



Against Medical Research in Poorer Countries

Zainab Sanusi*

* Philosophy, Logic and Scientific Method, London School of Economics, Houghton Street, London, WC2A 2AE, UK. Email: zainabosanusi@gmail.com. URL: <https://www.linkedin.com/in/zainab-sanusi-210718141/>

Abstract

This paper critiques the Liberal take that research cannot be exploitative if participants volunteer to undergo it. I argue that voluntary consent is not enough to guarantee non-exploitation when the status quo is unfair to begin with. Given the inequalities that exist between HICs and LMICs, both parties are not bargaining from a level playing field. Medical research policy should employ a framework that accounts for these structural and transactional inequalities between LMICs and HICs. This paper will discuss a *one price system* as a viable solution. It would be effective in levelling the playing field as demand for research is highly inelastic.

Keywords: Liberal; Consent; Medical Exploitation; LMICs

This essay disputes the Liberal claim: research cannot be exploitative if participants volunteer to undergo it. I argue that voluntary consent is not enough to guarantee non-exploitation in situations where the status quo is highly unfair to begin with as agents will rightly be motivated to proceed with an unfair transaction if it offers an improvement on the status quo. I will focus on using LMICs as case studies as significant disparities in health care has meant the status quo for agents participating in research transactions in lower-middle income countries (LMICs) is distinctively worse off relative to higher-income countries (HICs) (London 2005). To make my case, I will first present the Liberal view. Next, following Wenner (2018; 2016), I will explain that voluntary consent can only prevent exploitation when transacting individuals are bargaining from a level playing field. Then, I will present Liberal counter-arguments (Wertheimer 1996) as flawed because it mischaracterises exploitation and disregards structural inequalities. Overall, to productively address issues of research exploitation in LMICs, I emphasise that medical research policy must amend its existing conceptual framework.

To start, it is best to define the term in question: exploitation. Generally, a transaction is considered exploitative when party A, takes *unfair* advantage of another party B. Exploitation can either arise from a failure of the transactional process i.e. inadequate consent from the participating party or from a failure of the transactional outcome i.e. the benefits and burdens of the research are not shared equally between parties involved. The former is known as being *substantively* unfair and the latter *procedurally* unfair (Zwolinski and Wertheimer 2017). The debate on exploitation in medical research usually focuses on the failure of the

transactional outcome because consent from the participating party should be standard practice following resolutions like the 1976 Belmont report. So, exploitation '*is regarded as the unfairness in the distribution of the benefits and burdens generated in the process of the research interaction*' (Wenner 2018: 2). In Wenner's definition, fairness and the prevention of exploitation, is based on some underlying theory of distributive justice.

Contrastingly, the Liberal (e.g. Nozick 1974) take on fairness and exploitation is based on the premise that when individuals voluntarily undergo research, it is taken as *informed consent*. Through obtaining consent, researchers address issues of procedural exploitation; it is regarded as a *sufficient condition* for guaranteeing against substantive exploitation. Regardless of the distribution of the burdens and benefits between the participants and the researchers, liberals have no moral qualms as the participants are only entitled to the agreed upon share encompassed in giving consent. In short, voluntarism necessitates non-exploitative research and consent ensures distributive justice from the Liberal outlook. This attitude emphasises the primacy of individual's autonomy to give consent. Liberals go further in suggesting that preventing research in LMICs on the grounds of exploitation will do more harm than good. This is because any intervention will likely prevent participants in LMICs from access to healthcare or deter research. I refer to this viewpoint as 'liberals about exploitation' (Wenner 2016: 2).

However, this Liberal account of non-exploitation, by procedural and substantive standards, is inadequate given disparities between LMICs and HICs. Exploitation can still occur with informed consent because the status quo is unjust to begin with. That is, individual participants may voluntarily agree to all associated harms and benefits of the research but still fall victim to exploitation because informed consent can only operate as a tool for deterring exploitation when transacting parties are bargaining from a levelled playing field. In LMICs, the status quo is poor access to health care. By *voluntarily* giving consent to participate in research, the participants gain access to health care that would otherwise have been unavailable. Nevertheless, this is still exploitative as participants have limited bargaining power on the matter of the transaction. They are unable to negotiate more favourable conditions or turn down the offer especially if their primary reason for participating is to get access to healthcare that is unavailable or too expensive to the average person living in a LMIC (Wenner 2018). The magnitude of health inequality between HICs and LMICs is stressed through maternal mortality rates. According to WHO (2017), developing countries account for 99% of annual maternal deaths. This stark contrast evidences the desperate situation in LMICs thus reiterating that, usually, individuals seeking healthcare through research participation lack of alternatives. Even if participants collectively bargained they still face classic collective action problems as the researchers could simply relocate to a cooperative LMIC. Messer (2004: 279) describes this as a 'subtle controlling influence.' Researchers are acutely aware of the influence of disadvantage in LMICs. In the last 30 years in biomedical research has seen a dramatic increase in the amount of research being conducted in LMICs from 10% in the 90s to 40% in the mid 2000s (Wenner 2018: 2). Research stakeholders all benefit from the disadvantaged status quo that allows for lower standards of care during research which lowers costs while LMICs take on the risks of research and continue to lack access to basic health standards in HICs. In these circumstances, researchers capitalise on the desperation of participants, making the transaction exploitative even if participants volunteer to undergo it.

