Ethical challenges in research regarding aging population

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Abstract

Aging population is a global reality that forces public policies based on transdisciplinary research focused on older adults. This raises a series of issues, such as feasability, inequalities, inequities, vulnerability, access to the products generated, and ability to consent, among others. This essay's objective is to reflect on some of the questions that arise from this reality, review basic precepts of research ethics in human beings, and expose the challenges for updating the current guidelines for ethical biomedical research. Aged adults participating in clinical research should be respected, assured of an adequate risk/benefit balance, and selected fairly. The available guidelines generally recognize these basic principles, but they are not entirely guaranteed, as evidenced during the COVID-19 pandemic. This issue poses various ethical challenges and deserves to be considered in the guidelines and regulations for biomedical research with the participation of older adults.

Main messages

- The current epidemiological situation raises many questions related to the ethics of the participation of older adults in research.
- This essay reflects on the challenges of ethics in research in the face of aging population, highlighting the need to deepen new research.
- An overview of the Chilean legal framework regulating informed consent in scientific research involving human beings is offered.

Introduction

Population aging is a global reality that forces public policies based on transdisciplinary research focused on older adults [1,2]. Aging is multidimensional and is linked to the social determinants of health, so it is impacted by inequity. With new ethical dilemmas, research projects in this area have increased, aiming to improve the quality of life at older ages.

The current epidemiological situation raises multiple questions about the ethics of older people's participation in research. These questions are related to the gaps, inequalities, inequities, vulnerability, representation in research (especially biomedical), capacity to consent, patient follow-up, and access to the products generated. DuBois and Antes [3] pointed out that "research ethics is about doing good science, in a good way", which is fundamentally related to its social value. This paper aims to reflect on ethical questions raised by population aging by reviewing some basic precepts of research ethics. In addition, it seeks to consider some needs for updating the guidelines and directives that benefit the older adults who participate in it.

Research ethics with older adults

There is a consensus on the basic principles of research ethics with older adults. The following stand out as intransgressible principles: respect their capacity to make decisions, express their independence and autonomy or self-determination, and compliance with the principles of beneficence and nonmaleficence. Thereby ensuring that the benefits are maximized, the possible risks are minimized, and the procedures and protocols to be applied are justified, adequate, and fairly distributed [4].

A prerequisite for the participation of older adults in research is that it proposes interventions relevant to this group's diversity, including vulnerability aspects. The Universal Declaration on Bioethics and Human Rights [5] states that "in applying and advancing scientific knowledge, medical practice and related technologies, human vulnerability should be considered. Particularly vulnerable individuals and groups should be protected, and the personal integrity of such individuals should be respected." This statement adds to the Belmont Report [4], which recognizes social vulnerability, marginalization, and quality of life, among other challenges, to highlight principles of justice, common good, and solidarity.

Research with older adults in the COVID-19 pandemic

The COVID-19 pandemic revealed controversial aspects in research ethics regarding older adults who developed severe clinical conditions with significant well-being impairment [6]. The epidemic revealed their biological fragility and other aspects of quality of life, especially during confinement and restrictions on individual freedoms that affected their mental health [7]. During this period, research was conducted in high morbidity and mortality circumstances, with scarce resources, and making decisions quickly, sometimes based on partial information of uncertain validity [8].

In general, biomedical practices are adapted in times of health emergencies, as in the case of informed consent. This aspect is relevant in older adults impaired from consenting traditionally, such as those who depend on caregivers or present cognitive impairment. Other examples are the prioritization of access to drugs under the principle of equipoise, which justifies their random assignment to a placebo group or standard care; the prioritization for certain treatments (for example, age as a triage criterion in mechanical ventilation); as well as respect for the rights and duties of participants in clinical trials. In all these circumstances, it is necessary to unify criteria and train members of scientific research ethics committees for the prompt approval of protocols without lowering ethical standards [9].

