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Ethics in research

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ABSTRACT

Ethics in research and how it is translated into practice is fundamental to rule out any potential misconduct either with the scientific method or the way results are presented to the world, thus impacting patients outcomes.

The last two years of the Covid-19 pandemic were prolific in exposing the scientific community and healthcare professionals to the many flaws regarding the different studies either with promising simple treatments or sophisticated medications.

Supposedly high-profile papers with the antimalarial medication hydroxychloroquine either favoring its use or indicating the risk of death were retracted from very prestigious journals such as the Lancet and the New England Journal of Medicine.

Ethics in research became fundamental in reaction to abuses practiced against people as the Nazi studies on concentration camp prisoners or the syphilis study with American prisoners or the US governments radiation experiment.

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Introduction

Ethics in research and how it is translated into practice is fundamental to rule out any potential misconduct either with the scientific method or the way results are presented to the world, thus impacting patients' outcomes (Fig. 1).

The last two years of the Covid-19 pandemic were prolific in exposing the scientific community and healthcare professionals to the many flaws regarding the different studies either with promising simple treatments or sophisticated medications. Supposedly high-profile papers with the antimalarial medication hydroxychloroquine either favoring its use or indicating the risk of death were retracted from very prestigious journals such as the Lancet and the New England Journal of Medicine. This reality was also seen in various other journals, as indicated by a quick Pubmed search under "retracted papers Covid-19" that indicated a total of 54 retracted manuscripts [1]. A "red light" to how peer review has been conducted and how editors-in-chief have behaved towards the novelties and controversies regarding new treatments either medications or techniques has been triggered. According to Wendy Rogers, an Australian bioethicist, researchers and journals should have asked more questions about how datasets were gathered from hospitals around the world, in particular, under the Covid pandemic when everyone in the healthcare systems was loaded with work, while conjointly there was such a rush to come out with solutions, leading to abysmal papers being published [2].

Ethics in research became fundamental in reaction to abuses practiced against people as the Nazi studies on concentration camp prisoners or the syphilis study with American prisoners or the US government's radiation experiment [3]. These abuses exploited the imprisoned and disadvantaged vulnerable population, raising many concerns about how the research was being carried out, leading to guidelines and regulations on ethics and legal aspects. After all, all human beings are born free and equal in dignity and rights [4] and these are the basis for human ethics as well as research ethics. However, ethics in research extrapolates the fundamental care and concern with patients and should also move beyond to assess if studies are methodologic fit, data are adequately analyzed, and conclusions are correctly depicted and spread. Unfortunately, inadequate methods, plagiarism, and data spin, among others, have become major concerns in nowadays science.

In modern medicine, new hypotheses either related to medications or to technological developments have been spread very fast without appropriate fulfillment of every step of the research process. The latter, along with the growing sophistication of patients' knowledge supported by the mediatic availability of information, and the need to guarantee civil rights to disadvantaged populations, has prompted the discussion on how ethics in research has been conducted. In fact, there should be a mandatory discipline for all those willing to delve into this arena, but there is no [5]!

To better approach the topic, let us present the following situation: "TOD", a physician who has carried out little research throughout his postgraduation studies and, has published a few related manuscripts, thinks he/she now has a brilliant idea that may revolutionize the field he/she is interested in. He/she decides to translate his/her hypothesis into a publication, in which he/she allows himself/herself to elucubrate on the pathophysiology of the clinical condition hypothesis while proposing treatments to improve patient care under that situation, without testing them. The paper is promptly accepted with only minor comments from reviewers. Then, with the accepted published hypothesis and because he/she is a very ambitious person, he/she starts spreading the word at medical conferences and is supported by the industry interested in the use of their products as the solution for the non-tested hypothesis. After each new presentation, the audience, who is not familiar with such a "hot" topic but is enchanted by the powerful and convincing words of the presenter, starts to further spread the non-tested hypothesis while the prescription of the potential beneficial treatment, supported by the industry with the "right product", becomes the rule. A rollercoaster of inadequate practices becomes a routine, and the physician is praised for his hypothesis; the lay practitioners sustain the advantages of the product without assessing its efficacy with real scientific collected data, while the industry is happy because it is selling more. On the other hand, the patients, the real beneficiaries of the "phenomenal" hypothesis not tested by research methods, might suffer complications or even the risk of death, if the hypothesis when properly tested is flawed.