Even still, Liberals about exploitation challenge that the research is *not* exploitative because regardless of limited bargaining power, participants and their communities gain access to levels of care they would not have had if the status quo persisted. Even participants in the placebo-controlled group of the study are still privilege to check-ups, medical care and facilities the individual most likely could not have afforded. This critique is encompassed in

the none worseness principle (Wertheimer 1996). The principle undermines the case in favour of transactional exploitation because participants are not worse-off than they would otherwise have been. Thus, the research is not exploitative when participants volunteer to undergo it even if benefits are not proportionally distributed. In fact, the research participant is made slightly better off by the research transaction with access to health care. This approach to justifying research in LMICS as non-exploitative operates by abstracting the transaction of the research from the broader structural inequalities between LMICs and HICs. The status quo is accepted in the host communities as the 'normative baseline' (London 2015: 27) against which proposed research initiatives are evaluated. Hence, the status quo is treated as the threshold of a person's moral entitlements ignoring the realities of the non-ideal world we live in. The scope of moral claims that participants can legitimately assert against researchers is determined by the status quo in the counterfactual circumstance in which the trial does not take place and status quo in the host communities persists.

Although, this challenge can be refuted in 2 ways. Firstly, the NWC purports that all exploitation must be harmful. Exploitation can be mutually beneficial where both parties walk away better off than they were *ex ante* (Zwolinski and Wertheimer 2017). Moreover, these structural inequalities ignored are, in fact, relevant to claims of participants in LMICS. This is in the sense that HICs play a direct role in generating and exacerbating the health needs of developing world populations that also determines their bargaining position. So, researchers operating in a systematic framework propagated by HICs should have a historically-rooted moral responsibility towards ensuring that LMICs are not exploited if we accept that individuals, within their capacity, should help resolve what they have caused. For example, governments in LMICs have been established on the basis of neo-patrimonial (Chazan et al 1999) colonial legacies of HICs (e.g. Britain, France). The resulting corrupt and kleptocratic governments decide which healthcare concerns receive funding. The profound impact a government's behaviour can have on domestic healthcare system is portrayed in the trajectory of Senegal's management of HIV. Dedicated effort by the Senegalese government underlies the country's success in curbing its HIV population to 1%. This contrasts its Sah-Saharan Africa counterparts with as high as 30% of the population infected (London 2005). Further evidence of HICs causing social and political structures that perpetuate healthcare inequality is the fact that LMICs do not gain "social benefits of biomedical progress which serve to justify exposing participants to such risks" (Wenner 2016: 7). In line with this, we can distinguish two types of exploitation operating when researchers chose to carry out studies in LMICs: transactional and structural. According to Wenner, transactional exploitation concerns the unequal benefits to the *individual* participant whereas structural exploitation concerns the unequal benefits to the wider host *community*. Thus, frameworks for combating exploitation in research should address both injustices.

To reconcile the issue of exploitation when participants in LMICs volunteer, we must adjust our conceptual framework to account for these systemic structural inequalities that have significantly shaped the development of healthcare in LMICs and HICs respectively. As Wenner (2018) rightly highlights, research transactions in LMICs are not isolated instances by virtue of the role that HICs played in the historical development of LMICs and the role that clinical research plays as part of the mechanisms that determines what health systems look like. This reality of deep lasting impacts should empower host communities with a basic moral claim on questions over how the study will benefit the participants, their communities and their health systems to promote both transactional and structural fairness. Existing international policy on medical research in LMICS such as the fair benefits approach (Wenner 2018) or the minimalist view (London 2005) overemphasise the distribution of benefits to the host community disregarding individual participant's vulnerable circumstance. These frameworks deprioritise the individual's circumstance. Moreover, there is no account

for the structural background that LMICs exist in which lays objective criteria on the benefits owed to host communities. Medical research policy and regulation should look to benefit both the individual and the community irrespective of the fact that participants volunteer to undergo it.

Yet, the argument presented begs the question: what does it mean to employ a framework that accounts for both structural and transactional exploitation? A viable option to level the playing field and ensure that host communities and participants benefit is to implement a global **one price system** for different research. This will be effective in addressing structural and transactional exploitation as it removes all financial incentives for pursuing cheap research LMICs and treats the entitlements of research participants everywhere as the same. Moreover, excess fees can fund health sector development in LMICS, reducing global health inequalities. This paper will not address the specific details of exact how the one price system will operate but purports it will be regulated centrally by some third-party organisation. Liberals may challenge this proposition on the grounds that it could deter valuable research; or it will prevent participants in LMICs from access to healthcare. However, I dispute this on the grounds that, research is somewhat inelastic. Regardless of price, R&D is central to the pharmaceutical business model (Wenner 2016). Moreover, the pharmaceutical industry is a multibillion dollar enterprise that can afford higher research costs. Citing US listed pharmaceuticals as a case in point, they are eight times more profitable than the average of all other industries in Fortune 500 (Streckx 2004). Moreover, the purpose of researching in LMICs is not to provide healthcare to the population – it is about building medical knowledge amongst other things. It is open to debate whether this framework would result in the most optimal state of the world. Nonetheless, it is a sound option.

In this paper, I have argued that research can be exploitative even when participants volunteer. The unlevelled status quo between LMICs and HICs means that informed consent cannot operate as a bargaining mechanism to protect exploited participants. Participants are encouraged to consent to the study because it will necessarily be an improvement on their status quo. Thus, researchers in HICs knowingly exploit this disparity. For a fairer future of research, we must adopt more reflective policies that address both transactional and structural exploitation to ensure lesser privileged volunteers are not exploited. This paper discusses the viability of a one price system and concludes that, although its optimality as a solution is debateable, it withstands liberal scrutiny.

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