The interconnection between Law and Bioethics in the light of theoretical, institutional, and regulatory dimensions

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Abstract
This article aims to analyze the interconnection between Law and bioethics, focusing on the contributions of this new knowledge to the enforcers of Law in its function of social harmonization. For this purpose, we used the research line which features splitting bioethics into three perspectives: theoretical Bioethics, institutional and regulatory, and from each of these approaches, we analyzed the points of contact between the two fields of knowledge, and how bioethics contributes to the improvement of the Law. It was found that bioethics, helps the Judiciary Power and the ones who work with Law to deal with the complexity of issues related to life sciences, medicine and associated technologies.

Key words: Law. Bioethics.

Resumo
A interconexão entre Direito e Bioética à Luz das suas dimensões teórica, institucional e normativa
O presente artigo objetiva analisar a interconexão entre Direito e bioética tendo como foco as contribuições deste novo saber para os aplicadores do Direito na sua função de harmonização do convívio social. Para tanto, utilizou-se linha de pesquisa que propôe o recurso de dividir a Bioética em três perspetivas: teórica, institucional e normativa. A partir de cada um desses enfoques, analisou-se os pontos de contato entre os dois saberes, bem como o modo em que a bioética concorre para o aprimoramento do Direito. Constatou-se que a bioética pode auxiliar o Poder Judiciário e o aplicador do Direito a compatibilizar a racionalidade jurídica com a reflexão ética propiciada por novos paradigmas científicos, contribuindo, assim, para a diminuição das dificuldades surgidas na busca de soluções para questões complexas relativas a conflitos nas áreas das ciências da vida, medicina e tecnologias associadas.

Palavras-chave: Direito. Bioética.

Resumen
La interconexión entre el Derecho y la Bioética a la luz de sus dimensiones teórica, institucional y normativa
Este artículo tiene como objetivo analizar la interconexión entre el derecho y la bioética, centrándose en las contribuciones de este nuevo conocimiento para encargados de hacer cumplir la ley en su tarea de armonización de la vida social. Para este fin, se utilizó una línea de investigación que propone como recurso la división de la bioética en tres dimensiones: la bioética teórica, institucional y normativa. A partir de cada uno de estos enfoques, se analizaron los puntos de contacto entre los dos conocimientos, así como la manera que la bioética contribuye a la mejor comprensión del Derecho. Se comprobó que la bioética puede ayudar al Poder Judiciario y al aplicador de la ley a conciliar la racionalidad legal con el pensamiento ético fomentado por nuevos paradigmas científicos, contribuyendo de esa forma para las cuestiones complejas relacionadas a conflictos en ámbito de las ciencias de la vida, médica y tecnologías adjuntas.

Palabras-clave: Derecho. Bioética.

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In the twentieth century, humanity has watched the vertiginous techno-scientific development, as well as awakened to the need of constructing theoretical contributions, enabling reflection on the impact of this techno-scientific improvement on the planet and human beings. Thereby, it is asked if human species is ready to deal with the results of its creative potential, as this ability leads to the improvement of life conditions and, at the same time, its own decimation.

Considering this potential, the human power to change the geographic space and nature is evident. However, when considering the risks of such proposal, the question is if they really need to be changed indiscriminately. Add to this doubt and uncertainty context, the connotation of medical practice as atrocity, because it used to be performed by Nazi professionals at concentration camps, emerged after the Second World War. In other words, the current view that physicians and scientists always aimed their patients’ wellness changed to another view, closer to medical and scientific actuation’s complexity, which includes the possibility of harmful actuation by these professionals.

As an answer to these and other questions on the insecurity caused by the potentially harmful human ability and a nuanced view on Medicine, in the 70’s, Bioethics arises; an Applied Ethics confluence, which central aim is the application of ethical theories on specific social world scopes. This Movement of Bioethics, Business Ethics and Environmental Ethics aims to promote philosophical reflection on eminently contemporary ethical issues.

Facing the questionings’ complexity, the need to create multitasking spaces where it is possible to think over Theoretical Ethics’ application in the social world, to verify which concrete measures are indicated to each situation. Within Life Sciences, Medicine and Associated Technologies issues, this space was provided by Bioethics, which gathers complementary skills, creating solutions that are unthinkable for one or the other, if considered separately. As a consequence of this multidisciplinary nature, Bioethics approach is also eminently multiprofessional because of the active participation of Health and Law professionals, philosophers, theologians, sociologists, anthropologists – which leads to different analysis and methodology perspectives to focus and examine similar objects.

