**The research for a COVID-19 vaccine: reopening of the dilemma on unethical offshore clinical trials.**

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**ABSTRACT**

All around the world, healthcare systems are facing a battle against COVID-19 and different research groups are trying to develop a novel vaccine against it as fast as possible. Because of this, on 1st April 2020, an interview between two French professors reopened the controversy about conducting clinical trials in low- and medium-income countries to accelerate the research of this vaccine. This interview was broadly criticized and portrayed the current social belief that offshore clinical trials are always unethical. Our objective is to explain the origin of these ideas and why low- and medium-income countries have always been such an attractive place for conducting clinical trials. We also support the idea that these experiments are not per se immoral and, if all the ethical standards are met, there is a variety of scientific advantages, that place them as the best choice.

**INTRODUCTION**

In August 1947, the international community penalised all the human crimes committed by Nazi doctors in their clinical trials. They were accused of human torture and murdering during their experiments at the concentration camps. The *Nuremberg Code* appeared as a consequence of this disaster, not only setting the foundation for today’s medical ethics but with the aim of avoiding similar situations in the future. (1) Years later, in June 1964, in an attempt to reinforce this message, the international research community gathered again to write the *Helsinki Declaration*,creating a new robust ethical framework. (2)

Nowadays, in order to participate in health research, patients need to know the objectives, benefits and potential risks of the clinical trial they are enrolled in, through informed consent. These ethical codes are generally respected in the western world, however, in low income settings, the power differential between the researcher and participants and the presence of cultural differences may lead to the transformation of research candidates into victims of harmful research procedures. (3)

The literature on ethics of clinical trials is replete with notable instances of poor ethical conduct. One of the most remarkable examples that was brought to the attention of the media was the *Trovan* clinical trial in Kano in 1996 (3) where, according to the court, *Pfizer* never obtained authorisation and conducted “*an illegal trial of an unregistered drug*”, being “*a clear case of exploitation of the ignorant*”. (4) Nevertheless, this scandal did not prevent other unethical trials happening in this region. An example of this is the Tenofovir (Viread) clinical trials in Cameroon in 2004 where participants were neither adequately informed about the risks (since only English information was given to mostly French speaking volunteers), nor treated in case they became HIV-infected. Another important case was the antiretroviral treatment interruption trials conducted in several African countries from 2003 to 2006, where standard continuous antiretroviral therapy was compared with structured treatment interruption (STI). In these studies, although there was a remarkably high number of fatalities in the STI group, sponsors decided not to interrupt the trials even though a negative result was identified. (5)

In all the examples illustrated above the “double standard” is still evident. This principle justifies conducting research in low and middle-income countries (LMICs) that would not be ethically acceptable or permitted in a high-income country because of different standards of care. According to some experts, this way of thinking may be a demonstration that the moral imperialism and colonial frameworks still exist and continue to be articulated in the outsourcing of clinical trials to LMICs (6).

This phenomenon, which begun in the past during colonialism and has now evolved into a normal constant, was brought again into the public discussion after an interview between two medical professors on the French TV chain *La Chaîne info* (LCI) where they suggested the idea of conducting a clinical trial in Africa to test the efficiency of the BCG vaccine as a possible solution for COVID-19. They described Africa as the perfect scenario to carry out this kind of analysis as, quoted, *“* *[in Africa]* *there are no masks, no treatment, no intensive care, a bit like it is done in some studies on AIDS or among prostitutes”* (7). With such a statement, these two doctors were not only supporting this double standard principle but also ratifying other similar unethical cases of the past as acceptable.

The social response to this interview was remarkable. Various celebrities criticised the debate and even the Director-General of the World Health Organization, Tedros Adhanom Ghebreyesus, officially condemned the debate. He considered the ideas proposed as “*racist remarks*” and firmly claimed that "*Africa cannot and will not be a testing ground for any vaccine”.* Ghebreyesus insisted that "*these kind of racist remarks*" do not help in a time when the world needs solidarity. (7) Both French professors finally apologised for these statements.

While the possibility of conducting a clinical trial on the BCG vaccine in Africa remains unknown, these claims clearly reflect the current social belief that offshore clinical trials do not always respect ethical standards. It is acknowledged that the risk of taking advantage of LMICs may be bigger due to their unfortunate legal and financial situation. This is a global issue affecting all nations, and unless countries agree to cooperate taking a stronger action, the number of victims in these trials will continue to increase.