The reported imaginary case is not infrequent in the current competitive scientific world in which success is measured by the number of publications and their potential hot topics rather than the quality

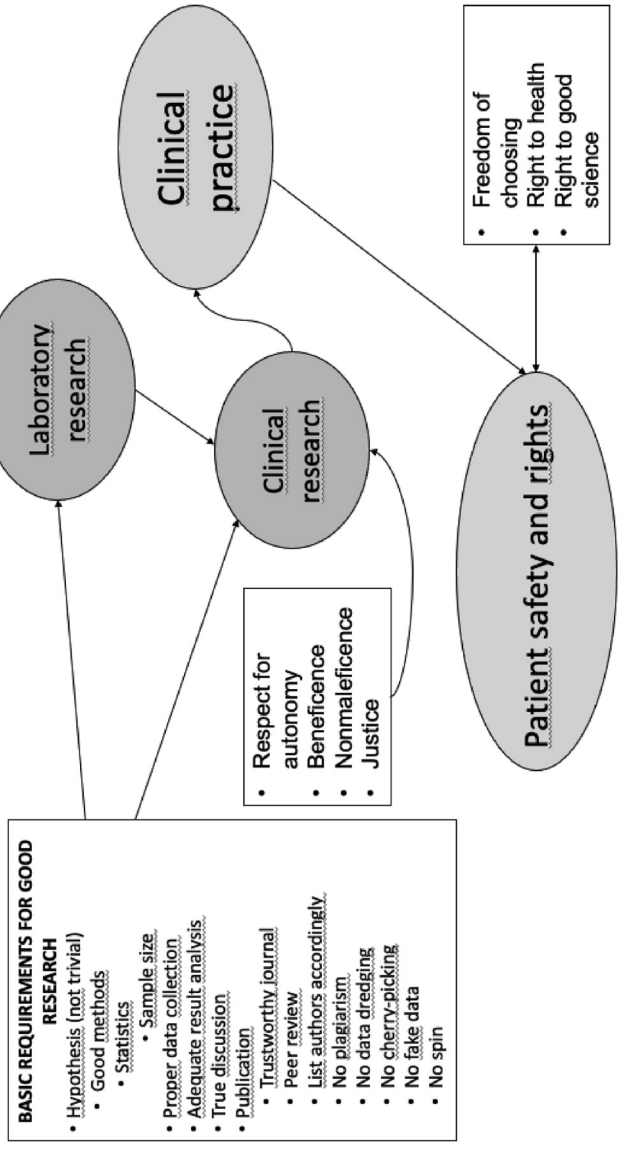

Fig. 1. Guarding and helping promote ethics in reseach.

of their content. Independently of the type of study, either basic science or clinical study, observational or interventional, in the end, it is the patients who will either benefit or be harmed by bad study conclusions. Therefore, it is of utmost relevancy that ethical aspects be discussed among researchers, especially, when new hypotheses are raised. It is the goal of the present review to discuss how ethics has failed at different levels using as an example the reported imaginary situation, and how it impacts patient care.

Historical perspective

Aristoteles was probably the first to discuss the principles of "êthikê theôria" by studying and offering criteria to assess human behavior. Thus, ethics has been a major western philosophy topic, especially, when individual and social values are at stake, as well as the relation and hierarchy of society are challenged.

The concept of ethics might be confused with that of morals, a word that has its origin in the Latin "mos, moris". The latter also refers to a habit or behavior, but it is more likely related to individual principles. The two – ethics and morals – should be thoroughly discussed in research as this impacts people's lives. "Science sans conscience n'est que ruine de l'âme (Rabelais)" (Rabelais, in Pantagruel) [5]; this is to say, science must be submissive to morals to prevent exaggeration.

