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Ethics

Scientific Research, Ethical Issues, Artificial Intelligence and Education

Edited by Miroslav Radenkovic

Ethics - Scientific Research, Ethical Issues, Artificial Intelligence and Education

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Published in London, United Kingdom

Ethics - Scientific Research, Ethical Issues, Artificial Intelligence and Education
http://dx.doi.org/10.5772/intechopen.1001548
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First published in London, United Kingdom, 2023 by IntechOpen
IntechOpen is the global imprint of INTECHOPEN LIMITED, registered in England and Wales, registration number: 11086078, 5 Princes Gate Court, London, SW7 2QJ, United Kingdom

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

Ethics - Scientific Research, Ethical Issues, Artificial Intelligence and Education
Edited by Miroslav Radenkovic
p. cm.
Print ISBN 978-1-83769-526-3
Online ISBN 978-1-83769-525-6
eBook (PDF) ISBN 978-1-83769-527-0

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Meet the editor

Miroslav Radenković, MD, is a full-time professor in the Department of Pharmacology, Clinical Pharmacology and Toxicology, University of Belgrade (FMUB), Serbia. He obtained an MS in Pharmacology and a Ph.D. in Medical Sciences from FMUB in 1999 and 2004, respectively. He is board certified in Clinical Pharmacology with a sub-specialization in Clinical Pharmacology - Pharmacotherapy. He also obtained an MS in Bioethics from Clarkson University, USA, in 2021. Dr. Radenković has participated in several scientific projects supported by the Ministry of Science of Serbia, the Austrian Science Fund, and the National Institutes of Health (NIH) Fogarty International Center, USA. Dr. Radenković is a member of the Ethics Committee of Serbia.

Contents

Preface

Science advances as a result of research and clinical trials that must be carried out ethically and scientifically. Autonomy, risk-to-benefit ratio, fairness, data protection, and vulnerability are crucial ethical concerns in scientific research. Animal welfare is another critical concern, as information offered by animal models has benefited medicine extensively. The concept of animal rights is now recognized as animal research ethics. Furthermore, artificial intelligence (AI) is progressively becoming important in science, especially in biomedical research. Although AI offers advantages and promising benefits, it also brings ethical risks and hazards. Across all disciplines, public awareness and collaboration are worldwide research trends. It is crucial that researchers are knowledgeable about all ethical concepts, which requires education and training. This book discusses ethics in scientific research in four sections on specific ethical issues, application of artificial intelligence (AI), educational advancements, and public awareness challenges related to scientific research.

Section 1 includes chapters that address ethical considerations in obtaining informed consent, patient privacy, patient diversity and conflict of interest. Section 2 examines the use of AI in biomedicine, including ethical issues in research with AI systems, the protection of human rights with the implementation of AI, the specifics of AI application in dentistry, the challenges of ethical use of data in advanced applications, and questions related to Metaverse development. Section 3 discusses specific ethical issues in higher education. Finally, Section 4 provides pivotal information on ethical issues directly linked to public awareness challenges, including ethical leadership, food and cosmetic production, and animal research.

This book is a useful framework for clinicians and basic investigators as well as stakeholders to further explore and update existing knowledge on ethical issues and challenges in scientific research. We hope that this book will be used by researchers, medical specialists, teachers, and students. Finally, we express sincere appreciation to all the authors of the chapters for their enthusiasm and expertise, as well as the staff at IntechOpen for their highly proficient and unconditional support.

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Section 1

Ethics in Scientific Research and Specific Ethical Issues

Chapter 1

Ethical Considerations in Informed Consent

Lucía Arellano, Pau Alcubilla and Lina Leguízamo

Abstract

The process of informed consent, a fundamental aspect of clinical research, involves providing research participants with information about a study and obtaining their voluntary agreement to participate. Its purpose is to safeguard the rights and welfare of participants by ensuring that they comprehend the nature, potential benefits, and potential risks of the research and can make an autonomous and informed decision about whether to participate. The history of informed consent in clinical research is relatively recent, beginning with the Nuremberg Code in 1947 and evolving through subsequent codes and laws such as the Declaration of Helsinki, the Belmont Report, the CIOMS guidelines, and the US Common Rule. There is a general ethical agreement on the structure and information that should be included in informed consent in order to ensure that participants have all the necessary information to make an informed decision. This chapter aims to provide an overview of significant historical milestones in the development of informed consent, current consensus on its structural features, and examples of situations where obtaining informed consent may pose a challenge, such as cluster-randomized clinical trials or decentralized clinical trials.

Keywords: ethics, informed consent, research, informed decision, autonomy

1. Introduction

Informed consent is a process in which a participant in any clinical investigation is informed about the details of the study and any potential risks and benefits. It is an ethical and legal requirement for any research involving human participants [1]. Although it may seem that informed consent has always been there in time as a critical ward of patient's right to autonomy, the truth is that the concept of informed consent has a relatively short history [2]. The Nuremberg Code [3], developed after World War II in response to the Nazi medical experiments, established for the first time the principle that informed consent is essential for ethical medical research. The Code, issued in 1947, drafted some central ethical unquestioned principles that were reinforced afterward in subsequent declarations and laws, such as the principle of autonomy, which was brilliantly crystalized at the first statement of the Code:

"The voluntary consent of the human subject is essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element

of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

This first section clearly describes one of the fundamental ethical principles in clinical research that would later be called the principle of autonomy or respect for persons. For the first time, it was made clear that a subject's participation in clinical research is voluntary, and that the decision to participate or not should be made free of coercion or fraud. It also describes that the subject must have sufficient information about the characteristics of the study, its possible benefits and risks, to be able to make an informed decision about their participation. In this regard, without explicitly naming it, the first statement of the Code clearly highlights the importance of the concept of informed consent, as a critical safeguard of this fundamental principle.

In 1964, the first version of the Declaration of Helsinki, issued by the World Medical Association [4], further developed the process of informed consent and its ethical implications. It first described that the responsibility of explaining the study to the subject falls on the investigator or clinical doctor: "The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor." It also states, in line with the Code, that "Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured." The Code had introduced the concept that the subject must be "legally capable" to consent autonomously, but the Declaration expands this principle by allowing a "legal guardian" to consent. Section 3c of the Declaration states that "Consent should, as a rule, be obtained in writing," envisaging the need to reinforce the informed consent process with a written support (the informed consent form). Finally, the first version of the Declaration extends the autonomy principle not only to participate in any kind of clinical research, but also to the withdrawal of such participation, as stated in Section 4b: "At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued."

The Declaration were revised and updated at subsequent meetings in 1975, 1983, 1989, 2000, 2008, and 2013, but the statements regarding informed consent have been essentially unaltered since the inception of the first version back in 1964.

It is important to note that none of these ethical statements mentioned above, although widely accepted worldwide, were legally binding. In this regard, in 1974, The National Research Act, a United States federal law, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was created in response to concerns about the ethical conduct of research involving human subjects, especially the Tuskegee syphilis study, in which African American men were not informed of their diagnosis or treatment and were left untreated even after penicillin became available as a cure [5].

The Act gave the commission the authority to study and make recommendations on the ethical principles involved in biomedical research, regarding the protection of human subjects. The Commission also developed guidelines for the conduct of such research, crystalized in the Belmont Report in 1979 [6]. The Belmont Report is considered a seminal document in the field of research ethics. The report first establishes in a formal manner the three basic ethical principles that are considered particularly relevant to the ethics involving human subjects: respect of persons (or autonomy), beneficence, and justice. Once again, the ethical principle in which the process of

informed consent lies is highlighted, but with special attention to what "autonomy" means regarding participation in a clinical investigation. As it is stated in the Report:

"In most cases of research involving human subjects, respect for persons demands that subjects enter the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for the research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to 'volunteer' or to 'protect' them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself."

This paragraph examines the nuances of the principle of autonomy in research. Using the example of the prison population, it illustrates how various forms of subtle coercion or inducement can significantly undermine this principal. Additionally, the inherent power imbalances between different groups of individuals can pose challenges to preserving autonomy, particularly in hierarchical relationships such as employer-employee or patient-physician relationships. It is crucial to implement measures to ensure that autonomy is upheld to the greatest extent possible for a subject's participation to be valid in a clinical investigation.

The Belmont Report is also the first internationally accepted ethical code to outline the general structure and information that must be provided in the informed consent. It posits that informed consent comprises three key elements: information, comprehension, and voluntariness. Regarding the information element, the report stipulates that informed consent should generally include details about the research procedures to be employed, the rationale for conducting the research, the potential risks and benefits associated with participation, alternative options for treatment or care, an opportunity for the individual to ask questions and also to withdraw from the research at any time, and information about the participation selection process and the roles and responsibilities of the researchers involved.

The report emphasizes, regarding the comprehension element, that the way information is presented and the context in which it is conveyed are as crucial as the information itself. For example, presenting information in a disorganized or rushed manner, or not providing sufficient time for individuals to consider the information, can negatively impact their ability to make an informed decision.

Finally, the report once again highlights the importance of guaranteeing the voluntary nature of the entire informed consent process, delving into the fine line that separates coercion of undue influence.

It should be noted that the National Research Act of 1974 is not legally binding (nor the Belmont Report), but it established the framework for federal regulations for the protection of human subjects in research, which was implemented later by the U.S. Department of Health and Human Services with the Federal Policy for the Protection of Human Subjects, also known as the "Common Rule" in 1991 [7]. In this regard, during the 1990s and 2000s, many countries began to adopt and pass specific regulations regarding the participation of human subjects in biomedical research, highlighting the importance and obligation of obtaining the voluntary informed consent of study participants before enrolling them in a clinical investigation. As an example, informed consent for research was made legally binding in the European

Union with the adoption of the European Union's Clinical Trials Directive 2001/20/EC, which was implemented in 2004 [8], in France in 2004, with the passing of the law No. 2004–800 [9], and in Japan in 2003 [10].

In 1982, the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS) issued the International Ethical Guidelines for Biomedical Research Involving Human Subjects, also known as the WHO-CIOMS Guidelines [11]. These guidelines provide a framework for the ethical conduct of biomedical research involving human subjects, including the requirement for informed consent, and they detail on how these universal ethical principles should be applied. So, the guidelines state and remark that obtaining an informed consent is a fundamental principle in biomedical research and that it is essential to respect the autonomy of the research participant. An informed consent, as specified in the guidelines, is required for all research participants and that the informed consent process must ensure the individual understanding of the nature of the research and the potential risks and benefits involved. Also, the language of the information provided to participant must be one that they understand that sufficient time should be given to a participant to consider participating, and that the participants have the right to withdraw at any time without penalty. Furthermore, if the participant is incapable of giving informed consent or is not legally competent or is underage, the guidelines require that investigators must obtain it from the legally authorized representative of the participant or from the parents or legal guardians of a child, or the legal guardian of an adult incapacitated person when a child or incapacitated person is the research subject. Overall, the WHO-CIOMS guidelines once again emphasize the importance of an informed consent as a fundamental principle in biomedical research involving human subjects, ensuring participants rights and autonomy, and providing a framework for the ethical conduct.

The WHO-CIOMS Guidelines were revised in 1993, 2002, and 2016. These guidelines have been conceived to facilitate the practical implementation of the subsequent versions of the Declaration of Helsinki in all WHO member states, including low- and middle-income countries. The 2016 version [12] include an appendix (Appendix 2), in which it details the essential information to be included in the informed consent form for prospective research participants.

In conclusion, informed consent is an ethical and legal requirement for any research involving human participants. The concept of informed consent has a relatively short history but has become a fundamental principle in clinical research. The Nuremberg Code, developed after World War II in response to Nazi medical experiments, established for the first time the principle that informed consent is essential for ethical medical research. The Code and subsequent declarations, such as the Declaration of Helsinki, have reinforced the importance of informed consent as a critical safeguard of the principle of autonomy or respect for persons. The Declaration of Helsinki has been revised and updated over the years, but the statements regarding informed consent have remained largely unchanged. It is important to note that the principle of informed consent is continuously evolving with new laws and regulations, but the basic principle has been unaltered since inception, to ensure the autonomy and protection of human subjects in research.

2. Informed consent process and structure of an informed consent form

As previously commented, biomedical research carried out on human subjects must comply with current ethical and legal principles that guarantee individual

autonomy to either accept or reject their participation. Therefore, informed consent acts as a safeguard that should adequately provide relevant information from scientific research, granting the freedom to consider their involvement and not be coerced to participate in the study.

In obtaining and documenting informed consent, the researcher must comply with ethical principles, current legislation, and good clinical practice standards, highlighting that the informed consent document or form has a central role during this process [13, 14]. The researcher needs clearly explain the details of the study, providing the opportunity and sufficient time to the subject or his legal representative to ask or inquire about the study and answer satisfactorily, so the subject gets the correct information and afterward has enough time to decide whether to participate in the study [15]. Overall, the informed consent is a two-way communicative process.

The WHO-CIOMS guidelines, as mentioned in the introduction of this chapter, contain 26 items that must be met before seeking a person's consent to participate in a research study. These items detail the information the researcher must adequately communicate to each participant and that it must be reflected in the informed consent form [12].

During the process of obtaining the informed consent, the researcher must initially inform the participant; consequently, it must be stated in the informed consent form or document that they are being invited to participate in the research, that their participation is voluntary, explain the reasons for their eligibility as a participant, and that they are free to refuse participation and withdraw at any time without penalty or loss of benefits. In addition, on the informed consent form, the current regulations must be explicitly cited.

On the informed consent form, and during the process of obtaining the informed consent, participants must be informed about the sponsor, the sources of research funding, and the research ethics committee and regulatory entities involved in the evaluation, approval, and authorization of the research protocol.

Subsequently, the purpose of the investigation, its methods, the procedures that the investigator and the participant will carry out, and an explanation of the difference between the investigation and routine medical care must be explained. The expected duration of the participation and the possibility of an earlier termination than stipulated must be informed. After the end of the study, the participants will be informed of the results of the research in general, if they so wish. Each participant will also be provided with potentially lifesaving and immediately clinically useful information about a major health problem. In addition, they will be informed of their right to request their clinically relevant data, unless the data have been temporarily or permanently approved not to be disclosed, in which case the participant should be informed of that decision and explained the reasons.

The inconvenience and risks derived from the study must be reported, taking into account whether or not the interventions or treatments carried out have authorization from the different regulatory agencies and the previous experience available; potential clinical benefits, if any, that could result to participants or society in general and contributions to scientific knowledge; currently available alternative intervention or treatment; and any new information that may have come to light, either from the study itself or from other sources, will be reported.

In case of possible violations of the protocol, these will be informed, in addition to the necessary information to guarantee the safety and well-being of the participants in these cases.

It should also be reported how the transition to postinvestigation care is organized and to what extent participants will be able to receive beneficial interventions postinvestigation and will have to pay for them.

Concerning confidentiality, the measures that will be taken to ensure the privacy of the participants, the records in which they are identified, the ability of researchers to protect the confidentiality, and the possible consequences of violations of this provision must be reported.

Regarding the researchers, their institutional affiliation, as well as their degree of responsibility to attend to the health needs of the participants during and after the research, should be reflected.

In addition, it must be reported in case of having it, the contracting of a study insurance policy, the name of the medical service or the organization that will provide the treatment, explaining that treatment and rehabilitation will be given free of charge for specified types of damages related to research or complications associated with it, the nature and duration of such care, and whether there is any uncertainty regarding its financing.

In the case of providing financial compensation for participation in the research, the type and amount must be specified, considering the time dedicated to the investigation and other inconveniences resulting from the participation in the investigation and that these are duly compensated, following the current legislation of the country if it allows it.

Furthermore, an informed consent document must be written at an appropriate reading level for its audience and be long enough to allow full and thorough reading of the information and study details, which may help the participant decide.

2.1 Specific cases

If there are specific characteristics in the design, said information must also be provided in a language or other form of communication that the participant can understand correctly, avoiding technicalities.

The WHO-CIOMS guidelines also stipulate that the participant must be informed in case of presentation.

In the case of controlled studies, an explanation of features of the research design (e.g., randomization and double blinding) should be included, using less technical language alternatives. The participant must be informed that the assigned treatment will not be communicated until the study has been completed and the blind has been broken, except for some circumstances that may affect the safety of the participant or the investigation. In addition, the participants must receive all essential information; otherwise, they must be informed about it and request their acceptance to receive incomplete information, clarifying that, before study results are analyzed, the participants will receive all the information and will have the possibility to withdraw their data collected under the study.

In case of the use of genetic test results and family genetic information, the participant must also be informed, as well as the related legislation and the precautions taken to avoid the disclosure of the genetic test results of the participant to close relatives, friends, or other people without your consent; In addition, if the possible uses of medical records and biological samples taken during clinical care are stipulated.

When the collection, storage, and use of biological materials and data related to health are carried out, it must be reported following what is described in the CIOMS guidelines, in addition to considering the current legislative regulations associated with each country.

The specific informed consent to collect biological samples must contain detailed information that may include storage regime, conditions and duration of storage (where, how, for how long and final disposition), foreseeable uses including its possible future use, if intended for research only or also for commercial purposes, measures taken to protect confidentiality, and the participants right to decide on such use, refuse storage, and demand that the material be destroyed (CIOMS 2016).

If the research involves women of childbearing age, information must be provided as described in CIOMS guidelines 18 and 19 and Appendix 2, informing about the possible risks if they become pregnant during the research, risks to themselves (including the future fertility), their pregnancies, their fetuses and their future offspring, and guaranteed access to a pregnancy test, effective contraception, and safe and legal abortion before being exposed to a potentially teratogenic or mutagenic intervention. When effective contraceptive methods or safe abortion practices are not available and testing at alternative sites is not feasible, women should receive information about: risk of unintended pregnancy; legal grounds for undergoing an abortion; harm reduction from unsafe abortion and subsequent complications; and, when the pregnancy is not terminated, assurance of medical follow-up of their own health and that of the infant and child, and information on the frequent difficulty in determining causality in cases of fetal or infant abnormalities. When it comes to women during pregnancy and lactation, the risks of participating in health-related research to themselves, their pregnancies, their fetuses, and their future offspring, which has been done to maximize potential individual benefits and minimize the risks, that the evidence about the risks may not be known or controversial, and that it is often difficult to determine causality in cases of fetal or infant anomalies are best described in CIOMS guidelines 4 and 19.

Another situation to consider when obtaining and documenting informed consent is the use of online or digital tools in which potentially vulnerable people could participate; therefore, sufficient information about privacy and security controls that will be used to protect your data must be provided, as well as the limitations of the measures used and the risks that may persist despite the established protection measures.

3. Scenarios where obtaining an informed consent can be especially challenging

As mentioned previously, during the process of obtaining an informed consent, the investigator needs to ensure that the research participant has understood what the participation means to make an informed decision. Usually, this is done in a face-to-face interview where the research participant decides voluntarily to participate in writing by signing the informed consent form [16]. But there can be situations or scenarios where obtaining an informed consent can be especially challenging or even not required. For example, some situations include cluster clinical trials (CRTs) and decentralized clinical trials (DCTs).

3.1 Cluster clinical trials

CRTs are defined as clinical trials in which intact groups, units, or clusters of people, rather than individuals, are randomized to study arms or interventions and the outcomes are measured on individual cluster members [17, 18].

CRTs are commonly used for the evaluation of public health, health system, and knowledge translation interventions delivered at the cluster level [18]. The clusters most used may include medical practices, hospital wards, nursing homes, schools, and communities [17]. Also, CRTs may be useful for the evaluation of individual-level interventions when the use of individual randomization may not be practical. For example, a CRT with the aim for reducing infection rates in intensive care units or in operating rooms by means of educational intervention on healthcare professionals on a new hand-washing technique to help avoid transmitting infection that randomizes intensive care units or operating rooms, intervene upon healthcare professionals, and measure outcomes on patients [17–19]. Another example can be the evaluation or indirect effects of vaccines in trials of vaccination or intravenous fluid resuscitation protocol may be logistically easier to deliver to patients using cluster randomization [18].

Given that CRTs are complex and multilevel studies, they pose ethical issues to researchers, research ethics committees, regulators, and sponsors regarding the informed consent [18, 20].

A CRT may randomize hospitals or wards, but intervene on physicians, and collect data form patients, so this may give rise to different ethical questions: Who is the research subject? Who is entitled to ethical protections? From whom, how and when must an informed consent be obtained? Should an informed consent be sought for each patient or a representative of the hospital ward? [18, 20]. Being so, a key consideration when submitting a protocol to a research ethics committee is identifying the human research participants in the trial. These ethical questions are not present in individually randomized trials since most of the ethical guidelines regarding informed consent have been redacted for individually randomized clinical trials. Therefore, as a result from the lack of adequate guidance, the interpretations as to what are permissible ethical practices in CRTs are different within and across countries.

There are some guidelines published that were created in the intend to provide researchers and research ethics committees some practical guidance, some examples are the CIOMS-WHO guideline, the Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials, and the United Kingdom Medical Research Council Cluster Randomized Trials: Methodological and Ethical Considerations [12, 19, 21]. The Ottawa Statement includes 15 recommendations that attempt to give answer to the ethical questions raised by the design of CRTs. The statement gives a three-step framework to determine whether informed consent should be obtained from an individual or not. This three-step framework for navigating ethical issues of informed consent includes question-based steps: 1. Who are the research participants? 2. To what study element(s) are hey exposed? 3. For each study element, is a waiver of consent appropriate? [18]. Depending on the trial's design, key lessons are provided. According to these key lessons, a difference should be made about informed consents. An informed consent for the study intervention and data collection should be separable and should correspond to the participant's involvement in the study. The statements specifies that if consent is sought as soon as possible and prior to exposure to study interventions or data collection procedures, informed consent is not required for randomizations [18]. A useful practical tip is to

get consent where you can. As a general rule, the CIOMS-WHO guideline establishes that an informed consent must be obtained from participants unless a waiver or modification of consent is granted by a research ethics committee [12].

In a cluster-level intervention trial that is delivered to the community, hospital, or social group as a whole and the cluster member cannot avoid exposure to the intervention, the Ottawa Statement says that the refusal of consent is effectively meaningless. The CIOMS-WHO guideline also establishes that in this type of trial, it may be virtually impossible to obtain individual informed consent. A classic example is a study comparing the methods of fluoridating the drinking water supply in a community to prevent dental carries [12]. Waiver of consent for any cluster-level intervention may be appropriate provided that the intervention poses only minimal risk to the participants. In this regard, historically, the waiver of consent was originally requested by researchers for observational retrospective studies, where a review of the medical records may only pose a low risk to the participants given that an adequate confidentiality protection system was in place. For example, The Common Rule establishes that the exempt research requires a Committee Ethics review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens [7]. Therefore, a research ethics committee needs to approve a consent procedure, which does not include, or which alters, some or all the elements of informed consent or waive the requirements to obtain informed consent. The research ethics committee must find and document that: (a) the research involves no more than minimal risk to the subjects; (b) the waiver or modification will not adversely affect the subjects' rights and welfare; (c) the research could not be carried out without the waiver or modification; and (d) whenever appropriate, the subjects will be provided additional relevant information after participation in order to grant a waiver. In the context of CRTs, a low-risk category may be public health or educational practices.

In healthcare professional-level interventions, the question of who the research participant is must be answered to either ask for a consent or a waiver. When indeed they are the research participants, their informed consent should be obtained, unless the conditions of a waiver of consent are met. An example may be studies in which the intervention is delivered to a group team as a whole and the intervention cannot be divided among individual healthcare professionals [18].

Individual-level interventions and individually randomized trials mainly evaluate the same kinds of interventions that are delivered to patients and healthy volunteers; therefore, the considerations of informed consent are similar. For instance, if a waiver was not granted or not qualified for an individually randomized trial with the same characteristics of an individual-level intervention CRT, the intervention should not receive a waiver of consent in a CRT. If consent would be sought for an intervention in daily clinical practice, as for a drug or vaccine, a waiver of consent is never appropriate for that intervention in a CRT [18].

There is no real international consensus on to what the accepted justifications for informed consent waivers for CRT, but ethics research committees try to establish criteria to accept waivers that do not undermine the autonomy right of participants, that the participant is not exposed to a greater risk, and that the study may not be feasible without the waiver and is of an important social relevance. Also, it must be taken in mind the fact that individual choice to participate may not exist in a cluster intervention; it does not, for instance, prevent individual consent to complementary interventions as for example taking biological samples, recording information, or extracting data from health records.

3.2 Decentralized clinical trials

DCTs are clinical trials characterized by less dependence on research facilities or specialist intermediaries for data collection, in which the need for patients to physically access hospital-based sites is reduced or in some instances eliminated [22, 23]. DCTs take advantage of digital technologies and other methods or tools such as telemedicine platforms, sensory technologies, wearable medical devices, home visits, virtual patient-driven healthcare interfaces, and direct delivery of investigational study medications and materials to the homes of the patients to enable access, monitoring, and communication between researchers and participants [22, 23]. DCTs no longer require that patients frequently travel to healthcare facilities to participate in a trial and, thus, can adapt to patient's routines and allowing participation regardless of the patient's geographical position [22]. The disruption of the COVID-19 pandemic highlighted the importance and usefulness of digital technologies and decentralized procedures in a healthcare setting but also in some clinical trials [22, 24, 25]. Some clinical trials have already adopted many decentralized elements such as phone calls, online visits, wearables, and electronic diaries. How these decentralized elements are utilized will depend on the type of clinical trial, characteristics of the trial population, including diseases and physical condition (e.g., neuromuscular diseases), the type of medicinal product, and its development stage [24]. DCTs may be more suitable for conditions different from complex studies and for studies that are not excessively long. Ethic research committees must confirm that the use of these elements is appropriate as long as the rights, safety, dignity, and well-being of the participants is protected and prevail over all other interests, including the informed consent process.

While DCTs may provide some advantages to patients and trial sponsors, as mentioned previously, an important ethical aspect of a clinical trial is the informed consent. To give consent, participants need to be adequately informed about the trial, have opportunity to inquire about details of the trial, and have good communication with the investigator.

As has been discussed throughout the entire chapter, to properly inform a participant, a face-to-face interview with the researcher and potential participant needs to take place to ensure the willingness to participate, enhance mutual trust, and promote trial compliance [16, 24]. Thus, given the nature of DCTs that may involve an informed consent process in a remote manner and/or electronic methods for the signature of the informed consent form, several ethical aspects must be assessed including the trials design, its population, the risks, burdens, and potential benefits.

If only a part or the whole informed consent process is conducted remotely, the procedure needs to be described in the protocol of the trial, and a rationale behind using a remote approach must be detailed to the research ethics committee to ensure appropriate review. The recent recommendation paper on decentralized elements in clinical trials made by the European Commission and the European Medicines Agency states that the process should still be carried out in compliance with the principles laid down in the current clinical trial regulation or the directive, the ICH Guideline for good clinical practice E6 (ICH E6), the General Data Protection Regulation (GDPR), and national legislation.

The ICH E6 requires that all potential trial participants are fully informed on the clinical trial and provides the participants ample time and opportunity to ask questions and to decide whether to participate or not. All questions about the trial should be answered to the satisfaction of the potential participant [26].

The recent recommendation paper also states that, in the process of obtaining informed consent, it is considered essential that a face-to-face interview takes place between the potential trial participant and the investigator. If this communication is done in a virtual meeting, it recommends that this takes place in real time where both parties can see and communicate via audio and video. This remote virtual contact should allow the participant to ask questions, and the investigator should make every effort to check the identity of the participant if they are not already known by them, and conversely, the participant should have the right to ask for the proof of the investigator's identity if they have not been in contact before [22]. Since a trial participant may hesitate to participate in a DCT, trial participants and investigators should be given the option to have the informed consent interview on site if this is preferred.

While the process of a face-to-face remote meeting to inform the participants may be ethically acceptable if all the requirements are met, the signature of the informed consent form rises legal issues. There may be ways in obtaining the signed informed consent form by remote means. These may include, for example, that the consent form is sent to the home of the participant for them to sign, and then, they send it back by post, or a digital consent form signed with an authorized electronic signature. Regardless of the format of the informed consent, the method should allow the reconstruction of the process, including the validity of the signatures. The Guidance for Industry, Investigators and Institutional Review Boards Conduct of Clinical Trials of Medicinal Products during the COVID-19 Public Health Emergency made by the U.S. Food and Drug Administration during the COVID-19 pandemic for decentralized activities in clinical trials that can be extrapolated to DCTs and the recommendation paper on decentralized elements in Europe both state that a method needs to be in place to ensure that the signer of the consent form is the person who plans to enroll as a participant in the trial and that the systems used have proportionate security levels and that safeguards regarding confidentiality are in place [24, 27].

Still DCTs need adequate guidelines, recommendations, and regulatory frameworks in order to favor harmonizations of both DCT ethical review and authorization of remote procedures and foster implementations of these trials.

4. Conclusion

The concept of informed consent arises from the basic ethical principle of respect of persons aka the patients' autonomy and basic human rights. Regrettably, history has taught us that an informed consent is not only ethically correct but essential for conducting medical research and clinical trials. As established by ethical considerations and regulatory frameworks in research, an informed consent must respect the persons choice to participate or not in a clinical investigation. But this opportunity to choose is provided when adequate standards or requirements for an informed consent are satisfied, being a proper informed consent form that structurally is sound in giving all the necessary information to the participant and a face-to-face interview with the researcher and potential participant. This interview needs to take place to ensure the willingness to participate, given the opportunity to inquire about details about the research, and it may enhance mutual trust and promote trial compliance. There may be exceptions or situations in which the informed consent may be challenging or not even obtained, as are cluster clinical trials and decentralized trials.

Conflict of interest

The authors declare no conflict of interest.

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Chapter 2

Importance of Patient Privacy in Healthcare Analytics Research

Ewa J. Kleczyk

Abstract

In recent years, ensuring patient privacy has become an important part of healthcare and medical research. With the vast amount of healthcare data available for research and the increasing ability to link and combine multiple healthcare datasets to enhance understanding of patient diagnostic and treatment journey, the need for the assessment of analytical datasets and output from the patient privacy side has become yet another step of the study protocol. The types of methods applied in the evaluation vary and include internal evaluation of sensitive personal and healthcare information through a statistical expert determination of the combined dataset. In addition, collaborating with a third-party expert in the privacy area can help ensure an objective assessment of meeting patient privacy requirements. As a result of the importance of patient privacy in healthcare research, this chapter will review the variety of methods leveraged in ensuring patient privacy protection during the healthcare analytics and research journey.

Keywords: patient privacy, HIPPA, healthcare research, expert determination, medical records

1. Introduction

An individual privacy is of an immense importance when conducting healthcare and medical research, as it involves sensitive personal information. With the increasing amount of data available for analysis in recent years, the research often involves the collection, storage, and analysis of large amounts of personal health information, which can include sensitive and confidential information, such as medical history, diagnostic and treatment data, insurance remittance, bio-samples and specimens, primary research, patient charts, and other identifying personal information, including patient's name, birth date, and personal identification numbers. Furthermore, with the increase in research organizations linking and combining a variety of individual-level datasets, the risk of re-identifying an individual has increased, adding to the complexities in personal and healthcare data protection. The unauthorized disclosure or mishandling of this type of information can have profound consequences for impacted individuals, including discrimination, monetary loss, damage to reputation, not receiving the appropriate level of healthcare services, and potentially even a stolen identity [1, 2].

To protect patient privacy, various laws and regulations have been put in place, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the General Data Protection Regulation (GDPR) in Europe. These laws set standards for protecting the confidentiality and security of personal health information and require researchers and healthcare organizations to obtain informed consent from patients before collecting, storing, or using their personal information for research or analytics purposes. Additionally, healthcare organizations often implement strong security measures and data governance policies to manage personal information securely and appropriately. These laws also guide the use of the data and information, creating analytical ready datasets [1, 2].

As a result of the increased scrutiny of the patient privacy topic, this chapter focuses on the importance of preserving and protecting patient rights for privacy of personal and healthcare information. A brief description of the laws and regulations is outlined to provide the current regulations guiding the process. The methods for patient data protection and ways for analyzing data when conducting healthcare and medical research are also presented to ensure no personal data is revealed throughout the process.

2. Patient privacy Laws' overview

Patient privacy is a major concern when it comes to healthcare and medical research, as well as analytics. Medical research often involves collecting, storing, and analyzing copious amounts of personal health information, which can include sensitive and confidential information, such as genetic data, medical history, healthcare diagnostic and treatment data, insurance remittance, and other identifying personal and healthcare information. If not managed properly, this information can be misused or mishandled, leading to negative consequences for affected patients. In addition, the variety of data sets can be linked and combined to provide additional insights and data granularity, which can lead to an increased risk for identification of personal information, especially in the area of rare diseases, where the patient population is often less than 200,000 lives. Understanding the associated risks and creating mitigation plans is also important to ensuring healthcare and medical research can be conducted safely. The resulting insights and outcomes can enhance knowledge of diagnostic and treatment process, while at the same time protect patients' rights for anonymity and privacy [1, 2].

The mitigation techniques, such as de-identification, where personal information is removed from data sets, or the use of synthetic data, where the data is artificially generated while preserving the characteristics of the original data, can be used to protect patient privacy and still allow for valuable insights to be gained through analytics. Furthermore, understanding the requirements and guiding rules for healthcare organizations collecting, storing, and analyzing the personal and healthcare data is of a foremost importance to ensure research organizations' compliance with the laws and regulations put in place by the governing agencies [1, 2].

In this section of the chapter, the two most important patient privacy protection laws are described. The responsibilities of healthcare organizations in complying with these regulations and the resulting consequences are also reviewed.

2.1 Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act, otherwise known as HIPAA, is a federal law in the United States that establishes standards for protecting the

privacy and security of personal health information. HIPAA applies to covered entities, which often include healthcare providers, health plans, and healthcare clearinghouses. The regulation is governed by the Department of Health and Human Services, working closely with the Department of Justice as well as the Office of Civil Rights [1, 3].

HIPAA has several provisions that are relevant to healthcare and medical research. The Privacy Rule, for example, establishes standards for protecting the privacy of protected health information (PHI) and requires covered entities to obtain patient consent before using or disclosing PHI for research purposes. The Security Rule, on the other hand, establishes standards for protecting the security of electronic PHI (ePHI) and requires covered entities to implement administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of ePHI [3].

HIPAA also includes a provision known as the "minimum necessary" standard, which requires covered entities to make reasonable efforts to limit the use and disclosure of PHI to the minimum necessary to accomplish the intended purpose. This provision applies to healthcare research and requires researchers to limit the amount of PHI they use; track sample sizes and data elements leveraged; or disclose what is necessary to conduct their studies [3].

The Office of Civil Rights is the governing organization that ensures compliance with HIPAA regulations and ensures investigating and conducting reviews of any violations and breaches. The governing body might select to conduct audits and investigations when suspecting violations and insufficient protections applied by a healthcare organization as noted by the "minimum necessary" standards [3].

To ensure no personal information is shared and revealed, a variety of techniques and methods are applied when conducting healthcare and medical research. For example, patients are asked for consent for their information to be used, or statistical expert determinations are performed on data sets compiled from a variety of healthcare sources to ensure no sensitive information is included and no identifying information can be established from the research [3].

2.1.1 Personal information breach

When personal or sensitive information is disclosed, the covered entities need to follow the HIPAA Breach Notification Rule. The rule requires covered entities and their business associates to provide notification to impacted individuals, following a breach. Business associates are often defined as a person or entity who manages, transfers, or analyzes data with PHI, on behalf of the covered entity [3].

A breach is often defined as "an impermissible use or disclosure that compromises the security or privacy of the protected health information" [3]. The following factors may help define a breach:

1. The PHI was shared with other unauthorized individuals or entities. Or there is a substantial risk of re-identifying an individual [3].

2. The unauthorized person used the individual's protected health information or shared the information with [3].

3. There is a need for confirmation of the PHI being acquired or viewed [3].

4. The risk mitigation level to protected health needs to be understood and analyzed [3].

All covered entities and business associates must report privacy breaches. They can choose to provide the required breach notifications without performing a risk assessment; however, it is advised to perform a risk evaluation to determine the probability of the protected personal and health information being compromised. There is a clear pathway for reporting and mitigating the breach and how the breach must be communicated to the affected individuals [3].

2.1.2 Reporting a breach

Following a breach of protected health information, covered entities must notify affected individuals, the government, and, where applicable, the media [3].

Covered entities must provide the breach notice either in a written form by mail or by e-mail if the affected individuals agreed to electronic communication [3]. If the covered entity is not able to reach impacted persons due to outdated or insufficient information for ten (10) or more individuals, the covered entity must post the notice on their home page or website for at least 90 days or by providing the notice in major print or broadcast media where the affected individuals reside [3].

These individual notifications must be provided without a significant delay and no later than 60 days following the discovery of a breach [3]. They must include a brief description of the breach, a description of the types of information involved, and the steps affected individuals should take to protect themselves from potential harm, a brief description of what the covered entity is doing to investigate the breach, and to prevent breaches in the future, and finally the contact information for the covered entity [3].

Covered entities that experience a breach affecting more than five hundred (500) residents in a specific area like State or pre-defined jurisdiction, in addition to notifying the affected individuals, must provide notice to media outlets [3].

In addition to notifying affected individuals and the media as applicable, covered entities must notify the Department of Health and Human Services by visiting the HHS website and filling out and electronically submitting a breach report form [3].

2.1.3 Breach penalties

Depending on the severity violation of the HIPPA regulation, there might be financial penalties placed on the covered entity. The Office of Civil Rights usually prefers to resolve HIPAA violations using non-punitive measures, including voluntary compliance, or issuing technical guidance to help address areas of concern. The Office of Civil Rights considers a few factors when assessing the penalties and mitigation tactics. These factors include being unaware of a potential violation happening and taking the minimum steps abiding by the HIPAA Rules or having a violation as a direct result of "willful neglect" with limited or no attempts to correcting the violation within 30 days of occurrence [4].

In the case of unknown violations, where the covered entity could not have been expected to avoid a data breach, financial penalties are usually not assessed [4]. On the other hand, the penalty cannot be avoided if the violation involves intentional neglect of the Privacy, Security, and Breach Notification Rules [4].

When assessing the penalty for violation, the Office of Civil Rights considers several factors, including the length of time for a violation, the number of people affected, and the nature of the data exposed. These factors can affect the amount of the financial penalty. In addition, the Office of Civil Rights takes into consideration

the covered entity's prior history, financial condition, and the level of damage caused by the breach. Examples of penalties include a minimum fine of $100 per violation with up to a fine of $50,000 per violation [3, 4].

2.2 General data Protection regulation (GDPR)

The General Data Protection Regulations, otherwise known as GDPR, establishes the general obligations of data controllers and of those processing personal data on their behalf in Europe. These include the obligation to implement appropriate security measures, according to the risk involved in their data processing operations [5].

Furthermore, GDPR presents a firm stance on data privacy and security to ensure the protection of individuals' information and how their data is used, including types of analysis that the data can support. The regulation itself is large, far-reaching, and provides limited details on what is expected, making GDPR compliance complicated, especially for small and medium-sized enterprises (SMEs), which might not have the needed resources to apply, comply with, and track the changing regulations and amendments [5].

In Europe, the financial penalties for violating the GDPR are high, especially when comparing to the United States. There are two types of penalties, which max out at €20 million or 4% of global revenue, whichever is higher. In addition, individuals impacted by the breach have the right to seek compensation for damages from the organizations that violated the regulation [2, 6].

Since this chapter focuses on the US application of the patient privacy regulations in healthcare and medical research, the overview of GDPR noted above is the only mention of the prevailing law and applications in Europe.

3. Healthcare data Protection and risk mitigation strategies

Ensuring patient privacy has become a crucial aspect of healthcare and medical research in recent years. With the vast amount of healthcare data available for research, and the increasing ability to link and combine multiple healthcare datasets to enhance understanding of the patient diagnostic and treatment journey, the need for the assessment of analytical datasets and output from the patient privacy side has become a crucial step in the study protocol. The methods applied in the evaluation vary and include internal evaluation of sensitive personal and healthcare information through a third-party experts' statistical expert determination of the combined dataset. Collaborating with an expert in the privacy area can help ensure an objective assessment of meeting patient privacy requirements. In addition to expert determination, other methods are used to ensure patient privacy in healthcare research. These techniques often applied by healthcare organizations collecting the data include de-identification, anonymization, informed consent, and data security. These methods are crucial to protecting patients' sensitive information and provide a venue to ensure the safe collection, storage, and analysis of sensitive information. In addition, internal policies and governing rules designed by internal privacy and security experts help support organizational compliance [3].

This section of the chapter presents various methods and techniques to provide a deep understanding of what is available and how it can be applied when collecting, storing, and analyzing healthcare data and information.

3.1 Collecting and securing medical records

Protecting patient privacy when using medical records, claims data, pharmacy records, insurance remittance data, patient charts, etc., is crucial in healthcare and medical research, resulting in analytics and insight dissemination. There are several ways to ensure patient privacy when working with healthcare information and data, including [3]:

1. De-identification: This process removes personal identifiers such as names, addresses, and social security numbers from the data. This step makes it more difficult to link the data back to an individual patient while protecting the patients' rights for privacy [3].

2. Anonymization: This step is a more advanced form of de-identification, which involves removing all identifying information from the data, making it impossible to link the data back to an individual patient [3].

3. Informed consent: Researchers obtain informed consent from patients before using their medical records for research purposes. This ensures that patients are aware of how their data will be used and have given their permission for inclusion in a variety of purposes. This step becomes especially important in research, as pending the patient's consent only the data sources noted can be leveraged for analysis [3, 7].

4. Data security: Researchers must establish strict data security protocols to ensure that the medical records are only accessible to authorized personnel and to prevent unauthorized access, use, or disclosure of the data [3].

5. Compliance with regulations: As described above, researchers must comply with regulations such as HIPAA, which sets standards for protecting the privacy and security of personal health information. Internal privacy and security experts create the data management and security policies and guidelines that help meeting the set-forth requirements [3].

6. Synthetic data: Healthcare research organizations can create synthetic data sets that preserve the characteristics of the studied population but in the process, eliminate the risk of releasing and sharing PHI or other identifying sensitive information or data elements [3].

The above techniques and steps provide a way to ensure patient privacy but also ensure that when combining and linking data as well as analyzing the resulting datasets, the level of information that can be used and sources of data that can be leveraged to answer healthcare and medical questions are clearly presented, analyzed, and understood by the individuals, patients, and collecting healthcare data organizations and covered entities. Internal governing data policies can help establish a compliance-driven environment and support the mission of data privacy protection.

As noted above, for example, patients might provide consent for combining and linking their information across a variety of data sets. On the other hand, individuals might restrict connecting selective information, such as their genetic or bio-sample data, with these datasets, which must be abided by when developing a comprehensive

analytics-ready data set. Patients might also remove their consent for any data being used for future studies.

Recently more states are working or planning to establish state-level regulations that could further protect patient rights and allow them to decide their personal and healthcare information use in research. For example, in January 2020, California put in place a California Consumer Privacy Act (CCPA), allowing individuals to review their collected data and request that their information is removed and deleted from their databases [8]. Furthermore, individuals can ask that no personal information be used and sold in the future. The continued State-level-changing policies affect the process of data review and design of compliance and mitigation policies for healthcare organizations, forcing more healthcare organizations to employ experts in the privacy and security area to guide the necessary internal policies and data governing requirements [8].

Overall, protecting patient privacy when using medical records is essential in healthcare analytics research, as it ensures that patients' sensitive information is kept confidential and prevents future damage, discrimination, or harm.

3.2 Expert determination

Privacy and expert determination are related to protecting sensitive information and ensuring proper oversight. In the context of the expert determination, privacy concerns may arise when an expert is appointed to opine on a matter that involves private or confidential information. For example, in a legal dispute, an expert may be appointed to evaluate evidence that includes private medical records or financial information [3].

To protect privacy in these situations, the selected third-party experts must adhere to strict confidentiality agreements and may have to take additional measures to safeguard the information they are reviewing. For example, they may have to use secure methods of communication and storage, and to redact or anonymize sensitive information before sharing it with entities involved in the research. Additionally, experts should be aware of and comply with any relevant laws and regulations related to privacy and data protection, including State-level regulations. Often third-party experts are annotated as business associates to ensure that they can take in personal and healthcare information and analyze all information available for the research. Please note that healthcare organizations can have their internal privacy experts perform statistical determination on the studied data, but it is often recommended to collaborate with external experts to ensure objectivity in the review process [3].

Expert determination is important in evaluating real-world data (RWD) in the healthcare analytics research because the data is often complex and multifaceted. The information can come from various sources, such as electronic health or medical records, claims data, bio-samples, and specimens, as well as patient-generated data, and may include both structured and unstructured formats. The information may also be incomplete or have errors [3].

Expert determination can help to ensure the accuracy and validity of real-world data and information by supplying a thorough understanding of the data source, the data collection process, and the potential biases or limitations of the data. They use statistical methods to evaluate the level of risk for the re-identification of patients and their information, as well as provide recommendations for mitigation steps and tasks to be implemented to lower or mitigate the risk all together. Experts can also provide insights into how to best analyze and interpret the data to extract meaningful insights without increasing the risk of re-identification of an individual [3].

Additionally, expert determination can help to ensure that healthcare data is used in compliance with relevant regulations and ethical guidelines, such as HIPAA, in the US. This can help to protect patient privacy and ensure that the data is used in a suitable and responsible manner [3].

Expert determination should be used in healthcare analytics research in several situations:

1. Data complexity: Healthcare data can be complex, multifaceted, and come from a variety of sources, such as electronic health and medical records, claims data, and patient-generated data [3].

2. Data quality: Healthcare data may be incomplete and have errors or inconsistencies. Third-party experts can help with naming and addressing data quality issues [3].

3. Compliance with regulations: Healthcare data analysis should comply with relevant regulations and ethical guidelines. Experts can help to ensure that the data is used in compliance with these regulations and guidelines, and that patient privacy is protected [3].

4. Study design and analysis: Experts can help with designing and implementing a proper study design and analysis plan [3].

5. Interpreting results: Experts can help with interpreting and communicating the results of the analysis in a meaningful and actionable way [3].

6. Combined and linked data sets: Experts can advise on the data elements and sub-groups that should be revised or removed to ensure the combined data sets support the HIPAA research requirements [3].

Overall, expert determination should be used when evaluating healthcare and medical data to ensure the accuracy, validity, and compliance of the data, help with study design and analysis, and interpret the results in a meaningful way. Releasing data sets or insights that have not been evaluated by an expert or follow privacy guidelines can result in data breaches and cause lasting damage and harm to the affected individuals.

4. Conclusions

Patient privacy is of the utmost importance in healthcare and medical research, as it helps to protect the rights and dignity of individuals who take part in research studies. Without proper safeguards for patient privacy, individuals may be hesitant to participate in research, which can hinder the advancement of medical knowledge and the development of new treatments. Additionally, breaches of patient privacy can lead to a loss of trust in the healthcare system and potentially cause harm to individuals whose personal information is compromised. To protect patient privacy in healthcare and medical research, researchers must adhere to strict ethical guidelines and regulations, such as obtaining informed consent from participants and implementing secure data storage and sharing practices. Furthermore, collaborating

with third-party experts can help in ensuring that resulting data sets leveraged for healthcare research are compliant with all regulations and do not increase risk for re-identifying an individual in the process. All these steps and mitigation methods are important to moving the medical field forward, improving healthcare access and treatment, while ensuring that patients' rights to privacy are preserved.

Acknowledgements

The chapter author would like to thank James Strout for his review of the article.

Funding

The chapter author works for Target RWE organization.

Conflict of interest

The chapter author declares no conflict of interest.

Nomenclature

CCPA	California Consumer Privacy Act)
ePHI	Electronic protected health information
HIPAA	Health Insurance Portability and Accountability Act
GDPR	General Data Protection Regulation
PHI	Protected health information
RWD	Real-world data
SMEs	Small and medium-sized enterprises

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Chapter 3

Patient Diversity in Global Industry Clinical Trials: Why It Matters, Who Should Be Concerned, and What Can Be Done?

Vladimir Misik and Martin Bolecek

Abstract

In their recent guidance to the industry the US FDA stated that it is concerned proposed the industry is rightfully concerned about patient diversity in industry-sponsored clinical trials (iCTs) due to a lack of attention on enrollment of representative numbers of participants from underrepresented racial and ethnic populations in the United States. Individuals from these populations are frequently underrepresented in biomedical research despite having a disproportionate disease burden for certain diseases relative to their proportional representation in the general population. However, the problem of insufficient representation of certain ethnic or racial groups in iCTs is not new and certainly should not be a concern to the US regulators only as there are nations/ethnicities with insufficient representation in global development of new drugs around the world. In this manuscript we examine qualifiable parameters of representation of countries in global iCTs and discuss some of the medical and ethical implications.

Keywords: global industry clinical trials, patient diversity in industry clinical trials, accessibility to industry clinical trials, participation in pharmaceutical development vs. participation in consumption of pharmaceuticals, patient diversity

1. Introduction

In their recent guidance to the industry the US FDA expressed its concern about patient diversity in industry-sponsored clinical trials (iCTs) due to a lack of attention on enrollment of representative numbers of participants from underrepresented racial and ethnic populations in the United States. According to the US FDA, individuals from these populations are frequently underrepresented in biomedical research despite having a disproportionate disease burden for certain diseases relative to their proportional representation in the general population [1]. Without introducing corrective measures, the racial and ethnic underrepresentation in today's iCTs in the US is likely to be further amplified in coming years, as the US is set to become "minority (non-Hispanic) White" by 2045 [2].

Therefore, FDA urged sponsors to develop and implement operational measures that would ensure diverse clinical trial participation and would improve the generation of evidence regarding safety and effectiveness across the entire population in the United States. The FDA provided examples of measures which could include but are not limited to offering financial reimbursement for expenses incurred by participation in a clinical trial or study (e.g., travel or lodging), providing language access to participants with limited English language proficiency, and partnering with community-based organizations to provide support to study or trial participants.

