

Gene therapy research in developing world raises ethical red flags: experts

July 9 2008

Early stage gene therapy clinical trials are recruiting patients from the developing world, providing medically deprived populations access to interventions that show promise but have largely unknown effects in humans. According to commentary by bioethicists at Carnegie Mellon and McGill universities published in this week's issue of *The Lancet*, the practice may be inconsistent with international ethics guidelines on justice.

"There are many reasons why researchers might look to the developing world for research subjects," said Alex John London, lead author of "Justice in Translation: From Bench to Bedside in the Developing World" and director of Carnegie Mellon's Center for the Advancement of Applied Ethics and Political Philosophy. "But serious ethical issues can arise when research relies on the deprivations experienced by people living in developing countries to advance research that is not responsive to the urgent health needs of their communities."

London and his co-author, Jonathan Kimmelman, an assistant professor in McGill's Biomedical Ethics Unit, urge organizations that sponsor research in low- and middle-income countries (LMICs) to ensure that they are addressing the most pressing health needs of those nations. The article also notes that any interventions developed as a result of such research should be affordable and easily implemented in those countries' health care systems.

While other authors have explored ethical issues in later stage clinical

trials, in which the interventions have already been deemed safe and effective, for the most part, London and Kimmelman are the first to discuss the more complicated considerations surrounding the riskier early-stage research.

"Our report centers on complex agents like gene therapies that are being tested for the very first time in human beings," Kimmelman said.

Researchers have various reasons for turning to developing nations for clinical trial subjects. In some cases, patients are recruited because diseases like malaria were much more common in LMICs. In other cases, diseases are so rare as to necessitate worldwide recruitment. However, some trials also appear to have recruited patients who did not have access to treatments routinely available in developed countries. Such patients provide a pool of "treatment naïve" subjects that would not otherwise be available to researchers. Treatment-naïve subjects are particularly valuable, as they offer the opportunity for researchers to observe an intervention's behavior on a blank canvas, of sorts.

Echoing requirements that have been articulated in a range of international ethics documents, such as that of the World Health Organization, London and Kimmelman urge organizations that sponsor research in LMICs to ensure that they are addressing urgent health needs of those nations. Ensuring that research meets this requirement represents an important step toward unlocking the substantial promise of innovative research like gene therapy for populations that often experience staggering health needs.

"Our goal is not to curtail research in low and middle-income countries," said London, who is also an associate professor of philosophy at Carnegie Mellon. "It is to make sure that project sponsors give careful consideration to relationship between a particular research study and the needs of the communities from which study participants are drawn."

Source: McGill University

Citation: Gene therapy research in developing world raises ethical red flags: experts (2008, July 9) retrieved 17 April 2024 from <https://medicalxpress.com/news/2008-07-gene-therapy-world-ethical-red.html>

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