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Ethical Considerations in Research and Medical Care of Menopause

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Abstract

Menopause is the permanent cessation of menstruation, and among the main symptoms reported have been night sweats, heat waves, increased body fat at the central level, dyslipidemia, hypertension, osteoporosis, insulin resistance, diabetes, mild cognitive impairment, depression, periodontitis, varicose veins, apnea, urinary genital discomfort, as well as dryness in the mouth and eye. The diagnosis, study, and care of menopausal or postmenopausal women have had great advances, such as recognizing the sub-inclusion of women and female animal models in basic and clinical studies and proposing in the same design of the study the analysis by sex. Subsequently, the need for specialized ethical training was identified, beginning in undergraduate, postgraduate, and clinical practice. To achieve this, several actions were carried out, such as the foundation of Women's Health Institutes, the implementation of the Institutional and Private Committees of Ethic, and the development of validated instruments to evaluate signs and symptoms. Currently, there is no consensus that meets the ethical requirements for care and research in these patients. Efforts have been made practically by pathology, without considering together the social and psychobiological condition. What is intended in this document is to present the ethical aspects related to the study and medical care of women in menopause.

Keywords: ethics, menopause, postmenopausal, woman, and clinical research

1. Introduction

The study of menopause and the medical care of women at this stage require a multidisciplinary approach, given that the signs and symptoms observed are multiple. Therefore, obtaining reliable data depends on the researcher's training, the experience and specialty of the medical treatment, the instruments used to obtain the information, and the degree of safety and security that the patient has both in the researcher and in the doctor.

The objective of clinical research is to obtain knowledge to incorporate it systematically in health policies. Specifically, research on women's health began in 1990, when the Office of Research on Women's Health (ORWH) promoted policies and funded research considering the influence of sex and gender on health. After, in 1991, the Women's Health Initiative (WHI) announced, under which menopause was studied to understand the treatment of cardiovascular diseases, cancer, and osteoporosis. In addition to promoting research in women's health methodologically, technically, and more recently, ethical aspects have been analyzed, in order to protect the patient's safety, in the social, psychological, and biological spheres. With respect to medical care, the influence of the sex of treating doctor or nurse has been studied, but no differences were observed; on the contrary, there was only predisposition to give preferential treatment to a family member, when in a hypothetical situation, the life was in high risk. Despite the fact that each gender is characterized by a type of ethical reasoning, is based on caring/protection for women and justice for men. Finally, for the study and medical attention of women, various surveys have been developed, with the aim to evaluate a specific sign or symptom. This fact highlights the importance of studying and attending multidisciplinary to women, given the complexity and diversity of the signs and symptoms.

The application of ethical norms for the investigation and medical attention of women requires that doctors and nurses from their professional formation have to approach to this concept. So also, the political authorities and administrators of economic funds must know the transcendence of ethics in their fields of action.

2. Social, psychological and biological characteristics of women in menopause

2.1. Hormonal profile, signs and symptoms

Menopause is the permanent cessation of menorrhagia, due to ovarian dysfunction, which marks the end of the reproductive stage in a woman's life and is characterized by low levels of estradiol and high concentrations of follicle-stimulating hormone and luteinizing hormone, although other complex changes have also been reported in systems such as immunological and nervous among others [1]. Hormonal changes begin about 3 years before menopause and continue for a similar period after menopause; in addition, there are metabolic disorders that induce characteristic signs and symptoms such as vasomotor and psychological, whose duration ranges from 3 months to 5 years after menopause [2]. Central obesity, dyslipidemia, sleep disorders, and high blood pressure, among others, are also identified [3–5].

Several symptoms have already been described widely; so here, only some will be described that require special mention given the complexity to diagnose or study them, or those of the major importance, or they have recent advances.