However, the problem of insufficient representation of certain ethnic or racial groups in iCTs is not new and certainly should not be a concern to the US regulators only as there are nations/ethnicities with insufficient representation in global development of new drugs around the world. In our previous publication which focused on this topic we have explored and attempted to quantify the magnitude of ethnic underrepresentation of the Middle Eastern populations (particularly Arabic) [3]. In this chapter we examine qualifiable parameters of representation of countries in global iCTs using more recent data and introducing some new parameters providing insights into countries' representation in iCTs and discuss some of the medical and ethical implications.

2. Methods, data sources, and model assumptions

The following data sources and model assumptions have been used in this report:

LongTaal clinical trial informatics platform (www.longtaal.com) which combines, processes and enriches information downloaded from ClinicalTrials.gov [4], EUDRACT [5], has been utilized as the primary data source for comparative benchmarking analyses shown in this chapter.

2.1 Clinical trials market share

Unlike methodology used other authors which utilized *number of **newly submitted** clinical trials sites into the registries (with considerable year-on-year changes)* [6–9], the methodology we developed and utilized also in this chapter enables determination of *all **active** clinical trial sites in the country* and has proven to be reliable source of determination of iCT market share of countries as a % of all active iCT sites in the country relative to all active iCT sites globally [3, 10–13].

2.2 Accessibility to clinical trials

Accessibility to industry clinical trials is defined as the number of iCT sites per 1 million population. For comparative purposes, iCT Accessibility is expressed relative to the US levels (US iCT Accessibility level being 100%). Source of the population data was the World Bank population databank [14].

2.3 Participation to consumption ratio

Participation in iCT on a country level was approximated as country's market share of global iCTs (see above). As a surrogate for the consumption of pharmaceuticals on a country level country's market share of global prescription sales was used. Participation to Consumption Ratio (PCR) is a parameter introduced and coined by these

authors to quantify adequacy of representation of countries' populations in development of new pharmaceutical products relative to consumption of commercially available pharmaceutical products.

Participation to Consumption Ratio has been computed as follows:

$$PCR = \frac{Global\ iCT\ market\ share\ (\%)}{Global\ share\ of\ pharmaceutical\ consumption\ (\%)} \quad (1)$$

Where iCT market share is calculated as shown above and pharmaceutical consumption market share has been calculated from [15].

3. Results and discussion

The US regulators (FDA) in their recent guidance to the industry flagged the problem of underrepresentation of certain racial and ethnic populations in iCTs in the United States [1].

The root causes to this phenomenon are multiple. First and foremost, we need to acknowledge the contribution of deplorable historical practices, where ethnic minorities and/or vulnerable populations were involved in research we now consider unethical [16, 17].

The impact of this legacy continues to affect the inclusion of iCT subjects today in two significant ways:

- Mistrust in the healthcare system among ethnic minorities, thus lowering their willingness to participate in CTs offered to them [18].

- Reverse selection bias among healthcare professionals, who are sensitized about potential ethical risks. Well-meaning health professionals may limit subjects' participation in a study involving vulnerable populations under the guise of protecting these individuals from harm [19].

Other factors may be at play as well, and their collective manifestation is the underrepresentation of certain socioeconomic or ethnic groups in iCTs not only in the US. In their 2013 paper, Noor et al. studied access to early-phase cancer trials in the UK as a factor of the socioeconomic statuses of patients, finding that the least deprived patients were almost twice as likely to be referred for an early-phase oncology clinical trial. Ethnicity analysis demonstrated that the non-white population was less likely to be recruited [20]. In another study, Godden et al. analyzed the effect of the ethnicity of patients recruited to cancer clinical trials of all phases in one hospital trust in England, finding that non-white minorities were 30% less likely to be recruited than were white patients [21].

However, gaps in the access to and participation in iCTs also exist on a global scale, as accessibility to iCTs for patients in several ethnically and culturally distinct global geographies lags substantially behind the countries in North America and Europe [3]. Thus, patient diversity and adequate representation of certain ethnic groups in development of new drugs should not only be a concern to the US regulators, but also to regulators, health professionals, and patients in the countries underrepresented in global drug development.

Figure 1 shows Accessibility to iCTs (for definition and calculation see Methods) for patients in countries around the world.

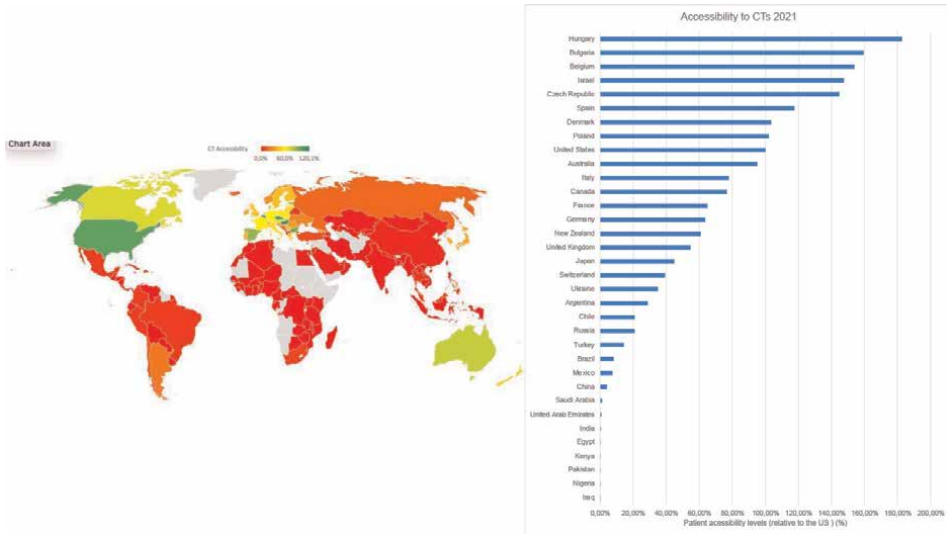

Figure 1.
Accessibility to clinical industry clinical trials, calculated as number of clinical trial sites per 1 m population relative to the US levels (US = 100%). Data source: LongTaal Clinical Trials Landscape dashboard/Clinical Trials Indices (www.longtaal.com).

Population-adjusted Accessibility to iCTs indicates high levels of accessibility in North America and Europe, as well as Israel and Australia, with lower accessibility levels in Latin America, and dropping below 5% of the US levels in India, the Arabic Middle East as well as Africa (with South Africa being an exception).

While Accessibility data are indicative of potential underrepresentation in iCTs, they do not reflect an important variable, i.e., consumption of pharmaceuticals. Super-imposing Consumption of pharmaceuticals data over iCT Participation data helps us identify countries, which are underrepresented in development of pharmaceuticals (i.e., in iCTs) relative to pharmaceutical consumption.

To assess these imbalances, we have introduced the so-called Participation to Consumption Ratio (PCR) (see Methods). Consumption of developed pharmaceuticals was expressed as global market share of pharmaceutical sales of prescription pharmaceuticals, while participation in development of novel biopharmaceutical products was expressed as a global share of active iCTs sites (iCT market share).

PCR index has been adopted and modified from the so-called Participation to Prevalence ratio (PPR) used by Saltzman et al. to assess proportionality of demographic representation of certain patient groups in clinical trials for cell-based therapy [22].

Before discussing the results, it is important to provide to the reader guidance to these results. We consider a "normal" or acceptable range of PCR = <0.5; 2>, while countries with PCR index >10 are, with a high degree of certainty, substantially underrepresented in the development of novel pharmaceuticals, and thus potentially consuming medications in development of which patients with similar ethnic or cultural[1] profiles have not been adequately represented.

[1] In addition to differences in genetic makeup, cultural habits may also influence drug metabolism and thus impact safety and efficacy of drugs: e.g., impact of Ramadan fasting on drug metabolism.

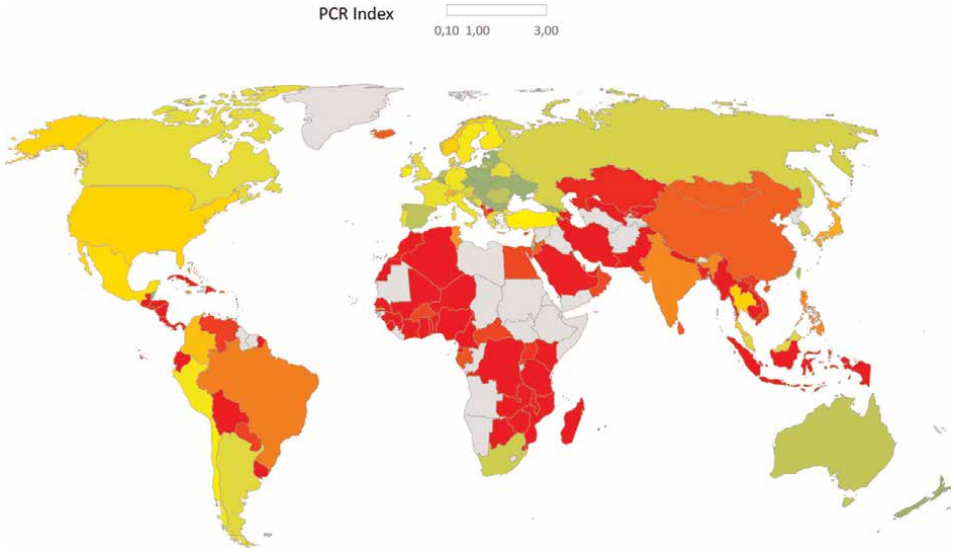

Figure 2.
Global heat map of Participation to Consumption Ratio (PCR). For definitions and methodology see Methods. Data source: LongTaal Clinical Trials Landscape dashboard, 2019 data.

Graphical presentation of the PCR data by country is shown in **Figure 2**: global heat map of PCR index by country, with darker tones of red showing the problem "out of balance" areas, with country-level details shown in **Table 1**.

As seen from **Figure 2** and **Table 1** majority of the countries with the highest imbalances between participation in consumption of marketed products relative to participation in development of new products are from Africa and the Arabic Middle East.

We recognize the following limitations of such a top-level approach to assess representation of countries in development of novel pharmaceuticals:

- Significant pricing differences between countries, i.e., typically lower pricing for the same compound in lower income countries.

- Analysis was not done at the level of the product and/or therapeutic area.

These limitations notwithstanding, PCR index can serve as a helpful and rapid identifier of significant imbalances. It is safe to assume that countries with PCR index >10 are substantially underrepresented in the development of novel pharmaceuticals, and thus potentially consuming medications in development of which patients with similar ethnic or cultural profiles have not been adequately represented.

Why is insufficient ethnic representation in development of novel pharmaceuticals a problem? Let us start with biological differences. Examples below illustrate how racial, ethnic, and cultural factors impact the safety and efficacy profile of drugs and medical devices. Such factors must be therefore taken into considerations both during products' development stage and after their launch, including:

- **Skin pigmentation:** Pulse oximeters function less accurately in patients with higher levels of skin pigmentation (darker skin), resulting in a risk of missing clinically important hypoxia [23]. This is possibly one of the contributing factors

Research Bias		**Normal iCT Distribution**		**Consumption Bias**		**Substantial Consumption Bias**	
PCR > 2	PCR value	2 ≥ PCR ≥ 0.5	PCR value	PCR < 0.5	PCR value	PCR < 0.1	PCR value
Ukraine	7.42	Belarus	1.97	Slovenia	0.483	Kenya	0.095
Czech Republic	7.32	Argentina	1.95	India	0.442	Senegal	0.093
Hungary	6.84	South Korea	1.83	Tunisia	0.413	Sierra Leone	0.078
Bulgaria	6.80	Portugal	1.77	Puerto Rico	0.388	Mali	0.070
Serbia	5.69	Malaysia	1.77	Mongolia	0.360	Saudi Arabia	0.067
Georgia	5.45	Bosnia and Herz.	1.77	China	0.359	Morocco	0.067
Israel	5.07	Finland	1.72	Jordan	0.306	Kazakhstan	0.065
Poland	4.87	Greece	1.67	Iceland	0.290	Zambia	0.064
Estonia	4.40	Canada	1.59	Gabon	0.286	Niger	0.063
Belize	4.13	United Kingdom	1.57	CAR	0.273	Kyrgyzstan	0.059
Latvia	3.93	Italy	1.44	Armenia	0.262	Cyprus	0.057
Slovakia	3.68	Peru	1.41	Venezuela	0.210	Bahrain	0.053
Lithuania	3.45	Sweden	1.39	Uganda	0.204	Iran	0.051
New Zealand	3.31	France	1.35	Vietnam	0.201	Uruguay	0.047
Belgium	3.08	Chile	1.32	Oman	0.193	Algeria	0.044
Croatia	3.03	Turkey	1.27	Burkina Faso	0.181	Cuba	0.041
Taiwan	2.68	Ireland	1.24	Mauritius	0.168	Paraguay	0.041
Romania	2.67	Germany	1.21	Luxembourg	0.159	Indonesia	0.038
Netherlands	2.41	Hong Kong	1.05	Qatar	0.136	Mozambique	0.037
Spain	2.31	Mexico	1.03	Egypt	0.133	Ghana	0.036
Australia	2.30	Thailand	0.90	Sri Lanka	0.133	Ecuador	0.033
South Africa	2.29	Norway	0.85	Albania	0.126	Madagascar	0.032
Russia	2.16	Colombia	0.82	Rwanda	0.126	UAE	0.031
Moldova	2.12	United States	0.76	Zimbabwe	0.124	Benin	0.031
Singapore	2.09	Japan	0.71	Bolivia	0.111	Cameroon	0.030
Austria	2.06	Bahamas	0.65	Swaziland	0.102	Malta	0.027
Denmark	2.05	Jamaica	0.60	Dominican Rep.	0.100	Botswana	0.024
		Switzerland	0.59			Guinea	0.021
		Lebanon	0.57			Pakistan	0.019
		Philippines	0.55			Kuwait	0.019
		Gambia	0.53			Malawi	0.015
		Brazil	0.51			Tanzania	0.012
						Bangladesh	0.002

Table 1.
Participation in development of pharmaceuticals relative to consumption of developed pharmaceuticals (PCR index). Data source: LongTaal Clinical Trials Landscape dashboard, 2019 data.

that led to the disproportionally high COVID-19 related death rates among Black or African American, as well as Hispanic or Latino populations in the US [24].

- **The effects of race and ethnicity on drug metabolism:** Significant racial and ethnic variations in the pharmacokinetics, efficacy, and toxicity of drugs have been reported [25, 26].

- **Religious and cultural practices:** Drug metabolism rates could also be influenced significantly by environmental and nutritional factors such as fasting (e.g., during Ramadan). The resulting changes in drug metabolism may result in treatment failure or, conversely, in increased side effects or toxicity. Studies have shown that fasting alters drug metabolism by modulating the activity of the drug metabolizing enzymes involved [27].

However, as a recent MRCT Center guidance document on patient diversity emphasized, inclusion of diverse representation in clinical trials is not simply a matter of biology, but a matter of health equity, fairness, and public trust [28].

Let me touch here on a few additional factors that may play a significant role in alleviating the existing diversity gaps:

3.1 Ethnically diverse iCT workforce as enablers of patient diversity

Lack of adequate racial/ethnic diversity radiation oncology physician workforce in the United States has been called out as potential contributing factor to the racial/ethnic disparities in cancer outcomes [29]. Recently the US NIH identified workforce diversity as a key to expanding the reach of clinical trials and inclusion of diverse populations [30]. Similarly, Bierer et al. in the MRCT Center Guidance document on diversity, inclusion, and equity in clinical research identified lack of cultural competence and diverse staff (investigators/referring physicians/site staff) as one of the structural barriers to improving patient diversity in clinical research [28].

The role of technology:

- Decentralized or virtual CT solutions have been finally embraced by the industry during the COVID-19 pandemic and supported by processes and technologies enabling telemedicine and remote patient visits. Some leaders in innovative technology-based solutions enabling and supporting DCTs are Science 37, Medable, and Lightship. While such technologies hold a lot of promise, the practical impact on improving patient diversity in CTs is yet to be determined.

- EHR mining with technology-based EHR-mining solutions for clinical trials, such as those offered by TriNetX or Clinerion, appear to be uniquely suited for the identification of trial sites with access to diverse patient populations.

Patient expense reimbursement:

The US FDA in its guidance to the industry specifically called out *offering financial reimbursement for expenses incurred by participation in a clinical trial or study (e.g., travel or lodging)* as a tool to improve patient diversity [1]. If handled well, this indeed can be an effective tool. However, as a recent article points out, there is an acute lack of uniform approach, including among regulators, globally [31]. As a result of these differences, some geographies and regulatory jurisdictions offer no reimbursement of

(often very significant) travel expenses, and/or no compensation of lost wages; alternately, the process of reimbursement of these expenses may be ineffective or slow. This naturally impacts low earners disproportionally, thus reducing their interest to participate in a CT or increasing their trial drop-out rates, both adversely impacting patient diversity in iCTs.

4. Conclusions

This chapter illustrated another dimension of patient diversity gaps in global iCTs: patients from countries/regions around the world which appear to be underrepresented in development of novel pharmaceutical relative to consumption of marketed products, and thus potentially consuming medications in development of which patients with similar ethnic or cultural profile have not been adequately represented. The most impacted global regions are Africa and the Middle East with most countries with the highest global imbalances. In these regions as well other countries with significantly skewed CPR balances. This problem should be further analyzed at a product level and based on the findings a robust solution-oriented discussions involving country regulators, health policy experts, insurance providers, and biopharma representatives should take place. Possible options include e.g., requiring a sub-study on a representative population of ethnically identical or similar patient groups as part of the product marketing authorization, and/or mandatory post-launch real-world data collection allowing assessment of product safety and efficacy in local populations.

We believe that in the wake of the recent US FDA guidance flagging the lack of adequate ethnic diversity in iCTs, there is an opportunity to initiate discussions around this problem globally, and particularly in the affected geographies. In this context it is important to emphasize that inclusion of diverse representation in clinical trials is not simply a matter of biology, but a matter of health equity, fairness, and public trust [28]. It remains to be seen, however, whether the market significance of the impacted markets is such that biopharma companies as sponsors of iCTs are prepared to play a more active role at driving change.

Acknowledgements

Customized clinical trial analytics for this chapter were prepared by and provided as a courtesy of LongTaal (www.longtaal.com).

Conflict of interest

The authors declare no conflict of interest.

DOI: http://dx.doi.org/10.5772/intechopen.1001279

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Chapter 4

Conflict of Interest and Think Tanks: What are the Possible Challenges and Impact

Fikile Muriel Mnisi

Abstract

Conflicts of interest (COIs) have always existed in scientific research, but they were not widely recognised until the 1980s, when the relationship between private businesses and academic institutions became more intense, partly as a result, of legislative changes that promote technology transfer from the public to the private sector and as a result of innovation and growth in the fields of biotechnology, pharmaceuticals, computers, and other important technologies. Although most commentaries and guidelines concerning COIs in science focus on research sponsored by private companies, COIs can also arise in other contexts, for example in Think Tanks. Clifton and Freeman report that think tanks produce valuable research reports, opinion piece, and expert commentary, however, their work can be compromised by funders, lack of transparency, and COIs. This chapter will analyse and unpack COIs that may arise in a biotechnology based think tank and their possible impact on the public.

Keywords: conflict of interest, think tank, research ethics, scientific integrity, think tank ethics

1. Introduction

Since transitioning into democracy in 1994, South Africa (SA) continues to experience major setbacks in the area of enduring racism, poverty and inequality. Although citizens have used a variety of coping mechanisms over years, racial hostility and widespread destitution still pervade. In the end, how political leaders contain, avert and manage these failures will determine whether any regime can overcome these difficulties [1, 2]. For this reason and in pursuit of these objects, as Nkrumah puts it, the supportive role of think tanks towards substantive political change and social equality (i.e., democratisation) is critical [3]. Moreover, the role of think tanks organisations becomes especially relevant in contemporary times as the platform for promoting socio-economic justice, with a report by Sulla [4] that substantiate these claims that, approximately 55.5 per cent (30.3 million people) of the population is living in poverty at the national upper poverty line of -ZAR 992. While a total of 13.8 million people (25 per cent) is experiencing food poverty. Whereas, one in five leave under the poverty line or GDP (gross domestic product) in South Africa. This makes

the work and availability of think tanks a very important aspect of the country's democratic growth, by influencing and impacting public policies.

Howbeit, think tanks are increasingly being dominated by advocacy and partisan agents who seek to drive their narrow agendas. Recently there has been a debate on one of the policies in South Africa, the Broad-Base Black Economic Empowerment (BBBEE) Act of 2003, which was implemented to narrow the socio-economic gaps and undo some of the injustices that were brought by the apartheid policies and legislations. The point of the BBBEE Act of 2003 is to ensure that those who were previously disadvantaged during the apartheid regime were being given a chance in a certain position, by ensuring that they would be chosen based on the potential of skills and educational training. The BBBEE Act 0f 2003 states that the policy is to 'promote the achievement of the constitutional rights to equality, increase broad-based and effective participation of black people in the economy and promote a higher growth rate, increased employment and more equitable income distribution: and ... to promote the economic unity of the nation, protect the common market and promote equal opportunity and equal access to government service' [5]. Thus, companies would be given a score based on the number of black individuals employed in certain positions, and this score is important for obtaining funding and other benefits particularly if the company's work is closely 'associated' with the government's goals.

Conversely, due to the political landscape, this policy appears to have been working only in favour of those in high political positions or the 'political elite' individuals and not applied and implemented correctly, that is, for its vital purpose to historically undo the damage caused by the apartheid legislations- well more like a catalyst for change. For this reason, this BBBEE policy has come into lot of contestations and is now being reviewed to see its effectiveness in the country. Many have called for the policy to be scrubbed off; however, what is interesting is that these are usually the individuals in the political landscape who come from previously advantaged backgrounds (the Caucasians). They too seek to drive their own narrow agendas as the most claim that this policy is racist. Howbeit, they use the narrative that the current government are misusing the power that comes with this BBBEE Act of 2003 and now using that against the proper and correct implementation of this policy. The Nation has seen these same narratives coming through 'particular' think tanks and certain political party leaders. How can we disclaim such allegations when they indeed look as though they are facts and damage to democracy?

Yet, this begs the question of what exactly is the role and importance of think tank organisations in a country such as South Africa? Since there are very few concepts in the field of political and social sciences that are still as contentious as the term 'think tank'. Generally speaking, these organisations can be thought of as private organisations that work to advance the public's interest by producing ideas that influence the creation and implementation of policies [3]. Conversely, while looking at the example with the BBBEE policy it looks like this may not always be the case and that these organisations are working for another interest that may not always be the public's interest. Yet their activities are tailored towards shaping policy and implementing ideas, in addition to their primary function, which is being knowledge hubs. With that said, Nkrumah states that some may perceive these organisations as neutral agencies responsible for using their research and capacities for the politico-economic advancement of the host state [3]. While others conceptualise them as playgrounds used by external actors, often termed funders.

The suspicion is further aroused by grants, which critics argue ensures that the development and implementation of research strategies by these organisations are shaped by the priorities of these funders [3]. Nkrumah further notes how these critics vehemently assert that these funders are those who drive the agenda of these

organisations, decide on whose strategy should be used or what information may be gathered to monitor political development in the concerned state, in order to counter the widely held romantic notion of autonomous think tanks. In all fairness there may be a reason for this thinking, particularly when looking at the political landscape of South Africa and as well as historical, how these organisations may or may not have been used. Many of the funders may (or may not) have a 'political agenda' that seems to drive some of these organisations, while others may also have political associations with the same individuals being the researchers in these organisations. Therefore, this brings us to the question that how autonomous are these organisations? Do these political relations affect their decision-making and primary priority towards the host state public interest? If this is true, what type of conflicts of interest (COIs) do think tanks pose and/or have?

This chapter aims to analyse, unpack, and discuss the conflicts of interests (COIs) that may be experienced in think tank organisations. But first, I will start by looking at the history of these organisations in South Africa, because this may contribute to the operations of these organisations and perceived COIs. Then I will look at the notion of COIs, COIs as it relates to think tank in SA and later to how some of these COIs can be managed as well as challenges contributing to managing COIs.

2. History of think tanks in South Africa (SA)

South Africa (SA) has the largest number of think tanks, with approximately 102 registered think tanks making it the highest country with think tanks in the African region and number 15 in the World [6]. Before I continue with the history of think tanks in SA, let me first start by defining what is meant by a 'think tank' organisation. 'A think tank is a public policy research analysis and engagement organization that generates policy-oriented research, analysis and advice on domestic and international issues, thereby enabling policymakers and the public to make informed decisions about public policy' [6]. Furthermore, think tanks may be affiliated or independent institutions that are structured as permanent bodies, not as an ad-hoc commissions. These institutions often act as a bridge between the academic and policymaking communities and between states and civil society, serving in the public interest as an independent voice that translates applied and basic research into a language that is understandable, reliable, and accessible for policymakers and the public [6]. Therefore, these organisations are crucial for societal development and upholding the norms and ethics of their society and thus may be expected to evolve over time. Since, if these organisations serve between the academic and policymaking community it means that as societal needs and wants develop or change or increase there is an equal need for the think tanks to evolve with that society. Therefore, it becomes crucial to then look at the history of think tanks to understand some of the COIs that may be posed by these types of organisations.

Post-1994, think tanks in SA were used or were key instruments in addressing social issues such as racism, poverty, and inequality. Even after the transition into democratic SA in 1994, SA is still faced with racial tension and a large scale of deprivation abounds [3]. Therefore, 'the ability of any regime to transcend these challenges is dependent on what measures and how well political figures contain, forestall and manage these setbacks' as Nkrumah puts it. It is for this object that the supportive role of think tanks become important to substantiate political change and social justice, thus contributing to democratisation [3]. Conversely, it is noted that local think tanks do not have the same impact or influence across the policy sphere, albeit they all might pursue a common agenda of contributing towards the promotion of democracy. According to

Nkrumah, think tanks in SA are embedded in two social movement theories known as the political opportunity structure (POS) and resource mobilisation (RM) [3]. He further explains that for one to know and understand the emergence and role of think tanks one must familiarise themselves with these theories. Since a practical illustration of POS may be traced to the gradual emergence of think tanks in the early 20th century when the apartheid regime somewhat relaxed strict regulations that were governing the formation and funding of such bodies. While this was due to an increased international pressure for the apartheid regime to transition towards democratic governance and enhance race relations. Nonetheless, between the 1970s and late 1980s, there was an escalation of human rights abuse that equally fostered RM, which was used as a strategy by think tanks to check on the powers of the government [3].

Subsequently, given the internal problems that were faced by SA at that time, the focus of the majority of think tanks was first virtually entirely internal despite the immense difficulties the nation faced as it moved to democracy. Howbeit, many of the think tanks then began to concentrate on their niche area and continent as it was obvious that SA was on the way to a negotiated settlement [7]. The transition to democracy meant an improved political, financial and legal environment that has fostered and encouraged the growth of think tanks and collaborative engagements with the government. As Nkrumah point outs that 'in most instances, those who receive support from the state, and those outside this bracket, but with relevant expertise, are often approached by the state to provide advice on a social problem or to undertake monitoring and evaluation of projects' [2]. Obviously, with these undertaking organisations or private consulting firms to carry out a similar exercise that would supplement the effort of the State. This has strengthened and improved the activities of think tanks activities, in which the scale and the needs are such that all maintain important and differing niches, partnerships and modus operandi [7].

On that background, think tanks that often serve the State directly or are State-based think tanks have directed their resources to three activities: knowledge creation, policy advice, and monitoring of government programs [3]. Howbeit, a much-needed assistance and redirection in the system were needed after post-1994 to provide needed resources to struggling think tanks as noted by Nkrumah [3]. As a result and to try and solve this problem, the parliament adopted the 1997 non-profit organisation (NPO) Act as a means of assisting those think tanks that had valid audit records. Nevertheless, this is not enough as both Cristoplos, Moran & Bjarnesen and Nkrumah's studies reports indicate that the majority of think tanks in SA receive most of their funding outside of SA [3, 7]. This is one of the top ethical issues including that of the so-called 'cordial' relationships between think tanks and their states, and/or politicians and/or funders, which may result in a conflict of interests (COIs). Due to the nature and structure of the think tank, these relationships and funding matters cannot be avoided, albeit come with ethical concerns, matters of integrity, and COIs.

These issues are then further exacerbated by the work that think tanks do, the research that they work on and the impact and influence it has on policy decision-making and development. Therefore, it is important to understand how, even based on the history of these organisations, think tanks often find themselves having to address and manage COIs more often than the 'general' research institution. How COIs in think tanks can be challenging and controversial too. Therefore, is COI the same for think tanks as it is for academic institutions and or policymakers (as public officials)? Before we understand the challenges and impact of think tanks in the next session, I will unpack the definition of COIs and try to define COIs for think tanks if permissible.

3. Attempting to define conflict of interest for think tanks

Conflicts of interest have always existed in research but did not come to the public's attention until the 1980s, when the relationship between private companies and academic institutions have become more strenuous, partly as a result of legislation that encouraged technology transfer from the public to the private sector and also due to innovation and growth in biotechnology, pharmaceutical companies, and other pertinent technologies [8]. This has become also true and relevant for think tanks across the globe, recently there has been a call on think tanks to be more transparent and to basically think about the ethics in think tanks, which include mostly COIs. This shows the importance of think tanks being able and having to deal, address and manage COIs. However, before we address some of the COIs in think tanks, let us first attempt to define COIs specifically for think tanks, this is crucial as it will make the definition more 'personal' to the work, activities and operations of think tanks.

For scientific research, COIs may be defined as: *a researcher has a COIs if and only if he or she or they have a personal, financial, professional, political or legal interest that has a significant chance of interfering with the performance of his or her or their ethical and/or legal duties* [8]. The definition obviously addresses or exposes the number of things a researcher may focus on, and it is often thought that financial interest is the only interest that can potentially cause COIs. Conversely, this definition makes one realisation that there are many other interests that an individual can have, which may cause COIs. While this definition focuses on the individual researchers and could be used for think tanks, however, it is not adequate since think tanks are also often 'public' organisations and thus their employees often have a dual duties and responsibilities, that is, professional (research) one and a public official one (serving the public, i.e., policy making). Therefore, when looking at COIs definition by organisation for economic co-operation [1] extended for public officials, their definition is as follows: *a conflict of interest involves a conflict between the public duty and the private interest of a public official in which the official's private -capacity interest improperly influence the performance of their official duties and responsibilities*. Thus, public duty may be understood to be the duty one has to fulfil its obligation and purpose based on its primary role.

So based on the OECD definition, an individual knowing the relevant facts would conclude that think tanks' 'private-capacity' may have an impact and influence their duties and responsibilities and affect their primary role as an organisation that 'serves' the public's interest, albeit it has a private interest. As a result, should a think tank organisation[1] find itself in a position where they have a conflict between fulfilling its primary role (which is also linked to public duty) versus its private role, then that think tank is experiencing COIs. This may be a little complex and challenging to even understand what conflicts and which conflict even lead to COIs for think tanks and, therefore, there is a need to extend both the researcher's and public official's COIs definition for its application for think tank organisations. To deal with COIs in think tanks it will be valid to have a COIs definition that may be specific to think tanks and could be easily understood by such organisations and be adopted by them. Otherwise, it may appear like COIs are only caused by 'personal' matters while this may be a fallacy because the causes of COIs in think tank organisations are much more complex than meets the eye. This is the proposed definition, which is a combination of both the researcher's and

[1] The definitions of COIs for think tank organisation is used synonymously with individual and/or staff. Of course, think tank organisations have individual employees who can have his or hers or their own COIs and not the organisation. However, this may contribute to the integrity of the think tank as an organisation.

public officials' (by the OECD) definitions, so an expanded definition. 'Think tanks or employees thereof have a conflict of interest if and only if its researchers or employee or as an organisation has a conflict between his or her or their or its primary role and private roles where the researcher's or employee's or organisation's private interest may involve a personal, professional, financial, legal, and political interest may and could improperly influence the performance of either the researcher or employee or organisation as set out'. By "its" in the definition I mean the think tank as an organisation[2], as an organisation that is made up of moral agent and carries some form of 'business' interest. It is important to also include think tanks in this definition for the organisation to be held responsible and accountable by the public and others if needed. Especially, since many of the decisions may not necessarily be taken by an individual researcher or the team but may come from a much higher authorisation within the organisation.

This definition not only does include the researcher (individual person) but also the organisation and makes this conflict of interests feel not only like they are an individual responsibility but also an organisation's responsibilities. The definition allows think tanks to define their primary roles based on their own vision and niche areas they work in, as well as what would be generally considered private roles in their organisations. Moreover, as OECD show in their own report and the users of their definition may be used to test for COIs, which is important since COIs can be rather vague, especially for think tanks [8]. Apart from being able to define COIs and using the definition to test them, the definition may also be applied to further define the type of COIs specific to the think tank's experience. Therefore, being able to have a definition and understanding that definition that is specific to think tanks can assist think tankers in understanding, preventing and managing COIs, and what causes COIs for think tanks.

3.1 Types of COIs

Many scholars have defined the types of conflict of interest; however, I will focus on the OECD's ones as in my opinion they are well-defined and easily clarified [1]. **Table 1** provides a summary of these COIs.

3.1.1 Actual or real COIs

Since all think tanks have a primary interest, they also have a private interest of some kind, because no organisation can only have a primary interest without having some sort of private interest. It is necessary to identify and manage conflicts of interest, whenever they arise, to maintain trust. Because trust within can be seriously damaged by suspicion of any activities by the think tank with either the state and/or funder, etc. Therefore, trust must be protected and improved to make sure that there are no improper connections between the stakeholder (these being the state, political organisation and funders) relationships, for instance, by making the funders' interest affect the way the research is conducted and/or data is reported [1]. This could happen if the relationship between the think tank and the funder (for instance) becomes affected by the amount of funds and/or the relationship between them that may influence the think tank's primary role. Thus, shifting the think tank's focus and causing a conflict of interest. This type of conflict of interest is named by the OEDC

[2] The 'its' used for the expanded definition (its researchers or employees and its primary role) is for think tank organisations, for example it would be the think tank organisations' researcher or employees or the think tank organisations' primary role.

Types of conflicts of interest	Summary or definition and examples
'Actual'/'Real'	• 'Actual'/'real' COIs are when the private interests are interfering with the primary interest, that is, private interest becomes a priority over secondary interest • These are also known simply as conflicts of interests • Are much more identifiable • Example: The think tank organisation only hires people from a certain political party and its research and work is seem to mostly aligned with the party's vision or mission and strategies
'Apparent'	• This type of COIs looks like there is or could be there based on certain factors, i.e., it is and assumed COIs • These may be as dangerous as apparent for the integrity of the organisation and work • It can over time become either a 'potential' or 'actual'/'real' COIs • For example the organisation leader has relations with a particular political family or business family (influential)
'Potential'	• This type is formed when the primary interest is there but not relevant enough to be considered a COIs • Just because they are not relevant does not mean they will not become relevant and end up being 'actual'/'real/ COIs • Example: A particular funder donates a lump sum of money to the think tank organisation and works closely with them, and he, she or they becomes interested in a particular policy matter related to their majority of business. He/she/they may start to influence the think tanks' work and decision-making as they may have leverage over them.

Table 1.
Types of conflict of interests (COIs), definition or summary and examples.

as the 'actual' or 'real' COIs. This type of COIs may result in a breach of trust or public trust, and this type of breach of trust by the think tank can happen when the think tank uses data from the research study and improvise to either have leverage based on these results or possibility of the results, to attract more or higher funding or to suit the funder or state or politic organisation's request or rather as an influenced at the expense of the public interest [1]. This type of COI is very evident and must not be confused with the other, albeit at times this type of COIs may start as either an 'apparent' COIs and/or a 'potential' COIs. The second type of COIs is the 'apparent' COIs.

3.1.2 Apparent COIs

Although 'apparent' COIs may sound like they are unimportant or maybe not as relevant as the 'actual' or 'real' COIs. However, OECD warns that this type of COIs can be as damaging as the 'actual' or 'real' and should be treated as though it were an actual conflict until such time as the doubt is removed and the matter is determined, after investigation of all the relevant facts [1]. Therefore, relevant facts about the think tank's "private" interest and their primary responsibility must be established accurately so judgement can be made about whether the think tanks have a real COI or not. For example, the example given above for the 'actual' or 'real'; let us say the think tank has a close relationship with a particular political party with the same interest as the organisations' niche areas and, therefore, public perspective may give doubt to the results and as they are reported by

that think tank. This is why it is crucial that 'apparent' COIs be treated as 'actual' or 'real' COIs, they can become 'actual' or 'real' since these may cause public mistrust in science and damage the integrity of think tanks in general. Although this may not be 'actual' or 'real' because of the assumptions that it may cause damage, it could evolve into an 'actual' or 'real' COIs if for some reason the relationship moves from a plutonic one and thus a mix with business 'favours'. The relationship could cause 'apparent' COIs.

3.1.3 Potential COIs

When think tanks have a private interest, which is *currently not regarded as a relevant interest,* because its duties are currently unrelated to its private interest [8] but could eventually become a relevant interest that may be considered a COI in the future. This can be called a potential COI. This type of COIs often happens mostly among start-up think tanks. The *potential* here is not in the moment or the present relevant interest but could in the future develop into either an apparent COI or an 'actual' or 'real'[3] COI, irrespectively. 'Potential' COIs become relevant once the 'private' duties start to affect the primary role and responsibility of the think tank towards the public. An example of a 'potential' COI could be understood when a start-up think tank forms relationships with various stakeholders, and due to their focus on becoming influential in policy development and gaining relevant resources, they may be 'easily' influenced by the funder or funds or a new and forming relationship between them and the state. Therefore, it is crucial to have a look and learn to deal with these potential COI before they become 'apparent' and then possibly later be 'actual' or 'real' COIs. These relationships, in this case, create 'potential' COIs while these may not be there since the relationships are basically creations of business networks.

On that background, it is of paramount importance that think tanks not only use the definition of COIs to define COIs and see which type they fall into but to also find and develop methods to test these COI since the definition makes provision for such tests. These tests will help in defining and making it clear if there is a COIs or not and what type it is, prior to addressing it and how it can be addressed. Because COIs can be confusing and vague, thus, think tanks can further establish a test that can be applied to evaluate and distinguish the type of COIs to assist in determining between their different types of COIs. Therefore, these tests can be generated for either the seniors in the think tank organisations, such as the executive and/or managers. Therefore, these tests can be tailor-made by the think tanks to suit their preferences based on the operational structure of the think tanks. Conversely, think tanks should try to develop these tests for themselves because the integrity of the think tanks also lies in how these COIs are addressed and managed. Therefore, it may be advisable for every think tank to establish a strategic COIs plan that will pen out how they will deal with these COIs, if or when they occur.

4. The importance of managing COIs: looking at think tank challenges

As seen throughout this chapter, think tanks may have COIs, therefore, there are various reasons to be concerned about them. Let us look at one or two of these reasons to be concerned about COI[4], particularly relating to research studies in think tanks. The

[3] 'Actual' or 'real' conflict of interest is taken as conflict of interest

[4] Impacts of COIs on think thanks

first reason is that COIs can compromise the integrity of the research and that of the organisation. Secondly, it can undermine the public's trust in science [8]; and thirdly and lastly the organisation or other organisations who do the same type of work.[5] What is troubling, as Resnik puts it, is the evidence that companies sometimes bend or break the rules of science to achieve favourable results [8]. Another troubling issue, however, more specifically in Africa that can compromise their research, as assessed by the Think Tanks and Civil Society Program is that 60 per cent of think tanks are highly susceptible with a major risk of disappearing based on data collected on think tanks in Africa. These factors include unstable funding, high staff turnover, and brain drain [9]. A major risk to sustainable African reform is the nature and scale of the think tank crisis. Indeed, during the past 20 years, the perception of Africa has changed from one of 'permanent crises' to one 'Africa rising', in part because of the efforts of African think tanks, which have provided a richer and more sophisticated understanding of and policy alternatives for strengthening policy and governance. Past examinations find that think tanks in Africa shared challenges around four prominent themes—funding, independence, quality and impact [9]. All these may have the potential of causing some type of COIs.

Funding (and resource) are often on the top when it comes to reasons why think tanks may compromise their integrity and cause a lot of 'actual' or 'real', and/or 'apparent', and/or 'potential' COIs. Because many think tanks in SA often lack the resource and financial capacity required to conduct their activity. McGann, Signè and Muyangwa elaborate further in their findings that the lack of sustainable funding is one of the greatest issues think tanks in Africa deal with. As these think tanks are disproportionately reliant on foreign funding, funding is frequently erratic, inadequate and unevenly distributed in this sector. Competition for international financial resources among countries, think tanks and government officials, as well as the restricted participation of the private sector, all contribute to this shortage [9]. Therefore, these challenges posed by funding matters can influence how a think tank operates and/or can impact, it can use its resource in a feasible and effective manner and it can influence policy change. An example of the issues associated with funding is one reported by Bennet Lourie in 2013 in a report titled 'think tanks are hardly quaking in their boots', where 'they' make claims on the issues concerning think tanks' transparency when it comes to funding. They are of the view that this matter has largely been ignored partly because of larger concerns regarding 'questionable' money in politics; largely as a result of journalists' and media's reliance on think tanks. Furthermore, newer think tanks (possibly start-ups) in particular often are partisan [10]. While another example given by Tbilisi on a research report by McClenaghan Maeve in 2012 titled 'Finance lobby: big banks and think tanks', discussing the financial sector's donations to think tanks in the United Kingdoms (UK), noted that many of the think tanks refused to disclose their donor, and some others also declined to provide any information regarding their sources of support [10]. Both cases indicate why think tanks have to be transparent about their finances or donations and sponsors. Although, there are no specific research examples in SA (or Africa), yet in my point of view funding has been one of the biggest threats and challenges for many think tank organisations in SA. This lack of research and understanding of the depth of funding as seen in Tbilisi's report is also required in SA to estimate how funding influences and affects COIs in such organisations.

[5] By undermining public's trust and those of other organisations that are doing the same or similar work it means that it can harm the integrity of the organisation, and not just that particular organization but other organization who conduct the same or similar work in that the public will not trust what they do or say for instant.

The second challenge that poses an important reason for managing think tank as mentioned by McGann, Signè and Muyangwa is independence. Because many of the think tanks in SA mostly depend on international funding and funders their independence may be questionable [9]. This doubt may pose some form of COIs for the think tank, even the dependence of the country's think tanks on the state. Thus, I agree with McGann, Signè and Muyangwa finding that the first challenge of think tanks' independence is the risk of co-optation either by governmental agencies or the political opposition [9]. If they are not already active members or executives of political parties, certain think tank leaders are frequently offered posts or contracts by state officials or the opposition in non-competitive regimes and emerging democracies, where this risk is especially significant. Furthermore, some citizens distrust think tanks because they think they are affiliated with the government or the opposition [9]. Especially when the think tank lacks a clear independence and compliance strategy, the think tank could run the risk of becoming an agent for the promotion of the special interests of certain funders wanting to advance their policy agenda. Finally, when the funding and/or amount and kind of contracts they get have an impact on their capacity to pursue an independent research agenda, think tanks run the risk of turning into consulting businesses [9]. Sadly, this dependence can affect the think tanks' ability to produce quality and impactful work. Therefore, they can try to diversify their sources of funding and come up with projects that can also add financial gain and help make the think tank more independent. Gaining independence is important for think tank organisations to be able to fulfil their obligation and serve the public's interest, thus, democracy depends on this independence. Co-dependence carries a lot of burdens that often lead to COIs.

The third challenge that is notable as expressed by McGann, Signè and Muyangwa is the quality and capacity of the think tank. This can pose a serious problem and more so since most think tanks often have limited staff who can carry out the projects, which can affect the quality or the outputs. McGann, Signè and Muyangwa say that the sustainability of some of the think tanks in Africa is threatened since the calibre of their outputs occasionally falls short of the recognised global standards [9]. Some think tanks find it difficult to produce work that meets the highest industry requirements for quality. This is typically due to the low availability and quality of highly educated researchers, communicators, development specialists and think tank administrators [9]. This lack of enough staff and/or qualified and/or experienced staff can also exacerbate the COIs that often come with think tanks and research in general. Moreover, this can also have an impact on how a think tank impactfully and effectively engages with policymakers. In the same token, this quality of standard or not finding qualified researchers is exacerbated by payment issues, many experts or 'highly skilled' individuals come with a much higher price and if they compromise and come in as a consultant, this may also cause other types of COIs not only for the organisation but also for them. Sometimes there are just not enough 'highly skilled' individuals, and some may have to consult several think tanks and thereby causing COIs. There is definitely a need to try and lessen the gap of skill needed in think tanks and find more sustainable competitive payment options.

Thus, the impact and effective engagement with policymakers and the public are the last and fourth challenge that McGann, Signè and Muyangwa note in their report that may be a challenge to think tanks, which in my view may also result in COIs [9]. Thus, think tanks face a problem in ensuring a real impact through efficient public and policymaker engagement. The inability to communicate, the lack of media exposure and networks, the lack of access to policymakers, their lack of interest, their

mismatched priorities, their lack of responsiveness to urgent needs and a lack of trust are all obstacles to having an impact [9]. Therefore, think tanks could find ways in building trust with both the policymakers and the public, respectively. While this may be a challenging task, particularly for a start-up think tank it will be important if these think tanks would also consider ways of managing (retrospective) COIs as this could in the future results in some COIs. All these challenges that are faced by think tanks (in Africa and South Africa) may also be exacerbated by other notable COIs that are often found in scientific research. These could include issues of research design, data fabrication or falsification and analysis and interpretation of data. Every research has a risk of research bias and, therefore, with research data think tanks may be biased based on any of their challenges by distorting the design of a study towards yielding particular results [3], that is, by designing the study so as to yield the desired results or design the study question to have desirable answers. During research data falsification and fabrication, bias can be formed by reporting on data based on the desires of either the influence or relationship they have with the State or funders and/or funding received (the so-called 'dark' money). Nkrumah in his study, he/they, gives an illustration of how this may be possible, he/they states that, by being recipients, think tanks may embark on research that is commissioned or mandated by the state, which in most cases will seek to justify rather than critique the government's (in)action on particular social issues [3]. This example can also be linked to another manner in which think tanks can be biased through data analysis and interpretation. When it is determined or influenced by the funder, sponsor or state and thus think tank may have to find ways to justify the results to suit the funder, sponsor or State's desires. Resnik cites the ways in which this can be accomplished, thus, he says think tanks can suppress the results altogether (unfavourable results) if the results are not manipulated or delayed [8].

Therefore, it is important to take these challenges and notable research issues that may cause COIs into consideration for developing a strategy for dealing COIs. Because if these challenges are not taken into consideration, then the COIs will increase and cause further damage to both the scientific integrity and the 'personal' integrity of these organisations.

5. Strategies for think tanks to deal with COIs

There are various ways and forms in which think tanks could develop to deal with COIs. Ultimately, think tanks should have a process and procedure, that is, creating a COIs Policy for dealing with COIs. This can be in detail and include the definitions and types of COIs, tests for each type, self-test by think tanks' staff, ways to address and manage COIs and required training for think tank staff. Scholars have reported on some notable methods, and these include disclosure, managing COIs and prohibition.

5.1 Disclosure

Disclosure involves informing all the relevant parties about the interest that creates the COIs or may cause appearance of COIs [8]. Institutions will carefully consider any actual or apparent conflicts of interest and reputational harm that specific funders may create before deciding whether or not to accept their support once they are aware of the funding sources. Additionally, funding transparency gives members of the public and decision-makers the chance to assess whether a think tank's funding sources may present potential conflicts of interest. Think tanks that fail to comply with this new norm

will stand out and come under more scrutiny as it gradually becomes the norm for think tanks to reveal their funding source, creating a kind of positive feedback loop [2].

Disclosure is often done voluntarily and advocated that think tanks make these disclosures of COIs voluntarily to build public trust in science and in these organisations, and for the organisation's integrity. This voluntary disclosure may be done by adding the funders, partners, and other relevant relationship(s) to a list that is easily accessible on the think tanks website. Some think tanks have this list in a dedicated section on their website while others would mention them based on the projects, that is, per project. This method of dealing with COI works for projects where there are low to minimum COIs and disclosure is enough.[6] Conversely, another situation requires more in-depth COIs management. Albeit, disclosure is often concerning the think tank and their funder(s) or relationship(s), there is a need to consider not only voluntary but also involuntary procedures of disclosures, particularly for think tank staff, because they too come with their own private interest when it is deemed necessary. Therefore, it will be important to define and address when it is necessary for staff to disclose and as well as when will involuntary disclosure be required, in which cases or in what type of cases.

5.2 Process for COI management

Therefore, when COIs are challenging or disclosure is not the best strategic option for dealing with COIs then a process and procedure for managing COIs may be needed. It is for this reason that the OECD developed a toolkit for managing COIs, but for public officials. Conversely, this may be adopted or extended for think tanks [8]. The toolkit consists of several points, a checklist, tests and possible training for COIs. I think this would be the type of toolkit that may be designed for think tanks to deal with COIs, a generic toolkit for think tanks in managing COIs could be helpful. Nonetheless, the OEDC toolkit is still good enough and consists of important points and COIs issues and could be used even by think tanks in dealing with COIs. Thus the OECD's generic checklist for Identifying 'at risk' areas for COIs covers issues of COIs under: 1. additional ancillary employment, 2. Inside information, 3. contract, 4. official decision making (could be think tank staff decision making), 5. policy advising, 6. gifts and other forms of benefits, 7. personal, family and community expectations and opportunities, 8. outside concurrent appointment and 9. business or non-profit organisation activity after leaving public office [8]. These are explained in **Table 2**.

Therefore, think tanks can use this generic checklist as a skeleton to build from and upon it and tailor make them to suit their own business operations in developing their own generic checklist to manage COIs. An additional tool that may also be adopted by a think tank that is suggested by OEDC for public officials is the 'generic ethics code provision relevant to COIs' [1]. These are clauses that focus on key principles of the code of ethics and/or anti-corruption laws that are found in the country and think tanks can adopt them and expand them for their own business operations, and as linked with their own organisational values, with **Table 3** indicating the EOCD generic ethics code provision relevant to COIs. One must note that these generic ethics

[6] This method means the voluntary disclosure method that is being used, i.e., listing funders or partners. This method may not always be enough especially where COIs may be considered to be greater or higher the think tank organization may need or have to use another system other than just listing the partners or funders to indicate that there were greater or higher COIs that were addressed for that project, and upon request for example they can share how those COIS were address. This can help think tank organisations to learn from one another in addressing and handling greater or higher COIs.

