



Regulation or Morality: The Problem of Legislation on Bioethics

Didier Raoult^{*1} and Philippe Brouqui¹

Abstract

The COVID-19 health crisis has allowed a number of highly questionable practices in the field of international clinical research whose ethics are mainly based on the Declaration of Helsinki. This is based on the principle of benevolence, informing the patient about the expected risks and benefits, and agreeing to participate in research and transparency. Here we discuss these principles and their application during the crisis, taking as examples the vaccination campaign, information and consent of individuals and conflicts of interest. On the other hand, we discuss research regulations, which sometimes depart from the primary concepts of the Declaration of Helsinki, taking as an example on the one hand non-inferiority tests and on the other hand low-risk samples. In conclusion, it seems that bioethics has drifted from these objectives in favor of strict compliance with regulations.

Keywords: Human research regulation, morality, bioethics, conflict of interest, clinical trials.

Introduction

The problem of morality in medical research, which semantic drift has transformed “bioethics”, has, in all Societies with a high level of government administration, been the subject of numerous laws and regulations. However, the purpose of these laws and regulations often ends up far removed from the moral framework that presided over the establishment of predefined rules that may differ from one country to another. Many countries refer to the Declaration of Helsinki, (1) which has several components to it, but which has become increasingly complex as participation and influence have increased. The essence of bioethics is benevolence, no hidden risk-taking, and transparency. It is true that there was a need for regulation to ensure that human experimentation was controlled, even if some experiments that are now disallowed played a critical role in the evolution of medical strategies, in particular Pasteur's seminal work on therapeutic rabies vaccination (2). Human experimentation culminated in the concentration camps during the Second World War, under the leadership of Dr Mengele, and continued in various countries on experiments to infect individuals with or without their consent, in exchange for the release of or financial compensation. There is, therefore, no doubt that therapeutic and/or vaccine trials, the effect of which is unknown, even when it is presumed to be negligible, must be strictly regulated.

The literature is replete with examples of unexpected effects occurring during vaccination, including recent evidence of thromboses after the administration of the AstraZeneca COVID vaccine and myocarditis following administration of the COVID RNA vaccine in young men. These rare events

Affiliation:

Aix Marseille Université, IHU Méditerranée Infection, 19-21 Blvd Jean Moulin, 13005 Marseille, France

*Corresponding author:

Didier Raoult, Aix Marseille Université, IHU Méditerranée Infection, 19-21 Blvd Jean Moulin, 13005 Marseille, France.

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are among the hazards that can only be discovered after testing thousands or millions of people. Others could have been discovered much earlier, such as the cardiac incidents which occurred after the prescription of Vioxx, and which should have been detected during the evaluation phase by the laboratory. This first point is essential. The danger of introducing new therapies must be clear and must be clearly explained to patients. Specific consent must be given for this type of experimentation. Likewise, the evaluation of a therapeutic strategy must be totally externalized from the institution that employs the researchers to avoid the manipulation of data or the elimination of the least favorable data, under various pretexts (be it methodological pretexts or cases considered as exceptions that cannot be evaluated). The nature of therapeutic trials cannot and should not be concealed under any circumstances. There must be full transparency about therapeutic trials and there is no scope for protection in terms of industrial secrecy. Until now, this type of data manipulation, when proven, has been punished with financial sanctions, as was the case of Merck-Pfizer for Vioxx. Criminal punishment has not arisen, even though it is estimated that tens of thousands of people have died because of treatment, the therapeutic risks about which they were not informed. This discrepancy in the criminalization of deaths resulting from concealing adverse events is a very clear anomaly in the legislative apparatus and is an area which needs greater clarification. Informed consent forms relating to this subject should not be confused with other such forms used in other types of medical research that do not put patients at risk. Some of these consents' forms, particularly in France, include a considerable number of elements which either maliciously or unintentionally obscure the substance of the issue, which is the risk to the patient.

Conflicts of Interest and Investigator Self-Interest

The principle of the conflict of interest is essential (3). Most of the officials who have addressed this issue (including three former Editors-in-Chief of the New England Journal of Medicine and the Editor-in-Chief of the Lancet), found that it was becoming difficult or impossible to resist pressure from the pharmaceutical industry regarding conflicts of interest. This is an issue that has not really been resolved. One of the barriers to its resolution has the confusion over different potential forms of conflict of interest. Direct funding or funding by an organization or foundation belonging to the investigator is a conflict of interest of the first order. Clearly, this type of conflict of interest should be indicated to all patients entering any type of therapeutic trial funded by industry. In France, for example, this type of information is not compulsory in the patient's information sheets. There is, however, a real need for this in terms of medical ethics

because the contract between the doctor and the patient then includes a third partner, the sponsor of the study. It is also clear that conflicts of interest are not systematically declared, and that conflict-of-interest databases (such as "Dollars for Docs" and "Euros for Docs") are not systematically consulted by publishers to verify the nature of the conflicts of interest.

