



Pan American Health Organization Ethics Review Committee

2021 Annual Report

Abridged version, March 2022

PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas

Overview

In 2021, PAHOERC continued to meet the challenges of the COVID-19 pandemic, which included a surge in research efforts –primarily COVID-19 studies– and increased demand for research ethics guidance and support. PAHOERC continued to operate under its emergency operating procedures to meet the increased needs for timely ethics review, prompting more frequent meetings and the sustained commitment of PAHOERC members and observers.

PAHOERC received 99 unique proposal submissions for countries and/or territories in the Region in 2021, 27 of which were related to COVID-19. Of the proposals requiring full PAHOERC review, 28 were reviewed by a quorum of members during 11 regular meetings. Seven auxiliary meetings were also held to accommodate the rapid review of COVID-19 protocols. Twenty-six proposals for research with human subjects were ultimately approved for implementation in the LAC region in 2021, 7 of which were related to COVID-19.

As the COVID-19 pandemic continues to stress the importance of research, ensuring that research is conducted in adherence to the highest ethical standards is more urgent than ever. The Region witnessed a mainstreaming of research efforts in 2021, such as the widespread use of digital surveys, at the same time that prominent cases of unethical research on COVID-19, including involving fraud and misconduct, were revealed and received ample coverage in the media¹. These events hamper trust in research as well as in the public health interventions that result from research, such as COVID-19 vaccines. It is therefore imperative to escalate efforts to ensure the ethical conduct of research in the Organization and across the Region.

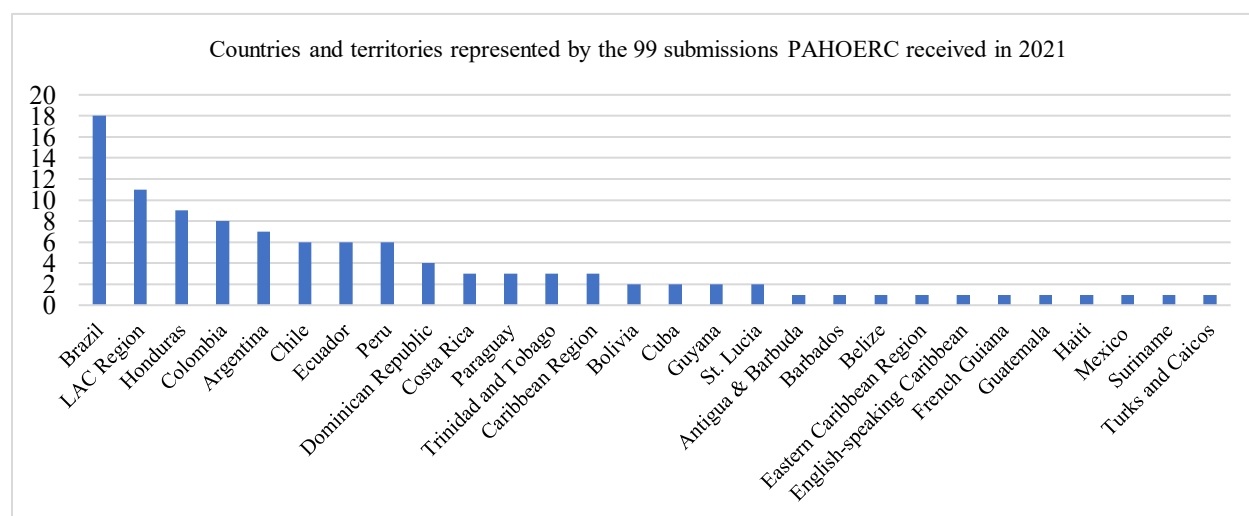
¹ For example:

- <https://saludconlupa.com/tags/vacunagate/>
- <https://www.bbc.com/news/world-latin-america-56093094>
- <https://www.scientificamerican.com/article/scandal-over-covid-vaccine-trial-at-peruvian-universities-prompts-outrage/>
- <https://www.bmj.com/content/375/bmj.n2819>
- <https://elpais.com/sociedad/2021-10-14/cobayas-humanas-en-brasil-las-autoridades-investigan-200-muertes-en-el-estudio-de-una-droga-experimental-contra-la-covid-19.html>
- <https://www.nexojournal.com.br/expresso/2021/09/22/7-pontos-chaves-para-entender-o-caso-da-Prevent-Senior>

1. Summary of activities

Ensuring that human subjects research in which PAHO is involved meets ethical standards

In 2021, PAHOERC received 104 submissions through its online portal, 99 of which were unique submissions aiming to conduct research in multiple countries (each country is accounted for in the figure below); most proposals targeting the LAC Region as a whole involved online surveys or regional databases.