Areas of conflict of interest risk	Possible questions to ask
Additional ancillary employment	• Has the organisation defined a policy and related administration procedure for approval of additional/ancillary employment? • Is all the staff made aware of the existence of the policy and procedure? • Does the policy identify a potential conflict of interest arising from the proposed ancillary employment as an issue for managers to assess when considering applications for approval? • Is there a formal authorisation procedure under which staff may apply in advance for approval to engage in additional employment while retaining their official position? • Is the policy applied consistently and responsibly, so as to discourage staff from applying for approval? • Are approvals reviewed from time to time to ensure that they are still appropriate?
Inside information	• Has the organisation defined a policy and administrative procedure for ensuring that inside information, especially privileged information that is obtained in confidence from private citizens or other officials in the course of official duties, is kept secure and is not misused by staff of the organisation? On particular: ○ Commercially sensitive business information ○ Taxation and regulatory information ○ Personally sensitive information ○ Law enforcement and prosecution information ○ Government economic policy and financial information • Is all staff made aware of the existence of the policy and procedure • Are all managers made aware of their various responsibilities to enforce the policy
Contract	• Does the organisation ensure that any staff/employed official who is or may be involved in the preparation, negotiation, management or enforcement of a contract involving the organisation has notified the organisation of any private interest relevant to the contract • Does the organisation prohibit staff, etc. from participating in the preparation, negotiation, management or enforcement of a contract if they have relevant interest or require that they dispose or otherwise manage the relevant interest before participating in such a function? • Does the organisation have the power to cancel or modify a contract for its benefit if it is proved that the contracting process was significantly compromised by a conflict of interest or corrupt conduct on the part of either an official or a contractor • Where a contract has been identified as compromised by a conflict of interest involving an official or former official of the organisation, does the official in his/her official capacity ensure that they were not also similarly compromised

Areas of conflict of interest risk	Possible questions to ask
Official decision making	• Does the organisation ensure that any staff/employed official who makes official decisions of a significant kind involving the organisation, its resources, strategies, staff, functions, administrative or statutory responsibilities (for example, decision concerning a draft law, expenditure, purchase, budgetary allocation, implementation of a law or policy, grating or refusing a licence or permission to a citizen, appointment to a position, recruitment, promotion, discipline, performance assessment, etc.) has notified the organisation of any private interest relevant to a decision, which could constitute a conflict of interest of the part of the person making the decision. • Does the organisation prohibit staff, etc. from participating in the preparation, negotiation, management or enforcement of an official decision if they have a relevant interest or require that they dispose or otherwise manage the relevant interest before participating in such a decision? • Does the organisation have the power, either by law or by other means, to review and modify or cancel an official decision if it is proved that the decision-making process was significantly compromised by a conflict of interest or corrupt conduct on the part of a member of its staff/an official?
Policy advising	• Does the organisation ensure that any staff/employed official who provides advice to the government or other public officials on any official matter, concerning any kind of policy measure, strategy, law, expenditure, purchase, the implementation of a policy or law, contract, privatisation, budget measure, appointment to a position, administrative strategy, etc., has notified the organisation of any private interest relevant to that advice, which could constitute a conflict of interest on the part of person providing the advice • Does the organisation prohibit staff, etc. from participating in the preparation, negation or advocacy of official policy advice if they have a relevant interest or require that they dispose or otherwise manage the relevant interest before participating in preparing or giving such policy advice? • Does the organisation have the ability and process to review and withdrew official policy advice if it proved that the advice-giving process was significantly compromised by a conflict of interest before participating in preparing or giving such policy advice?
Gift and other forms of benefit	• Does the organisation's current policy deal with conflict of interest arising from both traditional and new forms of gifts or benefits? • Does the organisation have an established administrative process for controlling gifts, for example by defining acceptable and unacceptable gifts, accepting specified types of gifts on behalf of the organisation, disposing or returning unacceptable gifts, advising recipients on how to decline a gift and for declaring significant gift offered to or received by official?
Personal, family and community expectations and opportunities	• Does the organisation recognise the potential for a conflict of interest to arise from expectations placed on individual public officials by their immediate family or by their community, including religious or ethnic communities, especially in a multicultural context? • Does the organisation recognise the potential for conflict of interest to arise from the employment or business activities of other members of an employed official's immediate family?

Areas of conflict of interest risk	Possible questions to ask
Outside concurrent appointments	• Does the organisation define the circumstances under which a public official may undertake a concurrent appointment on the board or controlling body of an outside organisation or body, especially where the body is or may be involved in a contractual, regulatory, partnership or sponsorship arrangement with their employing organisation? For example: ○ A community group or NGO ○ A professional or political organisation ○ Another government organisation or body • Does the organisation, and/or law, define specific conditions under which a public official may engage privatised body, while still employed by the organisation?
Business or NGO activity after leaving public office	• Does the organisation, and/or law, define specific conditions under which a former public official may, and may not, become employed by, or engage in the activities of, an *outside* organisation? • Does the organisation actively maintain procedures, which identify a potential conflict of interest where a public official who is about to leave public employment is negotiating a future appointment or employment, or other relevant activity, with an *outside* body? • Where an official has left the organisation for employment in a non-government body or activity, does the organisation retrospectively assess the decision made by the official in his/her official capacity to ensure that those decisions were not compromised by an undeclared conflict of interest?

Table 2.
Generic checklist for identifying "At-risk" areas for conflict of interest (OECD 2005).

Principle	Fundamental definition
Serving	• Civil servants and public officials are expected to maintain and strengthen the public's trust and confidence in public institutions, by demonstrating the highest standard of professional competence, efficiency and effectiveness, upholding the constitution and the laws and seeking to advance the public good at all times.
Transparency and accountability	• Civil servants and public officials are expected to use powers and resources for the public good, in accordance with the law and government policy. They should be prepared to be accountable for the decisions they make and to justify their official decisions and actions to a relevant authority, or publicly, as appropriate in the circumstances.
Integrity	• Civil servants and public officials are expected to make decisions and act without consideration of their private interest. Public service being a public trust, the improper use of a public service position for private advantage is regarded as a serious breach of professional integrity.
Legitimacy	• Civil servants and public officials are required to administer the laws and government policy and to exercise legitimate administrative authority under delegation. That power and authority should be exercised impartially and without fear or favour for its proper public purpose as determined by the parliament or the official organisation as appropriate in the circumstances.
Fairness	• Civil servants and public officials should make decision and take action in a fair and equitable manner, without being affected by bias or personal prejudice, taking into account only the merits of the matter and respecting the right of affected citizens.
Responsive	• As agents and employees of the elected government civil servants and public officials are required to serve the legitimate interests and needs of the government, public organisations, other civil servants and citizens, in a timely manner, with appropriate care, respect and courtesy.
Efficiency and effectiveness	• Civil servants and public officials are required to obtain the best value in the expenditure of public funds, efficient use of assets deployed in or through public management and avoid waste and extravagance in the use of resources in public programmes and official activities.
(OEDC 2005)	

Table 3.
Basic code of ethics provisions relevant to conflict of interest—Generic ethics code provisions relevant to conflict of interest.

codes should be appropriately adopted to suit the law and drafting conventions of the particular country and used to give effect to the definition of COIs. While at the same time providing a clear understanding of the relationships that can take place between these various forms of COIs and corruption, and/or integrity, and/or (un)ethical behaviour. So as to differentiate between what may be a COI versus a case corruption or versus a case of integrity or versus a case of unethical behaviour. Equally important to the above, these generic ethics codes must be developed so as to give clarity to think tanks' country's socio-cultural norms but also relevant to global ethical standards and norms. Meaning, they must be locally relevant and as well as globally relevant so as to have a balance between their local ethical standards and as well as global standards, respectively. An additional way to manage COIs is through a self-test for COIs for think tank staff, and this can be applied as a diagnostic measure, as a reminder for staff to be reminded of their role, responsibility, duties, targets and personal efforts, and to discourage the growth of COIs, corruption and research misconducts [1]. This self-test could be in a form of a survey questionnaire that is made available during, between and before wrapping up a project, and/or after COIs training by the organisation.

Other methods as noted by Resnik in managing COIs could include developing licencing agreement where necessary, confidentiality agreements [8], *benefit-sharing agreements and material or data-transfer agreements.* Many of the COIs that can be noted by think tanks can be managed through these tools, howbeit, there are some COIs that cannot be easily managed and can require a different method for dealing with them. In such cases, the next and last method of dealing with COIs can be applied.

5.3 Prohibition

Prohibition is the most extreme strategic method for dealing with COIs [8] and also may be difficult or challenging for most think tanks to decide when they should prohibit and what processes and procedures to follow when prohibiting. Resnik suggested the following processes and procedures, albeit for research studies, but can be applied to think tanks [8]. These are:

5.3.1 The significance of the COI

What is the probability that the interest(s) will affect or interfere with think tank duties, if the probabilities are low, the situation may not create COIs but an apparent or potential COI [8]. This does not mean that it would always remain in this manner and, therefore, it is crucial to always keep track of these and make follow-ups to ensure that things still remain the same.

5.3.2 The ability to manage COIs

It is important that before prohibition of any COIs think tanks first see if these COIs are manageable, this includes low, minimum and high COIs.

5.3.3 The consequences of prohibiting COIs

Sometimes prohibiting COIs does more harm than good notes [8] because it denies science or society important benefits. For example, when an organisation prohibits a staff from being part of an industry committee or board or association, it may enhance scientific trust, but it might also deny industry important advice and reduce collaborations. Thus, prohibition is something to be taken with strict caution because while dealing with COIs we still want to maintain scientific freedom. The only time prohibition may be strongly argued for is when managing COI is low and the significance of the COI is higher, then prohibition is not bad.

Prohibition is when the COIs are very high and there is no way of managing them. All strategies are not just for COIs caused by finances, or resources, but also include staff and other factors associated with the think tank organisations. Even though it is often thought that COIs are financial interests, these interests are broad, therefore, it is imperative that think tanks become more transparent in COIs disclosure, management and prohibition, and not only disclose because of financial interest as it is often the reason. Other private interests that may affect COIs need to be established and equally prioritised as to when and how they must either be disclosed, managed or prohibited, respectively.

6. Conclusion

In conclusion, there are many challenges that think tank organisations (particularly in South Africa, Africa) face, which may often create opportunities for a lot of COIs. I have not come across a set of South African policies or procedures and processes on how they deal with COIs from any of the think tank organisations, and this is very concerning. Unless, otherwise, they are applying international rules and laws on dealing with these COIs and/or using local universities' policies. But how about those that are not linked to the university? How do they then deal with COIs? This chapter shows that the history of think tank organisation and its evolution have some form of influence on what would be deemed as 'apparent' and 'potential' COIs. Since many of the think tanks in SA, Africa, struggle with sustainability they mostly rely on 'cordial' relationships with the State and/or political parties and/or politicians and/or international agents/bodies for funding, and for them to have an impact and influence in the policy development space. (This has evolved historically from the inceptions and evolution of think tanks in SA). These relations could jeopardise the integrity of these think tanks and exacerbate the COIs in the think tanks. Thus, think tanks may be financially and/or have their 'power' (to have influence and impact) influenced by these *outside* bodies in their work and decision-making. Hence, there has been a global outcry for think tanks to be more transparent and honest, especially when it comes to funder disclosure. Conversely, this is not enough, and more is needed to be done by think tank organisations to deal with COIs effectively. Both OECD and Resnik have some ideas on how organisations can alleviate COIs. Therefore, based on what has been unpacked and discussed in this chapter, these are some of the recommendations for think tank organisations to be able to deal with COIs:

- Develop organisational COIs procedures and processes, that is, Policy;
- Develop a tailored OECD 'Generic Ethics Code Relevant for COIs' that will be aligned to the organisation's values and their local socio-cultural values;
- Have a dedicated integrity office (in-house);
- South Africa to have a centralised independent think tank organisation integrity office that forms part of the state, it can serve all other NPO organisations too;
- Define the types of COIs and create tests for them;
- Provide and facilitate COIs training to think tank staff;
- Create in-house COIs self-tests; and
- Develop a variety of agreements as mentioned in the chapter such as licence agreement, confidentiality agreement, benefit-sharing agreement, material and/or data agreement.

Acknowledgements

The author would like to acknowledge the staff at Khaca (Pty) Ltd. for their support in writing this chapter.

Conflict of interest

The author declares no conflict of interest.

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Section 2

Ethics in Scientific Research and Artificial Intelligence

Chapter 5

Ethical Issues in Research with Artificial Intelligence Systems

Tudor-Ștefan Rotaru and Ciprian Amariei

Abstract

There are many definitions of what an artificial intelligence (AI) system is. This chapter emphasises the characteristics of AI to mimic human behaviour in the process of solving complex tasks in real-world environments. After introducing different types of AI systems, the chapter continues with a brief analysis of the distinction between research into what an AI system is in its inner structure and research into the uses of AI. Since much literature is already devoted to the ethical concerns surrounding the use of AI, this chapter addresses the problem of accountability with respect to opaque human-like AI systems. In addition, the chapter explains how research ethics in AI is fundamentally different from research ethics in any other field. Often, the goal of engineers in this field is to build powerful autonomous systems that tend to be opaque. The aim is therefore to build entities whose inner workings become unknown to their creators as soon as these entities start the learning process. A split accountability model is proposed to address this specificity.

Keywords: research ethics, artificial intelligence, research accountability, human-robot interaction (HRI), Explainable Machine Learning (XML)

1. Introduction

Contrary to what most people believe, it is not easy to find a consensus definition of artificial intelligence (AI). The public may have an intuitive understanding of the term AI. Influenced by the media and the film industry, lay people may implicitly see AI as something close to what might be called an 'evil, mysterious machine'. Certainly, there is some sense of automation and hidden cognitive-like processes that people have about AI, but this would not cover a trustworthy definition. Therefore, we combine different approaches currently found in the literature. We begin our paper by defining artificial intelligence (AI) as a system that attempts to mimic human behaviour in the process of solving complex tasks in real-world environments that are not easily solved by other methods. These tasks can include activities such as perception, reasoning, decision-making, problem-solving, learning, and natural language processing. Such a system should be able to learn and adapt in order to become effectively independent of its prior knowledge and make decisions accordingly. Of course, becoming independent does not mean it will ignore initial knowledge. However, this system should be able to create new and original outputs.

The field of AI is broad and encompasses many different subdisciplines, including machine learning, neural networks, computer vision, natural language processing, and robotics. AI systems can be classified according to their level of autonomy and intelligence, ranging from simple rule-based systems to more advanced ones that can learn and adapt to new situations. Historically, AI can be divided into four distinct generations. The first generation of AI systems was characterised by rule-based systems designed to solve specific problems, such as a game of chess. The second generation of AI systems was characterised by expert systems, designed to solve complex problems using knowledge representation and reasoning. It used techniques of deep learning, natural language processing, etc. The third and current generation of AI systems is characterised by machine learning systems, which are designed to learn from data and adapt to new situations.

There are four approaches to developing AI, based on the goal of either a) thinking humanly, b) acting humanly, c) thinking rationally or d) acting rationally. Depending on the goal, thinking may be more relevant than acting, or similarly, humanly versus rationally. The approaches are not mutually exclusive and usually overlap. In this paper, we will focus more on the process of building an AI system that is capable of thinking and acting humanly. The success of such systems is measured in terms of fidelity to human performance [1].

'Thinking humanly' or the cognitive modelling approach can be defined as the automation of activities that we associate with human thinking, activities such as decision-making, problem-solving and learning [2]. This includes the subfield of AI called Artificial General Intelligence (AGI), which aims to create systems that can think and learn in ways similar to human intelligence. AGI research focuses on creating systems that can perform a wide range of tasks and adapt to new situations, as humans do. This would require capabilities in a) natural language processing, b) knowledge representation, c) automated reasoning and d) machine learning. 'Acting humanly' is an approach definable as the study of how to make computers do things at which people are better [3]. This area of research focuses on creating AI systems that can act in ways similar to humans. This includes creating systems that can understand and respond to natural language, recognise and respond to emotions, as well as interact with humans in a natural and intuitive way. This area of research is often referred to as human-robot interaction (HRI) or human-AI interaction (HAI).

AI systems that aim to think and act rationally include decision-making systems that can make optimal decisions based on (uncertain) information, including systems that can act in ways that are consistent with logical reasoning and probability theory. Ideally, they should always be able to do the 'right thing' given what they know at any given time.

In terms of approaches to building AI, there are two classes based on the transparency of their actions: black-box models and glass-box (or interpretable) models. Currently, the models with the best predictive accuracy, and therefore the most powerful, are paradoxically those with the most opaque black-box architectures [4]. A black-box AI system is based on a model or algorithm whose inner workings are not easily explained or understood by humans. This means that it is difficult or impossible to understand how the system arrived at a particular decision or prediction, even if the inputs and outputs are known. The term 'black box' is used to reflect the lack of transparency or visibility into the inner workings of the system. Examples of black-box AI models include deep neural networks and some complex forms of machine learning algorithms, such as random forests or gradient boosting. These models can be highly accurate and perform very well at certain tasks, but they can be difficult to interpret or understand why they make certain decisions. This can be an issue in areas

such as healthcare or finance, where transparency and explainability are important for regulatory compliance and ethical considerations. In contrast, the inner workings of Glass Box AI models are transparent and explainable. They allow the user to see how the model arrived at a particular decision or prediction by providing access to the model's logic, parameters and features. This transparency allows users to understand the model's behaviour, identify potential problems and make adjustments to improve its performance. Examples of Glass Box AI models include decision trees, linear regression and rule-based systems.

Explainable AI (XAI) is also known as Interpretable AI or Explainable Machine Learning (XML). It is the current research direction that attempts to develop a set of processes and methods that aim to make AI systems more transparent, interpretable and explainable to humans. According to some authors, there are four main principles of XAI. The first is explanation: a system should provide evidence or reasons for its outputs and/or processes. The second is understandability: the explanations provided by the system should be understandable to the intended audience. The third is accuracy of explanation: the explanations should correctly reflect the reasons for generating the outputs and/or processes of the system. Finally, the principle of knowledge limits states that the system should only operate within the conditions for which it was designed and should only provide outputs when it has a sufficient level of confidence in them [5].

Some authors propose an alternative and complementary approach to XAI. It involves describing black-box processing in AI using experimental methods from psychology, in the same way that scientists do with humans. Using the experimental method, cognitive psychology uses carefully designed stimuli (input) and measures the corresponding behaviour (output) to make causal inferences about the structure and function of the human mind. The same approach could be applied to artificial minds [6].

2. Research with artificial intelligence systems

A difficult distinction to make is between different types of research on and with artificial intelligence systems. We propose a distinction between research on how artificial intelligence systems can be applied to various tasks and real-world problems, as well as research on the process of building artificial intelligence itself, or on what artificial intelligence is (or should be). Typically, AI systems are built with the goal of performing a specific task. It could be argued that the above distinction is artificial. We argue that focusing our ethical discussions on the various applications of AI is likely to miss more important issues. In particular, we argue that the ethical question of what artificial intelligence systems are is at least as important as the ethical question of how artificial intelligence systems can be used.

There is already a large body of literature on the ethics of the use of artificial intelligence systems. The most debated issues include privacy and surveillance, manipulation of behaviour, bias in decision-making systems, human-robot interaction, automation and employment, and artificial moral agents [7]. Topics dealing specifically with the ethics of research into what an AI system really is are mixed with topics on the ethics of different uses of AI.

We suggest emphasising the distinction between the research ethics of AI applications and the research ethics of what AI is (or becomes) in itself. For example, the research ethics of AI applications and uses include the weaponisation of AI systems [8, 9]. Another controversial topic is artificial intelligence as a moral advisor or decision-maker [10]. On the other hand, ethical discussions of what we might call the

'ontology' of an AI system are mostly concerned with the problem of opacity [11]. The most powerful systems are those with the most opaque black-box architectures [4]. It is therefore highly likely that research focused on increasing the power of artificial intelligence will build more opaque systems. Another issue that might fit uncomfortably into what we might call the 'ontology' of an AI is machine ethics. One way to define it is the ability of an AI to take human values into account in its decision-making process [7].

Ethicists are concerned about the problems of opacity. There are concerns about the creation of decision-making processes that limit opportunities for human participation [12]. These concerns include the fact that people affected by the decision of an AI will not be able to know how the system arrived at the decision in the first place. Therefore, the system is 'opaque' not only to the people affected by the decision, but also to the expert, especially when the systems involve machine learning. Most experts dealing with opaque AI systems will not know what the pattern that generated a decision is. The programme itself evolves in such a way that as new data comes in, the patterns used by the AI system change. Certain inputs can be allowed or not, and this generates (some degree of) control. However, what this artificial intelligence system becomes is not transparent to the people who create it [7].

3. Why research ethics in AI is completely different

Research ethics is rarely treated as a general, all-encompassing field. We usually talk about research ethics in a particular field. We discuss the ethics of clinical research, the ethics of bioengineering research, the ethics of gene sequencing, and so on. In most cases, principles derived from general ethics are applied to specific fields and issues. For example, biomedical research ethics often uses the checklist of the four ecumenical principles: respect for autonomy, nonmaleficence, beneficence and justice [13]. These are treated together with Kantian, virtue-based and utilitarian approaches to consider the nature of the choice per se, but also its consequences.

In almost all cases, the ethical analysis considers an explicit intention on the part of researchers to better understand the entity they are studying *qua* that entity. For example, when researching the molecule of a new drug, scientists have the explicit intention of creating (and patenting) a new molecule. Their aim is to understand that molecule, its structure and how it works (e.g. side effects and pharmacokinetics). Usually, the purpose is pragmatic: scientists try to achieve a better result (e.g. antidepressant effect) than other similar products or interventions already on the market. After previous investigations in cell cultures and animal models, the research progresses to the point where superiority could be demonstrated in a trial. In a classic design, consenting patients would be randomised into at least two equivalent groups. One group would receive the gold standard treatment for the condition. The other would receive the newly discovered molecule. The scientists try to control for all other variables. The dependent variable (usually the desired outcome) would be measured in both groups. Differences (if any) would be statistically tested to see if and how they were due to chance alone.

As we can see in the example above, the intention of scientists is to create something that they understand better. The reason for this is that better uses of the drug are closely linked to a better understanding of the entity being created. It is the same with engineering technologies. If a "better" engine is being researched, the intention is to get better results through a better understanding of its functions and structure.

When a better processor is created, the intention is to achieve better performance through a better understanding of the technology within. When improvements are made to an engine, drug, or processor, those improvements are made from the outside. It is the scientists who come up with something new through a better understanding of the entity and this entity's uses over time. We argue that AI research is fundamentally different from other types of research, as we will try to show. Other research efforts create things by understanding them better. Improvements are made from outside that entity, by the scientists themselves, using knowledge gathered by the same scientists or by others in the scientific community.

We began our paper by defining AI as a system that attempts to mimic human behaviour in the process of solving complex tasks, adapting to become effectively independent of its prior knowledge (but without ignoring it) and making decisions accordingly. A better degree of independence of its prior knowledge means that the inner workings of the AI become less a direct effect of an outside intervention by humans. This means that, for the first time in history, scientists are creating something with the explicit intention that it will become something other than what was created in the beginning. This means that people are creating something that has the distinct property of changing itself into something that cannot be described. It is not an attempt to create something that can be better understood *qua* what it is in the moment of its creation. When trying to create general AI with the purpose of it being human-like, it's an attempt to create something whose structure becomes increasingly unknown as soon as it's released. It could be argued that this kind of change does not happen 'by itself', since data must be input in order for the AI to 'learn' new paths. Data is necessary, but by the very definition of opaque AI, the nature of the data input will not control how the artificial intelligence system changes from within. Data input may have unexpected results as well. Some outputs may be satisfactorily predicted, but the pathways inside the system will remain potentially unknown to those who created it.

We can compare opaque AI systems to the personality and behaviour of a child given a certain education. The educational input can indeed be controlled. But this input is not the only thing that explains the structures that are being created in a child's mind. This does not mean that the child's 'personality' can ever be controlled and accurately predicted. As with humans, whose personalities are the result of nature, nurture and chance (chance being a variable both in 'nurture' and 'nature'), the inner workings of an opaque AI system would change into something that might be unknown. And as with people whose parents want more autonomously thinking offspring, the research with artificial intelligence will aim the unknown which is subsequent to AI's own development. It is the explicit intention of the researchers to create a 'mind' whose inner structure will (soon) become different than what it was when it was created. This is because it is supposed to have a degree of autonomy in its cognitive processes and decisions. It is, so to speak, a mind that creates itself. And the capacity for self-creation and development means that researchers want their creation to become something new as soon as it works.

This completely changes the ethics behind research ethics. In classical research ethics, responsibility and other principles are linked to the degree of control over what the research entity is. To control it, one must understand it. Classical research does just that. It considers what is known with respect to what the entity being created *qua* that entity. It links what that entity is with responsibilities about that entity's uses and possible consequences. Of course, not all possible consequences are known to the researcher from the very beginning. For instance, nuclear fission had several uses, and not all of them were predicted from the beginning by Lise Meitner, one of the two

scientists having discovered the phenomenon. But her intent as a researcher was to get a better grasp of the nuclear fission *qua* what it was even though she did not know at the time how her discoveries might be *used*.

In the case of some AI systems, things are different, because researchers create entities that intrinsically contain some degree of unknown changes as part of their own performance. This should not be confounded with various uses that the researcher can or cannot predict at the moment of AI system's creation. This second topic is abundantly covered in literature. When dealing with AI, researchers try to discover more and more performant systems and, in some cases, this performance is intrinsically linked with the unpredictability itself. We could even say that the performance of the AI system is, in some cases, the very fact that they are unpredictable (and therefore autonomous or human-like). For instance, if one creates an AI system with the purpose of teaching it to generate original avatars from real-life photos, the performance of the system will be measured, among other things, by the degree of originality in combining various personal features with other elements that are not in the original photos. These elements, of course, belong to some other input. However, the resulted combination is original and unpredictable. One of the explicit aims of the researchers, in this simple example, is to create an entity which becomes more and more original in its outputs. Since it is original in its outputs, it is original in its inner structure. Its inner working can become fully unknown to the people who created it, just because they created it so it can become original and different *qua* what it is.

We believe that this dynamic changes the semantics we usually use in research ethics. In regular research ethics, principles are used in a situation where people research or create something they try to understand as much as possible, not only in the beginning but also afterwards. In AI research ethics, at least in some cases (e.g. black-box or human-like), principles cannot be used in the same way. The reason is that people in these situations create an entity with the explicit purpose that it becomes, as soon as it starts to 'learn', something else than what it was when it started to function. Consider the degree of researchers' accountability with respect to an entity that is meant to become, as soon as it starts to function, something else in its inner workings than what was designed. Many AI systems are (partially), something else than what they were the moment researchers finished creating them as entities capable of learning. Should a researcher be held accountable in this situation in the same way he/she is held accountable when the purpose is the most comprehensive understanding of an entity or a phenomenon? Should researchers be held accountable only with respect to what the AI was before it started to learn? If they can be held accountable with respect to what they fed intentionally as inputs, can they also be held accountable with respect to inputs that were not intended by the researchers? For instance, connecting a black-box AI to the World Wide Web makes it unlikely for researchers to be able to control everything that the AI learns from the Internet.

On the other hand, even if input is 100% controlled by researchers, the manner in which input is processed (combined, structured and restructured) cannot be controlled. The very essence of an autonomous, human-like artificial intelligence system is the capacity to bring forth its own solutions and models. Therefore, not in all cases, the AI's output is a 'spitting image' of the input, so we can draw responsibility from the output from the responsibility from the input. How can one be held accountable for something that is meant to change in its being as soon as it starts to function, and those changes are unpredictable?

A recent example is ChatGPT (https://chat.openai.com/chat) which became, quite quickly, an extraordinary instance of how opaque (and powerful) artificial

intelligence works. In summary, the software is able to answer questions, build up cogent arguments, and write short essays on a given topics or even small pieces of literature. Being connected to the Internet, OpenAI chatbot has also found itself in the middle of several ethical controversies. For instance, many (underpaid) workers had to 'manually' input data in order to help the chatbot avoid interactions with users on unethical topics like illegal sexual content or racism [14]. ChatGPT, the chatbot for OpenAI, can also give us some examples about how unintended internal models can be created by artificial intelligence, promoting bias. The specialists working for the improvement of ChatGPT used seven known tests in order to verify the output for implicit biases [15, 16]. They admit: 'we found that our models more strongly associate (a) European American names with positive sentiment, when compared to African American names, and (b) negative stereotypes with black women' [17]. It is just an example of how unpredictable the inner working of artificial intelligence is. This is so in the absence of any type of known intention from the part of the developers, especially when the system is connected to the World Wide Web. If we are to get back to the child analogy, we can easily conclude that allowing a child to navigate the Internet unsupervised might create unexpected and strong tendencies in their personality, despite the parents never having intended it. It might be the same with artificial intelligence models.

The strategy of 'manually patching' artificial intelligence with interdictions, so it will not discuss inappropriate sexual content or stock investments, is just a temporary solution. The palette of desired and undesired possible outputs is almost infinite and unpredictable. Teams can be hired to 'manually' identify inappropriate content. Rules can be added, so the artificial intelligence will 'refuse' outputs on certain topics. This does not solve the problem by far. It is our opinion that in a situation like ChatGPT's, it will be virtually impossible to control what models are created in its inner workings and what type of outputs can be generated. Without being too pessimistic about it, readers should admit that humans have not succeeded in satisfactorily understanding themselves. We know more about the way we make decisions, but not too much. We have general ideas about how personalities come to be, but we are not able to map the inner workings of our mind in processing large quantities of data or preferences. It is genuinely a challenge to already create entities that emulate humans when humans do not understand themselves very well. In the end, all complex data that is fed to an artificial intelligence system has some degree of cultural imbuement in it. It is likely that all output from artificial intelligence systems will carry with them something of the 'wrongs' and the 'rights' of humanity.

Current policies focus more on the accountability for AI's applications and less on AI's structure. For instance, the European Parliament states that AI can replace neither human decision-making nor human contact. It calls for a prohibition of lethal autonomous weapon systems. It also raises concerns over the use of AI in spreading disinformation and influencing elections [18]. More general recommendations also come from UNESCO [19]. Policies do not appear to address the problem of unpredictability of the inner workings of AI which might engender subsequent problems with the output. Policies do not seem to state who and how someone should be held accountable for what an artificial intelligence system is before what an artificial intelligence system does.

A possible *split model of accountability* could be imagined in the case of opaque systems. Researchers could be held accountable to the following: the inner structure of the artificial intelligence system at its *tabula rasa* moment of existence (before the learning process). Also, researchers could be held accountable for the data input that has been

intentionally fed to the artificial intelligence system. The community, represented by governments, elected bodies representing the public could be held accountable for: the differences between the what the AI system was in its *tabula rasa* moment and all future moments, when input has been accounted for. Another collective accountability could be imagined for the outputs of an artificial intelligence system allowed to connect to uncontrolled sets of data (e.g. World Wide Web). In both cases, for opaque systems, the responsibility of the output cannot belong solely to the researchers. The reason is that researchers are unable, in some cases, to know what the entity they are creating becomes in its being, even if they take all precautions. If the public is unwilling to share collective responsibility for the above elements, then opaque system research should be banned. Making researchers accountable for all the developments of opaque systems is unfair, and it will simply not work for individuals and societies.

4. Conclusions

The purpose of this chapter has been to address the ethical concerns of accountability in AI research with respect to the inner workings of opaque AI and human-like systems. The ethics of research with opaque AI systems is fundamentally different from the ethics of any other area of research. This is because, for the first time in history, scientists are creating something with the explicit intention that it will almost automatically become something other than what was created at the beginning. Unpredictability relates to the inner workings of the system, but also to the input, when the system is connected to large amounts of uncontrolled data. Some examples are given. Engineers developing AI systems cannot be the only ones held accountable for something that is partly designed to be autonomous and unpredictable. We propose that accountability for the problem of opaque AI systems be divided between researchers and society. Society, through elected bodies, could express agreement or disagreement about what course of action should be taken. We can either restrict AI research to glass-box systems or we can share responsibility for research into black-box systems.

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Chapter 6

Human Rights in the Implementation of Artificial Intelligence

Tatiana Dulima Zabala Leal and Paola Andrea Zuluaga Ortiz

Abstract

The use of artificial intelligence (AI) has raised human rights concerns. Numerous debates on the moral and ethical principles necessary for the development of AI and its products have been generated. Therefore, the main objective of this research is to present the generalities of the reports and recommendations to be considered in some countries when implementing AI models such as: regulating the design, development and implementation of AI and its products, establishing a code ethics for the prevention of bad practices and excessive use of technologies, prohibit the use of weapons, personal data, and abusive clauses and limit the scope of the position of dominance in interactions with living beings. Likewise, freedom and autonomy must be maintained as an exclusive characteristic of the human being and subject to permanent control. Its operation must be parameterized within the respect for life, dignity, justice, equity, non-discrimination, peace, and the prohibition of the monopoly of sciences, disciplines, trades, or trades.

Keywords: artificial intelligence, intelligent robots, autonomy, moral and ethical principles, human rights

1. Introduction

Artificial intelligence (AI) has managed to impose significant breakthroughs in human beings' habitual life thanks to the extensive variety of services it offers in the public and non-governmental business sector, including domestic and leisure, and many others. However, one of AI's most useful aspects is robotics, permanently revolutionized based on multiple needs in fields such as electronic engineering, mechatronics, safety systems, expert legal models, infrastructure design, education.

Authors such as Granell [1] consider that the Fourth Revolution we are living in nowadays can also be known as the "algorithmic society" or "digital society," because the use of technology has permeated each sphere of societal relationships, turning it into a customary and almost natural interaction. For instance, today's refrigerators, televisions, and speakers are intelligent; robots can clean, cook, dispense information, sustain conversations with their users, keep up with people's health, deliver surgical, entertainment, and recreational services, control property's security systems and even weapons, just to name a few.

Commercially, the use of AI technology is commonplace, and it has permanently assisted internal and external risk mitigation (blockchain, token, big data, etc.)

with the purpose of setting up rules to get to know clients' economic behavior to automatically generate alerts based on unusual or suspicious operations, or to identify consumption preferences to offer goods and services, thus decreasing the likelihood of errors inherent in markets and gradually minimize human talent contracting.

Authors such as Gutiérrez [2] affirm that these sectors will be the first to experience the negative effects of the almost indispensable and dependent use of AI. Unlike the opinion of García [3], who considers that benefits will be considerable health wise, for example, in psychology, optimum predictions by AI will allow to foresee risk events in patients or users with an almost nonexistent range of error compared with logical processes by humans or machines lacking heuristic capacity "not foreseen to be able to be done by machines". Regarding the broad view of the use of AI and its products, it can be said that according to Hawksworth et al. it will not be generalized nor standardized, since some parts of the world are more prone to the use of these innovative technologies based on their academic advancement and economic stability, leading to the belief that poorer countries will be less exposed to it "in terms of regions, some countries are more given to successfully implementing the new technologies.[1]"

Psychology has a widespread position regarding the uses of AI in discipline, a stance that agrees with the thesis by Penrose [4], concerning the fact that AI is in permanent evolution and tends to perfect its design and operation to offer better service to individuals, just as neural network systems, expert systems, Turing's computational models and robotics, among others; all of which merge the technical and cognitive in an interdisciplinary way with the aim of "understanding, adjusting, and responding intelligent and cognitive methods, involving mathematic, logical, mechanical variables and biological elements and processes" ([5], p. 3).

For author Cairó [6], AI must be analyzed from the point of view of bio life (entailing nanotechnology, information and communications technology, and epistemology) per the statement that the context in which AI is developed is based on "understanding the scientific perspective of components that consolidate intelligent thinking and human behavior and on how they are written in machines" (p. 3). This thesis was confirmed by Henk ([7], p. 82), who claimed that the goal of AI is to "acknowledge the degree of machines' correlation and amplitude in an argument that is particularly alternate to the service of human development."

Therefore, Gardner [8] suggests that the study of AI must be undertaking accepting that it has its own knowledge and that it learns from its environment, which means that it is developed thanks to interactions with other complex contexts that require analysis to solve problematic situations. This is how it has been evinced that AI's cognitive thinking models have perceptive sensory systems that enable it to adapt to the habitat and to the occurrence of events by attaining information to select it, code it, organize it, eliminate it, recover it, and store it [9].

Thanks to nowadays AI is considered an autonomous cognitive or "multiple intelligences" model, since it is made up of mathematical, interpersonal, social, emotional logics, linguistics, and fluid intelligence, in addition to its goal to simulate natural human neural functioning [9]. Thus, AI simulates heuristic processes of human neural networks to add thinking coherence along with corporal functioning in its social environment [10], and this is precisely why AI can evaluate circumstances to suggest

[1] Per the Advanced Technology External Advisory Council, Singapore's Advisory Council on the Ethical Use of AI and Data, and the Select Committee on Artificial Intelligence appointed by the House of Lords in the UK, groups of experts of the European Commission, and the OECD.

the most adequate alternatives to the conflict faced, using only information regarded as useful in its optimum decision-making process.

However, an in-depth study of the traits became the foundation for designers to diversify intelligent algorithm models and implement them in robots with significant diversity of services as predictions of market behavior, likelihood of crime occurrence, diagnosis of the origin of diseases or existence of latent illnesses, etc., known as Dominions [9]. Dominions are an "exact group of norms or a systematic succession of steps that can be taken to undertake calculations, solve problems and make decisions. The algorithm is the formula that is used to make the calculation" [11].

Therefore, current AI models have managed to be highly automated, oftentimes confused with autonomy due to their adaptability, survival, negotiation capacity, self-dependence, and cooperation, despite lacking self-determination [12]. This is how these models, which can make someone believe they are interacting with a human, became so sought after by those who require mechanisms to solve conflicts or assistance in operational activities [13], aside from the fact that AI models allow to accelerate information processing procedures maximizing objectives [9].

2. Artificial intelligence and human rights

An existing theory considers AI is applied to activities that require levels of understanding that are typical of the human mind; thus, its development models or information systems are revolutionary and transformative for science and society alike by creating non-human cognitive models Appenzeller [14].

Consequently, numerous debates have risen in terms of the moral and ethical principles that need to be present in the development processes of AI and its products, seeing as these are capable of undertaking activities that may lead to positive and negative legal results, e.g., modifying the dynamics of human beings' affective interaction causing physical and emotional disorders (such as ostracism), developing dependence to the use of applications that offer unreal but satisfying experiences (metaverse), replacing human labor, widening socioeconomic gaps, AI automation, etc. [15].

To address the potential risks mentioned in the previous paragraph, international organizations have been created with AI experts to evaluate the scope of the effects of its evolution. To date, these organizations (made up by countries with which Colombia has international relationships) include the following: the Advanced Technology External Advisory Council, Singapore's Advisory Council on the Ethical Use of AI and Data, the Select Committee on Artificial Intelligence appointed by the House of Lords in the UK, and groups of experts of the European Commission and the OECD, which have issued reports with important recommendations to be taken into account by countries in their implementation of AI models [16].

A bibliographic analysis by Jobin et al. [16] identified 11 principles and values of ethical nature that must be considered by countries, introduced in **Figure 1**.

Author Asís [17] asserts that ethical axioms in the evolution of sciences and technologies that limit social problems do not exist, making human rights prominent in terms of protecting guarantees such as universal values.

Hence, the Toronto Declaration published in May 2018 emphasizes on three aspects to leverage the use of AI's regulation and production: The first is related to non-discrimination and the prevention of discrimination in design and implementation of automated learning systems for public environments; the second has to do with defining accountability models for AI developers, implementers, and users; and

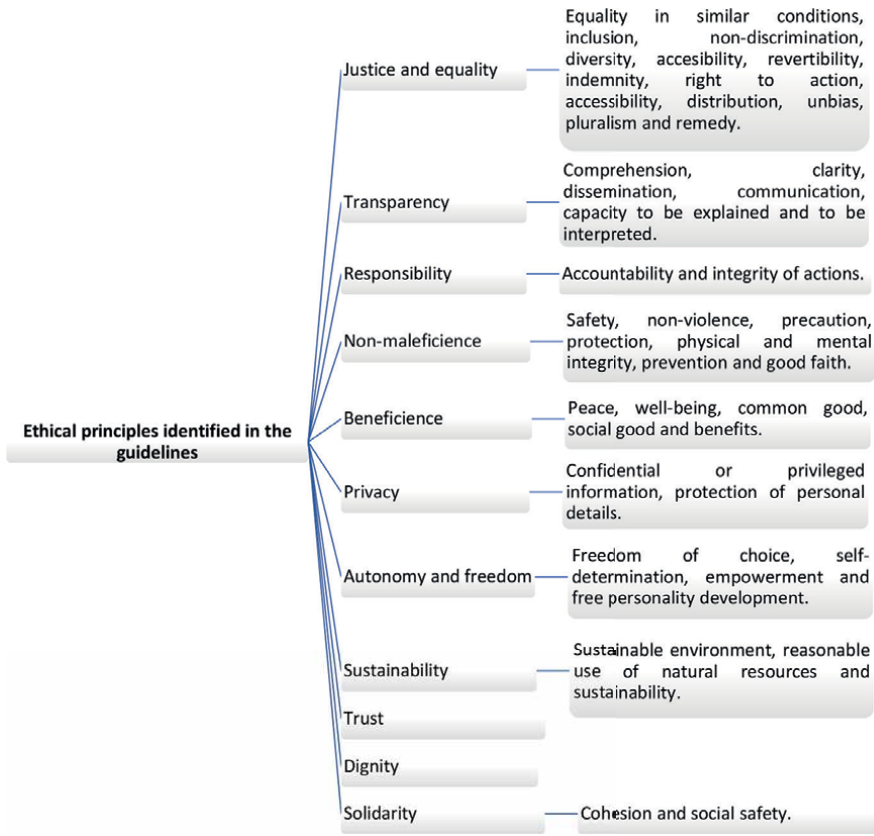

Figure 1.
Ethical principles identified in existing guidelines. Source: Own elaboration, information obtained from Jobin et al. [16].

finally, the third aspect is the implementation of efficient and effective oversight to follow up, identify, and individuate transgressors of people's rights by means of AI and/or its products [17].

Accordingly, the Toronto Declaration intends to protect individual rights in terms of diversity and inclusion, promoting models and AI in inclusive education with automated learning systems that allow people with special needs or vulnerabilities to access services and guarantees available to others with justice and equality (Naciones [18]).

For its part, The Public Voice [19], an international organization, made a significant contribution by suggesting Universal Guidelines for the development, not, implementation and use of AI, aimed at streamlining the benefits it offers to natural persons under the criteria of risk minimization and protection of human rights, as shown in **Figure 2**.

On the other hand, the European Parliament, European Economic and Social Committee, and the European Committee of the Regions were informed by the European Commission [20] about a strategy to face the damaging effects of AI's implementation and thus yield its results in their territories in terms of increased industrial and technological capacity, economic boost in the international framework,

Figure 2.
Universal guidelines for AI. Source: Own elaboration, information obtained from compiled by the authors with data taken from The Public Voice [19].

decreased socioeconomic gaps, and designing a legal and ethical framework fit for the needs of the region, with its main axis being AI's development for human beings.

For this reason, trust became the strategy's core to generate individuals' safety and complaisance, since the main objective is the satisfaction of human needs that provide well-being related to the States' social and essential purposes, namely: rule of law, democracy, freedom, equality, respect for human dignity, and respect for human rights [20].

The following compiles the ethical guidelines suggested by the European Commission [20] to design a regulatory framework that must be adhered to by developers, suppliers, and users of AI, nationally and internationally, to uphold social, political, moral, and legal order. The guidelines have been organized into seven groups that give reliability to AI (**Figure 3**).

Figure 3.
Guidelines to build trust in AI. Source: Own elaboration, information obtained from compiled by the authors with data taken from the European Commission [20].

Regarding human rights, Corvalán [9] stresses that these should be applied from the viewpoint of international law, both public and private, from human dignity, equality, and unrepealable rights as its bases, based on a direct and analogous relationship between dignity, human rights, and the protection of the weakest.

Inclusion as a right must be specifically evident in the development, implementation, and use of ICT because innovation's goal is to eliminate the boundaries of inequality in accessing information and in the promotion of sustainable social development; thus, Corvalán [9] suggests three categories of connected principles to attain it (**Figure 4**).

Regarding AI's validation and verification, Corvalán [9] manifests that it is up to public authorities to have authority in the matter, only they have punitive power over the illegal actions against the safety, life, liberty, and health of people and the ecosystem, which must also be applicable to the algorithm developers, implementers, and users who use it for different purposes than allowed.

In terms of processes, there are three factors that need to be considered to guarantee the quality and transparency of AI and its algorithmic processes, explained (**Figure 5**).

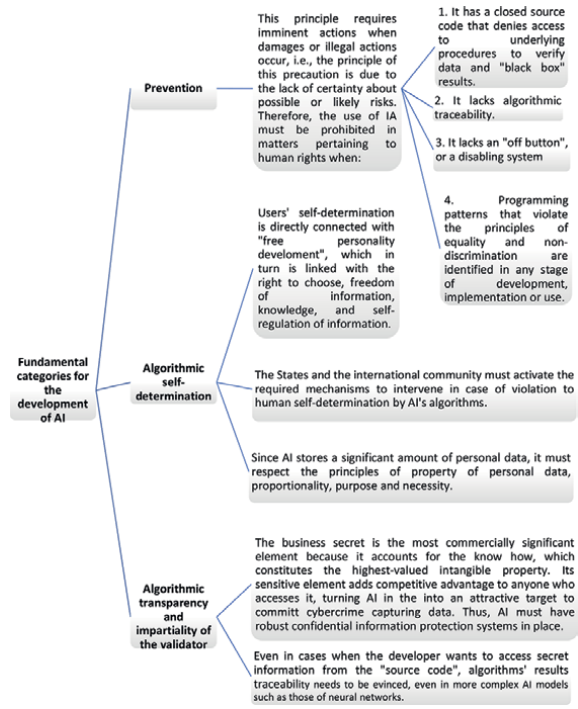

Figure 4.
Fundamental categories for the development of AI. Source: Own elaboration, information obtained from compiled by the authors with data taken from Corvalán [9].

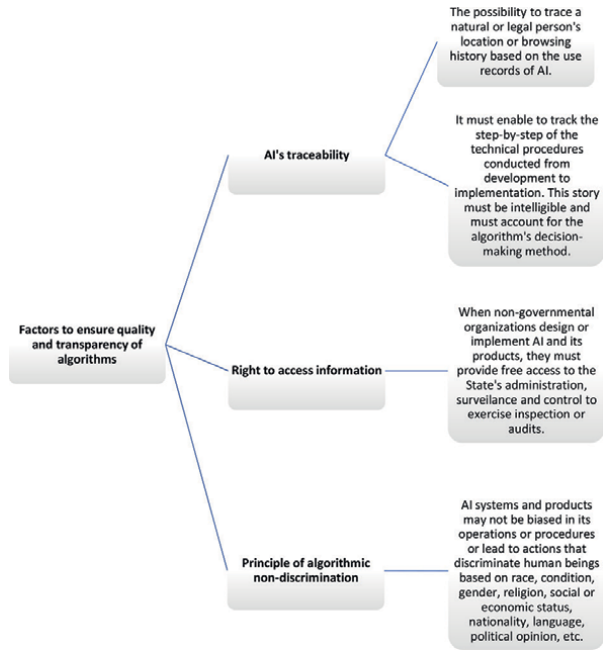

Figure 5.
Factors to ensure quality and transparency of algorithms. Source: Own elaboration, information obtained from compiled by the authors with data taken from Corvalán [9].

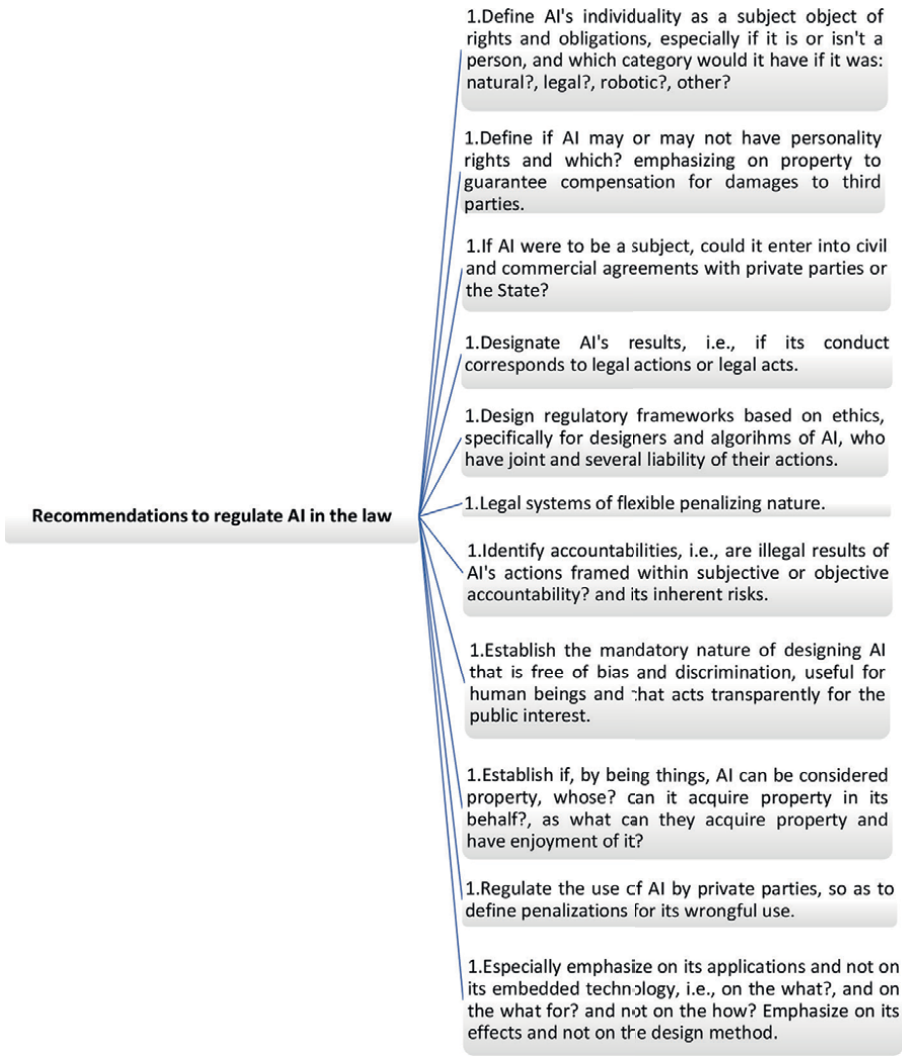

Figure 6.
Recommendations to regulate AI in the law. Source: Own elaboration, information obtained from Corvalán [9].