In France, a law was passed on conflicts of interest which has never really been applied. Theoretically, if someone intervenes publicly in a field to talk about therapeutic strategies for example (as has been particularly common during the COVID pandemic) and has a conflict of interest in that field (such as funding from a laboratory or industry), that person should declare their conflicts of interest. This has hardly ever taken place. Reviewers' conflicts of interest should also be systematically published, although this too has rarely been the case. Furthermore, some areas should exclude investigators with conflicts of interest, e.g. guidelines.

When Didier Raoult was Editor-in-Chief of Clinical Microbiology and Infection, he tried to get ESCMID to pass a regulation on this area excluding people with conflicts of interest from writing guidelines referring to molecules in which they had had an interest over the past five years. This conflict of interest came to a head when the Editor-in-Chief of Clinical Infectious Diseases, one of the top infectious disease journals in the world, was discovered to be a member of the board of Gilead during the COVID pandemic and was deciding which articles could and could not be reviewed in his journal. Early in the pandemic, this led to the paradox of observational studies with no comparator, which concluded that Remdesivir, produced by Gilead, was effective, (4) while comparative but non-randomized studies on hydroxychloroquine were rejected outright.

Conflicts of interest apply not only to investigators and reviewers but also to the journals themselves, especially those journals that advertise pharmaceutical industry products. Such journals should be obliged to declare their conflicts of interest. Mainstream newspapers, or even television or radio programs, which receive sometimes considerable funding from the pharmaceutical industry, should also declare their conflicts of interest. Medical foundations, whose strategies significantly influence global health policies, should systematically declare any conflicts of interest. In particular, the Bill Gates Foundation and Gavi, the primary funders of the WHO and who finance a considerable number of studies on vaccines and therapeutics, should declare the investments of these foundations and their Chairs in the pharmaceutical industry and in vaccination. Finally, the systematic and organized amplification of citations of articles from favorable therapeutic series leads to an over-representation in research of therapeutic trials which, in most cases during the 21st century, have not really changed the prognosis of human health. This

race to the top for new strategies has led to an increasingly obvious discord between the level of health funding in the richest countries and the evolution of life expectancy. The poorest countries, mostly using generic drugs, now have a life expectancy that is completely disproportionate to the therapeutic investment. For example, in 2023, life expectancy in the United States was lower than in the Maghreb countries, China, Cuba, and several countries that, until recently, were considered to be underdeveloped and unable to reach the life expectancy of the richest. This paradox of wealth and declining life expectancy leads naturally to a reflection on its causes. Even though (or perhaps because) the United States has the largest pharmaceutical industry, life expectancy is no longer increasing and is in fact significantly declining (5). One of the major illustrations of this issue came in the form of the oxycontin paradigm and the Purdue company, which was advised by the McKinsey company. Promoting the idea that oxycontin was non-addictive, unlike the morphine from which it was derived, was a blatant scientific lie that was hard to believe and would not have been believed without major influence upon prescribers and policy makers.

Moreover, the political decision to prioritize funding hospitals that promote access to opioid painkillers for their patients has encouraged the use of these addictive drugs, which are at least partly responsible for the appalling epidemic of overdose and addiction deaths that has been estimated in the United States at 100,000 per year in recent years (6). It should be noted that scientific and medical journals did not notice the conflict of interest until very late in Purdue's collapse. This revealed to the public the extent of Purdue. Pharma's funding of many institutions, including prestigious American universities, despite the fact that the evidence for the role of opiates in mortality was so clear that Didier Raoult had had the opportunity to publish a book on the subject a few years earlier (7). Due to the power of the industry and the company's ability to generate citations for its own papers, the case of the Purdue company went unnoticed.

One of the issues to be resolved in the field of conflicts of interest is the issue of whether there is a watertight separation between medical and scientific research sponsored by the pharmaceutical industry and by influential foundations, and that generated by academic research. It is notable that few academic journals remain today and that there is, once more, an essential conflict in these journals between direct funding from foundations and/or industry, indirect funding (the purchase of article vouchers), advertising and the added value through the number of citations generated by this mechanism. Under these conditions, it is very difficult for financially neutral research to find its place, given the scale of conflicts of interest at play. For example, in France, it has been noted that the conflicts of interest of infectious disease specialists were directly related to their positions on COVID therapies

(8). Interestingly, conflicts of interest were visible on the [Euros For Docs](#) website for more than 90% of infectious disease specialists in France, although this information has not been addressed by the judiciary or covered by the press.

