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Experience of a Research Ethics Committee, in Degree Thesis of Medical Specialists

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Abstract

Introduction: *Resident physicians neglect research in their training; the observations of Research Ethics Committees (CEI) and Research (CI) to their research projects are received with annoyance and anger by researchers and advisors; this project will allow the design of an educational strategy;*

Objectives: *1) Conduct a situational diagnosis: projects reviewed. Period 2014 – 2019.*
2) Explore organizational culture at the host hospital.

Materials and Methods: *Observational, analytical, retrospective, mixed type: total of projects evaluated 2014-2019 with variables: scientific validity, social relevance, risk-benefit and use of public resources. Qualitative study: one focus group; categories of analysis: organizational culture, public policies, gender perspective, gender violence and institutional violence.*

Results: *42% of the projects had insufficient arguments for the research problem, for example: evaluation of treatments and diagnostic methods already known and validated; 26% recommendations for plagiarism; 19.30% were questioned for excessive and unjustified use of hospital resources; 9.6% for lack of benefits. The focus group provided information: organizational culture, gender and institutional violence prevalent in the hospital context that hinder scientific and humanistic research and the development of resident doctors and the functioning of RECs and ICs.*

Conclusions: *There is a lack of knowledge of ethical and methodological criteria among students, tutors and reviewers, which is enhanced by the hospital culture, institutional and gender violence, where the paradigm of hegemonic knowledge of specialist doctors prevails. This study seeks to raise awareness of the difficulties of organizational culture that affect the quality of research projects.*

Keywords: Research Ethics Committees, Scientific Integrity Review, Organizational Culture.

Introduction

At the time of the study, a second-level general hospital, which trains human resources, endorsed by the National Autonomous University of Mexico (UNAM) and the Michoacana University of San Nicolás de Hidalgo (UMSNH), had 99 resident physicians and 19 medical interns in social service; the official regu-

lations for the organization and operation of medical residencies indicate that at least one research project must be carried out during their residency [1, 2]. Likewise, the Secretariat of Public Education (SEP) issues an annual call for medical interns in social service to be assigned to hospitals, carrying out a research project with direct mentoring from their professors who become advisors and reviewers [3].

It has been observed that resident physicians and medical interns in social service do not give due importance to the realization of their research project, until the end of their training, seeing it merely as a degree process [4]. There is often a lack of knowledge of the ethical criteria of research, they consider that only the bioethical principles in the informed consent should be evaluated, which leads to a rejection of the recommendations of the registered CEI, who monitors adherence to the guidelines of the National Bioethics Commission (CONBIOETICA); [5]. leading to leaving the research work unfinished, which has caused that there is currently a significant number of specialist physicians working without a professional license and medical interns in social service obtain their degree by other means.

One of the priorities of the National Health System in Mexico is the training and development of human capital with knowledge, skills, attitudes and values in the exercise of medical ethics to perform successfully in work settings, where they are able to demonstrate in practice the integration of care-teaching-research [6].

Nowadays, technological changes have modified social and cultural attitudes and behaviors in the health professionals' guild, promoting individualism in their scientific and academic development. Science brings new problems and new circumstances for old problems, however, research cannot be above ethical and bioethical principles; scientific decisions must be morally responsible. For Benítez Hernández I: "The ethical code of science supposes, fundamentally, love for intellectual freedom, sense of justice, constant defense of the truth, criticism of error, denunciation of farce, as well as assuming criticism and self-criticism as a powerful argument for moral self-regulation." Scientific work is strengthened if the person carrying it out has a clear conception of the social and cultural dimension, which is also in line with the development of the country [7]. Currently, it includes gender bias, recognized in recent times by European international health organizations [8]. It is the origin of multiple recommendations, but is not assumed by researchers, members of research ethics committees and private entities that finance Research [9, 10].

The ancestral approach that the teacher must be an example of desirable behavior, in the classroom and outside of it, not only remains valid, but has been enriched with new contributions that the educational sciences have developed in recent decades [11]. From this perspective, public universities must emphasize the development of moral conscience; the exercise of autonomy and freedom with responsibility; as well as awareness of otherness (of others). It is necessary to reinforce ethical and bioethical reflection with a gender perspective, to find real forms of coexistence among doctors, as well as in their professional practice, considering the right to difference and to an agreed tolerance between rational beings, as an unavoidable commitment to do things well, which we cannot fail to fulfill [12].

This is why in recent years there has been great concern about introducing ethics in research and bioethics into the curriculum of health professional schools, in view of the need to prevent the inertia of our society, where values are relegated by a more aggressive and individualistic society [13]. Currently, there are opportunities to establish an adequate relationship between these, in the various health-disease processes of the population and its social determinants in health, to help the medical student provide comprehensive care to the individual, family and community, in accordance with the commitment that our country has to strengthen Primary Health Care [14].

