PLACEBO AND THE DOUBLE STANDARD OF CARE IN CLINICAL TRIALS: WHEN INEQUALITY BECOMES AN ETHICAL PREMISE USING INEQUALITY AS AN ETHICAL JUSTIFICATION

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The article presents an ethical analysis of randomized placebo-controlled trials (PCTs) conducted in developing countries in situations where effective treatment already exists elsewhere in the world. The authors examine a fundamental contradiction: the use of a placebo often becomes feasible only because of global inequality in access to healthcare, whereby the actual standard of care for the local population is the complete absence of treatment. Through two case studies: trials of drugs for HIV prevention and for the treatment of infant respiratory distress syndrome (IRDS) — the ambiguity of ethical evaluation is demonstrated. The key criterion for the acceptability of a PCT is identified as the degree of potential harm: while in the case of HIV the risk to participants was high but not fatal, in the case of IRDS the use of a placebo directly endangered the lives of infants. To provide a philosophical foundation for the problem, the authors employ John Rawls' thought experiment of the "veil of ignorance" and Gerald Cohen's test of interpersonal justifiability. From Rawls' perspective, PCTs perpetuate injustice, because the standard of care cannot depend on a patient's place of residence, and no one would agree to risk their life due to the contingency of being born in a poor country. Cohen's test reveals the moral deficiency in the pharmaceutical companies' reasoning: they themselves contribute to the inaccessibility of medicines and then use this as a justification for placebo controls. The conclusions argue for the necessity of a differentiated approach: prohibition of PCTs when lethal risks are involved, and permissibility only under the condition that the research is aimed at developing accessible treatment for the same vulnerable population.

Keywords: placebo-controlled trials, clinical research ethics, ethics of placebo use, global health inequality, developing countries, Cohen's interpersonal test, Rawls' theory of justice, vulnerable patient populations

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ПЛАЦЕБО И ПРОБЛЕМА ДВОЙНЫХ СТАНДАРТОВ В КЛИНИЧЕСКИХ ИССЛЕДОВАНИЯХ: НЕРАВЕНСТВО КАК ЭТИЧЕСКОЕ ОПРАВДАНИЕ

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Статья посвящена этическому анализу рандомизированных плацебо-контролируемых исследований (ПКИ), проводимых в развивающихся странах в условиях, когда эффективное лечение уже существует в мире. Авторы рассматривают фундаментальное противоречие: применение плацебо часто оказывается возможным лишь из-за глобального неравенства в доступе к медицине, когда фактическим стандартом помощи для местного населения является ее полное отсутствие. На примере двух кейсов: испытаний препаратов для профилактики ВИЧ и лечения респираторного дистресс-синдрома (ИРДС) у новорожденных — демонстрируется неоднозначность этической оценки. Ключевым критерием допустимости ПКИ становится степень потенциального вреда: если при ВИЧ риск для участников был высок, но не фатален, то в случае с ИРДС использование плацебо напрямую угрожало жизни младенцев. Для философского обоснования проблемы авторы применяют мысленный эксперимент «завеса неведения» Джона Ролза и тест на межличностную оправданность Джеральда Коэна. С позиции Ролза, ПКИ закрепляют несправедливость, так как стандарт лечения не может зависеть от места жительства пациента, и никто не согласился бы рисковать жизнью из-за случайности своего рождения в бедной стране. Тест Коэна показывает моральную ущербность аргументации фармкомпаний: они сами способствуют недоступности лекарств, а затем используют это как оправдание для плацебо-контроля. В выводах обосновывается необходимость дифференцированного подхода: запрет на ПКИ при летальных рисках и допустимость — при условии, что исследование направлено на создание доступного лечения для той же уязвимой группы.

Ключевые слова: плацебо-контролируемые исследования, этика клинических исследований, этика применения плацебо, глобальное неравенство в здравоохранении, развивающиеся страны, межличностный тест Коэна, теория справедливости Ролза, уязвимые группы пациентов

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Randomized placebo-controlled trials (PCTs) are considered the most rigorous method for evaluating the efficacy of a treatment. As stated in the Declaration of Helsinki (WHO, 2024), a clinical trial is permissible only when its scientific value and ethical soundness have been confirmed. A particular ethical burden attaches to the use of a placebo, because randomly assigning participants to a control group exposes them to potential harm due to the absence of active treatment.

