

Chapter 16

Ethical Issues in Research in Aging



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Abstract Medical advancements have resulted in an increment in life longevity, which has led to an increment in the proportion of aging adults in the worldwide population, especially in the last half of the century, as a result of exceeding medical research. This chapter will argue that such exceeding medical research should always be accompanied by an ethical stance, specifically focusing on aging population. The ethical stance in research serves to, first and foremost, look to safeguard the dignity of those it researches. To protect the dignity is not only a matter pertinent to the research process itself, but also to the conclusion of research, and how it is placed within society and the health system. As a response to these important quandaries, the bioethical realm of research has developed methodologies and guidelines for the design and implementation of research protocols to guarantee the protection of dignity and human rights of all and each population studied.

Keywords Bioethics · Ethics · Ethics in aging research

16.1 Introduction

Current bio-demographic research shows that both life expectancy and longevity of the world population has notably increased in the last century. This phenomenon has been a result of medical research and advancement. However, this reality poses important questions for research going forward. It can be said that today's population reality poses a tension between utilitarian and ethical aspects of society [1]. On the one hand, a utilitarian would call upon the maximization of society's overall utility through research, which we seem to be complying too: but, on the other hand, ethics calls upon a more nuanced outlook on medical research. For example, ethics

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would call us to ask: who and how is this research really serving? We have expanded the years in our lives, but have we done the same with their quality? What are the social implications that our medical research has had on the aging? These questions point towards the fact that aging research is not without its ethical complications and, in fact, ethics should be a guiding point for research.

As a first ethical guiding point Baars [2] calls for aging research to always carry within the finitude life and the characteristic that being aware of such fact is what makes us human. This aspect is usually brushed aside because it demerits the idea of utility based on productivity that guides our society on a day to day basis [2]. However, to bring the reality of finitude to the fore, helps achieve a more meaningful and realistic understanding of the aging process, allowing the researcher to see old age as an ongoing learning process of how to confront such undeniable fact [2].

A manner which may result useful into bringing about a positive vision on old age might be to look into history. There are testimonies of previous times when old age was granted as the maximum authority in political, social and cultural aspects. Old age represented the memory of the community, its source of tradition and, therefore, the identity of the people. However, it must also be pointed out that, because their value depended deeply on their memory, if this was lost, they would cease to play an important role in society [3].

De senectute, by Cicero, is one of the first Latin works dedicated exclusively to old age; while it is not necessarily a medical book, it incorporates comments related to health and emphasizes the author's view on the matter. In the text there is an argument in favor of old age, representing advantages and possibilities for happiness and well-being [4]. This work by Cicero's holds particular importance to argue against the opinion of many physicians that deem old age as a synonym of diseases, which undeniable implies viewing such life process as an impediment to a good quality of life.

Another important work is that of Laín Entralgo, *The Company of Aging*, in which he does an analysis of old age by an anthropological, biological, and philosophical approaches. The analysis works by a juxtaposition of the idea of old age against different conceptions of society and different historical moments. In this manner Laín Entralgo is able to show that old age and social life is one of the most serious and urgent issues in the twenty-first century [5].

This chapter will thus, aim to show how aging research has an ethical responsibility to society, specifically to the aging population. The ethical responsibility is not only meant in the safeguarding of dignity for the person over 60 years old taking part in research, but also in the sense that aging research must ethically contribute to a better positioning of the idea of old age in society.

16.2 The Problem of Ethics in Aging Research

All research requires taking into account an ethical stance, especially when it deals with a particularly vulnerable part of the population. The ethical dimension of research should be included as a fundamental part in the training of graduate

students in the disciplines of health, and should provide logical, epistemological, methodological, philosophical, and ethical statements to researchers [6].

The function of ethics within clinical and epidemiological research is to guide the research without forgetting the dignity of the population being treated. Ethics will not clearly solve the problems that researchers face, but it should always lead the researcher to pause in every step and ask herself: Why am I doing this research? What is my purpose? What will the implication of my research be? The aim of ethics in research is, therefore, to improve the quality of decision making in every step by always having in mind dignity of those participants studied [7]. Within this ethical realm, the duty of health researchers (both applied and basic) is guided by the following criteria: to offer a dignified conception of old age. Such duty is one that covers all aspects of research (whether that be clinical trials, or merely observational), it includes also the very aspect of the motivation for the research itself, and it includes the interaction between researcher and any active participation individual. In short, the ethical is a pertinent and vital part of aging research at all moments and stages of the process.