Scientific integrity, denunciation and slander

A new phenomenon has appeared in the literature among the major publishers who have now become more commercial than academic companies with editors-in-chief who often do not come from the academic world and do not have legible scientific production. In order to combat competition from emerging newspapers from multiple countries (China, India, Middle East) classified as predatory newspapers, the evaluation of the scientific and ethical integrity of newspapers has been intensified. At the same time, a post-publication comment website, called PubPeer, was launched at the end of 2012 by neuroscientist Brendon Stell and brothers Richard and George Smith, with Boris Barbour and Gabor Brasnjo as advisors. Initially, the founders and advisors were anonymous, but they revealed their identities in 2015. On this site, anyone can comment on a scientific article, most of the time anonymously, the comments are only moderated on their outrageous nature. This platform has been widely used by Elisabeth Bik, a biologist with a scientific background who has a self-proclaimed "fraud hunter". She recently confessed in an interview (10), she was a victim of face blindness also called prosopagnosia. She said his brain has the uncanny ability to spot retouched or doctored images in a fraction of a second. She explains that his neurons, by a strange mechanism, launch themselves in search of repetitive patterns, replicated angles, points or similar lines scattered throughout the pages. She manages to spot copy-paste even when an academic has taken care to flip the original image or edit it in Photoshop (10). *"Before, I thought everyone was like me..."*. *"I only recently realized that I had some kind of special ability."* This donation will push her to flush out scientific fraud using the PubPeer platform.

Thus, anyone can denounce a breach of ethics or scientific integrity of the authors of a scientific article anonymously, bringing these researchers and their universities into disrepute, and without anyone being able to assess the qualification and expertise of this anonymous whistleblower allowing his comment to be judged appropriate. In addition, some malevolent people are using Pubpeer's comments to harass newspaper publishers to take these accusations seriously, to put these articles under "Expression of Concern" and to initiate the necessary investigations. An article by Frank et al. reports that 456 articles from the IHU Mediterranee Infection raised questions about ethics, in particular for 250 of them relating to research on bacteria isolated from humans in the context of care which had the same ethics committee number (12). A total of 455 emails were written to journals

publishers by the authors of Frank paper, but (44%) 202/455 of them only gave a response to this denunciation.

This harassment of publishers is sometimes very violent. For example, the editor of New Microbes and New Infections at ELSEVIER received 184 emails asking her to investigate the 124 articles published in her journal and for which the same ethics committee number was reported in table 3 of Frank's article. Thus, it seems that the authors of this article, far from describing a breach of scientific integrity as they claim, have used their article to harass journal editors and tried to have all the IHU articles reported in their article retracted. These investigations launched by journals publishers in the face of these accusations have been treated in a rather disparate way. Some publishers, realizing that these accusations were pure slander, closed the accusations without even investigation, some others reacted quickly by contesting this accusation and after meeting their ethics committee quickly cleared the authors of these slanderous denunciations (13). But some publishers launched these investigations on more than 450 articles. Faced with this situation, our university has created an ethics and scientific integrity unit (CEIS) to deal with these issues. In the exchanges with these publishers, it is remarkable to note that some of their ethical investigation teams, the most intransigent being that of the Nature Springer group, considered that the French bioethics law and international ethical laws were not sufficient to validate that the ethical conditions in these articles had been respected and that they were more demanding than these, for example by considering that the analysis of lice collected from humans was a human research project and required an IRB agreement. In practice, this means that a group like Nature Springer considers that French bioethics laws do not correspond to international ethical standards that are predefined by the Declaration

of Helsinki. The nature of this type of comment suggests that these scientific journal publishing groups have given themselves the power to define what is ethical and what is not outside the Declaration of Helsinki and outside the existing bioethics laws in the different countries. This is particularly serious given the fact that France now pays a lump sum to these large publishing groups, that most of the editors of these publication groups do not have scientific skills and that their sources are essentially an anonymous online whistleblowing site: PubPeer. Moreover, the legitimacy of a retraction, for internal reasons of the journal, after the acceptance of a scientific article by the publisher and its invoicing should eventually lead to legal proceedings. At the time of writing, investigations are still ongoing, but among the incriminated articles, 269 have been analyzed by the ethics and scientific integrity unit (CEIS) of Aix Marseille University (Table 1). Of these, 267 (99.3%) were considered to have complied with the rules of ethics and scientific integrity, 2 (0.7%) were considered problematic by the CEIS. A response was given to the editors by the unit in 262/269 (97.3%) of the cases, but at November 2024, for 225/262 (85.8%) of the articles reviewed by CIES and returned to journals, no editorial decision was given. Among the decisions taken by the journals, 59.3% saw the EOC raised (65.5% at PLOS), 3 saw the retraction abandoned and replaced in EOC by the publisher and 38.5% saw the retraction confirmed. It is noted that the most emblematic articles were analyzed first and that the continuation of the investigations, if it continues, will certainly change the balance in favor of the articles without problems. It is noted the difference of appreciation between the CEIS of the AMU and the ethical teams of the publishers. Among the explanations, we can imagine that the latter were victims of strong pressure influencing their decision as reported above.