Sexual dysfunction: In general, menopause is usually perceived as a stage of decline, because signs and symptoms are accentuated with aging. One of the symptoms that usually cause embarrassment in female patient is the sexual dysfunction, which has a final result, the reduction of sexual desire [6]. The events that lead to this can be pathophysiological such as vulvar and vaginal atrophy and lubrication reduction or psychological, due to women who present low self-esteem. Sexual function in this stage is influenced by several factors, such as previous sexual activity, co-morbidities, cultural environment, mental illness, and ethnic origin; for example, the prevalence of sexual desire reduction has been described in 47, 54, 42, and 24% in English, Italian, French, and German menopausal women, respectively. It has also been pointed out that black and Latina women had greater sexual desire than white and Asian women at this stage. Although even women from the same country, but of different ethnic groups, tend to have a different prevalence of sexual dysfunction, as shown in a study carried out in ethnic groups from Iran, that study showed that the prevalence of sexual dysfunction was 75.3 in Arabs, 86.1 in Lurs, and 83.2% in Persians [7]. Undoubtedly, the evaluation of the sexual function requires an ethical management by the treating medical personnel, since it must auscultate and interrogate the patient, without the woman feeling uncomfortable.

Osteoporosis: It is another important health problem in women postmenopausal, which usually occurs in the late phase but goes unnoticed because it is not painful or by patient's ignorance. This pathology results from the decrease in estrogen production, reduced calcium resorption, increased urinary excretion, reduced vitamin D synthesis, as well as less formation of its active metabolites, decrease in the number of vitamin D receptors. The analysis of the quality of life of women with osteopenia or osteoporosis is important, as it can guide pharmacological and non-pharmacological strategies [8].

Obstructive sleep apnea: It is neither a symptom usually asked by doctors nor does the patient report having more episodes in this stage. However, clinical research found a higher prevalence after menopause, and even more, it has been proposed that it predisposes to enuresis, coronary risk, and cardiovascular disease. Enuresis, occurs during the apnea as a result of a negative pressure against the glottis, which causes cardiac distension and greater release of the atrial natriuretic peptide, which finally results in an increased urinary volume and, consequently, enuresis [9]. Then, the knowledge factors to obstructive sleep apnea can also control the enuresis, improve the quality of sleep, and reduce cardiac risk, the mood, and, in general, the well-being. Common risk factors for obstructive sleep apnea and enuresis have been reported, such as obesity, snoring, restless sleep, sleep fragmentation, daytime somnolence, and hypertension; this has not been found in postmenopausal women (**Figure 1**) [10].

2.2. Influential factors in the symptomatology

As already mentioned, there are several condition factors of the presence and intensity of a certain symptom of menopause and therefore the type of treatment that they will receive to control

