AFRICA'S UNETHICAL CLINICAL TRIALS

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For over a decade, Wemos has done extensive research on clinical medical research and the global clinical trials industry in developing countries. We found that the risks involved for those who participate in pharmaceutical companies' trials in these regions are cause for concern. Because clinical trials are not always conducted according to leading ethical guidelines for medical research, like the Declaration of Helsinki, trial participants are vulnerable and at risk of being physically harmed or having their rights violated. Our recent report on clinical trials in Africa emphasized the need for more scrutiny of the pharmaceutical industry, in order to hold it accountable for unethical practices in clinical trials. Due to their vulnerable position, clinical trial participants, often sick people with a clear medical need, should be protected from the harmful situations they can find themselves in.

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Over the past years, Africa has become a popular destination for pharmaceutical companies to offshore their clinical trials. Our research in South Africa, Kenya, Egypt and Zimbabwe revealed that this increased popularity has unfortunately also led to a greater risk of ethically dubious practices in which the health and rights of participants are not protected well enough. Sometimes, the countries we focused on do not have robust legislative and regulatory frameworks in place. Foreign pharmaceutical companies do not always adhere to ethical guidelines that are meant to protect clinical trial participants.

Ethical concerns in clinical trials with vulnerable patients

Leading ethical guidelines, like the Declaration of Helsinki and the CIOMS Guidelines, mention several important ethical principles of research on human subjects. This includes:

- post-trial access to treatment;
- voluntary, informed consent, and;
- accessibility and availability of the tested medicine to the general population.

Most trial participants in Egypt, South Africa, Kenya and Zimbabwe have a weak socio-economic background. They often have no health insurance or access to health care, as the national health systems are weak. By joining a clinical trial, they can get treatment – however it is often their only choice. And unlike standard treatment, treatment in a trial is experimental and therefore not proven safe. We also found that participants were not always well-informed about the trial and risks, for example due to the complex nature of the consent form, or lack of transparency about the trial. We find this worrying, because patients who join clinical trials should have the right to know what they are agreeing to, and what the trial and potential (health) risks entail. And just like in affluent countries, clinical trial participants in low- and middle-income countries should have the freedom to choose between an existing and experimental treatment. As the Declaration of Helsinki states, participation should always be voluntary.

We also found that, if patients had side effects or were physically harmed during a trial, their right to receiving financial compensation was never respected, as trial researchers did not investigate or denied the relation between the symptoms and the trial drug. The tragic story of Grace (Zimbabwe report), a HIV-patient who became blind during a trial – after which her health deteriorated, leading to her death - is a clear worst-case scenario example of what can happen when emerging symptoms during a trial are not properly documented and investigated. Also, while trial sponsors ensured us that

they adhered to their policies which mention post-trial access to treatment, we did not find any case in which the patient was given treatment after the trial had ended.

In addition, we found that new medicines were not always available or affordable to the general population of the country where the trial(s) had taken place, despite pharmaceutical companies' policies mentioning this. Lastly, we found that pharmaceutical companies do not always require new medicines to be therapeutically more effective than existing medication. They only evaluate the new medicines' efficacy and safety, while not considering the true added therapeutic value and clinical need.

A way forward: our recommendations to the European Medicines Agency

We believe that there should be increased inspection and scrutiny from the European authoritative medicines body – the European Medicines Agency (EMA) – of clinical trials in low- and middle-income countries where health systems are fragile, oversight is weak and the risk of unethical practices is high. We applaud that in April this year, the European Parliament voted that EMA must annually report its actions to ensure that medicines are tested ethically in lower- and middle-income countries before they enter the European market. It is an enormous step forward that the European Parliament can now hold EMA accountable, but we think that there is more that EMA can do to ensure that clinical trials are ethical and participants are protected. We recommend the following to EMA:

- Make Good Clinical Practice (GCP) inspection reports public. This is an international ethical and scientific quality standard for designing and reporting clinical trials with human subjects. Compliance with GCP provides public assurance that clinical trial participants' rights and safety are protected, and that trial data is credible. The agency does not provide specific information regarding such inspections.
- Demand from the pharmaceutical company a justification for using vulnerable populations in a clinical trial, and a clarification of provisions taken to protect their safety and rights.
- In placebo-controlled trials, demand a justification for using a placebo drug, and seek assurance that the trial was ethical and in compliance with guidelines.
- Demand a description of the informed consent procedure, regardless of whether the appropriate procedure was apparently followed. Regulatory authorities should be aware that patients who participated in trials may not have had other medical treatment options. If the trial was the only treatment option available, then consent would not be truly voluntary.

- Ascertain whether the trial sponsor has made adequate provisions for post-trial treatment access for participants in low- and middle-income countries.
- Ascertain whether the trial sponsor has made adequate provisions for financial compensation for clinical trial participants with trial-related injury.

We believe that clinical trials should be safe and that the development of new medicine should benefit public health, but this should not be at the expense of those who offer their body and health for the sake of our medicines. The stories and lives of the people described in our report cannot be changed, but we can still make a difference for future clinical trial participants. Because when will we realize that, eventually, no one – not even the trial sponsor - truly benefits from clinical trials that are unethical?

Read our entire report about clinical trials in Egypt, Zimbabwe, South Africa and Kenya
More about Wemos and our work on medicines can be found on our website