data subject[4]—which is, according to Articles 5, item V, and 17 of the law, only the natural person, and not the legal entity—due to the phenomenon that the doctrine has been investigating for years about the construction of these projections from the incessant data flows.

For Laura Schertel Mendes, "(...) the vitality and continuity of the Constitution depend on its ability to adapt to new social and historical transformations, enabling protection of citizens against new forms of power that arise in society"[5]. In other words, it appears that the new technology of electronic

3 Doneda D. O direito fundamental à proteção de dados pessoais. In: Martins GM, Longhi, JVR (ed.). *Direito digital:* direito privado e Internet. 2nd edition. Indaiatuba: Foco, 2019, p. 37.

4 A divergente opinion in that of Tomasevicius Filho E., Sousa MA. A proteção de dados da pessoa jurídica e a Lei Geral de Proteção de Dados. *Consultor Jurídico,* 22 jan. 2021. Available at https://www.conjur.com.br/2021-jan-22/opiniao-protecao-dados-pessoa-juridica-lgpd. Accessed on Dec. 30, 2022.

5 Mendes LS. *Privacidade, proteção de dados e defesa do consumidor:* linhas gerais de um novo direito fundamental. São Paulo: Saraiva, 2014, p. 169, freely translated. In the original, "(...) a vitalidade e a continuidade da Constituição dependem da sua capacidade de se adaptar às novas transformações sociais e históricas, possibilitando uma proteção dos cidadãos contra novas formas de poder que surgem na sociedade".

communications has inaugurated a new era[6], and it is no longer possible to disregard the framework of data protection as an autonomous category of personality rights (positive freedom), in contrast to the fundamental right to privacy (negative freedom)[7].

In this sense, consent is often remembered[8], as it is listed, in the LGPD, as a hypothesis for the processing of personal data (Art. 7, I) and also for the processing of sensitive personal data (Art. 11, I), based on a concept structured in the law itself (Art. 5, XII), by which "consent" is the "free, informed and unambiguous manifestation whereby the data subject agrees to her/his processing of personal data for a given purpose". However, the possibility of processing personal data (Art. 7, VIII) and sensitive personal data (Art. 11, II, "f") is also foreseen for "health protection", configured, in both cases, "exclusively, in a procedure performed by health professionals, health services or health authorities".

Such doubts require careful analysis so that the scope of one or another data processing hypothesis is not too broad, to the detriment of the others, in effusive recognition of the virtues of one or the other, as the LGPD "brought little in terms of protection of health data, focusing mainly on the continued economic exploitation by the [health] sector"[9]. In subsequent topics, more detailed distinctive considerations will be presented on the chosen data processing hypothesis and some critical reflections on its scope of incidence.

2 "Health Protection" among the Hypotheses ("legal grounds") for the Processing of Personal Data

"Information" as a concept, considered and interpreted without context, not being sufficient to directly or potentially identify the natural person to which

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6 Brzezinski ZK. *Between two ages*: America's role in the technetronic era. New York: Viking Press, 1971, p. 11.

7 Bioni BR. *Proteção de dados pessoais:* a função e os limites do consentimento. Rio de Janeiro: Forense, 2019, p. 92-93.

8 Miragem B, Madalena J. Artigo 7º. In: Martins GM, Longhi JVR, Faleiros Júnior, JLM (ed.). *Comentários à Lei Geral de Proteção de Dados Pessoais*. Indaiatuba: Foco, 2022, p. 68.

9 Chaves JGP. Responsabilidade civil por danos à personalidade no tratamento de dados pelo setor da saúde. In: Tomasevicius Filho E. (ed.). *A Lei Geral de Proteção de Dados brasileira:* análise setorial. São Paulo: Almedina, 2021, v. 1, p. 324, freely translated. In the original, "pouco trouxe no que diz respeito à proteção dos dados de saúde, focando principalmente na continuidade da exploração econômica pelo setor".

it relates, is insignificant for the purposes described in the Brazilian LGPD. The informational context that inspired the legislator to define a vast repertoire of fundamentals (Art. 2), concepts (Art. 5), principles (Art. 6) and individual rights (Art. 18) related to the protection of personal data finds its ballast in the recognition that the change brought about by the digital transformation is inescapable and unstoppable.

That said, it is important to note that the protection of health has its own and undeniably challenging contours in the context of the protection of personal data. This is because such data are considered sensitive, but although there are legal grounds for it (Art. 11, II, "f", of the LGPD), sometimes consent will be the best option for their processing.

That said, it is important to remember that the legislator distinguished the legal grounds – technically considered "requirements" for the processing of data – in specific hypotheses for the personal data conceptualized in Article 5, item I, and for sensitive personal data, that article 5, item II, describes. The former are listed in Article 7 of the law, and the latter in Article 11.

Here's a comparative summary[10]:

Art. 7 Processing of personal data shall only be carried out under the following circumstances:	Art. 11. The processing of sensitive personal data shall only occur in the following situations:
I – with the consent of the data subject;	I – when the data subject or her/his legal representative specifically and distinctly consents, for the specific purposes;
II – for compliance with a legal or regulatory obligation by the controller;	II – without consent from the data subject, in the situations when it is indispensable for: a) controller's compliance with a legal or regulatory obligation;

10 Brazil. Law No. 13.709 of Aug. 14, 2018. General Personal Data Protection Law (LGPD). Available at http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm Accessed on Dec. 30, 2022.

III – by the public administration, for the processing and shared use of data necessary for the execution of public policies provided in laws or regulations, or based on contracts, agreements or similar instruments, subject to the provisions of Chapter IV of this Law;	b) shared processing of data when necessary by the public administration for the execution of public policies provided in laws or regulations;
IV – for carrying out studies by research entities, ensuring, whenever possible, the anonymization of personal data;	c) studies carried out by a research entity, whenever possible ensuring the anonymization of sensitive personal data;
V – when necessary for the execution of a contract or preliminary procedures related to a contract of which the data subject is a party, at the request of the data subject;	d) the regular exercise of rights, including in a contract and in a judicial, administrative and arbitration procedure, the last in accordance with the terms of Law No. 9,307, of September 23, 1996 (the "Brazilian Arbitration Law");
VI – for the regular exercise of rights in judicial, administrative or arbitration procedures, the last pursuant to Law No. 9,307, of September 23, 1996 (the "Brazilian Arbitration Law");	-
VII – for the protection of life or physical safety of the data subject or a third party;	e) protecting life or physical safety of the data subject or a third party;
VIII – to protect the health, exclusively, in a procedure carried out by health professionals, health services or sanitary authorities; (New Wording Given by Law No. 13,853/2019)	f) to protect the health, exclusively, in a procedure carried out by health professionals, health services or sanitary authorities; (New Wording Given by Law No. 13,853/2019)
IX – when necessary to fulfill the legitimate interests of the controller or a third party, except when the data subject's fundamental rights and liberties which require personal data protection prevail; or	-
X – for the protection of credit, including as provided in specific legislation.	g) ensuring the prevention of fraud and the safety of the data subject, in processes of identification and authentication of registration in electronic systems, respecting the rights mentioned in Art. 9 of this Law and except when fundamental rights and liberties of the data subject which require protection of personal data prevail.

It is to be noted that certain details were neglected by the legislator, which is something even repetitive and confusing in some aspects of differentiating personal data in relation to sensitive personal data. The presence of the word "only" in the caputs of the two provisions indicate the exhaustiveness of the hypotheses presented. However, with regard to sensitive personal data, the redundancy that was maintained stems from the need to indicate the purpose of the treatment, which is already contained in Art. 9, item I, of the law, and reappears in Art. 11, item I, when it reads that the manifestation of consent for data collection must be given "in a specific and prominent way, for specific purposes".

If there are no conditions for the application of the hypothesis of health protection, the consent of the data subject will appear as a plausible alternative for carrying out data processing. And, in this regard, it should be noted that consent is seen by the legislator as a true "trigger" for filtering the undue collection of data.

In summary, through the consented collection of personal data, including sensitive personal data (Arts. 5, X, and 11, I), the observance of a specific purpose (which is, in fact, a very important principle of the law, in Art. 6, I) is required. Thus, as consent becomes the fundamental criterion for data processing, it becomes essential that the individual knows how to discern the limits and risks to be faced when providing personal data to a certain agent.

In this regard, it is worth mentioning the distinction made between consent for medical care and consent for the processing of personal data. On the subject, Flaviana Rampazzo Soares explains that "it is possible to state that [the patient's consent to health care] is subject to the LGPD with regard to the data and information related to it, and not regarding the object and purpose of the consent itself (which is a specific service), and the incidence of the LGPD will be limited to what concerns data processing"[11].

Another particularly peculiar point is the use of items (ten in all) to list the legal grounds of Article 7 and, as for the legal grounds of Article 11, the use of

11 Soares, FR. Consentimento no direito da saúde nos contextos de atendimento médico e de LGPD: diferenças, semelhanças e consequências no âmbito dos defeitos e da responsabilidade. *Revista* IBERC, v. 4(2): 18-46, may/aug. 2021, p. 34, freely translated. In the original, "é possível afirmar que o [consentimento do paciente no atendimento em saúde] está sujeito à LGPD no que tange aos dados e informações a ela relacionados, e não quanto ao objeto e objetivo do consentimento em si (que é um específico atendimento), e a incidência da LGPD se circunscreverá ao que disser respeito ao tratamento de dados".

items and letters. One detail, in this regard, stands out: in the case of sensitive data, consent appears in a separate item (Art. 11, item I), while all other legal grounds for treatment appear listed in the seven letters (from "a" to "g") of the subsequent item (Art. 11, item II).

Article 59, in its sole paragraph, of the Constitution of the Federative Republic of Brazil commanded the legislator to enact supplementary law to provide for the elaboration, wording, amendment and consolidation of laws. It is important to remember that such legislation already exists and is extremely important: it is Complementary Law No. 95, of February 26, 1998, that states in Article 10 the existence of hierarchy between items and letters.

The aforementioned law is quite clear in hierarchizing the subdivision of items into subparagraphs, and these into items. There is, therefore, no horizontality between items and paragraphs, but there is verticality between items and letters. This leads to the following question, based on a literal and systematic interpretation of Articles 7 and 11 of the LGPD: would the legislator, when listing consent in a specific item of Article 11 and the other legal grounds in letters of another item, have chosen to confer greater value (and consequent preponderance) to consent? The question is difficult to answer and there is little investigation in this regard, but it seems to make sense, especially if analyzed in terms of the informational context illustratively presented in the first lines of this article.

In addition, there is a lack of clarity about what is meant by "health protection", especially due to the fact that the concepts of Articles 7, VIII, and 11, II, "f" restrict the scope of the norm "exclusively" to "procedures". The first term, an adverb, linked to the second, a noun, opens room for discussions about the extension of the very concept of "procedure" in health matters, which, strictly speaking, cannot be confused with the principle of "purpose" for processing data (Art. 6, I), which is necessarily orbital in relation to the person's clinical/medical care. In addition, the repetition of the hypothesis in the list of items in Article 7 is curious, since data related to health are considered sensitive because they are expressly included in the conceptual description of the law as such (Art. 5, II).

It is not denied that, in the collection of data orbitally treated to enable the protection of health in carrying out health procedures, "common" personal data and sensitive personal data are intertwined and it is impossible to separate them to assign different protection measures to each dataset. However, for the specific purposes of the health protection hypothesis, the very concept of

health-related data is extremely important and, in this regard, the European GDPR was much more detailed and elucidative than the Brazilian LGPD, as it identified a key condition for the characterization of these data, that is, "that reveal information about your health *status*"[12].

3 Peculiarities and Application Context

The hypothesis that best justifies the treatment of health-related data is the one that appears in letter "f" of item II of Article 11, as the wording also contains specific conditions: it must occur in a procedure carried out by health professionals, health services or health authorities[13]. It is noted, at first glance, the need to conceptualize the term "procedure" in order to discuss the invocation of this hypothesis. Furthermore, it should be noted that the aforementioned item was amended by Provisional Measure No. 869/2018 (later converted into Law No. 13.853/2019) to include "health services" in the list of those who are authorized to invoke health protection as legal grounds for processing data.

The scope of application of the LGPD, already explained in the previous topic, considers the protection of personal data and sensitive personal data. However, the data covered by the hypotheses described in Article 4 of the law, which makes clear the protective scope sought by the legislator. Regarding the principles applicable[14] to the processing of personal data, Article 6 of the LGPD indicates the legislator's objective of restricting the processing of personal data, requiring that there be strict observance so that the lawfulness of the activity is recognized.

The concern with net neutrality[15] and the principle of nondiscrimination (Art. 5, IX) take on special contours when investigating the protection of sensitive

12 European Union. *General Data Protection Regulation (2016/679(UE))*. Available at https://gdpr-text.com/pt/read/article-4/ Accessed on Dec. 30, 2022.

13 Brazil. Law No. 13.709 of Aug. 14, 2018. General Personal Data Protection Law (LGPD). Available at http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm Accessed on Dec. 30, 2022.

14 The list of principles brought by the law includes the following postulates: purpose, suitability, need, free access, data quality, transparency, security, prevention, non-discrimination, accountability and accountability.

15 Provided for in art. 9 of the Marco Civil da Internet (Law nº 12.965/2014), net neutrality defines the beacons of privacy, curbing the informational power of a few large corporations and aiming to guarantee that all information that travels on the network is treated in the same way, navigating at the same speed, that is, at the speed of contracting, preventing certain corporations from overlapping the State itself. Lloyd IJ. Information technology law. 6th. edition. Oxford: Oxford University Press, 2011, p. 40-43.

personal data, since, due to its nature, such data reveal an increase in the risks of personal stratification and stigmatization of people from profiles traced by processing collected data[16].

Consent is considered by the legislator as a trigger for filtering improper data collection. It was decided to admit data processing through the consented collection of personal data, including sensitive personal data (Articles 5, XX and 11, I), but the observance of a specific purpose is required. The problem—already signaled by the doctrine—is that ordinary citizens are not used to caring as much about digital information as about those stored on paper, even when they reveal the same facts: "having a stranger break into your house is inevitably more violating than having one hack into your email"[17].

Regarding consent as legal grounds for the processing of personal data, the debate is wide and deserves further investigation[18]. There are other issues to be considered, such as the unnecessary written form for consent (see Article 8 of the LGPD), or the distinction between the adjectives "specific" and "highlighted", which the law attributes to the form of consent in Article 11, item I. According to Chiara Spadaccini de Teffé, the term 'highlighted' "can be interpreted in the sense that it is important that the holder has full access to the document that will inform all the relevant facts about the processing of his personal data, and such provisions must be highlighted so that the expression of consent takes place in accordance with the law"[19].

As for the rest, without a doubt, the reiteration of a good part of the content of Article 7 in Article 11 indicates the legislator's intention in assigning special care to sensitive personal data: it was decided to attribute greater protection to that category of information considered most valuable. In the case of sensitive personal data, the context in which the data was kept or used turns out to be more important than the data itself.

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16 Rodotà S. *A vida na sociedade da vigilância:* a privacidade hoje. Translated by Danilo Doneda and Luciana Cabral Doneda. Rio de Janeiro: Renovar, 2008, p. 56.

17 Sumner S. You: for sale. Protecting your personal data and privacy online. Waltham: Syngress/Elsevier, 2016, p. 10.

18 Mulholland CS. Dados pessoais sensíveis e a tutela de direitos fundamentais: uma análise à luz da Lei Geral de Proteção de Dados (Lei 13.709/18), *Revista de Direitos e Garantias Fundamentais,* v. 19(3): 159-180, sep./dec. 2018, p. 160-162.

19 Teffé CS. *Dados pessoais sensíveis:* qualificação, tratamento e boas práticas. Indaiatuba: Foco, 2022, p. 149, freely translated. In the original: "(…) pode ser interpretado no sentido de que é importante que o titular tenha pleno acesso ao documento que informará todos

A list of names and addresses, for example, would normally not be considered sensitive, but this interpretation could change depending on context. Equally controversial is the consideration of the actions of each treatment agent (controller or operator, according to the concepts of Article 5, VI and VII), which may lead to civil liability, as expressly provided for in Article 42, § 1. This specific theme gives rise to a huge stir regarding the classification, for example, of the employee or public servant in the concept of "operator" (equivalent to the GDPR's data processor) that the law presents as someone in a subordinate capacity. Those are unsettling subjects, but for another time.

Alongside this, the studies of Helen Nissenbaum, who argues that there is a social value attributable to personal information, serving as a 'ruler' for the conceptualization of what is appropriate or not, should be expressly mentioned. The author defends the use of "contextual privacy" as a heuristic decision-making process in which the center of analysis results in the capture of the complete meaning of privacy and the substitutes for an eventual violation[20].

It means that, in addition to several specific and obviously harmful situations, it is to be expected that the investigation of a possible violation—especially for the purpose of assessing civil liability—transcends the mere objective verification of the fact and enters the contextual intricacies of damage and use of the data.

The last aspect to be considered concerns paragraphs 4 and 5 of Article 11 of the LGPD:

> Art. 11. (...)
>
> §4 Communication or shared use between controllers of sensitive personal data referring to health in order to obtain an economic advantage is prohibited, except in hypotheses related to the provision of health services, pharmaceutical assistance and health insurance, as long as the paragraph 5 of this article is observed, including auxiliary

os fatos relevantes sobre o tratamento de seus dados pessoais, devendo tais disposições virem destacadas para que a expressão do consentimento ocorra conforme a lei".

20 Nissenbaum H. *Privacy in context:* technology, policy and the integrity of social life. Stanford: Stanford University Press, 2010, p. 231-233.

> diagnostic and therapeutic services, in benefit of the interests of the data subject and also to allow:
>
> I - data portability of data when requested by the data subject; or
>
> II - the financial and administrative transactions resulted from the use and provision of the services referred to in this paragraph.
>
> §5 Operators of private health care plans are prohibited from processing health data for the practice of risk evaluation in any modality of hiring, as well as the hiring and exclusion of beneficiaries. (Included by Law No. 13,853/2019)[21]

The processing of personal data is conceptualized in Article 5, item X, of the LGPD: it is "any operation carried out with personal data, such as collection, production, receipt, classification, use, access, reproduction, transmission, distribution, processing, filing, storage, deletion, evaluation or control of the information, modification, communication, transfer, dissemination or extraction".

It should be highlighted that mere access or storage on the device already allows the action to be classified as an activity for the processing of personal data. However, §4 of Article 11 refers to a different concept: that of "shared use". This figure is also described in the law, in Article 5, item XVII, as the "communication, dissemination, international transfer, interconnection of personal data or shared processing of banks of personal data by public agencies and entities, in compliance with their legal capabilities, or between these and private entities, reciprocally, with specific authorization, for one or more types of processing allowed by these public entities, or among private entities".

It means that the controller who has access to health-related data must keep them with him, not being allowed to share them with third parties to achieve economic purposes. The exceptions are clearly listed in §4, which also mentions the subsequent §5, which prohibits the implementation of these data for risk assessment.

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21 Brazil. Law No. 13.709 of Aug. 14, 2018. General Personal Data Protection Law (LGPD). Available at http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm Accessed on Dec. 30, 2022.

On the subject, Analuza Dallari highlights the following:

> A unified, interoperable and fluid health system is planned to increase the competitiveness and efficiency of the sector, which can bring many benefits to health as a whole and to the journey of individual and collective care. In this sense, the principles set out in the current National Policy on Information and Informatics in Health (PNIIS), established by Ordinance GM/MS nº 1.768/2021. The PNIIS defines the guiding principles and guidelines for the public and private sectors to effectively integrate health information systems, promoting innovation, supporting the digital transformation of health work processes and improving governance in the use of information, health solutions information technology and digital health, as well as transparency, security and access to health information by the population and improvement of the citizen's health. But the institution of an open health system in the country does not escape the proper application of the LGPD and the scrutiny of the State's supervisory power and, most likely, the healthtechs that develop and provide ICT solutions will compose the complex digital health system of the "Sistema Único de Saúde". The deadline for society's contribution, offered by Technical Note No. 31/2022/CGN/ANPD ended on August 22, 2022. It is very likely that the health area is included in the Regulatory Agenda of the ANPD for the biennium 2023- 2024 and, in addition to article 11, paragraph 4 of the LGPD and 13 of the LGPD, article 11, paragraph 3 of the Law must also be observed. For this task, it is essential that the ANPD establish a dialogue with other key sector actors for the proper interpretation and regulation of the LGPD in the health area, even to avoid unnecessary obstacles for the sector: Ministry of Health, National Agency for Supplementary Health, Council National Health Agency, National Health Surveillance Agency, among others (Conep, Conass, Conasems, private associations).[22]

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22 Dallari AB. Interpretação do artigo 11, parágrafo 4º da LGPD no contexto pós-pandemia. *Consultor Jurídico,* Aug. 26, 2022. Available at https://www.conjur.com.br/2022-ago-26/analluza-bolivar-artigo-11-lgpd-contexto-pos-pandemia Accessed on Dec. 30, 2022. In the original version: "Planeja-se um sistema de saúde unificado, interoperável e fluído para aumentar a competitividade e eficiência do setor, o que pode trazer muitos benefícios para a saúde como um todo e para a jornada de cuidado individual e coletivo. Nesse sentido os princípios dispostos na atual Política Nacional de Informação e Informática em Saúde (PNIIS), instituída pela Portaria GM/MS nº 1.768/2021. A PNIIS define

Certainly, all this concern denotes the legislator's special care with data related to health, which allows a return to the question previously raised: should consent prevail for the treatment of these types of data? From everything observed, prudence seems to impose an interpretation of the list of legal grounds of item II of Article 11 of the LGPD in conjunction with the principles that the law itself describes, with emphasis on prevention (Art. 6, VIII) and for responsibility and accountability (Art. 6, X).

If it is possible to obtain consent, it must guide the treatment activities (and also those for shared use, in the restricted cases of the final section of article 11, paragraph 4 of the LGPD), striving for the protection of the data subject. The hypothesis related to the protection of health, contained in Article 11, II, "f", of the law, considered in a supplementary character and attached to the "procedures" mentioned there, must be adopted in restricted and more specific situations, waiving consent only due to total infeasibility (technical, practical or as a matter of time) to achieve it.

Conclusion

In this brief investigative path, an attempt was made to highlight the difference in regimes and requirements for the processing of "common" personal data and sensitive personal data, with emphasis on the different hypotheses defined by the legislator for each regime, in Articles 7 and 11 of the LGPD, especially the "guardianship of health". Its differences in relation to consent, in addition

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os princípios e diretrizes norteadores para os setores público e privado efetivarem a integração dos sistemas de informação em saúde, promovendo a inovação, apoiando a transformação digital dos processos de trabalho em saúde e aprimorando a governança no uso da informação, das soluções de tecnologia da informação e da saúde digital, bem como a transparência, a segurança e o acesso às informações em saúde pela população e melhoria da saúde do cidadão. Mas a instituição de um sistema de open health no país não escapa à adequada aplicação da LGPD e ao escrutínio do poder fiscalizador do Estado e, muito provavelmente, as healthtechs que desenvolvem e fornecem soluções em TICs comporão o complexo sistema de saúde digital do Sistema Único de Saúde. O prazo para a contribuição da sociedade, oferecido pela Nota Técnica nº 31/2022/CGN/ANPD encerrou-se em 22 de agosto de 2022. É bastante provável que a área da saúde esteja contemplada na Agenda Regulatória da ANPD para o biênio 2023-2024 e, além do artigo 11, § 4º da LGPD e 13 da LGPD, o artigo 11, § 3º da Lei também deve ser observado. Para esta tarefa, é primordial que a ANPD estabeleça diálogo com outros atores setoriais fundamentais para a adequada interpretação e regulamentação da LGPD sobre a área da saúde, até para evitar entraves desnecessários para o setor: Ministério da Saúde, Agência Nacional de Saúde Suplementar, Conselho Nacional de Saúde, Agência Nacional de Vigilância Sanitária entre outros (Conep, Conass, Conasems, associações privadas)".

to the disparity of elements characterizing the very concept of "data related to health" in Brazilian law, allowed us to identify the value of the conceptual detail brought by Article 4.º, n.º 15, of the European GDPR in order to advance in the interpretation of Brazilian law.

In matters such as the processing of personal data, identifying the context in which the principles of the law are applied expands possibilities so that a concept such as "health protection" can be properly assessed, and, in this concept, there is no doubt of the more restrictive scope of the law, which uses the adverb "exclusively" when referring to "procedures" in health matters as the only context for applying such hypothesis of data processing. It is possible to state, from this, that the term "procedure" is configured as an objective criterion for invoking the hypothesis; in addition, there is a subjective criterion, which involves the characterization of the treatment agent as a health professional, health service or health authority.

If one of the criteria is absent, the hypothesis designated by law as "health protection" will not be relevant and the treatment agent must resort to another. It is for this reason that we must reaffirm the importance of consent as a supplementary hypothesis for the processing of personal data, which must be adopted whenever necessary and feasible, including and especially for the legal security of the health professional or the health service, since health authorities may resort to constraints applicable to the administrative regime to which they are submitted due to the function they fulfill.

References

Bioni BR. *Proteção de dados pessoais:* a função e os limites do consentimento. Rio de Janeiro: Forense, 2019.

Brazil. Law No. 13.709 of Aug. 14, 2018. General Personal Data Protection Law (LGPD). Available at http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm Accessed on Dec. 30, 2022.

Brzezinski ZK. Between two ages: America's role in the technetronic era. New York: Viking Press, 1971.

Chaves JGP. Responsabilidade civil por danos à personalidade no tratamento de dados pelo setor da saúde. In: Tomasevicius Filho E. (ed.). *A Lei Geral de Proteção de Dados brasileira:* análise setorial. São Paulo: Almedina, 2021.

Dallari AB. Interpretação do artigo 11, parágrafo 4º da LGPD no contexto pós-pandemia. *Consultor Jurídico,* Aug. 26, 2022. Available at https://www.conjur.com.br/2022-ago-26/analluza-bolivar-artigo-11-lgpd-contexto-pos-pandemia Accessed on Dec. 30, 2022.

Doneda D. O direito fundamental à proteção de dados pessoais. In: Martins GM, Longhi, JVR (ed.). Direito digital: direito privado e Internet. 2nd edition. Indaiatuba: Foco, 2019.

European Union. *General Data Protection Regulation (2016/679(UE))*. Available at https://gdpr-text.com/pt/read/article-4/ Accessed on Dec. 30, 2022.

Lloyd IJ. Information technology law. 6th. edition. Oxford: Oxford University Press, 2011.

Mendes LS. *Privacidade, proteção de dados e defesa do consumidor:* linhas gerais de um novo direito fundamental. São Paulo: Saraiva, 2014.

Miragem B, Madalena J. Artigo 7º. In: Martins GM, Longhi JVR, Faleiros Júnior, JLM (ed.). *Comentários à Lei Geral de Proteção de Dados Pessoais*. Indaiatuba: Foco, 2022.

Mulholland CS. Dados pessoais sensíveis e a tutela de direitos fundamentais: uma análise à luz da Lei Geral de Proteção de Dados (Lei 13.709/18), *Revista de Direitos e Garantias Fundamentais,* v. 19(3): 159-180, sep./dec. 2018.

Nissenbaum H. *Privacy in context:* technology, policy and the integrity of social life. Stanford: Stanford University Press, 2010.

Rodotà S. *A vida na sociedade da vigilância:* a privacidade hoje. Translated by Danilo Doneda and Luciana Cabral Doneda. Rio de Janeiro: Renovar, 2008.

Soares, FR. Consentimento no direito da saúde nos contextos de atendimento médico e de LGPD: diferenças, semelhanças e consequências no âmbito dos defeitos e da responsabilidade. *Revista IBERC,* v. 4(2): 18-46, may/aug. 2021.

Sumner S. *You*: for sale. Protecting your personal data and privacy online. Waltham: Syngress/Elsevier, 2016.

Teffé CS. *Dados pessoais sensíveis:* qualificação, tratamento e boas práticas. Indaiatuba: Foco, 2022.

Tomasevicius Filho E., Sousa MA. A proteção de dados da pessoa jurídica e a Lei Geral de Proteção de Dados. *Consultor Jurídico,* 22 jan. 2021. Available at https://www.conjur.com.br/2021-jan-22/opiniao-protecao-dados-pessoa-juridica-lgpd. Accessed on Dec. 30, 2022.

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PATIENT AUTONOMY AND RIGHT TO INFORMATION: AN ANALYSIS ON THE RECENT DEVELOPMENTS OF BRAZILIAN JURISPRUDENCE IN THE SUPERIOR COURTS

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Abstract: There's a silent (r)evolution going on right in the middle of the relationship established between health professionals and patients. The doctrine of informed consent, which still struggles to be rightfully implemented among physicians is shifting into something more, something deeper and wider in concept and consequences. The notion that consenting is just a part of the process of choosing and is not enough to allow patients to exercise their right to autonomy, which can only be accomplished through the complete and understandable disclosure of all information regarding treatment, their options, and possible consequences. This paper aims to analyze recent developments towards civil liability originated from the lack of information given to patients, and how it is changing Brazilian jurisprudence in the superior courts.

Keywords: Informed Consent; Informed Choice; Right to Information; Informational Negligence; Autonomy

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I. Introduction

The modern relationship between physicians and patients from a legal point of view, is ruled by two center pillars, called Autonomy and Consent. And what binds these elements together is information. Not only the quality of information, but also the bureaucracy created to ensure patient ´s rights and to protect doctors from accusations of malpractice.

Over the last fifteen years, the theories of informed consent were added with the notion of informational negligence, i. e., the damages suffered by a patient that were caused by an unsatisfactory or inadequate amount of information given during the process of treatment, or information withheld from the patient, or even information that were transmitted in scientific terms that could not be properly understood by a lay person.

What we seek to demonstrate here is that informed consent is not the final objective of disclosing proper information in a medical relationship. Consent is but a part of the process of exercising choice. Only by letting the patient choose, and therefore, truly enforcing autonomy, it will be possible to avoid negligence.

In modern medicine, legal requirements are just as important as scientific skills to fulfil the duty of care, and safe practice cannot be achieved without proper knowledge of these concepts.

However, when one speaks about the right to information in the healthcare context, there is an almost automatic association to the expression “informed consent”. It is virtually unanimous nowadays in modern society the idea that every medical intervention or experiment must be previously understood and consented by the patient or subject of research, to prevent liability.

II. Informed Consent, the Duty to Inform and Informed Choice

There are several legal issues regarding consent, and litigation is increasing in relation to consent issues. Too many aspects need to be taken into consideration for consent to be considered valid, such as when consent was obtained and whether the risks have been explained; moreover, whether they were understood by the patient (sometimes, cultural issues or language barriers can be a complication); whether the patient is a minor (if so, mature or not to decide by him/herself); whether an adult patient has legal capacity to decide (and also, if having legal capacity to decide, clinical capacity is absent); whether an oral consent constitutes enough evidence that information has been given and understood. But above all – and that is precisely the object of this study – whether

the patients have been given sufficient, adequate, complete information, so that they can decide, and not just consent to a physician ´s suggestion.

Very often, tough, physicians and health care providers misunderstand the concept of the so-called *informed consent*[2].

Informed consent is the authorization given by the patient to undergo treatment, based on the knowledge of the nature of a medical procedure, and be submitted to risks, side effects, possible complications, benefits, and alternatives to the proposed treatment. In other words, it is the acceptance of the services to be delivered by a healthcare professional, after understanding what is being consented to.

It is necessary to understand that the process of consenting constitutes, at the same time, a patient ´s right and a physician ´s duty. The patient must be informed in a clear and comprehensible way, according to his cognitive capabilities, about his diagnostic, risks, prognosis, and existing treatment alternatives, even those the doctor does not think fit for the specific case.

It is also important to point out that the mere act of reading and signing a paper, a consent form, is not enough to release the physician from his duties, from his obligation to inform accordingly (even if this written form is an important piece of evidence of due diligence).

The right to be informed has nothing, or very little, to do with the true exercise of patient ´s autonomy. The act of consenting to some treatment, research, experiment, or surgical procedure is just part of a bigger process, where the patient can exercise its autonomy. Someone can consent, based on the trust put over the doctor, based on indifference, fear, or even *because* it didn´t receive all necessary information to really choose among different possible options.

Informed consent is often mistaken by informed choice – this last one being essential to achieve the fulfilment of the right to be informed (and the physician ´s duty to inform). The patient needs not only receive, but also understand the information that has been handed over, and not just simply receive it without processing it properly. Information without comprehension is legally void,

2 "It is always an open question whether an autonomous person with the capacity to give an informed consent actually has, in any specific instance, given an informed consent, in the sense of making an autonomous choice to authorize or refuse an intervention". Faden, R., Beauchamp, T. L. 'A History and theory of informed consent', Oxford University Press, 1986, p. 237.

because it could be proven that the patient consented (or signed a consent form) but did not exercise his right to free and informed choice. His autonomy would be jeopardized.

In the same direction, Sheila McLean[3] highlights the importance of information in the process of consenting and choosing:

> "One way, it seems obvious, that we can facilitate the making of a valid choice, is by ensuring that the patient is provided with the wherewithal to make a decision in the first place. In other words, the patient needs information on which to base his or her choice. The "informed", or more accurately informational, aspect of consent is the element that focuses on the patient ´s right to receive relevant and sufficient information in order to enable him or her to make a decision. It is generally assumed, then, that – in the absence of a competent refusal to receive any information that might be offered – a valid consent (or refusal) depends on the sharing of information with the patient. The doctor is, therefore, under an obligation to share information with his or her patient".

To the patient, it is necessary to be in possession of all the elements possible for his understanding, so that he can, in fact, exercise the faculty of consenting to the proposed treatment or intervention, choosing another of the existing alternatives, although less indicated by the attending professional, or even refusing to be treated. This procedure, which includes informed consent without being confused with it, is called an informed choice. Fernanda Schaefer adds transparency and trust as essential pillars of this relationship:

> "The doctor responds to the trust placed in him by placing his knowledge at the service of the patient, protecting his physical and mental integrity and ensuring his privacy and his clinical data, respecting his autonomy. The patient responds to the doctor's loyalty by revealing whatever is necessary for his diagnosis and treatment, fulfilling the therapeutic determinations and even fighting for his cure. Therefore, there is no doubt that fidelity, transparency and trust are basic principles that guide the doctor-patient relationship and the collection of clinical data, aiming to simplify the conduct, thus imposing a more humanized relationship and the recognition of special condition of the patient (...)

3 McLean, Sheila A. M., 'Autonomy, Consent and the Law', Routledge-Cavendish, 2010, p. 42

> Fidelity, transparency and trust are not only generic ethical references, but general clauses that go beyond mere ideals of behavior; they play a harmonizing role and, by assuming different features, impose on the doctor and the patient the duties of loyalty and mutual collaboration to achieve the intended ends, namely treatment and, when possible, cure for the ailments that afflict the sick — functionalized protection of clinical data as a guarantee of human dignity."[4]

Appropriate information seems to be the main element about patient ´s autonomy rights. The information, to be "appropriate", does NOT need to meet the doctor ´s assessment of the situation, but the patient ´s. All relevant data, alternatives (even those the physician thinks are not recommended to the case, based on its experience) and risks must be disclosed to the patient, in an understandable way, to provide sufficient elements for a decision – a choice – to be made. This – and not consenting – is the real exercise of autonomy.

In Brazil, Federal laws, such as Law 8.080/1990 (Consumer ´s Defense Code) article 7, section V, reinforces to the patient the right to information about his/her health conditions; Law 10.741/2003 (Elderly ´s Protection Act) ensures the right to choose the most favourable health treatment; Law 9.434/1997 (Organ and Tissues Transplantation) requires consent for every procedure. State Laws also regulates patient ´s rights, such as Law 10.204/1999 (São Paulo); Law 14.254/2003 (Paraná); and Law 16.279/2006 (Minas Gerais).

The Medical Ethics Code (Resolution 2.217/2018 – Brazilian Federal Council of Medicine) issues a series of deontological commands that leaves no room for doubt about the legal nature of the right to be informed, being at the same time a patient´s right and a physician´s duty:

> Art. 15 – [Doctors are forbidden] § 3. To practice a medically assisted procreation procedure without the participants being in full agreement and duly informed about it.
>
> Art. 22 – [It is forbidden for the physician] to fail to obtain consent from the patient or his legal representative after clarifying him about the procedure to be performed, except in cases of imminent risk of death.

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4 Schaefer F. *Telemática em saúde e sigilo profissional:* a busca pelo equilíbrio entre privacidade e interesse social. Curitiba: Juruá; 2010. p. 141-142.

Art. 24 – [Doctors are prohibited from] Failing to guarantee the patient the exercise of the right to decide freely about his person or well-being, as well as exercising his authority to limit it.

Art. 31 – [Doctors are prohibited from] Disrespecting the right of the patient or his/her legal representative to decide freely about carrying out diagnostic or therapeutic practices, except in cases of imminent risk of death.

Art. 34 – [The doctor is prohibited] Failure to inform the patient of the diagnosis, prognosis, risks, and objectives of the treatment, except when direct communication could cause harm, in which case, he must notify his legal representative.

Art. 42 – [Doctors are prohibited from] Disrespecting the patient's right to freely decide on a contraceptive method, always clarifying the indication, safety, reversibility, and risk of each method.

Art. 44 – [Doctors are prohibited from] failing to clarify the donor, recipient or their legal representatives about the risks arising from exams, surgical interventions, and other procedures in cases of organ transplants.

Art. 73 – [It is forbidden for the physician] to reveal a fact that he has knowledge of by virtue of the exercise of his profession, except for just cause, legal duty or written consent of the patient.

Art. 101 – [Doctors are prohibited from] Failing to obtain from the patient or their legal representative the term of free and informed consent to carry out research involving human beings, after due explanations about the nature and consequences of the research.

§ - In case the research subject is a minor, in addition to the consent of his legal representative, his free and informed assent is required to the extent of his understanding.

Art. 110 – [The doctor is forbidden] to practice medicine, in the exercise of teaching, without the consent of the patient or his legal representative, without ensuring his dignity and privacy or discriminating against those who deny the requested consent.

III. The Construction of Brazilian Jurisprudence

When it comes to the Brazilian courts of law, the recent years have been showing a steady and growing development towards the recognition of informational liability, a different kind of malpractice that doesn´t rely on the results of a medical treatment or intervention (i.e., doesn´t need an effective medical malpractice) to determine civil liability and the right to compensation in favor of patients who haven´t been properly informed, preventing them to exercise their true autonomy, even though consenting to a proposed treatment or intervention.

In 2007, another case, involving plastic surgery (AgRg in Ag 818.144/SP) had a similar result, with the court ruling that "the physician who do not inform his patient about the risks of surgery is negligent, being liable for all damages resulting from the intervention".

In the opposite direction, a case judged in 2009 (REsp 1.051.674/RS) exempted the doctor from being considered responsible for an unexpected result, because he proved the fulfillment of the duty to inform.

In 2010, The Superior Court of Justice (STJ) decided in favor of the plaintiff, helding a blood bank liable for lack of proper communication of test results (REsp 1.071.969/PE).

Another case, originated from the Justice Court of the State of Minas Gerais (Civil Appeal n. 1.0223.08.246703-4/001), and ruled in 2013, help in the task of defining the consequences of informational negligence. It refers to a litigation between a patient and his dentist. The dentist was forced to pay the patient a compensation for moral damages, due to a fracture caused in the patient ´s jaw, during a tooth extraction procedure. Compensation was not granted as a direct result of the fracture, which was proved to be a potential risk of that treatment, but because the dentist failed to fulfil his duty to inform the patient about the risks inherent to that kind of procedure.

In 2018, a paradigmatic decision was ruled by the Superior Court of Justice (REsp 1540580/DF) in the sense that there is an effective fulfillment of the duty of information when clarifications are specifically related to the specific case of the patient—generic information is not sufficient. For this reason, generic consent (blanket consent) should not be considered valid, needing to be clearly individualized.

There is a common belief that the doctor — holder of technical knowledge —, in the performance of his activities, can use whatever he considers to be in the best interests of the patient.

However, the decision taken by the STJ did not turn a blind eye to the evolution in the doctor-patient relationship and the irreversible mitigation of paternalism. The decision recognizes that the patient has "the ability to self-govern, to make choices and to act according to his own deliberations".

The rapporteur for the judgment, Justice Luis Felipe Salomão, recognized in his winning vote that the damage, and the duty to indemnify were configured in view of the "violation of the self-determination of the patient who could not freely choose to submit or not to the foreseeable risk".

Thus, based on the principle of the dignity of the human person, and on the constitutional guarantee that "no one will be forced to do or not do anything except if determined by the law" (Federal Constitution art. 5º, II), the STJ recognizes that it is the patient who must establish the limits of the physician's performance. This supports the need for the physician to act only after obtaining the patient's express consent.

In the words of Justice Salomão: "what is sought is the establishment of a negotiation relationship, in which the doctor shares his technical knowledge and guarantees the patient the decision-making based on his own values, in the exercise of his autonomy."

In addition, the STJ decision recognizes the legal value of the UNESCO Universal Declaration on Bioethics and Human Rights:

> Article 5 - Autonomy and individual responsibility
>
> The autonomy of people regarding decision-making, if they assume the respective responsibility and respect the autonomy of others, must be respected. In the case of persons unable to exercise their autonomy, special measures must be taken to protect their rights and interests.
>
> Article 6 - Consent
>
> 1. Any preventive, diagnostic or therapeutic medical intervention must only be carried out with the prior, free, and informed consent of the person concerned, based on adequate information. Where appropriate, consent must be express and the data subject may withdraw it at any time and for any reason, without this resulting in any disadvantage or harm.

This relevant decision by the STJ is a leading case, indicating that as a rule, for the medical act to be legitimate, it must be the result of information provided to the patient, and decided by him, the patient. This conduct guarantees legally valid medical practice.

The ruling is summarized by the court:

> SPECIAL RESOURCE. VIOLATION OF ART. 535 of CPC/1973. NO OCCURRENCE. PHYSICIAN'S CIVIL LIABILITY FOR BREACH OF THE DUTY TO PROVIDE INFORMATION. NEED FOR SPECIALIZATION OF INFORMATION AND SPECIFIC CONSENT. OFFENSE TO THE RIGHT TO SELF-DETERMINATION. VALUATION OF THE SUBJECT OF RIGHT. CONFIGURED EXTRA-BALANCE DAMAGE. CONTRACTUAL DEFAULT. OBJECTIVE GOOD FAITH. DOCTOR'S BURDEN OF PROOF.
>
> 1. There is no violation of article 535, II, of the CPC, when, although the motion for clarification was rejected, the matter under examination was duly faced by the Court of origin, which issued a reasoned ruling, even if in the opposite direction to the claim of the recurrent.
>
> 2. The relationship between doctor and patient is a special provision of services, the object of which encompasses extremely relevant attached duties, in addition to technical intervention aimed at treating the disease, among which is the duty to provide information.
>
> 3. The duty of information is the physician's obligation to clarify the patient about the risks of the treatment, its advantages and disadvantages, the possible techniques to be employed, as well as the disclosure regarding the prognosis and the clinical and surgical conditions, except when such information may affect you psychologically, at which time the communication will be made to your legal representative.
>
> 4. The principle of autonomy of will, or self-determination, based on the constitution and provided for in several international documents, is the source of the duty to inform and the related right to free and informed consent of the patient and advocates the appreciation of the subject of law behind the patient, emphasizing their ability to self-govern, to make choices and to act according to their own deliberations.

5. There will be effective fulfillment of the duty to provide information when clarifications are specifically related to the patient's case, and generic information is not sufficient. Likewise, to validate the information provided, the patient's consent cannot be generic (blanket consent), needing to be clearly individualized.

6. The duty to inform is a duty of conduct arising from objective good faith and its simple non-compliance characterizes contractual default, a source of civil liability per se. Compensation, in these cases, is due for the deprivation suffered by the patient in his self-determination, for having been deprived of the opportunity to weigh the risks and advantages of a certain treatment, which, in the end, caused him damages that could not have been caused, if the procedure was not performed, at the option of the patient.

7. The burden of proof as to compliance with the duty to inform and obtain informed consent from the patient rests with the doctor or hospital, guided by the principle of procedural collaboration, in which each party must contribute with the evidence that can be more easily provided. required.

8. The subjective liability of the physician (CDC, art. 14, § 4) does not exclude the possibility of inversion of the burden of proof, if the requirements of art. 6, VIII, of the CDC, and the professional must demonstrate that he has acted with respect to the applicable technical guidelines. Precedent.

9. In the absence of specific legislation to regulate the duty of information, the Consumer Protection Code is the diploma that performs this function, making the duties of informing clearly, loyally and accurately very strict (art. 6, III, art. 8, art. 9).

10. Special appeal granted, to recognize the non-pecuniary damage caused by the breach of the obligation to inform.

In the ruling, the Fourth Panel of the Superior Court of Justice highlighted that "the relationship between doctor and patient is a special provision of services, whose object includes attached duties, of paramount importance, in addition to the technical intervention aimed at the treatment of the disease, among which is the duty to inform".

Part of the doctrine calls the duties attached to contractual relationships as "additional duties of conduct", which are essential to the correct processing of the obligatory relationship in which the provision is part. These are duties that do not directly concern the preparation or the perfect performance of the service, but that are of interest to the regular development of the contractual relationship.

The attached duties of conduct derive from good faith, oblige the parties to consider the rights and interests of the contractual partner, are more pronounced duties in long-term contractual relationships than in instant performance obligations and are undeniably present in all legal relationships. mandatory.

In the economic sector, the shift from a goods-producing economy to a service-based one is the main characteristic of the transition from industrial society to post-industrial society. Services are the basis of a post-industrial society and in it what counts is not muscle power or energy, but information, which comes to represent the central resource and, within organizations, a source of power. In consumer relations, there is a true informational monopoly: the supplier concentrates all the relevant information regarding the products or services offered by him in the market.

Within the scope of contractual obligations, the limits of private autonomy, in the sense of freedom to contract or the self-regulation of legal relations by individuals according to their will, are today one of the fundamental issues of national contractual and private law, perhaps even the most fundamental from them.

In contemporary times, the ease of access to information – due to technological means – opposes the disinformation resulting from its excess. Consumers are constantly hit by an expressive volume of data, news, research, suggestions, and recommendations, from varied and often unreliable sources. The constant "bombardment" of data and information can confuse and accentuate the vulnerability of the consumer, who finds himself disoriented amid so many different and often conflicting recommendations. It is fundamental, therefore, to reach the balance point, since the excess of information, in fact, misinforms.

The Superior Court stated in the present case that the fulfillment of the duty to provide information will only be effective "when the clarifications are specifically related to the patient's case, the generic information not being sufficient", in such a way that "to validate the information provided, the patient's consent cannot be generic (blanket consent), needing to be clearly individualized".

The mass reality of the supply of health services commonly deviates from this guideline. As a rule, the informed consent terms are standardized, often written in technical language, not adequate to the unique and personal characteristics of each patient.

The use of imprecise or incomprehensible expressions due to their technicality is not compatible with the duty of good faith, from which the duty of information derives. It is also necessary that the information be transmitted in an appropriate way for its recipients.

It is the information that gives the consumer the possibility of using the products marketed with complete safety and in a way that satisfies their interests, medical services included, since only the well-informed consumer can fully enjoy the economic benefits that the product or service provides, as well as protect adequately from the risks they present.

Information is one of the techniques for coping with the imbalance of knowledge among contracting parties and, in the context of protecting the life and health of consumers, the right to information is an autonomous manifestation of the obligation of security. Hence the notion that the violation of the right to adequate and clear information removes from the consumer the possibility of self-determination.

A quadripartite classification of the main categories of information deductible from art. 31 of the CDC, namely: a) information-content, corresponding to the intrinsic characteristics of the product and service; b) information-use, to clarify what the product or service is used for and what it is used for; c) price-information, related to the cost, forms and conditions of payment of the product or service; and d) information-warning, which refers mainly to the risks of the product or service. Based on these distinctions previously highlighted by the STJ, the jurisprudential understanding of the true scope of the right and the related duty to inform was consolidated.

The exact delimitation of what constitutes adequate information, however, varies according to the nature and characteristics of the product or service, demanding an assessment in the specific case. And the burden of proof regarding compliance with the information requirements rests with the health care provider – it was stated in the judgment itself that "the subjective responsibility of the physician (CDC, art. 14, § 4) does not exclude the possibility of reversing the burden of proof, if the requirements of art. 6, VIII,

of the CDC, and the professional must demonstrate that he has acted with respect to the applicable technical guidelines".

In the specific case, "the change in previously agreed surgical procedures was made unilaterally by the doctor in charge, with the appellants not having been informed about the new approach or its risks". Even though the professional has mastery of the technique of providing services, it is the physician's duty to share with the patient all the necessary information so that he can understand the risks of the procedure or treatment.

Ultimately, it is the patient's right, which can only be well exercised when well informed, to decide whether to submit to the act. Deprived of basic and necessary information, the consumer cannot self-determine. And even if there is no error or harm to the patient's health by carrying out an intervention other than that initially planned, the violation of the attached duty of information may autonomously give rise to the duty to indemnify.

The autonomy of the damage subcategories is justified both by their own characteristics and by the different impacts they cause on human beings. In addition, individualization achieves greater concreteness of the right to effective compensation for damages.

However, for each modality or autonomous category of damage to be duly repaired, it is necessary to produce specific evidence of its differentiated aspects, as well as to petition, or contest separately for each claim. The Magistrate will also consider them individually, seeking congruence and adequate grounds for their decision.

IV. Closing Remarks

These are examples on how the understanding of the law, and its interpretation by the superior courts are shifting towards the recognition of information as the foundation of patient-physician relationship, and how it can redefine the concept of medical malpractice, making it wider and thus expanding medical responsibilities beyond technical knowledge, stressing the importance of legal compliance in the daily practice.

Its practical relevance – including for damage prevention purposes, serving as an incentive to implement preventive measures in the health care services – stems from its didactic character resulting from the precise identification of each of the different types of damage that are being indemnified.

As this author once wrote: "We´re used to talk and read about patients' rights and medical liability, but it´s time to start thinking about shared responsibilities, to start thinking about patients' duties, since they´re granted the power of actually choosing how their life and treatment must be conducted. And with great power, comes great responsibility."[5]

References

BEAUCHAMP, Tom L., CHILDRESS, J. *Principles of biomedical ethics*. New York: Oxford University Press, 1979.

BEAUCHAMP, Tom L., FADEN, Ruth R., *A history and theory of informed consent*. New York: Oxford University Press, 1986.

CHAVES, Marianna; DANTAS, Eduardo. Contemporary issues in Medical Law. Io de Janeiro: GZ Editora, 2018.

DANTAS, Eduardo. *Direito Médico*. 6th edition. Salvador: Editora JusPodivm, 2022.

_____ "Les différences entre le consentment informé et le choix éclairé comme causes d´exclusion de responsabilité civile dans la relation médecin-patient. L´autonomie du patient face au droit brésilien", *in Revue générale de droit medical,* n. 29, Bordeaux: Les Études Hospitalières, pp. 125-147, 2008.

_____ "When consent is not enough: the construction and development oof the modern concept of autonomy.", *in Lex Medicinae, ano 8,* n. 15, Coimbra: Coimbra Editora, pp. 101-111, 2011.

_____ "How informed should consent be? A brief analysis on consent and autonomy under the European Convention on Human Rights and Biomedicine", *in Lex Medicinae, ano 9,* n. 17, Coimbra: Coimbra Editora, pp. 51-63, 2012.

MANSON, Neil C.; O´Neill, Onora. *Rethinking informed consent in bioethics*. New York: Cambridge University Press, 2007.

McLEAN, Sheila A. M., *Autonomy, Consent and the Law, New York:* Routledge-Cavendish, 2010.

5 Dantas, Eduardo. Contemporary issues in Medical Law. GZ Editora, 2018, p. 86

PEREIRA, André Gonçalo Dias. O consentimento informado na relação médico-paciente. Coimbra, Ed. Coimbra, 2004.

SCHAEFER, Fernanda. *Telemática em saúde e sigilo profissional:* a busca pelo equilíbrio entre privacidade e interesse social. Curitiba: Juruá; 2010.

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LUSO-BRAZILIAN PERSPECTIVES ON ARTIFICIAL INTELLIGENCE AND BIG DATA IN THE DIAGNOSIS AND TREATMENT OF COVID-19: NEW CHALLENGES TO PERSONAL DATA PROTECTION

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Abstract: This study aims to identify and address the new challenges to the protection of personal data arising from the use of artificial intelligence and big data in combating the Covid-19 pandemic in the Luso-Brazilian context. This research proposes to investigate the parameters for an effective patient protection in the context of the Covid-19 pandemic, with regard to the appropriate assignment of civil liability for damages possibly caused by the use of the aforementioned technologies and to the delineation of guidelines for the implementation of artificial intelligence in strict compliance with personal data protection policy (in particular, sensitive personal data). For this purpose, this study adopts the logical-deductive method, particularly using Brazilian and Portuguese bibliographic sources. This theoretical path leads to the recognition that, despite the potential benefits, the algorithms developed for the diagnosis of Covid-19 can cause particularly onerous results, mainly due to their significant degree of inaccuracy. Furthermore, in the medical field, when it comes

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to the processing of sensitive personal data, among the main risks are the irregular processing of personal data, automated decisions in the processing of such data and the lack of information or consent on how the personal data was collected, processed and shared. Thus, it is extremely important to investigate compliance within these new frameworks of medical activities, in light of Brazilian and Portuguese laws concerning the protection of personal data. Ultimately, this study aims to formulate some possible hermeneutical canons to assist the interpreter-enforcer of the law in the task of ensuring the protection of human rights in the face of new technologies, without inhibiting their continuous development, whose importance is daily substantiated by the difficulty of combating the Covid-19 pandemic.

Keywords: Artificial Intelligence; Big Data; Personal Data; Covid-19

1. Introductory Notes: the Digital Revolution in the Healthcare Sector and the Implementation of Artificial Intelligence in Combating the Covid-19 Pandemic

New technologies have profoundly changed the doctor-patient relationship. From medical diagnosis to holistic patient care, artificial intelligence[3] is transforming the entire healthcare sector worldwide.[4] There are several studies that unveil the great potential of this technology in improving diagnosis and medical care.[5] Medicine, like many other fields, is experiencing a confluence of two recent developments: the rise of big data[6] and the emergence of

3 For an analysis of the concept and evolution of artificial intelligence, with an emphasis in the preponderance of algorithms, see generally FLASIŃSKI, Mariusz. **Introduction to Artificial Intelligence**. Cham: Springer, 2016, *passim*; TEGMARK, Max. **Life 3.0**: Being human in the age of artificial intelligence. New York: Alfred A. Knopf, 2017, *passim*; LEE, Kai-Fu. **AI Superpowers**: China, Silicon Valley, and the New World Order. Boston: Houghton Mifflin Harcourt, 2018; and TURNER, Jacob. **Robot Rules**: Regulating Artificial Intelligence. Cham: Palgrave Macmillan, 2019, *passim*.

4 On the subject, regarding the transformation in the healthcare industry with the new era of technological information and artificial intelligence, see GARCIA, Christine; UZBELGER, Georges. Artificial Intelligence to Help the Practitioner Choose the Right Treatment: Watson for Oncology. *In:* NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence**. Cham: Springer, 2020, p. 81.

5 In this sense, see SHABAN-NEJAD, Arash; MICHALOWSKI, Martin. **Precision Health and Medicine**. A Digital Revolution in Healthcare. Cham: Springer, 2020, See also DANIEL, Christel; SALAMANCA, Elisa. Hospital Databases. AP-HP Clinical Data Warehouse. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence**. Cham: Springer, 2020, p. 65.

6 See generally GOMES, Rodrigo Dias de Pinho. **Big Data**: desafios à tutela da pessoa humana na sociedade da informação. Rio de Janeiro: Lumen Juris, 2017, *passim*.

sophisticated artificial intelligence systems, which can be used to find complex patterns in those data.[7]

The emergence of big data, according to Nicholson Price, is a phenomenon characterized by the "three V's": volume (large quantities of data), variety (heterogeneity in the data) and velocity (fast access to the data).[8] These data come from various sources: electronic health records, medical literature, clinical trials, insurance claims data, pharmacy records, and even the data entered by patients into their smartphones or recorded on fitness trackers applications. In view of this large amount of data, artificial intelligence algorithms are making strides in providing diagnosis and treatment alternatives for some diseases by cross-referencing the health data of a specific patient with their entire database.[9]

Jacob Turner, in the book "Robot Rules: Regulating Artificial Intelligence" (2019), defines artificial intelligence (AI) as "the ability of a non-natural entity to make choices by an evaluative process".[10] According to the European Commission, artificial intelligence refers to "systems that display intelligent behavior by analyzing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications)".[11]

For artificial intelligence to work, algorithms, which represent a set of instructions or a sequence of rules, are used and applied to a number of data, allowing for the solution of similar classes of problems. In essence, algorithms are the guidelines followed by a machine. An artificial intelligence algorithm

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7 PRICE, William Nicholson. Artificial Intelligence in Health Care: Applications and Legal Issues. **University of Michigan Public Law Research Paper**, n. 599, 2017. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3078704. Accessed: Dec. 26, 2022.

8 PRICE, William Nicholson. Artificial Intelligence in Health Care, cit.

9 In 2015, a group of scientists at Mount Sinai Hospital (New York - USA) developed the *Deep Patient*, an intelligent software that predicts patients' future diseases, derived from a database composed of approximately seven hundred thousand electronic health records. To develop an analysis regarding Deep Patient, see generally MIOTTO, Riccardo; LI, L.; KIDD, Brian A.; DUDLEY, Joel T. Deep Patient: An Unsupervised Representation to Predict the Future of Patients from the Electronic Health Records. **Nature Scientific Reports**, v. 6, may/2016.

10 TURNER, Jacob. Robot Rules, cit., p. 16.

11 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe, Brussels, 25.4.2018 COM (2018) 237 final.

works based on the calculation of a probability, which is the result of an input vector multiplied by various parameters, whose values were obtained from a training set.[12]

The increase in the use of artificial intelligence algorithms (especially the more sophisticated systems containing machine learning and deep learning)[13-14] - in medical practice promoted a wide phenomenon of change from *conventional medicine to P4-medicine* (preventive, predictive, personalized and participatory).[15] In this new scenario, health care is no longer essentially

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12 FLASIŃSKI, Mariusz. **Introduction to Artificial Intelligence**, cit., p. 16.

13 Machine Learning algorithm "describes how to 'judge' that data, so that the machine will (hopefully) learn how to perform the task. The resulting model can then be used to analyse new situations. There are many approaches to Machine Learning, of which the best-known approaches are Supervised Learning, Unsupervised Learning, Reinforcement Learning and Deep Learning. Even though these techniques differ in terms of goals and approaches, they all aim to give computers the ability to act without being explicitly programmed how to do so. The goal of Machine Learning is to create a trained model that is able to make generalisations without human intervention. It should be accurate not only for the examples in the training set, but also on future cases that it has never seen before. To apply machine learning, the engineer starts with an existing dataset, which is then divided into a training set and a test set. The engineer then chooses a mathematical structure that characterises a range of possible decision-making rules with adjustable parameters (the algorithm). A common analogy is that the algorithm is a 'box' that applies a rule, and the parameters are the adjustable knobs on the front of the box that control its operation. In practice, an algorithm might have many millions of parameters whose combined result is hard to understand by observation alone. Hence, the use of the expression 'black box' to refer to the opacity of algorithms" (DIGNUM, Virginia. Responsible Artificial Intelligence. How to Develop and Use AI in a Responsible Way. Cham: Springer, 2019, p. 23). On the concept of *machine learning*, see also WISCHMEYER, Thomas; RADEMACHER, Timo (Coord.) **Regulating Artificial Intelligence**. Cham: Springer, 2020, p. 3.

14 "Deep learning algorithms are approaches to Machine Learning that use Neural Network models and are particularly useful in complex domains. Neural Networks are loosely inspired by the biology of our brains and consist of many simple, linked units (or neurons). They are, in essence, attempts to simulate the brain, which is why understanding how the brain works can help us discuss the specifics of artificial neural networks. (…) In ML, we use the terms that describe these processes in the brain to explain and understand Artificial Neural Networks (ANN), which are also composed of nodes (or neurons) linked by a complex network of connections of different strengths. However, unlike the brain, connections in a neural network are usually uni-directional. An ANN is then organized into input and output nodes connected through a number of in-between layers of nodes, known as the hidden nodes" (DIGNUM, Virginia. Responsible Artificial Intelligence. How to Develop and Use AI in a Responsible Way. Cham: Springer, 2019, p. 27). See also TAULLI, Ton. **Artificial Intelligence Basics**. New York: Springer, 2019, p. 71. FLASIŃSKI, Mariusz. Introduction to Artificial Intelligence, cit., p. 157-174.

15 "Prolonged life expectancy along with the increasing complexity of medicine and health services raises health costs worldwide dramatically. Advancements in ubiquitous computing applications in combination with the use of sophisticated intelligent sensor

limited to the treatment of pathologies (certainly, an endeavor that will never be neglected), focusing now, also, on the adoption of measures to prevent illnesses (*preventive medicine*)[16] or to enable the prediction of their diagnosis (predictive medicine). Relating to personal treatment, the patient is treated in a more individualized manner (therefore, less standardized), based on his genetic and health data (*personalized medicine*)[17]. Ultimately, the doctor-patient relationship becomes less of a one-off exchange and grows into a relationship that is continuously developed (*proactive medicine)*,[18] which is greatly facilitated by the implementation of artificial intelligence algorithms, since the patient no longer waits for his symptoms to worsen in order to seek medical care, considering that his vital information is constantly being acquired by monitors and wearable devices.[19]

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networks may provide a basis for help. Whilst the smart health concept has much potential to support the concept of the emerging P4-medicine (preventive, participatory, predictive, and personalized), such high-tech medicine produces large amounts of high-dimensional, weakly structured data sets and massive amounts of unstructured information. All these technological approaches along with 'big data' are turning the medical sciences into a data-intensive science. (…) Today, biomedical experts both in daily routine and science are no longer capable of dealing with such increasingly large, complex, high-dimensional and weakly-structured data sets. Consequently, effcient, useable computational methods, algorithms and tools to interactively gain insight into such data are a commandment of the time". (HOLZINGER, Andreas; RÖCKER, Carsten; ZIEFLE, Martina. From Smart Health to Smart Hospitals. *In:* **Smart Health**: Open Problems and Future Challenges. Cham: Springer, 2015, p. 1-9).

16 On the subject of preventive medicine and its relationship with new technologies, see BALICER, Ran D .; COHEN-STAVI, Chandra. Advancing Healthcare Through Data-Driven Medicine and Artificial Intelligence. *In:* NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence**. Cham: Springer, 2020, p. 9-15. CHAARI, Lotfi (ed.). **Digital Health Approach for Predictive, Preventive, Personalised and Participatory Medicine**. Cham: Springer, 2019, *passim*.

17 Precision Medicine is defined as "an innovative approach that takes into account individual differences in people's genes, environments, and lifestyles" while diagnosing people's illnesses and making decisions about different treatment options in a timely manner. Unlike the more traditional "one-size-fits-all" approaches and treatments, precision medicine intends to design tailored interventions and treatments with considering the differences between different patients and their diseases. Precision medicine can facilitate new drug development and discovery by providing better understandings of the interaction between genomics and drug response and potential treatment options of an individual patient's disease or condition" (SHABAN-NEJAD, Arash; MICHALOWSKI, Martin. Precision Health and Medicine, cit., p. V).

18 For an analysis of the benefits of proactive medicine see BALICER, Ran D.; COHEN-STAVI, Chandra. Advancing Healthcare Through Data-Driven Medicine and Artificial Intelligence, cit., p. 9-15.

19 NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence**. Cham: Springer, 2020, *passim*.

The transformation of medical care into this framework that is more proactive, preventive, precise and focused on the individuality of each patient has become possible, in recent years, through the combination of a large amount of health data and artificial intelligence software.[20] The Digital Age in health care has enabled patients' physical data to be transferred from paper folders to electronic health records. As a result, after decades of digitizing medical records (with expanding cloud storage), the healthcare sector has created a huge (and continuously growing) set of data.

Eric Topol, in his writings on the future of Medicine,[21] indicates that society is moving towards an increasingly present scenario of democratization of health care and of revolution of the doctor-patient relationship, which has acquired prominence, as the recipient of new technologies. This is what the author refers to as "the new era of patient engagement".[22] In the past few years, several big data[23] and artificial intelligence solutions have been developed in smartphones applications and wearable devices for medication management and frequent monitoring of physical and mental condition, diet and exercise, especially for people with chronic conditions - asthma, diabetes, cancer and cardiovascular diseases, and mental health illnesses - that are emerging as one of the main global health problems.[24]

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20 NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). Healthcare and Artificial Intelligence, cit., p. 10.

21 TOPOL, Eric. **Deep medicine**: how artificial intelligence can make healthcare human again. New York: Basic Books, 2019, *passim*. TOPOL, Eric. **The patient will see you now**: the future of medicine is in your hands. New York: Basic Book, 2015.

22 TOPOL, Eric. **The creative destruction of medicine**: how the digital revolution will create better health care. New York: Basic Book, 2012, *passim*.

23 TOPOL, Eric. The patient will see you now. cit., p. 159-179. "*Big data* in healthcare" refers to the abundant health data amassed from numerous sources including electronic health records (EHRs), medical imaging, genomic sequencing, payor records, pharmaceutical research, wearables, and medical devices. Three characteristics distinguish it from traditional electronic medical and human health data used for decision-making: 1) it is available in extraordinarily high volume 2) it moves at high velocity and spans the health industry's massive digital universe; 3) and, because it derives from many sources, it is highly variable in structure and nature. This is known as the 3Vs of *Big Data*. (Available at: https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0290. Accessed: Oct. 27, 2022). Furthermore, regarding the potential of big data in the healthcare sector, see HOUSEH, Mowafa; KUSHNIRUK, Andre W.; BORYCKI, Elizabeth M. (ed.). **Big Data, Big Challenges**: A Healthcare Perspective Background, Issues, Solutions and Research Directions. Cham: Springer, 2019, *passim*.

24 JEDDI, Zineb; BOHR, Adam. Remote patient monitoring using artificial intelligence. In: BOHR, Adam; MEMARZADEH, Kaveh. (Coord.). **Artificial intelligence in healthcare**. Amsterdam: Elsevier Inc., p. 203-234.

In addition, several types of health databases have been established since the beginning of the digital revolution (which is combined with the consequent multiplication of the power of computational analysis), as an example, it is worth mentioning: electronic health records, digital administrative data, data collected from medical equipment connected to the internet ("Internet of Things" in medicine), data from clinical and pharmaceutical research, genomic data etc.[25] It is said that electronic health records represent the largest source of health data, as they contain the sum of the majority of information about a patient in order to organize all stages of medical intervention, from anamnesis and related medical procedures to therapy, until the treatment progresses.[26] To exemplify this current scenario, it is worth observing that, in 2017, 80% of medical records and 100% of hospital records of patients in the United States were digitized, facilitating the exchange of information as a result of these digitized files, which are called electronic health records (EHRs).[27]

Considering the subject of this present study, it can be observed that this *digitization* in the healthcare sector was a key factor in facilitating the implementation of artificial intelligence in the efficiency of medical diagnosis, especially for the early detection of illnesses.[28] In an emblematic example of the development of artificial intelligence applied to the field of medical diagnosis, researchers from the University of Oxford (England), at John Radcliffe Hospital, developed the *EchoGo Core*, an intelligent device, which, by means of machine learning, provides an early diagnosis of heart diseases.[29] This echocardiography software is often considered to be the most

25 DEGOS, Laurent. International Vision of Big Data. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence**. Cham: Springer, 2020, p. 242. GRALL, Matthieu. CNIL (Commission Nationale de l'Informatique et des Libertés) and Analysis of Big Data Projects in the Health Sector. *In:* NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence**. Cham: Springer, 2020, p. 236.

26 DEGOS, Laurent. International Vision of Big Data, cit., p. 242.

27 As described by DEGOS, Laurent. International Vision of Big Data, cit., p. 245.

28 There are several companies in the world (such as Cerner, AIdoc and Arterys) that use the *Amazon Web Services (AWS)* cloud computing services platform to store and process large amounts of health data at a high speed, thus allowing for the creation of new intelligent digital tools. In this regard, see LANDI, Heather. Cerner taps Amazon Web Services to ramp up healthcare AI capabilities, predictive technology. *FierceHealthCare*, 12.3.2019. Available at: https://www.fiercehealthcare.com/tech/cerner-taps-amazon-web-services-to-ramp-up-healthcare-ai-capabilities-predictive-technology. Accessed: Dec. 26, 2022.

29 GILLESPIE, Stuart. The Oxford spinout company using AI to diagnose heart disease. **University of Oxford**, 10/15/2018. Available at: https://www.research.ox.ac.uk/Article/2018-10-15-the-oxford-spinout-company-using-ai-to-diagnose-heart-disease. Accessed: Dec. 26, 2022. For more information: https://ultromics.com/echogo/. Accessed: Dec. 26, 2022.

accurate software in the world and, for this to be possible, the algorithms were programmed using databases containing millions of echocardiograms, which are linked to the information on particular issues of each person examined and their clinical condition over time. The software reached the diagnostic accuracy of coronary heart disease at a rate of approximately 90%, which represents a better result than the average 80% accuracy rate achieved by doctors.[30]

At this stage and on a global scale, IBM was one of the companies that created more technological solutions for the healthcare sector. For seven years, the multinational had a division focused exclusively on artificial intelligence for healthcare - the "Watson Health"[31] – whose assets were sold to Francisco Partners on January 2022.[32] Among the intelligent products already available on the market, Watson for Oncology stands out, being "a solution that is fueled by information from relevant guidelines, best practices, and medical journals and textbooks".[33] This cognitive technology assesses the information from a patient's medical record along with medical evidence (from scientific articles and clinical studies), thus showing possible treatment options for cancer patients, categorized by a confidence level. In the end, it will be up to the doctor to analyze the conclusions brought by the artificial intelligence and decide the best treatment option for that specific patient. Since 2017, Watson for Oncology has been used in hospitals in Latin America, such as Brazil[34] and Mexico.[35]

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30 As expressed by GILLESPIE, Stuart. The Oxford spinout company using AI to diagnose heart disease, cit. The developers of this intelligent device founded the company Ultromics and recently received clearance from the *Food and Drug Administration* (FDA) to market EchoGo, which uses artificial intelligence to automate the analysis and quantification of ultrasound-based cardiac exams and, additionally, can detect cardiovascular diseases early. Relating to this subject, see PENNIC, Fred. FDA Clears AI-Powered EchoGo Core for Early Detection of Cardiovascular Disease. Hit Consultant, 11/15/2019. Available at: https://hitconsultant.net/2019/11/15/fda-clears-ai-powered-echogo-core-for-early-detection-of-cardiovascular-disease/#.XkBLijJKiUk. Accessed: Dec. 26, 2022.