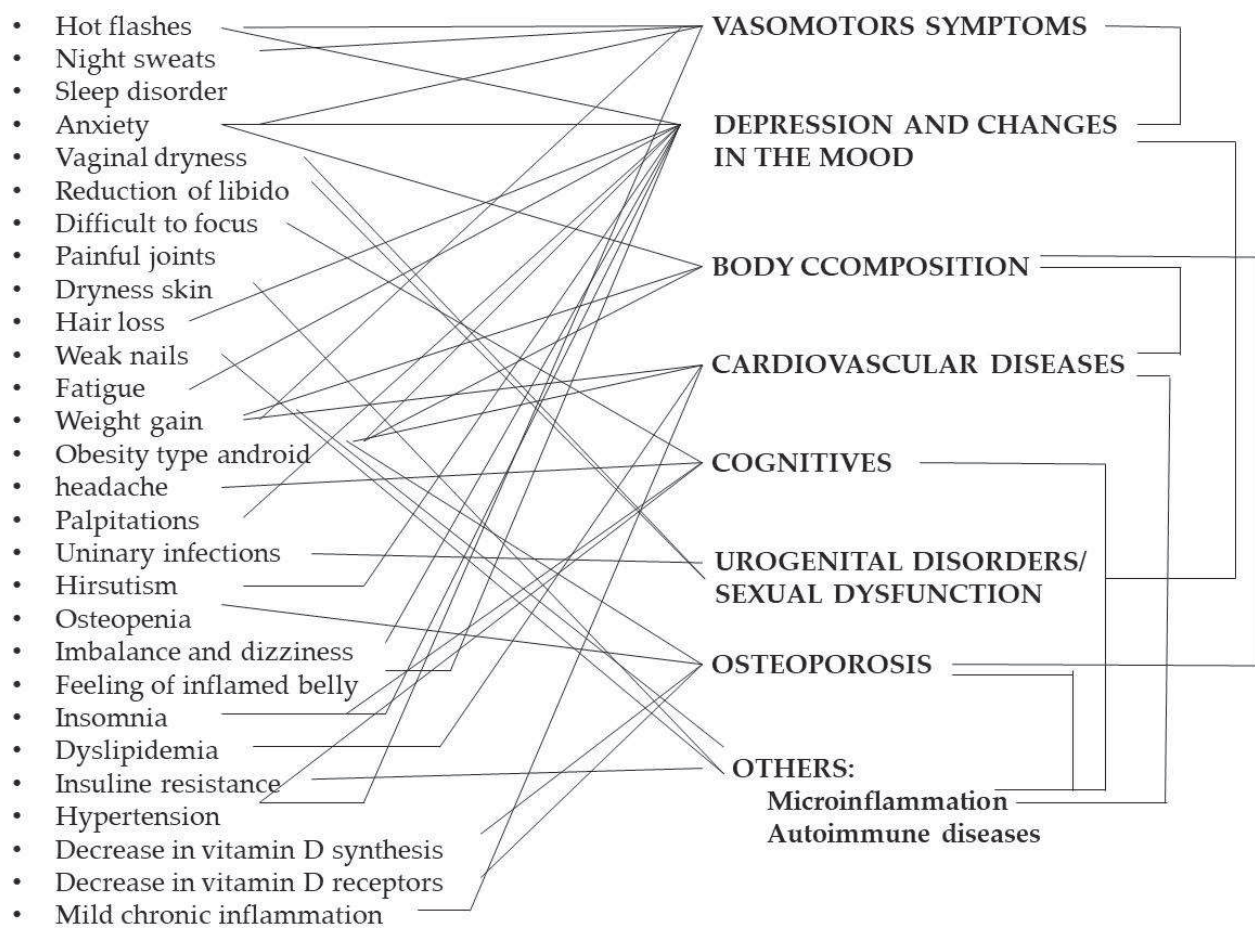


Figure 1. Interrelationship between signs and symptoms with diseases observed during menopause and its stages.

them. Several studies indicate that among these factors are the psychological, cultural, and family factors, additionally to events that usually occur around the age of menopause [11].

Personality is part of the human being and is defined as the series of features or characteristics that induce the behavior of a person, in turn, allowing us to intuit the way of acting in a given situation. The personality is defined by traits such as neurosis, extroversion, openness to new experiences, kindness, and scrupulousness. The identification of this traits could guide the pharmacological and non-pharmacological strategies to reduce the anxiety and to improve the self-esteem and, with that, the self-care of the patient [12]. Of the different personality traits, the one that has been most related to the presence of vasomotor symptoms is the neurosis, since it predisposes anxiety, stress, hostility, impulsivity, low self-esteem, and depression, which in turn conditions feelings such as sadness, anger, and guilt. Although results of clinical studies in postmenopausal women are contradictory, for example, it has been reported that neurosis and anxiety are associated with physical symptoms; in contrast, in others, no correlation has been found with the number of hot flushes [13].

Another aspect that is not usually considered in the consultation is the possibility that the woman suffers some type of mistreatment (sexual, economical, or physical) which has been proven to diminish physical capacity functioning (**Figure 2**) [14].