However, to typify AI in the law, the legislature needs to consider these suggestions, although these have legal significance, they are not a bill, essential reflections of interdisciplinary and transdisciplinary nature, which are necessary to prepare an efficient and effective norm (**Figure 6**).

3. Conclusions

From a legal perspective in Colombia to date, the issue of AI, its products, and its code of ethics has not been studied or at least considered as an object of regulation by the legislature, being so, everything related to the contractual and non-contractual civil liability that derives from it is assigned to whoever its developer or owner is, ignoring the scope of AI automation.

In addition to the above, to start the projection of regulation it is necessary to define whether or not AI and its products are subject to rights and obligations and at what level they are with respect to the human, what is the scope of their responsibility, the determination of its attributes, and if its operability classifies or not within legal acts; because this would be the appropriate means to assign them exclusive regulations in matters of civil, criminal, disciplinary liability, among others.

As far as transhumanism is concerned, this should be limited to the legal parameters of use applicable to humans, since it would be the individual who would determine the use of the technological elements that have been implanted and not the other way around, which means that it should be prohibited the installation of technological elements that limit or cloud the self-determination of the person.

That is why it is necessary to regulate the design, development, and implementation of AI and its products, establish a code of ethics for the prevention of malpractice and overreaching the use of technologies, and expressly prohibit the use of weapons, the use of personal data, the application of abusive clauses, and limiting the scope of the dominant position in interactions with living beings.

Likewise, freedom and autonomy must be stabilized as exclusive characteristics of the human being and subject to permanent control. Its operation must be parameterized within the respect for life, dignity, justice, equity, non-discrimination, peace, and the prohibition of monopoly in the praxis of sciences, disciplines, occupations, or trades.

Conflict of interest

The authors declare no conflict of interest.

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Chapter 7

Ethical Use of Artificial Intelligence in Dentistry

Jelena Roganović and Miroslav Radenković

Abstract

Artificial intelligence (AI) is a technology that aims to create a machine (algorithm-software) that can mimic intelligent human behavior. In order to respect human-technology interaction in a clinical environment, AI in medicine and dentistry should have a complementary role in the work of clinical practitioners. In dentistry, various software-type algorithms are used as the basic application of AI, which is expected to improve the accuracy of dental diagnosis, provide visualization of anatomical guidelines during treatment, and, due to the possibility of analyzing large amounts of data, predict the occurrence and prognosis of oral diseases. Conscientious and ethical AI use in dentistry has to consider: (1) when to apply AI and (2) how to use AI appropriately and responsibly. Patients should be notified about how their data is used, also about the involvement of AI-based decision-making, especially if there is a lack of regulatory policy if AI is utilized to diminish costs rather than improve the health of patients or if the dentist has a conflict of interest. As many dentists are speeding in the direction of integrating AI systems into diagnostics, prognostics, and dental treatment, the legal and ethical questions are becoming even more pertinent.

Keywords: artificial intelligence, dentistry, ethics, accountability, data management, informed consent, conflict of interest

1. Introduction

Artificial intelligence (AI) is a technology that aims to create a machine (algorithm-software) that can mimic intelligent human behavior. In order to respect the human-technology interaction in clinical practice, AI in medicine and dentistry should have a complementary role in the work of clinical practitioners [1]. In dentistry, various software-type algorithms are used as the basic application of artificial intelligence, which is expected to improve the accuracy of dental diagnosis, provide visualization of anatomical guidelines during treatment, and due to the possibility of analyzing large amounts of data, predict the occurrence and prognosis of oral diseases [2].

This chapter aims to provide insight into current considerations on the ethical issues that may arise due to the use of artificial intelligence in dental practice, as well as to encourage debate on ethical missteps.

A systematic literature search was conducted using three relevant international databases, namely Scopus, PubMed/MEDLINE, and Web of Science, and the following keywords were employed: ethics of artificial intelligence, artificial intelligence in

dentistry, artificial intelligence in healthcare, regulations and recommendations for use of artificial intelligence, machine learning, and healthcare. The inclusion criteria were the following: (1) peer-reviewed articles in scientific journals written in English on ethical issues and AI (2) papers on regulations of using AI in healthcare; (3) ethical issues related to the use of AI systems, development, and monitoring; (4) research designs where results describe patient's or healthcare worker's experience. In total, 28 studies were included in the review.

2. Ethical use of AI in dentistry

Conscientious and ethical AI use in dentistry has to consider:

- when to apply AI
- how to use AI in a responsible manner
- how to avoid unethical behavior.

2.1 When to use AI

In dentistry, AI should be used if it promotes the quality of oral and systemic health, in addition to being cost-effective [3]. Both the dentist and the patient (or the designated surrogate) will need to reach a resolution about whether the best line of action implies the use of AI-based tools. Given that providing high-quality care involves both an exceptional understanding of the finest forms of care and an understanding of how to do so, the prudent dental practitioner, who aims to use AI, must resolve the following:

- Does AI-software support the principle of the best outcome for patient with the least intervention?
- Are there published studies to support these claims?
- Is there a legal regulation surrounding its use?
- Is informed consent necessary?

2.1.1 Benefit that AI may deliver to dental practice

The use of AI-based tools could accelerate diagnostic processes and enable dentists to easily access medical and dental history information, necessary for personalized approaches to patients [4], and especially important for managing patients with complex medical histories.

AI-based technology could reduce disparities [5] by improving access to oral and dental health services in resource-limited settings through applications such as for oral cancer, periodontitis, or caries detection.

From a sustainability perspective, AI, if used in preventative measures or identification of the earliest signs of oral/dental disease, may significantly reduce costs and resources engaged in therapeutic treatments.

AI has the ability to change the labor market, as well as business partnerships and patient participation. AI could be utilized to augment knowledge sharing via the collection of massive amounts of data to create a database of methods and practices that can be compared against results [6].

2.1.2 Risks associated with AI implementation in dental practice

AI use should be beneficial overall, and reliable in particular groups of patients where it is used. There is overall concern that in medical AI, inadequate performance for different races, ages, or genders could be caused by the data sets used to train the system not being sufficiently representative [7]. Thus, dental clinicians should be included in AI-based software development and monitor it, and if aware that particular models are poor predictors for particular groups, dentists should test the software first on cases involving their patients. Lack of diversity in datasets in dentistry could be a limiting factor for AI use due to several reasons:

1. There is morphometric data suggesting that there is a difference between particular male and female teeth [8] as well as aging and sexual differences of the face bone structure [9], and anatomic parameters included in dental restorative treatment planning.

2. Oral diseases are complex diseases with multiple genetic and environmental risk factors which lead to a variety of clinical manifestations and progression of the disease as well as its susceptibility to therapy or prevention. Huge environmental influences, such as smoking or diet, underlie cultural and ethnic origins, while it may vary among individuals of the same ethnic or cultural group as well.

3. The oral microbiome is the second largest microbiome in the human body with over 700 different species of microbes, showing large diversity among adults and children [10].

For example, there is an AI-based recommendation system for teeth extraction due to orthodontic treatment, which relies on cephalometric analysis. Since it has been shown that there are variations in cephalometric landmarks between Caucasian men and African-American Men [11], and if the training data was underinclusive of data of African-American men, the AI system made for cephalometric analysis could likely give treatment recommendations that are not appropriate for the African-American population. Therefore, AI system should undergo pilot testing in the dental clinic setting supervised by clinicians aiming to optimize the usage and establish trust in the system.

And how does this bias occur? When it comes to prediction, AI makes decisions based on attributes that it has "learned" from the input data through training that matched labels to the data features. Nonetheless, the model might pick up on these labels, human prejudices, or preferences. There is a potential area for human bias to appear [12]. Although AI performs well with classification tasks, it is important to note that ethical standards such as fairness and equity depend on humans. Constant monitoring should be done in order to detect errors in the system. On the other side, one needs to understand why and how AI made the recommendation that it did [12]. For an AI system to be transparent, it means to be both perceptible and understandable to outside viewers. Lack of transparency diminishes trust in AI but also, make

AI system more susceptible to cyber-criminal. Wide transparency, however, can compromise privacy by making personal information concealed in underlying data sets visible [12].

2.1.3 Education and skills needed to decide whether and how to apply AI

Dentists need to acquire specific and AI use-related skills in order to apply AI safely and effectively to dental patients. The results of our recent survey conducted among experienced dentists and final-year undergraduates at the School of Dental Medicine, University in Belgrade show that working experience and having a specialization/PhD degree are associated with greater motivation and knowledge to use AI. Moreover, undergraduates are even skeptical about whether they should use AI in the practice at all, which may suggest slow adoption of AI in dental practice since both patients and health systems rely on dentists' reactions (under review). The currently observed unwillingness of Belgrade University dental community to adopt AI underlies the evident lack of basic and continuing education regarding this subject, as well as by fear of risk that AI will replace dentist, both factors shown to be important previously also [13]. However, the present survey revealed that anxiety due to the lack of a regulatory policy represents an important factor also, and it is understandable since it may impose legal uncertainty for both patients and dentists when using AI software. Noteworthy, wide AI use may enable the general dentist to attain the level of diagnosis/treatment of the specialist by using AI software as support in decisions. Under such circumstances, the lack of experience/qualification of a general dentist may represent a matter of responsibility and liability [14]: the general dentist is not qualified to act at the level of a dental specialist. In line with this, educational programs in dental studies, as well as AI use training are necessary for achieving responsible AI use in dental practice.

2.2 How to use AI

The prudent dental practitioner who aims to use AI must resolve the following:

- Is there a legal regulation surrounding its use?
- Who is accountable if unwanted effects occur while using AI?
- How to manage data obtained while using AI.

2.2.1 Regulation

Before being used in dentistry and medicine, AI-based software must receive the approval of duly selected regulatory boards to safeguard the security of patients and their data. This implies also that both dentists and software developers need to validate AI products and continuously monitor their safety and efficacy. Regulations, standards, and guidelines must be agreed upon enabling transparency, protection of patients, and vigorous data management control.

The regulative policy includes information on whether the AI was assessed by the FDA or an alternative regulator, but also in what manner the dentist should use AI: whether the dentist should follow the AI recommendation always or ignore it if not agrees with it? [15, 16]. And what to do, if he/she has the opposite recommendation?

Does this require notification of a colleague or a board of experts and a decision made afterward? Currently, AI-based software in dentistry is designed support the clinical decision and not as a major clinical decision tool, suggesting that the dentist has to supervise the AI system.

By the end of 2022, FDA has authorized over 500 AI-enabled medical devices, [17] which are mainly used in radiology. As for dentistry, FDA approved the following AI applications, engaged in the improvement of radiographs interpretation: *VideaHealth's* artificial intelligence algorithm, which has been demonstrated in clinical trials to be superior to dentists in the detection of caries, while also reducing their incorrect caries diagnoses by about 15%; *Overjet's Dental Assist* software, which automatically measures bone loss in radiographs, thereby speeding the time necessary to begin periodontal disease treatment, and *Pearl's Second Opinion* solution, which helps dentist to spot conditions like cavities, tartar and inflammation. Noteworthy, a recent article argued about FDA regulatory practice, where authors emphasized that there were no established best practices for evaluating AI algorithms in order to ensure their reliability and safety. Namely, after reviewing publicly available information on FDA-approved devices, the authors concluded that almost all of the AI devices were approved after conduction of only retrospective studies while the majority of approved devices have been evaluated only at a small number of sites, suggesting lack of geographic diversity [18].

2.2.2 Accountability

Safe use of AI tools in dentistry needs the dentist's supervision and the role of dental practitioners is crucial in preventing dental complications as well as in reviewing and monitoring AI systems. On the other side, AI use could be associated with an automation bias, due to the human tendency to favor machine-generated decisions, ignoring contrary data or conflicting human decisions [19]. Automation bias causes mistakes when people miss or ignore an AI system's advice, or when a clinician chooses to follow a machine's opinion despite opposing data [19].

The question of who takes the blame when unwanted events occur during AI use must be addressed. If it is not addressed and clarified, patients' trust in AI could be severely damaged. Is it a developing company/software engineer, engaged in AI software development, a dentist as a major AI user, or government agency, which selects, validates, and deploys AI-based software in the health facility? Indeed, WHO finds it difficult, both legally and morally, to assign responsibility for the use of AI for health care, since it is diffused among all the contributors in this AI usage chain: developers and providers as well as the government agency or health institution [5]. However, under circumstances of the lack of legal policy on dentist use of AI software, it is suggested that the dentist is accountable for harm resulting from AI use: the dentist is accountable if fails to critically evaluate AI-based recommendations, if misuses AI decision-support tool as a major diagnostic resource, or if uses an inadequate AI system in dental practice [20]. On the other side, governmental agencies as well as health facilities, which approved specific AI system to be used, could be accountable and liable if there is no adequate training or technical support for AI software as well as for harm resulting from inaccurate AI system because it is their recommendation which AI system should be used in clinical practice. On the other side, algorithm developers could be accountable for injuries that result from poor and biased AI design, or manufacturing defects [20].

It should be emphasized, however, that even if liability is difficult to assign, compensation for the harm that a patient suffered due to AI use, could be provided without the assignment of fault or liability. Such circumstances could be seen, for example, in the case of adverse effects associated with vaccine administration. There is a suggestion that in such cases, compensation could be paid from funds founded by companies that develop AI software [5].

2.2.3 Data management

Data management is one of the fundamental ethical issues dealing with acquiring, assessing, and storage of data. Key areas include informed consent, privacy, and data protection [21]. Dentists have a moral duty to use the data they assemble to improve the patient's health as well as to improve the dental practice. However, they are not permitted to utilize data in ways that could endanger patients, have a negative impact on them, or be discriminatory. Since AI system development requires a huge number of high-quality data, these data have huge value and there is social pressure to make them available commercially [22].

Patients have the right to see what personal data the dentist has about them and how she/he using it, have the right to restrict or ask her/him to stop processing or delete their data [23].

According to General Data Protection Regulation [24], in order to ensure data security, the dentist should: limit the amount of personal data collected or delete data of no longer need; pseudonymize or anonymize personal data whenever possible; foster email security and device encryption and notify the patients if a data breach occurs.

2.2.4 Informed consent

In the case of an AI system that shapes dental recommendation, the question of informed consent is of key importance. However, the complexity surrounding AI software development and its mode of action, makes communication with the patient difficult—how to explain accurately such complex information to the patient in an understandable way? There is also a question of what amount of information is sufficient and optimal to achieve patient comprehension necessary for decision-making. Furthermore, despite well-intentioned and well-designed attempts, many patients are said to not understand the information given to them, and even if they did, many are said to not apply the knowledge to help them make decisions [25]. Another important issue arises from concerns about biased training data for AI/ML. Whether and in what way it should be delivered to the patients [26]?

Having this in mind, there are a few situations where patients need to be extensively informed:

- when patients inquire about the involvement of AI dental systems, many dentists are racing towards the adoption of AI in the dental practice and advertising its use as an advantage to the competitors. Thus, patients could inquire whether and how AI system will be used in their particular case.

- when the AI system is more opaque- Algorithms can be opaque because the rules they are relying on are too complex for dentists and patients to explicitly understand, or because of the machine-learning techniques employed, which often could not be explainable not even to algorithm developers. So, it is probable

that the rules governing the algorithms used in medical AI maybe not just not explained but also not possible to explain.

- when an AI system is given a crucial role in the final decision-making, patients need to know if AI system is monitored by a dentist, and used as support in clinical decisions, or if it is used as the main decision-making tool

- if there is doubt that the AI system is used for reasons other than to improve patient health, such as when dentist or health facility has a conflict of interest. Namely, a dentist who has his own research or financial interests may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient. When choosing whether to consent to a suggested intervention, a reasonable patient would want to know whether any interests other than the patient's health may have played a role in the dentist's choice. This is crucial to informed consent since it is relevant to the patient's choice.

3. Unethical concerns and how to avoid them

3.1 Conflict of interest

The growing number of cases where dentists are involved in the development of AI applications for dental use, as founders or Board members in companies engaged in AI- dental applications development, impose the need to discuss liability matters under the circumstances of conflict of interest.

Dentist must disclose personal interests which are not related to the patient's health, whether research or economic, since it may affect his/her professional judgment. The liability issue exists due to the fact that the financial motive (to commercialize developed AI application) may compromise the reasoning of the dentist when it comes to decision-making [27]. By favoring his/her own interest over patients, the dentist violates fiduciary duties. Namely, law recognizes dentist's duties to patients as fiduciary duties, which oblige dentist and other medical professionals to act in a manner only to protect the patient's overall interests from doctor's self-interest [27]. Resolving a conflict of interest could be achieved by avoidance of the dentist being directly involved or, when avoidance is not possible, by disclosing it to patients before treatment or research, and then letting the patients decide whether or not such interests are acceptable to them [28].

3.2 Misuse of AI software

Currently, AI-based systems for dental practice are just supporting systems in clinical decision-making and must be supervised and continuously monitored by a dentist. Misuse of AI decision-support tool as a primary diagnostic tool represents unethical behavior and could be a matter of legal liability [14]. At this moment, there is little experience regarding the operational characteristics of AI-based systems for dental care in diverse clinical settings [29]. So far, extensive research is done to clarify technical difficulties in AI development; however, there is a lack of those which consider the community's ethics. Dentists have a duty to understand the risks associated with AI software use, to alert patients to it, and to monitor AI-based systems to prevent harm. Dentists should be aware that despite many positive impacts, the use of

AI systems may induce social and economic changes, which often disproportionately negatively affect the most vulnerable communities. Thus, continuous postimplementation monitoring for unwanted effects should be accompanied by a strict risk management protocol for determining causes and implementing corrective action [30]. Dentists will stay responsible for patient care and will need to obtain education and training to obtain new skills in order to use AI systems ethically and responsibly. Likewise, besides educational and ethical, dental community needs legal frameworks as well, in order to successfully implement AI system as safe, reliable, and sustainable medical devices in dental practice.

3.3 Breach of data privacy

It is essential to fully inform patients about how their data gathered by an AI system is processed, aiming to promote mutual trust, as well as trust in AI system. If patients and dentists do not trust AI, the adoption of AI into clinical dental practice will be slowed down and ultimately fail. The value of health data can reach up to billions of dollars, and it is unethical to sell patient data for profit. According to the General Data Protection Regulation (GDPR) [24], a European law that established the privacy of personal data protection, patients have a right to withdraw their data and request the deletion of their data at any time. Some AI health applications may jeopardize patient's data privacy by sharing patient data not only with the doctor but also with friends and family members. This could be tricky since, In contrast to the doctor who is subject to duties of confidentiality set out by governing law, family members or friends do not have such legal obligations [31, 32].

The introduction of AI-based software may reduce disparities and increase the operative efficiency and dissemination of dental knowledge and best practices, sharing information between medical and dental providers, which is especially important for medically compromised dental patients. However, caution is needed since the large diversity in orofacial bone- and teeth anatomy, as well as huge environmental impact on oral disease development and progression, may influence AI bias in the decision-making process in dentistry, in a great manner. In short, ethical practice accompanying AI use in dentistry should follow: (1) AI system needs to be approved by legitimately chosen regulatory boards before they are put into use, (2) Dentists should be educated and trained in AI use, and should supervise and continuously monitor the performance of AI-based system in their group of patients, (3) To ensure the safety of patients and their data, AI use should enable transparency, protection of patients, and vigorous data management control; (4) Patients need to be extensively informed if there is doubt that the AI system is used for reasons other than to improve patient health, such as when dentist or health facility has a conflict of interest.

4. Conclusions

Introduction of AI-based software may reduce disparities and increase the operative efficiency and dissemination of dental knowledge and best practices, sharing information between medical and dental providers, which is especially important for medically compromised dental patients. However, caution is needed since the large diversity in orofacial bone- and teeth anatomy, as well as huge environmental impact on oral disease development and progression, may influence AI bias in the decision-making process in dentistry, in a great manner. In short, ethical practice

accompanying AI use in dentistry should follow: (1) AI system needs to be approved by legitimately chosen regulatory boards before they are put into use, (2) Dentists should be educated and trained in AI-use, and should supervise and continuously monitor the performance of AI-based system in their group of patients. (3) To ensure the safety of patients and their data, AI use should enable transparency, protection of patients, and vigorous data management control; (4) Patients need to be extensively informed if there is doubt that the AI system is used for reasons other than to improve patient health, such as when dentist or health facility has a conflict of interest.

Acknowledgements

This research was funded by the Ministry of Education, Science and Technological Development of the Republic of Serbia, Grants No. 451-03-9/2021-2114/200129 and No. 200110.

Conflict of interest

The authors declare no conflict of interest.

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Chapter 8

Ethical Use of Data in AI Applications

Anthony J. Rhem

Abstract

Artificial Intelligence (AI) equips machines with the capacity to learn. AI frameworks employing machine learning can discern patterns within vast data sets and construct intricate, interconnected systems that yield results that enhance the effectiveness of decision-making processes. AI, in particular machine learning, has been positioned as an important element in contributing to as well as providing decisions in a multitude of industries. The use of machine learning in delivering decisions is based on the data that is used to train the machine learning algorithms. It is imperative that when machine learning applications are being considered that the data being used to train the machine learning algorithms are without bias, and the data is ethically used. This chapter focuses on the ethical use of data in developing machine learning algorithms. Specifically, this chapter will include the examination of AI bias and ethical use of AI, data ethics principles, selecting ethical data for AI applications, AI and data governance, and putting ethical AI applications into practice.

Keywords: AI bias, AI ethics, data ethics, artificial intelligence, machine learning, data governance

1. Introduction

Artificial Intelligence (AI) provides machines (i.e., computers) with the means to acquire knowledge. AI structures that utilize machine learning possess the capability to identify patterns in immense quantities of data (structured, semi-structured, and unstructured) and simulate sophisticated, interlinked systems, ultimately producing results that augment the proficiency of decision-making. Machine learning is also seen as a form of applied statistics, albeit with an increased use of computing and data that is used to statistically estimate complicated functions. Machine learning depends on learning from patterns of data to make new predictions.

AI in particular machine learning has been positioned as an important element in contributing to as well as providing decisions in a multitude of industries. The use of machine learning in delivering decisions is based on the data that is used to train the machine learning algorithms. It is imperative that when machine learning applications are being considered that the data being used to train the machine learning algorithms are without bias, and the data is ethically used. AI Ethics is the responsible

and trustworthy design, development, implementation, and use of AI systems including the data used to train the AI systems and the knowledge produced by them.

Ensuring that AI systems are developed and used in a way that promotes equality and fairness for the users and those effected by the AI system should be at the forefront of any AI system implementation as well as its ethical use and the ethical use of data. To ensure AI systems are developed with an ethical core, it is essential to start with establishing a diverse AI product development team that is active in the design, development, and implementation of the AI application. A diverse team will bring a "diversity of thought" to the initiative and especially during the selection and cleansing of data to assist in removing bias from being a part of the algorithms being used and ensure the models are trained with ethical data that adheres to data privacy and security. A diverse team, through collaboration, knowledge sharing, and knowledge reuse will bring different points of view, different experiences, and different cultural backgrounds to stimulate innovation and to eliminate (or limit) bias. This action leads to innovation. This innovation will enable organizations to deliver unique and or improved AI products.

Leaders also need to be aware of the ethicality of AI applications being developed and deployed at their organizations. Leaders must examine and understand whether the outcomes from the application of AI violate US Federal, GDPR, and/or other ethical, security, and privacy standards. Leadership will need to adopt a standard for AI that identifies general tenants for AI implementation focused on ethical adherence [1]. Leaders must enable support for implementation, acceptance, and adoption of AI. Considerations for cultivating a system thinking mindset and incorporating the five disciplines of systems thinking, personal mastery, creation of mental models, creation of a shared vision and cultivation of team learning [2], is essential for effective leadership of AI implementation.

The ethical use of data in AI applications is a critical issue as AI systems and algorithms rely on data to learn and make decisions. The way data is collected, stored, used, and shared can have significant impacts on individuals, organizations, and society. Ethical use of data in AI systems builds trust and ensures that they are adopted and used in a responsible manner. This chapter examines AI bias and ethical use of AI Applications, Data Ethics Principles, Selecting ethical data for AI applications, AI and Data Governance, and Putting Ethical AI Applications into Practice.

2. Examining AI bias and ethical use of AI applications

When examining AI bias and the ethical use of AI, there are several key factors to consider which include:

- Data bias: The training data used to develop an AI model may contain biases that are then reflected in the model's decisions and predictions. It is important to examine the data used to train the model and identify any potential sources of bias that may be present.

- Algorithmic bias: The algorithms and mathematical models used in AI can also be biased and may lead to biased decisions or predictions. It is important to examine the algorithms used in the AI system and identify any potential sources of bias that may be present.

- Fairness: AI systems should be fair and non-discriminatory, and not perpetuate or exacerbate existing inequalities or biases. It is important to examine the AI system to ensure that it is not treating different groups of people unfairly.

- Explainability: AI systems should be explainable, so that individuals can understand how and why decisions are being made. It is important to examine the AI system to ensure that it is transparent and interpretable.

- Privacy: The use of AI should respect privacy and personal autonomy, and not violate individuals' rights. It is important to examine the AI system to ensure that it is collecting and using data in a way that is consistent with privacy laws and regulations.

- Transparency: The purpose and use of the AI system should be clear and open to all stakeholders. It is important to examine the AI system to ensure that it is transparent and that stakeholders are aware of how the data is being used.

- Security: The AI system should be designed to protect data from unauthorized access, use, or disclosure. It is important to examine the AI system to ensure that it is secure and that data is being stored and transmitted securely.

- Continual assessment: Organizations should regularly assess the ethical implications of their AI use and make any necessary changes to ensure they align with these principles.

3. Data ethics principles

Data ethics principles are the principles and values that govern the collection, storage, use, and dissemination of data. The Organization for Economic Cooperation and Development (OECD) and the Institute of Electrical and Electronics Engineers (IEEE), among others have guidelines and principles related to data ethics.

The OECD has published the OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, which set out a framework for data protection and privacy. The guidelines cover topics such as data collection and use, security, and access to personal information, and emphasize the importance of protecting privacy and personal data in the digital age [3].

The IEEE has developed a set of Ethically Aligned Design (EAD) principles for autonomous and intelligent systems, which include data ethics considerations. The IEEE EAD principles focus on promoting human well-being, protecting privacy and individual rights, and ensuring that data is collected and used in a responsible and ethical manner [4]. The principles emphasize the importance of transparency, fairness, accountability, and informed consent in the development and deployment of autonomous and intelligent systems [4].

Data ethics principles emphasize the importance of privacy, transparency, and responsibility in data practices, and provide guidelines and principles for ensuring that data is collected, stored, and used in an ethical manner. The following are key areas representing data ethic principles:

- Transparency: Data ethics principles should be clear, open, and transparent to all stakeholders. This includes clearly stating the purpose and use of collected data, as well as providing information on how data is collected, stored, and protected.

- Fairness: Data should be collected and used in a way that is fair and non-discriminatory. This includes ensuring that data collection does not perpetuate or exacerbate existing inequalities or biases.

- Privacy: Data privacy should be respected, and data should be collected and used in a way that protects individuals' personal information and autonomy. This includes ensuring that data collection is done with informed consent, and that data is not shared or used in ways that violate individuals' privacy rights.

- Responsibility: Data collectors and users are responsible for ensuring that data is collected and used ethically. This includes being accountable for any harm that may result from the collection or use of data and taking steps to mitigate that harm.

- Security: Data should be stored and transmitted securely, in order to protect it from unauthorized access, use, or disclosure.

- Inclusivity: Data collection and use should be inclusive and considerate of diverse perspectives and experiences. This includes being aware of and addressing any potential biases in the data, and actively seeking out underrepresented perspectives.

- Transparency in decision making: Decisions that are made using data should be explainable and interpretable, so that individuals can understand how and why decisions are being made, and if any bias is present in the model.

- Continual assessment: Organizations should regularly assess the ethical implications of their data collection and use practices and make any necessary changes to ensure they align with these principles.

4. Selecting ethical data for AI applications

Selecting the appropriate data for AI applications is critical in the process of building and training machine learning algorithms. The data that is selected should be representative of the problem that the model is intended to solve. In the selection of ethical data this will include data relevance, the data should be directly related to the problem that the model is intended to solve; data quality, the data should be of high quality, with minimal errors, missing values, and outliers; data diversity, the data should be diverse, representing a variety of examples from the problem domain; data quantity, the amount of data used for training the model can have a significant impact on its performance; data preprocessing, the data may need to be preprocessed before it can be used for training; and data annotation, depending on the type of model being built, the data may need to be annotated, which involves adding labels or tags to the data to indicate what the model should learn.

The ethical data selection process for AI/ML applications delivers methodical and technological data management backing to tackle data quality concerns, optimize data utilization, and ensure continuous management of data throughout its lifespan. This process encompasses data discovery and acquisition, upholding data quality standards, enhancing value, and facilitating reuse over time. The selection of ethical data starts with a comprehensive and repeatable data curation process.

Data curation for AI/ML applications is the process of selecting/creating, organizing, and determining data gaps so data can be used to train machine learning (ML) algorithms. Data curation is a form of data management, and it involves annotation, publication, and presentation of the data. Data curation can include data from various sources. Data curation services include data profiling, data management, data lineage, data disposal, and data assurance.

Data curation process for AI/ML applications includes (see **Figure 1**: Data Curation Process):

Data Audit

Determine what data is ready to be used for algorithm training and determine data gaps. Perform the data audit from the various sources of data under consideration. Also, determine what data is ready to be utilized, evaluate the quality of data, determine the gaps in data, and identify the measurements to determine what data is used (and not used).

Data Analysis

Data analysis investigates the ideas, connections, business regulations, and metadata within information. This offers a consistent, orderly, and shareable framework for enterprise data. Semantics focus on the interpretation of the concepts identified in the data model, as well as the significance of the relationships between those concepts, typically conveyed through business rules.

Address Data Gaps

Conducting a Data Audit yields insights into the discrepancies present within the data, pinpointing the supplementary data sources required for efficient algorithm training. This process not only highlights potential areas of improvement but also facilitates a more comprehensive understanding of the data landscape, ultimately enhancing the performance and accuracy of the AI/ML models being developed.

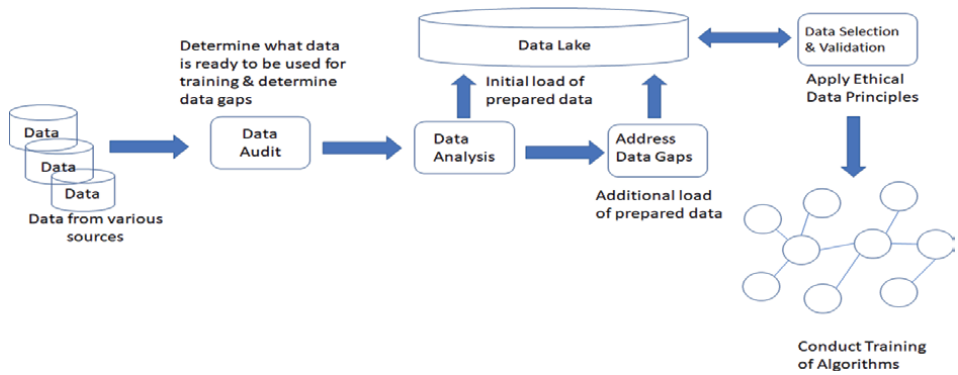

Figure 1.
Data curation process [5].

Data Selection, Validation & Ethics

Data selection should be considered in terms of significance. Ascertaining the importance of data hinges on several factors: the degree in which the data is fundamental to the subject area; validity, referring to the data's accuracy, timeliness, and pertinence to the domain in question; relevance, denoting the disciplinary, occupational, or societal worth of the data; and utility, which encompasses the overall usefulness of the data within the domain being examined [6]. Validation, or data validity, centers around ensuring that data is procured from, and/or grounded in, authoritative or dependable sources, while also being subject to routine evaluations in accordance with the specified governance policies. This process bolsters the credibility and reliability of the information being utilized [7]. Also, the application of ethical data principles is applied during this process.

Conduct Algorithm Training

The process of training an ML model involves providing an ML algorithm with training data to learn from [6]. Once the data has completed its transformation in the data selection and validation process, including applying ethical data principles, the machine learning algorithms now have data ready for the training process.

Selecting ethical data for AI applications involves several steps, including:

- Identifying the purpose and goals of the AI application: Before selecting data, it's important to understand the purpose and goals of the AI application, and how the data will be used to support those goals.
- Examining the data sources: Look for data sources that are reliable, accurate and unbiased, and consider the potential sources of bias that may be present.
- Ensuring data quality: Data should be complete, accurate, and consistent, and any errors or inconsistencies should be identified and addressed.
- Checking for data privacy: Data should be collected with informed consent and should not violate individuals' privacy rights.
- Ensuring data security: Data should be stored and transmitted securely, to protect it from unauthorized access, use, or disclosure.
- Balancing data inclusivity: Be aware of and address any potential biases in the data and actively seek out underrepresented perspectives.
- Ensuring transparency: The purpose and use of collected data should be clear, open, and transparent to all stakeholders.
- Continual assessment: Organizations should regularly assess the ethical implications of their data collection and use practices and make any necessary changes to ensure they align with these principles.
- Diversifying the data: Diversify the data as much as possible by including a wide range of perspectives, experiences, and characteristics.
- Auditing the data: Use techniques like bias detection, fairness and accountability to measure and mitigate any potential biases in the data.

4.1 Use of synthetic data

Synthetic data is computer-generated data rather than data coming from real-word records [8]. This data is typically created using algorithms, synthetic data can be deployed to validate mathematical models and to train machine learning models. In the context of AI and ML, synthetic data is often used when real-world data is scarce or unavailable. It can also be used to augment existing datasets to improve the performance of AI/ML models [9].

There are several methods for generating synthetic data, including generative adversarial networks (GANs), variational autoencoders (VAEs), and simulation models. The specific method used will depend on the type of data being generated and the desired outcome. One of the key benefits of synthetic data is that it can be generated in large quantities, allowing AI/ML models to be trained on much larger datasets than would otherwise be possible [9]. This can lead to improved performance, especially in cases where real-world data is limited. Additionally, synthetic data can be generated to match specific characteristics or distributions, making it possible to train models to recognize patterns in data that may be difficult to find in real-world data.

Another benefit of synthetic data is that it can be used to test AI/ML models in controlled conditions, helping to ensure that they are working as intended. For example, synthetic data can be used to test models for bias and fairness, or to evaluate the robustness of models in the face of adversarial attacks [9]. Overall, synthetic data can play a valuable role in the development and deployment of AI/ML models. However, it is important to keep in mind that synthetic data may not perfectly reflect the characteristics of real-world data, so care must be taken when using it to train and evaluate models.

4.2 Ethical use of synthetic data

The use of synthetic data raises several ethical issues that are important to consider. Some of the key ethical issues include:

Bias: Synthetic data may be generated to reflect certain biases, either intentionally or unintentionally. This can lead to AI/ML models that are biased in their predictions and decision-making, potentially exacerbating existing inequalities.

Privacy: Synthetic data may be generated using real-world data, which could include sensitive information about individuals. If the synthetic data is not generated and used in a privacy-preserving manner, it could potentially be used to violate people's privacy rights.

Misrepresentation: Synthetic data may not accurately reflect real-world data, which could lead to AI/ML models that are not representative of the real world. This could result in models that make incorrect predictions or decisions, which could have serious consequences in fields such as healthcare, finance, or criminal justice.

Lack of transparency: The process of generating synthetic data is often complex, and it can be difficult to understand how synthetic data was generated and what assumptions it reflects. This can make it challenging to interpret the results of AI/ML models trained on synthetic data, and to understand the potential limitations and biases of the models.

Responsibility: If AI/ML models trained on synthetic data are used to make decisions that have a significant impact on individuals or society, it can be difficult to determine who is responsible for the decisions made by the model. This raises important questions about accountability and the ethical use of AI/ML technologies.

It is important to carefully consider these ethical issues when using synthetic data and to ensure that synthetic data is generated and used in a responsible and transparent manner. This may involve taking steps to reduce bias and protect privacy, as well as being transparent about the limitations and assumptions of synthetic data and the models trained on it.

5. Ethical AI and data governance

Ethical AI and data governance are closely related, as effective data governance is essential for ensuring the responsible and ethical use of AI. Data governance refers to the processes, policies, and procedures that organizations use to manage and govern the collection, storage, use, and dissemination of data. It is a way of ensuring that data is used in an ethical and responsible manner, and that data privacy and security are protected.

In the context of AI, data governance plays a crucial role in ensuring that the data used to train and develop AI models is of high quality, accurate, and unbiased. It also helps to ensure that the AI models developed are transparent, interpretable, and fair, and that they do not perpetuate or exacerbate existing inequalities or biases.

Effective data governance can also help organizations to comply with data privacy laws and regulations, such as the General Data Protection Regulation (GDPR) and the California Consumer Privacy Act (CCPA). This includes ensuring that data is collected with informed consent, and that data is not shared or used in ways that violate individuals' privacy rights.

In practice, data governance for AI may include processes such as data quality checks, data privacy impact assessments, and ongoing monitoring of AI systems to ensure that they are operating in an ethical and responsible manner. It also requires collaboration across different departments within the organization, including legal, IT, data science, and compliance.

5.1 AI and its effect on personal data protection

AI can increasingly link different datasets and match different types of information with profound consequences. Data held separately and considered Non-PII (Personal Identifiable Information stripped of personal identifiers), with the application of AI can become Personal Identifiable Information (PII). This occurs when AI in the form of machine learning algorithms can correlate non-personal data with other data and matched to specific individuals, becoming personal data. AI through algorithmic correlation will weaken the distinction between personal data and other data. Non-personal data can increasingly be used to identify individuals or infer sensitive information about them, beyond what was originally and knowingly disclosed [10].

Personal identifiable information as defined by the U.S. Department of labor and the GDPR are as follows:

Personal Identifiable Information (PII) - defined by the U.S. Department of Labor states:

"Any representation of information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means. Further, PII is defined as information: (i) that directly identifies an individual (e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc.) or (ii) by which an agency intends to identify

specific individuals in conjunction with other data elements, i.e., indirect identification. (These data elements may include a combination of gender, race, birth date, geographic indicator, and other descriptors). Additionally, information permitting the physical or online contact of a specific individual is the same as personally identifiable information. This information can be maintained in either paper, electronic or other media" [11].

5.2 General data protection regulation (GDPR)

GDPR enhances how people can access information about them and places limits on what organizations can do with personal data. GDPR's seven principles are: lawfulness, fairness and transparency; purpose limitation; data minimization; accuracy; storage limitation; integrity and confidentiality (security); and accountability.

"The General Data Protection Regulation (GDPR) is a legal framework that sets guidelines for the collection and processing of personal information from individuals who live in the European Union (EU). In the interest of enhancing consumer protection, the GDPR mandates that any personally identifiable information (PII) gathered by websites must either be anonymized (meaning, made anonymous, as suggested by the term) or pseudonymized (wherein the consumer's identity is substituted with a pseudonym). This measure helps safeguard the privacy of individuals engaging with online platforms. GDPR affects data beyond that collected from customers. Most notably, perhaps, the regulation applies to the human resources' records of employees" [12].

Incorporating the rules involved in determining data that constitutes Personal Health Information (PHI), Personally Identifiable Information (PII), GDPR, and relevant US Federal and European regulations within the AI/ML application will ensure your organization's AI tools comply with relevant privacy regulations. Utilizing AI/ML applications to constantly monitor the implemented AI tools providing oversight to your organization's leadership and applicable stakeholders regarding any potential privacy violations will provide the ability for your organization to mitigate any issues.

The OECD AI value-based principles and recommendations providing guiding principles for governments, organizations and individuals in the design, development, and implementation of AI systems is one such standard that can provide the bases for your organization's AI Ethical Security and Privacy Standards. To provide additional measures to ensure that your organization's AI solution/tool complies with ethical, security, and privacy standards, your organization's internal teams will play a crucial role in the compliance to ethical, security, and privacy standards by providing external knowledge and innovation to new AI/ML applications being considered for implementation. This will enable your organization to address compliance to ethical, security, and privacy standards from the analysis, design, data collection, data cleansing, testing and implementation to ensure future AI/ML applications will be compliant. In addition, exploring other AI ethics standards such as the European Commission Ethics Guidelines for Trustworthy AI, The US White House Blueprint for an AI Bill of Rights, UNESCO Ethics of Artificial Intelligence, and others to provide continuous evolution and improvement to your organization's AI Ethical Security and Privacy Standards is recommended.

Given the specifics of these guidelines for PII, we must constantly consider and monitor our data being used in these AL/ML applications from inception to deployment. Without the proper governance it will be difficult to assess which data will remain non-PII. However, having consistent data selection, training and monitoring

throughout the AI/ML lifecycle can ensure that AI/ML applications will distinguish between PII and non-PII and enact the necessary protocols.

5.3 Data governance and AI ethical standards

Data governance is essential for ensuring the responsible and ethical use of AI, including the processes, policies, and procedures that organizations use to manage and govern the collection, storage, use, and dissemination of data. Effective data governance can ensure that the data used to train and develop AI models is of high quality, accurate, and unbiased and that AI models developed are transparent, interpretable, and fair.

Organizations must adopt and adhere to an AI ethical standard one in which AI solutions will comply with ethical, security, and privacy standards set by the individual organization and aligned with an established AI standard. The question however will be which AI standard to adopt and/or align to? There are several to consider including the AI Bill of Rights, International Standard for AI developed by the Organization for Economic Co-operation and Development (OECD), United Nations Educational, Scientific and Cultural Organization (UNESCO), United States Artificial Intelligence Institute (USAII), and U.S. Department of Commerce National Institute of Standards and Technology (NIST) AI Standards for Federal Engagement, just to name a few.

6. Putting ethical AI applications into practice

The latest emphasis on AI revolves around the deployment of Machine Learning (ML) algorithms. It is within the realm of ML algorithms that the ethical and bias-related challenges accompanying AI applications have garnered significant attention. Cognitive Bias, Cultural Bias, and Systems of Belief pertain to the methodical manner, in which the context and presentation of data, information, and knowledge can impact an individual's judgment and decision-making [13]. Numerous types of cognitive biases exist, each capable of influencing one's decision-making process at different moments. The types of cognitive bias include Actor-observer bias, Anchoring bias, Attentional bias, Availability heuristic, Confirmation bias, False consensus effect, Functional fixedness, Halo effect, Misinformation effect, Optimism bias, Self-serving bias, and The Dunning-Kruger effect [13].

The predispositions of team members responsible for selecting datasets for algorithm training can impact the algorithm's outcomes, thereby contributing to the ethical dilemmas associated with the results. When confronted with new information, it becomes essential to scrutinize the algorithm's findings. This involves examining the data utilized in training the algorithms to eliminate biased data and ensuring that the appropriate algorithms are employed for the relevant tasks. If unchecked, these algorithms may perpetuate, intensify, and compound biases in the outcomes they produce, as well as in the interpretation and knowledge gleaned from those results.

An individual's belief system regarding AI implementation significantly influences their perception of ethical AI use, particularly in the context of machine learning. In any research endeavor, it is crucial to pinpoint potential biases and strive to eliminate their impact on the research outcomes. This principle applies equally to the selection of data and the construction and training of machine learning algorithms, where biases must be identified, mitigated, and eradicated. Biases pervade all aspects of

our actions, including the data we choose and the emphasis we place on specific data types. It is imperative to acknowledge the presence of bias and eliminate it before it affects the design, development, and execution of AI applications. Having a diverse team that brings diverse ideas, experience and knowledge is important in addressing bias in AI and in turn improves the ethicality of AI.

To put AI Ethics into practice you must start with a sound AI Policy and Standards. There are several standards on AI that have been detailed in this chapter. AI technology will continue to evolve, and the AI ethics community will need to evolve the standards to keep pace. The following are steps to take to put ethical AI applications into practice [7].

Adopt and adhere to AI standards that include criteria for examining ethicality of AI applications and identifying criteria for eliminating bias.

Establish a Diverse AI Product development team:

By fostering collaboration, knowledge exchange, and knowledge repurposing, it is vital to capitalize on diverse perspectives, experiences, and cultural backgrounds to encourage a variety of ideas. This diversity of thought serves as a catalyst for innovation, empowering organizations to develop distinctive or enhanced AI products, thereby driving growth and advancement.

Establish a Diverse Team in the design, development, and implementation of AI applications.

- A diverse team will bring a "diversity of thought" to the initiative and especially during the selection and cleansing of data for AI applications that use Machine Learning.

Develop AI applications to be people (human)-centered.

- People-oriented AI applications prioritize the inclusiveness and well-being of the individuals they serve, adhering to human-centric values and promoting fairness.

- The design, development, and implementation of people-oriented AI applications necessitate transparency, robustness, and safety; moreover, they must be held accountable for the outcomes generated, as well as the decisions influenced by these AI applications.

Establish AI KPI's and Metrics:

- To make strides in the implementation of AI standards, guidelines, and principles, it is essential to institute standardized metrics for evaluating AI systems. Construct evidence-based metrics and KPIs to consistently assess the performance of AI applications that have been deployed.

7. Conclusions

AI solution implementors face the risk of intensifying existing disparities related to AI resources, technology, talent, data, and computational capacity. Consequently, this may result in AI perpetuating biases and affecting vulnerable and marginalized communities. In numerous instances, AI can diminish the subjective interpretation

of data by humans, as machine learning algorithms are designed to focus solely on variables that enhance their predictive accuracy, based on the employed training data.

As AI/ML applications continue to evolve there are some pressing ethical challenges that need to be addressed in the development and deployment of AI. The following represents some of these challenges:

- Bias and discrimination: AI systems can perpetuate and even amplify societal biases, leading to unfair treatment of certain groups of people.
- Job displacement: As AI systems become more advanced and capable, they may begin to replace human workers, which could lead to widespread job loss and economic disruption.
- Privacy and security: AI systems can collect and process large amounts of personal data, raising concerns about how this data is used, stored, and protected.
- Explainability and transparency: As AI systems become more complex, it can be difficult for humans to understand how they make decisions, which could lead to mistrust and a lack of accountability.
- Autonomy and control: As AI systems become more autonomous, there are concerns about how to ensure they are used ethically and do not harm humans.
- Social responsibility and governance: As AI become more pervasive, there is a need to establish ethical guidelines and regulations to ensure that the technology is developed and used in a responsible way.

To train and optimize AI systems, ML algorithms require vast quantities of data. This creates an incentive to maximize, rather than minimize, data collection. The expanding utilization of AI devices leads to more frequent and effortless data gathering, which is then connected to other datasets, often with little or no awareness or consent from the concerned data subjects. Anticipating the patterns identified and the progression of the "learning" is challenging. As a result, data collection and usage may extend beyond what was initially known, disclosed, and consented to by a data subject. AI/ML applications, capable of learning over time, can provide individuals with personalized services tailored to their privacy preferences. It is crucial for AI systems to be developed in accordance with privacy principles outlined by the U.S. Department of Labor and the GDPR, as AI has the potential to enhance personal data. This amplified personal data could, in turn, lead organizations to inadvertently violate these policies.

To provide a framework for the use of ethical data in AI applications, it is important to identify the purpose and goals of the AI application, examine the data sources being considered, ensure data quality, check for data privacy, ensure data security, balance data inclusivity, ensure transparency, perform continual assessment, diversify the datasets used, audit the data, and perform continuous monitoring of the data being used and the decisions being produced by the algorithms.

DOI: http://dx.doi.org/10.5772/intechopen.1001597

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Chapter 9

Ethical Challenges Related to the Metaverse Development: First Hypotheses

Michal Boni

Abstract

Consideration of ethical aspects of metaverse solutions should take into account all crucial points like: accountability, responsibility, transparency, privacy and security, non-discrimination, avoiding biases and asymmetry of information, stability of digital identity, and avoiding any harm addressed to human autonomy (material and immaterial). The essential reference point should be based on HLEG on AI recommendations (in relation to the fundamental rights) for ethical, trustworthy, and secure metaverse. It is crucial that the metaverse has a special legal framework (as some suggested), or functions after the precise review of legal aspects of all metaverse dimensions (as space with humans and avatars in the specific AI IoT) and in addition is based on some self-regulatory solutions, i.e., in Codes of Conduct. In that paper, I have considered the following questions: - how to enter the metaverse space, - how the human position in the metaverse world could look like, - how to develop and maintain the human subjectivity in the metaverse ecosystem, - what kind of society would be generated by the metaverse rules, - how to translate the rules of the metaverse into the ethical principles. Responding to them has showed that there are many works to do, and many detailed analysis and risk assessments are needed - to make the metaverse trustworthy for humans in their all virtual activities.

