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Edited by José Antonio Morales-González and María Eugenia Aguilar Nájera

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http://dx.doi.org/10.5772/intechopen.71309
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First published in London, United Kingdom, 2018 by IntechOpen
eBook (PDF) Published by IntechOpen, 2019
IntechOpen is the global imprint of INTECHOPEN LIMITED, registered in England and Wales, registration number: 11086078, The Shard, 25th floor, 32 London Bridge Street
London, SE19SG – United Kingdom
Printed in Croatia

British Library Cataloguing-in-Publication Data
A catalogue record for this book is available from the British Library

Additional hard and PDF copies can be obtained from orders@intechopen.com

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p. cm.

Print ISBN 978-1-78923-218-9

Online ISBN 978-1-78923-219-6

eBook (PDF) ISBN 978-1-83881-559-2

Meet the editors

José Antonio Morales-González carried out his undergraduate rotating internship year at the Hospital de Jesús, México (1995), graduating as Surgeon Physician in 1997 from the FES-Iztacala, National Autonomous University of Mexico (UNAM). He engaged in doctoral studies in biological sciences at the UNAM (2001). Dr. Morales-Gonzalez has been awarded diverse recognitions: the *Alfonso Caso* Medal for Academic Merit by the UNAM (2004); distinguished by the National System of Researchers (SNI) National Researcher level 2 (2017–2020). He is an author of 47 internationally published articles, in addition to more than 700 citations to their publications. He is also an editor and a coordinator of 28 specialized books. Dr. Morales-González is a full-time titular professor-researcher in Escuela Superior de Medicina, Instituto Politécnico Nacional, México.

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Contents

Preface

The book *Reflections on Bioethics* is an effort that brings together works grouped into the following five sections: "Bioethics and Health," "Bioethics and Education," "Bioethics and Technology," "Bioethics in the Use of Experimental Animals," and "Selected Topics of Bioethics." The fundamental concepts of bioethics are approached in each of these sections, as is their relationship with each of these branches of knowledge. The purpose is to deliver to the reader a document of specific themes. It is not intended to be a treaty, in which the study of any of the five sections is very broad. However, this is an endeavor that achieves amalgamating, into the interdiscipline, themes that are basic for professionals in all fields of knowledge.

Themes of great interest that are related with the bioethics of health, such as the theme of bioethical approach to patients in menopause, are presented in the book. This chapter, developed by Dr. Claudia Calzada and her investigation group, addresses clinical investigation, informed consent, the importance of this lifestage to a woman, and how to provide dignified treatment to these patients. The teaching of ethics and bioethics in institutions of higher education is very important because human beings, in their behavior and development within their entire social, familial, professional, and occupational surroundings, should act in a responsible manner, always guided by the principles of iron in ethics and bioethics. Moreover, as students have their formative period at middle-upper and upper educational levels, ethics and bioethics should be taught at this time.

The use of technology at present is of utmost importance for the development of life as we know it. Thus, its direct application in humans, for example, in health, should be employed with unquestionable bioethical principles and, in this fashion, be focused on improving the quality of life of human beings. The use of laboratory animals is highly important for basic investigation and so its usefulness in the clinic for any type of disease or in the search for new knowledge. Due to the latter, all experimentation animals should be used correctly, ethically, and bioethically. Excellent chapters are developed on the theme of bioethics and the use of experimental animals by Drs. Liliana Anguiano and Tomás Fregoso. Each of the themes under this heading of select topics of this book is very interesting and extraordinarily developed.

My congratulations go to each of the authors for their chapters in the book *Reflections on Bioethics*, for their absolute commitment to the "should be," and above all to the ethical and bioethical principles in each of their knowledge fields.

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Section 1

Bioethics and Health

Chapter 1

The Ethical Duty of Physicians to Strengthen Their Own Immunization and Childhood Vaccination

Bruno Rodolfo Schlemper Junior,
Vilma Beltrame and Fernando Hellmann

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.75716

Abstract

Vaccines are one of the most significant discoveries of humanity and are responsible for saving millions of lives around the world. However, their unquestionable successes are criticized and lead to the refusal of parents to vaccinate their children, which causes severe public health problems. There is an ethical duty to adopt various protective measures for the child population, and doctors are considered as decisive actors to help overcome this war. The vaccination rates among doctors and children are very meager, generating a lot of discussion about the implementation of compulsory vaccination for both groups. Thus, medical ethics and bioethics point out some ways for medical professionals to recognize the imperative need for self-vaccination and their patients' sensitization to vaccination, supporting the persuasion of their colleagues and patients. Moreover, the ethical/bioethical principles of the physician's highest duty to protect the society are anchored in beneficence, not maleficence and justice, and they surpass the autonomy right to vaccine refusal. Also, it is expected that the development and dissemination of altruistic ethical values by the physicians can give significant support in the conquest of the "common good."

Keywords: medical ethics, bioethics, vaccination, public health, responsibility, moral duty, altruism

1. Introduction

Vaccination is the medical sacrament corresponding to baptism (Samuel Butler, 1835–1902).

Never in the history of human civilization each person's well-being has been so intrinsically linked to others since plagues and pandemics do not respect national boundaries in a globalized

world, and also, the unprecedented scope and speed of these universal challenges require articulated responses from everyone [1]. Nowadays, we live in a global village and to live "well" we are going to depend on our ethical response to the idea of a single world for us all [2]. Globally, vaccines are considered one of the most significant discoveries of medicine due to the enormous reduction in mortality and morbidity of various infectious diseases, including the eradication of smallpox [3], and also considered the most efficient and cheapest medical intervention. The World Health Organization (WHO) goal is that mass campaigns promote, at least, the protection of 95% of the target population of a given community because only then those who could not be vaccinated are going to receive the benefits of the so-called herd immunity. Bill Gates, who is the patron of numerous vaccine research, said: "*It is a matter of the most basic human justice that we do all we can to extend these live-saving drugs throughout the globe*" [4]. It is true that the vaccine is not free from adverse events and it is not always effective although vaccine denials use arguments without any reason to generate a war of lies, expressed as follows: *a lie will go round the world while truth is pulling its boots on* [5]. As a result of these controversies, the scientific literature is rich in issues related to vaccination such as the incomprehensible low vaccination rates of physicians and other health professionals. Also, the discussion on compulsory vaccination of these professionals and children, ethical analyzes on physicians behavior that do not self-vaccinate, do not guide their patients and refuse to attend them. In fact, medical institutions and public health officials around the world are at war with these movements that are considered as significant perpetrators of new outbreaks in many countries. Thus, in the counter-offensive of public officials, laws, in several countries, are making child vaccination compulsory [6] and health institutions are beginning to require influenza vaccination from their health professionals. The success of global vaccination will depend on maintaining the population's trust in immunization programs, public policy makers and health professionals engagement [7], especially, physicians. In this call for war, it is affirmed: *There's a war going on out there—a quiet, deadly war* [8], and therefore, the war is literally on fire. On the one hand, there are parents bombarded by misleading propaganda about vaccine damage by irresponsible movements. On the other side, there are doctors tired of parents who do not wish to vaccinate their children, and then, they are refusing to care for these families. In the midst of this not-so-silent war, there are defenseless children because their parents are more afraid of vaccines than diseases. Moreover, new groups of parents are concerned about their vulnerable children who cannot be vaccinated for medical reasons [8]. Thus, in the middle of the crossroads, one can ask the doctors of the world: in which side of the trench are they? It is in this war zone that one hopes to contribute to the reflection on some ethical, bioethical and legal aspects related to medical autovaccination and child vaccination promotion, with the aim of sensitizing physicians to stand on the moral side of the trench and externalize their ethical values through effective and altruistic actions. We all have to aspire to excellence in what we do, and the current pursuit of excellence as in Aristotle's time is the first ethics objective and this is the moral obligation of every human being and, especially, of the professionals [9]. Epidemics are lurking because flu virus are unpredictable, continually changing and both H5N1 and H7N9 are the possible origins of a new pandemic [10].

Therefore, if there is a declared war, it will be urgent to identify characters and weapons so that the ethical side of combat will be victorious. Besides favorable public policies, the central characters are health professionals, especially physicians, who are expected to be ethically aware of the need for their immunization against epidemic and pandemic infectious agents,

http://dx.doi.org/10.5772/intechopen.75716

in preparation for war. Then, they should use as powerful weapons the strength of their altruistic examples and ethical and bioethics arguments, in daily battles, to convince the forces against children's vaccination. The present chapter aims at discussing applicable ethical and bioethical arguments so that the global community will be the victorious side in the war for vaccination and the common good.

2. Public health ethics—implications for health professionals

> *Para que la convivencia social sea ordenada y fructífera toda persona debe comportarse de acuerdo con ciertos principios éticos y sociales* (Francesco Torralba, 2016).

There is a health understanding regarding the context influences in which one lives. Thus, health does not mean the same thing for all people because it is guided by cultural, political, religious and scientific values. Actions and care to prevent illnesses prescribed by public health physicians follow health policy guidelines adopted by the government. Thus, such instructions may also be conflicting with the community values and, therefore, they are not entirely supported by the people. Individual health care is characterized by doctor-patient relationship and occurs in the clinical practice since public health focuses on the collective, and its actions emphasize the population health conditions in the prevention of diseases, as well as social, economic and demographic factors that influence health and disease process [11]. The public health goal regards diseases prevention and health promotion to prolong life through the society organized efforts, and then, it operates in four different fields. (1) Health promotion and disease prevention. (2) Risk reduction. (3) Research and (4) Socioeconomic disparities with actions to minimize consequences on health [12]. The public health started more than 100 years ago as an organized field and suffered the influence of several professions [11]. Professions diversity is a real challenge and becomes even more prominent when it aims to turn multiprofessional work into an interdisciplinary practice by taking into account the knowledge of professions involved, and also, by considering the cultural values and population knowledge they serve. Therefore, public health professionals should influence the patients' choices regarding support for therapeutic behaviors or conducts before a specific situation. It is also challenging because may generate ethical conflicts. The professionals' values and population they attend could be different, and professionals need to emphasize the importance of collective actions contained in public policies recommended by governmental institutions rather than actions that prioritize the individual [13]. Often, professionals face, in their daily practice, with ethical dilemmas and their conflicts may be due to the programs they need to develop and are mostly imposed on people without previously discussing their guidelines. Thus, it is up to the public health professionals to convince the community that the programs are beneficial and will achieve the objective of promoting the population's health without causing any individual damages [11]. A clear example is a lack of support to vaccination by the population because they believe that vaccines have more harmful effects than beneficial religious precepts, among others. Many times, the public health professionals need to recommend actions that interfere with people's lives, and therefore, they use the epidemiology knowledge, clinical practice, and guidelines contained in the programs. Undoubtedly, such actions aim to reduce

morbidity and mortality; however, they raise ethical questions regarding the means by which results are achieved. Again, it can generate ethical conflicts arising from knowledge scientific dichotomy and community values in which they operate, and thus, ethical precepts must mediate their decisions. Nevertheless, what moral rules are appropriate to public health decisions? Thus, public health, in addition to ensuring communities' health, also recognizes that individuals' health is linked to their lives in the community, and then, their non-appreciation would lead to the failure of all. That makes decisions regarding health protection and maintenance, which obey individuals' rights and duties, communities and populations, a central and profoundly complex task for professionals that justify the use of proper ethical principles for public health [13]. It is necessary to observe the ethical principles contained in the Ethics Code for Public Health and recommended by the Public Health Leadership Society, in 2002, to assist conflicts solution [13]. Therefore, the code has clear guidelines to standardize ethics issues about research and public health. However, it does not guarantee the professionals' skills acquisition. Then, ethical issues in public health must be discussed and studied continuously with the clarity that there will always be something new to add since such a field presents emerging and persistent ethical aspects.

The Editorial of Lancet Infectious Disease (January, 2018) warns that this month marks the 500th anniversary of the first attempts to control the plague infectious disease in England. However, the recent outbreak in Madagascar reminds us that it is not only confined to the past and many cases continue to be reported in Africa, the Americas, and Asia [14]. Why? Because public health measures have long been underestimated even though they are the most effective interventions regarding public health protection! Without proactive steps, the response will inevitably be reactive and, hence, some delays will result in some degrees of morbidity and mortality that could have been prevented. Many wealthy nations feel complacent about the distant nature of many of these outbreaks. Thus, it is worth remembering that 2018 will mark another infectious disease milestone: the terrible 1918 Spanish flu pandemic [14, 15]. Obviously, vaccines as a means of controlling harmful effects of epidemics are essential tools for humanity. Therefore, all of us, governments, population, health professionals, and others have the ethical responsibility to adopt these effective actions.

3. Vaccination: Between autonomy respect and collective common good

True solidarity begins where nothing is expected in return (Antoine de Saint-Exupéry).

The classical and ethical problem of public health—the balance between the individual autonomy respect and need for measures aimed at the common good of collective life—is quickly glimpsed in vaccination policies, especially, in mandatory vaccination policies. The ethical dimension is present in all decision-making and public policy-making processes. In the case of vaccination programs, it will be necessary to identify individual and collective risks involved to assess whether the prevalence or severity of such risks outweighs potential benefits to the mass to suspend personal freedoms [16, 17]. Indeed, the consideration of respect for autonomy, individual freedoms and the ethical perspective of utilitarianism vis-à-vis the collective common good is an essential reflection for decision-making in the face of mass vaccination. Respect for freedom protects the person's possibility to take control of his own life and live values that are significant to him. Respect for

autonomy relates to freedom respect insofar as freedom protects the personal autonomy expression. Autonomy, which can be characterized by different notions and theoretical approaches, generally symbolizes the "self-government." In other words, according to Beauchamp & Childress, this is the ability to make consistent choises with the values and goals of each person [18].

Some people characterize compulsory vaccination as a freedom violation and, therefore, an autonomy respect violation. Thus, for those who uphold the primacy of respect for individual freedom at all costs and situations, the laws that require acts such as compulsory vaccination would be incompatible with personal liberties. Autonomy and freedom cannot be dissociated from individual responsibility regarding issues that affect our neighbor or community since studies are pointing out that individuals who abstain from vaccination are at higher risk of contracting infections and endangering their communities. The State must respect the substantial autonomy of the citizen, especially, in measures that restrict freedom of choice. Therefore, there are cases in which they may be ethically justifiable to be limited to the vaccines for infectious diseases by using utilitarian and consequentialist considerations. Utilitarianism, in the promotion of public health, provides with ethical justification to support compulsory vaccination campaigns even though such a task violates the freedom and respect for individual autonomy. Utilitarianism bases on the idea that actions are right if they produce the best consequences for the highest number of people. John Stuart Mill points to the utility as a criterion that should guide choices of moral actions and aim to the happiness of as many individuals as possible [19]. The utilitarianism, actually, has a wield significant influence on bioethics and health policy, namely to improve human health as much as possible for as long as possible [20]. Other current trends in Bioethics that have emerged in Latin America such as the Bioethics of Intervention defend as morally justifiable the priority of public policies that result in the best collective consequences. However, to justify the restriction of individual freedoms in the name of collective good, the State must include, in the discussion, the magnitude of personal and community risks, the individual's conviction regarding his beliefs, the possible long-term consequences of decision-making, the best available scientific evidence and transparency in the decision-making process [21].

Any arbitrary decision-making by the State jeopardizes the very sustainability of vaccination policy. In summary, although most analysts believe that mandatory vaccination requirements can be ethically justified, restrictions should only be put into practice after complying with certain conditions to publicly assert the defense of that action [21]. The relevance of ethical considerations in vaccination policies has been increasingly recognized, and the attention to such issues will be essential to the continued success of global vaccination programs in the public good advance and health promotion [17].

4. The physician's ethical duty to autoimmunity

> *You may choose to look the other way, but you can never say again that you did not know* (William Wilberforce).

Initially, it is significant to highlight the references to the *Classic Hippocratic Oath—I will keep them from harm and injustice*, the *Modern Hippocratic Oath—I will prevent disease whenever I can, for prevention is preferable to cure,* as well as the *Corpus hippocraticum where medical art is present,*

love for humanity is also present. The Oath ends with a hope and a threat to the physicians: if he respected this ethical norm, he will maintain a good reputation among all human beings for an eternal time, but if, however, a doctor transgress such oath, it will happen the opposite. All quotations seem to imply the ethical duty that currently applies to the requirements for physicians' vaccination.

On the other hand, Thomas Percival's first Code of Medical Ethics (1803) emphasizes the physicians' duties and warns of the responsibility to society and value of their actions in the community. Such responsibility obliges the physician, necessarily, to give up the traditional individual good, "the good of patient," to the "public good," a reality of which Percival was a spokesperson [22]. Also, reinforcing the above view, it should be noted that the Code contains an article that covers the physician's duties with the public, as summarized: *As good citizens, it is the duty of physicians to be ever vigilant for the welfare of the community, … and in regard to measures for the prevention of epidemic and contagious diseases …* Then, the original AMA Code updates also include that physicians have an ethical responsibility to take appropriate measures to prevent the spread of infectious diseases in healthcare facilities [1]. It also emphasizes that *in such situations, physicians have a further responsibility to protect their own health to ensure that they remain able to provide care.* The AMA used to accept religious and philosophical questions in the vaccine negative; however, in 2015, these reasons were withdrawn and remained only as valid the exceptions of medical order [23]. The current US code, approved in 2016, renewed its principles and reaffirmed the ethical commitment regarding public health with an expressive phrase: *A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.*

The most well-known and most influential international code of current medical practice has been the Geneva Declaration, which is adopted by the World Medical Association (WMA) [24]. In the latest modification, in 2017, in addition to the traditional oath to dedicate his life to the service of humanity, for the first time, it addresses the promotion of the physician's self-care with his health: *I will attend to my own health, well-being …* ethical conduct pertinent to the topic of autovaccines. Therefore, there is no doubt it is an ethical imperative for the physician to be immunized against causal agents of outbreaks, epidemics and pandemics. In modern times, the practice of medicine is inconceivable without the moral responsibility that integrates the medical science itself, present not only in the professional acts performed but also in its omissions [25]. This type of responsibility moral omission is clearly present in situations in which physicians know the benefits of autoimmunization; however, by unjustified failure, they evade their ethical responsibility and do not accept being vaccinated. Thus, vaccination is a gesture of social responsibility of the utmost importance. In the context of social commitments of the physician, it is possible to say that the doctor serves, medicine is a profession and the person who does not serve is not fit to be a physician.

Therefore, the society expects physicians to make commitments to it both as social agents and technicians at the service of humanity, in the form of active solidarity. In this context, not only doctors but every health professional has a moral duty to avoid transmitting diseases preventable by vaccination to their colleagues, family members, and patients. In addition to such ethical duties that corroborate the mandatory vaccination, the most significant justification lies in the exemplary positive attitude physicians convey to their patients and colleagues,

functioning as a motivational force for others to adopt similar attitudes. How is the physician supposed to convince his patients if he does not protect himself against preventable infections? When physicians' obligatory vaccination is analyzed in light of the classic bioethical principles some findings support that attitude. Then, Beauchamps and Childress state that there are some moral rules regarding positive beneficence [18]: (a) to protect and defend other people's rights; (b) to prevent others from being harmed; (c) to eliminate conditions that will cause harm to others; (d) to help unsuitable people and (e) to rescue people who are in danger. All these moral rules are against the ethical justification that prevents medical refusal. The utilitarian benefit of mandatory vaccination is to reach the threshold percentage of vaccinated individuals required to achieve the herd immunity, according to Field and Caplan [26].

Regarding the physician's autonomy defense, it would be ethically acceptable if his attitude did not cause harm to himself or others, but the exercise of his autonomy in the present situation diminishes to the extent that the refusal may allow his illness or facilitate the infection spread to others [26]. The Supreme Court of the United States recognized for over 100 years that individuals could be subject to multiple restrictions such as submitting to a mandatory vaccine for the benefit of the "common good. At the same time, it is pointed out that defending autonomy does not only mean having freedom of action and rights but also assume responsibility for the consequences of his acts and omissions [27]. Regarding the principle of justice, the reasoning would be similar to that of autonomy because if the severity of a disease increases the public's interest in getting a universal access to a vaccine, it will also grow against it. Therefore, it raises the justice principle importance as the ethical basis for obligatoriness [26]. The ethical consideration of non-maleficence that addresses the risk of adverse drug-use events [28], should not even be discussed since vaccines benefits are so much higher than damages risks [18]. In summary, it is verified that when the seriousness of the disease is severe, contagiousness is high and the vaccine safety is unquestionable, also, there is a prevalence of interests in beneficence, utilitarianism, justice, and non-maleficence that surpass the respect for individual choice (autonomy) [26]. It allows concluding that for the public health is not significant to know what value must be respected but how they should be weighed against each other and for the community's benefit.

4.1. Compulsory vaccination of health care works

Knowing is not enough; we must apply. Willing is not enough; we must do (Goethe)

Health professionals (HCWs) are at increased risk of acquiring vaccine-preventable diseases, and then, the purpose is to protect them from occupational exposure and prevent the spread of infections to susceptible patients. According to several medical institutions, the HCWs should be vaccinated, at least, against influenza (annual), measles, mumps, diphtheria, varicella and pertussis, and also, those potentially at risk of contact with blood and secretions should receive the vaccine against Hepatitis B [29]. Despite these recommendations, studies continue to demonstrate that the goals are far from being achieved and many of them refuse vaccination. In the United States, the vaccination rates of these professionals varied from 13 to 83% [30]. They were less than 50% between 2003 and 2008 [31] and only 61.9% in the 2009–2010 pandemic [32]. Currently, as a result of the adoption of US public policies, more than 200 Health Institutions have turned vaccination into mandatory, and state law-

makers are beginning to enact laws requiring the HCWs vaccination. They are backed by the Supreme Court that gave the states the power to impose obligatoriness. Some studies in several European countries have revealed absurdly low rates of vaccination of health professionals of 6.4, 15, 25 and 26.3% [33] and even after nine consecutive years, the highest rate was 56% [34]. Compulsory vaccination in Europe is adopted by a few countries, and even then, for very limited indications. After three decades of official recommendations against influenza, the vaccination rates remained below 30% in Europe (**Table 1**).

Therefore, it is time to consider the mandatory vaccination policies for these professionals [35, 36]. This recommendation was approved by 63% [37] and by more than 98% of them [36] and the physicians accepted it better than nurses and other professionals [37]. Similarly, reduced numbers of vaccination of such professionals were reported in China and Australia, with less than 5% [38] and 22% [39] of influenza vaccinated professionals, respectively. There are several reasons explaining why these professionals avoid vaccination: (a) do not want vaccination; (b) the vaccine is unnecessary; (c) the vaccine is not effective; (d) it may cause adverse events; (e) it may cause influenza; (f) the risk of contracting the disease is low; (g) inadequate time and place of vaccination and (h) fear or aversion to needles [32]. Then, some motivational factors were identified such as the influence of other employees, managers' performance, incentives for vaccination and vaccine accessibility [33]. Several strategies have been developed in some countries to encourage voluntary influenza vaccination in health professionals (promotional and educational campaigns, reports, immunization follow-up, and recommendations), but none with a significant impact on the overall coverage rate. However, vaccination offer in the workplace has produced a more efficient result than other isolated measures. This comes to the observation that inadequate vaccine time and location were considered as a significant barrier to influenza vaccination, and it was one of the reasons for non-vaccination as reported by up to 59% of health workers [32]. There has been a tendency to recommend and accept more stringent measures such as compulsory vaccination as a result of these alarming numbers for human health [30, 31, 34, 40–44]. It should be added that ethical responsibility does not belong only to health professionals but also to each health institution, so that obligation constitutes a new care standard [45]. Some observational studies concluded that mandatory vaccination against influenza increased the vaccination rates to levels around 94% [43].

At the beginning of the nineteenth century, persuasion was considered to be more significant than mandatory. Today, the severity situation demands more extreme and protective measures. Regarding the physicians' refusal for vaccination, more radical measures such as compulsory vaccination and loss of employment have been implemented in several developed countries with the support of the Legal Power, medical entities, and bioethicists [46]. Caplan [47], an American bioethicist, when defending the mandatory vaccination against influenza from health professionals, contrary to the right of autonomy, asks: Rights? The right to infect your patient and the right to cause harm to the people involved in health care? The right to ignore all safety evidence and vaccine efficacy? Or the right to spread unreasonable fear to the public about better protection for babies, pregnant women, the elderly, and vulnerable people against the flu? These rights? It is time to put the patient's priority interest and recognize the professional duty by making vaccination of health professionals against influenza mandatory [41]. The main argument in favor of compulsory vaccination regards codes of

Author	Study year	HCW/observation	Country	Vaccination rate
Weingarten [80]	1986–1987	Nurses. Housestaff	United States	3.5%
Cui [81]	1996–1998	Staff of 43 nursing homes	Hawaii	38%
Haviari [82]	1990–2014	Doctors, nurses, midwives of primary care, hospitals, tertiary care (>90,000 HCW in 62 studies). Higher in USA and lower in Europe	25 countries	<5% in India to 82% in USA 40 studies with <50% vaccinated
Babcock [49]	1997–2006	25,980 active employees.	United States	1997–2006: ~35–41%
	2008	In 2008, vaccination was a condition of employment for all		2008: 98.4%
Russel [83]	1998	Staff of 136 nursing homes in Alberta	Canada	29.9%
Murray [84]	2000	269 staff of teaching hospital	Australia	48%
O'Rorke [85]	2001	228 staff of acute-care hospital	Ireland	17.5%
Canning [86]	2003	Acute-care hospitals, Liverpool	United Kingdom	7.6%
Stewart [32]	2004–2010	HCW	United States	2004–2005: 35.5%
		2009–2010 (H1N1 pandemic)		2005–2006: 41.8%
				2006–2007: 44.4%
				2007–2008: 49.0%
				2009–2010: 61.9%
Semaille [87]	2006	688 general practitioners	France	67.0%
Quian [88]	2006–2208	Physicians, nurses, and others.	Uruguay	2006: 24%
		2006: 286 HCW; 2007:?		2007: 31%
		2008: 300 HCW (after information and promotion actions vaccine)		2008: 55.3%
Seale [39]	2007	Hospitals allied health staff and ancillary staff, doctors, nurses	Australia	22%
European Centre [89]	2007–2008 2014–2015	The highest vaccination coverage rates were in UK (except Northern Ireland), Hungary and Romania	Europe (17 countries)	2007–2008: 13.4–89.4% 2014–2015: 5–54.9%
		The vaccination of HCWs is voluntary		
Rehmani [90]	2008–2009	502 hospital health care workers	Saudi Arabia	34.4%
Silveira [91]	2009	64pediatric residents of tertiary general hospital. Federal University of São Paulo	Brazil	3.1%
Vieira [93]	2009–2011	265 nurses, technical nurses, auxiliary nursing of a university hospital to get vaccinated after adequate operational/ educational strategies	Brazil	2009: 49.8% 2010: 92.4% 2011: 95.4%
Giannattasio [92]	2009 (H1N1)–2012	206 Physicians, residents, nurses, paramedics) of three Academic Departments (Infectious Diseases, Pediatrics, Gynecology/Obstetrics)	Italy	2009: 33.5% 2010: 15.0% 2011: 15.5%
		138 (67%) never been vaccinated		2012: 7.8%

Author	Study year	HCW/observation	Country	Vaccination rate
Domínguez [94]	2012	1749 primary HCW (family physicians, pediatricians, nurses)	Spain	50.7%
Alicino [34]	2013–2014	Teaching hospital in Genoa, tertiary adult acute-care reference center (1300 bed). Despite almost a decade of efforts, the vaccination coverage rates was very low	Italy	Physicians: 30% Nurses: 11% Other clinical personnel: 9%
Song [38]	2013–2014	All HCWs providing direct patient care at 10 healthcare institutions.	China	5.0%
Jorgensen [95]	2014–2015	All member states, except Denmark, with an influenza immunization policy had national recommendations for vaccination of HCW against influenza in 2014/2015. The survey was by email for the national immunization programme under the Ministries of Health	26 countries (Europe Region)	From 2.6% to 99.5%; median 29.5%. The majority of countries reported rates <40%
Black [96]	2014–2015	Health Care Personnel:	United States	77.3%
	2015–2016	2014–2015: 1.914		79.0%
		2015–2016: 2.258		
Public Health England [97]	2016–17	594,700 HCW	England	2016–2017: 61.8%
	2017–18	641,600 HCW		2017–2018: 63.9%

*Adapted from Weber and Rutala [29].

Table 1. Flu vaccine coverage in health care works (HCW) reported in the literature*.

ethics of physicians, nurses, nursing assistants, social workers, pharmacists and other health professionals who declare that patients' interests should prevail over professionals' ojnes [47]. The first ethical principle is not causing harm to others and, therefore, professionals must be vaccinated compulsorily since maleficence, whether intentional or not, is unacceptable [48]. Secondly, they must protect defenseless and vulnerable patients. In conclusion, mandatory vaccination against influenza should prevail over personal choices and, even more importantly, it is ethically significant that physicians give good examples when vaccinating as they can influence their patients' vaccination [47]. An increasing number of US hospitals require health professionals to vaccinate against influenza and other infectious diseases to protect their patients [49]. Therefore, obligatoriness should be preceded by a comprehensive educational program for current professionals, and new HCW understand that vaccination is an indispensable condition of employment [31, 46]. Vaccination is considered as a privilege and not an obligation, and those who do not wish to have the vaccine should consider the consequences of this act and know how to bear it, remembering that preserving public welfare and reducing diseases are important values [50]. Mandatory influenza vaccination for all healthcare works is ethical, just, and necessary to improve patient's safety and it is a crucial step in efforts to reduce healthcare associated with influenza infections [51]. When a person starts working at a healthcare institution as a professional, he has certain obligations and one of them is to take precautions to protect patients against infections. Only in the United States,

from 3000 to 49,000 deaths are attributed to influenza each year, and influenza vaccination is a significant method for reducing flu deaths [52].

The leading US medical organizations (Immunization Action Coalition) signed a document entitled *First Do No Harm: Mandatory Influenza Vaccination Policies for Healthcare Personnel, Help Protect Patients* [53]. This document was signed by medical leader organizations and additional professions groups claim that mandatory influenza vaccination for all healthcare personnel is imperative! Refer to the position statements of these medical organizations to guide and implementing a mandatory influenza vaccination policy at healthcare institution or medical setting. Then, the following conclusions can be drawn from these data: (1) the arguments in favor of compulsory vaccination against influenza from health workers to patients' safety are ethically, scientifically and financially attractive; (2) the misconceptions and lack of knowledge about influenza vaccines are persistent barriers to a better coverage among health professionals; (3) education alone has not been sufficient and (4) successful programs require the use of multiple strategies including training, incentives, accountability and a strong commitment at all levels [54].

4.2. The pursuit of altruistic attitude of doctors

Advice is judged by results, not by intentions (Cicero).

According to Comte (1798–1857), altruism is the tendency or inclination of an instinctive nature that incites the human being to concern with others, and it is one of the significant reference points for the choice of values in bioethical deliberation. The book Bioethics refers that the technical and biological term for people who take care of others, without thinking about themselves, is altruism and there is a moral sense allowing humans to do that. It is a metaphor—it does not necessarily mean the altruism that one refers when speaking of a right person [55]. Altruist people can assess different or changing situations and it is an act performed in the best interest of others and also for them. Therefore, human beings need the capacity to respond to such changes, especially those developed by other persons. The evolutionary theory offers the altruism origin explanation and other moral sentiments. Thus, social animals such as humans require the ability to help each other and, at the same time, reduce conflicts within the group. Then, persons that take their obligations with others seriously are more stable, work together in harmony and such patterns of behavior result from biological evolution [55]. On the other hand, it is understood that morality is an important dimension of ethics and to do what I must to others is part of living well and a characteristic of this century is the increasing recognition of each one's moral obligations to others [56]. According Appiah, honor is one important cause of the moral progress, in guiding us to a better future.

Selfishness is an opposed concept in which the unlimited love that a person feels for himself leads to serve his interests exclusively. It is a conduct characterized as narcissistic ethics [57]. The issue on "how to be good" differs from "how to do it right" since the good nature is the obligation to do all the good we can, considering all things and making the world a better place because being good is essential for ethics. These individual obligations and responsibilities constitute the moral arguments of our human condition to do good [58]. The central point of compulsory vaccination can be supported by people's moral responsibility, in the

understanding that self-vaccination of health professionals and other members of the community will also help in the protection of others. It is possible to make an analogy with organs donation to exemplify the situation since Singer [59] calls such action as an altruistic act that portrays the human moral obligation to others, especially the less fortunate. This act can be considered an insignificant sacrifice to save or protect another human life [59] and, by analogy, the health professionals' self-vaccination can also be understood as an altruistic action. Altruism can be defined in many ways, and a useful distinction for our purposes is between the behavioral and motivational definitions of the term. Motivational conceptions of altruism are identified with the medical attitude to self-vaccination because they are internal psychological states that produce altruistic behaviors and actions carried out by a person who wishes to contribute to the well-being of another person.

Thus, the behavioral definition of altruism, by contrast, focuses exclusively on the costs and benefits of action for the person in question. Many defenders of altruistic action consider altruism as a significant virtue with a combination of reasons in which there is a genuine desire to help others and a desire to improve their quality of life. It is precisely the altruistic sense that one wishes to mobilize and stimulate for the physicians' autovaccination. Yet, by exploring altruism a little more, there is a distinction between restricted and expanded altruism. The first includes only doing good to the closest ones like family and friends, while the second also includes, besides them, strange people. Therefore, self-vaccination medical altruism clearly identifies itself with the expanded form of doing good for others, benefiting physicians, family, and patients. Then, by analogy with the example of organs donation, it is expected that physicians' attitudes towards autovaccination will also expand in these professionals since effective altruism, which has Singer as one of its creators, is a breakthrough in people's ethical behavior. The effective altruism focuses on the attainment of goals, that is, on the vision of consequentialist ethics and as an ethical proposal for the contemporary world [60]. Here, it is reiterated that autovaccination is not an extreme procedure but the attitude is also a good for others, and it is done autonomously for the benefit of strangers. It is also possible to believe that parents who hesitate to vaccinate their children may be motivated by the altruistic action of their doctors and in the exercise of a selfless attitude they will be protecting their families. Effective altruistic actions performed by a large number of people can demonstrate an unimaginable power capable of contributing expressively to the common good ("The Most Good I Can Do"). However, the altruistic motivation is still an open field for investigations as it has not yet been considered in epidemiological studies on vaccination decisions or vaccination projects [61]. Thus, a higher dissemination of information combined with more precise guidelines on altruistic actions (and potentially specific of the vaccine) from health professionals and the general population may leverage towards the objectives of the vaccination policy. Therefore, the same situation regarding organs donation in which attitudes are changing and donations are increasing, altruistic behaviors are identified in large part of the population [59]. When the physician is committed to his work beyond the financial part, he is practicing altruistic attitudes. They are considered ethical virtues that imply a personal commitment and a consistent motivation with the essence of the medical profession, which means they will be at people's service. Of course, wealthy nations will need to decide if they are going to fund healthcare beyond their borders because by now, they will be familiar with the self-interested altruism argument [14]. In conclusion, the best assessment is that the evolutionary biology has

brought many new insights to the thinking about human life, including human moral nature. In the present situation of vaccination, it is worth believing that the act of taking vaccines by the healthcare workers means helping without expecting any rewards.