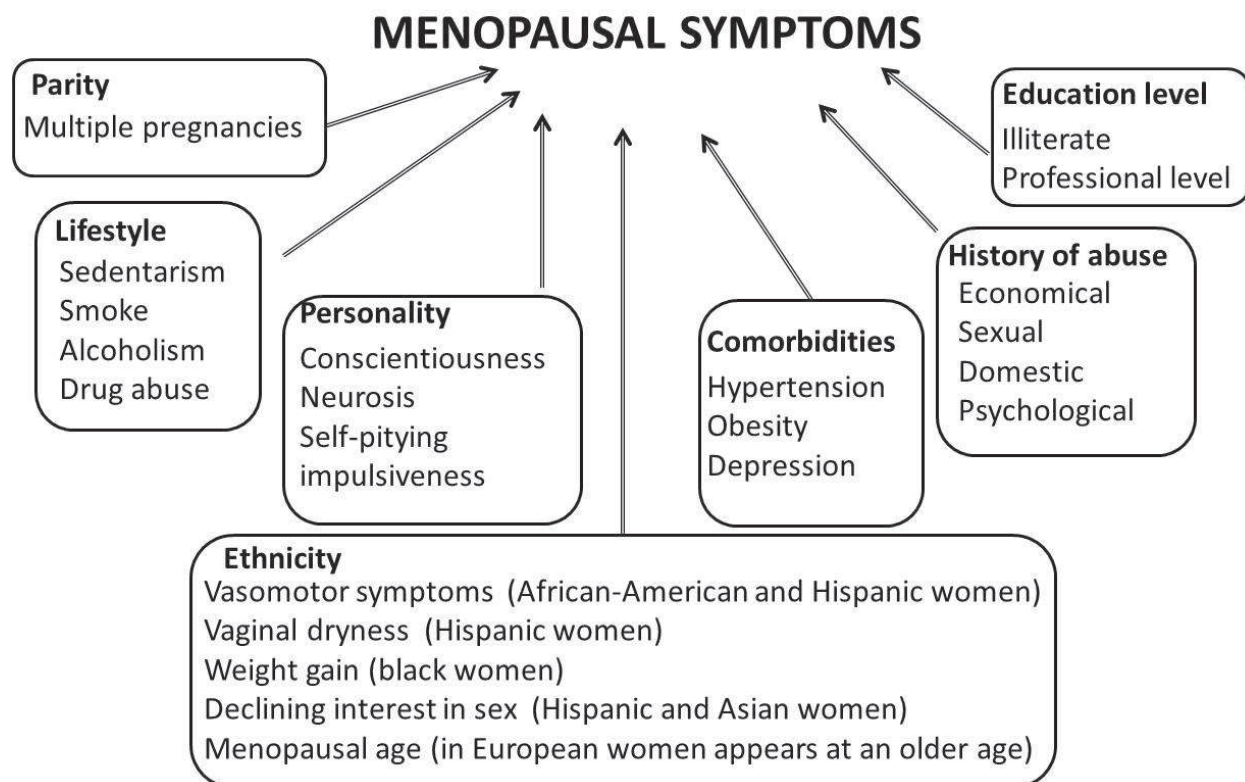


Figure 2. Factors and events that influence the presentation of symptoms during menopause.

2.3. Advantages of menopause

Many clinical research and medical care to postmenopausal patients has been focuses to treat diseases, uncomfortable symptoms, or family problems; without consider the advantages that menopause has; in example, there is no possibility of becoming pregnant, so, the women can enjoy their sexuality. Also, women can do activities that satisfy them [7].

The menopause is an opportunity to empower women. To achieve the above, it is necessary that the woman is better informed of physical and psychological changes she will undergo, of family and medical needs, as well as of the strategies she can carry out for her self-care [15]. Because approximately half of the world's population is woman, and the life expectancy is greater than that of man, it can be intuited that women spend two thirds of their lives in postmenopausal, so their functional status must be preserved, since it will impact on the family, society, and itself. It is important to recognize those factors that hinder empowerment, for example, co-morbidities present before menopause, marital status, family network, and health centers that can be accessed.

Currently, campaigns have been implemented to prevent and treat osteoporosis: follow a healthy diet and promote moderate physical activity, stress management, interpersonal relationships, and group education, which will improve the quality of life. If menopause is accepted with the inherent changes, it will bring the woman to face this stage better; in contrast,

it has been reported that women who do not accept this stage have more severe symptoms. In targeted studies, women in menopause have expressed that they need to be informed of this stage through different means [16].

3. Bioethics in the clinical care of women in menopause/postmenopause

3.1. Advances in bioethics

Defining “ethics” or “ethical thinking” is complex and has basically focused on two approaches; one is based on care and prior experience, and the other is on justice, as outlined by Gilligan and Kohlberg, respectively. The first one is manifested by women, while the second one, by men which, of course, should not be generalized, but its foundation is derived from biological traits and the activity of each sex. For example, Gilligan proposes that women understand ethics, based on their role in the family and society, that is, in caring for and supporting family members equally and providing them with care, while men focus on ethics, according to the rights and obligations of people; this means that people should receive the just [17]. Both theories raise divergences and difficulties to define ethics and all the components that integrate it, even if there are different types of ethics (professional, economic, and government, among others).

Conduct clinical studies in doctors and nurses with a gender perspective, who provide medical attention is very important, given that they can influence the ethical treatment received by menopausal patients, who are in the stage of emotional and physiological susceptibility [18].