31 For more information: IBM Watson Health - Cognitive Healthcare Solutions. Available at: https://www.ibm.com/watson-health. Accessed: Dec. 26, 2022.

32 Francisco Partners to Acquire IBM's Healthcare Data and Analytics Assets. Available at: https://www.franciscopartners.com/media/Francisco-partners-to-acquire-ibms-healthcare-data-and-analytics-assets. Accessed: Dec. 28, 2022.

33 FENG, XinYi. How AI works in the medical field. **Medium**, 08/03/2018. Available at: https://medium.com/writing-for-the-future-ai/how-ai-works-in-the-medical-field-455b5005847b. Accessed: Dec. 26, 2022.

34 Hospital Mãe de Deus será o primeiro da América Latina a utilizar a tecnologia Watson da IBM ["Mãe de Deus" Hospital will be the first in Latin America to use IBM's Watson technology. Free translation from original]. June 8, 2017. Available at: https://setorsaude.com.br/hospital-mae-de-deus-sera-o-primeiro-a-utilizar-a-tecnologia-watson-da-ibm/. Accessed: Dec. 26, 2022.

35 "Grupo Ángeles Servicios de Salud" implements IBM Watson for Oncology to Help

The use of artificial intelligence for the diagnosis and treatment of diseases demonstrated a great potential during the Covid-19 (illness caused by the new coronavirus, SARS-CoV-2 variant) pandemic. In the absence of specific drugs or therapeutic vaccines for the new coronavirus, it was essential to detect the disease at an early stage and, within reasonable parameters, isolate the infected people from the healthy population.[36] The pandemic sparked significant alarm across the globe since the first cases began to emerge in late 2019 in Wuhan (China). Although the majority of those infected with the new coronavirus do not develop severe symptoms, there were a considerable number of individuals within high-risk groups (such as the elderly and cardiac, asthmatic, diabetic and hypertensive patients) that may display severe and lethal respiratory syndromes. In these circumstances, the biggest concern pointed out by the medical community was the speed of propagation of the virus.[37]

As it is known, the diagnosis of infection by Covid-19 is carried out in two stages: clinical diagnosis and confirmatory diagnosis by laboratory tests. The clinical diagnosis depends on clinical and epidemiological investigation and physical examination. If the patient's situation is considered, from the clinical diagnosis, *a suspected case of Covid-19*, it is then determined the execution of a laboratory test. In spite of the benefits provided by the laboratory tests, factors such as high costs and supply shortage have led public authorities and hospitals to restrict testing to symptomatic patients - and, preferably, to those with severe symptoms.[38] It is precisely in this context - the impossibility

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Oncologists Identify Evidence-Based Cancer Treatment Options. June 29, 2017. Available at: https://www.prnewswire.com/news-releases/grupo-angeles-servicios-de-salud-implements-ibm-watson-for-oncology-to-help-oncologists-identify-evidence-based-cancer-treatment-options-300482073.html. Accessed: Dec. 26, 2022.

36 This is an extremely delicate subject, as it involves a sensitive dilemma between freedom and solidarity in dealing with COVID-19. In this case, referring to Thamis Dalsenter's article is of the utmost importance: https://www.migalhas.com.br/coluna/migalhas-de-vulnerabilidade/321211/direito-a-saude-entre-a-liberdade-e-a-solidariedade-os-desafios-juridicos-do-combate-ao-novo-coronavirus-covid-19. Accessed: Dec. 26, 2022.

37 SHAW, Rajib; KIMB, Yong-kyun; HUAA, Jinling. Governance, technology and citizen behavior in pandemic: Lessons from COVID-19 in East Asia. **Progress in Disaster Science**, v. 6, apr. 2020, p. 1-11.

38 MINISTÉRIO DA SAÚDE. **Diretrizes para diagnóstico e tratamento da Covid-19** [BRAZILIAN MINISTRY OF HEALTH. Guidelines for diagnosing and treating Covid-19. Free translation from original]. Available at: https://portalarquivos.saude.gov.br/images/pdf/2020/May/08/Diretriz-Covid19-v4-07-05.20h05m.pdf. Accessed: Oct. 28, 2022. It is also obtained from the press: CAMBRICOLI, Fabiana. Com alta demanda hospitalar, hospital Albert Einstein começa a limitar exames no novo coronavírus [With high hospital demand, Albert Einstein Hospital starts to limit tests for the new coronavirus. Free translation from original]. **Estadão**, 03/16/2020. Available at: https://

of carrying out laboratory tests in order to examine the entire population combined with the rapid spread of the disease - that the renewed importance of artificial intelligence (AI) in the diagnostic analysis emerges.[39]

In China, for instance, a software with AI algorithms, already used in thousands of patients (and granted free of charge for use by hundreds of medical institutions all around the world), is able to diagnose Covid-19 in a few seconds, from the analysis of thoracic computed tomography.[40] This intelligent software performs, with an accuracy rate of approximately 90%, the analysis of a tomographic image in 15 seconds; thus, it is able to distinguish, almost instantly, between patients infected with the new coronavirus and those with common pneumonia or another disease. This constitutes in a great advantage in dealing with the pandemic, especially considering that radiologists generally need around 15 minutes to read these images of patients with a suspected case of Covid-19.[41]

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saude.estadao.com.br/noticias/geral,com-alta-demanda-einstein-comeca-a-limitar-exames,70003235787. Accessed: Oct. 12, 2022.

39 A relevant point for a comprehensive analysis of the subject matter - not convenient for this paper - concerns the role of the patient's free and informed consent for the use of artificial intelligence to support the medical decision. According to The WHO guidance on "Ethics and Governance of Artificial Intelligence for Health", transparency is crucial to promoting trust among all stakeholders, particularly patients: "Physicians should be frank with patients from the consent and inform them of the use of AI rather than hiding the technology. They should try their best to explain to their patients the purpose of using AI, how it functions and whether it is explainable. They should describe what data are collected, how they are used and shared with third parties and the safeguards for protection of patients' privacy. Physicians should also be transparent about any weaknesses of the AI technology, such as any biases, data breaches or privacy concerns. Only with transparency can the deployment of AI for health care and health science, including hospital practice and clinical trials, become a long-term success. Trust is key to facilitating the adoption of AI in medicine" (Available at: https://www.who.int/publications-detail-redirect/9789240029200. Accessed: Dez. 12, 2022.). For a further analysis of the relevance of patient consent in new technologies, especially in the context of robot-assisted surgery and telesurgery, see KFOURI NETO, Miguel; NOGAROLI, Rafaella. Responsabilidade civil pelo inadimplemento do dever de informação na cirurgia robótica e telecirurgia: uma abordagem de direito comparado (Estados unidos, União Europeia e Brasil). In: ROSENVALD, Nelson; MENEZES, Joyceane Bezerra de; DADALTO, Luciana. **Responsabilidade civil e medicina**. Indaiatuba: Foco, 2020, *passim*.

40 Ping An Launches COVID-19 Smart Image-Reading System to Help Control the Epidemic. Available at: https://www.prnewswire.com/news-releases/ping-an-launches-covid-19-smart-image-reading-system-to-help-control-the-epidemic-301013282.html. Accessed: Oct. 12, 2022.

41 Ping An Launches COVID-19 Smart Image-Reading System to Help Control the Epidemic, cit.

In Latin America, it is reported that Ecuador was the first country to have an auxiliary system with an AI for the diagnosis of Covid-19. The technological software, based on an algorithm provided by the Chinese company Huawei, contains thousands of stored radiological images of patients around the world with suspected cases, confirmed and negative results of Covid-19, which allows for the comparison of the results obtained in Ecuadorian hospitals and, in this manner, provides a more accurate and fast diagnosis.[42] In Brazil, the *Hospital de Clínicas da Faculdade de Medicina da Universidade de São Paulo* [University of São Paulo Faculty of Medicine Clinics Hospital], in partnership with the *Ministério da Ciência, Tecnologia, Inovação e Comunicações* [Ministry of Science, Technology, Innovation and Communication] and several companies, created the RadVid-19 platform, that also uses the Huawei algorithm, and aims to collect x-ray and computed tomography exams of confirmed or suspected cases of Covid-19, thus becoming a large repository of cases in the country.[43]

In Portugal, a group of researchers from the *Instituto de Engenharia de Sistemas e Computadores, Tecnologia e Ciência* [Institute of System and Computers Engineering, Technology and Science] of the University of Porto developed an intelligent diagnostic system that identifies radiological characteristics of Covid-19 through thoracic X-ray images. The algorithm developed by INESC TEC, which is based on deep learning methods, automatically learns the most relevant image characteristics in order to provide a diagnosis.[44]

The brief demonstration of these examples of artificial intelligence being incorporated into medical practice in the context of the Covid-19 pandemic is to illustrate some of the various benefits that this technology can provide to the healthcare sector. These potential benefits, however, are accompanied by relevant ethical and legal concerns to be faced by the academic community, with particular emphasis on the protection and the processing of sensitive

42 Equador, pioneira na América Latina no uso de inteligência artificial para detectar COVID-19 [Ecuador, a pioneer in Latin America in the use of artificial intelligence to detect COVID-19. Free translation from original]. Available at: https://www.trt.net.tr/portuguese/america-latina/2020/04/01/equador-pioneira-na-america-latina-no-uso-de-inteligencia-artificial-para-detectar-covid-19-1389457. Accessed: Oct. 12, 2022.

43 CARMO, Diedre et. al. Rapidly deploying a COVID-19 decision support system in one of the largest Brazilian hospitals. **Health Informatics Journal**, v. 27, issue 3, set. 2021, p. 1-17.

44 Cientistas do Porto desenvolvem ferramenta que detecta a Covid-19 através de raio-X [Porto scientists develop a tool that detects Covid-19 through X-ray. Free translation from original]. Available at: https://www.porto.pt/pt/noticia/investigadores-do-porto-desenvolvem-ferramenta-que-deteta-covid-19-atraves-de-raio-x. Accessed: Oct. 26, 2022.

personal data. For that reason, the present study proposes to investigate the parameters for an effective patient protection in the context of the Covid-19 pandemic, with regard to the appropriate assignment of civil liability for damages possibly caused by the use of the aforementioned technologies and to the delineation of guidelines for the implementation of artificial intelligence in strict compliance with personal data protection policy (in particular, sensitive personal data). In essence, this is the guiding purpose of this paper and the subsequent items are devoted to this intent.

2. Benefits and Risks of Artificial Intelligence Algorithms in Assisting the Diagnosis and the Choice of Medical Treatment

Artificial intelligence programs in the healthcare sector provide extensive support for clinical decision, as previously mentioned, owing to their ability to quickly - and, tendentially, in an effective manner - process and analyze a large amount of data. The combination of artificial intelligence with medical expertise and knowledge, therefore, has the potential to significantly reduce error rates. It is not a matter of aiming for the replacement of healthcare professionals by an AI system, but only of recognizing the potential benefits of this new technology regarding, especially, the assistance to professionals in decision making. Among other potential benefits, it is remarkable that the provision of a rapid diagnosis by an artificial intelligence software can often be a key factor in the immediate start of treatment and the subsequent recovery of the patient, especially in rapidly evolving diseases or in emergency situations.

For instance, it can be considered the qualitative leap that could have been experienced in combating the Covid-19 pandemic had advanced diagnostic software already been available, in a large scale, since the beginning of the disease outbreak. In China, as previously mentioned, the AI software was developed in around two months after the first case of infection with the new coronavirus, being used in thousands of patients. This intelligent software performed, with an accuracy rate of approximately 90%, the analysis of a tomographic image in 15 seconds; thus, it was able to distinguish, almost instantly, between patients infected with the new coronavirus and those with common pneumonia or another disease. It was a great advantage in facing the pandemic in several countries, especially considering the lack of specific drugs or therapeutic vaccines for the new coronavirus. Artificial intelligence was extremely important to diagnose the disease as quickly as possible, even at an early stage - as well as to isolate the infected people from the healthy population. Furthermore, it is also relevant to point out that radiologists

generally needed around fifteen minutes to read these images of patients with a suspected case of Covid-19, a time significantly longer than the fifteen seconds used by the intelligent software.[45]

As it is known, data is the *fuel* of AI; after all, it is precisely from the data input that the algorithms governing the software in discussion herein are able to work, as in the case of systems capable of diagnosing patients with Covid-19. In the aforementioned example of the Chinese experience, data from thousands of infected patients and their respective thoracic computed tomography scans were inserted to program the algorithm. Thus, the intelligent system was able to read the tomographic image and distinguish, in fifteen seconds, between patients infected with the new coronavirus and those with other lung diseases. Therefore, it is necessary to understand that the quality of data used to program the algorithm is vital for the good performance of these intelligent systems, considering that this kind of algorithm - based on probability judgment - draws conclusions from the knowledge stored in its databases and from the data of each patient that is entered into the system.

It is also relevant to highlight the huge potential of the aforementioned Watson for Oncology, which uses a cloud database through which is able to cross-reference and analyze data from 20 million scientific works on oncology from research institutes around the world.[46] In January 2015, a 60-year-old woman was admitted to a hospital affiliated with the Institute of Medical Sciences at the University of Tokyo, Japan. Doctors initially diagnosed her with acute myeloid leukemia, a type of blood cancer.[47] However, after a successful round of chemotherapy sessions, doctors found that her recovery from post-remission therapy was extraordinarily slow, leading them to believe they were facing a different type of leukemia.

For that reason, the hospital's research team turned to the IBM's intelligent diagnostic instrument. Surprising the medical community, Watson for Oncology formulated the patient's diagnosis in just ten minutes, whereas human beings

45 Ping An Launches COVID-19 Smart Image-Reading System to Help Control the Epidemic, cit.

46 DAVID, Eric. Watson correctly diagnoses woman after doctors were stumped. *Silicon Angle*, 08/05/2016. Available at: https://siliconangle.com/2016/08/05/watson-correctly-diagnoses-woman-after-doctors-were-stumped/. Accessed: July 20, 2022.

47 NG, Alfred. IBM's Watson gives proper diagnosis for Japanese leukemia patient after doctors were stumped for months. New York Daily News, 08/07/2016. Available at: https://www.nydailynews.com/news/world/ibm-watson-proper-diagnosis-doctors-stumped-article-1.2741857. Accessed: Dec. 26, 2022.

would take an average of two weeks. Through the quick diagnosis of Watson, it was discovered that the Japanese patient had a rare secondary leukemia caused by myelodysplastic syndromes, a group of diseases in which the bone marrow produces very few healthy blood cells.[48] Immediately, the appropriate treatment for this type of leukemia was started.

Nevertheless, the positive outcome of a diagnosis supported by an AI does not prevent its risks of being exposed: in spite of Watson's impressive performance in the analysis of numbers and data processing, it has a significant degree of inaccuracy of 10%, in other words, there is a considerable possibility of some failure occurring in this diagnostic conclusion, which can cause damage to the patient after carrying out an inappropriate treatment. Precisely because of this, in 2017, Watson for Oncology was widely criticized by health professionals, claiming that it would not satisfy the criteria or even offer inaccurate diagnosis to medical users.[49]

In this sense, it is relevant to mention the research conducted by a team of fifteen researchers at Manipal Hospitals, in India, over the course of three years, with a thousand patients diagnosed with cancer, in order to assess the accuracy of Watson for Oncology's results.[50] In the end, the researchers observed a 90% rate of correct diagnosis by the artificial intelligence system. In cases where there was a divergence between the software and the doctors, the latter changed their own diagnosis, in 63% of the cases, to follow the one given by Watson.[51] This is a crucial point for the analysis proposed herein: artificial intelligence led the oncologists to change their final decision in several cases. In any way, the aforesaid research revealed that in 37% of the cases the professional did not change his diagnosis when it differed from the result obtained by the artificial intelligence. Therefore, it is legitimate to raise some concerns: in the event of a supervening damaging result that, in theory, could be avoided if the diagnosis proposed by an artificial intelligence had been followed, should the doctor be

48 DAVID, Eric. Watson correctly diagnoses woman after doctors were stumped, cit.

49 IBM's Watson supercomputer recommended 'unsafe and incorrect' cancer treatments, internal documents show. Available at: https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments/. Accessed: Dec. 26, 2022.

50 FLORENZANO, Cláudio. Computação cognitiva descobre 1.000 casos de câncer com precisão de 90%. [Artificial Intelligence detects 1,000 cancer cases with 90% accuracy. Free translation from original]. **BCSI**, 06/01/2017. Available at: https://www.cbsi.net.br/2017/06/computacao-cognitiva-descobre-1000-casos-de-cancer-com-precisao-de-90.html. Accessed: July 2, 2022.

51 FLORENZANO, Cláudio. Computação cognitiva descobre 1.000 casos de câncer com precisão de 90%, cit.

held responsible? If, on the other hand, the doctor follows the wrong diagnosis proposed by an artificial intelligence, can the professional be exempt from liability for the damages that the patient may suffer?[52]

Similarly, it must be taken into account that the algorithms created for the diagnosis of Covid-19 have a significant degree of inaccuracy, which can lead to particularly onerous results. This is because the false negative diagnosis is much more serious than in other diseases, since the patient can infect his family and other people close to him, in addition to becoming an involuntary and unconscious vector for the multiplication of infection and contagion rates. On the other hand, a false positive result leads to the patient being quarantined for fourteen days, which can affect his work activity and his personal and family relationships.

Therefore, it is indispensable to reinforce that, at least in the current state of society, diagnostic software should serve as an important support for the doctor's decision making, without the capability of replacing a medical professional. In effect, the final decision remains under the control (and responsibility) of the healthcare professional. However, this conclusion does not indicate a trivialization of the doctor's personal liability. In accordance with the current emphasis on the subject, it is also necessary to be cautious in the process of evaluating the doctor's conduct in the event of an indemnity claim. In this manner, it is possible to build solid basis for the rejection of frivolous demands, avoiding an increase in defensive medicine practices that would have little (or nothing) to contribute to combat the pandemic in its current stage.

Beyond the analysis of medical liability in the event of a medical error, it is also relevant to point out the existence of these risks of damages to the patient, due to inaccurate or unforeseen results that are, to some extent, particular of artificial intelligence.

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52 For a further analysis of the use of artificial intelligence in the diagnostic analysis of COVID-19 and its repercussions on medical liability, see SILVA, Rodrigo da Guia; NOGAROLI, Rafaella. Inteligência artificial na análise diagnóstica da COVID-19: possíveis repercussões sobre a responsabilidade civil do médico. *In*: ROSENVALD, Nelson; MONTEIRO FILHO, Carlos Edison do Rêgo; DENSA, Roberta (Coord.). **Coronavírus e responsabilidade civil**: impactos contratuais e extracontratuais. Indaiatuba: Foco, 2020, p. 293-300.

It is also worth mentioning that the disastrous results of the famous autonomous car accidents[53] serve as a warning to the possibility of an AI causing unpredictable damage,[54] mainly due to the AI's self-learning capability and the possibility of it evolving in a way that can generate some unwanted (and perhaps never foreseen) result. The ability of algorithms to generate results that could not be effectively predicted by their programmers - and neither by direct users - is widely discussed in the doctrine, [55] mainly because of its ethical and legal implications in the healthcare sector. In the decision-making processes of intelligent systems there is an issue known as the "*black box problem*"[56], i.e., the algorithms perform certain actions to reach a specific result, but they are not always able to really explain to a human how that decision was made.[57]

There are two symbolic cases that exemplify the problem of unpredictable behaviors arising from AI self-learning and the unreliability of the results generated by the algorithms. During an experiment conducted in 2002 by scientists at the Magna Science Center, in England, an unforeseen event occurred: two intelligent robots were placed in an arena to simulate a scenario of "predators" and "prey" in order to see if the robots would be able to benefit

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53 In 2017, a model of the Tesla S self-driving car, driving on autopilot in China, crashed into a truck, killing its passenger. (Tesla Model 3: Fatal Autopilot engaged during crash. Available at: https://www.bbc.com/news/technology-48308852. Accessed: Dec. 26, 2022). In 2018, a self-driving Uber car ran over a pedestrian in the state of Arizona, in the United States. (Self-driving Uber kills fatal Arizona woman in first crash involving pedestrian. Available at: https://www.theguardian.com/technology/2018/mar/19/uber-self-driving-car-kills-woman-arizona-tempe. Accessed: Dec. 26, 2022)

54 Regarding the unpredictable behaviors arising from machine learning, see generally MATTHIAS, Andreas. The responsibility gap: ascribing responsibility for the actions of learning automata. **Ethics and Information Technology**, v. 6, issue 3, sept. 2004, p. 175-183; and MITTELSTADT, Brent Daniel; ALLO, Patrick; TADDEO, Mariarosaria; WACHTER, Sandra; FLORIDI, Luciano. The ethics of algorithms: mapping the debate. **Big Data & Society**, v. 3, issue 2, dec. 2016. p. 3 ff.

55 MITTELSTADT, Brent Daniel; ALLO, Patrick; TADDEO, Mariarosaria; WACHTER, Sandra; FLORIDI, Luciano. The ethics of algorithms, cit., p. 5-7.

56 On the subject, it is essential to refer to PASQUALE, Frank. **The black box society**: the secret algorithms that control money and information. Cambridge: Harvard University Press, 2015, *passim*.

57 Therefore, when implementing algorithmic systems, it is essential to "know their limitations and what is effectively taken into account for decision making. Understanding the limits of algorithms will help the agent to better judge its decisions and suggestions, thus avoiding simplistic and reductionist views and incurring in the possibility of making humans, to a certain extent, hostages to decisions taken in the `black box´ of the algorithms" (TEFFÉ, Chiara Spadaccini de; MEDON, Filipe. Responsabilidade civil e regulação de novas tecnologias: questões acerca da utilização de inteligência artificial na tomada de decisões empresariais. **Revista Estudos Institucionais**, v. 6, n. 1, jan./apr. 2020, p. 325 [Free translation from original]).

from the experience acquired from machine learning to develop new hunting and self-defense techniques. However, Gaak, one of the robots, adopted an unpredictable behavior and found a way out through the arena wall and went to the street, where it ended up being hit by a car.[58]

It is also relevant to mention the incident reported by Sameer Singh, an assistant professor in the Department of Computer Science at the University of California (UCI), in the United States, in which a student created an algorithm to categorize pictures of huskies and wolves.[59] Initially, it seemed that the algorithm was able to classify the two animals almost perfectly. However, after numerous and subsequent cross-analysis, Singh found out that the algorithm was identifying wolves based only on the snow in the background of the images and not on the animal's own characteristics. Now take for example a poorly programmed algorithm, or one with some degree of fallibility, in the aforementioned cognitive technology that was used in some countries to diagnose patients infected with the new coronavirus. Undoubtedly, damages could rise to immeasurable levels if wrong data on infected patients were entered into the system or if the algorithm was poorly programmed.

Because of this, Nicholson Price explains that one of the biggest fears of the healthcare sector at this stage of artificial intelligence stems precisely from the unpredictable situations arising from machine learning and from a concept known as *black box medicine*, given the obscurity in the way information is processed by the algorithms.[60] Furthermore, the author describes his concerns

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58 CERKA, Paulius; GRIGIEN, Jurgita; SIRBIKYT, Gintar. Liability for damages caused by artificial intelligence. **Computer Law & Security Review**, v. 31, n. 3, june 2015, p. 376-389.

59 Husky or Wolf? Using a Black Box Learning Model to Avoid Adoption Errors. Available at: http://innovation.uci.edu/2017/08/husky-or-wolf-using-a-black-box-learning-model-to-avoid-adoption-errors/. Accessed: Mar. 26, 2021.

60 On the other hand, Price indicates some benefits associated with *black box medicine*: "many medical treatments affect different patients differently; the same treatment, given to two patients suffering from the same disease, may cure one patient but have no effect for the other. A black-box algorithm could guide treatment decisions by predicting that one drug might work better than another
for a specific patient, or might have fewer side effects, or that the patient would likely respond best to a particular dose on a particular schedule. Such algorithms could eliminate the need for physicians to experiment with different drugs, saving significant time and money. (…) difficult. Some diseases and conditions simply don't have reliable tests; others so closely resemble each other, or include so many subtypes, that it is hard to tell different diseases or conditions apart. And sometimes a
patient may have underlying risk factors that may develop into a problematic condition. Black-box algorithms could help diagnose these uncertain diseases and conditions. A black-box model might, for instance, identify the specific genes that predict who will develop a disease or condition; or it might tell physicians, earlier than they could

relating to privacy, since a large amount of sensitive information is collected by these systems and, in addition, can be shared with other entities, which increases the potential for data leaks and subsequently incurring in indirect or direct damages to the data subjects.[61]

On the subject, Frank Pasquale refers to an event that occurred in 2008, in the United States, in which medical prescription data were being used in the individual insurance market, as pharmacies passed on the list of drug purchase orders to insurance companies. With the collection of millions of order's information, companies readjusted their policies to exclude some illnesses from coverage and impose higher charges on certain people. Approximately a decade after the aforesaid episode, in the era of big data, the risk to privacy is inevitably accentuated. That is because, according to Pasquale, "companies don't even need to consult physicians' records to impute to us medical conditions and act accordingly. Do a few searches about a disease online, fill out an (apparently unrelated) form, and you may well end up associated with that disease in commercial databases".[63]

It can be observed that in spite of the potential benefits of digitizing data, its use may constitute in a violation of the obligations of secrecy and the principles of transparency and information, disrespecting the patient's autonomy and his right to give a broad consent to the processing of his personal data.[64] In the medical field, the risk of disclosure is deemed more serious, given that health

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otherwise tell, which of two similar diseases a patient has. Some of these benefits can be obtained through other means; others unique to black-box medicine. But even when other means are available, black-box algorithms could significantly reduce health-care costs by eliminating the need to perform other, costly tests or to waste time on ineffective treatments. And they could lead to better health outcomes as inappropriate treatments or dangerous side effects are avoided" (FORD, Roger Allan; PRICE, W. Nicholson. Privacy and Accountability in Black-Box Medicine, **Michigan Telecommunications & Technology Law Review**, v. 23, 2016, p. 5-7).

61 PRICE, William Nicholson. Artificial Intelligence in Health Care, cit. p. 31

62 PASQUALE, Frank. The black box society, cit. 26-30.

63 PASQUALE, Frank. The black box society, cit., p. 28. This issue is related to the general problem of algorithmic discrimination. In that case, see JUNQUEIRA, Thiago. Tratamento de dados pessoais e discriminação algorítmica nos seguros. São Paulo: Thomson Reuters Brasil, 2020, *passim*.

64 SCHULMAN, Gabriel. Tecnologias de telemedicina, responsabilidade civil e dados sensíveis. O *princípio ativo* da proteção de dados pessoais do paciente e os efeitos colaterais do coronavírus. *In*: MONTEIRO FILHO, Carlos Edson do Rego; ROSENVALD, Nelson; DENSA, Roberta. **Coronavírus e Responsabilidade Civil**. Indaiatuba: Foco, 2020, p. 344-357.

data is considered as a recurrent target of cybercrime.[65] The biggest challenge is to maintain "all of the advantages of digitization in healthcare without compromising its ethical and human side, reinforcing codes of conduct to protect clinical information and personal data",[66] ensuring, in the end, proper protection to patient privacy.[67]

Between 2018 and 2020, 562 episodes of breaches of data in healthcare organizations were reported to the US Department of Health and Human Services Office for Civil Rights.[58] In the United States, in 2015 alone, there were 51 incidents with hackers in healthcare institutions, involving, in most cases, illegal access to patient's sensitive data and electronic health records.[69] American Medical Tech, a healthcare company, announced in June 2020 the conclusion of an investigation into an episode that occurred in December 2019, in which the company was the victim of a cyber-attack. It is estimated that the data breach affected around 50 thousand patients and a large amount of personal data may have been available to the hacker during the incident, including: patient names, social security numbers, medical record data, diagnostic information, health insurance policy, medical history information, driver's license numbers etc.[70]

Several healthcare companies and hospitals in European countries, such as Spain, England and Portugal, have also been the target of cyber-attacks over the last few years.[71] In the United Kingdom, 16 National Health Service

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65 Why cyber-criminals are attacking healthcare - and how to stop them. Available at: https://www.forbes.com/sites/kateoflahertyuk/2018/10/05/why-cyber-criminals-are-attacking-healthcare-and-how-to-stop-them/#5efc83f57f69. Accessed: Dec. 26, 2022.

66 RIBEIRO, José Medeiros. **Saúde Digital**: um sistema de saúde para o século XXI. Lisboa: Fundação Francisco Manuel dos Santos, 2019, p. 27 [Free translation from original].

67 DONEDA, Danilo. **Da Privacidade à Proteção de Dados Pessoais**: elementos da formação da Lei Geral de Proteção de Dados Pessoais. 2. ed. São Paulo: Revista dos Tribunais, 2019, p. 128-129.

68 U.S. Department of Health and Human Services Office for Civil Rights Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information. Available at: https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf. Accessed: Nov. 2, 2022.

69 Breaches of Unsecured Protected Health Information. Number of individuals affected by protected health information breaches: 2010 – 2015. Available at: https://dashboard.healthit.gov/quickstats/pages/breaches-protected-health-information.php. Accessed: Nov. 2, 2022.

70 AMT healthcare data breach impacts nearly 50,000 patients. Available at: https://portswigger.net/daily-swig/amt-healthcare-data-breach-impacts-nearly-50-000-patients. Accessed: Nov. 2, 2022.

71 Empresas e hospitais sofrem ataque cibernético em massa [Companies and hospitals suffer massive cyber-attack. Free translation from original]. Available at: https://link.

hospitals were affected and some patients in emergency situations had to be transferred. In addition, patient's information, appointment schedules, internal phone lines and e-mails were temporarily inaccessible.[72] It is reported that Brazil is the leader in cyber-attacks in Latin America and 11th in the world,[73] having registered the occurrence of approximately 15 billion cyber-attacks in the first three months of 2020 alone.[74] In one of these episodes, the computers at the *Hospital das Clínicas de Barretos,* in São Paulo, suffered cyber-attacks that temporarily stopped some medical appointments. Interpol (International Criminal Police Organization) and several cyber security companies have been alerting hospital institutions and healthcare organizations to be extra cautious since they became some of the main targets of hackers during the Covid-19 pandemic.[76] In July 2020, an attempted cyber-attack occurred at the *Hospital Sírio-Libanês* in São Paulo, but the security systems themselves identified the attempted breach and disconnected the server from the internet before the crime could even take place. At the time, some tests such as magnetic resonance imaging and tomography became unavailable, and these services were stabilized only five days later.[77] A few days later, the Health Department of the city of Arapongas, in Paraná, opened an administrative procedure to investigate the leak and disclosure, on the Internet, of a list containing personal data of patients infected with Covid-19.[78] A few months before these episodes,

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estadao.com.br/noticias/empresas,empresas-e-hospitais-sofrem-ataque-cibernetico-em-massa-na-europa,70001776946. Accessed: Nov. 2, 2022.

72 Ciberataque paralisa 16 hospitais do Reino Unido. [Cyberattack paralyzes 16 hospitals in the United Kingdom. Free translation from original]. Available at: https://brasil.elpais.com/brasil/2017/05/12/internacional/1494602389_458942.html. Accessed: July 2, 2022.

73 Brasil é líder em execução de ciberataques na América Latina, aponta pesquisa [According to research, Brazil is the leader in executing cyberattacks in Latin America. Free translation from original]. Sept. 26, 2019. Available at: https://ipnews.com.br/brasil-e-lider-em-execucao-de-ciberataques-na-america-latina-aponta-pesquisa/. Accessed: Nov. 12, 2020

74 Brasil sofreu 15 bilhões de ataques cibernéticos em 3 meses, diz estudo [According to research, Brazil suffered 15 billion cyber-attacks in 3 months. Free translation from original]. Aug 6, 2019. Available at: https://exame.abril.com.br/tecnologia/brasil-sofreu-15-bilhoes-de-ataques-ciberneticos-em-3-meses-diz-estudo/. Accessed: Nov. 2, 2022.

75 Os crimes dos hackers que interrompem até quimioterapia em sequestros virtuais de hospitais [The crimes of hackers that are capable of interrupting chemotherapy in virtual kidnappings of hospitals. Free translation from original]. Available at: https://www.bbc.com/portuguese/brasil-40870377. Accessed: Nov. 2, 2022.

76 Após tentativa de ciberataque no Sírio-Libanês, setor da saúde teme invasões [After an attempted cyber-attack on Sírio-Libanês, the healthcare sector fears invasions. Free translation from original]. Available at: https://www1.folha.uol.com.br/cotidiano/2020/07/apos-tentativa-de-ciberataque-no-sirio-libanes-setor-da-saude-teme-invasoes.shtml. Accessed: Nov. 12, 2022.

77 Após tentativa de ciberataque no Sírio-Libanês, setor da saúde teme invasões., cit.

78 Prefeitura vai apurar vazamento de lista de pessoas com Covid-19. [City council will

Microsoft sent an alert to hospitals and healthcare organizations vulnerable to attacks by hackers, in Latin America, Europe and other locations, particularly because criminals know that hospitals are under pressure due to the pandemic and, therefore, have no time to install updates, or pay attention to details in the network settings.[79]

These incidents of data breaches can result from a variety of factors, such as the lack of security in the transmission of data, absence of access passwords and different permissiveness on the systems and applications that weaken the protection and exchange of information. The various risks in the use of artificial intelligence algorithms and the processing of sensitive data presented herein composes a complex scenario that prompts the need to discuss important ethical and legal issues, and the next chapter is dedicated to this endeavor.

3. Ethical and Legal Aspects of the Processing of the Patient's Sensitive Personal Data by Artificial Intelligence Algorithms in the Context of the New Corona Virus Pandemic

In the medical field, when it comes to the processing of sensitive personal data, among the main risks, as previously mentioned, are the irregular processing of personal data, the difficulty of assessing liability for the automated decisions in the processing of such data[80] and the lack of information or consent on how the personal data was collected, processed and shared.[81] Therefore, it is of the utmost importance to investigate the laws that protect personal data.

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investigate the leak of list of people with Covid-19. Free translation from original]. Available at: https://www.bonde.com.br/bondenews/parana/prefeitura-vai-apurar-vazamento-de-lista-de-pessoas-com-covid-19-520472.html. Accessed: Nov. 15, 2022.

79 Microsoft envia alerta 'inédito' para hospitais vulneráveis a ataques de hackers [Microsoft sends an 'unprecedent' alert to hospitals vulnerable to hacker attacks. Free translation from original]. Available at: https://g1.globo.com/economia/tecnologia/blog/altieres-rohr/post/2020/04/03/microsoft-envia-alerta-inedito-para-hospitais-vulneraveis-a-ataques-de-hackers.ghtml. Accessed: Nov. 12, 2022.

80 In this regard, it is relevant to refer to the debate over the existence or inexistence of the right of the personal data's subject to review, by a natural person, the decisions taken solely on the basis of automated processing. This controversy dates back to the circumstance in which the *Medida Provisória* [Provisional Measure] (MP) no. 869/2018 and the subsequent Law no. 13.853/2019 changed the art. 20 of the *Lei Geral de Proteção de Dados Pessoais* [Brazilian General Data Protection Law] (Law No. 13.709/2018) to suppress the provision, contained in the original wording of the document, according to which "The data subject has the right to request a review, *by a natural person*, of decisions taken solely on the basis of automated processing of personal data that affects his or her interests" (emphasis added) [Free translation from original].

81 GRALL, Matthieu. CNIL (Commission Nationale de l'Informatique et des Libertés) and Analysis of Big Data Projects in the Health Sector, cit., p. 235.

In recent years and in a variety of legal systems, there has been a profound change in the understanding of the protection of personal data, opportunely recognized as an aspect inherent to the privacy of the natural person.[82] In this context, it is important to highlight the recognition of the right to informational self-determination, reframing the meaning of what was traditionally understood as the right to privacy.[83] Particularly in the medical field, a complete advancement in informational self-determination presupposes transparency and clarification on which patient data will be processed, what is the destination given to it (principle of purpose) and with whom it will be shared.[84]

In Brazil, without prejudice to the difficulties faced for the complete effectiveness of the *Lei Geral de Proteção de Dados Pessoais* [Brazilian General Data Protection Law] (LGPD - Law No. 13.709/2018), there is an urgent need to reflect on its provisions relating to general concepts and principles of the processing of data, which are also supported by other normative sources and can be used in extensive interpretation. Even before the LGPD was in effect, it was already recognized that the fundamental right to the protection of personal data is "a principle implicit in the Brazilian law, but the protection that can be presumed from it extends its effects on the entire complementary normative framework, guaranteeing rationality to the legal system and providing protection even before the end of the vacatio legis of the LGPD".[85]

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82 DONEDA, Danilo. Da Privacidade à Proteção de Dados Pessoais, cit., p. 29.

83 For a further analysis of the reframing of privacy, today associated with informational self-determination, it is essential to refer to the traditional lesson of RODOTÀ, Stefano. **A vida na sociedade da vigilância**: a privacidade hoje. Org. Maria Celina Bodin de Moraes. Trad. Danilo Doneda e Luciana Cabral Doneda. Rio de Janeiro: Renovar, 2008, p. 15 ff. RODOTÀ, Stefano. Por que é necessária uma Carta de Direitos da Internet? **Civilistica.com**, Rio de Janeiro, ano 4, n. 2, 2015. Disponível em: http://civilistica.com/por-que-e-necessaria-uma-carta-de-direitos-da-internet/. Acessed: Dec. 26, 2022. In this sense, see also SOUZA, Eduardo Nunes de; SILVA, Rodrigo da Guia. Tutela da pessoa humana na Lei Geral de Proteção de Dados Pessoais: entre a atribuição de direitos e a enunciação de remédios. **Pensar**, vol. 24, n. 3, july-sept./2019, p. 9 ff.

84 SCHAEFER, Fernanda; GONDIM, Glenda Gonçalves. Telemedicina e lei geral de proteção de dados. *In*: ROSENVALD, Nelson; MENEZES, Joyceane Berreza de; DADALTO, Luciana (coord.). **Responsabilidade Civil e Medicina**. Indaiatuba: Foco, 2020, p. 194-195.

85 FALEIROS JUNIOR, José Luiz de Moura; NOGAROLI, Rafaella; CAVET, Caroline Amadori. Telemedicina e proteção de dados: reflexões sobre a pandemia da Covid-19 e os impactos jurídicos da tecnologia aplicada à saúde. **Revista dos Tribunais**, São Paulo, v. 1016, june 2020 [Free translation from original]. Still regarding the recognition of a fundamental right to data protection, it is expressed: "even though there is no constitutional provision in Brazil on the right to data protection as a category of Fundamental Right, it is certain that its recognition can be attained by several constitutional provisions: from the protection of privacy (art. 5, X), the right to

A Brazilian milestone in the discussion on the protection of personal data as a fundamental right implicit in the Federal Constitution is the recent judgment of the *Ação Direta de Inconstitucionalidade* [Direct Action for the Declaration of Unconstitutionality] no. 6.387/DF,[86] concerning the *Medida Provisória* [Provisional Measure] 954, of April 17, 2020, which obliged telephone companies to disclose, to the *Instituto Brasileiro de Geografia e Estatística* [Brazilian Institute of Geography and Statistics] (IBGE), their customer's mobile telephony, cell phone and address data during the Covid-19 pandemic.[87] The injunction that suspended this Provisional Measure was granted based on the principles of purpose and proportionality in the processing of personal data established in the LGPD (art. 6, items I, II and III). From the Brazilian Supreme Federal Court ruling, it can be ascertained that the irregular processing of personal data can cause "irreparable damage to the privacy and private life confidentiality of more than a hundred million users",[88] citing, among others,

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information (art. 5, XIV), the right to communications and data confidentiality (art. 5, XII), or the individual guarantee of knowledge and correction of personal information provided by habeas data (art. 5, LXXII) (...) privacy is the appropriate constitutional *locus* of data protection, and this is demonstrated in the recognition that 'data is a constituent element of a person's identity and must be protected to the extent that it forms a fundamental part of their personality, which must have a privileged development through the recognition of their dignity' (...) the recognition of the right to the protection of personal data as a Fundamental Right endows it with direct and immediate effectiveness, typical of this category of law, resulting in it being acknowledged not only in the relationship established between State and subject, but necessarily in the relationships between individuals" (MULHOLLAND, Caitlin; FRAJHOF, Isabella Z. Inteligência Artificial e a Lei Geral de Proteção de Dados Pessoais: breves anotações sobre o direito à explicação perante a tomada de decisões por meio de *machine learning*. *In:* FRAZÃO, Ana; MULHOLLAND, Caitlin; (Coord.). **Inteligência artificial e direito**. São Paulo: Revista dos Tribunais, 2019, p. 270 [Free translation from original]).

86 In Brazil, the "direct action for the declaration of unconstitutionality" is an instrument to declare the unconstitutionality of law or federal norms, with respect to the current Constitution. The current Brazilian constitutional jurisdiction is characterized by "the originality and diversity of the available legal actions, either to dispute the constitutional character of an act of the public power, or to protect the fundamental rights. Among these actions are "mandado de segurança" – a Brazilian innovation on the constitutional field -,"mandado de injunção", "habeas corpus", "ação civil pública" and "ação popular". In addition to these forms of diffuse constitutional control, there are other constitutional actions related to the abstract constitutional control by the Brazilian Federal Supreme Court, such as direct action for the declaration of unconstitutionality, direct action for the declaration of unconstitutionality by omission, action for the declaration of constitutionality and action against a violation of a constitutional fundamental right." (Available at https://www2.stf.jus.br/portalStfInternacional/cms/verConteudo.php?sigla=portalStfSobreCorte_en_us&idConteudo=120199. Accessed: Nov. 12, 2022.)

87 For more information: https://www.dataprivacybr.org/wp-content/uploads/2020/05/Report-2.pdf. Accessed Nov. 12, 2022.

88 STF, ADI 6387 MC-Ref, Tribunal Pleno, Rel. Min. Rosa Weber, julg. 7/5/2020. Ementa do acórdão [Free translation from original].

the article 5, item XII, of the Brazilian Federal Constitution - which ensures that the secrecy of correspondence and of telegraphic, data and telephone communications is inviolable -, to recognize that "[the] protection of personal data and informational self-determination are fundamental autonomous rights".[89] On February 2022, the Brazilian Congress enacted the Constitutional Amendment (EC) number 115, which establishes personal data protection as a fundamental right in article 5 of the Brazil's 1988 Federal Constitution: "under the terms of the law, the right to the protection of personal data is ensured, including in digital media".[90]

On the other hand, the recognition of the importance of personal data protection is even more explicit in Portugal, whose 1976 Constitution of the Republic provides, in its article 35:

> 1. Every citizen has the right of access to all computerised data that concern him, which he may require to be corrected and updated, and the right to be informed of the purpose for which they are intended, as laid down by law. 2. The law shall define the concept of personal data, together with the terms and conditions applicable to its automatised treatment and its linkage, transmission and use, and shall guarantee its protection, particularly by means of an independent administrative entity. 3. Information technology may not be used to treat data concerning philosophical or political convictions, party or trade union affiliations, religious faith, private life or ethnic origins, save with the express consent of the data subject, or with an authorisation provided for by law and with guarantees of non-discrimination, or for the purpose of processing statistical data that are not individually identifiable. 4. Third-party access to personal data is prohibited, save in exceptional cases provided for by law. 5. The allocation of a single national number to any citizen is prohibited. 6. Everyone is guaranteed free access to public-use information technology networks. The law shall define the regime governing cross-border data flows, and the appropriate means for protecting both personal data and other data whose safeguarding is justified in the national interest. 7. Personal

89 STF, ADI 6387 MC-Ref, Tribunal Pleno, Rel. Min. Rosa Weber, julg. 7/5/2020. Voto do Min. Luiz Fux [Free translation from original].

90 Data protection becomes a fundamental right in Brazil. Available at: https://www.zdnet.com/article/data-protection-becomes-a-fundamental-right-in-brazil. Accessed: Dec. 28, 2022.

> data contained in manual files enjoy the same protection as that provided for in the previous paragraphs, as laid down by law.[91]

In Portuguese law, the protection of personal data is ensured not only by the Constitution of the Republic of 1976 -[92] since its first version in 1976 -, but also by successive charters that regulate its application, until the recent *Lei Nacional de Proteção de Dados* [Portuguese National Law on Data Protection] (LNPD - Law No. 58 of 2019),[93] which came to regulate the implementation of the General Data Protection Regulation of the European Parliament (GDPR) in the Portuguese national law. Considering the precursor Law No. 67 of 1998 of Portugal (the former LNPD),[94] the GDPR established some relevant innovations regarding the processing of personal data, especially in five aspects: 1) recognition of the importance of protecting personal data; 2) expanding on the concept of personal data, to include any data that could identify the individual, even if indirectly; 3) strengthening of the rights of data subjects (right to be forgotten and data portability); 4) introduction of a sanctioning framework; 5) mandatory reporting to the *Comissão Nacional de Proteção de Dados* [Portuguese National Commission on Data Protection] (CNPD) of incidents related to personal data.[95]

In the Member States of the European Union, the current perspective on the fundamental right to the protection of personal data derives essentially from the legislative evolution of European countries, divided into four generations, as explained by Bruno Bioni:

> The first generation of personal data protection laws arises, as a result, from the concern with the massive processing of citizens' personal data in the context of the Modern State formation. At that time, the regulatory solution was to focus on the technology itself that should be

91 Available at: https://www.parlamento.pt/sites/EN/Parliament/Documents/Constitution7th.pdf. Accessed: Dec. 26, 2022.

92 To analyze the evolution of the formulation of the Portuguese Constitution's art. 35, examining the successive changes to the original wording of this constitutional provision, see generally CASTRO, Catarina Sarmento e. 40 anos de "Utilização da Informática" - O artigo 35.º da Constituição da República Portuguesa. *e-Pública: Revista Eletrónica de Direito Público*, vol. 3, n. 3, Lisboa, dec./2016, *passim*.

93 Available at: https://www.uc.pt/protecao-de-dados/legis/20190808_lei_58_2019_execucao_protecao_de_dados_e_livre_circ_de_dados. Accessed: Dec. 26, 2022.

94 Available at: https://www.uc.pt/protecao-de-dados/legis/19981026_lei_67_98_lpdp. Accessed: Dec. 26, 2022.

95 Informação Administrativa e Proteção de Dados. Available at: https://www.uc.pt/protecao-de-dados/protecao_dados_pessoais/da_privacidade_a_protecao_de_dados. Accessed: Dec. 26, 2022.

> domesticated and guided by democratic values. (...) In essence, what defines the first generation of protection of personal data is its focus on the governmental sphere, as well as on the premise of establishing rigid rules that could tame the use of technology. Nevertheless, data processing has transcended the governmental sphere, which increased the number of actors and, symmetrically, the number of databases to be regulated and authorized. This new scenario demanded a new regulatory framework. (...) The second generation of personal data protection laws is characterized by a change in the regulatory core. It is concerned not only with state databases, but also with those in the private sphere. (...) The expansion of the individual's leading role in the protection of personal data is the turning point for the third generation of laws. At this stage, the rules for the protection of personal data sought to ensure the participation of the individual in all movements of his personal data: from collection to sharing. In this manner, the perfect meaning of the terminology "informational self-determination" would be accomplished since that, with this kind of involvement, it is possible for the data subject to have extensive control over his own personal information. (...) The fourth generation came to cover this deficiency in the previous generations of laws. The dissemination of independent authorities for the application of personal data protection laws, as well as regulatory propositions which excluded from the individual the possibility of choice regarding the processing of certain types of personal data (e.g. sensitive), relativized the mentioned importance of consent. At the same time, however, this generational progress has not eliminated the leading role of consent. Its centrality remained the hallmark of the regulatory framework. So much so that, in the midst of this evolutionary process, consent started to be described as having to be free, informed, unambiguous, explicit and/or specific, as it occurred in the European Community Law.[96]

The European Community Law is a good example of the progression of the concept of consent in the generational course of personal data protection laws, indicating a trajectory in which the idea of consent emerges, is questioned and, finally, is reaffirmed as the core of the discipline. Thus, the personal data

96 BIONI, Bruno Ricardo. **Proteção de dados pessoais**: a função e os limites do consentimento. Rio de Janeiro: Forense, 2020, p. 109-121 [Free translation from original].

subject remains its central point, in a very valuable paradigm that can serve as an inspiration for the construction and interpretation of the rules regarding the protection of personal data in Brazil.[97]

In accordance with the very significance of personal data for the current policies on the protection of privacy, the Brazilian LGPD (art. 7, I, and art. 11, item I) and the European GDPR (art. 6, no. 1, a, and art. 9, no. 1) reinforce the need for the data subject's consent for the processing of personal data to occur. Both laws are categorical in the sense that, as a rule, the processing of personal data will only be allowed when the data subject or his legal guardian consents, distinctively, for specific purposes.[98]

Taking the LGPD into account, consent is considered to be "a free, informed and unambiguous manifestation whereby the data subject agrees to the processing of his or her personal data for a given purpose" (art. 5, XII, Free translation from original). The purpose in the processing of personal data is comprised in a principle provided for in article 6, item I, of the LGPD.[99] In the

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97 FALEIROS JÚNIOR, José Luiz de Moura. A tutela jurídica dos dados pessoais sensíveis à luz da Lei Geral de Proteção de Dados. *In*: LONGHI, João Victor Rozatti; FALEIROS JÚNIOR, José Luiz de Moura. **Estudos essenciais de direito digital**. Uberlândia: LAECC, 2019, p. 297-231.

98 In this regard, Aurelia Tamò-Larrieux explains the need for the data subject's consent to always be specific to a particular purpose: "The purpose limitation principle essentially states that personal data should be collected for specified, lawful, and legitimate purposes, and not be further processed in ways that are incompatible with those purposes. The underlying goal of this principles is '(…) not to let a one-time legitimization of a single instance of data processing provide a blank check for unlimited further uses of data.' The purpose limitation principle calls for an assessment of whether the originally stated purposes for collection of data are consistent with the actual processing that takes place. The principle encompasses three requirements. First, the definition of the purpose of the collection must be stated prior to the actual collection. This criterion has a time component (i.e., the specification occurs prior to the collection) and a quality component, namely the exposition of the purposes in concrete, specific terms (typically in writing). Second, the purposes must be legitimate. In this case, legitimate can mean lawful or have a broader meaning such as socially acceptable. Since data protection legislation exhibits a procedural character, legitimacy can be more narrowly understood to mean compliance with procedural norms. The third requirement states that the purposes for which the data is processed at a later stage (so-called secondary purposes), should not be incompatible with those that underlie the data collection in the first place" (TAMÒ-LARRIEUX, Aurelia. **Designing for Privacy and its Legal Framework**. Data Protection by Design and Default for the Internet of Things. Cham: Springer, 2018, p. 90).

99 *In verbis*: "Art. 6 Activities of processing of personal data shall be done in good faith and be subject to the following principles: (...) purpose: processing done for legitimate, specific and explicit purposes of which the data subject is informed, with no possibility of subsequent processing that is incompatible with these purposes" [Free translation from original].

event of changes in the purpose of the processing of personal data that are not compatible with the original consent, the LGPD provides that "the controller shall previously inform the data subject of the changes of purpose, and the data subject may revoke his or her consent if he or she disagrees with the changes" (art. 9, § 2 of the LGPD, Free translation from original).

The GDPR, in turn, in the article 4, item 11, defines consent as "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". The withdrawal of consent occupies a significant place in the GDPR. According to article 7(3), "The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent".[100]

Faleiros and Dresch describe the essential function of the personal data subject's consent in the LGPD, drawing a comparison with the European GDPR, which cites the word "consent" 72 times:

> In the article 4 on the definitions, [the GDPR] defines consent as "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 (...). " The Brazilian legislator treated the issue in a similar manner since article 7 of Law No. 13.709/2018 considered the data subject's consent as an essential requirement for the processing of personal data: if the consent is not free, informed and unambiguous (art. 5, XII), the measure becomes illegal.[101]

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100 The GDPR provides further guidance in article 7 and in Whereas Clauses 32, 33, 42 and 43 on how the controller should act to comply with the main elements of the requirement of consent. The provisions and Whereas clauses on the withdrawal of consent in the GDPR can be seen as a codification of the interpretation contained in the opinions of the Article 29 Working Party (Art. 29 WP) on this matter. Art. 29 WP addressed this issue in its opinion on consent - Opinion 15/2011 (WP 187) p. 9, 13, 20, 27 and 32-33, among others, in its opinion on the use of location data. See Opinion 5/2005 of Art. 29 WP on the use of location data with a view to providing value-added services (WP 115), p. 7. On the subject, refer to EUROPEAN DATA PROTECTION BOARD, Guidelines 05/2020 on consent under Regulation 2016/679. Available at: https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202005_consent_en.pdf Accessed: Dec. 26, 2022.

101 DRESCH, Rafael de Freitas Valle; FALEIROS JÚNIOR, José Luiz de Moura. Reflexões

In both laws, it is the burden of the data controller to prove that the data subject has given his or her consent for the data processing operation (art. 7, no. 1, of the GDPR, and art. 8, § 2, of the LGPD). It is important to highlight that there are established principles for the processing of personal data. Article 5 of the GDPR indicates the following principles: lawfulness, fairness and transparency; purpose limitation; data minimization; accuracy; storage limitation; integrity and confidentiality; accountability. The list of principles introduced in article 6 of the LGPD contemplates the following: purpose, suitability, necessity, free access, data quality, transparency, security, prevention, non-discrimination and accountability. The purpose of establishing these guiding principles is to restrict the processing of personal data, requiring that there be strict compliance in order to recognize the lawfulness of the activity.

In the context of Brazilian domestic affairs, the LGPD expressly included health data (although without defining it) in the concept of "sensitive personal data", which it defined as "personal data concerning racial or ethnic origin, religious belief, political opinion, trade union or religious, philosophical or political organization membership, data concerning health or sex life, genetic or biometric data, when related to a natural person" (art. 5, II, Free translation from original). According to the provisions of the GDPR, especially in the title of article 9 ("Processing of special categories of personal data"), personal data relating to health are considered to be a special category of data and can then be defined as "special personal data". Article 4, no. 15, defines data concerning health as "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". Additionally, Whereas clause 35 of the GDPR provides an extensive and important definition of the concept of *data concerning health*:

> (...) all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services (...) information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for

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sobre a Responsabilidade Civil na Lei Geral de Proteção de Dados (Lei Nº 13.709/2018). *In:* ROSENVALD, Nelson; DRESCH, Rafael de Freitas Valle; WESENDONCK, Tula (Coord.). **Responsabilidade Civil**: Novos Riscos. Indaiatuba: Focus, 2019, P. 74 [Free translation from original].

> example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.[102]

Despite the apparent significance given to the need for consent for the processing of personal data (art. 7, I, of the LGPD, and art. 6, no. 1, a, of the GDPR), especially for the data considered sensitive (art. 11, I, of the LGPD, and art. 9, no. 1, of the GDPR), the LGPD and the GDPR establish the unnecessariness of consent for the processing of sensitive personal data in certain exceptional purposes.

The GDPR, in article 9, no. 2, provides that the processing of *special personal data* is only authorized when: a) the data subject has given explicit consent to the processing of those personal data; b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights in the field of employment and social security and social protection law; c) processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is incapable of giving consent; d) processing is carried out by a foundation, association or any other not-for-profit body on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects; e) situations in which the processing relates to personal data made public by the data subject; f) is necessary for the establishment, exercise or defense of legal claims or whenever courts are acting in their judicial capacity; g) for reasons of substantial public interest, namely in the field of public health; h) processing is necessary for the purposes of occupational medicine; i) is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices; j) is necessary for archiving purposes in the public interest, for scientific or historical research purposes or statistical purposes.

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102 General Data Protection Regulation (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). Available at: https://eur-lex.europa.eu/legal-content/PT/TXT/?uri=CELEX%3A32016R0679. Accessed: Dec. 03, 2022.

For the implementation of healthcare services, it is important to underline the provision in item "c", of article 9, no. 2, which addresses the situation where the processing of data relating to the health of a person is necessary to protect the vital interests of the data subject or of another natural person, in the event of the data subject being physically or legally incapable of giving consent; In addition to the provisions of the GDPR relating to the processing of personal data in *special categories*, it is also necessary to comply with the provisions of articles 29 to 31 of Law no. 58/2019 which ensures the implementation, in the national legal system of Portugal, of Regulation (EU) 2016/679. According to Portuguese law, in the processing of health data and genetic data, the principle of the need to know information (art. 29, no. 1) governs the access to personal data. Furthermore, the processing of these data must be carried out by a professional obliged to secrecy or by another person subject to a duty of confidentiality, and appropriate information security measures must be guaranteed (art. 29, no. 2).

Concerning the LGPD, the processing of *sensitive personal data* can only occur when the data subject or his or her legal guardian specifically and prominently consents, for specific purposes (art. 11, item I), or in the following cases provided for in item II of article 11: a) controller's compliance with a legal or regulatory obligation; b) shared processing of data when needed by the public administration for the execution of public policies provided for in laws or regulations; c) studies carried out by a research entity ensuring, whenever possible, the anonymization of sensitive personal data; d) the regular exercise of rights; e) protection of the life or physical safety of the data subject or a third party; f) the protection of health, in a procedure carried out by health professionals or by health entities; g) ensuring the prevention of fraud and the safety of the data subject, in processes of identification and authentication of registration in electronic systems.

For this reason, it seems possible to state that, according to the terms of the LGPD, the doctor of a patient with a suspected case of Covid-19 could invoke the legal basis of "protection of the life or physical safety of the data subject or a third party" (art. 11, II, "e", of the LGPD) to promote the insertion of a patient's health data - such as x-ray exams and computed tomography - on the aforementioned Brazilian platform RadVid-19 or on the Portuguese diagnostic system with the algorithm developed by INESC TEC - to assist in the diagnosis generated by artificial intelligence algorithms.

Additionally, it can also be observed that, according to the provisions of the LGPD, the consent of the patient would not even be necessary for the retention

of his data in the cognitive diagnostic technology of Covid-19, for the purpose of studies carried out by a research entity (art. 11, II, "c", and art.16, II) ensuring, as far as possible, the anonymization of personal data. Within the scope of the GDPR, as previously mentioned, there is a provision in article 9, no.2, "j", concerning the legal basis for the processing of sensitive data when necessary for the purposes of scientific investigation.[103] On the subject, Whereas clauses 33, 156 and 157 are also noteworthy:

> (33) 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 recognised ethical standards for scientific research (...)
>
> (156) The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. Those safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation. The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfill those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data). (...)
>
> (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. (...) 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 the Union or Member State law.

Regarding the possibility of data processing, it is important to cite the matter of anonymization foreseen in article 12 of the LGPD and accepted, concerning data related to health, under a pseudonymization measure (art. 13, § 4). Pseudonymization is defined in the Regulation in article 4, no. 5, of the GDPR as "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 organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person". According to Whereas clause 26 of the GDPR, the principles of data protection do not apply to anonymous information, that is, information that does not concern an identified or identifiable natural person.

As it is known, under the terms of article 12 of the LGPD, as a rule, "anonymized data shall not be considered personal data, for purposes of this Law (Free translation from original)", and, therefore, it is not affected by the LGPD's protective provisions. However, it is important to be cautions when considering this legal provision, as the reversal of the anonymization process results in the incurrence of LGPD and, although article 12, § 1, attempts to shed light on the topic, there are no absolutely clear parameters about the limits of data re-identification.[104]

Furthermore, it should be emphasized that exceptions to the need for consent in the discipline of both laws must be interpreted restrictively and with caution, in deference to the primary protection given by the constitutional axiological table to the dignity of the natural person and to their privacy, also in the wake of the established understanding according to which the waivers must be restrictively interpreted (art. 114 of the Brazilian Civil Code). It is also important to point out that despite the exceptional exemption from consent, the LGPD expressly establishes the need for the processing of personal data to be observed in good faith and according to the principle of transparency (art. 6, *caput* and item VI).[105]

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103 The legal basis of article 9, no. 2, "i", of the GDPR ("necessary to ensure high standards of quality and safety of health care and of medicinal products or medical devices") could be argued for the retention of data in Covid-19's cognitive diagnostic technology, considering that the pseudonymized data of the patients improve the diagnostic algorithm of Covid-19 and benefit those who use it.

104 As advised by MARTINS, Guilherme Magalhães; FALEIROS JÚNIOR, José Luiz de Moura. A anonimização de dados pessoais: consequências jurídicas do processo de reversão, a importância da entropia e sua tutela à luz da Lei Geral de Proteção de Dados. *In:* DE LUCCA, Newton; SIMÃO FILHO, Adalberto; LIMA, Cíntia Rosa Pereira de; MACIEL, Renata Mota (Coord.). **Direito & Internet IV**: sistema de proteção de dados pessoais. São Paulo: Quartier Latin, 2019, p. 77.

105 *In verbis*: "Art. 6 Activities of processing of personal data shall be done in good faith and be subject to the following principles: (...) transparency: guarantee to the data subjects of clear, precise and easily accessible information about the carrying out of the processing and the respective processing controllers, subject to commercial and industrial secrecy" [Free translation from original]. In the GDPR, Whereas clause 58 describes the principle

From the foregoing considerations on the processing of personal data concerning health in the LGPD and in the GDPR, it seems to be necessary to recognize the duty of the physician to pass on information to the patient about the processing of their data, regarding the purpose (e.g., insertion in Watson for Oncology), as well as the retention of their health data (anonymized) in the cognitive technology after the end of the original treatment. It is worth clarifying that this is a question of a standard conduct being imposed on the healthcare professional including (*rectius*: above all) in the exceptional cases of unnecessariness of consent. Given the significance of the matter, the concern with integrity or compliance regarding the protection of personal data in the medical field takes on a distinguished importance.[106] The GDPR combines *digital compliance* with routines that prioritize the protection of personal data (such as *privacy* by *design*).[107] Precisely in this manner, the LGPD articulates general provisions concerning good practices and governance (art. 50 and art. 51). With this, it is possible to discuss *digital compliance*, which is intended to allude to solid guidelines for the implementation of personal data protection policies, manifesting itself "in a series of duties related to the ethical conduct of the data processing controllers".[108] To exemplify, it is worth mentioning that

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of transparency in data processing: "the principle of transparency requires that any information addressed to the public or to the data subject be concise, easily accessible and easy to understand, and that clear and plain language and, additionally, where appropriate, visualisation be used. Such information could be provided in electronic form, for example, when addressed to the public, through a website. This is of particular relevance in situations where the proliferation of actors and the technological complexity of practice make it difficult for the data subject to know and understand whether, by whom and for what purpose personal data relating to him or her are being collected, such as in the case of online advertising. (...)"

106 For an analysis of the origin and of some of the main legal effects of *compliance* in Brazilian law, refer to OLIVA, Milena Donato; SILVA, Rodrigo da Guia. Notas sobre o *compliance* no direito brasileiro. **Quaestio Iuris**, vol. 11, n. 4, 2018, *passim*.

107 Regarding the expression *privacy by design*, Faleiros and Martins demonstrate: "it is in article 25 of the European GDPR and imposes the imperatives of protection of personal data and privacy on any action taken by a company that performs the processing of personal data, at all stages. This includes internal projects, product development, software development, IT systems and more. In practice, it means that the IT department, or any department that processes personal data, must ensure that privacy is incorporated into a system throughout the system lifecycle or process" (MARTINS, Guilherme Magalhães; FALEIROS JÚNIOR, José Luiz de Moura. Compliance digital e responsabilidade civil na Lei Geral de Proteção de Dados. *In*: MARTINS, Guilherme Magalhães; ROSENVALD, Nelson. **Responsabilidade civil e novas tecnologias**. Indaiatuba: Foco, 2020, p. 291 [Free translation from original]).

108 MARTINS, Guilherme Magalhães; FALEIROS JÚNIOR, José Luiz de Moura. Compliance digital e responsabilidade civil na Lei Geral de Proteção de Dados. *In*: MARTINS, Guilherme Magalhães; ROSENVALD, Nelson. **Responsabilidade civil e novas tecnologias**. Indaiatuba: Foco, 2020, p. 264 [Free translation from original].

IBM, developer of the cognitive technology platform *Watson for Oncology*, provides a document on "Data Security and Privacy Principles for IBM Cloud Services", in which the company specifies data security and privacy measures in cloud services, policies and procedures designed to manage risks associated with applying changes to its cloud services.[109]

Data governance is also provided for in the European Commission's "Ethics Guidelines for Trustworthy AI", being considered a requirement directly linked to the principle of damage prevention and the fundamental right to privacy.[110] This is because, throughout the lifecycle of a system with artificial intelligence algorithms - such as *Watson for Oncology* –, data security protocols must be adopted, indicating information such as the means of the processing of user data, the people who will have access to them and the specific circumstances in which these access may occur.

4. Conclusion

In this century, the Digital Age and the new technologies completely transformed the possibilities of a better and more accurate diagnosis, as this research tried to point out. The *digitization* process allowed patients' physical data to be transferred from paper folders to electronic health records. As a result, after decades of digitizing medical records (with growing cloud storage), the healthcare sector has created a huge (and continuously growing) set of data. This digitization in the healthcare sector was a decisive first step into the implementation of artificial intelligence in the rationalization of workflows in hospitals, in the efficiency of medical diagnosis and, above all, in the early detection of diseases.

The digital revolution promoted by the spread of artificial intelligence and the phenomenon of big data has prompted profound transformations of the most diverse orders in the field of healthcare. In the current scenario, it was precisely the digitized data of the thousands of patients diagnosed with Covid-19 that allowed for the creation of an algorithm capable of identifying the disease from the analysis of thoracic tomography of new patients. Artificial intelligence systems in the diagnostic analysis of Covid-19 provides, as previously mentioned, are

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109 Data Security and Privacy Principles for IBM Cloud Services Available at: https://www-03.ibm.com/software/sla/sladb.nsf/pdf/KUP12494/$file/KUP12494BRPT.pdf. Accessed: June 23, 2022.

110 EUROPEAN COMMISSION. **Ethics Guidelines for Trustworthy AI, of 11 of August of 2019**.

an important support for clinical decision, owing to their ability to quickly and efficiently process and analyze a large amount of data. Therefore, this opens the possibility for a fast diagnosis of a disease with exponential growth of infected people and that has an extremely rapid evolution.

Nevertheless, celebrating the benefits of artificial intelligence in supporting the diagnosis of Covid-19 should not overshadow the attention to the risks underlying the implementation of this technology into medical practice. As remarkable as artificial intelligence is in the analysis of numbers and data processing, its natural fallibility cannot be ignored, since there is a significant degree of algorithmic inaccuracy, in addition to the possibility of unpredictable results due to the self-learning potential of these intelligent algorithms.

In essence, this is the fundamental purpose that is expected to have been accomplished with the present study, which sought not only to identify the possible risks associated with the digital revolution in the healthcare sector, but also to formulate some possible hermeneutical guidelines to assist the interpreter-enforcer of the law in the arduous task of ensuring the protection of the rights of the natural person in the face of new technologies, without inhibiting their continuous development. Ultimately, the critical investigations developed herein aspired to contribute to the pressing renewal of discussions concerning the legal impacts of the implementation of new technologies (in particular, artificial intelligence and processing of *big data*) into medicine and health care, a topic whose significance is daily corroborated by the difficulty of combating the Covid-19 pandemic in the Luso-Brazilian context.

5. References

BALICER, Ran D.; COHEN-STAVI, Chandra. Advancing Healthcare Through Data-Driven Medicine and Artificial Intelligence. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence.** Cham: Springer, 2020, p. 9-15.

BARROSO, Luis Roberto; MARTEL, Letícia de Campos Velho. A morte como ela é: dignidade e autonomia individual no final da vida. *In*: GOZZO, Débora; LIGIERA, Wilson Ricardo. (Orgs.). **Bioética e Direitos Fundamentais.** São Paulo: Saraiva, 2012.

BIONI, Bruno Ricardo. **Proteção de dados pessoais**: a função e os limites do consentimento. Rio de Janeiro: Forense, 2020.

BODDINGTON, Paula. **Towards a Code of Ethics for Artificial Intelligence.** Cham: Springer, 2017.

CARMO, Diedre et. al. Rapidly deploying a COVID-19 decision support system in one of the largest Brazilian hospitals. **Health Informatics Journal**, v. 27, issue 3, set. 2021, p. 1-17.

CERKA, Paulius; GRIGIEN, Jurgita; SIRBIKYT, Gintar. Liability for damages caused by artificial intelligence. **Computer Law & Security Review,** v. 31, n. 3, jun. 2015, p. 376-389.

CHAARI, Lotfi (ed.). **Digital Health Approach for Predictive, Preventive, Personalised and Participatory Medicine**. Cham: Springer, 2019.

DALLARI, Dalmo de Abreu. O habeas data no sistema jurídico brasileiro. **Revista Da Faculdade De Direito**, Universidade de São Paulo, São Paulo, n. 97, p. 239-253.

DANIEL, Christel; SALAMANCA, Elisa. Hospital Databases. AP-HP Clinical Data Warehouse. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence.** Cham: Springer, 2020, p. 57-67.

DEGOS, Laurent. International Vision of Big Data. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). Healthcare and Artificial Intelligence. Cham: Springer, 2020, p. 241-254

DONEDA, Danilo. **Da Privacidade à Proteção de Dados Pessoais:** elementos da formação da Lei Geral de Proteção de Dados Pessoais. 2. ed. São Paulo: Revista dos Tribunais, 2019.

DRESCH, Rafael de Freitas Valle; FALEIROS JÚNIOR, José Luiz de Moura. Reflexões sobre a Responsabilidade Civil na Lei Geral de Proteção de Dados (Lei Nº 13.709/2018). *In*: ROSENVALD, Nelson; DRESCH, Rafael de Freitas Valle; WESENDONCK, Tula (Coord.). **Responsabilidade Civil:** Novos Riscos. Indaiatuba: Foco, 2019, p. 65-89.

FALEIROS JUNIOR, José Luiz de Moura. NOGAROLI, Rafaella. CAVET, Caroline Amadori. Telemedicina e proteção de dados: reflexões sobre a pandemia da Covid-19 e os impactos jurídicos da tecnologia aplicada à saúde. **Revista dos Tribunais,** São Paulo, v. 1016, jun. 2020.

FLASIŃSKI, Mariusz. **Introduction to Artificial Intelligence.** Cham: Springer, 2016.

FORD, Roger Allan; PRICE, W. Nicholson. Privacy and Accountability in Black-Box Medicine, **Michigan Telecommunications & Technology Law Review,** v. 23, 2016, p. 1-43

GARCIA, Christine; UZBELGER, Georges. Artificial Intelligence to Help the Practitioner Choose the Right Treatment: Watson for Oncology. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence.** Cham: Springer, 2020, p. 81-84.