Table 1: Results of the preliminary analyses of the Aix Marseille University ethics and scientific integrity unit of articles suspected of fraud by the IHU Mediterranee infection and final editorial decision

Journal	CEIS*	CEIS	CEIS	Journal	Journal	Journal	Journal
	Received	Concerns	Answered	EOC removal	Retraction confirmed	Retraction abandoned	Still no decision
PlosOne	50	0	50	8	5	3	34
New Microbes and New Infections	160	1	160	0	0	0	160
SpringerNature	23	0	22	6	0	0	13
Wiley	3	0	3	0	0	0	3
Parasite	1	0	1	0	0	0	0
Scientific Reports	1	0	1	0	0	0	1
Frontiers	11	0	11	0	0	0	11
MDPI	4	0	4	1	0	0	2
Critical Care	1	0	1	0	0	0	0
Archives of microbiology	2	1	2	0	2	0	0
BMJ	2	0	2	0	0	0	1
International Journal of Infectious Diseases	6	0	0	0	0	0	0
Letters in microbiology	1	0	1	1	0	0	0
International Journal of Obesity	3	0	3	0	3	0	0
Clinical Microbiology and Infection	1	0	1	0	1	0	0
Total	269	2	262	16	11	3	225

*Ethics and Integrity Unit of Aix Marseille University

Clinical studies and samples taken from patients

Regarding clinical studies, three levels of samples must be distinguished:

I/Samples taken which constitute a danger (e.g. biopsies) or examinations which involve a danger, even a minimal one (radiology with irradiation), II/samples that do not present any danger, such as adding a tube of blood to a care procedure III/ samples such as urine, saliva, and stools which are human waste that could have been taken from nature or from a garbage can does not present any danger which requires neither information nor consent being assimilated to scientific products that no longer belong to man (see below)

In terms of drug evaluation, these two types of samples are regulated in France by the law on bioethics (known as the “Jardé law”) and must be authorised by an ethical committee institutional review board (IRB) before the beginning of collection. However, in our opinion, sampling which does not present any danger, such as urine, saliva, or stool collection, for example, in contrast to the invasive studies mentioned above, which require IRB approval, should be covered by a more general ethical opinion. While individual informed consent should still be required, this type of sampling does not require an ad hoc IRB opinion but rather a generic agreement by an independent local ethic committee.

The use of waste in medical research

Since Roman times, waste has been deemed to belong to no-one “Res derelictae” (14), whether it is organic or inorganic, human, or animal, and whether it goes down the drain or is thrown into the waste. More recently the French ministry of health confirmed that “since human waste is not people but things, research on this waste is not research involving human beings but “scientific” research (15). A specific point must be made on this type of sampling: it separates of the link between the person who issued it for reasons other than experimentation, and the researcher. This requires anonymisation and the absence of genetic identification on the samples being taken. This type of analysis must be granted extremely wide latitude and must only be prevented by the patient’s refusal to allow their samples to be used, whether they are the remains of tubes taken for other examinations or waste material, which in any case must be disposed of.

Non-Inferiority trials

Finally, the ethics of certain types of studies need to be clarified for the patient. In non-inferiority trials, which are very often sponsored by industry and for which investigators are paid directly or indirectly, patients should be informed that the trial is designed to prove that the new tested treatment is not substantially worse than the reference one (16) ! This

means that, in all cases, the patient cannot expect an additional benefit from the new treatment compared to the reference but that if this efficacy is between 0 and -10% it will nevertheless be considered equivalent. Most of the time, the patient is not informed and aware that he or she is taking an unnecessary risk for almost no benefit. In practice, non-inferiority testing is part of the product validation process that the public health authority will cover.