A study with doctors and nurses of both sexes was carried, to evaluate their impartial reasoning; starting from the assumption that women doctors and nurses have a partial thought (care orientation) and impartial men (focused on justice). The dilemmas presented situations of different severities and urgencies, whether the life of a relative was in danger or not. It was found that the response was partial, if the life of a relative was in danger, both in health professionals and in those who were not, while if it was a less serious situation that did not compromise life, the response was impartial, in both cases. In summary, what conditioned the response was the seriousness of the situation.

This ethical requirement for doctors has been diffused in several centuries and is raised in the “Hippocratic Oath,” which connects the responsibility of the doctor, with the result of his intervention. Subsequently, the principles of “first do no harm” and “beneficence and no maleficence” were included. Since then, several researchers have contributed to define “ethics and bioethics” as well as their scope. In 1979, Beauchamp and Childress concretized concepts and focused on “biomedical ethics.” On the other hand, in the Belmont report, “principlism” was defined, which focuses on respecting people with justice. In 1847, the American Medical Association began to define the doctors’ behavior [19].

In 1980, the teaching of bioethics was implemented in the undergraduate program and later in the specialties. Thus, the first thing that was emphasized was the basic concept of bioethics. Surgery residents surveyed indicated that they felt more confident to face ethical problems,

after a training program. A study in pediatric residents indicated that they needed ethical training, especially to make the decision to give or take life support [20].

Several studies indicate that (1) medical women trained in ethics perceive more benefits than men and (2) student women focused more on psychosocial aspects and men were based on the rights of the patients. This shows that women are more based on abstract and personal principles, while men focused on responsibility, authority, and control. It is necessary to make a systematic analysis by the specialty and educational level, considering areas of special interest such as the role of bioethics and the conceptualization of justice, obtaining the informed consent of the patient or from a legal representative, facing the rejection of the signature of the said document, as well as obtaining it from people who speak different languages and care for special people or with a certain degree of vulnerability. Recognizing the training needs of the different specialties and taking into account the evolution of bioethics, better-oriented ethics programs can be designed.

A survey at the School of Medicine of the University of New Mexico to better understand these problems was conducted. The hypotheses were that (1) medical students and residents would support the need for more curricular attention to the principles of bioethics, the issues of informed consent, and the special needs of the population; (2) women would more strongly support these curricular needs; (3) residents of psychiatry would more strongly support curricular needs than other residents; and (4) there would be a greater perceived need in these curricular domains of ethics among apprentices who were in more advanced stages of training (**Table 1**) [21].

3.2. Diseases and ethical considerations

Among the diseases that affect menopausal women, there are some that are deserved to be explained with ethical focus, for example, osteoporosis, periodontal disease, and vaginal symptoms.

Osteoporosis is a disease that occurs in women in late postmenopausal; in fact, according to the National Osteoporosis Foundation, every second, a woman suffers a fracture due to osteoporosis, and even the risk for this disease is higher than for other gynecological cancers. Therefore, studies have been developed that measure the quality of life of these patients, who are determined by their degree of functionality. This has been confirmed in women with osteopenia and osteoporosis; since they have limited physical activity, they have altered the physical position, suffering, and pain, with mental and emotional alterations [22].

There are many approaches that have been given for the prevention, treatment, and study of osteoporosis. Primary prevention means promoting habits that encourage the formation of good quality bones; also, at this stage, the primary detection is carried out, and the modifiable risk factors are identified, or they can be reduced or eliminated. Secondary prevention implies the opportune diagnosis and its pharmacological and non-pharmacological treatment, before a fracture occurs. Tertiary prevention is directed to limit the damage by osteoporosis.

Vaginal symptoms: Like the vasomotor symptoms, the vaginal symptoms are frequent. The clinical evaluation of these manifestations is not easy, and validated questionnaires are required that can be understood and answered by the same patient, as well as being able to be

