Promoting Ethical Payments in Human Challenge Studies Conducted in LMICs: Are We Asking the Right Questions?

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The paper by Lynch et al. (2021) raises interesting ethical questions regarding whether and how much SARS-CoV-2 Human Challenge Studies (HCS) participants should be paid. We appreciate the timely ethical framework they have proposed, but are concerned about its generalizability to low-middle income countries (LMICs). In this paper, we argue that the authors should consider the addition of a few more variables to their framework, to make it operable and more meaningful in LMICs. We start by noting that the study payments that they reviewed were based on 18 studies conducted only in high income countries (HICs) including Australia, Germany, Netherlands, Norway, United Kingdom and the United States. The amounts paid to participants in these 18 studies may not have raised serious concerns in HICs. These payments ranged from US $386 for participation in a study involving sand-fly bites to US $8,938 for a study conducted in the United Kingdom; and the studies had hourly pay rates of up to US $38.80. The authors duly acknowledge that their expertise and perspectives are limited to the “global North” and that additional considerations may be relevant when research is conducted in other parts of the world. Based on this acknowledgement, we can only conclude that the committee that they convened for the purpose of looking into the questions of study payments, was dominated by members from HICs.

In recent years, the complexities associated with payments for research participants in LMICs have been highlighted; such payments take a different meaning in such contexts and some countries have placed caps on the amounts of money that can be paid to research volunteers (Koen et al. 2008; Kwaagala, Wassenaar, and Ecuru 2010; Zvonareva and Engel 2014). There have also been discussions around ensuring the sharing of both the benefits and burdens of health research burdens and benefits between HICs and LMICs; with some arguing that despite ethical concerns about the vulnerability of populations in LMICs, there are strong ethical and scientific justifications to consider conducting more HCS in LMICs where the burden of diseases is higher (Selgelid and Jamrozik 2018). Others have reported on significant efforts to ensure that LMICs have the capacity to conduct complex studies including HCS, by strengthening both scientific infrastructure, as well as regulatory capabilities. A few HCS involving diarrhea and malaria have been conducted at sites in LMICs including Colombia, Equatorial Guinea, Kenya, Gabon, Mali, Tanzania and Thailand. Over and above the general concerns around the potential for “dumping” high risk research on LMICs, and the vulnerability of populations in such countries, HCS in such settings often raise additional concerns. These include challenges of truly informed consent and potential for ‘undue inducement’ based on payment to participants often described as financial compensation deemed too high in view of the social and economic status of the country (Jamrozik and Selgelid 2020).

Lynch et al. (2020), describe the three models of payment that are generally discussed in the literature on payment for trial participation; reimbursement, compensation and incentive. We however argue that in an environment of high unemployment and serious poverty, the differences between these models are not
substantive; for example, the reimbursement and compensation models make sense in environments where majority of individuals are employed and have some basic financial resources. In a study conducted in Kenya, respondents often described the payments as “benefits” (Molyneux et al. 2012). In LMICs, the operation of the incentive model is weakened by higher levels and prevalence of poverty which forces individuals to often take extreme risks; examples include the risky journeys in unsafe boats from Africa to Europe and reports of individuals who sell their kidneys to make some money to support themselves and their families.

In considering payments to research participants in LMICs, we suggest consideration of additional factors by researchers and IRBs. First consider whether the payment is too large in comparison to the average income of the majority of individuals living in that environment. For example, in a community where individuals make an average of $200 a year, a payment of $2,000 to participate in a HCS could potentially be irresistible. We agree with the authors’ (Lynch et al. 2020) description of “undue influence” as a payment offer that is so attractive that it leads potential volunteer to agree to participate in a trial potentially against their own interests. They specifically discuss payments that can make potential participants ignore important risk considerations while focusing on the payment value alone. They acknowledge that people with limited financial opportunities can be potentially exploited to participate in unreasonable activities in exchange for money. The authors however suggest that there is no evidence to suggest that HCS participants’ judgment may be negatively impacted by money and they quoted studies that were conducted in HICs that suggest motivations such as altruism, pursuit of scientific interests, curiosity, and thrill-seeking for participation. In many LMIC environments, these motivations may still exist, but people tradeoff with more practical needs in the context of high levels of poverty that contribute to their survival. To illustrate this point, during a HCS conducted in Kenya, the following headline appeared in one of the daily newspapers; “Want cash? Volunteer for a dose of malaria parasite, says KEMRI amid ethical queries” (Gathura 2018).