The ethics of trial methodologies

Trial methodologies have changed in recent years, largely due to the influence of the pharmaceutical industry, which has consistently promoted randomised trials that it alone can organise due to the considerable cost of such trials. There is no current evidence in the literature that randomised trials are superior to other comparative trials (17), either historical trials or trials comparing different institutions with patients who have been homogenised in terms of risk factors (propensity score). These randomised studies serve almost exclusively to prevent studies from being conducted outside the pharmaceutical industry. The only value of randomised studies was the risk of manipulating the data in non-randomised studies by selecting patients. However, in this area, as in all other areas concerning medical ethics, the problem is the motive for distorting the data. The motive may be related either to the financial interest of the sponsor or the investigator, which is the most common motive observed in data manipulation, or it may be related to passionate investigators who consider that the final interpretation will be justified by the results, even when they are not convincing. This was the problem with Jacques Benveniste’s narratives of the “memory of water” (18) .His work would not have been published if all the data from the different manipulations had been transparent. It was clear, with retrospect, that Benveniste was not trying to cheat, since all the data were present in his laboratory notebooks, including those that contradicted the final version of his interpretation. He had no intention of cheating, but he had been trained to consider that manipulation giving the opposite results posed technical problems. Finally, the continual increase in the regulation of bioethics has led to the creation of a whole series of jobs which are ancillary to real science, including ethics officers who do not have sufficient scientific training to answer questions, or even to analyse what is likely to constitute fraudulent manipulation, error, or simply the inability of analysts to really compare data. Whistleblower sites have thus been created online, such as “PubPeer”, which can be instrumentalised, including by the pharmaceutical industry and even by governments, to fight against information that is unfavourable to them. Some authors who have submitted reviews online then bombard publishers with these reviews and some, for reasons of their own, decide to harass the authors of publications that sometimes date back 20 or 25 years to request the originals of the work carried out.

The COVID crisis has shown that misinformation can come from the most recommended sources. Two such examples include the Lancet, with the “Lancetgate”, when it reported that one of the most prescribed drugs in the world, representing probably more than 50 billion treatments with chloroquine or hydroxychloroquine, led to cardiac arrest in 10% of the cases, a claim made by a totally unknown team (19). This retracted paper is still widely cited, and is still on the Lancet website. We are waiting to see what measures the Lancet will take to avoid this kind of gross error in the future and are also waiting to know whether the people who published this “fake” study are going to be prosecuted. The Lancet had of course previously appeared to be a reliable source of information. More recently, a study that reported 17,000 deaths related to the use of hydroxychloroquine in COVID-19 was also retracted for fraud (20). The second example is that of the FDA, which published an advert saying that ivermectin was a drug for veterinary use only, claiming “If you're not a cow or a horse, don't take ivermectin”(21). It can be questioned how much of this is ignorance and how much is propaganda, as ivermectin is one of the most widely used treatments for human parasitic infections in the world. When all is said and done, the pharmaceutical industry can be compared to the tobacco industry or the car industry; they all face similar scandals. So far, despite the number of direct deaths caused by several errors, the pharmaceutical industry has not been penalised but possibly fined, and many countries do not even have the possibility of imposing fines.

When we created our Institute in 2015, to prevent these abuses, we set up a conflict-of-interest committee and an ethics committee. The first was named the Committee for the Evaluation and Prevention of Conflicts of Interest (CEPCI). Its objectives are the establishment of a transparent and effective conflict-of-interest management policy, with the aim of strengthening confidence among members of the public and partners, to protect IHU authors against potential conflicts of interest and to ensure the transparency of the IHU at the international level. The work of this committee consists in informing, advising, and notifying actors within the IHU, and in presenting an annual report on the ethics and independence of scientific expertise in matters of conflict of interest. For example, the committee recommended ensuring that medical information provided by representatives of the pharmaceutical industry and the diagnostic industry, took the form of an annual information meeting open to interns and assistants, supervised by doctors and pharmacists, and that it took the form of the adversarial principle provided for by French law. Consequently, any canvassing by the pharmaceutical industry outside this information day was prohibited. The ethics committee was named the Research Medicine and Humanity committee and was also created in 2015. Its members included two former presidents of

the French national ethics committee, and social science and psychiatry experts, who shared the objective of putting morality back into ethics by 1) answering the ethical demands of investigators and 2) investigating the questions concerning information given to patients and their relatives, particularly in the context of biomedical research. The opinion they gave us on non-inferiority trials (see above) stated that they did not recommend these trials unless they clearly showed at least one secondary benefit for the patient, for example a new mode of administration of a drug which reduced adverse effects.

Conclusion

Bioethics has been diverted from its objective of an ethical approach to clinical research that contains, as stated in the Declaration of Helsinki, transparency, evaluation by external structures when there is a danger to the patient, and benevolence. These elements currently appear to be obsolete and ethics officers at various levels are more concerned with analysing strict compliance with their interpretations of the regulations than with the moral problem that a certain number of clinical trials may pose.

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