Organization	Aim
Women’s Health Initiative (WHI)	Was founded by the US National Institutes of Health (NIH) in 1991. This Initiative consisted of clinical trials and observational studies in order to conduct the main health issues causing morbidity and mortality in postmenopausal women
Women’s Health Initiative Clinical Trial (WHICT)	This study was initiated in 1992 and concluded in 2007, in which the patient was included in a trial clinic or an observational study. Both focused to study the prevention of cancer, cardiovascular diseases, or osteoporosis
Institute of Nutrition of Central America and Panama (INCAP)	Was constituted in 1949, under three principles: <ul style="list-style-type: none">• To identify the nutritional problems• To find practical solutions• To apply the solutions in the countries of the region (Belice, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panamá y República Dominicana)
National Research Ethics Service (NRES)	NRES is one of the functions of the Health Research Authority and is responsible for reviewing and supporting ethical research in the National Health Service “to guarantee the protection of the human rights, safety, dignity, and well-being of the participants in the research”
Canadian Institutes of Health Research	Is the main federal agency for health research in Canada. It is constituted by 13 institutes, among which is the “Gender and Health”
Office for Human Research Protections (OHRP)	The Office for Human Research Protections (OHRP) is responsible for protecting the rights and welfare of individuals who participate in research projects conducted under the authorization of the US Department of Health and Human Services (HHS)
Council for International Organizations of Medical Sciences (CIOMS)	The Council for International Organizations of Medical Sciences was established in 1949 by the WHO and UNESCO, who are integrated international researchers, academies of science, and medical research councils. CIOMS promotes the public health, applying guides of health research, ethics, new products, and its security
Canadian Medical Association (CMA)	CMA was founded in 1867, its members are volunteers, and doctors promote patient access to high-quality health services
World Medical Association (WMA)	WMA was founded in 1947 and is formed by several millions of physicians and medical associations, promoting the medical care, ethics, and health education
European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO)	ESCEO was founded in 2005; it is a not-for-profit organization that meets clinical scientists who study bone, joint, and muscle disorders, as well as pharmaceutical industry

Table 1. Organizations involved in women’s health.

applied in populations of different ethnic origins. For which, an instrument of 100 questions was developed, with a set of 100 structured items, which used ordered 5-point response options to assess the degree to which vaginal symptoms interfered with specific aspects of women’s daily activities, sexual function, emotional well-being, self-concept and body image, or inter-personal relationships. The aspects evaluated included sexual function, emotional well-being, the concept of self-perception, and personal interrelationships. According this questionnaire, the main symptoms were dryness, dyspareunia, and itching, and there was a lower prevalence

Name	Symptoms evaluated	Score
Female Sexual Function Index (FSFI) [26]	Dimensions of sexual function in women	Range: 1.2–36 points ≤ 26.55 is classified as FSD
Physical Function Scale (PFS) [27]	Physical function, social function, role limitations: physical problems, emotional problems, mental health, vitality, pain, and perception of general health	Range: 0–100 points High scores reflect better health status
Center for Epidemiologic Studies Depression (CESD) Scale [28]	Depression, such as restless sleep, poor appetite, and feeling lonely	Range: 0–60 points High scores indicate greater depressive symptoms
Epworth Sleepiness Scale [29]	Daytime sleepiness	Scores: 0–5 lower normal, 6–10 higher normal, 11–12 mild excessive, 13–15 moderate excessive, 16–24 severe excessive
Pittsburgh Sleep Quality Index [30]	Subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction	Range: 0–21 points < 5 have good sleep quality
STOP-Bang Questionnaire [31]	Consists of yes/no responses: “Do you snore loudly?” “Do you often feel tired, fatigued, or sleepy during daytime?” “Has anyone observed you stop breathing during your sleep?” “Do you have or are you being treated for high blood pressure?”	Range: 0–8 points ≥3 suggest obstructive sleep apnea
Charlson Comorbidity Index [32]	Categorize co-morbidities: each co-morbidity category has an associated weight (from 1 to 6)	0 = no co-morbidity 3 = severe co-morbidities
Dietary Inflammatory Index (DII) [33]	Related to the type of diet with the increase or decrease of inflammatory mediators IL – 1beta, IL-4, IL-6, IL-10, TNF-alfa, and PCR	-1 = pro-inflammatory foods 0 = they do not produce changes in inflammatory markers +1 = anti-inflammatory foods
Day-to-Day Impact of Vaginal Aging (DIVA) [34]	Assessing the impact of vaginal dryness, soreness, itching, irritation, and pain on functioning and well-being	Range: 0–4 points Higher score indicates major symptoms
Hospital Anxiety and Depression Scale (HADS) [35]	Depression and anxiety in hospitalized nonpsychiatric patients	Range: 0–42 points 0–7 normal 8–10 doubtful >11 clinic problem
Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) [36]	Pain, physical function, social function, general perception of health, and mental function	Range: 1–5 points The highest score refers to the quality of worse life
Health Behavior Inventory (HBI) [37]	Dietary self-management, preventive measures, healthy practices, and positive mental attitude	Range: 24–120 points The higher score indicates health behaviors