One of the ways in which the need for ethics in aging research can be seen in a more tangible manner is through the lens of vulnerability. When referencing the aging population, almost always there will be a mention to their (possibly) vulnerable condition, but what does this really mean? Is it a fair characterization? Vulnerability is defined by the Council for International Organizations of Medical Sciences (CIOMS) [8] as the diminution of a subject's capacity to protect their own interests, which, obviously, puts such a person in a disadvantaged position. Such a decrease in the capacity for protection of rights might be due to mental and physical limitations, which older adults have a higher probability of experiencing. This statement is not meant in a pejorative manner, or as a disqualification of old age, but as a stating of one of the possible characteristics of such age. Indeed, human beings can be vulnerable at any time of their existence because of a certain illness or injury, or due to particular circumstances of each of their lives. However, the conditions for vulnerability are usually more prominent in old age which situates the individual at disadvantage regarding the way they are conceptualized in society.

Vulnerability in old age is usually tied up with dependence: insofar aging adults become dependent they become vulnerable. Dependence and vulnerability lead for the people that undergo old age to be treated and understood as different from any other person. Aging adults become the "they" of society, different from the rest because of the negative understanding we have of their life process (one which we will undergo!). This negative understanding undoubtedly impacts the aging's adult quality of life, even more so when such individual is in need of care that is granted to them by someone who shares such a negative view of old age. Old age, thus, means—in most cases—a loss of autonomy. The quality of life that the individual over 60 years of age may expect will be, with no doubt, influenced by the way in which society understands and views such a moment in life. Therefore, the individual needs the protection of society and the existence of specialized health-care personnel [9].

The vulnerability of individuals, thus, has consequences for research. One of the most straightforward ways in which we can observe is this is in the repercussion that vulnerability has for the aspect of consent in a research project. As it has been said, one of the ways in which an aging adult is come to be seen as vulnerable, has to do with limited cognitive or physical ability, which may impact her capacity to make judgments and decisions. This is especially worrying when persons over 60 years of age are invited to participate in research protocol in which they can be coerced into participation by a family member, or by the researcher itself, particularly when legal competence has not been clearly established. And just because coercion does not appear evident, it does not mean it might not be there. For example, aging adults might feel pressured to agree on participation because they deem the researcher, or family member, as a figure of authority that they cannot deny. Or, it can also be the case, where the individual agrees to participate because they find comfort in the attention, and in cases as these, the researcher must be very careful not to take advantage of this situation.

However, the relation between vulnerability of subjects and research is more complex than that. Assuring that the individual has granted full and informed consent to participate in a research project is obviously important but vulnerability may play a bigger role than that. Vulnerability is not only at play in clinical trials but also in observational studies. For example, there could be a case in which a researcher is “merely” asking questions to the aging adult, and such questions may leave the individual distraught. Or, it may be the case in which during the observation, the researcher notices that the individual in questions suffers from certain conditions that she is not aware, and the researcher does not follow up to assure a suitable treatment. All of these are instances in which the role of vulnerability may not have been as evident as in the process of granting consent, but it was nonetheless there. It may be the case that the individual was not vulnerable from the start but suffered vulnerability at some point in the research.

Another matter which needs to be address is that the importance of research done ethically is not limited to the process of research itself and the way it might endanger such a vulnerable population but is also implicated in the connotations it serves to create in society regarding old age. A simple example of this is the common use of certain labels within research that are used to refer to the aging adults, like frailty. Even if the researcher does not make use of such a term with an intention of a negative connotation, she must take into account that the way which her research is done might lead to people understanding such a term in negative ways and, thus, have an impact on the individual’s life; because as it was just stated the quality of life of the person depends on the quality of care she receives, which will be connected to the value the care giver gives the life she is caring for. However, the use of such labels may also even impact aspects within the research itself such as the selection process in which certain persons of old age may be discriminated against. Even the selection process, hence, has clear bioethical implications for researchers and health professionals [10].