5. The ethical duty of physicians to vaccinate children

> *Parents can't do everything, but when you have the power to prevent something from happening, you do it!* (Cheryl Lieck, a mother)

Physicians should take advantage of the meetings with patients to educate them on how to minimize health risks and, thereby, fulfill the obligations to promote the patient's well-being and contribute to public health improvement [62]. Ethics is not individual. It is always relational whether in group or collective; therefore, it is possible to affirm that all thinking beings have ethics. Thus, if a person acts for his benefit and causes harm or damage to other people, it can be said that is a wrong attitude, narcissistic ethics or, in other words, an ethics whose value and the principle of solidarity and fraternity are not present [57]. It is the real situation regarding vaccination discussion and the conduct of those who refuse to vaccinate. It is called "Convenience Ethics," which contrasts with the "Ethics of Dignified Collective Life" or "Capital Ethics," which is a life protection ethics of the collectivity and one of the most robust ethical values of our human condition to live in a community [57]. Therefore, aiming at the search for the common good it is possible to justify the need to call the attention to such physicians' ethical commitment, which is anchored in the worldwide concern of reducing the vaccination rates of children. Every single study, on a worldwide scale, highlights that health professionals, especially physicians, are considered by parents as a primary and reliable source of information on childhood vaccination [63–66], and pediatricians and family doctors are more capable of convincing parents to make a decision. It is worth saying that it is the physicians' ethical duty to fulfill such a task by exploring their level of knowledge about vaccines, their underlying values and beliefs about immunization [67], highlighting, above all, the social reach of mass vaccination and possible consequences for other children if all parents refuse to vaccinate them.

In the face of a possible conflict and from the ethical point of view, the physician should deliberate with parents to show individual and community benefits such as herd immunity, so that parents can understand the risk that would arise if all mothers had the same negative behavior [68]. Thus, the Spanish bioethicists point out that after the information in the deliberation process, the next step is persuasion as a clinical and ethical resource that cannot be confused with manipulation or coercion because they are unacceptable. According to the circumstances and in the face of common good and autonomy conflict, it is quite ethical to consider that those responsible are ill-informed and it is not morally admissible or respectable to exercise autonomy based on error and irrationality, especially, when such a conduct entails a risk for other people's lives [68]. In other words, physicians should try to persuade resistant parents and remind them that vaccine is not a medicine that only benefits those who use it but also protects the individual against certain diseases, including his family members and community. After these attempts, if the refusal to vaccinate their children persists, physicians may try the

following alternatives. (a) Accept the rejection and merely conclude the consultation with the phrase "it is your choice;" (b) adopt other measures of social pressure such as the requirement of vaccination by schools and kindergartens, and (c) abandon the patient and refuse to attend that family. Which of these measures would be the most ethically appropriate? The first one, in which the professional considers himself defeated and leaves the decision to the parents knowing they will not vaccinate their children? The second form of referral, even though does not depend on the professional since he must follow the institutions' requirements and legal norms? And the third option, no longer to attend the family? The latter is going to be treated in a specific topic. It is possible to notice that numerous measures adopted in several countries use different strategies to overcome the declared war against the undecided people.

One of them, considered by some as a stimulating measure for vaccination, is the implementation of compensation programs for damages by vaccines. Such a program has been increasingly used as a component of vaccination programs for more than 50 years. Recently, a restrictive measure was adopted by the American Academy of Pediatrics recommending health institutions to eliminate non-medical exemptions in refusing vaccination because in the past 20 years the number of non-medical exemptions for school students, in the United States, has nearly doubled for philosophical or religious reasons, especially the first one. Then, coercive actions can be taken by the state, which has the responsibility to protect its citizens.

Thus, the adoption of restrictive measures of freedom such as isolation and quarantine can be ethical justifications [69]. Also, the European Convention on Human Rights, among the exceptions provided, allows the legal detention of persons to prevent the spread of infectious diseases. Several European countries have adopted punitive measures penalizing those who refuse to vaccinate their children. Italy is the most recent example. The country's Supreme Court of Justice has made compulsory the use of vaccines for children and adolescents, allowing the executive power to impose fines on these parents and prevent their children from attending public schools. Recently, 27 French medical entities have launched a public manifesto supporting compulsory vaccination of children with the condition that the phase is transient until population confidence and health professionals are restored, and then, it should be voluntary again [70]. These measures have been implemented with the focus on parental responsibility and anchored in the principle of justice because it is intended that they authorize their children's vaccination with the perspective of community protection [71]. Finally, confidence-building strategies in health institutions are vital to increasing public acceptance as well as disseminating information on vaccine safety and efficacy.

5.1. The refusal of physicians to attend parents who refuse to vaccinate their children

Hell isn't merely paved with good intentions, it is walled and roofed with them (Aldous Huxley)

As a result of persistent refusals by parents to vaccinate their children, even after physicians' recommendations, a new challenge arises among professionals, especially for pediatricians, such as to avoid attending children in these situations. The subject is worrying. In the United States, 25% of pediatricians would refrain, at some point, from attending families under these conditions, while in Europe 9% of pediatricians supported such a decision and 27% of them

would do so if there is a refusal for all vaccines [72]. This practice more than doubled between 2006 and 2013 among the US pediatricians [73], despite recommendations to the contrary from the CDC and AAP. The following arguments are presented to justify that medical attitude. (a) It could configure a professional unethical act; (b) represents an insurmountable difference of values between parents and professionals; (c) families with unvaccinated children constitute a danger to the clinic staff and other patients; (d) their counseling requires a lot of time from the physician and (e) they do not want to be responsible for vaccine-preventable infectious diseases of their little patients [74]. Under such circumstances, how should the physicians get prepared to fight epidemics and how to act on their obligations, responsibilities, rights, and values? [75]. Thus, is the physicians' reaction ethically justifiable? When analyzed in detail, it is worth noting that a renunciation behavior is not consistent with physicians' ethical obligations and none of these reasons are sufficient to support such a decision [72]. The AMA does not recommend this procedure because it is unethical to abandon the patients. The physician has the ethical commitment of beneficence and non-maleficence and this decision does not meet the best interest of the child (charity) since persisting the non-vaccination can make the physician responsible for possible harm (not maleficence) [73]. Remember that the most reliable source of vaccine information for parents is the doctor himself [76, 77].

It is also difficult to consider the physicians' attitude as a conscience objection of parents' immoral act because against that decision arises the principles of public health in which children could be a source of infection for others, in case they acquire a disease preventable by the vaccine [78]. Therefore, it is necessary to strengthen the relationship with parents, especially the families with low educational or socioeconomic levels [79]. As a guideline for the clinician in these pediatric care situations, an alternative could only occur in the following cases. (a) To exhaust all means of education with the family; (b) the family is informed of the physician's decision; (c) the geographic region is not in need of pediatric doctors and (d) he must continue to promote health care until the family finds another physician who agrees to provide care (usually 30 days) [78]. In extreme cases, some families will refuse vaccination regardless the method of communication used. In that case, the physician's reluctance may be an option accepted by the American Academy of Pediatrics since another physician agrees with the conditions and continues with medical care [67].

6. Final considerations

Sin ética no hay futuro posible, ni a nivel local ni a nivel global (Martinet de la Cerdanya)

Currently, it is acceptable to say that without ethics there will be no possible future in the world, and then, everyone must be aware of his duties and responsibilities to himself and the humanity's future. Therefore, it is essential that everyone helps each other since we live in a community, and it is also necessary to have a profound reflection regarding our behavior, attitudes, and acts that may help or cause harm to others. Such scenario of concern for public health fits very well with the physicians' vaccination issue and children of our planet in understanding their social role of protecting as many people as possible against the reemergence of old infections. Thus, it is the physicians' ethical and moral responsibility to act favorably in

gaining parental trust, and then, the best way to do that is to give their example by being vaccinated and explain that to the patients because they influence parents' decisions to authorize children' vaccinations. Moreover, the professionals need to have sufficient knowledge about proposed vaccination regimens, efficacy and possible adverse events that are essential for an adequate and honest orientation to their patients.

Then, abandoning the families whose parents resist authorizing the vaccination of their children is not an ethical conduct. It is worth emphasizing that one way of increasing the physicians' importance is to unleash their altruistic spirit, and then, as a fundamental bioethical reference, they can contribute in a striking way to the objectives' achievement. Therefore, the binomial of physicians' vaccination and childhood vaccines promotion are ethical duties and sisterly attitudes, and they are indispensable to make the ethical side of this war win in the name of human welfare and with decisive physicians' participation.

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Chapter 2

Bioethics in Critical Care Patients

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.75565

Abstract

Intensive care unit is a special medial environment for many reasons (the severity of the patients, the important technological advances). In recent years, the medicine has changed to a more focused practice on the patient, leaving behind the paternalistic medical approach, with a transparent new relationship with the patient and his family. The ethical principles-autonomy, beneficence, non-maleficence and justice-and the possibility of conflicts between them make decision-making very complex. The admission of these patients in our unit is justified based on a triangle-acute, severe, and recoverable disease-trying to optimize their treatment. Unfavorable later evolution is possible; a palliative management can often be considered, changing the patient's approach from the cure of his illness to the relief of his symptoms. Decisions about patient's future must be jointly made by the health care team, the patient and his family. We must look for documents about previous instructions and/or opinion of a substitute decision-maker. We must humanize our units, thinking about the best care for the sick person and his family, and improve the support to the family after his death. Therefore, the development of practice guidelines on palliative care should be promoted by the hospitals.

Keywords: bioethics, intensive care unit, patient's best interests, withdrawal treatment, withholding treatment

1. Introduction

The important advances made over the last decades in the field of critical care have led to an increase in survival and an increase in prevalence of chronic diseases. This in turn has focused growing attention on end-of-life care.

A significant number of patients (a value close to 10%) die in the intensive care units (ICU) [1]; in many of them, the so-called limitation of life support therapy (LLST) is carried out either because it is not possible to offer a curative treatment or because the patient expressly refuses to undergo further tests or treatment.

Spanish studies indicate that the limitation of life support is made between 10 and 12% of the patients admitted to the ICU [2, 3]. The current vision of intensive medicine is more focused on the patient's well-being and autonomy, in contrast to the older, more paternalistic one, that is, focused on the doctor and his decisions [4].

2. Ethical principles and decision-making

According to the principles of good medical practice that emanate from the recommendations of the Collegiate Medical Organization [5], the doctor must act in the best interest of the patient. The ethical framework for decision-making includes four basic principles, and religious and cultural issues are intimately related to their interpretation.

2.1. Principle of autonomy

Autonomy is the right that people have to make their own decisions regarding their health and illness in the absence of coercion and with the necessary information. It means knowing all the available treatments options and the possible consequences of their use of the fact of inhibiting their use. Underlying this principle is the importance of informed consent (IC) for any procedure.

This principle does not oblige the doctor to administer a treatment against his opinion due to the fact that the patient requests it. The intensivist on the other hand must administer the treatment that offers the greatest benefit to the patient, the least harmful, providing all the necessary information and obtaining the IC.

If there are doubts about the patient's ability to refuse treatment and there are no anticipated decisions, life support should be offered until the issue is clarified.

Consent for a treatment may not be sought in an emergency situation, if this treatment is necessary to save the life of the patient or if it prevents or can prevent serious harm.

2.2. Principles of beneficence and non-maleficence

It refers respectively to benefit the patient in the first place and to avoid physical, psychological, or moral damage in the second. All these followed the old Latin aphorism "primum non nocere". The risks and the potential benefit or each intervention should also be weighted in intensive therapy. In case of doubt, the intervention of the family could clarify what are the best interests of the patient. If still, there is no agreement, the participation of the Bioethics committee may be useful to define the case.

The intensivist must always pursue the best interest for the patient, and this does not necessarily mean saving his life, in cases where, for example, the prognosis is bad and the "cost to pay" is extremely high in time, resources and suffering of the patient [6].

2.3. Principle of justice (distributive)

Health professionals, patients, and their families share responsibility for the distribution of community resources for health problems. These resources are limited and should be used judiciously. The medical staff and the patient, and their family, should keep in mind that responsibility also concerns them. The management of the services provided by the health system must be careful, it must include respect for the individual decisions of the patient, and resources must be maximized. Resources should not be so scarce as to justify preventable deaths. The population should be aware that ICU beds are limited.

2.4. Principle of patient's best interests

It constitutes the sum of the principles of beneficence, non-maleficence, and autonomy; i.e., the patient's best interest is pursued if the doctor acts to benefit the patient, avoids the damage, and takes into consideration, together with the apparent prognosis of the patients and his favorable or not favorable response to the treatment, his wishes, values, and objectives, depending on the clinical circumstances of the case. This is paramount because the patients´ perception of what is best for them sometimes differs from the doctor's opinion. Every patient whose decision-making capacity is intact has the right to accept or refuse the treatment proposed by the medical team. Sometimes the best interest of the patient will be achieved with the withdrawal or not starting (withholding) treatment.

The role of the intensivist doctor is also relevant in end-of-life situations, because they are well acquainted with the natural history of critical pathology, such as the treatment options available in the ICU, as well as the risks and complications.

The sources of information that the intensivist doctor reviews for this transcendent decision-making are the medical history, anticipated decision-making, or the point of view of the parents, relatives, or legal guardian. In emergency situations, in which the wishes of the patient are unknown and there is no other source of information available, the available support maneuvers must be initiated until the situation is clarified.

2.5. Conflicts between bioethical principles

Bioethical principles have two levels: first level, public or collective (Justice and Non-Maleficence) and second level, private or individual (Beneficence and Autonomy). If there is a conflict between these principles, first level principles have priority; that is, the second level principles are mandatory if they do not conflict with those of the first level [7]. There may be conflict between bioethical principles from the point of view of patients between what they expect as a population (Distributive Justice) and what they expect at the personal level (Beneficence and Autonomy).

The intensivist also experiences conflict between his duties toward different patients outside and inside the ICU. The limitation of resources (available beds) may mean that the treatment that is desired to be administered or that is believed to be beneficial for the patient cannot be administered. Health resources must be localized so that they provide the greatest benefit to a greater number of patients. If the ICU is full, it may be necessary to transfer the patient to another hospital. When the intensivist must choose between patients, the priority should be those patients with the highest probability of benefit for admission to the ICU. The intensivists must perform reasonable actions (with the capacity to justify them) and with responsibility (clear knowledge of their obligations and knowing that the consequences of the decisions fall on them).

2.6. Cultural and religious issues

The relationship between the four bioethical principles can be modified by religious and cultural views of the patient and the doctor. The intensivist must respect the perspective and values of the family, and even sometimes he/she should look for someone with the capacity to interpret these topics that help to solve problems that fit in the perspective of the patient and his/her family. For example, it must be explained in a brain death situation that the brain has died, although the different point of view of the family should be accepted, and must explain that the heart will stop shortly afterward.

2.7. Removal of the treatment (withdrawal) and non start (withholding)

From a philosophical and ethical standpoint, there is no difference between these two options. This means that, if all the circumstances to be assessed in the decision-making are equal and if it is ethical not to initiate a treatment to patients, it would be equally ethical to withdraw it if already begun. Not initiate or withdraw a treatment, which the intensivist thinks is not helping the patient, is not killing the patient, but the evolution of the disease is influencing the poor prognosis. In spite of everything, many doctors consider that not starting a treatment is different from withdrawing.

If the patient has expressed clearly (though not in writing) his desire not to continue or initiate a particular treatment, the intensivist is obliged to follow the evolutionary course of the patient as a continuation of that desire [8]. When the wishes of palliative care by the patient agree with good medical care, there are sure reasons to withdraw the treatment.

Some circumstances surrounding the decision of withdrawing or withholding may be different; i.e., the first option is more frequent with the ICU, while the second one is usually outside the ICU. Sometimes, the chosen option may be a trial of treatment of limited time, proposing from the beginning to withdraw it if ineffective in this period; this plan allows collecting additional information about the patient's situation. If the intensivist does not have a clear option to withdraw a treatment, he should ask a question: knowing what he knows about the patient, would he enter the patient in the ICU and start an invasive treatment? If the answer is negative, the treatment should be withdrawn.

If the family is reluctant to withdraw a treatment, it may be useful to negotiate an initial agreement on not escalating the treatment if there is no improvement or to continue treatment

for a limited period with defined expectations for certain outcomes (consensus building), insisting on interrupting painful and unpleasant treatments because they do not cause benefits. It is useful to redefine the objective of treating the patient in a positive way, insisting on treatments that can help him/her more than those that do not help him. The best way to establish the patient's best interest is the doctor's conversation with the patient (when he/she can express him/herself) and his family [9].

This point is crucial because it constitutes the cornerstone in determining the best interest of the patient, especially if he has no ability to express himself. In short, if the doctor thinks that a certain treatment will not bring significant benefits to the patient, the one that does not initiate or suspend is irrelevant. What is really happening is that the natural history of the disease is acting.

There may be different points of view about what life means. Some people think that the value of life is infinite; others think that life has value only if it has quality. For those who have the first point of view, the agreement on withdrawing or not initiating a treatment may be difficult to achieve.

3. Legal framework: End of life care

The juridical international framework focuses on two reference elements in Bioethics: the Agreement on Human Rights and Biomedicine (Council of Europe 1997) [10] and the Universal Declaration on Bioethics of the UNESCO in 2005 [11]. Both standards recognize the right to decide, after appropriate information, by people, who can voluntarily decide for themselves which treatments or interventions they accept or reject. Legality has evolved to give priority to the principles of autonomy freedom, equality, and respect for sanctity—inviolability of human life. Adults able to decide can refuse treatment even if this is danger to their life. On the other hand, they have the right to effective communication to make the decisions they consider appropriate and to an informed choice.

The planning of early decisions, or advanced care directives (ACD), and a substitute decision-maker could also help to a patient that cannot make a decision.

The options of withholding and/or withdrawing supportive therapy are considered legal and appropriate in circumstances in which there is a valid recess of such treatment, either because the patient requests it or because the doctor considers that such treatment does not pursue the best interest of the patient. On the other hand, euthanasia, or assisted death, defined as those situations in which the doctor administers or removes substances in order to end the life of the patient or shorten it, is not legal under any circumstance in our current legal framework. An act is criminal according to the underlying intention. If a treatment is administered, a foreseeable shortening of the patient's life may occur, although that is not its purpose, and it is legal if its goal is not to shorten life (doctrine of "Double Effect"). That is, death is expected but not persecuted by that action. Intensivists should not use the term Euthanasia, and they should accurately describe the actions they carry out, such as removing ineffective and burdensome treatment and initiating palliative treatment.

It is essential for intensivists to familiarize themselves with the legislation in force in each territory in which they practice medicine. In some places, it is mandatory to have consensus with the patients or with the substitute decision-maker, to withdraw or not initiate a treatment, when it is thought that these do not pursue the best interest of the patient. The doctor who ignores a patient's desire to suspend a certain treatment (even if thus puts his life at risk) risks criminal prosecution.

By the other side, it is not true that the patient has the right to demand a certain treatment that he considers appropriate if the doctor does not agree with him.

When there is no agreement between intensivist and relatives, the case may be referred to the court or to the Supreme Court. The decisions made in accordance with the patient, especially if they are directed to their own benefit, must be well documented and sometimes even commented with a psychiatrist. If there are early decisions, in the sense of refusing a treatment, they must be followed. If the patient has appointed a substitute decision-maker, what he says must be respected.

Children and young people who have not reached a minimum age to make decisions; the best interest of the children is supreme, and usually intensivists rely on their parents to make the best decision in their favor. Sometimes, adolescents and older children are considered "mature" to make decisions, without the need for parental permission. If the child has his own point of view, he should be given the opportunity to express himself, and it will be given importance in relation to the development of the child's capacity and circumstances. For example, Jehovah's Witnesses who refuse to be transfused in situations of life-threatening anemia, despite the apparent maturity and intelligence of the adolescent, may be considered to have no ability to reject potentially life-saving measures; in these circumstances, the principle of the child's best interest may prevail over the principle of Autonomy.

The shared decision is the best model to follow in situations at the end of life and there is no room for unilateral decisions. The intensivist must be very careful about projecting their own point of view when it comes to assessing the quality of life of each patient, particularly when it comes to degenerative and chronic diseases, avoiding pejorative terms such as futility, very expensive, not beneficial, etc. Occasionally, medical interventions that cause suffering may be acceptable to the patient if a benefit in terms of prognosis or health status, or other objective value, can be achieved. If the treatment causes suffering, it should be avoided if it clearly does not bring any benefit [12]. The best interest of the patient assumes that the treatment should not be continued only to prolong life in any way.

It is very probable that a thoughtful, meditated, and consensual decision finds support in the legal framework. The laws recognize that in some circumstances, the mere prolongation of life does not follow the best interests of the patient. The withdrawal of life support treatment can shorten life, but not extending it to delay an inevitable end can follow the best interests of the patient.

4. Criteria for admission to the ICU

The success of intensive care should be measured by the quality of life preserved and not only by survival statistics. It should also be taken into account the quality of the process of death of

patients who end up dying and the quality of the human relationships involved in each death [13]. In general, admission to the ICU should be reserved for patients with reversible diseases whose prognosis can be improved with the human material and available technology. There may be other reasons: a treatment attempt limited in time when the degree of irreversibility is unknown, difficult management of symptoms (including palliative care), and consideration of organ donation.

At any time during admission, the goal of treatment can be changed from curative to palliative (**Figure 1**). The assessment of the suitability of the admission is based on the fact that the probable prognosis is acceptable for the patient, and that the burdens/risks of the treatment exceed its benefit. In patients with advanced age, frail, and with significant comorbidity, it is difficult to identify the possible benefits of their admission to the UCI. The prognosis scores are of limited value when applied to individual cases, especially in older people with comorbidities. The so-called "surprise questions" are useful when it comes to clarifying the picture: questions such as "Would you be surprised if the patient died in the following 6-12 months?" as well as others of functional character (more than 50% of time in bed, frequent hospital admissions, little autonomy in basic activities, loss of more than 10% of weight in the last 5 months).

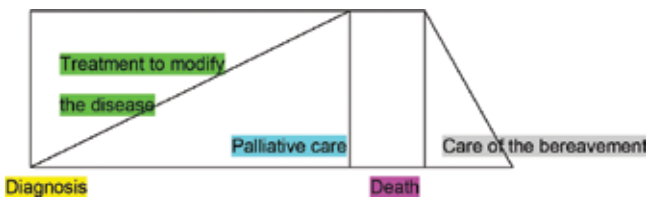

Figure 1. Continuity of the care of the patients at the end of life.

The decisions not to admit a patient to the ICU, as well as a limited time of treatment in the ICU, are ways of LLST. A deliberative process should be carried out by the treating team of the patient, with a collegial decision that allows offering other options than nonadmission, as admission with agreed treatment measures, assessing a response time, etc. This decision should be shared with other members of the team, as well as with the family and the patient. All these processes must be recorded in the clinical history.

The admission of patients with terminal or intractable diseases would not be considered, although exceptionally the admission of patients requiring palliative care to better manage end-of-life care could be considered.

5. Palliative care in ICU

The determination of the patient's prognosis before and during admission is extremely difficult. It involves integrating several data: current clinical assessment, information from other medical teams, impact of ICU treatments on life expectancy, and the chronic diseases of the patient.

As we have seen before, age should not be an exclusive factor when deciding to enter the ICU. Comorbidities, degree of dependency, chronic diseases in advanced stage, and dementia frequently occur with increasing age should be valued as a whole. Talking and mobility are also factors to be assessed. Baseline quality indicators of the patient, together with specific disease markers, may indicate that the patient has started an inexorable path toward death.

It is important to assess other failures such as terminal heart failure, respiratory failure with home oxygen, renal failure in hemodialysis, or advanced cancer.

When it has been decided to move from the goal of intensive to palliative care, efforts must be made to achieve its main objectives. The WHO definition of palliative treatment is [14]: "treatment approach that improves the quality of life of the patient and their families, and maintains the comfort and dignity of the patient, with prevention and alleviation of suffering, and assessing and treating physical, psychosocial and spiritual problems".

The intensivist frequently takes a leadership role in end-of-life discussions with patients admitted toward different to ICU, along with their doctors and their nurses (who have a key role in ensuring the continuity of care and goals), and the patients and their families. Other medical teams should be encouraged to take a leadership role in these discussions and to establish early advance care plans (ACP) and its written part (ACD). Discussion about the end of life should not be too fast or carried out with incomplete information.

Attention to these situations is complex. The intensivist must handle the symptoms, and in complicated cases, ask for help to a palliative care specialist. Detailed instructions of withdraw this or that treatment should be made. Care to the family is also difficult is also difficult; unrestricted family visits should be obtained, and if it is possible, an individual room for the patient and his family can be provided. The intensivist who has been involved in the decision-making should visit the patient and his family during the process of death of the patient. Religious support should be given when deemed appropriate. When family asks to intensivist if children can say goodbye to their family member, they (children) can be asked, explaining them carefully what they will see.

The Australian and New Zealand Intensive Care Society (ANZICS) describes the principles of end-of-life care [15]. The goal of ICU treatment is to return the patient to a quality of life acceptable for him, and if this is not possible, to compassionately support the death process; suffering must be minimized in all circumstances. All patients receive treatments for therapeutic purposes and symptom relief measures. This balance of treatments varies throughout the critical illness, reaching only measures of symptomatic relief and comfort at the end of life (Graph). The medical team and their patients and families should make a shared decision about treatment options. If there is disagreement, which cannot be resolved with discussion and time, an additional medical opinion or opinions of nondoctors (religious advisors, spiritual counselors, lawyers, etc.) can be sought. All decisions related to the withdrawal or withholding of treatment measures should be included in the medical record, including the reasons for making the decision, who participated, and the treatments to be withdrawn/withheld. The same principles govern the withdrawal and withholding of a treatment, and each ICU and each hospital must develop and implement clinical guidelines according to these principles, promoting the evaluation of end-of-life care as a measure of quality.

The quality of life at the end of life can be defined in several ways. Smith [16] gives us a definition that is based on 12 principles (**Table 1**):

It is difficult to evaluate the quality of end-of-life care. The main judge on this process, the patient, dies in a high percentage of occasions. The delivery of a long questionnaire to the family can be understood as intrusive by them. Attention may be paid to other indicators that things have been done well: expressions of gratitude from the family at the time of death, other indirect expressions of gratitude (such as financial donations to the hospital), absence of complaints about external interference, etc.

• know that death is coming, and understand what can be expected;
• be able to maintain control of what happens;
• ensure dignity and privacy;
• have control over pain relief and control other symptoms;
• control and choose where death occurs;
• have access to information and experience about what is necessary;
• have access to proximity care, not just hospital care;
• have access to any spiritual and emotional support required;
• control who is present and with whom we share the end;
• be able to direct the advance care directives that ensure that the wishes are respected;
• have time to say good-bye, and control other aspects of time;
• be able to leave when it is time, and not prolong life indefinitely.

Table 1. Definition of quality of end of life.

6. Consensus building, communication: Documentation

Consensus is an opinion or decision reached by a group as a whole, and it can be followed by all group members even if it is not the preferred option of each individual. This decision of shared decision makes the decision less subject to complaints or legal review than decisions reached by other methods (paternalistic exclusively by the doctor, majority vote, identification of a family member with the right to make any important decision in the patient). This consensus should ideally be achieved between the different medical teams before meeting with the patient, his family, or his decision-making substitute.

The relations between intensivists and other specialists, in order to build a common option, must be constructive.

The discussion must take place at different stages over time, and the meetings must be planned. They must include ICU nurses, social workers, chaplains, and patient families. Communication skills and the proper use of language are very important. Words such as "do everything," "do nothing," "futility," "uselessness" should be avoided, and the "value of treatment options" should be avoided, rather than "the value of the person." The documentation of the decision-

making process must provide transparency and ensure that the health professional fulfills his professional and legal obligations.

There may be misunderstood cultural themes or linguistic nuances that may introduce small changes of meaning in the discussion. The careful use of translators is recommended. Informal use of untrained interpreters, like other family members, should be avoided, because they may confuse their roles as a translator and as a family member and may misinterpret clinical information.

The determination of what therapeutic options may be clinically indicated and the recommendation of a plan that is the most appropriate considering the wishes of the patient are responsibilities of the intensivist. The intensivist must have leadership in the end-of-life discussions in the ICU and must respect the fact that each patient and each family differ in the discussion process: many families want to have weight in the discussions [17, 18] and described that some families involved in end-of-life decisions may experience long-term psychological harm [19]. It is important that families do not feel an unwanted responsibility or weight associated with these decisions. The careful use of language can limit that feeling of personal responsibility; consensus also serves to share that burden.

Rarely, ICU patients are able to participate in decisions about the end of life. Medication, illness, delirium, dependence, and dementia can alter your ability to make decisions. The formal evaluation of decision-making capacity is important in daily practice and must be applied to the decision to be taken in concrete. The intensivist should assess if the patient is capable of understanding the facts involved in the choices to be made, if he is capable of weighing the consequences, and if he has the ability to communicate his decision.

The agreement with the family is best achieved when they are helped to reach a conclusion by themselves, not when they are confronted with a medical decision previously made. Also when emergency treatment begins with doubts about whether it is appropriate, the family must be informed that a reassessment will occur and that the treatment plan may change.

Understanding the expectations of the decision process is important to avoid misunderstandings. Some patients want their decisions to be made, others prefer to delegate to others (a member of the family), others prefer to delegate to the doctor, etc. There may also be degrees of delegation: full responsibility for the decision process or only specific wishes.

When "devastating damage" occurs in the discussion process, it can be understood that family members want "everything to done," which can include a transfer to a tertiary hospital "with more resources." As a result, you should try to restore trust. The treatment in a tertiary hospital can be carried out by consultation, but not necessarily the patient must move to tertiary hospital, especially if the transfer has no benefit and may pose a risk, or harm, to the patient.

The presence of the social worker and the chaplain in the discussions is recommended, because both can dedicate more time to the family, and because they can be perceived by the family as a more neutral opinion to medical treatment. Also, the presence of cultural leaders is important if there are cultural or tradition issues not fully understood by the doctor.

If a patient professes a religion, he may have a fundamentalist or more superficial position. In each case, religion has an impact on decision-making, and the patient's beliefs should be explored.

It is recommended that a doctor speaks on behalf of the medical teams, since small differences in the explanation of the condition or progress of the patient can be seen as major disagreements in the medical teams. This physician must be experienced and veteran in carrying out these discussions, and he should have achieved the confidence of the patient and his family before discussing the limitation. It should be clarified what the family has heard from previous information; it can happen that what families understand is different from what doctors believe they have said. Additional assurances should also be given, such as that the medical team will remain involved in the treatment and will support the family.

If patients and their families are involved in decisions, the information on which decisions are based must be accurate. The recognition of the possibility of death allows families to understand the severity of the disease and assesses that prolonging life should not be the only objective. The word "die" should be used if death is a possibility. Sometimes the doctor avoids giving a realistic prognosis to patients and family for the belief that this will keep their hope. The overestimation of the prognosis by the patient or his family can lead to being misinformed, with inappropriate treatment choices.

The relevant elements of a meeting are listed in **Table 2**.

The reached agreement must be noted in the clinical history. This documentation should provide transparency and responsibility. It should include date and duration of the meeting; people involved in the meeting; medical facts that lead to the decision; written notes about the wishes of the patient, including the ACD/ACP; discussed options, agreed objectives treatment, and agreed consensus; which treatments are going to be withdrawn/withheld and which treatments have to be continued, including medications and symptomatic relief.

• update the situation of the patient with recent data, also from other medical teams, before the meeting;
• meetings must take place in a private room designated for this purpose;
• appropriate time for the meeting should be allocated; during it the family must receive nonfragmented information from the doctor, without interruptions;
• the medical team must always have an intensivist and a bed nurse;
• ensure that all members of the medical team have a consistent message before the start of the meeting, and that each member understands their role;
• ensure that all important members of the family are present at the meeting before initiating it;
• it is necessary to find out what the family has understood up to now of the evolution of the patient; provide new information with simple language;
• emphasize continuous patient care when treatments have been limited or not offered;
• show empathy, active listening, and allow silences as a form of respect and compassionate communication;
• encourage asking the family, and answering completely.

Table 2. Important elements to fulfill in a meeting with families of a patient.

7. Conflicts with family and among professionals

7.1. Basic ideas

Disagreements can arise in several aspects: patient's prognosis and wishes; points of view about what is a successful outcome or a good prognosis; understanding of cultural and religious values; the family fell responsible of the death of the patient; emotional overlap of previous unsatisfactory interactions between health personnel and the patient or their family. These disagreements can also arise at different levels: between family members, between family and doctors, and even between different medical teams. The desire to avoid a painful treatment or dependency is often as important for the patient as the possibility of survival; therefore, the probable prognosis should be included in the discussion. The disagreement taken to the extreme, or extreme disagreement, is the conflict.

7.2. Conflicts between family members and medical team

An open and early communication about the risk of death is a priority in critical situations. The patient and his/her family will be offended and will resist the withdrawal of the treatment if the death expectancy is discovered at the end of the course of the disease.

The possible outcomes should be early discussed with the patient and his family, especially if the patient is seriously ill. An honest and sensitive communication, from the beginning of the disease, on the risk of death makes all parties aware of the possible evolutionary courses, and creates the confidence necessary for joint decision-making and preventing most disagreements.

As already mentioned, doctors consider an appropriate treatment according to the possibility of survival, but the treatment burden, the expected duration of the treatment and the probable prognosis are important aspects for the patient and his family.

The communication must be early and proactive, it must clarify the objectives of the treatment and guide the treatment plan to the patient's values. Listening and empathizing with the opinions of the other party is a way to handle any disagreement. The conflict can be harmful for all parties, and it is better to prevent or treat it early to avoid the negative effects [20].

When detecting these behaviors, a plan should be drawn that prevents the progression of these behaviors. The family that experiences a conflict should receive adequate support. Health personnel should provide clear information, thus avoiding the deterioration of relationships. Finally, threats to health personnel should not be tolerated.

Despite good communication training and proper family management, there may be families with a different perspective of intensive care and management of the patient's end of life. Some sensitive families may not assimilate the information. Families may not be aware of the patient's wishes. The explanation that the treatment plan is made based on your wishes can help resolve the conflict.

Several indicators of conflict regarding end-of-life care can be recognized (**Table 3**).

• circular conversations: the family avoids discussing withdrawal of treatment and revisits previous discussions repeatedly. The solution to this problem is to stop and announce the discussion topic (ensure that the discussion is focused)
• request for second opinions: can be sought in the ICU or out of it, including people without medical knowledge, or religious beliefs
• request to see the medical records, with the help of a member of the team to clarify doubts
• avoidance behaviors of medical or ICU personnel,
• criticism or rejection of individual members of the team, especially nurses, and accusations of not attending properly or incompetence; in a extreme case, transfer requests to another ICU
• request that a specific treatment be administered or interrupted (for example, withdrawal of opiates by the belief that they have been deliberately administered to shorten life). Petitions and demands can be increasingly inappropriate if the process continues, until attempts to control medical decisions.