Due to its recent existence and because it embraces different fields of knowledge, Bioethics epistemological statute is still being developed. In regard to legal area, it is possible to determine little familiarity on its theoretical and regulatory content, as well as about institutions which perform, mostly, Bioethical-nature functions. Under this vision, the present study aims to collaborate in Bioethics dissemination to the legal realm, demonstrating to researchers and enforcers of Law that Legal Knowledge must open more spaces for zetetic-nature disciplines.

Therefore, this article aims to examine, specifically, the relationships between Law and Bioethics, from the study of Bioethics’ theoretical, institutional and regulatory dimensions, contributing to anchor this new field theoretically. Scanning its interconnection with Law, it aims to help defining theoretical-pragmatic Bioethics limits, and this way, to contribute for its academic consolidation.

Bioethics: history and concept

The term Bioethics was used for the first time in the early 70’s, by the North American oncologist Potter, who linked it to an extended focus on the growing field, in other words, knowledge focused on men and biosphere’s relationship ethical evaluation, demonstrating, this way, its concern with environmental issues and ethical reflection interaction. Then, Potter recommended the establishment of Bioethics based on respect for human values, rather than deep technical knowledge expertise.

According to the Potterian thought, Bioethics arises as a type of reflexive knowledge on human survival in this planet, allied to Biological Sciences and Humanist Values. Despite the fact that the term Bioethics was arisen at that time, some bioscientists argue that Bioethics is fruit of the Nazi Doctors’ Trial that happened in Nuremberg, 1947. In the judgment, it was verified that experiments in the name of scientific advance were performed by physicians on people arrested in concentration camps, regardless of their consent.

This flagrant Hippocratic Oath’s violation – doing no harm to the patient – puts in check the belief that the physician always works aiming to the patient’s interests. This history of mankind’s chapter has created the vision that scientific development must not shirk ethical evaluation and that medical practice’s beneficence is not immanent, because the conditions on its presence are socially forged. Although the word Bioethics still did not exist, the Nuremberg Judgment and its derived principles, which established ethical parameters to researches involving human beings, predict the core of Bioeth-
ics concern on scientific development ethics and its technological application, as well as about moral values and judgment on medical-patient relationship. Based on all facts exposed, Nuremberg Code and the ethical concern accompanying it are supposed to represent the prehistory of Bioethics. However, there are arguments claiming that the discipline’s prehistory has begun in the 50’s, from the Biotechnological Revolution due to DNA structure’s discovery by Crick and Watson and the subsequent ethical issues on human genetics. Other authors point out the creation of a hospital ethics committee composed by non-medical professionals in the early 70’s, in the city of Seattle, USA, as a fundamental milestone of ethics reflection insertion within health sphere’s deliberative process. The committee was responsible for selecting patients to dialysis sessions due to the lack of resources to accomplish the treatment.

In regard to Bioethics’ birth, besides all facts mentioned in this paper, Potter marks the equally important role performed by Hellegers, of Georgetown University, Washington. Hellegers, a pioneer, founded the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics, introducing the word Bioethics within academic environment. Unlike Potter, he focused on the rising knowledge about medical issues and the challenges brought by technological development, due to lack of resources or the need to link it with population issues.

Potterian Bioethics is focused in Ethical Reflection applied to ecological issues, whereas Hellegarian Bioethics is distinctly focused in Medicine and its interfaces, characterized as Biomedical Bioethics. Analyzing both perspectives, it is observed that in the course of this field’s historic construction, Bioethics has been adapted to Hellegarian vision and, consequently, being constructed during the subsequent decades as theoretical-practical knowledge applied to moral dilemmas on Biomedical field.

The apex of Bioethics, from theoretical origin, characterized as Biomedical, consists in the publication of Beauchamp and Childress’ book, in 1979, about the four principles of Biomedical Ethics: autonomy, beneficence, non-maleficence and justice. Despite of manifestly useful for the resolution of ethical issues in Biomedicine and Biotechnology spheres, these four principles were characterized by strong individual connotation. As a consequence, they seemed not well-suited neither for analysis of social environmental issues nor global issues, like medicines patent and Multicentric Biomedical Research.

