Ethical considerations of recruiting migrant workers for clinical trials

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ABSTRACT
Migrant workers in dormitories are an attractive source of clinical trial participants. However, they are a vulnerable population that has been disproportionately affected by the COVID-19 pandemic. Guidelines on recruiting vulnerable populations (such as prisoners, children or the mentally impaired) for clinical trials have long been established, but ethical considerations for migrant workers have been neglected. This article aims to highlight and explain what researchers recruiting migrant workers must be cognizant of, and offers recommendations to address potential concerns. The considerations raised in this article include: three types of illiteracy, power dynamics, the risks associated with communal living and potential benefits to the migrant workers as well as researchers.

To this day, the term ‘human experimentation’ evokes discomfort among researchers. This can be attributed to the morally reprehensible history of using vulnerable human subjects for research. Infamous examples include Josef Mengele’s experiments on Jewish twins during the Holocaust and the Tuskegee syphilis study on African American males.1,2

Today, researchers conducting clinical trials adhere to ethical principles, in hopes of avoiding these moral transgressions of the past. The 1979 Belmont Report’s guidelines—respect for persons, beneficence and justice—are ubiquitously recognised by ethics committees. Additional ethical considerations have been delineated for certain vulnerable populations, such as children, prisoners and the mentally disabled.3,4

In our increasingly globalised world, a vulnerable population with much contemporary relevance is migrant workers, who have been disproportionately affected globally by the COVID-19 pandemic. They face being stranded in their host country, a high risk of SARS-CoV-2 transmission due to overcrowding, and mass unemployment resulting in suspended wages and remittances. The plight of migrant workers across the globe—in Chile, Kuwait, India and Singapore to name a few countries—has been recognised by the likes of Amnesty International and WHO.5,6

Despite special considerations extended to other vulnerable populations, ethical considerations specific to recruiting migrant workers for clinical trials have not been published. There are certainly parallels between migrant workers and other vulnerable members of society. For example, distributive justice states that an already burdened population should not be further disadvantaged by having to bear the costs of research for which others reap the benefits—this is a principle that is applicable to all disadvantaged groups. However, this article highlights special considerations to be cognizant of when recruiting migrant workers in particular, and offers recommendations to address potential concerns, informed by the author’s personal experiences with migrant workers.

THREE TYPES OF ILLITERACY
A sizeable proportion of migrant workers lacks literacy in three aspects: linguistic, scientific and technological.

There is a spectrum of linguistic literacy among migrant workers due to diverse educational backgrounds. Many of them are able to pen their name and the date in the host country’s language, and orally have a working proficiency in that language. This does not mean that they are able to decode the informed consent form (ICF), even if it is translated into their first language. A Mexican study on consent given by poorly-educated study participants reported that half of the participants felt that the ICF was difficult to understand even though the average readability score was of an eighth grade level.7

Scientific literacy is particularly relevant when administering a controversial drug like hydroxychloroquine, one of the most contentious drugs being researched in the fight against COVID-19.8 Migrant workers without a strong scientific education may be unable to properly evaluate the risk involved with drugs for which the dialogue is evolving and the evidence is conflicting. Moreover, participants with poor scientific literacy may fall victim to what is called the ‘therapeutic misconception’, as they may not be familiar with the concept of medicine being given experimentally or the nature of research itself.9 Indeed, for migrant workers unfamiliar with scientific research, even translations of ‘voluntary participation’ may be incomprehensible jargon.

Lastly, migrant workers may exhibit limited technological literacy. Although the vast majority of them possess smartphones and use applications to communicate with family or send remittances, researchers should not rely on technological tools such as online videos or Frequently Asked Questions (FAQ) webpages as a means of briefing study participants.

POWER DYNAMICS AT PLAY
There are multiple social, economic and political power imbalances between migrant workers and those recruiting study participants. Migrant
workers are typically unskilled or semiskilled labourers, ethnic minorities and of non-citizen status. Hence, they are prone to coercion or inducement, which is possibly exacerbated by any remuneration provided by the study. Some may reflexively nod to anything researchers tell them, even if they do not understand. Particularly in the context of the COVID-19 pandemic, migrant workers fear losing their jobs permanently and being deported to their home country. They may thus feel pressured to comply with citizens of their host country. This pressure can also be present in the absence of a pandemic, as is the case with undocumented or trafficked immigrants, who may perpetually live in anxiety.10 11

This form of coercion, in which broader social, economic and political contexts act on individuals to compel them to enrol as subjects in clinical research, has been described as structural coercion.12 Coercion by definition must be tied to a threat of violence. In structural coercion, the violence itself is also structural. In contrast to conventional forms of coercion, the threat of violence is not tied directly to the research opportunity. Rather, it can manifest as the threat of unemployment or deportation stemming from a precarious immigration status, for example.

