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## **Innovative practice in Latin America: medical tourism and the crowding out of research**

by Felicitas Holzer & Ignacio Mastroleo

In an insightful article, Jacob Earl (2019) outlines the concept of innovative practice, addresses ethical problems and presents a permissive oversight proposal to deal with the ethical concerns identified. We agree to a large extent with Earl's approach and, therefore, decided to develop his comprehensive analysis further. In particular, we want to extend it from national to global contexts. In this regard we argue that innovative practice in countries with poor regulation of the sale and marketing of new drugs carries a higher risk of crowding out research. In turn, this entails the potential harm to global public health caused by a significant reduction or exclusion of sound and socially valuable research. We think that analyzing innovative practices performed in a global landscape of poor regulation, like the one we find in many Latin American countries, can provide us with useful insights into Earl's approach.

To begin with, we would like to clarify that our reasoning is in line with the ethical core of Earl's approach; we think that innovative practice is ethically permissible if carried out under the aegis of a responsible policy or regulatory framework such as the one defended by Earl (2019) against the proscriptive approach or patient caps. Here, however, we want to draw the reader's attention to a certain class of *irresponsible* international innovative practices, which are commonly labeled as medical tourism. In the following, we will outline two recent cases of medical tourism in Latin America and point to what Earl calls "patient-focused concerns".

Let us consider the first example. Stem cell treatments are on the rise not only in Latin America, but also all over the world. Jim Gass underwent several stem cell therapies at clinics in Mexico, China, and Argentina, paying tens of thousands of dollars each time for

injections to recover from a stroke he had in 2009. The evidence supporting these interventions consisted only of testimonies of recoveries and papers in vanity journals. Eventually, Gass developed a tumor in his lower spinal column. The following tests showed that the tumor mass was made up of abnormal, primitive cells that were growing aggressively (Kolata 2016). In Argentina, Gass underwent interventions made from his own stem cells at a private clinic (Gass 2016, personal communication, June 30, 2016). In Mexico, he received an injection of fetal cells shipped from Russia (Kolata 2016). The Gass case provoked an outcry in international media that illustrated a growing concern about the number of stem cell tourists worldwide.

Another case concerns the use of mitochondrial replacement techniques (MRTs), an assisted reproductive technology. MRTs offer women with deleterious mitochondrial DNA the option of producing healthy biological offspring via the use of a donor egg. One of the first successful mitochondrial replacement procedures took place in Mexico where scientists from the U.S. carried out the procedure. In 2016, the baby resulting from the intervention was born. The story began when Dr. John Zhang was leading a scientific group on MRTs and founded the New Hope Fertility Clinic in New York City. At that time, a Jordanian couple consulted his clinic after two of their children had died from Leigh's syndrome, a neuro-metabolic disorder caused by deleterious mitochondrial DNA disease (Palacios-González and Medina-Arellano 2017). In the U.S., the National Academy of Sciences panel also recommended accepting MRTs with certain limitations, but Congress blocked the novel techniques for prevention of maternal transmissions of mitochondrial DNA diseases, meaning that the FDA was unable to consider these techniques in certain exceptional circumstances (Palacios-González and Medina-Arellano 2017, 4). Due to these regulatory issues, Dr. Zhang and colleagues decided to carry out the procedure in Mexico. To do this, they opened two branches of his fertility clinic, one in the State of Mexico City and one in the city of

Guadalajara in the State of Jalisco. According to public statements and the abstract of a conference paper, Dr. Zhang claimed that he performed the MRT procedure in Mexico because “there are no rules”, most likely referring to the rather loose regulation in Mexico. There are laws regulating reproductive technologies but they are fairly permissive and moreover, neither explicitly allow nor forbid MRTs (Palacios-González and Medina-Arellano 2017, 9).

The two cases reveal that Latin American countries are among the places where an increased use of innovative practices can be observed, notably due to a lack of appropriate international regulation and poor support for national and local health authorities to enforce existing legal and ethical guidelines (Rosemann et al. 2018, Chan and Arellano 2016). Two major ethical concerns arise from this.

First, similarly to Earl, we think that there are strong patient-focused concerns. Deviating from standard care usually entails significant uncertainty about an intervention’s likely harms and benefits for the patient. Earl states that it is therefore unclear that innovation is necessarily consistent with clinicians’ duty of beneficence, which is, treating patients for the sake of their own well-being. Cases of irresponsible and unsuccessful medical tourism, such as that of Jim Gass, show that the duty of beneficence may be overshadowed by the monetary benefits sought by profit-driven clinics or conceited medical doctors obsessed with performing “cutting-edge” interventions with insufficient sound scientific evidence. However, not all cases of irresponsible innovative practice are unsuccessful. Here we maintain that Dr. Zhang’s apparently successful case was still irresponsible because it was performed in an institutional context without a regulatory framework that could justify the potential harms to others it may have caused.

This brings us to our second concern, that is, the higher risk of research being crowded out in countries with poor regulation for sale and marketing of new drugs. We understand research crowding out as a significant reduction or exclusion of the production of generalizable knowledge, which, in turn, entails a potential harm to global public health (Holzer and Mastroleo 2018, Holzer and Mastroleo 2019, ACOG Committee on Ethics 2015). Here we share Earl's (2019, 8) concern that innovative practice can result in runaway diffusion, that is, the widespread adoption in regular healthcare of a harmful or non-beneficial intervention. However, we argue that runaway diffusion not only entails the harms of medical reversal and loss of public trust in medicine as Earl recognizes. It also endangers the conduction of sound research in countries with poor regulation of the sale and marketing of new drugs. What is more, in poorly regulated countries there is a great incentive for patients, doctors, clinics, and even authorities to crowd out sound scientific research. It is commonly argued that the application of innovative interventions leads to less research, especially when patients have the incentive to receive their preferred intervention in one hundred percent of the cases rather than, for example, having only a fifty percent chance of receiving it in the course of a randomized controlled trial (ACOG Committee on Ethics). Furthermore, as the cases of Jim Gass and the MRTs in Mexico show, the (short-term) incentive of physicians, clinics, and authorities to generate revenues with innovative care rather than spending resources on expensive research trials may encourage this tendency even more (ACOG Committee on Ethics, 3-4). As Earl (2019) recognizes, the contribution to the risk of research being crowded out from any particular instance of innovative practice is likely to be quite small in countries with authorities that properly regulate the sale and marketing of new drugs to the general public before they have been proven safe and effective. However, recurrent cases in poorly regulated countries do increase that risk and may justify international regulations that prevent unintended crowding out of sound research to protect global public health.

Finally, we believe that the considerations presented above are consistent with Earl's ethically permissive approach. However, more work needs to be done in poorly regulated countries in order to develop international regulations that can achieve the right balance between responsible innovative practice and sound scientific research.

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