Nevertheless the importance of topics approached by Bioethics, this field was kept asleep, crystallized and restrict to academic environment and specific committees until the late 90’s, when the thunderous announcement of sheep Dolly’s cloning disseminated Bioethics Reflection through the media, surpassing the academic limits and starting to be introduced in public debate. From now on, due to the need to expand Bioethics playing field and aiming to face issues related to specific problems that used to scare lower-income populations, adding the importance of adopting critical look in regard to theoretical production importation, from Northern countries, emerged criticism on this approach which started being called Principalism.

Then, emerged in many countries, new currents that aimed to construct theoretical contributions adequate in the resolution of moral dilemmas characterized by social, economic and cultural scopes, in which they were included. To name a few theoretical lines, in Brazil there is Intervention Bioethics, which proposes confrontational position with focus in poverty and social injustice issues. In Argentina, the defense on respect for human rights is prioritized; in Cuba, the focus is social solidarity under strong State’s protection; in Mexico, the focus is corrupt public policies allocation; in Colombia, to restore civil dialogue; in Chile, Protection Ethics at the service of vulnerable people.

The diversity of Bioethics’ constructions focused in Latin America’s social problems demonstrates that Bioethics is not a discipline that has theoretical base of one voice, but a set of theoretical lines characterized by social demands, which are reflected by their thinkers’ academic activity. So, there is not one type of Bioethics, but many. In fact, in 2005, from the approval of the Universal Declaration on Bioethics and Human Rights, was confirmed Bioethics’ pluralist nature and its agenda was definitely amplified beyond Biomedical and Biotechnological scopes, covering Social and Environmental scopes.

Due to this variety of approaches, the task of establishing a unique definition on Bioethics is very difficult and it also makes difficult the understanding of this skill. However, from particular essential characteristics, it is possible to delimit a basic concept. For this purpose, we used the concept proposed by Oliveira: Applied Ethics, of interdisciplinary nature, presented through speeches and practices, given that the aspect that makes it different of other Ethical Analysis is to focus in decision making.

At this point, it is necessary to emphasize there is still resistance in labeling Bioethics as Ethics.
However, even people who think this way, eventually label Bioethics within this scope, whenever mentioning it on expressions like ethical issues, ethical reflection or ethical choices. Such difficult is caused by Bioethics’ nature itself, which allows combining its interdisciplinary nature, that is to say, which covers many disciplines, such as Medicine, Biology, Law and Philosophy, with its ethical nature.

To make this point clear, it is necessary to differentiate the method, nature and goal of Bioethics, in other words, its nature and goal are essentially ethical, as it aims ethical reflection and construction of theoretical-practical knowledge on life and health related issues; however, its method is interdisciplinary. In fact, Bioethics is understood as a skill which aims to issue prescriptions, besides thinking over its own object: ethical issues raised by Medicine, Life Sciences and Associated Technologies, applied to human beings. Therefore, this field of knowledge not only appears within theoretical scope, but also as institutionalized regulatory praxis.

This article is based on these three Bioethics’ dimensions to enhance its connection with Law. For this purpose, it was adopted the research line, already published, developed by Oliveira in an academic study of doctorate which author proposes the following three-way split: Theoretical Bioethics, Institutional Bioethics and Regulatory Bioethics — such cutting enables this discipline, for being object of knowledge, to be studied in its various perception modes.

Bioethics and its dimensions: theoretical, institutional and regulatory

Theoretical dimension can be defined as the set of theories and principles derived of Applied Ethics with focus in moral dilemmas related to health and life. In this approach, are emphasized the theories and argumentations which structure Bioethics reflection. This does not mean that it is constituted within a set of unique and universal principles and theories, because Bioethical Reflections tend to take more or less adequate guidance to cultural-historic environments where they were developed or philosophical/religious orientations that support them. The existence of many Bioethical Lines and Schools with distinct theoretical and practical bases, sometimes even antagonistic, under ideological, philosophical, religious and political perspectives is due to Bioethics’ theoretical plurality.