The question of justifying the ethical acceptability of placebo controls is critically important, and the Declaration of Helsinki establishes clear criteria for their permissibility:

1) when no proven effective treatment exists;
2) when there are compelling and scientifically sound methodological reasons for using a placebo, necessary to obtain a reliable assessment of the efficacy of a new intervention, and provided that withholding active treatment does not expose participants to a risk of serious or irreversible harm.

The most contested issue remains the legitimacy of placebo controls in situations where an effective treatment already exists. The problem of placebo-controlled trials conducted in developing countries deserves particular attention. This refers to cases in which the necessary treatment is available but remains inaccessible to the local population due to poverty and the low local standard of healthcare. The present article is devoted to an analysis of the ethical dilemmas associated with the use of placebos in these circumstances.

INEQUALITY AS A PREREQUISITE FOR RESEARCH

A situation often arises in which an effective drug exists but remains inaccessible to patients in need due to its high cost, and this situation is most typical of developing countries. In such cases, pharmaceutical companies may initiate new trials aimed at finding a cheaper and more affordable alternative. These trials are conducted directly in developing countries, where, for economic reasons, a placebo is frequently used as the control rather than the existing effective medication.

A telling example is the case of COVID-19 vaccines. After effective vaccines had been developed in 2021, a special expert group of the World Health Organization concluded that countries with limited or no access to known effective vaccines could ethically justify conducting placebo-controlled trials of new vaccines, even when effective vaccines had already been approved and were being sold in other countries [1]. Subsequently, a number of trials of new COVID-19 vaccines were conducted precisely using placebo controls [2].

TWO CASE STUDIES: HIV AND IRDS

One of the first and most prominent debates regarding the ethics of PCTs in developing countries centered on the prevention of mother-to-child transmission of HIV [3]. In 1994, the efficacy of the drug Zidovudine in preventing infection in newborns was demonstrated in the United States. Subsequently, trials were launched in several African and Asian countries in which researchers sought to evaluate the efficacy of a shorter and cheaper course of the same Zidovudine, while the control group received a placebo [4]. It is important to note that these trials were funded by public funds from developed countries and were approved by World Health Organization (WHO) experts, who concluded that the use of a placebo in this case represented the best way to quickly and scientifically evaluate more affordable treatment regimens for preventing HIV transmission [5].

A different situation, distinct in its ethical outcome though similar in its circumstances, arose around trials of surfactant drugs for the treatment of Idiopathic Respiratory Distress Syndrome (IRDS). This disease accounts for 25% of deaths among premature infants and results from insufficient surfactant production, which leads to disruption of lung structure. In 2001, Discovery Laboratories Corporation proposed conducting a trial of its drug simultaneously in Europe and Latin America [6]. The fundamental difference lay in the design: in the Latin American arm, the control group of infants was to receive a placebo, whereas the European arm planned to use an active control, i.e., an existing effective drug. At the time, effective treatments for IRDS were widely available in Europe but were absent in Latin America.

Notably, the FDA (U. S. Food and Drug Administration) explicitly stated that conducting a placebo-controlled trial of surfactants for premature newborns with IRDS would be considered unethical in the United States itself [7]. Following an active campaign by activists, Discovery Laboratories revised the trial design and eliminated the use of a placebo, so that all infants involved in the trial could receive effective treatment in one form or another [8].

INEQUALITY AS A PREMISE, HARM AS A CRITERION

The cases described above well illustrate the ethical ambiguity of PCTs in developing countries. A comparative analysis reveals a significant difference. In the case of Zidovudine, the greatest potential harm threatened participants in the placebo group: without treatment, HIV could be transmitted from mother to fetus. However, even if a child was born with HIV, with timely initiation of antiretroviral therapy, that child has a chance to live a long life (although the question arises whether such therapy would be available in a poor country) [9]. Unlike HIV, IRDS is a fatal disease within the first days of life. Here, random assignment to a placebo group would directly threaten the lives of infants. Therefore, despite low local standards of care, the use of a placebo in trials of surfactants when an effective drug already existed was deemed unethical.