The Hippocratic oath set forth the precepts of beneficence, nonmaleficence, confidentiality, and prohibition of abortion, euthanasia, and sexual relations with patients [6]. A sect of Greek physicians, followers of Hippocrates, seem to have authored the oath. However, an alternative hypothesis postulates the oath to have been developed by physician-priests of the cult of Asclepias, also in Greece [7,8]. No matter the origin of the oath, there is an outstanding aspect related to its principles, which is extremely relevant in modern times: codes and guidelines. The oath is a covenant between doctors and the community, and this must be translated into research practices, between researchers and the community.

The XVIII century, in England, was marked by local epidemics leading hospitals to be overcrowded, which required medical ethics to be further discussed as young and less qualified physicians were hired to attend to the increased demand. At the time, Thomas Percival wrote a document that established the regulations for proper etiquette and conduct at the infirmaries. In this regard, physicians had to "unite tenderness with steadiness and condescension with authority as to inspire the minds of their patients with gratitude, respect, and confidence" [9]. The same words were used by the American Medical Association code of Medical Ethics [10]. In many other countries worldwide, ethical codes to guide physicians' conduct in medical practice led to the writing of the Declaration of Geneva, and then of Helsinki, in 1964. The latter reemphasized the importance of informed consent for volunteers in biomedical research, especially, after what had been seen in the German concentration camps during the second world war. Therefore, there is a parallel with the above-reported imaginary case that failed to test the hypothesis either in the laboratory or with observational or intervention research before announcing it to the lay world and being supported by the industry without any confirmation.

Principles

Ethical principles are supported by the Belmont report into 3 precepts: 1) respect for persons; 2) beneficence and 3) justice [11].

Respect for autonomy has its origin in the Latin "self-rule" which establishes there is an obligation to respect the autonomy of others to decide on their lives. This principle is also seen as one of human dignity. Healthcare professionals should expect patients to be empowered to make their own choices. Therefore, in research, patients and families must be informed about every detail pertaining to the study if they consent to participate, allowing them to abandon it under any circumstance, without any consequence.

The principle of beneficence is based on the mandatory aspect related to guaranteeing good attitudes and preventing harm to patients. Thus, it is of utmost importance that patients should only be offered the possibility of participating in a study if whatever the hypothesis/treatment is being tested

has undergone previous laboratory assessment while respecting the various clinical study phases [12]. As for the reported imaginary case, such an aspect was not contemplated.

Nonmaleficence is equal to "do no harm" to others, and in this regard, healthcare professionals must avoid causing harm to the patients, or when not possible, harm should be minimized. Applying this percept to the ethical approach requires a similar principle to that of contemplating beneficence [12]. This principle could not be shown in regard to the imaginary case scenario as no studies were performed before it was announced to the community.

Justice is the obligation to offer individuals whatever they deserve or owe. Justice, in healthcare, is equal to treating everyone with equity; this is to say equally, fairly, and impartially. Therefore, such a principle must also be adopted in the conduction of research, especially, since the era of evidence-based medicine (EBM). The background supporting EBM, a paradigm shift in medical practice, aimed to provide a solid scientific foundation for medical decision-making by results from supposedly well-conducted research. Furthermore, the validity of evidence-based medicine depends on reliable data from adequate research, in particular, clinical trials [13,14]. Once again, the above imaginary example failed to apply this percept, as no evidence-based conclusion was reached before it was promoted.

Karl Popper, one of the most influential philosophers of science, defended the integrity and the role of research in a democratic society. A science of real integrity should be one in which practitioners ought to be careful not to hold on to miraculous and adorable hypotheses, but instead, they should seriously consider the results of the most strict experiments [15]. Prasad and Cifu, more recently, have extensively discussed the impact of inadequate conducted research with flawed results, many times boosted by the industry, in their phenomenal book "Ending Medical Reversal: Improving Outcomes and Saving Lives [16]. Medical reversal occurs when a new clinical trial considered superior due to better design, size or endpoints – goes against the current clinical practice [17]. There are many examples that support the maleficence of medical reversal, as such a situation harms patients and triggers a loss of faith in the medical community. Therefore, the reported conduction of the fictional previously presented case faces similar criticisms as those highlighted by Popper, Prasad and Cifu [15–17].