Some proposal submissions represent research that will take place in more than one country or subregion; all countries represented here.

Of these 99 submissions:

- **61** were granted an exemption from full PAHOERC review, in accordance with the criteria established by its SOPs.
- **34** proposals were deemed research with human subjects thus requiring full review by the committee or further action by the Secretariat (similar to previous years).
- **28** proposals were reviewed by a quorum of members during 18 meetings in 2021 (some proposals are still pending review as of 2022).
- **26** proposals were ultimately approved for implementation in countries of the LAC Region in 2021 (including three proposals submitted in 2020).
- **7** of the 26 proposals approved were COVID-19 studies.

Proposals submitted in 2021 reflect the context of the pandemic: a surge (28 submissions) of COVID-19-related projects and fewer proposals on regular annual cluster projects. Other topics included a high volume of proposals focused on migrant needs related to reproductive health and infectious diseases, (managed by FPL/CLAP); proposals on the topic of Operational Research in the Context of Advancing Towards TB Elimination in the Americas (funded by the TDR-Structured Operational Research and Training Initiative

(SORT IT)); alcohol/tobacco use, HIV/AIDS prevention, and online surveys focusing on mental health. The total number of proposals received represents a slight increase from 2020 and is consistent with the average submitted during the previous five years.

PAHOERC Member and Observer Contributions

The remarkable commitment of PAHOERC members and observers to their duties ensuring all research in which the Organization is involved is ethical was further tested during the second year of the COVID-19 pandemic. A significant number of COVID-19-related research proposals created a greater workload for members by prompting 7 additional PAHOERC meetings in 2021, and many proposals required more attention due to newly emergent evidence related to SARS-CoV-2. Member and observer contributions included:

- Reviewing materials and evidence on tight deadlines, time spent in virtual meetings or preparing written comments, responding to follow-up requests from the Secretariat.
- Additional meetings with research teams and detailed reviews of protocol components via email on areas of member's expertise.
- Participating in Organization-wide refresher trainings for staff on the PAHOERC requirement.

A new member was added in 2021 to help accommodate an increased volume of proposals toward the end of 2021. The pandemic has opened the possibility of including members that are not based in Washington D.C., which had not been successfully accomplished previously. The Committee continues to seek a new member from the Caribbean to enhance geographical representation among members.

2. Building capacity in research ethics

Capacity-building requests at PAHO and through the Region — and overall requests for support — continue to be very high because many teams that usually do not conduct research are pursuing COVID-19 research projects.

Trainings

Internal capacity-building activities in 2021 included a combination of individual consultations via phone and email; trainings targeted to certain grant project teams; and general trainings for specific departments and to the Organization more generally, including:

- Organization-wide refresher training sessions (in English and Spanish) on PAHO’s ethics review requirement with a focus on the context of the pandemic (October);
- Training sessions on research ethics and ethics review processes for awardees of the CDE/TDR Small Grants Training Program (SORT IT) (July) and CLAP’s EVISIP 21 research grants (September); presentation on PAHO’s ethics review requirements for PAHO’s Risk communication and community engagement (RCCE) regional group (October) and Colombia’s teams conducting COVID-19 research projects funded by the Korean International Cooperation Agency (KOICA) through PAHO.

Capacity-building efforts in the LAC Region in 2021 mainly focused on the challenges posed by COVID-19 research, and on the topics addressed in [PAHO’s COVID-19 ethics guidance documents](#). Numerous training sessions in both languages on these topics were delivered at the request of national authorities or key institutions of many countries in the Region (including Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Guatemala, Mexico, Panama, and Peru). The health authorities of Bolivia and Costa Rica further requested training series for their research ethics committees involving monthly sessions, supplemented by an additional four-session weekly series focused on training in procedural issues for Bolivia.

Communications materials

Several communications materials were developed in 2021 to disseminate quality information in research ethics (in English, Spanish, Portuguese, and French):

- Two videos on the work of research ethics committees:
 - [When does health research need ethics review?](#) (also in [Spanish/Portuguese/French](#))
 - [What do research ethics committees review?](#) (also in [Spanish/Portuguese/French](#))
 (The videos were collectively viewed more than 16,600 times by the end of 2021); infographics were produced with the same content (English/Spanish).
- Three [animated videos, infographics, and social media cards were](#) produced highlighting the role of research in the COVID-19 response and the importance of conducting ethical research.
- [Nine additional videos](#) (in English/Spanish) on ethics and clinical research that were originally developed by Argentina’s Proyecto ACERCA were adapted and revised by PAHO.