We consider, however, that in certain situations it is undeniable that offshore clinical trials present some advantages for global research. We believe that if individuals are respected and treated equally, matching the ethical standards and conduct with that of more developed countries, there would be no reason not to collaborate globally with these countries for the benefit of Medicine.

**CIOMS GUIDELINES: CORNESTONE OF ETHICS IN CLINICAL TRIALS**

The Council for International Organizations of Medical Sciences (CIOMS) is an international non-governmental organisation in official relationship with the World Health Organization (WHO). Since the late 1970s, CIOMS has worked with the WHO to prepare guidelines on ethics in biomedical research. More specifically, the aim of the guidelines is to provide internationally vetted ethical principles and detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research in low-resource settings. (8)

In an attempt to avoid future unethical research scenarios as those previously discussed, some of the most relevant principles of the CIOMS’s guidelines must be borne in mind. For instance, prior to a study, the researcher, sponsor and research ethics committee must ensure that risks to participants are minimised and appropriately balanced in relation to the prospect of potential individual benefit and the social and scientific value of the research.

Additionally, in the interest of participants’ health needs, researchers and sponsors must make adequate provisions for each individual involved both during the research and, if necessary, for the transition of them to care when the research is concluded. The information related to this researchers’ responsibility must also be included in the informed consent process.

With regards to consent, researchers have a duty to ensure that participants provide free and informed consent, with the right to decline enrolment in the trial or withdraw from the research at any time without penalty or loss of benefits to which they would otherwise be entitled.

In cases where vulnerable individuals and groups are involved, researchers and research ethics committees must ensure that specific protections are in place to safeguard the rights and welfare of these individuals and groups in the conduct of the research.

**CONSIDERATIONS OF THE ADVANTAGES OF INTERNATIONAL TRIALS**

Although international clinical trials may allow LMICs to benefit from the creation of new innovative drugs they could not otherwise afford, the likelihood of unethical practices such as a misunderstanding of informed consent and exploitation of participants in these countries are relatively high.

Considering the standards and benefits of international trials, it should make no difference in which country a clinical trial will be conducted. All trials should be exclusively based on a set of values that professionals can refer to in the case of any confusion or conflict, such as those detailed by CIOMS. These values include the respect for autonomy, non-maleficence, beneficence, and justice. (9) If all these conditions are met, there is a variety of scientific advantages that encourage medical entities to conduct clinical trials in these countries.

**Endemic diseases**

In certain settings, conducting an international clinical trial is the only way to test a specific drug or vaccine. There are certain diseases such as malaria that predominantly affect people in a delimited geographical area. For example, the only way to assess the efficacy of a new antimalarial drug would be by running a clinical trial in Sub-Saharan Africa rather than in Europe or North America where the number of infected people is clearly minor. Additionally, these trials offer a huge advantage regarding seasonal conditions around the planet since it would allow companies to go directly to the countries suffering from that disease rather than waiting for half a year for that disease to come to their local country. Furthermore, this would accelerate ongoing research benefiting both low- and high-income nations, particularly in the setting of global epidemics. (10)

**Characteristics of the patients enrolled**

In many of these studies, enterprises are enrolling so-called naïve patients. These are patients who do not regularly take any medications before the start of the research, avoiding some relevant concerns such as drug interactions or statistical biases.

Epigenetics is another important factor to consider when talking about drugs. For example, it has been seen that some commonly used drugs like ACE inhibitors present a higher risk of angioedema in the Afro-Caribbean population than in other ethnic groups. (11) If such a study were conducted in a country where the Afro-Caribbean population is considerably small, the duration would be excessively long. On the other hand, if this study was rather conducted in any other country with a predominant Afro-Caribbean population, it would be considerably quicker. (10,12)

**Faster market launch and access to the patients**

It is important to consider the time to market launch as measures that are too strict may slow down the approval of a vaccine that could save the lives of thousands of patients. Having the opportunity to conduct faster clinical trials would help the population, particularly during emergency situations, when there is an urgent need of the drug in question.

