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### **BIOETHICS: TOWARD THE INTEGRATION OF ETHICS IN HEALTH: FINAL REPORT**

#### **Background**

1. Recent events have brought international attention to the importance of bioethics. The 2014 Ebola outbreak in West Africa posed the challenge of assessing whether it was ethically acceptable to use interventions that had not previously been evaluated in humans (1). In the Region of the Americas, the Zika virus was found to cause severe congenital malformations in 2016. The first mosquito-borne virus known to cause such an effect, it raised numerous ethical challenges, such as determining the duties toward pregnant women and women of reproductive age, and what an ethical public health response should entail in the midst of the uncertainty that characterizes an outbreak of an emerging disease (2). Furthermore, in response to the commitments to universal access to health and universal health coverage assumed by the World Health Organization (WHO) and the Pan American Health Organization (PAHO) (3, 4), countries across the world are facing the challenge of deciding how to prioritize ethically when moving toward these goals (5). These events, along with the increasing complexities posed by novel technologies and the diversity of contemporary societies, have enhanced the demand for guidance on bioethics as the discipline that seeks to elucidate the ethical problems that arise in relation to health (6).

2. In 2012, approval of the concept paper *Bioethics: Towards the Integration of Ethics in Health* by the PAHO Member States during the 28th Pan American Sanitary Conference (Resolution CSP28.R18) (6, 7) marked an important milestone in the regional commitment to advance bioethics and ultimately integrate ethics in health. This milestone resonates with the Organization's core function of articulating ethical and evidence-based policy options (8).

#### **Analysis on Progress Achieved**

3. During the 2012-2017 period, Member States made remarkable progress in bioethics. Capacity for ethics analysis was strengthened at all levels, prioritizing the health authorities and taking specific regional needs into account (9). The Region is

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committed to the ongoing discussion of bioethical issues. It contributed regularly to the development of international ethics guidance (10) and participated actively in global bioethics forums, which further strengthened regional networks (11, 12).

4. The Region continued to devote special attention to ensuring that research with human subjects is ethical. A total of 25 countries now have legal frameworks aimed at ensuring ethical standards in research (13). Ethical treatment of research participants was strengthened during the period through the following interventions: guidance for the operation of committees that review research protocols (14), detailed guidelines for their ethics analyses (10), ongoing training for ethics review committees (15), implementation of online tools (e.g., PAHO-developed ProEthos) to facilitate processes and promote standards in ethics reviews, and mobilization of enhanced support from governments and research institutions. Taken together, these measures have led to increased adherence to the ethics review requirement for research involving humans. Within the Pan American Sanitary Bureau (PASB), similar progress took place to ensure that research with human participants conducted with the Organization's involvement was ethical. The PAHO Ethics Review Committee (PAHOERC) received almost five times more submissions in 2017 than it did in 2012.

5. Ensuring that research is ethical is challenging because ongoing ethics examination leads to more nuanced guidelines (e.g., for pregnancy research), which, along with novel research fields (e.g., gene editing or biobanking research), may pose the need to revise existing standards (16). Furthermore, the extensive commitment to advance research ethics in the Region has led primarily to interventions that target specific elements of research ethics systems. Yet a systemic approach is critical to ensuring that research is always ethical; that all relevant parties are committed; that ethical standards are upheld; and that compliance is secured so that nothing falls through the cracks. Member States need support to establish research ethics systems, which are vital to catalyzing the research on which great improvements in public health depend (17).

6. Public health ethics has been given special attention, pursuant to the resolution adopted by Member States in 2012 (7). It was introduced then on the regional agenda as a key component of the technical cooperation of the PAHO Regional Program on Bioethics, which emphasized ethical priority-setting in health and the procedural integration of ethics into the decision-making process using the Accountability for Reasonableness (A4R) framework (18). As a result, capacity to conduct moral deliberations increased across the Region and countries received support on the integration of ethics into their decision-making processes. Since 2014, procedural ethics guidance has been supplemented with substantive ethics guidance, based on the principles that are embedded in the concept of universal health (5). As they move toward universal access to health and universal health coverage, Member States are making progress with the integration of ethics into decision-making processes, especially in health technology assessment.

7. Public health ethics has gone from being an unfamiliar concept to a subject on which Ministry of Health personnel, including high health authorities, now receive training. Indeed, the field has been strengthened not only through the development of training materials that focus on the application of ethics analysis (19), but also through the development and dissemination of ethics guidelines for public health (2, 20, 21) and the integration of public health ethics into the technical work of PAHO (e.g. in immunization and the surveillance of noncommunicable diseases), which in turn shapes the policies and plans of the Member States.

8. Public health emergencies pose a number of ethical challenges that often go beyond the realm of public health. The Zika virus outbreak, for instance, tested the Region's bioethics strength at various levels. In response to a prior consultation with Member States, PASB led an ethics consultation focused on the key issues that Member States had previously raised, and the subsequent development of ethics guidance (2), which received global recognition (22) and was incorporated into PAHO technical cooperation in response to the outbreak. While this experience exemplifies the progress achieved by the Region, it also reveals the need to enhance our ethics preparedness. Some of the ethics challenges that arose could have been avoided if available ethics guidance had been taken into account (23). In summary, while the Region of the Americas leads globally in the advancement of ethics in public health, there is still need to intensify PASB ethics support for Member States in order to ensure that it is an integral part of public health work and decision-making.

### **Action Necessary to Improve the Situation**

9. In light of the progress made and the challenges that remain, it is imperative to continue integrating ethics into the different areas of health work in the Americas. It is therefore recommended to further escalate these efforts in order to effectively accomplish the goals of: *a*) strengthening research ethics systems so they will be capable of ensuring that research is always ethical; and *b*) systematically integrating ethics into ongoing public health work and decision-making processes that impact on the population of the countries in the Americas.

### **Action by the Executive Committee**

10. The Executive Committee is invited to take note of this report and provide any comments it deems pertinent.

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