Population aging has revealed multiple aspects of quality of life that represent ethical challenges. The Council for International Organizations of Medical Sciences (CIOMS) [10] highlights the relevance of respect for older adults with an adequate study design to produce scientifically valid results. It also highlights the importance of fair selection, with appropriate criteria for inclusion or exclusion of participants, equitable distribution of the burdens and benefits of participation, and realistic assessment of the intervention's risks and possible individual benefits. The pandemic allowed an ethical reflection on the protection of these people, reducing paternalistic, denigrating, and discriminatory treatment, such as ageism, which

"impoverishes their physical and mental health, in addition to reducing their quality of life, and costs society billions of dollars every year" [11].

It is necessary to recognize and improve some ethically reprehensible practices applied to older adults in periods of crisis and to conduct research that improves their resilience. Protocols should be reviewed and redesigned to address health situations in the context of social determinants to improve well-being and health comprehensively. Research participants should be respected, with an adequate risk/benefit balance, and be selected equitably. However, these principles are not entirely guaranteed. The issue merits reflection to update the current guidelines and ethical regulations for biomedical research involving older adults.

Inclusion versus exclusion of older adults in clinical trials

This population group has the highest prescription drug consumption [12] but is underrepresented in drug research. Lau et al. [13] analyzed clinical trials conducted in the United States over ten years, verifying an underrepresentation of those over 75 years, considering that they were the main users of the therapies investigated. Exclusion is attributed to difficulties in recruiting and retaining older adults in the studies (especially if they are frail). Other barriers include obtaining consent, multimorbidity, polypharmacy, logistical problems, compromised insurance, additional care, economic vulnerability, social isolation, and treatment adherence. This makes it necessary to adapt the forms of administration that complicate the evaluation of trial results, multiple confounding variables, the preferences of the investigator, and the exclusion criteria applied [14–16]. The use of chronological age as a selection criterion is highly questioned, given the heterogeneity of the age group, so it is recommended instead to apply geriatric assessment instruments [17].

The underrepresentation of older adults is widely recognized. Two decades ago, the International Council for Harmonization (ICH) [18] produced the ICH E7 Guideline, which includes the geriatric population. However, underrepresentation still remains, while clinical trials to evaluate geriatric drugs are extraordinarily scarce [19,20].

It is paradoxical that in the search for therapies for COVID-19, older adults were underrepresented, mainly due to comorbidities, primarily due to frailty [21,22]. This is despite the disease being considered a "geriatric emergency" [23]. This underrepresentation in biomedical research is attributed to the multiplicity of factors that complicate their selection as probands. However, without valid reasons, older adults should not be excluded from clinical trials, ensuring the principle of justice by granting the required facilities. Discriminatory practices reduce the social value of research, leading to the generation of valuable knowledge that would be directly applicable to these people.

Respect for older adults in research

Research with scientific integrity requires methodological and ethical rigor regarding its social value. The design must consider social aspects, preventing the obtaining of non-applicable results, thus harming those who could have benefited [24]. Casado et al. [25] point out that "the elements that make up responsible research and innovation must have a real impact on the research system and society, with tangible and valuable results. The institutions that fund research and the research community itself should establish the rules for its adequate evaluation". The impact of research with "tangible and evaluable" results mandates non-discrimination in trials.

The CIOMS guidelines [10] refer to critical elements, such as respect for the autonomy and protection of dependent or vulnerable individuals and groups. In them, vulnerability corresponds to "elements of judgment about both the likelihood and degree of physical, psychological, or social harm; increased sensitivity to deception or breach of confidentiality". This concept applies to the capacity to give participatory consent, which is essential when older adults cannot protect their interests. Older adults in poverty [26] are vulnerable and at risk of exploitation in research. They may feel pressured to consent by incentives, coercion, or the need for acceptance by authority figures (such as the treating physician), especially in a non-rewarding environment.