Table 3. Elements that are associated with end of life conflicts.

The advantages of the medical consensus decision are important, but if this can't be achieved, both options should be presented to the patient and family. Patients and family members may find themselves confused if the treatment options and the possibility of interrupting any of them are carried out at a late stage in the evolution. Honest, sincere, and precocious communication is always the best option.

The word "die" should be used if death is a nonremote possibility. Here is an example: "It is very likely that you will die from this disease, we are doing the indicated treatment, we would like to talk again tomorrow in the morning and tell you if this situation has changed or not, we are offering you the best treatment available".

Conflict prevention is an essential part of communicating with patients, family and nonmedical staff. Here are some key points:

- take the appropriate time (unless it is an emergency); families need time to understand at their own pace, often with discussion at home, rather than being forced by the medical team;
- if this is the case, explain to the family that the decisions about the interruption of a treatment are based on consensus;
- facilitate a second opinion if the family requests it and that this "external opinion" has access to all available information; Sometimes, a general practitioner (GP) in whom the family has confidence, with their own ethnic values, will probably understand the medical situation and may communicate it to the family in an appropriate manner. Others, however, as alternative healers, may not make progress in understanding the case.
- in some circumstances, the presence of an involved third party (facilitator) can clarify and address the concerns of the patient and their family.

When the aforementioned steps have not resolved the dispute, and although rarely effective, the possibility of transferring the patient to another ICU should be considered. Finally, the courts and the Supreme Court can intervene in situations with no way out. If an organization

experiences repeated conflicts about the end of life, the established protocols on this matter should be reviewed.

7.3. Conflict between medical teams

There may also be a lack of agreement between two medical teams and may be due to several factors.

- disagreement about the prognosis;
- different concepts about what "treatment success" represents;
- different understanding of what the patient wants;
- personal refusal to accept death as a result, including feelings of guilt (frequent in the case of iatrogenic complications);
- doubts about administrative or legal requirements;
- emotional overload, frequent in situations of previous unsatisfactory interaction with the patient.

Respect must be shown to the other doctor, and if necessary, involve a veteran colleague to help resolve the conflict. It is important that doctors respect the disagreement that may exist between them, and recognize the need for consensus, accepting it. There must be a desire to negotiate and to remain objective, and on all occasions, to maintain the focus on the patient's best interests.

Conflict is considered a burden on all sides, and has been associated with symptoms of post-traumatic stress and burn-out syndrome [21]. Disagreement among the treatment objectives is the most common source of conflict among ICU staff [22], although disagreement about prognosis is also frequent. Occasionally, doctors and nurses may be forced to apply treatments at the request of the family or other medical teams, and that they do not believe follow the best interests of the patient. This can make them feel undervalued and lead to a moral conflict with short- and long-term consequences. Active professional support programs should be part of the routine functioning of the ICU, with professional advice and supervision for those with exposure to complicated end-of-life decision-making situations.

There is a general belief that the intensivists are downright pessimistic and that the doctors of other teams are too optimistic [23, 24]. All specialties must be aware of the prognostic uncertainty of the critical patient and of the primacy of the personal values and the quality of life of the patients facing the burden and the benefit of the treatment. Misunderstandings can be avoided if the other medical teams visit the ICU frequently and keep informed of the patient's progress. No doctor has the right of veto over other doctors. Although it is useful to consider how much weight, it is reasonable to have the point of view of each specialist when reaching an agreement. A specialist who has taken the patient for a long time, or who has special knowledge about the prognosis of the disease in particular, can provide useful information.

In case of increased difficulty, over the years between medical teams, the doctors involved should take further measures to get an acceptable consensus for the medical team and may involve the hospital's medical administration or human resources.

Conflicts in relation to end-of-life decisions may reappear. When an intervention or procedure has been developed, the other specialist may find it difficult to withdraw the treatment, especially if he has invested a lot of time and effort in that solution. Empathy with the family has traditionally been emphasized, but the relationship with other doctors is also important. Without empathy, problems may reappear.

Doctors must always adhere to the Code of Good Medical Conduct [5]. These good behaviors require doctors to communicate effectively with other team members, and the consequences of bullying and aggression must be made clear. Some doctors can maintain a position of conscientious objection in relation to end-of-life management; in these cases, the doctor should stop evaluating the aspects related to the patient's care.

7.4. Conflict between family members

Sometimes conflicts arise between the family members, and health personnel must help by providing clear information and helping to minimize the breakdown and damage of relationships. Long relationships are tested by emotion, fatigue, or interest in the patient. The ICU environment can generate positive emotional responses and unmask previous tensions, for example, unrecognized sentimental relationships, habits, practices or orientations of the patient, etc.

There is no single solution to these situations. It may be necessary the support of social workers, priests, family counselors, and even security guards. First of all, UCI staff cannot lose sight of their primary responsibility for the patient, although the duty of care can be extended to the interests of the patient's family.

7.5. Conflict between the patient and his/her family

There may be serious disagreements involving patients and their families. The wishes of a patient who maintains their ability to make decisions are supreme and remain so when they have been expressed in advance. If the wishes about acceptance or rejection of active treatment are known, the wishes of the patient should prevail over those of his family. It is important to explore why the family wants to disobey the patient's wishes or believes that their wishes are not valid.

The request of the family that the patient should not be informed should be managed with great care. On these occasions, the family should be informed that the patient has the right to choose if they are going to be fully informed. The family should be told that most patients want to be informed, and that the intensivists are very careful and compassionate in their explanations. The family will be notified that the patient will be asked, with the family present, if he wants that the family is informed. Most patients do not want to be excluded and the patient's preference for the inclusion of their family in the information must be respected. Few patients want to be protected

from information, and expect their family to take a decision-making role; this is acceptable if the intensivist perceives that the decision is taken freely and without coercion, clarifying that in addition to delegating the information, decision-making is delegated.

8. Decision-making, advance care planning, advance care decision

The treatment of critically ill patients has two objectives: intensive treatment, which tries to restore the health and functionality of the patient to a level acceptable to him, and the control of symptoms, which tries to reduce the burden of suffering caused by the disease and by your treatment. In certain cases, in the face of poor clinical evolution, pursuing the best interest of the patient is to change the treatment approach from intensive treatment to palliative care, rather than extending life in any way [25]. Applying the principles of palliative care means maintaining comfort and dignity, attending to psychological and spiritual needs, and supporting the family.

Doctors and family members must make decisions based on the wishes of the patient. He has sometimes made ACP or formal opinion heard. But those desires can also be deduced in other ways: extrapolation of how he has led his life, general statements during his life, and sometimes appointment of a substitute decision-maker (who will inform the medical team of their preferences regarding this point if the patient cannot).

ACP allows the patient to plan and make clear his preferences and to take care of his health in case he gets sick. They usually include end-of-life decisions (although not necessary). It is based on the principle of Autonomy, and on the right to be fully informed about the treatment options of their pathology, and to be treated in a way that respects their dignity and avoids their suffering. ACP improves end-of-life care, meets the preferences expressed by the patient, improves family satisfaction, and reduces anxiety depression and the post-traumatic effect on survivors. It should be reflected in writing (ACD) and included in the medical report, with an adequate alert system. The intensivists must be familiar with their inclusion in the decision-making of patients, especially in end-of-life treatments.

However, the ACP may be inadequate to provide the degree of certainty necessary to support the end-of-life decision, for example, to include generic phrases such as "no reasonable possibility of cure." It can be established an order of reliability about the validity of the patient's wishes:

- 1st, ACP that is relevant in the current situation;
- 2nd, ACP that does not mention the current situation of the patient, although it allows conclusions to be drawn "by analogy";
- 3rd, informal discussions of the patient with his family and friends about his wishes;
- 4th, belief of the family and friends of the patient's knowledge about what the patient would like to do;

- 5th, evaluation of the doctor, based on the limited knowledge of the patient, based on what other patients have wanted to do in similar circumstances.

The ACP process is developed with personnel that support health professionals, with the help of their families, to reflect their values and preferences for current and future treatments. These preferences will guide doctors and the family in providing appropriate medical treatment in the best interests of the patient [26]. It also allows registering the preference over certain treatments or documenting your point of view about an unacceptable evolution.

It is advisable that the ACP be discussed at the out-of-hospital level, with a GP or at the geriatric care center, without stress that implies an acute medical condition. This allows individuals, with the support of their families, to have time to discuss, reflect, and identify what is really important for them to "live well" and "die well." However, ACPs that are made in the hospital are also considered valid, even those made in extreme situations (for example, preoperative). GPs, in which the patient has placed their trust, are basic for the initiation of ACP discussions [27] and can be introduced in their routine evaluation, in case there is any change in the general situation of the patient. This confection is associated with greater family satisfaction in caring for him [28].

ACP is usually performed in hospitals with discussions with nurses for 20–45 minutes, which is accompanied by greater congruence between the patient and the substitute decision-maker, a feeling of being better informed, more confident in knowing benefits and loads of proposed treatments, and feeling that less pressure is transmitted in the decisions to be made [29] (although other works show the contrary, more discussions between patients and substitute decision-makers for end-of-life decisions) [30]. Intensivists should follow the expressed preferences of the patient, except if there is a good reason to believe that the preference of the patient changed recently.

9. Care of the patient who dies imminently; family and medical equipment

9.1. Patient care

The death of a patient after carrying out an LLTS plan is a very complex situation, and the way in which patients die and families coexist with it is variable. The palliative care plan should be individualized to the particular needs of each case and should include pharmacological and nonpharmacological measures. Practical and emotional support should also be offered explaining that dying could cause the presence of noisy and agonizing breathing. Attention should be paid to these signs (especially when they appear as a result of the withdrawal of respiratory support) to administer preventively sedation and analgesia; the withdrawal of renal or cardiovascular treatment does not require support measures for de-scaling. Palliative treatments will always be administered with the intention of relieving symptoms, not accelerating death. Properly document what therapies are removed such as mechanical ventilation, dialysis, inotropes, cardiopulmonary resuscitation, etc.

Some patients will die and some will leave the hospital [31]. Predicting the time of death is difficult. Several factors influence which palliative treatment measures are required:

- the patient's wishes in relation to their care and end-of-life needs;
- what treatments are removed and which are not initiated;
- the patient is conscious;
- how much dependence on UCI treatment the patient has;
- death is imminent;
- what are the patient's needs for analgesia and ansiolysis;
- what are the treatment needs of dyspnea and other symptoms;
- what are the family's treatment needs.

Once a decision has been made about not to initiate or suspend life support treatment, a palliative plan should be initiated. This will have to be properly documented. The ICU nurse has an essential role of caring for the patient and offering support to the family.

Nonpharmacological interventions aim to offer emotional and spiritual support through:

- offer an environment as private as possible;
- consider the visit of her/his favorite pet;
- nursing care: mouth, eyes, skin, intestinal, etc.
- removal of tubes and monitoring devices.
- nasal air to relieve dyspnea in a conscious patient, etc.

In some patients, noninvasive mechanical ventilation (NIMV) may be indicated. It can be used to reduce dyspnea in acute respiratory failure. Even in patients without indication of invasive mechanical ventilation (IMV), NIMV can be used to increase survival, although a clear consensus must be achieved before use [32]. No study has been made aimed at assessing the quality of death in patients with NIMV compared to patients with habitual treatment with sedoanalgesia. But it supposes greater discomfort, greater medicalization of the dying process, and ambiguity in terms of treatment, especially when removing it and initiating sedatives [33]. Therefore, its role should be evaluated patient to patient, and attention should be given above all in other aspects of palliative care.

When considering the interruption of ventilatory and circulatory support, the impact to the patient and his family must be anticipated. The patient can become dyspneic and that can be distressing for both. Prior medication should be administered to help prevent any resulting discomfort. Morphine can be administered at 5 mg/h and propofol al 50 mg/h. An important fact: the withdrawal of respiratory support followed by programmed extubation has been associated with higher rates of family satisfaction during the end-of-life process [34].

http://dx.doi.org/10.5772/intechopen.75565

The pharmacological control of the symptoms is extensive and includes alleviating pain, agitation, dyspnea, and excessive respiratory secretions. A prepared medication checklist can be useful to ensure immediate access to the necessary medication. Muscular relaxants have no place in palliative management, only in association with sedatives and in certain circumstances such as adult respiratory distress syndrome. After extubation, the patient may die quickly, and the cause of death is the underlying disease; Sedation ensures that there is no awareness during the death process [35].

The dose of drugs can be increased, depending on age, the presence of multiple organ dysfunction, previous exposure to benzodiazepines or morphics, the current level of sedation, the underlying disease, and the wishes of the patient in relation to sedation in the end of life. There is no maximum dose in the relief of pain and suffering at the end of life, and the dose should be individualized for each patient and each situation. Although they have cardiodepressive effects, the proper use of opioids has been associated with longer life [36]. Morphine can be used for pain and dyspnea, midazolam for agitation and restlessness, haloperidol for delirium, and glycopyrrolate for respiratory secretions. The evaluation of the palliative treatment can vary according to the situation of the patient: in a conscious patient, we can ask him; in an unconscious patient, the signs of respiratory work and distress include restlessness, diaphoresis, high blood pressure, hyperventilation, tachycardia, grimacing or vocalizing after nursing care, etc. Always doctor must try to preserve the dignity of the patient.

If patients are awake before removing ventilatory support (e.g., motor neuron disease or high spinal cord injury). Sedatives or anesthetics may be administered to make them unconscious and spare them the suffering of dying [37, 38]. A consensus must be reached that allows the patient to have control over the dying process and fulfill his desire to "not die fighting, drowning." The slow withdrawal of sedation is accumulated by increasing the dose of sedation to achieve a respiratory frequency less than 20/minute.

If death is not imminent and the patient has a very minor distress, it should be made clear to the family that it is often difficult to predict the time of death. Nonpharmacological measures are important, and the opportunity for the family to spend time with the patient before he or she dies must be emphasized. The interruption of fluids and medical nutrition must be assessed individually. Oral food must be offered, although most patients reject it and reduce its intake [35].

All medical equipment should provide good end-of-life care. When death occurs in a short time, times are best handled in the ICU, the team being attentive to the needs of the patient and their family; if the process is longer, the patient should be transported to a palliative care area or even allowing the patient to die at home. Communication with the family must be clear, and the proper transfer of medical and nursing information is important to ensure a gradual transition of care.

The patient should be supported in their pain/suffering. The loss of autonomy, control of body functions, body image, and mobility should be remembered. This one is not with the people who they would like to be with. Although communication is limited, the patient should be insisted on our commitment to comfort and dignity. Your family should be asked to think with

the patient's perspective. Death is part of life and requires an individualized management of the situation.

9.2. Care of families

Families must have everything necessary to accompany the patient and carry out their grieving process. Sometimes the family asks to delay the withdrawal of treatment "to give time to arrive on time to members of the family"; this request must be overspent with what the sustained burden of treatment implies. We must collect data on the perception of family members to improve aspects of the care of the patient who dies. The reaction of bereavement changes over time, and its absence is abnormal: it can manifest with shock, distress, anger, fear, denial, confusion, guilt, numbness, etc.; even desolation and complete isolation. Religious stereotypes should not be followed but ask your family what they think is appropriate from the spiritual point of view, according to a holistic approach.

The behavior of the ICU is also important after the death, giving support to the family. The risk of postdeath bereavement is greater, and support may be needed in several situations: sudden death, traumatic death, preventable death, death of a child, social isolation, past history of mood disorders or other significant losses, and prolonged reactions mourning. The society ends soon the death, but the duel can be a long trip with a first year with experiences without the presence of the deceased. Contact with his GP can help restore physical and emotional well-being, although additional resources may be required, especially in frail and elderly people.

9.3. Care of the medical team

The death of the patient can imply a reduction in the personal and professional worth of the doctor and nurse. Regular multidisciplinary discussions should be integrated into the usual practice of the ICU. These discussions will help create an open, cohesive, and flexible teamwork culture, especially during a conflictive end-of-life process. It also facilitates a greater consistency of communication with the patient and his family. During the discussions, there are no successes or mistakes, but questions are opened for dialog. This shared experience can help team cohesion and prevent the team from being divided into complex end-of-life situations.

All ICU members are vulnerable to emotional stress, with complex clinical and ethical decisions. The presence of conflict increases the risk of adverse effects on health care workers. If the conflict is prolonged, and a legal action is taken, the risk is even greater. Also taking care of the patient and the people involved (families, friends, caregivers) is exhausting, and there is little time to recover; immediately, the door opens and another patient comes into.

There are other ways to support the staff. The intensivist must be separated from the family in a conflict. There must be flexibility in the support of the staff members; nobody is immune to the conflict. Sometimes the doctor can even be relieved of his work overload, if he is involved in a prolonged conflict; and this will allow you to focus on good communication and conflict resolution, with adequate rest periods.

10. Special situations

There are special end-of-life situations that involve different actions.

10.1. Suicide

Suicide is the leading cause of death among young people. For every completed suicide, there are about 30 suicide attempts, and many enter the ICU. Suicide damage affects the family and society broadly. Although suicide is not illegal, helping a suicide is punishable.

Many patients who make a suicide attempt have expressed their rejection of the treatment prior to admission. They may be mentally ill, but also nonill people who find in suicide the solution to a delicate situation or even in the bosom of a serious progressive disease. Life support measures may be withdrawn or not started in patients with serious organ damage after attempted suicide (i.e., severe hypoxic damage). That decision will be guided by the best interest of the patient. The severities of mental illness, and the absence of response to treatment, are relevant data when considering a life support treatment. Decisions can be made with the substitute decision-maker, and you can try to answer the question "would it be reasonable to withdraw active treatment given the clinical circumstances if there were not an attempted suicide?" It is accepted that patients with capacity have the right to refuse life support treatments. When the patients lose this capacity, these options are legally reinforced by the ACD, without the need to be agreed and even without clear reasons. Some patients may have freely decided suicide as an option. The consensus of the medical team must be achieved.

10.2. Chronic respiratory diseases

Patients with chronic respiratory diseases, such as Chronic Obstructive Pulmonary Disease (COPD), are at risk of suffering an acute exacerbation leading to admission to the ICU with mechanical ventilation or other supports. The decision-making in these patients is complicated, because of the unpredictability of their recovery, ignorance about the acceptable prognosis (unless the patient has ACD), their high levels of anxiety, depression, and fear of the sensation of drowning.

Several factors are associated with a poorer prognosis: poor lung function, exercise tolerance/functional stage, low body mass index, use of home oxygen, comorbidities, frequency of hospital admissions due to decompensation, etc. Recent studies show that 60% of patients with COPD intubate survive and can return to an acceptable situation; the average survival after admission to the ICU due to COPD is 2 years; and among COPD patients who required prolonged IMV with tracheostomy, 78% were weaned successfully and 43% were still alive 12 months later [39].

Patients with advanced respiratory diseases ideally have a good understanding of their life history, with gradual respiratory deterioration and exacerbations that follow recovery. Based on that, they will make their ACP; however, very few patients have done so for many reasons: uncertainty of the prognosis, slightly progressive disease, difficulties of the doctors to find

where and how to make these ACPs. Even when the ACP is done, many patients want a "treatment trial" without clear guidance on how to make limitation decisions. Also, the health professional is afraid that this discussion "will take away his hope." These conversations are useful for patients, and they allow them to maintain a certain degree of control; they can be stated in terms of "hoping for the best, planning the worst." Anxiety and fear disproportionate to lack of air influence the efforts of weaning and tolerance to the NIMV. The family and the patient can be battling to accept the information that the doctor gives during episodes of deterioration.

10.3. Chronic neurologic diseases

Patients with motor neuron diseases die due to progressive respiratory muscle weakness, aspiration pneumonia due to involvement of the bulbar muscles, and difficulty in coughing. Patients are aware of their poor prognosis, maintain their consciousness until advanced stages, and often have ACP (documented or not). The reasons for not using NIMV are the progressive nature of the disease that impairs their quality of life, the amount of resources required in daily care, the possibility of remaining not communicated, unable to express their treatment preferences, or having that you make a future decision to withdraw treatment. These situations are emotionally difficult, and most patients would prefer to avoid them. Weaning success of IMV is <50%, and most patients need NIMV. In these patients, IMV can only be considered in two scenarios: diagnosis of the pathology that has not given time to pose ACP, with infection or another reversible disease; and respiratory failure prior to the diagnosis of motor neuron disease.

A peculiar profile of neurological patients is the persistent vegetative states. This concept refers to patients persisting in a coma with eyes open at least 4 weeks after the initial damage. Each case must be treated individually, respecting the usual end-of-life criteria and the ACP of the patient and working with the substitute decision-maker to determine a reasonable care plan. Hydration and artificial nutrition are part of medical treatments and should be discontinued like other treatments. The belief in the sanctity of life is universal, but it can be confused with the most extreme version of vitalism. The National Health and Medical Research Council guidelines [40] make it clear: "the question is not whether the life of the patient is worthwhile, but whether it is worth the treatment".

10.4. Childhood

We usually do not have clear views of the child about their treatment. Intensivists and parents are obliged to act in the best interests of the child, although it may be difficult to know with certainty which option is valid. Sometimes there may be a difference of opinion between the medical team and the parents; parents believe they know what is best for the child, but as with adults, meeting family requests is not always appropriate. Parents sometimes ask the intensivists "what would you do if I were your son?"; if answered honestly, it can improve the relationship with parents, but they may not share their values and beliefs, and care should be taken to avoid influencing parents.

http://dx.doi.org/10.5772/intechopen.75565

The child's ability to make decisions changes over the years. The views of the child are important and should be involved in decision-making, if they have considerable experience in medical treatment and according to their ability to interfere. Sometimes families do not want to make decisions and prefer doctors to make decisions for them; but on most occasions, parents want to be involved in decision-making. The best approach is shared, with joint deliberation over what course of illness would be best for the child.

Intensivists should be as safe as possible in any situation. A consensus among colleagues should be sought, a second opinion sought, information obtained from other experts, etc. Even if there is still uncertainty, the values and points of view of the parents play an important role in determining whether to administer a treatment, after being informed of all the possible benefits and associated risks. "Compassion fatigue" and caregiver frustration are not legitimate reasons to interrupt treatment, but deliberation about the end of life should be ethically rigorous and robust.

When the life of a child is endangered or there is risk of significant damage that will affect their health in a decisive way, it is not necessary to ask for consent. The decisions must ideally be agreed with the parents in situations of stability and must seek and follow the ethical principles of beneficence and not maleficence.

When discussing the prognosis with the parents, it is necessary to define the panorama that awaits the child in his daily life, that is, if he is going to be able to communicate properly, be able to procure self-care, sit-down and mobilize himself. All these will help parents to imagine this hypothetical situation and make a wise decision. A question that arises quickly is "under what circumstances is ethical to consider the limitation of life support therapy". Here some of them:

- the patient has a limiting disease and probably dies despite all efforts;
- it is very unlikely that the patient will benefit from any treatment if his life is prolonged. The "additional" time we offer does not give you other option to receive treatment.

As with adults, decisions at the end of life should be made with as much consensus as possible. All those involved in patient care should have one or more meeting prior to the one with the family, the intensivist and other specialist, nurses psychologists, social workers, etc., and have a "common idea" about how to approach the meeting with the family. The family should fell that all efforts from this point will be aimed at providing comfort and that does not mean leaving or abandoning him and that the team will continue to provide excellent care to the child.

It seems logical to think that early decisions do not take place when it comes to a child, and that the substitute decision-maker is usually the parent and must always be present when decisions of this type are made. Many children suffer from chronic and limiting illnesses. The doctors who regularly monitor these children must take part and be involved in the process, providing data, both technical and personal, as they know the patient and their family well.

Sometimes consensus may not be reached. When medical treatment suggests that life support benefits a child, it must be provided even if there is no agreement with your family. If there is a risk of relevant damage to a child for a treatment, without the corresponding benefit, it should

not be administered even if the parents request it forcefully. Clinicians must remain faithful to their integrity. Sometimes parents find offensive that doctors think about a subjective issue such as their child's quality of life. The task of the intensivist is to consciously determine the benefit of life, in terms of the child's pleasure to live and to face the burdens of the current treatment. This act of comparison must be carried out, and the terms "quality of life" and "futility" must be avoided.

The term "allow a natural death" seems more appropriate than "not resuscitate," since it avoids giving the impression that some potential benefits of the treatment are withdrawn [41]. The discussion with the parents must include which interventions are appropriate and which are not (nasogastric tube, orotracheal intubation, aspiration, intravenous access, etc.) the result should be clearly documented in the story. ACDs have less relevance in the pediatric patient because children have no ability to communicate their treatment options and because substitute decision-makers, parents, are almost always present when treatment decisions are made. When planning the LLTS, several issues can be proposed to the parents: petting the child while extubating (maintaining the role of parent caregivers), preventing them from seeing signs of agonizing breathing but that the child will be sedated, and having a single room and withdraw monitoring. Also when possible, they should have enough time and space to say goodbye.

A follow-up to the parents is accurate even weeks after the death, this follow-up must include the doctors involved, social worker, psychologist, etc. A subsequent meeting is the opportunity to clarify doubts and eliminate misunderstandings from parents.

10.5. Emergency situations

Emergency situations are outside end-of-life care. The definition of emergency is a situation in which the patient is unable to give consent for a treatment that is immediately needed to:

- save the patient's life, or
- prevent serious damage.

An authorization or a renunciation to consent is limited. The only treatments allowed are those that pursue those objectives. If the treatment carries a risk of permanent disability, it is best to obtain the informed consent if possible within a reasonable timeframe.

11. Organ donation

Donation is an integral part of end-of-life care and it is necessary to know how to recognize donation opportunities and to identify those situations in which death is a possibility. It is necessary to contact the local transplant organization, if such situations arise, to discuss the availability of the donation, the physiological support with active treatment of the potential donor, determine brain death, and assess the need to send information to the court and documentation of brain death. Most patients who die in the ICU are able to donate tissues.

http://dx.doi.org/10.5772/intechopen.75565

12. Decision of not to reanimate (DNR)

Cardiac arrest is the immediate, unexpected and potentially reversible interruption of the circulation and spontaneous breathing. The objectives of cardiopulmonary resuscitation (CPR) are to preserve life, restore health, and limit the sequelae.

Bioethical principles apply in the general CPR situation in several aspects:

- CPR should be attempted in all patients suffering from cardiac arrest;
- patients can accept or reject any treatment, including a CPR; in most cases, it is assumed that the patient has not carried out a previous instruction and acts under the presumed consent for the benefit of the patient;
- all patients who can benefit from resuscitation efforts should have equal access to these efforts. In an emergency, we must prioritize the common good over the protection of individual autonomy, maximizing the number of survivors or years of life saved.

CPR makes sense if recovery expectations are reasonable. On the contrary, CPR should not be attempted in the following circumstances:

- obvious signs of biological death (rigor mortis, livicedes),
- reliable evidence that the patient doesn't want to be reanimed,
- chronic, debilitating and terminal illness,
- final stage of an acute process in which all available therapeutic options have been tried,
- permanent brain damage,
- danger for the resuscitating team,
- delay of more than 10 minutes between the start of the stop and the start of the resuscitation maneuvers.

Age is an element that doesn't influence the decision to reanimate or not to reanimate.

A "resuscitation plan" should be prepared and visible in the patients´ medical records when appropriate. It must be completed if there is a possibility of worsening and that it is not a candidate for invasive measures. The purpose is to provide clinical guidance to the nursing staff of the general ward to avoid inappropriate activation of the Emergency Medical Team. In previous articles, this document has been named as "not-for-resuscitation form" or "decision not-to reanímate" (DNR). Recently, a "positive" designation was chosen, and it must include other global treatment decisions, such as whether the patient agrees to a subsequent surgery or other intervention if his condition deteriorates.

This document must be completed by the intensivist if the treatment limitation follows the best interests of the patient or if it is in accordance with the preference of the patient or his substitute decision-maker. Also nonintensivist physicians must make a resuscitation plan if the limitation of treatment is appropriate. We could consider candidates for this option: older than 75 years, advanced cancer, COPD, heart failure, etc.

Filling that plan does not mean that the treatment is limited; in some cases, the patient can be a candidate for a full CPR.

13. Clinical practice guidelines for the terminal patient

- Palliative care plan
- Training in palliatives
- Institutional responsibility

Table 4 shows the 12 "good dying" points that must be contributed in the ICU [15].

These aspects should be included in the Clinical Practice Guide for the Comprehensive Management of Palliative Care. This guide should direct the palliative care plan, in patients in whom the goal of treatment has ceased to be healing, and has become comfort and symptomatic relief. It is highly recommended to implant in hospitals, first at the academic level, and then at the training level, training in palliative care. And there is no doubt that the hospital has an important responsibility in that its health professionals know how to apply palliative care to their patients.

• know that death is coming and understand what can be expected;
• have some control of what is happening;
• offer dignity and privacy;
• have control over the relief of pain and other symptoms;
• choose where to die;
• have sufficient information and technical skill;
• have access to spiritual and emotional support;
• have control over who will be with the patient;
• be able to ensure that the patient's wishes are respected;
• have time to say goodbye;
• be able to leave when it is time to leave and not prolong the situation indefinitely.

Table 4. Items associated with a good dying.

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Chapter 3

Ethical Considerations in Research and Medical Care of Menopause

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.74666

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 Lors, 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

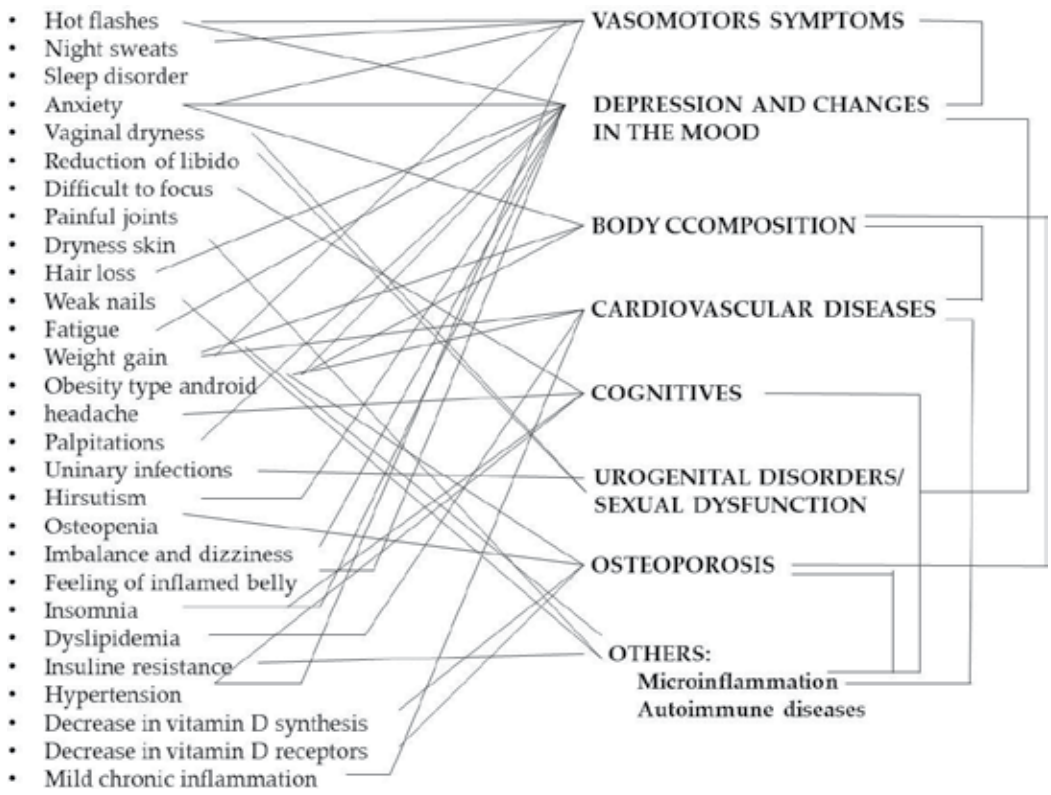

Figure 1. Interrelationship between signs and symptoms with diseases observed during menopause and its stages.

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].

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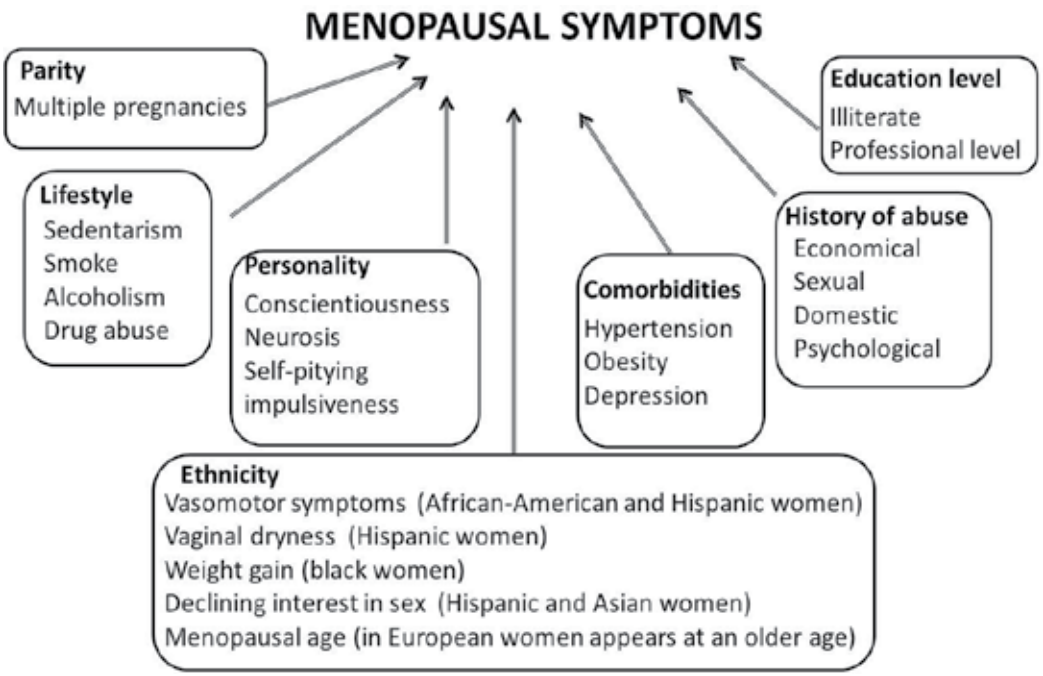

Figure 2. Factors and events that influence the presentation of symptoms during menopause.

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: • 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 interpersonal 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 elderlies (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 stablished 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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Chapter 4

Bioethics and Palliative Care in Primary Health Care

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.76864

Abstract

In order to respect the patient's right to die at home, with quality and respect, discussions about bioethical problems involving palliative care in the context of primary health care are relevant. Among bioethical problems, communication problems regarding the diagnosis and treatment, the maintenance or discontinuation of futile treatments, the adoption of aggressive and lifelong measures by the emergency mobile service, and the problems involving equal access to care stand out. It is important to emphasize that health systems must incorporate palliative measures in primary care and enable professionals to provide this type of care.