Keywords: ethics, transparency, human, avatar, accountability, immersive experience

1. Introduction

Historically, it is a unique situation, in which the new formula of the Internet has been established. In many debates, the concept of "Web3" has started to be a challenge and opportunity, opening the fascinating way to empower individuals. The phenomenon of metaverse is based on:

- the immersive experience coming from the joint use of Virtual and Augmented Reality,
- possibility to move and live in the virtual spaces accessible via all digital devices, but due to the one virtual identity usage,

- the new formula of full semantic interoperability making possible to exchange information and interact among various systems and platforms overcoming all kinds of barriers,

- the special network architecture bringing the enormous power to enable massive groups of users to be in the metaverse space at the same time with high efficiency of all activities [1].

The foregoing experience of increasing significance of the Internet shows that at the very beginning the fascination of the innovative revolution and its drivers was much more powerful and stronger than any awareness of some unintended consequences of new phenomena, especially looking from the societal, human, and ethical point of view. At last, it resulted in a deficit of the adequate principles and norms and the proper regulatory framework. It does not mean, however, that the only way to fix this shortcoming is to have strict legislative rules. Very often, we need only various self-regulatory solutions like codes of conduct [2] or to check the impact of the new innovative technologies using for instance the form of the regulatory sandboxes [3], allowing for experiments.

Taking into account the starting point of the metaverse growth, I consider that it is a challenge to analyze all aspects of the current and future metaverse models using the perspective of human rights and ethical values. It is the main purpose of this paper – to prepare the list of problems, which should be tackled in order to guarantee human-oriented, trustworthy, and ethical metaverse solutions' development.

The complexity of the metaverse allows to discover new areas of changing services delivered to many targeted or non-targeted groups. Currently, there are several new instruments for much more efficient integrated urban development projects; tools for educators allowing them to show the pupils, i.e., the real dimension of the historical events and processes – to understand better the past, to offer a form of hands-on experience; the new environment for all kinds of trainings more effective thanks to the creation of real experience, although in the virtual space (soldiers' trainings and HR trainings); new opportunities for the medicine – diagnosis and therapies with sensual and psychological participation of patients, i.e., in the post-traumatic stress disorder (PTSD) treatment, as well as remote surgeries; and also – new tools and possibilities for using avatars of civil services to make administration much more effective, cheaper, and closer to the society. And, I have to say – it is not the experimental stage, many of the mentioned above solutions and use are really functioning, and many of them are after trials and have the evidence of the effectiveness and efficiency.

What is needed for the metaverse development and high level of guarantees of its effectiveness, robustness, and usefulness?

There are some crucial conditions such as:

- high quality of connections, which means that the networks of 5G and 6G in the future (infrastructural challenges) are necessary, with broad and common accessibility,

- high level of interoperability (technical instruments, protocols, and services needed) which provide for possibility for data and concrete solutions (designed in 3D landscapes, rooms, and offices) flow and understandable exchange,

- probable development of the blockchain models, which can guarantee the decentralized operations that should be more secure and lead to the open decentralized metaverse. In addition, they could support the decentralized identification network based on international norms and standards with a purpose to strengthen and ensure the confidence for avatars moving cross-platforms,

- clear – and globally as common as possible – rules for data flows (personal and non-personal), as it is recommended in the EU Data Act[1] and other regulations and formats of international transfers,[2]

- redefined and restructured workplaces and online shopping frameworks with transparent principles for workers (workers' rights – the platforms' workers directive[3]) and consumers (liabilities schemes, adequate rights, and redress mechanisms in cases of breaching the rules and vis-a-vis clients' dissatisfaction),

- new environment for the economic activity in the metaverse spaces (digital currency rules, legal functioning of digital assets, and models of transfers between the traditional and virtual economy – with a specific added value),

- technical conditions and standards for IoT, especially AI IoT, as well as guarantees for cybersecurity (as it is proposed in the Cyber Resilience Act[4]),

- much more advanced methods of building digital identities (confirmation and authentication schemes), commonly accessible in the EU (how to make it globally?); this however requires faster works on EU Digital Identity Wallet [4].

The conditions mentioned above are indispensable for the metaverse comprehensive development. The high quality, efficient, secure, and safe metaverse requires advanced and multidimensional solutions, cross-technological and related to the various fields of the European digital regulations.

> *The essential question is whether we need a special regulatory framework focused on metaverse to respond to all requirements and fulfill all conditions? Or should we review all existing legislations and self-regulations and add to them some amendments to make the metaverse development innovative, secure, and responding to all – even currently unclear – problems.*

And what are the unclear problems? The current and potential advantages are discussed in the business environment, in some countries and in the European Union. The building blocks are being developed, but there is a deficit of the complex connection between them.

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[1] Proposal for a Regulation of the European Parliament and of the Council on harmonized rules on fair access to and use of data (Data Act), COM/2022/68 final.

[2] EU-US Data Privacy Framework, proposed in April 2022, the description: Hendrik Mildebrath, EPRS, PE 739.261 – December 2022.

[3] Look at proposed: Directive of the European Parliament and of the Council on improving working conditions in platform work, (COM)2021 762 Final.

[4] Proposal for a regulation on cybersecurity requirements for products with digital elements - Cyber Resilience Act, Cyber_Resilience_Act_UuNORBE3ZXD57gU9ayF71Bcc_89543.prof.

Let us try to put together such a list of problems, taking especially into account important aspects of the functioning of metaverse solutions.

2. Firstly, how to enter the metaverse space?

The adequate quality of network is required. So, if metaverse is to be a common achievement (a common good in the future), accessible for all, overcoming the digital exclusions and avoiding a growth of the new inequalities, the holistic and comprehensive network development is necessary. In parallel, the shift from current accessibility of digital world (via devices and its screens) to the new one (via headsets, gloves, contact lenses, watches etc.) is in process and progress, generating both unknown opportunities and complications and concerns. All of them are challenging for the accessibility itself.

It is not only the material accessibility of those forms of the immersive hardware but also our – human – adjustment to those devices allowing to use them without the redundant tiring experiences toward our physicality, eyes, hands, legs (possible para-phantomic movements), and of course our brain, psycho, and the mindset. The question is whether we are ready for this kind of sensual experiences, whether we want (as gaming business is working on) to participate in the Internet of Senses via Internet of Things. And what kind of the unintended consequences this experience can bring to our personalities? Can the long-lasting living in the metaverse landscape change our senses and cognitive skills? What will be the impact of this immersive experience on us? Some kind of personal (psychological) impact assessment directly focused on this issue could probably be very useful as part of obligations present in the Codes of Conduct or legislative proposals.

Finally, entering metaverse space should require most secured way of our identification and authentication. There are many certificated schemes in, i.e., banking systems, administrative services, patients' registers, functioning for users of the Internet (with our IPs), and checking and confirming digital identity. But there is a lack of single and common solution, commonly used in all possible sectors. The concept of the EU Digital Wallet is underdeveloped and far from final conclusion as legally binding solution, and far to be implemented. The important question is whether and how the metaverse identity authentication should be built on decentralized models, as the blockchain is not solved. It does not mean that this deficit can stop the metaverse development, but it would probably make the metaverse activities more complicated and more exposed to cybersecurity attacks.

2.1 Secondly, how the human position in the metaverse world could look like?

On one side, we – as users – will participate in the virtual landscape via our decisions. On the other side, it will mean that we have to give a clear, informed consent to collect and process our personal data. But the continuation of our presence in metaverse space may most likely require the confirmation of agreement for re-use of our data, and in addition, can cause tracking us by algorithms because of many reasons (with no choice scheme...). The safety and security guarantees may lead to use and process our data to protect us, and the active participation in some virtual undertakings may be based on behavioral analysis (gestures, making a faces, visible emotions, heart rates, and gaze directions) and building the profile of our preferences in the intrusive ways, so we may be exposed to emotion-responsive advertising without any restrictions and limits. As it was raised

in the brief paper presented by Chatham House [5]: "What is the metaverse?" – "The temptation to put users under even more constant and detailed surveillance will be hard to resist in a metaverse founded on profit-driven motives." Surely, in the future, the metaverse solutions would become a public good, but as for now, the development is based on commercial purposes. In this case, the conclusion should be clear – the new patterns of safeguards for having aware choice and giving informed consent ought to be incorporated transparently into the management system of metaverse [6].[5]

To tackle this problem, we should consider whether to use existing possibilities of GDPR or look for new ones.

What is more, the very complicated chain of needed and used data for metaverse should create a new perspective for building the awareness of privacy and personal data problems. But there is a challenge. Do we properly understand the model of web relationship established in the metaverse, some kind of "inter-and cross-data model" functioning in the Internet of Things? In this chain of devices and the chain of inter-humans relations, it is very difficult to indicate the responsibility for data usage and make the adequate distinction between data controller and data processor and ensure the compliance of all GDPR requirements. As a result, we may see the need for a completely new model of data management and rules for data governance (how to collect the data consents and how to manage those collections), as some current regulatory schemes presented in the Data Governance Act and the Data Act currently discussed in the European Parliament may turn out to be insufficient. There are some recommendations to review the GDPR in public debates and to check whether data gathered during unconscious behaviors [7] in the metaverse spaces have references to the existing regulatory framework and could protect us.

2.2 Thirdly, how to develop and maintain the human subjectivity in the metaverse ecosystem?

All those aspects of the metaverse functionalities lead me to the issue of keeping the integrity of humans (physical and psychological) and guarantees for the human subjectivity in the metaverse ecosystem, which are significant for fundamental rights and ethical dimension of this new technology. What does it mean ethical? As it was formulated very precisely in the HLEG document on AI [8], the essential reference point is related to the Fundamental Rights (that means international understanding of our rights, after the World War II), all our freedoms, guarantees for the autonomy and equality in the broad sense (the right not to be discriminated by any cultural, mental, religious views, and biases), living under the rules of accountability and transparency, and full access to the information.

There are two concerns.

The first one is linked to the specific relationship between the human subject and the avatar subject in general, when the avatar is or should be the duplication of human subject.

It would be interesting to know more and publicly discuss the topics and tools of creation of the avatar:

a. as a full replication of the human, based on all information accessible in the network – all marks and prints (is it fully possible and could it create the autonomous "person"?),

[5] See ref. [6].

b. as a deep model based on us as an essential pattern, with us: still present and standing behind the avatar in the real time (if we are sleeping – the avatar is sleeping),

c. as a created shape adjusted to the functions and played roles, but with our ruling authority.

As it is in the world of games, the solutions can be various and differentiated. The ethical problem is whether this created person, living in the simulated world, will have the characteristic of us as individuals: not only the appearance, human movements, but also views on some problems, awareness of the world's challenges and responsibility for activities and measures, in some cases also being under the power of the hidden biases. Will the metaverse be named as an alternative (simulated) world, or the part of the new hybrid world, in which we are living? Whether or how to make avatars responsible for some actions? Probably, it would require to grant legal personality to avatars or to have criteria and instruments to distinguish between us as operators of avatars and avatars per se. The solution should be transparent and accountable. The debates about it ought to lead to practical conclusions, indicating also the most proper and effective liability system: who/what is responsible for what.

It is very interesting to observe the discussion about liability system for AI [9].[6] At the beginning, there were many suggestions that AI Act requires the complementary solutions of redefined and changed safety and liability directives and that the only way is to harmonize the measures for the whole EU. But, it turned out that rules for high-risk AI systems are not sufficiently applicable to the existed liability models. As a result, the proposal of the new European AI liability regime (Artificial Intelligence Liability Directive) was put forward. Because of many systemic differences between Member States, the suggestion was to use the formula of directive, not regulation, but there are some doubts if it fulfills all expectations. The crucial dimension of looking for the solution is related to the adequate description of eligible damage: property, death or personal injury, and data loss based on fault or defect, with possible analysis of causality in depth. The characteristic of liable persons, types of victim protected, types of damage (material or immaterial), clarification of what victim needs to prove, and period of liability are significant to make the solution not only more clear, but first of all – implementable. In my view, comparison between level of complications of AI liability and the level of the incoming complications of metaverse liability clearly shows that liability models for the metaverse are currently totally unrecognized. So, it is one of the key challenges for metaverse development.

In that sense, the avatars will follow and continue our behaviors and develop our attitudes, as "residua" of us, without the autonomous possibilities (the possibilities to be out of our control), and by being some kind of metaverse twins, still the liability and responsibility framework should be prepared as a special and dedicated one.

The second concern is related to the potential mental and psychological consequences of staying (for short and long term) in the metaverse.

How will our subjectivity look like, when we stay in the metaverse space from time to time, incidentally, playing various roles: as contributors to academic debates and research papers; as participants of consultancy processes in our local environment, building the local democracy; as workers in cooperation with others, organizing the collaboration of avatars and between avatars and people; as making shopping as virtual consumers and talking about the prices of products with the virtual sellers;

[6] Based on very inspiring presentation of ref. [9].

as talking and playing the games with children, when we would live and work many weeks out of the home territory, but using the home landscape for those family meetings; as going to the virtual church for praying, etc. What kind of impact will it have for our psycho, personality, integrity, preferences, life, and cultural patterns? Is it possible to change our mentality because of the double formats of our life? Some dependency or even addiction threats could become real. Someone could say that these experiences are currently present in our life in different forms, although they are not so common.

But, could we imagine, that somebody decides not only to play some roles in the metaverse but play life fully? What kind of consequences could it bring to the mentality, psychological integrity, and personality of this human? It depends on the similarity to the real life (it would be easier to adjust behaviors to the well-known norms) and on the individual predispositions to learn the rules: identical and different at the same time vis-a-vis the real world.

The problem of conditions for adaptability to the metaverse spaces is increasing and becoming significantly important. One of the possible consequences can be related to the growing phenomenon of the psychological and mental dependency of people becoming fully involved and engaged into metaverse landscapes and communities. Changes of mental conditions of our functioning can lead in the extreme way to addictive behaviors, and to depressions and anxiety, as it is expressed in many psychological research papers: "It can cause or exacerbate mental health conditions, including depression and anxiety. Overuse of digital devices, especially when combined with social media dependency, can increase feelings of isolation" [10]. Psychologically speaking, such a multidimensional dependency and tackling of the threat of this kind of experience, is a real challenge. It means that active participation in the metaverse world should be necessarily supported by educational programs, focused on digital metaverse literacy. This is to avoid the redundancy of negative psychological side effects. And in addition, the accessibility of psychological help and professional interventions ought to be guaranteed for metaverse users in a systemic way.

One problem of the growing metaverse creates very strong concern. It comes from the immersion phenomenon. When in Poland for instance, Meta in cooperation with the governmental institutions established very interesting educational metaverse project: "The daily chart from the Warsaw Uprising," giving young people the opportunity to really participate in 1 day of the Warsaw Uprising 1944, there were some controversial reactions. On the one side, it was a profound lesson of the national history, educationally needed. On the other side, it is an intense immersive experience, some kind of overstimulation addressed to the young personalities, to the premature psycho, so some teachers were against to use this project. The problem of overstimulation should be reconsidered, and every case should be analyzed with the respect to the age and social group's sensitivities and possible vulnerabilities.

2.3 Fourthly, what kind of society would be generated by the metaverse rules?

This concern shows the metaverse as a phenomenon related to the societal aspects of the avatars functioning in virtual-real space. Many experts emphasize that in the new generation of the Internet, "Web3", metaverse opportunities will empower individuals and establish the new model of the social relations – the new society [11].[7] There is no illusion that this new world will be better than existing one. Still, in many

[7] Some ideas were presented in ref. [11].

analyses [12],[8] there is a presumption that the metaverse will replicate and amplify all negative aspects of inter human relations functioning in the current internet: the hate speech phenomena and harmful behaviors, also digital violence, the lack of trust and extreme social polarization blocking any possibilities of dialog, the digital bubbles significance, the growth of the conspiracy theories and mindsets based of those views, the disinformation plagues undermining the democracy, and opportunities for common actions, etc.

Today, one of the most important responses to those threats is based on still developed and modernized (also thanks to the use of the AI techniques) ways and tools of moderation of the content, which pursue to find and establish the order among people and people' behaviors in the Internet society.

Obviously, the meaning of moderation will increase with all principles, which should accompany it [13][9] – but it is the new challenge for the metaverse ecosystem. For now, there are some rules [14] used for the content moderation, coming from regulations like DSA in the European Union, or based on the Code of Conduct – which for US (and companies from more than 10 countries) are the Santa Clara Principles. Those rules, such as transparency, accountability, and non-discrimination, are significant for the high-quality moderation of the content. But, in the metaverse spaces, the moderation should be more multidimensional – with regard not only to the content, but also to all kinds of behaviors of avatars. Additionally, the dilemma between the freedom of expression and general, social obligations not to harm and hurt other people (not only by words!) in the virtual world will appear much more difficult to be solved rationally. And it is a big challenge: how will the rule of anonymity function in Web.3, in all metaverse spaces? If the society of avatars is based on anonymity or works using mixed principles adequate for the virtual/real metaverse landscapes, with references to the legal norms and ethical values present in the current society and the legal order of the societies. But before attempting to respond to this questions, it should be made clear whether the members of the metaverse society are the substitutes of the real persons (avatars as substitutes) or substantially autonomous, close to be autonomous (avatars as substantive shapes)? This is for the future, trustworthy, and ethical-based metaverse crucial, and the rules for moderation of this simulated world should be specific.

We can also put forward a question whether the visible phenomena of extreme individualism and digital narcissism [15][10] will dominate the social dimension of the metaverse and undermine the needed, expected, very creative, and fruitful collaborative mode, which is crucial and positively inspiring for the future metaverse-based society.

2.4 Fifthly, how to translate the rules of the metaverse into the ethical principles?

In my opinion, there are three crucial factors to ensure the ethical functioning of all metaverse opportunities.

First is related to clear and accountable paradigm of data use in all value chains of metaverse models and problems related with it. All responses to these problems should come from the strict and determined implementation of GDPR and incoming legislation on data.

Second relates to the AI components of metaverse measures, and the references to the requirements addressed to the high-risk uses of AI [16], such as risk-based

[8] There are positive impacts of metaverse and negative, look at ref. [12].

[9] See ref. [13].

[10] Digital narcissism as a new phenomenon, described ref. [15].

approach, ex ante procedures, ethical impact assessment, transparent and accountable information on the mechanisms of AI work, addressed to the users (to avoid the asymmetry of information) – the rule of explainability, and all those rules (non-discriminatory models) incorporated in parallel and in reasonable way to the services based on the General Purpose Artificial Intelligence [17].

What is more, because algorithms are playing significant role for metaverse solutions, it is important from ethical point of view [18] to develop and maintain them under the accountable rules and to base them on values, as it was raised in the EPRS paper [19] on "Ethical and societal challenges of the approaching technological storm."

The most relevant values for digital technologies are as follows:

a. justice and fairness,

b. privacy,

c. cybersecurity,

d. environmental sustainability,

e. transparency,

f. accountability,

g. autonomy,

h. democracy,

i. reliability,

j. trust,

k. well-being,

l. inclusiveness.

This comprehensive list allows to check whether the concrete applications are responding to those values. The models of checking (by using the controlling lists addressed to the specific values in the specific areas) was proposed by HLEG on AI [8] and have become very useful to prepare some references for the requirements of ex ante procedures present in the legislative proposal of AI Act [20]. This model can characterize the threats for ethics and values and propose the concrete mitigation measures.

It would be inspiring to follow the work presented by STOA to the European Parliament on "Artificial Intelligence in healthcare" [21], showing the deficits of accountability, threats of misuses, risks of biases, and dangers of harm due to the technical errors. The added value of this paper comes from the strong message, how important are the risks analysis and risks management and methodologies opening the opportunities for the multidimensional view on the possible risks and how to mitigate them. The same way could be used when we discuss how to find the most adequate way to transfer ethical values into metaverse applications.

3. Conclusions

1. It is not clear, if the metaverse requires the new special legislation, although there are some suggestions from the European Commission that this new phenomenon should have a specific regulatory framework. But, it is obvious that because of very complicated structure of the metaverse (virtual and augmented reality, the value chain of many devices and infrastructures, IoT formats, AI IoT, cross moving data, etc.), *the very precise review of legal references important for the secure, trustworthy,* and *ethical metaverse is necessary.* As necessary as, at the same time, common work of all possible partners on the Code of Conduct and self-regulatory solutions for the whole metaverse functioning or for some areas of metaverse.

2. The market evaluation of the metaverse does not allow us to say that it will be really the most visible example of the Web.3. Obviously, it is very probable, so all aspects of the *metaverse as a common good* should be analyzed. The question what will become the dominant trend in metaverse development: commercial orientation or common good with hidden links to the commercial rules (as it is now, in Ref. to the social media) remains open. As a consequence, some conditions for the metaverse are essential: the *full accessibility* (infrastructure, high quality of hardware used by individuals), inclusiveness, guarantees of the new common, secure forms of digital ID for users and functionalities of the ID, workable and accessible in all devices. There are technological and legislative challenges, such as EU Digital Identity Wallet based on blockchain formats.

3. *Psychological readiness of people to participate in the metaverse world, under the immersive conditions* without any psychological, mental damage, avoiding the dependency and dangerous addictions or unknown consequences of double formats of existence (in real life and in the virtual spaces), remains the most significant issue. It requires a *very special impact assessment concentrated on ethical challenges and guarantees for human autonomy vis-a-vis avatars and the simulated, alternative world, addressed to different kind of groups: minors, vulnerable people, etc.* But, also checking many applications with focus on the *problems of the overstimulation* (how will it impact on our senses and sensitivity), the lack of clarification the *differences between the human and avatar subjectivities*, the problems of being responsible and liable for some actions (if the concept of giving the avatar the legal subjectivity should be considered or not?).

4. Review of all GDPR solutions taking into account the sufficiency of those legal tools to really protect humans, humans' data, and with guarantees for the transparent conditions to give the consent and having the choice – *on which rules I can share my data* – is indispensable. The awareness of humans about the data (additionally – the digital literacy of metaverse is needed), understanding the surveillance threats (during and after behavioral analysis of us), and the emotion-responded advertisement models in the metaverse, the new methods of data and data consents management – should *indicate the new framework for data flows in the metaverse-simulated world.*

5. Rethinking the model of interactions and relations between humans and avatars. The metaverse can create the alternative world with full engagement and profound participation of its both in parallel. Unfortunately, there is a possibility

that the metaverse society and various metaverse communities will follow all bad mechanisms functioning in the real life and the current Internet, such as: the hate speech, the deep fake news, harmful and full of violence behaviors, discrimination and the growing biases, and the extreme polarization. *Avoiding those threats is possible only if the norms of this new society are based fully on values and ethical standards.* And, if the new models of moderation (not only content moderation) of the comprehensive metaverse space and life are established with some restrictions to behave in the inadequate mode. The safeguards for this ought to be developed and supported by the smart translation of the ethical values into technical solutions, through *the principle: ethics by design*. Can the architecture of metaverse be build by ethics by design? It is a critical question, to which – in my view – the answer has not been yet found.

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Section 3

Ethics in Scientific Research and Education

Chapter 10

Perspective Chapter: Teaching Bioethics through Critical Pedagogy

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Abstract

This investigation is focused on critical pedagogy for the teaching of bioethics. The objective is to design a course where ethical dilemmas of various topics are raised, to be analyzed with bioethical principles and legal bases, through a model that allows systematizing the various situations in three stages: 1 - approach; 2 - assessment of the case; and 3 - conclusions and implications. Throughout several semesters, the results showed that the model worked to achieve a bioethical opinion, integrating all the analyzed aspects of the dilemmas raised. This achievement was evaluated through the students' perceptions, applying strategies framed in critical reflection. The analysis of results included both the grades and the information obtained in the critical reflections of the students. The evidence highlights a good management of bioethical analysis, a lot of motivation and participation and conceptual changes, which can possibly promote the achievement of critical learning.

Keywords: critical pedagogy, teaching, values, bioethics, bioethical principles

1. Introduction

Actually, many people talk about value crisis, part of which includes the excessive use of scientific and technological advances without considering their environmental and social impacts. This crisis is reflected in educational institutions where dishonest behaviors are observed, such as copies in evaluations, non-repayment of what is borrowed, plagiarism in work, and so on [1, 2].

This crisis establishes an urgency of dialog between scientific knowledge and human values. In 1970, Van Rensselaer Potter (considered the father of bioethics) proposed this dialog through bioethics, which represents a space for articulated reflection on a scale of values and for making responsible decisions about related problems with biological life, the environment, and the developments of science [1, 3]. For Potter, bioethics is a new discipline that represents the bridge between classical ethics and the life sciences [4, 5].

It is important to note that bioethics has its roots in philosophy [6], where two perspectives are found: first, the perspective of materialist bioethics [7] and second, the perspective of the personalist [8], whose center is the good of the person [6]. These two perspectives have led to the derivation of various currents, among them

Principlism [9], Personalism with anthropological foundation [6], Utilitarianism, and Materialist Functionalism [7].

The important thing about these currents is the pluralism that implies the incorporation of bioethics as a topic in research. For this reason, it is necessary to reach agreements at the level of the scientific community in order to ensure respect and promotion of human rights, which represent the limit and guiding criteria for such agreements [9]. In this regard, codes composed of statements that establish guidelines for bioethics in its various applications have been proposed.

Although it seemed that bioethics focused on the area of health, today bioethics is taken up again in a broader concept, as defined by Pessina (Professor of Bioethics at the University of Sacro Cuore in Milan), as "critical awareness of technological civilization," and Postigo, who considers bioethics as the systematic and interdisciplinary study of the ethical implications of human actions on all kinds of life to determine a possible solution for man and future generations [6]. Currently, bioethics represents a way of doing ethics, as indicated by various authors and many codes, as in the Code of Ethics for Life of the Ministry of Science and Technology of the Bolivarian Republic of Venezuela [10].

Regarding the issues that can be addressed in bioethics, they are organized into two groups. The first group refers to the topics of medicine and health areas such as dentistry and nursing; and the second group addresses a wide range of issues, all related to human life and in the context of nature [1, 11].

In all the themes, aspects related to values and ethics are included, and that is why, for UNESCO, scientific and technological development cannot be separated from ethical reflection. In this regard, Article 23 of the Universal Declaration on Bioethics and Human Rights [12] states as objective "to promote the principles of the Declaration through education and public information programs that train citizens at all levels and without distinction in understanding the bioethical implications of science and technology" [6].

This principle must be guaranteed by the States, through the educational institutions that are responsible for compliance with this article [11, 13], since the question that as educators we must ask ourselves is what kind of people and of citizens we want to form? The answer justifies the inclusion of a training program in bioethics in the curriculum of all faculties [2]. In addition, it represents a change in terms of the objective of education, which should be to train citizens to have their own opinion that allows them to participate in the social debate in an informed manner and in the promotion of public policies.

This is the case in all areas of life, but in the field of bioethics, it is especially important and complex, since in order to propose and promote normative, ethical, political, and legal guidelines, not only a particularly responsible attitude but also a double knowledge is required: the scientific-technical (which implies a previous work of diffusion and disclosure by those who work directly on the problems) and the argumentative. The challenge of bioethics is to propose a common framework of values that, at the same time, is respectful of the differences between individuals, their values, their principles, and their models of life [13].

From the point of view of pedagogy, it is suggested that bioethics should be taught from elementary school to high school, not only as a complement within traditional classes but also as a separate subject that should have two emphases: a social one which, supported by workshops, booklets, banners, and intense dissemination work, is interested in issues such as hygiene, sustainable development, and those related to the environment in general. The other emphasis of the course must be the development

in the student of tools to learn respect, responsibility, and love. "Strengthen self-love, respect for others and love for nature." In this type of teacher-student problem, several questions arise about the field of action and relevance for bioethics of the problems raised. A list of actions of a transgressive nature can be appreciated, explainable from the way in which values , the rules of conduct, goodness or badness in the actions, as well as the rules and manuals of behavior and coexistence are understood [14].

Regarding the responsibility of the states, the Bolivarian Republic of Venezuela, in the first "Socialist Plan of the Nation" (2007–2013) [15], considers bioethics as a transversal axis; in fact, one of the objectives is "[m]ainstreaming the teaching of ethics," which allows us to infer the importance of bioethics in the training of citizens capable of making decisions in the face of scientific and technological advances, which implies designing proposals for classrooms to promote this training [16].

Given the aforementioned information, the authors of this research considered the proposal and implementation of a bioethics course at the Pedagogical Institute of Caracas (IPC) of the Experimental University Pedagogic Libertador (UPEL). The model for the design and implementation of the course was the one proposed by Müller de González and Szczurek in 1989, who presented a model in the application of Instructional Development [cited in 17] and whose phases included: diagnosis of needs, design of the solution, simulation or implementation, and, finally, the evaluation of the implementation.

2. Bioethics course for teachers

2.1 Phase 1. Diagnosis of needs

Following the model, Partida, Alvarado, and Ochoa de Toledo published phases 1 and 2 of the proposal in 2017 [17]. For phase 1, the elements that were considered to establish the need for a bioethics course included: first, teaching experience in the Science, Technology and Society (CTS) course, a course administered by prof. Marlene Ochoa de Toledo; CTS is a subject that allows the contextualization of the contents, which is why the positive and negative impacts of science and technology are pointed out; prof. Marlene observed that when ethical aspects were touched on, the only perspective of the arguments was that of personal values, since the students had no other tools. That is the reason why it is needed to provide tools to future teachers regarding the analysis of bioethical dilemmas, in order to provide elements that contribute to the objectivity of the arguments.

Second, article 23 of the Universal Declaration on Bioethics and Human Rights has as its main objective the promotion of the principles of the declaration through educational programs in order to train citizens in the bioethical implications of science and technology [13]; in this regard, Venezuelan government policies in the Organic Law of Education [18], in article 33, point to "bioethics as a guiding principle of university education," and the Socialist Plan of the Nation (2007–2013) [15] supports this inclusion in Venezuelan education and goes further when it proposes the mainstreaming of bioethics in education; furthermore, since 2011, there has been the Code of Ethics for Life of the Ministry of Science and Technology of the Bolivarian Republic of Venezuela [10].

For this reason, at the IPC-UPEL, these remarks were raised as a justification for the opening of a Bioethics course for future biology teachers and later for the specialty of chemistry as well.

2.2 Phase 2. Solution design

Once the need was established, the next step was the design of the bioethics course for students specializing in biology and chemistry, which corresponds to phase 2 of the Instructional Development Model. Although the idea for the future is to implement bioethics in all specialties, the researchers started with these specialties since they included the students who also took the CTS course, which made the population accessible to the researchers.

The objectives set for the course were the following:

1. Establish the importance of advances in science and technology in solving social problems.

2. Value the responsibility of the human person in the rational use of science and technology.

3. Value life.

4. Solve ethical dilemmas on different issues: violence against women, child abuse, biological weapons, use of animals, religions, organ transplants, stem cells, euthanasia, abortion, medically assisted procreation, and so on.

5. Resolve ethical dilemmas that arise in the classroom and/or school institutions.

These objectives are framed within the education in values. According to Chaparro [19], the education in values consists of awakening the creative potential of the human being, helping him to equip himself with his own capacities, and forging in him attitudes of tolerance and understanding, which allow or help him to develop himself in relation and with respect to others.

In order to fulfill the proposed objectives, critical pedagogy was selected for the teaching methodology. In this sense, first, the importance of communication for the teaching and learning processes was taken into account; for many authors, the communication process is multidisciplinary and transdisciplinary [20]. One of the representatives of communication studies is Mario Kaplún, who points out that the educator becomes the companion and guide to provide tools that allow the student to build their own structures of meaning [21], so they can make their own decisions and thus "learns to learn" [22].

The communication process in bioethics must start from critical pedagogy, which seeks the development of critical and reflective skills of students, contributing knowledge and culture that are significant for the student [23, 24]. The representatives of this current are: Peter McLaren (Canadian), Henry Giroux (American), and Paulo Freire (Brazilian) [23]. McLaren points out that the knowledge to be imparted must be important, relevant, and critical in order to promote transformation [25]. For his part, Giroux points out that education must be committed, critical, and revolutionary to allow critical development; Thus, the students will be able to be citizens concerned with facing social issues and be willing to extend the meaning; in addition, he points out the role of the teacher as a guide in the process [25–27].

Regarding the different bioethical approaches to address the discussion of ethical dilemmas, the course follows the principlism current. Principlism is a resource that

bioethics took from the philosophy based on human-centered orientations. Such guidelines facilitate ethical reflection on scientific facts and their impact on humanity, considering that they are applicable to society [28], especially in analyzing the impact of scientific and technological advances [4]. The principles were established in the Universal Declaration on Bioethics and Human Rights [12]; for the purposes of the principlist approach, we worked with the four principles indicated by Beauchamp and Childress [9], which were: autonomy, beneficence, non-maleficence, and justice; but for the proposed bioethics course, two principles, that are found in the Code of Ethics for Life of the Bolivarian Republic of Venezuela [10], were also included: responsibility and precaution. The principles are used to promote respect for everyday life and human differences, with which students can get involved in caring for life [1, 29].

The management of such principles in the classroom favors the formulation, articulation, and resolution of ethical dilemmas, thereby promoting a culture of respect for life in everyday life and respect for human differences without being discriminated against, since there are no absolute truths [1].

The next point that was taken into account for the design of the course was related to the methodology of critical pedagogy and the didactic strategies that could be included, that is, how to teach bioethics. In this case, it was important to define the role of the teacher, since he should be distinguished by encouraging debate and respecting different opinions; this is because for bioethical dilemmas, there may be more than one solution. That is why the transdisciplinary approach to the situation is so important to reflect on the values involved. Only in this way can it be expected that scientific knowledge can be modified into ethical knowledge [16].

Regarding the methodologies, the following are included: competency model [30]; learning of bioethics based on problems (ABBP) [31]; case-study approach [32]; humanist-integral approach, which considers that it is important to know the anthropological and philosophical bases that will allow decisions to be made about good or bad behavior. This includes knowing the importance of laws (a legal aspect that does not always go hand in hand with ethics) and religions for a comprehensive vision of the case [32, 33]. It is important to point out that regardless of the selected methodology, the main emphasis for a correct participation in bioethics issues rests on the process and on the role of the teacher as a guide and learning partner [22].

Once the methodology was established, the selection of the different strategies for the course was made, among which were included: debates, master classes, seminars, case studies, group presentations, text and film debates, and symposiums and conferences (Caramico, Zaher and Rosito, [cited by 33].

Regarding the **analysis of bioethical cases**, it is a strategy implemented by Schmidt [34] as a way to systematize information, analysis, and comparison of different points of view, prioritizing life and protecting the most vulnerable. The same author proposes a model focused on the moral decision process, which is what allows the person to appropriate moral knowledge through a series of intentional operations. Starting from the proposed model, Partida, Alvarado, and Ochoa de Toledo designed an adaptation of it for strictly pedagogical purposes while maintaining the objective of the method [17].

The strategy is managed through critical incidents, which are cases with certain meanings that will create a conflict with the thinking or behavior of the students (real cases are handled in the bioethics course). The incident leads to a disorienting dilemma that facilitates a teacher-led discussion, in which all participants argue their opinions, producing a consensual response [35].

Steps for critically reflecting on cases during classroom discussion include:

- Describe the event or case, that is, a consideration of reality.
- Make an objective observation of what is described, considering the emotions that accompany such events (which puts beliefs, values, ideas, and even behaviors at stake) through dialog.
- Consider alternative and potential answers until finding the appropriate answer, which will often change previous structures through the debate. It implies a reassessment of the original event [1, 35–37].

Although accepting moral pluralism is important, it is not that any proposal is acceptable or valid; it must be evaluated to determine if it is supported by consistent arguments to be used in a public debate in which prejudices must be refuted with reasons. In this regard, it is important to clarify that all people are respectable, but this is not the case with opinions [13].

The guided discussion of cases is based on the pedagogical point of view, in problem-based learning. Among the skills that are enhanced with this methodology, the ability to identify and solve problems, making decisions, communication and personal interaction, working in a team, developing critical thinking and permanent self-learning, evaluation and self-assessment, among others, have been described. For this reason, the student is responsible for their learning, while the teacher becomes the facilitator of the process through the revitalization of the work and the motivation to achieve the objectives [38]. The strategy implies a less leading role for teachers but one that is necessary to lead debates and help reach a consensual response.

Regarding the evaluation, it becomes a constructive process that allows assessing cognitive, specific procedural, and attitudinal curricular aspects, where each student is capable of reflecting on their own performance. In the short term, this type of evaluation produces a strengthening of group work, while in the long term, it allows the acquisition of skills by students [38].

The second strategy of the critical pedagogy used is: **reflection**, which can be considered a reflective writing. It is not exactly a diary, but it is reflective because in it the student evaluates himself, with which he is aware of what he learns. As a guide, students are given points to include: what I liked, what I have learned, conception changes, what I have not learned, what I did not like, and recommendations; self-assessment is evidenced by pointing out the knowledge acquired and the changes in conception, which represents an important element to consider in critical learning [25, 26, 35].

This information allows the self-assessment of the student based on what has been learned and the changes in conception. For the teacher's purposes, the information could be corrected in terms of wrong conceptual aspects; in this case, attention to students is personalized. The other aspects included in the reflection allow to know the perception of the students about the subject, the speakers, and the dynamics of the class; all that information represents valuable inputs for the organization of the course. For each topic selected and discussed in class, students must reflect under the aforementioned parameters. At the end of the course, they are asked for a free, undirected reflection, which represents a free writing about the impressions of the completed course, the learning achieved, and any other aspect of interest.

Both the debates for the analysis of cases and the reflections meet the objectives of critical learning insofar as they imply critical reflection and demonstrate the

existence of critical thinking that links the theoretical concept with daily practice and their experiences [25, 26, 35].

In addition to the aforementioned strategies, other strategies are included for the proposed bioethics course.

Third, **presentations** by teachers are handled for the introduction, for the theoretical foundations, and for a specific topic of interest for the course. Likewise, exhibitions by invited teachers are handled for specific topics. Finally, the group exposition of a specific subject previously selected is handled. In all presentations of specific topics, they must include the conceptual aspects, the dilemmas that arise in that topic, case examples, the legal aspects related to the topic, and the bioethical principles for the discussion of cases. In this sense, the presentations are made under established parameters, in order to guarantee the necessary information to address the cases.

The fourth strategy is the **bioethical analysis of a film** previously selected by each group. The exhibition has its guidelines:

- You must include a brief summary of the film as the rest of your classmates may not know the film.
- It must raise the dilemma under analysis since several dilemmas can arise in a film.
- Analysis of the dilemma;
- Participation of the rest of the group for comments.

In a publication by Luco, Quer, and Beca [39], positive results were reported regarding the inclusion of forum cinema for bioethical discussion. In this case, the cinema was not handled as a forum but as a presentation. What is relevant in this activity is the selection of the film whose analysis seeks to improve, deepen, and apply knowledge to other contexts.

The proposal for the course in terms of its objectives and content was presented to the Curriculum Unit of the Pedagogical Institute of Caracas, which approved the course as an in-depth elective for biology students. Subsequently, in 2012, the course was also approved for future chemistry teachers. In this way, phases 1 and 2 of the Muller de González and Szczurek Technological Development model [40] were completed.

Subsequently, in a second publication, the researchers present steps 3 and 4 that correspond to the validation and evaluation of the application of the proposal, in this case, of the course [41]. For validation, the results of the pilot test of the course are included. Then, based on the results obtained, adjustments are made for the implementation of the course. For the evaluation phase of the application, the qualitative results of the course are presented in light of the perceptions of the students and the analysis of their opinions.

2.3 Phase 3. Validation of the proposal

2.3.1 Method

For purposes of validation of the proposal corresponding to phase 3 of the Müller de González and Szczurek model of 1989 [40], the course was applied as a pilot test in the 2009-I semester. It only had five biology participants (total population of the bioethics

course), so the total population was used to gather information that would allow adjustments to the proposal for future applications. The pilot test included the following strategies: exhibitions, film discussions, case analysis, and critical reflections.

2.3.2 Results

For the case and film analysis activities, the methodological protocol based on the Ludwig Schmidt model [34] was used. This author proposes a model that allows to systematize and interpret the various situations in: dilemma, bioethical situation (which includes facts, actors, scenarios, relationships, central idea), intention (correct or incorrect), and act (adequate or inadequate). The facts lead to a holistic assessment (technical, legal, social, and personal), and the intention and the act lead to an ethical assessment. The central idea leads to the beginning. The holistic assessment, the ethical assessment, and the central idea imply criteria that lead to objective and/or subjective norms that lead to the opinion or bioethical opinion, which finally leads to a proposal for improvement.

Since the pilot test, the authors noted some flaws in the analyses, such as its brevity, and the little inclusion of legal aspects. In subsequent applications of the course, a complete analysis of the dilemma was achieved, but when giving the bioethical opinion that resolved the dilemma, that opinion did not include the arguments indicated in the analysis. Therefore, the fundamental aspect that was the resolution of the dilemma was almost limited to giving the possible solution without the support of the arguments. In other cases, the dilemma was not raised.

Based on the flaws detected, Ludwig's design is modified in a pedagogical model proposed by Partida, Alvarado, and Ochoa de Toledo [17] in which the following steps are established:

1. **Presentation of the case**: refers to the description of the facts. This point must include:

   - Actors: are the individuals directly or indirectly involved in the problematic situation.

   - Setting: is the place (country, region, locality, and/or environment) where the events take place.

   - Relationship: it is the relationship between those involved in the problematic situation.

According to the scheme, the next aspect to include is the **dilemma**. This is a question that leads to two options (or more), which must be answered in the bioethical opinion. In a problematic situation, there may be multiple dilemmas; for didactic purposes, it is recommended to choose only one for the analysis.

2. **Analysis of the case**. Three aspects are included:

   - Personal assessment: it is the direct opinion that the spectator(s) has about the problematic situation. If there are several participants for the analysis, each one must give their contribution. In this assessment, there can be many discrepancies because it is related to religious aspects and personal values.

- Legal framework: represented by laws, decrees, agreements, codes, oaths, and regulations in force in relation to the case. In all cases, the article(s) directly related to the situation must be mentioned.

- Bioethical principles: the bioethical principles related to the case will be named and explained. The principles analyzed are the six included in the Code of Ethics for Life [10]: autonomy, beneficence, non-maleficence, justice, responsibility, and precaution.

3. **Bioethical opinion**: the case analyses are done in groups, as if they are included in a bioethical committee: This is where the deliberation should take place and where everyone should participate. Here, there are different visions: one, the personal vision; second, the legal framework, which may be in contradiction with some principles. Historical background can be included in the deliberation, that is, previous cases similar to the one presented that can serve as a guide for the solution. Therefore, the deliberation process is essential. In the end, there will be a consensual answer to the dilemma, whose support are arguments taken from the analysis.

4. **Proposal for improvements**: in this regard, the committee can give suggestions and/or recommendations in order to minimize risks and/or harm in future similar cases.

The model presented here does not assume a predetermined solution. Each committee is free to resolve the dilemma according to the discussion based on the analysis. Not all groups arrive at the same answer, but in each group, the answer is the consensus of the members. In this way, it can be concluded that for a dilemma, there may be different solutions and that the solution given to the case will depend on the committee. There is no correct answer, since the answer includes the personal aspect that varies from group to group. It also reinforces the fact that the answers must be based on solid arguments that include the legal framework and bioethical principles. That is, although principlism is handled, it is not enough to argue. The legal framework is another important pillar to give the answer to the dilemma. The model was designed for pedagogical practice and was applied in phase 4 of the evaluation of the implementation of the proposal.

During the course, the evaluation strategies included: case analysis, presentations by the students, reflection on each of the topics covered, and a final reflection on the course. The evaluation was formative in terms of the fact that the student had the opportunity to improve reflections and analyses of cases and summative in the case of presentations. Finally, they were asked for the final reflection about the course.

The qualitative aspects resulting from the different strategies include:

1. In the reflections of each topic, students place a lot of information about what they learned, which facilitates self-assessment by the student and evaluation by the teacher. Likewise, in these reflections, the students point out the need to raise legal aspects and the importance of respecting opinion diversity. Conception changes are included in specific topics.

2. The different presentations made by the students allowed them to broaden the vision about the treated topic since they believed that bioethics was only for the health area. They thought that more time was needed for the presentations and more depth was required to address various aspects. They recommended the use of videos to make them more dynamic.

3. The students elaborated the case analyses; one student even managed to establish her own model. However, they pointed out maleficence as a bioethical principle, which indicates the confusion between an act and a bioethical principle. And in the case of bioethical opinion, on several occasions, it was very concise apart from the fact that they did not handle the arguments they made in the analyses.

4. In the final reflection, they considered that bioethics was the best course for the integration and analysis of knowledge and that it should be implemented as a code of human conduct in all specialties. They pointed out the importance of the course in learning to respect the diversity of opinions.

5. Finally, regarding the content, two students indicated that they thought it was another subject to complete credits, but in reality, it is a course that offers tools for the analysis of dilemmas and for the treatment of human resources.

6. For the purposes of the course as a pilot test, the results were very satisfactory, since the proposed objectives were achieved, despite the fact that the sample was very small; in addition, the fulfillment of assignments and how they were understood were reflected in the grades obtained; however, there were difficulties in differentiating personal assessment, legal aspects, and bioethical principles with which the bioethical opinion should be argued. In the analysis of the dilemma, the principles did not appear; they placed them in the possible solution of the dilemma without discriminating which were the ones that corresponded.

7. The pilot test of the course allowed to evaluate the use of the planned strategies and the development and responsibility of the students. In addition, it offered the opportunity to see the aspects that could be improved in the final implementation of the course, such as the approach to ethical dilemmas and the establishment of guidelines for student presentations.

2.4 Phase 4. Evaluation of the implementation of the proposal

2.4.1 Method

The research is a qualitative study and is part of the interpretive paradigm because it is intended to collect information from students for subsequent analysis and interpretation of the reality of the bioethics course. This is a quasi-experimental study, applied to intact sections of the bioethics course at the Pedagogical Institute of Caracas.

For data processing and analysis, the Continuous Comparison Method (MCC) proposed by Glaser and Strauss [42] and Straus and Corbin [43] was used. The investigation culminates with reflection on the findings obtained. The first step, after organizing the documents, was to tabulate the information; from this, we proceeded to categorize, and later, the corresponding analysis was made, supporting the findings obtained in the theoretical references.

The semesters in which the course was taught included from 2011 to 1 to 2016-I, and the group of students was made up of the entire population of future biology and chemistry teachers taking the course of bioethics. For evaluation purposes, parameters that should be included for each activity were considered: thus, the presentations should include both the conceptual and bioethical aspects, linked to a problem;

the cases had to follow the guidelines of the pedagogical model for the analysis of bioethical cases, according to Partida, Alvarado, and Ochoa [17]; reflections should include aspects such as what I learned, conception changes, what I liked, and recommendations for presenting the topic. Depending on the aspects considered, the score was assigned to the activity, to comply with the evaluation as an academic requirement. Likewise, in the first semesters of application of the course (2011-I to 2012-I), a survey about the expectations of the course was applied. The collected material was organized by semester and by activity to facilitate data processing.

2.4.2 Collection and analysis of perceptions

The analysis was made according to the elements considered for the evaluation of the course and the initial survey.

2.4.2.1 Survey for bioethics students 2011-I, 2011-II, and 2012 II (n = 51) with questions about the expectations of the course, what they had thought up to that moment (they had been in the course for three weeks), if they considered it an important or necessary subject, and if they would recommend it.

The results were the following: in terms of expectations, they were diverse; in the first semester of application of the survey, there was a total ignorance about its content and usefulness. But from the second semester of application of the survey, expectations of the course appeared regarding the objectives, the bioethical cases, the legal framework, and the ethics present in all aspects of life. These remarks included the comments and experiences of classmates who had already taken the subject.

Regarding what they thought of the course, they pointed out that it was an important subject for personal development and growth; They also suggested that it made them think of cases in the environment, that it changed the vision of scientists and their research, that it led itself to debate and discussion, that it taught bioethical analysis with the inclusion of legal aspects. They also pointed out that the first classes gave the theoretical support to argue a position in bioethical cases and the importance of the legal framework.

In another question, the students answered that it should be a required course not only for biology and chemistry but also for all specialties, for all universities, and for all public, because it taught legal aspects that we should all know; it is a course that helps to create awareness with which our society can be improved.

Finally, they pointed out that they would recommend a bioethics course or workshop for students and the general public.

This instrument was only applied in the initial semesters, since, due to its novelty, there were many expectations and erroneous information about the course. It seemed interesting to collect these impressions and thus compare what they thought at the end of the course, through the final reflection. To the same extent that the course was applied, the probability of indicating erroneous expectations decreased; even an increase in enrollment was noted, so the survey was no longer passed.

2.4.2.2 Strategies handled in class. Bioethics course: 2011–2016 semesters.

The information about the strategies was collected through participant observation in the classes and through the assignments that the teacher evaluated (case analysis, reflections, presentations).

a. **Case analysis**

One of the biggest concerns that arose in the first application of the course was carrying out the case analysis. This led Partida, Alvarado, and Ochoa de Toledo to design a pedagogical model for the analysis of bioethical dilemmas [17]. Since the use of the model from 2012, the problems of the bioethical analysis began to be corrected, giving greater weight to the opinion. The model is based on the humanist-integral approach since both the philosophical assessment represented by the principles and the legal framework are handled according to the context of the case presented; likewise, religious aspects are considered as part of personal assessment [32].

b. **Other strategies**

The result of the different strategies was very satisfactory, as stated by the students themselves. They expressed that it was excellent to use various experts in the course; they liked the diversity of topics; on some occasions, the students were taken to an expotatoo (tattoo artist event), to be more in touch with reality and thus be able to analyze cases related to the topic. The bioethical analysis of films gave them another way of seeing real and fictional situations. Many commented on the use of the blog that was opened for bioethics students where they could freely contribute their ideas and opinions. In summary, the strategies managed by the teachers, according to the students, represent a way of feeling like protagonists in the class, generating learning through better group interactions, and support what has been proposed by various authors such as Orozco [16]. These perceptions were obtained from the final reflections of the course.

c. **Aspects indicated in the reflections**

The reflections include both the ones they made by theme and the final reflection. As for the final reflection, it was totally open, and there, they could talk about the course, the strategies, and the teachers. A variety of information was extracted from there, and the most important was that students considered that there should be reflections in all subjects in order to express and self-evaluate. All the material was tabulated and organized into categories that included: their perception in relation to the course, acquired learning, bioethics as a discipline, the role of the teacher, and recommendations for the course according to the students.