Advancing ethical standards in research

In conjunction with the Regional Program on Bioethics, ethical standards in research were advanced in 2021 through a systemic approach using indicators, which entails providing support to countries to assess

their national research ethics systems using the indicators and developing national research ethics policies (e.g. Guatemala), laws (e.g. El Salvador) or specific interventions (e.g. Costa Rica) to meet the indicators that are not currently achieved. Activities in support of this approach in 2021 included:

- Three bilingual regional dialogues (attended by almost 400 participants and viewed more than 1,100 times after) to present the indicators and discuss their use by national authorities, and share regional assessments using the indicators (Following PAHO's 2021 publication of [Indicators for Strengthening National Research Ethics Systems](#)).
- Submission for publication (to *The Lancet Global Health*) of the regional assessment that was initiated with NIH's support before the pandemic.
- Publication of a WHO-funded external regional assessment on the indicator pertaining to emergencies.

Other activities carried out in 2021 in the Region to advance ethical standards in research included:

- Implementation of [PAHO's COVID-19 ethics guidance documents](#), which entailed close coordination with the Incident Management System Team (IMST) and numerous presentations of these documents in national, regional, and global meetings.
- A regional bilingual webinar to present and discuss PAHO's [Guidance for ethics oversight of COVID-19 research in response to emerging evidence](#) involving discussants from national authorities took place in March (attended by ~ 500 participants and viewed almost 900 times).
- Promotion of ethical standards for research with children (a concern in the Region due to the initiation of COVID-19 vaccine trials with children):
 - Development of related content for [PAHO's website](#) (also published by media in Trinidad and Tobago), [infographics](#), social media cards.
 - Facebook live sessions with experts in [English](#) and [Spanish](#) (with more than 4,000 attendees and viewers), and coordinated efforts with FLP.
- Ethical standards advanced in coordination with WHO for COVID-19 human challenge trials, human genome editing –with regional sessions to advance community engagement and disseminate WHO's new governance framework–, and gene drive research –in collaboration with NIH Foundation and CDE, and building on WHO's Guidance on ethics and vector-borne diseases.
- Promotion and support toward the implementation of the PAHO-developed ProEthos system:
 - Presentations to committees/institutions in Bolivia, Costa Rica and Guatemala, in coordination with their national health authorities; to a network of research ethics

committees in Ethiopia and to the WHO's Eastern Mediterranean Regional Office; WHO-ERC's Ad-hoc COVID-19 committee.

- Support to the United States Office of Human Research Protections (OHRP) 2021 revision of the International Compilation of Human Research Standards, which features 28 countries of the Region.
- A General Information Bulletin ([GIB-HQ-CO-Centers-21-1333](#)) was issued in October in collaboration with PAHO's Ethics Office to advance the ethical conduct of research conducted by PAHO personnel or with PAHO's financial or technical involvement (with supplementary informative sessions in English and Spanish).

Maintaining PAHOERC's institutional memory

2021 was PAHOERC's second full year utilizing ProEthos as the sole platform for process facilitation and institutional recordkeeping, which has eliminated subscription and maintenance costs incurred by the Organization for a digital platform. In 2021 the Secretariat conducted additional testing and worked with BIREME on adjustments to optimize the platform, which have included substantive modifications to adhere to WHO's new cybersecurity standards.

An abridged version of PAHOERC 2020 annual report was developed at the request of the Deputy Director's Office for dissemination with broader audiences. PAHOERC continues to make updated lists of COVID-19 submissions available at www.paho.org/pahoerc, whose traffic increased in the last year by 1,827%: from 155 viewers in 2020 to 2,939 in 2021.

3. Recommendations

1. Fund the STP position to support PAHOERC in the 2022-23 biennium to ensure PAHOERC can sustainably fulfill its corporate function.
2. Continue in-house training on research ethics and the Organization's ethics review requirement, focusing on challenges posed by the COVID-19 pandemic as appropriate.
3. Continue supporting IMST, as needed, and operating under the emergency procedures. Conduct an assessment, based on an analysis of the experience in the 2020-2021 biennium, of the need to adjust the emergency procedures described in the PAHOERC SOPs to improve the Committee's response to emergency scenarios.
4. Adapt WHO's Code of Conduct for responsible Research and WHO's Policy on Misconduct in Research for inclusion in PAHO's E-manual to advance adherence to ethical standards in research among PAHO personnel.
5. Continue supporting the implementation of ProEthos.
6. Disseminate PAHOERC's 2021 Annual Report and abridged version outside the Organization.