Current challenges

Inadequate or inappropriate methods which cause misleading results and interpretation are a considerable problem in the modern world, in particular, in the academic arena where the motto is "publish or perish" [18]. Promotion and funding in academic healthcare professions are directly linked to the number of publications and not to the quality of the content. Such pressure leads to a large number of inadequate practices, including trivial studies, rapid results, needless or repeating reporting, wrong listing of authors once people who marginally participated in the study are cited, plagiarism, and fake data, as well as data spin (table 1) (Table 2).

Trivial studies are either the repetition of well-known practices without any novelty or simply absurd possibilities such as the need for a parachute to prevent death when jumping from an airplane [19,20]. It is obvious that the two referred manuscripts are a joke directed at the triviality of many current studies with improper hypotheses and no biological plausibility.

Rapid results have largely been seen during the Covid-19 pandemic which has led to many retractions and unsafe practices [21]. When scientists are not cautious in assessing databanks or when disregarding basic principles, for example when ignoring many missing data, these potentially lead to data bias. The need for rapid results is prone to incur sloppy data collection and analysis.

Needless or repeating reporting, the latter also known as "salami slicing or publication" are harmful to healthcare and societal interests [22]. Such conduct certainly falsely inflates the authors' curricula and introduces data dredging, also known as data fishing or cherry-picking. The latter is a consequence of a data mining practice in which large data are analyzed to find any potential association/relation. Supported by these large data with spurious analyses, one can form hypotheses about any relationship. This practice means that initially unplanned analyses end up reporting salient results sometimes without a biological connection [23]. Data analysis should be guided by the initial hypothesis and its biological plausibility. Essentially, it is also important that various decisions, previously defined in the methods, such as how to handle outliers, combine groups, and include or exclude covariates are contemplated.

Table 1
Inadequate or inappropriate methods related to misleading results and interpretation of science.

- Trivial studies
- Rapid results
- Needless or repeating
- Wrong listing of authors
- Plagiarism
  - o Salami slicing or publication
  - o Data dredging
- Fake data
- Data spin

Table 2
Recommendation of authorship according to the ICMJE

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Wrong listing of authors means that many times, individuals who were marginally enrolled in the study/protocol conception, data acquisition, and analysis, as well as supervision of all the study phases, are listed. The International Committee of Medical Journals Editors recommends that authorship be based on four criteria (table 1). To be an author, it is required that all four criteria for authorship are met, otherwise, individuals should be acknowledged [24]. All authors should have confidence in the integrity of the contributions of their co-authors.

Plagiarism is a serious ethical issue, that has become quite common nowadays, mostly, in predatory journals, a universe of scientific publications focusing solely on financial goals. Although predatory journals announce that manuscripts undergo peer review, they generally offer rapid publication in open-access platforms which challenges the quality of the review process. Furthermore, these journals have developed increasingly sophisticated techniques to mislead people into believing their legitimacy [25]. In these journals, it is possible to also find articles originating from paper mills. Paper mills produce essentially fraudulent data and are profit-oriented unofficial/illegal organizations that produce fabricated or manipulated manuscripts that may seem genuine science. They are a threat to science since they are not transparent, this is to say no one knows if the results are real or fake, and usually, these papers are published in Science Citation Index journals [26]. Image manipulation is also common in such manuscripts. A hundred and thirty-seven articles published in between 2017 and 2020, in the Journal of Cellular Biochemistry, which represents 3.7% of all papers published in that journal, were shown to have some type of manipulation. Of these, 23 investigations led to manuscript retractions while the others were still under investigation [27]. Retracting a paper is important, however, it is also known that many times it takes a long time for this to happen, and meanwhile, some of the papers are cited and help the redaction of clinical guidelines [28]. Kataoka *et al.* identified 587 systematic reviews and clinical practice guidelines which cited retracted papers; among these 43% were published after the retraction of the original manuscript. These authors indicated that many of these systematic reviews or guidelines, unfortunately, did not correct themselves after the publication of the retractions [28].