Several social movements have been created to fight against the obstacles that delay the approval of a drug such as rigid legislation or time-consuming bureaucratic procedures. (10) By way of example, in 1988, activists from AIDS Coalition to Unleash Power (ACTUP) lobbied the FDA to protest the delay of a drug approval process that was costing the lives of thousands of patients. They protested to improve access to emergent therapies and pushed the FDA to modify some regulations regarding the Investigational New Drugs policy implemented in 1987, facilitating the access of ill patients to promising new therapies. (10,13) As a consequence of this type of stringent regulations, clinical trials started to move abroad in the 1980s, looking for less bureaucratic procedures.

However, on the other hand, it is important to consider that launching a product to the market rapidly may result in fatal consequences. For instance, if a drug has not fully been tested before its launch, it may produce some severe adverse effects. (10) A clear example of this is the *Vioxx* (rofecoxib) drug. (14) This product merchandised by *Merck* was a COX-2 selective anti-inflammatory drug for arthritis, acute pain, and painful menstrual cycles. After being launched to the market, it transpired that this drug could increase the risk of severe cardiovascular events such as myocardial infarction and stroke during chronic use. In the light of such devastating news, the company was forced to withdraw the drug from the market to avoid future adverse events. (14)

It is the responsibility of any regulatory institution to balance these two situations and to provide the population with the most beneficial solution. Nevertheless, there is an incentive to delay the process to ensure its safety, especially because lives lost due to drug delays usually result in fewer negative headlines than lives lost due to dangerous drugs approved too soon. (10) We acknowledge the risk of launching drugs that are not fully tested to the market, but we consider the risk of this event to be the same in LMICs if the trial is conducted under the same conditions.

**WHY ARE OFFSHORE CLINICAL TRIALS SO ATTRACTIVE TO SPONSORS NOWADAYS?**

Cost is the primary reason for the trend in offshore clinical trials. The average drug requires roughly $2.6 billion to bring to market, more than half of which is spent on clinical trials. International clinical trials do not only offer the possibility of creating a faster clinical trial but also a cheaper one. (15)

In places such as China, India and Russia, international firms usually find doctors and centres with a more competitive price which enables them to reduce costs. For instance, it is estimated that the management of a clinical trial could cost up to $10000 per patient in Europe while in Russia the same trial would cost up to $3000. Similarly, some first-rate medical centres in India charge one-tenth of the fees required by a second-tier American institution. (12,15)

In addition, regarding how the health industry has evolved in the last few years, a faster patient enrolment process is beneficial for the development of the study as trials often require a high number of patients. In the past, many new drugs launched into the market presented a huge benefit in comparison to their precursors and not many patients were needed to demonstrate a statistically significant difference. With the current biosimilars trend, some pharmaceutical giants are generating new drugs that confer only a very small or identical benefit over an already existing treatment, requiring even larger sample sizes. (16) These small differences require larger trials to measure improvements with statistical significance. (10) Nevertheless this faster enrolment process could be a direct consequence of a precarious health system, lack of resources and unstable political situation in LMICs.

Besides that, this faster completion of these trials represents cost savings for the manufacturers. Indeed, it is estimated that conducting clinical trials abroad enable pharmaceutical companies to reduce the length of their clinical trial by 19%, saving up to $100 million in the process. Additionally, these trials benefit from a faster launch to the market and a better profitability of the intellectual property rights of the new compound. (12)

**ETHICAL DISCUSSION**

Even though offshore clinical trials present many advantages for global research, there are some disadvantages that should be considered. There is no doubt that health research aims to acquire not only theoretical knowledge but also to benefit individuals and society. The challenge posed is how such an important, universal purpose can be pursued with full protection of individuals and communities, particularly those most vulnerable. (2,17)

In developing countries, the decision made by individuals to participate in scientific research is usually influenced by their level of comprehension and the meaning attached to the information communicated to them regarding the purpose and the procedure of the treatment or research. The free and informed consent was born with the formulation of the Nuremberg Code in 1947. At the time, society’s need was to never again endure the cruel human trials Nazi doctors executed on the so-called “*Untermensch*”. This racist term literally meant “*subhumans*”, referring to non-Arian people as “*inferiors*”. (18) The risk of making such hazardous statements such as the one made on the French TV interview is not acceptable. When physicians and scientists discuss offshore clinical trials in LMICs, they absolutely should not support the concept of the “double standard”. (6) Such beliefs could promote unethical claims at the base of the clinical research that recall a past we must never forget.