Second, investigators and research ethics committees have to consider the comparative impact of large payments in HCS, on other (non-HCS) studies when it comes to willingness to participate. If certain types of studies pay more, members of the public may refuse to participate in those studies that pay less; this may cause the unintended potential negative impact of harming future research. In many LMICs for example, locally funded studies are not able to pay participants for their time or their quantum of money is far less than internationally funded studies; this may have potential negative consequences for enrollment and community engagement of local studies (Mita and Ndebele 2014).

Third, we strongly argue that payments in HCS be harmonized within a country and across studies. This is important for consistency and should be done within the country—ideally by a focal office of research or national research ethics committee for example. This ought to be a national decision and use local expertise and experience; rather than being dictated by global or international perspectives (Koen et al. 2008). We believe that regional learning is important, especially from neighboring countries, but the regional diversity within countries makes this an important national exercise and need for HCS research.

Finally, we agree with Jamrozik and Selgelid (2020) that for ethical HCS in LMICs, researchers, RECs and sponsors need to also focus on the number of potential risks to participants as well as their magnitude, risks to others who may not be participating in the trials (third parties), challenges around obtaining true informed consent, as well as the engagement of communities that participate in the studies. In addition, we suggest other benefits be provided that are not directed at individual participants, as a way of compensating for the reduced dollar amounts to individual volunteers. Such indirect benefits could be directed at institutions, communities and even participating countries.

Therefore, based on our expertise and understanding of the environments in LMICs, we argue that instead of focusing on whether and how much participants should be paid, researchers and IRBs in LMICs should firstly focus on ensuring that potential trial participants understand what they are agreeing to when they accept to participate in HCS. To ensure relevancy of the proposed “payment worksheet” to a global especially LMICs context, we suggest the addition of five columns to the worksheet; average local wages earned in the country; a measure of economic vulnerability of potential participants in the country (e.g. socio-economic status measure); number of (or summary of) direct benefits to individual participants in the country; list of (number of) indirect benefits to the country and institutions involved; and the strategy (or list of strategies) that researchers will utilize to ensure participants truly appreciate the implications of volunteering for the particular study at hand. This
recommendation of 5 variables is in line with Lynch et al. (2020) suggestion that researchers should consider study location and economic vulnerability in making decisions on study payments; and that high payments that are not based on local contexts, can affect public trust, especially if there are reports of serious adverse reactions.

In multi-country trials involving sites in both HICs and LMICs, participants in HICs are often paid higher dollar amounts compared to those in LMICs. We do not argue for the same level of payment across countries; but at the same time we call out very low payments to participants in LMICs in the same study as they may raise concerns of exploitation for LMICs. We are not against payments to research participants but argue for payments that take into consideration the context, and are paid out to volunteers after ascertaining that they have a clear understanding of the implications of research participation.

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REFERENCES


Mita, K., and P. Ndebele. 2014. Payment of research participants. In Research ethics in Africa: A resource for research ethics committees, 135–42. Africa Sun Media.


OPEN PEER COMMENTARIES

Research Participants Should Be Rewarded Rather than “Compensated for Time and Burdens”

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Paying research subjects for their participation in biomedical studies is an increasingly common and acceptable practice. Nevertheless, it continues to raise numerous conceptual, ethical, and practical controversies. There is still a substantial disagreement between bioethicists, IRBs, and other members of the research community over why, what for, and how much research participants should be paid. Payment-