Fake data, like plagiarism and image manipulation, affects the quality of science and implies serious risks to patients. Carlisle carried out an analysis of the baseline summary data of 526 randomized controlled studies submitted to Anaesthesia, from February 2017 to March 2020. He identified 14% with false data and categorized 8% as zombies when he considered the study was fatally flawed. The majority of the authors of these manuscripts came from five countries: China, South Korea, India, Japan, and Egypt [29].

Data spin is another anti-ethical practice that some researchers have adopted to take advantage (consciously or unconsciously) of their results when they intentionally or unintentionally report data

that fail to truly reflect the nature and range of the findings, which could affect the analysis of their results [30]. Boutron and Ravaud use the definition provided by a dictionary which defines data spin as "a form of propaganda, achieved by providing a biased interpretation of an event or campaigning to persuade public opinion in favor or against some organization or public figure". To the authors, "Spin doctors" change the perception of their results to reduce any negative impact or to boost any positive impact on public opinion. Usually, this practice goes along with "cherry-picking" specific data or quotes [30]. Bruns *et al.* reviewed 130 abstracts of systematic reviews and meta-analyses to assess post-operative nausea and vomiting. They found that 29.2% of the abstracts contained spin, with the majority contemplating selective reporting or overemphasis on the efficacy or beneficial effects of the experimental intervention. The authors also identified there was a straight relationship between "high" versus "low" quality studies with the former more likely to spin data [31].

In summary, ethics and the quality of research have been influenced by many flaws, despite the various criticisms raised by serious authors [32–34]. Naji *et al.* in a conversation with Prof. Dr. John Ioannidis, one of the most cited scientists in history, defend collaboration and mentorship to succeed in health research. Ioannidis highlights the relevancy of passion, enthusiasm, and sincere pursuit of high-quality research as the cornerstones to success and productivity [35]. Furthermore, Prasad and Cifu [16] discuss how medical reversal has tremendously caused harm to the community by mentioning several initially impacting studies published in relevant journals that were later seen as either inadequate due to flawed or "spin" conclusions. No doubt the scientific enterprise is business-like, but it cannot undervalue methodology and ethics that will help improve quality and patient safety.

Nutrition and clinical nutrition articles, in particular, are common "victims" of inadequate research practices and ethics. Once food is essential for any human being to survive and the current knowledge that many diseases are attributed to dietary risk factors, there is a huge potential for data spin, from miraculous advocated results derived from studies with specific diets and nutrients, which are not supported by adequate methods. Not only observational nutrition studies but also randomized have shown "too good to be true results" with implausible findings associated with either lack of biological plausibility but mostly with inappropriate associations between small amounts of servings of a single nutrient and highly positive benefits [36]. According to Schoenfeld and Ioannidis [36] many effects seem to be inflated due to inadequate study populations and sample sizes, but also study arm imbalances despite randomization, and unmasked designs that may have impacted certain clinical outcomes, such as stroke. Food and nutrition undoubtedly make a difference in various outcomes, in particular, for malnourished individuals but also for the general population. However, we must be cautious with ethics, especially when those running the studies do not declare their conflicts of interest regarding results associated with the interventions, and widely tout the benefits of the products.

Perspectives

Ethics is fundamental to guarantee the quality of research and thus patient safety and well-being. On the 10 of December of 1948, the day that the world's government made history by signing the Universal Declaration of Human Rights, whose goal is to ensure the universal and effective recognition and observance of the precepts of freedom to guide human behavior, a step was set to link ethics to human rights. In the health context, the human rights principle of the freedom of the patient to choose what he/she wants and deserves must be acknowledged. Health, science, and human rights are absolutely intertwined since without health there is no good living and well-being, and without good healthcare practices supported by proper science, human rights are infringed.