The Mc Master School, in Hamilton, Ontario, Canada [15]. It also points out that in order to train the health professionals that society needs, it must prepare its students with the essential knowledge and characteristics of the profession, as well as knowing and understanding the sociocultural environment in which they will operate. In addition, the student must be provided with the ability to reflect with theoretical and practical principles, and issues various recommendations on how to implement and evaluate the Gender Perspective (GP) throughout the entire teaching and research process. The Horizon 2020 program, which funds research and innovation projects in various thematic areas in Europe during the period 2014-2020, includes the GP specifically regulated in the projects it supports [16].

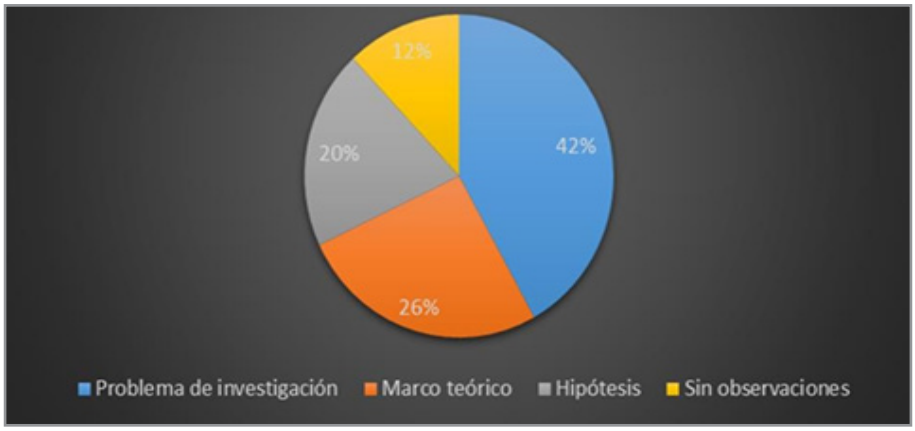
Gender bias or perspective is defined as the differences in treatment in medical care and scientific research provided to men and women; the impact of which can be positive, negative or neutral for the public health of individuals, as well as the community. Gender bias in research is considered to be the lack of gender sensitivity and the consolidation of androcentrism, understood as the primacy of men and their point of view on the world, culture and history, in the design of the study, in the analysis of the results or in the review and analysis of research projects, which can lead to systematic errors [17].

Methods

Observational, analytical, retrospective, quantitative research project, through the total opinions issued by the CEI-CEI of the period 2014-2019; a total of 284 projects, of which 87 were rejected, representing 30.6%, and 197 were accepted, representing 69.4%. The observations issued in the opinions were analyzed with the following categories of Analysis: scientific validity (methodological congruence), social relevance (scientific contribution), participant selection criteria (justice), risk/benefit proportionality (non-maleficence), independent evaluation (conflict of interest) and informed consent; The results were analyzed with the SPSS 25 program. Qualitative: focus group with 12 members of the CE.CI, with a semi-structured interview exploring the organizational culture and violence they suffer in their work in the committees, with prior informed consent, maintaining the principle of confidentiality. The analysis was carried out with the Atlas ti program triangulating information with the literature, approved by the CEI, CONBIOÉTICA-16-CEI-004-20161212 [18-24].

Results

Regarding scientific validity: Insufficient argumentation of the research problem was found in 42% of the reports. Sometimes they only present a research question directed to what they want to do, without providing new knowledge that has not been proven or is controversial. Frequently they try to evaluate some treatments and diagnostic means already known and validated. 26% of the projects had recommendations for situations of plagiarism, writing, the theoretical framework is copy and paste of articles, computer screenshots, some were rejected because they were total plagiarism of complete articles. Regarding the working hypothesis, 20% of the projects received recommendations for the frequent use of the statistical hypothesis and not the methodological one, in addition to not agreeing with the research problem; as can be seen in graph 1&2.



Graph 1: Observations Regarding Scientific Validity
Source: Database

Graph 2
Source: Database

Social value: 9.6% of the projects received recommendations for lack of benefits; 19.30% were questioned for excessive and unjustified use of hospital resources. It should be noted that there was a lot of pressure from the teaching and research authorities to act in a flexible manner, arguing that they were doctors in training who needed to graduate, and that it was very important to have a timely graduation rate, so only those that were copies of articles already published, entailed risk for patients; as well as those that meant abuse of hospital resources were rejected.