Keywords: palliative care, bioethics, primary health care, health personnel, health systems

1. Introduction

The preferred place to die among people throughout the world is their home; however, many still die in hospitals, with at least one admission in the last year of life [1–3].

Thus, it is essential that palliative care (PC) be seen as a responsibility of all health professionals, not only of those in the secondary and tertiary level of care but also in primary health care (PHC) [1].

However, several bioethical problems still persist when it comes to respecting this right of patients. These problems must be debated in order to seek the benefit of patients and their families, respecting their right to die with dignity.

2. Bioethical problems in the context of PHC

2.1. Bioethics and PC: Concepts and definitions

The emergence of bioethics took place in the 1970s, from the concern with the extent that advances in science, especially in the field of biotechnology, have acquired [4].

The word "bioethics" emerges as a neologism originating from the Greek words *bios* (life) and *ethos* (ethics), being conceptualized as the "systematic study of human conduct in the area of life sciences and health care while this conduct is evaluated in light of values and moral principles" ([5], p. 116).

Among the various models of analysis and reflection in bioethics (libertarianism, virtues, casuistry, narrative, care, and principialist ethics) [6], we have chosen a more detailed approach in this chapter, also known as principialist ethics, proposed by Tom Beauchamp and James Childress in the book *Principles of Biomedical Ethics*.

This model has been widely used to solve problems related to biomedical ethics in Brazil. It focuses on four principles: beneficence, non-maleficence, autonomy, and justice. None of them has a hierarchical position in relation to each other, and the situation in question is what will determine the principle that will have priority [7].

The principle of beneficence requires that actions aim at the creation of a good or result in benefit to the human person. It means the duty to maximize benefits and minimize damages [7]. The principle of non-maleficence underscores the moral obligation not to inflict intentional harm and to avoid all foreseeable harm [8]. The principle of autonomy means recognizing the patients' ability to deliberate about their personal goals and act in the direction of their deliberations [9]. The basic conditions for this autonomy are acting intentionally, without restrictions or external or internal influences that may determine the control of the action and fully understand its meaning [10]. The principle of justice emphasizes that provisions must be made to each one according to his needs and demands must be expected from each one according to his abilities, and it is argued that equal cases require equal treatment. There can be no justification for discrimination based on economic, social, racial, or religious criteria [11].

The bioethical principles cited express the search for the protection of the human person as a guideline for the current and future practice of medicine [12].

In this context, it becomes relevant to discuss the bioethical problems related to PC because they raise dilemmas involving rights and quality of life of patients under PC and their families.

The World Health Organization (WHO) defines PC as "assistance promoted by a multidisciplinary team that aims to improve the quality of life of patients and their families in the face of a life-threatening disease, through prevention and relief of suffering, early identification, impeccable assessment and treatment of pain and other physical, social, psychological and spiritual symptoms" ([13], p. 83). PC measures seek to guarantee the patient's quality of life to the detriment of prolonged life [2, 14].

The demand for PC is a current public health problem worldwide, given the progressive aging of the population, with consequent substantial increase in the number of elderly people who experience a greater incidence of chronic degenerative noncommunicable diseases. The importance of PC is evident in this context, as well as the reorganization of health systems in order to ensure the provision of health care [15, 16].

In Brazil, activities related to PC need to be regularized in the form of a law. There is still a great deal of ignorance and prejudice, especially among physicians, health professionals, hospital managers, and the judiciary branch [17].

PC measures are still confused with euthanasia, and there is a huge concern related to the use of opioids, such as morphine, for pain relief. There are still few PC services available and even fewer offering care based on scientific and quality criteria. The vast majority of services still require the implementation of standardized models of care that guarantee efficacy and quality [17].

Before the growing demand for PC, it is difficult to count on a sufficient number of specialists to provide this care. This perspective of health care should not only be relevant among specialists, but the concern with PC measures should also involve general healthcare professionals, caregivers, and family members who provide primary care to such patients [18]. Thus, discussions about the structuring of PC measures in PHC become necessary, given the patients' preference for receiving this kind of care at home.

2.2. PHC context

Since the middle of the last century, movements have gradually redefined health systems around the world in order to promote better health for the population. Two initiatives were internationally impactful and affected health policies in Brazil: the health promotion movement and the PHC movement [19].

Health promotion was first defined in the early twentieth century, encompassing health education actions and structural actions of the state to improve the living conditions of the population [20].

The WHO promoted the First International Conference on Health Promotion in 1986, issuing in that moment the Ottawa Charter for Health Promotion [19, 21]. This document reinforces the expanded concept of health and its determinants, including biological, social, economic, cultural, educational, political, and environmental conditions [19].

In 1975, the expression "primary health care" was first incorporated into the WHO documents and an international conference on the topic culminated in the Declaration of Alma-Ata (1978), where health was recognized as a fundamental right, emphasizing the universal access to services and the intersectoral actions [19, 22]. PHC has been defined as "essential health care based on scientifically sound and socially acceptable methods and technology, which make universal health care accessible to all individuals and families at a cost that the community and the country can afford to maintain at every stage of their development" ([19], p. 7).

However, the epidemiological, demographic, and social transformations fueled by globalization, urbanization, and aging populations pose challenges of a magnitude that was not foreseen three decades ago [23].

PC practices are inserted in this context, although poorly structured and incorporated by the trend toward health systems focused on a limited supply of specialized curative care, consisting of services fragmented by approaches to disease control and with immediate objectives, and an expansion of the deregulated marketing of health [23].

2.3. Bioethical issues in PHC

2.3.1. How to prioritize patient preferences?

Meeting patient preferences continues to be the major concern in PC quality. For these preferences to be met, medical support and the involvement of the patients and their family in decision-making are essential [2].

In a study carried out with families of deceased patients who received PC, it was observed that their level of satisfaction with the care offered was almost twice higher among those whose relatives died at their preferred place [3].

It is known that home PC measures are related to higher chances of meeting these preferences [2], thus highlighting the importance of PHC in this process. In a study [1], PHC health professionals reported the desire to prioritize the patients' preferences; however, they did not know when and how to have end-of-life conversations with them. Such difficulty arises from the resistance of patients and of the society itself in talking about "death" and PC.

Another study [24] showed that knowledge of religious beliefs and values around death can be useful for preparing professionals to care for patients under PC. This study also stressed that while planning such care, the wishes of the patients should be communicated or documented so that they may be maintained in case of incapacity, as in the decision-making with respect to maintenance of treatments. Studies have shown that more religious patients prefer to maintain life-prolonging treatments [25, 26].

Decisions involving treatments and the end-of-life process also run through legal issues. Regulations differ from one country to another, and such differences may affect the patient's choices. In general, the principle of autonomy dictates that physicians have the duty to provide detailed information on the available therapeutic options and that patients have the right to refuse measures that go against their personal values [27].

However, in situations where such autonomy cannot be exercised, advanced directives can be adopted to ensure that patients' wishes are met when they are conscious. However, the adoption of this type of document by patients is still not common, and an educational and informational process is necessary with the society to raise awareness about its importance [28].

A study mentions three distinct situations involving bioethical problems in existential decision-making: the first situation concerns the ethical responsibility of informing patients about the available treatment options and future implications of the diagnosis; the second

situation concerns the retention or implementation of long-term supportive therapies without therapeutic utility; and the third situation relates to the continuation or discontinuation of measures that sustain life in different cases. In some countries, there is a fourth option, which is of hastening death through the application of active drugs [27].

Regarding the continuation of life support or maintenance therapies, this problem arose with the discovery of mechanical ventilation. On the one hand, the physician has the authority to limit treatment in cases of requests for prolonged futile therapy; however, the right of the patients or their families to actively participate in decision-making should be respected [27].

It is worth mentioning that in the context of PHC, the action of mobile urgency and emergency services, which often end up starting to provide aggressive and life-prolonging therapies still in the home setting, which may be in direct conflict with the objectives of care to a patient under PC [29].

Considering the patients' preferences for rejecting aggressive and life-prolonging measures, besides the preference to die at home, a study pointed out that patients want to avoid visits from mobile care because they are tiring, distressing, and disturbing and because many times this service ends up leading them to a hospitalization [30].

Some factors are reported as having the potential to prevent urgent mobile care and/or hospitalization, namely, the respect for patients' preferences, functional status, and family support that the patient is subjected to. As factors related to the health system, we can mention the existence of primary interdisciplinary domiciliary care teams [30].

Thus, it is necessary that countries invest in models to integrate the different services and levels of care in order to guarantee access to quality PC to patients and their families [31].

2.3.2. How to guarantee access to palliative care in PHC?

Lack of access to home palliative care is still a problem in several countries. It may result in non-compliance with the patients' preferences on care and place of death [2]. It is also known that, despite advances, access to PC measures is still greater among cancer patients than among patients affected by other chronic conditions [32].

Regarding the inequality of access related to the different chronic conditions eligible for PC, a study pointed out that for this discussion one must invoke the bioethical principle of justice, which requires that similar cases must be treated in a similar way. That is, patients with conditions eligible for PC need treatment similar to that offered to cancer patients, regardless of diagnosis [32].

Among other reasons for the lack of access to PC in PHC, the limited resources, the lack of support equipment, and the lack of home care services prepared to assist patients eligible for PC are worth mentioning [2].

This issue should also be discussed under the scope of the principle of justice in the allocation of health resources and services, so as to ensure to all not only equipment and drugs aimed at the control of physical symptoms but also non-pharmacological interventions focused on the

psychosocial-spiritual aspects of these patients, seeking to reduce the suffering and existential anguish attached to the dying process [14, 33].

The lack of trained professionals in PHC for providing PC can also be an obstacle to access. A study [1] reported that PHC professionals identified themselves as "generalists" in PC and most of them demonstrated a lack of confidence and skills needed to identify and care for patients at the end of life, making mention of lack of experience in this type of care.

Thus, the importance of training PHC professionals to nonspecialized PC measures is paramount. They must seek to develop skills in the management of incurable symptoms, communication with patients and their families, and identification and treatment of basic psychological and spiritual problems [1, 33]. A systematic review [34] showed that participating in PC training programs reduces the stress of nurses and improves their communication, attitudes, knowledge, and confidence in caring for PC patients.

Another issue that may influence the access to PC in PHC is the lack of integration within the healthcare network. It is known that the integration of services facilitates the continuity of care, improves the quality of life, and reduces the occurrence of unnecessary hospitalizations for patients. A study [35] highlighted the importance of integrated systems and multidisciplinary meetings.

3. Conclusions

The discussions presented here demonstrate the need for a better structuring of health systems around the world for the incorporation of PC into PHC, considering the importance of this level of attention for the improvement of the quality of life and respect for the patients' right to decide on the place of death. Moreover, such incorporation will result in benefits in terms of cost-effectiveness, reducing unnecessary expenses with hospitalizations and unnecessary therapies. It should be emphasized that for this purpose, PHC professionals must be trained to acquire the necessary skills to provide this type of care.

Conflict of interest

The authors declare that there is no conflict of interest in the work presented.

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Section 2

Bioethics and Education

Chapter 5

Bioethics in Education

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.74519

Abstract

In dynamic ambits, systems have to be maintained in a constant process of adaptation. Thus, in the present chapter, we explore the integration of bioethics in all areas of higher education (physics-mathematics, the engineering sciences, social and administrative sciences, the biological-medical sciences, and the humanities), with the objective of establishing, as an essential part, bioethics in all disciplines of knowledge. All undergraduate university degrees converge in the relation among living beings, through knowledge-based interdisciplinary or multidisciplinary study. A close relationship has to be established between education and bioethics within the context of higher education, as teaching at the university level with values and ethics, achieves a contribution to the science of industry in terms of a greater professional ethical sense. Therefore, this work concludes that bioethics should form a fundamental part of every university undergraduate degree.

Keywords: bioethics, education, higher education, postgraduate, learning

1. Introduction

The learning process in higher education is based on the theoretical learning model defined as andragogy, which is an ensemble of techniques for teaching adults. The main characteristics of

this model are the following: the students have a motivation for learning and they possess previous knowledge or prior experience in the areas of interest; in addition, they entertain values that they have achieved throughout their personal and academic lives. They are capable of making moral judgments concerning their environment and the situations in which they live [1]. As andragogy takes for granted that the student already has a set of values, the majority of higher education programs of study, do not have courses on ethics and values.

Bioethics in higher education seeks to contribute to undergraduate degree studies by not only offering knowledge on the science or the technique, but also by forming professionals endowed with moral excellence. It plays a part in science or industry by producing trained and morally formed professionals who can face the bioethical dilemmas present in the ambits in which they develop their activities with acumen [2].

Figure 1 represents how the higher education knowledge areas are interrelated within a system that interacts in a bioethics environment. This system has input elements that can cause a change in the system, for example: the inputs of ethical values and moral will generate in the system the formation of an ethical and moral professional.

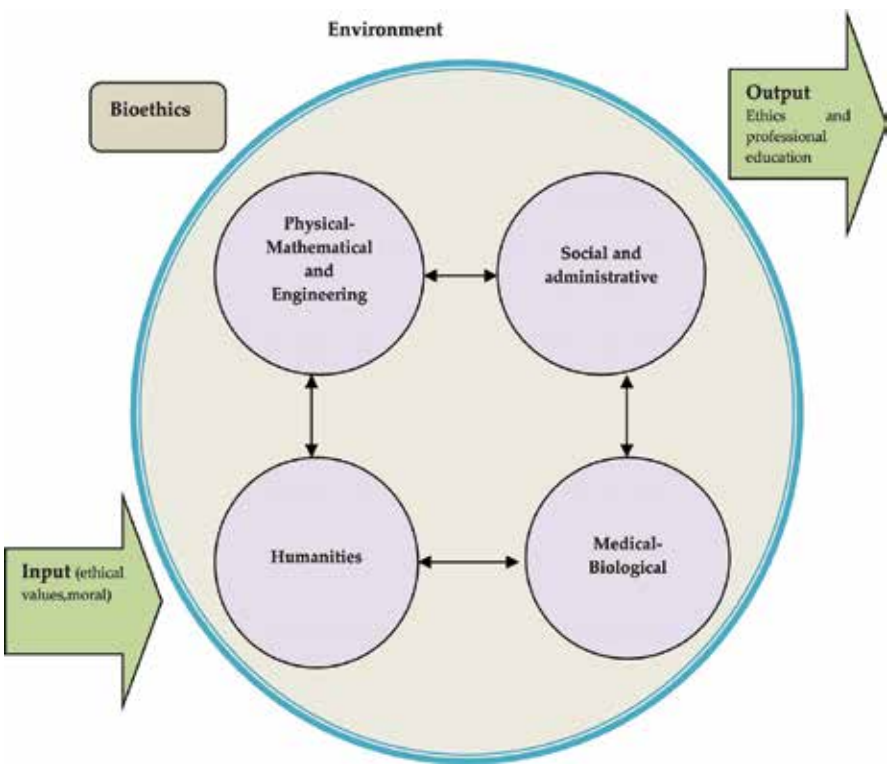

Figure 1. Bioethics in higher education.

http://dx.doi.org/10.5772/intechopen.74519

2. Relationship between bioethics and education

With respect to bioethics in education, it is important to know the different concepts contained in the former in order to be able to focus on a determined area that would be applicable in education. There exist many concepts; however, all converge at the same point: respect for life. On the other hand, morals based on universal principles is where bioethics in education plays a very important role, because it aids the individual to develop in a better manner independent of their way of looking at things.

The teaching of ethics cannot be treated as an exact science, because there are different gradients in terms of morals and education that the individual possesses in a specific zone. One of the principal objectives that bioethics possesses is that of promoting critical thinking. The morals and ethics of each person depend on his/her life environment and of the childhood that this individual experienced. Nonetheless, according to the moral development theory of Jean Piaget, these ethical values can change or be developed depending on the life experiences that the person has as an adult age.

On certain occasions, bioethics can be learned or imitated according to the society or environment in which the person develops. As is noted in a case study, corruption, intransigence, or the abuse of power can be transmitted to an individual who comes into this ecosystem for the first time. Therefore, education is the basis of any culture, and the substrate of the culture comprises human values [3, 4].

The current challenges of educative institutions include responding to the needs of the society, presenting plans of study that contain bioethical themes inserted into experimental areas. Thus, it can be concluded that the teaching staff should understand the theme of bioethics and its effect on future generations; they should work in a preventive manner to plan natural resources and to have the human capital necessary without displacing it.

Stage 1	Punishment and obedience (heteronomy)	Blind obedience, avoid punishments
Stage 2	Purpose and exchange (individualism)	Follow a rule only when it benefits someone
Stage 3	Expectations, relationships, and interpersonal compliance (mutuality)	Live according to what close people expect
Stage 4	Social system and conscience (law and order)	Fulfill the duties that have been accepted by a group
Stage 5	Previous rights and social contract (utility)	Aware of the diversity of values and opinions and their relative origin
Stage 6	Universal ethical principles (autonomy)	Universal ethical principles that are met by the use of reason

Table 1. Stages to identify the behavior of an individual.

Table 1 shows the stages that can identify an individual's behavior according to Kholberg. Kholberg establishes three levels of morals—level 1: preconventional morals, level 2: conventional morals, and level 3: postconventional morals, each of these levels with two stages [5].

2.1. Bioethics

Under this rubric, we present some definitions of bioethics, which considers the ethical aspects of the life sciences, as well as the relationships of humans with the rest of the living beings.

According to the World Health Organization (WHO), bioethics is a discipline that seeks to clarify ethical problems presenting in relation to health while conducting investigations on human beings, designing or implementing a health policy, and providing medical care (e.g., a regional bioethics program) [6].

According to the Joseph and Rose Kennedy Institute of Bioethics Encyclopedia, bioethics is the systematic study of human behavior in the area of the biological sciences and health care, to the extent that this behavior is analyzed based on moral principles and values [7].

According to Vallero,

Bioethics is the assemblage of moral principles and values needed to respect, protect, and enhance life. Engineers, medical practitioners, and all technical professionals must be clear regarding this meaning [8].

Bioethics should provide interdisciplinary and multidisciplinary training for any area of the natural and social sciences [9].

2.2. Education

We live in a globalized world in which we must, every day, seek a better society, a society in which one can coexist with others, have respect for others, and in which the practice of these values is not simply by chance. That is, we are seeking a values-educated society.

Nonetheless, to speak of education and define it is not easy, in that it is an extremely broad theme. Therefore, it is important to situate ourselves within the context. For the latter, we will start by mentioning here some concepts of education cited by diverse authors.

2.2.1. Aristotle

Education consists of directing the feelings of pleasure and pain toward an ethical order [10].

2.2.2. Marañon

Education is an ethical overcoming of the instincts [11].

2.2.3. Spranger

To educate is to transfer to another, with self-less love, the resolution to develop, from the inside out, all of one's capacity to receive and forge values [12].

http://dx.doi.org/10.5772/intechopen.74519

2.2.4. Gottler

Education is the elevating influence, integrated by psychic caring (release from obstructions, teaching, inspiration, exercise) that the adult generation exercises on the development of the generation of individuals who are maturing, with the object of preparing that next generation to personally lead their own existence among the societies surrounding them in vital fashion, and with that the intelligent realization of the values that form the foundation of these societies [13].

On the other hand, education can also be considered as the basis for the growth of all societies. Education allows us to know, experience, and propose everything that is necessary to achieve the integral development of each individual, thus the development of a society. In this vein, Fernando Savagery has noted: "We are born humans but that is not sufficient: we also have to become one", which we will achieve through education of the individual based on human development [14].

Individuals as well as nations benefit from education. People achieve a better quality of life, obtain greater opportunities for employment and with this, sustained economic development. For nations, the potential benefits are mirrored in economic growth and the development of shared values that strengthen social cohesion [15].

UNESCO contributes to the creation of sustainable societies by accelerating progress toward the objectives of "education for all," while it aids member states to increase their human and institutional capacities within the ambit of education [16].

According to the latter, different international organizations seek education for all, equality of opportunity, and access to education. In order to achieve this, we cannot omit the four essential pillars of learning presented to us by Jacques Delors in his report entitled "The treasure within; learning to know, learning to do, learning to live together and learning to be" [17].

2.2.5. Learning to know

This pillar has as its purpose the acquisition of the elements of understanding and can be simultaneously considered as the means and the end of human life. In this knowledge, the importance of scientific reasoning and the need for a wide-reaching general culture is highlighted. This type of learning stimulates the critical sense, permitting one to decipher reality. The importance of "learning to learn, exercising the attention, memory, and thought" is emphasized [17], mentioning that the process of learning happens during one's entire life.

2.2.6. Learning to do

The purpose of "learning to do" is to be able to exert an influence on one's own ambit and improve it.

2.2.7. Learning to live together

This pillar emphasizes the ability to learn to live together in order to participate and cooperate with others in all human activities.

2.2.8. Learning to be

This pillar of learning comprises the integrating of the other three pillars, in which development, in all of its aspects, is sought of the human being. Education must be pursued to create thinking human beings, creative, and free-thinking, so that they can be the creators of their own destiny.

This pillar of learning is found to be directly related to Edgar Morin's seventh pillar of learning in "The Ethic of the Human Gender" (130): "One necessarily human ethic, that is, an anto-ethic, should be considered as an ethic of the individual-societal-species loop, from which our properly human conscience and spirit arise" [18].

Finally, the objectives of an education are very diverse, depending on the context and focus desired. Nonetheless, something on which we can agree is that higher education should foster in the individual a necessarily human ethic that takes into account the individual-society-species triad with the purpose of forging a true relationship between the society and the individual in its midst, that is, forming the individual for a life in society.

2.3. Bioethics in higher education

From its origins, education has always been related with the formation of values in individuals. Thus, the belief has been established that values are universal. Based on this belief, an ethic may be considered to be not just about the rights and obligations of the subjects, but rather concerning obligations, contents, and points of view [19]. This could have contributed to the fact that, in the 1990s, Latin America began to demonstrate interest in generating a higher education of quality, perceiving in this a tool for confronting the educative demands driven by globalization. [20].

This transformation of education cannot be considered an easy process to be conceived of by one or two individuals, as it not only comprises implementing values or moral issues. Transformation takes place, from the teacher who transmits values, regulations, and moral rights, and motivates the student to create a critical conscience, and learn to be and live together in society [21].

In any educative profession, without excluding the specialized area of study (the social sciences, the medical-biological sciences, the engineering sciences, the applied sciences, etc.), novel processes should be proposed to foster the autonomy of the student body, for example, information and communications technologies (ICT), in order for there to be a beneficial end for both the professor and the student. Similarly, educative institutions can promote the process of communicative interaction, fostered by new technologies, with the purpose of encouraging persons to seek, select, understand, and interpret the information engendered by the media in areas of public life through ethical responsibility [22].

The importance of producing critical thought in students of higher education lies in being able to provide the said students with the tools of defense for use when they are confronted with a moral or ethical problem—these tools will help students to choose the best values, norms, and moral rights to solve a contrariety in the social ambit.

http://dx.doi.org/10.5772/intechopen.74519

Universities in each of their knowledge areas generate professionals who require the society. Thus, their graduates must know the social and cultural environment. The graduates must consider the discipline of bioethics in each of their knowledge areas as an essential part of the profession [23].

There has been great interest in bioethics in field of medicine. However, it should not be forgotten that bioethics is important in other branches of knowledge too, such as the physical-mathematical sciences, the social sciences, the administrative sciences, and the humanities.

Higher education is centered on the creation of professionals who are trained to drive development. Knowledge acquired in the classroom presents utopic scenarios that are, on occasion, far from the social, economic, and environmental reality in which the world finds itself, thus generating knowledge without considering the fact that the constant change occurring in the student's ambit can create an erroneous focus for decision making.

The application of science and technology in knowledge fields generated from higher education is modified by the changes taking place at the global level. This means that the professionals carrying out this application need to know the external factors that affect their knowledge area, in order to achieve results that benefit the population but that do not affect the environment in which they are developed [24]. For this to happen, it is necessary for educative systems to offer adequate preparation to ensure that the actions undertaken do not have repercussions on living systems or the physical beings with which they interact.

2.4. Bioethics as a discipline in higher education

The design or planning of systems of education should be constantly updated for the creation of professionals who are not only experts in their respective knowledge areas, but in addition, are able to solve the bioethical problems with which they may be confronted. This is the reason why, within the modifications of the curricular system, the insertion of bioethics is of vital importance for achieving human development.

Educative models cannot be identified as neutral. From the deontological, that is, the normative ethical position's perspective, each of the degree program studies imparted should be constantly updated in terms of its values and world view. The views should be promoted from the historical perspective and from the reality encountered by each profession [24].

Professionalism as an implicit objective of higher education can be expressed in terms of an array of values, attitudes, and behaviors that are in the interests of the society around oneself. Within this concept, it is also necessary to include the environment and living beings in general. Professionalism should aid in maintaining values above the social, economic, and political pressures to which a student during his/her formation can find him/herself submitted.

The teaching of bioethics throughout the academic lives of the student is, on occasion, regarded as an independent process that may or may not be present in curricular maps, but that occurs in study assignments, whose teaching objectives include facing ethical situations in daily life. However, it is necessary for teaching to impart the most basic values of respect for life and for living beings, as well to prepare the student for new forms that put values to the

test. Bioethics as an independent discipline is important for achieving the integral formation of the students, but teaching bioethics in an integral and systematic fashion in all of the students' courses permits the latter to have a broader panorama concerning the decisions and dilemmas that they must face, so that they may respond to these in the best manner possible [25].

Bioethics from a transversal perspective allows students to position, in the best way, the situations that they will encounter and for them to bear in mind, according to their university degree studies, the ethical problems that they will be called upon to solve.

It is easy to believe that bioethics would only be necessary in the area of the biological sciences, in that the investigation and practice of these specialities are in close proximity with human health. Notwithstanding this, in view of the current rate of technological advance, the areas of the exact sciences have acquired a greater need for the intervention of bioethics to solve bioethical problems. Therefore, it is necessary to offer a bioethical education in order to produce professionals who are prepared and who can provide solutions that are not always binary responses. In moral problems, there is the need for the capacity to analyze, understand, and provide solutions in not only an individual manner, but also one that benefits the society.

The process of teaching and learning bioethics should be characterized by transdisciplinarity that leads to integral reflection on the proposed situation by means of the values obtained through bioethical knowledge. It complies with the development of science and technology in a responsible fashion, generating spaces and activities allowing for the development of values and the solving of ethical problems and the problems surrounding the context of the courses that require this throughout their higher education [25].

Bioethics, in addition to forming professionals with the moral caliber to make decisions that solve dilemmas in terms of their knowledge, also helps to form citizens who have the capacity to choose to be motivated in their actions to a greater degree by their moral quality than by the judicial terms imposed upon them.

The Institutes of Education Sciences (IES) are recognized for the driving of their students in the scientific ambit, by means of seeding in them the curiosity for carrying out investigations in the search for solutions. However, within the bioethical environment, an attempt is also made to offer quality goods and services that benefit the population on the part of health professionals who give importance to the implementation of values and roles [26, 27].

World-class institutions should impart knowledge on bioethics in higher education. There is an overwhelming need for implementing professional transformation in schools in Latin America, such as an integral and complete transformation from the standpoints of morals and ethics in students in all disciplines. The objective of this transformation should be directed toward improving the conditions of human life [28, 29].

As of now the theme is scarcely known and it is of great concern that professionals emerge from their undergraduate degree studies without a clear idea of ethical values and legal questions, knowing that they are about to come face-to-face with an independent professional life. The need to create and implement a bioethics program arises due to the results of a study carried out in two Latin-American institutions of higher education, specifically teaching courses that leads to

an undergraduate odontology degree. Here, the students were unaware of the importance of informed consent, as well as of the legal bases that they should take into account prior to providing care for a patient [30].

Similar to the views of Henríques [31], the importance of bioethics in the transformation of the pharmaceutical professional is highlighted. The author mentions the multidisciplinary relationship that exists among the pharmacist, the physician, and the nurse in terms of recommendation and administration of the drug. Because of the bioethical values acquired, the pharmacist possesses responsibilities concerning the regulations and control of the pharmaceutical products, as well as having knowledge on the properties and management of the medications, in addition to therapeutic alternatives and adverse consequences—overall, the priority is the well-being of the patients.

Bioethics is not only limited to inclusion in the disciplines of the medical-biological sciences area; it is also taking on a presence in administrative areas, as companies work by means of, with, and for persons through a link known as "human capital." Administrators carry out activities that involve management of the human factor; for this reason, they should possess the knowledge of, an attitude toward, and the management of bioethics so as not to cause harm to the mental and physical health of the persons contributing to the functions of the enterprise [32].

2.5. Bioethics in electronic learning

Online or electronic learning refers to the utilization of information and communication technologies (ICT) as support for academic formation at a distance, combining pedagogical elements and multimedia resources for learning, in addition to using it as a platform that allows instructors and students to maintain contact in real or deferred time by means of communication tools such as electronic mail.

The principal advantages of electronic education are ease of time management, the freedom to carry out other activities such as work-study programs, information by distant media, and allowing the students to use learning styles that best suit them, for example, videos, audios, and written texts [33].

Bioethics, while it has not been fully adopted in the present higher educational system, appears to be even further away from being adopted by institutions offering online education. Nonetheless, this presupposes a greater possibility of having students who participate under the concept of less effort in academic activities and in participating with fellow students, to the point that they engage in the dishonest behaviors, rendering it difficult to discover that they have received a non-presential education.

Online education has a great advantage in that it gives access to education to persons who did not have this previously, but without a sound teaching of bioethics, it is not possible to ensure that the professionals emerging from online courses are prepared to make decisions that entail the best benefits for the society in which they are developed.

2.6. Bioethics in postgraduate education

Bioethics, viewed from the medical scope and in the postgraduate area is considered as an analysis of human behavior, encompassing the activities and roles engaged in by the health professional in society [34].

Incorporation of bioethics in the pre- and postgraduate components of these fields is essential and invaluable for improving the quality of medical care and for continuing with scientific advances that benefit persons in terms of disease. Frequently, the professional solely takes into account the biological risks, that is, he/she attempts to avoid physical harm but forgets that the psychological, moral, or social damage that can arise can be greater than damage to physical integrity [35].

The importance of bioethics in postgraduate studies lies in that any investigation protocol that involves the participation of human beings should have the approval of an Ethics Committee, which should provide the informed consent document containing the following information: data of the investigator; data of the subject-under-study; explanation of the procedure that will evaluate the subject; benefits of the study; risks of the study, and the revoking of the informed consent if the subject wishes to withdraw from the project.

Customarily, this type of evaluation has as its objective the provision of the legal and ethical requirements that protect the subjects-under- investigation, in this manner safeguarding their physical, emotional, and moral integrity [36].

Therefore, there can be a difference between bioethics at the higher education level and that in the postgraduate area. While in the former, an ethical education is inculcated in the student by the professor and the academic authorities, in postgraduate studies, it is the result of the formation and evaluation of a committee charged with assessing the legal requirements for protecting the physical integrity of the patient.

3. Conclusions

Bioethics should be considered as a compulsory discipline within the curricula of different areas of university knowledge, not only in the area of medical-biological sciences. This is due to the dynamic environments of higher and postgraduate education systems. Bioethics is also considered as a learning framework that is the best way to teach decision-making based on ethics and human values that is necessary for the development of a country and even the world.

The main objective of university education is transformative. It makes beneficial changes in human beings transforming their character and personality. Education is a moral enterprise because it expands the values that have been received. Bioethics education has a similar objective; it invites individuals to participate in a professional community, in the construction and reinforcement of its identity through ethics in knowledge and professional practice.

Bioethics needs to be adopted in online higher education programs because more and more universities offer degrees in this modality, and ethics and values should not be left aside in any form of education.

Finally, it is observed that it is necessary to incorporate the principles and norms of bioethics in the areas of higher education and postgraduate studies in such a way that it is involved in the development of the students' professional life, highlighting human values and responsibility, honesty in work. This involves a change of paradigm with the aim of increasing knowledge keeping in mind ethical principles in daily procedures.

Acknowledgements

Al Instituto Politécnico Nacional. Supported by SIP Project, No. 20180098, 20170393 y 20170471 ESCOM-IPN. Al Consejo Nacional de Ciencia y Tecnología, CONACyT, México.

Conflict of interest

The authors declare no conflict of interest.

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Chapter 6

Russian School of Bioethics: History and the Present†

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.74526

Abstract

This chapter presents the results of a comparative analysis of the Genesis of the word "bioethics" in Russian and foreign scientific literature. It is inferred that from the beginning, "bioethics" carried in itself a philosophical content that becomes deeper in the conditions of globalization and development of modern technologies. The philosophical content gives the opportunity to create interdisciplinary dialog in heated discussions on bioethical issues. An important feature of the Russian school of bioethics is its interdisciplinarity. This reliance is mainly on medicine, philosophy, law, sociology, and education. Serious attention is paid to the Russian bioethics, the ethics of clinical research, and ethical committees of different levels. At the moment, we can talk about new topics of Russian bioethical discourse such as agrobioethics, nanobioethics, genetic editing, and ethical issues of medical and psychological enhancement of human.

Keywords: bioethics, philosophy, globalization, Russian school of bioethics, modern technology, interdisciplinary dialog

1. Introduction

Today in the twenty-first century, it can be stated that our civilization has encountered a number of global problems such as the problem of preservation of peace on the Earth, ecology, food and demographical problems, the problem of overcoming the poverty of the majority of the humankind, and the problems of health and quality of life. As a consequence, they give rise to large-scale tasks that are waiting for their solution, and bioethics plays not the least important role in this context. It is important to mention that the uprising of bioethics

†Dedicated in the memory of Professor Boris Yudin.

is of a multiple-factor character rather than just a combination of causes. It is a system of interrelated factors which caused a synergetic effect in the form of bioethics which is a science about search, assessment, and choice of a criterion of moral attitude to all living things.