Because of the implications pointed out, it is clear that as difficult as it may be, there must be a careful and reflective analysis of the values and principles in conflict

during every stage of research: the decision making cannot consist of a pure mathematical equation [6].

As Weber pointed out, we must consider our ethical responsibility in the consequences of our actions: when we make decisions, we must also assess the consequences and assume responsibility [11]. We must therefore assess the consequences of every step of the research process, even of such preliminary steps as the decisions made regarding how we refer to the individuals whom we are studying. We must accept that the use of word “elderly” over “individual” will have an impact, whether that was our intention or not, and different connotations and judgments will arise. We must ask ourselves if through our research we are ensuring the respect of those studied. We must never lose sight of whom the individual is, we must never cease to recognize her as human, and our responsibility towards her. This is a vital part of our responsibility and obligations as researchers. David Oliver notes that the only way to avoid getting old is to stop living [12]. In other words, to get old is an undeniable part of human life for the privileged ones that made it so far. Why then, do we treat old age, as something wrong and undesirable?

16.3 Ethical Considerations in Aging Research

Having argued in favor of an ethical realm within ageing research, it is now prudent to discuss the considerations that such realm imposes on research. In “Bioethics as a discipline” (1973) Daniel Callahan [13] foresees the appearance of a discipline called bioethics and reflects on the role that ethics could take in the world of health and biology. Callahan states that philosophers must be a part of health and biology research in order to offer intellectual rigor to the problems that arise within such instance; for example, to help health professionals, researchers and biologists in making concrete decisions. Bioethics, thus, serves to define ethical problems, methodological strategies and procedures for making decisions that are sensitive to the complex cases. This shows that bioethics is interested in the adequate application of the ethical statements and ethical dilemmas; it is more concerned with solving ethical dilemmas than with the formation of character and the search for excellence in the health professional and in the researcher [14].

However, even bioethical research seems as relatively new development, the reality is that in some way or another, bioethical aspects of research regarding humans have always been part of research since the beginning of Medicine. However, it was not until the second half of the twentieth century that bioethics took a more prominent role, due to very disturbing and worrying historical events, that enforced a more thorough evaluation of research protocols. The example that undoubtedly comes to mind is the way that “medical research” was performed by the Nazis. Such atrocities gave rise to the Nuremberg Code (published 1947), which served not only to install an undeniable ethical base for future research, but also served to judge the researchers during the Nuremberg Trial processes [15].

Another case that is important to mention is that of Jewish Chronic Disease Hospital [16], in New York (1963), where cancer cells were injected into 22 patients of old age without their consent. The “justification” rationale given by the researchers was that they sought to discover whether in cancer patients there was a decrease in the body’s ability to reject transplants with cancer cells because of weakness or the aging process. Of the 22 patients, none were informed of what was being done to them, and only some knew they were a part of an ongoing medical research.

These are just some of the cases that led Henry K. Beecher to work upon the distinction between the therapeutic and the non-therapeutic experiments, which in turn resulted in the Declaration of the World Medical Association, signed in 1964 in Helsinki. Such document, of which Beecher was one of the main drafters, remains valid to this day, even if it has undergone several successive reforms. In its most recent version (2013) [17] it states: “Medical research is subject to ethical standards that serve to promote respect for all human beings and to protect their health and their fundamental and individual rights”.

Following such declaration, Beecher published an article titled “Ethics and Clinical Research”, where he denounced investigations with serious ethical problems. The main problems to which he signaled to were: informed consent, the evaluation of risk-benefit (in very high risk), and the fact that the experiments involved vulnerable populations (children and the persons over 60 years of age). Upon this, Beecher concluded: “An experiment is or is not ethical from the beginning; it does not become ethical post hoc, the end does not justify the means” [18]. Beecher’s article showed, that even if Declarations and Codes are drafted, they are not necessarily enforced in research. One of the manners in which this has been tried to solve is by posing more importance into the aspect of informed consent as a fundamental part of the evaluation of research protocols.