Institutional Bioethics covers two types of institutions: those of Bioethical nature functions and those of various functions, which are manifested by Bioethical thematic. The first ones are named Bioethics Organizations. In this first group are included three types of committees: Ethical Review on researches involving human beings; Ethical Advice on clinical decisions; and those with broader functions related to Scientific and Technological Development Evaluation, Bioethical Guidelines Formulation and promoting debate on Bioethics Education.

In the second type of institution are included establishments which, despite not performing essentially Bioethics functions - no matter if these are functions of Ethical Review or Ethical Analysis - is able to deal with Bioethical Issues when examining Ethical Principles of determined actions or promoting the strengthening of Bioethical Reflection. These institutions are named Bioethics Producing Organizations.

In regard to the third perspective studied, Oliveira informs that Regulatory Bioethics can be defined as the set of Bioethical regulations. With the aim to classify a particular regulation as Bioethical Normative, two assumptions must be included: one is formal and the other, material. The author defines that a regulation is Bioethical when, besides being the fruit of differentiated and qualified production process, it also brings commands that are, in fact, Bioethical principles.

In regard to formal aspect, the requirement is about the way the regulation was created, in other words, it must be the fruit of negotiated and democratic collective production. In this classification, it does not matter if the law has been previously accepted by any State power or international organ. The characterization required here is related to debates that happened during the legislative procedure, in which differentiated standpoints could have been expressed and considered impartially.

The other requirement of regulatory construction in Bioethics is related to regulations’ material content, that is to say, all that has been incorporated to its text. Then, for a legal instrument to be inserted in Regulatory Bioethics, it must contain Bioethical Principles. This way, its content is eminently Bioethical, usually derived from Theoretical Bioethics’ prescriptive prepositions.

The adoption of Bioethics’ three-dimensional perspective does not imply to ensure that there are distinct Bioethics, but to recognize that, when analyzing its interconnection with another field of knowledge, what matters is to define the base benchmark. In fact, the theoretical link between Bioethics and Law will present specific characteristics. Likewise,
the approach based on Regulatory Bioethics, the vision on the interconnection between Bioethics and Law Regulations also has specificities that need to be faced to prevent the production of a generalized formula on Bioethics and Law’s relationship.

**Interconnection between Bioethics and Law**

In regard to regulatory bias, the interface between Bioethics and Law is explicit, since there are Bioethical Regulations that also have legal nature, such as the *Universal Declaration on the Human Genome and Human Rights*\(^{17}\), the *International Declaration on Human Genetic Data*\(^{18}\) and the *Universal Declaration on Bioethics and Human Rights*\(^{11}\). It is observed the interpenetration between Bioethics and Law fields, in other words, a same regulation can be perceived through Law and Bioethics’ vision, due to its dual nature\(^{6}\).

So, Law and Bioethics share the reflective thinking that reveals the tie between that discipline and this field of knowledge and impose that researchers of both types of knowledge cross their borders to deal with the implementation of these instruments. This happens because, if interpretation and application are based on just one discipline, it will not be able to deal with the complexity of the thematic involved within regulations. Therefore, the study and application of instruments which integrate Regulatory Bioethics presuppose the dialogue between Law and Bioethics and the incorporation of theoretical contributions derived of both.

However, although both types of knowledge share principles-implicit regulations, which leads to the construction of a new legal-ethical model based on regulations that formulate rational source for argumentation towards particular direction\(^{19}\), it is important to mention that Regulatory Bioethics must not be confused with Biolaw. Biolaw is a legal microsystem which regulates human behavior considering the advances of Biomedicine and Biotechnology\(^{2}\), covering all legal regulations which have inter-face with Bioethics issues, regardless material and formal assumptions, listed in the previous topic. It is observed, clearly, that Biolaw’s concept is broader than Regulatory Bioethics’ concept\(^{6}\).

In this line, it is observed that Regulatory Bioethics currently adapts on principles that, according to Alexy\(^{20}\), are optimization commands, regulations which order something to be done as effectively as possible, considering the factual and legal arrangements where are included.

Such principles are inserted in declarations and documents of obligatory nature, like the *Oviedo Convention*\(^{21}\), opened to Member States of the Council of Europe, and others of non-binding nature: the *Universal Declaration on the Human Genome and Human Rights*\(^{17}\); the *International Declaration on Human Genetic Data*\(^{18}\) and the *Universal Declaration on Bioethics and Human Rights*\(^{11}\).