GOMES, Rodrigo Dias de Pinho. Big Data: desafios à tutela da pessoa humana na sociedade da informação. Rio de Janeiro: Lumen Juris, 2017.

GRALL, Matthieu. CNIL (Commission Nationale de l'Informatique et des Libertés) and Analysis of Big Data Projects in the Health Sector. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence.** Cham: Springer, 2020, p. 235-240.

HOLZINGER, Andreas; RÖCKER, Carsten; ZIEFLE, Martina. From Smart Health to Smart Hospitals. *In*: **Smart Health:** Open Problems and Future Challenges. Cham: Springer, 2015, p. 1-20

KFOURI NETO, Miguel. **Responsabilidade civil do médico.** 10. ed. São Paulo: Revista dos Tribunais, 2019.

HOUSEH, Mowafa; KUSHNIRUK, Andre W.; BORYCKI, Elizabeth M. (ed.). **Big Data, Big Challenges:** A Healthcare Perspective Background, Issues, Solutions and Research Directions. Cham: Springer, 2019.

KFOURI NETO, Miguel; NOGAROLI, Rafaella. Responsabilidade civil pelo inadimplemento do dever de informação na cirurgia robótica e telecirurgia: uma abordagem de direito comparado (estados unidos, união europeia e brasil). In: ROSENVALD, Nelson; MENEZES, Joyceane Berreza de.; DADALTO, Luciana. (Coord.) **Responsabilidade Civil e Medicina.** Indaiatuba: Foco, 2020, p. 159-186.

LEE, Kai-Fu. **AI Superpowers:** China, Silicon Valley, and the New World Order. Boston : Houghton Mifflin Harcourt, 2018.

MARTINS, Guilherme Magalhães; FALEIROS JÚNIOR, José Luiz de Moura. A anonimização de dados pessoais: consequências jurídicas do processo de reversão, a importância da entropia e sua tutela à luz da Lei Geral de Proteção

de Dados. *In*: DE LUCCA, Newton; SIMÃO FILHO, Adalberto; LIMA, Cíntia Rosa Pereira de; MACIEL, Renata Mota (Coord.). **Direito & Internet IV:** sistema de proteção de dados pessoais. São Paulo: Quartier Latin, 2019, p. 77.

MARTINS, Guilherme Magalhães; FALEIROS JÚNIOR, José Luiz de Moura. Compliance digital e responsabilidade civil na Lei Geral de Proteção de Dados. *In*: MARTINS, Guilherme Magalhães; ROSENVALD, Nelson (Coord.). **Responsabilidade civil e novas tecnologias.** Indaiatuba: Foco, 2020, p. 263-297.

MATTHIAS, Andreas. The responsibility gap: ascribing responsibility for the actions of learning automata. **Ethics and Information Technology,** v. 6, issue 3, set. 2004, p. 175-183.

MITTELSTADT, Brent Daniel; ALLO, Patrick; TADDEO, Mariarosaria; WACHTER, Sandra; FLORIDI, Luciano. The ethics of algorithms: mapping the debate. **Big Data & Society,** jul. 2016. p. 1-21

MULHOLLAND, Caitlin; FRAJHOF, Isabella Z. Inteligência Artificial e a Lei Geral de Proteção de Dados Pessoais: breves anotações sobre o direito à explicação perante a tomada de decisões por meio de machine learning. *In*: MULHOLLAND, Caitlin; FRAZÃO, Ana. **Inteligência artificial e direito**. São Paulo: Revista dos Tribunais, 2019, p. 265-290.

NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). **Healthcare and Artificial Intelligence.** Cham: Springer, 2020.

OLIVA, Milena Donato; SILVA, Rodrigo da Guia. Notas sobre o *compliance* no direito brasileiro. **Quaestio Iuris**, vol. 11, n. 4, 2018, p. 2708-2729.

PASQUALE, Frank. **The black box society:** the secret algorithms that control money and information. Cambridge: Harvard University Press, 2015.

PASQUALE, Frank. Toward a Fourth Law of Robotics: Preserving Attribution, Responsibility, and Explainability in an Algorithmic Society. **University of Maryland Francis King Carey School of Law Legal Studies Research Paper,** n. 2017-21. Disponível em https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3002546. Aceso em 02 jun. 2020.

PEREIRA, André Gonçalo Dias. **O consentimento informado na relação médico-paciente.** Estudo de Direito Civil. Coimbra: Coimbra Editora, 2004.

PRICE, William Nicholson. Artificial Intelligence in Health Care: Applications and Legal Issues. **University of Michigan Public Law Research Paper,** n. 599, 2017. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3078704. Accessed: Dec. 26, 2022.

RIBEIRO, José Medeiros. **Saúde Digital:** um sistema de saúde para o século XXI. Lisboa: Fundação Francisco Manuel dos Santos, 2019.

RODOTÀ, Stefano. **A vida na sociedade da vigilância:** a privacidade hoje. Org. Maria Celina Bodin de Moraes. Trad. Danilo Doneda e Luciana Cabral Doneda. Rio de Janeiro: Renovar, 2008.

RODOTÀ, Stefano. Por que é necessária uma Carta de Direitos da Internet? **Civilistica.com,** Rio de Janeiro, ano 4, n. 2, 2015. Disponível em: http://civilistica.com/por-que-e-necessaria-uma-carta-de-direitos-da-internet/. Acessed: Dec. 26, 2022.

RUS, Daniela. Artificial Intelligence: A Vector for Positive Change in Medicine. *In*: NORDLINGER, Bernard; VILLANI, Cédric; RUS, Daniela (Coord.). Healthcare and Artificial Intelligence. Cham: Springer, 2020, p. 17-22.

SCHAEFER, Fernanda; GONDIM, Glenda Gonçalves. Telemedicina e lei geral de proteção de dados. *In*: ROSENVALD, Nelson; MENEZES, Joyceane Berreza de; DADALTO, Luciana (coord.). **Responsabilidade Civil e Medicina.** Indaiatuba: Foco, 2020, p. 187-202.

SCHULMAN, Gabriel. Tecnologias de telemedicina, responsabilidade civil e dados sensíveis. o *princípio ativo* da proteção de dados pessoais do paciente e os efeitos colaterais do coronavírus. *In*: MONTEIRO FILHO, Carlos Edson do Rego; ROSENVALD, Nelson; DENSA, Roberta. **Coronavírus e Responsabilidade Civil.** Indaiatuba: Foco, 2020, p. 344-357.

SHABAN-NEJAD, Arash; MICHALOWSKI, Martin. **Precision Health and Medicine.** A Digital Revolution in Healthcare. Cham: Springer, 2020.

SILVA, Rodrigo da Guia; NOGAROLI, Rafaella. Inteligência artificial na análise diagnóstica da COVID-19: possíveis repercussões sobre a responsabilidade civil do médico. *In*: ROSENVALD, Nelson; MONTEIRO FILHO, Carlos Edison do Rêgo; DENSA, Roberta (Coord.). **Coronavírus e responsabilidade civil:** impactos contratuais e extracontratuais. Indaiatuba: Foco, 2020, p. 293-300.

SILVA, Rodrigo da Guia; TEPEDINO, Gustavo. Dever de informar e ônus de se informar: a boa-fé objetiva como via de mão dupla. *In*: **Migalhas**, 09/06/2020. Available at: https://www.migalhas.com.br/depeso/328590/dever-de-informar-e-onus-de-se-informar-a-boa-fe-objetiva-como-via-de-mao. Acessed: Dec. 26, 2022.

SHAW, Rajib; KIMB, Yong-kyun; HUAA, Jinling. Governance, technology and citizen behavior in pandemic: Lessons from COVID-19 in East Asia. **Progress in Disaster Science,** v. 6, abr. 2020, p. 1-11.

SOARES, Flaviana Rampazzo. Veículos autônomos e responsabilidade por acidentes: trajetos possíveis e desejáveis no direito civil brasileiro. *In*: ROSENVALD, Nelson; DRESH, Rafael de Freitas Valle. WESENDONCK, Tula (Coord.). **Responsabilidade civil:** novos riscos. Indaiatuba: Foco, 2019, p. 149-176.

SOUZA, Eduardo Nunes de; SILVA, Rodrigo da Guia. Tutela da pessoa humana na Lei Geral de Proteção de Dados Pessoais: entre a atribuição de direitos e a enunciação de remédios. **Pensar**, vol. 24, n. 3, jul.-set./2019.

TAMÒ-LARRIEUX, Aurelia. **Designing for Privacy and its Legal Framework.** Data Protection by Design and Default for the Internet of Things. Cham: Springer, 2018.

TAULLI, Ton. **Artificial Intelligence Basics.** Nova Iorque: Springer, 2019.

TEFFÉ, Chiara Spadaccini de; MEDON, Filipe. Responsabilidade civil e regulação de novas tecnologias: questões acerca da utilização de inteligência artificial na tomada de decisões empresariais. **Revista Estudos Institucionais,** v. 6, n. 1, jan./abr. 2020, p. 301-333.

TEGMARK, Max. Life 3.0: Being human in the age of artificial intelligence. New York: Alfred A. Knopf, 2017.

TOPOL, Eric. **Deep medicine:** how artificial intelligence can make healthcare human again. Nova Iorque: Basic Books, 2019.

TOPOL, Eric. **The creative destruction of medicine:** how the digital revolution will create better heath care. Nova Iorque: Basic Book, 2012.

TOPOL, Eric. **The patient will see you now:** the future of medicine is in your hands. Nova Iorque: Basic Book, 2015.

TURNER, Jacob. **Robot Rules:** Regulating Artificial Intelligence. Cham: Palgrave Macmillan, 2019.

VOIGT, Paul; BUSSCHE, Axel von dem. **The EU General Data Protection Regulation (GDPR).** A Practical Guide. Cham: Springer, 2017.

WISCHMEYER, Thomas. Artificial Intelligence and Transparency: Opening the Black Box. In: WISCHMEYER, Thomas; RADEMACHER, Timo. (Coord.) **Regulating Artificial Intelligence.** Cham: Springer, 2020, p. 75-101.

WISCHMEYER, Thomas; RADEMACHER, Timo. (Coord.) **Regulating Artificial Intelligence.** Cham: Springer, 2020.

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INFORMED CONSENT, DATA PROTECTION, AND TECHNOLOGICAL CHANGE IN EUROPE

Rui Cascão[1]

Abstract: This article explores the relationship between informed consent for medical treatment (or for medical research) and the role of consent as a lawful basis for processing data concerning health (or genetic data). It explores the challenges posed by the ongoing technological change taking place in the provision of healthcare in Europe and identifies the solutions, including legislative measures at a European Union level, aiming at addressing those challenges.

Keywords: Informed Consent; Data Protection; Big Data; Electronic Health Records, Artificial Intelligence; Patient Rights; EU Law; Health Literacy; GDPR; Secondary use of Data

1. Introduction

Informed consent is a key concept in contemporary medical law. It is a projection of patients' autonomy and their fundamental right to self-determination. It also plays a decisive role in the dynamics of the relationship between the patient and the healthcare professional(s) in the context of medical treatment, as well as a decisive role in regulatory compliance in the context of medical experimentation in human beings.

The medicine sector is becoming increasingly dependent on advanced technology and more and more (big) data hungry: e.g., electronic health records (EHR), ePrescription, healthcare data sharing, telehealth, cloud computing, distributed healthcare and mHealth (the application of the internet of things to medical devices). Also, artificial intelligence (hereinafter abbreviated as AI) and machine learning (hereinafter abbreviated as ML) technologies are

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being gradually deployed in healthcare facilities: robot-assisted surgery; interpretative AI/ML (e.g., in the field of medical imaging), and also "affective" AI, directly providing care to patients[2].

Technological change in the field of healthcare translates to a considerable benefit to society and to patients, expanding the range and efficacy of medical treatment, as well as unprecedented tools for medical research, as the response to the COVID-19 demonstrates[3].

However, it is evident that technological change will bring forth significant ethical implications, as well as shifts in medical practice, medical research, and how the law deals with it. It will affect the rights of patients (autonomy, privacy, safety), the responsibilities of healthcare professionals, providers and researchers, the patient-healthcare professional relationship, and society at large (inequality in access to high-tech healthcare (the "digital divide", bias and discrimination risks, cybersecurity risks, commodification of personal data, etc.)[4].

The doctrine of informed consent has evolved significantly since its inception and needs to further adapt to technological change. This article will examine the evolution of informed consent for medical treatment and medical research in Europe, its relationship with consent as a lawful basis for processing personal data under the European Union (hereinafter abbreviated as EU) General Data Protection Regulation (hereinafter abbreviated as GDPR[5]), as

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2 Yu, KH, Beam, AL & Kohane, IS. Artificial intelligence in healthcare. Nat Biomed Eng 2, 719–731 (2018). doi: 10.1038/s41551-018-0305-z; Simshaw D, Terry N, Hauser K, & Cummings ML, Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks, 22 Rich. J.L. & Tech 3 (2016); De Togni G, Erikainen S, Chan S, Cunningham-Burley S. What makes AI 'intelligent' and 'caring'? Exploring affect and relationality across three sites of intelligence and care. Social Science & Medicine, Volume 277 (2021) 113874. doi:10.1016/j.socscimed.2021.113874.

3 Pham QV, Nguyen DC, Huynh-The T, Hwang WJ, Pathirana PN. Artificial Intelligence (AI) and Big Data for Coronavirus (COVID-19) Pandemic: A Survey on the State-of-the-Arts. IEEE Access. 2020 Jul 15;8:130820-130839. doi: 10.1109/ACCESS.2020.3009328; Haleem, A., Javaid, M., Khan, I.H. et al. Significant Applications of Big Data in COVID-19 Pandemic. JOIO 54, 526–528 (2020). doi: 10.1007/s43465-020-00129-z.

4 Mittelstadt B, The Impact of Artificial Intelligence on the Doctor-Patient Relationship (2021). Council of Europe, Strasbourg.

5 Regulation (EU) 2016/679 of the European Parliament and 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) (Text with EEA relevance).

well as the challenges presented by AI/ML and other information technologies to informed consent, and how to deal with those changes.

This article focuses on European law, in particular EU Law (while attempting to make the subject accessible to readers from other geographic regions), with the ancillary contributions of comparative law and bioethics. It has some limitations: on the one hand, the input of comparative law does not intend to be exhaustive but rather illustrative; on the other hand, important aspects of the doctrine of informed consent, data protection, and AI/ML regulation are not thoroughly and systematically covered. This was a deliberate decision, considering that those issues are already exhaustively covered by authoritative works, and also considering the length constraints.

2. Informed Consent in Medical Treatment and Medical Research

The principle of patient autonomy became notorious in 1914, with the eloquent statement by Justice Benjamin Cardozo in his court opinion in the *Schloendorff* case: "*every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages*"[6].

Developing from this principle, the doctrine of informed consent takes momentum after the 1940's: it is affirmed by the French Cour de Cassation in 1942 (*arrêt Teyssier*[7]), in Canada in 1949[8] , and in the US in 1957[9]. As backlash

6 *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (New York Court of Appeals). Ultimately, the court did not hold the hospital liable for damages under the principle of charitable immunity.

7 de Cassation, 28 janvier 1942 quelques remarques sur une décision "oubliée". Histoire des Sciences Médicales, Tome XXXV, N°3, 2001, p. 299-304: "*Confirming the judgement of the Appeals Court of Bordeaux in 1937, the judgement of the supreme Court in the Case of Teyssier confirmed the duty of the doctor to inform the patient in order to obtain his informed consent. Such information was considered as necessary to respect the person and the rights of the patient*".

8 *Murray v McMurchy* [1949] 2 DLR 442

9 *Salgo v Leland Stanford, Jr University Board of Trustees*, 154 Cal App 2d 560, 317 P2d 170 (1957). On the historical development of the doctrine of informed consent: Bazzano LA, Durant J, Brantley PR. A Modern History of Informed Consent and the Role of Key Information. Ochsner J. 2021 Spring, 21(1):81-85. doi:10.31486/toj.19.0105; Beauchamp, T. L. Cambridge Quarterly of Healthcare Ethics, Volume 20, Issue 4, October 2011, pp. 515 – 523; doi:10.1017/S0963180111000259; Manson NC, O'Neill O (2007). Rethinking informed consent in bioethics. Cambridge University Press, Cambridge; Dias Pereira, A

from the atrocities perpetrated during WW2, in particular the grim medical experiments carried out by Nazi physicians and scientists on people interned in concentration camps, the "Nuremberg Code" set down the core principles of medical research and consent was enshrined as an essential element in medical treatment and research: "*The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision*"[10].

The centrality of informed consent in the context of medical research on human beings was reaffirmed in the 1964 World Medical Association (WMA)'s Declaration of Helsinki[11].

Currently, informed consent is solidly consolidated in the law and in medical practice standards in Europe. It is enshrined in Chapter II of the Council of Europe's 1997 Convention on Human Rights and Biomedicine (hereinafter abbreviated as the "Oviedo Convention")[12], whose article 5 (general rule) reads: "*An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time*."

Whereas the provisions of the Oviedo Convention cannot be directly invoked before the European Court of Human Rights[13], the case law of the Strasbourg

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(2004). O Consentimento Informado na Relação Médico-Paciente: Estudo de Direito Civil. Coimbra Editora, Coimbra.

10 *United States of America v. Karl Brandt et al*., Nov. 21, 1946 - Aug. 20, 1947; Shuster, E. Fifty Years Later: The Significance of the Nuremberg Code. N Engl J Med 1997; 337:1436-1440. doi: 10.1056/NEJM199711133372006.

11 WMA Declaration of Helsinki- Ethical Principles for medical research involving human subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, §25-32

12 European Treaty Series - No. 164, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997.

13 Though the ECHR often refers to a Council of Europe Convention in order to ascertain whether or not there is a consensus between contracting states on a certain matter: ECHR *Demir and Baykara v Turkey* No 34503/97. 12/11/2008); Abdelgawad EL. European Court

court has consistently applied the doctrine of informed consent in its decisions, considering that lack thereof is tantamount to a breach of articles 3 (prohibition of torture) and 8 (right to respect for private and family life)[14].

As regards EU Law, Article 3 of the Charter of Fundamental Rights of the European Union enshrines the right to the integrity of the person, providing that "everyone has the right to respect for his or her physical and mental integrity"[15]. More specifically, in the field of medicine and biology, section 2 (a) of this article provides that the free and informed consent of the person concerned must be obtained, according to the procedures laid down by law. Furthermore, there is provision in secondary EU law on informed consent in the context of medical research on human beings, such as the Clinical Trials Regulation (hereinafter abbreviated as CTR)[16].

With a view to giving the patient a free choice regarding treatment, the treatment provider is under a duty to disclose, in a clear and understandable way, all the information regarding his health condition, the nature of the proposed treatment, its potential advantages, risks, alternatives, and the prognosis. As a

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of Human Rights in Schmahl S, Breuer M. The Council of Europe: Its Law and Policies (2017). Oxford University Press, Oxford. doi: 10.1093/law/9780199672523.001.0001. As regards direct domestic application of the Convention, it appears not to be self-executing, considering that article 1 provides that "*each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention*": Crawford J. Brownlie's Principles of Public International Law (8th ed.: 2012). Oxford University Press, Oxford; Taupitz J. (ed.). Das Menschenrechtsübereinkommen zur Biomedizin des Europarates — taugliches Vorbild für eine weltweit geltende Regelung? (2013). Springer Berlin, Heidelberg. doi: 10.1007/978-3-642-59424-3.

14 ECHR *V.C.* v. *Slovakia*, no. 18968/07 (non-consented sterilisation of a patient of Roma ethnic origin); ECHR *Y.F. v. Turkey, no. 24209/94* (forced gynaecological exam of wife); Buelens W, Herijgers C, Illegems S. The View of the European Court of Human Rights on Competent Patients' Right of Informed Consent. Research in the Light of Articles 3 and 8 of the European Convention on Human Rights. Eur J Health Law. 2016 Dec;23(5):481-509. doi: 10.1163/15718093-12341388.

15 The Charter of Fundamental Rights of the European Union is directly applicable to EU institutions and member states and the fundamental rights vested by the European Convention of Human Rights are recognised as general principles of Union Law, resulting from the constitutional traditions common to the Member States (article 6 Treaty on the European Union).

16 Regulation (EU) Nº 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance).

rule, without duly obtaining the patient's free and informed consent (express or implied), medical treatment may not be carried out[17].

In the context of medical treatment, as well as medical research on human subjects, informed consent fulfills several functions: i) it facilitates the transfer of information between the patient and the healthcare professional; ii) it builds and reinforces trust between these two parties; iii) it has a symbolical value to patients as a token of their autonomy and agency[18]; iv) a compliance function, operating as a waiver, rendering the physical invasion related to medical treatment/research lawful[19]; non-compliance can be, under certain circumstance, grounds for liability for medical malpractice, for instance by shifting the burden of proof of negligence to the healthcare provider[20].

While it is tempting to healthcare providers and research promotors to attempt to achieve compliance with merely having the patient/research subject signing a standardized form with precise and complex technical jargon, genuine informed consent must be "meaningful", in the sense that it must fulfil the

17 Council of Europe, European Treaty Series - No. 164, Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997; Von Bar, C, Clive E. Principles, Definitions and Model Rules of European Private Law: Draft Common Frame of Reference (DCFR) (2010). Oxford University Press, Oxford, § IV.C. - 8:104-8:108; Barendrecht M, Jansen, C, Loos, M, Pinna, A, Cascão, R and Van Gulijk, S Principles of European Law: Service Contracts (2007). Oxford University Press, Oxford.

18 Walker T. Value of choice Journal of Medical Ethics 2022;48:61-64. doi: 10.1136/medethics-2020-106067

19 Manson/O'Neill (2007), *op.cit*.; Laurie, G, Harmon, S, Dove, E Mason and McCall Smith's Law and Medical Ethics (11th edn: 2019). Oxford University Press, Oxford; Andreotta AJ, Kirkham, N. & Rizzi, M. AI, big data, and the future of consent. AI & Soc 37, 1715–1728 (2022). doi: 10.1007/s00146-021-01262-5; Pickering B. Trust, but Verify: Informed Consent, AI Technologies, and Public Health Emergencies. Future Internet. 2021; 13(5):132. doi: 10.3390/fi13050132.

20 E.g in France (*Arrêt Hédreul*, Cass.1 civ, 25/02/1997, 94-19.685); Germany (BGB §630h Beweislast bei Haftung für Behandlungs- und Aufklärungsfehler). While comparative law suggests that this is a trend, some authors view this approach with scepticism. It is "*a false alibi to compensate a medical adverse event*", according to Lambert-Faivre, Y. Droit du dommage corporel: Systèmes d'indemnisation (5 ed.: 2004). Dalloz, Paris. Hellner, J. "Sweden" in Medical Responsability in Western Europe (1985). Springer Verlag, Berlin, Heidelberg, New York, Tokyo, states that "*it is very rare that a patient brings forth a claim for breach of the duty to inform if everything goes well*".

following requirements: i) information disclosure; ii) comprehension; iii) aptitude; and iv) voluntariness[21].

The information that must be provided to patients (procedures, risks, alternatives, prognosis, etc.) is complex by its very nature and the task of reducing technical complexity in terms that can be understood by a layman (plain language) is a significant challenge[22]. Nevertheless, "*This information must be sufficiently clear and suitably worded for the person who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks (…)*"[23]. For instance, under article 29 (2) (b) CTR, the information provided must "*be kept comprehensive, concise, clear, relevant, and understandable to a layperson*". Studies suggest that participants in clinical trials in developed countries frequently do not understand the information provided[24] and that misunderstandings are even more frequent amongst patients in developing countries[25].

In addition, factors such as age, disease severity, cognitive impairment, anxiety, health literacy, poverty- or exposure to misinformation or disinformation[26]- can significantly decrease the aptitude of patients or clinical trial participants to have a genuine chance to give consent[27]. Likewise, these factors, together with concerns regarding access to healthcare (e.g. medical insurance/social

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21 Kadam RA. Informed consent process: A step further towards making it meaningful! Perspect Clin Res. 2017 Jul-Sep;8(3):107-112. doi: 10.4103/picr.PICR_147_16. PMID: 28828304

22 Jefford M, Moore R. Improvement of informed consent and the quality of consent documents. Lancet Oncol. 2008 May; 9(5):485-93. doi: 10.1016/S1470-2045(08)70128-1.

23 Council of Europe, European Treaty Series - No. 164, Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997, §35.

24 Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. Lancet. 2001 Nov 24;358(9295):1772-7. doi: 10.1016/S0140-6736(01)06805-2.

25 Kadam (2017), *op.cit*.; Fitzgerald DW, Marotte C, Verdier RI, Johnson WD Jr, Pape JW. Comprehension during informed consent in a less-developed country. Lancet. 2002 Oct 26;360(9342):1301-2. doi: 10.1016/S0140-6736(02)11338-9.

26 For instance, misinformation and disinformation are significant root causes of denial and vaccine hesitancy in the context of the ongoing COVID-19 pandemic: Lee, SK, Sun, J, Jang, S. Misinformation of COVID-19 vaccines and vaccine hesitancy. Sci Rep 12, 13681 (2022). doi: 10.1038/s41598-022-17430-6.

27 Kadam (2017), *op.cit*.

insurance coverage), cultural aspects (in particular in more paternalistic societies), power imbalances (between the patient and the healthcare provider/clinical trial promotor), emotional factors and other sources of cognitive bias might taint the voluntariness of consent[28].

Technological change brings novel challenges to informed consent: to comprehend the information received, besides health literacy, patients will also need technological literacy. As increasingly more sophisticated smart medical devices are being deployed, the more difficult it will be to provide understandable information to patients.

This is a particularly significant challenge as regards the use of AI/ML in healthcare: it might be problematic to explain to a patient how the algorithm functions and to explain the output of AI/ML. On the one hand, there might be unwillingness by the AI/ML developer to be transparent in order to protect intellectual property rights. On the other hand, transparency might be impossible because ML/deep learning algorithms can be so complex, that not even its developers can understand their inner workings, much less provide a meaningful explanation (the "black-box algorithm" problem)[29].

In this respect, "*ethical standards need to be developed around transparency, bias, confidentiality, and clinical efficacy to protect patient interests in informed consent, equality, privacy, and safety. Such standards could serve as the basis for deployments of Al in healthcare that help rather than hinder the trusting relationship between doctors and patients*"[30]. The EU Proposal on the Artificial Intelligence Act Regulation includes provisions on algorithm transparency in high risk AI systems (article 13). Also, in all AI systems intended to interact with natural persons, providers shall ensure that they are designed and developed in such a way that natural persons are informed

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28 Kadam (2017), *op.cit*; Pickering (2021), *op.cit*.; Dantas, E. Droit Médical au Brésil: Essais et Réflexions sous la Perspective du Droit Comparé (2013). GZ Editora, Rio de Janeiro; Manson/O'Neill (2007), *op.cit*; Jefford/Moore (2008), *op.cit*.

29 Yu, KH., Beam, AL & Kohane, I.S. Artificial intelligence in healthcare (2018), *op.cit*.; De Togni G, Erikainen S, Chan S, Cunningham-Burley S. (2021), *op.cit*.; Andreotta, AJ., Kirkham, N & Rizzi, M. AI, big data, and the future of consent (2022). *op.cit*.; Ebers M. Regulating AI and Robotics. Ethical and Legal Changes in Ebers M, Navas S. Algorithms and Law (2020). Cambridge University Press, Cambridge; Lacruz Mantecón ML, Inteligencia Artificial: Daño y Prejuicio. Jurismat, Revista Jurídica, Número 15, 2022.

30 Mittelstadt B, The Impact of Artificial Intelligence on the Doctor-Patient Relationship (2021), *op.cit*.

that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use (article 52)[31].

3. Informed Consent in Data Protection

In Europe, personal data must be "*processed lawfully and shall be proportionate in relation to the legitimate purpose pursued and reflect at all stages of the processing a fair balance between all interests concerned, whether public or private, and the rights and freedoms at stake*" (article 5 Convention 108+)[32]. In EU Law, the fundamental right to data protection is enshrined in article 8 of the Charter of Fundamental Rights of the European Union. Section 2 of this article provides that "*such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law*".

According to article 6 of the GDPR[33], the basis for lawful processing of personal data are: consent of the data subject (article 6 (1) (a) GDPR); contract and precontractual relationship (article 6 (1) (b) GDPR); compliance with a legal obligation to which the controller is subject (article 6 (1) (c) GDPR); protection of the vital interests of the data subject or of another natural person (article 6 (1) (d) GDPR); performance of a task carried out in the public interest or in the exercise of official authority vested in the controller (article 6 (1) (e) GDPR); and legitimate interest pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child (article 6 (1) (f) GDPR)[34].

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31 Regulation of the European Parliament and the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts, 2021/0106 (COD)

32 Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108), modernized version (Adopted by the Committee of Ministers at its 128th Session of the Committee of Ministers (Elsinore, 18 May 2018)..

33 According to article 288 of the Treaty on the Functioning of the European Union (TFEU), "*a regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States*".

34 For a thorough analysis of this article: Kotschy W in Kuner, C, Bygrave LA, Docksey C, Drechsler L (eds), The EU General Data Protection Regulation (GDPR): A Commentary (2020); Oxford University Press, Oxford, doi:10.1093/oso/9780198826491.001.0001.

It must be highlighted that consent is the only lawful basis for processing personal data that is expressly mentioned in article 8 of the Charter of Fundamental Rights of the European Union, which appears to attribute to it a certain reinforced constitutional value over the other basis for processing. This is criticised by specialized literature, considering that, in practice, consent is viewed as a last resort to be relied on only and insofar as other lawful basis for processing are not feasible (consent requirements are demanding, it must be thoroughly documented and can be withdrawn at any time: article 7 (3) GDPR). Also, it is sometimes regarded as a legal fiction that translates a symbolical sense of control by the data subject, is prone to power imbalances; frequently data subjects give consent without reading the privacy policy or understanding the consequences of consenting or not (a phenomenon known as "consent fatigue")[35].

Data concerning the health of natural person, as well as genetic data, are considered special categories of data under article 9 GDPR. According to article 4 (15) GDPR, "'*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*". Such data is highly sensitive and its processing is likely to pose a significant risk to the fundamental rights and freedoms of the data subjects. According to Bygrave/Tosoni, "*Data concerning the health of natural persons ('health data') have traditionally been re- garded as sensitive. This is reflected in long-standing rules to protect the confidentiality of the medical records that doctors keep on their patients- rules that predate the emergence of modern data protection laws. The sensitivity of health data is tied to a commonly held perception that they reveal some of the most intimate and private aspects of ourselves- not least our core vulnerabilities- and to a concomitant fear that if the data are widely disclosed, they may lead to stigma and unfair discrimination. In a more utilitarian perspective, there is also concern that people will not seek health care, communicate candidly with health care providers, or willingly participate in health research projects, for fear of data disclosure*"[36].

Besides specific consent by the data subject, other appropriate lawful basis that a controller can rely on to process health and genetic data are: vital interests of the data subject or of another natural person where the data subject

35 Menezes Cordeiro AB, Comentário ao Regulamento Geral de Proteção de Dados e à Lei n.º 58/2019 (2022). Almedina, Coimbra.

36 Bygrave LA, Tosoni L in Kotschy W in Kuner, C, Bygrave LA, Docksey C, Drechsler L (eds) (2020), *op.cit*.

is physically or legally unable of giving consent (article 9 (2) (c) GDPR); substantial public interest (article 9 (2) (g) GDPR); 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 (article 9 (2) (h) GDPR); public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices (article 9 (2) (i) GDPR); archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (article 9 (2) (j) GDPR, in accordance with Article 89(1) GDPR).

As such, consent by the data subject to processing "*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) GDPR)[37].

The controller bears the burden of proof of consent: article 7 (1) GDPR. Consent can be given by oral or written statement, including by electronic means[38], however a written form or electronic consent protocol is highly advisable. Consent must be freely given (voluntariness): the data subject must have a genuinely free choice and must be able to refuse or withdraw consent without detriment. As such, consent cannot serve as a lawful basis for processing when there's a clear imbalance between the data subject and the controller (e.g. if the controller is a public authority) or if consent is a condition for the performance of a contract ("*Einwilligung gegen Leistung*"): article 7 (4)

37 Article 29 Data Protection Working Party. Guidelines on consent under Regulation 2016/679. Adopted on 28/11/2017, as last Revised and Adopted on 10/04/2018.

38 Recital 32 GDPR: *"Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject's consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided"*.

GDPR[39]. Consent must also be specific and informed: the data subject must be made aware of the identity of the controller and all the purposes of the processing; if the processing has multiple purposes, consent must be obtained for all of them and separate consent is necessary for different processing operations[40]. Furthermore, considering the stricter requirements of article 9 (2) (a) GDPR for the processing of special categories of data, consent must also be explicit, i.e., explicitly refer to the special categories of personal data concerned by the intended processing[41].

Finally, another issue concerns the secondary use of data (re-purposing) on health and genetic data. Article 5 (1) (b) enshrines the principle of purpose limitation: "*personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes"*, however, it can be further processed "*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"* (presumption of compatibility)[42]. This

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39 Buchner, B. Die Einwilligung im Datenschutzrecht. DuD 34, 39 (2010). doi:10.1007/s11623-010-0010-x; Recital 43 GDPR; European Data Protection Board (EDPB). Guidelines 05/2020 on Consent under Regulation 2016/679 Version 1.1, Adopted on 4 May 2020

40 Recital 42 GDPR: *"Where processing is based on the data subject's consent, the controller should be able to demonstrate that the data subject has given consent to the processing operation. In particular in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware of the fact that and the extent to which consent is given. In accordance with Council Directive 93/13/EEC (10) a declaration of consent pre-formulated by the controller should be provided in an intelligible and easily accessible form, using clear and plain language and it should not contain unfair terms. For consent to be informed, the data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended. Consent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment"*.

41 Voigt P, von dem Bussche, A, The EU General Data Protection Regulation (GDPR) A Practical Guide, (2017) Springer, Berlin.

42 Article 89 (1) GDPR: "*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*"; Recitals 50, 159 GDPR.

places controllers under a dilemma, especially controllers of biobanks[43]: either they seek the consent of data subjects for each new research project resorting to their health/genetic data, or they will have to rely on appropriate safeguards for the rights and freedoms of data subjects, such as pseudonymisation (article 4 (5) GDPR), anonymisation, data minimisation (article 5 (1) (c) GDPR), and data security[44].

Novel technology being deployed in healthcare also affects data protection, such as mHealth[45] and, in particular AI/ML. The "black-box algorithm" problem is also very relevant as regards data protection, as it can have a bearing on the validity of consent (it must be specific and informed), it can prevent the controller from discharging his obligation to provide an explanation to data subjects on how their information is being used (article 15 GDPR)[46].

4. The Relationship between Informed Consent for Medical Treatment or Research and Consent as a Lawful Base for Processing Data Concerning Health

What is then the relationship between informed consent by the patient for the purpose of medical treatment (or medical research, under Chapter V CTR Regulation) and consent as a lawful basis for processing health data? We have seen that there are many similarities between the two as regards its requirements (informed, meaningful, voluntary, unambiguous) and that they serve similar functions (ethics, autonomy and free agency, regulatory

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43 Annaratone L, De Palma G, Bonizzi G, Sapino A, Botti G, Berrino E, Mannelli C, Arcella P, Di Martino S, Steffan A, Daidone MG, Canzonieri V, Parodi B, Paradiso AV, Barberis M, Marchiò C; Alleanza Contro il Cancro (ACC) Pathology and Biobanking Working Group. Basic principles of biobanking: from biological samples to precision medicine for patients. Virchows Arch. 2021 Aug;479(2):233-246. doi: 10.1007/s00428-021-03151-0: "*Biobanks are large collections of human biological materials linked to relevant personal and health information, which may include health records, family history, lifestyle and genetic information that are held predominantly for use in health and medical research*".

44 Article 29 Data Protection Working Party. Guidelines on consent. *op.cit*.; Communication from the Commission to the European Parliament and the Council. Guidance on the Regulation on a framework for the free flow of non-personal data in the European Union COM(2019) 250 final; Teare HJA, Prictor M, Kaye J. Reflections on dynamic consent in biomedical research: the story so far. Eur J Hum Genet 29, 649–656 (2021). doi:10.1038/s41431-020-00771-z.

45 EDPS Opinion 1/2015 Mobile Health Reconciling technological innovation with data protection; Article 29 WP Opinion 2/2013 of 27.2.2013 on apps on smart devices (WP 202);

46 Andreotta AJ, Kirkham N, Rizzi M. AI, big data, and the future of consent (2022). *op.cit*.

compliance, communication and transfer of information, trust). Is it a single complex consent for different purposes, or are we facing overlapping different consents for different purposes?

The answer to the first question is negative: it follows from article 7 (2) GDPR that consent of the data holder to processing of personal data is autonomous: the request for consent must be clearly distinguishable from any other matters, in an intelligible and easily accessible form, using clear and plain language. Consent is specific and granular, i.e., separate consent is necessary for each purpose If this provision is breached, consent is not binding[47]. As such, we can safely reach the conclusion that we have different consents, of a different nature, which follow a different regulatory framework and serve diverse functions, albeit some similarities in their scope, objectives and *raison d'être:* informed consent for medical treatment or research must therefore not be confused with the notion of consent as a legal ground for the processing of personal data under the GDPR[48].

Furthermore, according to the Article 29 Data Protection Working Part Guidelines on consent, "*when consent is the legal basis for conducting research in accordance with the GDPR, this consent for the use of personal data should be distinguished from other consent requirements that serve as an ethical standard or procedural obligation. An example of such a procedural obligation, where the processing is based not on consent but on another legal basis, is to be found in the Clinical Trials Regulation. In the context of data protection law, the latter form of consent could be considered as an additional safeguard. At the same time, the GDPR does not restrict the application of Article 6 to consent alone, with regard to processing data for research purposes. As long as appropriate safeguards are in place, such as the requirements under Article 89(1), and the processing is fair, lawful, transparent and accords with data minimisation standards and individual rights, other lawful bases such as Article 6(1)(e) or (f) may be available. This also applies to special categories of data pursuant to the derogation of Article 9(2)(j)*"[49].

This means that there is no absolute necessity to rely on consent as a lawful basis to process health data or genetic data related to medical treatment or medical research on grounds that these depend on previous informed consent

47 Recital 32 GDPR; Article 29 Data Protection Working Party. Guidelines on consent. *op.cit.*

48 EDPB. Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR). §15.

49 Recital 33 GDPR; Article 29 Data Protection Working Party. Guidelines on consent. *op.cit.*

given by the patient: there is no linkage between the two[50]. The healthcare provider or the research sponsor/promotor can, as a controller, choose to rely on consent, but is not legally obliged to do it; if it relies on consent as legal basis for processing and consent is withdrawn, all data processing operations that were based on consent remain lawful in accordance with Article 7(3) GDPR. In this case, the controller shall halt processing and, if it is not possible to rely on a different lawful basis for the retention of data for subsequent processing, the data must be deleted by the controller: Article 17 (1) (b) and (3) GDPR[51]. In fact, under certain circumstances, relying on consent might not even be advisable: consent could be deemed not to have been freely given by a participant belonging to an economically or socially disadvantaged group in a clinical trial, if there would be a clear situation of imbalance between the sponsor/researcher and that participant, even though of all conditions of Chapter V CTR Regulation were fulfilled[52].

For instance, a hospital could rely on article 9 (2) (h) or 9 (2) (i) as legal basis to process patient data related to the provision of medical treatment, while a clinical trial might rely on article 9 (2) (j) for processing data for a clinical trial (and secondary use under article 5 (1) (b) GDPR). They would still need to obtain the patient's informed consent for medical treatment or participation in medical research according to the applicable national law or Chapter V CRT Regulation.

However, considering the regulatory risks arising from the technical limitations and feasibility of appropriate safeguards required under Article 89(1) GDPR, and taking into that the domestic privacy law of member states can provide for more stringent conditions for processing health data and genetic data (article 9 (4) GDPR), it might be worth privileging, to a certain degree, the consent of data subjects as a lawful basis for processing[53]. This has

50 EDPB. Opinion 3/2019. *op.cit*. §15 ff.

51 EDPB. Opinion 3/2019. *op.cit*. §23 ff.

52 EDPB. Opinion 3/2019. *op.cit*. §16 ff.: "Provisions of Chapter V CTR on informed consent, in particular Article 28, respond primarily to core ethical requirements of research projects involving humans deriving from the Helsinki Declaration. The obligation to obtain the informed consent of participants in a clinical trial is primarily a measure to ensure the protection of the right to human dignity and the right to integrity of individuals under Article 1 and 3 of the Charter of Fundamental Rights of the EU; it is not conceived as an instrument for data protection compliance."; Gefenas E, Lekstutiene J, Lukaseviciene V, Hartlev M, Mourby M, Cathaoir KO. Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road. Med Health Care Philos. 2022 Mar; 25(1):23-30. doi: 10.1007/s11019-021-10060-1.

53 Consent is not privileged in Belgium, Bulgaria, Croatia, Cyprus, Czechia, Finland,

the merits of demonstrating due respect for the autonomy of the data subjects and "*establishing a communicative bond between the controller and the data subject, whereby both can inform the other of their interests, rights, and duties*"[54]. This poses a significant technological challenge when processing activities are carried out in a large scale involving large datasets from a large amount of data subjects (e.g. biobanks).

One possibility to achieve this, in particular in the context of medical research and biobanks, is resorting to "Dynamic Consent (DC)", a solution presented by modern eHealth information technology. It consists of a personalised communication interface that enables more participation in decision making by data subjects in clinical and research activities, giving interactive, personalised, granular, tailored, control to data subjects. This would allow data subjects to give and withdraw consent to the use of their heath data and modify their privacy preferences in real time. DC has the potential to enable better communication and trust, provide a high level of regulatory compliance, improve health literacy, and improve transparency and risk management[55].

In this context, the EU Proposal for a Regulation on the European Health Data Space (hereinafter abbreviated as EHDS)[56] has the aim of improving "*access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation,*

Hungary, Latvia, Lithuania, Luxemburg, Poland, Portugal, Romania, Slovakia, Slovenia and Sweden; moderately privileged in Liechtenstein, Italy, Germany, Greece, Netherlands; strongly privileged in Iceland, France, Norway, Malta, Denmark, Estonia, Ireland and Austria; and required in principle in Spain: Chen J, Dove ES, Bhakuni H. Explicit Consent and Alternative Data Protection Processing Grounds for Health Research in Kosta E, Leenes R, and Kamara I. Research Handbook on EU Data Protection Law (2022). Research Handbooks in European Law series. Elgar. Cheltenham, Northampton.

54 Dove, Edward & Chen, Jiahong. (2020). Should consent for data processing be privileged in health research? A comparative legal analysis. International Data Privacy Law. doi:10.117-131.10.1093/idpl/ipz023.

55 Stoeklé HC, Deleuze, JF, Vogt, G, Hervé C. Med Sci (Paris) Volume 33, Number 2, 02/2017. doi:10.1051/medsci/20173302015; Kaye J, Whitley E, Lund D. et al. Dynamic consent: a patient interface for twenty-first century research networks. Eur J Hum Genet 23, 141–146 (2015). doi: 10.1038/ejhg.2014.71; Teare HJA, Prictor M, Kaye J. Reflections on dynamic consent in biomedical research: the story so far. Eur J Hum Genet 29, 649–656 (2021). doi:10.1038/s41431-020-00771-z.

56 Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (Text with EEA relevance). {SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} - {SWD(2022) 132 final}.

policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data)"[57]. According to the European Commission, "*The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support to their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high risk AI systems (primary use of data) and providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data)*"[58].

The EHDS Regulation proposal envisages the patients' seamless access to their electronic health records (ECR), their portability and interoperability, to facilitate free movement, as well as control over their data. On the other hand, the secondary use of data for research and personalised medicine is facilitated, thus removing the regulatory risks previously mentioned, bringing forth legal certainty, and encouraging scientific development. It is a balancing act between the interests of the different stakeholders and the fundamental rights of the data subjects[59].

5. Conclusion

Informed consent to medical treatment or experimentation is a core principle of bioethics and is deeply rooted in the law in Europe: at national level, at EU level, as well as in the treaty law, secondary law, as well as the standard setting activity of regional international organisations, such as the Council of Europe. It is anchored to the principle of the autonomy of patients and aims at protecting their human dignity with regard to the application of biology and medicine, in the wording of the Oviedo Convention.

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57 Recital 1 EHDS Regulation Proposal.

58 URL: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

59 Horgan D, Hajduch M, Vrana M, Soderberg J, Hughes N, Omar MI, Lal JA, Kozaric M, Cascini F, Thaler V, Solà-Morales O, Romão M, Destrebecq F, Sky Gross E. European Health Data Space-An Opportunity Now to Grasp the Future of Data-Driven Healthcare. Healthcare (Basel). 2022 Aug 26;10(9):1629. doi: 10.3390/healthcare10091629.

On the other hand, we have seen that consent is a possible (and maybe ideal), albeit not necessary, lawful basis for processing data on health or genetic data, which are special categories of data, due to their sensitivity, and worthy of additional safeguards to the rights and interests of data holders. In this context, the fundamental right to data protection is balanced out against other interests, such as public interest or the legitimate interest of the controller or a third party- in particular as regards public health and medical research interests.

While often these two forms of consent appear to overlap, and some of their requirements and aims appear to coincide, there is no linkage between them: they are two different categories of consent, following different legal frameworks and methodology.

Novel challenges to informed consent and data protection caused by technological change- EHR, mHealth, big data, mass misinformation and disinformation propagated in social media- and in particular AI/ML can be adequately addressed by technological implementations (such as dynamic consent), as well as by legislative intervention (such as the EU Proposal on the Artificial Intelligence Act or the EU Proposal on the European Health Data Space).

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BLOOD TRANSFUSION

LEGAL ASPECTS[1]

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Abstract: As the object of a right protected by the Brazilian Constitution, life has a boarder meaning the merely biological, including inviolability of freedom of conscience and belief, as also as rights of person, and mainly, the right to physical integrity and freedom of will. What if there is, during the performance of a medical-hospital procedure, invocation, on the part of the patient's family, of excuse of conscience, founded - as it happens more frequently - on religious reasons, to prevent blood transfusion that would be essential to the maintenance of the patient's life? Is the doctor forbidden to perform the medical procedure without the consent of the patient or his legal guardian, even in imminent danger of life? The issue is not new, at least for jurisprudence; nevertheless, we have always had to face it cautiously, due, in most cases, to the absence of specific legal regulation on the subject and, moreover, in view of the very peculiarity of the issue. Starting from this theme-problem, the article aims to treat

1 Article developed from an exposition given by the author in a roundtable on the theme "Blood transfusion: ethical, religious and legal aspects", promoted by the Events Commission of the Nursing Division - UNESP, Botucatu campus, and ABEN, on October 18th, 1999.

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the hypotheses of medical conduct, introducing at the end a proposal for a solution.

Keywords: Rights to Life, to Physical Integrity and Freedom of Will; Refusal of Blood Transfusion; Jehovah's Witness Patient; Medical Law; Medical Ethics

I.1.

Life, as the object of a right protected by the Constitution of the Republic, has a broader meaning than the merely biological. As JOSÉ AFONSO DA SILVA[4] warns, "it is yet another process (vital process) that is established with conception (or plant germination), transforms, progresses, maintaining its identity, until it changes its quality, then ceasing to be life for be death". Everything that interferes to the detriment of this spontaneous and incessant flow is contrary to life.

The right to life, protected by the 1988 constituent legislator, as the right to existence, consists, according to the same author, of the "right to be alive, to fight for life, to defend one's own life, to remain alive. It is the right not to have interrupted the vital process except by natural and inevitable death".

The right to life, as explained CRETELLA JÚNIOR, is "the right to remain alive, although one is healthy (...), linked to the physical safety of the natural person, regarding human agents or not, which could threaten his or her

4 *Curso de Direito Constitucional Positivo*. São Paulo: Revista dos Tribunais. 6th edition, 1990, pages 176/177.

existence"[5]. That is why "in the first place, it is necessary to ensure everyone the right to simply remain alive, to remain in existence until the interruption of life due to natural causes"[6].

As such, it is ensured to every individual (being endowed with life) by art. 5, *caput*, of the Constitution of the Republic, when dealing with individual rights and guarantees, as being the most basic, the primary source of all other legal interests.

It is known that "the protection that is given to life, freedom, security, and property is extended to all those who are subject to the Brazilian legal system. It is unthinkable that a person could be injured in one of these protected legal interests without Brazilian laws giving him or her the due protection"[7].

Needless to say, that the right to life, guaranteed by the Political Charter of 1988, brings with it the right to physical integrity. As JOSÉ AFONSO DA SILVA teaches, "the content of its concept involves the right to human dignity (...), the right to privacy (...), the right to physical and bodily integrity, the right to moral integrity and, especially, the right to existence"[8].

2.

Brazilian criminal legislation punishes all forms of violation of the physical integrity of the individual because our Constitution guarantees the right to life. The *ratio* is extracted from the scholium of PAULO BONAVIDES: "fundamental rights, strictly speaking, are not interpreted, they are implemented"[9].

FRANCISCO DE ASSIS TOLEDO[10] teaches the characteristic of the criminal legal system that first strikes the eye, "is its preventive purpose: before punishing, or with punishing, it intends to avoid crime. Thus, through the elaboration of criminal types (models of human behaviour) the criminal law legislator reveals, in a clear and visible way, to those who are subject to the laws of the Country, what they are vigorously forbidden to do or not to do

5 *Comentários à Constituição* de 1988. Rio de Janeiro: Forense Universitária. 3rd edition, 1997, I/183.
6 TAVARES, Andre Ramos. *Curso de Direito Constitucional*. São Paulo: Saraiva. 2002, page 387.
7 BASTOS, Celso Ribeiro, et al. *Comentários a Constituição do Brasil*. São Paulo: Saraiva. 2nd edition, 2001, 2/4-5.
8 Comentário Contextual à Constituição. São Paulo: Malheiros. 3rd edition, 2007, page 66.
9 Curso de Direito Constitucional. São Paulo: Malheiros. 13th edition, 2003, page 592.
10 Princípios Básicos de Direito Penal. São Paulo: Saraiva. 4th edition, 1991, page 03 et seq..

(...).Through the imposition of penalties, for behaviour typified as a criminal offence, the lawmaker aims to achieve the feeling of fear (intimidation) or the ethical feeling of people, so that the prohibited conduct is avoided (general prevention). Failing this threat, or this appeal, the abstractly imposed sentence, with the criminal sentence, becomes a concrete reality, and starts, in the execution phase, to act on the person of the convict, giving rise to its possible amendment or effective neutralization (special prevention)".

Among all the types of penalties provided for in the law for the protection of physical integrity, we are mainly interested, for the purposes for which these lines are proposed, the offenses of bodily injury and illegal embarrassment.

"The crime of bodily injury", teaches NELSON HUNGRIA[11], "consists of any damage caused by someone, without *animus necandi*, to the physical integrity or health (physiological or mental) of another. It is not, as the *nomen juris* might suggest *prima facie*, just the harm inflicted on the anatomical whole of the person. *Bodily injury* comprises any offense caused to the functional normality of the human body or organism, whether from an anatomical point of view, whether from a physiological or psychological viewpoint. (...) Either as a change in physical integrity, or as a disturbance of the organism's functional balance (health), bodily injury always results from *violence* against the person".

As for the crime of illegal embarrassment, which translates into *constraining someone, through violence or serious threat, or after having reduced, by any other means, the ability to resist, not to do what the law allows, or to do what it does not command* (Criminal Code, art. 146, *caput*), teaches the same HUNGRIA, "the basic crime against personal freedom. It is the impediment of *freedom of action or inaction*, ranging from free self-determination for one's own reasons (autonomy of the intimate formation of the will, psychic or internal freedom) to bodily movement in the external world or abstention from movement (free will or physical freedom)"[12].

II.

Blood transfusion, among us, has not received greater attention from the lawmaker. However, it is a constitutional command (Federal Constitution, art.

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11 *Comentários ao Código Penal*. Rio de Janeiro: Forense. 4th edition, 1958, V/323-4.

12 *Op. cit*. 4th edition, 1958, VI/149.

199, § 4) to draft a law that will provide, among other topics, *on the collection, processing and transfusion of blood and its derivatives, with all types of commercialization prohibited*.

The theme also deserved attention on the part of the Brazilian constituent, as can be seen from art. 225, and paragraphs of the São Paulo State Constitution of October 5, 1989.

At the infra-constitutional level, Law No. 7649, of January 25, 1988, provided for the mandatory registration of blood donors, which law was regulated by Decree nº 95721 of February 11, 1988. This law, prior to the Constitution of 1988, was approved by it and was in force until the enactment of Law n. 10205 of March 21, 2001, originated from Bill nº 1064/91 authored by Congressman Roberto Jefferson (PTB-RJ), which came to regulate § 4 of art. 199, of the Federal Constitution, regarding the collection, processing, storage, distribution and application of blood, its components, and derivatives, as well as establishing the institutional order essential to the proper execution of these activities.

III.

1.

The 1988 constituent legislator provided, on the other hand, for the inviolability of freedom of conscience and belief (Federal Constitution, art. 5º, VI) and, as its consequence, for the possibility of invoking religious belief or philosophical or political conviction to exempt a person of a legal obligation imposed on all persons, so that he or she may thereby refuse to perform an alternative provision established by law (Federal Constitution, art. 5, VIII).

There is, then, an apparent conflict with the fundamental guarantee of the right to life, provided for in art. 5, *caput,* of the *Federal Constitution*, when it comes to medical intervention (blood transfusion) to which the patient and family are opposed, under the invocation of excuse of conscience.

In the specific case of Jehovah's Witnesses, people have clear objections to blood transfusions, for religious and medical reasons. By invoking biblical verses, by which they guide their beliefs, such as prohibiting the transfusion of whole blood, red blood cells and plasma, as well as leukocyte and platelet concentrates, they refuse to undergo transfusion treatment – but not so, at least in an absolute way, the use of other components, such as albumin,

immunoglobulins and haemophiliac preparations, about which it is up to each person to decide, individually, whether or not to accept them.

In the hermeneutics of the abovementioned constitutional provisions, therefore, the exegete must weigh the conflicting legal interests, in order to harmonize the apparently contradictory provisions and give the hypothesis the most accurate solution.

As CLÈMERSON MERLIN CLÈVE and ALEXANDRE REIS SIQUEIRA FREIRE teach, "the principle of proportionality plays a key role in contemporary Constitutional Theory. It is of necessary application in the hypothesis of collision and restriction of fundamental rights. There is no doctrinal consensus around a conceptual delimitation. The reasons vary between the intrinsic complexity of the nature of the principle and terminological oscillations and conceptual inaccuracies. The principle of proportionality comprises, as the best doctrine warns, the partial principles of *adequacy*, *necessity*, and *proportionality in the strict sense*. The *principle of adequacy* determines, as far as is factually possible, the means chosen to achieve the established end, showing itself to be apt and appropriate. The means chosen must be required for the specific case, and it is not possible to choose another means of equal effectiveness. The *principle of proportionality in the strict sense* requires a legally adequate correspondence between the end to be achieved by a normative provision and the means chosen. (...) The *principle of proportionality in the strict sense* expresses the balance resulting from the confrontation between advantages and disadvantages caused by the restrictive measure of a fundamental right, necessary for the protection of another fundamental right or constitutionally protected good. (...) The principle of proportionality in the strict sense requires a weighing of the fundamental rights or goods of a constitutional nature that are at stake, according to the weight attributed to them. According to Karl Larenz, 'weighing' and 'pondering' only imply images, that is, they are not equivalent to quantitatively measurable quantities, resulting only from valuations that should not only be oriented to a general agenda but, in the same way, to concrete problematizing situations. In this way, the weighting of goods must be carried out in the concrete case through a problem to be solved. Therefore, it is based on the principle of proportionality that the 'weighing' of fundamental rights as well as of legal assets when they are in a state of contradiction, offering the concrete case an adjusting solution for the coordination and combination of the assets in collision"[13].

13 *Et al*. *Estudos de Direito Constitucional em homenagem a José Afonso da Silva*. São Paulo: Malheiros. 2003, pages 238-9.

2.

The so-called rights of the person constitute a very special category of rights, essential and inherent to the human species, indispensable to members of a society that intends to live with dignity, tranquillity, and social peace.
Of a constitutional nature, the matter did deserve a greater regulation by the lawmaker in the Civil Code of 2002 (arts. 11, *et seq*.). Although part of the doctrine sees in the French Revolution a first systematization of the idea, on the occasion of the proclamation of the rights of man in 1789, it seems more accurate that since Roman Law, there was already news of the *actio injuriarum*, intended to compensate for injuries to honour and privacy.

Developed with greater intensity in the 20th century, rights of the person concern life, health, physical integrity, autonomy of will, honour, image, and privacy of the person.

The denomination, derived from the German doctrine of the second half of the 19th century, was chosen to distinguish it from other recurrent designations (human rights, fundamental rights, public freedoms, civil rights, personal rights, etc.); human rights and rights of the person are distinguished by patrimonial antagonism – non-patrimonial, and by the division of law into public (aiming to establish limits to the State's action in relation to the individual) and private (aiming to establish limits to the actions of individuals in relation to the individual). They are powers that one exercises over his own person (*jus in se ipsum)* and that are opposable *erga omnes*, distinguished by the characteristics of being absolute (implying a generic obligation of abstention to all other individuals), of generality (because they belong to any and all people), of extra-patrimoniality (*rex extra commercium*, not susceptible of composing the factual support of legal transactions), of non-transferability (because they are strictly personal), of unavailability (because they grant prerogatives limited to the subject himself, being therefore inalienable), of irrevocability (which the holder may even not actively enjoy, but never abdicate), of imprescriptibility (because they do not lose or expire), of inexpropriability (because, making up the fundamentals and ethical foundations of the Democratic State of Law, they cannot be suppressed in their essence, although they admit regulation in their secondary aspects, the establishment of limits and conditions for their exercise and protection), and of unlimitedness (given the possibility of recognizing an unlimited number of rights of the person, according to the needs and convenience imposed by the degree of development and improvement of culture and Law).

Of particular interest to this work are the rights to physical integrity and freedom of will. The first is gender, of which the right to one's own body is a species, an extension of the constitutional principle that imposes respect for the dignity of the human being.

The right to physical integrity, derived from the right to life, deserved attention – albeit timid – from the lawmaker in art. 13 of the current Civil Code. They make up the concept of physical integrity *lato sensu*, according to the doctrine, in addition to anatomical intangibility, also the right to physical safety in the face of contagions by infectious diseases transmitted through negligence, or by poisoning, or even, through damage to psychomotricity or to the functioning of limbs, organs and body parts. Parts of the body that, because they are regenerable, do not cause a permanent reduction in physical integrity (hair, nails, skin, blood, liver), which is why they can, in theory, be removed from the body with authorization from the holder.

The right to one's own body should not be protected as a social demand for order and security, but as an instrument for the realization of the person. Its protection is not superior to the protection of other manifestations of the person, which may justify, in the specific case, the permanent reduction of physical integrity, such as the freedom of belief, freedom of expression or social solidarity, as is the case in the area of organ transplantation[14].

2.1.

The need for dialogue between doctor and patient is old, and the matter has been addressed in different ways over time.

The evolutionary environment came from the Renaissance, with the emergence of university courses in Medicine and the influence of the Arabs, especially from the 7th century, and particularly from the Enlightenment, with the creation of medical specialties, technical studies, and scientific discoveries[15].

The doctor-patient relationship, however, was still marked by paternalism: for most doctors in the 1800s, the patient should not be informed if he suffered from a serious illness – and the first reference to the patient's right to information,

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14 SCHREIBER, Anderson. *Direito Civil e Constituição*. 1st edition, São Paulo: Atlas, 2013, page 35.

15 SOARES, Flaviana Rampazzo. *Consentimento do paciente no Direito Médico – validade, interpretação e responsabilidade*. Indaiatuba: Foco Jurídico. 1st edition, 2021, page 10.

provided that absolutely necessary, has only appeared in 1847, with the Code of Medical Deontology of the World Medical Association.

According to the thinking at that time, the information should come from the patient, not in a dialectical-cooperative way, but as an integral part of the treatment process, in order to carry out a more accurate diagnosis and to better manage the case[16].

The change in thinking would only come from the 19th century, with the development of scientific knowledge about human physiology and anatomy, consolidating itself with the evolution in the area of ethics and, above all, with the emancipation of Bioethics as an autonomous discipline and of the very Law, especially Constitutional Law, with the paternalistic or Hippocratic paradigm being overcome by that of autonomy[17].

The patient's will, expressed through consent, gained prominence in Common Law countries, leading to the recognition, in the North American courts, of the need for *informed consent* (an expression coined from a ruling by the Court of California, in the case in which a patient was operated on without being informed of the risks of the surgery, in 1957), despite the lack of a consolidated doctrine regarding medical interventions in humans – at least, until the middle of the 20th century.

This scenario changed with World War II, when cruel experiments were carried out by the Germans on human beings (Jews, Gypsies, Russians, and Poles), bringing to light the questioning on the possibility of carrying out procedures unrelated to consent.

The doctrine records as a milestone the conviction of twenty-three doctors for crimes against humanity, genocide, and biomedical experiments in 1946, in the case *United States* vs. *Karl Brandt*, by the Nuremberg Military Tribunal, whose judges established 10 principles of obligatory observance in experiments on human beings – which became, in 1947[18] or 1948[19], a part of the Nuremberg

16 SOARES, Flaviana Rampazzo. *Op. cit.*, page 10.

17 SOUZA, Valdinar Monteiro de *Direito de recusa do paciente à transfusão de sangue e a outros procedimentos médicos*. Rio de Janeiro: Gramma. 1st edition, 2018, page 26.

18 CABRAL, Hildeliza Lacerda Tinoco Boechat. *Consentimento informado no exercício da Medicina e tutela dos direitos existenciais – uma visão interdisciplinar Direito e Medicina*. 2nd edition, Curitiba: Appris, 2018, page 55.

19 KFOURI NETO, Miguel. *Op. cit.*, page 262.

Code, the first text to proclaim the rights of patients. It can be said, therefore, that voluntary consent was a result of the objectionable conduct that gave rise to the Nuremberg Trial[20].

In Brazilian law, the patient's autonomy of will stems primarily from the constitutional principle of human dignity (Federal Constitution, art. 1, III), established as the foundation of the Federative Republic of Brazil itself, and the right to health (Federal Constitution, art. 196), while the Civil Code ensures the protection of rights of the person, which are non-transferable, non-waivable and cannot be voluntarily limited (art. 11), prohibiting the practice of an act of disposing of one's own body, except for medical requirements (art. 13), such as for the purposes of transplantation (art. 13, sole paragraph), safeguarding the right not to be compelled to submit, at risk to life, to medical treatment or surgical intervention (art. 15), whereas the Consumer Defence Code guarantees the right to information (art. 6, III) and Law n. 13709/2008 requires specific consent for the processing of sensitive personal data, except for compliance with a legal or regulatory obligation (art. 11), which includes health-related data (art. 5); in the field of bioethics, the Code of Medical Ethics expressly forbids the doctor to fail to obtain the consent of the patient or his legal representative after clarifying him about the procedure to be performed, except in cases of imminent risk of death (art. 22), or failing to guarantee the patient the exercise of the right to decide freely about his or her person or well-being, as well as exercising his or her authority to limit it (art. 24). Federal Medical Council (CFM) Opinion-Consultation no. 10/96 decided that "the physician must explain to the patient about diagnostic and therapeutic practices, as prescribed by the Code of Medical Ethics, not being considered mandatory the setting of a written term"[21], consent may be registered in the medical record; only a simple, objective, approximate and honest explanation is required (principle of adequate information).

The need for the patient's prior consent to carry out any and all medical acts is justified by the right that each individual has to protect his or her integrity and self-determination (principle of autonomy), stating that consent does not create obligations in the face of what is serious or harmful to health (principle of beneficence). All and any significant changes in the therapeutic or propaedeutic course demand continued consent (principle of temporality).

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20 CABRAL, Hildeliza Lacerda Tinoco Boechat. *Op. cit*., page 55.

21 FRANÇA, Genival Veloso de *Comentários ao Código de Ética Médica*. 7th edition, Rio de Janeiro: Guanabara Koogan, 2019, page 114.

The patient's manifestation of will must be free (without coercion or external influences) and conscious (matured from the information provided).

Although the existence of a written consent term signed by the patient can serve as proof *juris tantum* of compliance with the informative-decision-making process, if it contains the affirmation of receipt of information, the verbal form of manifestation is more usual. For probative purposes, however, the physician may use other means than necessarily the written term, *v. g*., audio, or video recordings.

Federal Medical Council (CFM) Recommendation no. 01/2016 contains a recommendation for the use of a written term in medical procedures involving further or greater complexity, such as invasive exams, surgeries, or transplants (item "9") and that, in case of a simple verbal consent, it must be registered in the medical record.

Informed consent presupposes ability, information, and consent, free and informed[22].

Consent must be prior, free, and clear, preceded by complete information provided in understandable language, allowing the exercise of autonomy (a bioethical principle that represents people's freedom in self-determination and in the choice of interventions that may be carried out in their own body) in a proper way.

In terms of bio-law, it is exercised through the Free and Informed Consent Term (TCLE), which is applicable to research involving human beings (Resolution no. 466/12 and 510/16 of the National Health Council - CNS) and, as far as this work is concerned, in the doctor-patient relationship (Federal Medical Council (CFM) Recommendation no. 01/16). Consent is an essential requirement to legitimize the action of a third party on the person and, in the doctor-patient relationship, the Free and Informed Consent Term (TCLE) is the instrument for externalizing the acts and wills of the parties that unite in favour of an object (the medical practice), and is recognized by the doctrine not only as an instrument to guarantee the patient's autonomy, but as a limiting element of the physician's civil liability, when the procedure for obtaining free and informed

22 ROBERTO, Luciana Mendes Pereira. *Responsabilidade civil do profissional de saúde & Consentimento informado*. 2nd edition, Curitiba: Juruá, 2010, page 167.

consent is carried out in an adequate manner, even if one of the predicted negative consequences occurs, especially considering iatrogenesis[23].

For example, discussing the legal liability of parents who, as Jehovah's Witnesses, did not consent to their minor daughter, suffering from a serious illness (sickle cell anemia), receiving a blood transfusion (right to conscientious objection), and the doctor, also a Jehovah's Witness, who recommended that the parents not carry out the blood transfusion, in which the failure to carry out the medical intervention resulted in the patient's death, the Superior Court of Justice recognized the atypical conduct of the victim's legal guardians[24].

2.2.

It is recognized, as seen, the physician's duty to inform.

In the precedent *Natanson v. Kline* (1960), it was decided that the disclosure of information should be in simple language regarding the nature of the disease, the proposed treatment, the possibility of success or the therapeutic alternatives available, the risks of adverse results, and the unexpected conditions[25].

Indeed, for the patient to be able to make an informed choice, he or she must go through an adequate information process, integrated by the physician's corresponding duty to inform.

This duty has its genesis in the principle of objective good faith, informing contractual relations in general, and in particular, the doctor-patient relationship.

The doctrine mentions that the informative-decision-making process consists of two phases, the first being the clarification for the exercise of self-determination, and the second, the therapeutic clarification to those who chose to decide[26], being excepted the right of the patient to refuse to receive information (*v.g.*, Spanish Law n. 41/2002, art. 4, "1").

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23 SÁ, Maria de Fátima Freire de, SOUZA, Iara Antunes de, *Op. cit.*, page 71.

24 BOARO, Guilherme, SOUZA, Paulo Vinicius Sporleder de, *A negativa de transfusão de sangue por testemunhas de Jeová: uma análise jurídico-penal da objeção de consciência a partir do julgamento do Habeas Corpus n. 268.459/STJ* (article), *apud* CRIPPA, Anelise, PITHAN, Lívia Haygert, BONHEMBERGER, Marcelo (coordinators), *Bioética como análise de casos*, 1st edition, Porto Alegre: EdiPUCRS, 2019, pages 107 *et seq.*.

25 SOARES, Flaviana Rampazzo. *Op. cit.*, page 106.

26 SOARES, Flaviana Rampazzo. *Op. cit.*, p. 159.

Once the doctor has confirmed that the patient is able to receive the information, and having decided that he wants to decide, once he has the psychophysical conditions to do so, he must transmit them about the diagnosis (nature and characteristics of the disease, even if severe), the prognosis (expected benefits, purpose – preventive, diagnostic, curative or palliative) and the therapeutic options for treatment (with the respective care, chance of success, foreseeable risks involved – whether serious, even rare, or not – , and the personal ones – arising from of the patient's personal condition or aggravated by it). When refusing to decide, the patient can postpone the treatment to another time – at which point he should be warned of the main harmful consequences for his or her health – or simply delegate the decision to the doctor himself, who will then only be liable for any damages if he departs from the good medical practices.

The information must be correct – according to the current state of scientific knowledge – and it is necessary to emphasize whether it is an experimental procedure or technique, or the *off-label* use of medicines. It should also be complete – of a common content in professional medical practice, tailored to the patient – and also cover the existence of specialized centres or facilities that are more suitable for care, especially when there is a risk to life or of serious sequelae. It must also be comprehensible - with language suitable for the understanding of the average man, containing explanations when necessary, using technical terms – and readability indexes can be used to assess the level of education compatible with the text structure proposed for the patient, among them the Flesch-Kincaid (ILFK).

The information must be efficient, that is, it must have the necessary level of detail, and for that, the patient's corresponding duty to provide accurate information during the medical evaluation is emphasized, in order to enable the correct composition of the diagnosis.

A precedent of the Superior Court of Justice established that the physician fulfils the duty to provide information effectively, generic information not being sufficient[27].

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27 STJ, 4th Division, REsp 1.540.580, reporting judge (for court decision) Justice Luís Felipe Salomão, j. 02.08.2018 (Source: https://www.stj.jus.br/websecstj/cgi/revista/REJ.cgi/ATC?seq=87116219&tipo=5&nreg=201501551749&SeqCgrmaSessao=&CodOrgaoJgdr=&dt=20180904&formato=PDF&salvar=false).

IV.

Quid juris if there is, during the performance of a medical-hospital procedure, invocation, on the part of the patient's family, of excuse of conscience, founded - as it happens more frequently - on religious reasons, to prevent blood transfusion that would be essential to the maintenance of the patient's life?

The issue is not new, at least for jurisprudence; nevertheless, we have always had to face it cautiously, due, in most cases, to the absence of specific legal regulation on the subject and, moreover, in view of the very peculiarity of the issue.

What is the solution?