PAHOERC Members

Ana Luciañez
Andrea Vicari
Bernardo Nuche Berenguer
Carolina Chávez Cortes
Carla Saenz (Secretary)
Fernanda Alonso (External member) *
Hannah Kurtis
Jonás Gonseth-García
Lúcia Helena de Oliveira
Ludovic Reveiz (Vice President)
María Paz Ade (President)
Maristela Monteiro
Omar Sued**
Pedro Ordúñez
Vilma Gawryszewski
** Member since November 2021.

PAHOERC Observers

Christina Marsigli, Department of External Relations, Partnerships and Resource Mobilization
Gabriela Gergely, Ethics Office
Pamela Zúñiga, Office of the Legal Counsel
Roberto Samayoa, Department of Procurement and Supply Management

Secretariat Support

Marcie Neil

* Until December 2021.

Annex: Proposals submitted to PAHOERC in 2021

TITLE	COUNTRIES
Evaluación de la respuesta clínica y tolerabilidad de intervenciones locales para el tratamiento de la leishmaniasis cutánea	Brazil
Estudio exploratorio de la salud sexual y reproductiva de la niña y mujer migrante proveniente del triángulo norte	Guatemala
Proyecto parte del esqupo FPL/IM	Colombia
Nursing Research Priorities in Latin America	LAC Region
Mobility of nurses and physicians from the English Caribbean region	English-speaking Caribbean
Generating evidence to address concerns and attitudes of health care workers towards COVID-19 vaccine in the Caribbean countries	Caribbean
Proyecto Santuarios Alimentarios	Honduras
Uso de servicios de salud sexual y reproductiva en una población venezolana en situación de movilidad humana en Quito, Ecuador: análisis de situación.	Ecuador
Living with NCDs during the COVID-19 Pandemic	Caribbean region
Identificação de espécies de leishmania em áreas endêmicas de leishmaniose tegumentar americana no Brasil	Brazil
Concerns, attitudes and intended practices of health care workers to COVID-19 vaccine in the Caribbean	Caribbean region, Barbados
Estimativa da prevalência da Esporotricose Felina em área hiperendêmica no Brasil	Brazil
Luz, Câmera, Educação: ressaltando a vigilância em saúde no controle da doença de Chagas	Brazil
Análise do uso de repelentes contra carrapatos da espécie <i>Amblyomma sculptum</i> (ACARI: IXODIDAE) transmissores de febre maculosa	Brazil
Suscetibilidade de <i>Lutzomyia longipalpis</i> sl (Diptera: Psychodidae) em áreas com uso de coleiras impregnadas com inseticida no Brasil	Brazil
HEARTS technical package	St. Lucia
ViGeCoV2: Núcleo de vigilância genômica em tempo real do SARS-CoV-2 no Brasil	Brazil
The evidence-to-policy process in the context of COVID-19 in the Americas region	LAC Region
Incidencia y mortalidad por Cryptococosis, Histoplasmosis y Tuberculosis en personas viviendo con el vih en el Paraguay	Paraguay
Análisis de retorno de la Inversión (ROI) por inmunización con PCV 10 en Ecuador.	Ecuador
Evaluación de los factores de riesgo de enfermedad por el coronavirus de 2019 (COVID-19) entre trabajadores de salud: protocolo para un estudio de casos y controles (Estudio multicéntrico en Colombia)	Colombia
Estudio nacional de seroprevalencia (COVID-19)	Ecuador
Diagnóstico Salivar de Toxoplasmosis para levantamientos epidemiológicos em situaciones de surto: proposta visando implementação em LACENS	Brazil
Documentación de los mecanismos de participación juvenil en salud y sus resultados en Chile	Chile