In terms of risk-benefit, it was observed that 25.8% of the projects had no ethical classification by the researchers, they only copied and pasted the Nuremberg and Helsinki declarations; and 22.30% of them were subject to observations regarding the risk that this meant for the research subjects (Chart 2); it should be noted that in only 7 projects, less than 1%, a conflict of interest was manifested between researchers and members of the Committee; when in reality, conflict of interest is frequently observed between researchers, advisors and members of the committee for the authorization of research projects.

Regarding the second objective of exploring the organizational culture and the violence suffered by the members of the committees, with the following trigger questions.

1. What do you understand by gender perspective?
2. Do you think that the gender perspective is analyzed within the Committees?
3. In what way has the organizational culture and the gender perspective favored or hindered the actions of the CEI, CI, ¿researchers and professors?
4. Do you perceive deference in the acceptance or not of the opinions when these have been made by female members or notified by women of the Committee to residents? The focus group session was carried out, it was transcribed in the ATLAS TI 8 program, where bibliographic articles on the subject were included, running the program, results: analysis tree with 5 categories:

- 1) Organizational culture. 2) Gender perspective. 3) Public policies. 4) Gender violence. 5) Institutional violence.

Subsequently, the frequency of citations by analysis category was analyzed, observing that, in the discourse of professionals, the gender perspective is most frequent with 212 citations; organizational culture with 108; gender violence with 98; institutional violence with 77 and public policies only 27 citations. The co-occurrence of categories was analyzed, observing that the organizational culture related to gender violence and institutional violence is mainly recognized, leaving the gender perspective and public policies very low, as shown in Table 1.

Table 1: Co-Occurence Of Analysis Categories

	Cultura organizacional Gr=28	Perspectiva de género Gr=60	Políticas públicas Gr=7	Violencia de género Gr=30	Violencia institucional Gr=21
Cultura Organizacional Gr=28	0	5	0	12	12
Perspectiva de género Gr=60	5	0	3	3	0
Políticas públicas Gr=7	0	3	0	0	0
Violencia de género Gr=30	12	3	0	0	17
Violencia institucional Gr=21	12	0	0	17	0

Source: Database

By making a causal diagram, it can be observed that the organizational culture is seriously affecting the work of the Committees, by trying to incorporate the gender perspective, only as a public policy discourse in a superficial way, covering gender quotas, which generates gender violence and institutional violence that are reflected in the perception of the members of the Committees; also recognizing that there are conflicts of interest of various groups of professionals as represented in figure 1:

Figure 1: Cause And Association Diagram

The participants identified the following as main problems: organizational culture, gender violence and institutional violence; their comments can be seen graphically in figures 2 and 3:

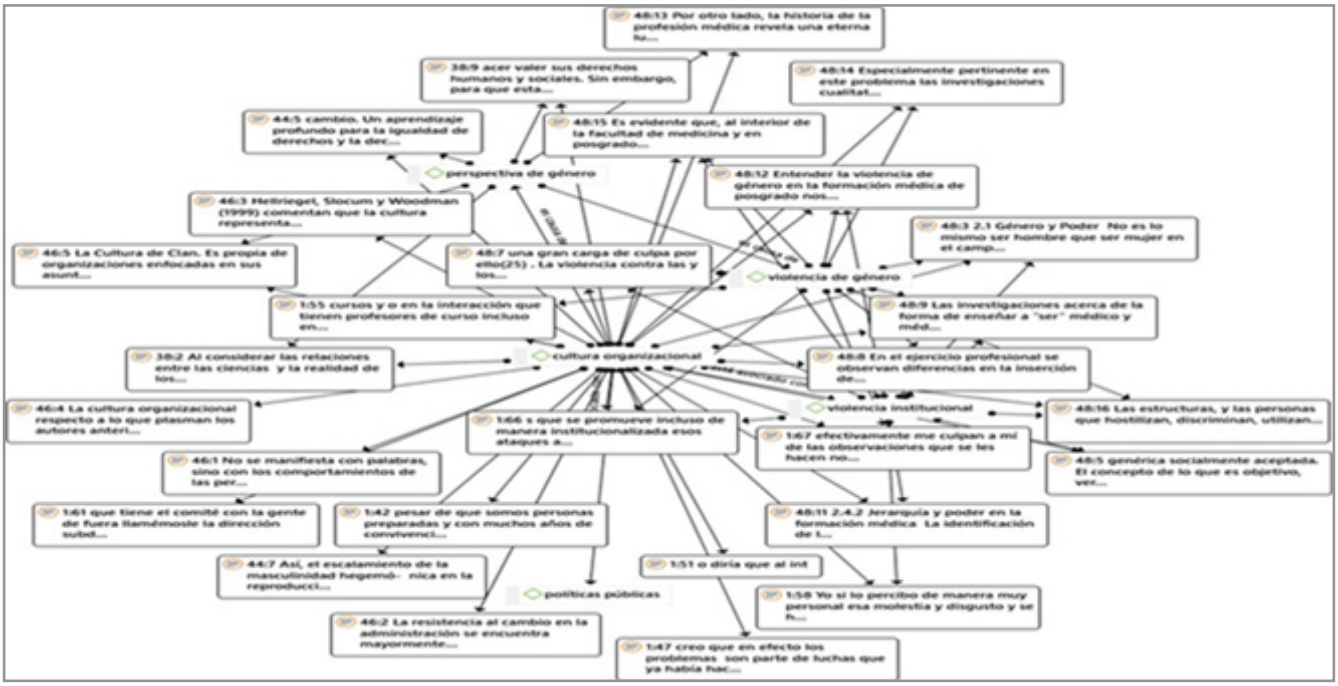


Figure 2: Quotes In Relation To Organizational Culture

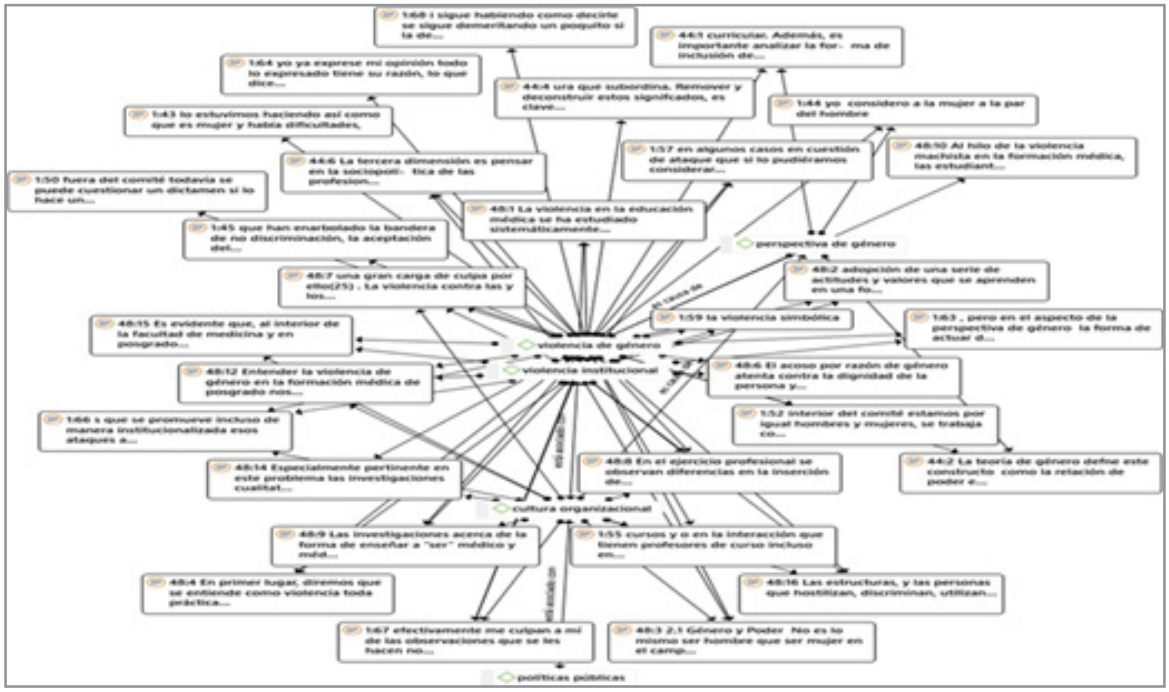


Figure 3: Quotes On Gender Violence

Discussion and Conclusions

There is a lack of knowledge of ethical and methodological criteria in students, tutors and reviewers, which generates: lack of scientific integrity when copying and pasting complete texts, repetitive projects that do not provide new knowledge, poorly stated objectives and where the research participant is also taken as an object of study, the process of obtaining informed consent is frequently inadequate; a problem according to the literature reviewed; generated mainly by a confusion of what is ethics in research and clinical bioethics, which biases the perception of

the observations that their research projects receive from the CEI-CI.

The committee members recognize the institutional and gender violence that prevails in the host hospital, mainly due to the paradigm of hegemonic knowledge of specialist physicians, who, as experts in science, demand absolute recognition of their knowledge and, when they feel challenged with the observations on their projects, violate the members of the CEI-CI, mainly women.

This study seeks to raise awareness of the difficulties that resident physicians face in the organizational culture in hospitals, which is replicated in the following generations of specialist physicians and which impacts the quality of the acquisition of teaching and research skills in health professionals required by Evidence-Based Medicine.

It is necessary to continue with this line of research to seek educational strategies that impact organizational culture, institutional and gender violence that contribute to improving the quality of scientific research.

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