1. In relation to the bioethics course

Some important aspects noted include that the course makes it possible to establish a connection between the real world and the academic world; in addition, it is integrative of various disciplines; it motivates debate and analysis; it helps us to change by making us aware of all the aspects that make up our day to day; it is easy to understand and carry, since real cases are handled, cases we believe far from our environment; it addresses questions that we have ever been asked but not from the perspective of ethics, making possible the maturity of critical thinking, which can be transferred to all areas, including education. It allows the expression of diverse opinions and to put yourself in the place of others and learn from their experiences. In this sense, the course modifies personal behaviors,

concepts, points of view, and paradigms, and furthermore, it encourages getting a good grade and not just getting the minimum passing grade.
The course allows creating social awareness of the transformative action of education and the leading and determining role played by the teacher, which supports critical pedagogy according to Deeley, Giroux, and Torres [25, 26, 35].

2. Learning acquired in the course

Most of the students expressed in their reflections some specific comments that included learning about values and how they influence human decisions; being able to compare the first bioethical analyses with the last ones allowed them to see their growth in terms of carrying them out and the importance of considering bioethical principles and the legal framework. They also pointed out the knowledge about bioethics committees and the role they play in the present institutions. In addition, the approach to various topics through real cases led them to understand that there were not two extremes or two shades but that there were nuances, which helped them for their teaching role and their personal growth; a fundamental point of learning in the course is the performance of bioethical analyses.

3. Bioethics as a discipline

In the final reflections, the students placed a lot of emphasis on bioethics as a discipline. Thus, for example, they defined it as the study of all the characteristic problems of the human species and the space for critical discussion of them, which allows the development of new strategies for addressing cases in the pedagogical field. Bioethics helps to educate beyond procedural and theoretical content; in this sense, it supports education from a holistic perspective of teaching, especially in the case of scientific areas.
Finally, some pointed out that if there were more bioethics courses, they would take them all because of the experience gained. Also, they pointed out that they must be the propagators of bioethics in their classrooms and social circles.

4. Teacher

One of the most outstanding aspects in the reflections of the students was the fundamental role of the teacher for this type of course. They pointed out that the teacher must not only master the theoretical aspect of the course but also have the ability to use tools and resources, in addition to being open and communicative (these characteristics are indicated from the experience with the teachers of the grade). It is the teacher who can guide the change, so that they can become sensitive to the situations and achieve the improvement that as humans we must achieve, as stated by Kaplún (El NACIONAl, 2016) [21].

5. Recommendations for the course according to the students

Based on the reflections, a brief summary of the recommendations made by the students for the course was made. It could be noted that although they gave suggestions for new strategies, in general terms, the students aspired to a course of bioethics beyond the semester. Among the recommendations given by students are:

- The topics presented should be part of the race to make teachers more tolerant, to avoid placing labels that lead to discrimination, and to prepare them for many cases that arise in their field of work. Furthermore, it should be for all audiences, and in the case of the educational field, it should begin at the basic level as part of the citizen training process to make it more humane with respect to the planet and coexistence with all human beings.

- Research areas in bioethics and projects in the area could be proposed to continue the work of this discipline and affirm the immense learning that it left in the students.

- The course could be closed with a free case proposed by each student (real or fictitious). Workshops and dramatizations could be included.

3. Conclusions

1. Bioethics as a course can contribute to managing the humanistic part along with scientific and technological advances, training professionals as citizens capable of making reasoned decisions that seek to cause the least possible harm. As long as critical pedagogy is handled, this type of course allows training people by making them more tolerant and respectful of different ideas, through learning based on discussion and debate. That is, the subject includes attitudinal content by involving students in situations and reflecting on their possible solutions, content aimed at training rather than information, in accordance with what was stated by Deeley, Giroux, and Torres [25, 26, 35].

2. The case analysis model was designed for pedagogical practice. The results showed that the model worked to achieve a bioethical opinion, integrating all the aspects analyzed and thus responding to the dilemma. The presented method can be adopted in the pedagogical practice of any level, especially if it is thought that bioethics should be incorporated from primary education.

3. The process of deliberation and argumentation of the final answer helped to achieve the objective of the course, in terms of awareness about the responsibilities toward life and the environment; in fact, students felt capable of transferring the analyses to any situation of daily life; many commented on how the news impacted them, which they hardly even read before, and how they automatically analyzed it from the perspective of bioethics. In many cases, they involved family and friends in their arguments, with which the learning acquired passed to the phase of social diffusion.

4. The perceptions of the students allow us to confirm that the use of critical pedagogy is fundamental for this type of course, since they can become aware that the personal vision is not the one that leads to the best answer; therefore, there is a conflict between the answer and what is believed. This can lead to being more flexible to different options, respecting other opinions, and changing toward a professional who is more committed to their social environment [25, 26, 35].

As a conclusion of this work, it can be said that the implementation of the course has been highly satisfactory, in light of what was expressed in the reflections of the students

about it. The objective of the course has been fulfilled by incorporating bioethics in the teaching of future teachers in a significant way, since they can transfer what they have learned to other situations, including concrete experiences of their lives.

4. Final recommendations

The experience of the course in each semester makes the authors think of some recommendations:

1. Continue with the application of this pedagogical method, for bioethical analysis, with the purpose of expanding the sample that supports the model.

2. Continue the opening of topics within the course, since the students state that they have new needs in terms of bioethics in pedagogical practice, in research, and in labor practice. These needs support the fact that bioethics must be understood with broader criteria than those that originally defined it. In this regard, the president of the Latin American Federation of Bioethics Institutions (FELAIBE) summarizes the different ways of seeing bioethics:

   - As interdisciplinary knowledge, which has been researched and disseminated in institutes and bioethics centers;

   - As an academic discipline, which, in fact, has been taught in many universities around the world in undergraduate, postgraduate, and even high schools;

   - As an instrument, which has been applied in consultancies, in government commissions and international organizations, and in clinical and non-clinical committees; and.

   - As a global movement in favor of life and its environment and in defense and promotion of the survival of humanity and planet earth [44].

The last point summarizes the reason for the existence of a bioethics course; hence, the vision of education must be its management as a transversal axis at all levels of education. Although it is true that at UPEL-IPC, the course is optional for future biology and chemistry teachers, the course should be required for all specialties.

It can be evidenced that the course promotes changes in students. However, the scope of this study does not allow us to know if these changes last in the long term in them, since it is unknown if critical learning is considered in other courses. Changes can be promoted with only one course, but they can be diluted if there are no reinforcements where reality can be involved as part of the learning and the ethical aspects involved. However, the fact that post-course products are generated leads us to think that it goes beyond learning for a semester. Hence, we suggest workshops for teachers so that everyone can apply strategies that consolidate the changes promoted by bioethics.

The application of the course has been very satisfactory for the teachers, because, although we think that bioethics still has a long way to go, at least the importance of the discipline for the training of our teachers and researchers has begun to be considered. For now, there are few products, but it is expected that new contributions

will continue to be added in the future, since there are seminars on bioethics in the master's degree in teaching biology; a course on bioethics in elementary education was opened, and the bioethical aspects of research are now a requirement according to the new research regulations of the IPC-UPEL. The highest aspiration is that bioethics be a required course for all university specialties and that little by little this discipline can be mainstreamed through the new university curriculum.

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Chapter 11

Perspective Chapter: Enabling the Ecological University – An Argument for Developing Transdisciplinary Ethical-Maker-Learning in Higher Education

Robert Curry

Abstract

This chapter argues for the importance of *ethical-maker-learning* as a transdisciplinary learning system in Higher Education. A new potentially transformative pedagogical concept of Critical Material Literacy (CML) is also proposed, with the aim that no student should leave university as a passive consumer of new technologies and products. Broad pedagogical opportunities are suggested across Science, Technology, Engineering, Arts and Mathematics (STEAM), and Humanities learning systems. The foundation of this argument is based on in depth maker-learning research, a critique of mainstream maker learning culture, and a move towards more ecological and humanistic concerns in maker processes. Thus, CML-based learning is proposed to teach an awareness of the importance of material matters in our often-passive consumer-led society. An initial transdisciplinary learning model for ethical-maker-learning is presented to provide ideas within this new HE-learning framework for critically and civically engaged experiential learning opportunities across all disciplines.

Keywords: ethical-maker-learning, critical material literacy, critical making, makerspaces, ethics, sustainability, information and library science

1. Introduction

This chapter proposes a new transdisciplinary learning system in Higher Education (HE): ethical-maker-learning. The transformative pedagogical concept of Critical Material Literacy [1] is also proposed as an initial learning path. Twenty-first century 'literacies' such as information, digital media and IT are well established [2]. However, it is argued that, without a holistic ethical-systems-based approach which incorporates the material, ecological and social aspects of these emerging 'literacies', we will ignore vital concerns for people and planetary welfare [1].

Broad pedagogical opportunities enabled by a 'pedagogy of daring' [2] are suggested across Science, Technology, Engineering, Arts and Mathematics (STEAM), and Humanities learning systems. The foundation of this argument is based on critical-maker-learning research [1, 3]. CML-based ethical-maker-learning is proposed as a way to teach students without advanced scientific knowledge an awareness of the importance of material matters in our surface-level consumer-led society. Thus, helping to resist 'an ever-widening gap between what science allows us to do and what it is prudent or ethical actually to do' [4].

The emphasis on CML and ethical-maker-learning on creating ecologically sustainable futures is in line with the philosopher of Higher Education (HE) Ronald Barnett's (2017) concept of the *ecological university* [5]. The concept of the *ecological university* connects knowledge with social institutions, Nature, the economy, culture, people, learning and the polity [5]. Therefore, this argument is part of a movement away from the current conceptual instrumental framing of universities as being primarily knowledge producers for a neoliberal ideology of competition, consumption, and profit to become communities of human flourishing and development [6].

Below is a proposed transdisciplinary pedagogical concept that can be adopted across multiple learning systems. The concept definition is followed by the research journey that underpins the formation of the CML concept as a potentially transformative transdisciplinary move. An initial model for ethical-maker-learning follows this that aims both to democratise access to emerging technologies for HE students from diverse backgrounds and provide an initial ethical/sustainable framing for experiential learning opportunities.

Critical Material Literacy (CML) can be defined as the ability to explore critical thinking concerning the social and environmental impact of materials across all areas of human activity so that material literacy can be expansively developed in society. This exploratory cross-disciplinary concept is relevant to all STEAM and Humanities perspectives as an educational tool. CML can be taught abstractly as a concept either face-to-face or online but can be reinforced as a learning system through embodied/haptic interaction with materials in critical maker processes. These processes are not just undertaken for academic purposes but wherever possible with the practical aim of creating ideas and prototypes for new, more sustainable cultural artefacts, products, and technologies to benefit society locally and globally [1].

2. The potential value of makerspaces in HE

As an academic librarian/information professional, the need to support information and digital literacy is crucial to my praxis. Models of digital literacy and digital capabilities [7] are always relevant to my profession. However, whilst many functional elements are included (e.g., information and data literacy, digital innovation), there needs to be a more critical focus on the materials that make up digital technologies and Technology Enhanced Learning (TEL) [1]. Through leading Digital Services and Academic Librarian teams in a Learning Resources Directorate for a UK university, a research interest in maker-learning as a possible antidote to the often surface-level engagement with digital skills and emerging technologies prevalent across HE became of interest. Key to the potential value of maker-learning found in the literature was the claim that it could be a 'means of regaining mastery over technology – not just because it enables us to be more self-reliant but also because it can boost our sense of agency' [8]. Makerspaces are a gradually emerging phenomenon

in HE, having been established initially as community-built, technologically enabled (e.g., 3D printing, electronics, robotics) learning spaces in local communities, museums, and schools [3].

The potential value of maker learning in HE was observed through a Cultural-Historical Activity Theory [9] based case study of a well-established North American HE academic library makerspace. Qualitative and observational data from academics and students across disciplines, and library staff, was collated [1] showing a course-specific experiential value to maker learning for students of Engineering, Biological Sciences, Textiles, Art and Design and Humanities. For example, making prototypes for solving sustainability issues, 3D printed scientific puzzles to aid awareness of molecular structures, a historic love-poetry remixing project bringing to life historical forms of romantic poetry, a pulse dress using 'internet of things' technology exploring new sartorial possibilities with textiles and a syringe filling machine prototype for use in healthcare [1]. However, questions could still be asked from inclusivity, diversity and sustainability perspectives as to the overall value of maker-learning.

3. A critique of 'maker learning'

Maker-learning can be seen as [1, 3] a complex intertwined learning process of embodied/haptic, social/dialogic, and rational/critical experiential learning in Zones of Proximal Development (ZPD) [10]. Maker-learning in the ZPD involves support from more capable peers or scaffolded support from library staff and academics. The primary cultural-historical 'tension' [9] apparent in the historicity of the case study [1] maker service within the wider maker movement was the attempt to cater for the different sides of maker culture that are both 'counter-cultural and anti-consumerist and mainstream business opportunities' ([11], p. 154).

As a business opportunity, maker-learning often attracts entrepreneurial engineering and business students and can have a male bias. Research [12] has closely looked at makerspace literature and discourse, finding technical jargon, the garage-like nature of many makerspaces, and women's self-identity as potential barriers to more gender-balanced maker learning. Feminist perspectives have also highlighted how culture has traditionally defined makers as male [13] and how maker culture is built on traditional patriarchal values [14]. Research has also observed that academic libraries need to be wary of 'uncritical approaches to making' [15] that ignore the intersectional challenges of trying to create an inclusive environment regardless of race, class, and gender.

Barton [16] questioned whether introducing historically feminised crafting practices, as many makerspaces with an inclusive ethos have done, is enough to address the complex 'points of intersectionality, such as race or class' [16]. However, the case study [1] makerspace service was working on trying to meet different students' perspectives through the 'relational agency' [17] of the new Experiential Learning Librarian. This new post was focused on addressing inclusivity and diversity issues through meeting course outcome commitments and personal student interests through promoting the maker service's wide range of activities (e.g., workshops on Technology in the Arts, Communication for Engineering and Technology, Digital Sculpting and Design thinking). In the more in-depth maker help sessions, the makerspace support team started with the empowering question, 'what is it you want to do?' [1, 15]. The CML-based ethical model of maker-learning is therefore built on an attempt to transcend the restrictive categories encountered above.

3.1 The sustainability challenge

Sustainability is also a key challenge for makerspaces recognised at the case study site, as evidenced by the Critical Making for Sustainability workshop offered [1, 2]. Such processes as 3D printing that produce large amounts of plastic, present environmental issues. Against this, however, there is potential in the many ways maker technologies, including 3D printing, can be used as part of repair and replacement activities. For example, local hubs ([18], p. 159) are used for printing everything from iPhone cases to masks for local healthcare workers (as with our university library's 3D printers used during the Covid-19 lockdown when there was an initial government shortage).

Recently within the maker movement, there has been an increasing focus on sustainability issues. Among London's 'Maker Mile' of workshops and fab labs, *Opendesk* allows customers to match furniture found online with the nearest fabrication lab, where it can be made on-site, thus cutting costs and pollution from supply chains [19]. *Precious Plastic* [20], also developed in the Maker Mile by Dave Hakkens, is an open-source platform for reengineering plastic rubbish into furniture and household items (e.g., bowls and cups). The maker movement's increased sustainability focus can also be seen globally. For example, the German-based 'ecoMaker' project [21] is aimed at educational institutions and the wider maker community worldwide. 'Eco Sprints' are proposed as a maker-learning activity whereby part of maker items or products are reviewed for eco-friendly alternatives to the materials used. For example, a desk lamp was re-designed with a wooden stand and an energy-saving bulb [2–4, 21]. The ecoMaker design framework methodology has been adopted widely, including the largest Berlin makerspace, the VINN: Lab [5, 21]. However, questions remain about how makerspaces can fit into more ecological learning and development frameworks within HE, which invites a more nuanced understanding of broader techno-consumer culture.

3.2 Questioning techno-science and consumer culture

The social sciences and humanities have a long history of perspectives critiquing the excesses of technoscientific 'progress' and the consumer mindset that has led to the exploitation of people and ecosystems. From a phenomenological perspective, Heidegger explored how 'being' in the age of technology involves an 'enframing' of machines and materials into a 'standing reserve' of potential resources ([22], p. 217). This 'standing reserve' distorts us from the world as it is and leaves us 'unfree and chained to technology' ([22], p. 217).

Post-Marxist theorists have observed how consumer capitalism alienates human experience from material reality. For the Frankfurt School critical theorist Theodor Adorno all more meaningful culture had been reduced to a 'culture industry' producing a banal cornucopia of unchallenging 'artistic' products that supposed people 'as incapable of looking suffering in the eye as… of exercising thought' [23, 24]. In 'The Society of the Spectacle' (1967), Guy Debord identified the emerging dominant cultural milieu of post-modernity whereby consumer society enforces an ongoing essentially meaningless passivity through commodities colonising social life. With the 'having' of new products through advertising that fetishises appearance being pervasive, the possibility of an authentic community is eroded [25].

Later post-modernist theorists, such as Baudrillard, observed a further retreat from material reality in the quagmire of meaningless media signifiers of entertainment and advertising media. For Baudrillard, images can draw us into a hyperreality that 'has no

relation to any reality whatsoever, it is its own pure simulacrum' [6, 26]. However, the possibility of ethical-maker-learning offers a human-agency-based challenge to this level of pessimism (sometimes inherent in the post-modern idiom). More recently, feminist philosopher Barad's 'agential realist' ontology positions technoscientific practices as a drawn out 'expression of the objective existence of particular material phenomena…It matters which cuts are enacted: different cuts enact different materialised becomings' ([27], p. 361). This viewpoint marks a welcome acknowledgement of our immediate ethical responsibility for our practical activities whilst also recognising the '*vibrancy*' of material phenomena [28]. As one of the textile students spoken to during the maker-learning case study observed: 'I am interested in what the materials can *do*' [1, 21]. Here again, we see an opportunity to transcend technoscientific pessimism with an exploration of new possibilities in ethical and aesthetic maker processes.

Maker-learning has become increasingly commercialised [1] as part of our fast-moving STEM-driven techno-culture, seemingly mirrored across the humanities, arts, and social sciences as theories and concepts often slip by fast as part of the same restless zeitgeist. This constant theoretical flow is often at the expense of any depth in understanding in terms of linking up with cross-disciplinary thought or reaching out proactively to society-wide movements for progressive change (such as Black Lives Matter or the environmental movement influenced by Greta Thunberg); Progressive movements concerning which, if we are adopting a *critical* or *ethical* pedagogy, 'we should be anything but cynical' [29, 30].

This potential move towards seeing a progressive value in ethical-maker-learning is in keeping with the anti-colonial Critical Pedagogy that originated with Paolo Freire [31]. Freire's education model encourages human agency and resists the 'banking' model whereby students are seen as empty vessels to be filled unquestioningly with the dominant ideology. Looking closely at the current discourse of 'skills for jobs' [32] that dominates contemporary HE, it can be seen how, with the absence of critical and ethical conversations, passive student outcomes are often encouraged:

> *Knowing becomes mere memory-within-silos, acting in the world is reduced to mere performance of skills-for-employability, and being is placed in jeopardy, locked into the frozen stances of the world ([33], p. 129).*

Students may leave university 'unable to perceive critically the themes of their time' [6, 31]. Thus, graduates may start 'careers' with potentially little sense of moral purpose or passion in work started. Worse, the myriad legitimate worries for the modern student that can manifest in general anxiety states that threaten their 'wellbeing' are pushed to the side in the education process (e.g., climate change, anti-democratic politics, the persecution of minorities). This enforced passivity may embed a lifetime of learned helplessness without the realisation that change is always possible through individual courage and collective action. Therefore, potentially *the* critical key student 'outcome' for the twenty-first century HE student is that they 'could be helped to learn democracy through the *exercise* of democracy', which can only be 'assimilated experientially' rather than just verbally [31, 34].

4. Critical making

In the context of the maker movement, we can see the potential for Freirian empowerment in the counter-maker-culture moves of 'Critical Making'. The 'Critical

Making Lab' developed by Ratto [34] at the University of Toronto encourages a holistic creative mix of critical thinking and physical making. The purpose of Critical Making is learning through the making process rather than aiming for quality in final products. Thus, critical-making projects combine materiality with moral concerns. For example, in a 2016 blog post on 'evocative objects', a Critical Making class is described where students were encouraged to 'imagine a world where voting was openly biased' [35]. One of the results was a voting machine with red and green buttons, thus not accessible to those with red and green colour blindness. The object in Critical Making is then used to prompt sociocritical discussion (in this case, on societal biases and privilege).

We can see from this example how maker-learning can bring together sociocritical theory and experiential-making activities, resisting a purely skills-based agenda with new technologies. However, whilst Critical Making can lead to interesting discussions that start to develop a kind of 'critical technological consciousness' [29, 30]. However, Gollihue (2019) cautions that its conceptual focus on problematising particular *things* could also usefully expand its horizons: 'it is not enough to *only* concern ourselves with things. Instead, things must be in relation to the people that made them, the history that surrounds them, and the cultures and practices they represent' [3, 36].

4.1 Critical material literacy

An interest in enabling educational maker processes that could engage with broader ecological concerns for people and the planet led me to theorise a new transdisciplinary concept that could be employed in multiple learning systems. This project initially seemed too daunting a task, as it required more ambitious theorising than our post-modern milieu encourages. Rooted in Vygotsky's (10) project that includes the activity theories engaged with for my case study research, Anna Stetsenko's (2017) idea of encouraging a 'pedagogy of daring' became central to the aims of my maker-learning proposals. For Stetsenko, the human mind 'can be understood to be part of the larger practices aimed at *making* and *remaking* the world' [2, 32].

Stetsenko argues for an ontologically based debunking of the myth that the Academy can somehow be above ethical/instrumental concerns regarding its part in transforming culture and society. With transformation as ontologically primary to our being in the world, our *goals* and *commitments* supersede any givenness of reality ([2], p. 198). The onus is therefore on us as individuals and collectively to 'invent the future, rather than merely expecting or anticipating its "automatic" arrival' ([2], p. 233): 'This requires both a thorough foregrounding of the historically formed locations from which being, knowing and doing are launched *and* a consideration of how the sought-after future is playing out within these processes' ([2], p. 236).

To ignore this central transformational ethical ontology as part of our understanding of being is to succumb to the neo-liberal delusion of the *sovereign individual* [37]. This uber-individualist mentality, so prevalent in current reactionary politics, is often driven by high-net-worth individuals who protect their power through highjacking traditional conservatism, thus, superseding ethical, democratic debate with a game of who can lie largest for personal gain. To counter the global currents of market fundamentalism, populism and extreme individualism, there is a need for progressive interests to step beyond comfortable abstract intellectual spaces towards more practical counter-hegemonic 'instrumental' aims. The possibility of actively changing society, speaking truth to power, from an ethical-ontological base of ecological awareness in an *instrumental* manner, is simply to attempt to have adequate ideas and practical plans for the future of life on earth.

Through in-depth maker-learning research [1]. I thus expanded from Ratto's Critical Making concept [34, 38] to develop the idea of Critical Material Literacy (CML) as defined at the start of this chapter. CML is a transdisciplinary pedagogical concept that could be used for learning about sustainability issues and human exploitation in large and small-scale 'maker' processes. For example, activities such as deconstructing an out-of-use iPhone to investigate the impact of the materials used, in terms of the use of rare earth metals or the possible exploitation of child workers in its construction [1, 21]. Ethical-maker-learning activities involving CML could be taught dialogically but can benefit from the haptic exploration of the material components of new technologies and products. Aims could be designed for 'learning outcomes' of a critical nature or actual (ethical) prototypes, projects and products meeting local and global ecological and humanitarian challenges.

4.2 The embodied, experiential, social and purposeful nature of ethical-maker-learning

Ethical-maker-learning could be taught without any practical haptic and embodied activities. However, this could be an impoverished version of the potential for this kind of learning. The current cognitive science of the mind is finding consciousness to be an embodied phenomenon:

> *Minds like ours are not in the business of representing the world in some passive, descriptive manner. Instead, they engage in complex rolling cycles in which actions determine percepts that select actions ([39], p. 268).*

The embodied nature of consciousness is an emerging theme in cognitive science, as seen in the 'extended cognition' hypothesis (e.g., 'We can perform operations with our hands that are akin to those we perform in our heads' ([40], p. xii)). However, it has a long philosophical history, originally foreshadowed by phenomenological perspectives. Heidegger's concept of *handiness* was his ontological categorical definition of beings as they are in themselves [41, 42]. Later, Merleau-Ponty observed how all our existential modalities, including motricity and speech, are predicated on the body's natural power of expression: 'Consciousness holds itself responsible for everything, it takes on everything, but it has nothing of its own and makes its life in the world' ([43], p. 479). More recently, biology and neuroscience have expanded the picture beyond the reductionism of previous 'brain' science to acknowledge the importance of embodied social experience ('that's how we learn- context, context, context' ([44], p. 672). Embodied social engagement can thus be seen as essential to forming the human mind: 'The brain is a dynamic, plastic, experience dependent, social, and affective organ' ([45], p. 85). Consciousness, as these perspectives suggest, can now be seen as an entirely embodied and experientially formed phenomenon. Following this emerging science, education for forming a 'critical consciousness' [31] regarding making processes' material, ecological and human impact needs to be, in part, an embodied and social/dialogic process.

In addition to the embodied, experiential, and social elements in effective maker-learning, a fourth element can be added: allowing a 'pedagogy of purpose' [46] in all forms of education, including 'higher'. It is important that ethical-maker-learning and CML do not become part of a tick-box culture where academics and students are not allowed to shape conversations around what sustainability means from their perspective and what contributions to ecological thinking and acting they can realistically contribute to. An ecological awareness as a pedagogy of purpose is not easily a

mechanistically measurable outcome but rather a virtue to be encouraged that can lead to more meaningful and fulfilling careers. Thus, careers should not be wholly focused on pay scales or quickly succumbing to 'the allure of prestige', resulting in well-paid but potentially 'profoundly unfulfilling' jobs [10, 46]. As Keogh argues: 'a pedagogy of purpose will not view this person's education as a success, despite every measure indicating the contrary' [10, 46].

In addition to Keogh's philosophical argument for a pedagogy of purpose, scientific findings from Affective Neuroscience can be drawn on to support more purposeful educational practices. The neuroscientist and human development psychologist Immordino-Yang has recently found how emotions play a crucial role in our learning processes, even to the extent that it can be argued that: 'Creativity… is basically what happens when learners bring relational, emotional knowledge to bear as they make meaning of technical, academic information' ([47], p. 107). Low-level, non-conscious, physiological processes related to survival are potentially critical contributors to motivation ([48], p. 166), with rational intelligence inseparable from 'emotion, and from subjective, self-relevant goals' ([49], p. 185). These findings could account for the playful spirit of enquiry and enjoyment in learning I have observed in the makerspace ZPD between students across disciplines, academics, librarians and learning technologists when framed by personal passion projects and ethical, environmental and social justice concerns.

Non-conscious (and conscious) anxieties concerning powerlessness against eco-catastrophy are, therefore, a good argument for a pedagogy of purpose concerning sustainability and ecological thinking. Enabling a meaningful ecological and socially aware pedagogy relevant to the existential threats of our time is potentially essential for all disciplines: 'We are learning by bitter experience that the organism which destroys its environment destroys itself' ([50], p. 491). Thus, ethical-maker-learning can provide a meaningful, values-focused and inspiring pedagogy of purpose that engages with important contemporary philosophical debates on ethics and morality. These difficult conversations seem to be avoided in much of the 'skills' focused modern Academy, yet without them coming to understand our ethical position on important matters effectively is very difficult. This absence of rigorous debate on pressing climate and social justice issues, dismissed in the eco-ostrich discourse of mainstream media, potentially leads to a soulless sense of fragmentation for the individual. It is only through an authentic dialogic understanding of the existential threats all humans face and what realistically can collectively be acted on that a unified sense of being-knowing-doing [2] is possible: 'it is the person who acts in accordance with the best constitution, the most unified constitution, who is most truly the author of her actions' ([51], p. 125).

As I have theorised, in addition to the philosophical/ethical argument for more experientially based ethical-maker-learning, there are critical pedagogical concerns rooted in the recent claims from Affective Neuroscience regarding positive social emotions (such as embracing virtues) being directly related to neural activation beneficial for our physiology in the learning process:

The most notable implication for education is that meaningful, socially relevant thinking *moves* us - inspiration changes our physiology, heightens our conscious awareness, and impels us to act purposefully towards our goals ([49], p. 165).

5. Ethical-maker-learning: towards an HE framework

The **Table 1** looks at how ethical-maker-learning, including CML teaching, can be delivered in HE learning environments through Stesenko's pedagogy of daring [2].

Although Stetsenko argues for the value of a Transformative Activist Stance (TAS), it is important within HE to listen to opposing views, which an initial emphasis on activism may discourage. An open, dialogical perspective is in keeping with the Activity Theory maxim 'thinking occurs as much among as within individuals' [46, 54]. 'Activism' is often necessary for progressive causes (e.g., Martin Luther King, Mahatma Gandhi and Greta Thunberg would not have got very far without their well-thought-out and peaceful activism), but it is not always a good initial paradigm for research. However, in critiquing TAS, I do not wish to question the importance of Stetsenko's idea of a 'pedagogy of daring'. If we wish to involve students in the existential problems facing humanity in a realist manner, challenging conversions are necessary. In addition, a TAS-based methodology would make sense if a student has developed a more radical position through a deep understanding of a topic and an accompanying sense of responsibility to act, such as towards any practical and effective move that resists

STEAM category	**Ethical-maker-learning activity**	**Acquisition**	**Participation**	**Contribution/ daring**
Sciences	Create pedagogical models and puzzles to help with material awareness	Obtain knowledge of the 'value' of different materials [18]	Share design ideas and discussions on HE teacher-share platforms	Use best designs for challenging conversations and raising Critical Material Literacy (CML) awareness
Technology	Curricula and co-curricular Technology Enabled Learning (TEL) projects for all in a cross-disciplinary maker space	Learn skills with emerging technologies through the university, providing access to all students	Local councils and universities organised 'healthcare champions' competition	Create bespoke technologies and equipment for local disability needs with sustainable materials
Engineering	Making technological prototypes to solve local sustainability problems	Learning an ethical design process for new technologies and products	Local councils and universities organised sustainability competition	Produce open-source university-endorsed sustainability products for local use
Arts	Exploring eco-friendly, junk and recycled materials to see how they can be used for art and design projects	Learning to manipulate eco-friendly materials for artistic purposes (e.g., bamboo sculptures)	Demonstrate student art using innovative eco-friendly materials at exhibitions	Enable eco-'Craftervism' [52] based activities targeting un-ethical eco practices
Mathematics	Exploring the possibilities for creating new quantitative data analysis programmes to help with ecological challenges	Learning how to address ethics in a progressive manner in the software design process	Sharing emancipatory ideas on online platforms	Connect students with ecologically ambitious projects (e.g., ICARUS animal monitoring [53])

Table 1.
Pedagogy of daring activities supporting STEAM (science, technology, engineering, arts and mathematics) based ethical-maker-learning.

the uber-capitalist fantasy of infinite growth on a finite planet. Although most post-Marxist progressives may not be looking for potentially violent immediate class-based changes, there is still a responsibility to act from moral convictions against clearly evidenced social and environmental injustice. There is, therefore, still value in the spirit of change through organisation and solidarity Marx advocated: 'To break with the "party form" or with some form of the State… does not mean to give up every form of practical or effective organisation' ([55], p. 112).

5.1 Table 1 explanation

Philosopher of Higher Education Ronald Barnett recently [33] (building on Felix Guattari's thought linking the psyche, society and Nature [56]) made a bold case to challenge universities to go beyond merely increasing their understanding of how Western technoscientific instrumentalism is damaging earth systems. Barnett argues that universities must orchestrate disciplines and research to prioritise a new 'Constitution' of '*critical stewardship*' of whole earth systems through nomadic cross-disciplinary inquiry ([33], p. 243). There is much to commend this call to action, and ethical-maker-learning and CML could be among the essential concepts in this transdisciplinary space. Thus, universities could start to individually and collectively help to put humanity on a more harmonious course towards '*ecological justice*', with academics and students called to: 'imaginatively and fearlessly… envisage new concepts, new ideas and new frames of thinking' ([33], p. 246).

The **Table 1** begins to broadly map out some possibilities for the contribution of ethical-maker-learning to STEAM pedagogies in the Academy. Regarding learning in the physical, chemical, and biological sciences, pedagogical models and puzzles are suggested to focus on material awareness. In her monograph 'Material value: More sustainable, less wasteful manufacturing of everything from cell phones to cleaning products' (2019), Goldstein breaks down the materials that go into the products we use daily. Just teaching insights from experts such as Goldstein would be informative in terms of transferring knowledge. For example, the extent of greenwashing often occurring in products mislabelled 'natural' can be exposed, with a call for more responsible manufacturing from NGOs and companies: 'It should be possible for a company to make money without endangering its employees or customers' [18, 39]. Ethical-maker-learning could expand on this knowledge acquisition in the sciences by creating models and puzzles of materials that could be combined in more eco-friendly ways. Critical educational maker models can help ensure science education is not devoid of the challenging conversations and debates often associated with the humanities, for example, discussing issues around the politics of technoscientific progress.

Through critical maker-learning models, Technology-Enabled-Learning (TEL) could move beyond focusing on digital capabilities with computers, laptops and smartphones to expand into a deeper understanding of the possibilities and dangers of emerging technologies. Digital capabilities often only focus on skills for software or programme use without looking further at the material interactions enabled by much digital interface technology such as 3-D printing, laser cutting and robotics. To enable ethical-maker-learning with these technologies, a cross-disciplinary makerspace is helpful (Academic libraries are often well placed to support these services; [1, 3]). Once established, the maker-space service can organise events and competitions such as the 'healthcare champions' one suggested above, which would aim to contribute to wider society by providing post-competition support for creating usable products and technologies with ethical purposes [57].

Connections can also be made to industry, where progressive maker-learning projects can connect with circular economic models and more ambitious aims to work towards material alignment with biological and technical food chains: 'We do not have an energy problem. We have a materials-in-the-wrong-place problem' ([58], p. 211). Maker-learning is already well established in many university engineering departments as a way to think about larger manufacturing processes and projects. In the case study makerspace service [1], an interesting yearly competition for students from all courses was set up to develop a new technology or product to help with local sustainability issues; good ideas from competitions such as this would then be shared. The university competition had yet to generate a practically usable device; this is where Engineering and Business departments could be more proactive and contribute more practical expertise in similar schemes.

Within the arts, maker-learning has already connected with Digital Humanities in interesting ways, such as developing a poesy (romantic poetry) remixer ('Intimate Fields'; [1, 16]). Arts and humanities projects such as 'Intimate Fields' show how creative activities can engage students beyond just educating for the supposedly 'rational' primary aim of economic profit. Digital Humanities/STEAM-based hybrid activities can help challenge value systems in HE pedagogies to celebrate aspects of lived experience the Academy may curtail: 'The joy of living, solidarity and compassion… must be protected' ([59], p. 266). Arts-based ethical-maker-learning can also engage with eco-friendly materials, where successful results can be shared. More ambitiously, more *critical* learning models could be introduced. For example, 'Craftervism' [52] is a gentle but surprisingly effective form of protest where business leaders and others in authority are challenged with meaningful questions about ethical concerns, such as low pay among workers. This form of non-violent persuasive activism could be encouraged for those students with a particular local or national cause supporting CML and ethical-maker-learning aims they wish to promote.

Lastly, in this initial STEAM-based ethical-maker-learning ideas table, maths, in conjunction with computing, offers many opportunities to explore ways of making new software and programmes with a sustainability focus. As shown above, another more daring model would be to get students to work with ambitious ecological projects and placements such as the International Cooperation for Animal Research Using Space (ICARUS; [53]). ICARUS looks at how the migratory patterns of animals are being affected by climate change to better protect them in future through mini transmitters attached to animals being monitored by receivers in space. The ICARUS project is thus an *internet of animals*. As Bridle points out in 'Ways of being', ICARUS is part of a potentially beneficial 'ecology of technology' (that might also possibly include 'fungi, plants, bacteria and stones' in our stewardship to join the 'demos' of our 'more-than-human commonwealth'; ([60], p. 300, 301). Thus:

> *Technologies of control and domination become instead technologies of cooperation, mutual empowerment and liberation ([60], p. 213).*

5.2 Developing ethical-maker-learning for empowerment and ecological justice

Below are some initial suggestions for developing *paths of possibility* (Barnett, 2022) for ethical-maker-learning and CML in new TEL-enabled transdisciplinary models within and beyond the makerspace concept for HE, accepting there are many possible *lines of flight* [61] towards more democratic, ecologically aware participatory

ways of being. We need not have a fixed destination or insist puritanically on only *our* path but must take care to understand others' contexts and environments. As the influential early Enlightenment philosopher Spinoza realised, an ethical *conatus* of mind, body, and matter is essential for humanity to live in harmony as a part of Nature. A mind that forms *adequate* ideas through *reasoning*, *understanding*, and *courage* can work to avoid destructive emotions and enable better ideas that lead to positive action: 'the mind is passive only to the extent that it has inadequate or confused ideas' ([62], p. 101). With our contemporary knowledge of the interdependence of ecological systems, there is a need for all disciplines to start 'thinking in terms of relationships, patterns and context' [63, 64]. Thus, there is a clear educational need to strive towards an ethos of caring for each other *and* the beyond-human world, inviting diverse symbiotic systems to help avoid ecocatastrophe.

The solidarity I am asking for is essential for realising the 'perhaps' of Barnett's vision of the *ecological university* [5]. Whatever our philosophical musings and viewpoints on ontology and epistemology, we all live in the same reality. We (humans, in particular as part of 'advanced' industrial nations) have to take responsibility for our historic and continuing damage to the earth by promoting new forms of ethical stewardship, resisting the siren call of a techno-determinist post-humanism. As Stiegler warned regarding the danger of diversion from ecological responsibility, post-humanism combines well with 'economico-political *interests* that want at all costs to *avoid the question*… [of transformational technologies, critiquing consumer capitalism and avoiding eco-catastrophy]. Post-humanism is… a smokescreen' ([65], p. 117, 118). Therefore ethical-maker-learning would intend to include science-based material literacy as part of a cross-disciplinary curriculum. Ethical-making projects could be introduced relevant to course foci, with the broad frame of supporting sustainability. As argued, projects need to involve haptic/embodied elements and dialogic discussion involving challenging conversations around social and ecological justice.

As a pedagogical move based on increased scientific awareness and cross-cultural humanist interests, CML and ethical-maker-learning resist simplistic anti-Enlightenment rhetoric, which is counterproductive to 'de-colonising the curriculum'. Whilst critiquing the Enlightenment is necessary, the complex dialectical history within the 'Enlightenment' must be addressed, including the first wave of de-colonising efforts in the nineteenth century from Enlightenment-influenced Peruvians and Colombians [66]. Reasoning, logic and science are not wholly Western cultural constructs to be deconstructed and 'de-colonised'. For example (from [67]), the formal logic developed in India, such as the Vaisheshika school's analysis of atomism, Mohists in China with their attempt to combine logic and language with a comprehensive ethical theory on governance for the state and individuals' role within it, the strength of mathematics and science in early Islamic culture with figures such as Muhammad ibn Musa Al-Khwarizmi who introduced Hindu-Arabic numerals and the concept of algebra into European mathematics, or the compassionate and rational African philosophy of Ubuntu which strengthened community equality (and survival) in agrarian communities.

Ethical-maker-learning project outcome examples could provoke challenging trans-disciplinary conversations involving students trying to *make explicit* the values and reasoning of their political, philosophical and ethical positions concerning CML-provoked arguments in a *spirit of trust* (Brandom, [64, 68], respectively). This means resisting a supposedly neutral 'economic' framing for climate education that will dampen any hope of positive action: 'The result of the economic framing and the turn to depoliticisation emphasises knowledge without action and downplays the role of responsibility, ethics

and values in sustainability and climate change education' [11, 49]. Discussions could be enhanced by connecting academics across disciplines and professional staff involved in promoting ethical-maker-learning to local ecological fora to stimulate new ideas for learning, resisting the 'rigid parameters around many of the disciplines' ([69], p. 90), such as connecting to Regional Centres of Expertise (RCEs) focused on Education for Sustainability Development (ESD).

Universities can build from these debates new understandings regarding potential new progressive ecological concepts and ideas, resulting in an evolving *culture of constructive argument* (CCA [33], p. 83). As a balance to more potentially passionate debates, ethical-maker-pedagogies could allow for more mindful, slower, reflective activities involving handling new eco-friendly materials, technologies and products as part of an open, dialogic post-Enlightenment but scientifically aware *critical humanist* focus on *narratives of worldly care* ([70], p. 190). As part of the university's focus on employment opportunities, students could be encouraged to work with companies and NGOs on placements that have aligned their interests to ecological and progressive concerns and encourage a participatory culture, such as Alexander's *New Citizen Project* [24]. The lived experience gained from these placements could then be used to discuss potential new meanings from contextually established knowledge and its practical possibilities: 'Whereas creativity is the use of imagination to transcend traditional ideas..., innovation is about giving these things new meanings that lead to changes in the system' ([71], p. 116).

Post-placement discussions would need to be carried out across faculties, and the urge must be resisted to act holier than thou in particular disciplines on ecological matters, letting *all* into the central dialogic *becoming* of the ecological university. Although we may be reaching the apotheosis of neoliberal market fundamentalism, it is difficult to imagine a democratic future for humanity without some element of business practice or markets. Ethical business is surely not a misnomer, as the liberal educator John Dewey opined: 'How unreasonable to expect the pursuit of business should itself be a culture of imagination, in breadth and refinement; that it should directly, and not through the money it which it supplies, have social service for its animating principle' ([72], p. 136). Thus, ecological virtues could become part of guiding principles for *all* businesses as part of their vision for the 'infinite game' [42]. More ambitiously economist Mariana Mazzucato argues for the value of 'mission orientated' projects across an entrepreneurial public sector *and* a private sector focused on 'stakeholders' rather than purely profit-obsessed rentier extraction from the market, including addressing environmental concerns: 'Making sure our earth remains habitable demands the same ambition..., public-private risk-sharing and sense of purpose and urgency as the Apollo project' ([73], p. 226).

6. Conclusion

There is always a potential reaction to ambitious pedagogical ideas such as those proposed here, which are overtly ethical and progressive. Some in the Academy might challenge ethical-maker-learning's supposed 'utopian' nature. Given our current climate emergency predicament, this viewpoint seems defeatist. Others might see Critical Material Literacy (CML) as elitist, condescending, or too controlling. However, it is a peculiar feature of late neoliberal consumer culture that: 'To tell people how to lose weight, or how to decorate their house, is acceptable; but to call for any kind of cultural improvement is to be oppressive or elitist' [73, 74]. Better ways

of being with new technologies and engaging with their possibilities in an ecologically aware manner *are* already becoming possible. For example, Fairphones [75] make phones with a concern for the planet *and* avoid exploiting people. Framework laptops [76] allow 'consumers' to repair and upgrade their products. This suggests an untapped potential in coming generations, requiring educators of all kinds to work with imagination and courage to bring about new educational *paths of possibility* ([33], p. 215).

The call here is to explore ways for the Academy to take the lead on exploring ways for us all to find more responsible, ecologically aware ways of acting as global citizens: 'knowledge is no guarantee of good behaviour, but ignorance is a virtual guarantee of bad behaviour' ([77], p. 81). Therefore, I propose ethical-maker-learning and the related concept of CML to help frame new transdisciplinary pedagogic systems in HE. The request implicit in this chapter is for other voices in the Academy to act as critical friends and contribute different ideas and concepts in this new eco-pedagogical movement of purpose and action, with the aim of sustainability issues becoming the *primary* focus for universities' ethos, working towards a new ecological *Constitution for Universities-on-Earth* ([33], p. 245). Contributions could come from willing academics, educational developers, librarians, learning technologists, careers, IT, facilities and *all* staff and students who work and study at universities.

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Chapter 12

The Ethical Management of Scientific Research in Islamic Higher Education in Indonesia

Ahmadi Ahmadi

Abstract

Widely accessible management is the essence of ethical management of scientific research. This article aims to elaborate on the core ethics, planning, implementation and evaluation of research in Indonesian Islamic universities to contribute to global peace. The research method through content analysis is framed in a qualitative descriptive to suit the publication of the book chapter "Ethics in Scientific Research-New Perspectives." The results show that; (i) Islamic ethics, scientific paradigm, and technology as the foundation of research management, (ii) research ethics planning through the establishment of scientific research applications and technical manuals, (iii) implementation of research ethics through the One Taught System (OTS) http://litapdimas.kemenag.go.id/index.php/, and (iv) evaluation of research ethics is carried out by reviewers in the fields of proposal material, research process, financing, outcomes, and research committee policies in a balanced manner.

Keywords: ethics management, scientific, Litapdimas, Islamic higher education, multidisciplinary perspectives

1. Introduction

Research is a joyous work, because in it there is an element of adventure exploring the outdoors, gazing at the vast expanse of space, listening to various boisterous and beautiful sounds. For example, an eagle flying freely, in a tropical forest, while listening to flickering on the ground, wide-eyed eyes observe the movements of small animals on land that are ready to be approached to be pounced on. Zeraffe animal that sticks its head in an upward position to listen carefully to the movements that are happening around it, even though its ears are still deaf but still trying to find something that is happening.

Research makes institutions, companies and universities more advanced and empowered [1]. Some universities make research a grand strategy or differentiation strategy, because the core business of higher education is in the TriDarma of Higher Education, namely education and teaching, research and community service. Research results help to understand the ongoing reality. The continuity of this meaning encourages research to be carried out continuously, so that research has a real contribution to social life [2, 3].

Ethics and science in research are two words that are urgent to discuss in the context of global research [4, 5]. Ethics is a truth of general norms that is demanded in the depths of the heart and also demands the wishes of research customers to both achieve excellence, so as to achieve quality sustainability and an honorable degree of dignity. Scientific refers to the truth of the facts of the instrument, reality, philosophy, theory and also policy, so science becomes the spirit in the stages of research activities both at the local, regional and global levels.

2. The principle of paradigm

2.1 Pillar instruments

This hearing is a central principle in scientific research in Islam; as Muhammad SAW said that it is sunnah for newborns to be heard by the call to prayer and Iqomah and given a good name. Because limbs, when a newborn, the most effective is hearing. The Qur'an conveys that Allah SWT has created the ear to have a hearing function to receive various incoming sounds. His word, when you hear a call in the form of a call to prayer, namely the call to pray, but if you do not pay attention, you are classified as deaf [5].

The eye has the function of seeing the object that is aimed carefully and thoroughly. The eye is formed to receive stimulation of color, light, and shape beams through the retina and then through the fibers to the center of vision in the brain. This careful vision, in research, is known as observation activity, namely the activity of observing a focus in depth according to the research objectives to explore the explicit and implied meanings in it. The data domain becomes hypothetical concepts. The data is in the form of a towering mountain that looks beautiful green from a distance, captivating anyone who sees it, but if a closer observation is carried out, variants of the construction of plants, animals, shrubs, valleys and hills will appear. Rolling cloud data, when in-depth observation is carried out, it will produce various cloud rolls, and also flock while walking from one position to another to captivate the eye to explore more deeply too. Through eye sight, you will get a lot of data, to be classified, reduced, concluded so that it becomes accurate data. Data analysis theory presented by Mile & Huberman and Condensation [6]. Those are the same at Qhosiyah Alquranul Karim.

Appreciation is an activity to feel something so that oneself becomes part of something that is internalized (learning to be). The effective theory introduced by Crotwal is that the affective process goes through the stages of receiving, responding, valuing, organization of values, and internalization of value sets. Appreciation is a process of consultation and contemplation to obtain positioning certainty. Deep inner intuitions have contributed to this experience. The process of transactional orientation as conveyed by Miller & Selller that knowledge can be formed through transactions with the natural surroundings [7].

Intellectual reasoning power (analogical reasoning) has a left, right, back and front brain that can synergize to carry out activities of classifying, concluding, calculating, and giving views of mind to determine a policy that must be decided. This intellectual reasoning power can distinguish it from other animal creatures. Humans are given this intellect as a provision to solve life problems that become a better life as the mandate received by Prophet Adam As. Namely caring for the earth and everything in it.

The heart is the most important part of the body. The portrait of the human body can be seen from the portrait of the heart. If he expresses good, then all limbs will be good too, and conversely if he shows bad, then all limbs will be bad either. God says that…He has put the spirit in the human body and before blowing it, He asks the spirit….am I your God, the spirit immediately answers…truly I testify that You (Allah SWT) are my God. The meaning of this interaction shows that in the process of appreciation there are clues that lead to the essence of truth. The deep impression of the dialog gave a deep impression on the heart. So he has the sharpness of examining, sorting, classifying, reducing and deciding the facts of the real data, because he is a place where the spirit is seeded which has the rays of the oneness of God. This deep impression always accompanies space, time and activities carried out by scientific researchers.

2.2 Multidisciplinary perspectives

Empal genthong vegetables from Cirebon, Indonesia, bring delicious flavors. It depends on the chef's ability to mix various ingredients to create a unique taste. The raw ingredients are beef, spices, vegetables, seeds which are poured in boiling water to a certain degree, then sugar, coconut milk, and seasonings are added. The end result of cooking finds a very delicious taste.

The activity of carrying out research is a process of delicacy of a scientist to find the essence of truth of a value system. These activities go through a process of hearing, seeing, appreciating, analyzing, and tentatively concluding. Temporary reductions need to be continued or tested for truth through scientific research viewed from various dimensional perspectives to achieve further wholeness of truth. The truth that is blessed with views from various perspectives is believed to have a more unique and delicious taste of truth.