FELIPE P. BRAGA NETTO notes, in this regard, that "the questions raised in relation to blood transfusion without the patient's authorization are delicate. They almost always involve religious reservations, in relation to which we place ourselves in distant respect. Whenever constitutional principles collide, the solution is to consider them, in the light of concrete circumstances, verifying their specific weights. There is a position in the doctrine that tends to treat situations differently: a) if the patient is older, and is in full possession of his mental faculties, his wish not to receive blood must be respected; however, if b) the patient is a minor, the transfusion must still be performed against the parents' will, since it is not known what religion the children will be (a situation that must be made more flexible when dealing with adolescents) (Maria de Fátima Freire de Sá and Ana Carolina Brochado Teixeira, "*Responsabilidade médica e objeção de consciência religiosa*", *RTDC*, v. 21, pages 133-137, Jan/Mar 2005). It is unnecessary to extol the sublime importance of religious freedom, the value of which no one can reasonably doubt. We do believe, however, that one should not compromise with the value of life"[28].

Since blood transfusion is a recommended measure (although, at first, not yet essential), the invocation, by the patient's family, of the excuse of conscience has the power to prevent the procedure from being carried out, under penalty of the health professional, in doing so, answering in theory for the crimes of bodily injury or illegal embarrassment.

The recipient of the transfusion, in fact, if he or she is conscious, may express resistance to this procedure, as well as request the use of alternative therapies to transfusion, or even request his or her transfer to another hospital, better

28 *Responsabilidade civil*. São Paulo: Saraiva. 2008, page 311.

equipped for transfusion-free treatment. And even so, the doctor will be prevented from carrying out the transfusion.

Let us remember, in this step, that the Code of Medical Ethics itself is expressed when it says that it is forbidden for the doctor *to perform any medical procedure without the prior clarification and consent of the patient or his legal guardian, except in imminent danger of life* (art. 46).

And, regarding the proposed theme, the Federal Council of Medicine has already deliberated: *In case of refusal to allow the blood transfusion, the doctor, obeying his Code of Ethics, must observe the following conduct: 1st) If there is no imminent danger to life, the doctor will respect the wishes of the patient or those responsible for them; 2) If there is imminent danger to life, the doctor will perform the blood transfusion, regardless of the consent of the patient or his or her guardians*[29].

Another is the solution, therefore, if the measure proves to be essential, the only one capable of guaranteeing or ensuring the survival of the patient, in which the use of alternative therapies would compromise the patient's general condition, and hospital transfer would still be unfeasible, due to the worsening risks.

In such cases, there is no question of resistance on the part of the patient, who is usually unconscious, either because of the severity of his condition or because of the action of sedatives that alleviate his or her suffering.

Then, the family members speak for the patient.

The family's resistance to authorizing the transfusion, when this procedure is revealed to be essential for maintaining the patient's life, even if based on religious reasons, no longer has the power to prevent medical action in this regard[30].

It being that, although the doctor's conduct remains typical, that is, it continues to correspond to the abstract prediction of the criminal figure of bodily injury, it is, due to the need for transfusion, of defence of lawfulness, consistent with flagrant necessity (Criminal Code, art. 24, *caput*).

FRAGOSO recalls that "one who acts in flagrant necessity does not act illegally, that is, 'who commits the act that the law defines as a crime to save from actual danger, which he did not provoke by his will, nor could he otherwise avoid,

29 CRM/PR Files, 16/June/1962.
30 RT 742/78.

own or third-party rights, whose sacrifice, under the circumstances, it was unreasonable to demand' (art. 24, Criminal Code). What justifies the action is the need that imposes the sacrifice of an asset in a situation of conflict or collision, in the face of which the legal system allows the sacrifice of an asset of lesser value"[31].

HUNGRIA, dealing with the hypotheses of consent of the passive agent, already mentioned the "special cases in which the injury of the consenting party is immune from penalty, such as, for example, (...) in the extraction of blood for transfusion (humanitarian purpose) (...). In such cases, however, it is not *the consent of the subjectum juris* that excludes the crime, but rather the absence of intent (*voluntas sceleris*) that *exempts it from punishment*; the agent does not proceed with *animus delinquendi*, but for a socially useful purpose or approved by practical morality, when not regulated by the public power itself"[32].

In these hypotheses – in which the passive agent consents – it is technically characterized, as a case of regular exercise of law.

As MIRABETE shrewdly teaches, "medical and surgical interventions are also indicated as a regular exercise of the right, as they are activities authorized by the State, which recognizes, encourages, organizes, and supervises the medical profession. (...) For the regular exercise of rights, the consent of the patient or his legal representative is essential. If this does not exist" – he continues, entering the area of interest for this study – "there may be a flagrant necessity in favour of a third party (the patient himself or herself), as provided in art. 146, § 3, I [of the Criminal Code]"[33].

The hypothesis under examination, as can be seen, is another, in which there is no consent from the patient or his family members.

Again, we resort to HUNGRIA's scholium:

> "Positive criminal law generally rejects the principle defended by GRAF ZU DOHNA, that 'the means to a just end is fair', but there are particular cases in which it yields to such a criterion. This is what happens, for example, in the case of the so-called 'arbitrary medical treatment', provided that it

31 FRAGOSO, Heleno Cláudio. *Lições de Direito Penal (Parte Geral)*. Rio de Janeiro: Forense. 16TH edition, 2003, pages 231-3.

32 Op. cit., V/325.

33 *Manual de Direito Penal*. São Paulo: Atlas. 19th edition, 2003, I/191-2.

> is justified by its indeclinability and urgency. Paragraph 3, item I, of art. 146 expressly declares the criminal lawfulness of 'medical or surgical intervention, without the consent of the patient or his legal representative, if justified by imminent danger to life'. As the SÁ PEREIRA Project had already done (art. 223, sole paragraph), whose formula was reproduced almost *ipsis litteris*, the Code accepted the thesis defended, among us, by LEONÍDIO RIBEIRO (*Right to heal*). It was thus expressly resolved, in the face of our positive law, an issue that has provoked a wide doctrinal debate"[34].

And further on, he notes: "FLORIANO DE LEMOS (*Direito de matar e curar*) rightly argues: 'Modern law considers life a collective good. Man does not belong only to himself, but to society, of which he is an integral part. The hypothesis therefore falls, without the slightest doubt, into a matter of public order. And since, as in fact, life is a collective good, it is clear that, in such exceptional circumstances (*danger of life* or *imminent death*), the doctor can and must act arbitrarily, because there is a legal reason to invoke: the agent's interest is legitimate, the manifest utility to society'"[35].

The hypothesis under study is also remembered by MIRABETE, when dealing with the rule in § 3, I, of art. 146, of the basic repressive statute: "The law provides for two cases of exclusion from unlawfulness, special cases of flagrant necessity in favour of a third party. The first is a medical or surgical intervention without the consent of the patient or his legal representative, if justified by imminent danger to life. A classic example would be any medical intervention that, for religious reasons, does not have the consent of the patient or her guardians when there is a risk to her life"[36].

Hence DAMÁSIO says that "for Criminal Code, even without the consent of the victim or his legal representative, there is no typicality of constraint, as long as the intervention or surgery is determined by imminent danger to life"[37], and this because, as reminded by PAULO JOSÉ DA COSTA JUNIOR[38], "Criminal law is the balancing of goods and interests. With the good of 'life' and 'individual freedom' at stake, the latter must be sacrificed to preserve the former".

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34 *Op. cit.*, VI/174 *et seq*.
35 *idem*, VI/178-9.
36 *Código Penal interpretado*. São Paulo: Atlas. 1999, page 830.
37 *Direito Penal*. São Paulo: Saraiva. 15a ed., 1993, 2/220.
38 *Comentários ao Código Penal*. São Paulo: Saraiva. 4th edition, 1996, page 436.

GENIVAL VELOSO DE FRANÇA brings to the fore, when dealing with blood transfusions in Jehovah's Witnesses, a precedent of Anglo-Saxon law:

"The Court of the State of Ohio, in 1962, was consulted by a hospital regarding permission to perform blood transfusions on a three-year-old child, with generalized burns of 2nd and 3rd degrees, reaching a body area of 40%, and whose parents didn't give to authorization because they were Jehovah's Witnesses, a religious form contrary to blood transfusions. The Court authorized the doctors not only to perform the transfusion, but to use all means capable of saving the patient.

The parents filed an appeal, stating this time that there was no imminent danger to life, to justify the arbitrary conduct. The attending physician replied that, even though the little patient was not in imminent danger of life, the worsening would be progressive, and death would certainly occur if that treatment was not carried out. And so, the transfusion was performed, with favourable results.

Parents felt that transfusion against their will violated constitutional principles. However, that Court settled on the decision that a therapeutic measure considered necessary by medical science had been practiced. Parents can, on certain and rare occasions, deprive their child of some freedoms. However, at no time can they take away the child's right to live.

Finally, the parents' last argument for not allowing that treatment was based on the biblical prohibition of blood transfusion, which was once again refuted by the Court, saying that the theological interpretations, written centuries ago in Greek and Hebrew, prove to be sometimes quite confusing, and as that decision was a civil court, only civil laws mattered. Dogmas are of dubious interpretation, but a life is always indisputable. Parents enjoy absolute religious freedom. They have the right to believe what suits them and what pleases them. However, their rights end when children's rights begin. These belong to the parents, but they also belong to the State, which has the duty to take all measures towards the preservation and personal safety (*Jehovah's Witness and Blood Transfusions*, JAMA, 195 (2,7), 1966)"[39].

39 *Direito Médico*. Rio de Janeiro: Forense. 9th edition, 2007, pages 193-4.

It should be borne in mind, regarding this topic, what art. 15 of the current Civil Code, when dealing with rights of the person: *no one may be compelled to submit, at risk of life, to medical treatment or surgical intervention* - from which it follows, *a contrario sensu*, that in the event of a risk to life, embarrassment may occur, with the aim of saving it.

Here is the praetorian guideline:

ILLEGAL EMBARASSMENT - Intelligence of art. 146, § 3, I, of the Criminal Code.

Once the actual danger to the life of the victim has been proven, the doctor who, even against the express wishes of those responsible for the victim, would have administered a blood transfusion would not be committing any crime[40].

Interesting, regarding the issue, are the considerations made by JOSÉ CARLOS MALDONADO DE CARVALHO[41]:

"The social interest must prevail over the power of the holder of the subjective right whenever it is understood that this power deviates or translates into suicide by action or omission. A democratic society, of course, cannot lose interest in the face of the absolutely unjustified death of one of its members.

On the subject, Minister LUIZ VICENTE CERNICCHIARO, in the review vote given in RHC 7785/SP, explains as follows: *The Brazilian State is secular. Unlike the 1824 Constitution, it has no official religion. Hence the provisions of art. 5, VI – 'freedom of conscience and belief is inviolable, the free exercise of religious cults being ensured and the protection of places of worship and their liturgies guaranteed under the law'. And in item VIII – 'no one shall be deprived of the right for reasons of religious belief or philosophical or political conviction, except if they invoke them to exempt themselves from the legal obligation imposed on all and refuse to comply with the alternative provision, established by law'.*

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40 RJDTACRIM, v. 7, July/September/90, page 175, Rel. Marrey Neto.

41 "A responsabilidade civil do médico e o consentimento informado", in *Responsabilidade Civil – Estudos e Depoimentos no Centenário do Nascimento de José de Aguiar Dias (1906 – 2006)*. Rio de Janeiro: Forense. 2006, pages 153 *et seq*..

> In national law, he continues, *blood is considered an essential substance for the life of man and some animals; it may be the material object of the crime of bodily injury (art. 129), as it is necessary for health. Adherents of Jehovah's Witnesses, on the contrary, in addition to reality and physical characteristics, give it a sacred nature and, therefore, untouchable, then rendering impossible, as a consequence, the practice of transfusion.*
>
> (...)
>
> If there are religious or cultural objections from the spouse, parents or, in their absence, the patient's legal representative regarding the medical intervention or blood transfusion if it proves necessary, the doctor is legitimated to act according to the procedure that best meets the interests of the victim, that override any other (articles 5, 7, 98, II and 101, V, of the Child and Adolescent Statute).
>
> The physician, in view of the imminent danger of patient's life, does not require the express consent of the patient or his legal representative for the treatment that the case requires, since the good faith of the one who acts in favour of the patient is presumed (art. 146, final part of the Criminal Code).

And in this case, characterizing the imminent danger to life, and carrying out the blood transfusion, even if contrary to the will of the patient, his family or legal guardians, the legality resulting from the conduct would not authorize them, patient, and family, to demand in court, against the medical professional, any compensation.

> In that regard:
>
> *INDEMNITY. Damage repair. Jehovah's Witness. Receiving a blood transfusion upon admission.- "Religious convictions that cannot prevail in the face of the greater good protected by the Federal Constitution, which is life. The conduct of physicians, on the other hand, was based on the law and professional ethics, as they only performed blood transfusions after exhausting all alternative treatments. Furthermore, there was no express refusal to receive a blood transfusion at the time of admission of the plaintiff to the hospital. Reimbursement, on the*

other hand, for expenses incurred with medical examinations, among others, does not warrant acceptance, since the amounts were not spent by the appellant. Appeal not granted[42].

v.

Not withstanding the lawfulness that the medical conduct would assume in such cases, the Courts recommend that the hospital be helped, in these emergency situations, by the Judiciary, through a court order[43], as a way of obtaining the essential authorization to vulnerate the physical integrity of the patient, without the risk of seeing the medical professional sued for the practice, in theory, of bodily injury or illegal embarrassment.

In this sense, in fact, an opinion[44] was approved by the Regional Council of Medicine of State of São Paulo, in November 1974, with a forecast of four conducts for different situations:

1. A seriously ill patient, unconscious, unaccompanied by family members and in need of transfusion. Which transfusion must be performed without delay.

2. A patient that is unconscious but accompanied by relatives who prevent the transfusion, at what time the doctor should try to dissuade them, alleging that the opinion expressed does not correspond to that of the patient himself, whose life is in danger with the postponement of the transfusion. In case of reluctance, the doctor will resort to the police and judicial authorities, safeguarding his responsibility and trying other resources to prolong the patient's life, while waiting for the police intervention to take place.

3. A lucid patient, who refuses to receive a transfusion. He must sign a term of responsibility before a police or judicial authority and the doctor shall try to persuade him to accept the transfusion, while using all alternative scientific means.

4. A minor patient, whose parents deny authorization for the transfusion. The doctor will appeal to the judicial authority, demanding a decision that preserves his position, characterizes the culpable or intentional responsibility of the parents, and that provides consent for transfusion use.

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42 TJSP, 3rd Chamber of Private Law, AP. 123.430-4/4-00, Court of Appeals Judge Flávio Pinheiro, j. 07.5.2002, *in* JTJ-LEX 256/125.

43 RT 735/389.

44 FRANÇA, Genival Veloso de. *Direito Médico. Op. cit.*, page 194.

It would be argued that the procedure, perhaps instituted, based on the *notitia criminis* offered by any of the aforementioned interested parties, due to the practice of transfusion carried out without the authorization of the patient or, as the case may be, of his family members, to save the life of the first, could be summarily filed, *ex officio* by the judicial authority, or at the request of the Public Prosecutor's Office, or, if not verified in a safe way, from the outset, the characterization of defence of lawfulness, the final decision in the criminal action that would follow would inevitably lead to the doctor's acquittal; In this line of thought, a respectable branch of doctrine considers that obtaining judicial authorization to carry out the said procedure is unnecessary.

And it is even likely that this would happen. But the request for a court order – also used, *mutatis mutandis*, in extreme cases, as to perform a legal abortion – a quick and effective measure, which, doubtlessly saves the doctor, his team and even, in some cases, the hospital management, from the possible inconvenience of a criminal process.

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THE PHYSICIAN'S AUTONOMY IN THE REAL WORLD PERSPECTIVE: CONTEMPORARY REFLECTIONS

Lívia Abigail Callegari [1]

Abstract: TThe countless changes provided by scientific evolution, in the most varied areas, have caused changes in the life habits and values of society. In the health area this was no different. However, what should bring only benefits, sometimes carries distortions that are reflected in the doctor-patient relationship. In search of profits and contaminated by corruption, in not rare situations the professional adopts the logic of industrial production, making this relationship totally depersonalized. Consequently, a solid bond is not established, mistrust prevails and medical conduct based on scientific knowledge is subjected to lay judgment. As an illusory attempt at protection, the physician adopts a defensive conduct. Without adequate clinical reasoning, they order more exams and adopt protocols that suppress professional autonomy and do not benefit the patient. In order to get out of this equivocal scenario, the ideal is that the physician knows how to listen, inform, know the patient's values and plans in order to provide appropriate care.

Keywords: Professional Autonomy; Bioethics; Health Care System; Evidence-based Medicine; Empathy

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1. Introduction

In the current context, the health system undergoes major changes in various directions, either by the advancement of science or by the change in society's values. The world scenario is altered every day due to the numerous changes provided by the evolution of technology in various aspects of everyday life, including the doctor-patient relationship. This brings a very beneficial aspect, but can also lead to disconnected paths and out of an ethical reality. Therefore, the autonomy and the discernment of the physician are fundamental to annihilate any possibility of deviation, regardless of the condition of the environment in which he/she exercises the profession.

It is well known that social relations were massified, thus becoming impersonal. For this reason, the figure of the general practitioner - family doctor - lost relevance, since this type of care was restricted to a minority of higher purchasing power. Two very important factors have contributed to the depersonalization of the figure of the doctor: the dissemination of care in large hospitals and health centres, and the increasing level of specialization of professionals. The line of thought of industrial production was used in medical work, which is based on the productive logic focused on the profit of companies. Compliance with schedules, attendance to a determined number of patients per working day, imposing the number of examinations requested or procedures to be performed, or their limit, depending on the objective of the Institution[1].

However, it is not too much to remember that, as the human doctor-patient relationship is mainly based on biological events, there are subjective conditions and variables inherent in the very essence of the human being and the interaction with nature, which end up annihilating any logic of industrial production or any imposing clinical protocol[2].

Moreover, the unjustified excessive use of technology, far from the vision of acting in the best interest of the patient, ends up having a bias totally focused on profit, generates insecurity for the patient and the system, results in waste and lack of sustainability, not to mention the possibility of bringing environmental problems.

In this context, the existence of a demand for technology is justified, as long as it is used in a rational and effective manner to solve the needs in health, under penalty of bringing a serious collapse to assistance. Unnecessary profits and frauds should be kept away, making a model that places the patient in the centre of attention to prevail in order to keep the balance of relationships, as provided in the Code of Medical Ethics[3] that permeates the profession.

2. Brief Lines about Autonomy in the Doctor-Patient Relationship

Different from the relationship that was established between doctor and patient when medicine was introduced in Brazil, due to the positivist philosophical basis, the dominant figure before was the contact of strict trust. The physician often made decisions about the procedures to be applied in the place of the patient himself. He had the power to observe, understand and dominate the patient, under a system that analysed the disease according to a reductionist scheme, in which the human being was objectified, without taking into account the organism and the person in its magnitude.

According to Foucault[4], there are three stages in this relationship of objectification: isolation, involvement with the disease, and reconstruction. In the first stage, we observe the isolation of the patient before the disease, in which, due to his evident fragility, his autonomy is mitigated. In the second stage, the patient is involved by the speech, generally unintelligible to the layman, who starts to carry a stigma due to the scientific definition of the disease that afflicts him. Finally, in the third stage occurs the reconstruction of the ego, according to which the patient internalizes the medical recommendations and their various therapies, even if they are unknown or unpleasant.

However, this context began to change and, due to innumerable regrettable cases that negatively marked the history of humanity, the movement for the study of the autonomy of the will grew, born in the 18th century, but with concrete effects only in the 1960s and 1970s.

It was glimpsed, then, a molded doctor-patient relationship with new contours, bringing the patient as an outstanding element in this scenario. Supported by the right to information, the patient is now able to interact more extensively for the success of the therapeutic application adopted, as from the understanding of the facts his intention is materialized with absence of influence, directly converging to the full exercise of autonomy. Remember that, in the literal sense, the word "autonomy" derives from the Greek "autos", me, and "nomos", law, that is, each one is responsible for his acts and, therefore, these must be respected within his beliefs, moral values and wills[5] .

As a consequence, the medical autonomy conquered throughout the 19th and early 20th centuries has undergone profound conceptual changes, notably in the last 50 years[5]. This is because, irrespective of the place where he carries out his activity, whether in a consulting room or in hospital structures, the physician, who at the beginning of the last century placed himself in the role

of uncontested commander of all actions, without even giving full prestige to the patient's autonomy, changed the conformation of his conduct in face of the full possibility of the patient's decision making, which started to be widely recognized, protected and consigned in the Codes of Medical Ethics of most countries.

3. Medical Decisions

Due to the aforementioned reformulation of values, one cannot forget that, within the aforementioned attribution of each health professional, the physician will take on the role of reconnecting the elements of individuality of the patient affected in the totality of his being by a disease that, in some way, disarranges his constituent elements and makes him, at the same time, reality and phenomenon, transcendence and appearance. In this sense, the word "reconnect" has its origin in *"re-ligare*", the same root as the word religion. The doctor, therefore, should not only have the function of taking care of the appearance, but of trying to reach the sick person with an integral look at the *person of the sick person*, not only at the disease[6] .

In the face of the picture that presents itself, it is necessary to *decide o*n the conduct to be adopted. Remember that, etymologically, the verb "to decide" is formed by the prefix "*de*" (from Latin, meaning to stop, extract, interrupt) and by "*cadere*" (which means to split, cut). In this way, the word decision means "to stop cutting" or "to let flow", and its opposite, "indecision", means stagnation. Thus, whenever there is an alternative for an action the need to choose will arise, because every decision is a choice between alternatives. If there is no choice, there is no decision, but only a fact[7].

For this reason, it is immanent that every decision making process goes through internal elements, such as individual values, as well as the values of a group, assumed not by intimate conviction, but by mere tradition, becoming part of the way individuals conduct themselves.

However, according to Martin[8], there are times when the legislation leaves no loophole for the doctor to make decisions, both as a professional and as a member of society, because in some situations where his state of conscience comes across, this points to a path totally different from what is limited and imposed by the law.

Therefore, the exercise of autonomy is never materialized in a broad and unrestricted manner, even because it may affect the rights of third parties. Thus, it is natural that, even though autonomy may be included as a fundamental right, it is known that no guarantee in the eyes of the Federal Constitution[9] is absolute, because there are always exceptions. In this perspective, Segre points out that t*he principle of autonomy does not give absolute freedom, it determines how much a person can be free. This principle is linked to the conditions imposed by the other two principles of Bioethics*[10] .

For a correct conduct, in which the possibility of conflicts is minimized, in the so- called Code of Medical Ethics (Resolution CFM 2.217/2018)[3] numerous devices are listed to ensure the full performance of the medical activity, which will be enumerated below, in a non-exhaustive list, by way of example:

> *FUNDAMENTAL PRINCIPLES*
>
> *(...)*
>
> *VII - The physician shall exercise his profession with autonomy, not being obliged to render services that are contrary to the dictates of his conscience or to whom he does not wish to render services, except in situations of absence of another physician, in cases of urgency or emergency, or when his refusal could bring harm to the health of the patient.*
>
> *VIII - The physician may not, under any circumstances or under any pretext, renounce his professional freedom, nor may he allow any restrictions or impositions that might impair the efficiency and correctness of his work*
>
> *(...)*
>
> *XVI* - No *statutory or regulatory* provisions *of a hospital or public or private institution* shall limit the physician's choice *of scientifically recognized means to establish the diagnosis and execute treatment, except when it is for the benefit of the patient.*
>
> *XVII - The relationship of the doctor with other professionals should be based on mutual respect,* freedom and independence *of each one, always seeking the interest and well-being of the patient*

(...)

It is the doctor's right: (...)

III - To point out flaws in norms, contracts and internal practices of the institutions in which he/she works *when he/she judges them unworthy* of the exercise of the profession or harmful to him/herself, *the patient or third parties and should communicate them to the Regional Medical Council of his/her jurisdiction and to the Ethics Commission of the institution, if any. IV -* Refuse to exercise his profession in a public or private institution where the working conditions are not dignified or may harm his own health or that of the patient, as well as that of other professionals. *In this case, he shall communicate his decision with justification and as soon as possible to the technical director, the Regional Medical Council of his jurisdiction, and the Ethics Commission of the institution, if any.*

V - To suspend his activities, individually or collectively, *when the public or private institution for which he works does not offer adequate conditions for the professional exercise or does not remunerate him with dignity and fairness, except in situations of urgency and emergency and must immediately communicate his decision to the Regional Council of Medicine*.

(...)

VIII - Decide*, in any circumstance, taking into account their* experience and professional capacity, the time to be dedicated to the patient *without allowing the accumulation of charges or consultations to impair their work*.

IX - Refuse to perform medical acts *that, although permitted by law, are* contrary to the dictates of their conscience.

(...)

It is forbidden for the doctor:

(...)

Art. 20 - To allow pecuniary, political, religious or any other interests of *their employer or hierarchical superior or of the public or private financer of health care to* interfere in the choice of *the best means*

of prevention, diagnosis or treatment available and scientifically recognized in the interest of the health of the patient or of society.

(...)

Art. 36 Abandoning a patient under their care.

§ 1. Should any facts occur that, at their discretion, jeopardise the good relationship with the patient or the full professional performance, the doctor has the right to resign from the service, provided that the patient or their legal representative is notified in advance, ensuring the continuity of care and providing all necessary information to the doctor that will succeed them.

§ 2. Except for justifiable reasons, *communicated to the patient or his family members, the physician shall not abandon the patient because he is suffering from a chronic or incurable disease and shall continue to assist him even for palliative care*[3].

Thus, the Code of Ethics contributes to extirpate demeaning situations with which the physician is faced in the performance of his activity, providing recognition and protection of his autonomy, without leaving unprotected the full respect for the patient's will.

It is true that the aforementioned statute will have the power to direct the professional in the exercise of medicine to conduct himself in a deontologically approvable manner. However, as the resolution is an infra-legal instrument, when questioned in court about an act, the physician should obviously use the legislation in force, as the resolution is only a supplementary instrument, in spite of its inestimable value.

4. Ethical Dilemmas Regarding the Patient's Will: the Art of Balancing Values and Autonomy

In not rare situations, the physician faces dilemmas linked to moral and/or religious beliefs, which may conflict with the patient's wishes. Therefore, it is necessary to develop tolerance and a certain dose of humility, recognizing in the other no superiority or inferiority, but a different point of view, because elevating scientific knowledge to a form of truth morally superior to other values is to ideologically appropriate reason and deny it to others[11] .

Thus, the professional is driven to reflect about all the problems introduced by technocracy, conflicting with his conscience, structured in a tradition of millennial morality[12]. This is because, besides all the elements exposed, the physician is not even prepared to live with suffering and to face death[13]. It is instilled in their core during the graduation course that the physician should fight for life, as if it did not bring death itself.[14]

Over time, situations of possible failure or limitations in the treatment affect the professional many times and, therefore, he begins to carry a painful feeling of failure. The lack of psychological support generates emotional marks, sometimes insurmountable, and may affect the clinical reasoning and decision making. It is a surprising situation because, contrary to what should be expected, the health system does not even provide emotional support to individuals, not only in medicine, but also in other health professionals. Nor do universities prepare students for this scenario, which they will invariably encounter in their professional path, as they are trained to cure, and not to care.

However, this is a panorama that has been undergoing change, because the management of the patient, which was limited to a more incisive model for the cure, due to the change of some conceptions of the study of diseases, began to glimpse a much more directed aspect of care. This is justified because, in a previous moment in history, it was more common the appearance of acute diseases, which quickly led the patient to death. Currently, the number of chronic diseases is increasing, providing the physician with an increased relationship not only with the patient, but also with the family, as he/she accompanies the various stages of the disease and its aggravation[15]. Thus, the disease affects not only the patient, but also the family and caregivers, who have the aggravation of stress and the feeling of impotence to bring relief to the loved one when he/she is affected by a disease with presence of pain.

In these peculiar situations, the physician has a fundamental role in the conduct of the clinical case, because both the decision and the direction of treatment should consider not only what is right for him/herself, as if the other were pure object of his/her action, but also what is right for the other, who is the end of this action[16]. For this, it is fundamental to establish a dialogue and the ponderation of values, risks and benefits. The adoption of active listening is fundamental to overcome barriers that may arise and is an excellent instrument of approach and understanding for a shared decision. However, when it becomes impossible to establish an acceptable parameter for the parties, and the act or the therapeutic refusal of the patient, although permitted by law, is contrary to the dictates of

his conscience, the professional may use, in exceptional circumstances, the conscientious objection, provided in the Code of Medical Ethics[3].

5. Provocations and Reflections on Medical Activity in the Current System

The advancement of science and innovation in technology has brought about numerous changes in various directions, namely: in the social structure, in interpersonal relationships and in the *modus vivendi*. In short, society has changed because technology has changed, but the human being remains the same, with its individual biological responses.

For this reason, obviously, this reflex has also expanded to the health system which, notoriously, undergoes constant transformations, including the re-signification of some concepts and primary approaches. This is because, with the improvement of health devices in the most diverse aspects, the probability of prevention and early detection of diseases has grown, resulting in the chance of immediate initiation of treatment. As for diseases for which until then there was no management option, nowadays it is possible to offer an alternative to the patient to annihilate or control its progress. In this avalanche of innovations, much is invested in the health sector, and every day new drugs are created, or new applications are discovered for existing ones.

Full health and a hypothetical society free of disease are the most desired precious goods[17]. Thus, it is to be believed that clinical studies that may represent gains in quality of life should have the fundamental support of society as a whole, even more so when the development of this praiseworthy direction of science follows real ethical guidelines.

However, this ideal does not always match reality, because sometimes a scabrous scenario is hidden, which supplants the appropriate and patient-centered care in favor of goals and profit. In these situations, differently from what was previously described, the human person, who should be the end, becomes the means, in the condition of a mere object.

Diseases and syndromes continue to be created in an extensive production line, and in many cases do not even represent major threats to life span. There is wide dissemination and valorisation of such discoveries, which are combated by various types of treatments, often unsafe, unreliable and of dubious scientific nature[18].

It starts from a cruel, inappropriate and ostentatious *marketing*, destined to explore the human affliction, to sell advantages, illusions and, perhaps, fads. In most of the speeches, it is always embedded the promise of cure/control of diseases in a fast, safe, definitive way and without considerable shakes. Scientific events, congresses and other academic insertions are usually used for this pernicious disclosure. Incomplete, biased and manipulated knowledge is presented, or even - what is worse - they favor the constitution of associations supposedly in favor of the patients, but which, in reality, hide the true face of mere captors, maintained and managed solely by the pharmaceutical industry and medical devices. They create chimeras about greater suffering, generate stigmatisation, adoption of unnecessary treatments which, in many situations, generate damage to patients and families, besides irrational use and waste in the health area. Thus, the concept of total health becomes something distant and unattainable, which may cause permanent anguish, and the experience of life becomes medicalized.

This is just one of the results of the so-called disease mongering, which is directed as a true promotion of the disease and is embodied in the phenomenon of convincing healthy individuals, or with some risk factor, that they are sick[19]. Therefore, the fear of the possibility of developing a certain disease is explored, through the most varied forms of propaganda, suggesting an immediate treatment. For this reason, one starts to believe in this need, which becomes a desire and, repeatedly, leads to a demand.

Successively there is an increase in diagnostic investigation to the detriment of clinical medicine, and the focus shifts from the patient to the mere reading of complementary tests which, in many situations, are inadequate to clarify the hypothesis of the pathology, since some bring the possibility of false positives, not to mention the risks to the patient's health, caused by iatrogenic (complications or adverse events as a result of health care) which may manifest themselves in the short or long term.

The fact is that for a long time these decoys have been announced against companies and large laboratories that operate in the health area, especially when related to cases of corruption and fraud in which industry, government, health institutions and professionals participate. This perspective is justified and consolidated only because there are no clear rules on safety tests and supervision. The concrete accountability of these companies is also insufficient. Working, therefore, in the limbo of the lack of limits, in a faulty system of approval, which counts on precarious regulation, makes possible an unjustified scheme of enticement and bribery[20]. This, in practical criteria,

ends up constituting true shielding on the part of some companies in the sector, which practically start to enjoy free transit for placing new products on the market and with the connivance of the governments[21]. Consequently, much is invested in this attractive sector in the certainty that the gains will be absolute and without concrete penalties.

According to Fortes[22], the excessive use of technology, in addition to being influenced by lucrative interests, increased prestige or even the pleasure of prescribing "new goods", can be motivated by a sincere desire to help, especially when based on a traditional vision that is based on the imperative to act in the best interest of the patient. Then, as the demand for technology is expansive, and should be conceived as an enabling, rational and effective instrument to solve health needs, the overuse should keep the fear of being, somehow, in breach of legal obligations, under penalty of analysis of legal and deontological responsibility.

6. The Human Relationship in Health

It is undeniable that the change of values that society is experiencing has, in some aspects, brought much benefit, but in another step, paradoxically, it has brought immense degeneration. Human relations have been massified and have become impersonal[23]. As a consequence, the health care model adopted the dissemination of care in large hospitals and health centres. Likewise, the level of specialization of professionals also contributes greatly to the depersonalization of the figure of the doctor, because until today the biomedical model applies the scientific mechanistic conception brought by the philosophers Galileo, Descartes, Newton and Bacon in the seventeenth century[24]. The figure of the family doctor and its respective legacy in the way of acting was scarce, as already pointed out. This trend may denature the essence of the doctor-patient relationship, considered of a *sui generis* nature, since what leads the patient to seek a doctor, in general, is a pathology, a misfortune or any other state of fragility, in its broadest sense, besides being *intuitu personae,* that is, a relationship based on trust[25].

According to the conception adopted, frequently the physicians are unknown and the patients are anonymous and, in these circumstances, no connection is established, not even a relation of trust, which greatly shakes the essence by which the activity was conceived. Along the same lines, the entrance of the health operators/insurers in the activities also had an important role to maculate the core of the doctor-patient relationship, according to the thought of part of

the doctrine. With this, in not rare situations, derisory values of remuneration are fixed for the work, which allowed the definitive constitution of a scenario totally devoid of the essence that the profession is destined for. In this sense, Barros Júnior warns about the fallibility of the system:

> *Those doctors who have not prostituted themselves seem to be starving, working more and more and earning less and less, studying and learning less and less. Some of the many who have prostituted themselves make up the statistics of neglect and, under the pretext of gaining clients (and not patients), not infrequently misinform the population and harm society and the profession. The medical class is in the front line, receiving all the fury of the artillery of a society in collapse, lost and desperate as much as the health professionals*[26].

Consequently, in the current medical practice there has been an expressive increase in the demand for medical assistance, which triggers a blatant lack of time, and hurried professionals end up offering quick consultations. The establishment of a distorted culture of a supposed immediatism for the solution of all and any evil that isolates the individual's well- being contributes to this panorama. We do not look at the patient, we do not make an adequate anamnesis and we do not establish an efficient dialogue. Everything happens quickly, without time to listen, evaluate and make decisions.

Therefore, to optimize time and equate gains, there is an unjustified increase in requests for exams, unconnected to a careful scientific evidence or at least an expected clinical reasoning. This is because achieving goals has become the driving force of some health establishments, especially those that adopt the model called *fee for service* (payment per procedure)[27]. In this chaotic aspect, the financial incentives of hospitals, laboratories and physicians should also be included in this type of remuneration, which generates a deplorable vicious circle, according to the American report of the State Health Care Cost Containment Commission[28].

For Bobbio[29], this model is what is called *fast medicine,* according to which it works with the fragmentation of medicine, constituting the care through several specialists who, most of the time, do not exchange information among themselves and are not concerned with the totality of the patient. There is no commitment with the patient for the most adequate help and for the decision making process. Unjustifiably, and without a deep thought of the concrete case, there is an increase in medicalization, since, as in part of clinical research, there

is no interest in the human being and his peculiarities, because in a distorted view the focus is only the disease.

It is very true that technology is fascinating, but only when well and intelligently used, as it makes daily life much easier, creating good prospects. However, it should never cause an upset or distance in relationships, even because, no matter how advanced it is - and the new does not always surpass the existing -, who creates, operates and interprets the result of machines are still human beings. One cannot forget that the clinic is sovereign, and one does not learn medicine by messing with machines, but in direct contact with the patient. A laboratory or image test is not capable of explaining a disease by itself, because it will always depend on a professional to conduct the diagnosis, no matter how much artificial intelligence advances. The precision that can be obtained by innovations should never represent a rush or volume of production, but a fundamental gain in quality.

The same author mentioned above, Bobbio[30], in the work "Too much medicine: excessive use can be harmful to health", rightly points out that, despite technological evolution, the available tests are still imprecise, and the treatments are not free of health risks. For this reason, our dream of early detection of a disease clashes with a less enchanting reality. In a perfect world, screening would bring only benefits, but in the real world, early diagnosis is associated with well-known risks[31]. Therefore, correct information and honest use of currently available data should be considered, so as not to create false illusions, nor feed the myth that it is possible to prevent any disease, or lead people to believe in miracle cures.

In this diapason, when the possibility of identification of the disease, it would be expected an appropriate treatment, which may include a do or not do, not only focused on the disease, but centered on the patient, who should be treated in a holistic way, relating his life history, behavior and goals to reach a shared decision. It is the ideal direction, because it can lead to greater life expectancy, with quality, besides having favourable reflections on the survival of the health system itself. Wisdom in choices should be used, which arises mainly from the observation of the exaggerated or inappropriate use of health resources, considering that, in this case, in many situations, less is more[32].

With the scenario presented, it is noted an excessive waste, lack of increase of resources and damage to the environment, in addition to the lack of sustainability, factors that generate an unreasonable increase in costs for health care. Just to put it more deeply, according to the National Supplementary Health

Agency (ANS), in the 2017 report[33], statistical surveys proved the growth in the amount of requests for complementary exams, per person, of up to 21% for computed tomography and 25.2% for magnetic resonance imaging.

With this, the saga of overdiagnosis[34] and overtreatment is instaured, which invariably result in the conduction of the case with absence of adoption of the best technique, without counting with the total unraveling of an ideal clinical practice. According to Moynihan, Doust and Henry35 is clearly a direction that brings more harm than benefits to those who make use of the service. The principle *primum non nocere* (first do no harm), which is umbilically linked to the bioethical principle of nonmaleficence and recommends, among other aspects, to weigh risks and possibilities of unnecessary harm to patients, the increase of costs when requesting non-indicated exams, elaborating diagnoses, performing procedures or even prescribing medication, is put aside. It is not assimilated with parsimony that, for the concrete case, the less cannot represent more[36].

And when the results of the exams come back, the communication process between doctor and patient is fragile and, invariably, generates a patent stigmatization of the individual who, reduced merely to a disease, feels weakened and is only led to a futile medicalization, without even receiving guidance on the need to introduce some daily behavioral change. In his haste, the professional forgets the importance of adequate guidance to the patient, since a bad habit of life can never be supplanted by medication. In fact, this whole scenario is hidden, which is also a reflection of the most evident failure in teaching and preparation since graduation - the starting point -, for launching to society professionals with strong technical knowledge, but extremely distant and lacking a humanized vision. Including, no space is directed in the curricula for the necessary reflections brought by bioethics, because many consider the theme of minor importance.

Such state of affairs has generated great dissatisfaction in patients, doctors and other health professionals. In short, in the practical aspect, the disease or any subject related to human health has become part of the aspect related to the mass society, fitting with the inadequate bias of mercantilization, exactly contrary to what is established by the deontological codes. Social relations, by becoming more and more devoid of personality, result in the loss of the bond of trust and in the qualitative loss of the communication process. The totality of the being, including his suffering, his expectations and his cultural understanding, is often limited by a utilitarian vision which only aims at patrimonial experimentation. According to Birolini[37], when the doctor-patient relationship is not established, there is mere business.

For this reason, to base the origin of this excess in health care solely as a consequence of the so-called "defensive medicine" is somewhat puerile as it does not analyse all the issues from their point of origin.

7. Of the Supposed Defensive Medicine and the Invisibility System

Inappropriate conduct in a segment that does not prioritize the safety of the patient, the institution or the professional brings disruption not only to the individual who uses the provision of services, but also to the health system as a whole, which ends up in the legal risk. Thus, confrontations arise in the Judiciary, which are often supported by theses that are excessively lay and totally devoid of any basis[38] , since they are based on merely vulgar knowledge, with a low degree of scientific security, arising from mere observation and which do not offer an adequate causal relationship, but always focus on the professional. This adds nothing and only increases even further the distance between the areas of knowledge.

Strangely enough, unless I judge better, it is not verified with some constancy actions against the manufacturers of products used in the health area, even though in some cases they are alerted to the deficient points for its approval and introduction in the market and the lack of quality control. With this reasoning it is worth, therefore, to ask how many surgical complications occur due to failure in the material, and not due to technical error? This question is not usually raised, because it is assumed that it would succumb on its own, considering that, on the one hand, the expert structure - extremely fundamental to a process - is limited and, on the other hand, the vision of some courts is totally outdated, because they use outdated theories of law, disassociated from an analysis with systemic scope, according to which a broader view of the concrete case is necessary in order to, in fact, ascertain the truth.

As if that were not enough, in some concrete cases, in order to intensify the inadequacy of thoughts, theories of comparative law inappropriate to our legal system are absorbed. In this context, it is disregarded that the health area has peculiarities that do not affect other areas and, therefore, the line that we have seen consolidate nowadays with the adoption, in some judgments, of the theory of loss of a chance, which works on the reckless hypothesis of potentialized uncertainty, is inappropriate. According to Lovato Neto[39], this is due to the lack of a greater commitment in the study, ignoring the correct interpretation and extension of the theory, which results in the understanding of impossibility and inapplicability of its application in the country for lack of adequacy of structure and for incompatibility with the requirements of civil liability.

Thus, for mere convenience and shallow thinking, the adoption of the culture of "more of the same" will be maintained, which will possibly move towards making the health service provider responsible, whether an individual or a legal entity, but without ever reaching the real responsible party, who will remain under the cloak of unbelievable protection and invisibility, thus strengthening even more the scenario of impunity in health and an inoperative system that encourages fraud.

Medicine, which used to be an outstanding and unshakable science, has become part of the behaviour of society, through which the lay interpretation of phenomena inherent to science prevails, with connotations of futility, involving supposed medical damages in even technical and lay forums, by common sense, despising scientific knowledge under the fanciful argument of corporativism26 . Both sides, however, forget that, according to the state of science, no matter how safe the techniques may be, the risk is never completely eliminated, since it is not restricted only to the technique, but also to the reactions of the organism itself.

On the other hand, totally degenerating the doctor-patient relationship, there is also the incentive to insure medical error, which ends up causing a total breakdown of ethics and morals in the health professions.

Thus, the so-called industry of professional insurance, in the vision of many, besides not stabilizing the relationships, causes imminent distancing in the treatment of the professional with the patient, because it is concerned with patrimonial questions which eventually arise at the end of the treatment, forgetting the main object, which is the human relationship. The illusory patrimonial armouring is sold, forgetting that the way to avoid conflicts is the good structuring of the doctor-patient relationship.

The consequence of this distancing of focus is the worsening of the provision of services, in which the patient is at a minimum, and the professional is without a minimum anteparo to act, whether in the technical or psychological sense, by being pressured in various aspects of society[40].

8. Evidence-Based Medicine (EBM): Reflections on Medical Practice

In view of the panorama presented, in which the lack of credibility of theories put forward to justify degradation in the health area was pointed out - which, in reality, keep the scope of trying to mask deeper aspects, such as unjustified waste, frauds, excess of information not so safe for an adequate diagnostic

and therapeutic decision process - and the need to resume the patient as the focus of assistance, parameters have been developed for the adoption of better conduct and clinical reasoning for the concrete case.

In an attempt to establish a minimum of safety for the patient and the health system, as well as to moralise and filter existing information, some social movements seek to rescue the values of health care[41].

Recalls Varella[42] that, for a long time, medicine was based on empirical, improbable theories, individual experiences, ideologies and popular beliefs. With studies advanced in time, this paradigm of possible subjectivism has been broken. This does not mean, however, that there will be mathematical accuracy in actions in medicine, because achieving a result depends on other factors. The primary objective is the construction of knowledge closer to concrete data and without conflicts of interest.

Because of this, there is an urgent need for countries to create independent and impartial bodies to make concrete studies to serve the community as a whole. It is a direction to be taken, since few undergraduate health institutes pass content that sharpens the search for the concepts of efficacy, effectiveness, efficiency and safety of drugs, for example, and how to seek evidence for each case.

Thus, with the purpose of putting an end to some directions so disconnected in the health area, clarify doubts about the new forms of treatment, that in some situations do not correspond to the expectations created, and enable selection with probity of some information released, was created at McMaster University in the early 1980s, in Canada, the movement called *evidence-based medicine* (EBM). This movement has the objective of aggregating the concepts of epidemiology with clinical medicine, outlining the need for learning

methodology, probability and statistics, besides the usefulness of exams and therapies, which resulted in an increase in the discussion on the teaching and practice of medicine. This is reflected in decision-making based on scientific knowledge of the highest quality, i.e. better information and better evidence, which assists professionals in the selection of conducts and examinations to be ordered, and takes into account the *experience of the medical professional and the will of the patient* (experience-based medicine).

Objectively defined by Sackett and collaborators: *Evidence-based medicine is the conscientious, explicit and judicious use of the best available evidence when making decisions about a patient's care (...) it is not "cookbook"*

medicine, because it requires a bottom-up approach that integrates the best external evidence with individual clinical experience and patient choice, and therefore cannot result in servility.[43]

The Cochrane Library synthesizes knowledge, in the broad spectrum, and is considered a world reference. To this end, it uses an independent network of researchers and health professionals, whose mission is to maintain and disseminate systematic reviews of randomized controlled trials (secondary study that aims to gather and compare similar studies with critical evaluation of methodology and other points), considered the best level of scientific evidence and the highest quality for health decision-making, which benefits the population, patients, managers, health professionals, public managers and the World Health Organization (WHO).

For a first step in the search for accurate evidence, it must be accompanied by the aim of analysing what is currently available, be imbued with a conscientious spirit (being careful and thorough in what you do), explicit (being open, clear and transparent) and judicious (using common sense and appropriate judgement)[44].

Such studies should be in Cochrane's pyramid of levels of evidence. Thus, didactically, a question should be formulated (what is the problem?), which may be addressed to a population with a particular disease. Then, one must ask: which intervention works, in comparison with those already used; what is the outcome; in comparison with which therapy among those already used; and for which outcome? In summary, one seeks: 1) a problem; 2) a prediction factor; 3) an alternative; and 4) a result or event.[44]

This way of formulating the questions derives from the technique called PICO (acronym for *patient, intervention, comparison, outcomes*), according to which the population with a problem is the P; I means the intervention that will be used; C is the control group, which is the intervention with which one wants to compare; and O is the *outcome*, or outcome, that is, the expected result. The metanalysis studies form a set with the same PICO.[45].

It is important, in this sense, to choose appropriate designs for each question and the one with the highest level of evidence. To explain these concepts more adequately, Atallah clarifies:

> *The first level for treatments is the systematic review of previous studies with meta-analysis. The second is the large double-blind randomised controlled trial, called large trial, with more than 1,000 cases. The third level of evidence is the small clinical trial, which usually has 100 to 200 cases in each group. The fourth is the cohort study (study of groups of people), which follows a different treated group, but it is not double-blind, patients are not randomized and therefore loses a lot of quality. The fifth level is a retrospective study, which takes the data and tries to set up a comparative study, but with some gaps. The sixth category corresponds to case series. If a doctor treated 50 patients like this and had these results, but did not compare them with anyone else, he did not do the blind test, because he did not have enough exemption.*
>
> *Finally we have the expert opinion, which is not science but an opinion. This is, however, a stimulus that can turn into a structured question and becomes the seed of progress in medicine*[46].

Lopes states that, in order for the professional to be considered suitable for EBM cotexting, must be able to:

1. *Identify the patient's relevant problems;*
2. *convert the problems into questions that lead to the necessary answers;*
3. *Search efficiently for information sources;*
4. *evaluate the quality of information and the strength of evidence, favouring or denying the value of a given conduct;*
5. *reach a correct conclusion as to the meaning of the information;*
6. *apply the findings of this evaluation to the improvement of patient care*[44].

Due to the security it provides to the exercise of medicine, as well as to other areas, the EBM solidifies an adequate work for institutions to formulate *guidelines for the* standardization of activities, as long as they are based on scientific evidence. This is justified because the fact of having a protocol does not mean that it is harmless, as it may contain a clear conflict of interest when it is being prepared, or even some distortion to reach an objective other than the patient[47].

It does not mean that the fact that protocols exist should make them compulsory to be followed, as in a ready-made formula. The protocols should serve as a guide, without ever forgetting the necessary individualization when treating the patient for a specific case, because what is in the protocol cannot always be used for some specific circumstances. Using it without the due clinical reasoning and as if it were something to be followed to the letter, without allowing exceptions, may cause more harm than good. This is why there is the danger of some trends in Law whereby if the professional follows the protocol, he or she is immediately protected from any demand. This is not the case; the specific case must be analysed, as well as the way in which the protocol was created, as this can also lead to a real conflict of interest.

EBM extends to a huge range of applications and structuring in healthcare, so this subject is extremely important, which needs to be further explored by healthcare professionals and legal professionals practising medical and healthcare law, as there is currently an important reflection in the judiciary regarding EBM. This is because of the necessary improvement in various areas so that justice, as an important institution, is also used correctly.

As exposed, many discourses are based on the fact that judicialisation is the only villain due to the budget leakage it causes in the health system. It is known that it may be causing some imbalance, but it is not the main culprit. What is masked are precisely the major corruption schemes involving human healthcare, as exposed at length, and for this reason the EBM brings adequate clarification to the technical probity of what is judicially requested or used in medicine to achieve the expected outcome, or closer to the outcome in the patient. In the current scenario, the judicial responses to the technical aspects brought by EBM are still very timid, as verified in the study by Dias and Silva Júnior48 . The authors48 reveal that the majority of the judgments assigned to the analysis of medication requests have not made use of EBM and have not contributed to a more adequate analysis of the patient's situation. Legal arguments related to the superiority of the right to health, based on article 196 of the Federal Constitution9 , and the abusive and illegal nature of restrictions on the supply of medications and treatments, based on the Consumer Defense Code[49], prevail. This disregarded to the supply of unnecessary or inadequate medications and treatments, ignoring alternatives made available by health plans and the Unified Health System, generating unnecessary burdens. Therefore, it is necessary to intensify a responsible, adequate and joint technical basis among all the knowledge so that possible distortions, illusions and hidden interests are definitively barred.

EBM must be allied to health care, and no longer a contributing factor to intensify ruptures, and, above all, it must combine the best scientific knowledge with clinical reasoning and adapt these factors to the patient's values. It cannot be an assessment tool from a purely monetary or budgetary perspective, but must be at the service of the person and for the best clinical experience.

9. The Medicine of the Future: Humanised Care

The world trend, as explained, is to place the patient on a differentiated basis of passivity, the physician having the duty to provide the individual with all the necessary information for ample and adequate decision making, which will be materialized by means of free and informed consent. Consequently, the focus of responsibility changes, and may be shared, since the patient interacts all the time, before treatment, during and after[50].

Sacomani[51] adopts a strict ethical stance, in which the patient and those close to him are at the centre of interventions, the aim of which is to increase psychic and physical well- being and autonomy in decision-making. This is why patients are not allowed to be manipulated in their fragility with the aim of creating dependence. To this end, the information offered cannot be mistaken or incomplete, nor can it denigrate other forms of treatment, so as not to mislead the patient.

Even before being a competent technician, the doctor is an educator, which derives from the communication and relationship aspects, in addition to the concrete impacts throughout the treatment.

To achieve a reconstruction of values related to health, in the face of the perspective presented, a deceleration of the decision-making process in some possible and common clinical situations in medical practice is proposed, with the incentive to adopt the basic and traditional principles of patient care, enhanced by the sensible and judicious use of all technological advances, both diagnostic and therapeutic[52].

With the resources of Narrative Medicine, the patient can be analysed from an integral perspective, as it does not see him as a disease, but as a patient, from his history, clinical manifestations, signs and symptoms, which may have different meanings. As to communication, the verbal language is observed, but also the set of other languages. It is not a question of ignoring the advances in medical science, but only of recognising that they alone will not be capable of providing solid bases which prepare the physician for the

complexity of a fruitful encounter with his patient. From this point of view, this approach is of utmost importance, as it will not only be at the core of the linguistic exchange between doctor and patient, but also as a formative instrument capable of providing means for interpretation with the aim of promoting a more attentive and perceptive attitude towards the various modes of expression of the patient[53].

Thus, it is the duty of the professional involved in the relationship with the patient to have sufficient knowledge of the human emotional to capture the possible reactions of the patient during the transmission of information. Note that such information should be in clear and concise language, always taking into account the level of education of the patient, as well as his emotional condition. The physician must also inform the diagnosis or prognosis through a true message, always leaving room for hope, even if it is limited[5].

Therefore, the old Hippocratic model no longer prevails, and the physician nowadays has the duty to advise and inform the patient and, if applicable, relatives or persons close to him, of the conduct to be followed and the risks of the operation and treatment recommended. Furthermore, due to the close relationship of trust established between physician and patient, lying is not compatible with it, and for this reason the physician owes the patient the truth, although subject to certain limits. For Krieger[54], the professional must have a minimum of communication technique for bad news, when this is the case, for the very protection of the patient. It is a moral principle that the lie is legally a fault, and the physician cannot believe himself above it. The patient's trust in the doctor is twofold: from a layman in a professional; and from a weakling in a protector. But the doctor does not "own" the patient. The patient must be the object of deep respect and consideration by the professional and has the right to be informed of his condition, his perspectives and possibilities, existing treatments and risks arising from each one, except when the direct communication may cause him harm, in which case, for his protection, the communication must be made to the legal guardian or relative[55].

Ample information about the various aspects of the treatment is a real element for the full exercise of the patient's autonomy. Regarding the patient's autonomy, the professional has the obligation to respect beliefs, values and personal choices after the clarifying information. The consent is mature and not only informed or clarified, and becomes a safe final point of communication, according to which the patient, within the binomial evaluation/understanding, may express his/her self-determination by means of decision making. The decision, on its turn, is shared. It is based on the patient's beliefs, convictions,

expectations and preferences. It is a right that must be exercised free of coercion or intimidation, arising from a clearly provided language that does not induce an essential error, under penalty of nullity.

The patient, thus, is well directed and therefore becomes more aware and participatory. In this process, in collaboration for care, support networks of care are also constituted. The doctor-patient relationship is born well constituted and, therefore, it will be difficult to have a confrontation, because there is ethics in the established bond.

10. Concluding Remarks

In view of the current situation, it can be seen that the medical professional, who is constantly questioned, must be free to make decisions within certain limits.

The patient, who until yesterday was reduced to a system that assisted him in a paternalistic way, today finds himself in a differentiated level, where he must receive all the necessary information, in clear and concise language, and always taking into account his level of education, as well as his emotional condition, so that he can exercise his volitive element through decision-making.

It is obvious that the physician, who also faces dilemmas related to moral and/or religious beliefs in conflict with the patient's wishes, must develop, within his autonomy, a mechanism of tolerance with a different point of view. As far as possible, he will also not allow himself to be evolved by ties, notably the economic ones, acting in the best way within his internal dictates.

That is why the concrete restructuring of health care, as a whole, is urgent and necessary. A perilous situation has long been established, in which only difficulty remains for all the actors in the system: patients and professionals. At the same time, the existing projects for humanization are thrown to the margin of the system due to bad management and by the installation of policies of obscure objectives and of undeniable intention of prevalence of unilateral interests.

If corruption exists, it is because there is, in addition to the behaviour, the permissibility for it, without any impediment from the system. It is a distorted aspect in which an important change is expected. Perhaps this can be intensified by compliance programs in health to establish rules of conduct that will inevitably reflect on the system of risk management and patient safety, whose definitions should be interpreted in the most comprehensive way possible.

This is because the conclusion has been reached that to act in the wrong way generates inconveniences of countless aspects, which are not worth it.

In effect, there is no use in starting re-education and realignment actions at the macro level, if at the micro level there is no change in attitude. It is true that the great majority of physicians act in a correct manner, and these will always do their best for a more appropriate care, even though there is a fraction of physicians who benefit from the perverse incentive of this universe of fraud, directing the health of others as a mere business (or commerce), which is strictly forbidden by the codes of ethics of most health professions.

Furthermore, the huge adoption of technology without concern for outcomes can increase risks without bringing any benefits. What is new is not always safe, and making a new technology available does not always mean innovation. Insufficient training without criteria to deal with the "new technology" also contributes to the increased complication rate, annihilating lives in its widest spectrum and generating unnecessary expenses. If it does not bring improvement and the risks are accentuated, better that nothing is done.

Therefore, the time has come for an application of unbiased directions, whose main objective is to bring the application of medical and scientific knowledge with the highest degree of evidence. Allied to this, an adequate dialogue process must be constituted with the patient, which will lead him to be the centre of the relationship, because, after full clarification, he will be able to conduct the exercise of decision making without blemishes, glimpsing his values and needs. Therefore, in this scenario, the sparing use of technology is fundamental and indispensable, without ever despising it.

A fundamental redemption is needed, concluded by Bottoni's thought, expressed at a meeting of the Slow Medicine Brazil movement, which ultimately translates the essence and social importance of the physician and the result of their autonomy well used: *Listening, informing, sharing the decision and even developing techniques to prepare for a consultation are of paramount importance. Always care, not always cure. Blaming the system alone does not solve anything, but it is necessary, above all, to check and analyse personal attitudes. Remember that society is me, and then others. In assistance it is fundamental to know the patient, respect the value of the person and give in a little, when necessar.*[56]

11. References

1. Luna F. Breve comentario acerca de la autonomía de los profesionales y de los pacientes en la medicina actual. Rev Asoc Med Argent. 1996;109(3):6-9.

2. Pereira Filho A. Autonomia do médico nas instituições. Bioética [Internet]. 1998 [access 17 Dec 2022];6(1):[3 p]. Available: https://bit.ly/2Vhluwo

3. Conselho Federal de Medicina. Código de Ética Médica: Resolução CFM nº 2.217, de 27 de setembro de 2018 [Internet]. Brasília: Conselho Federal de Medicina; 2019 [access 17 Dec 2022]. Available: https://bit.ly/2VdwpHf

4. Foucault M. The birth of the clinic: an archaeology of medical perception. New York: Vintage Books; 1976.

5. Fabriz DC. Bioética e direitos fundamentais. Belo Horizonte: Mandamentos; 2003.

6. Vasconcelos EM. A proposta de empowerment e sua complexidade: uma revisão histórica na perspectiva do serviço social e da saúde mental. Rev Serviço Social Sociedade. 2001;65(22):5-53.

7. Fonseca JGM. Decisão médica. In: Petroianu A. Ética, moral e deontologia médicas. Rio de Janeiro: Guanabara Koogan; 2006. p. 25-34.

8. Martin LM. A ética médica do paciente terminal: leitura ético-tecnológica da relação médico paciente terminal nos Códigos de Ética Médica. Aparecida: Editora Santuário; 2003.

9. Brasil. Constituição da República Federativa do Brasil, de 5 de outubro de 1988. Diário Oficial da República Federativa do Brasil [Internet]. Brasília, ano 126, nº 191-A, p. 1-32, 5 out 1988 [access 17 Jan 2023]. Seção 1. Available: https://bit.ly/36opsq6

10. Segre M, Cohen C. Bioética. São Paulo: Editora da Universidade de São Paulo; 2002.

11. Ferraz FC. A relação entre o profissional de saúde e o usuário de suas atenções, vista a partir do princípio da autonomia. In: Segre M. A questão ética e a saúde humana. São Paulo: Atheneu; 2006. p. 55-61.

12. Rodrigues AC. Relações do médico consigo mesmo. In: Gonçalves EL.

Moral médica. São Paulo: Sarvier, 1984. p. 55-66.

13. Moraes IN. Erro médico e a lei. São Paulo: Lejus; 1998.

14. Casarini K, Basile-Filho A. A relação com o doente sem possibilidade de manejo terapêutico. Medicina (Ribeirão Preto) [Internet]. 2005 [access 27 Dec 2022];38(1):69-3. DOI: 10.11606/issn.2176-7262.v38i1p69-73

15. Kovács MJ. Relação do médico com familiares responsáveis pelo doente. In: Petroianu A. Ética, moral e deontologia médicas. Rio de Janeiro: Guanabara Koogan; 2006. p. 91-98.

16. Barros MRS. O médico e problema ético: carisma, formação do médico. São Paulo: [s.n.]; 1980.

17. Albuquerque CMS, Oliveira CPF. Saúde e doença: significações e perspectivas em mudança. Millenium Rev ISPV [Internet]. 2002 [access 27 Dec 2022];25. Available: https://bit.ly/2XJoGlZ

18. Melo M. A promoção da doença: a quem interessa? Rev Port Clin Geral. 2007;23:361-4.

19. Moynihan R. Disease-mongers: how doctors, drug companies, and insurers are making you feel sick. BMJ [Internet]. 2002 [access 27 outubro 2022];324(7342):923. Available: https://bit.ly/3evPvA1

20. Gotzche P. Medicamentos mortais e crime organizado. Porto Alegre: Bookman; 2016.

21. Ayçaguer LCS. The drug industry and the obstacles for timely flow of information and their effects on the public health. Rev Cubana Salud Publica [Internet]. 2010 [access 27 Dec 2022];37(5):631-43 Available: https://bit.ly/2XR7NFM

22. Fortes P. Breve reflexão ética sobre os aspectos da gestão de serviços de saúde. In: Vecina Neto G, Malik AM. Gestão em saúde. Rio de Janeiro: Guanabara Koogan; 2016. p. 381-384.

23. Bauman Z. Modernidade líquida. Rio de Janeiro: Zahar; 2014.

24. Mayer E. Toward a new philosophy of biology. Cambridge: Harvard University Press; 1988.

25. Godoy R. A responsabilidade civil no atendimento médico e hospitalar.

São Paulo: Revista dos Tribunais; 2000.

26. Barros EA Jr. A responsabilidade civil do médico: uma abordagem constitucional. São Paulo: Atlas; 2007.

27. Hickson GB, Altemeier WA, Perrin JM. Physician reimbursement by salary or fee-for-service: effect on physician practice behavior in a randomized prospective study. Pediatrics [Internet]. 1987 [access 07 Jan 2023];80(3):344-50. Available: https://bit.ly/2xH0o1l

28. Miller Center. Cracking the code on health care costs: a report by the State Health Care Cost Containment Commission. Charlottesville; 2014. Available: https://bit.ly/2VBVpHh

29. Bobbio M. O doente imaginado: os riscos de uma medicina sem limite. São Paulo: Bamboo Editorial; 2016.

30. Bobbio M. Medicina demais: o uso excessivo pode ser nocivo à saúde. São Paulo: Manole; 2019.

31. Bonaldi A. Verdadeira e falsa prevenção: os rastreamentos e os perigos da sobreutilização de procedimentos diagnósticos. Slow Medicine [Internet]. 13 fev 2019 [access 28 outubro 2022]. Available: https://bit.ly/3cvo8o2

32. Velho JCC. As 10 recomendações da Choosing Wisely Internacional. Slow Medicine [Internet]. 6 ago 2017 [access 29 Dec 2021]. Available: https://bit.ly/3bk74AW

33. Brasil. Agência Nacional de Saúde Suplementar. REA-Ouvidorias: relatório estatístico e analítico do atendimento das ouvidorias: ano base 2016. Rio de Janeiro: ANS; 2017. Available: https://bit.ly/2M46Umg

34. Welch HG, Schwartz LM, Woloshin S. Overdiagnosed: making people sick in the pursuit of health. Boston: Beacon Press; 2011.

35. Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. BMJ [Internet]. 2012 [access 28 Dec 2022];344:e3502. DOI: 10.1136/bmj.e3502

36. Lown B. A arte perdida de curar. São Paulo: Petrópolis; 2013.

37. Birolini D. Entrevista com prof. Dário Birolini. Slow Medicine [Internet]. 22 ago 2016 [access 28 Dec 2022]. Available: https://bit.ly/2XKAcO3

38. Grimberg M. Medicina defensiva. Bioamigo: bioética da beira do leito [Internet]. 7 jul 2015 [access 17 outubro 2021]. Available: https://bit.ly/2XLh8Pu

39. Lovato Neto R. Aplicação da teoria da perda de uma chance na seara médica e críticas da doutrina pátria [Internet]. In: Anais do XXI Congresso Nacional do Conpedi; 31 out – 3 nov 2012; Niterói. Florianópolis: Funjab; 2012. p. 395-414. Available: https://bit.ly/3aoMMFq

40. Jacovella PF et al. Buena/mala praxis médica em cirugía estética. Buenos Aires: Ad Hoc; 2004.

41. Boff L. Saber cuidar: ética do humano, compaixão pela terra. Petrópolis: Vozes; 1999.

42. Varella D. Medicina baseada em evidências. Drauzio [Internet]. 27 abr 2011 [access 17 Dec 2022]. Available: https://bit.ly/2Ke5yVd

43. Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ [Internet]. 1996 [access 17 Dec 2022];312:71. DOI: 10.1136/bmj.312.7023.71

44. Lopes AA. Medicina baseada em evidências: a arte de aplicar o conhecimento científico na prática clínica. Rev Ass Med Brasil [Internet]. 2000 [access 07 Jan 2023];46(3):285-8. DOI: 10.1590/S0104-42302000000300015

45. Santos CMC, Pimenta CAM, Nobre MRC. A estratégia PICO para a construção da pergunta de pesquisa e busca de evidências. Rev Latinoam Enferm [Internet]. 2007 [access 07 Jan 2022];15(3):508-11. DOI: 10.1590/S0104-11692007000300023

46. Atallah A. O que é e como funciona a medicina baseada em evidência? Portal Namu [Internet]. 27 set 2019 [access 07 Jan 2022]. Available: https://bit.ly/2wR1MOw

47. Mendes JP. Guidelines ou blindlines? Da evidência à clarividência. Rev Port Imunoalergologia. 2007;15(3):213-25.

48. Dias ER, Silva GB Jr. A medicina baseada em evidências na jurisprudência relativa ao direito à saúde. Einstein [Internet]. 2016 [access 13 Jan 2023];14(1):1-5. DOI: 10.1590/S1679-45082016AO3363

49. Brasil. Lei nº 8.078, de 11 de setembro de 1990. Dispõe sobre a proteção do

consumidor e dá outras providências. Diário Oficial da União [Internet]. Brasília, p. 1, 12 set 1990 [access 05 Jan 2023]. Available: https://bit.ly/3beJqpD

50. Couto Filho AF. Responsabilidade civil médica e hospitalar. Belo Horizonte: Del Rey; 2001.

51. Sacomani C. Slow medicine não é uma especialidade médica: saiba por que. Slow Medicine [Internet]. 28 set 2017 [access 10 Jan 2023]. Available: https://bit.ly/3ah2Ys3

52. Birolini D. O exercício da Slow Medicine: à guisa de um conceito. Slow Medicine [Internet]. 25 jun 2018 [access 27 Dec 2022]. Available: https://bit.ly/2KgBHLI

53. Fernandes I. A pertinência da medicina narrativa na prática clínica. Rev Port Med Geral Fam [Internet]. 2014 [access 27 Dec 2022];30(5):289-90. Available: https://bit.ly/2Kd7bCv

54. Krieger MV. Comunicação de más notícias em saúde: contribuições à discussão bioética, através de uma nova ética das virtudes [dissertação]. Rio de Janeiro: Fiocruz; 2017 [access 10 Jan 2023]. Available: https://bit.ly/3bkmO7d

55. Castro JM. Responsabilidade civil do médico. São Paulo: Método; 2005.

56. Callegari L. Operação enganosa. Slow Medicine [Internet]. 3 set 2018 [access 13 Jan 2023]. Available: https://bit.ly/3grQiTx

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PUBLIC POLICIES AND REPRODUCTIVE BIOMEDICINE SURROGACY, BUSINESS AND HUMAN RIGHTS

João Proença Xavier[1]

Abstract: This Study, about subrogated maternity, wants to put out a brief commentary concerning the natural impact on Law of the new reproductive possibilities brought out from new Medically Assisted Reproduction techniques, through the comparative of RMA European legislation on surrogacy, which is nowadays suspended in the Portuguese case, creating social and medical impacts that, in the eye of a jurist, will give indication they (society and medical community) are not actually prepared for …

Keywords: Human Rights; Surrogacy; Biomedicine; Medically Assisted Reproduction; Reproductive Rights; Biolaw

INTRODUCTION

According to the author González Moran in his book of 2006 "*From Bioethics to Biology…*"*:* Surrogate motherhood is "the one that originates by gestation of

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a human being in the woman's womb, on behalf of and at the request of another woman to whom the new-born will be delivered as his/her own mother".[2]

About this problem[3], in 2014, the esteemed Vera Lúcia Raposo, in her phenomenal PhD thesis, "The right to Immortality – the Exercise of Reproductive Rights through assisted reproduction techniques and the statute of the embryo *in vitro*, writes: "Another problem on the content of the right to reproduction is to know whether it is required that the subject who claims it, uses his/her own genetic material (which implies to place the tonic accent on any biological link), though the subject may dispense with the child and give it to third parties (…) "as is the case of subrogated maternity". (…) Can these women play that role, invoking their reproductive rights, i.e., is it sufficient that the genetic material of the respective spouse or partner is involved, associated with the reproductive right to the protection of the family unit (which reminds us particularly of the female element of the contractor couple, in a contract of subrogated gestational and genetic maternity, in which the sperm belongs to the male element); or, on the other hand, if nothing like this is required, is it enough that the subject wants to bring to the world a child to educate and raise (which only relieves the social, affective and legal filiation aspects) and, thus, establish with it legal ties (as it is the case of the contractors in a contract with any biological material). Even authors, who prove to be lavish the moment productive rights must be outlined, seem to demand some type of genetic connection[4].

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2 Our translation: Cit. González Morán L. *"De la Bioética al Bioderecho…"* page 672.

3 See: Article 8 no 2 of the PMA Portuguese Law - 32/2006 (*…)"subrogated maternity" any situation where the woman is prepared to bear a pregnancy on behalf of others and deliver the child after birth, giving up maternity powers " (…)*

4 Raposo, V. L. in, *"Direito à imortalidade…"* page 162 *in fine*: *"We believe the figure of* reproductive right implies, cumulatively, the intention to transmit genetic material and establish *with the child a legal affiliation bond, so that the respective responsibilities are assumed. When there is only a first dimension, we are in the presence of the right to dispose of one's own body and respective genetic code; when there is only the second dimension, we are in the presence of the right to form a family. None of them is confused with the reproductive right, though this is one of the various dimensions of the right to form a family."* See also Raposo, V. L. op. cit.: (Roberttson, J. "Genetic Selection of Offspring Characteristics", B.U Law review, 76, 1996, page 438) *"It is the case of Robertson who, when discussing whether cloning should be inserted in the context of reproductive rights, restricts its acceptance to the cases where the person who wants to reproduce replicates their own genes."*

Joan Bestard Camps, Professor at the University of Barcelona, explains, in this regard, the meaning of having *"one's own progeny"*, arguing that "own" means several things and the treatment context defines the meaning of this relationship: 1 – genetically related, 2 – having given it birth, 3 – having gestated it during pregnancy.