Informed consent, it has been established, is an important ethical condition of research as it signifies that respect for the subject’s autonomy is being taken into account. Hence any participant of research must always be informed in a clear and concrete manner about what their participation in the research entails. To highlight the importance of informed consent in research is to safeguard the dignity of vulnerable parts of the populations, which as we have seen is a characteristic of old age. This is why such a parameter is one of the outmost important conditions imposed by the ethical real in research. The old age population has a greater probability of living with conditions that limit them physically and mentally, which situates them in a position of complete disadvantage use of their diseases and might not be able to grant or reject informed consent themselves and are vulnerable to influence from the researchers.

Ethics in research has, thus, resulted in methodologies and regulatory rules for clinical trials in order to protect the human rights of research subjects. These normative measures, though existent in some form or another throughout history, were expressly written out from the aftermath that followed the horrific historic events of the mid twentieth century. Such guidelines should be seen a living organism always to be analyzed and allowed to evolve, in order to truly protect humans and in order

to meet the debates of the current times, like those of embryonic stem-cell research or euthanasia.

16.4 Research Ethics Committees for Aging Research

In order to better guarantee the ethical conditions that research must meet, institutions that do research on humans must have a Research Ethics Committees (REC) that regulates the research protocols. A REC is made up of a multidisciplinary group of people within a health institution (independent of the government system), and such institution may conduct research on both animals and humans. Such group of people should include researchers from different fields of scientific knowledge, both from the institution itself and external to it and it should also include members of the community [19].

The fundamental objective of the REC is to safeguard the human rights and dignity of the research subjects. This implies knowing and evaluating the probable benefits risks of the research for the participating subject before the research is performed and evaluated. Both benefits and risks should be clearly stated in the research protocol, as well as other ethical aspects, such as the financing of the research and the relationship of the principal investigator with the pharmaceutical industry, among others. However, as it can be inferred, REC is not alone in ensuring ethics in research. Currently there are other important set of norms and directives that also set guidelines to ensure the respect of human rights within research: UNAIDS, 2000; CIOMS, 2002; Nuffield, 2002 [20, 21].

Without a doubt the knowledge generated by research on humans is necessary and valuable, it has allowed the development of medicines and vaccines, for example. But these advancements in themselves are not enough to justify an undignified treatment of research subject, which is why all research must be first and foremost scientifically and ethically adequate, especially in the case of the vulnerable parts of the population. Herein rests the importance of the REC.

16.5 Discrimination of the Problem in Aging Research

To safeguard the dignity of individuals can be also be phrased as to protect them versus discrimination. All human beings have the right to live their lives fully and in a meaningful way. Aging research should, therefore, have such a right of human life as the ultimate objective for any medical advancement. Nonetheless, as this chapter has been trying to show, certain aspects of aging research have generated negative connotation in the way that society sees old age which has cause such individuals to be seen as less worthy of a good life. One of the manners in which aging research, purposely or not, has negatively impacted the lives of the aging adults, is by the

creation and subsequent use of certain labels. One of the labels we have already exemplified is that of frail.

The term frail references an accumulation of deficits which signify a distinct clinical syndrome insofar it involves a specific co-morbidity, such as physical disorder and functional impairment. Frailty has become an increasingly common component of aging research insofar the probability to become frail in old age is higher. A fundamental goal of geriatric medicine has, therefore, become how to maximize functionality, independence, and quality of life during the years lived with frailty for as long as possible [22].

Nonetheless, the reality is that the concept of frailty is still under development and analysis within aging research; it has “little robustness” and is in need of more scientific evidence to validate it and its transcendence. Even more so, more research is needed specifically regarding frailty’s clinical aspects and unique psychological aspects, so as to be able to accurately define, recognize, and treat frail individuals. Therefore, research regarding old age should not just scientifically enhance the concept of frailty, but also help to construct a positive narrative regarding such condition. As of today, frailty is quickly equated with many negative aspects which ultimately cause several types of discriminations towards old age. Thus, any research on aging should be careful to not imply that frailty lessens the person’s life value to society.