This comparison shows that the ethical acceptability of conducting a PCT depends largely on the balance between potential harm and benefit. Note that a similar trial in a developed country would be unethical, because there the effective drug has already become the standard of care. At the same time, in a developing country, the actual standard is often the complete absence of any care (that is, a placebo). In other words, if the trial were not conducted, patients would not receive the effective drug in any case. It thus appears that the ethical acceptability of clinical trials in this context is conditioned by differences in standards of care — that is, by global inequality in access to healthcare. It would seem that the harm is caused not by the use of a placebo per se, but by the socioeconomic conditions in which patients find themselves.

Furthermore, in an ideal model of a PCT, both sides derive benefit. Pharmaceutical companies acquire valuable scientific data. Patients receiving the experimental drug gain access to a treatment that would otherwise be unavailable to them. And patients in the control group typically receive compensation for participation and regular access to medical supervision, which they might not otherwise have had. None of these advantages would arise without conducting the trial. And this remains true even if the exact same protocol would be considered unethical in another country, simply because the standard of care for the control group in poor countries is objectively lower than in rich countries.

In other words, in both cases considered, PCTs became feasible precisely because of inequality in global healthcare. However, ethical acceptability is determined not only by the fact of inequality but also by the degree of potential harm. Whereas in the case of HIV, researchers could appeal to the fact that

these mothers would not have received therapy anyway, in the case of RDS such an argument is inapplicable, because what is at stake is the life of an infant. This brings us to the need for a more rigorous philosophical justification of the permissibility of PCTs.

To assess the moral legitimacy of PCTs in developing countries, we turn to two thought experiments: John Rawls' "veil of ignorance" and Gerald Cohen's test of interpersonal justifiability.

WHY IT MATTERS WHO SPEAKS: COHEN'S TEST IN ETICAL ARGUMENTATION

The philosopher Jamie Webb [10] proposed examining the problem of PCTs precisely through the interpersonal test developed by Cohen [11]. This test examines whether a given claim would sound equally convincing (or equally unconvincing) coming from any person. If a claim sounds reasonable when uttered by one person but begins to raise doubts when uttered by another, then something is wrong with the argument. The strength of a moral reason should not depend on who is presenting it.

The test consists of three sections (or steps).

1. An ethical principle that is uncontroversial. For example, the claim that "pay should correspond to the quality of work."
2. A factual assumption: this is a claim about how things are in reality. It answers the question: "What will happen if we act in such and such a way?" In our example, this would be the assumption that "if a worker is paid little, he will perform poorly."
3. A conclusion: the action that is proposed to be taken, based on the principle and the assumption. We conclude that "this worker's salary should be raised."

The essential point is that the factual assumption often depends on the actions of the speaker themselves, and if the speaker can influence whether this assumption comes true or not, their argument becomes suspect.

Consider the same argument, but advanced by the worker themselves: pay should correspond to the quality of work; if I have a low salary, I will perform worse; therefore, I need a raise. In the first case, when the argument comes from an outside observer, it sounds like an objective statement of fact. But coming from the worker themselves, it acquires a hint of manipulation or even a veiled threat. After all, the quality of work depends on the worker themselves, and it is they who are responsible for confirming or disproving their own assumption.

A MEDICINE FOR SOME, A PLACEBO FOR OTHERS?

Let us now apply this test to the ethics of PCTs in developing countries. Recall that, according to the Declaration of Helsinki, research involving vulnerable groups is justified only when it is directed at supporting the health of precisely these groups and cannot be conducted on other groups, and moreover, the group itself must benefit from the results of the research.

Consider the argument in favor of PCTs advanced, for example, by philosophers at a scientific conference, in an impersonal context:

1. Research in developing countries should benefit both participants and their community.
2. Placebo-controlled trials improve the situation for both participants and the community, even when such trials would be impossible in wealthy countries.
3. Therefore, placebo-controlled trials in developing countries should be allowed.

