



Advancing research ethics systems in Latin America and the Caribbean: a path for other LMICs?

Low-income and middle-income countries (LMICs) need to do research to achieve improvements in public health,¹ which comes with the imperative to do research ethically. Countries in Latin America and the Caribbean have continuously strengthened their capacities to advance ethical research over the past few decades, though challenges remain in ensuring that all research is ethical.

During the 56th Pan American Health Organization (PAHO) Directing Council in September, 2018,² countries in Latin America and the Caribbean assessed the outcomes of the 2012 regional mandate to incorporate bioethics in health.^{3,4} They agreed on the need to escalate their efforts in bioethics. Regarding research ethics, countries acknowledged progress but noted that interventions mostly focused on one specific element of research ethics systems, thus not advancing research ethics comprehensively and ensuring research is always ethical. A systemic approach for research ethics was therefore deemed a regional priority. Improving ethics preparedness for emergencies that would incorporate the lessons learned from Ebola and Zika virus outbreaks was also prioritised.²

In response, PAHO's Regional Program on Bioethics devised strategic lines of action to strengthen research ethics systems (table) and enhance emergency ethics preparedness. Corresponding objectives and indicators, aimed at assessing a country's research ethics systems and triggering action, were developed after a review of the literature and the scrutiny of bioethicists from

the region. The initial plan to use the indicators to produce a regional baseline assessment was met with an unexpected challenge: countries that received a chart summarising their current research ethics landscape for validation purposes requested immediate support to improve their situation and meet the indicators.

Following an initiative that started in Trinidad and Tobago in late 2018 to develop a national policy focused on research ethics, PAHO began to advance national research ethics policies as a tool for countries to achieve the indicators. National consultations were encouraged as part of the process, which often implies expanding the scope of ethics governance from clinical trials with drugs and devices to all research with humans, establishing entities to do research ethics oversight, and formalising existing practices that could be susceptible to variable political or institutional support. Technical support to countries developing these policies—facilitating national consultations, revising drafts, and advocating for adequate and sustainable governance structures—has been prioritised throughout 2019. However, efforts to establish a regional baseline in research ethics are also underway.

Peru best illustrates rapid action in response to the indicators. Following a discussion of the country's research ethics assessment with the National Institute of Health (Instituto Nacional de Salud) in January, 2019, Peru began developing a national policy to supplement its existing framework, which currently governs only

Objectives	Indicators
Strategic line of action: strengthening research ethics systems	
Adopt ethical standards for research with human participants in accordance with international guidelines	Number of countries with legislation or other legally binding instrument governing health-related research with human participants that is consistent with international ethical standards, including requirements for ethics review by an independent committee
Establish effective mechanisms for ethics oversight of research	Number of countries with a national body tasked with the oversight of ethics review committees, including establishing mechanisms for registration, training, and compliance
Enhance ethics capacity among researchers and ethics review committees	Number of countries with policies that support research ethics training for investigators and ethics review committees
Advance transparency and integrity in research	Number of countries requiring the prospective registration of clinical trials in accordance with WHO standards; number of countries with policies on responsible conduct of research
Strategic line of action: strengthening ethics preparedness for emergencies, epidemics, and disasters	
Strengthen the capacity to do research ethically during emergencies, epidemics, and disasters	Number of countries with established procedures to do thorough accelerated ethics review of research during emergencies, epidemics, and disasters

Table: Research ethics strategy

a subset of clinical trials. A national consultation took place in February, 2019; by May, 2019, the technical document had gathered widespread input and been finalised, and by September, 2019, the policy (Consideraciones éticas para la investigación en salud con seres humanos [ethical guidelines for health research with human subjects]), which allows Peru to meet all the indicators, was awaiting official approval for publication.

Because we believe LMICs beyond the Latin America and Caribbean Region can benefit from a similar exercise, we do not want to delay in sharing this strategy to assess and advance research ethics systemically. By outlining key elements in a research ethics system, the PAHO strategy provides a tangible framework to plan action along with a tool—a national research ethics policy—that can be rapidly implemented to achieve such progress sustainably. Robust research ethics systems in LMICs are crucial to catalyse ethical research and thus improve the health and wellbeing of our populations.

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- 1 WHO. Research for universal health coverage: world health report 2013. Geneva: WHO, 2013. https://apps.who.int/iris/bitstream/handle/10665/85761/9789240690837_eng.pdf?sequence=2 (accessed Aug 8, 2019).
- 2 Pan American Health Organization. Bioethics: towards the integration of ethics in health: final report. 56th Directing Council, 70th Session of the Regional Committee of WHO for the Americas; Sep 23–27, 2018; Washington, DC: PAHO. <http://iris.paho.org/xmlui/bitstream/handle/123456789/49706/CD56-INF-21-e.pdf?sequence=1&isAllowed=y&ua=1> (accessed Sept 12, 2019).
- 3 Pan American Health Organization. Bioethics: towards the integration of ethics in health. 28th Pan American Sanitary Conference, 64th Session of the Regional Committee of WHO for the Americas; Sep 17–20, 2012; Washington, DC: PAHO; 2012. <http://iris.paho.org/xmlui/bitstream/handle/123456789/4457/CSP28-14-e.pdf?sequence=1&isAllowed=y> (accessed Sept 12, 2019).
- 4 Pan American Health Organization. Bioethics: towards the integration of ethics in health. 28th Pan American Sanitary Conference, 64th Session of the Regional Committee of WHO for the Americas; Sep 17–20, 2012; Washington, DC: PAHO. <https://www.paho.org/hq/dmdocuments/2012/CSP28.R18-e.pdf> (accessed Sept 12, 2019).