This chapter considers the arguments supporting the following statements:

1. Bioethics appeared as a result of global changes both at the level of the depth conversion and achievements of modern science and the consequence of the globalization process manifested in the speed of its development and in the increasing influence of the importance of the global community joint activities in the solution of global problems.
2. On the one side, bioethics is an interdisciplinary field of knowledge, while on the other side, the level of understanding of the problems bioethics is solving, such as the ultimate grounds of human existence, its identity, dignity and justice, boundaries of the good and the evil, eco-axiological orientations of scientific research, and political solutions decision making, without any doubt giving priority to the philosophical matrix of its content existence.
3. A high level of potential and real hazards of achievements in modern biotechnologies, and the prevention and non-admittance of their use without preliminary humanitarian expert evaluation assign special social-regulatory status to bioethics. In this respect, "the search," "choice," and "assessment" of moral attitude to the living are the key notions. They become tools of "advanced experience" (Yudin) when situations of possible harm for the living are "played over" in the expert environment, remaining within the scenario "What if….?" that possibly will never be used to make a film [1, 20].
4. Bioethics is already an established independent branch of science of the epoch of the post-non-classical science, the subject of which is the assessment and the choice of a criterion of moral attitude to all flesh, the last being the congregation of living systems and its separate elements including the nature, a human being, and so on.
5. D. Callahan thinks that bioethics could not have appeared as a separate branch if at the same time there were no cultural and public achievements. Those decades were the soil for a great number of social changes and cultural reforms and the increasing role of human rights. This also shaped up as a revival of the subject of moral philosophy, growth of interest in regulatory and applied ethics, as well as dissatisfaction with the then predominant academic stress put on theoretical problems and striving to cultural radical changes [2].
6. Today, as Potter predicted, bioethics has expanded beyond an interdisciplinary dialog and the geographic range [1, 45]. It has become global in all respects. We can find the bioethical discourse in different scientific disciplines and technological practices. Representatives of different countries and confessions take part in bioethical discussions; bioethical schools and international communities of bioethicists are being formed and work successfully.
7. This chapter explains about the Russian school of bioethics which is a multidimensional phenomenon. However, before passing on to the history and modern time of its development, it is necessary to remind about the origins of bioethics and its founders. It is important as Russian bioethics blends seamlessly with the world context. Not only does it develops main areas of bioethics but also creates new platforms for bioethical discourse.

http://dx.doi.org/10.5772/intechopen.74526

The range of questions bioethics covers astounds by its diversity. Nevertheless, they are all united by the priority of such human values as life, health, well-being, and justice. Another characteristic trait of bioethics is its interdisciplinary nature, when representatives of medicine, law philosophy, biology, and of different religious confessions take part in bioethical discussions.

In fact, how can one define boundaries between life and death, who has the right to choose the limits of his existence—a professional or a common human being—what is the legal status of an embryo conceived *in vitro*, is the surrogate maternity justified, what will a person think about his or her possible genetic engineering and possible cloning, is it moral to use a human being or an animal as a clinical test object, is it possible to "dissemble" a human being for "spare parts" and organize their public bidding because of the total "deficit," are genetically modified products of agriculture and of medical nanotechnology safe for man, are medical-social resources distributed fairly, and so on?

These questions have been heatedly discussed in both foreign and domestic literature for more than 90 years already.

2. Brief history of notion of "bioethics"

Two events, important for all those dealing with bioethics, occurred not long ago. First, 47 years ago in 1971, Potter published his book "Bioethics: the bridge to the future" in which he introduced the notion of "bioethics." He defined it as "a new field of knowledge integrating biological knowledge and the system of human and moral values …. I used ***bio*** to represent biological knowledge, the science of live systems, and I used ***ethic*** to represent knowledge of systems of human moral values" [1].

Second, it has been 92 years since the German theologian and Pastor Fritz Jahr (1895–1953), whom Hans-Martin Sass justifiably called the father of bioethical research, proposed the term "bioethics" (Bio-Ethik) already in the distant 1926 [3].

According to Potter, the development of the new discipline of bioethics was supposed to build a bridge between two notions—science and the human nature. In his work "Bioethics: the bridge to the future," Potter defined the priority of the problem, namely the problem of survival in the conditions of the modern world. His aim was to define and in the best way to develop changing environmental conditions and the optimum adjustment of a human being to this environment with the aim of improving the civilized world and of defending the scientific, cultural, and intellectual progress necessary for the survival of the humankind [4]. Potter thought that the final aim of bioethics was "not only in enriching the life of every person but also in extending the survival of humankind and in the suitable structure of the society" [5]. Later, Potter also included medical aims and aims related to health into his prospects. Reich, the chief editor of the Encyclopedia of Bioethics in five volumes [6], which stood several publications and became the classical theoretical basis for all those, who deal with problems of bioethics, underlines that Potter's subjective understanding of bioethics was anthropocentric (survival of a human being) rather than biocentric (survival and state

of the biosphere) [7]. At the same time, in his other work "The Global bioethics," Potter says that his understanding of bioethics was influenced by the work "The land ethic" by Leopold (1949), and he formulated his concept proceeding from the close relation between the bioethical theory and the ecological ethics [7]. In this book, Potter continues to develop the idea of close interaction of ethics with ecology, medicine, and science and puts the main accent on the ethics of survival and the global ethics. Stating that bioethics should be built on interdisciplinary relations and on the basis of many disciplines, he proposed two important spheres, which seem independent but at the same time need each other. Medical bioethics and environmental bioethics do not intertwine as the former deals with short-term topics such as options proposed to individuals by their doctors in the efforts to prolong their life by using organ transplants, man-made organs, experimental chemotherapy, and all the latest findings in the field of medicine. "Environmental bioethics has a long-term view concerning what we should do to maintain the ecosystem in a form compatible with reproduction of future generations. Nevertheless, these two branches of bioethics should intertwine reliably in the cause of protection of the individual health, control over reproduction and in respect of the meaning of human population growth" and he introduces the terms "global bioethics" and environmental bioethics [7].

Still earlier, Fritz Jahr, who was inspired by the comparative studies of Wilhelm Wundt concerning physiology and psychology of humans, animals, and plants as well as by philosophic contemplations of Fechner about the potential life of plant soul, transformed and broadened the categorical imperative of Kant into a bioethical imperative. He understands it as follows: "Respect every live creature in principle as a goal in and of itself and – if possible – consider it as such" [3]. Sanctity of law of God (moral law) was the foundation of the categorical imperative of Kant while the sanctity of life was the foundation of Jahr's bioethical imperative. While Kant's model was formal and rigorous, Jahr, who admitted interrelation between taking care of oneself and care for others, replaced the dignity of respecting the law by the dignity of compassion to all "live factors of growth" that is both to life and all its forms. It goes without saying that it was not Jahr who invented live ethics. Referring to European and Oriental traditions, in 1926, he published an article entitled "Natural sciences and teaching ethics" where he gave the subtitle "Old Knowledge in new clothes" describing the function of natural sciences for education and teaching biological research ethics [3].

Ideas and work of a scientist Andre Hellegers from the University of Georgetown became an important contribution into the uprising and development of bioethics as a term and a discipline [8]. According to Reich, he confirmed the term "bioethics" and with this the field of knowledge, social movement in the academic world, in biomedical sciences, governments, and mass media. He was the first in the world to establish an institute of bioethics on the basis of interdisciplinary research and approaches, namely the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics. Together with his colleagues, he believed that bioethics would be a unique field integrating science and ethics, and so much attention should be paid to studies of underlying moral values appearing in bioethical concepts. At the same time, he thought that his role was to be "a link" between medicine, philosophy, and ethics. Andre Hellegers is justifiably thought to be "the chief architect of ideas of this science" [9]. He developed the work plan for the Kennedy Institute, having organized

http://dx.doi.org/10.5772/intechopen.74526

the first permanent interdisciplinary research group. Its work reflected the main directions of bioethics and brought the international recognition.

The first encyclopedia of bioethics was published in 1978. In his article "The word 'Bioethics' its birth and heritage of those who created it" published in 1994, its chief editor Reich confessed that he was in a serious doubt as whether to use the word "bioethics" in the title of the encyclopedia, which supposedly should have been entitled "Encyclopedia of medical ethics" [10]. He wrote: "On the one side it seemed acceptable to use the established name of the discipline to name it, but on the other I was inclined to use the new word of 'bioethics' because I felt the term of medical ethics was too narrow as it ran counter to ethics of life sciences. Nevertheless it was too bold to give the title of 'bioethics" to encyclopedia as the word 'bioethics' appeared in the works of only one man and was included into the name of only one institute" [11]. At that moment, Reich thought that he was facing such difficult questions as "whether the discipline or the field of knowledge name 'bioethics' will really develop; whether it will last and whether the word 'bioethics' will be used to name the whole field of science" (*i.e., biomedical studies and their consequences for human beings—F.N.*). In addition, it is significant that he addressed not specialists in biology and medicine but to the editor-in-chief of the 16-volume encyclopedia of the social sciences, David Sills, who confirmed that "word will be established and the interest to this sphere will grow" [11].

Potter's "Global bioethics" was published in 1988 [12]. Together with dividing bioethics into two branches, Potter stressed that it was necessary to go further than Leopold and further than medical bioethics and that super-specialization in any sphere can stand against aims of admissible survival in the global scale. Two branches should be integrated, brought to one point of view and called global bioethics, stressing two meanings of the word "global." On the one hand, the system of ethics is global if it is united and comprehensive, and in the more common sense, if it is of the world scale [13].

In the introduction of the second issue of the "Encyclopedia of bioethics," Reich defines bioethics as "a systematical study of the field of moral – including moral views, decisions, behavior and policy – in life sciences and medical care, that uses diversity of ethical methodologies in interdisciplinary space." Proceeding, he specifies that "publishers consider bioethics to *be a discipline going beyond medical ethics* (italics supplied by F.N.). It integrates the moral interpretation of medical and scientific points of view on health of the population, environment, public ethics and protection of animals" [14]. It is important to pay special attention to the article "Bioethics" written by Daniel Callahan, one of the scientists who was one of the originators of bioethics both as a term and as a branch of science. He defined bioethics as a science "which is the product of biomedical achievements related to the environment and social sciences" [15]. In his article, he also stresses that bioethics is the further transformation of medical ethics, and while the primary center of bioethics is medicine and health care, the possibilities of bioethics cover multiple spheres and disciplines widely classified as "**life sciences**": "Bioethics appeared to steer people to a wide field of moral life problems, which usually cover medicine, biology, environment, population and social sciences" [15]. It is important to mention such fundamental works as "Foundations of bioethics" by Engelhart Jr, and "The principles of biomedical ethics" by Beauchamp and Childress which played the key role in the development of bioethics [16, 17].

The Beauchamp and Childress concept of bioethics includes four principles and a set of rules, validate it using the principles. Rules in turn are used to justify moral decisions and actions in specific situations. The basic principles of bioethics, according to Beauchamp and Childress, is the principle of respect for patient autonomy, which has grounded, in particular, the concept of informed consent; dates back to the Hippocratic principle of "do no harm," which requires minimization of damage to the patient during the medical intervention; the principle of "do good" (beneficence), emphasizing the physician's responsibility to take positive steps to improve the condition of the patient; finally, the principle of justice, emphasizing the need for fairness and equal treatment of patients, and equitable distribution of resources (which are always limited) in the provision of medical care [17].

This brief history of notion of "bioethics" and ideas that influenced the formation of the Russian school of bioethics can be illustrated in a table form (**Table 1**).

Name	Where/Time	The main idea
Van Rensselaer Potter	Bioethics: the bridge to the future, 1971 Global bioethics, 1988	"…a new field of knowledge integrating biological knowledge and the system of human and moral values …. I used *bio* to represent biological knowledge, the science of live systems, and I used *ethic* to represent knowledge of systems of human moral values" [1].
Fritz Jahr	Natural sciences and teaching ethics, 1926	The term "bioethics" (Bio-Ethik) understands it as follows: "Respect every live creature in principle as a goal in and of itself and – if possible – consider it as such" [3].
Andre Hellegers	Bioethics center formed // Chemical and engineering news, 1971	He used the term "bioethics" to refer to interdisciplinary research moral problems of biomedicine, primarily associated with the need to protect the dignity and rights of patients [8, 9]. He was the first in the world to establish an institute of bioethics on the basis of interdisciplinary research and approaches, namely the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics. Together with his colleagues, he believed that bioethics would be a unique field integrating science and ethics, and so much attention should be paid to studies of underlying moral values appearing in bioethical concepts. At the same time, he thought that his role was to be "a link" between medicine, philosophy, and ethics.
W.T. Reich, chief editor	Encyclopedia of bioethics/ W.T. Reich Editor-in-chief. N.Y. 1978, 1995	Defines bioethics as "a systematical study of the field of moral – including moral views, decisions, behavior and policy – in life sciences and medical care that uses diversity of ethical methodologies in interdisciplinary space." Proceeding, he specifies that "publishers consider bioethics to *be a discipline going beyond medical ethics* (italics supplied by F.N.). It integrates the moral interpretation of medical and scientific points of view on health of the population, environment, public ethics and protection of animals" [14].
Daniel Callahan	Bioethics. Encyclopedia of bioethics. N.Y., 1995	He defined bioethics as a science "which is the product of biomedical achievements related to the environment and social sciences" [15]. In his article, he also stresses that bioethics is the further transformation of medical ethics, and while the primary center of bioethics is medicine and health care, the possibilities of bioethics cover multiple spheres and disciplines widely classified as "**life sciences**": "Bioethics appeared to steer people to a wide field of moral life problems, which usually cover medicine, biology, environment, population and social sciences" [15].

Name	Where/Time	The main idea
H. Tristram Engelhart, Jr.	The Foundation of Bioethics, 1996.	"Moral diversity is real. It is real in fact and in principle. Bioethics and healthcare policy have yet to take this diversity seriously. Those who teach bioethics, those who engage in bioethics committees, even those who produced textbooks tend to discount the diversity of understanding regarding the morality of particular health care choices (e.g., regarding abortion, commercial surrogacy, euthanasia/ germline genetic engineering, inequalities in access to health care, infanticide, organ sales) or the nature of morality (e.g., theological, deontological, virtue-based) [18].
Tom L. Beauchamp and James F. Childress	The principles of biomedical ethics, 1994	The basic principles of bioethics, according to Beauchamp and Childress, is the principle of respect for patient autonomy, which has grounded, in particular, the concept of informed consent; dates back to the Hippocratic principle of "do no harm," which requires minimization of damage to the patient during the medical intervention; the principle of "do good" (beneficence), emphasizing the physician's responsibility to take positive steps to improve the condition of the patient; finally, the principle of justice, emphasizing the need for fairness and equal treatment of patients, and equitable distribution of resources (which are always limited) in the provision of medical care [17].

Table 1. Main authors and ideas that influenced the formation of Russian school of bioethics.

3. Outlook of Russian school of bioethics

A special place, in our opinion, the development of bioethics, has been made by Russian scientists.

Russian school of bioethics originates from the late 1980s of the twentieth century [19]. Among Russian authors, one should first of all mention the well-known Russian philosopher, the academician of Russian Academy of Science (RAS), Professor Boris Grigoryevich Yudin, starting with such fundamental work "Ethics of science. Problems and discussions" [19] written together with the scientist Frolov, four of eight chapters of which are dedicated to problems of bioethics (however, this term was not used at that time yet and Yudin himself confessed that he first heard about bioethics in 1989, when American philosophers came to the Institute of Philosophy of Russian Academy of Sciences) [20]. In 1990, he, as a member of a Russian delegation, visited the leading bioethical centers in the USA. In 1991, he gave the first educational course of bioethics at the philosophy department of Moscow State University, in Russia. The sector of bioethics was organized in the Institute of Human of the Russian Academy of Sciences (RAS) in 1992, and Yudin became the head of it by the invitation of Frolov. The bioethics sector was one of the most active departments of the Institute of Human. It started carrying out research of such issues as the informed consent, ethical problems of experiments with animals, and ethical aspects of new reproductive technologies. Yudin can justifiably be called one of the founders of the domestic scientific school of bioethics, a leader of the Russian bioethics [21, 22]. Together with the Russian national committee on bioethics, the sector studied social-ethical problems, arising during implementation of the "Human genome" project [23, 24]. Yudin also took an active part in another direction of work of the Institute of Human,

namely humanitarian expertise. The staff of the institute prepared expert reports for governmental bodies and international organizations. Under the guidance of Yudin, the Institute of Human was the first to develop a project "The human potential of Russia" [25].

In 2005–2013, Yudin was the head of the department of comprehensive problems of the study of man at the Institute of Human of the RAS and made a crucial contribution into the development of bioethics as both a research area and an academic subject. He trained young specialists in philosophical bioethics and organized a number of conferences and trainings in bioethics with the participation of international specialists. Several projects in humanitarian issues of biology and medicine were implemented at the Institute of Fundamental and Applied Research by means of Russian and international grants.

Yudin carried out huge international work in the field of bioethics. Since 1998, he was an expert from the Russian Federation, and from 2000 till 2004, he was a member of the Committee on Bioethics of the Council of Europe. He participated in elaborating and passing protocols, regulating the use of achievements of genetics in medicine, scientific studies on a human being, and organ transplants. He made presentations at the world congresses in bioethics. In recent years, Yudin paid much attention to the ethical regulation of a matter of biotechnological engineering, "improvement" of a human being, to the imperative of fidelity in research and understanding of philosophy as an expertise [26]. The multi-author book "Philosophy of biomedical studies: the ethos of the beginning of the third millennium" (2004) under the editorship of Yudin is very interesting by its choice of material and the number of covered problems [27].

Together with the famous Russian scientist Frolov, Yudin was the founder of not only the Institute in the Study of Human but also the "Human" journal [28]. In Russian, it is called "Chelovek." This journal has become a main public platform of the most interesting discussions and became a blood vessel supplying fresh "blood" in the form of new, original ideas and approaches, which were first of all related to bioethical problems.

Sadly, Professor Yudin passed away in 2017, but his scientific works and ideas are still popular and continued by his colleagues.

Doctor of philosophy, Professor Tischenko, who held the same views as those of Professor Yudin [24], became his associate, and his scientific interest covered such fields as bioethics (issues of justice, ethics of genome studies, euthanasia, and transplantology), bio-power and bio-politics, and the philosophy of post-classical science. Tischenko develops the idea of "local contingent rationality" of scientific and moral discourses, competing for recognition in the sphere of the secular language, and introduces the understanding of the genesis of a new configuration of "bio-power" related to decentered social biomedicine institutes which function controlling procedures of interpretation of being, the fact of existence, and the appropriate number of people. One should specially mention a number of his books and articles, such as "Phenomenon of bioethics" and "To the origins of bioethics" which have already become classical for bioethical discourse [29–31]. His fundamental work "Bio-power in the era of biotechnologies" was published in 2001. Tischenko emphasizes that "bioethics is the field of interdisciplinary research of ethical, philosophical and anthropological problems arising due to the progress of biomedical science and introduction of advanced technologies into the healthcare practice" [32].

http://dx.doi.org/10.5772/intechopen.74526

Yudin and Tischenko are the authors of the concept of social-humanitarian support of innovative activity, including ideas of ethical and social-humanitarian expertise (proactive diagnostics, assessment, and risk management) developed earlier [33]. They think that it is not only scientists who must understand something and engineers, who must develop something, but also representatives of different social groups who must realize the personal, professional, and (or) public meaning of discoveries and inventions (both already existing and the future ones). While solving these tasks, bioethics in the mode of joint work with biomedical sciences and technologies brings the sphere of social relations in order practically in the same way as science brings order into the world of relations in nature, and this is the meaning of the idea of social-humanitarian support of innovative activity [34].

Honored Scientist of the Russian Federation, Doctor of Philosophical Sciences, Doctor of Juridical Science, full professor, the head of the Russian Unit of International Network of the UNESCO chair in bioethics, the head of the Department of the ethical, legal, and sociological expertise in medicine of the Volgograd Medical Research Center, Sedova has made a significant contribution into the development of Russian and international bioethics. Since 1985, she has been the head of the department of philosophy, bioethics, and law. She is also the founder and co-chairwoman of the Regional Ethical Committee (REC) which began its work in 1985. In 2002, she organized and headed the department of ethical and legal expertise of scientific research in the Volgograd Scientific Centre of the Russian Academy of Medical Sciences (RAMC), which was also the first in Russia. She made a great theoretical contribution into the validation of the three-level structure of bioethics, the development of a hierarchic model of ethical committees for Russia. Sedova also developed a concept of feedback in the system "the moral- the law" and legal institutionalization of bioethics ("Legal foundations of bioethics," M, 2004) [35], worked out principles of organization and structure of ethical committees in Russia ("Applied bioethics," M, 2002—in collaboration with the Academician of RAMC, Petrov) [36], and wrote works on the issues of informed consent ("The Law and the Ethics in pediatrics: the issue of informed consent," M, 2004) [37]. Sedova has established and successfully publishes the magazine "Bioethics" which is the first in Russia and prints articles of current concern in bioethics from the interdisciplinary point of view: philosophy, medicine, law, sociology, and other scientific fields. This magazine enjoys a well-deserved respect and is included into the base of the Russian Scientific Citation Index (RSCI) and into the list of peer-reviewed journals of the State Commission for Academic Degrees and Titles of the Russian Federation [38].

Doctor of Sciences in Philosophy, Professor Siluyanova, who is a pioneer in teaching biomedical ethics at the higher medical school of Russia, can be quite justifiably attributed to founders of modern Russian bioethics. She approached bioethical issues from the point of view of Russia Orthodoxy. In her works such as "Modern medicine and Orthodoxy" (1998) [39], "Ethics of the art of treatment" (2001) [40], "Anthropology of disease" (2007) [41], and others, she states that the main difference between "an Orthodox doctor" and "a non-Orthodox one" is in understanding the nature of a disease of a person. For an Orthodox doctor, a disease is always a result of malfunctioning of the unity of spiritual and physiological in a human being. The Orthodox doctor also understands that the cure depends on restoring this unity as well, as the basis of the personal integrity that is the attainment of cure depends not only from the organism but also from the personality. She also considers the problem of human rights through the

lens of Orthodoxy. The basic rights stated and listed in the Universal Declaration of Human Rights (1948, the UN) [42] are unconditional, and the difficulty arises when the list of these rights grows unlimitedly and such rights as "reproductive rights" and "sexual rights" become attached to it. Their real nature lies in willfulness and seeking to change the human nature itself with inevitably fatal consequences for it. Bioethics is the knowledge, the task of which is to protect human life from possible kinds of "artificial" and "invented" rights on changing one's nature, on the denial of moral laws protecting the nature, society, and human life.

Starting from 2009, the Institute of Philosophy of Russian Academy of Sciences publishes "Work books in bioethics" dedicated to its different branches; in 2010, it started to publish international e-journal "Medical anthropology and bioethics" [43].

In Kazan (Republic of Tatarstan), professor of philosophy Nezhmetdinova obtained the grant to develop a course of bioethics for students in 1994. This course passed attestation by the University of New York, and in 1996, it was approved and supported by the University of Kent (Great Britain). This program became the basis for the course in biomedical ethics, when Nezhmetdinova started lecturing it to students of the medical university by the initiative of Professor Albitskiy. At that time, it was regarded as something exotic. In the following 3 years, it became possible to prove the livability of this field and to "capture" the wider public, and the independent chair of biomedical ethics and medical law with the course in the history of medicine was established in 1998, which was the first to be developed in Russia. As the desire to study the new scientific field was enormous and there was no methodological support, a textbook "The law and medicine: bioethical foundations" was written in 1998 [44], and bioethical issues became part of scientific research work of the staff, doctoral students, and degree-seeking applicants of the chair. In 2000, Nezhmetdinova and Guryleva developed legal and regulatory documents, and with the support of the rector of the Kazan Medical University, Professor Amirov organized an ethical committee with local functions. Three years later, due to the growth of multicenter clinical studies and the appearance of legal regulatory actions, namely the law of the Russian Health Ministry "On approval of Rules of clinical practice in Russian Federation," there appeared the necessity to organize a Regional Ethical Committee (Regional Committee of ethical issues in clinical drug trials under the Ministry of Healthcare of the Republic of Tatarstan). This situation was an exception rather than a rule for Russia. There was a disastrous lack of knowledge, but the Kazan school of bioethics has the great stroke of luck. Since 2002, the topical nuts-and-bolts course was organized with the support of UNESCO for ethical committees of the post-soviet countries, and representatives of the Kazan school Nezhmetdinova and Guryleva took an active part in conferences and workshops, first as trainees and then as full participants of discussions. The Forum of committees in ethics of the CIS member-countries organized by Kubar enabled the whole commonwealth to take a common stand in issues of ethics of clinical studies and to think about legal aspects not only of clinical trials but also about medical practice as is evidenced by such model laws as "On protection of human rights and dignity in biomedical studies in the CIS member-countries" and "On ethical-legal protection and safety of genetic medical studies in the CIS member-countries" passed by the Inter-Parliamentary Assembly of the CIS countries.

One can say about the birth of a new research area of agrobioethics developed by the initiative of Nezhmetdinova [45]. This is due to global challenges and bio-technologization of economy [46].

Agrobioethics is understood as a mechanism of social control and regulation of new "material viability" in bioeconomics [47, 48]. Agrobioethics represents a new approach to the solution of ethical dilemmas, which can arise in everyday practice of using new technologies in agriculture. It is an experience of solving disputes, inter-personal and social communication for solving controversies both between producers and customers and between the state and the civil society [45, 46].

4. Conclusion: Global trends to global bioethics

Global challenges and strategic and social-economic priorities of the future of the humankind have made it necessary to fasten the study, forecast and development of means which should promote sustainable development, provide population safety and quality of life, protect ecology, and improve the rational use of nature. Currently developed countries are starting the formation of a new technological base of economic systems based on the use of the latest achievements in biotechnologies, information science, and nanotechnologies including agriculture, medicine, veterinary, ecology, and other spheres. This will make it possible for the humankind to solve four main problems it is facing today—food supply, quality of health care, degradation of environment, and problems connected with the exhaustion of power, raw materials, and other recourses.

On the one hand, we are contemporaries of the global problems that need urgent solution as we are talking about the future of the humankind. On the other hand, we witness or directly participate in scientific fundamental cutting-edge achievements which make it possible to change fundamentals of being on the level of life and artificial matter or their synthesis. In 2002, the National Scientific Fund of the USA and the American Ministry of Economy using forecasts of scientists prepared and published a well-known Report on Convergent technologies NBIC (NBIC: N—nano, B—bio, I—infor и C—cogno). It stressed out that the convergence of NBIC technologies would become the basis of a new technological structure [49].

In 1998, a famous Russian scientist who is currently the directors of the Institute named after Kurchatov, Mikhail Kovalchuk, proposed his own version of uniting together these four fields of knowledge. In 2011, in his article named "Convergence of sciences and technologies is a breakthrough into the future," he gave both conceptual basics and serious arguments supporting the convergence of NANO-BIO-INFO-COGNO (NBIC). It is important that when compared with pure technological solutions of the NBIC technologies future development forecast, he includes humanitarian sciences in this process. According to Kovalcuk, the main objective of today's post-industrial stage of development of the society is reproduction of systems of live nature. The first stage is combining technological possibilities of modern microelectronics with achievements in studies of live nature (nano-biotechnologies). This means creating hybrid anthropomorphic technical systems of bionic type. The second stage is the integration of nano-biosensor platforms created at the first stage, that is, the development of technologies of atomic-molecular design and self-organization on the basis of atoms and bioorganic molecules, the result of which are biorobotic technical systems [50].

Another factor that makes the notion of bioethics preferable is the NBIC technologies convergence, which represents a mutual interaction of information technologies, biotechnologies,

nanotechnologies, and cognitive science. The term was introduced in 2002 by Mikhail Roko and William Bainbridge, the authors of the most important for today's work in this direction, the report "Converging Technologies for Improving Human Performance 1" prepared in 2002 in the WTEC [51]. NBIC convergence has not only huge scientific and technological importance. Technological possibilities appearing during the NBIC convergence inevitably will cause serious cultural, philosophical, and social disturbances. In particular, this concerns the revision of traditional understanding of such fundamental notions as life, mind, a human being, nature, existence. It is quite possible that from the certainty based on everyday experience, the humankind has to move to understanding that in the real world there are no clear boundaries between many phenomena, which were previously considered to be of dual nature. First of all, due to recent research, the traditional difference between live and inanimate loses its meaning. In the same way, the difference between a rational system possessing mind and free will and rigidly programmed system is gradually fading. Already today, live beings are created "artificially" with the help of gene engineering. One of these days, it will become possible to create complex live beings (also with the help of nanotechnologies from separate molecular-size elements.) In addition to broadening the boundaries of human creativity, this will also mean the transformation of our understanding of life and death. All this is in the center of bioethical discourse.

Also, today we witness futuristic or manifesting scenarios of the development of the human society. In his presentation made already in the autumn of 2010 at the scientific conference "Future talk" in Vienna, which discussed technologies of the future, a futurologist and trans humanist Raymond Kurzweil [52] spoke about fantastic possibilities that could become quite real: in the nearest 20 years, the humankind would be able to make the so-called "reserve copy of a brain," which would contain records of all reminiscences; a person will be able to look though his or her past which will be projected into his eyes: special nano-robots regulating the health of human being will be implanted into his blood system; in the 30s of the current century, the computer will prove existence of the artificial intellect, and it will be able to understand human words as a man does and will be able to pass the Turing test; the implantation of a special chip into the brain which will create virtual reality of "complete submersion" will become feasible; by 2040, a human body will be able to transform into any form which will also be made of a huge number of nano-robots, and all internal organs will be replaced by cybernetic devices. In conclusion, Kurzweil forecasts the coming of the complete "technological singularity" by 2045, the result of which will be turning the Earth into a single gigantic computer, and gradually this process will involve the whole of Universe [53].

In 2011, the "Project 2045" was developed in Russia, and a Manifesto of a strategic public movement "Russia 2045" was published. The Manifesto proclaims the demand for creating a new ideological paradigm for the necessity of "using breakthrough technologies for improvement the man himself and not only his habitat. We think that it is possible and necessary to eliminate aging and even death, to overcome fundamental limits of physical and psychological abilities, defined by restrictions of a biological body" [54].

The appearance of new options of the humankind future can form new moral Decalogues. They differ substantially from Biblical, Muslim, and other confessional variants of ethical codes. Currently, most official documents in bioethics, to which professional medical, biological,

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and nanotechnological communities refer, are mainly based on principles and approaches developed within the secular liberal bioethics. At the same time, positions of religious concepts, in particular of modern Christian social doctrines, are barely reflected in official international, state, and professional documents even though the substantial part of the society keeps Christian or Muslim ethical norms. The religious understanding of the world first of all is based on the creative mission of God. It is in the creation of all the living: life, a man, the nature. Modern NBIC technologies undermine the belief in creationism. Hence, a necessity arises in both the new interpretation of sacred books and the development of religious ethics.

Speaking about technological challenges, modern researchers and scientists cannot help but use the chance to express their anxiety and call to vigilance. Analyzing characterizing traits of the modern society (using the American one as an example), an American scientist Nesbitt calls it the Zone Poisoned by Technology, where

1. We feel fear about technology and worship it.
2. We are unable to tell reality from fantasy any more.
3. We take violence as a norm of life.
4. We love technology as children love toys.
5. Our life has become estranged and erratic [55].

The last 25 years of the twentieth century and the beginning of the twenty-first century gave rise to such a specific phenomenon which the German sociologist Ulrich Beck named "other modern" or "the society of risk" [56]. And we think that he quite correctly stressed the change of the meaning and use of the notion "risk" which from the category of the personal area only moves to the global level.

Second, if the previous century risk was considered to be a result of insufficient development of technologies and scientific knowledge, today risk appears where there is redundancy of technological and scientific progress [57]. This emerges the following questions: "Should we worry about this or leave it to the discretion of scientists-technologists? If we should then are there any humanitarian practices providing our bodily safety and fundamental basics of nature?"

In the Kazan school of bioethics, great attention is paid to the applied nature of bioethics. Updating of applied ethics seems quite natural in this respect. Here, we should remember the meaning given to ethics by classics of antique philosophy Plato and Aristotle. For Plato, ethics being the structural part of philosophic knowledge should teach the art of life. He thought that this was the real and highest possible good for a man [58]. While distinguishing theoretical and applied levels of the philosophical knowledge system, Aristotle also defined their aims as the truth and the good. He included ethics, politics, and economy into applied philosophy, thus emphasizing that ethics was the applied philosophy and so philosophical foundation of ethics is definitive in its character [59]. Judging from all said above, it is possible to make the following assumption: when this or that scientific discipline claims to be bioethics in interdisciplinary discussions, its philosophical origin is logical and crucial.

"*In the framework of applied ethics, the theoretical analysis, public discourse and direct morally responsible decision-making merge together and become a content of a real practice organized correctly. It is a special form of theorization. Theorization directly integrated into the life process, a kind of theorization in the terms of life.*" (italics by F.N.) [60]. As a consequence, the interpretation of the meaning of the adjective "applied" related to the noun "ethics" gains a special meaning. In this respect, the view point of Bakshtanovskiy and Samogonov, which states that what it involves is first of all the integration of both sides of ethics—both moral practice and ethical knowledge into the field of reflection about the nature of the applied ethics, seems most trustworthy and well reasoned. This finds its reflection in ethical know-how for the interaction of two sides of applied ethics (rational analysis of moral choice situations, ethical design and modeling, ethical expertise and consulting, etc.). And further, the meaning of the word "applied" used with the noun "ethics" is considered as a supplement understood as a process of moral creative art, concretization procedure, an *act of a moral choice* (italics by F.N.) The concept of these authors considers the modus Vivendi of the applied ethics to be the moral choice, and the applied ethics is defined as "regulatory and value subsystems concretizing moral (business ethics, ethics of journalism, bioethics and etc.) and the theory of concretizing of moral, project-oriented knowledge" [61].

A number of researchers divide bioethics into three levels—theoretical, practical, and applied. In particular, philosopher Sedova gives the following explanation:

"Theoretical bioethics is a combination of knowledge about attitude of man to all the living represented in the form of an axiological discourse.

Practical bioethics is the institutionally shaped standardizing regulation and value expertise of the attitude of man to all life forms. Corresponding standards are documented in the form of oaths, charters and declarations, which are not legally binding in their essence.

Applied bioethics is the description of concrete situation of human behavior related to the living" [62].

At the same time, based on the definition of bioethics as a search, assessment, and choice of a criterion of moral attitude to all the living [63], the following definition to these three levels can be proposed:

1. The theoretical level is an interdisciplinary and complex analysis of ethical and axiological aspects in theory and practice of various kinds of human activity with respect to the living

   In this case, we can speak about concepts and theories (e.g., humanism, utilitarianism, deontology, etc.), which shape and define the moral attitude of a man to the living in historical-cultural and social context. Here, we can lay emphasis on the peculiarities of recurrence and non-recurrence of moral decision making as an axial principle depending on existing technological possibilities of live systems transformation.

2. The applied level is bioethical aspects of regulatory and value subsystems of concrete types of activities (medicine, science, politics, sport, agriculture, etc.), which are controlled and regulated by professional codes and moral commandments, laws and regulatory acts, which include those lens of the public discourse.

Here, we can speak about concrete types of bioethics, institutionalization of which we witness today, such as biomedical ethics, agrobioethics, sports bioethics, ecological bioethics and global bioethics, scientific bioethics, and so on. The peculiarity of biological aspects of regulatory and value subsystems on this level is the frequent use of the complementarity principle, which presupposes combination of elements of professional codes and regulatory acts with principles of bioethics on a case-by-case basis rather than consistently [64].

3. Practical or clinical bioethics is a concrete bioethical expertise or visualization of a problem, which demands to make moral choice right here and now in the situation that (as a rule) is not supported by previous experience in medicine or any other sphere of human activity

   This is translated into bioethical know-how. Examples of these solutions form a bank of bioethical casuistry which becomes a practical and methodological basis of project-oriented "advanced knowledge" that provides research of and transforming influence on "small regulatory-value systems" [65].