Even if the researcher does not make use of such a term with an intention of a negative connotation, she must take into account that the way which her research is done might lead to people understanding such a term in negative ways and, thus, have an impact on the person’s life; because as it was just stated the quality of life of the person depends on the quality of care she receives, which will be connected to the value the care giver gives the life she is caring for. However, the use of such labels may also even impact aspects within the research itself such as the selection process in which certain persons of old age may be discriminated against. Even the selection process, hence, has clear bioethical implications for researchers and health professionals [10].

16.6 Aging Research, Ethics and Health Systems

Discrimination, as the previous section argued, does not arise out of thin air, but as a result from human action. There is a legal and a moral dimension to discrimination: a fundamental human right is being violated, and such violation is considered unfair. And in the same manner that discrimination is enacted by humans, so is morality and our capacity to become ethical in our going about life. Our capacity to be moral and ethical is particularly important when analyzing the ends, we pursue, because it is in such a manner that the responsibility we hold with our actions becomes truly evident. Our actions, thus, should not be concealed by the way things are, but by the ideal of the way things should be. What this chapter has tried to outline is that this is true also in aspect of health and aging research. In this last section,

we will know try to show that aging research done ethically could also help health systems in avoiding discrimination.

Ethical guidelines, for example, could help set up strategies regarding the allocation of economic and health resources. In this sense, and ethical outlook, could help with difficult decisions where the most prudent allocation might not seem the fairest at first sight, a matter which is not talked about enough and endangers the optimal distribution [23].

Another aspect in which the health systems could gain from an ethical outlook is regarding specifically to policy aspects. The policy decision, in many countries, to shift the burden of health care and social security for the persons over 60 years of age from families to the State has had major socio-economic consequences. Moreover, the economic pressure on families has not been alleviated, especially in the cases where the person is in need for long term care, whether that be institutional or home based. Needless to say, that as the proportion of the aging adult increases so does, the economic pressure on the State [1]. These difficulties lead us to ask more in-depth questions regarding the role of the State in such instances: where is the line drawn in the State's obligation to the older individuals? What should the scope of public health systems be in regard to care? What is the interplay that should be expected between health research and State to be? In other words, should the State have a say in the type of research being done? Should it guide the prioritizing of certain parts of the population over others as research objectives?

A manner, in which the previous questions could be tackled, would be by a sort of ethical principle to accompany the decision making of health systems. In this sense Norman Daniels has argued in favor of a principle that can be applied, both on the matters of the need for aging research and the urgency of care: "[...] meeting the needs of health care is a matter of special importance because it favors equal opportunities. It serves to guarantee individuals a fair option to enjoy the normal range of possibilities of the society in which they live" [24]. Daniels claims, thus, that such code that should lead policy decision making should be one that favors equal opportunities as such condition will work in favor of guaranteeing quality of life.

To point towards this difficult relation between aging and health systems is not meant as a demerit of the achievement from modern health and science, which has signified the rise of the aging population. It is merely a signaling towards the aspects that we should further problematize and analyze in order to grant the possibility for persons over a certain age to continue to be a driving force in society; a matter which depends on our ability to safeguard their dignity [7].

16.7 Conclusions

Ethics is as old as Medicine. However, even though in theory ethics and medicine should be found to go hand in hand, this has not always been the case. Horrific historic instances have showed how vulnerable the human being can be in the name of medical advancement; these moments lead to a better questioning of how to truly

achieve and safeguard ethical standards in research. Declarations and rights have been written and set out with the purpose of protecting the dignity of those who participate in medical research, especially in the case of vulnerable parts of the population.

A particularly vulnerable part of the population is the aging adult, and so, this chapter has also tried to reflect how research can also signify a risk for old age if not done by ethical terms. Given the particular vulnerability of the aging population (frailty, dependence, disability) it is of the outmost importance that ethical standards guarantee the voluntary participation of such individuals in any research and that their dignity is safeguarded all along the process. However, the importance of ethics in aging research does not end there. Any researcher should also be concerned about the consequences of their research and the connotations which it will have in society. Therefore, aging research should pay particular attention to the fact that their research should serve, overall, to better the quality of life of all aging adults with regards to their place in society. In other words, all aging research should treat old age with the respect that they expect society to do so. If any aging research is serving towards the advancement of medicine but feeding into the palpable and worrying discrimination of the old because of negative connotations, we have to ask ourselves, as researchers, how valuable such research actually is.