Name	Symptoms evaluated	Score
Health Promoting Lifestyle Profile II (HPLP II) [38]	Health responsibility (HR), spiritual growth (SG), physical activity (PA), interpersonal relations (IR), nutrition (N), and stress management (SM)	Score: ≥ 2.50 is considered to be a positive response
Neuroticism-Extroversion-Openness Five-Factor Inventory (NEO-FFI) [12]	The NEO-FFI is integrated by 60 items, which measures the five main domains (neuroticism, extraversion, openness to experience, agreeableness, conscientiousness)	Higher scores in neuroticism is related to severe menopausal symptoms
Menopause-Specific Quality of Life Questionnaire (MENQOL) [39]	MENQOL evaluates the quality of life after menopause through: vasomotor, physical, psychosocial, sexual, and global quality of life question	Range: 0–6 points (0 none, 6 severe)
Kupperman Index [40]	Hot flashes, paresthesia, insomnia, vertigo, nervousness, melancholia, weakness, arthralgia or myalgia, headache, palpitations, and formication	Scores: 15–20 = mild 20–35 = moderate >35 = severe
Psychological General Well-Being Index [41]	Anxiety, depressed mood, positive well-being, self-control, general health, and vitality	Range: 0–100 points A high score is indicative of high levels of psychological well-being
Hot Flash Related Daily Interference Scale (HFRDIS) [42]	Work, social activities, leisure activities, sleep, mood, concentration, relations with others, sexuality, and enjoyment of life	Range: 0–100 points High score indicates interference
Menopause Rating Scale (MRS) [43]	Hot flushes, heart discomfort, sleep problems, depressive mood, irritability, anxiety, physical and mental exhaustion, sexual problems, bladder problems, dryness of vagina, joint, and muscular discomfort	Range: 9–21 points Higher score is related to more postmenopausal symptoms

Table 2. Questionnaires, survey and index used to evaluate women’s health.

of irritation and pain. The questionnaire was useful to evaluate the vaginal function, since it also evaluates feeling good, sexual function, and self-perception of the image [23].

Periodontal disease: A study carried out in postmenopausal women reported that 97% thought they had healthy gums, but when were evaluated, it was identified that 62% had at least one affected site, with the risk of losing a dental organ. In addition, women were unaware of the effects of periodontitis. Although women reported that they visited their dentist semiannually, in several teeth, the biofilm was observed, but in several teeth, biofilm was observed, which indicated a poor periodontal state; what makes us suppose is that they considered that they had healthy gums, because they did not present abscesses, a symptom that seems to be the best known, not considering important events such as the loss of periodontium and depth of probing. Periodontal disease is not well known among women, although they know the risk factors for developing caries, such as the infrequency of brushing, poor dental technique, and sugary foods. The study showed that most of the patients neither had knowledge about the risk factors nor of all the signs and symptoms, but once it was explained to them, they showed greater interest in self-care and assisted a periodic review by the specialist [24].

Physical activity: The index of healthy behavior considers four areas: healthy eating habits, preventive actions, positive mental attitude, and recreational activities. Using this instrument, a comparison was made between young and old women, in which it was found that the elderly (between 56 and 69 years) have a high level of healthy behavior, although in a particular way the alimentary habits were similar and women with the higher educational level and who are divorced had more healthy habits. Women with some pathology had higher scores; this is expected, since they know that they have an illness and they understand that they must have more care and carry out actions that benefit their health and control the disease. On the other hand, women without pathologies had less healthy habits, a situation derived from their perception of their health, since they considered their health status as good. This type of instrument is of fundamental application in postmenopausal women, since it has been proven that a healthy state will condition symptoms of less intensity or frequency [25]. There are several survey questionnaires or scales to evaluate women's health but, however, is not usually used all at the same time (**Table 2**).