The level of clinical bioethics represents the brightest from of "bioethical feasibility." It is here that the identification of bioethical problem and its detection take place. Tischenko emphasizes that "visualization, detection (from the bottom to the top) of the real moral order is a prerequisite of correction, moral healing both of a separate human being and the society in the whole. Bioethics in particular is trying to solve this problem in modern biomedicine by clarifying the essence of relations between moral entities, existing in it, and proposing ways of their arrangement" [66].

Speaking about the clinical level of bioethics, it is necessary to emphasize that it is influenced by the American tradition, including the US legislative system as it is based on precedence which does not allow mandatory and generally binding nature and compulsoriness of legal norm and the law. In this case, the question arises as to whether bioethical casuistry is compulsory and valuable. Suffice it to recall the legislative mess with the right to organize ethical committees in the Russian Federation, beginning with the possibility to organize them which first appeared due to the Article 16 of the federal law "On foundations of public health protection in Russian Federation," which was later withdrawn and did not appear in the last federal law "On foundation of public health protection in Russian Federation" passed in 2011 [67].

These three levels of bioethics are closely interconnected. Within the bioethical discourse, the theoretical analysis, public discourse, and direct making of a morally responsible decision fuse together and become the subject matter of a real practice that is properly organized. We would like to point that it is a special form of theorizing which is included into the process of life and a special form of responsible decision making.

Based on the above, it is possible to make the following conclusions:

1. Being the interdisciplinary field of knowledge by its birth, bioethics leans toward philosophy by its content's "specific gravity" and reflects results of global social changes affecting the ultimate foundations of man, nature, and the society.

2. The subject of bioethics as a new scientific discipline is search, definition of principles, and criteria of moral attitude to all the living, and as a social technology—evaluation and choice of the moral criteria for the living.

3. Bioethics is a new type of scientific knowledge which is based on procedures and methods of "advanced experience" when the theoretical analysis and gaining new knowledge, public discussion, and practical moral decision making take place simultaneously.
4. Considering the place and role of bioethics in the conditions of global changes, one can see that its social-regulatory status, the aim of which is to prevent negative consequences of breakthrough technologies, becomes evident.

The present rector of the Kazan State Medical University Professor Sozinov has been the head of the chair of biomedical ethics and medical law since 2003. Due to his efforts, it has become the first in the country among chairs of educational institutions providing teaching bioethics together with legal foundations of health, study of patients' rights, and their implementation in modern conditions as well as rights, responsibilities, and protection of medical workers themselves. The following events were organized in Kazan: the workshop in ethics of clinical trials for members of ethical committees and researchers, the conference in ethics and law, the first Russian congress "Bioethics and human rights," the workshop of the Forum of committees in ethics of the CIS member-countries, the international research and practice conference under the auspices of UNESCO "Gender equality and bioethics," and numerous round tables in ethical and legal issues of health care and medical science within large medical forums. Since 2003, Professor Sozinov has been the head of the Regional Committee in Ethics, and starting from 2006, he is the member of the Russian Committee in Bioethics under the Commission of the Russian Federation for UNESCO and since 2007—the head of the Forum of committees in ethics of the CIS member-countries. Professor Sozinov also is a member of the Managing Council of "The Strategic Initiative for Developing Capacity in Ethical Review (CIDCER)" of the World Health Organization (WHO). The study of ethical-legal problems arising in different fields of medicine (pulmonology, infectious diseases, dentistry, orthopedics and traumatology, obstetrics and gynecology, pediatrics, etc.) is the main scientific direction of the chair.

Today, a great number of books and articles are published, and conferences and symposia are held every year. Significant in this respect is the Encyclopedia of global bioethics which was recently published under the editorship of philosopher Henk Ten Hava and which contains 358 articles by more than 400 authors [66, 68].

In the present time, Kazan studies in the field of bioethics have a comprehensive and interdisciplinary character and cover different fields of medicine and biology, sport, food, and ecological safety. In the recent years, we witness broadening of the discourse in the field of bioethics, and there are studies related to the philosophical analysis of consequences of breakthrough technologies implementation for the solution of global problems.

Acknowledgements

The authors want to thank ANO "Kazan open University of talents 2.0" (ANO "KOUT 2.0") for supporting our publication.

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Section 3

Bioethics and Technology

Chapter 7

Marching for 3D Printing: Its Potential to Promoting Access to Healthcare in Africa

Solomon Tekle Abegaz

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.75649

Abstract

Technology has the capacity for helping African citizens realize their basic rights. The recent introduction of the disruptive technology—3D printing—has the potential to impact millions of lives through a variety of revolutionary medical solutions, including surgery and the treatment of intractable health conditions. As the technology progresses, so does the practical enjoyment of health rights. This chapter argues that the human rights-based approach to 3D printing technology can be helpful in focusing discussions and actions on health well-being and security for individuals in Africa. Having first analyzed the impact of the technology in revolutionizing healthcare, the chapter provides an overview of the complex health challenges this young continent is faced with. Further, it also explores the most relevant African regional laws and standards, guidelines and policy initiatives requiring African governments to use technologies that can advance the human right to health. It concludes that the healthcare agenda of African countries needs to be better integrated and coordinated to ensure that the technologies have a positive impact on health rights. It further concludes that the African Union Commission should promote the researching and utilization of this technology in the implementation of national health policies and strategies of African countries.

Keywords: 3D printing, access to healthcare, Africa, human rights, technology

1. Introduction

Relatively new in its adoption, 3D printing technology is a rapidly expanding method of manufacturing that has found numerous applications in areas such as automotive, aerospace and defense industries [19]. 3D or three-dimensional object printing is an additive manufacturing process that creates a physical object from a digital design. It is a set of processes in

which material is joined or solidified under computer control to create a three-dimensional object, with material being added together. 3D Printing is used in both rapid prototyping and additive manufacturing [13]. In the realm of health, the introduction of the disruptive technology—3D printing—has the potential to impact on millions of lives through a variety of revolutionary medical solutions including surgery and the treatment of otherwise difficult health conditions. The application of technology in the area of health is wide ranging. 3D printing can help generate a part of the human body that is an accurate replicate of a patient's own structure. Experts have developed 3D printed skin for burn victims and airway splints for babies. Also, 3D printed models made of different materials representing bone, organs and soft tissue are produced in a single print procedure. 3D printers are also playing significant roles in improving the success rates of stages, but first tests are looking promising in a variety of areas, operations and for crafting amazing artifacts. Many 3D printed medical solutions are still in their experimental stage.

Despite the revolution being brought about by technology in the medical sector together with some developments seen on the continent concerning the application of technology in general [13, 14, 15], access to healthcare remains a huge challenge in Africa. The continent is confronted with an increased demand beyond the treatment of AIDS, malaria and other communicable diseases to address the non-communicable ones such as heart attacks and cancers. There are a variety of illnesses throughout the continent—half the population still lacks adequate health services. According to researches, fewer than 50% of Africans have access to modern health facilities [16]. Further, many African countries spend less than 10% of their Gross Domestic Product (GDP) on healthcare. This is in contradiction with African governments' political commitment they made to allocating 15% of their GDP to the health sector pursuant to the Abuja Declaration of 2001. Only very few African countries have implemented this objective [17]. Africa is faced with a dearth of trained healthcare professionals as many of them prefer to live and work in places like the USA and Europe.

In order to address the challenges of access to healthcare to their needy populations, African States have assumed several obligations under regional human rights treaties and non-binding political commitments. These norms and standards obligate States Parties to those treaties and declarations, *inter alia*, to fulfill the right of access to healthcare—a duty is placed on States to actively implement the right. There are several ways in which access to healthcare will be enjoyed, such as through adoption of cost-effective technologies. As the technology progresses, so does the practical enjoyment of health rights. African countries have to embrace technology to close the healthcare gap, thereby performing their heath rights' obligation to their people in accordance with agreed regional human right norms and standards.

Due to the relatively new introduction of the 3D printing, the link between this technology, the human right to healthcare and the obligation of States has not been fully explored. This chapter therefore seeks to critically examine whether the human rights-based approach to 3D printing can be helpful in focusing discussions and actions on health well-being and security of individuals in Africa. The chapter is structured into six sections. Preceded by a brief introduction about 3D printing, health and human rights obligations to healthcare in general in section one, section two describes the 3D technology and its application with a focus on its

medical application, section three assesses the situation of access to healthcare as a challenge in Africa and the African countries' obligation to create conditions which would assure to all medical services and medical attention in the event of sickness of their needy population. Capitalizing on the State obligation to make healthcare available and accessible, section four and five are allocated for the discussion on the essentials of utilizing the benefits of 3D technology as a human right to address access to healthcare gaps in Africa. Finally, the chapter closes by concluding the entire discussion.

To do this research, the writer reviewed the scholarly literature, reports, technology-focused websites, human rights law and relevant organizational statements. The chapter relies heavily on elaborations given by relevant United Nations (UN) treaty bodies to identify substantive rights of access to healthcare and the obligation they entail against African governments that signed relevant human rights treaties. The sources for institutional statements are the primary websites of UN agencies and treaty bodies, major government bi-lateral organizations and international Non-Governmental Organizations (NGOs) working actively in health. The overall objective is to promote the capitalization of the technology by informing the African governments and people of Africa, disseminating information, educating people and popularizing the subject so people can claivm the benefit of the technology. It is hoped that the work will eventually lead to leveraging 3D printing as a driving force in Africa's health rights' safeguards.

2. Evolution of 3D technology and its utilization in the healthcare

Undoubtedly, technology can be utilized to disrupt or promote human security. Technology can facilitate repression through censorship of expression, block or filter access to information, monitor online activity and more effectively and efficiently control populations than in the pre-digital world [35]. Equally, it can also be innovatively, creatively and very effectively used to sensitize communities regarding issues that require advocacy, promotion and protection, such as health rights [18].

An example of innovative technology that recently emerged with many benefits for human security is 3D printing. The modern history of 3D printing dates back to the 1980s when Charles Hull invented the stereo-lithography apparatus (SLA) Printer around 1987 [24]. Since then, there is an ever-growing list of astounding accomplishments using 3D printing. In 2004 and 2005, a Chinese company WinSun developed a 3D printing spray nozzle and automatic material feeding systems. Three years later, in 2008, they printed an actual wall for a building [27]. In 2015 WinSun printed a five-storey residential apartment building [27]. But they did not stop there. To top off this feat, they also built a 3D printed 1100 square meter villa that came complete with internal and external decorations. Today, the technology is expanding rapidly; almost every week new printers and printing materials offering novel possibilities as well as excfiting new applications appear [19]. In the case of Dubai-based construction firm Cazza Technologies, the company's large robotic 3D printers already allow them to construct architecturally complex buildings at unprecedented speeds. All of the essential structural

components for tall buildings, including reinforcements with steer rebar, can be 3D printed using this technology [20]. The leading countries in the world immersed with this technology are the USA followed by the United Kingdom and New Zealand.

Coming to the medical application of the technology, this is rapidly creating new ways by which the medical industry can enhance our lives and save billions of dollars in healthcare costs. As highlighted in the introductory section, the additive manufacturing applications within the medical community are diverse. It is recognized that medical uses for 3D printing, both actual and potential, will bring revolutionary changes [21]. They can be organized into several broad categories including: creation of customized prosthetics, implants and anatomical models, tissue and organ fabrication, manufacturing of specialty surgical instruments, pharmaceutical research regarding drug fabrication, dosage forms, delivery and discovery as well as manufacturing medical devices [24]. Concerning implantation, researchers are now using 3D printers to cheaply create medical devices that can be directly implanted into the human body. Doctors have fashioned 3D-printed splints to help children with rare breathing disorders and have successfully implanted a 3D-printed titanium sternum and ribs into a cancer patient [23]. Benefits provided by application of 3D printing in medicine include not only the customization and personalization of medical products, drugs and equipment but also cost-effectiveness, increased productivity, the democratization of design and manufacturing and enhanced collaboration. The technology enables quick, cost-effective development of new medical devices as well as customized end-use products that improve the delivery and results of a patient's care [26].

In terms of its cost, except in recent years, the average cost of a 3D printer was floating around the $50k mark, but due to consumerism and an increase in demand and subsequently production, one can now purchase a respectable 3D printer for the substantially lower cost of $1800 [27]. If that is still too expensive for our pockets, there is even a $49 3D printer available for pre-order on Kick starter [27]. Despite the seeming affordability of the technology in some areas, it is the majority of the Western world that embraces the benefits of advanced technology, with Sub-Saharan Africa still working to provide for the most basic needs such as adequate healthcare, food and sanitation. Healthcare development without an eye toward improving technological capacities is likely to further hamper Sub-Saharan Africa's overall well-being [1].

Whereas 3D technology is not an end in itself, its effective usage empowers people and communities to become self-sufficient in meeting their basic needs and reach their full potential. The 3D technology has several connected advantages for the continent Africa, ranging from the provision of an impetus to the democratization process and good governance; facilitating Africa's integration into the new information society by use of its cultural diversity as a leverage; helpful tools for a wide range of applications such as remote sensing and environmental, agricultural and infra-structural planning. While technology in general and 3D printing in particular offers several of these possibilities to promote healthcare and the overall the development of the African region, there is limited influence of technology in healthcare. The deprivation of technology in general prevents individuals in certain parts of the world, for instance in the countries making up Sub-Saharan Africa, from realizing certain fundamental, internationally recognized rights, such as the right to health [1]. Partly for this

http://dx.doi.org/10.5772/intechopen.75649

reason, patients in Sub-Saharan *Africa, thus have* very *limited* or no access to *healthcare* clinics and basic *health. The section that follows gives an overview of some of the challenges of healthcare service in the region.*

3. Challenges to healthcare in Africa: An overview

Not all things in Africa are going bad, despite that it is considered as a backward or dark continent. There are initiatives in the health sector that are moving in the right way. A large number of African countries, such as Senegal, Ghana, Gabon, Cote d'Ivoire, Kenya and Benin, have begun to work at setting up various types of universal medical insurance coverage in an effort to reduce social inequalities. In addition, international solidarity (Global fund, Gates Foundation, etc.) and pressures from civil society have made possible a number of successes against diseases such as onchocerciasis (river blindness), polio, human immune-deficiency virus and tuberculosis. Here, mention must be made of the 300 or so medical doctors trained at the School of Medicine in Dakar (Senegal) by French professionals between 1918 and 1950, who made a major contribution to the almost complete eradication of the epidemic and endemic diseases that took a heavy toll on West African peoples, such as trypanosomiasis (sleeping sickness), plague, yellow fever and smallpox [30]. As a result, Africa's healthcare coverage to the rural population has grown exponentially.

Despite the efforts made in improving the healthcare systems by African countries, enormous challenges exist within this sector. Unfortunately, preventable deaths of children under five remain very high in Sub-Saharan *Africa* due to poor *access* to timely and quality *healthcare* interventions [28]. While child mortality rates have plummeted since the 1990s, evidence shows that progress on its reduction in most developing countries has witnessed a widening *gap* as well as a concentration of 'under-five' deaths in the most deprived communities [28]. Eighty-three per cent of the highest number of people in rural areas who are not covered by essential *healthcare* services is in *Africa*. However, it is not only rural Africa that the center of access to healthcare is a challenge. It seems even those who lead Africa are not in a different position. It is not uncommon to see many African leaders and government officials traveling to get their medical treatment abroad. Ian Taylor has observed that from 2000 to 2012, 10 African heads of states who have died from natural causes had been receiving medical care abroad and except 2, the rest have died abroad while receiving treatment [29]. This demonstrates that African leaders lack confidence in their own country's healthcare systems. A failure to invest in national healthcare systems in Africa, which ultimately will lead to extreme shortages of healthcare facilities, goods and professional personnel, is the potential cause of the problem.

Another unfortunate fact in Africa is it bears one-quarter of the global disease burden, yet has only 2% of the world's doctors. While medical professionals in neuron-related diseases are in demand, whether in the area of neurosurgeons, or neurologists, or neuroradiologists, there is not a single facility in all of sub-Saharan Africa (except South Africa) dedicated to diseases of the nervous system on the level of the criteria followed in the countries of the northern hemisphere [30]. Unfortunately, the ratio of neurosurgeon/capita in sub-Saharan

is 1/3,000,000 while it is 1:200,000 in the northern hemisphere. On the other hand, in medical imaging, sub-Saharan Africa's ration is 1 MRI/25 million inhabitants, while it is 25 MRIs/one million inhabitants in the northern hemisphere [30]. Life expectancy in Africa is 15 years lower than the global average because the continent has to deal with the significant burden of epidemics without the infrastructure to fight them. The continent is, according to the Gates Foundation, a mix of new and persistent healthcare challenges [30].

Researchers predict that non-communicable diseases such as diabetes, cancer and cardiovascular disease will overtake communicable and nutritional diseases by 2030. Right now communicable diseases such as malaria, pneumonia, Ebola, HIV/AIDS and even leprosy have a negative effect on continental growth [30]. It was in view of addressing the physical and mental challenges that disease or ill-health might bring about to humans that human rights laws promised the right of everyone to the highest attainable standard of physical and mental health, which includes *access* to all medical services.

4. Access to healthcare as a human right in Africa

The African continent is faced with a myriad of human rights challenges—"surveillance, privacy laws, threats, imprisonment, intimidation and killings have been happening across the continent, lending to the assertion that regional institutions with a human rights mandate are largely failing to protect the victims" [18]. However, human rights interests in Africa are not limited to the protection from unlawful detention, freedom from censorship of opinion and arbitrary killings. Equally, human rights are also about the ability to enjoy a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health [3]. True, ensuring a healthy life is the spindle upon which a person's whole personality and well-being depend. To be without healthcare is a frightening prospect, for death is the inevitable consequence [29]. Access to healthcare helps people identify and seize opportunities to grow and develop and to better their lives and those of their families and communities. It also facilitates an individual's participation in society, in the economy, in government and in the development process itself.

Human rights lay standards, norms and principles—they aim to ensure human well-being. Focusing on the right to health, it is one of the fundamental human rights enshrined in the leading and binding human rights documents, including the Constitution of World Health Organization (WHO), 1946, where health is defined as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity" [2]. The preamble further states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." The 1948 Universal Declaration of Human Rights also mentioned health as part of the right to an adequate standard of living [8]. Again, the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) [5]; the 1969 International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) [34]; the 1975 Convention on the Elimination of All Forms of Discrimination Against Women

(CEDAW) [32]; the 1989 Convention on the Rights of the Child (CRC) [11] and the Convention on the Rights of Persons with Disabilities [33] stipulate that the right to health is to be enjoyed by everyone without discrimination. Moreover, States have committed themselves to protecting this right through international declarations, domestic legislation [12] and policies and at international conferences. In this way, the right in question has also been proclaimed by resolution 1989/11 of the Commission on Human Rights, the Vienna Declaration and Program of Action of 1993, the Millennium Development Goals (MDGs) and the Sustainable Development Goals (SDGs).

Parallel to global human rights treaties, regional human rights conventions, including the 1996 European Social Charter (as revised) [31], the 1999 Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social And Cultural Rights [7], the 1981 African Charter on Human and People's Rights (also known as the "Banjul Charter") [10], as well as the African Charter on the Rights and Welfare of the Child [9] uphold that the right to access to healthcare is a fundamental human right that needs to be respected, promoted and fulfilled. Every State has ratified at least one international human rights treaty recognizing the right to health. Thus, they have the obligation to respect, protect and fulfill the right to healthcare to their needy populations.

The incorporation of health as a human right in the various global and regional treaties implies that everyone has the right to the highest attainable standard of physical and mental health, which includes access to all medical services. Again, the human right to healthcare means that hospitals, clinics, medicines and doctors' services must be accessible, available, acceptable and of good quality for everyone on an equitable basis, where and when needed [3]. Except those obligations that have immediate effect, (i.e., States' immediate obligation in relation to the right to health are that they have to guarantee that the right will be exercised without discrimination of any kind and the obligation to take steps toward the full realization of the right) [3], States have the obligation to progressively realize the right to health over a period of time. Meaning that, States' parties that have ratified a treaty which incorporates the right to health have a specific and continuing obligation to move as expeditiously and effectively as possible toward the full realization of the right. The realization of their obligation may be pursued through numerous, complementary approaches, such as the formulation of health policies or the implementation of health programs, or the adoption of specific legal instruments [3]. This chapter focuses and suggests the African States' obligation to adopt programs aimed at ensuring their healthcare—needy population enjoys the benefits of the 3D technology and its application for the realization of the right.

5. The obligation to benefit 3D technology in realizing access to healthcare

The link between the right to enjoy the benefits of scientific progress and other human rights, notably the right to health, has been underscored. Scientific and technological advancement are crucial in health development and poverty reduction. According to Yvonne Donders, the

right of individuals to enjoy the benefits of scientific advancement implies the right of access to scientific and technological advancement. In this regard, the African States adoption of the Universal Declaration of Human Rights (UDHR) and ICESCR that guarantee the right to enjoy the benefits of scientific progress and its applications is a step in the right direction [5, 8]. The African States' obligation to healthcare moves further to ratifying global and regional treaties. Equally, they have the responsibility for incorporating into their domestic legal and policy framework an individual's right to enjoy the benefits of the 3D technology (which is a result of advancement or practical application of science) progress and its applications in the area of health. This emanates not only because the enjoyment of benefits of science and its application is a fundamental right, but also the realization of the right to healthcare imposed an obligation on the part of the States to make administrative, financial, educational, social and other measures, including judicial remedies [4].

In implementing the right to enjoy the benefits of scientific progress and thereby to foster healthcare services, States are under an obligation to invest, to the maximum possible, in scientific and technological advancement and share the benefits. Against this background, the development of vaccines and medicines against widespread diseases has done much to improve life expectancy. In the same way, science and research in the field of information technology, including mobile telephones, the internet and satellite television, have accelerated the flow of information throughout the world, which has proven particularly beneficial to developing countries. It is thus submitted that African States have the obligation to invest, to the maximum possibility, in 3D technological advancement and share the benefits to promote access to healthcare services. International co-operation and solidarity are equally crucial in this regard for African countries to discharge their obligation. This is especially important for ensuring availability of resources from the international community when resources are scarce within African States.

5.1. Africa Union Commission: Its mandate to promote healthcare in Africa

The *African* Charter on Human and Peoples' *Rights* is the foremost African legal instrument intended to protect and *promote* human rights and basic freedoms on the continent. As noted previously, the right to healthcare is protected under article 16 of this instrument. In addition, the Charter also crafts mechanisms of promoting the spectrum of rights enshrined there. The African Commission on Human and Peoples' Rights (hereinafter "the African Commission or the Commission") is a mechanism designed to promote human rights [10], including the right of access to healthcare in the region. The Commission is composed of 11 members chosen from among African personalities of the highest reputation, known for their high morality, integrity, impartiality and competence in matters of human and peoples' rights. In particular, the Commission's promotional mandate includes [10]:

> *To collect documents, undertake studies and research on African problems in the field of human and peoples' rights, organize seminars, symposia and conferences, disseminate information, encourage national and local institutions concerned with human and peoples' rights, and, should the case arise, give its views or make recommendations to governments;….*

Using the foregoing mandate, the Commission has made several efforts to promote the realization of the right to healthcare on the continent. For instance, the Commission adopted Resolution 141 (Access to Health and Needed Medicines in Africa) following advocacy by the Human Rights and Access to Medicines Clinical Group, a collaboration of the Centre for Human Rights at the University of Pretoria and the Washington College of Law at American University. In its resolution the Commission states that "access to needed medicines is a fundamental component of the right to health and that States Parties to the African Charter have an obligation to provide where appropriate needed medicines, or facilitate access to them" [6].

In the same vein, the Commission can use a wide range of promotional activities, including dissemination of information, making recommendations on the gaps in access to healthcare on the continent and the need to critically study and design strategies for the application of 3D technology for the progressive realization of the right through available resources.

6. Conclusion

Increasingly, African governments express their commitment to the defense of human and peoples' rights of access to healthcare on the continent by issuing various norms and standards as well as setting up various institutions relating to human rights protection and promotion on the continent. Among the various norms included are article 16 of the African Charter on Human and Peoples' Rights, article 14 of the African Charter on Human and Peoples' Rights, Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, article 14 of the African Charter on the Rights and Welfare of the Child, as well as article 16 the African Youth Charter.

Regrettably, in spite of these lofty ideas, the daily lives of Africans do not always manifest the concrete benefits of these initiatives. Africa remains beset, as it were, by gaps in implementing healthcare rights caused by factors such as socio-economic and political problems, corruption, poverty, armed conflicts and the abuse of individuals' fundamental rights. More remains to be done in order to translate the benefits of human rights protection and promotion into the daily healthy lives of the peoples of Africa. To address the challenges, African States must focus on building better healthcare infrastructures. Africa's existing promotional activities need to be catapulted by amalgamating 3D technology in implementation. This needs to happen in a flawless manner.

To better adopt the technology, the African Commission should urge African States to guarantee the full scope of access needed to 3D technical applications in medicine. There is a need for developing a communication strategy aimed at strengthening the Commission's corporate identity and the positioning of its activities in the area of advancing medical care. Such a strategy should build and maintain creative and effective communication partnerships, particularly with the technologically developed world; promote 3D technology usage; ensure responsiveness to the rapidly changing 3D technology and environments and advocate for media

liberalization and deregulation to ensure a more central, dynamic and effective contribution of communication to the work of the Commission. Driven by technological convergence, it is here argued that the concentrated use of 3D technology can bring unprecedented comparative advantages to the continent. The knowledge-based economy of the future will depend more and more on the effective use of this technology. Rapid advances in technology coupled with the low-cost of acquiring 3D technology tools are opening new windows of opportunity for Africa to accelerate access to healthcare services. The 3D printing revolution can accelerate Africa's goals in the right to health, fostering intra-regional trade, integration into the global economy, as well as realizing its security needs. This must be reinforced by African governments' political will to improving knowledge, skills and resources and creating collaboration and consensus among key stakeholders.

Acknowledgements

My first impression to ponder upon the link between 3D technology and its medical application happened in a collaboration research discussion conducted with colleagues at the University of Gondar in Ethiopia in early 2017. Hence, my thanks goes to the University of Gondar for providing a platform for the meeting of experts in the field of law, technology and human rights. My special thanks goes to my friend and colleague, Dr. Hailemichael Demissie, who first tabled the importance of 3D printing technology for harnessing Africa's development, on the basis of which I personally appreciated the significance of linking 3D printing as a useful avenue for promoting the right to healthcare in Africa.

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Section 4

Bioethics in the Use of Experimental Animals

Chapter 8

Bioethics in the Use of Experimental Animals

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.74520

Abstract

This chapter deals with the history of the humanitarian use of animals in laboratory experiments from ancient times to the present day. It emphasizes the various criteria that have been established to try to improve the quality of life of an animal and its sacrifice with euthanasic techniques, since the emergence of Russell's statement of the three Rs (replacement, reduction, and refinancing). In addition, there is a review of the application of bioethical principles in scientific institutions in developing countries, such as Mexico. It also reviews some aspects of the humanitarian treatment of experimental animals at the time of designing an experiment protocol.

Keywords: bioethics, laboratory animals, experimental design, three Rs, bioethics in Mexico

1. Introduction

"The greatness of a nation and its moral progress can be judged by the way its animals are treated," Mahatma Gandhi.

Since many centuries ago, the human being understood that animals, in addition to providing companionship, food and protection, could also be a source of knowledge. In this way, indiscriminate use has been made of many animal species throughout civilizations. Different species, including humans, have served to enhance the well-being and the art of human science, but it was not until the twentieth century, when it began to prohibit experimentation with humans, to use species phylogenetically very close to humans with scientific purposes; this was without considering how to design experiments and without taking into account the animal suffering infringed on them. Moreover, it was not until the mid-twentieth century that

some scientists began to consider designing experiments on animals, trying to cause as little suffering as possible and creating the first ethical committees for experimentation in science.

When men were trying to know the why of biological processes and their pathologies in antiquity, the vivisection of men and animals was allowed alike; there are records that Persian physicians experimented with subjects condemned to death. In the time of Ptolemy, medical practice in criminals was allowed, reaching the point that Celso, in the second century, justified these practices saying that "it is not cruelty to inflict suffering on a few, when the benefit is for many" [1].

2. Historical review

Since transition from nomadic to sedentary life, with the discovery of agriculture and the formation of the first settlements, prehistoric man became aware of the need to use animals to obtain meat, clothing and help in the transport of materials, thus emerging the basis of domestication.

It is in ancient Greece when a more "scientific" approach to the treatment of diseases with Galen and Hippocrates is obtained; however, it was not until the time of Andreas Vesalius, a doctor born in Belgium in the sixteenth century, when he changed the medicine, doing dissections of corpses of humans and animals. In the Middle Ages, great medical knowledge was obtained using animals, but in many cases, this knowledge was obtained by considering them as mere use and disuse objects, as René Descartes did, who claimed that animals had a lack of thought and conscience, concluding therefore that they did not have the capacity to feel pain. On the other hand, some scientific people of that time already began to think about the way in which studies were made in living beings; as an example to this, history has that in the works of Leonardo Da Vinci (1452–1519), he made contributions to the anatomy with dissections in dogs and cats but predicted that "one day, animal experimentation would be judged as a crime" [2]. It is in the seventeenth and eighteenth centuries, when men like Graff, Harvey, Malpighi, Aselli and Haller obtained physiological and histological knowledge from animal experimentation, in many cases, they were not anesthetized [3]. However, Schopenhauer (1788–1860) affirmed in his philosophical essays that animals were aware and could perceive pain. From this moment, currents of thought began to emerge that questioned the suffering of the animal in exchange for knowledge generation; in this sense, Jeremy Bentham (1748–1832) made clear that the questions were not: can they reason ?, can they talk ?, but rather: can they suffer? [3, 4].

In the second half of the nineteenth century, the Royal Society for the Prevention of Cruelty to Animals was founded in the United Kingdom and specifically in 1876, this country passed a law against cruelty to animals [4, 5].

Already entered the twentieth century, the English-speaking countries continued to set the guideline in terms of legislation in favor of the protection of animals, but it must be clarified that in the course of the two world wars (1914–1918 and 1939–1945), these issues and his

achievements went to the background. In the 1960s, movements for the rights of oppressed minorities appeared, which, using the same arguments toward animals, led to the famous animal liberation movements. Reaching its climax with the Australian philosopher Peter Singer (born in 1946), who wrote in 1975 his work "Animal Liberation" [6], Singer proposed an ethic that, starting from man, was also directed toward the rest of the animals. He attacked what he called "speciesism" or belief in the superiority of one species (the man) over others. A few years later, in several parts of the world, the idea of "animal rights" arose when in 1978 the "Universal Declaration of the Rights of Animals" was proclaimed by the UNESCO and the UNO [7], affirming among others things that animals have the right to: (1) live without hunger and thirst, (2) live comfortably, (3) live without suffering and illness, (4) express normal behavior and (5) live without fear and anguish [5–8].

3. Contemporaneous panorama

With the previous historical review, it could be inferred that currently there is an entire series of guidelines about ethical animal use in the laboratory, albeit they are not necessarily respected in all those countries where research is taking place on this matter or where subjects in relationship with the biomedical areas are taught. That is, in many places investigation and teaching remain using animals without the adequate measures (humanitarian) for their maintenance, handling and sacrifice. Talking about an ethic in the laboratory, animal handling looks like a utopic idea in many developing countries. Although some countries try to respect the international guidelines about animal experimentation, it is possible to claim that there is backwardness of many decades in comparison to the developed countries.

It has understood that a laboratory animal is any animal species used for the purpose of scientific experimentation. In this regard, a laboratory animal can be used as:

1. Raw material: being exposed to different experimental variables, waiting for a result**;**
2. Biological reagent: the animal is considered like a biological substratum that can be put down to treatment in order to observe the result; this answer is reliable, duplicated and comparable; and
3. Biological model: to extrapolate the results of a treatment from one specie to another, generally the human, with the purpose of improving the existing treatments [3, 9].

On the other hand, it is necessary to give a definition of animal experimentation too. In accordance with Mrad-De-Osorio and Rosenkranz [10], and Tobón-Marulanda [11], this concept refers to any experimental procedure that causes an alteration on the animal's well-being with the likelihood of causing it pain, suffering, anguish or discomfort. The objective of this procedure is always to make evident biological phenomena in that specie, even if these results are not compatible with human beings. The most complex designs are of the clinical type although there is no perfect model that can be extrapolated with humans.

As the reader will understand, the concepts mentioned above establish some criteria of laboratory animal handling, but it does not classify those considering ethical aspects about the use of species in laboratory. For this reason, in many cases, the ethical aspects about the inclusion of animal experimentation depend on the exclusive experimenter judgment, who designs the treatment to obtain results in a short or medium term to use them for human treatment or, at least, to publish the researcher's scientific results in a scientific magazine which will be rewarded with "points" for the curriculum vitae or for receiving scholarships. This leads to keep ethical aspects aside at the point of making an experiment design. This leads to putting aside the ethical aspects when designing an experiment, to which is added that in countries like Mexico, in many of the institutions where research is done, just a few years ago, it has begun to integrate committees of bioethics that evaluate and ensure that animals are treated in accordance with international ethical statutes. On the other hand, problems can arise when submitting an article to be published in a scientific journal, when an author comes from a country where there are different ethical laws that do not follow these rules to the letter [12]. Even worse, in many countries, there is an infinity of laws for the ethical animal handling regulation and the author (with the editors) must decide which one of these to follow to write the article. As an example, in the United States, in 2004, 2100 laws for animal well-being were proposed [8]. However, in a certain way, in 2006, it was intended to be solved when the International Committee of Medical Journal Editors recommended the authors to report if animal experiments had been conducted according to the institutional and national guidelines about the use and care of laboratory animals [12]. In general, a laboratory animal should be kept in appropriate conditions, including its storage place, its feeding and its genetic characteristics (**Figure 1**).

In 1959, Russell and Burch marked a milestone in ethics in the handling of laboratory animals when they published their book titled *The Principles of Humane Experimental Technique* [13], which, through time, became a reference for animal handling. The essence of this proposal is summarized in the famous three R's:

Figure 1. Critical factors for the welfare of the laboratory animal.

Replacement: This includes conscious animals for unconscious animals or insensitive materials. To get this it is necessary to consider the use of *in vitro* systems, audiovisual aids, sacrificed animals, slaughterhouse material, use of invertebrates, human material, human volunteers or other more modern techniques.

Reduction: This includes reducing the number of animals without accuracy diminution. For this, it should consider the use of genetically homogeneous colonies without environmental influences; the animal model selected; sanitary, genetics and environmental quality; cryopreservation; advanced biostatistics methodology; data bank (publishing negative results to avoid repetition); and specialized literature access.

Refinancing: It involves pain and discomfort reduction techniques taking into consideration animal care and well-being, dexterity and training of laboratory personnel to make methods perfect for pain detection, use of analgesics, analgesics and tranquilizers, use of radiography (tomography) to detect tumors or organic deterioration and application anticipated euthanasia [10, 13].