The deceased past UN head Kofi Annan highlighted, in 2005, the relevancy of implementing human rights, especially, the operationalization of the right to health, which included its judicialization as the mainstream in global health organizations, with rights-based approaches to health programming and grassroots advocacy [37]. Furthermore, the reasons that justify science as a Human Right are straightforwardly linked to the precept of empowerment of the individual and the community to enhance the quality of life of all. Thus, the practice of science without ethics and morals is against the benefits associated with the best healthcare services, which are fundamental rights that every human being should be entitled to. Moreover, flawed science is against the 29 topics covered in the 2018 publication by the Economic, Social, and Cultural forum of the United Nations on the right to benefit

from science and the intellectual property of the knowledge translation [38]. Furthermore, science translation must be free from political control or any other conflict of interest. Ignoring this aspect is an attack on ethics and morals!

Thèrese Murphy [39] in her paper "Health and Human Rights' Past: Patinating Law's Contribution" focuses on international human rights law, by depicting histories of health and human rights notably the international human right to health and human rights-based approaches to health. She highlights some neglected histories, namely those exploring the low levels of attention to certain problems, such as the right to science. According to her these particularities are relevant to health and human rights, and she defends the utmost important role of international institutions. However, she critically appraises these institutions as "Palaces of Hope," because, according to her, they act precariously and far from those who need their protection. In this regard, a parallel could be made between healthcare associations, expert societies, and academia who should be the "Palaces of Hope" by straightforwardly guarding and defending good science while at the same time protecting the community. However, similar to her point of view regarding these institutions, they are weak when facing power, and are also poorly focused on excused and mudded support due to the lack of reforms, while populist and authoritarian entities are on the rise.

Finally, but not least relevant, it is mandatory that the discussion on ethics in research encompasses healthcare innovation once this truly may affect patients not only economically - unequal access to diagnostic tests and treatment options for marginalized communities - but also by exposing personal data either from electronic medical records or healthcare apps. Also, of utmost importance to be highlighted and discussed is the use of artificial intelligence and machine learning. Both may unequivocally help in supporting medical access/information/results. The former may be a solution to support far away vulnerable geographic populations or those in war zones with difficult healthcare coverage, while the latter, with combined large data sets, various algorithms, and results derived from huge petabytes of information, may solve conflicting or complex problems. Suffice it to say, though, that machine learning data might be bias by improper collection, important missing information, and typing mistakes. Furthermore, according to Obermeyer and Emanuel [40] "machine learning does not solve any of the fundamental problems of causal inference in observational data sets. The usual common-sense caveats about confusing correlation with causation apply; indeed, they become even more important as researchers begin including millions of variables in statistical models." After all, and despite the current widespread use of these computational techniques in healthcare research, machine learning models may be black boxes, once it is important to understand the reasons behind predictions as well as it is of utmost relevancy to trust the models [41,42]. In essence, algorithms may be good at predicting outcomes, but predictors are not causes [43].

Conclusion

Ethics in research is a highly relevant topic that should be more frequently taught and discussed to positively benefit the community, without the influence of any potential conflict of interest. It encompasses various steps from how research is conducted from conception to data analysis and publication. In the absence of ethics, bad science abounds and is prone to jeopardize healthcare practices infringing harm to the community. Healthcare institutions, as expert societies and associations, and especially the academia should be the guardians of ethics, but unfortunately, they are not, as many of these favor unfair and unethical practices to excel in the competitive environment. Finally, with the advances of new technologies in the healthcare scenario, we must pay attention to how these are made available to vulnerable individuals. Also, of primordial discussion is how patient data are protected and used, in particular when artificial intelligence and machine learning techniques become more widely incorporated. Numbers without biological plausibility and interpretation might be untrustworthy and even cause harm. We must change it to protect patients!

Conflict of interest

No conflict of interest.

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