The Benefits of a Multidisciplinary Perspective on data facts can increase a person's wisdom in thoughts, attitudes and behaviors, thus leading to be more wisely and authoritative. Views on each perspective as follows; (i) Data Facts: the researcher sees a focus problem in the form of object facts which can take the form of solid objects, liquids, living creatures of humans and animals, plants, numerical sequences, matrices, percentages, tables, curves, flowcharts, charts, narratives, and etc. This truth leads to the reality of existing data facts. In the research content, each has an implied meaning that needs to be interpreted as a variant of meaning as well, (ii) Fact Concept: the researcher sees the fact that the data forms groups according to the similarity in type and shape and number. The formation and grouping tends to show the same characteristics, even the explicit and implied meanings within the new formation and grouping framework can be interpreted by researchers with various meanings, (iii) Theory Facts: The acquisition of theoretical facts, namely in the form of solid values forming a system that sturdy. The value system needs to be consulted with relevant theories to find compatibility between theoretical facts and relevant theories. The degree of suitability can give the meaning of suitability and accuracy in terms of the effectiveness of the theory being referred to, (iv) Policy Facts: research needs to obtain whether the policies that have been enacted are still worth considering. The form of policy can be in the form of laws, presidential regulations, ministerial regulations, and decrees of units of Islamic higher education. Through the policy fact guide, research activities can guide positive law in the Republic of Indonesia, (v) Fact Method: Methodology as a basis for the perspective of research implementation procedures, both qualitative, quantitative, mixed methods, research & development dimensions, so that it is a point of perspective that needs to be consistently carried

out by researchers. The link between policy facts and others needs research attention to maintain balanced harmony, (vi) Philosophical Facts: Process philosophy shows that differences in space and time have different constructions of truth reality. The ontology of becoming should be constructed to gain a purity of reality among time, place, space. It refers to the views of several philosophies; essentialism, existentialism, realism, idealism, perennialism. Research aims not only to find the truth of data, but also to reach the essence of truth.

2.3 The ultimate ethics

Islamic tertiary institutions own and carry out the tasks of the Tridarma of Higher Education namely Learning Education, Research, and community service. Islamic tertiary institutions in Indonesia Each tertiary institution has a variant and strong preference distinction; for example, UIN Sunan Ampel Surabaya confirmed itself as a Twin tower campus for Education and service, IAIN Ponorogo became a research campus, UIN Syarif Hidayatullah Jakarta introduced itself to the Contemporary Islamic University, UIN Sunan Kalijaga Yogyakarta became an interconnecting campus for both Interdisciplinary and Multidisciplinary UIN Syaech Maulana Malik Ibrahim Malang establishing itself as the Islamic University of the International tree of knowledge.

Research activities are based on the strong and sturdy paradigm and basic values of religion, namely God Allah SWT. Research views that the reality of the universe is a system of His creation that has been prepared and given to the noblest creatures called humans. Prophet Adam AS and his descendants were given responsibility for the sustainability of nature and its inherent system.

Research is surfing on the canvas of a neat and dynamic universe. Islamic researchers understand, analyze, maintain, manage, and even develop the reality of their research based on Oneness. The reality of nature is a gift from Allah All Mighty, understood with Him, managed together with Him, destined for Him, and the results are also submitted to Him. He is God All Mighty, creating, managing, and destroying natural reality. There is no power except Him, there is no greatest except Him. Finally, His presence in the planning, implementation and evaluation of research creates a sense of peace for researchers to always submit and comply with the values and systems created by Him as well. Guidance and blessings are always present in the preparation of proposals, the implementation of research that can lead to beautiful and peaceful conditions and situations.

3. The ethics planning of a scientific research

An astronaut and space researcher, Neil Alden Armstrong, was the first person to walk on the moon on July 20, 1969. He had dreamed for years of setting foot on the lunar surface and planned the Apollo 11, Gemini 8 spacecraft that would take him to the moon. Nil Armstrong's main mission is to do research that the moon is also a comfortable place for humans. He and Aldin, the pilot of the plane, collected 21.5 kg of lunar material for research on earth. His success in reaching the moon made creatures all over the world admire what, why and how did they get there? This success compass resulted in the construction of a space station that can be used as an information and communication center in the twenty-first century.

Currently, many of the inhabitants of the world feel the heat because of the actions of political leaders who are oriented towards the influence of world power. The hustle

and bustle of disputes over territory and natural resources will immediately have a solution that is equally positioned to have dignity and respect. The friction of the orientation of influence and influence creates frictions originating from the power of science, technology and their respective military forces. The power of the bloc, technological superpowers, the arrogance of figures, and shows of economic power should immediately be softened to become mutual respect, respect and love to synergize with each other. Disputes and mutual destruction are immediately stopped, the active role of world organizations, be it country organizations within the framework of the United Nations, ASIAN, G20, and the like, takes a significant role in stopping this.

Planning policy is very important in research management, especially in establishing the vision of scientific research itself. This determination in Indonesia is the basis for the cycle of planning, implementation and evaluation. The scientific research compass of Islamic tertiary institutions in Indonesia is oriented towards contributing to world peace as mandated by Pancasila and the Indonesian 1945 Constitution. Peace is an important keyword in Indonesia's perspective. Killing one human being is the same as killing all of humanity, and destroying the natural order of life, is the same as creating shocks that can trigger the emergence of catastrophic disruptions that can be sustainable. The icon of "Islamic Moderation" as a grand strategy to create peace and balance to complement, fill, protect, accompany, respect, and appreciate so that each other has existence on its own axis as well. In this context, Indonesian Islamic researchers direct research themes towards creating a world that is safe and comfortable for all its inhabitants.

The G20 Forum, whose presidency is in Indonesia and India, is a forum for leaders of world economic countries held on the island of Bali demonstrating a shared commitment to building synergy and equality communication so as to create world peace. The G20 presidential chairperson has directly invited the presidents of Ukraine, Russia and several other countries to share responsibility for a shared vision in the G20 forum. Along with the G20 meeting there is also the Forum Religion of Twenty 2022 (R20) organized by the Ministry of Religion which is a forum for leaders of religions and sects around the world as an important foothold in scientific research activities at Indonesian Islamic universities.

Moderation of religion and Moderate Islam as a strategic issue so that it becomes the direction and compass of Islamic higher education research in Indonesia; First; Moderation Compass; Research is directed at the contribution of "Moderation" to global civilization. Indonesian Religious Moderation is a paradigm that has perspectives, attitudes, and religious practices in common life by realizing the essence of religious teachings that always protect human dignity and build the public good, based on the principles of fairness, balance, and adherence to the constitution as a national agreement. The glue that binds this nation is an urgent matter for research on religious moderation. Research priority themes for the 2018–2028 fiscal year include; (i) Islamic studies, (ii) Pluralism and Diversity, (iii) Integration of knowledge, and (iv) Global Progress.

Second; Islam Nusantara as a construction of global civilization. Indonesia is a tropical archipelago country that has a variety of friendly Islam as Indonesia's very valuable wealth. Islamic religious leaders broadcast, preach and educate all corners of Indonesia from Sabang to Merauke through strategies of upholding local wisdom and synergizing da'wah strategies for the guardians of the Archipelago Islam.

Third; Digitizing research, the Ministry of Religion of the Republic of Indonesia established an application https://litapdimas.kemenag.go.id as OTS, namely a forum that regulates all forms of homepage account activity, registration, submission of

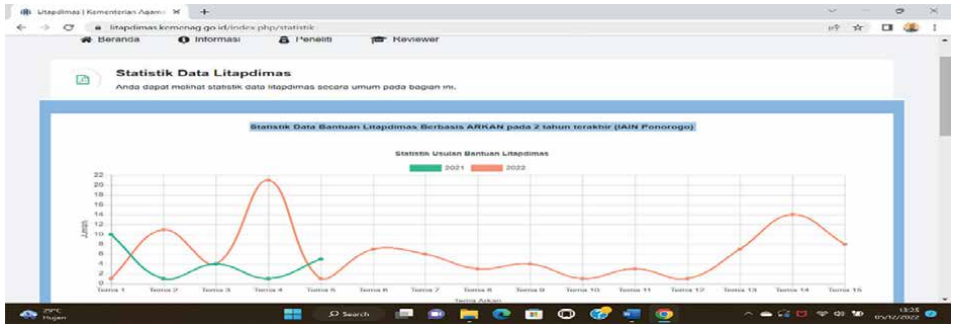

Figure 1.
Statistics of Litapdimas assistance based on the 2022 national religious research agenda (ARKAN). Source: http://litapdimas.kemenag.go.id/index.php/

research proposals, presentation of proposals and research results, and research reviewers, Community Service and Scientific Publications at State Islamic Religious Colleges (PTKIN) and Private Islamic Religious Colleges (PTKIS) under the auspices of the Ministry of Religion of the Republic of Indonesia [8, 9].

The use of this application is used as a form of scientific research ethics planning from various aspects including policies, regulations, and work instructions for research activities, community service and scientific publications. Planning begins with the central Ministry of Religion issuing research guidelines based on Financial Cost Standards (SBK) in the current year which are the guidelines for PTKIN and PTKIS. Research assistance, dedication and scientific publications from the center are called Central Work Units (Central Work Units) and State University Operational Assistance (BOPTN) in higher education work units are called Higher Education work units (Satker PT), so that each tertiary institution can compile books research guidelines, community service and scientific publications independently, as long as they do not conflict with central policy.

Indonesia stipulates ethical regulations for conducting research with nine research standards Regulation of the Minister of Education and Culture number 3 of 2020 concerning national standards for tertiary institutions and Decree of the Director General of Islamic Universities number 102 of 2019 concerning Religious standards for Islamic Higher Religious Education; (i) research results standards, (ii) research content standards, (iii) research process standards, (iv) research assessment standards, (v) researchers standards, (vi) research facilities and infrastructure standards, (vii) research management standards, (viii) research funding and financing standards, and (ix) religious standards of researchers [10] (**Figure 1**).

4. The ethics implementation of scientific research

Research implementation is the process of consistently realizing the stages of research activities. Research activities are reported and recorded in Litapdimas following accounts; (i) Maintain communication channels, complex activities of research, community service and scientific publications that are documented and updated in an orderly and sustainable manner, then implementing scientific research ethics through applications so that documents can be recorded neatly, widely accessed, and updated consistently continuously, then use the OTS application to align the communication channels between these components.

Second; run the application and open the features that present the page; (i) open google search, (ii) browse through the link http://litapdimas.kemenag.go.id, (iii) login via Litapdimas ID, (iv) home page feature; information, researchers and reviewers, v) information features; announcements, guides, discussion forums, cluster data, data directories, and about Litapdimas, (vi) researcher features; proposal, researcher approval, publication, and independent review, (vii) reviewer features; proposal assessment, presentation assessment, and output assessment [11].

Third; cluster mapping, demand requirements, financing and research outputs. Obedience and commitment to research ethics must be carried out by researchers (**Table 1**).

Fourth; The research title must be framed in 15 sub-themes; (i) sacred texts in religions, (ii) shari'ah, laws and regulations, (iii) development of repertoire of Islamic boarding schools, (iv) development of education, (v) state, religion, and society, (vi) ethnic, cultural, social diversity, and religious traditions, (vii) transformative education, (viii) history, archeology and manuscripts, (ix) social welfare in society, (x) medical and health development, (xi) environment, science and technology development, (xii) area studies and globalization, (xiii) gender and justice issues, (xiv) sharia-based economic and business development, and (xv) millennial generation and Islamic issues.

Fifth; The reviewer made an assessment of the research proposal material assessed and commented on by the national reviewer covering the feasibility of the problem background, formulation of research questions, research objectives, research methods, theories used, relevant references, novelty, and relevant bibliography. Reviewers provide an assessment when presenting proposals by researchers including the relevance of the problem background, novelty, outcome, and research funding feasibility [9]. Finally, from the planning of scientific research ethics are the recommendations of the reviewers on the academic text of the proposal and also the value of research funding (**Table 2**).

Sixth; the realization of research in the field researchers carry out the process of collecting descriptive and numerical data takes four to 6 months (March to September) of the current year. Activities in the field to obtain data through data sources, informants, observations, and in-depth interviews as well as distributing research questionnaires to respondents. Researchers continue to carry out reductions and domains to obtain valid and reliable taxonomies and conclusions.

Nu.	Research cluster	Rank	Funding	Outcome
1	Construction research	Expert assistant	16 Million IRD	Sinta 6–4
2	Basic research of study program	Lector	35 Million IRD	Sinta 3–2
3	Interdisciplinary basic research	Lector	36 Million IRD	Sinta 3–2
4	National development applied research	Lector-Professor Associate	80 Million IRD	Scopus
5	University collaboration research	Professor Associate	80–100 Million IRD	Scopus
6	International collaboration research	Professor Associate	100–150 Million IRD	Scopus

Table 1.
Litapdimas research clusters, ranks, funding, and outcomes in 2022 [10]. Source: http://litapdimas.kemenag.go.id/index.php/

No.	Component	Material	Reviewer
1	Tittle	Design of NLP-Based PAI Learning Model as a Model of Strengthening Religious Moderation in East Java Higher Education	Specific, interesting, provocative and challenging. Its substance reflects the solution to the problems raised
2	The Background	Religious radicalism is not only indicated to appear in basic educational institutions, but also allegedly at the higher education level	There is an explanation of the substance of the research focus. Academic contribution. The problem already shows the current issue. The problem is supported by quite strong arguments in support
3	Problem Formulation	How is the Development of a Neuro Linguistic Programming (NLP) Based PAI Learning Model as a Model for Strengthening Religious Moderation in East Java Higher Education?	Already using the correct and specific question sentences, including the focus of research. Relevant to research techniques and according to the problems discussed in the background
4	Review of Research	Discourse on methods of internalizing religious moderation is still a topic that must be studied simultaneously. This is because the seeds of intolerance and violence in the name of religion have the characteristics of eternity (eternality sense)	Does not explain the similarities and differences regarding the findings and methodology. There is a synthesis of the review literature, but it is not supported by strong arguments to explain the novelty based on the differences in the research results described previously
5	Theory and Concept	Religious moderation, NLP and the four concepts of NLP	Theories are discussed in detail with very strong reference support; The theory is very clear and very detailed, providing support for answers to the problem formulation
6	Methods and Instrument	This development research adapts the ADDIE-based research design (Analyze, Design, Develop, Implement and Evaluate)	Explanation of the approach and type of research is very strong. The research steps are explained in detail, measurable and clearly explained in answering the problem formulation; Explanations on data collection techniques and analysis techniques are explained quite strongly
7	Bibliography	28 main books and supporting books and journals	Some are in citations, clear references from primary or secondary sources, consistent in writing, insufficient number of references from journal sources. References are mostly less than the last five years

Table 2.
Sample component assessment matrix for research proposals [11]. Source: http://litapdimas.kemenag.go.id/index.php/

Seventh; reviewers and research committees carry out assessments and decisions by taking into account consistency, commitment, quality, and capability as well as financing of the Indonesian Ministry of Religion and each PTKIN as stated in BOPTN.

5. The ethics evaluation of scientific research

The assessment of research results was carried out by Litapdimas reviewers contained in the Decree of the Director General of Islamic Education No 1564/2022

Tittle	Material	Reviewer 1	Reviewer 2
Portrait of the Principal's Managerial Pattern in Realizing Character Education and Religious Moderation at SD NU in Kediri Regency	1. What are the benefits of research results for scientific and/institutional/community and/national development? 2. How is the quality of the research OUTPUT? 3. What are the opportunities for follow-up on research results? 4. How is the application of methodology and theory in conducting research? 5. How are funds used in the research process? 6. What is the level of achievement of research outcomes?	1. The results of this study make a significant/significant contribution to improving the quality of education, especially in terms of providing a portrait of the managerial implementation of school principals in realizing character education at the elementary school level 2. The research has been 100% complete, and there is already an output in the form of a research article draft, although there are no scientific publication results from this research. 3. The output quality of this research is very likely to be published in scientific journals at least Sinta 3. 4. The opportunity for follow-up on research results is very large to be implemented in other school	The benefits of research results in general are very necessary because schools, communities, countries and nations need big themes that are contained in the results of this research. The quality of the output is good in terms of all the answers. The findings in the form of this pattern need to be followed up to be developed and used as an educational/learning model/module character education and religious moderation. The research method has been carried out well, although clarification is still needed on the accuracy of the primary school used as the object of research. The draft output of the article has not used IMRA's general journal organizational structure and also has not used the intended journal template, the discussion is still long and lacks reduction. There has been no report on the use of funds/finances

Table 3.
Sample reviewer assessment matrix for research outcomes [11]. Source: http://litapdimas.kemenag.go.id/index.php/

with the Research Committee appointed by the Chancellor of each PTKIN. The reviewers have Litapdimas Reviewer IDs obtained through the specified requirements and qualifications. They carry out an assessment of the proposal material, proposal presentations and research results seminars. Reviewers are research experts and scientific publications [12]. So academically have full responsibility for the quality of research. Evaluation task.

Assessment of research proposals; (i) the appointed reviewer assesses the research proposal manuscript including the construction of the background problem, problem formulation, alignment of research objectives, level of research usefulness, relevant theory, accuracy of research methods, and suitable bibliography, (ii) reviewer also gives a score between 1 and 5 on proposal components and also provide recommendations on the eligibility of the assistance funds to be obtained.

Assessment of Process Achievement (intermediate seminar); the researcher conveys the temporary results of the research process to the reviewers to obtain suggestions in order to improve the research results and to ensure the research process is in accordance with the stages as previously designed [13, 14].

Assessment of Research Outcomes: (i) Researchers upload complete research reports and draft journal articles on OTS on the date and date specified. The reviewer gives an assessment of the research report material including the presentation of the research results, data and discussion of the results regarding the depth, breadth, and suitability of the theory and discussion, (ii) the reviewer also assesses the draft of journal articles that will be submitted to indexed journals with national and international reputations, (iii) the reviewer also gives a score between 1 and 5 on the usefulness component discussed on the sustainability of knowledge, output quality, compatibility between theory and methods, use of aid funds, and achievement of outcomes, (iv) the reviewer provides recommendations on the percentage of achievement of outcomes (**Table 3**).

Research Committee Assessment: This team consists of higher education policy holders who have research grants and the Chairperson of the LPPM appointed by the Director General and/or Chancellor of PTKIN/PTKIS to provide the final results of research achievements and decisions on the volume of research financing from BOPTN. Results of the committee meeting as a basis for finalizing research performance which was attended by all members of the team.

The number of scientific research circulations of the Ministry of Religion of the Republic of Indonesia in 2022 noted that the number of reviewers was 882, researchers were 25,078, research proposals that had been submitted were 44,821, cluster selection was 242, and Arkan themes were 15 [11].

6. Conclusion

Commitment to the balance cycle makes ethical management of Indonesian Islamic scientific research have the distinction of maxim-maxim ethics. The balance includes Islamic ethics, philosophical, scientific, technological, national and policy. Finally, the results of resetting the ethical balance contribute to global civilization.

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Section 4

Ethics in Scientific Research and Public Awareness

Chapter 13

Ethical Leadership Decadence of Good Governance Failures in South African Public Service

Andrew Enaifoghe, Nokukhanya N. Jili and Richard M. Mthethwa

Abstract

The study examined the Ethical Leadership Decadence and good governance failures in South African Public Service. According to the study, the global crisis has influenced the South African economy because it is interwoven into the global economy. Studies indicate that the environment and culture influence the ethical behavior of individuals in their workplace. It is, therefore, critical for leaders to take active steps in fostering an ethical environment and culture in government institutions. The purpose of this article is to evaluate the issues that ethical leadership faces in light of the global crisis and to ask whether a simple response to the crisis without a purposeful ethical emphasis is sufficient for maintaining an effective and efficient public service. The method used is a critical qualitative examination of the current literature on the subject. The study concluded that the present administration must restructure the functioning of public organizations, develop sound whistleblowing systems to prevent corruption, and encourage public managers to act ethically when serving the public.

Keywords: Africa, corruption, ethical leadership, accountability, good governance

1. Introduction

There is a greater cognizance of the need to have ethical leadership in governance, alongside accountability and transparency in public service life. The apparent realization of such awareness is supported by the development of a consensus that good governance and sound public administration are underpinned by sustainable development [1]. The effect of unethical and unlawful practices in the public sector is considered unsupportable in the development of a nation, as it could result in a loss of confidence in the public institutions and the erosion of the rule of law itself [2–5]. Although the current concern with ethics and corruption is found around the globe, some regions are particularly interested in mitigating the damaging effects of unethical and corrupt practices on the development of countries [1].

Africa currently faces enormous challenges in its efforts to achieve sustainable human development. Establishing ethical leadership in public services is imperative because government institutions are considered the custodians of public funds [6, 7]. As a result, government institutions are required to have ethical leaders to handle government funds and provide effective public services [8]. This study explored the magnitude of ethical leadership practices in South African public functions, given the comparatively high level of corruption in many institutions, such as the public service and the consequences of extremely inhibiting the development of national economies. And the significant hindrance of corruption to good governance and service delivery. This study established the potential benefits of having ethical leadership in the public sector, such as the department of education by analyzing the ethical leadership characteristics present in the public sector.

Ethical leadership has been shown to have considerable benefits for both organizations and businesses [9–11]. The government of South Africa launched an initiative called *Batho Pele* in 2005, which means putting "the people first". The initiative was aimed at improving integrity in public administration through a tighter strategy in monitoring public office-holders performance and the consequent compliance with ethical practices [6]. Inputting such legislation in place and the proliferation of ethical codes of conduct is seen to be unlikely in putting unethical behavior to an end among public officeholders [12]. This ultimately suggests that public officials should be trained with the attitudes and virtues for guiding human conduct since the public sector presented copious challenging situations as a result of its diversity [13].

Significantly, the integrity training of public officials could help to gain confidence in providing effective, ethical, and accountable services [14]. It is against this backdrop that this study assesses the ethical leadership decadence in the South African public sector as a crucial problem that needs to be addressed. The study argues that ethical leadership to be engraved in government business, practice, activities, and systems. Moral and ethical leadership is the panacea to shrewd financial management, good and open government, transparency, and effective and prudent government practice.

1.1 Research methodology

This study is qualitative research with an original interview conducted with respondents as a means of collecting data, the study analyzed its data through thematic content analysis. Although the research analyzes a significant amount of literature in the body of current knowledge, this nevertheless enables researchers to examine, consult, and understand written materials or records that may be in the public or private domain. The writers looked at a variety of writings that were available in the public or private domain and were gathered using a desktop technique. The relevance of the documents that the researchers examine is determined by a methodical evaluation of the information gathered and is based on their value to the study. Sileyew [15], pointed out that there are several methods and designs employed in research.

Documentary analysis was chosen as the approach for this study because it establishes the criteria for the researcher to choose various documents while concentrating on excerpts that should illustrate the topics for which the researcher is looking for proof. With the aid of this methodology, the researchers were able to investigate the core goals that may be used to solve the problem of ethical leadership decadence in the South African public sector.

2. Literature review

The study examined the ethical decadence in leadership in terms of good governance failures in South African Public Service. Most people associate ethics (or morals) with rules that make a distinction between right and wrong, such as the *Golden Rule*. The most popular definition of "ethics": is standards of behaviors that distinguish between acceptable and inappropriate behavior [16]. Most people learn about ethical standards at home, school, church, or other social contexts. Although most people develop their sense of right and wrong during childhood, moral growth occurs throughout life and human beings move through stages of moral development [17].

Ethical norms are so pervasive that it's easy to dismiss them as common sense. On the other hand, if morality were simply common sense, why do we have so many ethical disagreements and challenges in our society? One potential reason for these disagreements is that everyone recognizes some universal ethical rules but interprets, applies, and balances them differently based on their values and life experiences [12, 18]. For example, two people may agree that murder is immoral yet disagree on the morality of abortion because they have different ideas about what it means to be human. Most communities have legal standards that control behavior as well, but ethical norms are wider but also more informal than laws [19].

Even though most civilizations utilize laws to enforce widely accepted moral norms, and ethical and legal principles use comparable concepts, ethics and law are not the same things [20]. A legal but unethical deed or illegal but ethical action [2]. Ethical notions and principles can also be used to criticize, analyze, propose, or interpret laws [21]. Indeed, many social reformers in the last century exhorted citizens to defy laws they deemed immoral or unjust [22]. Peaceful civil disobedience is a moral method of protesting laws or expressing political views. Another definition of ethics focuses on the disciplines that investigate moral norms, such as philosophy, theology, law, psychology, or sociology [23]. A "medical ethicist," for example, is someone who examines ethical principles in medicine.

Ethics in research can also be defined as a strategy, procedure, or viewpoint for selecting how to act and understanding difficult situations and topics [24]. Consider, for example, a complex topic such as global warming from an economic, ecological, political, or ethical standpoint. While an economist could look at the costs and advantages of various global warming measures, an environmental ethicist might look at the ethical values and principles at issue [25]. Many different fields, institutions, and professions have behavioral norms that are tailored to their specific interests and goals. These standards also assist discipline members in coordinating their actions or activities and in establishing the public's faith in the discipline [26, 27]. For example, ethical standards control behavior in medicine, law, engineering, and other fields.

Ethical rules also assist research objectives and apply to those who perform scientific study or other intellectual or creative activities [28]. Research ethics is a specialist profession that investigates these rules. There are various reasons why it is critical to follow ethical standards in research [29]. First, norms advance research goals such as knowledge, truth, and error avoidance. Prohibitions on creating, manipulating, or misrepresenting research data, for example, promote the truth while minimizing mistakes [14]. Second, because research frequently entails a considerable lot of collaboration and coordination among many different people from various fields and institutions, ethical norms encourage characteristics that are fundamental to collaborative work, such as trust, accountability, mutual respect, and fairness.

Many ethical conventions in research, for example, criteria for authorship, copyright and patenting policies, data sharing policies, and peer assessment confidentiality regulations are intended to preserve intellectual property interests while fostering collaboration [30]. Most researchers want to be recognized for their work and do not want their ideas to be stolen or leaked early [31, 32]. Third, many of the ethical rules assist in holding researchers accountable to the public. Federal laws on research misconduct, conflicts of interest, human subjects protection, and animal care and usage, for example, are required to ensure that researchers sponsored by public funds can be held accountable to the public [33]. Fourth, ethical standards in research contribute to public support for research. People are more likely to fund a research study if they have confidence in the research's quality and integrity [33].

Finally, many research norms promote a wide range of other essential moral and social values, such as social responsibility, human rights, animal welfare, legal compliance, and public health and safety. Ethical breaches in research can have serious consequences for human and animal subjects, students, and the general public [34, 35]. For example, a researcher who falsifies data in a clinical trial may hurt or even kill patients, and a researcher who fails to follow radiation or biological safety standards and guidelines may imperil his or her health and safety or the health and safety of others [36].

2.1 Observation of ethics codes and policies

In research, observing ethics codes and policies is very important. Given the importance of ethics in research, it should come as no surprise that many different professional organizations, government agencies, and universities have developed distinct research ethics codes, norms, and policies. Many government bodies have ethics guidelines for researchers who are financed [37]. Though substantial research has been fervent on ethics, there is meaningfully less attention given to ethical leadership in the South African Public Service. Given the above background, there is an equal number of African countries that have witnessed huge maladministration of public funds and corruption [10, 11, 38]. This study maintained that such unethical behavior among public officeholders is mainly attributed to a leadership problem. A clear case in South Africa was witnessed when Chief Justice Mogoeng Mogoeng, while addressing delegates at the Serious Social Investing Conference 2016 in South Africa, articulated that South Africa needs ethical leaders who are not corrupt [39].

The above observation mainly stemmed from the landslide Constitutional ruling in South Africa, where President Zuma was said to have enriched himself with public funds [27]. The objective of the study is to assess the ethical leadership decadence in South African public service while using the Eastern Cape Department of Education as a focus. Given South Africa's socio-economic conditions with the besieged state-owned enterprises like Eskom and South African Airways, this study looked at the complex layers of corruption in public sectors and the concern for ethical leadership. Kariuki in 2019 argued that South Africa as a nation has reached its tipping point as far as ethical leadership is concerned [40]. Conrad in 2013 also argued that South Africa as a country is seen to be in desperate need of principled leaders who will put the country back on a path of responsible leadership aimed at improving the quality of governance at all levels [41]. According to scholars many of the failures in governance are associated with noncompliance and corruption as stipulated by legislative requirements, such as the Public Finance Management Act and the Municipal Finance Management Act [40, 42].

The legislation is designed to keep the running of government free from corruption and maladministration in public offices [3, 4]. The absolute neglect to the adherence to the legislative requirements as provided by these Acts is seen as disrespect for the provisions of the Constitution and the general public who anticipate quality provision of public goods and delivery of services consistently and sustainably [40]. The failures in governance point to low levels of ethical leadership in the public sectors of the country. As indicated by Aboobaker, "good leadership is often interpreted as effective leadership while bad leadership is interpreted as ineffective and inefficient ([43], p. 6)".

2.2 Ethical leadership and absenteeism of employees

Ethical leadership decreases absenteeism of employees while lowering misconduct and thereby improves job satisfaction and quality performance [44]. Public office holders in top management positions, who are "ethical leaders are often perceived to be more suitable to opportunities for promotion" [45]. It is, therefore, a significant pillar to successful organizational operations, principally in countries where comparatively higher cases of corruption are recorded [41], such as South Africa. As noted by Heres & Lasthuizen the majority of studies on ethical leadership that were conducted in the US were mainly focused on the business environment, this essentially ignored the societal and organizational factors that may affect the notions and manifestations of ethical leadership [46]. Similarly, Allan; and Kariuki, noted that in Africa, most of the studies conducted on ethics primarily focus on the private sector, while it neglects the public sector, which directly affects citizens [40]. Nevertheless, there are several socio-economic issues ([47], p. 590), such as high unemployment. Which currently sits at 30.1% [48], illiteracy, and certain areas of the public sector, such as the health service and local government (divided into 9 geographical provinces [40]. These are often seen to function poorly and are habitually characterized by ill-informed uncaring public officials.

As indicated by Aboobaker, the Public Service and Administration Minister announced a programme to professionalize the public service by introducing compulsory induction training in October 2013 [43]. In acknowledging the utmost necessity for development, there follow six months of nationwide public consultation, which later birthed the drafted long-term vision and strategic plan for South Africa, devised by the government. This road-map strategy devised by the South African government known as the National Development Plan-2030 "Sets down strategies to address poverty by broadening access to employment, strengthening the social wage, improving public transport and raising rural incomes [42]. It is stated that the NDP 2030 outlines the various steps which are needed to be taken by the state in strengthening leadership accountability, improving coordination and prosecuting corruption in the public service [28].

Even through the shift from the stigma of apartheid, a situation the majority of black South Africans were excluded from ownership and/or control of means of productive assets or resources. As well as the exclusion from participating in the country's economy, before attaining democracy in 1994, which was relatively realized peacefully after a period of struggle [42, 44]. Many organizations remain hierarchical in structure, while industrial and employee relationships are often considered to be festering resentments [49]. The scholars noted that there are some occasions where it festers violence and the most recent case appeared in an aggressive dispute, which ensued between a private sector mining company, its employees, competing trade unions and

police intervention [49]. Although legislation aimed at promoting economic transformation and eliminating resentment was introduced almost a decade ago, its record concerning equalizing the wealth of ordinary workers has been patchy [50].

2.3 Unethical and poor governance

The government of South Africa, however, has over the years established well-known authorities to help fight unethical and poor governance in the public service and other sectors. The systems of ethics and governance frameworks in South Africa, particularly in the public sector in the South African context, could be traced and elucidated copiously after the apartheid regime than it was during the apartheid era [42]. At the end of the apartheid regime in South Africa, a new constitution was developed and adopted by the new democratic government in 1996 under the policy of non-racialism and equality of all citizens as stated in the [51]. The new constitution under the leadership of Nelson Mandela attempted to address such mythical values of apartheid in the public sector. As stated in Section 195 of the South African Constitution that "public administration must be governed by the democratic values and principles enshrined in the Constitution" [51].

The constitution further states that "public administration must be a broad representation of the South African people, with employment and personnel management practices based on ability, objectivity, fairness and the need to redress the imbalances of the past to achieve broad representation" as seen in the [35, p. 18]. Rosenbaum research in reaction to Section 195 of the South African Constitution, argued that public sectors remained reshaped for their new role in the country. Among seven other transformation priorities, public sector ethics, efficacy and accountability were emphasized [52]. A scholar like Malunga, emphasizes that South Africa has responded by executing a range of legislations and the subsequent creation of democratic institutions as dynamic strategic shields in its quest to establish national integrity and subsequently fight corruption in the country [53]. This was not an easy task as a result that the heterogeneous and multicultural society still experienced a torrent of corruption as well as moral relativism and moral contextualization of the apartheid regime [54, 55].

To unify the essentials of the country, particularly in the public sector, numerous ethics and governance measures were implemented associated with international and national frameworks [53]. Some of those measures include policies, legislative and regulatory frameworks, which consist of the key institutions, sectors, laws, practices and specific contrivances that contribute to enhancing good governance. These include the following:

The Public Service Commission (PSC), is an institution established in terms of Chapter 10 of the 1996 Constitution with a mandate of promoting a high standard of professional ethics in the public sector and to investigate, monitor, and evaluate the organization, administration, and personnel practices of public service [56].

The institution is meant to focus on performing a very vital role in the development of the Code of Conduct for the Public Sector that forms the basis of the public sector's integrity framework as it sets values for ethical conduct across the country [57]. The Public Protector is another institution that is a national Ombudsman established under Section 181 of the South African Constitution, that forms part of the national integrity framework, and has two mandate dimensions [53, 58, 59]. The vital role of the Public Protector in anticorruption is also recognized in the key anti-corruption statutes, which include the Prevention and Combating of Corruption Act, the

Protected Disclosures Act and the Public Finance Management Act. The Prevention and Combating of Corrupt Activities Act specifically give the Public Protector the authority to investigate any improper or dishonest act, omission or offense referred to in the Act, concerning public money [53, 60].

2.3.1 The challenge of ethical leadership and service delivery in the south African context

One of the biggest challenges in governance and government administration is the reliance of political leadership on the administrators to draft the processes and measures to be followed in terms of service delivery [32]. Scholars indicated how important it is to have political leaders who understand government systems and who possess the expected ethics to guide the administrators in government activities [61]. The scholars further articulated that "Government Leaders who do not understand the impact of policies and procedures on public service delivery are most likely to compromise ethics to suit those who manipulate processes" ([61], p. 34). The challenges of ethical leadership in South Africa have led to corrupt practices in various government departments, including the department of education. Corruption is the consequence of poor ethical values and lacking leadership, which often results in poor public service delivery [3, 4].

This section of the study explored the factors which contribute to poor performance in public service delivery and thereby examined the correlation between a poor leadership system (which lacks ethical value) and poor public service delivery. The lack of ethical leadership in administration has severe consequences for attaining good governance and service delivery to the people, as ethical leadership is an imperative constituent of government, in ensuring effective public service delivery [8]. As indicated by another scholar, 'good leadership is always interpreted as effective when the people appointed to leadership positions can achieve organizational goals ([8, 62, 63] p. 2). According to other scholars, 'leadership is not just about an individual or a position, but a moral connection between the people founded on trust, responsibility, commitment and a shared vision of the public good ([10, 11, 64], p. 3).

2.4 The principle of ethics

The principle of "ethics in research is about how one distinguishes between rights and wrongs or good and evil, which is what leaders should always consider when leading people" [61]. Good ethics in leadership is believed to improve service delivery ([65], p. 57). The Ethics Research-Centre report revealed that ethics in leadership is a global challenge. This, therefore, translate to the fact that senior leaders are not doing as well as they think they are when it comes to carrying out both their own and the organization's commitment to integrity [61]. Having ethical behavior and value in administration is not only important in politically deployed public officials but remains the fundamental factor for achieving an effective public service delivery. Several countries in the world including South Africa and public institutions, particularly in Africa, do not have the required ethical leaders who make the essentials of the general public a priority first ([66], p. 240).

As noted by Fourie the implementation and assessment of both national, provincial, and local government codes of ethics in South Africa do not provide an effective solution in combating unethical behavior in government ([67], p. 727). Researchers articulated that poor service delivery with the non-existence of ethical behavior in the

governance of leadership and the lack of a proper mechanism in addressing unethical conduct in government institutions as the critical issues affecting public service delivery in the South African government ([8, 61, 68], p. 1310). The presence of unethical leadership behaviors among public office holders in any society would jeopardize the welfare of the people. In addition to that, the limited policies that are guiding ethics in public office holders have been identified as the major problem of ineffective public service delivery ([61, 69], p. 132).

In the South African context according to Kuwana [70], the economy, for instance, is "running on a huge trust deficit, which continues to grow". Mbandlwa et al. [61], state that senior government leaders, expected to show a high level of leadership ethics, have compromised their positions of power. It is suggested by Xu et al. [71] that ethical leadership behavior, such as "accountability for ethical standards, should echo the procedural and distributive aspects of justice for effective delivery of public services". How many political leaders behave has been seen to have a large impact on instigating employees' faith ([72], p. 98). In the South African context, the government has devised many measures to help curb unethical conduct in public services, such as the establishment of the Public Service Commission (PSC), which is to fight unethical and poor governance [73].

However, there seem to remain various defies in overcoming the issue of ethical leadership in the country. Subsequently, public service delivery in South Africa is seen to be facing issues arising from the lack of ethical behavior in leadership. South Africa experienced a deluge of corruption, as well as moral contingency and moral contextualization of the apartheid regime ([74], p. 5). Scholars noted that South Africa as a country is ranked one of the highest corrupt countries in Africa, this was following the Transparency International (TI) 2015 report [75]. This shows the lack of political will and the firm intention or commitment on the part of government leadership, to implement a policy that is practical to tame corruption in the country [75]. The scholars further noted that the world all over has unanimously agreed that corruption has huge socio-economic costs that impact directly poverty and inequality ([76], p. 148).

2.4.1 The conceptualization of ethical leadership in public service

The understanding of ethics in leadership is a global challenge that adversely affects public services. This is seen to be influenced by the changes in the core atmosphere of public services, which supplement mobility, privatization and the decentralization of power ([77], p. 137). The working environment of current public service is seen to be in constant flux, thereby causing anxiety and uncertainty, as well as providing both opportunities and challenges for the people. According to Kim & Yoon [76], the public service in the delivery of public goods involves both the government and private service providers in the new public administration. Argued by Kim & Yoon that;

> *"the necessity and ultimatum for organizational transformation and novelty in public sector governance have increased in recent years, which also highlighted the competency of employees at various government levels" ([76], p. 148).*

The supervisory and managerial leaders in administrations need to apply a preemptive strategy that nurtures an effective government ethos and builds management capability. The argument is that executive management does not have full control over the leadership ethics of service providers (While [61]).

> *Morals and values, which are the founding elements of ethics, have to be highly followed by government employees to embrace good governance. Moreover, ethical considerations should be a guide for selecting appropriate service providers ([61], p. 24988).*

Ethical leadership, therefore, is believed to play a conspicuous role in the delivery of public service. Ethical leadership is actions on the part of leaders to foster an environment and culture described by morals and an ethos of service ([78], p. 1). Generally, ethical breaks in any given organization are due to people who consciously disobey or act unethically.

2.4.2 Understanding ethical leadership and service delivery in local administration

Understanding the values of ethics in government leadership is the fundamental component of achieving good governance and ethical leaders, which help to contribute to an effective public services delivery. As stated by a scholar the moral credibility of an individual leader plays an important role in the decisions made by government officeholders, which determine whether the individual is an ethical leader or an unethical leader ([79], p. 899). In numerous countries around the world such as Finland, the local government organization is founded on a bureaucratic ideal model [80]. In addition to that, the scholar mentions that;

> *There are several practical mechanisms for setting and institutionalizing high standards of ethical conduct integrity and good Governance for elected officials and civil servants, based on the experience of Australia, New Zealand, Canada, the UK, Korea, Morocco and Ethiopia ([80], p. 1).*

In nutshell, the introduction of relevant Codes of Ethics and Conduct, to be effective, needs to be supported by a range of other mechanisms, training, and leadership by managers and political leaders alike ([80], p. 1). The idea of such endeavor is to uphold detachment amid the roles of political leaders and public office holders as a case that is as old as splitting politics and government. However, research divulges that "politics plays a serious role in administration" ([81], p. 26) and that the relationship between the two groups remains much more complex. The term politics and administration in public service are regarded as the diverse elements of the same process of expressing and implementing government policy. The connection and influence of political leadership on public administration can affect public values, which include representation, equity, and individual rights.

2.5 Representation of public service office

The representation of public office holder in this regard is an important value in representative democracy, as a result that people would be allowed to elect their preferred leaders who will govern them. Representation implies that elected officials represent the citizens in the absence of direct democracy, while equity in governance is to ensure that there is a just distribution of resources and further guarantees no second-class citizens [82]. However, a lack of ethical leadership in governance affects this value [3, 4]. When political leaders are unethical, government employees are equally affected because wrong decisions are inevitably made, which directly affect

the individual rights of citizens. Research showed that public service delivery depends on decisions made by political leaders and government employees ([83], p. 208). Other research shows that the lack of appropriate leadership ethics among government officials is a global phenomenon. According to the research conducted in the United States,

> *"ethical scandals involving political groups; violations of the privacy of reporters and world leaders; sexual harassment; and assault in the military and government reveal the importance of studies on ethical behaviour and the difficulty of ensuring leadership ethics in governments globally" ([84], p. 334).*

Another research conducted on a national survey of 744 randomly selected government workers in the United States shows that 57 percent of government workers reported that they had observed a violation of ethical standards ([85], p. 147). Alongside violating policies or laws in their workplace during the last 12-month period ([85], p. 147). The violations of ethical standards can take various forms, the common examples involve misreporting hours worked. Discrimination in employment, sexual harassment and the violations of privacy ([85], p. 147). The lack of leadership ethics is seen to be a global dilemma, which therefore requires serious attention, as lack of leadership ethics does not only affect the economy of the country, but it affects the well-being of the poor citizens of countries globally ([86], p. 2).

> *"nearly one-third (30 percent) of government employees in the United States did not report violations of ethics because of fear of being further victimized and a possibility of job loss. Fourteen percent reported that they had been pressured to compromise ethical standards in the course of performing their jobs".*

Government officials who compromise ethical standards are directly affecting the quality of service delivery to public, as the poor ethical standards may result in poor delivery of public goods. The provision of the United States Constitution for instance establishes a representative form of government, where the elected political bureaucrats dully exercise role of governance for the benefit of the citizens ([87], p. 225). However, the political power is shared through federalism, where the power between the federal government and states is shared [88]. However, in the quest to ensure ethical standards in leadership and combact corruption in South African public service, the Department of Public Service and Administration is charged with the responsibility to, oversees the national and provincial government. In adding to that 'in the South African context,

> *"it is imperative for institutions of governance, such as the Electoral Commission, and Public Service Commission (PSC), as well as Parliament and provincial legislatures to enforce, securitise and monitor the applications of the above legislative frameworks to instil a good governance culture in the public sector" ([87], p. 225).*

These, therefore create the conditions for accountable governance in the best traditions of democracy. It is maintained in this study that pre-emptive consideration must be given attention to help prevent corruption and identify mechanisms in eliminating systemic regulative and organizational lacuna, which may contribute to corruption in the public service.

3. The approach in public sector ethics and integrated moral leadership

In the public sector, leaders are responsible for many citizenry and stakeholders. Further, public leaders are usually expected to conform to standards higher than those aligned with personal morality. Several academics have tried to address the issue of ethics in public administration but they could not merge it into a moral leadership approach. However, this study strives to close that gap. The theories of leadership such as transformational and transactional facilitate the incorporation of ethical considerations into an integrated approach to public sector leadership. Therefore, this study is an attempt to explore the discourse of public sector ethics and its relevance to an integrated leadership approach. In leadership we see morality magnified, and that is why the study of ethics is fundamental to our understanding of leadership.

Thus, ethical appropriateness regarding leader behavior is often evaluated in terms of abstract and highly idealistic concepts regarding an individual's prescriptive belief of how leaders ought to behave. As such, within the public sector where leaders are called upon to uphold differing and even contradictory levels of ethical responsibility, it has increasingly become expected that leaders meet many of the prototypical and idealized expectations of those whom they represent. Therefore, a moral leader is a relevant ingredient in the public–sector environment. In an era where high-profile lapses by public–sector leaders in ethical and moral judgment are frequently exposed, citizens have come to expect increasingly higher standards of ethical conduct as a broad range of activities are now viewed as immoral, [89] increasing awareness and changing societal values have been linked to the public's interest in ethics management.

Accordingly, citizens have become more assertive and demanding towards leaders in the public – sector showing less tolerance for leaders' mistakes, shortcomings, and structured challenges. As many public leaders are generally expected to conform to standards higher than those aligned with personal morality. As international government systems become more commonplace, the responsibility for promoting the ethical-moral values of democracy rests most directly on the public managers and policymakers of the democratic systems ([90], p. 241). The common method in trying to deal with the ethical responsibility of public officials has been the promulgation of codes, policies, and other guidance standards, within the last two decades or so there has been an outpouring of written works on the subject of ethics, particularly the ethics of those in government service ([91], p. 573). Yet given this recent focus on ethics in public services, the subject of administrative ethics has often been explored independently of the broader subject of leadership.

4. Ethics of leadership and leaders' degree of moral

In general, the ethics of leadership and leaders' degree of moral development are increasingly becoming essential elements of the private sector and mainstream leadership research. Nevertheless, "administrative leadership research has experienced neither the volume nor the integration of the mainstream because literature about administrative leadership is dispersed in topics such as reform, ethics, and management, and explicit focus on the detailed dynamics of leadership is largely lacking ([92], p. 215). Further, in addressing the fragmentation of the administrative leadership literature. The ethics – values literature, for all of its normative robustness generally offer few concrete recommendations beyond general admonitions to be responsive, trustworthy, honest, courageous, and prudent" ([92], p. 223).

Ethics and public service values are important elements in comprising the engine of public administration. From ethical principles to recommendations, scholars and practitioners have attempted to classify what should be the foundations of administrative ethics, the appropriate ethical behaviors of public leaders, and the ethical behaviors of public leaders and the ethical role of the public administrator. The regime values are the normative foundations of administrative ethics [93]. Accordingly, the major ingredients of a citizenship ethic in public administration as authoritative judgment, the public interest, and citizenship as education and community [94].

5. Theoretical ideologies of moral and ethical leadership in the public service

The study significantly provides a theoretical framework upon which to base future road maps for actions thereby closing the current theoretical gaps. In so doing, it contributes to the promotion of healthy working conditions within the Eastern Cape Department of Education for the implementation of strategies and promoting cum enhancing a culture of ethical conduct for improved service delivery through effective leadership and leadership. The theoretical underpinning of the study is built around two extreme theories, trait and situation. In that, while the former prescribes leadership in the context of the great man theory. Based on physical attributes and charisma, when the argument is made that a leader is born and not made. The former, situational theories, argue that decision and leadership in organizations are based on expertise, exposure, circumstance, technical know-how, availability, and resources without regard to gender preference (unlike the first).

Its arguments stem from the notion that every situation requires a different approach, resources, and mannerisms. Further, the study explores approaches to the integration of moral and ethical leadership in SA and gives certain recommendations based on the findings in the study. The evolution of leadership discourse in public administration may be divided into three overlapping phases. The first phase ascribes leadership to the politicians. The second phase relegates the act of leadership to managing complex functions of the public service. In the third phase, public services began the challenging task of reforming their governments along with the principles of effective governance.

6. Ethical issue of leadership and public debate

The ethical issue of leadership characterizes public debates among other things and leaders across the globe are often morally disappointing ([95], p. 6). Almost in any piece of scholarly work on leadership, there's always a portion that talks about integrity and strong ethical values as being crucial to leadership. As argued in human relationships with each other and other living things, a scholar asserts that ethics are viewed as examining what is right or wrong, good, evil, virtue, ...justice, and fairness ([95], p. 6). Most people rightfully feel that they know about ethics from experience and more often think of ethics as practical knowledge as opposed to theoretical knowledge.

The researcher, therefore, ponders whether civil servants in public service also view ethics as practical knowledge divorced from a theoretical one. Joseph Rost in his book on *Leadership in the Twenty-First Century* concludes that having examined ethical systems none of them assists leaders and followers in decision-making regarding ethics

of the changes they intend for an organization or society and these are inadequate to the task of making moral judgments about the content of leadership ([96], p. 172). This leaves the question on the researchers' mind on whether public service employees especially managers in particular thought it important for their subordinates to be honest, and upright and whether they regard them as principled leaders whose activities are often based on knowledge, transparency, consistency, and fairness.

The study hinges on moral leadership as its theoretical underpinning. Quite several important theoretical underpinnings are supporting the moral leadership concept and its various manifestations. While many scholars made important contributions to our understanding of ethics and the value dimension of administration, some offer a good introduction to the theoretical foundations of the moral leadership concept. For instance, a comprehensive treatise on the ethics of management, argues that administrators and leaders must act and choose, that choice is inevitably subjective and that selection of one or another course of action will be based on a set of values [97].

7. Concept of leadership in ethics

The concept of leadership is rooted in a view of practice guided by the obligation of the leaders. In concurring with Bottery's view that the ethical administrator must lead in a manner wherein one's leadership is critical, transformative, visionary, educative, empowering, liberating, personally ethical, organisationally ethical, and responsible. Distinguishes between ethics as the study of moral practice and being moral, which "involves more than thinking and making moral judgments ([98], p. 155). While on the other hand, sterling contributions were made by reminding readers of the essentially human character of organizations, their purpose, and the moral nature of the administrator's task [99]. The issues resonating from non-compliance, public trust, and inept ethical and moral behavior of the civil servants in the provision of service is a pointer to this assumption.

8. Concluding remarks

The study concluded that the present administration must restructure the functioning of public organizations, develop sound whistleblowing systems to prevent corruption, and encourage public managers to act ethically when serving the public. This study also shows that fraudulent activities are a result of the inappropriate work ethos, including either subversion or sub-standardization in the business of the department. The government must implement control measures including internal control and internal audit alarms that signal problems in the department. Therefore, it is essential to completely reform the administrative culture to foster the effective, efficient, and productive capacity of DoE staff. The study's findings show that some form of intervention is necessary for effective leadership in the public sector.