Though this article aims to prevent ethical violations against migrant workers, researchers and ethics committees must be cautious not to be paternalistic towards them. An overprotective attitude towards participants is demeaning, compromises the impartiality expected of researchers, and infringes on participants’ autonomy. Migrant workers are more vulnerable than some other populations but they are no less competent or capable of making their own decisions. They have the right to participate in clinical trials even when there seems to be an unfavourable risk/benefit profile. They might, for example, be altruistically motivated and want to participate in trials that are socially valuable.13 14 Researchers and ethics committees cannot ascertain the motives of individuals, and thus should consider their role to be ensuring that consent acquired is valid—that is, participants have been sufficiently informed and in language they are comfortable with—rather than judging whether the level of risk is acceptable for individuals.15 16 Competent individuals, including migrant workers, are ethically and epistemologically in the best position to decide the level of acceptable risk for them.15 Should researchers deem migrant workers’ participation in clinical trials unacceptable because it is risky, they are expressing a paternalistic attitude toward those who might informally wish to participate in such a trial.14

THE DANGERS OF COMMUNAL LIVING

Globally, it is common for migrant workers to live in densely populated dormitories provided by employers.16–19 These dormitories may house thousands of migrant workers, with over a dozen workers in one room.19 Thus, for the sake of maximal efficiency, researchers may be tempted to recruit participants in large batches. Indeed, in the midst of a pandemic, researchers may experience a sense of urgency to complete the trial swiftly. This poses ethical challenges because it compromises the validity of informed consent.

When recruiting illiterate subjects, the informing of the informed consent process is delivered orally rather than through a written ICF that the participant reads. In this situation, researchers must recognise the tendency for words to be lost during transmission in a communal living environment. This is particularly a risk when obtaining informed consent from multiple migrant workers simultaneously. Subjects may transiently lose interest or become distracted, loud noises may dominate (especially in an open environment like a dormitory facility), or subjects may simply fail to understand certain words.

In a group setting, participants may also hesitate to ask questions. However, the opportunity to ask questions is crucial to the informed consent process to ascertain understanding of the study. Furthermore, migrant workers recruited in large batches may exhibit groupthink and peer pressure; one member in a room denouncing the trial may be enough for the entire room to immediately withdraw their participation, or participants may question their friends on why they ticked certain boxes on the ICF.

Another complication of communal living is the lack of privacy and thus violation of confidentiality. A participant’s roommates can easily become aware of his participation in the trial. Roommates may even infer personal medical information based on which drug arm the participant is assigned to, as participants can be excluded from certain drug arms based on underlying health issues.

MIGRANT WORKERS CAN BENEFIT TOO

Just as there are ethical concerns specific to the recruitment of migrant workers, there are benefits specific to the recruitment of migrant workers. Migrant workers generally have limited accessibility to healthcare, and a clinical trial can offer them a free health screening, allowing for myriad undiagnosed illnesses to be discovered among potential participants. Hypertension is just one condition to have been found to be prevalent among migrant workers, in Latino and Chinese migrant workers alike.20 21 In addition, respiratory and dermatological symptoms were found to be over 30% prevalent among Indian migrant workers.22 Uncovering these ailments provides useful public health information, which can be used to alert government agencies and migrant worker employers, so as to better address migrant worker needs.

Additionally, migrant workers’ participation in clinical trials can provide a means of feeling more integrated into the host country’s society. Migrant workers are often victims of xenophobia, prejudice and discrimination.23–26 Because clinical trials often aim to benefit wider society, their participation in clinical trials can help dissolve the ingroup/outgroup dichotomy they face, and they may find exercising their altruism empowering.

GOING FORWARD

There is a pressing need for high-quality randomised clinical trials investigating COVID-19 prophylaxis and treatment. Researchers may be drawn to the massive pool of migrant workers in dormitories as a concentrated source of thousands of study participants. Moreover, migrant workers in dormitories live similar lifestyles in an identical environment, allowing for relatively controlled variables. There is certainly a way to recruit them for clinical trials ethically. The benefits of migrant workers participating in clinical trials are not trivial, and the potential concerns are not insurmountable.

The concerns associated with linguistic literacy can be partially addressed by ensuring that there are readily available approved translators and translated ICFs, so as to not pressure migrant workers to consent in a language that is not their first. To address scientific illiteracy, translators should avoid simply reading out the ICF, taking care to explain any scientific terms. They should also continually ask potential participants questions to test their knowledge and understanding of the study. Emphasising the voluntary aspect of participation
requires particular attention for this population. Those recruiting study participants must also be educated on special considerations such as the therapeutic misconception and any sociocultural circumstances, such as Muslim migrant workers fasting during Ramadan. To address the risks associated with communal living, researchers must recruit in small batches, ideally informing participants one-on-one through counselling and conversation. This also somewhat addresses the problematic power dynamics by encouraging migrant workers’ active involvement in the consent-taking process. Moreover, the relatively high risk of ethical transgressions overall demands frequent audits throughout the recruitment process. Clearly, there is a need for developing a standardised and detailed guideline on informing migrant workers when recruiting them for clinical trials.

Once the global scientific community is engaged in this overdue discussion, ethics committees can deliver more informed decisions and researchers can refer to clear guidelines addressing the unique needs of this vulnerable population. The same consideration that has been given to children, prisoners and the mentally disabled must be extended to migrant workers. Only then can migrant workers be recruited for clinical trials in a way that upholds our integrity.

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