Respect for older adults considers their ethical protection by reducing paternalistic, demeaning, and discriminatory treatment. Respect for their wishes and choices should protect their right to autonomy. The consent process must be adequately informed and fully understood without coercion or undue influence [4]. In the equitable selection of probands in a clinical trial, gaps, inequalities, and inequities affect older adults.

Autonomy is a fundamental right. It is necessary to ensure its exercise, which is made difficult by the social gap that makes it very unequal. Older adults who are stigmatized (due to ethnicity, multiculturalism, or other causes) or highly vulnerable should not be marginalized, such as selecting those with a better aging phenotype at the same chronological age as others with physical and/or mental deterioration. This practice constitutes discrimination and an absence of distributive justice, reflected in a selection for convenience [27]. Inequity causes more harm when the social value of research is placed on favoring people such as those who have been rejected as probands.

Thus, respect for older adults should be manifested throughout the research process. It is always necessary to be cautious about what happens to the participants when a study concludes, preventing the research team from withdrawing and losing contact. This is avoided by allowing the community access to the products generated and continuously monitoring their welfare [28]. Ethics committees should investigate these situations, as well as the motivation of the research proposal: health and welfare versus profit-making business. Protocols should also incorporate the education of participants, who have the right to understand the social value of their participation and the research results.

In sum, research with older adults should propose interventions sensitive to the group's diversity, considering social vulnerability, marginalization, quality of life, and others that challenge the principles of justice, common good, and solidarity [29]. Respect is manifested by always considering that each participant has beliefs, principles, and values, which he/she will exercise whenever he/she is free to make decisions.

Informed consent process with older adults

In clinical research, informed consent corresponds to "the process of the doctor-patient relationship, in which the former informs the latter of the diagnostic and/or therapeutic procedures indicated, their risks, benefits, and alternatives, to obtain his or her prior consent, thus fulfilling the bioethical and legal principle of patient autonomy" [30]. The final document should reflect the entire meeting and dialogue process, express the patient's right in a voluntary, express, and informed manner, and certify that this process was actually carried out. In order to sign it, the patient must have the necessary information, understand it, be free of pressure to decide according to his or her values, and be competent to make his or her decision.

The Chilean legal framework obliges researchers to provide complete information about the study in which people will participate. Law 20 584 [31] recognizes the importance of the right to complete information about the disease, treatments, risks and benefits, among other aspects. Law 20 120 [32] recognizes the obligatory nature of informed consent for all persons who participate in clinical studies or biomedical research. The right to consent is based on respect for the autonomy of will. Each person is the owner and responsible for his or her body and must assume responsibility and determination regarding his or her health.

Among the difficulties in obtaining the consent of older adults are those related to comprehension, sensory impairment, educational level, and the time required. This has led to the proposal of adapting the process, including the presence of a witness [33]. Cognitive impairment is a dynamic and progressive situation, ranging from mild cognitive impairment to dementia. This complicates the process and does not directly imply the inability to consent. Research teams and ethics committees should be able to differentiate competence from the assessment of overall cognitive performance. Law 20 584 [31] states that even if the person cannot express his or her will, some interventions may be performed, provided an ethics committee authorizes it. It indicates that these persons may be treated involuntarily and establishes that their opinion should be required whenever and wherever possible and that no person with a mental or intellectual disability who cannot express his or her will may participate in scientific research.

The law does not clarify some situations, and the decision is left to the clinician's ethics and professionalism [34]. Compliance with the law may be insufficient in the face of professional ethical judgment, which applies more stringent standards, including skills referred to as the "hidden curriculum" [35]. Experimental psychology, neuroscience, and cognitive neuroscience indicate that rationality alone does not determine decision-making. Moreover, integrating cognitive, emotional, and motivational information is necessary, with no threshold for determining decision-making competence and no linear relationship between the intensity of dementia and loss of competence [36]. The assessment of decision-making competence in these individuals is complex. There is no universally accepted test for this purpose, and there are various ways of establishing the "mental capacity" of older people [37], such as the widely used Mac CAT-T (MacArthur Competence Assessment Tool for Treatment) [38]. In a systematic review of decision-making in people with dementia, Bhatt et al. [39] point out that cognitive impairment is not always the most crucial dimension for decision-making in people with some degree of dementia, given that it is a complex and multidimensional situation.