Now let's imagine that the same argument comes from representatives of a pharmaceutical company planning to recruit volunteers in a poor country, that is, in an interpersonal context.

1. Research in developing countries should benefit participants and their community.
2. If we conduct placebo trials here, it will improve the situation of your community (even if we cannot conduct such trials in rich countries).
3. Therefore, we should be allowed to conduct clinical trials (PCTs) here.

The similarity to the example of the wage increase becomes obvious: both the worker and the pharmaceutical companies act as directly interested parties. They themselves influence the very conditions to which they subsequently appeal in their argument. The heart of the problem is that the impossibility of conducting a placebo-controlled trial in a wealthy country is a consequence of global inequality in healthcare. The cause of this inequality lies in the high cost of effective drugs, which makes them inaccessible to the populations of poor countries. But who sets these prices? It is precisely the pharmaceutical corporations. Thus, a vicious circle arises: the companies themselves set high prices, as a result of which drugs become unavailable in developing countries, and then they come to these countries with a proposal to conduct a placebo-controlled trial, arguing that this will be a benefit for the local population, since they have no access to treatment anyway.

Just as a worker cannot appeal to their own poor quality of work, because that depends on them, pharmaceutical companies cannot simply appeal to inequality, since they themselves perpetuate it through their pricing policies. Of course, the situation is more complex: pharmaceutical companies do not operate in a vacuum but within a global system, and high drug prices are often explained by the need to recoup enormous costs of development and of meeting stringent regulatory requirements. Indeed, without costly research, new drugs would not appear at all, and it is quite understandable why the prices of innovative drugs are so high that poor countries cannot afford them.

Nevertheless, it is difficult to deny that pharmaceutical corporations bear their share of responsibility for this inequality. As part of the system, through their actions they directly influence the truth of their own argument. Therefore, when this argument is voiced on their behalf, it loses moral force, and the test of argumentative neutrality is not passed. In practice, this means that the proposed strategy is not fully, or comprehensively, justified.

PLACEBO THROUGH THE VEIL OF IGNORANCE OF JOHN RAWLS

While Gerald Cohen's test focuses on the personal responsibility of the agent — in this case, the pharmaceutical company — for creating the conditions of inequality, John Rawls' theory of justice allows us to view the problem from the perspective of the structure of the original agreement on the rules of the game. Rawls proposes a thought experiment that he calls the "veil of ignorance" [12]. Its essence is as follows: we design society without knowing what place we will occupy in it — whether we will be rich or poor, healthy or ill, residents of a developed or a developing country. Moreover, even our gender, age, ethnic affiliation, level of intelligence, and other abilities are hidden from us. According to Rawls, only under such conditions can we understand what a just society should be like and create it. Only those rules, laws, and values are just that we would

be willing to approve without knowing what position we will occupy in society.

In essence, Rawls reasons along the same lines as Cohen: in real life, when we reflect on justice, we are unconsciously drawn to choose those rules that will benefit us personally. A rich person will advocate for low taxes, while a poor person will advocate for generous social benefits. Talented people may believe that society should reward talent, while a person with disabilities may believe that caring for the vulnerable is more important. The veil of ignorance eliminates this bias, of which we are not always fully aware when reasoning about justice. Since no one knows who they will turn out to be in the new society, everyone has a powerful incentive to make that society as just as possible for all.

Let us apply Rawls' thought experiment to the problem at hand. Imagine that we are behind the "veil of ignorance" and are developing global principles for conducting clinical trials. We do not know whether we will be born in Zurich, where the best surfactants are available, or in a remote village in Latin America, where the standard of care is limited to paracetamol and hope placed in a local healer. Would we agree that conducting placebo-controlled trials in countries with a low standard of care, when an effective treatment exists elsewhere in the world, is just and ethically justified? Let us rephrase this question in Rawlsian terms: would we agree to the risk of receiving a placebo (and possibly dying, as in the case of IRDS) instead of existing effective treatment, simply because we were unlucky enough to be born in a poor country?