If the meaning of these three R's is carefully analyzed, it will be clear that these three criteria can implie a debate in which, for some researchers (teachers) or institutions, the interpretation of these guidelines may depend on questions such as the individual morality of the experimenter and the resource account for compliance with the three Rs, or even that the price increases to implement *in vivo* animal-replacement techniques.

Despite these apparent obstacles, it must be clear that first individually, then institutionally and at last nationally, it is possible to gather agreements that legislate and delimitate the animal handling ethics (bioethics) following the established legal guidelines (even if there are few of them) and to try and fulfill the three Rs and the different legal regulations for the case. In some instances, attempts have been made to solve some of the suggestions of the three Rs, arguing that the required specifications would represent a considerable cost for the institution and that the budget for the experiments would increase considerably, even while using stray dogs and stray cats. The latter, of course, in the long-term could represent an additional expense when designing an experiment and generate the respective results because by not knowing the previous state of health and metabolic integrity of these animals, there would be the risk that many of them die in the course of experimental manipulation or that valid or uniform results are not obtained due to the individual variability (heterogeneity) of the animals used [4, 15]. Therefore, one would necessarily have to return to the similar approach to that proposed by the three Rs.

In reference to Mexico, in the last two decades, laws or regulations for animal handling have been promulgated, taking into consideration the ethics aspect. For instance, on June 28, 2001, the Agriculture Ministry, Livestock, Rural Development and Fisheries and Food published in the Official Journal of the Federation the Official Mexican Standard NOM-062-ZOO-1999 "Technical specifications for the production, care and handling of laboratory animals," which specifies, among other things, "it is SAGARPA duty to promote the production, care and handling of laboratory animals through the application of techniques that assure the production, protection health and the advantage of using laboratory animals" [14].

Currently, the lack of planning in the production of laboratory animals, the lack of homogeneous criteria related to the activities addressed to care, handling and utility of animals with scientific, technological development and innovation purposes have caused that the care, the treatment and the application of experimental techniques practiced in these animals be exercised in an inadequate way and, therefore, representing severe damage to animal welfare. To achieve reliable results in scientific research, biomedical teaching and quality control, as well as to minimize the number of animals available, it is necessary to have laboratory animals in optimal conditions [4].

The above is more relevant when the experimental designs include non-human primates (NHP), due to the closeness and similarity with the human being [15]. For this reason, a workshop was organized in 2014 on "alternative methods for the use of NHP in biomedical research," under the international exchange program of European Primate Network (EUPRIM-Net II) [16], which reinforced the application of the concept of the three Rs in the improvement of the techniques for the use of non-human primates in biomedical experiments that serve for research or for education.

In other countries, such as those in the European continent, efforts are being made to improve the conditions of animals when they are used in laboratory experiments. For this, there are studies such as the "EXEMPLAR" scale, whose meaning is "Excellence in Editorial Mandatory Policies for Animal Research" [17]. This article was published in Portugal and conducted a sampling of 170 journals from 20 countries, dedicated to the dissemination of studies with animals in the medical-biological area. These studies were classified into four categories according to the publication policies used in those studies. The categories evaluated were (a) regulatory compliance, (b) quality of research and reporting of results, (c) animal welfare and ethics and (d) criteria for exclusion of papers. Although this study emphasized the good application of policies to approve a paper, describing experiments with animals, it is also made clear that there is very little progress in the policies of each publisher about the ethical treatment of animals [17]. This may be because many researchers still do not recognize that laboratory animals are vulnerable living beings to which they must be recognized as a great part of the raw material for the advancement of science [18].

At this point it is good to comment on a study carried out with 217 students from two university faculties in Silesia (Poland) in the year 2015, who were asked to answer a questionnaire on issues such as "to granting animals personality, consciousness and the right to life," and although no differences were found in their responses due to gender, religion, educational level and so on, it was seen that they had very little knowledge of animal protection laws and about alternative methods in animal research [19].

In 2016, another work was published based on previous reviews on the freedoms that should be granted to laboratory animals to maintain their well-being [20, 21], and five provisions were proposed to ensure non-abuse of laboratory animals, such as (1) good nutrition, (2) good environment, (3) good health, (4) appropriate behavior and (5) positive mental experiences—all this in order to make a clear guide for the management of animals, both for researchers and for people not specialized in the subject but who work in research laboratories [22].

4. Status of bioethics in superior schools of Mexico

These actions are trying to be implemented also in higher educational institutions in Mexico, although with some discussions and problems. Sometimes the bioethics committees of each of these educational institutions could consider that the teachers-researchers are not properly handling animals in their charge, due to the high number of them that are used both for teaching and for research. However, the researcher could argue that, especially in the biomedical area, the use of many animals distributed in several lots that are submitted to different treatments could guarantee, statistically, reliable results and results compatible with human studies. In this sense, the discussion arises when some of the bioethics local committees propose the total or partial animal replacement in this kind of experiment (or in laboratory practices for teaching courses), arguing that current technology already offers tools to elaborate computation models to simulate and even predict some effects on organisms when most of the variabilities are controlled in an experiment. As an evidence of this, some medicine schools have replaced the use of animals in classes (like pharmacology, pathology, neuroanatomy, etc.) for computer simulation models or computerized mannequins which are programmed to respond to different variables that simulate some metabolic disorders, psychological disorders and so on. However, these teaching-research methods could have the disadvantage that the student (future researcher) does not deal with real situations, where it is not enough to have the theoretical knowledge about the kind of response an animal or a human being could have when any of them are exposed to a specific experimental handling; the fact that, with those methods it maybe not cause suffering to the animals which can be considered an advantage, but the student would lose the ability to react and make decisions when handling real situations with humans and animals. Even then, it is necessary to highlight that despite these ethic-philosophic issues, many universities around the country are trying to create their own bioethics committees that work following the national and international guidelines, without removing the student training aspect that the experimental animal handling provides. As an evidence of this, it is possible to mention some institutions such as the Autonomous Juarez University in Tabasco (2010), which has published a manual for the handling of animals with experimentation and teaching purposes and in the introduction, comments that: "When it did not count on alternative tools for the use of animals and required the use of it, the procedures performed must follow a scientific and teaching justified propose, have a reasonable expectation as far as an increase of knowledge is concerned about the biological processes and provide the necessary ability for the correct technique handling. It is necessary to take account that this technique it is justified only in the case of science knowledge for the good of humanity or animals." This manual ends, arguing that: "It is obligation of who is handling animals with study purposes to provide them with a real treat and proper care, from its capture procedures and along its captivity previous to laboratory handling" [23].

One more example is the National School of Biological Sciences (ENCB by its initials in Spanish) of the National Polytechnic Institute, in which was recently established, in 2008, the bioethics committee, which has issued a regulation that is periodically revised in accordance with the scientific and social changes that come through the country. This committee's achievement is that many researchers take its advice about the ethical procedures for the

medical-biological sciences experimentation, and for the teaching aspect, it has seen to it that the practice manuals of subjects such as human physiology, general physiology and pharmacology systems include instructions for the animal handling and slaughter in accordance with the corresponding standards, and in the case of human experimentation (students), a questionnaire is filled and signed by parents or legal tutors specifying the type of experimentation they are participating in. In the mentioned regulation, the bioethics committee of the ENCB propose as a principal objective the following: "To establish and to enforce the fundamental ethics principles in the human experimentation, and to assure a minimal suffering to animal handling in laboratory" [24]. It should be necessary to keep a balance between institution-teacher and researcher-user for the development of the medical, biological and technological knowledge, focusing on society and the own subject of investigation so that the established goals might be reached.

The functionality and authority of this committee have been developed in all this time so that the regulations and the established rules are complied with and respected under a legal framework. Of course it is important to take into consideration the National Autonomous University of Mexico' efforts, which has bioethics committees focusing on the same principles' optimization in the use of animals avoiding senseless suffering. As an evidence of this rationale, it is possible to mention the medicine faculty publication (Research coordination, ethic committee) titled *Ethical considerations for the usage of experimentation with animals in research projects* [25], in which detailed specifications of the type of facilities about animal accommodation are listed and what they should consider to provide animals shelter, the appropriate equipment, feeding issues, water provision as well as experimental techniques that include analgesia, anesthetic and euthanasia according to the regulation NOM-062-ZOO-1999.

5. Conclusion

From the abovementioned, it is evident and obvious that, although it has achieved a great deal of progress in the ethical field toward experimentation animal handling, there are still agreements to reach, based on legal, moral and ethical procedures that allow respect for all those species used in experimentation and, at the same time, obtain reliable experimentation results to justify its implementation in science (and teaching).

It would be desirable to achieve uniform acceptance of the concepts of animal bioethics already in use in some countries of the American continent, with the most recent proposals arising in Europe. Perhaps this could be achieved by combining the concepts outlined in the three Rs with the proposal of the five provisions for the welfare of a laboratory animal. In addition, this must, perhaps, be reflected in international bioethics laws that not only establishes the guidelines followed for a good handling of laboratory animals but also to impose legal sanctions for those investigators or institutions that inflict harm to animals.

Finally, we must bear in mind that knowing how to manipulate a laboratory animal implies the education of the researcher, so students should be educated in these aspects from the

elementary school so that when they enter a higher-level school, they have the principles of animal welfare in scientific research as a basic principle of their academic training.

It is the task of all of us who are dedicated to scientific work to be aware of the provisions that will surely apply in the future regarding the ethical management of animals, all this always in the constant search for knowledge.

Acknowledgements

The authors want to thank the ENCB-IPN for the support received for this work through the SIP Project 20170800.

Conflict of interest

The authors have no conflict of interest in the publishing of this material.

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Chapter 9

Alternatives to Animal Experimentation: Its Institutional Teaching and Scientific

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Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.74941

Abstract

Although it is desirable to replace scientific procedures with live animals by other methods that do not use them, the use of animals in scientific procedures should be restricted to those areas that benefit human, animal, and environmental health. The use of animals as experimental models of observation of biological phenomena has evolved with man, to this day. The use of animals for scientific or educational purposes should be considered only when there is no other alternative and it is governed by the principles of replacement, reduction, and refinement. The scientists should be sure that the information obtainable with the experiments is not yet available or that the protocol was designed taking into account animal protection considerations. The chosen methods must use the least number of animals; provide satisfactory results; use the species with the least ability to experience pain, suffering, anguish, and damage; and be optimal for the extrapolation of results to the target species such as humans. It will be fundamental to guarantee on a scientific and ethical basis that the use of an animal is subject to a careful evaluation regarding the scientific or educational validity.

Keywords: animal experimentation, animal model, laboratory animals, research design, animal testing alternatives, animal

1. Introduction

The research is focused today on the ethical, logistical, economic, scientific, and legal requirements. At the European level, Directive 2010/63 of the European Parliament and of

the Council of September 22, 2010, on the protection of animals used for scientific purposes [1] must be highlighted, which is translated into Spanish legislation by Royal Decree 53/2013 [1, 2]. Researchers have to demonstrate the real need to use animals in scientific and teaching applications. These regulations aim to ensure animal protection and, in particular, adequate care for animals; not unnecessarily cause pain, suffering, anguish or prolonged injury; avoid duplication of procedures; minimize the number of animals used in procedures; and apply possible alternative methods.

Russell and Burch [3] formulated for the first time the "principle of the three Rs" that was adopted by the aforementioned regulations. Russell and Burch considered that the replacement was the ultimate goal of the investigation. Its main message is, in summary, that, if we are to use a criterion to choose which experiments to carry out, that of humanity is the best we can ever conceive and that the greatest scientific achievements have always been the most human and the most esthetically attractive, those that best transmit that sense of beauty and elegance that constitutes the very essence of science in its best aspect. Animals should be replaced by less sentient alternatives such as invertebrates or *in vitro* methods whenever possible. Only an experiment with live animals should be carried out if there is no alternative method for the procedure we wish to perform (replace), for example, using audiovisual media or virtual reality techniques [4].

Secondly, if the alternative method does not exist and we have to perform the experiment with live animals, the number of animals should be reduced to the minimum consistent with the scientific objectives of the study, recognizing that important biological effects may be missed if too few animals are used [4].

And thirdly, we are also told that we must modify the procedures used so that animals suffer as little as possible (refine). Experimental protocols should be refined to minimize any adverse effects for each individual animal. For example, appropriate anesthesia and analgesia should be used for any surgical intervention. Death is not an acceptable endpoint if it is preceded by some hours of acute distress, and humane endpoints should be used whenever possible. Staff should be well trained, and housing should be of a high standard with appropriate environmental enrichment. Animals should be protected from pathogens [4].

Its main message is, in summary, that, if we are to use a criterion to choose which experiments to carry out, that of humanity is the best we can ever conceive and that the greatest scientific achievements have always been the most human and the most esthetically attractive, those that best transmit that sense of beauty and elegance that constitutes the very essence of science in its best aspect. Royal Decree 53/2013 aims to establish the applicable standards for the protection of animals used, bred, or supplied for the purpose of experimentation and other scientific purposes, including education and teaching. For this, it regulates the following:

1. Basic investigation
2. The application of the scientific method in which a problem is first identified and observations, or other relevant data are then used to construct a solution:
3. Prevention: prophylaxis, diagnosis or treatment of diseases, or their effects on humans, animals, or plants

4. Evaluation: detection, regulation, or modification of physiological conditions in humans, animals, or plants
5. The welfare of animals, particularly the improvement of the conditions of production of animals
6. Evaluate the efficacy and safety of new pharmaceutical products
7. Research directed to the conservation of the species
8. Protection of the natural environment in favor of the welfare of human beings or animals
9. Higher education or training for the acquisition or improvement of professional skills
10. Legal and forensic medicine

The use of animals in scientific experiments likely to cause pain, distress, or lasting harm generates important ethical issues. Animals should be used only if the scientific objectives are valid, there is no other alternative, and the cost to the animals is not excessive. "Validity" in this case implies that the experiment has a high probability of meeting the stated objectives, and these objectives have a reasonable chance of contributing to human or animal welfare, possibly in the long term [4].

Scientists who use animals in research must justify the number of animals to be used, and committees that review proposals to use animals must review this justification to ensure the appropriateness of the number of animals to be used. Obtaining satisfactory scientific results, it will depends of sample size calculation should be performed as well as, the election of more suitable animals [5].

2. Criteria for the evaluation of a project

Regulation D2010/63/EU aims to establish the applicable standards for the protection of animals used, for scientific purposes [6]. It establishes for the first time in EU legislation the principle of "the three Rs" and imposes it as a firm legal requirement in all aspects of the care and use of animals in that area. The directive, in its application, goes beyond the initial interpretation and also regulates the breeding and care of the animals, that is, guarantees refinement during housing, breeding, and care, even if the animal is not object of any scientific procedure, regulating the following:

1. The experimental protocol should be with respect to the project objectives.
2. The use of animals for scientific or teaching purposes should be considered only when there is no alternative.
3. The objectives cannot be achieved by alternative methods.
4. Ethical considerations in the use of animals are the basis of the authorization of projects.

5. The application of the principles of replacement, reduction, and refinement must be guaranteed.
6. The means are put in place so that the animals do not necessarily suffer, and they are provided with analgesics and anesthetics to minimize the suffering or anguish.
7. Euthanasia methods appropriate to the animal species and the procedure performed are used.
8. The personnel participating in the procedures have the appropriate training (training and experience) to carry out the tasks entrusted to them.
9. The procedures are classified according to their degree of severity.

An experiment is a procedure for collecting scientific data in a systematic way to answer a question correctly or for the generation of new hypotheses. All research should be described in such a way that the study design could be repeated elsewhere [1, 2] (**Table 1).**

Animal research has made major contributions to the health and welfare of humans and domestic animals. These and many other advances have enabled physicians to treat a wide range of human diseases. Many experiments appear to be poorly designed and inadequately analyzed and reported. As a result, some are found to be unrepeatable, leading to a waste of animals and scientific resources. Critical appraisal is an essential part of the scientific process designed to assess the validity of scientific findings. The new techniques of systematic reviews and meta-analyses are hampered by poorly written papers. The importance of randomization and blinding does not always seem to be understood, and it seems that many scientists have inadequate training in experimental design and statistics [7]. Animal studies differ from clinical studies in some aspects, such as the diversity of animal species studied, experimental design, and study characteristics. These methods used in animal studies are explained in [8]. Systematic reviews "can help improve the methodological quality of animal experiments, make the choice of an animal model and the translation of animal data to the clinic more evidence-based and implement the 3Rs," according to [9].

(1). The objectives of the research and/or the hypotheses to be tested
(2). The reason for choosing their particular animal model
(3). The species, strain, source, and type of animal used
(4). The details of each separate experiment being reported, including the study design and the number of animals used and
(5). The statistical methods used for analysis.
(6). Accommodation conditions, for the care of animals
(7). Euthanasia methods
(8). As well as training of the people who participated in the project

Table 1. Considerations in the study design.

3. Importance of animal experimentation

For ethical and economic reasons, it is important to design animal experiments well, to analyze the data correctly, and to use the minimum number of animals necessary to achieve the scientific objectives—but not so few as to miss biologically important effects or require unnecessary repetition of experiments [4]. The 3Rs—replacement, reduction, and refinement—can be applied to any animal experiment by researchers and other bodies seeking to conduct those studies in as humane manner as possible. Key to the success of this endeavor is an appreciation of the principles of good experimental design and analysis; these need to be considered in concert before any data is collected and understanding of animal welfare plays a central role in laboratory practice—are to the betterment of research per se [40]. Careful choice of the animal model is essential, if research is to be conducted efficiently, by using the minimum number of animals in order to provide the maximum amount of information. Inbred strains of rodents provide an excellent way of controlling and investigating genetic variation in characters of interest and in response to experimental treatments. Outbred stocks, in which genetic and nongenetic factors are inextricably mixed, are much less suitable, because random and uncontrolled genetic variation tends to obscure any treatment responses [10].

There is concern about the lack of repeatability of many preclinical experiments involving animal toxicity tests in rodents used to assess the safety of drugs to detect adverse effects that have not been formally evaluated. However, the test does not specify the strain of animals in which the genetic variation, is unknown and uncontrolled; a better strategy would be to use small numbers of animals of several genetically defined strains of mice or rats instead of the undefined animals used in the present. Inbred strains are more stable providing more repeatable data than outbred stocks [11].

4. Choice of animal model

One of the uses of animal models is related to the evaluation of new drugs for the treatment of human diseases. For this type of use, the animal model must respond adequately to the effects of different therapeutic agents. The failure rate of investigative new drugs is excessively high, ranging from about 80 to 97% depending on the therapeutic area. Some of this may be due to poor design of the animal studies. But in some cases, the animal model may not be truly representing the human condition. It is suggested that a good model of a human disease should also have the same human biomarkers of that disease [7]. Compounds that are active in routine clinical practice should show activity in the model (positive controls), and compounds that show no activity in clinical practice should not show effects in the animal model (negative controls) [12].

4.1. Classification of animal models

Most animal laboratory models have been developed and used for the study of the cause, nature, and cure of diseases in humans. There are five categories of experimental models, of which the first three are the important ones, since they are the most used:

a. Induced animal models

b. Models generated by genetic modification

c. Spontaneous animal models

d. Negative animal models

e. Orphan animal models

The selection of any animal model for research should be based on the following considerations: models based on analogy (similar structures involve similar functions) and models based on homology (structures derived from the same evolutionary precursor have the same or similar functions). The most appropriate selection of an animal species for the experimental purpose should not be based on its easy management due to its small size, availability, familiarity, or cost [13].

However, scientists recognize that there are no real substitutes in the use of laboratory animals. Studies with bacteria, tissue cultures, and computer simulations can provide useful information, but the complexity of living organisms requires research and analysis on animals similar to humans to achieve reliable results. When considering which can be the best animal model to use, it is important to take into account the extrapolation or generalization of results that this model generates. For example, in neuroscience it simplifies the results obtained between models in a simplified way [41]:

a. Homologous models: causes and symptoms are identical animal/man. It is only possible in the case that in the animal model, the respective injuries to the associated syndromes resemble each other.

b. Isomorphic models: similar symptoms but the cause does not have to be the same. For example, in a neural zone degeneration pathology, we can alter that same area in rat brain and see that the symptoms are identical.

c. Partial: Some of the models do not completely imitate the human disease, but they can be used in the study of certain aspects or treatments of the human disease, considering that an optimal model would be one that develops a comparable symptomatology, etiology, and neurophysiological background and that responds similarly to the effects of different therapeutic agents.

5. Practical aspects of experimental design in animal research

To designing any scientific investigation once, having an idea for a research project is necessary to make a review of the literature and to get the information that is necessary for the experimental design phase. A null and an alternate hypotheses that address the problem statement are then formulated, and only then is the specific design of the experiment developed. The identification of the most appropriate animal model to address the experimental

question being asked is very important. Other aspects are the considerations that include the number of animals needed per group and evaluating the most appropriate statistical analyses [14]. Nowadays models of human diseases are necessary for experimental research into the biological basis of disease and for the development of treatments. They have an enormous impact upon the success of biomedical research. However, in spite of this, a consistent system for evaluating, expressing, and comparing the clinical validity of disease models is not available [14].

Usually, studies are performed on animal species such as genetically heterogeneous (GH) mice, and rats continue to be used in research even though the case for using isogenic strains has been argued repeatedly. GH stocks represent poor material for controlled studies because genetic heterogeneity normally leads to phenotypic variability and a decline in experimental sensitivity. Isogenic strains are a vital, proven, and powerful resource for biomedical research and should be used in preference to GH stocks by all scientists who use laboratory rodents [15].

It is impossible to give specific rules for the selection of the best animal model; however, it is convenient to make many considerations before an experiment. These are some general rules regarding the criteria for choosing the model [16] **(Table 2**).

It is also important to identify in usual practice among other criteria for the selection or rejection of a model the presence of diseases or special conditions of the animal and that the microbiological status of animal can influence their response [13]. These factors should be

(1). Suitable as analogous
(2). Ability to transfer information
(3). Genetic uniformity of the organisms used
(4). Knowledge of biological properties
(5). Cost and availability
(6). Generalization of results
(7). Ease and adaptability to experimental manipulation
(8). Ecological consequences
(9). Ethical implications
(10). Availability of accommodation
(11). Size of the animal
(12). Number of individuals needed
(13). Life expectancy
(14). Sex
(15). Amount of data needed
(16). Age of animals
(17). Need of offspring

Table 2. Alternative procedures in teaching and training.

considered when choosing the animal model that best suits the experimental purpose. Many models that do not use animals have also been developed, refined, and characterized. These models are useful in some types of research and testing, and they can often be used to complement work with live animals.

6. Alternative procedures in education and training

Animals have been used in research and teaching for a long time. However, ethical guidelines and pertinent legislation were instated only in the past few decades; even in developed countries guidelines for animal experimentation vary. With the advent of newer methodologies in human cell culturing, novel/emerging methods aim to minimize, if not avoid, the usage of animals in experimentation [17]. The European Partnership for Alternative Approaches to Animal Testing (EPAA) activities are focused on international cooperation toward alternative methods. The EPAA is one of the leading organizations in Europe for the promotion of alternative approaches to animal testing [18].The alternative methods are based on the principle of the 3Rs [19] established by Russell and Burch in 1959: R of reduction, using only the number of animals needed to obtain a reliable and accurate information; R for refinement understood as any system that allows to reduce the severity of the damage inflicted on the animals; and R for the replacement of vertebrates by any other method that uses nonsensitive material. All methods or techniques that could substitute the experiments carried out with animals, reduce the number of animals used in each trial, or improve existing procedures in order to reduce stress and avoid the suffering of the animals that are included. The principle of the 3Rs has been responsible, in large part, for the drastic reductions in the use of laboratory animals that have occurred in the last century and for the significant changes in the techniques of research, testing, and education for the benefit of science and public health, as well as animals.

Undoubtedly, the promotion of alternative approaches is one of the basic aspects that permeate the new animal protection regulations. This is the terminology used in Directive 2010/63/EU and consequently in Royal Decree 53/2013 [1, 2]. Experimental alternative methods include any procedure that replaces the use of animals, that reduces the need for animals in a particular test, or that refines a technique in order to reduce the amount of suffering endured by the animal. To be used in the toxicity tests required for the register prior to the commercialization, transportation, and use of a new chemical compound, it is necessary for the experimental procedure to be accepted by regulatory authorities. Thus, after its development, the method has to fulfill the phases of prevalidation (previous interlaboratory assessment), validation of its reproducibility and relevance to *in vivo* toxicity (final interlaboratory assessment), and the independent assessment of the study by a panel of experts and the progression toward regulatory acceptance. Also there must be the acceptance by international regulatory authorities of the fixed-dose procedure *in vivo* as an alternative to the classical assay of the determination of the toxicity by the mean lethal dose (LD50) which are key points on the promotion of the validation and acceptance of *in vivo* and *in vitro* alternative methods [20]. The principles of good laboratory practice (GLP) are designed to help ensure the proper management and conduct of studies. GLP compliance demonstrates to regulatory authorities that studies were

undertaken in a manner which promotes confidence in the data and reporting. Formal validation of *in vitro* toxicity studies is being recommended as an interlaboratory activity. Study management of interlaboratory studies in compliance with GLP is discussed [21].

The alternative approaches undoubtedly provide alternatives available to animal research to raise awareness of viable and, at times, even better options outside of animal experimentation. Outside of the well-established alternatives to animal experimentation like tissue culture methods including primary/continuous/immortalized cell lines, explant cultures, and organ cultures, several recent strategies have been recently mooted to curtail animal experimentation and simultaneously (and surprisingly) improve efficacy of data-gathering, while alternatives to animal experimentation may reduce research dependence on animal (through replacement). They currently cannot replace animal testing altogether. This impossibility exists despite several ethical, political, and financial "incentives" to persevere in this direction. The extant alternatives serve to complement animal experimentation in current research [17].

6.1. Ideal learning endpoints

In this way utilizing a multiple-choice test at the end of a course, the course participants would be assessed for a "reasonable" comprehension of percentile scores or percentage cutoffs [17]:

1. The spectrum of ethical issues pertaining to animal experimentation
2. A scientist's ethical responsibilities
3. A practical application of Russell's and Burch's 3R principles [3]
4. Application submission procedure to the local animal ethics committee
5. Recognition and relief of distress and pain in experimental animals
6. Basic animal handling, anesthetization, blood collection, drug administration, and euthanasia

6.2. Classification of alternative methods in teaching

The development of alternative methods for teaching is not new, and so in the report of the meeting of experts in alternative methods in teaching, organized by ECVAM in 1999 [24, 39], several types of methods were already identified:

There are several modalities of alternatives that can be used in teaching [22–24] **(Table 3).**

If an adequate system is not located, the bibliographic databases could also be revised. In general systems, the terms "education, training, teach*, instruct*, mannequin, manikin, simulat*, video, virtual, cadaver, software, computer'', etc., can be used. There are also systems aimed at improving the preparation of people who handle experimental animals.

The mechanical models consist of reproductions of animals or organs that allow training in management techniques, administration, extraction, and surgery. The classical audiovisual systems were the first used to show the techniques of animal handling, to learn comparative anatomy and various specific techniques. From the initial films, they were

(1). Mechanical models
(2). Audiovisual systems: Movies, videos, CD-ROM,
(3). Computer simulations and virtual reality systems
(4). *In vitro* tests: Ex. With cell cultures
(5). Observation and field studies
(6). Waste materials from slaughterhouses
(7). Clinical practices: human and veterinary
(8). As well as training of the people who participated in the project

Table 3. Alternative procedures in teaching and training.

converted into videos and are currently produced in digital format, CD-ROM, DVD, or downloaded from the Internet. Computer simulations and virtual reality systems have made a fundamental breakthrough that allows the student's interaction, which greatly accelerates learning [22].

6.3. *In vitro* models

The most interesting "animal substitute" to buttress preclinical drug development is the organs on chips (OOC) [26]. The OOC looks promising as a pathophysiologically pertinent model of experimentation.

In vitro models of skin pathophysiology and drug testing have been around for some time. Pioneering testing of human skin equivalents (HSE) included EpiDerm [27] and full-thickness EpiDerm [28]. Presently, HSE models are used to demonstrate simple physiology, to analyze autoimmune (disorders to malignancies) [29, 30]. These models may be better than animal models because the skin samples are human-derived. Additionally, these tissue models are grown *in vitro* in a biochemical and physiological simulating human homeostatic conditions, and they use Russel and Burch's principle of replacement [3].

However, animal testing will still be required for the foreseeable future. For example, a bacterial toxin had effects which were different from that on cultured cells [31] than its *in vivo* effects in a live animal [32]. Similarly a tested drug, owing to a multitude of reasons, may work fine on an *in vitro* model, but may not work (or may work differently) on a live animal. Therefore, *in vitro* models will effectuate manifold prescreening processes prior to animal experimentation but may only serve partially in reduction. Furthermore, only *in vivo* animal models can account for complex and/or unknown biological systems and pathways that *in vitro* models cannot encompass. Another example was a study conducted performed in *in vitro* systems and zebrafish embryos as alternative models for reducing rodent use in assessments of immunological and oxidative stress responses to nanomaterials demonstrated that some nanomaterials (NMs) stimulate oxidative stress and inflammation, which may lead to adverse health effects. The development of strategies for NM hazard assessment that promotes to use alternative models and non-rodent is being an important point of investigation of inflammation, and oxidative stress could make nanotoxicology testing more ethical, relevant, and cost- and time-efficient [33].

6.4. Computer modeling in silico

Pathophysiological simulations have been using high-tech computer modeling programs (in silico modeling) [33, 34]. Toxicity screening [35] and fundamental pharmacokinetic can be done rapidly *in vitro* depending on specific in silico modeling program availability [36]. There are additional software-based techniques (quantitative structure-activity relationships or QSARs) [37] that utilize estimates of a molecule's hazard-inducing capacity, based on its similarity to existing molecules, and extant human physiology. However, such simulations generally focus on major aspects and tend to overlook smaller but equally (if not more) important aspects.

6.5. Research involving human volunteers

Positron emission tomography (PET) and functional magnetic resonance imaging (fMRI) pertaining to brain activity has been used of research involving human volunteers is broached. However, there are several other "human testing" investigative methods which have been used. A classic example is microdosing; microdosing is implicated to early drug development; the pharmacokinetic data are acquired in humans using safe sub-pharmacologic "doses of drug" [38]. We currently still require animals to devise and test the efficacy and safety of therapeutic approaches as in mortality or toxicity studies. On the other hand, microdosing cannot predict adverse reactions of drugs that may occur at therapeutic levels, which animal studies clearly can. Therefore, microdosing can only assist in partial reduction of animal use in research. The way in which society views the use of animals in university learning and teaching has changed dramatically in the last 30 years. Debate by teachers and animal welfare advocates about the pros and cons of using animals in learning and teaching is widespread in the published literature, nationally and internationally, but rarely gives the students a voice. A study demonstrated the perspectives on the use of animals in learning and teaching, using on a survey of students at three Australian universities. The biology students value the authenticity of such experiences, the consolidation of theoretical learning, and the chance to use multiple learning modes via hands-on experiences. In particular, students see the benefits of such experiences as improving their understanding of biological concepts and opportunities for future employment [39].

When was compared upper level undergraduate students' evaluations of psychology laboratories using live rats with their evaluations of using a virtual rat (Sniffy). Students reported that the live-rat labs were ethically acceptable and that working with live rats enhanced their learning to a greater extent than working with Sniffy. These results support the retention of laboratories using live rats in psychology courses [25].

7. Conclusions

Animals have been used in research and teaching for a long time pretending to simulate human biology. The principle of the three Rs enunciated by Russell and Burch 3Rs (replacement, reduction, and refinement) is currently the most used animal ethics compliance guidelines for animal experimentation. Research pertaining to the efficacy of institutional ethical reviewing of animal research is sparse. The institutional ethical reviewing may work better in countries (and circumstances) which are more developed, have better

funding for animal facilities, have lesser bureaucratic impediments, have simpler/more direct processes, and have flexible common/statutory law providing allowance for better reviewing and penalty implementation. An animal experimentacion as a teaching resource contributes to the process of teaching-learning in bioethics for undergraduate students or university students.

Conflict of interest

All coauthors declare no conflict of interest.

Nomenclature

Directiva 2010/63 UE

Real Decreto 53/2013

3Rs principles

Normativa D2010/63/EU

Guidelines (OECD TG 407 and 408)

The European Partnership for Alternative Approaches to Animal Testing (EPAA) Directiva 2010/63/EU

The principles of Good Laboratory Practice (GLP)

Nanomaterials (NMs)

European Directive 2010/63/EU

Positron emission tomography (PET)

Functional magnetic resonance imaging (fMRI)

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Section 5

Selected Topics of Bioethics

Chapter 10

An Exploration of Religiously Based Opposition to Clinical and Scientific Interference with the Embryo

David Gareth Jones

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.74549

Abstract

The advent of *in vitro* fertilization (IVF) into clinical practice highlighted to ethicists and theologians, ways in which scientists and clinicians are interfering with the development of human embryos in the laboratory. This is because an increasing amount of research is being directed onto embryos, frequently involving their destruction. These procedures range from IVF and pre-implantation genetic diagnosis (PGD) to gene editing. Some religious groups are implacably opposed to all such developments on the ground that the human embryo is to be protected from the 'moment of conception'. Widespread opposition to abortion and fetal destruction has been translated into opposition to the destruction of embryos. By viewing embryos as having a value commensurate with that of postnatal moral persons, opposition to all recent biomedical developments becomes inevitable. The rationale for this stance in the writings of certain Roman Catholic and Protestant scholars is outlined, as are implications for theology's relationship with science, the church community and the public square. Does this mean that these groups are unable to contribute to ethical debate in each of these areas? The reasoning behind embryo protection stances will be critiqued, and the importance of finding common ground by examining core values and accepting the centrality of dialog will be stressed.

Keywords: embryo, moral status of embryo, IVF, religious opposition to embryo research, theological perspectives, public square

1. Introduction

The year 1978 marked a watershed year in reproductive technology, since it was in that year that the first baby was born artificially—in the sense that the fertilization had been brought about in the laboratory and hence outside a woman's body [1–3]. However, as so often happens, the event that caught the attention of the world was merely the end result of a series

of revolutionary steps that had taken place over a number of years previously in achieving fertilization *in vitro* in the laboratory in various experimental animals [4–6] and then in humans [7]. The development of *in vitro* fertilization (IVF) is the story of the experimental manipulation of the human embryo [8], since apart from this there can be no IVF or any of its associated procedures, spanning intracytoplasmic sperm injection (ICSI) to preimplantation genetic diagnosis (PGD), and from the derivation and use of embryonic stem cells (ESCs) to gene editing.

Regardless of the scientific, clinical and social consequences of these developments, there can be no escape from the underlying fact that none of these would have been possible were it not for the ability of scientists to experiment on the human embryo [9, 10]. Consequently, for the first time, the living and maturing embryo was exposed to human gaze. For the embryologist, this meant that its characteristics and development could be analyzed and potentially modified. With the increasing availability and power of genetic analysis, the potential offered by analyzing embryos has increased exponentially, especially by various forms of gene editing [11–13].