The first article of the Nuremberg Code states, “*The voluntary consent of the human subject is absolutely essential.* […] *and (the human subject) 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*”. (1) When speaking about LMICs, we have to face some linguistic and cultural barriers for achieving a well-understood, free and informed consent. For instance, participants in a malaria vaccine trial in Mali reported difficulty understanding several concepts including withdrawal from the study, side-effects from the vaccine, and the difference between a research study and therapy. This example suggests that better communication strategies, including the consideration of professional interpreters, should be in place to ensure proper consent across cultures. (19)

In addition to language barriers, it is important to understand the cultural differences regarding illness in other countries. Indeed, in most African cultures, illnesses are understood from a completely different social, spiritual and natural perspective, which could infer a misunderstanding of the true meaning of giving informed consent, and all it entails. (3)

As mentioned previously, conducting international clinical studies in LMICs may be economically beneficial. However, we should consider that this phenomenon is a direct consequence of the financial situation of the participants enrolled in the trial. Most of them consider clinical trials as a unique opportunity to receive a treatment that they could not otherwise afford. (3) Additionally, patients enrolling in these trials are often illiterate, coming from the most deprived backgrounds. According to the Declaration of Helsinki, vulnerable populations include ill people, the elderly, those with cognitive impairments, children, women, ethnic and racial minorities, prisoners, and those with educational and economical disadvantages. All populations, the aforementioned in particular, should always be protected and no research institution or centre should ever take advantage of them. (20,21)

Citizens from LMICs should not only have the right to participate in these trials, but also be properly informed by researchers about the potential risks of the novel drug or vaccine, which may often be more harmful than the disease *per se*. Physicians and researchers should provide a comprehensive overview of the procedure through a variety of means to ensure participants fully understand the potential consequences.

However, being in vulnerable groups should not mean patients are excluded from these studies without a valid reason. In fact, this could lead to a disadvantageous situation for researchers, research subjects and for the society through excluding an important patient group. This would be unethical in itself since it violates the ethical principle of justice governing fair subject selection. (21)

**CURRENT SITUATION**

COVID-19 is the biggest pathogenic coronavirus epidemic of the twenty-first century. While there is clearly a mortality linked to the virus, the most concerning problem is undoubtedly the saturation of hospitals. This may mean that other urgent medical conditions are jeopardised without patients obtaining the necessary care. In order to avoid this, the current aim of the global response is to flatten the epidemic curve by reducing and interrupting the transmission of the virus where possible. (22) Although the development of therapeutics and vaccines for the treatment of COVID-19 is still in process, there has been some significant progress in the research area, from complete genome sequencing of SARS-CoV-2 to the beginning of clinical trials for COVID-19 vaccines. (23)

In such a critical situation, it is important to consider the value vaccines have as the most obvious way to protect global health against acute diseases such as COVID-19. They are undoubtedly the most effective strategy for preventing infectious diseases, being not only more cost-effective than treatment but also reducing mortality and morbidity without presenting long-lasting effects. (23)

However, there is still no approved vaccine for human coronaviruses, thus encouraging research groups around the world to accelerate the development of a brand-new vaccine. Several approaches are being tested, from creating new recombinant vaccines to re-utilising already common vaccines such as the Measles-Mumps-Rubella vaccine or the BCG vaccine for tuberculosis. (23,24)

Currently, during the COVID-19 pandemic, both healthcare personnel and the public around the world are urgently requesting a vaccine. In this scenario, Africa has become an attractive place for several sponsors aiming to lead the pharmaceutical industry by rapidly launching a vaccine with fewer costs. Although this reality has always been present, this should not be a justification to allow interests to outweigh patients’ rights as happened with the *Trovan* case (4). Notwithstanding the urgency of the COVID-19 pandemic, it does not imply that ethical standards should be violated endangering the life of a large number of participants for the benefit of the minority.

**CONCLUSION**

We strongly believe in the cooperation between research units from different countries for the benefit of medicine, particularly in such difficult times. Additionally, we support the idea of conducting offshore clinical trials in LMICs as long as all the ethical standards are met. A study in any country should be the same irrespective of the particular conditions they may present. Any clinical research should always ensure candidates are treated equally and fully informed in order to guarantee one of the key points of the Universal Declaration of Human Rights, “*All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood*”. (25)

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