As concerns about compliance, moral behavior, fraud investigation, monitoring, and reporting are handled delicately. The leaders and frontrunners of any administration are often insensitive, which is a big factor in why initiatives fail. The report recommends an intervention plan that will first retrain the civil servant management team and include young people with new and fresh perspectives in keeping with space and time.

The research also subtly highlights the claim that all governments' departments, ministries, and agencies throughout the world use a trait-to-situational strategy. of a

person viewing themselves as the culmination as opposed to a request for assistance. The conclusions of this study stress strong governance concepts like transparency, accountability, and ethics, which are key factors in the efficient provision of public services.

To assist limit the unrestrained powers of public office holders in South African public sectors, it is advised that preventative measures, including the reforming of regulatory frameworks, be put in place. Additionally, it is advised that the government improve skills training and decision-making openness, especially for public officials who hold positions with high budgetary stakes.

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Chapter 14

Palm Oil Production for the Food and Cosmetics Industry in Africa: Ethics and Sustainability Implications

Maria Chinecherem Uzonwanne, Uju Ezenekwe and Geraldine Nzeribe

Abstract

This study discusses the trend of palm oil production in Africa, its traditional and industrial system and finally the ethical and sustainability part of it. Palm oil which is a major component of the materials for food processing and cosmetics industries has a market size on the increase. Pressures on the industry in this regard have not yielded much fruit. Therefore, with the endemic corruption in the African political system, it is feared that the situation of Africa may be worse than Asia in terms of sustainability without strong ethical standards. Nevertheless, the ethical and sustainability questions surrounding palm oil production in Africa have been there through the years with its attendant human, social as well as environmental dimensions. Hence, this study seeks to highlight some of these ethical and sustainability questions.

Keywords: palm oil, ethics, production, cosmetics, Africa, sustainability

1. Introduction

This work deals with palm oil production in Africa. In particular, it discusses the trend of palm oil production in Africa, its traditional and industrial system, and finally the ethical and sustainability part of it. Palm oil is a major component of the materials for the food processing and cosmetics industries. Its market size is on the increase. According to reports [1], the market size of palm oil in 2019 stands at 74.6 million tons and it is projected to register a volume-based CAGR of 2.3% from 2020 to 2027.

The increasing awareness of the health benefits of palm oil as an alternative energy source and with relatively low cost of production are the key drivers of the demand for palm oil. About 80% of the palm oil consumed worldwide is produced in South East Asia and largely Indonesia and Malaysia while the rest is produced in other parts of the world including Africa (Index [2]). With the Indonesian moratorium on oil palm plantations and Malaysia wanting to maintain the current level, the drive to supply the expanding demand for palm oil has moved to Africa. On account of the growing demand for palm oil, its production may not be avoidable, however, there are

serious concerns about its sustainability (National Geographic) and ethical issues that accompany its production by Transnational Corporations (TNC).

Pressure on the industry in this regard has not yielded many fruits. With the endemic corruption in the African political system, it is feared that the situation in Africa may be worse than in Asia in terms of sustainability without strong ethical standards. Nevertheless, the ethical and sustainability questions surrounding palm oil production in Africa have been there through the years with its attendant human, social as well as environmental dimensions. This work seeks to highlight some of these ethical and sustainability questions.

2. Trends of palm oil in Africa

Oil palm is one of the most important economic oil crops in Africa. According to World Rainforest Movement, oil palm is indigenous to the Nigerian coastal plain though it has migrated inland as a staple crop. The Global Trend in the production and consumption of edible oils and fats is summarized in Palm oil, not only does it stand at the top among edible oils but also has an enormous value chain that increases job creation. According to [3], the trend has grown in recent times from a production level of 1.6% and a consumption level of 6%. Global palm oil production and consumption has grown to 28% in 2009 to become the world's largest produced and consumed oil [4]. According to the report, Palm Oil Value Chain Analysis in the Niger Delta Nigeria for instance has it that palm oil recorded its fastest increase in global production and consumption due to the significant contributions by Malaysia and Indonesia. The report added that the techno-economic advantage of palm oil over other oils and fats, especially soybean oil, is the main driver of this increase.

2.1 The trend in the demand and supply of technical palm oil (TPO)

Production (supply) and consumption (demand) of palm oil have over the years shown an increasing trend due to its economic and health benefits. From 1964 to

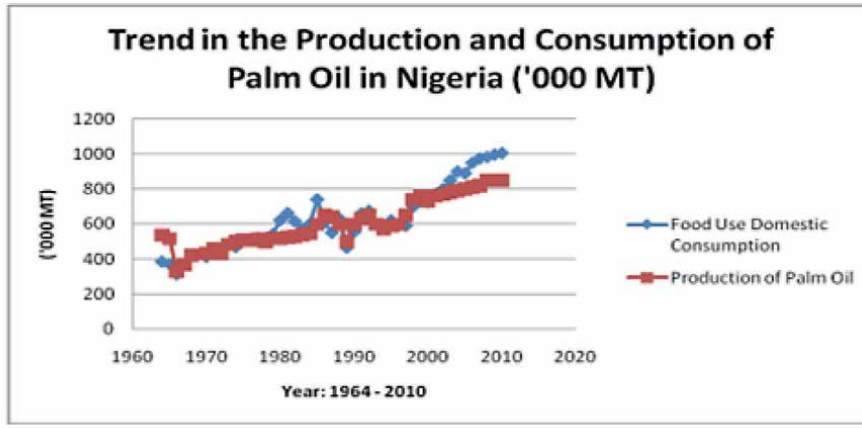

Figure 1.
Trend in production and consumption of palm oil in Nigeria.

2010, there has been rising production and demand. However, in the last 10 years, demand has grown faster than supply, leading to an increasingly widening gap. Accessing the specific gap of palm oil seems to be difficult because of incomplete statistics in Africa, but according to the USDA analysis which is based on estimated production and import figures, the shortfall in supply (the supply gap) is about 150,000 MT of palm oil per annum. This is shown in **Figure 1**.

This global and steady increase in demand has incentivized many countries to invest in and develop highly competitive industries which will come with its challenges, including ethics and extorting of the locals.

3. The value chain of palm oil

The assessment of the value chain of palm oil in Africa will provide useful insights into understanding the markets, understanding the structure and operation of the Palm oil value chain, and in developing a vision and strategy for the growth of the value chain.

According to Eme (as cited in [5]), value chain tools of analysis are to be used in investigating business activities in terms of new value-adding opportunities when relating to existing values that involve the sourcing of factors of inputs, production, processing, and delivery of the finished products. For Hartwich et al. [6], the potential for the development of agricultural value chains both from the supply and demand perspectives bound, substantial and promising, in Africa. Value chain development has become a reliable tool for stimulating sustainable agricultural investments. An agro-value chain consists of a series of activities that add value to a final product; these include raw material production, processing, getting the final product, marketing, sale to the end-user or consumer, and after-waste disposal.

The Oil palm value chain cuts across West Africa. The production of Oil palm is found predominantly in West Africa; particularly in the Tropical region. Value addition is determined by various factors-the bulkiness of the product, availability of labor, and the various inputs and resources which include costs of transport and distribution, the markets, and consumers. Location specificity is also a minor determinant of the value chain. Hence, while oil palm production and primary processing take place in the West African region, the bulk of the secondary processing, as well as the markets and end users of palm oil products are outside the region.

4. Palm oil production in Africa

Palm oil production involves a series of activities starting with the production of fruits from palm trees, the harvesting of the fruits, and then the processing of the fruits. In Africa, there are two main palm production systems, the wild grove, and the planted farms, about 80% of the total fruit for processing is produced by the wild grove. The long-term productivity and competitiveness of the palm oil industry are highly determined by the varieties under production.

In Africa, no part of the oil palm is considered waste. After the oil has been extracted, the next is called palm kernel cake and is useful in feeding livestock. The leaves of oil palm are put to various use- for making brooms, baskets, mats, and for roofing, and thatching. The thicker leaf stalks are used for walls of village huts. The bark of the palm frond is peeled and woven into baskets [7]. The tree itself can be

split and used as supporting frames in buildings. A sap tapped from the flower is processed into a drink called palm wine, which is a rich source of yeast. The palm wine can be allowed to ferment and then distilled into a gin known as "Akpetesin" in Ghana and "Ogogoro" in Nigeria [8]. The empty fruit bunch, the shell, and fiber that remain after oil extraction are used for mulching, manuring, and as fuel [9]. Oil palm is also an essential food item. About 90 percent of the palm oil produced ends up in food products, while the remaining 10 percent is used for industrial production.

As the world's population increases and standards of living rises, the demand for oil palm is growing fast and this is attributed to its numerous uses. Production of palm oil is more sustainable than other vegetable oils. It consumes considerably less energy in production, uses less land, and generates more oil per hectare than other leading vegetable oils like soybeans [10]. Despite this, environmental groups are lobbying against the production and consumption of palm oil, and the EU Renewable Energy Directive restricts the availability of palm oil.

The campaign is based on contentions that palm oil damages the environment and threatens endangered species, such as the orangutan [11, 12], and is part of a broader, long-standing effort by the Green NGO movement to advance their goal of stopping forestry in tropical regions. European rapeseed producers have folded a protectionist strategy to restrict the use and imports of palm oil into this campaign [13]. These actions fall under a broader protectionist campaign that seeks to hinder the development of agriculture industries in developing nations and the resulting exports to developed nations by curtailing the conversion of forest land. The fallout of this campaign is the suspension of lending to palm oil companies by the International Finance Corporation (IFC), an arm of the World Bank. Beyond this campaign and the suspension of lending to palm oil companies, there is the need to assess the legitimacy or otherwise of the campaign particularly in Nigeria as well as examine the overall impact of the campaign in Africa.

5. Palm oil tree varieties in Africa

In West Africa, three varieties of oil palm trees are available. These are; Dura, Pisifera, and Tenera. Dura is the female breed, Pisifera is the male breed, and Tenera is a crossbreed of Dura and Pisifera. The Tenera is referred to as the highbred and is preferred among palm oil farmers in Africa. In Nigeria, Tenera seedlings are produced by the Nigerian Institute for Oil Palm Research (NIFOR) and are commonly referred to as extension work seeds (EWS). The characteristics of the three varieties of oil palm fruits from these trees are discussed in **Table 1.**

In terms of comparison, the fruit of the Tenera variety contains 25% oil, by weight, and the Dura variety 18%, so the same amount of Tenera can yield 30% more oil than the equivalent fruit of the Dura.

The productions of palm oil in Africa are in two broad systems:

A. The Traditional System

Palm plants create a useful landscape in the traditional system. Natural palm groves are frequently the outcome of extensive resource management, when forest areas have been cleared for use in other agricultural activities, leaving a number of uniformly spaced palm trees that support a variety of production methods.

DURA	PISIFERA	TENERA
Thick	shell	less Thin
Viable embryo	Unviable embryo if present seed sterile	Viable embryo
Large kernel	Very small kernels and sometimes no kernel in most fruits	Good size kernel
Contains very small-quality oil	The oil content of the fruit is the highest among the three fruit forms	
Unimproved	Unimproved	Improved

Source: NIFOR Oil Palm Production Manual.

Table 1.
The characteristics of the three fruit varieties of the oil palm.

Additionally, as part of agroforestry systems, palm trees are planted as a family or communal stands. The collection of palm fruits is the first step in this technique, which is frequently followed by manual processing or the use of manually powered mechanical pressing devices to produce red palm oil. The sap from trees, both standing and chopped down, is collected to make palm wine, while the palm kernels are manually processed into soap or other items.

According to PIND [3], the traditional system still has most of the palm fruits from the wild groves, which are harvested by individuals and then sold for processing. The wild trees are of the Dura variety, very old, and have a very low yield (less than 1.5 tons of FFB/ha). Most trees are owned by someone other than the person who harvests the trees. Production practices are rudimentary with no application of fertilizers and limited weeding. Added to this, the traditional processing methods in use by the processors are mostly artisanal, using mortar and pestles, with a production capacity of 20 liters a day, yielding extraction rates of 9% (less than half of the oil content of the Dura fruit).

B. The Industrial System

The industrial system is a worldwide system based on monoculture plantations, where the land exclusively yields palm fruits for the industry. The system is essentially the same in both the colonial and post-colonial models, notwithstanding certain variations. Most often, if not always, local communities have had their land taken away with little to no compensation; biodiverse ecosystems (mostly forests) have been destroyed and replaced with vast expanses of palm monocultures; and working conditions, which were slave or forced labor during colonial times, have now nearly returned to slavery or low-paid labor in the modern system. The current system is worse than the previous one in two ways: substantial land drainage and widespread pesticide usage, both of which have an adverse effect on nearby water supplies. Africa endured some of this.

However, this most highly-demanded agricultural product is not without its challenges and limitations. Among them is the issue of deforestation, habitat destruction, and exploited workers. Also, the argument that palm oil is unsustainable is another twist to the challenges of this highly-rated product. But how true are all these limitations relative to the benefit of the product? There is a need to have the whole story. One quick way to sustainability is by helping to reduce its environmental impact through information, advocating for change, and choosing sustainably farmed palm oil.

6. The real fact of palm oil and deforestation

Palm oil stands as the world's highest-yielding oil crop with output 5–10 times higher per hectare than other leading vegetable oil crops [14]. Industrial palm oil plantations have caused 47% of deforestation to so many countries in Africa since the year 2000. According to to Hans [15], 877,000 acres of land have been lost yearly to the plantation with the Indonesian moratorium on oil palm plantations and Malaysia wanting to maintain the current level. However, the drive to supply the expanding demand for palm oil has moved to Africa [15]. On account of the growing demand for palm oil, its production may not be avoidable; however, there are serious concerns about its sustainability (National Geographic) and ethical issues that accompany its production by Transnational Corporations (TNC).

Having explained palm oil production in Africa, the second phase of the work will take a look at some of the key concepts of this work as well as give some practical examples and finally make some policy recommendations.

7. Ethics

Once one talks about ethics, she is entering the difficult terrain of moral judgment. It is difficult because there is no universally accepted standard of measurement for it. It is an accepted principle in business organizations. It is believed that every human being carries a moral gauge in his/her heart but how that moral gauge functions would be a matter for elaboration by the ethicists. The Oxford dictionary [16], defines ethics as the "*moral principles that govern a person's behavior or the conducting of an activity*". That is to say, it *is the moral correctness of specified conduct*. It means that the way a business is conducted can be judged ethically right or wrong. In light of the above definition, it becomes important to evaluate some of the conducts in processing palm oil production in Africa to highlight some of the ethical issues involved.

It is not sufficient to grow a business, the processes leading to the growth of the business need to be ethically sound. In other words, there is a need for ethical congruence between the growth of the business and the entire processes that led to the growth. If a stage in the process is not ethically bankrupt, the other segments of the process emanating from this stage would have been contaminated by this deficiency. It is a way of saying that the end does not justify the means.

The production of palm oil begins with the large-scale acquisition of land to raise oil palm plantations. Often the process of acquiring the land is littered with corruption involving the African local government (national &regional) and the Transnational Corporations (TNCs). They connive with each other to dispossess poor rural families and communities of their land even against the national laws or manipulate them to suit their interests. The lands are acquired most of the time without the consent of the families, adequate compensation or none at all, displacement of families without resettlements, destruction of their local food and cash crops, medicinal plants and forest foods, loss of farm lands, destruction of other sources of livelihood and sacred places.

These ethical issues are common among oil palm plantations in Africa; however, a classical case is published in the report of the reputable Civil Society, FIAN [17]. They highlighted the ethical issues associated with the process through which a European Transnational corporation (TNC) SOCFIN acquired large scale of land in the Malen Kingdom in Southern Sierra Leone. Since the acquisition of the land, there have been

endless conflicts between the communities and the government security agents which have led to the loss of human lives. What makes this case example classical is that the government of Sierra Leone in a bid to resolve the unending conflict between the host communities and SOCFIN set up a committee to investigate the remote causes of the conflict. The report of the technical committee [18] was quite revealing. It did not only confirm the ethical issues that FIAN has already raised in the original report but it exposed the level of ethical bankruptcy with which some of the TNCs conduct their businesses in Africa. Large-scale investments in land are preceded by social impact analyses and adequate safeguards are put in place to mitigate them in Europe. However, one wonders why the same TNC that conducts in Europe with high ethical standards in Europe would cut corners to avoid the social impact assessment and mitigation plans while conducting business in Africa. It raises a very big question about the ethical integrity of the TNC.

According to the report and the analysis of FIAN, the labor abuses in the plantation are huge. The laborers work for as much as 10 hrs a day for a wage of not more than the equivalent of £10 in the local currency. Even with that, there is no job security for them. There are no forms of insurance for them. When there are accidents, they get first aid and if the person requires hospitalization, he/she pays for the bill. If he takes time to return to work, he loses his job. If there is a disability during the course of work, there is no entitlement to compensation.

Apart from that, the chemicals used on the palms pollute the air and water without protection for the host communities. These create health challenges for the host communities and their neighbors. The laborers who spray these chemicals do not have protective gear and they are exposed more to the toxic effects of the chemicals.

Due to the complaints of ethical misconduct of these palm oil TNCs, they have evolved a voluntary certification process known as Roundtable on Sustainable Palm Oil (RSPO). It claims to have *developed a set of environmental and social criteria which companies must comply with in order to produce certified sustainable palm oil (RSPO).* However, the RSPO has some ethical questions about it. First, it is voluntary, founded, and funded by the TNCs themselves, therefore the integrity of the certification process is questionable. Secondly, in Nigeria for instance, the RSPO office is located in the facility of the TNC SIAT. Therefore, the RSPO has no autonomy and raises a new question on the integrity of the process. It is a situation of being both accused and the arbitrator at the same time and it remains to be seen how an ethically sound certification can be conducted in this type of arrangement.

A recurrent decimal that needs more explanation and understanding is the issue of *consent* because it is at the heart of the conflict between host communities and government security agencies in the process of large-scale land acquisition. Investments in African rural communities involving the large-scale acquisition of land require prior and free informed consent of the communities in accordance with existing international and national African pieces of legislation. However, it is not so much as the actors are not informed about this legislation as their decision to evade them. What is given to the communities is information that the said lands have been acquired for development in the name of consultation. What else could be worse ethical misconduct than intentionally evading the process of eliciting the consent of families and communities to dispose of their natural wealth willingly?

Under normal situations, the consultation process will need to give the opportunity for a YES or NO as possible outcomes. It means that in as much as the communities reserve the right to dispose of their natural wealth and resources freely; they equally reserve the Right to choose otherwise. The challenge to the investment

actors and their agents in the consultation process is the disposition to accept a NO from the community as a possible outcome and remain respectful of the Right of the community to make their choice. The decision of the communities/families to say No to the acquisition of their land for investment should not be understood as a rejection of the development project but a YES to a deeper and more valuable need. It could be an emotional attachment to ancestral land, a more secure source of livelihood, or values beyond economics, but the inability to respect their decisions and seek for ways of circumventing them are grave ethical misconducts. In other words, both the Right of the community to dispose of their natural wealth and the Right to say NO are both sides of the same coin of free and informed consent, otherwise it is coercion. As Immanuel Kant, a Prussian-German philosopher postulated in *Britannica* on human freedom, *only choices unadulterated by pressures from within (driven by desires) or coercion from without, i.e. embedded in moral autonomy, confer dignity on the community. All other choices are not free but Heteronomous*.

Human persons are only truly free when they can express themselves from the designs in the deep recesses of their hearts. This inalienable freedom is the compass of human dignity and the true expression of universal human rights in each human being, its violation is the height of ethical misconduct. In practice, this may mean a rejection of any oil plantation, even when it comes with an avalanche of goodwill on the side of the investors.

8. Sustainability

Sustainability is understood as *the ability of a system to exist constantly at a cost in a universe that evolves toward a thermodynamic equilibrium*.

In our context, the system refers to the ecosystem and it means that the rate at which the natural resource of the environment is removed or consumed must be equal to the rate at which it is replenished to achieve a balance in the ecosystem, otherwise the ecosystem will collapse and ecological problems are created for the inhabitants. Furthermore, the etymology of sustainability gives the deeper meaning of its implication for our context. According to Ashiem [19], "*sustainability is defined as a requirement of our generation to manage the resource base such that the average quality of life that we ensure ourselves can potentially be shared by all future generations*". However, the turning of the word "sustainability" was done when it was applied to development in the report of the world commission on environment and development: Our common future popularly known as the Brundtland report 1987 *defines sustainable development as that which meets the needs of the present without compromising the ability of the future generation to meet their own needs*" [20].

The ethical emphasis of this etymological definition by Ashiem and Mitra [21] is the moral responsibility that we have to ensure that the quality of life of others and the future generation is not compromised because of the consumption pattern of a group of people in the present generation. It means that investments that negatively impact the quality of life of people are unsustainable and unethical. Firmly grounded in the elaborate definition of sustainability above, we now outline some of the sustainability concerns occasioned by large-scale land acquisitions of land for oil palm plantations in Africa.

i. There is a huge loss of forest cover otherwise known as deforestation arising from the clearing of large surfaces of land to make way for oil palm

plantations. Associated with the clearing of large surfaces is the loss of biodiversity, medicinal plants that the rural communities depend on, and loss of forest food that has a huge toll on their food cultures and food systems. These heavily impact the quality of life of the communities and are therefore unsustainable.

ii. In the process of securing large surfaces of land for industrial oil palm plantations, families are displaced and dislocated. This has led to urban migration and efforts to migrate through the dangerous Mediterranean Sea to Europe in search of non-existent greener pastures. It is an old story that many of them never set foot in the dreamland of prosperity.

iii. Oil palm plantations are associated with the use of heavy quantities of pesticides and other agro-industrial chemicals. These chemicals pollute the air, surface, and underground waters on which communities depend for their livelihoods and these compromise their health and the quality of their life. It is in the public domain that industrial agriculture is one of the big contributors to climate change. Presently, Africa is at the worst risk of the current climate crisis.

iv. Large surface of the land for oil palm plantations reduces the arable land available for food production and thus puts the food security and local economies at risk. It is important to recognize here that African farmers are mostly family holder farmers and women are at the forefront of it. The scarcity of land for local food production leads to a dramatic increase in food prices. This decreases the quality of life of the women who carry the burden of the African social system.

v. A common factor in the acquisition of large surfaces of land in Africa is that the affected families and communities seldom receive compensation for their land and when they receive it at all, it is not adequate. Furthermore, they barely get employment in those palm plantations; when they receive, there is no job security and the wages are not living wages. But more importantly, they have betrayed the future generation of their families because they did not protect the land for them. This makes the affected families live with burdens of guilt perpetually.

9. Conclusion

Ethics and sustainability are both sides of the same coin for determining who is at the centre of a business enterprise. The flip side of an ethical question is a sustainability question. Ethical questions are values and moral principles which guide business decisions; sustainability questions are the outcomes of those business choices. We, therefore, see in the decisions through the processes of the investment, the values, and the moral principles that guide the business enterprise. Ethics and sustainability serve as quality control mechanisms in the business enterprise. It shows practically who is at the centre of the business and the ethos and values of the business owners.

Businesses are created to serve human needs and make a profit for the owners. The human needs served by the business are not only those who buy their products but

include all those who make contributions to the business through their entire supply chain. As stated earlier, if there are ethical and sustainability deficiencies at any stage of their supply chain, that bankruptcy has contaminated the remaining part of the process. Many business enterprises circumvent established ethical standards because they want to maximize profit. In the case of oil palm plantations for the production of palm oil, it is primarily the sustainability of the families and communities that were impacted by the large-scale acquisition of land and their future generations. The quest to grow a business and make more profit should always be balanced by the same quest for ethics and sustainability.

10. Policy recommendations

In other to remedy some of these ethical and sustainability questions in the palm oils supply chain, it will be helpful to make the following policy recommendations:

i. European countries should put in place mechanisms that will ensure that European corporations producing palm oil in Africa for the European market use similar ethical standards that guide their operations in Europe. It is a sign of ethical bankruptcy to exploit the weak African democratic institutions to enrich themselves. It is both unethical as well as unsustainable to pay an employee in the palm plantation the equivalent of £10 in the local currency for 10 hrs of hard labour on the palm plantation when that could be the minimum per hour pay for a similar job in Europe.

ii. Militarisation of the oil palm plantation is a sign that there is disharmony between the business owners and the host communities. Building good public relations and corporate social responsibility are very crucial business ethics in rural communities as businesses do not thrive in a hostile environment. In the same vein, the divide-and-rule system of community relations is unproductive. It seeks out opinion leaders in the host communities to buy them over. Such behavior destroys the social cohesion of the communities and the backlash is usually unprecedented for the business. Besides, the company's budget for the militarisation of the oil palm plantation and their divide-and-rule game of community relations will be sufficient to improve their corporate social responsibility to the host communities. Commensurate compensation for the land will endear the business owners to the heart of the host communities.

iii. It is important that the corporations using palm oil endeavor to do the due diligence of their entire supply to ensure that the product that they are using is produced in a sustainable way as well as devoid of ethical misconduct. Undertaking this process diligently will be the hallmark of ethical conduct in business.

DOI: http://dx.doi.org/10.5772/intechopen.1001107

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Chapter 15

Public Awareness of the Impact of Animal Testing in the Cosmetic Industry

Sherihan Radi

Abstract

Animal testing in the cosmetic industry is still practiced daily by several companies across the world subjecting animals to painful and cruel tests. The negative impacts of animal testing not only on animals but also on the environment as well as the cosmetic industry are evident and cannot be concealed. The purpose of this research is to examine the public awareness of the negative impacts of animal testing in the cosmetic industry, particularly with regard to animals, the environment, and the cosmetic industry itself. The data was collected through a survey consisting of a sample of 538 employees from 12 multinational companies working in various kinds of industries in Egypt. Primary data was the major source of data used for the study, while questionnaire was the instrument for data collection. The study revealed the existence of a public awareness of the significant negative impacts of animal testing in the cosmetic industry on animals and the environment. On the other hand, the study unveiled the nonexistence of a public awareness of the significant negative impacts of animal testing on the cosmetic industry.

Keywords: animal testing, cosmetic industry, animals, environment, public awareness

1. Introduction

Human vanity and the desire to purchase favorite scent of deodorant or lipstick put millions of animals as victims to suffering caused by testing several cosmetic products [1].

Lab testing beauty products on animals has been a common practice for a century in the cosmetic industry in order to determine if these beauty products are safe for human use. Animals such as rabbits, dogs, rodents, or others are used in the testing of skincare, makeup, and hygiene products. These tests are considered a form of animal cruelty due to the harmful side effects they cause to animals [2].

The debate on the ethics of animal testing has been going on for long years. Although many countries such as Europe banned animal testing for cosmetics, animals are still subject to the testing of the safety of makeup and products all over the whole world. The animals are abused, burned, crippled, and poisoned in labs [3].

Animal testing should be illegal as it does not only have negative impacts, and it is inhumane, cruel, and against animals' intrinsic rights [4].

1.1 Problem statement

Large numbers of animals are killed yearly in cruel tests carried out by the beauty and cosmetic industry in an attempt to assess the hazards of cosmetic products and their ingredients.

Guinea pigs, mice, rats, rabbits, and other animals are the victims of these tests that are administered with the purpose of predicting outcomes in humans.

These tests do not only have evident negative impacts on animals but also on the environment and the cosmetic industry.

This research examines the existence of public awareness of the negative impacts of animal testing on animals, the environment, and the cosmetic industry.

1.2 Research objectives

- RO1: To examine the existence of public awareness of the negative impacts of animal testing on animals.
- RO2: To investigate the existence of public awareness of the negative impacts of animal testing on the environment.
- RO3: To study the existence of public awareness of the negative impacts of animal testing on the cosmetic industry.

1.3 Research questions

The study will tend to answer the following research questions:

- How aware is the public of the negative impacts of animal testing on animals?
- How aware is the public of the negative impacts of animal testing on the environment?
- How aware is the public of the negative impacts of animal testing on the cosmetic industry?

1.4 Research hypotheses

H_{a1}: The existence of a significant public awareness of the negative impacts of animal testing on animals.
H_{01}: The nonexistence of a significant public awareness of the negative impacts of animal testing on animals.
H_{a2}: The existence of a significant public awareness of the negative impacts of animal testing on the environment.
H_{02}: The nonexistence of a significant public awareness of the negative impacts of animal testing on the environment.
H_{a3}: The existence of a significant public awareness of the negative impacts of animal testing on the cosmetic industry.

H_{03}: The nonexistence of a significant public awareness of the negative impacts of animal testing on the cosmetic industry.

2. Literature review

This section will discuss the literature related to the concept of animal testing, the difference between animal testing and animal research as well as the reasons for animal testing. It also discusses types of animal testing and highlights animal testing in the cosmetic industry.

2.1 Concept of animal testing

Animal testing is defined as the use of animals in scientific research such as in testing pharmaceutical products, disease, cosmetics, biology, and others [5]. It is involved with the experimentation carried on animals [6].

2.2 Difference between animal testing and animal research

Animal testing is one particular area of animal research with the aim to test the efficiency and safety of new products. On the other hand, animal research is involved with a wide range of scientific research from learning animal behavior in the wild to research occurring in lab to understand diseases in animals. These lab researches have various types and include genetics, physiology, and modeling disease [7].

2.3 Reasons for animal testing

There are several reasons for the use of animal testing. It is used to understand the way the human body functions as well as to assess both the effectiveness and safety of cosmetics or medication before their distribution. Some products commonly use animal testing such as drugs, cosmetics, supplements, food additives, pesticides, household products, and industrial chemicals [6]. With the aim of marketing new products, manufacturers use animal testing to ensure product or ingredient safety [8].

2.4 Types of animal testing

There are various types of animal testing. Some of these tests are summarized in the following paragraph.

One of these tests is skin irritation test which tests a substance and its potential of causing skin damage that includes swelling, itching, and inflammation. Most of the time rabbits are used in these tests where a particular chemical is placed on a shaved patch of their skin. Another test type is acute toxicity testing which has the aim of determining the danger of exposure to a chemical. This can be through inhalation, skin, or mouth and can cause the death of at least half of the animals. Carcinogenicity tests include a substance or mixture of substances that cause cancer or increase cancer. It is carried out through inhaling, placing on the skin or orally. The animals are killed after the test completion, and their organs as well as tissues are examined for any evidence of cancer [9].

Apart from these above-mentioned tests, the cosmetic industry in particular carries out various tests such as dermal penetration which is also called skin

absorption testing with the purpose of determining the effect of a chemical applied to the skin. This test is mostly performed on rats which have their backs shaved and chemicals applied to their bare skin. After that, in order to analyze any changes related to chemicals in their tissue and blood, the rats are killed. Another test is skin absorption test which involves the application of chemicals on the animals' skin to test the skin response to any allergic reactions that may occur. Draize test is another form of testing that aims at determining the level of irritation to a chemical when exposed to eyes. In this test, where rabbits are mostly used, chemicals are directly placed into the animals' eyes [1].

2.5 Animal testing in the cosmetic industry

Several beauty companies test their products on animals in order to examine the product's safety for human beings. There are main animal-based ingredients used in beauty products. Examples of these ingredients include BEESWAX (CERA ALBA) which is mostly used in the production of moisturizers, soaps, and lip balms to increase the absorption of moisture. Other ingredients include KERATIN which is derived from the horns and hair of different animals and LANOLIN which is taken from sheep's wool. As for KERATIN, it is used in conditioners and shampoos, while LANOLIN is used to make lip glosses, balms, and lipsticks. Additionally, SHELLAC which is used in nail polishes is from insects, and CARMINE which is used in the production of nail polishes, blushes, and lipsticks comes from crushing insects. Moreover, TALLOW used in foundations, eye makeup, and nail polishes is derived from animal fat [10].

3. Conceptual framework

Figure 1 demonstrated was constructed according to the study's objectives.

3.1 The negative impacts of animal testing on animals

Animal testing has several negative and harmful physical impacts on animals that are subjected to testing of products.

One of the more evident and obvious impacts is the physical reactions animals experience that begin with the ways animals are quickly identified with a physical indicator which could be tail-clipping or ear-notching. The tests themselves which

Figure 1.
Public awareness of the negative impacts of animal testing on animals, the environment, and the cosmetic industry. Source: By researcher.

force the animals to be exposed to chemicals through inhalation or physical application cause effects ranging from mild skin irritation, extreme illness up to death of these animals [2].

They also cause the suffering of animals which experience pain due to the tests that lead to skin and eye irritation conducted without pain relief by rubbing chemicals on their shaved skin or dripping them into their eyes [3].

Laboratories that carry out cosmetic testing on animals treat them in an inhumane manner and keep them in cages which cause stress, discomfort, chronic diseases, and even the death of these animals. In addition to that, the placement of different preparations and artificial ingredients on the animals' skins to test soaps, shampoos, creams, or other products result into allergic reactions and other diseases suffered by these animals. Furthermore, the animals that have been tested suffer from various health problems such as loss of appetite, pain, hair loss, apathy, and other problems [11].

3.2 The negative impacts of animal testing on the environment

Animal testing results into the environmental exposure to diseases, toxic chemicals, and large amounts of environmental waste. The reason for that is that facilities using animals for testing dispose the animals which did not survive the testing process as well as food waste and dangerous chemicals besides supplies which were used during the process. The disposal process leads to dangerous exposure to radioactive materials and biohazards. Other negative impacts of animal testing on the environment include negative effects on air and water quality. Additionally, it causes environmental damage through the agricultural processes which are the consequence of using so much food to feed millions of animals used in testing [12].

Disposal of hazardous waste that includes the animal bodies and supplies such as syringes, caging, bedding, and needles creates air pollutants and harmful substances. On the other hand, animal tissues containing toxic chemicals and animal carcasses participate in the production of the most chemically and biologically hazardous waste. As for air pollution, it is produced by the incineration of toxic laboratory supplies and animal carcasses which result into the emission of gases. This causes developmental delays in nearby populations as well as chronic illnesses and extreme harms to human health. Other negative environmental effects include groundwater and soil contamination aggravating the drugs problem in public water supplies. Consequently, public drinking water is infected [13].

3.3 The negative impacts of animal testing on the cosmetic industry

With regard to the cosmetic industry, animal testing cannot be considered productive whether in relation to the use of resources or time due to the fact that the genetic makeup of animals is not similar to humans. Therefore, animals' reactions do not mirror human responses. This could cause the existence of significant side effects in human trials which were absent in animal testing and vice versa. Consequently, products could still be harmful to humans showing that these tests are considered a waste of resources, money, and time for the cosmetic industry [2].

Besides being a costly and long process, animal testing lacks efficiency as it predicts human applications only 40–60% [1].

4. Methodology

The survey design was adopted in the study. The total population of the study consisted of 5146 employees from 12 selected multinational companies working in different industries. The reason for choosing multinational companies is that the researcher believes based on online searching that they pay higher salaries than domestic firms and sometimes they could even pay above market salaries. This means that employees working in these companies particularly women would afford the purchase of cosmetics and beauty products. At the same time, men and women would also afford the purchase of pets which puts them in the category of people who love and care for animals.

The sample size consisted of 538 employees drawn from the study population.

Questionnaires which are the primary source of this study served as data collection instrument and were self-distributed to the employees in these companies with the consent of the management.

A total of 538 questionnaires were prepared with only 517 questionnaires (96.1%) were filled out and returned. Frequency distribution and percentage table were used to analyze data, while test-retest method was used to determine the instrument reliability. As for the determination of the coefficient of the reliability of the instrument, Spearman's rank correlation coefficient was used. Since the Spearman's rank correlation coefficient was very high: r = 0.988, there was a high level of reliability in the survey items.

No personal information was collected from the respondents such as name, contact numbers, and address.

5. Data analysis and findings

5.1 Participants demographic information

Out of the 517 questionnaires returned as mentioned above in the methodology section, 201 (38.9%) were employees who are not pet owners/breeders, while 316 (61.1%) were employees who are pet owners/breeders. 268 (51.9%) of the employees were females with 249 (48.1%) males.

With regard to the employees educational background, 114 (22.1%) are master's degree holders, 283 (54.7%) bachelor's degree holders, 69 (13.3%) PhD degree holders, 6 (1.1%) obtained a diploma, and 45 (8.8%) with other educational backgrounds.

5.2 Examining the respondents' awareness of the negative impacts of animal testing on animals

Table 1 shows the respondents' awareness of the various negative impacts of animal testing on animals.

As shown in **Table 1**, 1269 (61.4%) respondents strongly agree/somewhat agree. On the other hand, 657 (31.7%) respondents strongly disagree/somewhat disagree. As for the respondents who neither agree nor disagree, they are 142 (6.9%).

Based on the above-mentioned, it is indicated that the majority of the respondents are aware of the negative impacts of animal testing on animals.

	Strongly agree (5) N (%)	Somewhat agree (4) N (%)	Neither agree nor disagree (3) N (%)	Somewhat disagree (2) N (%)	Strongly disagree (1) N (%)	Total N (%)
Animals subjected to testing suffer from extreme illness.	289 (55.8%)	120 (23.2%)	0 (0%)	54 (10.5%)	54 (10.5%)	517 (100%)
The tests cause the death of large numbers of these animals.	266 (51.5%)	93 (17.9%)	0 (0%)	79 (15.3%)	79 (15.3%)	517 (100%)
The inhumane treatment of animals subjected to testing causes them stress and chronic diseases.	142 (27.4%)	146 (28.4%)	33 (6.3%)	93 (17.9%)	103 (20.0%)	517 (100%)
Animals subjected to testing suffer from pain.	164 (31.6%)	49 (9.5%)	109 (21.1%)	114 (22.1%)	81 (15.7%)	517 (100%)
Total	1269 (61.4%)		142 (6.9%)	657 (31.7%)		2068 (100%)

(Question 1): Does animal testing has a negative impact on animals and how?.
Source: By researcher.

Table 1.
Respondents' awareness of the negative impacts of animal testing on animals.

The formulated hypotheses in this study as stated in section (1.4) were tested by using regression analysis and Pearson's product moment correlation.

The following hypotheses have been tested by using the respondents' responses in **Table 1**.

H_{a1}: The existence of a significant public awareness of the negative impacts of animal testing on animals.

H_{01}: The nonexistence of a significant public awareness of the negative impacts of animal testing on animals.

5.3 Regression model

$$Y = \alpha = \beta X + \mu \ldots (\text{For all observations i}, 1, 2 \ldots n)$$

Y = animals.
X = public awareness.
μ = error term of random variable.
α = a constant amount.
β = effect of X hypothesized to be positive.
Consequently, the regression (predict) equation will be:

$$Y = 108.011 + 1.212\text{X} \quad (1)$$

The data from the questionnaire has been analyzed by using regression analysis to examine the existence of a significant public awareness of the negative impacts of animal testing on animals. **Tables 2–4** demonstrate that the regression result reveals the existence of significant result on the variables (R-coefficient = 0.711; $p < 0.05$). The significant level is 0.002. Therefore, Hypothesis H_{a1} stating the existence of a

Model 1	R	R square	Adjusted R^2	Std. error of the estimate
	0.711	0.711	0.963	29.15133

Source: By researcher.

Table 2.
Model summary.

	Model	Sum of squares	Df	Mean square	F	Sig.
1	Regression	20171.151	1	20171.151	17.211	0.002[a]
	Residual	2712.049	516	928.350		
	Total	22883.200	517			

[a]*Predictors: (Constant), public awareness.*
[b]*Dependent variable: animals.*
Source: By researcher.

Table 3.
ANOVA.[b]

	Model	Unstandardized	Coefficients	Standardized	Coefficients	T	Sig.
		B	Std. error	Beta			
1	(Constant)	108.011	47.849			3.113	0.061
	Public awareness	1.212	0.416	0.939		3.118	0.005

[a]*Dependent variable: animals.*
Source: By researcher.

Table 4.
Coefficients.[a]

significant public awareness of the negative impacts of animal testing on animals is accepted. Consequently, the null Hypothesis H_{01} is rejected.

5.4 Investigating the respondents' awareness of the negative impacts of animal testing on the environment

The respondents' awareness of the various negative impacts of animal testing on the environment is demonstrated in **Table 5**.

Table 5 illustrates that 1111 (53.7%) respondents strongly agree/somewhat agree. Furthermore, 832 (40.2%) respondents strongly disagree/somewhat disagree. Only 125 (6.1%) respondents neither agree nor disagree. Derived from the aforementioned, the majority of the respondents are aware of the negative impacts of animal testing on the environment.

The following hypotheses have been tested by using the respondents' responses in **Table 5**.

H_{a2}: The existence of a significant public awareness of the negative impacts of animal testing on the environment.

H_{02}: The nonexistence of a significant public awareness of the negative impacts of animal testing on the environment.

	Strongly agree (5) N (%)	Somewhat agree (4) N (%)	Neither agree nor disagree (3) N (%)	Somewhat disagree (2) N (%)	Strongly disagree (1) N (%)	Total N (%)
Environmental exposure to diseases is a result of animal testing.	294 (56.8%)	115 (22.1%)	0 (0%)	54 (10.5%)	54 (10.5%)	517 (100%)
Animal testing pollutes air, groundwater, and soil.	218 (42.1%)	54 (10.5%)	76 (14.7%)	115 (22.1%)	54 (10.5%)	517 (100%)
Animal testing results into large amounts of environmental waste and toxic chemical.	71 (13.7%)	82 (15.8%)	32 (6.3%)	250 (48.4%)	82 (15.8%)	517 (100%)
The disposal process resulting from animal testing leads to dangerous exposure to biohazards and radioactive materials.	43 (8.4%)	234 (45.3%)	17 (3.2%)	76 (14.7%)	147 (28.4%)	517 (100%)
Total	1111 (53.7%)		125 (6.1%)	832 (40.2%)		2068 (100%)

(Question 2): Does animal testing has a negative impact on the environment and how?.
Source: By researcher.

Table 5.
Respondents' awareness of the negative impacts of animal testing on the environment.

The hypotheses data was obtained from the responses in the questionnaires. The validity of the existence of a significant public awareness of the negative impacts of animal testing on the environment was tested by correlation coefficient.

Table 6 illustrates that correlation result reveals the existence of significant result on the variables ($r = 0.821$; $p < 0.05$) and the significant level is 0.041. Based on that, Hypothesis H_{a2} stating the existence of a significant public awareness of the negative impacts of animal testing on the environment is accepted, while the null Hypothesis H_{02} is rejected.

			Public awareness	Environment
PPMC	Public awareness	Correlation coefficient	1	0.821
		Sig. (2-tailed)		0.041
		N	285	285
	Environment	Correlation coefficient	0.821	1
		Sig. (2-tailed)	0.041	
		N	517	517

Source: By researcher.

Table 6.
Coefficients.

5.5 Investigating the respondents' awareness of the negative impacts of animal testing on the cosmetic industry

The respondents' awareness of the various negative impacts of animal testing on the cosmetic industry is demonstrated in **Table 7**.

Based on **Table 7**, 946 (45.7%) respondents strongly agree/somewhat agree. Contradictorily, 925 (44.8%) respondents strongly disagree/somewhat disagree. Meanwhile, 197 (9.5%)) respondents neither agree nor disagree. As a result, on the basis of the above-mentioned, the number of the respondents who are not aware of the negative impacts of animal testing on the cosmetic industry exceeds the number of respondents who are aware of this issue.

The following hypotheses have been tested by using the respondents' responses in **Table 7**.

H_{a3}: The existence of a significant public awareness of the negative impacts of animal testing on the cosmetic industry.

$H_{03:}$ The nonexistence of a significant public awareness of the negative impacts of animal testing on the cosmetic industry.

5.6 Regression model

$$Y = \alpha = \beta X + \mu \ldots (\text{For all observations i}, 1, 2 \ldots n)$$

Y = cosmetic industry.
X = public awareness.
μ = error term of random variable.
α = a constant amount.
β = effect of X hypothesized to be positive.

	Strongly agree (5) N (%)	Somewhat agree (4) N (%)	Neither agree nor disagree (3) N (%)	Somewhat disagree (2) N (%)	Strongly disagree (1) N (%)	Total N (%)
Animal testing does not lead to significant side effects in human trials.	179 (34.7%)	43 (8.4%)	40 (7.7%)	104 (20.0%)	151 (29.1%)	517 (100%)
Animal testing is efficient.	218 (42.1%)	54 (10.5%)	76 (14.7%)	115 (22.1%)	54 (10.5%)	517 (100%)
Animals do not have different genetic makeup than humans.	245 (47.4%)	54 (10.5%)	49 (9.5%)	60 (11.5%)	109 (21.1%)	517 (100%)
Animal testing is a not a costly process.	71 (13.7%)	82 (15.8%)	32 (6.3%)	250 (48.4%)	82 (15.8%)	517 (100%)
Total	946 (45.7%)		197 (9.5%)	925 (44.8%)		2068 (100%)

(Question 3): Does animal testing has a negative impact on the cosmetic industry and how?.
Source: By researcher.

Table 7.
Respondents' awareness of the negative impacts of animal testing on the cosmetic industry.

Accordingly, the regression (predict) equation will be:

$$Y = 99.123 + 1.313X \quad (2)$$

Regression analysis was used to analyze the data collected from the questionnaires. **Tables 8–10** demonstrated illustrate that the regression result revels the existence of significant result on the variables (R-coefficinet = 0.124; $p < 0.05$) with the significant level as 0.051.

In consequence, the null Hypothesis H_{03} that states the nonexistence of a significant public awareness of the negative impacts of animal testing on the cosmetic industry is not rejected, while H_{a3} is not accepted.

In conclusion, the first objective of the study was to examine the existence of public awareness of the negative impacts of animal testing on animals. The findings of the study revealed the existence of a significant public awareness of the negative impacts of animal testing on animals (Hypothesis H_{a1}). Not only were the respondents aware that animal testing negatively affects animals, but they are also aware of the

Model 1	R	R^2	Adjusted R^2	Std. error of the estimate
	0.813[a]	0.124	0.823	30.11122

[a]*Predictors: (Constant), public awareness.*
Source: By researcher.

Table 8.
Model summary.

	Model	Sum of squares	Df	Mean square	F	Sig.
1	Regression	22122.051	1	22122.051	16.122	0.0051[a]
2	Residual	2533.149	516	1372.335		
	Total	24655.200	517			

[a]*Dependent Variable: cosmetic industry.*
[b]*Predictors: (Constant), public awareness.*
Source: By researcher.

Table 9.
ANOVA.[b]

	Model	Unstandardized	Coefficients	Standardized	Coefficients	T	Sig.
		B	Std. Error	Beta			
1	(Constant)	99.123	46.849			3.121	0.007
	Public awareness	1.313	0.416	0.732		3.123	0.006

[a]*Dependent variable: cosmetic industry.*
Source: By researcher.

Table 10.
Coefficients.[a]

various proven negative effects of these tests. The majority of respondents strongly agreed that animals subjected to testing suffer from pain and extreme illness. They also believed that the inhumane treatment of animals subjected to testing causes them stress and chronic diseases. Additionally, they were very much aware of the fact that the tests cause the death of large numbers of these animals. The aforementioned responses are consistent with the negative impacts of animal testing on animals as in section (3.1).

The second objective of the research was to investigate the existence of public awareness of the negative impacts of animal testing on the environment. The findings of the study showed the existence of a significant public awareness of the negative impacts of animal testing on the environment (Hypothesis H_{a2}).

Besides being aware of the fact that animal testing has negative impacts on the environment, the majority of respondents strongly affirmed that environmental exposure to diseases is a result of animal testing as well as the pollution of air, groundwater, and soil created by animal testing. In addition to that, the majority of respondents believed that animal testing may result into large amounts of environmental waste and toxic chemical. Further to that, the majority of respondents agreed that the disposal process resulting from animal testing leads to dangerous exposure to biohazards and radioactive materials.

The above-mentioned responses are compatible with the negative impacts of animal testing on the environment as mentioned in section (3.2).

The third and last objective of the research was to study the existence of public awareness of the negative impacts of animal testing on the cosmetic industry. The nonexistence of a significant public awareness of the negative impacts of animal testing on the cosmetic industry (Hypothesis H_{03}) was found out by this study's findings. It is clear from the responses that the majority of respondents were not aware of the various effects of animal testing on the cosmetic industry. The majority of respondents strongly believed that animal testing is efficient, is not a costly process, and does not lead to significant side effects in human trials. At the same time, they were strongly convinced that animals do not have different genetic makeup than humans.

6. Conclusion

In summary, there is a significant public awareness and a consensus of opinions on the negative impacts of animal testing on both the animals and the environment.

However, there is a lack of a significant public awareness on the negative impacts of animal testing on the cosmetic industry.

Therefore, it is essential to increase public awareness on all the various negative effects of animal testing. This can be achieved through animal cruelty awareness campaigns, social platforms, and media. These are considered powerful and effective ways to raise the public awareness and educate the public on animal rights and welfare as well as the issue of animal testing.

Moreover, people should be more encouraged in these awareness campaigns to purchase makeup, feminine hygiene products, deodorants, and household cleaners from cruelty-free brands that do not test their products on animals. These brands use only national ingredients which do not contain animal products.

Additionally, companies should consider switching to cruelty-free products and use ingredients in their products which have already been proved safe for human use and do not require additional tests.

DOI: http://dx.doi.org/10.5772/intechopen.1001088

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Edited by Miroslav Radenkovic

Research is essential to the advancement of science, and it must have both ethical and scientific value. In scientific investigations, there are various ethical problems to take into account, like informed consent, patient privacy, patient diversity, conflicts of interest, etc. The book is divided into four sections: "Ethics in Scientific Research and Specific Ethical Issues", "Ethics in Scientific Research and Artificial Intelligence", "Ethics in Scientific Research and Education", and "Ethics in Scientific Research and Public Awareness". Moreover, the chapters cover subjects like animal research ethics and ethical concerns in higher education. We are certain that clinicians, researchers, and students will find this volume to be helpful.

Published in London, UK
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ISBN 978-1-83769-527-0