4. Clinical research

Since its inception in 1906, the Food and Drug Administration (FDA) has been committed to the health of women and established the Office of Women's Health (FDA OWH) in 1994. The US Food and Drug Administration Guide developed a Guide for the Study and Evaluation of Gender Differences, which made it possible to include women in phase 1, 2, and 3 studies. Later, between 2002 and 2004, trials on hormone therapy were designed to test the effects of estradiol and combined estrogen/progesterone therapy on the prevention of cardiovascular diseases, fractures, and breast and colorectal cancer. The studies found that estradiol did not protect against cardiovascular disease and that the risks outweighed the benefits. In the year 2010, it was recognized that it was necessary to carry out research with female animals with a focus on the study of common diseases. Finally, the inadequate number of women included in clinical trials is noteworthy [44].

In that same year, the NIH Office of Research on Women's Health proposed a strategic planning process with scientists, public policy experts, women's health advocates, healthcare providers, elected officials, and the public to generate priorities research. In 2014, federal agencies collaborated with women's health research. The NIH Office of Research on Women's Health and the Office of Women's Health of the FDA plan to collaborate on a national campaign to promote the importance of participation in clinical trials focusing on women; due to evidence of the effect of estrogen in the secondary prevention of coronary disease, published in *The Journal of the American Medical Association* in 1973, was conducted only with men, enrolling 8341 men and not women [44].

Three main reasons seem to explain the exclusion of women: (1) experimental exposition to risk during fertile years (2) erroneous perceptions that consider that women are less affected by certain disorders or health problems or that women respond to the same treatment as men; and (3) it is perceived that women provide complexity, increased cost, and the need for greater analytical capacity.

However, the Institute of Medicine concluded “being male or female is an important basic human variable that must be considered when designing and analyzing studies in all areas and at all levels of biomedicine and health-related research.” Until sex and gender differences are routinely investigated, there will be many opportunities to gain a better understanding of the pathogenesis of disease and human health.

Currently, the review of clinic protocols by the Research Ethics Committees (REC) is the key to the regulation of clinical research. The RECs have to comply with several requirements, such as (1) the minimum members is five; (2) membership must be diverse (by race, gender, cultural background, sensitivity to the problems of the community), with at least one scientist and one nonscientist [45]; (3) there are no rules about how fast decisions should be made or how many times you could apply; (4) the consequences of REC’s work for investigators or research funders, in terms of time or resources, were not a consideration of REC; (5) the scientific quality of a project is considered an ethical prerequisite; (6) the legality (to ensure that laws and other regulations are followed and the protection of institutes and responsible researchers); (7) the choice of researchers is determined by the professional location of the principal investigator, which a REC within the health institute could be chosen. The researchers did not choose the REC; (8) the REC had “responsibility of state public officials”; (9) transparency in the selection process to accept protocols; (10) compulsory education of REC members about ethical topics; (11) the variability in the work and decisions of REC had been recognized as a problem, but not solved; and (12) quality assurance investigation complicates the topic, but some defended the exemption from quality assurance studies of the ethical approval requirement.

5. Challenges in bioethics research and medical care

Currently, it is recognized that health is fundamental to development of a society. Most studies describe the costs of poor health in women, particularly the costs of poor maternal health.

There are a lot of challenges that REC and national or international organizations have to solve, for example:

1. Girls from the United States exhibited physical signs of puberty by age 7.
2. Pollutants of land and livestock can impact on man’s reproductive abilities.
3. Good health among women is important for child development and the production of future human capital.
4. The mass and nonprofessional media can be the main source of knowledge about the symptoms and coping methods in postmenopausal women.
5. Determining the association of quality of life of the postmenopausal women with that of their spouses.
6. Promoting the health and health behavior must be a priority [11, 25, 46].

6. Conclusions

Menopause is a very important stage in a woman's life, and the attention provided at this stage, whether for research or medical attention, must be carried out by personnel trained in ethics, because the woman is in the stage of major susceptibility; also, several symptoms can be confusing. Moreover, in medical consultation or the clinical studies, do not usually apply all the questionnaires, indexes, or scales, either due to lack of time or to focus on the main symptom, without considering that the symptom that was the reason for consultation may be the result of not treating other minor symptoms. The research clinic based on ethical principles will contribute to obtain specific and reliable results on women's health.

Conflict of interest

The authors declare that there is no conflict of interest.

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