References

1. Callahan D (2004) *Poner límites: los fines de la medicina en una sociedad que envejece*. Triacastela, Madrid
2. Baars J (2017) Aging: learning to live a finite life. *Gerontologist* 57:969–976. <https://doi.org/10.1093/geront/gnw089>
3. Gracia D (1998) *Ética de los confines de la vida*. Editorial El Búho, Santa Fe de Bogotá
4. Cicerón M (2001) *Acerca de la vejez*. Triacastela, Madrid
5. Laín-Entralgo P (2001) *La empresa de envejecer*. Galaxia Gutenberg, Madrid
6. Gracia D (2008) *Fundamentos de bioética*, 2a edn. Triacastela, Madrid
7. Zúñiga T (2013) *Bioética y calidad de vida en ancianos con demencia*, 1ra edn. Médica Panamericana, México
8. Council for International Organizations of Medical Sciences (2002) *International ethical guidelines for biomedical research involving human subjects*. CIOMS, Geneva
9. Zúñiga T (2015) *Bioética en la investigación con ancianos. Ensayos sobre ética de la salud: investigación Volumen 2: Aspectos sociales*. 1a. ed. Universidad Autónoma Metropolitana, México, pp 83–90
10. Gracia D, Júdez J (2004) *Ética en la práctica clínica*, 1a edn. Triacastela, Madrid
11. Hans J (1995) *El principio de responsabilidad Ensayo de una ética para la civilización tecnológica*, 1ra edn. Herder Editorial, Barcelona
12. Oliver D (2017) How can we plan for old age if we won't discuss it honestly? *BMJ* 357:j2759. <https://doi.org/10.1136/BMJ.J2759>
13. Callahan D (1997) Bioethics as a discipline. In: Jecker NAS, Jonsen AR, Pearlman RA (eds) *Bioethics: an introduction to the history, methods, and practice*. Jones and Bartlett Publishers, Massachusetts, pp 87–92
14. Gracia D (1998) *Hacia un enfoque socrático de la enseñanza de la Bioética. Fundamentación y enseñanza de la bioética*, 1era edn. Editorial El Búho, Santa Fe de Bogotá, pp 45–57

15. Curran WJ (1969) Governmental regulation of the use of human subjects in medical research; the approach of two federal agencies. *Daedalus* 98:542–594
16. Alliance for Human Research Protection. (1962) Dr. Chester Southam injected live cancer cells into 22 elderly patients n.d. <http://ahrp.org/1962-dr-chester-southam-injected-live-cancer-cells-into-22-elderly-patients-at-jewish-chronic-disease-hospital-in-brooklyn/>
17. Declaración de Helsinki de la Asociación Médica Mundial (2013) Principios éticos para las investigaciones médicas en seres humanos
18. Beecher HK (1966) Ethics and clinical research. *N Engl J Med* 274:1354–1360. <https://doi.org/10.1056/NEJM196606162742405>
19. Zúñiga T (2014) Ética y bioética en las instituciones de salud. In: Malagón LG, Pontón Londoño JR (eds) *Auditoría en salud: para una gestión eficiente*, 3ra edn. Médica Panamericana, Bogotá, pp 22–8
20. UNAIDS (2000) AIDS: palliative care. UNAIDS Technical update, Geneva
21. Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries*. Nuffield Council on Bioethics, London
22. Fillit H, Butler RN (2009) The frailty identity crisis. *J Am Geriatr Soc* 57:348–352. <https://doi.org/10.1111/j.1532-5415.2008.02104.x>
23. Gracia D (2004) Ética de la no-discriminación. In: Médicos (ed) *Clínicas Geriátricas*. Editores Médicos, Madrid, pp 259–269
24. Daniels N (1985) Family responsibility initiatives and justice between age groups. *Law, Med Health Care* 13:153–159. <https://doi.org/10.1111/j.1748-720X.1985.tb00911.x>