This way, it is concluded that Bioethics production brought the regulatory definition on Ethical Issues related to Medicine, Life Sciences and Associated Technologies applied to human beings to legal sphere, innovating by extending the legal scope to the social world. Principles not seen before within the International Law of Human Rights were inserted in this sphere in innovative way: the principle of consent; the principle of respecting human vulnerability and personal integrity; the principle of non-stigmatization and the principle of beneficial and harmful effects, all contemplated at the *Universal Declaration on Bioethics and Human Rights*\(^{11}\).

So, Regulatory Bioethics offers a range of new principles to students and enforcers of Law, which will help legal practice, through access to such principles, enabling the definition of specific issues. To mention an example, the European Court of Human Rights took hold of the principle of consent, in Article 6 of the *Universal Declaration on Bioethics and Human Rights*\(^{11}\), for the appraisal of the case Evans versus United Kingdom in regard to the use of human embryos for assisted reproduction\(^{22}\). Therefore, Bioethical Principles embodied in legal documents are skillful tools to construct new legal theses, especially those which aim Life Sciences and Medicine.

To understand the interface between Theoretical Bioethics and Law, it is important to resume the notion of the first one, that is to say, Theoretical Bioethics, concisely consists of the gathering of many theoretical lines that develop differentiated theories and methods. Within Theoretical Bioethics, there is a range of schools revealing that *Bioethics has never been unique or unitary, but, on the contrary, since its genesis, has always been plural and diversified*\(^{23}\). Considering the theoretical pluralism within its genesis, we ask “how could Bioethics, as a field of knowledge, interconnect with Law and contribute for its theoretical-practical improvement?”

Initially, it is important to emphasize that Theoretical Bioethics and Law share principles, although there is no consensus between many currents, one could affirm there is triumph of principles-implicit Bioethics\(^{5}\). Therefore, Theoretical Bioethics is based, mainly, on a theoretical model from moral principles...
to rules and the final result is a concrete resolution for the case examined.

In line with Bioethics, with the advent of Post-positivism in the last century, the classical separation of Law and Ethical aspects involved within the topics, Theoretical Bioethics arises as fundamental theoretical contribution to legal standards’ interpretation, providing the interpreter Ethics basis, sometimes not found in Law.

In fact, Theoretical Bioethics provides the interpreter and enforcer of Law, moral essence theoretical basis, to improve their interpretative task, as it considers Ethical Principles of standards. It is also provided to the bundle of enforcers of Law, the possibility to approach the analysis on standards’ validation criteria, because the correspondence between its material content and values or system of morality integrates the search of validation or non-validation of the legal standard.

Furthermore, considering that the current constitutional horizon in which principles have regulatory strength and maximum stature in legal system, Theoretical Bioethics, due to its principles-implicit profile and plasticity, allows the approximation of Law with moralities that cross topics as Life Sciences, Health and Associated Technologies. Therefore, the study of Bioethics by the academic student and enforcer of Law is essential for the comprehension of particular topics, as well as legal standards’ interpretation. This is due to the fact that Theoretical Bioethics, considering its constructs, principles and knowledge framework, allows that the analysis of such topics is not excluded of its ethical and technical conformation, opening Law to other disciplines and, especially, assuming the axiological nature of its standards.

In turn, Institutional Bioethics covers the space where effectively is Bioethical Practice. In this Institutional Bioethical Space, as pointed out in this work, there are three types of committees: Ethical Review on researches involving human beings; Ethical Advice in clinical decisions; and those with broader functions related to the evaluation of Scientific and Technological development, formulation of Bioethical Regulations and promotion of debates on Bioethics education. Acting as confluence locus between Law and Institutional Bioethics, Bioethics Organizations are standards producers, laying prescriptions to society and aiming the harmonization of social coexistence.

Human Research Ethics Committees analyze research protocols and through specific regulations deliver opinion approving or not the conduct of the submitted research. This means that as Legal Power, they emit concrete nature permissive or prohibitive guidelines, which have deep impact on scientists’ actuation. Ethics Advisory Committees on clinical or hospital ethics decisions, in general terms, are expressed in Bioethics conflicts that arise within health professional practice, aiming to solve them – task similar to legal instances that aim conflicts resolution, especially those which use techniques of mediation.