For this anthropologist, "*own*" "means mainly a biological relation of some kind". Thus, he argues that, in our self-knowledge culture, this is fundamental for the identity development, in which the knowledge of genetic origins and biological fatherhood is included. This intention is evidenced by diagrams and family trees and by the idea of continuation of family offspring.

For Bestard Camps: "The basic relation is a biological relation; the others are a metaphor between them (the godparents, adopted children, stepfathers). However, given the possibilities of donations ("dações") of gametes in the assisted reproduction techniques, new "fictions" and new meanings for the **"**own**"** are included[5].

For this author (where the culture has its own nature), the reproductive process replicates in the microcosm of the individual this modern cosmology of nature (where): "parents have their own children"…" And these take after their parents and throughout their childhood develop some aspects of their nature, which make them different and individual. For that, the interaction, or better, the relation established between parents and children, the day-to-day relationship of which our scholars speak, a relationship not only based on "nature", but also on the "child"[6].

In the same way, like Vera Lúcia, we speak here of the right to have children and not of the obligation to have them, unlike the Italian theories of Mussolini's II World War period, who taxed all those who did not want to have children, arguing that population growth enriched the motherland and was a National imperative duty of every citizen. According to the Professor of Coimbra working in Macau, "*we do not sympathize either*" with the official Church doctrine, which considers procreation a marital duty, the main and first reason of catholic wedding.

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5 Cit.: Bestard Camps, J. *"Tras la Biología – La moralidad del parentesco y las nuevas tecnologías de reproducción"*, Ediciones de Universidad de Barcelona, Barcelona 2004, page. 30 and 31.

6 See: Bestard Camps, J. *"Tras la Biología* –…, pág. 32.

Luis González Morán draws the attention to the terminological plurality used to name this image: "*subrogated maternity*", *"replacement maternity", "surrogate mother" or "carrier mother",* or even *"belly or rental womb"*.

REPRODUCTIVE BIOTECHNOLOGY AND HUMAN RIGHTS…

Brief European Vision – Public Policy and Subrogated Maternity in Europe

In Spain, in article 10 of Spanish Laws 35/1988 and 14/2006, it is determined that: (Article 10) Gestación por sustitución *"1. Será nulo de pleno derecho el contrato por el que se convenga la gestación…"* (and in the current PMA Spanish Law)[7], in the same sense as the Portuguese Law (Law 32/2006):

In Portugal (in the original PMA law), the article 8 (Subrogated Maternity): "1 – *The free or costly subrogated maternity legal transactions are null. 2 – Subrogated maternity is any situation in which the woman is willing to support the pregnancy on behalf of someone else and deliver the child after childbirth, giving up the powers and duties of maternity. 3 – The woman who supports someone else's replacement pregnancy is, for all legal purposes, the mother of the unborn child"*[8].

In England, in the minutes of agreements or subrogation provisions of 1985, the subrogated maternity is not forbidden. However, the negotiation of such agreements for profit is condemned. The English Law (Human Fertilisation and Embryology Bill) of 1st November 1990 (Act) Meaning of "mother": **E+W+S+N.I.** *"(1)The woman, who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child. (2)Subsection (1) above*

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7 See: Art. 10 of Law 14/2006.

8 See on this matter González Moran's opinion, *"De la Bioética al Bioderecho…"*cit. page 672 and 674 *in fine*: *"quiere ponerse en evidencia que, si a pesar de la calificación jurídica de dicho contrato, éste se realiza al menos en su aspecto material, no tendría efectos: es decir, que los comitentes no estarían obligados a entregar a la gestante el precio convenido, si lo hubiere habido, ni la gestante estará obligada a entregar al hijo nacido. De ahí que la filiación será determinada…"* For this author: *"Así firmada la nulidad de este contrato, entiendo que no tiene mayor trascendencia encasillarlo dentro de los negocios tipificados en nuestro Ordenamiento, como hacen con diversa fortuna los autores, que suelen calificarlo jurídicamente o como un contrato de arrendamiento de obra entre el médico, la mujer, la madre y la madre gestante, o un contrato de arrendamiento de servicios o un contrato de alquiler en el que lo que se alquila es el vientre la gestante."*

does not apply to any child to the extent that the child is treated by virtue of adoption as not being the [woman's child] .(3)Subsection (1) above applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs."[9] [10]

In Germany**,** the German law of 13 December 1990 indicates in a single paragraph[11] (our translation) - *The German Law of the embryo protection, n. 745/90 of 13/12/90*[12] *establishes/states"– Art. 1- Abusive use of reproduction techniques (…) Punishment by deprivation of liberty up to three years or fine penalty will be applied to those who:*

1. Proceed to transfer to a woman the egg of another woman; 2) Artificially fertilize an egg with the aim of starting a pregnancy in another woman the egg belongs to; 3) Transfer to a woman more than three embryos in a same cycle; 4) Fertilize by intratubular gametes transfer (GIFT) more than three embryos in a same cycle; 5) Fertilize more eggs than the ones possible to transfer to a woman in a same cycle; 6) Remove an embryo from a woman before its implantation in the uterus, so that it can be transferred to another woman or using it with different purposes from its protection; 7) Practice artificial fertilization or human embryo transfer to a woman willing to abandon it definitively in favour of third parties immediately after its birth.

2. The same penalties will be applied to those who: 1) favour the artificial penetration of human sperm or human egg or 2) Artificially introduce human sperm in a human egg, with a purpose different from starting a pregnancy in the woman the egg belongs to (...)3) Punishment will not be applied 1) in the cases referred to in paragraph 1, inc. 1, 2 and 6, the woman the egg or embryo comes from, or the the egg has been transferred to, or the woman the egg will be transferred to. 2) in the cases referred to in paragraph 1, inc. 7, the replacement mother or the person who wants to take care of the baby

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9 Version: "Latest available" (Revised) 2008.

10 On this matter, Gonzáles Moran's opinion *"De la Bioética al Biooderecho…"*cit. page. 674 *in fine: "presunción legal de maternidad"* (…) "*y en el art. 30.1 y b* (dista ley inglesa) *prevé la posibilidad de que un tribunal pueda determinar la paternidad legal del matrimonio o de la pareja que hayan recurrido a esta técnica reproductiva*. And in article 36 (of the same law) changes the law: *Ley de acuerdos de Subrogación de 1985: "Ningún acuerdo de subrogación podrá ser ejecutado coactivamente por o contra ninguna de las personas participantes."*

11 German Embryo protection law, n. 745/90 - 13/12/90.

12 http://www.cgajdh.salud.gob.mx/descargas/rh/03_sistema_regional_europeo/01_consejo_de_europa/CE001.pdf (Consulted in 20/08/2015).

definitively. 4. In the cases referred to in paragraph 1, inc. 6 and paragraph 2, the attempt is liable to criminal penalty."

In Germany, the recipients and the pregnant woman will not be punished, and the penal sanctions are EXCLUSIVELY ASSIGNED TO THE MEDICAL/CLINICAL PRACTITIONERS performing these techniques.

In France, the French law 94-653 provides for sanctions for those who mediate between person and couple who want to have a child and a woman who authorizes a pregnancy "on request" and returns the child at the end…

In Greece, the Greek Law 3089/2002 of 23 December on PMA, strangely in our understanding, authorizes subrogated maternity, but subjects this option to very restrictive guarantees: proven sterility of the concomitant woman, judicial authorization with written agreement between all parties in which the written consent of the pregnant woman's husband, in case she is married, is included, etc…[13]

For my dear master, the retired full Professor of Family and Succession Law of Coimbra University, Guilherme de Oliveira, author of, among many other very good texts on Bioethics, the controversial work of the beginning of the nineties, "Mother, there is only one (two)! The Pregnancy/Gestation Contract", in the words of his student S. M. Magalhães, cit. *"The subject is of sensitive nature and assiduously touches the legal approach."*[14]

Up to then, motherhood was exclusively associated and determined by the phenomenon of childbirth and adoption was the only legal exception to this reality.[15]

However, different orders have been deciding differently. See the famous case of the "Baby M" of 1987, where the couple Stern, Elisabeth and William, made a pregnancy/gestation contract with Mary Witehead and her husband Richard. The surrogate mother, in this case Mary, gave up all maternity rights over the child born by artificial insemination, in favour of the Stern couple, who would

13 In a related sense, Neves Barbas, S. M., *"Direito ao Património Genético…* Footnote page 197, *"A Lei Mesopotâmica, Código de Hammurabi, though it was favourable to monogamy, Authorized the husband, in case a woman is sterile, to have sex with another woman with the procreative purpose or gave the sterile woman the faculty of choosing her own slave to that hshe could have children. According to that Code, the slave's child was excluded from inheritance."*

14 Magalhães, Sandra Marques, *"Aspectos sucessórios da procriação."* Footnote page (80).

15 Oliveira, Guilherme, *"O Direito Civil em face das novas técnicas de investigação genética"…*, page 157.

be responsible for all charges and would still have to pay to the carrier mother (of their child) $ 10.000. After many vicissitudes, New Jersey Supreme court decided, in 1988, that the daughter born in these circumstances would stay with the ones who have better conditions to raise the child, and at the end, the Court reached the conclusion that the child would stay with the Stern couple.[16]

According to Neves Barbas, in the United States of America (USA)[17] **"***in 1983, a man rented for 10,000 dollars a married woman's womb (with her husband's consent) to implant in it an egg with his sperm. The contractor determined that the woman could not have sex for a month. After the child's birth, it was found that the child had Down Syndrome. The biological father refused to both pay the agreed amount and receive the child. The surrogate mother, on the other hand, did not want the child.*[18]

According to Principle 11 of the European Parliament resolution of 16/03/1989, about *In Vivo* and *In Vitro* artificial insemination, in the words of the Coimbra researcher I quote "*…any form of subrogated maternity is, in general, to reject: the commercial mediation with host mothers must be subject to sanctions and the companies with such activity, as well as the trade in embryo and gametes, must be forbidden."*[19]

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16 Oliveira, Guilherme, *"Mãe há só (uma) duas! O contrato de gestação*... page 94.

17 About the distinct American position: Neves Barbas, S. M.: *"Direito ao Património Genético"*…pag. 150, where he says that in the USA several parenting associations of subrogation were founded, cit.: *"Nacional Center for Surrogate Parenting (N.C.S.P.) in Washington (…),"Infertility Center of NewYork"* in NewYork *(…),"Surrogate Parent Foudation" (I.N.C.)* in California.*"* See also Magalhães, Sandra Marques: *"Aspectos sucessórios da procriação."* (…) pág. 50 cit.: *"In Brazil there is no express legal (formal) seal to subrogated maternity, and the practice is performed by assisted reproduction clinics with support under the resolution of the Federal Council of Medicine no 1.358/92, whose item VII admits it (with the name of "replacement gestation" or "womb temporary donation"), since the "womb temporary donor" does it for free and belongs to the "genetic donor's family" in kinship up to second degree"*.See also an author who criticizes the PMA Spanish Law, because it is not more liberal with the possibility, for these special cases, to grant "authorization" of subrogated motherhood: Lacadena, Juan Ramón, "La Ley 14/2006 sobre técnicas de reproducción humana asistida: consideraciones científicas y éticas" en *Revista de Derecho y Genoma Humano*, nº 24, 2006, pág. 168: *"verdaderos casos de altruismo cuando una mujer no tiene útero pero sí ova genetic donorrios y otra (una hermana, por ejemplo) se ofrece a gestar los embriones producidos por una fecundación in vitro"…*

18 Neves Barbas, S. M., *"Direito ao Património Genético"…* footnote, page 229.

19 Neves Barbas, S.M., *"Direito ao Património Genético"…*page 151.

In Portugal, the Portuguese proposed law on Medically Assisted Procreation Techniques, Law no 135/VII of 1st August 1997, forbids the subrogated maternity and determines the nullity of the legal transaction, free or onerous. It also determines that its promotion is, by any means, considered crime…

The Article 1882 of the Portuguese Civil Code with the epigraph (Irrevocability) postulates "*Parents cannot give up parental responsibilities or any right they are especially conferred, without prejudice to what is provided in this code on adoption".*[20]

Similarly, according to the Master in Civil and Legal Sciences of the Faculty of Law of the University of Coimbra, Stela Marcos de Almeida Neves Barbas, and according to the researcher, also from Coimbra, Sandra Marques Magalhães, "the complexity o*f the theme generates such discomfort that the trend is not to admit subrogated motherhood in any case…"*

We shall quote it here, as a critical conclusion of this chapter, since it can be applied to both PMA Laws of 2006, Portuguese and Spanish, on which our analysis on this controversial issue, Subrogated Motherhood, was focused:

"PMA claims a redensification of the legal concept of affiliation and progenitoriality, which does not derive necessarily from biological data, but also depends on social values of responsibility, which can even contradict the biological truth", and, thus, are strictly linked to the socio-affective domain"[21]

Conclusion

To all that has been said, we must add that the Spanish order of 2006 remains completely unchanged, but the same does not happen with the Portuguese order, which, since 2006, has suffered four controversial alterations to the original model by Law 32/2006 of 26th July, originating the Portuguese *"New Laws",* namely: Law no 17/2016 of June 20, which *"extends the scope of the beneficiaries of medically assisted procreation techniques, making the second amendment to the Law no. 32/2006, of July 26 (medically assisted procreation");* Law no 25/2016 – Republic Diary, no 160/2016, Series I of

20 Text provided by Law no 496/77 of November, 25.

21 Annotation to Article 20 of the Authors' Portuguese Law: Silva, Paula Martinho e Costa Marta, *"A lei da Procriação Medicamente Assistida – Anotada…"* pag. 109, que citam: Amadeo Santosuosso, "Utero in affito: il difficile contratto*",* in *Questione Giustizia*, nº 2, 2000, page. 375.

August 22, which "*Regulates the access to* subrogated maternity*, making the third amendment to the Law no 32/2006, of July 26 (medically assisted procreation)" and Law no 58/2017 of July 25 "Fourth alteration to the Law no 32/2006, of July 26 (medically assisted Procreation) on the destiny of sperm, oocytes, testicular tissue and ovarian tissue…"*

Being certain that the "New Law" on subrogated maternity: Law no 25/2016 of August 22 currently regulates the access to subrogated maternity, making the third amendment to Law no 32/2006, of July 27 (medically assisted procreation), currently in force in Portugal, very different from its initial project and from that planned by its Iberian counterpart, offering a new reproductive solution, which is far from being consensual for the Medical and Scientific Community, and that the Portuguese Society did not have time to debate or internalize fictitiously, which will undoubtedly have a lot of impact on the National Society and on the Current Medicine…Here I only quote the first Article the Object for future Reflection:

The "present" Law regulates the access to subrogated maternity *in the case of absence of uterus/womb, injury or disease of this organ, which prevents pregnancy absolutely and definitively…"* – Making the third amendment to Law no 32/2006, of July 2006, changed by Laws no 59/2007, of September 4, and 17/2016, of July 20. My view is that many public debate and reflection initiatives will be necessary, so that this difficult task can be carried out. As a conclusion, I can say that, at the public and deep discussion level of these matters, the goal has not yet been met, at least in Portugal, where the Portuguese legislation, since 2006, has suffered four controversial changes to the original model by Law 32/2006 of July 26, originating the four Portuguese "New Laws" and this structuring and necessary debate still remains to be done..

The Portuguese Constitutional Court has recently ruled on this matter in the judgement 225/2018 from May 7, 2018, declaring the unconstitutionality, with general obligatory force, of several rules of Law no 32/2006, of July 26: nos. 4, 10 and 11 of Article 8, and the rules of nos. 2 and 3 of the same article, where they accept the subrogated maternity business celebration, exceptionally and subject to prior authorization; no. 8 of Article 8, in conjunction with no. 5 of Article 14 of the same Law, where it does not accept the replacement pregnant woman's consent revocation until delivery of the child to the beneficiaries; as well as, no 7 of article 8; no 12 of article 8; rules of no 1, where they impose an obligation of absolute secrecy with regard to persons, who were born as a result of medically assisted procreation process,

using the donation of gametes or embryos, including subrogated maternity situations, on the use of such procedures or subrogated maternity, and on the participants' identity in these procedures as donors or as replacement pregnant, also determining that the declaration of unconstitutionality effects should not be applied to the subrogated maternity contracts authorized by the running National Council of medically assisted procreation, where the medically assisted procreation therapeutic processes, referred to in article 14, Law no 32/2006, of July 26, have already started.

This demonstrates that the discussion of these controversial matters, which was not made in the past, will, undoubtedly, have to be made in the future, as this reflection suggests…we can conclude that the subrogated maternity in Portugal is, at the moment, suspended *sine dia*, and the families' lives are frozen like the embryos, whose destiny remains uncertain and undetermined, and that the donors' anonymity seems dangerously finished, without appeal or grievance, remaining the escape to Spain. Here, though the subrogated maternity contract is null, the anonymity of donors of genetic material essential to human assisted reproduction techniques is granted (for the moment)…it is also essential to Medical Biotechnology Business, essential itself, in many cases, to make possible the realization/concretization of human reproductive rights in modern times…

BIBLIOGRAPHIC REFERENCES

ABELLÁN, F., "*Reproducción humana asistida y responsabilidad médica": consideraciones legales y éticas sobre casos prácticos,* Comares, Granada, 2001.

ABELLÁN, F., "El Diagnóstico Genético Embrionario y Eugenesia: Un Reto para el Derecho Sanitario", *in Derecho y Salud,* 15, 2007.

ABELLÁN, F., "El Estatuto jurídico del Embrión en España: De la ley de reproducción de 1988 a la Clonación Terapéutica de nuestros Días", *in Revista de Derecho y Genoma Humano,* 28, 2008.

ALMEIDA, F., "A criança nascida de PMA – o direito do mais fraco", *Bioética e Vulnerabilidade,* Edições Almedina, Coimbra, 2008.

ALONSO BEDATE, C., "Terapia Genética", *in Genética Humana. Fundamentos para el Estudio de los Efectos Sociales de las Investigaciones sobre el Genoma Humano,* Cátedra de Derecho y Genoma Humano, Fundación BB, Bilbao, 1995.

Alvarenga, Raquel de lima soares, "Considerações sobre congelamento de embriões", *Biotecnologia e suas implicações ético-jurídicas,* Belo Horizonte: Del Rey, 2004, págs. 229 -247.

Álvarez Díaz, J. A., "A El Estatus Biológico del Embrión Humano. Nuevas Repercusiones Bioéticas y Bio – jurídicas", *in Revista de Derecho y Genoma Humano,* 2008.

Andorno, R., *"?* El Derecho Europeo ante las Nuevas Técnicas de Reproducción Humana: Primacía de la Técnica o Primacía de la Persona?", *in Derecho y Persona,* 1993.

para o Direito Penal", Coimbra Editora, Coimbra, 2010.

Ara pinilla, i., "El concepto de Derechos Fundamentales", *in Problemas Actuales de los Derechos Fundamentales,* Universidad Carlos III de Madrid, BOE, Madrid, 1994.

Archer, luís, *"Desafios da Nova Genética",* Brotéria, Lisboa, 1992.

Assembleia da república portuguesa, *"Questões de Bioética"*, Vol. II, Procriação Medicamente Assistida, Utilização do Embrião, Colecção Temas 1, 1992.

Berger, s. d., "La Declaración Universal de la Unesco sobre el Genoma Humano y los Derechos Humanos", *Cuadernos de Bioética, 2,* 1998, págs. 387 – 405.

Biscaia, J., "O casal e a fecundidade", *Novos desafios à Bioética,* Porto Editora, Porto, 2001.

Campos, diogo leite / S. marcos neves, "O início da pessoa humana e da pessoa jurídica", *Revista da Ordem dos Advogados,* ano 61, Dezembro 2001, págs. 1257 – 1268.

Cárcaba Fernández, M., "*Los problemas jurídicos planteados por las nuevas técnicas de procreación humana*"; J.M. Bosch, Barcelona, 1995.

Centro de direito Biomédico, "*Comissão para o Enquadramento Legislativo das Novas Tecnologias – Utilização de Técnicas de Procriação Assistida (Projectos) ",* Publicações do Centro de Direito Biomédico da Faculdade de Direito da Universidade de Coimbra, nº 1, 1990.

Comissão da condição feminina, *Conselho da Europa – Procriação Artificial Humana: princípios orientadores,* Lisboa, 1990.

Comissão para o enquadramento legislativo das novas tecnologias*: Utilização de Técnicas de Procriação Assistida (Projectos) ",* Publicações do Centro de Direito Biomédico da Faculdade de Direito da Universidade de Coimbra, nº 1, 1990.

Conseil de l ´Europe, "*Le Droit au Respect de la Vie Privée et Familiale",* Dossier sur les Droit de L´Homme, 7, Strasbourg, 1985.

Côrte- real, Carlos Pamplona, "Os efeitos familiares e sucessórios da procriação medicamente assistida (PMA) ", *Estudos em Homenagem ao Professor Doutor Galvão Teles,* Vol. I, págs. 347 – 366.

Cortina, adela, "Bioética y Nuevos derechos humanos"*, in Problemas actuales de los Derechos Fundamentales,* Universidad Carlos III de Madrid, BOE, Madrid, 1994.

Costa, Cardoso da, "*Le Principe du Respect de la Dignité de la Personne Humaine dans les Jurisprudences Européennes"*, Editions du Conseil de l`Europe, Strasbourg, 1999.

Council of Europe, steering committee on Bioethics, "*Medical, Ethical and Social Aspects of Assisted Reproducción"*- (2001), Edited by Vayena, Effy/Patrick, Rowe/Griffin, David, in:**http://whqlib-doc.who.int/hq/2002/9241590300.pdf** (30/12/2022).

Gomes, José Antonio Cobacho, "*Comentarios a la Ley 14/2006 de 26 de Mayo, sobre Técnicas de Reprodución Humana Asistida",* Thomson Aranzadi, Madrid, 2007.

González Morán, L., "*Aspectos Jurídicos de la Procreación Humana Asistida: Aspectos Técnicos, Éticos y Legales",*(Javier Gafo Ed.), Publicaciones de la Universidad Pontificia Comillas, Madrid, 1998.

Guimarães, Ana Paula, "*Alguns Problemas Jurídico-Criminais da Procriação Medicamente assistida",* Coimbra Editora, Coimbra, 1999.

Human fertilisation and embryology authority (HFEA), "*The HFEA guide to infertility and directory clinics",* 2005/2006.

Idiákez Itiziar, Alkorta, "*Regulación Jurídica de la Medicina Reproductiva – Derecho Español y comparado",* Thomson Aranzadi, Navarra, 2003.

Idiákez Itiziar, Alkorta, "El caso Evans y el Derecho a no ser forzado a procrear", *in Revista de Derecho y Genoma Humano,* nº 24, enero/Junio 2006, págs. 129 – 153.

Lacadena, Juan Ramón, "La Ley 14/2006 sobre técnicas de reproducción humana asistida: consideraciones científicas y éticas*" in Revista de Derecho y Genoma Humano*, nº 24, 2006, págs. 157 – 184.

Lledó Yague F. y Ochoa Marieta C. y Monje Balmaseda O., "*Comentarios científico – jurídicos a la Ley sobre Técnicas de Reproducción Humana Asistida: Ley 14/2006 de 26 de Mayo",* Dykinson, Madrid 2007.

Machado, J. P., "Problemas éticos relativos à reprodução/procriação medicamente assistida", *Novos desafios à Bioética,* Porto Editora, Porto, 2001.

Melo, Helena, "Problemas jurídicos suscitados pela inseminação artificial com recurso a dador de gâmetas", *Genética e reprodução humana,* Gráfica de Coimbra, Coimbra, 2000, págs. 159/ss.

Mota Pinto, Paulo, "Indeminização em caso de "Nascimento Indevido" e de "Vida Indevida" ("Wrongful Birth" e "Wrongful Life"), *Lex Medicinae,* 4, 7, 2007.

Moutinho, Sandra, *"Tudo por um filho – Viagem ao mundo da infertilidade em Portugal",* Dom Quixote, 2004.

Neto, Luísa, *"O Direito Fundamental à Disposição sobre o Próprio Corpo (A Relevância da Vontade na Configuração do Regime),*Coimbra Editora, Coimbra, 2010.

Neto, Luísa, *"Novos Direitos (Ou Novo (s) Objectos para o Direito?),*Porto Editorial, Porto, 2010.

Neto, Margarida, "A fertilidade e infertilidade humanas-: a mulher, as técnicas e a ética", *A ética e o direito ao início da vida humana,* Gráfica de Coimbra, Coimbra, 2001, págs. 117 – 127.

Neves, Maria do Céu Patrão, "PMA: do Desejo de um Filho ao Filho Desejado", *Do início ao fim da vida – actas do colóquio de bioética,* Funchal, 18-19 Março 2005, Publicações da Faculdade de Filosofia da Universidade Católica Portuguesa, Braga, 2005, págs. 113 – 137.

Oliveira, Guilherme de, *"Mãe só há uma (duas)! O contrato de gestação"*, Coimbra editora, Coimbra 1992.

Osswald, Walter, "As Técnicas de procriação medicamente assistida com recurso a gâmetas estranhos ao casal (fertilização heteróloga) ", *Cadernos de Bioética,* Revista Portuguesa de Bioética, nº 40, Abril, 2006, págs. 7 – 11.

Pérez Luño A.E, "*La Tercera Generación de Derechos Humanos",* Aranzadi, Navarra, 2006.

Raposo vera Lúcia, "*O Poder de Eva – O Princípio da Igualdade no Âmbito dos Direitos Políticos – Problemas Suscitados pela Discriminação Positiva",* Almedina, Coimbra, 2004.

Raposo vera Lúcia, "*De mãe para mãe – Questões Legais e éticas suscitadas pela maternidade de substituição",* Coimbra Editora, Coimbra, 2005.

Raposo vera Lúcia, "*O direito á Imortalidade – O exercício de direitos reprodutivos mediante técnicas de reprodução assistida e o estatuto jurídico do embrião in vitro"* Almedina, Coimbra, 2014.

Romero Casabona, C., "*El derecho y la bioética ante los límites de la vida humana",* Ramón Aceres, Madrid, 1994.

Romero Casabona, C., (ed.) *"Código de Leyes Sobre Genética."* Cátedra de Derecho y Genoma Humano – Universidad de Deusto, Bilbao 1997.

Romero Casabona, C., "*El Convenio de Derechos humanos y Biomedicina - Su entrada en vigor en el ordenamiento jurídico español",* Comares, Bilbao-Granada, 2002.

Romero Casabona, C., "La Constitución Europea, un núcleo de los Derechos Humanos de la Medicina y la Biología", *Revista Lex Medicinae,* Revista Portuguesa de Direito da Saúde, Centro de Direito da Família da Faculdade de Direito da Universidade de Coimbra, ano 2, nº 3, Coimbra, 2005, págs. 5 – 8.

Romero Casabona, C., (ed.) "La cuestión jurídica de la obtención de células troncales embrionarias humanas con fines de investigación biomédica.

Consideraciones

Silva Paula Martinho e Costa Marta, " *A Lei da Procriação Medicamente Assistida Anotada",* Coimbra Editora – Grupo Wolters Kluwer, Lisboa, 2011.

Santos, Agostinho Almeida, "Reprodução Humana", *Ética em cuidados de Saúde",* Porto Editora, Porto, 1998, págs. 133 – 151.

Toro Pablo de Lora, *¿"*Que hay de malo en tener hijos*?", Anuario de la Facultad de Derecho de la Universidad Autónoma de Madrid – Derecho, Sociedad y Familia*: Cambio y Continuidad, n. º 10, 2006, págs. 45 -63.

Vale e reis, R., "Filhos depois dos 20…! Notas ao acórdão do Tribunal Constitucional nº 486/2004, de 7 de Julho", *Lex Familiae,* nº 3, ano 2, 2005, págs. 127 – 134.

Vale e reis, R., "*O direito ao conhecimento das origens genéticas",* Coimbra Editora, Coimbra, 2008.

Vale e reis, R., "Responsabilidade Penal na Procriação Medicamente Assistida – Criminalização do Recurso à Maternidade de Substituição e Outras Soluções Criminalmente Duvidosas"*, Lex Medicinae,* 7, 13, 2010.

Xavier, João Proença, "*Ensayo sobre la Problemática de los Embriones Excedentarios en la Reprodución Medicamente Asistida",* Tesina Doctorado *"Pasado y Presente de Los Derechos Humanos*, Salamanca, 2012.

Xavier, João Proença, "*Temas Fuertes de la Reproducción Asistida (en contexto ibérico)-Análisis comparativo da la Ley Española 14/2006 y la Ley Portuguesa 32/2006",* Universidad de Salamanca, 2016.

LEI PORTUGUESA de Procriação Medicamente Assistida:

http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=903&tabela=leis&so_miolo= (Lei 32/2006 pgdlisboa.pt versão Actualizada Lei 59/2007 de 4 de Setembro

http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?artigo_id=930A0004&nid=930&tabela=lei_velhas&pagina=1&ficha=1&nversao=1 (versão Actualizada Lei 59/2007 de 4 de Setembro onde o Artigo 4.º DA LEI nº59/2007 de 04 de Setembro - Aditamento à Lei n.º 32/2006, de 26 de Julho):

3 - É aditado o artigo 43.º-A à Lei n.º 32/2006, de 26 de Julho (procriação medicamente assistida), com a seguinte redacção: 'Artigo 43.º-A
Responsabilidade penal das pessoas colectivas e equiparadas
As pessoas colectivas e entidades equiparadas são responsáveis, nos termos gerais, pelos crimes previstos na presente lei.'

LEY ESPAÑOLA de Procreación Medicamente Asistida:

http://www.boe.es/buscar/pdf/2006/BOE-A-2006-9292-consolidado.pdf

(Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida.

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TECHNOLOGIES, VULNERABILITIES AND THE DOCTOR-PATIENT RELATIONSHIP

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Abstract: the most different technologies are daily involved in various human activities, and it is no different with medical practice. Over the last few decades, Medicine has been strongly influenced by the adoption and development of different technologies that not only brought solutions to secular medical problems, but also brought with them new ethical and legal challenges. This article, based on doctrinal research, seeks to discuss how technologies can contribute to bringing doctors and patients closer together, while, if misused or misunderstood, they can deepen vulnerabilities and even hinder access to health systems. If in fact Medicine and new technologies are inseparable, it is also true that comprehensive care can only be achieved from a dialogued relationship between doctor and patient capable of establishing true bonds of trust between them.

Keywords: Technology; Autonomy; Vulnerabilities; Physicians; Patients; Medicine

1. INTRODUCTION

Etymologically, the word technology originates from two Greek radicals: *téchné* (designates an ability to do something) and *lógos* (reason, thought). In the way it has become popular today, its origin is associated with the English term *technology*, closely linked to the projects of Modernity (from the 18th to 19th centuries), the period in which it was developed and structured, being

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understood generically as "the knowledge of the relationships, the order and division of disciplines"[2]; "set of essential principles for knowledge"[3-4].

According to Paiva[5], "most concepts refer to something related to producing, but which is not essentially the mode, but an intelligence that both conceives the organization of these modes, articulates them and optimizes an objective realization, as well as manages the development of the process and results".

Understood as a set of activities aimed at satisfying human needs, throughout the 20th century and in this first quarter of the 21st century, technologies gained important spaces in medical practice, establishing themselves not only as a special component of great clinical discoveries[6], but also, spreading out in the doctor-patient relationship itself[7], being, to a certain extent, inseparable from it. Technology, then, ceases to be just knowledge for production, to be understood as essential knowledge about the process itself[8] and, in the case of Medicine, about health and disease processes.

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2 HERBON, João Henrique Alstead. **Enciclopedia**. [s.l.]: [s.n.].

3 PAIVA, José Eustáquio Machado. Um estudo acerca do conceito de tecnologia. **Revista Educ. Tecnol.**, Belo Horizonte, jan./dez. 1999, p. 5-10. p. 5.

4 According to Paiva "technology, if understood within the scope of the human capacity to build itself (environmental structures, in a broad sense, processes and projects, in a strict sense) firstly translates a logic that cannot be understood in an atomized way, but from a more globalized view of man himself and his intentions, objectives and actions, and which is revealed through the notion of 'plan' – 'world project'. The very notion of 'projecting' implies a belief in being able to control the future […]" (*id*., 1999, p. 7).

5 *Id*., 1999, p. 5.

6 What is interesting is that a good part of the discoveries and development of medical procedures at the end of the last century and beginning of this century involved the participation of engineers (from the most diverse areas), to the point of affirming the disease as a technical problem and every technical problem must have a technical solution. (HARARI, Yuval Noah. **Homo Deus**: uma breve história do amanhã. São Paulo: Companhia das Letras, 2016. p. 32).

7 See, for example, the broad development of health telematics characterized by the combined application of telecommunication and information technology to health activities aimed at promotion, prevention and cure, individually or collectively, and which allow communication between health professionals or between these and their physically distant patients (telemedicine), as well as can be used to promote improvement and training courses for health professionals, dissemination of knowledge, health management (public and private), exchange of information between professionals about patients unidentified (telehealth) (SCHAEFER, Fernanda. Telemedicina: conceituar é preciso. *In:* SCHAEFER, Fernanda; GLITZ, Frederico (Coords.). **Telemedicina**: desafios éticos e regulatórios. São Paulo: Foco, 2022).

8 PAIVA, *op. cit.* , p. 6.

This article, based on a doctrinal study, proposes a reflection on how the doctor-patient relationship has been influenced by using different technologies and how these can aggravate or reduce the various vulnerabilities inherent to this relationship. To do so, it starts with the concepts of communication and information and communication technologies[9] (ICTs) to then analyze how the doctor-patient relationship develops in an environment marked by attempts at domination leveraged by seductive discourses that promote the most varied technologies of health.

2. TECHNOLOGIES IN THE DOCTOR-PATIENT RELATIONSHIP

The end of the 20th century and the beginning of the 21st century present a promising package called Information and Communication Technologies (ICTs)[10], understood as a set of different solutions that come together in different resources, to facilitate communication, enabling fast access, storage, the processing, and dissemination of information of the most varied contents (including Medicine).

9 "The MIT mathematician Norbert Wiener, the man who popularized cybernetic theory, defined information as the 'name for the content of what is exchanged with the outside world when we adjust to it and for those adjustments to fall on it. The process of receiving and using information is a process of adjusting ourselves to the contingencies of the external environment and of living effectively within that environment'. Thus, information consists of countless messages and instructions that go back and forth between things and their environment" (RIFKIN, Jeremy. **O século da biotecnologia**. São Paulo: Makron Books, 1999. p. 192).

10 "Information and Communication Technologies (ICTs) can be defined as the total set of technologies that allow the production, access and dissemination of information, as well as technologies that allow communication between people. […]" (RODRIGUES, Ricardo B. *et al*. A cloud-based recommendation model. *In*: *Euro American Conference on Telematics and Information Systems,* 7., 2014). There is some controversy about the concept: "However, there are researchers (such as KENSKI, 2008) who use the term Digital Technologies of Communication and Information (TDICs) to refer to digital technologies connected to a network and there are still others (VALENTE, 2013, for example) that name the TDICs from the convergence of various digital technologies such as: videos, *softwares*, applications, *smartphones*, images, consoles, virtual games, which come together to compose new technologies. TDICs refer to any electronic equipment that connects to the internet, expanding the possibilities of communicability for its users (VALENTE, 2013). We can also apply the definitions on ICTs, in a more comprehensive way, when it becomes possible to include in the scope of its definition, in addition to digital technologies – such as the computer –, other types of technologies, such as optical and analogue ones" (ANJOS, Alexandre Martins; SILVA, Glaucia Eunice Gonçalves. **Tecnologias digitais da informação e da comunicação (TDIC) na educação**. Universidade Aberta do Brasil. Ministério da Educação. [s.l.]).

Technological (r)evolution supported by these technologies has had substantial development in recent decades, and since then, the possibilities and tools offered are simultaneously and paradoxically bigger and smaller, undoubtedly amazing and require constant improvement of human relations.

According to Tatiana Malta Vieira (2007, p. 21)[11] "the world is dazzled by the new paths of knowledge; information technology illuminates horizons in all spheres: it invades everyday life, changes the way companies produce, modifies activities in the public and private sectors, transforms people's cultural patterns and forms of relationships, in short, it revolutionizes the way conception of life that until then guided the actions of individuals, and man awakens in the universe of technology, lets himself be captivated by the machine that offers perspectives of interaction never experienced before, exposing himself, and the other side, more and more in his intimacy and private life, given the new computational resources".

It is from the seductive and captivating magic of the new ICTs that a major problem results: the foundation of what is intended by technology is still concentrated in the principles of Modernity that inform its *ethos*.

Two centuries ago, it was understood that technology allowed man to dominate and manipulate the means of production. However, today, the person has also become a means, which, stripped of its most elementary subjectivities, becomes an object of domination again. The subject, protagonist of his choices, becomes a production resource, separated from his self-determination and, therefore, forgotten in decision-making processes (which now, ingeniously, can even be replaced by artificial intelligence *software*).

So, how would it be possible to talk about dialoguing relationships and respect for freedoms, when new technologies (in the best "Matrix" style – 1999 science fiction film) brings the perpetuation of situations of domination that do not even allow people to notice that their conduct is being determined by companies and governments?

This is so because of its "pervasiveness in all spheres of human activity [...]. Of course, technology does not determine society. [...]. In fact, the dilemma of technological determinism is probably an unfounded problem, given that technology is society, and society cannot be understood or represented in its

11 VIEIRA, Tatiana Malta. **O direito à privacidade na sociedade da informação**. Porto Alegre: Sérgio Antonio Fabris, 2007. p. 21.

technological tools. [...]. However, although it does not determine technology, society can stifle its development mainly through the State. Or else, also mainly through state intervention, society can enter into an accelerated process of technological modernization capable of changing the fate of economies, military power and social well-being in a few years"[12].

There is no doubt: technologies allow the potentialization of resources to optimize results[13]. But it is also true that these same technologies can bring different forms of manipulation, discrimination, and destabilization. According to Harari[14], "even doctors are easy opponents for algorithms[15]. The first and main task of most of them is to diagnose diseases and suggest the best possible treatment", as for example the *Watson Heatlh*, artificial intelligence of IMB[16].

And how artificial intelligence *softwares* were tested during the Covid-19 pandemic! Doctors from all over the world joined forces to try to speed up diagnoses and propose effective treatments for the then mysterious disease that was plaguing the world[17]. But maybe they forgot two basic premises: to insert test data or the test itself in applications or *softwares* for analysis and diagnostic aid, it is necessary to obtain the informed consent of the patient, which many simply left aside, trusting in a supposed pseudo-anonymization and generically invoking collective interest. In addition, they forgot that artificial intelligence devices learn from the data they are receiving. So, depending on the samples inserted, biases (representation or assimilation errors) not noticed by physicians can lead to absolutely wrong or ineffective diagnoses and treatments.

What is meant by this example is that medical technology and its potential advantages are not enough. It must be associated with the physician's own

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12 CASTELLS, Manuel. **A sociedade em rede**. 6a. ed. São Paulo: Paz e Terra, 2005. p. 43-44.

13 PAIVA, *op. cit*., p. 7.

14 HARARI, *op. cit*., p. 319.

15 "Algorithms are mathematical structures. Equations and formulas that represent paths for processing information (signs and symbols), generating results that predict probabilities" (TEIXEIRA NETO, Felipe; FALEIROS JÚNIOR, José Luiz de Moura. Dano moral coletivo e falhas algorítimicas: breves reflexões. *In*: Miranda; BRAGA NETTO, BARBOSA, Mafalda Miranda; BRAGA NETTO, Felipe; SILVA, Michael César; FALEIROS JÚNIOR, José de Moura (Coords.). **Direito digital e inteligência artificial**: diálogos entre Brasil e Europa. São Paulo: Foco, 2021. p. 235-260. p. 236).

16 See: https://www.ibm.com/br-pt/watson-health . Accessed on 15 Jan. 2022.

17 One of the *software* that quickly became popular is Lunit Insigth CXR, a digital diagnostic tool and cloud computing that reads radiological exams and helps to screen, identify and monitor patients with Covid-19. See: https://news.microsoft.com/pt-br/ia-e-raios-x-identificando-as-muitas-faces-da-covid-19/

knowledge, clinical experience, and proximity to the patient[18], in addition to taking into account the user's own needs. Technologies should not be considered a threat to the general doctor or the specialist! They must be considered as promoters of a rapprochement between all the protagonists of the doctor-patient relationship, who must keep their conduct guided by bioethical principles such as responsibility, beneficence, and non-maleficence.

According to Harari[19], "of course, not all human doctors are going to disappear. Tasks that require a higher level of creativity than routine diagnostics will remain in human hands for the foreseeable future." But provokes the author, although it is said that nothing is capable of replacing true human communication[20], "would you like to receive the news [a bad diagnosis] from a caring and sympathetic human doctor or from a machine"? Knowing that not all doctors are empathetic and the lack of empathy of machines can be technically solved, the author continues: "how about receiving news from a caring and friendly machine that models the words you pronounce according to your personality type rather than receiving it from an emotionally distant doctor?

The collective unconscious seems to be molding archetypes to technology, which would lead many people to immediately answer the previously proposed questions, without even going through a process of interiorization and reflection. Security, stability, reliability, predictability seem to be

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18 It should be emphasized here that the use of the expression "proximity to the patient" is not referring to the presence of medical acts. Proximity is what is close to something, neighboring, it is the one who knows the clinical history of his patient and keeps an eye on him. Although face-to-face contact is still considered the gold standard of consultation (art. 6th., §1st., Resolution n. 2.314/22, Federal Council of Medicine), there is no denying the importance of telemedicine and telehealth for current medical practice. See Resolution n. 2.314/22: https://sistemas.cfm.org.br/normas/arquivos/resolucoes/BR/2022/2314_2022.pdf . Accessed on 15 Jan. 2022.

19 HARARI, *op. cit.*, p. 319-320.

20 According to the author, "the idea that humans will always have an exclusive aptitude, beyond the reach of non-conscious algorithms, is a chimera. Science's current response to this impossible dream can be summarized in three simple principles: 1. Organisms are algorithms. Every animal – including *Homo sapiens* – is an assembly of organic algorithms shaped by natural selection over millions of years of evolution. 2- Algorithm calculations are not affected by the materials with which the calculator is built. Whether you build an abacus from wood, iron or plastic, two beads plus two beads always equal four beads. There's no reason to think that organic algorithms can do things that non-organic algorithms won't be able to match or surpass. If the calculations remain valid, what does it matter whether the algorithms manifest themselves in carbon or silicon?" (*id.*, 2016, p. 322).

watchwords when talking about ICTs and even more when associated with medical practices. Excessive attachment to technologies is perverse and leads to the creation of artificial needs or false perceptions that can lead to dangerous herd behavior.

It is not uncommon for a patient to feel uncomfortable when entering an office in which the doctor does not use computers, but clinical files still written by hand. The feeling that that doctor is not up to date would be present throughout the consultation and, without a doubt, would bring fears to the patient who, possibly, will leave their insecure about the diagnosis and ready to look for another professional who has at least one computer on the table.

The worst thing about this situation is that it is known that this patient's assumptions can be fallacious: the lack of a computer does not mean that the doctor does not keep up to date, but on the contrary, it can be one of those situations in which the physician invests more in dialoguing with the ill than taking notes in electronic medical records. Likewise, the presence of a computer cannot be associated with knowledge, as it may result from a simple choice to facilitate filling out medical documents.

However, the collective unconscious has created that first scenario, which the patient cannot immediately get rid of. The adoption of standardized behaviors and the attachment to technology do not allow reflection on the situation that is presented to them, the patient succumbing to appeals that do not always reflect the reality of the professional who consulted.

According to Parchen, "to combat normosis, it is necessary to break with the paradigm of technological dependence: what one should truly expect as excellence from each individual who wants to be free and have their plurality and diversity respected, is the rebellion against any and all attempts to mitigate or annihilate the complex and nuanced human condition [...]. In this sense, it can no longer be consistent with mediocrity matters due to the massive use of, for example, social networks and algorithms"[21].

The dilemma is set and there is no single solution or possible choice. Complex dilemmas are just that, the choice between choosing one of several equally

21 PARCHEN, Charles Emmanuel. Virtude e rebeldia contra a normose da tecnologia. *In*: COLOMBO, Cristiano; ENGELMANN, Wilson; FALEIROS JÚNIOR, José de Moura (Coords.). **Tutela jurídica do corpo eletrônico**: novos desafios ao direito digital. São Paulo: Foco, 2022. p. 263-279. p. 276.

possible moral solutions. The advancement of technology in Medicine is inseparable from it, just as it seems necessary that human communication between doctor and patient needs to be maintained (at least because of the fallibility of the resources available today) and constantly improved.

3. TECHNOLOGIES, COMMUNICATION AND VULNERABILITIES IN THE DOCTOR-PATIENT RELATIONSHIP

Communication, whatever its modality (written, verbal, gestural, digital) is essential to human nature and sociability since people constantly seek to "lead other people to adopt the point of view of the speaker"[22]. And what is the doctor-patient relationship if not communication (as a relational process)?

It starts from the general idea that although technology does not determine society, it is (or lack thereof) a decisive factor in social transformations and their development. It is in the face of this scenario that we can ask: is it still possible to talk about patient autonomy?

In general terms, for Bioethics, autonomy means that one can not only resort to self-determination (proper of Law), but help the patient to go to the limits of himself, helping him to discover and choose what is in accordance with his their own values. "In Bioethics, respect for autonomy includes, therefore, everything that the law says about self-determination and adds attention to the good of the other and others, concern for each one, the attitude that helps"[23]. It is not, therefore, all or nothing (like Kantian autonomy), but rather the possibility of making thoughtful decisions after processes of broad and qualified information. It is about respect for the capacity for decision and action (self-government), regardless of the rules of civil capacity.

For Law, autonomy, as a decision-making power in existential legal situations, is associated with what is called self-determination, which is closely linked to the idea of positive freedom, that is, the possibility of individuals guiding themselves according to their own will, a corollary of the dignity of human person. It is, therefore, about protecting life choices, respecting the legal limits.

"It is linked to the meaning that belongs to man – in his intrinsic value – in the fulfillment of his mission in this world, implying a commitment of the State

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22 BERLO, David. **O processo da comunicação**: introdução à teoria e à prática. 10ª. ed. São Paulo: Martins Fontes, 2003. p. 9.

23 DURAND, Guy. **Introdução geral à bioética**. São Paulo: Loyola, 2003. p. 177-178.

and people – mutual respect and protection – towards the life and freedom of each one, with the certainty that the virtues of each one will be able to expand and become concrete. It is consistent with the *ratio juris*, whereby 'dignity is a spiritual and moral value inherent in the person, which is uniquely manifested in the conscious and responsible self-determination of one's own life and which brings with it the claim to respect on the part of other people', in the aspect not to underestimate the esteem of anyone as a human being"[24].

Recognizing the importance of communication and ICTs for medical practice is easy, see the recognition of the value of Telemedicine[25] during the pandemic caused by Sars-CoV-2 (Covid-19), a value that until then was highly questioned by many Brazilian doctors who ended up adhering to it and today defend it. The challenge focuses on verifying if doctors and patients are prepared to accept, use and benefit from ICTs and their promises.

In this context, in which the informational model is based on technology for generating knowledge, fast processing of information and communication of signs and symbols, the doctor's functions are bound to change, since part of his classic authority is transferred to the patient, who must be recognized and valued as the protagonist of their health process.

Until recently, communication was divided into three distinct objectives: to inform (teaching); persuade (advertising) and amuse. However, recent studies show that every use of language has some persuasive dimension, that is, "no one can communicate without some attempt to persuade, in one way or another"[26], which is enhanced in relationships in which knowledge can be used as an object of domination (such as medical practice).

Although medical paternalism has been abandoned for some time[27], remnants of domineering behavior, resulting from the knowledge about health and disease

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24 COAN, Emerson Ike. Biomedicina e biodireito. Desafios bioéticos. Traços semióticos para uma hermenêutica constitucional fundada nos princípios da dignidade da pessoa humana e da inviolabilidade do direito à vida. In: SANTOS, M.C.C.L. (Org.). **Biodireito** – ciência da vida, os novos desafios. São Paulo: Revista dos Tribunais, 2001. p. 246-266. p. 258.

25 SCHAEFER, Fernanda. Lei geral de proteção de dados pessoais, telemática e saúde e proteção de dados de saúde durante a pandemia. *In*: SCHAEFER, Fernanda; GLITZ, Frederico (Coords.). **Telemedicina**: desafios éticos e regulatórios. São Paulo: Foco, 2022.

26 BERLO, *op. cit.,* p. 9.

27 SCHAEFER, Fernanda; FALEIROS JUNIOR, José de Moura. Inovação, novas tecnologias e a relação médico-paciente: algumas perspectivas sobre telemedicina e desenvolvimento algorítmico. *In*: SÁ, Maria de Fátima Freire; ARAÚJO, Ana Thereza

processes, can be verified daily in different types of consultations and is still present in several medical documents. The professional, even if unconsciously, tries to convince his patient of his truths and choices, forgetting to treat the patient as someone, who, with multiple intelligences and experiences, may be able to self-determine, interact, decide.

So, when analyzing the communication, it is necessary to consider the behavior of the sender and the receiver, and not just the intended or transmitted message. Therefore, the objective of the communication must be specified in such a way that: it is not logically contradictory or inconsistent with itself; focus on behavior, that is, be expressed in terms of human behavior; be specific enough that we can relate it to actual communication behavior; be consistent with how people communicate[28]. It is about clear, precise, objective, true[29], empathetic communication that we are talking about here, even when mediated by ICTs.

ICTs can and should be part of the doctor-patient relationship, but they cannot be used disconnected from the patient's social, educational, and personal reality. If, on the one hand, they can bring the health professional closer to the patient, on the other hand, they can distance them in a way that causes irreparable damage. It is about balance that you are talking about here. The use of ICTs that can approximate and *humanize*[30] the relation, allowing communication to be more sensorial, multidimensional, and coherent.

Meirelles; NOGUEIRA, Roberto Henrique Pôrto; SOUZA, Iara Antunes (Coords.). **Direito e Medicina**: interseções científicas. Relação médico-paciente. Belo Horizonte: Conhecimento, 2022. p. 185-199.

28 BERLO, *op. cit.,* p. 10.

29 About the elements of information, according to Fernanda Nunes Barbosa (2008, p. 61-62) that "clear information would be that in which the most appropriate qualitative signs are used, to enable the receiver to correctly interpret the message. Precise information, in turn, would be that in which the characters of accuracy, punctuality and fidelity participate, which also occurs through the correct choice of symbols by the sender of the message. This requirement responds to a principle of message economy. Complete information is that in which the sender, in the coding operation, uses signs (linguistic sounds, graphic signs, gestures) and symbols that fully represent the novelty. Truthful is the characteristic of information that corresponds to the truth of what is intended to be made known to the other. It is the correspondence between what one wants to make known and objective reality. Finally, comprehensible information will be the one that most context analysis will request, as it will require the sender to apprehend the reality of the receiver, so that the message can be effectively understood by him [...]. The adequacy requirement, according to Neto Lôbo, depends on the means of information used and the respective content. The means must be compatible with the product or service offered [...]" (BARBOSA, Fernanda Nunes **Informação**: direito e dever nas relações de consumo. São Paulo: Revista dos Tribunais, 2008. p. 61-62).

30 The expression humanize is used for lack of a better one. In fact, it is not the most

For this, it is necessary to understand the "displacement of the subject and his conscience from the center of the social world, which faces the language and discourses that define the performed as in constant movement". That is why a doctor, when adopting communication and information technologies in his clinical practice, must first consider the different realities and needs of his patients.

For this, the physician must understand that technological archetypes cannot be taken as premises for action. This means stating that the limitations and individual characteristics of the patient must be considered before introducing ICTs into the relationship. We can start from the most basic hypothesis: does the patient have access, for example, to a *smartphone* and an *Internet network*? Having, he knows how to use them easily or will need help from a third party? Can the patient see the instructions on the screen? Does the user know or can read, write, and interpret? Does the camera to which the patient has access have sufficient quality for image transmission? Simple questions, but not always anticipated due to technological archetypes: "everyone has them and everyone knows how to use them".

The truth is that "what will determine whether technology dehumanizes, depersonalizes or objectifies is not the technology itself, but the way in which they are operated in the most different contexts and the meanings that are attributed to them in the most diverse spaces of medical practice"[31]. Thus, for example, the adoption of any technology by the doctor will necessarily imply the adoption of assistive technologies[32] that guarantee access and comprehensiveness of the service with the required and expected quality. The focus of medical conduct must be on the patient (humanism) and not on the disease (paternalism) or on technologies.

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appropriate term when referring to a relationship that takes place between two people and whose object is special: health.

31 BODDINGTON, Paula. Big Data, Small Talk: Lessons from the ethical practices of interpersonal communication for the management of biomedical Big Data. *In*: MITTELSTADT, Brent Daniel; FLORIDI, Luciano (Ed.). **The ethics of biomedical Big Data**. Cham: Springer, 2016.

32 From the definition brought by the *American with Disabilities Act* (ADA), Cook and Hussey use the expression assistive technology as "a wide range of equipment, services, strategies and practices designed and applied to alleviate the functional problems encountered by individuals with disabilities" (COOK, AM; HUSSEY, SM Assistive Technologies: Principles and Practices. St. Louis, Missouri, USA. Mosby - Year Book, 1995). Taken in its broadest sense, assistive technology should be understood as an aid that will promote the expansion of a deficient functional skill or enable the performance of the desired function that is impeded by circumstances such as disability or aging.

Thus, for communicative interaction to take place, it is necessary for the doctor and patient to be fully aware that the relationship established between them, even if it may be mediated by technological devices, that's because human relationships have several complexities (including the produced by the disease itself) from different experiences[33] - which are not easily understood and apprehended by the algorithms currently available on the market.

As noted, this article is far from trying to present any ethical or legal solution for the adoption of information and communication technologies by physicians. It is concerned with revisiting the alerts to prevent vulnerabilities widely known by Law and Bioethics from being aggravated by the unconditional adoption of new technologies.

The medical practice that privileges the technique, instead of the person, is doomed to failure, not only because the patient will feel like just another number in the medical record, but because his personal values were ignored in a very sensitive moment of his life: the disease. The evaluative interactions, so appreciated today, cannot be replaced by relations of subordination to technical knowledge or technology.

And this is where the need arises to talk not only about digital education, but also about health literacy[34], that is, the subject, in addition to having minimal skills in handling technologies, needs to be able to understand health information, read instructions that are forwarded to him, to understand the prescriptions and make appropriate decisions.

In *The Lancet* Editorial of November 12, 2022[35], *Why is health literacy failing so many?,* the journal highlighted the importance of health literacy for good health and well-being and as an instrument that informs communities, making them able to adopt a more balanced lifestyle.

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33 "What exactly are experiences? It is not empirical data. An experience is not made of atoms, proteins or numbers. An experience is indeed a subjective phenomenon that includes three main ingredients: sensations, emotions and thoughts. In each moment, my experience encompasses every sensation I have (warmth, pleasure, tension, etc.), every emotion I feel (love, fear, anger, etc.), and any thoughts that run through my head. […]. Experiences and sensibility increase reciprocally in an endless cycle" (HARARI, *op*. cit., p . 243-244).

34 , Lara Miguel Quirino; CÂNDIDO, Viviane Cristina; ARAÚJO, Luciano Vieira. Envelhecimento e telemedicina: desafios e possibilidades no cuidado ao idoso. **Poliética**, São Paulo, v. 9, n. 2, p. 40-72, 2021.

35 See: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)02301-7/fulltext a

Health literacy was expressly recognized by the 2016 WHO Shanghai Declaration[36] and is now considered an important tool for achieving Goal 3 of the United Nations Sustainable Development Goals (SDGs)[37]. This instrument helps to enable people to take care of and take responsibility for their own health, preventing diseases, preventing the worsening of certain conditions, and making healthier choices. It is also with health literacy that users get to know the health system and the actions and services offered, how to access them and how to benefit from them.

However, health literacy cannot be reduced to just these aspects. The approach must take social, structural, and commercial factors that define the choices and lead to certain behaviors and health decisions of the general population. It should also advance in addressing non-communicable diseases and issues related to aging, conducted not only by health professionals, but also by community organizations of different natures and by inclusion in school at different levels of training. The Editorial concludes by stating that "every person has the right to health. The ability to realize this right depends on everyone understanding their health, being able and empowered to make healthy choices, and being able to access effective interventions".

Therefore, in addition to technology literacy, health literacy cannot be neglected when inserting ICTs in the doctor-patient relationship. Technologies must be treated as a means for carrying out medical acts, never as an end in themselves, nor as a substitute for the doctor-patient relationship.

The fact is that it is not enough to provide access to technology, it is necessary to ensure both the health professional and the patient are trained in its use, in addition to guaranteeing the full exercise of autonomy in these environments (which is not limited to the assumptions of the informed consent). Human participation, whatever the technological modality present, will always be a central element of the doctor-patient relationship and, therefore, communication, regardless of the medium in which it is developed, must always be able to establish bonds of trust between the healthcare professional and the patient.

36 Shanghai Declaration, WHO, 2016: https://www.who.int/publications/i/item/WHO-NMH-PND-17.5a

37 To learn about the SDGs, visit: https://brasil.un.org/pt-br/sdgs

4. FINAL CONSIDERATIONS

In the words of José Manuel Moran "there is a new re-enchantment for technologies because we participate in a much more intense interaction between the real and the virtual", which naturally imposes the reorganization of theoretical references of different social, political, professional structures and educational[38]. The present can no longer be analyzed only with its relations with the past but must also address the possibilities pointed out for the future.

If in the past Medicine was associated with priests, shamans, witches, and disease linked to divine punishment, today the practice of medical acts is associated with qualified professionals who must have respect for the human condition as a prerequisite for their work. To trust blindly in technological resources is to go back to the time when everything happened because some deity so determined, or, nowadays, because an algorithm like that said it should be.

This is what the present article intends to affirm: Medicine, which today is inseparable from communication and information technologies, cannot forget its human side, after all, it should not be the technology that determines social relations, but rather a means through which these develop.

If the disease is no longer a divine punishment, but a technical problem to be technically solved, doctors should not distance themselves from the most essential element of this relationship: dialogue, intermediated or not by communication and information technologies, but which necessarily respect all the subjective dimensions and the capacity of understanding, apprehension, and self-determination of the receiver of the message.

If ICTs cause substantial advances in Medicine, their use must be associated with patient protection in all its dimensions and complexities. The introduction of new technologies cannot deepen existing vulnerabilities or cause new inequalities in health systems. On the contrary, they can and should be associated with increased communication between health professionals and patients and the facilitation of access to health, also because it is impossible to standardize subjectivities to establish a single form of communication and action.

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38 MORAN, José Manuel. Novas tecnologias e o re-encantamento do mundo. **Revista Tecnologia Educacional**. Rio de Janeiro, v. 23, n. 126, set.-out. 1995, p. 24-26. p. 25.

Doctors and patients must be direct collaborators in the healing or treatment process, encouraging constant communication and active dialogue, in a context that requires both to collaborate reciprocally and constantly adjust, with technologies as an important intermediary and not as a defining archetypes dissociated from social realities.

5. REFERENCES

ANJOS, Alexandre Martins; SILVA, Glaucia Eunice Gonçalves. **Tecnologias digitais da informação e da comunicação** (TDIC) na educação. Universidade Aberta do Brasil. Ministério da Educação.[s.l.].

ARAÚJO, Lara Miguel Quirino; CÂNDIDO, Viviane Cristina; ARAÚJO, Luciano Vieira. Envelhecimento e telemedicina: desafios e possibilidades no cuidado ao idoso. **Poliética**, São Paulo, v. 9, n. 2, p. 40-72, 2021.

BARBOSA, Fernanda Nunes. **Informação**: direito e dever nas relações de consumo. São Paulo: Revista dos Tribunais, 2008.

BERLO, David. **O processo da comunicação**: introdução à teoria e à prática. 10ª. ed. São Paulo: Martins Fontes, 2003.

BODDINGTON, Paula. Big Data, Small Talk: Lessons from the ethical practices of interpersonal communication for the management of biomedical Big Data. *In*: MITTELSTADT, Brent Daniel; FLORIDI, Luciano (Ed.). **The ethics of biomedical Big Data**. Cham: Springer, 2016.

CASTELLS, Manuel. **A sociedade em rede**. 6a. ed. São Paulo: Paz e Terra, 2005. p. 43-44.

COAN, Emerson Ike. Biomedicina e biodireito. Desafios bioéticos. Traços semióticos para uma hermenêutica constitucional fundada nos princípios da dignidade da pessoa humana e da inviolabilidade do direito à vida. In: SANTOS, M.C.C.L. (Org.). **Biodireito** – ciência da vida, os novos desafios. São Paulo: Revista dos Tribunais, 2001. p. 246-266.

COOK, A.M. & HUSSEY, S. M. Assistive Technologies: Principles and Practices. St. Louis, Missouri, EUA. Mosby - Year Book, 1995

DURAND, Guy. **Introdução geral à bioética**. São Paulo: Loyola, 2003.

HARARI, Yuval Noah. **Homo Deus**: uma breve história do amanhã. São Paulo: Companhia das Letras, 2016.

MORAN, José Manuel. Novas tecnologias e o re-encantamento do mundo. **Revista Tecnologia Educacional**. Rio de Janeiro, v. 23, n. 126, set.-out. 1995, p. 24-26.

PAIVA, José Eustáquio Machado. Um estudo acerca do conceito de tecnologia. **Revista Educ. Tecnol.**, Belo Horizonte, jan./dez. 1999, p. 5-10. p. 6.

PARCHEN, Charles Emmanuel. Virtude e rebeldia contra a normose da tecnologia. *In*: COLOMBO, Cristiano; ENGELMANN, Wilson; FALEIROS JÚNIOR, José de Moura (Coords.). **Tutela jurídica do corpo eletrônico**: novos desafios ao direito digital. São Paulo: Foco, 2022. p. 263-279.

RIFKIN, Jeremy. **O século da biotecnologia**. São Paulo: Makron Books, 1999.

SCHAEFER, Fernanda. Lei geral de proteção de dados pessoais, telemática e saúde e proteção de dados de saúde durante a pandemia. *In*: SCHAEFER, Fernanda; GLITZ, Frederico (Coords.). **Telemedicina**: desafios éticos e regulatórios. São Paulo: Foco, 2022.

_____. Telemedicina: conceituar é preciso. *In:* SCHAEFER, Fernanda; GLITZ, Frederico (Coords.). **Telemedicina**: desafios éticos e regulatórios. São Paulo: Foco, 2022.

_____. SCHAEFER, Fernanda; FALEIROS JUNIOR, José de Moura. Inovação, novas tecnologias e a relação médico-paciente: algumas perspectivas sobre telemedicina e desenvolvimento algorítmico. *In*: SÁ, Maria de Fátima Freire; ARAÚJO, Ana Thereza Meirelles; NOGUEIRA, Roberto Henrique Pôrto; SOUZA, Iara Antunes (Coords.). **Direito e Medicina**: interseções científicas. Relação médico-paciente. Belo Horizonte: Conhecimento, 2022. p. 185-199.

TEIXEIRA NETO, Felipe; FALEIROS JÚNIOR, José Luiz de Moura. Dano moral coletivo e falhas algorítimicas: breves reflexões. *In*: BARBOSA, Mafalda Miranda; BRAGA NETTO, Felipe; SILVA, Michael César; FALEIROS JÚNIOR, José de Moura (Coords.). **Direito digital e inteligência artificial**: diálogos entre Brasil e Europa. São Paulo: Foco, 2021. p. 235-260.

VIEIRA, Tatiana Malta. **O direito à privacidade na sociedade da informação**. Porto Alegre: Sérgio Antonio Fabris, 2007.

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HEALTH LITERACY AS AN ESSENTIAL TOOL FOR GOOD COMMUNICATION IN THE PROCESS OF OBTAINING INFORMED CONSENT

Ronaldo Piber[1] and Clovis Francisco Constantino[2]

Abstract: In the doctor-patient relationship, communication is one of the foundations for obtaining informed consent (IC). However, for the patient to make a decision based on accurate information, he needs to understand the information that is offered by the doctors during the consultation. Thus, the processes associated with Health Literacy (HL) were investigated in this study as a precise measure of communication with patients, regardless of their level of education.

Keywords: Health Literacy; Communication; Informed Consent; Physician-Patient Relationship; Autonomy

1. Introduction

From a moral, social and legal point of view, the notion of autonomy today is based on the inherent freedom of the human person[3]. Individual freedom requires rationality, the capacity for spontaneity and the ability to resolve their own disputes[4]. This is referred to as our "free will".

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3 Atkins K. Autonomy and autonomy competencies: a practical and relational approach. Nurs Philos [Internet]. outubro de 2006;7(4):205–15. Available at: https://onlinelibrary.wiley.com/doi/10.1111/j.1466-769X.2006.00266.x

4 Müller S, Walter H. Reviewing Autonomy: Implications of the Neurosciences and the Free Will Debate for the Principle of Respect for the Patient's Autonomy. Cambridge Q Healthc Ethics [Internet]. 12 de abril de 2010;19(2):205–17. Available at: https://www.cambridge.org/core/product/identifier/S0963180109990478/type/journal_article

It is essential to note that the concern for autonomy appears in themes that allude to the individual's intimacy and privacy[5]. In other terms, according to their own project, the person is his or her own life's leader.

A high level of protection to the person and to their dignity, once understood as the maximum value of the democratic rule of law, is required by the bioethics of the new millennium[6], which is attuned to the growing process of humanization of the sciences and seeks to give the individual special attention and respect by honoring autonomy and the free expression of their will.

In the medical area, the dignity of the person is incorporated in the physician's requirement to inform the patient about the procedures to which he will be submitted and for which he must provide informed authorization[7]. This is because, following the axiological valuation of the characteristics and existential elements of the person, the current approach considers the patient a subject of rights, and not just a spectator of medical action or even an object of scientific research.

Competence, communication, comprehension, willingness, and consent are the five distinguishable elements of IC[8]. This means that, they are the requirements that establish the legitimacy of IC. When a patient's IC to treatment is the result of a clear[9], comprehensive[10], and engaging communication process[11], both patients and health care teams benefit.

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5 Zhang H, Zhang H, Zhang Z, Wang Y. Patient privacy and autonomy: a comparative analysis of cases of ethical dilemmas in China and the United States. BMC Med Ethics [Internet]. 2 de dezembro de 2021;22(1):8. Available at: https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-021-00579-6

6 Potter VR. Bioethics: bridge to the future. 1º ed. Englewood Cliffs: Prentice-Hall; 1971. The author teaches us that bioethics emerges in a context that is influenced by human life, the environment, and new technologies, particularly after World War II.

7 Convie LJ, Carson E, McCusker D, McCain RS, McKinley N, Campbell WJ, et al. The patient and clinician experience of informed consent for surgery: a systematic review of the qualitative evidence. BMC Med Ethics [Internet]. 11 de dezembro de 2020;21(1):58. Available at: https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-020-00501-6

8 Brehaut JC, Carroll K, Elwyn G, Saginur R, Kimmelman J, Shojania K, et al. Elements of informed consent and decision quality were poorly correlated in informed consent documents. J Clin Epidemiol [Internet]. 2015 Dec;68(12):1472–80. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0895435615001201

9 Belim C, Almeida CV De. Communication Competences are the Key! A Model of Communication for the Health Professional to Optimize the Health Literacy – Assertiveness, Clear Language and Positivity. J Healthc Commun [Internet]. 2018;03(03). Available from: http://healthcare-communications.imedpub.com/communication-competences-are-the-keya-model-of-communication-for-the-healthprofessional-to-optimize-the-health-literacy-assertive.php?aid=22761

10 Campos CFC, Leão J, Dohms M. Comunicação clínica efetiva. In: Dohms M, Gusso G,

In today's doctor-patient relationship, there are a number of problems with the IC. Both clinicians and patients often view IC as a mere formality – an obstacle to care[12]. Even after signing a consent form, many patients do not understand basic information about the benefits, harms, and risks of the proposed treatment, including the possibility of poor outcomes[13]. Some patients may also be unaware of their rights, including the ability to refuse any treatment[14].

Better communication and understanding are key to increasing people's quality of life through HL, as this approach encourages patients to be active participants in their own health decisions, including better understanding their rights, as well as making decisions with autonomy when understand IC[15]. Therefore, a significant portion of the patient's comprehension of acquiring information and explanations from the healthcare professional is dependent on their capacity to comprehend texts, drawings, visual materials, and animations that are offered throughout the consultation[16].

People, regardless of age or education, can only remember about half of what they hear in clinical conversations[17]. Thus, there is no autonomy without knowledge, and there is no knowledge without effective communication. So that's what we're going to cover in this essay.

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editors. Comunicação clínica: aperfeiçoando os encontros em saúde. 1st ed. Porto Alegre: Artmed; 2021. p. 25–33.

11 Atkins K. Autonomy and autonomy competencies: a practical and relational approach. Nurs Philos [Internet]. 2006 Oct;7(4):205–15. Available from: https://onlinelibrary.wiley.com/doi/10.1111/j.1466-769X.2006.00266.x

12 Zaganelli MV, Borsellino P. Regras sobre consentimento informado e disposições antecipadas: uma conquista para pacientes e profissionais da saúde. Rev Jurídica da Presidência [Internet]. 2021 May 28;23(129):47. Available from: https://revistajuridica.presidencia.gov.br/index.php/saj/article/view/2314

13 Souza MK, Jacob CE, Gama-Rodrigues J, Zilberstein B, Cecconello I, Habr-Gama A. Termo de consentimento livre e esclarecido (TCLE): fatores que interferem na adesão. Arq Bras Cir Dig [Internet]. 2013 Sep;26(3):200–5. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-67202013000300009&lng=pt&tlng=pt

14 Esham ADB. The Doctrine of Informed Consent and Duty of Disclosure: A Comparative Essay between the US, UK, Australia and Malaysia with Indonesia. Indones Comp Law Rev [Internet]. 2019;2(1). Available from: http://journal.umy.ac.id/index.php/iclr/article/view/8037

15 Almeida CV, Piber RS. Literacia em saúde: aspectos filosóficos, sociais e jurídicos. J Healh NPEPS [Internet]. 2022;7(1):e6235. Available from: https://periodicos.unemat.br/index.php/jhnpeps/article/view/6235

16 Weiss BD. Removing barriers to better, safer care | Health literacy and patient safety: Help patients understand - Manual for clinicians [Internet]. 2nd ed. American Medical Association Foundation, editor. Vol. 1, American Medical Association Foundation. Chicago: American Medical Association Foundation; 2009. 62 p. Available from: https://www.ufjf.br/getmedicina/files/2015/11/BARRY-WEISS.pdf

17 Sheridan SL, Halpern DJ, Viera AJ, Berkman ND, Donahue KE, Crotty K. Interventions

2 – Health Literacy (HL)

Literacy is a phenomen that results from the process of learning to read and write; it is the state or condition that a person – or a social group – attains after appropriating writing and its social practices[18].