Rawls' answer to these questions would likely be negative. He argues that social and economic inequality is permissible only when it works to the greatest benefit of the least advantaged members of society. For example, if a doctor earns more than a cleaner, this is justified only if such a system ultimately improves the cleaner's position by enabling doctors to treat everyone better, including the least well-off. However, a scheme in which the poor are offered placebo to test a cheap generic on the grounds that they cannot afford the original drug does not maximize benefit for the poorest; rather, it exploits their vulnerability and perpetuates existing inequality.

From the perspective of the "veil of ignorance," a rational individual would never approve a rule that creates a two-tiered system of morality: protection under the Declaration of Helsinki for the rich, and exceptions to it for the poor. The moral rules governing clinical research should be developed from the standpoint of the "veil of ignorance," which precludes knowledge of the geographic and economic position of potential participants, and research should not use those who find themselves in the worst situation as a resource. Thus, from the perspective of ideal theory, PCTs in developing countries when effective treatment exists in developed countries are unjust by definition, because they institutionalize inequality and violate the principle of the universality of human dignity.

Proponents of PCTs start from the factual assumption that the population of developing countries lacks access to expensive treatment, so that even participating in a PCT with the risk of being assigned to a placebo group is beneficial for them, as it provides access to physicians and a chance to receive the new drug. However, from Rawls' critical perspective, no one would agree to the risk of receiving a placebo instead of existing effective treatment simply because they were born in a poor country. Justice requires that the standard of care in a trial be determined not by local poverty and inequality, but by global medical consensus and recognition of the equality of human dignity. It follows from this that permitting placebo controls in developing countries when effective treatment exists in developed countries is unjust, because it penalizes people for circumstances beyond their control, which contradicts the idea of fair play underlying Rawls' theory.

«PROHIBIT CANNOT PERMIT»: SEARCHING FOR AN ETHICAL BALANCE

The confrontation between Rawls' and Cohen's approaches provides us with a comprehensive picture of the ethical problem. Rawls points to structural injustice: PCTs in developing countries are a symptom of global inequality, and from the perspective of an ideal contract, they should not exist at all, because they violate the principle of universality and use poverty as a resource. Cohen, for his part, shows that even under conditions of this injustice, when pharmaceutical corporations propose PCTs as a solution, their argumentation proves morally deficient, since they themselves bear responsibility for the conditions that make such research "beneficial" for the poor.

What follows from this? Does it mean that PCTs should be prohibited?

Let us return to the analogy of the worker and the employer. Recognizing the worker's argument as unconvincing does not negate the fact that it may be in the employer's interest to raise the worker's salary if the employer truly values the worker's labor. If the employee is valuable and necessary, the employer will likely agree to a raise, because it is in the employer's own interest. Similarly, recognizing the moral deficiency of the pharmaceutical companies' position does not negate the fact that for the population of a developing country, PCTs are often the only hope of gaining access to modern medicine. A ban on PCTs in such a situation would not eliminate inequality; it would merely entrench it, depriving the poor of even the minimal assistance they might otherwise receive.

At the same time, it is important to understand that placebo control is not the only possible methodological option. Alternative approaches exist: for example, one can compare the condition of patients receiving a new drug with data from medical records of similar patients from past years, or assess changes in the condition of the same patients before and after treatment. Such methods have already been successfully applied, particularly in studies of anticancer drugs in developed countries [13].

CONCLUSIONS

Thus, the ethical assessment must be differentiated and take into account the specific circumstances of each case. PCTs appear to be unethical if their sole purpose is to obtain marketing or scientific benefit for the company in the presence of a lethal risk to patients, as was the case with surfactants. Here, a categorical prohibition from Rawls' perspective is applicable. At the same time, PCTs may be deemed permissible if they are aimed at finding a cheaper, more accessible, and adapted treatment specifically for the developing country, and the disease itself does not carry an imminent lethal threat, as in the case of HIV. In this situation, despite the imperfection of the conditions, the research works to mitigate the very inequality that gave rise to it.

The key factors become the intention of the trial and the provision of post-trial access to the resulting drugs. If the outcome of a PCT is a drug that remains inaccessible to the population of the country where the trial was conducted, this represents pure exploitation. If, however, the outcome is an affordable drug, this represents an attempt to rectify injustice within an imperfect world.

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