Although hospital committees also emit prescriptions, one cannot attribute them a judging role, because they only pursue the assessment of the case and prescribe non-disciplinary nature conducts. In regard to National Bioethics Committees, the ones related to scientific and technological development’s evaluation, they design Bioethics guidelines, in other words, they also express extensive nature prescriptions because they are directed to the whole society and aim to define behaviors, this way, approaching legislative framework.

In regard to Institutional Bioethics’ contribution into legal sphere, Clinical Decisions Ethics Advisory Committee operates aiming social pacification through moral conflicts’ resolution. In the same way, Human Research Ethics Committee demonstrates practices to prevent legal conflicts, as it ethically regulates the relationship between researcher and subject. Whereas Institutional Bioethics exercises a dual function – besides being an open space to dialogue, it operates mediating moral conflicts –, it also represents another mean of legal conflicts resolution and relief to Judiciary Power. In this case, the contribution of Institutional Bioethics to Law is in the fact that Bioethics Organizations operate as alternative means of conflicts resolution, among
which is Bioethical Mediation; such fact is very important for the culture of dialogue’s establishment process and the mitigation of Bioethical Nature contentions’ judicialization.

Concluding remarks

In this study, it was aimed to verify the connection between Bioethics and Law, in the light of Bioethics’ three dimensions: regulatory, theoretical and institutional. It also aimed, especially, to examine how this inter/multidisciplinary opened to diversity field of knowledge can operate to improve Law by helping its enforcers and Judiciary Power solving complex unprecedented issues, with regard to conflicts in Life Sciences, Health and Associated Technologies fields.

This way, in Normative Bioethics sphere, it was verified that Bioethical Regulations, embodied in international declarations and conventions, add new principles to Legal Field, expanding the list of principles-implicit standards, which makes Law more eligible to deal with topics that did not use to exist until recently in the history of humanity, like research using embryonic stem cells and genetic biobank. Regulatory Bioethics is, in fact, a Law’s update and, simultaneously, an extension of its action spectrum; covering by legal standards, topics that used to be in the free zones of Law and consequently, used to cause legal uncertainties and fragility in vulnerable populations.

Within theoretical scope, Bioethics, through its argumentative constructions, of principles and technical speech from Medicine and Life Sciences, allows the enforcer of Law to deepen its investigation on Ethical complexity and perspective and addresses the moral nature of such standards when these ones are about constitutional principles linked with such topics. The acknowledgement inserted in Post-positivism, on the moral nature of some standards, imposes its study under this perspective, which inexorably leads to Bioethics Field, with its own knowledge and theories.

Also, it was observed that the operation of Human Research Ethics Committees and Ethics Advisory Committee on Clinical Decisions demonstrates genuine instances which prevent legal demands and foster the culture of dialogue. Ethics Review Committees operate preventing conflicts and Ethics Advisory Committees operate when conflicts are already established, through different methods of solution. Therefore, Institutional Bioethics’ instances help Judiciary Power to keep social peace, as well as help to ease its overload in meeting population’s demands.

It was found that Bioethics and Law have evident interconnections and Bioethics, in its three dimensions, can help to strengthen Law, notably, in the comprehension of legal standards while axiological prescription. It was also verified that from the acknowledgement on Bioethics topics’ complexity, arises the enforcer of Law’s need to use other types of knowledge in the resolution of conflicts in regard to Life Sciences, Medicine and Associated Technologies.

Finally, the definition of Bioethics’ penetration modes within legal field contributes not only for the legal field, but also for the epistemological construction of Bioethics. Bioethics, for being a skill which borders are still being limited and theoretical contributions still being developed, demands analytical studies – as proposed by this article – which aim to scan its theoretical, regulatory and institutional dimensions, as well as its dialogue modes in regard to other fields of knowledge. So, this article, although presenting the analysis of Bioethics penetration within Legal Sphere as main focus, concomitantly examining such interface, strengthens reflection on Bioethics perspectives and its ways of application, allowing to think of Bioethics as a discipline open to others, as it enlarges the communication channels with other regulatory means of social control.

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Natália Carreiro collaborated with research, data collection, text elaboration and grammatical review. Aline Oliveira collaborated with orientation, suggestion of topics, adjustments in text and grammatical review.