Applying this notion to the realm of health yields HL, which is the cognitive ability to comprehend, interpret, and apply written or oral health information. The World Health Organization (WHO) defines HC as the accumulation of personal knowledge and abilities via everyday activities, social interactions, and across generations. Individual knowledge and abilities are mediated by organizational structures and the availability of resources that enable individuals to acquire, comprehend, assess, and use information and services in ways that promote and preserve their own and others' health and well-being[19].

Individuals and communities may make more informed decisions with the help of HL[20]. It is founded on the idea that everyone should have the opportunity to participate in and benefit from high-quality education and continued training. It may be quantified as a direct outcome of the function of health education in that attempt. Cultural and environmental variables influence individuals, institutions, and communities' health literacy. It is not just up to individuals to act, as all information providers – including government, civil society and health services, must make credible information available in a form that is understandable and actionable by all people[21].

The truth is that formal education is not the essential requirement for a person or community to be health literate. The social resources that contribute to HC

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for Individuals with Low Health Literacy: A Systematic Review. J Health Commun [Internet]. 2011 Sep 30;16(sup3):30–54. Available from: http://www.tandfonline.com/doi/abs/10.1080/10810730.2011.604391

18 Soares M. Letramento: um tema em três gêneros. 3rd ed. Belo Horizonte: Autêntica Editora; 2009. 128 p.

19 World Health Organization. Health Promotion Glossary of Terms 2021 [Internet]. World Health Organization. Geneva; 2021. Available from: https://www.who.int/publications/i/item/9789240038349

20 Nutbeam D, McGill B. Improving health literacy in clinical and community populations. In: Okan O, Bauer U, Levin-Zamir D, Pinheiro P, Sørensen K, editors. International handbook of health literacy: research, practice and policy across the lifespan. 1st ed. Bristol: Policy Press; 2019. p. 219–32.

21 World Health Organization. Health Promotion Glossary of Terms 2021 [Internet]. World Health Organization. Geneva; 2021. Available from: https://www.who.int/publications/i/item/9789240038349

include the regulation of the information environment and the media (oral, print, broadcast, and digital)[22] through which individuals get and utilize health information.

The low level of HL is associated with a decline in quality of life and refers to the difficulty in reading, absorbing and applying health recommendations (such as information on food labels and drug inserts), as well as understanding medical guidelines and health documents, including IC[23]. In reality, health services often overestimate the HL of the population (for the implementation of procedures and decisions related to treatment behavior)[24]. Because of this, it is natural for health practitioners to assume that the information conveyed is already known, which is incorrect.

According to one of the major studies conducted in this field by the World Health Communication Associates (WHCA), 20% to 50% of the population in the United Kingdom, United States, Australia, and Canada have inadequate HL capability, which can impair individual and group health[25]. Another poll of over 10,000 individuals from 60 nations (including Japan, Pakistan, Spain, and the United States) covered patients, physicians, and healthcare students. Results indicate that the majority of participants lack the fundamental abilities necessary to make informed health-risk-based decisions[26].

Between the years 2000 and 2019, Noncommunicable Diseases (NCDs), often known as chronic illnesses, were the largest cause of mortality worldwide, accounting for 277 million deaths among persons aged 30–70 years old. The majority of these fatalities occurred in low and middle income countries[27]. HL

22 Pallett AC, Nguyen BT, Klein NM, Phippen N, Miller CR, Barnett JC. A randomized controlled trial to determine whether a video presentation improves informed consent for hysterectomy. Am J Obstet Gynecol [Internet]. 2018 Sep;219(3):277.e1-277.e7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0002937818305325

23 Khan A, Spector ND, Baird JD, Ashland M, Starmer AJ, Rosenbluth G, et al. Patient safety after implementation of a coproduced family centered communication programme: multicenter before and after intervention study. BMJ [Internet]. 2018 Dec 5;k4764. Available from: https://www.bmj.com/lookup/doi/10.1136/bmj.k4764

24 Rogers ES, Wallace LS, Weiss BD. Misperceptions of Medical Understanding in Low-Literacy Patients: Implications for Cancer Prevention. Cancer Control [Internet]. 2006 Jul 30;13(3):225–9. Available from: http://journals.sagepub.com/doi/10.1177/107327480601300311

25 World Health Communication Associates Ltd. Health Literacy Part 2 "Evidence and Case Studies." Birmingham; 2010.

26 Garcia-Retamero R, Wicki B, Cokely ET, Hanson B. Factors predicting surgeons' preferred and actual roles in interactions with their patients. Heal Psychol [Internet]. 2014;33(8):920–8. Available from: http://doi.apa.org/getdoi.cfm?doi=10.1037/hea0000061

27 World Health Organization. Global health estimates: life expectancy and leading causes

prevents and controls NCDs, as they are influenced by genetic, physiological, environmental, economic, commercial, cultural and behavioral variables at individual and community levels. When healthy alternatives are not readily available, efforts to change behavior are futile. Thus, people, organisations, social circumstances and public policy concerns are crucial in supporting health literacy. A whole-of-society strategy is needed that combines multisectoral policy actions and top-down and bottom-up practices to increase HC for prevention and control of NCDs[28]. For this reason, the goal of HL development is to help WHO Member States create and implement public and/or private health policies, systems, services and professionals that can meet the HL requirements of their respective populations and communities for the protection and management of NCDs in all contexts.

It is critical to note that the goal of HL is not limited to NCDs, since health education may, but does not always, involve the development of HL skills to enable individuals to seek, analyze, evaluate, and share health-related information[29]. Thus, HL would be the product of health education. Individuals may learn to make healthy decisions and attain excellent health outcomes through health education and HL for any pathology[30], which also includes IC, since HL can assist foster autonomy.

3 - A Global and Brazilian view of IC

In several nations around the globe, IC for consultations and treatments is required for ethical, moral and legal reasons, since the administrative, civil and criminal obligations arising from the doctor-patient relationship require it.

Ethically, professionals participating in the doctor-patient relationship are obliged to choose the optimal therapy for each patient based on known scientific findings

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of death and disability [Internet]. 2020 [cited 2022 Dec 20]. Available from: https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates

28 World Health Organization. Health literacy development for the prevention and control of noncommunicable diseases: Volume 2. A globally relevant perspective. Vol. 2. Geneva; 2022.

29 Moraes KL, Brasil VV, Mialhe FL, Sampaio HA de C, Sousa ALL, Canhestro MR, et al. Validação do Health Literacy Questionnaire (HLQ) para o português brasileiro. Acta Paul Enferm [Internet]. 2021 Mar 5;34(eAPE02171):1–10. Available from: https://acta-ape.org/article/validacao-do-health-literacy-questionnaire-hlq-para-o-portugues-brasileiro/

30 Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M, et al. Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review. Med Decis Mak [Internet]. 2020 Feb 16;40(2):119–43. Available from: http://journals.sagepub.com/doi/10.1177/0272989X19896348

and inform patients about the anticipated benefits and potential risks[31]. This obligation stems from physicians' ethical need to provide patients with the best possible treatment[32]. The patient should be allowed to ask the doctor questions about recommended treatments, benefits and dangers, and the doctor should answer based on his professional experience and the relevant medical literature[33]. This exchange of information and ideas between patient and healthcare professional is the foundation of doctor-patient collaboration and facilitates informed decision-making even in the most difficult medical conditions.

It is critical to recognize that the IC for consultations and procedures is a process, not a single act. This is because a good doctor-patient relationship, awareness of past information for adherence to therapy, understanding of risk factors in invasive procedures, and compliance with postoperative instructions all have a direct influence on the IC. Understanding was identified as an important component of the informed consent process; however, this was also recognized as problematic because understanding is a highly subjective notion[34].

Certain countries demand IC (written) forms, particularly for invasive procedures. However, there is no such requirement in Brazil because, according to the legislation, the IC is the record in the medical record of a voluntary decision by the patient or his legal guardians, taken after an informative and clarifying process, to authorize a specific medical treatment or procedure, while being aware of its risks, benefits, and potential consequences[35].

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31 Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension—systematic review. Trials [Internet]. 2021 Dec 14;22(1):57. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-04969-w

32 Tiselius E. Informed Consent: An overlooked part of ethical research in interpreting studies. INContext [Internet]. 2021 Nov 30;1(1):83–100. Available from: http://incontextjournal.org/index.php/incontext/article/view/4

33 Morain SR, Joffe S, Largent EA. When Is It Ethical for Physician-Investigators to Seek Consent From Their Own Patients? Am J Bioeth [Internet]. 2019 Apr 3;19(4):11–8. Available from: https://www.tandfonline.com/doi/full/10.1080/15265161.2019.1572811

34 Heywood R, Macaskill A, Williams K. Informed consent in hospital practice: health professionals' perspectives and legal reflections. Med Law Rev [Internet]. 2010 Mar 1;18(2):152–84. Available from: https://academic.oup.com/medlaw/article-lookup/doi/10.1093/medlaw/fwq008

35 Hirschheimer MR, Constantino CF, Oselka GW. Consentimento informado no atendimento pediátrico. Rev Paul Pediatr [Internet]. 2010 Jun;28(2):128–33. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0103-05822010000200001&lng=pt&tlng=pt

There are several denominations used to refer to IC: “awareness and consent”, “after-information consent”, “free and informed consent”, “post-information consent”, “treatment authorization form”, “term of acceptance of the outpatient medical-surgical treatment”, “informed consent form”, “clarification and consent form”, “clarification term”[36].

Despite the fact that the Informed Consent Form is not expressly provided for in the Brazilian legal system, references to it can be found in a number of provisions, both constitutional and infra-constitutional, such as those found in the Civil Code, the Consumer Defense Code, and the Code of Medical Ethics.

The Principle of Human Dignity is already mentioned in article 1, item III of the Republic’s Constitution[37]. This concept regulates human connections, and we perceive the human being as the major character in relationships as a result. Further on, in article 5, item II, we find that: “no one shall be required to do or refrain from doing something except by virtue of the law”[38]. We consider here the right of every individual to make decisions, and we apply this concept to the doctor-patient interaction. As a result, in constitutional terms in Brazil, the CI is required for the practice of medicine, and its absence may even be deemed an insult to the Right to Personality, which is part of the Principle of Human Dignity.

Article 5, item X, of the Federal Constitution of Brazil determines that “The privacy, private life, honor and image of persons are inviolable, ensured the right to compensation for material or moral damage resulting from its violation”[39]. Again, we find in higher law the patient’s right to have his private, his body maintained, and to have his privacy infringed only after agreeing. Thus, after getting all of the necessary information, the patient will be able to

36 Hirschheimer MR, Constantino CF, Oselka GW. Consentimento informado no atendimento pediátrico. Rev Paul Pediatr [Internet]. 2010 Jun;28(2):128–33. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0103-05822010000200001&lng=pt&tlng=pt

37 República Federativa do Brasil. Constituição da República Federativa do Brasil de 1988 [Internet]. Brasil; 1988 p. 1–139. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

38 República Federativa do Brasil. Constituição da República Federativa do Brasil de 1988 [Internet]. Brasil; 1988 p. 1–139. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

39 República Federativa do Brasil. Constituição da República Federativa do Brasil de 1988 [Internet]. Brasil; 1988 p. 1–139. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

select the less traumatic option and consent to continue therapy. That clause also allows for civil restitution in the event that the patient's bodily integrity is not preserved.

In item XXXII of the same article 5[40], the obligation of the State to protect the rights of the consumer is foreseen. As the doctor-patient relationship came to be seen as a consumer contractual relationship, they are covered by the Consumer Protection Law. Finally, articles XIV, XXXIII and LXII of Article 5 of the Federal Constitution[41] deal with the right to information of every individual, and it is reasonable to assume that this right also refers to the patient, since he must have unrestricted access to information about his health status and therefore the freedom to choose the therapy that will be least invasive for him.

In Brazil, the doctor-patient relationship is considered contractual and, therefore, some sections of the Brazilian Civil Code deal with this issue. The doctrine defines the declaration of existence, that is, the manifestation of the will of two or more individuals, as the first subjective need of any contract, followed by the ability of the parties. Another distinguishing feature is the ability to negotiate and, finally, consent. It is vital to note that the lack of these standards has an impact on the legal transaction's efficacy.

In Art. 13 in the Brazilian Civil Code states that "Except for medical requirements, the act of disposal of one's own body is prohibited, when it involves a permanent decrease in physical integrity, or goes against good customs. Single paragraph. The act provided for in this article will be admitted for the purposes of transplantation, as established in a special law"[42]. And in Art. 15 "No one may be compelled to undergo, at risk of death, medical treatment or surgery"[43]. It is crucial to highlight that the Civil Code codified, in Articles 13 and 15, the idea of autonomy and disposition over one's own body, which are

40 República Federativa do Brasil. Constituição da República Federativa do Brasil de 1988 [Internet]. Brasil; 1988 p. 1–139. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

41 República Federativa do Brasil. Constituição da República Federativa do Brasil de 1988 [Internet]. Brasil; 1988 p. 1–139. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

42 República Federativa do Brasil. Código Civil - Lei nº 10.406 de 10 de janeiro de 2002 [Internet]. Brasília; 2002 p. 196 Available from: http://www.planalto.gov.br/ccivil_03/leis/2002/L10406.htm

43 República Federativa do Brasil. Código Civil - Lei no 10.406 de 10 de janeiro de 2002 [Internet]. Brasília; 2002 p. 196 Available from: http://www.planalto.gov.br/ccivil_03/leis/2002/L10406.htm

applied via the exercise of IC, recognizing the significance of these rights for the full development of the individual[44]. When there is some type of injury to the patient, even if it is only in the moral scope, the Brazilian Civil Code also allows for various forms of repairing the damage, which can be used.

As it is a consumer relationship, the doctor-patient interaction will be governed by the Consumer Defense Code. Faced with such an order, the patient will be seen as a client and the doctor as a service provider. In this context, the figure of the IC emerges as a means of assuring the patient (consumer) of all the necessary information regarding the "service" that he is "acquiring", that is, the physician has the duty to inform the patient, in detail, about all the treatment to which he will have to undergo, and this service must be done in an adequate way, thus guaranteeing the understanding of the patient and avoiding future unpleasantness[45].

Article 46 of the Brazilian Consumer Protection Code establishes that "Contracts that regulate consumer relations shall not oblige the consumer, if he is not given the opportunity of prior knowledge of their content, or if the respective instruments are written in such a way as to make it difficult to understand its meaning and scope"[46]. That is, the IC gives the consumer the possibility of knowing the contract that will govern the health care provided. If the customer is not aware of the conditions of his contract, he is not obliged to comply with them. This is undoubtedly a legal provision that may no longer apply if the IC is created in accordance with the legal rules in force.

From the outset, we see in Article 4 of the aforementioned Code[47] the stipulation that consumer contacts must be permeated by openness, which may be viewed here as the customer's fundamental right to knowledge. Furthermore, according to article 6º of the Brazilian Consumer Defense Code[48], every consumer has the

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44 Dantas E. Direito Médico. 5th ed. Salvador: Juspodivm; 2021. 448 p.

45 Piber RS. A Importância do Letramento em Saúde para o Direito Médico e da Saúde. In: Barbosa M da GV, Barbosa RCV, editors. Direito médico e da saúde. 1st ed. João Pessoa: Ideia; 2022. p. 126–42.

46 República Federativa do Brasil. Código de Defesa do Consumidor - Lei no 8.078 de 11 de setembro de 1990 [Internet]. Brasília; 1990 p. 24. Available from: http://www.planalto.gov.br/ccivil_03/leis/L8078.htm

47 República Federativa do Brasil. Código de Defesa do Consumidor - Lei no 8.078 de 11 de setembro de 1990 [Internet]. Brasília; 1990 p. 24. Available from: http://www.planalto.gov.br/ccivil_03/leis/L8078.htm

48 República Federativa do Brasil. Código de Defesa do Consumidor - Lei no 8.078 de 11 de setembro de 1990 [Internet]. Brasília; 1990 p. 24. Available from: http://www.planalto.gov.br/ccivil_03/leis/L8078.htm

right to adequate and clear information about various products and services, including correct specification of quantity, characteristics, composition, quality, and price, as well as the risks they present. This clause modifies the substance of the IC by outlining how the information should be provided, making it clear that the phrasing must be agreeable to the patient, and giving the patient more voice in the process comprehension in reference to the topic[49].

Another notion addressed in the Consumer Defense Code is that the consumer will always be the weakest side of the connection, the most vulnerable, which is why he must be protected. is what we call the Principle of Vulnerability, in which everyone is equal before the law and bringing this maxim to the field of consumer relations[50], we can understand the IC as a mechanism that comes to restore the balance of relations, being a protective process both for the doctor who is certain that he has adequately conveyed the necessary information, and also for the patient who is certain of the possibility of having his right restored if any procedure is performed against his will[51].

In article 14 of the Consumer Protection Code, the lawmaker stated that the provider should be held accountable for the insufficient information supplied. It even went so far as to call for a jail penalty for providers that supply inaccurate or distorted information, as outlined in article 66[52].

In addition, it is important to note that the Brazilian legal system, the medical area has a series of regulations, and it is possible to highlight the legislation that deals with the IC in resolutions of the Federal Council of Medicine, as well as in regulations of the National Council of Health and the Code of Medical Ethics.

Article 22 of the Brazilian Code of Medical Ethics[53] explains that it is forbidden for the physician to fail to obtain consent from the patient or his legal representative after clarifying him about the procedure to be performed, except

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49 Dantas E. Direito Médico. 5th ed. Salvador: Juspodivm; 2021. 448 p.

50 Rosa LCG, Faria DES, Borges GOA, Nunes R de S. Consentimento informado defeituoso e presunção de culpa na relação entre médico e paciente. RJLB. 2019;5(5):1143–68.

51 Crespo Brauner MC, dos Santos Pereira S. O consentimento ao ato médico no Brasil: entre o paternalismo médico e a busca pela proteção dos pacientes e responsabilidade dos médicos. RID [Internet]. 11 de Outubro de 2021;2(1):158-77. Available from: https://revistaibericadodireito.pt/index.php/capa/article/view/56

52 República Federativa do Brasil. Código de Defesa do Consumidor - Lei no 8.078 de 11 de setembro de 1990 [Internet]. Brasília; 1990 p. 24. Available from: http://www.planalto.gov.br/ccivil_03/leis/L8078.htm

53 Conselho Federal de Medicina. Código de Ética Médica: Resolução CFM no 2.217, de 27 de setembro de 2018, modificada pelas Resoluções CFM no 2.222/2018 e 2.226/2019. Conselho Federal de Medicina. Brasília: Conselho Federal de Medicina; 2019. 108 p.

in cases of imminent risk of death. This concept must always be followed in the doctor-patient connection in any medical decision, which should never be made alone by the professional, but with the patient or a family member, in the latter instance if the patient is incapable[54]. In truth, the patient simply delegated powers to his doctor to intrude on your body under the concept of autonomy.

The Code of Medical Ethics still establishes in its Art. 31 that physicians are prohibited from disrespecting the right of the patient or his/her legal representative to decide freely about carrying out diagnostic or therapeutic practices, except in cases of imminent risk of death[55].

The Federal Council of Medicine also issued Recommendation No. 1 in 2016[56], which views IC as a doctor's duty and a patient's right, and the process of obtaining it as a stage of communication between both, with a triple function: the first is to respect the freedom of patient choice, which is translated as autonomy. After receiving the required explanations regarding the diagnosis, indicated procedures, and advised therapy, the patient may make an informed decision. The second role is to enhance the link between the two parties by promoting their intersubjective relationship. Finally, based on this communication, the final role is to determine the professional's performance parameters[57].

In Brazil, the Recommendation of the Federal Council of Medicine is the most comprehensive guideline on assertive communication between doctor and patient. This recommendation provides information on the process of obtaining IC in medical treatment. This standard is not intended to promote the practice of defensive medicine; rather, it is designed to promote effective communication and the intersubjective relationship that exists between both parties. Furthermore, it is interesting to note that at no time is it required that the IC be written.

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54 Barros Júnior E de A. Código de ética médica: comentado e interpretado - Resolução CFM 2217/2018. 1st ed. Timburi: Editora Cia do eBook; 2019. 835 p.

55 Conselho Federal de Medicina. Código de Ética Médica: Resolução CFM no 2.217, de 27 de setembro de 2018, modificada pelas Resoluções CFM no 2.222/2018 e 2.226/2019. Conselho Federal de Medicina. Brasília: Conselho Federal de Medicina; 2019. 108 p.

56 Conselho Federal de Medicina. Recomendação CFM No 1 de 2016 [Internet]. Jan 21, 2016 p. 1–33. Available from: https://portal.cfm.org.br/images/Recomendacoes/1_2016.pdf

57 Pazinatto MM. A relação médico-paciente na perspectiva da Recomendação CFM 1/2016. Rev Bioética [Internet]. 2019 Jun;27(2):234–43. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1983-80422019000200234&tlng=pt

4 – Using HL Techniques in CI

In the CI process, HL basics can lead to better informed judgments. It is vital to consider both verbal and textual communication in this context[58]. In terms of the first, patients with a low level of HL tend to recall just half of what is spoken and do not feel prepared to ask questions[59]. As a result, basic language is advised, with no medical jargon or technical terminology, reflected vocabulary in the patient, clear and calm speaking, and information separated into little sections. It is beneficial to use simple language, regardless of education level and type of patient. If the specialist uses "technical jargon", he should explain and exemplify what he means in a health education process, because most of the time, the patient likes to learn[60].

The teach-back approach, which avoids the typical inquiries "Did you understand?" or "Do you have any questions?" while avoiding replies like "yes" or "no," is one strategy to verify that patients completely received the material[61]. The technique seeks the patient's return based on the following request: "I want to make sure I explained everything correctly. Could you just repeat what you heard from what I said?" In this manner, the individual describes the new material in his own words, allowing the researcher to evaluate his comprehension[62]. Thus, the question that must be asked to employ the Teach-Back approach suggests that the "weight" of the question and the

58 Ownby R, Acevedo A, Goodman K, Caballero J, Waldrop-Valverde D. Health literacy predicts participant understanding of orally-presented informed consent information. Clin Res Trials [Internet]. 2015;1(1). Available from: http://oatext.com/Health-literacy-predicts-participant-understanding-of-orally-presented-informed-consent-information.php

59 Sheridan SL, Halpern DJ, Viera AJ, Berkman ND, Donahue KE, Crotty K. Interventions for Individuals with Low Health Literacy: A Systematic Review. J Health Commun [Internet]. 2011 Sep 30;16(sup3):30–54. Available from: http://www.tandfonline.com/doi/abs/10.1080/10810730.2011.604391

60 Almeida CV De. Clareza de linguagem. In: Almeida CV De, Moraes KL, Brasil VV, editors. 50 técnicas de literacia em saúde: um guia para a saúde. 1st ed. Beau Bassin: Novas Edições Acadêmicas; 2020. p. 36–7.

61 Weiss BD. Removing barriers to better, safer care | Health literacy and patient safety: Help patients understand - Manual for clinicians [Internet]. 2nd ed. American Medical Association Foundation, editor. Vol. 1, American Medical Association Foundation. Chicago: American Medical Association Foundation; 2009. 62 p. Available from: https://www.ufjf.br/getmedicina/files/2015/11/BARRY-WEISS.pdf

62 Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M, et al. Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review. Med Decis Mak [Internet]. 2020 Feb 16;40(2):119–43. Available from: http://journals.sagepub.com/doi/10.1177/0272989X19896348

duty rests with the health professional and not with the patient[63]. The health professional is the one who wants to know if he communicated effectively with the patient and not the other way around.

In turn, the written content, in conjunction with vocal information, should reinforce the patient's understanding. Whatever the case may be, the printed communication should correspond to the reading level of the fifth to sixth year of basic education[64], at most, and should be confined to vital themes, avoiding superfluous and unneeded material.

Some research have also looked into novel methods of obtaining informed consent in surveys and services. Some literacy assumptions were evaluated in a clinical experiment with low-income persons. There were two forms used: one reduced and one conventional[65]. The simplified form had the same information as the conventional version, but it was given in a more concise manner, with less medical jargon, in the active voice, and with simpler formatting and grouping of processes and information, making it easier to understand.

Depending on the circumstances, numerical data might be critical for making decisions, particularly when agreeing to health treatment. These data are expected to assist comprehension by including statistics on the advantages and hazards of preventative activities, as well as disease and prognosis[66]. Many people, however, struggle with numbers, which is a crucial component of health literacy. Therefore, it is vital that the health professional utilize creative tactics, unfolding the statistics in visuals, phrases, simple graphics and addressed to the specific population that they wish to enlighten. To express the significance of the numbers, the advice is to be visual and employ a series of pictures and clearly identifiable forms[67].

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63 Almeida CV De, Brito M. Teach-back. In: Almeida CV De, Moraes KL, Brasil VV, editors. 50 técnicas de literacia em saúde: um guia para a saúde. 1st ed. Beau Bassin: Novas Edições Acadêmicas; 2020. p. 104–5.

64 Cangussú LR, Alho EAS, Cardoso FEL, Tenório AP de O, Barbosa RH de A, Lopes JM, et al. Concordância entre dois instrumentos para avaliação do letramento em saúde. Epidemiol e Serviços Saúde [Internet]. 2021;30(2). Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S2237-96222021000200305&tlng=pt

65 Huhta A-M, Hirvonen N, Huotari M-L. Health Literacy in Web-Based Health Information Environments: Systematic Review of Concepts, Definitions, and Operationalization for Measurement. J Med Internet Res [Internet]. 2018 Dec 19;20(12):e10273. Available from: http://www.jmir.org/2018/12/e10273/

66 Carthery-Goulart MT, Anghinah R, Areza-Fegyveres R, Bahia VS, Brucki SMD, Damin A, et al. Performance of a Brazilian population on the test of functional health literacy in adults. Rev Saude Publica [Internet]. 2009 Aug;43(4):631–8. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0034-89102009000400009&lng=en&tlng=en

67 Moraes KL. Facilitar a numeracia. In: Almeida CV De, Moraes KL, Brasil VV, editors.

Visual aids, such as schematics and photographs, can help patients better understand information, especially when risks and probabilities are presented[68]. In certain instances, it may be various approaches, including as iconography and the presenting of graphic representations of afflicted persons from a specific demographic at risk, are utilized[69]. Visual representations of information may provoke powerful emotional reactions and, if easily remembered, can have a bigger impact than vocally transmitted information. Some people have a better memory for seeing events and objects, whilst others are more auditory and hence memorize more orally and through the sounds they hear[70].

According to other researches, the sentiment is best comprehended when delivered in straightforward English, with shorter words, images, white space, and the appropriate font size[71]. To enhance the discussion between researcher and participant, this format, which makes the materials accessible to those with poor reading skills, should be established with the assistance of communication professionals[72]. Furthermore, developers must have a strong cultural background as well as research experience.

Creative tools, such as movies that highlight the risks and advantages of a certain approach or research, can also help people grasp the IC[73]. This method was found to be beneficial in a trial with women in the preoperative period of hysterectomy who learnt the processes of the surgery and the postpartum period so well that the length of hospital stay was reduced.

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50 técnicas de literacia em saúde: um guia para a saúde. 1st ed. Beau Bassin: Novas Edições Acadêmicas; 2020. p. 58–9.

68 Garcia-Retamero R, Galesic M. Who proficts from visual aids: Overcoming challenges in people's understanding of risks. Soc Sci Med [Internet]. 2010 Apr;70(7):1019–25. Available from: https://linkinghub.elsevier.com/retrieve/pii/S027795361000002X

69 Nascimento FL da S. Visual Law Aplicado aos Documentos Médicos. In: Barbosa M da GV, Barbosa RCV, editors. Direito médico e da saúde. 1st ed. João Pessoa: Ideia; 2022. p. 57–67.

70 Wyer RS, Shrum LJ. The Role of Comprehension Processes in Communication and Persuasion. Media Psychol [Internet]. 2015 Apr 3;18(2):163–95. Available from: http://www.tandfonline.com/doi/full/10.1080/15213269.2014.912584

71 McCarthy DM, Waite KR, Curtis LM, Engel KG, Baker DW, Wolf MS. What Did the Doctor Say? Health Literacy and Recall of Medical Instructions. Med Care [Internet]. 2012 Apr;50(4):277–82. Available from: https://journals.lww.com/00005650-201204000-00001

72 Mendes CF, Sampaio HA de C, Passamai M da PB. Letramento funcional em saúde dos responsáveis por crianças com cardiopatia congênita: tecnologia educativa para a promoção da saúde e do cuidado [recurso eletrônico]. 1st ed. EdUECE E da UE do C-, editor. Fortaleza: EdUECE; 2019. 83 p.

73 Pallett AC, Nguyen BT, Klein NM, Phippen N, Miller CR, Barnett JC. A randomized controlled trial to determine whether a video presentation improves informed consent for hysterectomy. Am J Obstet Gynecol [Internet]. 2018 Sep;219(3):277.e1-277.e7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0002937818305325

Ask Me 3 is an effective patient empowerment tool. The Ask Me 3 technique was created by the National Patient Safety Foundation's Partnership for Clear Health Communication as a solution to America's silent health literacy epidemic. Ask Me 3 "is a patient education program designed to increase communication between health-care providers and patients in order to improve health outcomes," according to the website (http://www.npsf.org/for-healthcare-professionals/programs/ask-me-3/). The program promotes patients to comprehend the following three questions: 1. What is my main problem? 2. What do I need to do? 3. Why is it important for me to do this?[74]

Professionals' body language reveals a great deal about themselves and their emotions. As a result, it is critical to pay attention to nonverbal expression during the consultation, specifically: make eye contact at the start of the interview; avoid looking at the computer screen or the registry too much; keep hands, feet, and objects at rest or without repeated movements, without showing apprehension; and maintain a facial expression that demonstrates care, respect, and empathy. Patient satisfaction with the consultation is greatly influenced by the combination and interplay of verbal and nonverbal communication[75].

Information gathered in summary this strategy improves the data's dependability, actuality, and validity. We present the patient a summary of the data, finishing with the following questions: "Do you believe this summary reflects well what occurs to you? What more would you add? What would you leave out? The application of this approach yields unexpected outcomes. The patient feels heard, but he also contributes actively in the ultimate vision that builds in our thoughts. The flow of communication and the quality of data are also improved.

Printed instructional materials have been utilized to increase patient understanding, satisfaction, treatment adherence, and self-care. It is advised that instructional material created by health experts be used to reinforce verbalized guidelines. Teaching materials can benefit patient education by assisting them in answering questions that may arise while the patient is not there engaging with the healthcare professional.

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74 Six-Means A, Bauer TK, Teeter R, Segraves D, Cutshaw L, High L. Building a Foundation of Health Literacy with Ask Me 3TM. J Consum Health Internet [Internet]. 2012 Apr;16(2):180–91. Available from: http://www.tandfonline.com/doi/abs/10.1080/15398285.2012.673461

75 Barreiros BC, Franco CAG dos S, Freitas FL, Dohms M. Habilidades essenciais para a comunicação clínica efetiva. In: Dohms M, Gusso G, editors. Comunicação clínica: aperfeiçondo os encontros em saúde. 1st ed. Porto Alegre: Artmed; 2021. p. 1–16.

When the patient is able to understand, information becomes communication. Both IC and HL include aspects of the patient's response to the treatment, as well as the patient's understanding of both the risks and benefits of the therapy, and the patient's adherence to the treatment.

5 - Final Considerations

To increase adherence to treatment and empower citizens, the HL must be examined from the interpersonal to the transmission of information, from individual care to the community. As a result, it is critical to effectively internalize the information presented, particularly while making decisions.

Numerous ways have been developed throughout time to extend the knowledge of participants in medical services, but there are still many flaws and inconsistencies in getting this permission. When developing this approach, researchers and professionals must include HL.

It is ideal to know the level of HL in the target group; however, because this is not always possible, documentation accessible to everyone, including persons with low HL, can be developed to ensure autonomy in consent.

More ideas and operational tactics will arise as teams absorb the principles of HL while developing the IC, enhancing and facilitating the process.

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ASSISTED REPRODUCTION AND "SAVIOUR SIBLINGS": THE ETHICAL AND LEGAL DEBATE

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Abstract: The scientific advances in medicine and the dissemination of the human assisted reproduction techniques had made necessary the imposition of ethical and legal limits to their use, considering the dignity of the human being as the main reason for such limit. The human assisted reproduction techniques have caused considerable transformations in the Law, especially in parenting aspects. It is also recognized that the right to the artificial procreation is one of the dimensions of the right to the familiar planning. But should the use of reproduction technique in this case have limits? The main aim of this study is to discuss the use of these techniques, especially the use of Preimplantation diagnosis (PGD) for cases in which the parents of a sick child wish to have another child whose tissue can be used to provide a treatment for the condition of the sick sibling. This new baby is called "saviour sibling". Moreover, this paper addresses the question of whether this form of selection should be banned or not, focusing on two main prohibitionist arguments: (a) the claim that it involves bringing a person into being for the sole purpose of assisting his or her sibling infringes the principle that people should not be used solely as a means to an end. Furthermore, how might the child´s welfare be when this child perceives himself or herself to have been created as merely a means to save his or her sibling; (b) This practice will lead to the creation of so-called ''designer babies'', if the limits are not clearly defined. All in all, the study intends to show the importance of a regulation about the

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use of this technology to avoid its misuse. The lack of specific legislation about human assisted reproduction makes it difficult for reaching a solution for possible conflicts related to autonomy, justice, and beneficence in the cases of the "saviour sibling".

Keywords: Assisted Reproduction; Saviour Siblings; Ethics in ART

1. Initial Considerations

As a matter of fact, innovations in this field of science have placed humanity before such unimaginable situations as gene therapy and human cloning. In one hand, genetic manipulation has brought hope of cure for various diseases and has indeed improved the quality of life. On the other hand, it has also brought a series of anxieties and uncertainties that deserve special attention from society.

Thus, such innovations encompass a dual character: protection and having to face various principles of human rights, as they involve situations of protection to them and of offense to the axiological nucleus of the principle of the dignity of human beings.

Consequently, it is natural and necessary that ethical concerns arise from such progress. The possibility of changing human nature brings into question the ethics of future generations' law; bringing about the need to reflect upon which values are to be appraised by society, so that it guarantees a healthy future for humanity. It is plain to see that in order to recover this ethical valuation it is imperative to bring to light which criterion is sought so as to maintain what is the most essential and dear to our society.

In the lights of Immanuel Kant's thoughts, it can be understood that it is the humans who hold this greater value. For him, the idea of dignity arises from the ethical autonomy of humans, as the autonomy is the foundation of the dignity of men; bearing in mind that the human being can not be considered an object, since a person should be considered as an end in oneself, and not as means, that is, man is an end in himself, and cannot be used as a means in any case.

This must be applied in all one's actions, those that are addressed to oneself and to others, so the value of all the objects that the human beings can acquire by their own actions is conditional.

Hence, this means that the human being is free to carry out research in order to preserve the human species, discover cures for diseases, develop technologies that can bring quality of life to people, without, however, forgetting the responsibility towards future generations, preserving the characteristics that are essential to the human beings.

At this point, it is of capital importance to bring to light the connection between medical law and bioethics, considering that many cases the courts have been willing to accept that, particularly in controversial cases in which they are being asked to decide what treatment a patient should receive, ethical issues will play an important role in deciding how the court will reach a decision.

As a result, numerous legal instruments and cooperation agreements recognize the freedom of scientific research, without forgetting its limits. Article 13 of The Charter of Fundamental Rights of the European Union enshrines the fundamental right to scientific research (Art and scientific research are free), and also the Universal Declaration on Bioethics and Human Rights of UNESCO establishes as one of its objectives "to recognize the importance of freedom of scientific research". In turn, the Universal Declaration on the Human Genome and Human Rights, also from UNESCO, enshrines the free exercise of research activities on the human genome. Within the framework of the Council of Europe reference should be made to the Convention on the Protection of Human Rights and Human Dignity concerning the applications of biology and medicine and its additional protocol on biomedical research.

Such freedom, however, is by no means absolute, because it is limited by the fundamental rights of the individual and especially by reason of dignity, identity, integrity and non-discrimination. Therefore, there are objective limits in relation to scientific research, as a logical consequence of the principle of the dignity of the human being.

In this context, the manipulation of embryos for the birth of "saviour sibling", so called primarily by the media, occurs through the accomplishment of two genetic pre-implantation diagnoses in order to select healthy and histocompatible embryos with siblings who need to receive transplantation of hematopoietic stem cells.

The embryo is conceived by in vitro fertilization and subjected to a double pre-implantation genetic diagnosis (DGPI), in order to select a healthy and histocompatible embryo with the sick sibling. The double Pre Implantation

Genetic Diagnosis (DGPI) is a breakthrough in the quest for cure for hereditary diseases such as thalassemia, anemia, immunodeficiencies, leukemias, as well as lymphomas.

It is worth mentioning that in the past, in the same circumstances, when the search for a donor was unfruitful, many parents tried to have a natural birth child in the hope that he/she would be compatible with their brother. This attempt, most of the times did not reach the expected result either, and was not feasible, since the probability of a brother being compatible is only 25%, on top of that, the newborn could also present the same disease.

This medical practice has been carried out in several countries around the world. The first British ''designer baby'' was born in 2003 as a result of an in vitro fertilization and pre-implantation diagnosis (IPD) in the United States. The couple Michelle and Jayson Whitaker had to go to a United States clinic to undergo an in vitro fertilization treatment after British authorities denied such permission. Jamie was born able to provide identical tissue to the ones his four-year-old brother needed, as he suffered from a rare disease called "Blackfan Anemia Diamond" (DBA).

In the United States, in 2005, Adam Nash was the baby chosen among fourteen embryos because his cells were compatible with those of his sister Molly, who had Fanconi's disease. In Spain, the first designer baby was born in 2008. The blood of his umbilical cord brought cure to his brother who had a serious congenital anemia. In France in 2011, Amut-Talha was born, a baby free from the serious genetic disease, beta-thalassemia, which affects his older siblings. In Portugal, in 2015, the National Council for Medically Assisted Procreation (CNPMA) authorized the implantation of the embryo in order to help in a bone marrow transplant of a couple whose 5-year-old daughter had lymphoblastic leukemia. There are a number of successful cases recorded around the world. However, they are not less impactful and they also lead to debates in society and the scientific community.

There are a number of ethical and legal dilemmas arising from this practice. Having stricter legislations (in the case of Germany) and more flexible ones (in the case of the United Kingdom), which, however, are in themselves not a solution to the various cases that arise, requiring from the judge to apply the principles of autonomy, non-maleficence, beneficence and justice in each particular factual situation.

2. The Savior Siblings and the Limits to Embryo Research: Designer Babies?

The use of the Pre-implantation Diagnosis in order to bring to life a child who is compatible with another sick brother brings the discussion about the limits of the autonomy of the will and the embryo research.

One of the most robust arguments against embryo research is the danger that manipulation leads to the extreme autonomy of the individual, to the point of generating human beings designed not to have a series of characteristics imposed by heredity, culminating in eugenics.

On the other hand, it is argued that science and technology ought to be at the service of humankind, and that if there are conditions to wipe out diseases that cause suffering and, in the last case, the absence of a dignified life, there is no point in speaking of any obstacle to its use.

In this scenario, it should be noted that the practice of pre-implantation diagnosis has long been permitted in several legislations, but only in a restricted way, solely to avoid the transmission of genetic diseases.

When a new egg is fertilized and the process of cell division begins, it is possible to remove one or two cells without compromising the normal developmental capacity of the embryo. Cells are taken out and tested for genetic abnormalities. The affected embryos are discarded or donated for research, and only the embryos which are not affected by the disease are either transferred to the woman's uterus, or frozen to be used in a future treatment. It is also possible to find out the sex of the embryo in order to avoid transmission of diseases associated with the chromosome, such as those that affect only boys, namely haemophilia.

The technique of pre-implantation diagnosis, which it is allowed in most legislation, is well accepted due to the argument that the severe disease affects the dignity of the human being. Therefore, avoiding it would be a way of safeguarding such dignity. On that perspective, however, another issue arises: to delimit what type of illness affects the dignity of the human being. For instance, would a genetic pre-disposition for cancer justify such diagnosis? Could diseases such as diabetes which compromises a person's quality of life also be considered for this purpose? As scientific research with embryos evolves, certainly more and more genetic predispositions could be detected in earlier stages and the limits whether it justifies performing the diagnosis or not, become increasingly tenuous.

Soren Holman explains:

> *"Its very difficult to produce a non-arbitrary dividing line between severe and non-severe conditions … It is disabling to be blind and deaf at the same time, and no amount of redescription can change that …. There are, however, many conditions where the situation is not nearly as clear. Many conditions are not universally disabling but only disabling in specific circumstances. Severe myopia (near-sightedness) is only marginally* disable in our society, whereas it was a severe disability before the invention of glasses… *A more serious problem is that severity varies not only historically but according to the precise social context of each affected person. Even if we assume that the physical and psychological manifestations of a given condition are constant, there will be many conditions where the impact on the person with the condition will vary quite markedly. The degree to which for instance a severe case of club foot will affect a person will depend on the kind of family he or she is born into – whether physical or more sedate pursuits are the centre of family life – and kind of other abilities which the person has. The severity in the global sense of a severe case of club foot is thus not determined by the medical severity of condition. Two persons with the same medical severity might end up being widely separated on the global severity"*[2]

In Britain, since 2008, the statute has contained detailed provisions which set out the circumstances in which it is lawful to carry out PGD (Pre implantation Genetic Diagnosis). In short, embryo testing is acceptable where there is a significant risk that the child to be born will have or develop a serious illness, disability or other condition. HFEA 8 th Code of Practise paras 10.4, 10.5 and 10.6 try to assume an objective assessment of seriousness, and consider relevant whether to offer PGD the family´s particular circumstances and their subjective views of the condition.[3]

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2 Ethical Issues In Pre implantation Diagnosis" in John Harris and Soren Holm (eds), The future of Human Reproduction. Claredon Press: Oxford, 1998.

3 10.4.. When deciding if it is appropriate to provide PGD in particular cases, the centre should consider the circumstances of those seeking treatment, rather than the particular heritable condition. JACKSON, Emily. MEDICAL LAW: TEXT, CASES AND MATERIALS. FOURTH EDITION. OXFORD UNIVERSITY PRESS UNITED KINGDOM, 2016, p. 851

Another important issue is to distinguish what a "disability" would be from both points of views: social and medical, health problem. Jonathan Glover explains:

> *Belonging to a minority that suffers discrimination is not a disability. One consequence may be needed to reclassify some conditions now thought of disabilities. For instance, achondroplasia, severely restricted height resulting from a genetic mutation, is normally classified as a disability. But the purely functional impairments are trivial, such as needing a stool to boost height when speaking in public. Provided that there are no associated medical complications, the only serious disadvantages result from the reactions of other people. This makes it the same as being Jewish in an anti-Semic society or gay in a homophobic society. This could push us towards saying that sometimes ethnic or religious affiliation, or sexual orientation, can count as disability. Or, with less offence to our linguistic and moral intuitions, we can say that achondroplasia is not a disability*".[4]

As it can be inferred, the acceptance of the PGD is quite controversial, and there are still voices against its use. Concerning that, David King opposes, in the following terms:

> "In PGD, parents adopt a far more pro-active, directing role, choosing their children in a way which is not so far removed from their experience as consumers, choosing amongst different products. There are a number of reasons why unrestricted free-market eugenics would be highly undesirable. Firstly, selecting the "best" amongst multiple embryos sets up a new relation –ship between parents and offspring… They are no longer a gift from God, or the random forces of nature, but selected products, expressing, in part, their parents´ aspirations, desires and whims… Clearly, there is likely to be a tendency for parents to select offspring which conforms best to social norms, with regard to health and physical ability, appearance and aptitudes. Disabled people have often expressed fears that expanded free-market eugenics would correspondingly lessen society´s tolerance for those with congenital and genetic disorders… It is also possible to imagine selection on grounds of IQ, skin colour, physical build and facial features, etc. It does not seem desirable to allow such forces to operate at the level of

4 _____.Choosing Children: Genes, Disability and Design. Claredon Press: Oxford, 2006, p 10.

> selection of who is permitted to be born. Rather, we should combat the social forces which lead us to disvalue some individuals and ideal others…[A] logical consequence of a system of free-market eugenics in societies where large disparities of wealth and social class continue to exists a gradual polarisation of society into a genetically privileged ruling elite and un underclass.",[5]

The dissemination of Pre implantation Diagnosis practice, according to Casabona, would consist of true eugenics, since parents would choose the healthy embryos to be implanted, thus avoiding the birth of sick children. The author points out that "*[...] It is difficult for a couple who undergoes an in vitro fertilization and request a pre-implantation genetic diagnosis to avoid the transmission to their offspring of a hereditary disease, will strive to transfer the woman an embryo with the pathology to be avoided*.[6]

Roberto Andorno puts out:

> [...] Indeed, pre implantation diagnosis seeks, in a first stage, to subject the embryos to a prior genetic analysis in order to transfer to the mother only the normal ones or those that best suit the wishes of the parents, which supposes to eliminate those that do not respond to the established standard. In a second stage, as highlighted by Testart, the objective, which at first sight could be considered as worthy of encouragement, presents its dark side when it comes to specifying which characters have to be encouraged or standardized and who will be in charge of fixing them. On the other hand, the fact that we are completely unaware of the long-term effects on public health of these various genetic pressures should not be forgotten. In this way, a new eugenics, sweet, democratic and insidious, silently installs itself in society, without anyone knowing for sure where it will lead.[7]

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5 Preimplantation genetic diagnosis and the "new" eugenics (1999) 25 Journal of Medical Ethics 176-81.

6 ROMEO CABONA, Carlos Maria. El convenio de Derechos Humanos y Biomedicina: su entrada em vigor em el ordenamento jurídico español. Granada:Comares, 2002.

7 ANDORNO, Roberto. *El derecho frente a la nueva eugenesia*. **Revista Chilena de Derecho,** Santiago**,** V. 21, n° 2, pp. 321-328, 1994. Original text: "*[...] En efecto, el diagnostico preimplantatorio persigue, en uma primera etapa, someter a los embiones a un analisis genético prévio a fin de transferir a la madre solo los normales o aquellos que mejor se adapten a los deseos de los padres, lo cual supone eliminar aquellos que no responden al estandar fijado. En una segunda etapa, tal como lo destaca Testart, el objetivo, que a primera vista podria ser considerado como digno de aliento, presenta*

The term *eugenics* was defined by Francis Galton as the science that deals with all the facts that improve the qualities inherent to the race, including the ones that develop optimally. Nevertheless, throughout history, eugenics has been spoken of in the works of Plato and Aristotle, which influenced Darwin's work and his theory of evolution based on natural selection.

With the development of embryo research, neo-*eugenics* is now talked about. This is not to be confused with the eugenics put forward in the early twentieth century, with practices of sterilization of the physically or mentally disabled, elimination of ethnic groups, extermination of people of certain sexual orientations, promoted by totalitarian political regimes, but presents itself as a medical issue, restricted to the medical - patient sphere, as a matter of individual nature, of a right to health - to be born healthy - in relation to their parents and their reproductive faculties.

However, as far as I can see, applying the pre-implantation diagnosis does not mean an eugenic pract ice, since it is limited to the individual sphere of those who submit to the techniques, and it cannot be stated that its permission mean the authorization of a eugenic policy.

Of course, and here I insist, this is not a simple issue. On the contrary, this theme generates restlessness throughout the scientific community and society.

In the work entitled "*Against Perfection: Ethics in the Age of Genetic Engineering*" Michael J. Sandel reports: "Some years ago, a lesbian couple decided to have a child, preferably deaf. The two partners were proud of being deaf. Like other members of the Deaf Pride community, Sharon Duchesneau and Candy McCullough viewed deafness as a trait of cultural identity, not a deficiency to be cured (...). In the hope of conceiving a deaf child, they sought for a sperm donor whose family had had a history of five generations of deafness. And they did so and their son Gauvin was born deaf.

This recently reported situation by Michael J. Sandel shows that, since the international scientific community, through the Human Genome Project, announced the decoding of the DNA molecule, thus unravelling the biochemical

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su lado oscuro cuando se trata de precisar que caracteres han de ser alentados o estandarizados y quienes seran los encargados de fijar tales caracteres. Por outro lado, no debe olvidase el hecho de que ignoramos completamente los efectos a largo plazo sobre la salud publica de estas diversas presiones genéticas. Por esta via, una nueva eugenesia, dulce, democrática e insidiosa se instala silenciosamente en la sociedad, sin que nadie sepa a ciência cierta adonde la conducira".

secret of life, enabling in a continuous way, to hold the power to manipulate and instrumentalize this knowledge. Some philosophical, ethical, bioethical reflections have been necessary. This was indeed needed because, as Robert Shattuck warns in the work Prohibited Knowledge, "the power in itself does not bring danger. However, the imagination associated with power can exceed the limits of the human condition and seek for the divine one.[8]

The evolution of science and technology has not always followed criteria, and there have been reported cases of transgressions within the limits of what was acceptable as ethical. Thus, the ethics applied to biology started to be called bioethics. Such term that emerged in the 1970s and was used by Van Rensselaer Potter of the University of Wisconsin, Madison, United States, in the article "*The science of survival"*, who, in turn, published, in January of 1971, the work *Bioethics Bridge to the Future*. However, we cannot fail to mention the milestone of bioethics as the Nuremberg Code of 1947, designed in order to no longer allow the atrocities practiced at the time of World War II to be repeated.

Bioethics occupies a prominent place in the study of conduct, health and human life, since it addresses issues related to medical deontology and everything related to human life and health. As a discipline, Bioethics encompasses principles, ethical guidelines inherited from the North American approach to the theme that are adopted by most countries. These principles, mentioned before (autonomy, beneficence, non-maleficence and justice) will nurture the content of norms that will be established to define the ethical and juridical boundaries of clinical interventions and scientific experimentation with human beings.

Therefore, whether from the standpoint of bioethics or law, the question of the boundaries of scientific research involves the weighting between things or values.

It is imperative to highlight that there is also no consensus on this aspect. We can cite here three positions in legal doctrine on this matter: firstly, the one that argues that scientific knowledge cannot be limited, since knowledge as such is not contrary to law and only the use of knowledge can be done in a harmful way. A second position includes a finalist element, so that research can be impeded if its purpose is to obtain knowledge that will be used to harm the personality rights or groups of people. Finally, a third position argues that the prohibition of obtaining knowledge is incompatible with the standards of

8 SANDEL, Michael. The case againist perfection : Ethics in the age of Genetics Engineering. , Belknap Press, 2009.

the Democratic State of Law, even though it is legitimate to establish limits or prohibitions of methods that imply violation of fundamental rights, by establishing weighting mechanisms.

It´s understood that in a State of Law freedom is not unlimited. All freedom finds limits, and with the freedom of scientific research, which is a fundamental right, it is not different. Random deviations do not corroborate to justify the prohibition of the application of scientific techniques or knowledge which might improve the quality of life of individuals.

Such limits must be obtained by harmonizing this freedom with other fundamental rights, other conditioning values and other structuring principles, in particular the inviolability of the right to life and the dignity of the human being.

Whenever these boundaries are well defined science will be at the service of humankind and the scientific development will serve to accomplish the principle of the dignity of the human person.

3. Saviour Sibling and the Argument that it is using People as a Means to an End

The main criticism against the use of the technique of *designer babies* refers to the supposed instrumentation of the baby to cure an older sick sibling, which would violate the principle of the dignity of the human being and especially the best interest of the child. Taken from Immanuel Kant's famous dictum "*Never use people as a means but always treat them as an end*."

It is widely known that the principle of the dignity of the human being proposes boundaries to the State's action, so that the public sector cannot make actions, which violate it, and should have as a goal the promotion of a dignified life for everybody. On the other hand, it also imposes limits on the relationships between individuals, restraining inter-relational behaviours that violate dignity.

The central aspect of this discussion is therefore to verify whether there is, in fact, a violation of the dignity of the child who was born with the objective to save his sick sibling. The difficulty in answering such evidence lies, firstly, in the very concept of human dignity.

Human dignity stems from philosophy. Therefore, in the first place, it is a value, which is an axiological concept, associated with the idea of good, just, and virtuous. It is on this ethical realm that dignity has become, for many authors, the moral justification of the human and fundamental rights.

Kant concludes that their value must be absolute, and not comparable to the value of anything else. If their value is "beyond all price," it follows that rational beings must be treated "always as an end, and never as a 'means only." This means; on the most superficial level, that we have a strict duty of beneficence toward other persons: we must strive to promote their welfare; we must respect their rights, avoid harming them, and generally "endeavor, so far as we can, to further the ends of others." But Kant's idea also has a somewhat deeper implication. The beings we are talking about are rational beings, and "treating them as ends-in-themselves" means respecting their rationality. Thus we may never manipulate people, or use people, to achieve our purposes, no matter how good those purposes may be.[9]

Mary Neal argues that we need to accept that there is not one single concept of dignity, but rather different conceptions that are used in different contexts, and suggest that we consider dignity to "*reflect a valuing of the sense in which human existence (perhaps uniquely) embodies a union between the fragile/material/finite and transcendent/sublime/immortal. In valuing us because of, and not in spite of/regardless of our vulnerability."*[10]

On a different sphere, it encompasses international and constitutional documents, becoming considered one of the main foundations of the Democratic States. At first, however, its implementation was seen as a Legislative and Executive Powers' matter. Only in the last decades of the twentieth century did dignity come closer to Law, becoming a legal concept, deontological - an expression of a normative duty, not just moral or political. Moreover, consequently, it starts being verified by the Judiciary.

In this way, human dignity, while remaining a fundamental moral value, also gains status of a legal principle. Although always present in the history of ideas, it was not until the end of the second decade of the twentieth century that the human dignity began to appear in legal documents, beginning with the Constitutions of Mexico (1917) and Weimar's Germany (1919). After World War II, human dignity was incorporated to main international documents, such as the UN Charter (1945), the Universal Declaration of Human Rights (1948), and countless other international treaties and pacts, placing itself in a central

9 RACHELS, JAMES. Kantian Theory: The Idea of Human Dignity. http://public.callutheran.edu/~chenxi/phil345_022.pdf

10 NEAL, Mary. Not gods but animals": human dignity andvulnerable subjecthoodhttps://strathprints.strath.ac.uk/39942/1/Neal_LLR_2012_Not_gods_but_animals_human_dignity_and_vulnerable.pdf .

role in speeches on human rights. It was particularly stressed in the European Charter of Fundamental Rights of 2000 and in the European Constitution Project in 2004.

As for constitutional law, since the second post-war time, various Constitutions included the protection of the human dignity in their texts. The primacy, in particular, concerned the German Constitution (Fundamental Law of Bonn, 1949), which provided, in its 1st art., the inviolability of human dignity, giving rise to a vast jurisprudence, developed by the Federal Constitutional Court, which raised it to the status of fundamental value and axiological centre of the entire constitutional system. Several other Constitutions bring explicit reference to dignity in their texts- Japan, Italy, Portugal, Spain, South Africa, Brazil, Israel, Hungary and Sweden, among many others - or in its preamble, like the case of Canada. In addition, even in countries in which there is no explicit mentioning of dignity in the Constitution, such as the United States and France, jurisprudence has invoked its legal and argumentative force in important decisions. From then on, the constitutional courts of different countries started to dialogue. As for comparative Law, special attention should be drawn to the Federal Constitutional Court, whose decisions are cited in different jurisdictions. In cases (most hard cases) decided by Courts, human dignity has always been at the core of many discussions, such as the declaration of unconstitutionality of the decriminalization of abortion (Abortion I), the flexibility of this very decision (Abortion II), the prohibition of putting down hijacked planes by terrorists, and the prohibition of using personal diary as a means of evidence, among many others. German jurisprudence is abundant on the subject.

The challenge of applying the principle of dignity is to provide it with minimum content that gives unity and objectivity to its interpretation and application, especially in difficult cases. This becomes possible from a secular conception, with political and universal neutrality. Thus, it is based on a conception that one must examine the turmoil involving the dignity of the saviour sibling.

On this matter, there are countless voices that support and that are contrary to the realization of the Pre implantation Diagnosis for the birth of the *saviour sibling*.

In France, in 2014, the archbishop of Rennes commented that such instrumentation is contrary "*to the most basic respect granted to every human being, in detriment of the primary interest of the child*," citing the National Consultative Commission on Human Rights. The statement also declares that every child "*has the right to be born on his/her own, to be loved by him/herself*

and to be welcomed by him[11]/herself." He highlighted that "*this birth is unique because it involves questions such as: Who could remain insensitive towards life and suffering? Who could deny the legality of an altruistic scientific act?*" He concluded that using a more vulnerable human being to cure another one violates human dignity.

Jean Longeneaux doubted the existence of a child who had been conceived solely because of him/herself. He argues that there are other reasons that determine the decision to conceive a child, which is also used, and are indeed socially accepted, for other reasons, such as to keep company of another child, to have children of different sex, etc., these reasons that relate to the will of the parents rather than any concern with the being that is going to be conceived.

Jonathan Herring relates the following key case in England that highlights some of the issues involved:

> Key Case Quintavalle (on behalf of Comment on Reproductive Ethics) v HFEA [2002] UKHL 28 The House of Lords was asked to consider the legality of the HFEAs licence to permit a clinic to use human leukocyte antigen (HLA) typing to test embryos for stem cells that could provide a cure for a couple's son. Under the HFE Act 1990, section 3(1), it is a criminal offence to bring about the creation and use of an embryo, except under license from the HFEA. The proposed treatment involved the creation and use of an embryo, and required license, which the authority granted. The granting of the licence was challenged in the court by the group Comment on Reproductive Ethics (CORE). Its application succeeded before Maurice J, but failed before the Court of Appeal and the House of Lords The key provision was the section 11 of the 1990 Act, which permitted the HFEA to license certain activities. In Schedule 2, paragraph 1(3), these included '(d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose The HFEA argued successfully before their Lordships that the word 'suitable' meant 'suitable for the woman to whom the services are provided'. The mother was entitled to regard an embryo as suitable only if it was compatible for treatment of her sick son.

11 (free translation) LONGNEAUX, Jean Michel. Apud. FÉO, Christina. VIEIRA, Tereza Rodrigues. Eugenia e o Direito de nascer ou não com deficiência: algumas questões em debate. In: VIEIRA, Tereza Rodrigues (org). Ensaios de bioética e direito. Brasilia: Consulex, 2012, p.58.

> CORE argued that this is too wide an interpretation of the provision and would allow the HFEA to license treatment to test for a whole range of idiosyncratic wishes, such as hair colour. The interpretation of paragraph 1(3) advanced by CORE was that 'suitable' meant that the child would be healthy and free from abnormalities. This would allow PGD to test for abnormalities, but not to test for whether the child's tissue matched a sibling's. This argument was rejected. First, it was pointed out that although the HEA's interpretation meant that a licence could be given for frivolous reasons, there was no reason to believe the HFEA would grant such a licence. Second, and more importantly, the HFE Act was designed to leave these complex moral issues with the HFEA. The Act was structured to outlaw some things (such as the cloning of an embryo), but to leave other things open to the HFEA to license if it thought it appropriate to do so. The issue in this case was not outlawed specifically in the Act and therefore was licensable by the HEA. If Parliament felt that the HEA was using its powers improperly, it was for Parliament to reform the HFEA. It is worth emphasizing that the House of Lords approached this case by addressing the narrow legal issue of whether the HFEA had statutory authority to license the treatment. The ethics of it, or whether it would be lawful to use the tissue of any resulting child, were not considered in any detail.[12]

In 2008, when reforms of HFEA were being discussed, the creation of "saviour siblings" was one of the issues that sparked the greatest debate. Susan M. Wolf, Jeffrey P. Kahn, and Jonh E Wagner raised some arguments on the topic:

> [Wle know almost nothing about the psychological impact of being conceived to serve as an HLA-matched donor and save a sibling's life. The effects on the donor child are potentially profound. Indeed, if the cord blood transplant fails or the donor child is otherwise repeatedly considered for harvest over a prolonged period of time, there may be a potential for serious effects. The potential may be all the greater if the donor child comes to resist or refuse further procedures Moreover, even if one debates whether using GD solely to conceive an HLA-matched donor may be said to harm the donor child, this use of PD exclusively to create an opportunity for later harvesting may be wrong

12 HERRING, Jonathan. Ethics and Medical Law. 6th Edition. Oxford: Oxford University Press, 2016, p. 412.

> on other grounds, such as violating the ethical injunction to respect each individual and avoid using persons as mere means .The donor child is at lifelong risk of exploitation, of being told that he or she exists as an insurance policy and tissue source for the sibling, of being repeatedly subjected to testing and harvesting procedures, of being used this way no matter how severe the psychological and physical burden, and of being pressured, manipulated, or even forced over protest.[13]

On the other hand, Sally Sheldon and Stephen Wilkinson make the following considerations in relation favour of the technique:

> "The first prohibitionist argument is that a saviour sibling would be 'a commodity rather than a person' and would be wrongfully treated as a means rather than an end in itself... (T) his argument fails to say what is wrong with creating a child as a saviour sibling, when creating a child for a number of other 'instrumental' purposes is widely accepted… We turn now to the idea that saviour siblings will be psychologically harmed…But even we concede for the sake of argument that it would be hurtful or upsetting for a selected sibling (A) to discover that she had been conceived for the primary purpose of saving the life of an existing child (B), is it really plausible to suppose that A would be less happy than another, randomly selected sibling (C) who was unable to act as a tissue donor? For it could surely be argued that A would benefit from B's company and may well derive pleasure from knowing that she has saved B's life. In contrast, imagine the psychological impact on C, born into a bereaved family, later to discover that she was a huge disappointment to her parents because of her inability to save B's life… [W]e can at least say that it is far from obvious that child welfare considerations should count against, rather than for, the practice of saviour sibling selection.[14]

The HFE Act 2008 amended the 1990 Act to make it clear that embryo testing to ensure that an implanted embryo may be a "saviour sibling" is permitted.[15]

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13 Susan M. Wolf, Jeffrey P. Kahn, and Jonh E Wagner. Using preimplantation genetic diagnosis to create a stem cell donor: issues, guidelines, and limits. (2003) 31 Journal of Law, Medicine and Ethics 327.

14 SHELDON, Sally; WILKINSON, Stephen. In JACKSON, Emily. Medical Law: Text, Cases and Materials. Fourth Edition, Oxford: Oxford University Press, 2016, p, 862

15 Paragrapha IZA(d) of Schedule 2 of the 1990 Act allows a testing where: … (a person

However, it is important to point out that such permission requires the fulfilment of some requirements such as the use only in case of siblings, not extending to other relatives, the impossibility of carrying out embryonic selection in order to perform a future organ transplantation, like other relatives in the family, the child to be saved as well as the child to be born.

In present study, we do not intend to deny that, in fact, the baby is generated conditionally with an objective. Nevertheless, seeing this child only as a "medicine" is to assume a lesser perspective of the reality faced by the families that adopt this technique.

The family will see this new family member as a whole person, with full rights, and especially with the affectionate characteristic of the contemporary family relations. If we were to investigate the reasons why the parents long to have a child, many of them would certainly represent an apparent instrumentation of the human being, since these reasons are not always so noble. This subjectivity, however, should not be investigated, since respect for the child's dignity is analyzed as an objective data.

In an article written by B.M. Knoppers, she states that most parents have a broad range of reasons and expectations when they decide to have children, which, she explains, instrumentalizes them to a degree. This leads some authors to write that as long as the tissue donation would be ethical if performed on an existing child, bringing a child into the world to serve as a tissue donor is ethical if the child is also valued for him or herself.[16] As long as the parents intend to rear and love the donor child, this practice is acceptable. Supporters of this practice argue that since these parents are making the focused effort to try to save their child, it suggests that they are caring and loving parents and makes it unlikely that they would treat a newborn as a child that was only used to save another child.[17]

(`the sibling`) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or either of these persons) suffers from a serious medical condition which could be treated by umbilical cord stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling.

16 B.M. Knoppers, Preimplantation Genetic Diagnosis: An Overview of Socio-Ethical and Legal Considerations: Annual Review of Genomics and Human genetics, 201-221, 212 (2006).

17 K. Devolder, Preimplantation HLA typing: Having Children to Save Our Loved Ones, 31 J. MED. ETHICS 582- 586, 584 (2005).

The child is being reated to be loved in his or her own right, as well as to assist the sibling.

For these authors, the argument that when the child may suffer psychological problems when he/she gets to know that he/she was born to save his/her brother, is mere assumption. Guesses about possible emotional harms for the "savior siblings" do not justify denying treatment that would save a life.[18]

They argue that, therefore, it cannot be stated that the technique turns the human being into a thing, firstly because the new being will not simply be used for the other child. In addition, because birth is prohibited for the purpose of organ transplantation, and, given the complexity of human beings, and the different ways that this new member of the family will be welcomed, one cannot say that he will be either happier or less happy because he is a donor, rather than the other brother.

It should be noted that the dignity of the family member is inherent in its condition of being human, despite any condition.

4. Conclusion

From what has been exposed, it is clear that few topics raise as many ethical concerns as the debate on the acceptability of the "saviour sibling". In fact, the situation involves the consideration of principles such as reproductive autonomy, responsible parenthood and family solidarity and the best interest of the child, which intersect in an uncertain and potentially problematic way, bearing in mind, however, the greater value of the legal system, which is the protection of human beings against any type of instrumentalization.

Based on this premise, Luc Ferry[19] questions how to decide on what should be authorized or prohibited in terms of genetic engineering, how to choose and according to which criteria among the three possibilities that open up to totally prohibit genetic manipulations, as requested by bio conservatives: limit them to exclusively therapeutic issues, as many want, or put them at the service of

18 HERRING, Jonathan. Ethics and Medical Law. 6th Edition. Oxford: Oxford University Press, 2016. p. 414

19 FERRY, Luc. La revolución trasnshumanista. Como la medicina y la uberizacion del mundo van a transformar nuestras vidas. Traducción de Alicia Martorell. Madrid: Alianza Editorial, 2017.

improving the human being, however, in the latter case, what improvement should it be about? Moreover, under what conditions? Just for a few or for all? Who can legitimately decide in the last instance when the collective and not just the individual is called into question?

Preliminarily, it is important to bear in mind that the concepts that Law uses from other branches of science are not always consistent with them, since Law, as a standardization of facts, is influenced by several factors in addition to techno-scientific factors, in particular the historicity.

The rules do not exist in a vacuum, but are found side by side with moral and social codes of greater or lesser complexity and definition, or with the ethics that is before and beyond all Law. , thus connecting the concepts again (of closed valuation) and the principles/values (of rarefied content). It must be considered that it works in an open system, with mobility, heterogeneity, in which a functional realization or realization prevails, a teleological perspective of weighing the consequences of the decision of permanent interaction between center and periphery.

It cannot be forgotten that the birth of the "saviour sibling" has the purpose of saving a child's life, which should have weight in any ethical-legal analysis.

On the other hand, we cannot ignore the potential for abuse, or the ease with which this procedure can be misused.

The scenario demands a multidisciplinary reflection to avoid a mismatch between the bioethical values adopted by the medical community and the values contemplated by the current legal system, as deserving of protection, reaffirming the need for regulation in the face of the legislative void that prevails and the ethical-legal questions that arise in a context of accelerated biotechnological advancement.[20]

20 FERRAZ, Ana Claudia B. de B. Correia. Filhos para a cura. Bebê medicamento como sujeito de direito. São Paulo: Thomson Reuters Brasil – Revista dos Tribunais, 2020.

REFERENCES

ANDORNO, Roberto. *El derecho frente a la nueva eugenesia*. **Revista Chilena de Derecho,** Santiago**,** V. 21, n° 2, pp. 321-328, 1994.

B.M. Knoppers, Pre implantation Genetic Diagnosis: An Overview of Socio-Ethical and Legal Considerations: Annual Review of Genomics and Human genetics, 201-221, 212 (2006).

DEVOLDER, K. Pre implantation HLA typing: Having Children to Save Our Loved Ones, 31 J. MED. ETHICS 582- 586, 584 (2005).

FERRAZ, Ana Claudia B. de B. Correia. Filhos para a cura. Bebê medicamento como sujeito de direito. São Paulo: Thomson Reuters Brasil – Revista dos Tribunais, 2020.

FERRY, Luc. La revolución trasnshumanista. Como la medicina y la uberizacion del mundo van a transformar nuestras vidas. Traducción de Alicia Martorell. Madrid: Alianza Editorial, 2017.

HARRIS, John and HOLM, (eds), Ethical Issues In Preimplantation Diagnosis" in The future of Human Reproduction. Claredon Press: Oxford, 1998.

HERRING, Jonathan. Ethics and Medical Law. 6th Edition. Oxford: Oxford University Press, 2016

JACKSON, Emily. Choosing Children: Genes, Disability and Design. MEDICAL LAW: TEXT, CASES AND MATERIALS. FOURTH EDITION. OXFORD UNIVERSITY PRESS: UNITED KINGDOM, 2006.

KING, David. Pre implantation genetic diagnosis and the "new" eugenics (1999) 25 Journal of Medical Ethics 176-81.

NEAL, Mary. Not gods but animals": human dignity and vulnerable subjecthood https://strathprints.strath.ac.uk/39942/1/Neal_LLR_2012_Not_gods_but_animals_human_dignity_and_vulnerable.pdf .

RACHELS, JAMES. Kantian Theory: The Idea of Human Dignity. www. http://public.callutheran.edu/~chenxi/phil345_022.pdf

ROMEO CABONA, Carlos Maria. El convenio de Derechos Humanos y Biomedicina: su entrada em vigor em el ordenamento jurídico español. Granada:Comares, 2002.

SANDEL, Michael. The case against perfection : Ethics in the age of Genetics Engineering. , Belknap Press, 2009.

SHELDON, Sally; WILKINSON, Stephen. In JACKSON, Emily. Medical Law: Text, Cases and Materials. Fourth Edition, Oxford: Oxford University Press, 2016, p, 862.

WOLF, Susan M; KAHN, Jeffrey P; WAGNER, John E. Using preimplantation genetic diagnosis to create a stem cell donor: issues, guidelines, and limits. (2003) 31 Journal of Law, Medicine and Ethics 327.

