GUATEMALA NEVER AGAIN: PROGRESS AND CHALLENGES IN THE PROTECTION OF RESEARCH SUBJECTS

The history of research involving human subjects is plagued with unfortunate wrongdoings, which have prompted the development of the field of research ethics, the formulation of guidelines and regulations, and the call to political action. Research involving the intentional infection of vulnerable persons with syphilis and gonorrhea in Guatemala between 1946 and 1948 brought to light late last year is ethically deplorable. It however provides us with an opportunity to review the actions taken by the Pan American Health Organization/World Health Organization (PAHO/WHO) and PAHO's Secretariat, the Pan American Sanitary Bureau (PASB), in terms of the protection of human participants in research in the Region, and to reflect on what still needs to be done to prevent such ethical violations from ever taking place again.

What Has Been Achieved

The protection of research participants has come a long way since the 1940s: from the Nuremberg Code's emphasis on informed consent (1946), to the Declaration of Helsinki's requirement that research protocols be reviewed by an independent board (1963), the statement of the ethical principles guiding research in the Belmont Report (1979), and the enforcement of ethical guidelines through national regulations.

In Latin America and the Caribbean, PAHO/WHO has, in recent years, become a central actor in the protection of ethical standards for research. PAHO's Policy on Research for Health stipulates as a first objective the promotion of relevant, ethical, and quality research.

As a matter of fact, as per the mandate of the World Health Organization, all research that is either financially or technically supported by PAHO/WHO is currently overseen by the PAHO Ethics Review Committee (PAHOERC). PAHOERC was revamped and strengthened in 2006 in response to the growing complexity of international health research and follows the model of WHO's Ethics Review Committee (WHO-ERC). The PAHOERC review process—as dictated by its Standard Operating Procedures (SOPs)—ensures that research with human subjects meets ethical standards; i.e., that it is in accordance with the ethical principles of respect for persons, beneficence, and justice, and that it is methodologically sound.

PAHOERC also promotes transparency in research by requiring that research in humans be registered in PAHO's Research Registry. This also promotes public trust. Researchers in the Member States are also encouraged to register clinical trials in national or international registries recognized by the WHO International Clinical Trials Registry Platform (ICTRP). The registration of all interventional trials is an ethical responsibility that promotes transparency and contributes to the minimization of known risks and potential harm from unnecessary exposures, as required by the principle of beneficence.

As part of its technical cooperation programs in the countries of the Region, PAHOERC provides training in research ethics and on methodological aspects relevant to research involving human subjects (e.g., Effective Project Planning and Evaluation in Biomedical Research, Webinars). WHO-ERC cooperation and partnership with PAHO collaborating centers, such as the University of Miami and its Collaborative Institutional Training Initiative (CITI) program, contribute to PAHOERC's systematic and effective efforts to build capacity in research ethics in the Region. CITI online courses on research ethics are currently being incorporated in PAHO's Virtual Campus, and several other training initiatives are being conducted. One such example is the series of workshops on research ethics for relevant PAHO/WHO staff organized by PAHOERC with support from WHO-ERC and the WHO Center in Ethics and Global Health Policy. Similar activities are also being carried out with partners and researchers in Member States. In order for these workshops to have a multiplier effect, participants have been provided with the capacities, tools, and support necessary to replicate these learning experiences with researchers in their respective countries and teams. PAHOERC is also supporting efforts of the WHO-ERC to develop an Internet-based training tool for all staff involved with research. These activities are complemented by the technical cooperation and training being offered through PAHO's Regional Program of Bioethics (established in 1994, and being monitored and supported by Member States), coordination with regional agencies (e.g., the Human Rights Commission of the Organization of American States), incentives for the advancement of bioethics by the Pan American Health and Education Foundation, and guidance from PAHO's Advisory Committee on Health Research.

The contribution of PAHOERC to training initiatives (both online and person-to-person) is crucial: the review of a pool of proposals from the Region allows for the identification of specific weaknesses and key ethical issues. PAHOERC is thus in a position to address the specific problems faced by researchers, especially those working in Latin America and the Ca-

ribbean. With a view to that goal, discussion cases and targeted training activities have been developed on the basis of actual proposals reviewed by PAHOERC.

The Remaining Challenges

Research ethics does not operate in a vacuum: it is an inherent part of the health research system. Knowing what is available and what is missing in national health research systems is crucial in order to provide strategies to strengthen these systems and thus strengthen research ethics in the Region. PAHO has partnered with the Council on Health Research for Development (COHRED) to develop the Health Research Web, an interactive platform that facilitates the collection of and access to baseline data on national health research systems in the Americas. Furthermore, PAHOERC is mapping all the ethics review committees and networks in Latin America and the Caribbean with the goal of accurately assessing the situation in this region and identifying the specific areas that need to be strengthened.

Ethical review of research proposals, research registry, and capacity-building in research ethics are essential for the protection of human participants in research. However, they need to be supplemented by adherence. In order to secure adherence within the Organization, PAHO aims to lead by example by integrating the ethical review process into its administrative activities and tools, preventing proposals from bypassing ethical review, and facilitating evaluation and accountability. The Organization is currently working on strategies to ensure that all research is recognized as such by its staff and is conducted with ethical approval. With a view to achieving adherence overall, PAHO will call its Member States to action so that they commit to requiring that all research with human subjects in the Americas be subjected to an adequate ethical review process. PAHO will further support and maintain PAHOERC's robust ethics review processes to the best possible standards, and train researchers both in Member States and the PASB to deliver top-quality research. PAHO will strengthen its requirement that all research in the Organization be registered at the same time it continues to support the development of regional registries for clinical trials that fulfill WHO-ICTRP standards.

PAHO, through the establishment and support of PAHOERC, expresses its institutional commitment to the protection of research participants and assures that abuses, such as those related to the Guatemala case, will not happen under PAHO's watch.

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