Barreras de acceso en gestantes y mujeres con hijos menores de 5 años, usuarias de los servicios de salud	Ecuador
Knowledge, attitudes and behaviours of young people in Trinidad and Tobago during the COVID-19 pandemic	Trinidad and Tobago
Impact of childhood pneumococcal conjugate vaccination on mortality in adults and elderly in selected Latin American countries	LAC Region
A prospective cohort study investigating maternal, pregnancy and neonatal outcomes for women and neonates infected with SARS-CoV-2 in Brazil: REBRACO/WHO	Brazil
Cambios en la movilidad a partir de la COVID-19 en Argentina, Chile y Uruguay. Nuevos desafíos para la movilidad sustentable en la Segunda Década de acción por la Seguridad Vial	Argentina, Chile, Uruguay
Epidemiología de SARS-CoV-2 no Amazonas	Brazil
Evaluating the programmatic and economic impact of SINOVA in Honduras	Honduras
Psychological responses to the climate and COVID-19 crises in young people in four Caribbean Countries, and their agency to build the world they hope to see	Peru
S. masoni intermediate hosts in St Lucia	St. Lucia
Estudio nacional de costos catastróficos que experimentan las personas afectadas por la tuberculosis en Colombia año 2021.	Colombia
Eficacia de sistemas de etiquetado frontal de alimentos en centroamérica (Costa Rica)	Costa Rica
Can multidrug resistant Escherichia coli isolates that harbor mobile colistin resistance genes be recovered from water bodies and their sediments and contribute as reservoirs of colistin resistance?	Ecuador
Prevalence, serotyping and antimicrobial resistance pattern of Salmonella in faecal samples obtained from pigs with suspected salmonellosis analyzed at the University of Antioquia, Colombia, 2019-2021	Colombia
COVID-19 em Fernando de Noronha	Brazil
Blood culture and antibiotic sensitivity patterns of WHO priority bacteria in a regional referral hospital in Colombia (2019-2020)	Colombia
Levantamiento de información para saber cuáles son las necesidades de las personas con discapacidad intelectual	Dominican Republic
Epidemiology of antimicrobial resistance in bacteria isolated from patients at community (primary health care) and hospital settings in Ecuador, 2018	Ecuador
Health Mapping in French Guiana	French Guiana
Análisis del estado de la regionalización de la atención perinatal, resultados y nuevas líneas de acción en la provincia de Entre Ríos	Argentina
Netcode toolkit monitoring the marketing of breast-milk substitutes: protocol for periodic assessments	Suriname
Implementación del diagnóstico de laboratorio HTLV en Brasil: programa de red de apoyo a laboratorios de extensión en seis capitales.	Brazil
Medición del acceso a la tecnología de asistencia mediante el cuestionario de evaluación rápida de la tecnología de asistencia (rATA)	Dominican Republic
Survey on NCDs and COVID-19 using mobile phones	Antigua and Barbuda
Survey on NCDs and COVID-19 using mobile phones in Honduras	Honduras
Survey on NCDs and COVID-19 using mobile phones in Bolivia	Bolivia
COVID-19 Vaccine Effectiveness Study: a multicenter regional evaluation	LAC Region
Diagnóstico de los sistemas de atención de emergencias sanitarias en Argentina	Argentina

Mobile Phone Survey - Protocolo para PAHOERC - Paraguay	Paraguay
Evaluación del manejo del dolor procedimiento de AMEU bloqueo paracervical	Colombia
Impacto de la pandemia COVID-19 en la atención a pacientes en situación de aborto, embarazo ectópico o molar en un hospital universitario de Brasil	Brazil
Resultados del manejo médico ambulatorio de mujeres en situación de aborto de primer trimestre en el Hospital San José, Santiago de Chile, 2018-2021	Chile
Impact of the Caribbean regulatory system on marketing authorization, registration and access to pharmaceutical products	LAC Region
SURVEY: Critical interventions to eliminate AIDS as a public health threat: perception from the communities impacted	LAC Region
Prevalencia del uso de metodos anticonceptivos post aboro inmediato, en el Hospital Materno Infantil San Lorenzo de los Mina, enero 2018 a junio 2021	Dominican Republic
Complicaciones asociadas al aborto tardío en el servicio de obstetricia del hospital materno infantil san lorenzo de los mina en el periodo enero 2018 a junio 2021	Dominican Republic
¿Qué tanto disminuye el fentanilo el dolor durante el aborto quirúrgico? Análisis entre usuarias de la Fundación Oriéntame en Colombia	Colombia
Comportamiento de la Interrupción Voluntaria del Embarazo en Adolescentes en un hospital Cubano	Cuba
El Embarazo no intencional: ¿influye en la elección en la del método anticonceptivo posterior a un aborto?	Chile
Papilomavirus humano e câncer cervical em pernambuco: acessibilidade ao diagnóstico molecular no sistema público de saúde	Brazil
Evaluation of the effectiveness of COVID-19 vaccines in Latin America and the Caribbean	LAC Region
Protocolo para conocer el impacto de la pandemia por sars-cov-2 sobre el acceso a los servicios de atención intercultural del parto en Paraguay	Paraguay
AGIR: cov saúde mental	Brazil
Estudio de cohortes prospectivo para investigar los resultados del embarazo, maternos y neonatales, en mujeres y recién nacidos infectados por el SARS-CoV-2	Argentina
Risk factors for mother-to-child transmission of Trypanosoma cruzi and Hepatitis B in the cross-border area of Argentina, Bolivia, and Paraguay	Argentina, Bolivia, Paraguay
Pre-Transmission Assessment Surveys to evaluate the impact of Mass Drug Administration to eliminate Lymphatic Filariasis in Guyana	Guyana
Estudio para precisar la estimación del consumo de alcohol no registrado en Chile	Chile
Evaluación del componente de salud y desarrollo de los adolescentes en la formación en enfermería	Colombia, Ecuador, Peru
Estimación de las necesidades de sangre y sus componentes en Costa Rica	Costa Rica
Composición de bebidas alcohólicas de consumo humano no registradas en Lima 2021: ¿Solo la concentración de etanol es el problema?	Peru
OMS/OPS estudio de prevalencia puntual de uso hospitalario de antimicrobianos Honduras en los hospitales: General San Francisco Juticalpa, Olancho y Santa Teresa, Comayagua.	Honduras
Barreras y facilitadores de la adherencia a las medidas de prevención de la infección por SARS-CoV-2 en centros educativos de Costa Rica	Costa Rica
Comunicación para el rastreo de contactos de COVID-19	Honduras
Análisis de las barreras de acceso los servicios de salud e identificación de opciones de política en el marco de los procesos de reforma sectorial en salud en el Perú	Peru