Population aging is a fact of life, and obtaining informed consent from aging persons with cognitive impairment can be expected to become increasingly frequent and complex. The increasing prevalence of dementia, the most common pathology in which competency conflicts may arise, leads to the determination of required care and emerging ethical conflicts. Assessing capacities and drafting an advance directives document are problems of the early stages, while containment measures or institutionalization arise in the more advanced stages [40,41]. Law 21 331 [42] aims to recognize and protect the rights of persons with mental illness or mental or intellectual disability, especially "their right to personal freedom, to physical and psychological integrity, to health care and social and labor inclusion" and states that it is the duty of the State to "respect, promote and guarantee them". Likewise, this law adds that "people have the right to exercise free and informed consent concerning therapeutic alternatives proposed to them. For this purpose, support will be articulated for decision making, to safeguard their will and preferences".

At the Latin American region level, it would be desirable to share the experiences and reflections of the ethics committees on issues related to research in times of accelerated population aging. In this way, working groups could be created to provide periodic training for all those involved in conducting clinical research with the participation of older adults.

Conclusions

The accelerated increase in older adults raises the need to rethink some aspects of their research participation. Aspects such as vulnerability, equitable selection, and respect for probands must be considered, along with abandoning ethically reprehensible practices. These issues should be approached from the perspective of moral conscience and ethics and be considered in the guidelines and regulations for their participation in research, which require constant updating, as well as reflection-action in the work of ethics committees. The bodies in charge should establish recommendations for appropriate conduct to

prevent the marginalization and underrepresentation of older adults in studies by improving their accessibility to them and their social value.

These considerations also guarantee other ethical principles related to the participants, which would improve the social value of clinical trials by positively impacting older adults. In addition, population aging is associated with an increase in the prevalence of cognitive impairment, affecting some people's ability to consent. Each person affected by neuroimpairment has unique qualities within a spectrum of progressive dementia, influenced by socio-environmental determinants. The idea of achieving a consent process that ensures the autonomy and rights of the older person is not always achieved, and unethical situations can occur.

The challenge of closing the current gaps in the guidelines and regulations for research ethics with older adults requires reflection and considerations that place this group at the center. The epidemiological change is already in place, and it is no longer possible to delay satisfying the needs presented here.

Notes

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Desafíos a la ética en la investigación frente al envejecimiento poblacional

Resumen

El mundo está experimentando un acelerado proceso de envejecimiento poblacional. Este cambio epidemiológico se asocia a la necesidad de incrementar la investigación orientada a mejorar la calidad de vida en las edades avanzadas. Esta investigación requiere de la participación de personas mayores, tanto en áreas del ámbito científico-tecnológico como en el sociocultural. Esta realidad lleva a plantear una serie de interrogantes relacionadas con la forma como se desarrolla esta actividad con las personas mayores, relacionadas con las brechas, desigualdades e inequidades, su vulnerabilidad, su acceso a los productos generados, su capacidad para consentir, entre otros. El objetivo del ensayo es reflexionar acerca de algunas de estas interrogantes, revisando algunos de los preceptos básicos de la ética de la investigación en seres humanos, y plantear algunas necesidades y desafíos para la actualización en las pautas y guías que la orientan. Se espera que las personas mayores que participan en investigación biomédica sean respetadas, se les asegure un adecuado balance riesgo/beneficio y se seleccionen en forma equitativa. Estos principios básicos, aunque reconocidos en términos generales por las guías y regulaciones éticas disponibles, no están completamente garantizados, como evidenció la pandemia de COVID-19. El tema plantea diversos desafíos y amerita su consideración en las pautas y guías éticas para la investigación biomédica con participación de personas mayores.