In their different ways, each of these procedures has posed profound challenges to ethicists and theologians who have placed considerable, and in some cases absolute, value on embryos. If embryos are viewed in this light, as entities to be protected at all costs, opposition to any form of embryo manipulation is inevitable.

In following the consequences of a stance such as this one, attention will be confined to the theological foundations employed by those Christian communities that adopt protectionist positions on the embryo. While their views are not representative of those of all Christian churches or organizations, and while they do not of necessity represent all other religious persuasions [14], their opposition to research on embryos constitutes a valuable case study in religious opposition to scientific investigations. From what does this opposition stem? Should it be taken seriously or ignored? And if taken seriously how might it be countered?

2. Understanding the context of religious opposition to embryo research

In the early 1970s as I followed the developments taking place in efforts to achieve *in vitro* fertilization in mammals and then humans, I was optimistic that the stalemate experienced over abortion could be avoided [15]. The diametrically opposing views on abortion had led to an either-or situation, characterized unhelpfully in my estimation by simplistic pro-life and pro-choice positions. All the nuances of the debate were ignored as this two-position oppositional stance emerged as the predominant model driving the debate to its inevitable end of bioethical stalemate and political stagnation. My hope was that this could be avoided when attention turned to the embryo, with its emphasis on much earlier development than that represented by the fetus. Sadly, this was to be a forlorn hope, as the vehemence of the abortion debate was transferred to the embryo debate [16–18]. Any scientific distinctions between the embryo (ranging from fertilization to 8 weeks' gestation) and the fetus (from 9 weeks' gestation to term) disappeared as the whole weight of ethical interest shifted to fertilization itself [19] or conception as it is frequently referred to in theological circles [20].

The result has been that the embryo has become the center of theological attention, and in some circles the litmus test of theological orthodoxy [21, 22]. And yet there are major differences between the two, differences that are downplayed or even ignored in theological ethical debate. Abortion is characterized by the conflict that centres on the women who request abortions and the clinicians who undertake them. In the case of the manipulation of embryos and the inevitable destruction of many of them in IVF, the conflict centres on the fertility specialists responsible for the IVF procedures, and scientists whose work has made IVF possible. The clinicians in abortion clinics are responsible for bringing a (fetal) life to an end at the behest of the pregnant women, regardless of the rationale for this. The clinicians in fertility clinics have the role of bringing new life into existence, although this is accompanied by the loss of other embryos that are found to be unsuitable for implantation into the mother, or are surplus to the requirements of the mother/couple. Hence, there is not a simple parallel between the two scenarios, quite apart from the differing stages of development of the nascent human life.

The result of this conflation of the two procedures is that the distinction between fetal destruction and embryo destruction has been obliterated, meaning that the stage of development of embryonic/fetal life has become irrelevant for ethical and theological debate. This in turn has had two consequences. It has led to a downgrading of the significance of scientific input into ethical and theological analyses of prenatal existence. Scientific input is not required, having been replaced by theological input that is not dependent upon scientific contributions. The second consequence is that the controversies over abortion have been seamlessly transferred to debate over the reproductive technologies. Destruction of the fetus and destruction of the embryo are regarded as morally and theologically equivalent [23].

Against this background it is unsurprising that opposition to abortion leads to opposition to the use of ESCs, since both are regarded as on a par ethically and theologically. This is because both are seen as leading to the destruction of human life, which in the eyes of certain theological commentators has equal moral value to postnatal life [24, 25]. In these terms, destruction of a 3-day-old embryo is viewed as ethically and theologically equivalent to the killing of a 3-year-old child or a 30-year-old adult. In light of this paradigm, research on human embryos is considered to be unethical and theologically untenable, and any opposition to abortion leads inevitably to opposition to embryo research and embryo destruction.

What stands out as one views these developments has been a major paradigm shift in approaches to the embryo. A largely metaphysical question, centering on the moral status of the embryo, has become an intensely practical question as to the manner in which embryos are treated *in vitro*. This is because until the 1960s–1970s embryos were inaccessible to scientific investigation, being located within women's bodies and hence largely unknown to all but embryologists and reproductive biologists. They could not be, and were not, a subject of interest to theologians, whose interest lay in abortion and the loss of fetuses from around 8–12 weeks' gestation onwards. The advent of *in vitro* fertilization in the late 1970s and into the 1980s heralded, not only a scientific and clinical revolution, but also a challenge of immense proportions to theological thinking with its lack of signposts on how best to view these once hidden entities. This was a new world for which they were ill-prepared, since the notion of the

high moral status of the embryo, and its consequent inviolability, led to total rejection of any interference with human embryos [26]. This immediately put many theologians, as well as large swathes of the Christian community, at odds with the scientific community and unable to contribute productively to bioethical debate.

I shall argue that this dissonance is unnecessary and should be dispelled by re-examining a religious approach to the embryo, and providing a means for those with religious perspectives to engage productively with biomedical scientists.

3. The emergence of IVF

The first clear evidence that it was possible for fertilization to be achieved outside the body was provided in 1969 [7], with the first birth of a baby in 1978. The scientific work behind this momentous outcome was accompanied by considerable controversy within scientific circles [2], based largely on its questionable safety, the relatively low importance given to the treatment of infertility, and the perceived experimental nature of the procedure [27]. Ethical issues were integral to all that was being accomplished, and some of these had religious overtones, such as the triumph of human design over natural processes, threats to the dignity of procreation resulting from use of a technical procedure, the possible abnormality of resulting children, and its failure to 'cure' infertility [28, 29].

In the laboratory and clinic daily ethical issues were encountered, since the success rates of IVF were low, and as many as 5 or 6 embryos per cycle were inserted by some clinicians in a desperate attempt to improve success rates [3]. This led to the destruction of large numbers of embryos, and serious questioning about the ethical acceptability of what was being done. Moreover, fundamental research questions had to be addressed regarding the criteria for defining embryos, the legitimacy of donating sperm, eggs and embryos, the freezing of embryos, and what one did with embryos with extra chromosomes and other abnormalities. All these issues pointed to the need for ongoing research on embryos [2, 3].

The driving force behind this work was provided by the perceived plight of the infertile, and not the welfare of embryos [30]. The major contributor was Robert Edwards, who forged ahead with it even though many around him viewed it as 'impossible scientifically and untenable ethically'. For Edwards, there was only one goal: 'the most important thing in life is having a child' [29]. Edwards was a fascinating hybrid, a basic scientist who longed to know more about human fertilization, an applied scientist who was driven to help those with infertility issues, and a human being who longed for meaningful ethical debate [30]. This latter commitment drove him to engage with politicians, philosophers, and theologians, on the ground that he wanted society to take informed decisions [31]. In the early 1970s, he could see that IVF would 1 day extend well beyond its immediate clinical dimensions to the production of chimaeras, nuclear transfer and clones [32], while more realistically in 1989 he discussed topics ranging from embryo donation and embryo freezing, to the prenatal diagnosis of genetic defects, sex selection, and stem cells [3]. In 1999 Edwards stirred controversy by stating that parents should never be allowed to bring into the world children afflicted by genetic

http://dx.doi.org/10.5772/intechopen.74549

diseases, and even more pointedly in 2003 claimed that it was scientists who were in charge rather than God.

Aside from provocative pronouncements of this nature, Edwards wrote perceptively about the ethical implications of his work. Looking back in 2007 he wrote that he and his team had been determined to achieve the first IVF birth and would continue unless something seriously wrong appeared [29]. It was this goal that drove him relentlessly on, in spite of many claims by others that what he was doing was immoral, illicit, dishonest and illegal. Throughout, he wrote provocatively and forcefully about the ethical implications of his work, repeatedly aiming to integrate his scientific expertise with an understanding of the ethical dimensions of his work [30].

It is noticeable that up to this point there has been practically no reference to any theological input into what he was doing, beyond contributing to the negative consensus emanating from diverse perspectives. This was seen as erudite research with no practical relevance, at least until 1978, when the birth of the first IVF individual transformed everything. IVF now entered the medical mainstream, and within a remarkably short space of time it had become an established and generally accepted procedure for bypassing infertility. While this recognition meant that it was now supported and acknowledged by scientists and clinicians, religious authorities were awoken from their stupor and began to realize that reproduction could be changed forever, with major repercussions for the moral standing of embryos. However, these reactions did not surface until 1984 with the production in the UK of the Warnock Committee of Inquiry Report [33].

According to this Report, IVF should be considered an established form of treatment. Egg and sperm donation along with embryo donation were accepted, as were the freezing of semen and embryos. Of particular interest for the current debate was the special, but limited, status given to the embryo, with some protection in law. This allowed research on embryos up to 14 days after fertilization. At that time, research was to be limited to those 'surplus' to the requirements of IVF programs, although in the UK this has controversially been widened to include those specifically created for research purposes.

While much has changed in succeeding years, the Inquiry set the benchmark for IVF and research on embryos, and in essence vindicated the work of Edwards and colleagues over the years leading to the establishment of IVF as a viable clinical procedure. It was also this Report that awakened the religious establishment and opened the floodgates for one UK Christian writer after another to strenuously object to the Report and in particular to its view of the human embryo.

4. Theological responses

The official Roman Catholic position on IVF stems from *Donum Vitae* in 1987, with its basic dictum that unconditional respect is to be given developing human life from 'the moment of conception' [34]. On this basis the early embryo (zygote) is inviolable and is not to be destroyed. Hence, the voluntary destruction of *in vitro* human embryos for research purposes is condemned.

By choosing those embryos that are to be allowed to live and those that are to be killed, researchers are usurping the place of God (**Table 1**). The freezing of embryos is equally problematic, since this process subjects them to human decision-making and leads to technological domination over 'the origin and destiny of the human person.' This opens the door to what is

Characteristics of embryos from fertilization	**Practical consequences**
Fully human	Protectionist/precautionary stance
Sacrosanct	Opposition to:
Absolute right to life	IVF/PGD
Creations of God	Embryo research
Called by God	Freezing of embryos
Images of God	Selection of embryos
Personally loved by God	Spare/surplus embryos
	Biology irrelevant
	Needs of infertile ignored
	Opposition to genetic analyses
	Embryo viability irrelevant
	Embryos are untouchable
Additional science-based concerns	**Result**
Increasing power of science	Antagonism towards science
Possible harm to subsequent children	Rejection of reproductive technologies
Threat to role of God in reproduction	Reject 'common morality' approach
Impact of the artificial on human life	
Children are 'made'	
Excessive human dominion	
'Playing God'	
Usurps place of God	
Slippery slope	
Positive religious perspectives	**Outworking in practice**
Humans participate in work of God	Support in principle for medical research
Gradualist view of embryonic development	Care of family and child
Importance of relief of suffering	Benefits to outweigh harms
Support efforts towards healing	Take note of needs of infertile
Cautionary perspective	Cautious approval of ARTs
Pro-research as a principle	Pastoral support for childless
	Actively participate in public sphere
	Openness to dialog

Table 1. Major reasons for religious opposition to the reproductive technologies.

http://dx.doi.org/10.5772/intechopen.74549

described as 'radical eugenics'. Consequently, IVF and indeed all the ARTs are branded unworthy means of bringing human life into existence, so that a child obtained in this way has to be seen as a product to be judged by its quality rather than by who he or she is [35].

In 2008 the Congregation's document, *Dignitas Personae*, sought once again to defend the dignity of the human embryo from conception onwards. More specifically, it objected to ICSI, the freezing of embryos and oocytes, PGD, and embryo donation. It claimed that embryos are fully human from fertilization, and are to be treated as sacrosanct. In these terms, there is no room for any technological interference into, or human control over, them or the reproductive process. An inevitable outcome of this stance is that the Vatican is unable to contribute in a positive way to ongoing discussions about any facet of how the reproductive technologies are to be adapted or used, let alone about the nature or direction of research on embryos [36].

Underlying these views is the premise that the sole object of moral reflection is to be directed onto the embryo, with little attention given to infertility issues and their repercussions for the health of a marriage and the partners in the marriage, nor for the welfare of the prospective child. For some Roman Catholic writers these are crucial considerations that open the door to the possibility of employing the artificial reproductive technologies (ARTs) [37]. Others opt for an alternative approach based on prudence that takes account of an ethic of feminist care [38], while yet others condemn what they regard as an outdated physicalist version of natural law and excessive fears about a eugenic mentality [39]. Each of these alternative Roman Catholic visions wishes to take seriously the scientific data and discover how they may best be utilized to contribute positively to the human condition.

Other Roman Catholic contributions that deviate from the official Vatican position challenge the view that full moral value commences at 'conception', placing the embryo's acquisition of individuality of personhood at some later point, whether 4–6 days [40] or 2–3 weeks after fertilization [41]. Neither the precise dates nor the reasoning behind them are of concern here, except to state that they all take into account other parties in the reproductive process. These revolve around two questions: whether human beings can ever act as God's instruments to interfere with new life from continuing on its developmental pathway, and whether they can alter that trajectory; and whether the integrity of human relationships in marriage and family life should have any bearing on the ethical and theological stance adopted. Despite the assurance of the official Vatican statements, that would answer these queries unequivocally in the negative, there are dissenting voices.

Protestant voices can largely be dated back to the latter part of the 1980s, although there are examples of input in the 1970s. Paul Ramsey spearheaded ethical debate from 1970 onwards, although his emphases are instructive when viewed from many years into the future. His central concern was that there was no way of knowing whether experiments on the unborn would harm the fetuses and subsequent children [42–44]. This concern far outweighed the plight of infertile couples desiring a child [45]. More speculatively, Ramsey was worried that the use of IVF would ultimately lead to the widespread adoption of artificial means of producing children. Threaded throughout his thinking was a fundamental concern that the increasing power of scientific manipulation was becoming a threat to the role of God in upholding and sustaining human beings through illness and infirmity [46] (**Table 1**).

Ramsey's concerns are fascinating from today's perspective, when the welfare of the embryo has such a prominent part to play in religious discussions on the ARTs. He paid little attention to the embryo. Was this because he was writing in the early 1970s before IVF had been shown to be capable of producing a living healthy child? And yet, Edwards was publishing prolifically in the 1970s and was calling out for theological and ethical debate. Ramsey was writing in the US whereas Edwards was in the UK, and Ramsey may have been unaware of the scientific debate. Nevertheless, his writings on it were well informed. One can but speculate, and assert that Ramsey's theological interests placed greater emphasis on fetuses and resulting children than on embryos.

In an analysis of religious responses to IVF from the 1980s onwards, Jones [46] has categorized them as essentially negative or positive. Simplistic as this distinction appears it represents the distinction between suspicion of IVF due to stress laid on the wellbeing of the embryo, as opposed to openness to IVF with stress placed on the needs of the infertile. Further categorization by Jones [46] recognized five categories: A–E. Of these, A–C are embryo centered: categorical (A), precautionary (B) or human dominion (C) driven. D is child and family centered, placing stress on infertility, while E is desire centered, driven by technological imperialism. In their differing ways, A–C all look to protect embryos.

Of the three, A is the most idealistic, since its categorical assertion that 'human life commences at conception' leads to total protection of all embryos on the ground that they have a value equivalent to that due to all other human beings [47, 48]. If all embryos are to be protected there can be no situation in which they are sacrificed for any end other than their own thriving [49]. Some writers are far more emotive than this referring to the killing of innocent human life [50]. However, one does not have to be emotive to follow the rationale of such a position—the total rejection of any of the ARTs, along the lines of the Vatican stance. It also follows that any procedure involving the production of an excess number of embryos, let alone the manipulation of embryos, are deviations from God's creation pattern [51, 52]. IVF becomes morally and theologically indefensible and children produced in this way fall far short of being seen as gifts of God [12, 53].

Category B is driven by the same basic presuppositions, but is less categorical, looking instead to a precautionary approach. It ends up at the same point, but seems to concede that there is some uncertainty around the proposition that all embryos deserve total protection at all times. The onus is placed on those who do not accept this position to demonstrate that all human embryos are not persons [54]. Their interest appears to be in presuming that all embryonic life is innocent and inviolable, rather than in addressing the immediate question of whether IVF and its allied procedures are tenable. The presumption is that they are not, but one is left wondering what the precautionary principle would say about the benefits held out by IVF for many in the population.

Category C, with its stress on the role of human dominion is not primarily concerned with the embryo and yet has implications for the way in which embryos are treated. The emphasis in this instance is on the perceived dangers emanating from technological inroads into reproduction resulting in children being 'made' technologically rather than begotten naturally [24]. Use of the word 'begotten' points to the religious underpinnings of this stance, and the practical

outworking of the position is to reject the ARTs, all of which are viewed as acts of manufacture. The concern here is that these technologies are being used to dominate other human beings like us. Hence, its outworking is to question the involvement of medical science in research on the embryo, on account of its being a threat to humans standing before God.

Category D, with its focus on the wellbeing of the family and the negative consequences of infertility, encompasses within its ambit a large number of religious spokespeople [30, 55, 56]. For writers such as these, emphasis is placed on the nature of human life in the image of God and a duty to respect it, the importance of marriage and the family, and the centrality of pastoral support for those suffering from childlessness and infertility. The standing of the embryo is viewed alongside these broader principles and does not predominate in ethical decision-making. Consequently, whatever moral values are attached to it do not emerge as of greater importance than the context within which it is being considered and the other participants within this. The result in practice is that the embryo is viewed as of considerable moral significance, but in practice that will be less than absolute. This allows for a diversity of views on when during gestation the moral value of the embryo increases to such an extent that it should not be used for research or therapeutic ends. Those fitting within the category will be in a position to accept the 14-day upper limit for research suggested initially by the Warnock Report [33].

Category E, with its technological imperialism, points to the many ways in which the simple case of IVF encountered in the 1980s has been extended socially and technologically in the intervening years. The importance of these for the reproductive technologies cannot be denied, as PGD is now used to detect a wide range of conditions, including late onset genetic disorders, and sex selection for social reasons, overcoming mitochondrial disorders using a three parent IVF procedure, next-generation sequencing to check embryos for abnormal chromosomes, and whole genome sequencing to read the DNA of IVF embryos before choosing which to implant. These and numerous other procedures fit within the ambit of contemporary medicine, and are accepted by Christian (and other religious) scholars with a Category D worldview. Where they will diverge from Category E exponents is in their rejection of a posthuman future characterized by highly speculative visions of a technologically enhanced and physically transformed future [11, 57]. It is safe to say that few, if any, religious writers will be found within Category E thinking.

5. Theological case studies

As evidenced by the above categories, there is a diversity of religious stances on the embryo. Nevertheless, the fallback position is invariably a protectionist one, with protection to extend from the earliest point of its existence, namely, fertilization. A clear example of this was provided by a statement provided by an *ad hoc* group of Christian theologians from the Anglican, Catholic, Orthodox and Reformed traditions in the UK, in their response to a House of Lords Select Committee on stem cell research in 2001 [58]. While the theologians involved came from a variety of religious traditions and theological persuasions, they concluded with

five principal considerations to inform any Christian evaluation of the moral status of the embryo. These included: "each human being is called and consecrated by God in the womb from the first moment of his or her existence, before he or she becomes aware of it. Traditionally, Christians have expressed the human need for redemption as extending from the moment of conception." The wording of this statement is intriguing, since it refers to the 'traditional' position, and to the need for redemption from conception onwards. It is far from clear what this means in practice, since it is not self-evident what prenatal redemption amounts to. The statement explains that concern over the fate of embryos destined for research is inspired by the narratives of the Annunciation, the Visitation and the Nativity, plus the parables of the Good Samaritan, and the sheep and the goats. From this it concludes that an ethically serious position "should be to regulate the procedures in fertility treatment and non-destructive medical research on human embryos such that these human individuals are adequately protected." Intriguingly, the statement is titled 'A theologian's brief', giving the impression that all those engaged in discussion were united in their final conclusions, and possibly that this is the only tenable theological position to hold on the status of the embryo. It also presumes that there are no legitimate alternative theological positions, especially ones based on a gradualist view of embryonic development [36, 59, 60]. It is also noticeable that a theological position can be reached without any reference to scientific input. What is being set forth here is an embryo protection framework, that has been most precisely outlined in Vatican documents [35, 36].

One theological work directly addressing the status of the human embryo is MacKellar's 2017 book [23], *The Image of God, Personhood and the Embryo*, aimed at casting light on the status of the human embryo from the perspective of the image of God and personhood. While it cannot be taken as representative of all theological positions on the embryo, it comprehensively embodies a swathe of conservative theological thought on the topic. As such it underscores the conclusions reached by many theologians on the status of the human embryo, and that stand in stark contrast to the conclusions reached by embryologists and developmental biologists. It leads to questions such as the relevance of theological inquiry for the thinking and practices of biomedical scientists, including those who are Christians. On the flip side, it raises the question of whether clinical and research studies on human embryos are theologically and morally untenable.

For MacKellar [23] embryos are always completely whole, no matter what their stage of development. Each new embryo is a creation of God and an expression of profound and real love; to be made in the image of God is to be made from the personal love of God. He writes: "God's love is always behind the creation of a human child and this love always continues towards the child. There is never a moment in all the existence of the child (even at the very beginning of his or her existence) wherein he or she is not loved by God" (p. 86). Consequently, God's love continues to exist for the embryo at every stage of its development. In other words, "there can be no discontinuity between the love of God who brought this embryo into existence and the same love of God who continues to love this embryonic person" (p. 92). In light of this, there can be no increase in developmental potential or enhancement of status throughout an embryo's development. The 1-day-old embryo is loved in precisely the same way as the 14-day-old or the 28-day-old embryo; God's love is absolute at all these stages. It follows,

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according to MacKellar, that God's love is equally great for an embryo brought into existence by rape as for an embryo brought about through loving union in a loving family. This is because the social and family context is irrelevant, as is the location of the embryo—in the uterus, in the abdominal cavity, or *in vitro* in the laboratory.

MacKellar [23] also contends that the viability of embryos is irrelevant, since God loves them irrespective of whether they do or do not possess the capability of developing into a child. Inevitably, therefore, biology has become unimportant, since theologically an early embryo has 'a complete, intrinsic and inherent potential' regardless of any biological potential. It is on these theological grounds that "full respect and protection must be given to the human embryo from the moment of conception" (p. 190). This low view of biology is explicitly expressed by MacKellar when he contends that: "biology or any other scientific discipline will never be able to demonstrate, logically, that a rational, autonomous, sensitive being has any moral worth. It can only show that the human being is a pile of biological cells of the species *Homo sapiens*" (p. 193). Even more explicitly, "From a theological perspective …. The number of cells or their state of differentiation in a person may not actually matter … it is whether the embryo exists, is complete and is a whole that is important" (p. 201) (**Table 1**).

In MacKellar's eyes [23] the location of the embryo, whether *in vitro* or *in vivo*, is irrelevant since it has full moral status no matter where found and whether or not it has any potential, biologically and environmentally, to develop any farther. All that matters is the existence of an embryo, even if this has only been for as little as a few seconds (p. 207). The biological irrelevance of his theological position is accentuated by the claim that the absence of neural configurations does not signify that the embryo is incapable of feeling pain and of suffering (p. 215).

Surprisingly, MacKellar [23] admits that the moral status of an embryo will never be completely determined, but he still insists on its complete protection (p. 236). This is unexpected in light of his repeated stress on the theological and ethical significance of the 'moment of conception'. For instance, he claims that: "from the moment of its creation, the human embryo is an organized, living unity. It has the right to be protected as any other human being and not used for the sole benefit of others in their quest" (p. 236). What he is doing is giving the embryo the benefit of doubt, and presuming that it has a moral status equivalent to that of adults (p. 231). Even more emphatically, it is asserted that destroying them is equivalent to waging war against God personally (p. 237; see also [61]), a war in which Christians should be actively involved.

6. Implications of theological positions advocating opposition to embryo research

Few theological commentators advocating absolute protection of embryos grapple to any extent with the implications of their stance for the reproductive technologies, patients confronted with infertility or genetic issues, or research scientists and fertility specialists. The implications fall into a number of categories.

6.1. Implications for theology's relationship with science

The main message to emerge is that theology overrules science in the prenatal area, since the only data and interpretations of relevance are theological ones. Consequently, there is no room for any scientific contribution to a Christian understanding of early embryonic development. Theology has all the answers since these are clearly discerned in Scripture. Theology trumps science, leaving no place for scientists who are Christians. From this it follows that biomedical scientists should not investigate the human embryo. From this one has to conclude that all embryological knowledge should be obtained from research on non-human mammalian embryos. Issues raised by depending upon experimental animal models are not discussed (**Table 1**).

A prohibitionist theological position is not only anti-abortion, but also anti-IVF since the destruction of embryos is implicit in the procedure [10]. The production of spare embryos in IVF is categorically rejected, as is PGD with its selection of embryos; and no genetic analysis is to take place that might lead to selecting one embryo over another. Following on from this, there can be no genetic manipulation of embryos and no gene editing, no matter what their goal. Any research using human embryos is viewed as intolerable, and is compared "to some kind of human sacrifice of children to the benefit of biomedical research" (MacKellar [23], p. 200). The proscription of embryo manipulation applies to non-viable embryos as much as to viable embryos, since all have the same value in God's sight with no difference in personhood between the two groups. This applies even though non-viable embryos are, by definition, incapable of developing beyond a few days (**Table 1**).

Conclusions along these lines are isolationist in that they ignore the prenatal environment, suggesting that there are no theological perspectives available on the environment. This comes as no surprise, since little would have been known about it by the biblical writers or church fathers. The understanding of the embryo available to us today are modern ones, based upon embryological work spanning many decades. In the absence of any interdisciplinary dialog, and by placing embryos outside the reach of other human beings and of the community within which they reside, they have become untouchable in a way in which postnatal persons are not untouchable. They are one of us in the human community, but are isolated from us in that they cannot contribute to any others within this community. By stressing their extreme vulnerability and need for total protection, they have been placed beyond the reach of those who could contribute to their future welfare.

6.2. Implications for theology's relationship with the church community

These stances pose challenges for Christian practitioners dealing with infertility issues in their patients. It is clear they are not to recommend IVF or any of its offshoots, but to what degree can they recommend drug treatments such as clomiphene or metformin? While these drugs influence ovulation and hence are not directly affecting embryos, they may have long-term effects on embryos. A precautionary approach may hesitate to use them, in the same way that the precautionary approach is being used to enhance the moral status of the embryo [54]. They are a challenge for the church when confronted with IVF children. One imagines these children will be accepted and loved for the human persons they are, and yet they also represent a

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flawed origin. Should they exist since they have benefitted from the destruction (killing?) of many embryos, who are loved of God and should have been allowed to flourish (or disintegrate naturally).

The challenge for Christian reproductive biologists and embryologists is manifest. They have no contribution to make to the embryo debate, since only theology has a contribution to make. A logical outcome of this is that this is an area of science that should be closed to Christians (and possibly those of some other religious persuasions). There should be a 'no entry' sign, if they are to be faithful to the biblical revelation, as interpreted by these theologians.

The challenge for theological bioethicists is that, according to these theological viewpoints, every single embryo that is spontaneously aborted (lost) is loved by God and is destined to show forth his glory. Every embryo that is spontaneously aborted has a value equal to that of every embryo that successfully implants. Every embryo with abnormal chromosomes and will not develop normally (and will probably be spontaneously aborted) is as much loved by God as is every embryo that develops to term. Every embryo and every fetus that fails to develop past 12 weeks due to cervical incompetence is as much loved by God as every embryo that develops to full term. The onus on bioethicists to cope with these anomalies theologically, and to work through their implications for clinical practice is immense, and little discussed by theologians who do not find themselves in clinical situations.

6.3. Implications for theology's relationship with the public square

There tends to be a gap of immense proportions between the debate carried out within academia and that encountered in the public domain. This is particularly the case when it comes to the embryo and much of the debate around the reproductive technologies, especially ESCs. The literature on this is considerable, arising whenever there is political debate on changes in legislation to allow new research techniques involving embryos. A case study was provided by the US situation in the year 2001 when then president George W Bush became embroiled in the debate and introduced a ban on federal funding for research on newly created ESC lines [62, 63]. The policy was an uneasy compromise, that confined the use of ESCs to those currently in existence: extracted prior to 9 August 2001, but no new cells were to be extracted. The goal was to protect embryos, by preventing any additional ones from being destroyed (in the extraction of stem cells from them), but it was also intended to support in a limited way ongoing ESC research. In practice, it turned out to be a very unsatisfactory position both ethically and scientifically. The relevant point for the present discussion is that it was religiously motivated, but ultimately failed to satisfy either side. It was essentially a political construct with a tenuous ethical basis [62].

In delving into one example of public debate, I shall refer to the situation in New Zealand and attempts that have been made to allow research to be conducted on embryos. The details of the legislation are not of concern here, except to state that the reproductive technologies are governed by the Human Assisted Reproductive Technology (HART) Act 2004. Embryo research is not prohibited by the Act, but before it can take place it has to be approved by the Minister of Health on the recommendation of the Advisory Committee on Assisted

Reproductive Technology (ACART). ACART has to consult with the public prior to making a recommendation, to ensure the latter reflects the breadth of public opinion including the different ethical, spiritual, and cultural perspectives in society [64].

The range of responses received by ACART in 2007 provides a helpful indicator on public perceptions of the embryo, since much of the public opposition to embryo destruction has a religious base, even if it has not always been made explicit. Of the 58 organizations that put in submissions in 2007, 32 were explicitly religious. While all these were not opposed to this research, in all probability a majority was [65, 66].

Repeatedly, embryo research involving embryo destruction was condemned on grounds that it was 'playing God.' Religiously based responses frequently employed this language, without explaining why 'playing God' is to be decried. Unfortunately, there was little way of knowing to what extent the religious input was representative of any one religious community. One pro-life organization objected on the basis that human life begins at conception, claiming that this point signifies the time when the embryo is endowed by its creator with human rights [67]. Since every embryo is regarded as a miracle of God's loving creation, its destruction is akin to murder, the killing of 'innocent and defenseless unborn children,' even when these embryos are surplus to the requirements of IVF programs. There is no indication in these positions how the moral significance of 'conception' (fertilization) has been arrived at, even though it dominates much of the religiously inspired submissions in the public sphere.

Responses of this kind are not universal, and there are more nuanced protectionist positions within religious contributions. With the possibility of contributing to fundamental research on fertility and infertility, and the prevention and treatment of disease, another organization recognized that these accord with the Christian belief in a healing, redeeming God. As a result, they considered that humans are called upon to participate in God's work in relieving suffering, bringing healing and establishing justice. This led to the adoption of a moderate position, with its conclusion that "the ethical justification of research projects using human embryonic stem cells will depend on the potential benefits of the research and the quality of the scientific questions being asked" [67]. In light of this, a number of organizations saw a place for supporting those in need of healing, as long as the benefits outweighed the harms, and if the use of stem cells or other approaches can be justified clinically (**Table 1**).

By far the most detailed account of a religious position on embryo research was that of the Nathaniel Center, the New Zealand [Roman] Catholic Bioethics Center [68]. Its fundamental premise was the inviolate dignity of the human embryo, leading to the inevitable conclusion that no form of embryo destruction could be considered morally licit. There is to be no deviation from the stance that the human embryo has an absolute right to life from the moment of fertilization. The impression is given that the use of surplus embryos for research is ethically and theologically more problematic than allowing them to thaw.

This case study illustrates how public debate on ways of dealing with human embryos tends to be swayed by religious voices that oppose any interference with embryos. They do not of necessity reflect schools of theological thought that attempt to attain equipoise between the respective values of human embryos and those likely to benefit in future from this research. By

casting the spotlight exclusively onto embryos and their status, these viewpoints ignore the clinical and scientific possibilities and hence it is this one-dimensional message that dominates the religious contribution to public debate.

7. Seeking common ground

The dominance of what amounts to an anti-science, or irrelevance-of-science, standpoint poses problems for the influence that religious voices can have on public debate, other than to serve as voices that repeatedly oppose latest developments. This perpetual negativity does religious perspectives a disservice, that fails society as much as it does the religious communities themselves. Some theologians, however, reject a 'common morality' approach, limiting the potential for theologians to contribute to discussion of contemporary bioethical problems [69]. As an antidote, the following are worth considering.

First, all are to seek common ground and common values, rather than adopt impregnable and inflexible positions on novel procedures in a state of ethical and clinical flux. A problem with certain religious positions is that they assume they have infallible insights into questions such as the moral status of the *in vitro* embryo, insights that have to be accepted by everyone else including those who do not accept the validity of their theologically-derived premises [70]. By the same token, some secular thinkers claim the opposite, that the *in vitro* embryo has no moral standing [71]. Both positions reject the notion that any common ground exists, and that productive dialog is possible. Decision-making bodies have to be helped to find a way through this apparent impasse.

Second, all sides have to determine what are their core values, and the degree of overlap between these, regardless of their source. This requires finding models for relating to others in a pluralist culture. There also has to be honesty in sketching which medical advances are realistically possible using embryo research, the genetic editing of embryos, and germ line gene therapy.

The genius of the 1984 Warnock Report in the UK was that it achieved this, in spite of vehement criticism and denunciation by many protagonists at the time and subsequently [25, 47, 51]. Its limitation of embryo research to 14 days has also stood the test of time, even though there are voices raised against it now [72]. There was nothing definitive about this delineation, but it seemed to identify enough commonalities, both moral and scientific, to convince policy makers of its virtues. No matter how flawed it may have been it has worked remarkably well for over 30 years.

Third, no one within society has watertight answers to fiendishly new developments, and everyone should be grateful for the various perspectives brought to the debate, even when these stem from premises foreign to one's own. Religious perspectives tend to bring to the debate a cautionary perspective that may have implications for the source of embryos to be used in research, and the extent of manipulations on embryos [66]. This will satisfy neither end of the pro- and anti-research spectrum, but it provides fertile ground for dialog and constructive assessment within the boundary of moderately liberal legislation.

Those with religious voices need to reflect together on the core thrusts of their varying positions and how these can best serve society at large. Openness to dialog is central if religious perspectives are to be integrated into the diverse concerns and interests of those in a pluralist society. But this will only occur when those with religious perspectives regard themselves as integral to society and capable of making a contribution that will stand alongside, and complement, a range of other perspectives. Ongoing negativity will ensure their isolation within the debating chambers of society.

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Edited by José Antonio Morales-González and María Eugenia Aguilar Nájera

The book *Reflections on Bioethics* is an effort that brings together works grouped into five sections: "Bioethics and Health," "Bioethics and Education," "Bioethics and Technology," "Bioethics in the Use of Experimental Animals," and "Selected Topics of Bioethics." In each of these sections, the fundamental concepts of bioethics and their relationship with each of these branches of knowledge are covered. The purpose is to give the reader a specific document of topics, it is not intended to be a treaty because the study of any of the five sections is very broad. However, this is an effort that manages to combine in interdisciplinary subjects that are fundamental for professionals of all fields of knowledge.

"The only answer to a person without ethics or values is to show that we are not the same"
Irene Durante Montiel
Facultad de Medicina, UNAM

Published in London, UK

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ISBN 978-1-83881-559-2