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SELF-INSEMINATION IN BRAZIL AND INFORMATION AS A STRATEGY TO MINIMIZE HEALTH RISKS

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When there are scientifically considerable facts about the causes, probability and nature of possible harm, that is, when certain human activities may be scientifically plausible and inter esting but cause morally unacceptable harm, action must be taken to prevent or lessen such harm[5]

Abstract: Family planning as a constitutional right and infertility recognized as a disease demanded the Brazil's Public Health Unified System to offer fertilization to needy families, who are unable to conceive naturally. As the government does not support the burden of offering fertilization to everyone, people that cannot afford the costs of a specialized clinic to perform artificial insemination will find self-insemination as the modest and informal solution. That is the reason for it growing alarmingly, with supporters throughout Brazil, which interacts on social networks: the "trying to conceive" women choose the "donor" in a kind of "online semen bank" to accomplish the procedure. However, there is scarce information about the risks that the method offers, health consequences and legal effects. Information is believed to be an instrument of prevention, because awareness of the risks, people

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will be able to seek alternatives from genetic counseling to minimize damage.

Keywords: Self-Insemination; Health Risks; Information; Prevention; Medically Assisted Human Reproduction

Introduction

Since family planning has become a constitutional right of citizens, by virtue of Law nº 9.263/96 and as a result of the success that the techniques have been achieving, two realities are revealed: on the one hand, people in conditions to afford the costs of procedures, medications and exams, elect Medically Assisted Human Reproduction (MAHR) to fulfill the dream of the parental project; on the other hand, couples who do not have a good financial conditions and cannot afford the costs of MAHR techniques, resort to other forms of carrying out the parental project.

Based on the recognition of infertility as a disease by the World Health Organization (WHO), the person is entitled to free fertilization, in accordance with Ordinance No. 426/2005 of the Brazil's Public Health Unified System (SUS)[6] which the National Policy for Comprehensive Care in Assisted Human

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5 Pessini L. Elementos para uma bioética global: solidariedade, vulnerabilidade e precaução. Online [Internet]. 2017 [access in: 15 jan. 2023]; 10(19): 75-85. Available in: file:///C:/Users/Patricia/Downloads/1983-5636-2-PB.pdf.

6 BRASIL. SUS – Sistema Único de Saúde. Portaria nº 426/GM/MS, de 22 de março de 2005. Cria a Política Nacional de Atenção Integral em Reprodução Humana Assistida. Ministério da Saúde. 22 mar. 2005.

Reproduction. However, few public hospitals perform the procedures and the offer of treatment by the SUS is limited. In addition, increasing occurrence of infertility in society (and also associated with late reproduction, imposed by the philosophy according to which the couple prioritizes acquiring assets and achieving better living conditions to later have children), expressively increases the number of people who seek MAHR techniques to fulfill the dream of having descendants. Therefore, research in this area is increasingly advanced, with growing successful results, rising the rate of positive results. However, MAHR techniques have a towering cost, due to the high degree of specialization of the professionals and the quality of the latest technological equipment, materials and inputs.

Faced with this fact, homemade insemination or self-insemination (SI) appears in the context of needy families as a response to those people that wish to fulfill the parental dream of having a child, but do not have the financial resources to pay for the MAHR techniques performed in specialized clinics. They then search for SI because it is a very economical procedure compared to conventional MAHR techniques, however without medical or legal support with possible consequences in the medical and juridical spheres, besides the bioethical issues inherent to the ho procedure, such as the vulnerability of the subjects involved in this relationship, that do not have enough information about the procedure and frequently are unaware of the countless consequences that may result from it.

The objective of this article is to explain the vulnerability of people that use the SI procedure and the dangers to which they are exposed, in view of the risks to the health of the woman, the child to be conceived, and in some cases, the damage may reach the public health sphere (genetic diseases, for example, can harm future generations). It is intended to awaken society to the need to inform about these health risks, to lead to critical reflection on these issues, in order to minimize the vulnerability to which people who opt for the procedure are subject. This study is justified by the need to protect the subjects involved in the procedure (woman, semen donor and child resulting from insemination). Warning about the risks of SI becomes relevant, because the access grows exponentially due to the interaction and dynamics of digital social networks that optimize communication among subjects participating in this informal artificial reproduction procedure. There are uncountable risks to which women and their offspring are subject and at least three important categories can be identified: bioethical, legal and medical risks, with doctors being of particular interest in this last approach.

Lastly, it is emphasized that the unbureaucratic and informal way of conception offers several risks to the woman and her offspring, making SI an interdisciplinary topic, whose practice involves several areas of knowledge such as law, medicine, genetics, bioethics, psychology, biology, technologies and other areas of human health. In this perspective, seeking to present a response to so many routine situations that are difficult to solve, information to society, women and families is proposed as a transforming instrument so that the choice of procedure does not become a legal demand or a serious health issue (human and collective) in the future, which can impact the offspring and, by extension, society. In this study, information will be analyzed as an important resource in order to contribute to discouraging the SI procedure, in order to protect the health and dignity of the subjects involved in this relationship.

SI: The Unveiling of a New Way of Conceiving

In Brazil, MAHR techniques count on laconic legal discipline, even the Civil Code is shy when disciplining them, as highlighted by the jurist Dantas (2021)[7]:

Brazil, despite dealing with the matter in the Civil Code, did so in an insufficient and superficial way, a fact that finds justification in the social understanding of family and in the existing technologies at the time of elaboration of the Code project, in the 1970s, when not even Louise Brown, the world's first "test tube baby" was born.

SI consists of a procedure in which individuals that wish to have children resort to it because they do not have the financial conditions to provide MAHR techniques. Before starting the procedure, it is necessary to explain how communication occurs between the trying to conceive (TTC) woman and the semen donor: the woman that wants to perform the homemade procedure uses Facebook or WhatsApp groups, usually into specific groups for this purpose, in order to clarify doubts about the procedure, as well as looking for a donor, which constitutes a real "online semen bank", a name given due to the similarities among the semen bank of specialized clinics and those found in digital social media, however they are different in terms of to the technical, medical and legal rigor that does not exist in SI. In these groups, donors expose their characteristics, such as skin and eye color, hair, tastes, body type and any

7 Dantas E. Contraditor [homepage na internet] A reprodução humana assistida e a "contribuição legislativa" do congresso nacional [access in: 17 jan. 2023]. Available in: https://www.contraditor.com/reproducao-humana-assistida/.

other information necessary for the TTC. Most donors expose their photos in the groups, as well as photos of children born through SI. In the same way, the TTC ones expose the characteristics that they want to transmit to their children. It is possible to observe that:

Many women join the groups through referrals from well-known people, through TV reports or articles in local newspapers. When they are accepted, they become part of a space that can vary depending on the group, but which, in general, are places for exchanging information and studying. Some groups offer materials that explain the SI process, give tips on how to prepare to receive the semen donation, the exams that the woman should take and the ones that she should ask the donor, etc. Women can also write publications asking for information, giving testimonials of their experiences and exposing donors or other women who have some behavior that they dislike[8].

Some TTC ask for tests to prove that the donor does not have a sexually transmitted infection or comorbidity, however, as it is a homemade procedure, simply performing laboratory tests does not guarantee that the donor is healthy and able to donate semen. It is important to mention that, in the period between the exams and the time of donation, he may have contracted an illness, in the same way that some illnesses are more difficult to detect, requiring medical follow-up and specific exams.

When finding the donor of her choice, the TTC arranges a date and a place to perform the procedure, usually in a hotel or in the house of one of them. After choosing the donor and combining them, preparations for the procedure Begin some women seek medical advice to find out if they are physiologically able to get pregnant, also asking help from other women who have already managed to get pregnant through the procedure, as well as home remedies and teas. Some women even in advanced age or with certain diseases such as polycystic ovary try to perform the procedure. When they meet, the donor collects the biological material, stores it in a sample container and delivers it to the TTC woman, that introduces it into the vaginal canal, with the help of the materials as[9]:

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8 Felipe MG, Tamanini M. Inseminação caseira e a construção de projetos lesboparentais no Brasil. Nanduty [internet]. 2020 [access in: 28 out. 2022]; 8: 18-44. Available in: https://ojs.ufgd.edu.br/index.php/nanduty/article/view/15301.

9 Ferreira MC. Fecondare [homepage on internet]. Mito ou verdade: Inseminação artificial caseira funciona? [access in: 28 out. 2022]. Available in: https://fecondare.com.br/artigos/mito-ou- verdade-inseminacao-artificial-caseira-funciona/.

[...] materials used are 10 and 5 mL syringes and sterile sample containers, both disposable. Other materials such as vaginal specula and catheters can be used. The practice consists of quickly storing the ejaculated sperm inside the sample containers to be sucked by the syringe, which will inject the material as close as possible to the cervix of the recipient woman[10].

It is worth mentioning that some donors already have more than 50 children resulting from SI, and this information is easily proven through the references that the trying ones expose in the groups so that other women know that the donor is reliable. This fact generates an additional risk in the field of genetics: the tryers opt for donors with a greater number of references, leading to the existence of several children of the same man in the region, and most of them do not know their paternal ancestry, thus arising the risk of marriage or inbreeding among siblings in the future[6]. It is also not difficult to observe in the groups that the TTC women from the same region sometimes agree to have the SI with the same donor in order to share the donor's expenses with transportation, food and accommodation.

By exposing themselves on social networks, the donor and the TTC end up getting to know each other, which removes the expected anonymity for donations, which can have several consequences in the legal sphere. The relationship between donor and TTC mediated by social media is established through:

[...] important exchanges, in the first place because they are autonomous reproduction practices, that is, TTC women and donors come into contact for the first time, in general, in these spaces, or through indications of other trying women and donors, and establish a relationship that extends until the moment of donation, when these people will meet in person[11].

It is possible to highlight at least three categories of risks in relation to the procedure: legal, bioethical and medical, since in future upheavals they may suffer severe consequences in different spheres. Among the bioethical issues are vulnerability, the risks of non-observance of the anonymity of the donor of

10 Felipe MG, Tamanini M. Inseminação caseira e a construção de projetos lesboparentais no Brasil. Nanduty [internet]. 2020 [access in: 28 out. 2022]; 8: 18-44. Available in: https://ojs.ufgd.edu.br/index.php/nanduty/article/view/15301.

11 Felipe MG, Tamanini M. Inseminação caseira e a construção de projetos lesboparentais no Brasil. Nanduty [internet]. 2020 [access in: 28 out. 2022]; 8: 18-44. Available in: https://ojs.ufgd.edu.br/index.php/nanduty/article/view/15301.

genetic material and its genetic treatments, the unauthorized transport of genetic material and its incorrect manipulation, the absence of treatment, quarantine and tests necessary for semen to be used in fertilization. In the legal sphere, the first and serious obstacle concerns the fact that a request for acknowledgment of filiation/paternity is unwanted by one of the parties: in 2017, the Federal Supreme Court, through general repercussion nº 622[12], signed the thesis that socio-affective paternity, declared or not in public record, does not prevent recognition of the concomitant filiation bond, based on biological origin, with its legal effects.

Socio-affective paternity, in the case of heterologous artificial insemination and adoption are irrevocable, according to article 48 of Law No. 8069/90 of the Brazil´s Statute of Child and Adolescent (ECA), the investigation of the identity of the semen donor will have a purely cognitive effect, it will not involve recognition of the bond due to biological kinship, as adoption dissolves the legal bond with the original family. However, the same does not occur in IC, these devices will not be applied, since the biological identity is known from the contact of the trying woman with the semen donor[13]. The second obstacle is that the CI does not have a regulatory norm, since the legislative gap becomes an inconvenience insofar as it leads magistrates to resort to analogy, general principles of law and customs to judge the legal demands arising from this relationship, such as disputes for nourishment, custody, the right to family life and also property and social security rights. These facts, consequently, will generate legal uncertainty for the subjects of the procedure, as there is no uniform line to guide decisions. For this reason, in the technique developed in the reproduction clinics, anonymity is observed:

The donation of embryos and gametes is anonymous: people who use donated gametes, as well as those who adopt embryos, will not have access to the data of the donor(s) – and these will not know the identity of the recipients[14].

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12 Fux L. Supremo Tribunal Federal [homepage na internet]. Prevalência da paternidade socioafetiva em detrimento da paternidade biológica [access in: 14 jan. 2023]. Available in: https://www.stf.jus.br/portal/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=4803092&numeroProcesso=898060&classeProcesso=RE&numeroTema=622.

13 Portanova R. IBDFAM [homepage on internet]. Será que mudou alguma coisa com a decisão do STF sobre filiação? [access in: 14 jan. 2023]. Available in: .https://ibdfam.org.br/artigos/1235/Ser%C3%A1+que+mudou+alguma+coisa+com+a+decis%C3%A3o+do+STF+sobre+filia%C3%A7%C3%A3o%3F#:~:text=Tese%20firmada%20no%20Tema%20 622,com%20os%20efeitos%20jur%C3%ADdicos%20pr%C3%B3prios%22.

14 Maia T, Munhoz L, Silva BM. Reprodução Assistida: Um guia fácil e descomplicado de Saúde

People who opt for MAHR techniques are surrounded by a series of medical and legal care, to avoid future problems.

Considering that these are complex procedures, patients should be very well informed so that they can give their consent for the application of the techniques in question[10].

Other difference between SI and MAHR is

In addition to improper handling, the materials used in the process can be contaminated by bacteria and fungi present in the environment, especially in open places. As the sperm is also in contact with the external environment, there is still a risk of it being contaminated with microorganisms, even if it is exposed for just a few seconds[15].

The Vulnerability of Families and the Medical Risks of SI

Faced with the lack of information, women who undergo SI are vulnerable, as they cannot imagine the consequences they may face as a result of the procedure. However, the most vulnerable person is the child, who is already born and may be the subject of legal disputes, as well as suffering from illnesses resulting from the procedure. Some authors report on social and economic vulnerability, among others:

It is evident that this kind of vulnerability referred to by Pessini (2017)[16] is, conceptually and literally, a fragility to which these people are exposed, thus requiring greater care, greater protection. This would be the first type of vulnerability to be studied, understood and contextualized. It is a group of vulnerable people who, as explained by Schramm (2017)[17], do not have

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e Direito [publicação online]; 2018 [access in: 15 jan. 2023]. Available in: https://sbra.com.br/wp-content/uploads/2018/09/Ebook-Reprodu%C3%A7%C3%A3o-Assistida.pdf.

15 Ferreira MC. Fecondare [homepage na internet]. Mito ou verdade: Inseminação artificial caseira funciona? [access in: 28 out. 2022]. Available in: https://fecondare.com.br/artigos/mito-ou- verdade-inseminacao-artificial-caseira-funciona/.

16 Pessini L. Elementos para uma bioética global: solidariedade, vulnerabilidade e precaução. Online [Internet]. 2017 [access in: 15 jan. 2023]; 10(19): 75-85. Available in: file:///C:/Users/Patricia/Downloads/1983-5636-2-PB.pdf.

17 Schramm FR. A bioética de proteção: uma ferramenta para a avaliação das práticas sanitárias? Ciência e saúde coletiva [internet]. 2017 [access in: 15 jan. 2023]: 22(5): 1531-8. Available in: https://www.scielo.br/j/csc/a/G5RtQq4GXZb8SXJYSYbPb8s/?format=pdf&lang=pt.

mechanisms to defend themselves by themselves, therefore, they need protection from the family, society, the State (CABRAL, 2022, p. 43)[18].

In addition to vulnerability in the strict sense of Bioethics (people who cannot defend themselves on their own), there are other obvious weaknesses such as those affecting the legal sphere, already mentioned in this study.

In the context of medicine, the risks are many and of different origins, which may come from technical ineptitude for the introduction of semen into the vaginal canal, resulting from pre-existing unscreened infections in the parents, lack of knowledge of the donor's genetic information and poor hygiene conditions during the SI procedure.

In view of the imminent risks, ANVISA in its Resolution 771/2022[19] provides for good practices in germ cells, germ tissues and human embryos, for therapeutic use in Assisted Human Reproduction (AHR) techniques. Although this regulation deals specifically with MAHR, as it is scientifically based and recognized by the Federal Council of Medicine, compliance with biosafety rules is also essential for reducing biological risks, preserving maternal and baby health, and increasing cases of reproductive success by SI.The Resolution became mandatory to perform the karyotype examination among candidates for screening for gamete donation. The Resolution brings the minimum technical-sanitary requirements and applies to all establishments, public or private, that carry out activities with germ cells, germ tissues or human embryos, for therapeutic use in MAHR techniques, aiming at their own use or donation. Therefore, to be able to donate male gametes (sperm) or female gametes (oocyte), the candidate must obligatorily undergo a karyotype exam. This exam allows investigating whether, even if the person is healthy and without specific symptoms, it would have a chromosomal alteration that increases the risk of generating aneuploidies in the embryos that are generated from its gametes. When there are found alterations in the karyotype, it is necessary that the person search for a genetic counseling service, to analyze the consequences of the specific alteration identified by the exam and strategies for family planning.

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18 Cabral HLTB. A autoinseminação à luz dos referenciais da bioética global. In: Cabral HLTB, Ribeiro PD, Almeida JCA. Inseminação caseira: múltiplas faces – volume 1. Campos dos Goytacazes, RJ: Encontrografia Editora; 2022. p. 39-54.

19 Brasil. Resolução RDC Nº 771, de 26 de dezembro de 2022. Dispõe sobre as Boas Práticas em Células Germinativas, Tecidos Germinativos e Embriões Humanos, para uso terapêutico, e dá outras providências. Agência Nacional de Vigilância Sanitária (ANVISA). 18 jan. 2022.

One of the possibilities may be an *in vitro* fertilization treatment along with genetic evaluation of the couple's embryos in order to select embryos without aneuploidies for uterine transfer. Thus, there is a tendency of changes in relation to the legislation to narrow the possibilities of genetic anomalies arising from the artificial insemination process, which increasingly highlights the risks in homemade procedures, as in IS, which does not consider such aspects related to child health.

The selection of semen donors should not be carried out exclusively by physical characteristics (phenotype), which normally happens in SI processes, but by favorable clinical and genetic conditions. The semen screening requirements determined by ANVISA consist of laboratory tests for: HIV 1 and 2, hepatitis B, hepatitis C, syphilis, HTLV I and II, Zika virus, *Neisseriagonorrhoeae*, *Chlamydiatrachomatis*, sickle cell traits and karyotype (cytogenetic analysis that evaluates mutations numerical and structural in the chromosomes). Altered results in any of these tests are donor exclusion criteria, as they constitute potential sources of congenital malformations, mental, physical or neurosensory weakness, spontaneous abortion, intrauterine growth restriction and/or premature birth.

Information as a Strategy to Minimize Health Risks in SI

There is no doubt that, in this nebulous scenario, with no legal discipline, nor regulation by health agencies, it is necessary to think about the SI procedure from the point of view of ethics and caution, as Dantas warns: "As far as you can, or should you go? What are the frontiers of genetic engineering that must not be crossed, under penalty of jeopardizing what makes us human?"[20]. The issue of limits must be pondered in order to prevent even greater harm from occurring to women who use SI.

Information is believed to be the greatest weapon that society employs to make conscious decisions, which is why it is so necessary to discuss about SI, as most women who undergo the procedure are not aware of the medical risks that may arise from it for she and the baby, just as she is unaware of the legal battles they may face, which can cause various psychological and emotional disorders. Therefore, information cannot be disregarded, as it is the key element for a conscious decision:

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20 Dantas E. Contraditor [homepage na internet] A reprodução humana assistida e a "contribuição legislativa" do congresso nacional [access in: 17 jan. 2023]. Available in: https://www.contraditor.com/reproducao-humana-assistida/.

[...] the person is only able to decide on the adoption of a certain technique through the proper information that must be previously provided by the physician. This with maximum clarity, objectivity and through the use of accessible language, which makes you understand what your real possibilities are, your chances of obtaining a satisfactory result, or even cure, as well as the risks and consequences that may arise from the procedure for which he will give his consent, with a view to his adoption later. Thus, the need arises for clear and precise information, in language appropriate to the intellectual level of the recipient (patient) in order to provide him with elements capable of helping him to freely decide on the adoption of a certain technique or surgical treatment, or even, therapeutic[21].

For this reason, "[...] only information analyzed in the light of critical thinking can support safe and appropriate decisions"[22], that is, bioethical analysis can be used as a tool to reduce vulnerability and thus enable supporters to opt or not for the informal procedure, being aware of the possible risks that may arise from it.

In the case of SI, it is imperative that various clarification and information measures be adopted in order to make information material available to the population, women who wish to become pregnant and donors themselves about the complex consequences that may emerge from HF. Information campaigns from public bodies, the Ministry of Health, Health Secretariats, in the three spheres of federal entities (Union, States and Municipalities), through radio broadcasting channels, television campaigns, public health websites, pamphlets printed on the bulletin boards of easy access to the population of the neighborhoods, such as service stations, hospitals, Basic Health Units (BHU). It is essential to create printed booklets with free distribution, among other information tools capable of spreading the reality about the risks of SI. It is also necessary that the community gets involved, that the campaigns are also carried out by the institutions (family, school, university, church), in co-responsibility, as they can exert a lot of influence on society through their performance when dedicated to a specific cause of great social value like this, striving for society with more health, dignity and well-being.

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21 Cabral HLTB. Consentimento informado no exercício da medicina e tutela dos direitos existenciais: uma visão interdisciplinar – Direito e Medicina. 2ª ed. Curitiba: Appris; 2018.

22 Cabral HLTB, Souza LFB, Souza RLS. Autoinseminação e informação a educação transforma vidas. In: Couto CB., Araújo RC, Gregório TCC. Leituras em educação. São Paulo: Editora Opção; 2022. p. 283-98. Available in: https://desleituras.com/index.php/desleituras/article/view/86/101.

The relevance of information as a protection of existential interests, has the purpose of safeguarding the dignity of the person, acting in a preventive sense to avoid serious violations of people's rights through the misinformation and naivety of women who choose a procedure that could cause trouble later. And not only that, also having the clarifying role so that the people concerned know the limits and scientific possibilities in the field of fertilization. In addition, it is important that the information meet the criteria set out by Cavalieri Filho (2021)[23]: it must be adequate, sufficient and true, in order to demonstrate the importance of the subject, awaken people to the risks and possible consequences for families and the community society.

In view of the circumstances and arguments presented so far, it is concluded that the information offered to the subjects of the SI relationship constitutes the secret for the resolution regarding the best reproductive technique option to be adopted. Thus, critical competence in information as a basic premise of the thesis of the ethical dissemination of information and understanding for the exercise of citizenship. In the eagerness to transcend and understand the artifacts that adulterate the truth, the citizen becomes desirous of information literacy, capable of providing him with elements capable of ensuring critical thinking, critical awareness and reflective thinking (BRISOLA; ROMEIRO, 2018)[24]. It is necessary that, adopting a prospective view, people with infertility respect the main ethical rules, seeking other means in addition to SI, or at least, adopting a greater number of exams, complying with the schedule of their own periodic exams, consulting a program of fertilization and/or genetic counseling in order to receive instructions capable of changing directions in relation to vulnerability, risks, adopting ways to safeguard life, health, well-being and, ultimately, the dignity of the human person, no more as a mere principle, but as a value of the rule of law and the guiding principle of all projects and conduct within the sphere of collective interests concerning health.

In this case, it is imperative to adopt the bioethical framework of precaution, to reduce the risks that Pessini (2017, p. 83)[25] calls "morally unacceptable damage", taking information as an instrument to prevent (or even minimize) the risks of SI, because:

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23 Cavalieri Filho S. Programa de Responsabilidade Civil. 15ª ed. São Paulo: Atlas/Gen; 2021.

24 Brisola AC, Romeiro NL. A competência crítica em informação como resistência: uma análise sobre o uso da informação na atualidade. Revista Brasileira de Biblioteconomia e Documentação [internet]. 2018 [access in 15 jan. 2023]: 14(3): 68-87. Available in: https://rbbd.febab.org.br/rbbd/article/view/1054/1054.

25 Pessini L. Elementos para uma bioética global: solidariedade, vulnerabilidade e

Applying the "precautionary framework" means acting in an attempt to avoid or reduce these "morally unacceptable damages", due to their seriousness and irreversibility, which affect the lives of human beings and the environment. When there are considerable scientific uncertainties about causes, probability and nature of possible damage, that is, when certain human activities may be scientifically plausible and interesting, but cause morally unacceptable damage, action must be taken to avoid or reduce such damage[26].

This is, in the long term, a possible solution to be achieved, through many joint actions on the part of the Government, institutions, health care services, mobilizing for an authentic co-responsibility in which society will benefit and the future generations will certainly be free of the harmful results arising from the risks of SI.

Conclusion

In Brazil, MAHR techniques are disciplined in a timid way, with no regulation for SI and despite recent Federal Council of Medicine (FCM) resolutions, which guide professional practice within the scope of medical deontology. However, the FCM resolutions do not have normative force in the legal scope, they are treated in a restricted and superficial way by the Civil Code, therefore, lacking legal regulation.

Research is advanced in the area of reproduction and clinics are achieving an increasing number of successful results. Since people with infertility have been able to fulfill their dream of having descendants through MAHR techniques, those who cannot afford the costs of fertilization in specialized clinics due to the cost of increasingly specialized procedures have found in SI the answer to carry out the parental project in an economical, quick and unbureaucratic way.

However, based on research and studies carried out, it is possible to verify the enormous vulnerability to which families who use this informal, home-based and simplified procedure are exposed. These are possible risks of various natures, in different areas and which, due to their future consequences, may lead to illness or real disorders for the family. This article clarifies the existence

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precaução. Online [Internet]. 2017 [access in: 15 jan. 2023]; 10(19): 75-85. Available in: file:///C:/Users/Patricia/Downloads/1983-5636-2-PB.pdf.

26 Cabral HLTB, Pontes-Ribeiro DH, Pinho LG. Mistanásia no Brasil: o silencioso holocausto 26 do século XXI. Ensaios interdisciplinares em tempos líquidos - Homenagem a Zygmunt Bauman. 1ª ed. Campos dos Goytacazes, RJ: Encontrografia, 2020.

of potential risks in the scope of law, bioethics and medicine (human health), the latter being the one of direct interest to this analysis. In Law, there can be several developments inherent to Family issues, such as action for recognition of the bond of filiation by one of the parties (unwanted by another) and the consequences and developments of this claim. Within the scope of Bioethics, we explain the vulnerability, in the strict sense, of people who cannot defend themselves and need protection from the family, society, the Public Power and in the broadest sense, such as the violation of anonymity, the manipulation and illegal transport of genetic material, among other issues.

Since the practice of SI occurs outside the health services, with no medical assistance or adequate social, clinical and laboratory screening of the donor, several situations of vulnerability to the health of the mother and the child can be cited, such as: injuries caused by lack of anatomical and technical knowledge; semen contamination with microorganisms present in the environment; contagion by sexually transmitted infections; congenital malformations; embryonic chromosomal abnormalities and miscarriage.

In view of the potential risks and the dimension of the consequences, information is believed to be the key to releasing these possible effects, which, although potential, can affect families in a serious way, and it is unreasonable to wait for situations to become even more critical for looking for the best form of intervention. What is intended is to clarify, explain and inform so that people, if they so wish, continue to use the procedure, but they will do so from a new perspective: aware of the possible consequences, aware of the vulnerabilities and risks they are assuming for themselves and for others.

It is believed that information, as a fundamental right that it is, can bring to light the importance of prevention towards the search for safer fertilization methods, genetic counseling and other equally legitimate ways of making use of the bioethical reference of precaution, which refers to the reduction of these risks for the benefit of human and collective health for future generations.

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THE IMPACTS OF JUDICIAL DECISIONS ON THE DOCTOR-PATIENT RELATIONSHIP IN BRAZIL

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Abstract: This study has the objective of making a brief analysis of the impacts of judicial decisions in the evolution of the doctor-patient relationship in Brazil over the last two decades. The text seeks to trace the evolution of this relationship from the perspective of the impacts of judicial decisions and of the brazilian laws in these relationships. The text pretends, unpretentiously, to address the consequences for the doctor-patient relationship and also for health professionals specifically. All this, without, obviously, the intention of exhausting the issue, more with the objective of enabling a better understanding of this reality.

Keywords: Doctor-Patient; Impacts of Judicial Decisions; Law 8.078/1990; Superior Court of Justice (STJ); Free and Informed Consent Term; Compliance; Responsibility; Liability; Medical Act; Autonomy; Patient; Commodification; Contractualization

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INTRODUCTION

The evolution of the patterns of the doctor-patient relationship throughout the world underwent considerable changes over time, especially with the arrival and development of Bioethics and legislation in each country.

In Brazil it was no different, however, in addition to the legislative framework, the doctor-patient relationship has been severely impacted by the Courts, through jurisprudence and decisions that directly affect that relationship.

The Brazilian Courts mostly support the understanding that the Consumer Protection Code[2] applies to the doctor-patient relationship, a brazilian consumer law that seeks to protect the consumer from commercial and abusive actions by suppliers and service providers, a fact that already leaves the doctor vulnerable in several ways.

It is important to draw attention to the fact that today many doctors still not aware of how essential it is to obtain this document for the safe and calm practice of medicine.

The understanding of the Courts is that it is essential to verify compliance with the medical duty of information for the patient through the free and informed consent term.

It is absolutely necessary that the document be redistributed containing relevant information on possible procedures and complications of the procedure, as well as the description of all the care related to pre and post-operative, with the use of a simple and accessible language.

It is also important to highlight the information about the limitations regarding the results of the procedure to be performed.

The doctors must treat the consent term as an essential tool in the care protocol for the patient. It is a medical document whose relevance is not only applied from the point of view of the patient, as it is normally assigned, but also from the point of view of the medical defense.

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2 Law 8.078/1990 - . Consumer Protection Code.

Considering the application of Law 8.078/1990[3], the entire documentary framework was already recommended to protect the doctor in case of prosecution, transforming the doctor-patient relationship into a consumer-service provider relationship.

In fact, in practice, contractualization affects the relationship, since it is necessary for the doctor to understand his patient as a client.

Despite the fact that in the application of the Consumer Protection Code[4] some particularities involving the doctor-patient relationship are considered by the Courts, even so there is greater vulnerability of the health professional.

THE IMPACTS OF JUDICIAL DECISIONS ON THE DOCTOR-PATIENT RELATIONSHIP IN BRAZIL.

In addition to Law 8.078/1990 (Consumer Protection Code)[5], since 2018 with the judgment of the Special Appeal 1.540.580 of the Superior Court of Justice (STJ)[6], in which a surgeon was sentenced despite the fact that there was an expert report in the process that did not find bad praxis or medical error, the vulnerability of health professionals increased even more.

In these trial, the doctor was sentenced because the file did not show that the professional informed the patient of all the possible consequences of the procedure, the doctor did not record the consultations and could not demonstrate that he provided all the information to the patient, and with this, with no papper to prove, he was left without verifying compliance with the duty to inform.

> "SPECIAL RESOURCE APPEAL 1.540.580/2015[7]- STJ . Violation Of Article 535 Of Cpc (Civil Procedural Law). No Occurrence. Medical Civil Liability Due To Failure To Develop Information. Necessity Of Specialization Of Information And Specific Consent. Offense Of The Right Of Self-Determination. Valorization Of The Subject Of Right. Configured Non-Equity Damage. Contract Non-Implement. Objective

3 Consumer Protection Code.
4 Law 8.078/1990.
5 Consumer Protection Code.
6 STJ is the court responsible for standardizing the interpretation of federal law throughout Brazil. It is responsible for the final solution of civil and criminal cases that do not involve constitutional matters or specialized justice.
7 Superior Court of Justice (STJ).

Good Faith. Doctor's Burden Of Proof. 1. There is no violation of article 535, II, of the CPC (civil procedural law), when the embargoes of declaration were rejected, the matter under examination was duly confronted by the Court of origin, which issued a well-founded ruling, even though in the opposite sense to the claim of recurrent.

2. The relationship between doctor and patient is a special provision of services, the object of which encompasses extremely relevant attached duties, in addition to technical intervention aimed at treating the disease, among which is the duty to provide information. 3. The duty of information is the physician's obligation to clarify the patient about the risks of the treatment, its advantages and disadvantages, the possible techniques to be employed, as well as the disclosure regarding the prognosis and the clinical and surgical conditions, except when such information may affect you psychologically, at which time the communication will be made to your legal representative. 4. The principle of autonomy of will, or self-determination, based on the constitution and provided for in several international documents, is the source of the duty to inform and the related right to free and informed consent of the patient and advocates the appreciation of the subject of law behind the patient, emphasizing their ability to self-govern, to make choices and to act according to their own deliberations. 5. There will be effective fulfillment of the duty to provide information when clarifications are specifically related to the patient's case, and generic information is not sufficient. Likewise, to validate the information provided, the patient's consent cannot be generic (blanket consent), needing to be clearly individualized. 6. The duty to inform is a duty of conduct arising from objective good faith and its simple non-compliance characterizes contractual default, a source of civil liability per se. Compensation, in these cases, is due for the deprivation suffered by the patient in his self-determination, for having been deprived of the opportunity to weigh the risks and advantages of a certain treatment, which, in the end, caused him damages that could not have been caused, if the procedure was not performed, at the option of the patient. 7. The burden of proof as to compliance with the duty to inform and obtain informed consent from the patient rests with the doctor or hospital, guided by the principle of procedural collaboration, in which each party must contribute with the evidence that can be more easily provided. required. 8. The physician's subjective responsibility (Consumer Defense Code - CDC, article 14, paragraph 4) does not exclude the possibility of inversion of the burden

> of proof, if the requirements of article 6, VIII, of the CDC (Consumer Defense Code), and the professional must demonstrate that he has acted with respect to the applicable technical guidelines. Precedent. 9. In the absence of specific legislation to regulate the duty to inform, the Consumer Defense Code is the diploma that performs this function, making the duties of informing clearly, loyally and accurately very strict (article 6, III, article 8, and article 9). 10. Special appeal granted, to recognize the non-pecuniary damage caused by the breach of the obligation to inform."

(STJ - REsp: 1540580 DF 2015/0155174-9, Minister LÁZARO GUIMARÃES (JUDGMENT SUMMONED FROM THE TRF 5TH REGION), Judgment Date: 08/02/2018, T4 , Publication Date: DJe 09/04 /2018).[8]

After that ruling and the understanding applied and signed by the Courts, contractualization became absolutely necessary, especially in the doctor-patient relationship.

Currently, the need for a good Free and Informed Consent Term in writing, signed and dated by the patient is essential so that the doctor can use it as proof of compliance with the duty of information in case of prosecution.

Another jurisprudential position of the Brazilian Courts has also recklessly innovated against doctors in lawsuits involving the doctor-patient relationship in aesthetic procedures.

They established the understanding that plastic surgeons, when performing "aesthetic" surgeries, have the duty of the result and began to judge a medical/surgical act as an obligation of result.

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8 REsp: 1540580 DF 2015/0155174-9, Minister LÁZARO GUIMARÃES (judgment summoned from the trf 5th region), Judgment Date: 08/02/2018, T4 , Publication Date: DJe 09/04 /2018. STJ

INTERLOCUTORY APPEAL IN SPECIAL RESOURCE – STJ - number AResp 328110:

"According to vast jurisprudence, aesthetic plastic surgery is an obligation of result, since the patient's objective is precisely to improve his appearance, the surgeon committing himself to provide him with the desired result."[9]

SPECIAL RESOURCE – STJ - number REsp 985888:

"In a surgical procedure for aesthetic purposes, although the obligation is for the result, there is no objective liability for the failure of the surgery, but a mere presumption of medical fault, which implies the reversal of the burden of proof, with the to the professional to elide it (eliminate it) in order to exonerate himself from the contractual responsibility for the damages caused to the patient, due to the surgical act" .

SPECIAL APPEAL. 236.708 - STJ - MG (1999/0099099-4):

"Summary: Civil. Civil Procedure. Special Resource. Civil Responsability. Nullity Of Judgments Delivered In Connection With Remedies Of Non-Configured Declaration. Aesthetic Plastic Surgery. Obligation Of Result. Proven Damage. Presumption Of Fault Of The Physician Not Removed. Precedents.

…The obligation assumed by the doctor is normally an obligation of means, since the object of the contract established with the patient is not the assured cure, but the commitment of the professional towards the provision of precise care and in line with medical science in the field. search for the cure.

Despite authoritative doctrine to the contrary, this Superior Court of Justice has understood that the situation is different, however, when the doctor commits to the patient to achieve a certain result, which occurs in the case of merely aesthetic plastic surgery. In this case, according to the understanding of this Superior Court, what we have is an obligation of results and not of means.

9 INTERLOCUTORY APPEAL IN SPECIAL RESOURCE – STJ - number AResp 328110.
10 SPECIAL RESOURSE – STJ - REsp 985888

> In the case of obligations of means, it is up to the victim, more than demonstrating the damage, to prove that this was due to the doctor's fault. As for the obligations of result, such as the one that gave rise to the controversy, it is enough for the victim to demonstrate, as he did, the damage (that the doctor did not achieve the promised and contracted result) for guilt to be presumed, with, therefore, the Reversal of the burden of proof.
>
> This does not deprive the doctor of the possibility of demonstrating, by means of admissible proof, that the harmful event was caused, for example, by force majeure, acts of God or even the exclusive fault of the "victim" (patient)."[11]

Obviously, these decisions, over time, began to reach other areas of medicine and not only plastic surgery, in an extremely dangerous way, with understandings also in the sense that medical acts have a duty to result.

The impact of the understandings in this sense makes medicine increasingly contractual and less humanized, contrary to what is currently sought, since they place the doctor in a position of contractual vulnerability, forcing him more and more to document and contractualize. the doctor-patient relationship.

The doctor-patient relationship in the Brazilian scenario has gradually and increasingly deteriorated, as the understanding and decisions of the judiciary, the insecurity of health professionals, the structural and cultural litigation of Brazilian society, the futile and unfounded demands, the access to judiciary for free, the understanding of duty of result for certain medical acts, the real costs of litigation and the encumbrance of the judiciary have caused a real unsustainability for the much desired humanization in the doctor-patient relationship. And all these factors have been contributing to the gradual deterioration of the doctor-patient relationship every day.

CONCLUSION

It is possible to state that in Brazil, civil liability arising from the lack or non-compliance with the specificity of the duty to inform about any treatment or surgical procedure impairs informed consent, as it denotes the lack of manifestation of the fundamental right of self-determination of the patient.

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11 SPECIAL APPEAL.STJ - 236.708 - MG (1999/0099099-4).

It is important to emphasize that there is no law in the Brazilian legal system that requires the doctor to expressly express the patient's written consent in a signed document.

The Federal Council of Medicine impose through the Code of Medical Ethics[12] that "it is forbidden for the doctor to fail to obtain consent from the patient or his legal representative after clarifying him about the procedure to be performed, except in cases of imminent risk of death"[13], that is, although there is no ordinary law in the Brazilian legal system that determines the obligation of written consent for all treatments and medical procedures, the Code of Medical Ethics provides for this obligation.

Precisely because of this lack of specific ordinary legislation in Brazil, regulating the duty to provide information in the doctor-patient relationship, the Brazilian Courts apply the Consumer Defense Code considering exactly from the perspective of the contractual relationship.

In this way, as provided for in article 6, III, of the Consumer Defense Code[14], the doctor-patient relationship is considered a consumer relationship and therefore, the duty to inform becomes a basic right, an instrumental duty, of conduct and of protection.

Also, considering consumerist legislation, specifically article 14 of the Consumer Protection Code[15], damages caused by faulty service must be compensated. Thus, the absence of the informed consent term is considered a defect in view of the fact that:

> "the service provider is liable, regardless of the existence of fault, for repairing damages caused to consumers by defects related to the provision of services, as well as by insufficient or inadequate information about its fruition and risks"[16].

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12 RESOLUTION 2.222/2018 – The Code of Medical Ethics contains the norms that must be followed by physicians in the exercise of their profession, including activities related to teaching, research and administration of health services, as well as any others that use the knowledge derived from the study of medicine and the transgression of deontological norms will subject the violators to the disciplinary penalties.

13 Federal Council of Medicine, Resolution 2.222/2018, article 22.

14 LAW 8.078/1990.

15 Law 8.078/1990.

16 Law 8.078/1990 - Consumer Protection Code, article 14.

It is possible to conclude that the evolution of the doctor-patient relationship in Brazil, considering the understandings of the Courts and the current legislation, matter in the reality that an indemnifiable damage supposedly practiced by a doctor is no longer just a physical damage or the worsening of health conditions of the patient, because there may not even have been a technical failure on the part of the doctor.

The understanding today is in the sense that the damage could have been avoided if the information about the risk of its occurrence was provided to the patient, because, in these cases, the patient could choose not to assume the risk of undergoing the treatment.

In this way, considering that the complete information allows the patient to effectively exercise his right to autonomy and that the medical professional who does not fulfill this duty to inform, or better said, does not materially prove that he fulfilled and gave this chance to the patient in a specified way, in writing, describing the possible risks, harms, pre and post treatment care, as well as the benefits of the treatment means that the doctor prevented the patient from exercising his right to autonomy.

Therefore, currently, in Brazil, this conduct imposes on the physician the duty to indemnify. Therefore, it is possible to state that, in Brazil, the contractualization and commodification of the doctor-patient relationship is a worrying and growing reality changing the relationships that were previously untainted by commerce into relationships that essentially become commercial.

BIBLIOGRAPHIC REFERENCES

1. BOBBIO, Norberto. Teoria da Norma Jurídica, 1ª edição, Edipro, 2001.

2. Constituição Federal da República Federativa do Brasil 1988. www.planalto.gov.br/ Acesso em: 15.jan. 2023.

3. Codigo de Ética Médica; Resolução CFM n° 2.217, de 27 de setembro de 2018, modificada pelas Resoluções CFM nº 2.222/2018 e 2.226/2019. https://portal.cfm.org.br/ Acesso em:15.jan.2023

4. Código Civil Brasileiro, Lei nº 10.406, de 10 de janeiro de 2002. www.planalto.gov.br/ Acesso em: 15.jan. 2023

5. Código de Processo Civil Brasileiro, Lei nº 13.105, de 16 de março de 2015. www.planalto.gov.br/ Acesso em: 15.jan. 2023

6. CRETELLA JR., José. Comentários ao Código do Consumidor. Rio de Janeiro: Editora Revista dos Tribunais, 1995.

7. DANTAS, Eduardo Vasconcelos dos Santos. Direito Médico; Rio de Janeiro: GZ Ed.,2009.

8. DANTAS, Eduardo Vasconcelos dos Santos. Comentários ao Código de Ética Médica; Rio de Janeiro: GZ Ed.,2022.

9. DINAMARCO, Cândido Rangel. A instrumentalidade do processo. 6ª edição. Ed.São Paulo: Malheiros, 1998.

10. REALE, Miguel. Lições Preliminares de Direito, 27ª edição, Saraiva, 2002.

11. RACHLINSKI, Jeffrey J. Gains, Losses, and the Psychology of Litigation. Southern Californa Law Review, v. 70, n. 1, p. 74, 1996

12. SHAVELL, Steven. The Fundamental Divergence Between the Private and the Social Motive to Use the Legal System. The Journal of Legal Studies, 1997.

13. http://www.stj.jus.br/

14. http://www2.cirurgiaplastica.org.br/

15. https://www.tjrj.jus.br/

16. WOLKART, Erik Navarro. Análise Econômica do Processo Civil [Livro Eletrônico]: como a economia, o direito e a psicologia podem vencer a tragédia da justiça. 2. ed. São Paulo: Thomson Reuters Brasil, 2020.

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CHILDREN'S AND ADOLESCENTS' ABILITY TO CONSENT: A STUDY OF THE BRAZILIAN REALITY

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Abstract: The care of children and adolescents has always been guided by ethical and bioethical issues, although with no adequate treatment and direction. It is possible to consider the child or adolescent patient as vulnerable from two perspectives: the health issue and the age issue. A third vulnerability should also be raised because it has a direct impact on care: the social. They are patients who deserve a differentiated study and treatment in view of the biases existing in the doctor-patient dynamics. This dynamic has important characters, the parents, or legal representatives, whose expressions of intent end up overlapping any choice of the patient. Sometimes we are talking about a triangular and non-direct doctor-patient relationship, which generates countless noises and some stress. The absence of any regulation or positioning on the matter gives rise to numerous divergences when it comes to the understanding and inapplicability at the other end, causing the failure to comply with the right of choice according to the will of the child or adolescent, among other rights provided for under the Brazilian legislation and international documents that become marginalized. There is a scarcity of studies on this topic in Brazil, which can lead

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to biased conclusions far from the reality of the country, when only international studies are used as a basis. Suitability to the level of maturity of a specific society is very important for the analysis of this and many other bioethical dilemmas. The predominance of the paternalistic model in the doctor-patient relationship worsens when the patient is a child or adolescent, a reflection of a protectionist and interventionist government model that eventually curbs the expression of the individual's will. This study will seek to address the main aspects of the doctor-patient relationship in pediatric care in Brazil, focusing on the prerogative of the expression of will from children and adolescents as subjects of rights.

Keywords: Bioethics; Autonomy; Children and Adolescents; Ability to Consent

I – CHILDREN AND ADOLESCENTS AS SUBJECTS OF RIGHTS

When a child or adolescent enters the medical facilities, automatically, their legal guardian are automatically sought to be asked about all aspects involving that patient, from the least significant to the most complex.

Throughout the process of care, the legal guardian is urged to speak out replacing any and all expression of will of the child or adolescent, even when they are already able to communicate and capable of understanding.

In the national scenario, children and adolescents were recognized as subjects of rights only under the Federal Constitution of 1988, when they were included in the category of vulnerable persons. They were given priority treatment in relation to the compliance with rights and guarantees.

In order to make the provisions of the Federal Constitution effective, in 1990 the Child and the Adolescent Statute *(Estatuto da Criança e do Adolescente – ECA)* was published, providing for the full protection of children and adolescents from the perspective of Human Rights.

The scope thereof brought an approach of equal treatment to all children and adolescents without any type of discrimination. It should also be pointed out there is a provision stating that it is the duty of the family, the community, society in general and the government to ensure the effectiveness of health rights.

Despite the attempt of our lawmakers, the Government still fails to guarantee such rights to children and adolescents, especially those in a situation of greater social vulnerability, which causes a major impact on health care.

If today we are facing a scenario of non-effectiveness of the recognition of children and adolescents as subjects of rights, capable of deciding on their health treatments, there is a significant worsening when it comes to a subject in social vulnerability, directly affecting health care.

The high poverty rate in our country and the increasingly latent social inequality force us to establish this focus on the analysis of all issues involving health in Brazil, particularly in relation to the expression of will.

Brazilian social problems, which are the basis and support of this social vulnerability, play a central role in determining the suffering and affect the health and well-being of the population in this context (SOUZA, PAD-PINTO, FIORATI, 2019).

In September 1990, the same year as the ECA was published, the Brazilian government ratified the Convention on the Rights of the Child *(Convenção sobre os Direitos da Criança – CDC),* the main international document providing for the rights of children and adolescents, enacted through Decree No. 99,710/1990.

It is possible to say that this triad (the Federal Constitution, the ECA and the CDC) addresses the rights of children and adolescents at their highest level, but leaves gaps with regard to effective health care.

Ensuring the right to health is not synonymous with regulating the way in which this child or adolescent will be treated and cared for. The access of these patients to treatments, exams, medications and other health services is extremely important, however, once this stage is overcome, another one, equally relevant, must be discussed, namely, the stage of the care itself (ELER, 2020).

The moment health care is provided concentrates most of the problems related to the expression of the intent coming from the children and adolescents, enhancing their situation of vulnerability and weakening the doctor-patient relationship.

II – CAPACITY FOR DECISION-MAKING ON HEALTH MATTERS

The rights of the patients, from a Human Rights perspective, are those set out in international documents, among which we stand out the right to participation, the right to information and the right to privacy when the topic is the capacity for decision-making (ELER, 2020).

All of them are part of the Human Rights of the Patient category, focused on the rights of patients in an environment of care, after going through the stage of access to health.

In order for the decision-making capacity to be complied with and respected, the right to participate, guaranteed under the Convention on the Rights of the Child, has a certain main role. It provides that:

> Article 12. States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.

This right concerns any kind of expression of will about situations that might affect the child's life. Health, unquestionably, is one of them.

The child and the adolescent, progressively, evolve in their autonomy, no longer making decisions based on the will of their parents, and starting to decide by themselves in their own projects (SILVA AND GAUDÊNCIO, 2021).

It is worth noting that when we talk about participation in decisions related to health, we automatically think of extremely serious issues, such as terminality, palliative care, surgical intervention, or sequelae arising from some procedure. However, the child's participation should occur in all situations involving their body and health, from the moment they can have minimum understanding.

This understanding, by the way, does not need to be absolute and overall. It is enough for the child to have a minimum level of discernment about the facts. From this minimum level, they must participate, to the extent of their understanding, in all decisions.

It is not only the verbal expression that must be taken into consideration, but also the visual, facial and any other way through which the child can express themselves. The goal is to ensure that the child and the adolescent share the decision.

The analysis of the understanding of the child and the adolescent should be measured by all those involved, especially by the multidisciplinary team responsible for their treatment. Age alone is not an absolute criterion for this measure, but rather their maturity in understanding the facts.

There is no doubt that age, as a chronological criterion, is the most commonly used by health organizations. In addition, there is great resistance from the caring team to make the age criterion more flexible and adopt the maturity criterion. Perhaps because it brings insecurity to the professional; perhaps because it is more practical to use an objective criterion.

The minimum age stipulation model is easy to be implemented and understood by society. Nevertheless, despite its wide acceptance, this model disregards the assessment of the evolving capacities of children, placing them all on the same level, which proves harmful for those who already have decision-making skills (ELER, 2020).

The fact is that today we have no commitment to the observance and acceptance of the expression of will at different levels. What exists is an atmosphere of mistrust regarding any expression of will, leading to the requirement of documents, witnesses, attorneys. This impairs the quality of the doctor-patient relationship, generates a distance between the characters and corroborates the cycle of Defensive Medicine.

For the exercise of the child or adolescent patient's ability to choose, it is assumed that the physician and other health professionals collaborate in ensuring that the individuals will be given information regarding their health, to the extent of their understanding, even if this is not the desire of their parents or legal guardians. It is also up to the team to clarify the importance of including the child or adolescent in this type of decision, demonstrating the damage that this exclusion can bring.

In this context, the concept of the "mature minor" appears, still underexplored in Brazil, a reflection of the discussions about human dignity, who, in certain circumstances, is capable of understanding and consenting, autonomously, upon health treatments without the prior consent of their parents or legal representatives (SILVA, CARPENTER AND NEGREIROS, 2021).

Urgent or emergency situations, which make adequate communication with the child impossible, and might put them at risk, do not require the patient's participation in the choice of what conduct should be followed. Expressions

of intent previously declared, however, should not be annulled, but rather taken into consideration by those responsible for the treatment, if they become aware thereof.

This point is quite critical in the treatment not only of children and adolescents, but also of adult patients, since doctors in Brazil have the safeguard that, in an urgent or emergency situation, consent is waived. Thus, doctors and their team perform the acts they understand as pertinent, focused on the principle of beneficence and non-maleficence, to the detriment of autonomy.

In order for children and adolescents to be able to participate in decisions involving their health, the assumption, therefore, is that they should receive adequate information. This information should be transmitted smoothly, with clarity, transparency and in an accessible language.

It is up to the health professional to measure the patient's ability to understand so that they do not go beyond the limit of the information that the recipient is able to absorb. Adequate information does not mean informing everything, but doing so according to the limit of each patient, whether regarding their maturity, sensitivity, fragility, social vulnerability and even schooling.

Again, it is important to bring up how unattainable this practice becomes unreachable in precarious health facilities, with a lack of professionals and without the minimum structure of health care.

The expression of will in the current Brazilian scenario is measured according to the economic capacity and level of education of the individual.

With regard to the right to privacy, compliance therewith assures the patients that any data about their health and their life will be safeguarded.

Information confidentiality is one of the main and oldest principles of the doctor-patient relationship. It is the basis for establishing a relationship of trust through which the patients can provide information about their life and their health.

Hippocrates, in his oath, said that "whatever I have seen or heard, either while practicing the profession and living in the Society or not, that it is not necessary to disclose, I will keep entirely secret."

For the patient to feel comfortable with this opening, the doctor must make sure, in return, that this information will not be disclosed.

This right unfolds in additional ones related to patients' information, and has some exceptions. Confidentiality is not absolute, i.e., if the child or adolescent is going through any situation that poses risk to their lives or may put the health of third parties at risk, for example, information regarding their health can be revealed. Other situations of breach of confidentiality may be provided for under the legislation, such as cases of compulsory notification of diseases or situations of mistreatment and sexual violence.

As a rule, therefore, including the parents or guardians in the care of children or adolescents who have the capacity to understand should not be required. If this inclusion is necessary, the recommendation is that the patient should spontaneously include this person in the decision-making process, without the coercive inclusion of the parents or legal guardians.

The inclusion of family members in decision-making should occur with caution and upon the patient's express desire. In health services, this stage is ignored and the family is included without the patients expressing their will in this sense. And worse, the family's decision, as a rule, replaces the patient's will, particularly if it is a child or adolescent.

All these rights, when observed and respected, without excluding any other that guide health care, support the decision of the child or adolescent to exercise their capacity to choose when it comes to health.

Once again, it should be highlighted that this capacity has no direct relationship with civil capacity.

Even if, according to the civil parameter, the patient is absolutely or relatively incompetent, the doctor should include them in the decision-making process, as they develop and are identified as capable of evaluating their problem (SILVA AND GAUDÊNCIO, 2021).

Referred to as health capacity, its use depends on the presence of cognitive, affective, volitional and psychological skills (ELER, 2020). Once these skills are present, the patients will be able to make their health decision after been provided with adequate information.

It is recommended that the decision be transcribed in medical records. Only in cases of actual health risk or sequelae, the expression of the patients' intent should be included in a written document, the informed consent form (termo de consentimento livre e esclarecido – TCLE) or assent form, the latter for children and adolescents.

Assent is a concept of modern ethics, which has become the basis of pediatric patient care, as well as the foundation of the principle of moral freedom, autonomy and dignity (SILVA AND GAUDÊNCIO, 2021).

The TCLE has gained a certain main role in health-related decisions and has been used overtly and excessively, without meeting its function of providing information. The stage of signing the TCLE has become mandatory and automatic without due information for such and, in return, the expression of the free and willful intent of the patient.

Its application is quite dysfunctional and even irrational. The main purpose of this application has become proving that the information has been provided if it needs to be submitted in any court or administrative proceedings; rather than the true and genuine information, which is the duty of doctors to provide and the patient's right to receive. Once again, Defensive Medicine is present and motivating many actions and behaviors in health facilities.

The use of the courts, the main motivation for defensive behaviors and actions, could be avoided if there were a consistent and symmetrical dialogue between doctor and patient, based on understanding and acceptance (VASCONCELOS, 2020).

The assent form, in turn, is not even mentioned in health care, corroborating the statement that the will of children and adolescents is not taken into account in health decision-making in Brazil.

III – DUTIES OF DOCTORS IN THE CARE OF CHILDREN AND ADOLESCENTS IN BRAZIL

The conduct of doctors in Brazil is regulated by the Federal Council of Medicine (*Conselho Federal de Medicina* – CFM), an authority that supervises the medical activity.

In addition to the standards issued by the CFM, the legislative framework brings commands of mandatory compliance to physicians that must also guide the conduct of these professionals.

When it comes to the care of children and adolescents, the focus of this study, there are specific standards that use international documents as a model and have the courage to advance in the way this topic is addressed.

The current Code of Medical Ethics brings an important improvement by establishing that doctors must not "disclose professional secrecy related

to any child or adolescent patient, provided that they have the capacity for discernment, including to their parents or legal representatives, except when non-disclosure may cause damage to the patient."

There are others, however, that go against this evolution and establish a retrograde paternalistic model for the treatment of children and adolescents, starting from the mistaken assumption that they are not subjects capable of making their own choices.

One of the most striking examples is CFM Resolution No. 2232/19, which, upon setting out the standards on therapeutic refusal and conscious objection, expressly points out at the very beginning that the patient of legal age, capable, alert, orientated and conscious, at the time of the decision, is assured of the right of refusal to the therapy proposed in any elective treatment.

While much of the world, including countries in South America, evolves in the sense of respecting the autonomy and capacity of children and adolescents, Brazil uses the term "of legal age", which has been in disuse for years in this type of approach, and eliminates the right of these patients to make their own choices in health treatments.

Additionally, the same Resolution sets forth that, in case of any divergence between the health professional and the legal representative regarding the therapy that will be adopted for the "minor" patient, this fact must be communicated to the relevant authorities (the Public Prosecution Service, the Police, the Child Protective Service, etc.).

At no time, not even alternatively, the expression of will from the child or adolescent is considered. Moreover, the mistaken assumption that the legal representative replaces the will of this patient in any situation is used as a starting point.

Often, doctors and legal representatives talk about the child or adolescent who is there, and do not ask them what their opinion or their feeling is in relation to the diagnosis and treatment.

Therefore, we can see that all the "minors" were placed on the same level, which can cause weird situations such as that where a 17-year-old patient's will is not taken into account in decision-making.

Even though the concept of civil majority is no longer regarded in most part of the world for health treatments, in Brazil this is the first criterion to be evoked.

This irregular scenario with advance and retreat movements, brings great insecurity to the physicians in their practice, who choose to stay in their comfort zone, that is, to lead the choices and the treatment that will be given to that patient or to establish a minimum age, which is seen as quite mistaken from the perspective of the Patient's Human Rights.

If for capable adults the doctor already shows difficulties and resistance in sharing decisions and accepting their expression of will, this behavior is enhanced in the case of children and adolescents.

When such cases are taken to court, which should occur in situations of extreme exceptionality, the chance of the child or adolescent patient being heard and having their will observed decreases considerably, since the judge will use the federal protectionist and interventionist laws that hold the 18-year-old milestone so that the subject can practice any acts of civil life.

In fact, we still confuse concepts of Civil Law and Bioethics, which only worsen this scenario and demonstrate how much we need to advance in terms of recognizing the ability of children and adolescents to make their choices in health.

This change must start from an active movement of physicians and their teams to include the child or adolescent in the debate and choices about their body and their health.

This theoretical perspective is far from being implemented in practice, unfortunately.

The *Sociedade Brasileira de Pediatria de São Paulo* (the Brazilian Society of Pediatrics of São Paulo) has developed some tools to facilitate decision-making, which express the prevalence of the family's will, as follows (CONSTANTINO; ZOLLNER; HIRSCHHEIMER, 2020):

1. Since the parents are defenders of their children's interests, they are, theoretically, the ones who make the decisions, but the agreement of patients should be considered

2. When there are divergences or conflicts between the principle of beneficence defended by the health team and that of the autonomy of the family and there is no imminent risk of death, the dialogue must be broadened, involving other members of the multidisciplinary team and the extended family.

It is possible to observe that in the two guidelines pointed out above parents and family take on a leading role to the detriment of the respect for the will of the child or adolescent, a faithful portrait of the doctors' stance in Brazil.

Obviously, the intention is not to simplify a complex situation that depends on numerous evaluations and factors, but we notice the fear to bring this patient to the center of the decision. The more the health team keeps this stance, the further away from guaranteeing the rights of children and adolescents we will be.

Such guidelines also do not solve the problem, leaving an open end to the attitude that the professional should adopt. Faced with doubt and the absence of any direction given, the professional will certainly adopt the path that will bring them greater comfort, i.e., that of paternalism.

Even in view of this unfavorable scenario, it is up to doctors and health teams, based on the Patient's Human Rights, professional ethical standards and international documents, such as the Convention on the Rights of the Child, to make people aware of the need to include children and adolescents in the decision-making scenario, within the individual limit of understanding, with respect to beliefs, wills, culture.

The participation of the family, whether in the figure of their parents or guardians, or of any trusted adult, is highly recommended, provided that the child or adolescent agrees with this participation.

Respecting the adolescent's right to start their sexual life and receive medical care without the presence of parents and guardians cannot be one of the only references accepted by the medical society with regard to the autonomy of children and adolescents.

It is possible for doctors and their teams to be much more active in listening and including the child or adolescent in the various scenarios that involve health care, whose role is also to teach them, from an early age, that they are the owners of their lives and their bodies.

CONCLUSION

The stages of childhood and adolescence bring together peculiarities and aspects related to the development of the human being that deserve attention and care. An important part of this development concerns the way in which these evolving beings are treated in the healthcare environment.

The ability of human beings to choose the direction of their life and the health treatments they will endure must be exercised from the moment the individual can understand what is happening, even incompletely.

Despite the attempt of lawmakers to ensure the capacity of children and adolescents, as well as the evolution of the matter in the world, in Brazil there is great resistance and insecurity from health professionals in making sure that this capacity becomes effective.

Parents or legal guardians take the reins of the entire health treatment, along with health professionals, leaving the child or adolescent only as the recipient of decisions made.

The staleness of paternalism shows up in the provision of health services, with doctors and their teams behaving self-righteously and deciding, based on their own values, what is best for the patient.

The message passed on to children and adolescents who depend on health services is that their will does not prevail. Plus, someone is going to decide for them.

The existential problem of health organizations in relation to the failure to comply with the expression of will goes beyond treatment in children and adolescents, as it also encompasses adults with 100% capacity and discernment.

The absence of age for decision-making is a safe subterfuge used by an entire system that does not bother to listen to the patient. Therefore, doctors work even more actively in the decision.

At best, they include parents or legal guardians on this journey without including the main person interested in that decision.

Obviously, there are several situations in this context, including urgent and emergency situations, that admit the absence of consent, but as a rule the patient's will is subsidiary or ignored in health care.

As pointed out, non-observance of will also occurs in the case of adult patients. The difference is that for those who have not reached a certain age, there is a universal excuse widely accepted.

For the sake of progress in the inclusion of children and adolescents in the sharing of health-related decisions, it is necessary to revisit this process also in the adult patient.

The culture that doctors and their teams are the owners of technical knowledge and, for this reason, know what is best for the patient still prevails.

This attitude generates negative consequences for the entire health system, such as mistrust between the parties involved, the provision of services with no quality and, ultimately, resorting to courts.

The path that society has to take to achieve autonomy in the healthcare environment is huge, but it needs to start. For children and adolescents to use their capacity, it is even bigger.

This change of posture will depend on actions by health teams to include the patient, the main person interested in that decision, after industry awareness and broad debate.

The patient should be the center of care and attention, with the guarantee that their wills and desires are going to be met, through the wide and transparent provision of information.

BIBLIOGRAPHICAL REFERENCES

BEAUCHAMP, Tom; CHILDRESS, James. **Princípios de Ética Biomédica.** 3**.** ed. São Paulo: Loyola; 2013.

BERLINGUER, Giovanni. **Bioética Cotidiana**. Brasília, DF: Universidade de Brasília; 2004.

BRASIL. **Constituição da República Federativa do Brasil de 1988.** [Access on: May 21, 2022]. Available from:

http://www.planalto.gov.br/ccivil_03/constituicao/ConstituicaoCompilado.htm

_____. Lei Federal nº 8.609 de 13 de julho de 1990. **Estatuto da Criança e do Adolescente**. on-line]. [Access on: July 02, 2022]. Available from: http://www.planalto.gov.br/ccivil_03/leis/l8069.htm

_____. Decreto nº 99.710 de 21 de novembro de 1990. **Promulga a Convenção sobre os Direitos da Criança.** [on-line]. [Access on: July 02, 2022]. Available from: http://www.planalto.gov.br/ccivil_03/decreto/1990-1994/d99710.htm

_____. Conselho Federal de Medicina. Resolução nº 2.217, de 01 de novembro de 2018. **Dispõe sobre o Código de Ética Médica**. [on-line]. [Access on: May 21, 2022]. Available from: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2018/2217

_____. Conselho Federal de Medicina. Resolução nº 2.232, de 16 de setembro de 2019. **Estabelece normas éticas para a recusa terapêutica por pacientes e objeção de consciência na relação médico paciente.** [on-line]. [Access on: May 21, 2022]. Available from: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2019/2232

_____. Lei Federal nº 10.406 de 10 de janeiro de 2002. **Institui o Código Civil.** [Access on: May 21, 2022]. Available from: http://www.planalto.gov.br/ccivil_03/leis/2002/l10406.htm

CARVALHO, P. C. de A.; LOPES, A. L. de J.; CORTEZ, C. K.; PEREIRA, G. M.; BRANDÃO, L. C. B.. **Direito Médico:** Temas atuais. Curitiba, PR: Ed. Juruá; 2019.

CONSTANTINO, C.; ZOLLNER, A. C. R.; HIRSCHHEIMER, M. R.. **Aspectos éticos, bioéticos e legais relacionados à assistência à saúde da criança e do adolescente**. In: COHEN, Claudio; OLIVEIRA, Reinaldo Ayer. **Bioética, Direito e Medicina.** 1. ed. Barueri, SP: Manole, 2020. cap. 29, p. 336-347.

DINIZ, Maria Helena. **O Estado atual do biodireito.** 9. ed. São Paulo: Saraiva; 2014.

ELER, Kalline. **Capacidade da Criança e do Adolescente na Saúde**. Rio de Janeiro. Lumen Juris; 2020.

SEGRE, Marco; COHEN, Claudio. **Bioética.** 3. ed. São Paulo: Editora da Universidade de São Paulo; 2008.

SILVA, Josimário; CARPENTER, Luiz; NEGREIROS, Ítalo. **Teoria do menor maduro.** In: SILVA, Josimário; JOUAN, Carlos Eduardo; MEDEIROS JUNIOR, Pedro. **Bioética em Pediatria**. São Paulo: Memnon, 2021.

SILVA, Josimário; GAUDÊNCIO, Anibal. **Assentimento Informado: Proposta ética na relação médico-paciente.** In: SILVA, Josimário; JOUAN, Carlos Eduardo; MEDEIROS JUNIOR, Pedro. **Bioética em Pediatria**. São Paulo: Memnon, 2021.

SOUZA, Larissa de Barros; PANÚNCIO-PINTO, Maria Paula; FIORATI, Regina Célia. **Crianças e adolescentes em vulnerabilidade social: bem-estar, saúde mental e participação em educação.** Cad. Bras. Ter. Ocup., São Carlos, v. 27, n. 2, p. 251-269, 2019. [on-line]. [Access on: May 21, 2022]. Available from: https://doi.org/10.4322/2526-8910.ctoAO1812

OSELKA, Gabriel Wolf (coord). **Bioética Clínica: reflexões e discussões sobre casos selecionados**. 3. Ed. São Paulo: Conselho Regional de Medicina do Estado de São Paulo. Centro de Bioética, 2011.

PESSINI, Leo; BERTACHINI, Luciana; BARCHIFONTAINE, Christian de P. de; HOSSNE, Willian S. **Bioética em tempos de globalização**. São Paulo: Ed. Loyola; 2015.

UNESCO**. Declaração Universal sobre Bioética e Direitos Humanos**. Tradução e revisão final sob a responsabilidade da Cátedra UNESCO de Bioética da Universidade de Brasília (UnB) e da Sociedade Brasileira de Bioética (SBB). Translation: Ana Tapajós e Mauro Machado do Prado. Revisão: Volnei Garrafa. [on-line]. [Access on: May 21, 2022]. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/declaracao_univ_bioetica_dir_hum.pdf

VASCONCELOS, Camila. **Direito Médico e Bioética: história e judicialização da relação médico-paciente**. Rio de Janeiro: Lumen Juris, 2020.

WAKSMAN, Renata Dejtiar; HIRSCHHEIMER, Mário Roberto; PFEIFFER, Luci (coord.) **Manual e atendimento às crianças e adolescentes vítimas de violência.** 2.ed. Brasília, DF: Conselho Federal de Medicina, 2018.

Websites:

https://pt.wikipedia.org/wiki/Juramento_de_Hip%C3%B3crates

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AUTONOMY, CONSENT AND RIGHT TO INFORMATION IN THE CONTEXT OF ART IN BRAZIL

Marianna Chaves[1]

Abstract: Infertility is a reality that has always been present in human history. While *infertility in the past represented a sentence to life without genetically linked children,* reproductive medicine has dramatically changed the scenario. At present, assisted reproductive technologies allow any person or couple to have children genetically related to one or both. We stopped asking ourselves how far we can go and started questioning how far we should go. Any scientific development must be accompanied by a dose of caution and respect for the autonomy of the parties involved in the processes. We've set aside the medical paternalism of the past and began to view the choices of each medical act as a collaborative decision-making process. In this way, the choices made by physicians must be the result of an informed choice made by the patient. This article addresses autonomy, consent, and the right to information in the context of the resolution of the Brazilian Federal Council of Medicine on Assisted Human Reproduction.

Keywords: Assisted Reproduction Technologies; Autonomy; Informed Consent; Right to Information

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Introduction

Among all the themes of Health Law, few are as controversial, dynamic and involve as many branches of Law and other areas of knowledge as assisted human reproduction. Assisted reproduction technologies (ART) are a scientific development that invokes a multitude of ethical and legal considerations, with various social, religious, and political aspects.

In a not distant past, people or couples who were infertile or had great difficulties in procreating were doomed not to have children with whom they were genetically linked or simply not to have any offspring.

In the modern world, this scenario has changed with the aid of reproduction techniques. The range of reproductive opportunities available to couples or infertile individuals has expanded. Similarly, opportunities have been provided to couples who, by their very nature, cannot reproduce as a couple, such as same-sex couples or transgender people who have undergone sex reassignment surgery.

As observed by Vera Raposo, the desire to reproduce constitutes "one of the oldest aspirations of humankind, a mix of instinct and culture".[2] No longer considered a punishment or divine will, infertility is now considered an illness that affects individuals and couples all over the world.

In a short period of time, society has seen events and advancements whose transcendence and impact will impact the lives of present and future generations. The dizzying development of scientific techniques has paved the way for a range of medical possibilities and procedures that used to be considered unimaginable. According to the Brazilian Constitution, family planning must be based on human dignity and responsible parenting. As some doctrine warns, "there is no exercise of autonomy in the legal system which is unaccompanied by due responsibility".[3] The dignity of the human person is not just a right, it is "the source of all rights".[4]

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2 RAPOSO, Vera Lúcia. "'Dá-me licença que tenha filhos': restrições legais no acesso às técnicas de reprodução assistida", *In: Revista Direito GV*, v. 15, n. 2, e1915, pp. 1-27, 2019, p. 2.

3 KONDER, Carlos Nelson; KONDER, Cíntia Muniz de Souza. "Autonomia reprodutiva e novas tecnologias no ordenamento brasileiro: violações e ameaças ao direito a gerar e a não gerar filhos", *In: Revista da Faculdade de Direito da UFMG*, n. 69, pp. 113-131, 2016, pp. 115-116.