Equidad y barreras para el acceso a los servicios de salud: análisis e identificación de opciones de políticas en Honduras	Honduras
Equity and access barriers to health services: analysis and identification of policy options in Guyana in the context of the Covid-19 pandemic	Guyana
Investigación cualitativa exploratoria sobre los procesos de implementación de PCI durante la pandemia de COVID-19 en la Region de las Américas: percepciones y experiencias de puntos focales	LAC Region
Conocimientos, creencias, actitudes y aceptabilidad de la vacuna contra COVID-19 y factores asociados, en estudiantes de la UNAH	Honduras
Public Health and Social Measures (PHSM) Implemented in Response to COVID-19 in the Barbados, Eastern Caribbean Countries and Territories	Barbados, ECC and Territories
Survey on NCDs and COVID-19 using mobile phones in Belize	Belize
Herramienta de recolección de datos de Servicios Farmaceuticos en Atención Primaria de Salud (Fase Piloto)	LAC Region
Survey on NCDs and COVID-19 using mobile phones in Turks and Caicos	Turkes and Caicos
WHO survey among providers of services for pre-exposure prophylaxis (PrEP) for HIV prevention	LAC Region
Encuesta monitoreo en torno a derechos en el parto, nacimiento y puerperio, para evaluar la situación de la implementación de la Ley N° 25.929	Argentina
Evaluating the potential for enhancing care and quality of life in cancer survivors through a survivorship program in Trinidad and Tobago with a capacity for expansion across the Caribbean	Trinidad and Tobago
Encuesta regional de migración y salud (ERMS) Chile 2021-2022	Chile
Mental health self-efficacy among participants from the disaster-related psychological trauma and mental health training for nurses in the Caribbean	LAC Region
Implementation of rapid diagnostics assays for detection of histoplasmosis and cryptococcosis in people with advanced HIV disease	Trinidad and Tobago
Estudio prospectivo en chagas congénito: aspectos del parásito y del hospedero humano y validación de diagnóstico molecular neonatal	Argentina
Diagnóstico Xpert Ultra-Contactos TB - Cuba	Cuba
Tasa de infección por COVID-19 post vacunación anti-COVID-19 en el personal de salud de Honduras	Honduras
Lettre d'accord entre le Ministere de la Santé Publique et de la Population et l'Organisation Panamericaine de la Sante/Organisation Mondiale de la Santé	Haiti
Línea de base de los problemas y necesidades de salud de las personas refugiadas y migrantes procedentes de Venezuela en Lima metropolitana	Peru
Los mecanismos de participación juvenil en salud y sus resultados en Honduras	Honduras
Entrenamiento en un nuevo método para realizar autopsias utilizando procedimientos mínimamente invasivos	Brazil
Câncer de colo uterino como marcador de exclusão a serviços de saúde e vulnerabilidade social	Brazil