4 ANDORNO, Roberto. "´Liberdade´ e ´Dignidade´ da Pessoa: Dois Paradigmas Opostos

From such a constitutional provision, it is possible to derive an understanding of a fundamental right to reproduction and the consequent constitution of a family. A person cannot be forced to reproduce, nor is it legitimate to obstruct their ability to procreate. Therefore, that right exists both positively and negatively.[5] It is what we can call reproductive autonomy.

In addition to constitutional standards, it should be noted that reproductive rights are regarded by the United Nations as human rights. For the UN,[6] reproductive rights represent a constellation of freedoms and rights already recognized in domestic law, international human rights instruments, and other consensus documents. Reproductive rights are a range of civil, political, economic, social, and cultural rights which affect the sexual and reproductive lives of individuals and couples.

Any place that denies the right to parenthood to a portion of individuals violates their fundamental rights to equality, freedom, and non-discrimination. It also hinders the exercise of citizenship and calls into question the democracy and dignity of individuals by not promoting the fundamental freedoms of all its citizens in a positive and equal manner. Thus, the concept of reproductive autonomy is viscerally related to the principle of freedom, namely the freedom of family planning.

1. **The Regulation of Assisted Reproduction in Brazil**

Unlike other countries, the Brazilian legislator forgot about assisted reproduction. Although the Civil Code, that comes from a project prepared in the 1970s, has not dealt with the matter, nothing justifies the fact that, to date, there is no special regulatory law. It is a highly dubious option, especially as it deals with issues related to fundamental rights.

As I have already had the opportunity to state on several occasions, the lack of legislative response ends up exposing the parties to a high-risk scenario, based on legal uncertainty and often economic exploitation, due to the absence of

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ou Complementares na Bioética?", *In: Bioética e Responsabilidade*/ Judith Martins-Costa; Letícia Ludwig Möller (orgs.). Rio de Janeiro: Forense, pp. 73-93, 2009, p. 81.

5 SHIVAKUMAR, Pryianka. "Count Your Chickens before They Hatch – How Multiple Pregnancies AreEndangering the Right to Abortion", *In: Brooklyn Law Review*, Vol. 78, n. 1, pp. 201-230, 2012, p. 214.

6 UN. "Reproductive Rights are Human Rights: A Handbook for National Human Rights Institutions", p. 21. Available in: http://www.ohchr.org/Documents/Publications/NHRIHandbook.pdf Accessed in: 18/03/2017.

regulation and sanctions for legal deviations. That is exactly the case in Brazil, since 1992, with Resolutions of the Federal Council of Medicine (FCM) No. 1358/92, 1957/2010, 2013/2013, 2121/2015, 2168/2017, 2294/2021, and 2320/2022 (the latter being the one currently in force).

It should be noted that Brazilian physicians themselves, as can be seen from the explanatory memorandum for each of the Federal Council of Medicine resolutions, call for legislation. It means that physicians, biologists, and other health-related professionals are not satisfied with guidelines based solely on deontology or professional conviction. Such professionals aim for the Law to determine with certainty what is and what is not lawful. Unable to find the frontiers of their practice on their own, at a time when civil and criminal liability for medical acts is expanding, professionals are aware that "corporate ethics to legitimize scientific practice" is no longer enough.[7]

Such an understanding is closely followed by Vera Raposo,[8] who considers the FCM Resolutions documents without a legal nature and, therefore, not legally binding. For the author, the merit of its substantial content cannot erase the many weaknesses that surround its genesis and, therefore, the effectiveness that can be recognized. In fact, the Resolutions do not have the force of law, being, on the contrary, mere deontological proclamations, which, although they may be more than that, and may be taken into consideration by the court, are not binding.

In the Brazilian legal system, there are no rules and restrictions, except those of a deontological nature created by the FCM, which do not bind anyone other than doctors and health services.

Therefore, it can be said that Brazil ended up making a medical system for coping with infertility and promoting parenthood feasible but forgot to legitimize the techniques through laws. It is inconceivable that such a matter – of public order – be left to autonomous bodies without legislative competence, in a kind of extrajudicial self-regulation or regulation "by norms of a non-legal nature".[9]

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7 As states Guilherme de Oliveira in an article published before the Portuguese law on assisted reproduction was enacted (Law no. 32/2006). OLIVEIRA, Guilherme de. "Legislar sobre Procriação Assistida", *In*: *Temas de Direito da Medicina*/ Guilherme de Oliveira. 2. ed. Coimbra: Coimbra Editora, 2005, pp. 91-92.

8 RAPOSO, Vera Lúcia. "'Dá-me licença que tenha filhos': restrições legais no acesso às técnicas de reprodução assistida", cit., p. 5.

9 RAPOSO, Vera Lúcia. "'Dá-me licença que tenha filhos': restrições legais no acesso às técnicas de reprodução assistida", cit., p. 5.

2. **Autonomy, Consent and Right to Information**

Bioethics was built on four fundamental pillars: non-maleficence, beneficence, justice, and autonomy. Contemporary bioethics reveals the awareness that there is a need to respect people's values, viewing medical decision-making as a human function, without guidance from any divine or supernatural entity. It incorporates different philosophies and encourages questioning of the processes, instead of demanding blind obedience to any authority or acceptance of ideas of hierarchy.[10]

In the chapter dealing with human rights, article 22 of the Brazilian Code of Medical Ethics prohibits the physician, after clarifying the patient or her legal representative about the procedure, from failing to obtain consent, except in imminent death risk. In the same sense, article 34 of the Code prohibits the physician from not informing the patient of the diagnosis, prognosis, risks, and objectives of the treatment.

Article 24 expressly prevents the physician from failing to ensure that patients exercise the right to choose freely about themselves and their well-being. It also prohibits doctors from exercising their authority to restrict or limit that right in any way. That provision harmonizes with principle XXI of the same Code, which indicates that in the decision-making process, the physician will accept the patients' choices, concerning the diagnostic and therapeutic means chosen by them, if they are appropriate to the case and scientifically recognized.

That canon of the deontological diploma, in turn, is viscerally linked to the principle of autonomy and individual responsibility. These principles are enshrined in Article 5 of the Universal Declaration on Bioethics and Human Rights, which defends respect for people's autonomy in decision-making, in overcoming what some doctrine calls "infantilization of the patient".[11]

Although the notion of autonomy has been used in many different senses, in biomedical ethics there is a common basic understanding about the meaning of this concept: autonomy means self-government.[12]

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10 As we stated in DANTAS, Eduardo; CHAVES, Marianna. *Aspectos Jurídicos da Reprodução Humana Assistida:* Comentários à Resolução 2.121/2015 CFM.. Rio de Janeiro, GZ, 2015, p. 55.

11 ALVES, Cristiane Avancini. "A Conexão entre a Autodeterminação e a Formação Familiar na Esteira do Princípio da Responsabilidade". In: Bioética e Responsabilidade/ Judith Martins-Costa; Letícia Ludwig Möller (orgs.). Rio de Janeiro: Forense, pp. 113-144, 2009, p. 117.

12 In the same sense, see VARELIUS, Juka. "The value of autonomy in medical ethics". In: *Medicine, Health Care and Philosophy*, vol. 9, pp. 377–388, 2006, p. 377

The Code of Medical Ethics expressly establishes in Article 31 the prohibition against the patient's or his representative's right to freely decide on diagnostic or therapeutic methods, except in imminent risk of life. Informed consent is an element of such importance in medical practice that the Federal Council of Medicine drafted a Recommendation (No. 1/2016) that provides for the process of obtaining informed and clarified consent in medical care.

In this logic, one can say that the principles of patient autonomy and self-determination are constant in the deontological norms that govern Medicine in Brazil. Thus, in respect of these commandments, physicians shall respect all capable persons´ options relating to their bodies and lives. Therefore, all medical acts - except in cases of unmistakable urgency - must be consented to by the patients or their representatives.

People's autonomy - materialized in the capacity for self-determination - can be identified as one of the noblest human prerogatives. In this logic, freedom is much more than a mere ethical orientation, "it is the *conditio sine qua non* of ethics, as it is also for the law".[13]

Patients must have all the elements possible for their understanding to exercise the faculty of consenting to the proposed treatment or intervention, choose another of the existing alternatives or even refuse to be treated. This process, which encompasses informed consent without being confused with it, is called "informed choice"[14]. And to honestly fulfil its purpose, informed consent and the consequent informed choice must be present in each act or, at least, in each set of medical acts, bringing the perspectives of the advantages and risks for the parties.[15]

If they can decide what they should and should not do, the patients are responsible for their actions. Respect for the patients' autonomy represents a shift in the way of looking at the doctor's role, giving the patients a share of responsibility for the definitions and results of their treatment or intervention. With the expansion of freedom of choice comes the burden of sharing responsibility for the effects of the decision.

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13 ANDORNO, Roberto. "´Liberdade´ e ´Dignidade´ da Pessoa: Dois Paradigmas Opostos ou Complementares na Bioética?", cit., p. 74.

14 DANTAS, Eduardo. Direito médico. 3ª ed. Rio de Janeiro: GZ, 2014, p. 77.

15 OLIVEIRA, Guilherme de. "Estrutura jurídica do acto médico, consentimento informado e responsabilidade médica", In: *Temas de Direito da Medicina*/ Guilherme de Oliveira. 2. ed. Coimbra: Coimbra Editora, pp. 59-72, 2005, p. 68.

Having made these general considerations, we will move on to specific acts within the scope of assisted human reproduction that demand the exercise of the patient's autonomy, information from the physician and obtaining informed consent.

2.1 *Age of the Woman who will Carry the Child*

Pursuant to paragraph 3.1 of Resolution No. 2320/2022, the maximum age of candidates for pregnancy by assisted reproduction techniques is 50 years. However, the document provides exceptions to the rule.

In accordance with paragraph 3.2 of the Resolution, exceptions to this limit will be accepted based on technical and scientific criteria. Exceptions must be substantiated by the physician in charge. The justification should be based on the absence of comorbidities unrelated to the woman's infertility. Likewise, it will demand clarification from the beneficiaries about the risks involved for the patient and for any descendants born because of assisted reproduction. The deontological norm also indicates that the autonomy of the patient and the doctor must be respected.

Article 226, §7 of the Brazilian Constitution establishes that family planning is "the couple's free decision", and "any form of coercion on the part of official or private institutions" must be prohibited.

At the 1st Health Law Conference of the National Council of Justice, Statement No. 41 was approved with the following wording: "The establishment of a maximum age of 50 years for women to undergo treatment and pregnancy by assisted reproduction affront the constitutional right to freedom of family planning"

When the risks relate solely to the woman's health, it is the doctor's duty to duly inform the beneficiaries of all the risks inherent in pregnancy. However, this argument alone is not a reasonable basis for impeding access to ART, as it would undermine reproductive autonomy and return to excessive paternalism.

It is what Teresa Hellín calls "hard-line beneficence", in which a patient is treated in the same way that parents treat their children. According to the author, the root of such a posture lies in the unreasonable idea that an individual who needs health care would not only be a "biological invalid, but also a moral one".[16]

16 HELLÍN, T. "The physician-patient relationship: recent developments and changes", *In: Haemophilia*, vol. 8, n. 3, pp. 450-454, 2002, p. 450.

Some doctrine states that a limitation as a general and abstract rule, with no room for exceptions, would be a restriction on the fundamental right to reproduction, "extrapolating the competence of the body of the medical profession".[17]

Obviously, it should be noted that it is unlikely that a risk inherent in a late pregnancy will pose a threat to the fetus. For this reason, an eventual overcoming of such age limitation should be the subject of an exhaustive analysis of the health of the woman who will bear the pregnancy.

Decision-making should always be the result of discussions between the doctor and the parties, who must be informed in detail. The dynamics that involve a synergy between the self-determination of patients and the autonomy of physicians, encompassing informed consent without being confused with it, is called informed choice.

2.2 *Informed Consent of Beneficiaries*

According to paragraph 4 of the general principles of FCM Resolution, free and informed consent is mandatory for all patients undergoing assisted reproduction techniques. The medical aspects involving the totality of the circumstances of the application of an ART must be exposed in detail, as well as the results obtained in that treatment unit with the proposed technique. The information must also reach biological, legal, and ethical data. The free and informed consent document must be prepared in a specific form and will be complete with the agreement, in writing, obtained from discussion between the parties involved in assisted reproduction techniques.

Complementing the mentioned paragraph, the FCM Resolution also establishes that assisted reproduction techniques are available to all capable persons, whose indication does not depart from the limits of the Resolution. Candidates for assisted reproduction techniques must be in full agreement and duly informed. Once again, we see the prestige given to the right to information, consent, and autonomy of patients.

According to article 15, paragraph 3 of the Brazilian Code of Medical Ethics, it is forbidden for the doctor to practice a medically assisted procreation procedure

17 However, the authors do not contest the legitimacy of preventive measures to avoid high-risk pregnancies. They argue that a restriction should be a measure taken considering the particularities of each medical case. See NAVES, Bruno Torquato de Oliveira Naves; SÁ, Maria de Fátima Freire. "Panorama bioético e da reprodução humana assistida no Brasil", *In: Revista de Bioética y Derecho*, vol. 34, pp. 64-80, 2015, p. 68.

without the participants being in full agreement and duly informed about the method. It is stated in the doctrine that informed consent in the provision of health care is an expression of the free development of the personality.

As already mentioned, Bioethics was built on four fundamental pillars: non-maleficence, beneficence, justice, and autonomy. The more private the choice, that is, the more it concerns the integrity of one's own projects and the individual's self-conception, and the less it directly affects third parties, the more robust people's right to autonomy will be.[18]

Relationships between physicians and those who need health care are no longer vertical and asymmetrical. It is no longer the physician who must make the choice for the patient. Professionals should not put people in an immature position to make decisions about their own lives. Gone are the days when patients were given only a position of passivity and compliance with what was decided by the doctor.

The current FCM Resolution correctly replaced the expression "bilateral discussion between the involved parties" with "discussion between the parties". The change makes perfect sense, as an assisted reproduction process will not always involve only two parties. If, for example, it is the case of ART using surrogacy, the parties involved will be the doctor, the beneficiary individual or couple, the surrogate and a possible spouse or partner of the surrogate.

To make informed decisions, the parties are entitled to factual and objective information about all available alternatives. Likewise, the chances of success and the risks involved in each technique must be made known.

The importance of a trusting relationship between patient and doctor can never be overestimated because in most cases the success of treatments directly depends on the quality of this relationship.[19]

It is necessary to understand that the consent process constitutes, at the same time, a patient's right and a doctor's duty. The patient must be informed, in a way that is comprehensible about the diagnosis, risks, prognoses and existing alternatives for treatment. It is important to point out that the simple act of

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18 See SCHUCK, Peter H. "Rethinking Informed Consent", *In: Yale Law Journal*, vol. 103, n. 4, pp. 899-960, 1994, p. 924.

19 As states HELLÍN, T. "The physician-patient relationship: recent developments and changes", cit., p. 452.

reading and signing a paper is not enough to fulfill the duty to properly inform (although the signature of a document is important to prove diligent conduct).[20]

Perceiving the consent process as an end does not meet the principles of the Brazilian legal system, creating a failure in fulfilling the duty of information. It is a mistake to think that obtaining the signature of an informed consent form means the exclusion of civil liability.

In summary, informed consent forms must cover legal, ethical, and psychological issues related to ART. The informed choice process presupposes understanding and active participation of the parties, which some doctrine calls "deliberative consent process".[21]

2.3 *Surplus Embryos*

According to paragraph 2 of Chapter V of the FCM Resolution, the total number of embryos generated in the laboratory will be informed to patients so that they can decide how many embryos will be transferred fresh. Viable surpluses must be cryopreserved.

Although this paragraph may imply that there is great autonomy for beneficiaries, the decision must be guided by the limits established by the Resolution. The maximum limits of embryos to be transferred depend on the age of the woman who will carry the child. Women aged up to 37 years may have up to two embryos transferred. Women over 37 years old can have up to three embryos transferred.

The Resolution, therefore, divided the limits into two groups: women aged up to 37 years and women aged 38 to 50 years (age limit that may be exceeded by analyzing the specific case based on the criteria indicated in point 3.2 of the Resolution).

In 2021, Resolution No. 2294/2021 brought as a novelty an implantation limit of two embryos per cycle, regardless of the woman's age, when euploid embryos identified after Pre-Implantation Genetic Diagnosis are concerned. This rule was maintained by the current Resolution.

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20 In this sense, see DANTAS, Eduardo. *Direito médico*, cit., pp. 71-78.

21 SWAIN, Margaret E. "The Essentials of Informed Consent", In: Family Advocate, vol. 34, pp. 18-22, 2011, p. 19.

The novelty brought by the limit imposed on the transfer of euploid embryos reveals an effort to avoid the dangers of multiple pregnancies based on the increased success rates when euploid embryos are implanted. Some doctrine [22] even advocates that the transfer should be restricted to a single euploid embryo, since the transfer of two euploid blastocysts, according to the study, resulted in an exceptionally high rate of twins. Although most infertile patients and couples are happy to receive two babies, the authors advocate, especially in older patients (over 38 years), the transfer of a single embryo. The researchers argue that twin pregnancies are six times more likely to deliver prematurely and three times more likely to have perinatal mortality compared with singletons, as well as increased risks of maternal complications, including hypertensive disorders and hemorrhage.

Therefore, even if space is given for the patients' autonomy regarding the number of embryos to be transferred per cycle, it can be said that the minimum number can always be chosen, but they cannot exceed the maximum, according to age. Such limitation to beneficiaries' autonomy is justifiable, considering that the risks of multifetal pregnancy increase with each additional fetus.

Under paragraph 3 of Chapter V of FCM Resolution, before the embryos are generated, patients must express their will, in writing, regarding the fate of the cryopreserved embryos in case of divorce, dissolution of stable union or death of one or both, and whether they wish to donate them.

I have long argued that before IVF is performed, or, at most, until the time of cryopreservation of the embryo, its fate should be provided for in a contract or in the informed consent form used by the clinic. Otherwise, that is, in the absence of documentation to prove the decision of the beneficiaries, many problems may arise, namely in the event of separation or death.[23]

Thus, if the parents agree about the destination of the embryos and, obviously, this destination is lawful, there will be no problems. However, if the couple disagrees, the resolution of the situation should be left to another authority, preferably judicial, based on what is understood to be the best interest of the embryo. Disagreement can manifest in several ways. Both parents may

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22 GORDON, Catherine *et al*. "Patients of advanced maternal age should only transfer a single euploid blastocyst", *In: Clinical Obstetrics, Gynecology and Reproductive Medicine,* vol. 4, n. 2, pp. 1-4, 2018, p. 1.

23 CHAVES, Marianna. "Algumas notas sobre os embriões excedentários". In: *Direito, Linguagem e Sociedade*/ Virgínia Colares (org.). Recife: APPODI, pp. 124-162, 2011, p. 138.

want the embryos for their own reproduction. One of them may want to use it and the other oppose getting involved in a parental project, considering the presumption of maternity and paternity that would exist at the time of cryopreservation. One of them may want to donate them to other people or couples, and the other may want to discard them.[24]

Obviously, even if the FCM Resolution determines that there is a written agreement of the parties before cryopreservation, there may be a flaw in the process and disagreements must be resolved in another way.

Concerning the disputes between living parties in the absence of agreements, I agree with the solution proposed by Vera Lúcia Raposo,[25] where the jurist states that a resolution should be chosen based on the following considerations: a) in the absence of prior agreements, the emphasis should be on the will of each party to use or not the embryos. The jurist maintains that there should be a prevalence of the right to non-reproduction, especially when the other party's desire is to donate the embryos to third parties; b) however, if the man or woman who wants to use the embryos does not have an alternative way of reproducing, the right to reproduction must prevail. Such an option would be justifiable since the initial parental project had the support of both sides, even from the party that now opposes the implantation.

2.4 ***Preimplantation Genetic Diagnosis (PGD)***

According to paragraph 1 of Chapter VI of the FCM Resolution, assisted reproduction techniques can be applied to the selection of embryos submitted for diagnosis of genetic alterations that cause disease. In case there are non-viable embryos or with alterations, they can be donated for research or discarded. The donation or disposal of embryos depends on the decision of the patients, duly documented with free and informed consent.

The CFM Resolution does not clarify whether recourse to the PGD is free or subject to certain criteria. In the absence of clear indications by the Resolution, it seems that the PGD will always be authorized, being restricted, however, to

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24 CHAVES, Marianna. "Algumas notas sobre os embriões excedentários", cit., p. 138.

25 RAPOSO, Vera Lúcia. "O dilema do rei Salomão: conflitos de vontade quando ao destino dos embriões excedentários", *In: Lex Medicinae* – Revista Portuguesa de Direito da Saúde, ano 5, n. 9. Coimbra: Centro de Direito Biomédico/ Coimbra Editora, pp. 55-79, 2008, pp. 78-79.

research related to genetic anomalies, not serving as a mechanism for futile choices (such as gender for non-medical reasons, height, eye or hair color, etc.) for certain genetic traits.

It is important to emphasize that the choice of gender, called by some "sexist eugenics"[26] is expressly prohibited by the FCM, except when it is applied to prevent the potential child from carrying diseases linked to one of the sex chromosomes, such as Becker's muscular dystrophy, Duchenne's muscular dystrophy and hemophilia. Therefore, unless medical reasons are involved, sexing is not permitted by the Federal Council of Medicine. The same position is followed by article 14 of the Convention on Human Rights and Biomedicine, also known as the Oviedo Convention.

PGD was developed by Professor Lord Winston and Professor Handyside at Hammersmith Hospital in the late 1980s. It is a clinical diagnostic procedure that was originally developed to provide an alternative to conventional prenatal diagnosis (by chorionic villus sampling or amniocentesis) for couples at substantial risk of transmitting a genetic disease to their children. It is a multi-step process that includes oocyte extraction, IVF, cell biopsy, genetic analysis, and embryo transfer. In deciding whether to transfer a particular embryo, cellular material is then removed from the embryo in vitro and tested for a specific genetic abnormality.[27]

Used in the context of Reproductive Medicine, PGD can provide prospective parents with a vast amount of information about the genetic makeup of embryos conceived by IVF. As Vera Lúcia Raposo[28] warns, although it does not work (yet) as an absolute guarantee of a healthy child, it is certain that it is currently feasible to rule out a series of critical illnesses, such as the various aneuploidies.

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26 REIS, Rafael Vale e. "Responsabilidade penal na procriação medicamente assistida – A criminalização do recurso à maternidade de substituição e outras opções legais duvidosas". In: Lex Medicinae – Revista Portuguesa de Direito da Saúde, Ano 7, n. 13, pp. 69-93, 2010, p. 79.

27 See ODELL-WEST, Amanda. "Preimplantation Genetic Diagnosis, The Medical Exclusion and the Biotechnology Directive", In: *Medical Law International*, vol. 8, n. 3, pp. 239-250, 2007, p. 240.

28 RAPOSO, Vera Lúcia. "Pode trazer o menu, por favor? Quero escolher o meu embrião – Os múltiplos casos de selecção de embriões em sede de diagnóstico genético pré-implantação", *In: Lex Medicinae* – Revista Portuguesa de Direito da Saúde, ano 4, n. 8, pp. 59-84, 2007, pp. 59-60.

PGD is also already being used to detect abnormal BRCA1 or BRCA2 genes that confer up to an 85% risk of developing breast cancer at age 70. BRCA1 abnormality is also associated with a 55% increase in lifetime risk of ovarian cancer, and BRCA2 with a 25% increase in the risk of ovarian cancer.[29] Likewise, it has been used to screen for Cystic Fibrosis and Tay-Sachs.[30]

The option to do PGD should be presented to beneficiaries, but the choice to do so should be left to patients. The option not to take the test should always be respected by the doctor, even if it involves a person or couple with a history of genetic diseases. Doctors should clearly state that PGD is not an absolute guarantee of having a healthy child.

Physicians should inform patients that most existing genetic tests examine disorders and pathologies that arise from mutation of a single gene. Furthermore, they shall explain that vast majority of inherited conditions and traits result from interactions between multiple genes or between genes and the environment.[31]

One of the complications is embryonic mosaicism, which occurs when two or more populations of cells with different genotypes are present in the same embryo. The interpretation of mosaicism is complicated because the transfer of some mosaic embryos resulted in live births. Mosaic embryos may represent a third category between normal (euploidy) and abnormal (aneuploidy). This category of embryos may be characterized by decreased implantation and pregnancy potential, as well as increased risk of genetic abnormalities and adverse pregnancy outcomes. Thus, physicians should explain what a mosaic embryo is and why euploid embryos should be preferred in transfer over mosaic embryos.

Because of the risks involved in mosaicism, patients should be encouraged to undergo another cycle to obtain euploid embryos, rather than transferring a mosaic embryo. If it is impossible to carry out a new cycle, a decision to

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29 ODELL-WEST, Amanda. "Preimplantation Genetic Diagnosis, The Medical Exclusion and the Biotechnology Directive", cit., pp. 140-141.

30 DEENEY, M. Shelby. "Bioethical Considerations of Preimplantation Genetic Diagnosis for Sex Selection", *In: Washington University Jurisprudence Review*, vol. 5, n. 2, pp. 333-360, 2013, p. 335.

31 See KING, Jaime S. "And Genetic Testing for All - The Coming Revolution in Non-Invasive Prenatal Genetic Testing", *In: Rutgers Law Journal*, Vol. 42, n. 3, pp. 599-658, 2011, 601.

transfer mosaic embryos can be respected, provided that the beneficiaries are fully aware of all the risks involved. The transfer should not just be consented to, but the result of a truly informed choice, based on detailed information.

2.5 ***Surrogacy***

In Brazil, if there is a condition that prevents or contraindicates pregnancy, surrogacy may be used. In the case of heterosexual couples, single women or lesbian couples, the use of surrogacy is subject to the medical impossibility of the beneficiary carrying the pregnancy. In these cases, therefore, the surrogacy takes on a subsidiary character. For single men or gay couples, surrogacy is the only way to have a genetically linked child without sexual contact with a woman.

The option of the Resolution is correct. Forcing a gay man to have sexual intercourse with a woman to initiate a pregnancy violates his fundamental right to sexual orientation and, consequently, vilifies his freedom and dignity. The idea of alternative only exists when it is possible for the person to reproduce through sexual intercourse without clinical risks or without "drastically compromising basic life options".[32] Since reproduction is a fundamental right, any rule that prevents its exercise must be accompanied by an indication of the public interest directly related to this restriction.[33]

According to the FCM Resolution, the surrogate must: a) have at least one living child; b) belong to the family of one of the partners in kinship up to the fourth degree. If it is impossible for a relative to be a surrogate, authorization from the Regional Council of Medicine must be requested.

According to paragraph 2 of Chapter VII of the Resolution, the surrogacy cannot be profitable or commercial, and the choice of surrogate cannot be mediated by the clinic responsible for the ART procedures. Therefore, the choice of the surrogate is the result of the autonomy of the beneficiaries of assisted reproduction techniques, and the clinic cannot interfere, unless the candidate does not meet the requirements demanded by the Resolution.

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32 RAPOSO, Vera Lúcia. *O direito à imortalidade*: o exercício de direitos reprodutivos mediante técnicas de reprodução assistida e o estatuto jurídico do embrião *In Vitro*. Coimbra: Almedina, 2014, p. 730.

33 HOLLAND, Michelle Elizabeth. "Forbidding Gestational Surrogacy: Impeding the Fundamental Right to Procreate", *In: UC Davis Journal of Juvenile Law and Policy*, vol. 17, n. 2, 1-28, 2013, p. 13.

According to paragraph 3 of the same Chapter of the Resolution, when a surrogate is involved, the following documents and observations must be included in the patient's medical record:

a) Informed consent form signed by the patients and the surrogate. The document must address the biopsychosocial aspects and risks involved in the pregnancy-puerperal cycle, as well as legal aspects of kinship;

b) Medical report attesting the suitability of the physical and mental health of all those involved in the process;

c) Agreement between the patient(s) and the surrogate, clearly establishing the issue of the child's affiliation.

d) Commitment of the beneficiaries, taking responsibility for the treatment and medical follow-up, including by multidisciplinary teams, from the surrogate until the puerperium;

e) Commitment of the civil registration of the child by the patients, and this documentation must be provided during the pregnancy; and

f) Approval of the spouse or partner, presented in writing, if the surrogate is married or living in a stable relationship.

Subheading c) seems to be a repetition of subheading a). Of all the subparagraphs of this paragraph, the one that causes the greatest astonishment is subparagraph f), mainly regarding the requirement of a partner's authorization.

With marriage, spouses do not become holders or possessors of each other's reproductive organs. The fact that a woman becomes the wife of a man does not give him the right to prevent her from resorting to contraceptive methods. Likewise, marriage does not grant her husband the right to impose an unwanted pregnancy on her or to prevent her from generating a child for third parties as a surrogate. Even if she is married, the body still belongs to her.

Even more astonishing is the requirement for a partner's permission. A stable union does not change a person's marital status in Brazil and, therefore, does not generate presumption of paternity for the partner. With marriage or stable union, the woman does not lose the right to dispose of her body in the way that is convenient for her, since marriage does not make the woman an object.

Regarding any medical act, it is only up to the woman to give her consent. As stated by André Dias Pereira, "consent is strictly personal, the doctor-patient relationship does not involve third parties, not even the spouse".[34]

At present, legal equality between men and women is a structural point for the affirmation of human dignity and a guiding element of family relationships. There is a collaborative exercise of conjugality, but marriage or stable union does not (or should not) grant rights to object to medical interventions in the other, even in the reproductive sphere.

If judgment permits, decisions in this area are highly personal. The exercise of the right to self-determination in health care and the free disposal of physical integrity must be governed by the principle of autonomy.[35] In this logic, the right to intimacy and privacy applies even in confrontation with the family, namely spouses or partners.

Unreasonable demands for authorizations from men take us back to the iniquitous times when women – single or married – were considered an incapable being, always dependent on the authority of a man, be it the father or the husband. It goes without saying that women have always gone through – and still go through – an arduous process of discrimination in society, based on gender. This violence, which can be physical, verbal, psychological, cultural, or symbolic, based in this patriarchal vision rooted in and directed towards the figure of men.[36] The place given by the Law to women was a "non-place", where the female presence was the "history of an absence", as she existed subordinate to her husband, without a voice and marked by the legal regime of incapacity.[37]

Conditioning the possibility of a woman being surrogate to the authorization of her husband or partner is to consider a woman incapable of deciding what she will do with her own body. Limiting the exercise of such a right, which will not bring any physical or legal harm to the husband or partner is unreasonable, disproportionate, and illegitimate.

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34 PEREIRA, André Gonçalo Dias. *O Consentimento Informado na Relação Médico-Paciente* – Estudo de Direito Civil. Coimbra: Coimbra Editora, 2004, p. 213.

35 PEREIRA, André Gonçalo Dias. *O Consentimento Informado na Relação Médico-Paciente*, cit., p. 205.

36 See LISBOA, Elder Lisboa Ferreira da Costa. *O Gênero no Direito Internacional*: Discriminação, Violência e Proteção. Belém: Paka-Tatu, 2014, p. 204.

37 PEREIRA, Rodrigo da Cunha. Direito de Família: Uma abordagem psicanalítica. 4. ed. Rio de Janeiro: Forense, 2012, p. 107.

Conclusion

Infertility is currently considered an illness. We moved away from the pristine conception that it was a punishment or divine will, paving the way for the development of assisted reproduction techniques, which materialize the remedy for the problem. Science in this field is moving at a frenzied pace. What was in the not-so-distant past thought of as science fiction, quickly became a common reality.

People who seek to circumvent infertility have different particularities such as gender, sexual orientation, marital status, and the need for third parties. The only thing that any patient looking for ART shares with others is the human desire to have a child and become a mother or father.

The technological revolution in reproductive medicine has occurred not only in the scientific domain, but also in the domain of the family institution. In addition to offering a solution to the problem of infertility, medicine has made it possible to create other family structures and models that would not exist without the help of biotechnology. These advances, however, have brought with them numerous doubts and dilemmas.

Brazil has left the regulation of medically assisted reproduction in the hands of the medical deontology. Currently, the standardization of AHR is mainly found in FCM Resolution No. 2320/2022.

All the Federal Medical Council's resolutions on ART indicated in their explanatory note the need to create specific legislation in Brazil. Similarly, all the documents emphasized the lawmaker's lethargy in fulfilling this obligation. Brazil must therefore go ahead and legislate in this field.

The Brazilian doctrine raises doubts regarding the legal nature of FCM's resolutions. In my opinion, FCM's resolutions have no force of law and are not binding on the parties or the judge who settles a dispute. In fact, Article 1 of the Resolution indicates that its standards are ethical standards for the use of ART, ethical rules to be followed by physicians. Therefore, there seems to be no doubt as to the nature of this document and who is subject to these standards.

One thing that is clear is the need to adequately inform patients about all medical procedures and protocols performed during the ART process. It is a matter of respect for the bioethical and constitutional principle of autonomy that materializes in the informed choice and consent of the beneficiaries.

Scientific practice should not be an outcome of professional taxation. It must arise out of a relationship of trust. It must result from a partnership where physicians detail the information so that patients can choose what respects best practices with their autonomy.

There was therefore a move beyond the infantilisation of patients, who were once placed in a passive position, without having a say in the choice of procedures to adopt.

A major pillar of the physician-patient relationship is the duty to provide information. The doctor is obliged to provide the beneficiary with all possible information on his case. With all the clear and accurate information, patients can decide for themselves, supported by the principle of autonomy.

This collaborative process allows patients to choose the course of treatment concisely. Being properly informed of the potential risks and benefits of their decision allows them to make a truly informed choice.

Autonomy is undoubtedly among the most important human prerogatives. Informed consent results from informed choice and is an essential component of medical practice. It is a basic human right of the patient and an unavoidable obligation of the doctor.

References

ALVES, Cristiane Avancini. "A Conexão entre a Autodeterminação e a Formação Familiar na Esteira do Princípio da Responsabilidade". In: Bioética e Responsabilidade/ Judith Martins-Costa; Letícia Ludwig Möller (orgs.). Rio de Janeiro: Forense, pp. 113-144, 2009.

ANDORNO, Roberto. "´Liberdade´ e ´Dignidade´ da Pessoa: Dois Paradigmas Opostos ou Complementares na Bioética?", *In: Bioética e Responsabilidade*/ Judith Martins-Costa; Letícia Ludwig Möller (orgs.). Rio de Janeiro: Forense, pp. 73-93, 2009.

CHAVES, Marianna. "Algumas notas sobre os embriões excedentários". In: *Direito, Linguagem e Sociedade*/ Virgínia Colares (org.). Recife: APPODI, pp. 124-162, 2011.

DANTAS, Eduardo. Direito médico. 3ª ed. Rio de Janeiro: GZ, 2014.

_____; CHAVES, Marianna. *Aspectos Jurídicos da Reprodução Humana Assistida:* Comentários à Resolução 2.121/2015 CFM.. Rio de Janeiro, GZ, 2015.

DEENEY, M. Shelby. "Bioethical Considerations of Preimplantation Genetic Diagnosis for Sex Selection", *In: Washington University Jurisprudence Review*, vol. 5, n. 2, pp. 333-360, 2013.

GORDON, Catherine *et al*. "Patients of advanced maternal age should only transfer a single euploid blastocyst", *In: Clinical Obstetrics, Gynecology and Reproductive Medicine,* vol. 4, n. 2, pp. 1-4, 2018.

HELLÍN, T. "The physician-patient relationship: recent developments and changes", *In: Haemophilia*, vol. 8, n. 3, pp. 450-454, 2002.

HOLLAND, Michelle Elizabeth. "Forbidding Gestational Surrogacy: Impeding the Fundamental Right to Procreate", *In: UC Davis Journal of Juvenile Law and Policy*, vol. 17, n. 2, 1-28, 2013.

KING, Jaime S. "And Genetic Testing for All - The Coming Revolution in Non-Invasive Prenatal Genetic Testing", *In: Rutgers Law Journal*, Vol. 42, n. 3, pp. 599-658, 2011.

KONDER, Carlos Nelson; KONDER, Cíntia Muniz de Souza. "Autonomia reprodutiva e novas tecnologias no ordenamento brasileiro: violações e ameaças ao direito a gerar e a não gerar filhos", *In: Revista da Faculdade de Direito da UFMG*, n. 69, pp. 113-131, 2016.

LISBOA, Elder Lisboa Ferreira da Costa. *O Gênero no Direito Internacional*: Discriminação, Violência e Proteção. Belém: Paka-Tatu, 2014.

NAVES, Bruno Torquato de Oliveira Naves; SÁ, Maria de Fátima Freire. "Panorama bioético e da reprodução humana assistida no Brasil", *In: Revista de Bioética y Derecho*, vol. 34, pp. 64-80, 2015.

ODELL-WEST, Amanda. "Preimplantation Genetic Diagnosis, The Medical Exclusion and the Biotechnology Directive", In: *Medical Law International*, vol. 8, n. 3, pp. 239-250, 2007.

OLIVEIRA, Guilherme de. "Estrutura jurídica do acto médico, consentimento informado e responsabilidade médica", In: *Temas de Direito da Medicina*/ Guilherme de Oliveira. 2. ed. Coimbra: Coimbra Editora, pp. 59-72, 2005.

_____. "Legislar sobre Procriação Assistida", *In*: *Temas de Direito da*

Medicina/ Guilherme de Oliveira. 2. ed. Coimbra: Coimbra Editora, 2005.

PEREIRA, André Gonçalo Dias. *O Consentimento Informado na Relação Médico-Paciente* – Estudo de Direito Civil. Coimbra: Coimbra Editora, 2004.

PEREIRA, Rodrigo da Cunha. Direito de Família: Uma abordagem psicanalítica. 4. ed. Rio de Janeiro: Forense, 2012.

RAPOSO, Vera Lúcia. "'Dá-me licença que tenha filhos': restrições legais no acesso às técnicas de reprodução assistida", *In: Revista Direito GV*, v. 15, n. 2, e1915, pp. 1-27, 2019.

_____. "O dilema do rei Salomão: conflitos de vontade quando ao destino dos embriões excedentários", *In: Lex Medicinae* – Revista Portuguesa de Direito da Saúde, ano 5, n. 9. Coimbra: Centro de Direito Biomédico/ Coimbra Editora, pp. 55-79, 2008.

_____. *O direito à imortalidade*: o exercício de direitos reprodutivos mediante técnicas de reprodução assistida e o estatuto jurídico do embrião *In Vitro*. Coimbra: Almedina, 2014.

_____. "Pode trazer o menu, por favor? Quero escolher o meu embrião – Os múltiplos casos de selecção de embriões em sede de diagnóstico genético pré-implantação", *In: Lex Medicinae* – Revista Portuguesa de Direito da Saúde, ano 4, n. 8, pp. 59-84, 2007.

REIS, Rafael Vale e. "Responsabilidade penal na procriação medicamente assistida – A criminalização do recurso à maternidade de substituição e outras opções legais duvidosas". In: Lex Medicinae – Revista Portuguesa de Direito da Saúde, Ano 7, n. 13, pp. 69-93, 2010.

SCHUCK, Peter H. "Rethinking Informed Consent", *In: Yale Law Journal*, vol. 103, n. 4, pp. 899-960, 1994.

SHIVAKUMAR, Pryianka. "Count Your Chickens before They Hatch – How Multiple Pregnancies Are Endangering the Right to Abortion", *In: Brooklyn Law Review*, Vol. 78, n. 1, pp. 201-230, 2012.

SWAIN, Margaret E. "The Essentials of Informed Consent", *In: Family Advocate*, vol. 34, pp. 18-22, 2011.

UN. "Reproductive Rights are Human Rights: A Handbook for National Human Rights Institutions", p. 21. Available in: http://www.ohchr.org/Documents/Publications/NHRIHandbook.pdf Accessed in: 18/03/2017.

VARELIUS, Juka. "The value of autonomy in medical ethics". In: *Medicine, Health Care and Philosophy*, vol. 9, pp. 377–388, 2006.

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AUTONOMY, INFORMATION, AND FREE AND ENLIGHTENED CONSENT IN THE DOCTOR-PATIENT RELATIONSHIP

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Abstract: Consent to the medical act has been receiving heightened attention in health law, keeping in mind the need to respect the patient's will, to be wielded according to their legitimate wishes. Considering this, this paper contemplates the exposure of the main aspects that surround consent to the medical act, covering its genesis; it deals with the necessary information for the adequate exercise of the right to decide, the informative content and extension which lead to the validity of the patient's deliberation.

Keywords: Informed Consent; Medical Law; Health Law; Patient's Rights

Summary: **1.** Introduction. **2.** The patient's decision as the effectiveness of self-determination. **3.** Necessary information content for the validity of the patient's deliberation. **4.** Final considerations.

1 INTRODUCTION

It is a huge challenge to write about themes that involve aspects of the human essence and what is essential for preserving its integrity and dignity, such as health.

In general, patients are people without specific technical instruction and, therefore, the language of medicine is not familiar to them. As if that were not enough, a good part of the consultations that demand a prior informed choice process is carried out to treat diseases, and not to prevent them, that is, the patient is not in a comfortable and happy situation and is usually confronted with information or data that was not part of their routine before, and which you will hardly be able to sneak over.

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The junction between an atypical moment of life propitiated by a disease and the patient's technical ignorance form fertile and challenging ground for the definition of the premises of an effective informative-decision-making process, which demands evaluations of questions that, if isolated, are difficult in themselves, together they are even more.

They involve the ability to decide, the type of decision to be made, and what information must be provided so that the patient can adequately decide.

The ability to decide is an essential aspect, which calls for a specific study, not contained within the strict limits of this text. The type of decision to be taken is a topic that is closely linked to the capacity to consent, since the range of capacity is of wide gradation and, therefore, it is possible for the occurrence of cases in which a patient has a wide decision-making possibility and, in others, experiences partial cognitive limitations (temporary or permanent) that restrict their decision-making scope, which refer to the use of other isolated or joint measures for a better solution in defining the path to be followed, such as delegating the power of choice to a chosen third party by the patient themself, the Judiciary or even the care team, according to the circumstances involved in each case and the governing legislation of each country.

That said, this text will focus on an aspect that must be discussed with due attention, which is the information to be passed on to the addressee so that their decision can be considered adequate and valid.

It will explain the characteristics of the set of information that must be passed on to achieve the purpose of legal validity and the efficiency of the decision, which is to allow the patient a choice that is consistent with their ideals, their biography, and their legally acceptable objectives.

The text will bring notes based on the premise of patients with the capacity to consent and civil capacity in elective care. This cut is necessary because changing one variable could bring other directions to the suggested paths and exceed the established writing limits.

Thus, the text will begin with an explanation of the importance of granting the patient the opportunity to make a decision, as it is a product of respect for autonomy; then, it will go through the set of information necessary for a decision to be considered adequate for taking into account variables and necessary and admissible assumptions and will end with an indication of the consequences of a medical act performed without the patient's decision having been legally valid.

2. THE PATIENT'S DECISION AS THE EFFECTIVENESS OF SELF-DETERMINATION

Contemporarily, most people are born at the hands of a health professional and, throughout their lives, will need medical care. Therefore, unlike many other fields of existence that involve several options, health care tends to be an almost inexorable part of human existence. However, in general, this intervention cannot be carried out without the consent of the interested individual. This is because the principle of the integrity of the legal spheres expresses that no one can interfere in the legal sphere of others, except if there is permission from their holder or in cases of interference permitted by an authorizing legal rule.

Knowing that an unjustified interference can even be criminalized, it is necessary that professionals in the health area observe the postulate that the service must serve to meet the legitimate interests of those who are served, and not what the professional themself understands to be the correct or the best, under the technical paradigm. This finding is the final step of transposition between an outdated vertical and paternalistic model, to the modern horizontal and autonomous model of assistance in the health area.

The current model has its genesis in the integration of the human condition through the rights to life, psychophysical health, and to the body itself (by itself and in its parts), which are absolute rights, enforceable against third parties and whose disposal, according to the law called into question, is limited to its exercise, and not to the right itself or to its ownership.

Life and health are high interests of the human person, as they deal with what keeps them alive and allows them to fulfill their plans. Thus, the practical manifestations in terms of facts of any interference in someone's health can give rise to repercussions of the highest importance, which will only be directly felt by the person who owns them and cannot be delegated to a third party due to their inherent characteristics.

Accordingly, if someone improperly intervenes in the psychophysical integrity of others, in the civil sphere, this interference may be legally qualified as an unlawful act.

The dignity of the human person has self-determination as one of its structuring axes, thus being recognized as an expression of freedom, whether in the patrimonial sphere or in relation to existential aspects. Every individual undergoing treatment has the right to be informed and to make decisions

regarding its course, although decisions are subject to gradations, in the sense that in some cases the decision is limited (for example, in situations of severe appendicitis, the decision is limited to intervening or not intervening because, if the appendectomy is not performed, the patient may have a ruptured appendix and will be at risk of death), in others, it is wide (in cases of patients with early-stage cancer of elective treatment, hypothesis in which the space for decisions in the course of treatment will be vast) and in a third category are those in which the field of decisions is very limited or non-existent (as occurs in emergency care).

The definition of the informative and decision-making spectrum also involves differentiations, especially in acts of medium or high complexity, or whose risks may be high under qualitative or quantitative criteria. The greater the complexity of the acts, the greater the patient's knowledge of his condition and the greater his participation in decision-making. Likewise, the greater the risks involved in the care, the more pronounced the obligation to provide care and pass on information to the health service user must be, since, it should be noted, it is the patient who will effectively experience the practical result of each medical act.

Having been duly informed, the patient becomes able to decide, and this decision can be in the sense of doing or letting an act be performed; opting for a particular embodiment if there is more than one possible; stop doing or preventing it from being done; postponing the decision to a later date or transferring the power to decide to a trusted third party.

The patient's consent for the medical action is a decision voluntarily taken by the subject to be assisted and the way in which they wish to be assisted. This consent requires that the person has legitimacy, that is, that they combine civil capacity and the capacity to consent, to sustain both clinical and legal conditions to express their will (with discernment), regarding the conduct of their health, after going through the prior information process.

Consent is a permissive act of medical performance, which can be verbal or written, tacit or expressed. It is an exclusive act of the holder of the right (patient), exercised due to his self-determination, directed at a certain professional regarding the aspect that affects their sphere of physical or mental health. Consent depends, in order to be valid, on the prior dialectic process of informed choice having been followed correctly, whose course is individual, with content and length that varies according to the type of care recommended and the risks involved, and the recipient of the information, who is the person that will decide.

Consent to medical care is a demonstrative act of knowledge and will, resulting from the analysis of convenience and opportunity of the subject who issues it, in their self-interest, according to their convictions and knowledge, both prior and acquired during the process of informed choice.

As it is an exclusive act of the patient, the act issued by another person in the patient's place is not considered "consent". When the decision rests with someone other than the patient, it will be an "authorization" hypothesis.

Consent to the medical act represents the culmination of the patient's decision-making process, composing specific permission granted by the patient for a certain intervention or medical care, with the observance of predefined guidelines (even if the decision is due to non-compliance with a certain guideline, allowing others), or considering circumstances previously defined.

The patient's consent does not include in its concept expressing information transferring or receiving nor the apprehension and processing of these by the patient (this is an assumption and part of the decision-making process[2]), although this aspect acts in the plan of validity and, above all, of effectiveness, since the omission of information that should be passed on or the transmission of defective information, with or without malice on the part of the physician, may give rise to the duty to indemnify, precisely because the information, in the consent to the medical act, is a prior and qualifying component of the patient's statement or behavior in decision-making.

3. NECESSARY INFORMATION CONTENT FOR THE VALIDITY OF THE PATIENT'S DELIBERATION

The patient, in order to make a decision that can be considered valid, must pass – to a greater or lesser extent, according to the concrete circumstances considered – through an antecedent informative process, which will lead them to that choice (consent, dissent, transference of the power of decision to a third party or decision by a subsequent deliberation).

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2 "In termini molto generali, potremmo dire che le caratteristiche per un'espressione valida del consenso, dal punto di vista dei processo decisionali atti a raggiungere una determinazione, sono che il soggetto abbia un insieme relativamente stabile di scopi e fini, sia capace di comprendere le conseguenze della sua decisione, inclusi i rischi e i benefici ad essa associati, e sia in grado di rendersi conto di come la sua scelta realmente inciderà sulla sua vita". CANAVACCI, Laura. *I confini del consenso*: Un'indagine sui limiti e l'efficacia del consenso informato. Torino: Edizioni Medico Scientifiche, 1999. p. 7.

As for the doctor and their team, technical aptitude is not enough: preparation is required (or delegation for those who have it) to verify whether the patient is able to go through the information chain. Subsequently, it is necessary to verify if the addressee can receive the information and explanations, which includes the skills to receive, memorize, and process the information, in addition to deciding and rationally justifying their decision. If the answer is positive, attesting that the patient is able to decide, the transfer of adequate, sufficient, and clear information will follow, at the appropriate time, manner, and place; allowing the decision-maker to make their appropriate choices and that these choices are the result of maturation, insofar as this is possible.

The duty to inform has its genesis both in the law and in trust and the duty of care, and the decision-making procedure takes place in two *phases*, the *first* being clarification for the exercise of self-determination, and the *second* consisting of therapeutic clarification to those who chose to decide.

It is the doctor's duty to inform, although multidisciplinary care allows information to be passed on to the recipient by a member (doctor) of the team, under the responsibility of their superior. In the teams of different specialties, each one should have a designated professional, who will transmit the relevant information, admitting the possibility that the nursing team can help in this work. Technological tools are being used more and more to serve as information instruments, combining the transfer through technological and traditional means, with generic and more impersonal information, followed by personal and individualized information.

Ideally, the transfer of information should be carried out on an individual basis because each patient has their own peculiarities from a clinical point of view. However, if it is done concurrently for more than one patient (because the similar level of efficiency between the collective and individual transfer was recognized[3]), the opportunity to go through an additional step of specific clarifications that are relevant to enable a decision. However, to preserve their privacy and the undue dissemination of sensitive data, the collective transfer of information should be avoided when this unduly exposes the patient to the dissemination of information about their health condition.

3 GOLDIM, José Roberto; *et al*. O processo de consentimento livre e esclarecido em pesquisa: uma nova abordagem. *Revista da Associação Médica Brasileira*. V. 49, n. 4, 2003. p. 372-374.

The information is complex and depends on the phase in which the service is involved: if it is the clarification phase for the exercise of self-determination, which concerns the advantages and disadvantages of deciding, the moment of deciding and defining who will decide; or if it is the phase of therapeutic clarification, for those who chose to decide. The therapeutic clarification phase involves the care to be provided under the admissible techniques, in their nuances, including (among other information) the diagnosis, prognosis, and available treatments, with contraindications, associated risks and benefits, applicable relevant measures, costs involved, the influence of the "time" factor for the best result of the treatment, the effective need for treatment, and, thus, it is legitimately expected that these people involved in the legal relationship will be able to develop a fruitful dialogue in order to optimize and efficiently promote this understanding.

The patient's decision requires discernment compatible with the level of complexity of the decision to be taken, the time when it will be taken and the concrete circumstances at the time of the decision. This involves *wanting* or *not wanting* to be seen or continue to be seen; *wanting* or *not wanting* to be informed or continue to be informed during their link to the health service; and *wanting* or *not wanting* to decide on the service, intervention, or treatment, in its measure and technical or temporal extension.

According to what was mentioned in this text, in the *clarification phase for self-determination*, the doctor must present the patient with the ways of care, trying to find out if they are interested in being informed to decide. In practice, the doctor presents a more generic and superficial explanation regarding the patient's situation, informing which decisions should be taken, and inquires about the patient's interest in deciding, delegating the decision to a third party or the doctor themself, or even not decide and remain without treatment, considering that, if you opt for the choice by a third party or by the doctor themself, no decision can be contrary to good practices and the patient must always be communicated as to what will be done, as they may at any time exercise the power of veto or even change of opinion, in what is technically possible to be implemented.

If the patient expresses an interest in receiving additional information and in effectively making his choices, the second phase of the process is passed, which is the *therapeutic clarification*, in which the possible paths will be reported, with their onus, benefits, and risks, exposing the chances of success in achieving the objective of cure, quality of life or maintenance of life,

according to the legitimate objectives of the patient. As a subsequent act, the doctor themself, with sensitivity and considering his experience.

The therapeutic *informative phase* is the one that will define the contours of the medical action in the patient's health care. The *decision-making phase* (for care) is the one in which the recipient will deliberate, and, when deciding on assistance, will define the type of act, treatment, or intervention that will be implemented, which generally follows the *phase of therapeutic clarification*, in which the doctor starts to inform the conducts that fit the patient or that depend on their collaboration (in their actions or omissions applicable), so that the treatment or procedure has a greater chance of attainable success within the possibilities that the concrete circumstances allow[4].

The information essentially covers the diagnosis (obtaining and result), means used (both in the diagnosis and in the prognosis); treatments available or proposed and their respective purposes; the prognosis; the effects of treatments or consequences of non-treatment and the risks and benefits of the paths that can be adopted, along with their costs.

The rule is that the patient must receive the information, have time to reflect, and make the decision. However, it is possible in certain cases to considerably reduce the transfer of information that is simple and secondary, regarding simple treatments (without relevant qualitative or quantitative repercussions on the patient's health, which is recognized in the medical literature), or in hypotheses in that the patient seeks care, needs and wants urgent support, and there is only one option to save them, in which case more superficial information and generic consent are enough.

If this single treatment option does not pose a risk of qualitatively or quantitatively expressive sequelae, it can be done without further details regarding information to the patient, simply informing the patient of the diagnosis, the need for immediate surgical intervention, and obtaining the patient's consent, who has the right to undergo (or not) the procedure, but who, by consenting, dispenses with going through a detailed decision-making process.

The situation is different in a treatment that can be performed by more than one technique and each one has its particularities regarding its mode of action (for example, one is more conservative, requiring greater postoperative care,

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4 This division is in PEREIRA, André Gonçalo Dias. *O consentimento informado na relação médico-paciente*: estudo de direito civil. Coimbra: Coimbra Editora, 2004. p. 71-73.

but with a greater chance of success, and another more innovative one, with a shorter period of convalescence, but with a lower chance of success or with a higher cost to the patient), in which case, if there are conditions for obtaining consent, the physician must present the possible and available therapeutic alternatives, allowing the patient adequate decision-making.

Regarding the *diagnosis*, the patient must be informed about the nature and characteristics of the disease that will be identified. The circumstances of the concrete case will indicate whether this information will come in a single and complete way or gradually. Even for serious illnesses, the rule is that he is informed to allow them to organize his life in advance for the due confrontations.

The information must be true, in frank, respectful, positive, and welcoming dialogue. Hiding the truth can reduce the authority and trust in the doctor-patient relationship, it can reduce the patient's willingness to collaborate, in addition to depriving them of the opportunity to make the decisions about their life that they deem necessary, including regarding the establishment of directives advance health care, the definition of a proxy for health care, the opportunity to establish the *postmortem* asset disposition, among other measures. The rule does not affect those situations where the patient's consent is dismissed, especially when the information can generate more harm than good, a typical situation of therapeutic privilege.

Regarding the *purposes* of health treatment, the correct action is to specify the expected benefits, including whether the purpose is palliative, curative, preventive, or diagnostic. And, as for the *means* to be used in health treatment, it is up to the doctor to indicate whether it involves the use of medication, surgical intervention, or other technically indicated or possible measures, their effects, and foreseeable consequences (especially those that entail limitations to the patient), admissible risks or qualitatively or quantitatively relevant effects, alternative methods offered, in addition to the treatment recommended by the physician. Pereira clarifies that, in interventions where there is the possibility of submitting the patient to blood transfusion, this contingency must be informed, with the granting of an opportunity to refuse or seek alternatives, if any, even if they do not have equivalent efficiency or are more burdensome[5].

If in the diagnosis the doctor says "what it is", in the *prognosis* the professional says "how it will be" from different therapeutic possibilities, according to what

5 PEREIRA, André Gonçalo Dias. *O consentimento..., cit*. p. 392.

was diagnosed. The patient will have a dimension of the duration, its chaining, and the possible outcomes of a disease or a clinical condition. Therefore, the *secondary effects* that often affect the patient's quality of life or that are relevant must be informed, as occurs in the examples of scars, side effects resulting from the use of drugs, the loss or decrease of mobility, of some sense of the sensorial system or of organic-functional function[6].

In the field of *risks* involved, the doctor will pass on to the patient those that are qualitatively or quantitatively relevant or recurrent, involving predictable, serious (even when their occurrence is rare), and personalized risks (which occur due to the conditions or personal circumstances of the patient or that are aggravated by these, which may be known by the doctor)[7].

As for the time of information, this must precede decision-making, whose measure of advance is greater as time is needed for assimilation, reflection, decision, and any conduct required by the patient (for example, care in the treatment), the complexity of the case, the level of damage that can occur either as a side effect, or as a result of some treatment or non-treatment, and it is the lesser the urgency of the care.

The information must be correct, complete, and understandable, being considered correct and truthful and in accordance with the current state of science, especially medical and pharmacobiological. Therefore, if there is an experimental procedure that may be available to the patient, this should be made known to the patient[8]. Furthermore, being complete and comprehensible means that it must provide conditions for an adequate decision by the patient. While it is not necessary to get down to minutiae most of the time, the level of detail is higher in relation to what could cause harm or expose the patient to qualitatively or quantitatively relevant risks.

Complete does not mean excessive information (since an excess of information can be similar to not informing, due to the difficulties in understanding it can cause), but that which is important and common in professional medical

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6 PEREIRA, André Gonçalo Dias. *O consentimento..., cit*. p. 393.

7 RAGAZZO, Carlos Emmanuel Joppert. *O dever de informar dos médicos e o consentimento informado*. Curitiba: Juruá, 2008. p. 93-95.

8 As this is an experimental practice, as long as the patient is aware and in accordance with its terms, this referral attracts the incidence of norms that deal with medical research, which go beyond the limits of this work.

practice, adjusted to the patient specifically considered, since in the exceeding information[9], the patient may lose focus on the type of data that is actually useful for decision-making.

As Monteiro warns, "there is no need for any clarification on what falls within the scope of the general knowledge of the experience of the circle of users", since "this type of clarification not only does not reduce the danger but even increases it, as it can lead to serious warnings are not read."[10]. The doctor must pay attention to the level of education of their patient, because what may seem obvious to the doctor may not be so for the patient or may be seen differently or wrongly in the popular imagination.

Also complete is the information regarding the existence of specialized care centers or centers with more adequate facilities for care when there is a risk of death or serious sequelae for the patient being cared for, and that this special care can effectively make a difference to the service user.

When the doctor is faced with a lack of care structure or with another structure that is decisively more advantageous, they must notify the patient, allowing them to decide to look for other means and a place with an improved or specialized structure, if this is practicable. If not, the doctor should make the care possible according to the present circumstances[11].

Regarding the qualifications of the professional, the doctor does not have the duty to inform the time in which they practice medicine because, when qualifying to exercise the profession before the competent body, their aptitude is presumed. However, if the patient requests it, the professional will inform and, if the professional understands that the care requires specialization or experience that they do not have, they have the duty to inform the patient about this situation[12].

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9 The criterion to be considered is not that of the average patient (outdated criterion), but rather that of the individual patient, the one who has particularities that will give rise to different modes of action by the doctor, especially in terms of information demand.

10 MONTEIRO, Jorge Ferreira Sinde. *Responsabilidade por conselhos, recomendações ou informações*. Coimbra: Almedina, 1989. p. 327. In the original text: "não é necessário qualquer esclarecimento sobre aquilo que cabe no âmbito do conhecimento geral da experiência do círculo de utilizadores", since "esse tipo de esclarecimento não só não faz diminuir o perigo como até o eleva, pois pode conduzir a que os avisos sérios não sejam lidos".

11 PEREIRA, André Gonçalo Dias. *O consentimento..., cit*. p. 420.

12 PEREIRA, André Gonçalo Dias. *O consentimento..., cit*. p. 421.

Regarding language, "vocabulary adequacy" is essential for a correct decision, to justify the application of words that can be understood by the patient. If technical expressions are used, explanations should be given as to the meaning of each one, and elements that represent what is intended can be used[13].

The layout of the informative text written or transmitted by some electronic means must be intelligent, useful, and precise, to avoid difficulties both in reading and in understanding words, sentences, or paragraphs. The patient needs to receive effective information as to what needs to be said, and effectively understand what was said. The verification of this adequacy can be done through "readability indexes", capable of "assessing the level of education compatible with the text structure that is being proposed for a person", and the most used is the readability index of Flesch-Kincaid (ILFK), for which it is considered "adequate for reading by an average person when it has ILFK values compatible with an education between 6 and 10 years of study"[14].

The information must be efficient, it correlates with its concrete usefulness. The transmission of unnecessary information, which causes a loss of focus in relation to what is important, is dismissed. Efficiency in general comprises the diagnosis (disease, main characteristics, and evolution); risks, prognosis; the most relevant costs, and possible therapeutic alternatives[15], in addition to the patient's respective confrontations in adopting each possible path.

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13 GOLDIM, José Roberto. Consentimento e informação: a importância da qualidade do texto utilizado. *Revista HCPA*. Vol. 26, n. 3, Porto Alegre, 2006. p. 117-122. Excerpts from p. 118.

14 GOLDIM, José Roberto. Consentimento e informação..., *cit*. Excerpts from p. 119. Still according to Goldim (https://www.ufrgs.br/bioetica/ilfk.htm), this index applies the following formula: ILFK = ((0.39 x average of words per sentence) + (11.8 x average of syllables per word)) - 15.59. For him, "the result obtained with the formula estimates the years of study necessary for the text to be adequately understood. The Flesh-Kincaid Readability Index values considered most effective for a text are those between 6 and 10."

15 RAPOSO, Vera Lúcia. *Do ato médico ao problema jurídico*. Coimbra: Almedina, 2016. p. 221-222.
There are those who maintain that it is the physician's duty to only warn the patient about the most common (frequent) risks. LORENZETTI, Ricardo Luis. *Responsabilidad civil de los medicos*. T. 1. Buenos Aires: Rubinzal, 1997. p. 204-208.
Cordeiro states that they would be the typical ones: "The scope of the medical duty of clarification extends to the typical effects of the prescribed therapies and not to all the possible effects that these may cause; it also varies in depth, depending on the intelligence and knowledge of the patient and the needs of the case". CORDEIRO, António Manuel da Rocha e Menezes. *Da boa-fé no direito civil*. Coimbra: Almedina, 2001. p. 606.

The information must be intelligently arranged, starting with the most relevant and essential aspects and then being subsequently detailed in short and objective sentences, with links to details. Important information cannot be disguised or inserted together with non-essential or detailed information, as this may remove the patient's focus or make understanding difficult.

The efficiency of information involves indicating the appropriate options, allowing comparisons. Therefore, the use of comparative examples can be a tool that will enable decision-making with greater risk awareness.

Efficiency is associated with care, as the doctor must, for example, inform the patient about the possibility of performing a two-step procedure, if this is convenient to reduce risks or bring less suffering. For example, the case of a patient who had not been advised of the possibility of carrying out a two-stage intervention, using local anesthesia in each of them, instead of a single, more complex surgery using general anesthesia, on an occasion when there was a need for intubation, what caused tooth fracture, which would not have occurred if they had the opportunity to choose to divide the surgical procedure into two simpler stages.

And, considering technological progress, an additional informational layer can be attached, in which the patient must be informed about the common risks linked to the diagnosis, prognosis, etc., but also about the associated risks due to the technological means used. In telemedicine, for example, the possible loss of image quality as a result of technological failure, or the possibility that a monitoring mechanism transmits wrong readings to the professional who will perform the interpretation. In these cases, it is suggested that the patient be warned that the service using technology may not be accurate or effective enough, or that it will depend on the analysis of a local non-specialist, which may lead to errors. Also, the patient must be informed of the need for face-to-face care, as the case may be, or combined, for greater efficiency.

In French law, it was established that the patient should receive information on three magnitudes in telemedicine, the first regarding the type of care itself, its differences in relation to conventional care and the specific risks; the second regarding care, covering the medical act to be performed (art. L. 1111-2 CSP) and the telemedicine process to be used (art. R. 6316-2 CSP), and the third on obtaining, access, analysis and storage of data, as well as sharing data and ensuring the confidentiality of medical data[16].

16 Ministère du Travail, de l'Emploi, et de la Santé. *Télémédecine et responsabilités*

In telemedicine, guidance continues the use of accessible language, as each patient has a distinct and particular ability to understand, which should be reflected in the level of language to be used and the form of communication to be adopted. Thus, in the case of a patient with conditions to undergo a consent process, which covers perception, understanding, memorization, deduction, and inference, considering the previous use of the language and the language accessible to them, the process decision-making process is full and regular.

If the patient has some limitations in the information process, but with help manages to reach it, this help should be sought. When the patient is largely limited, it is necessary to verify whether this amplitude occurs in the horizontal aspect (the patient cannot associate the information because they are broad and related to several aspects of the diagnosis, prognosis, and available treatments) or in the vertical aspect (the difficulty of the patient stems from the complexity of the information).

Based on this assessment, a context must be built for obtaining the patient's direct consent insofar as this is possible and for authorization by a legally qualified third party (the person in charge, or the health care attorney, etc.) when that consent is not possible.

Each case must be investigated so that a solution can be constructed based on the patient's level of understanding and the degree of transfer of information that may be required of the physician, especially considering: (a) the amount and level of information that the patient can process; (b) reasonableness in the amount or degree of detail regarding the information that may be required from the doctor and (c) the different amounts of information that must be passed on, considering the complexity of the problem and the severity of the consequences of the decision for the patient. In this sense, semi-structured questionnaires (such as the *MacArthur Competence Assessment Tool* - MacCAT-T by Paul Appelbaum and Thomas Grisso)[17] can decisively help in this work.

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juridiques engagées. Sous-direction des ressources humaines du système de santé. 18/05/2012. Available on: http://www.sante.gouv.fr/IMG/pdf/Telemedecine_et_responsabilites_juridiques_engagees.pdf, Information from page 3 of the guide.

17 GRISSO, Thomas; APPELBAUM, Paul S. *Assessing competence to consent to treatment*: a guide for physicians and other health professionals. New York: Oxford University Press, 1998. p. 102-126.

Still in this context, it is worth explaining these two dimensions to be considered in the decision-making process, which are the *horizontal* and the *vertical* dimensions.

The *horizontal* dimension represents the breadth of information in its quantitative extension, that is, the magnitude of the volume and variability of information content, which may be partial or total. Thus, the patient with chronic renal failure will receive a quantitatively considerable volume of information due to the chronicity and severity of the disease, combined with the fact that it affects not only the kidneys but other systems and functions of the body, requiring specialized and high-quality care. multiple areas of health (especially when the disease stems from another, as is the case of chronic kidney disease associated with diabetes).

In the *vertical* dimension, there is the depth of information, which may be superficial or in-depth, as there are cases in which superficial information will not be enough for correct decision-making and, in others, very detailed information can cause undue fears in the patient, or even impair their understanding or decision-making.

On that account, there are patients who demand the receipt of vertically and horizontally in-depth information. In other cases, the vertical information must be widely respected, and the horizontal partially attended to, or even, the opposite is admitted, a restricted vertical information and a deep horizontal one. And yet, there is the hypothesis of a service that is correct with a decision-making process with less horizontal and vertically considered information coverage.

The setting up of each scenario depends on several factors, and is even dynamic, notably in the continued service, in which it will be possible to envision the flat information phase: greater depth phase, and less detailed information phase.

It is up to the doctor to inform what is known to them or whose knowledge is reasonably within his reach. For this reason, *v.g*., when administering medication, the doctor must warn about known qualitatively or quantitatively relevant risks and cannot be held responsible for an occurrence not previously described as possible in the specialized literature.

Lastly, one cannot speak of the patient's duty to self-inform, in view of the high technical level of the information involved in health care and which is necessary for consent, and it is even advised against the patient who is not versed in the area involved to obtain information autonomously, as this patient does not even know how to identify which are the appropriate sources of

information suitable for this purpose. It may happen, however, that the doctor indicates sources for obtaining additional reliable information to the patient, or even that the patient seeks this information and later talks to the professional to identify which ones are useful in his case. However, simple self-care recommendations or general knowledge should be known to the patient and are part of the onus of self-information.

The patient does not always know how to distinguish between important and unimportant data to be passed on, and it is up to the doctor to ask the appropriate questions to obtain the efficient information that the patient must expose.

Both the duty to inform and the onus of self-information find their boundaries in what is considered to come from a reasonable effort.

It is expected, on the other hand, that the patient observes the normal precautions of diligence and common sense, in addition to medical recommendations, acting in the sense of promoting, where appropriate, the achievement of the expected result in the care to which he is submitted, as damage resulting from non-compliance with the recommendations received or the admissible diligence cannot be imputed to the doctor who treated them.

It is necessary to accept and warn that there are no universal formulas to resolve all legal questions related to the matter of the duty to inform and the patient's consent, and that, while this duty cannot be too much of a burden for the professional, it must also serve for the purpose of allowing patient self-determination to the extent that it is factually possible and legally acceptable[18].

4. FINAL CONSIDERATIONS

Throughout the text, the importance of overcoming the outdated paternalistic model of health care was demonstrated to recognize and promote the necessary autonomy of the patient.

This autonomy is only validly exercised when the decision-maker previously receives information to exercise their right to choose, that is, if there is an adequate transfer of information, allowing a correct and mature decision. This can only be achieved if the information is adequate and sufficient, transmitted at the appropriate time and in an appropriate manner, observing understandable

18 PEREIRA, André Gonçalo Dias. *O consentimento..., cit*. p. 372-373.

language, and intelligently passed on, without excesses or shortages. In addition, the right to clarification must be granted and the possibility of revoking the decision at any time must be informed, as a right of the patient.

The text did not intend to present universal and unquestionable solutions, which are impossible to achieve, but rather to launch some premises that can reach a minimum consensus regarding their acceptance as a basis for a decision to be considered legally valid.

Furthermore, the importance of respecting the patient's valid decision should be emphasized, even if it is not considered usual or is far from the usual archetypes of health service providers. Those who will not directly experience the consequences of the decision must have a keen awareness of the need to understand "the other" according to the lens of "that other" (the decision-making patient). The paradigm for the evaluation process of the patient's decision is in their own premises and points of view, and not in the one who judges or evaluates the patient's decision.

If, for some, suffering can be seen as something positive, to be faced because there will be a later reward or because the person would need this experience as a learning experience, for others this statement would not always be acceptable, as a patient may not see suffering as a gift, a lesson, or a means of awakening them to their connection to life. For certain patients, suffering is not a stimulus to continue, an opportunity for coping and transcendence, or a necessary route to Christian edification. Therefore, adequately informing and knowing the reasons for the decision of the capable patient are essential for effective care in respect of their autonomy.

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