



Research reporting and Trial registration in Latin America and the Caribbean (LAC)

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Ludovic Reveiz
Health Systems Strengthening
Pan American Health Organization

Content

1. Mapping progress on research reporting in LAC
2. Potential solutions for improvement of health research literature

1. Mapping progress in LAC

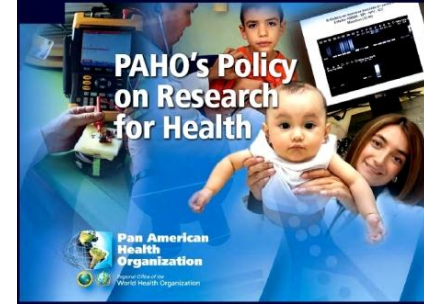
Policy context



WHO Research for Health Strategy approved by the 63rd World Health Assembly

- Actions to achieve the goal: Working with Member States and partners, the Secretariat will:
 - b) develop, in line with the guiding principles of this strategy, norms and standards for best practice in the management of research to cover, for example: ethical and expert review and the accreditation of ethical review committees; the reporting of research findings; the sharing of research data, tools and materials; the registration of clinical trials; and the use of evidence in the development of policy, practice and products;*
 - (c) continue to facilitate the development of, and set standards for, publicly accessible registries of clinical trials; and*
 - (d) engage in technical cooperation with Member States in order to enable them to adapt and implement norms and standards for research, and monitor subsequent adherence and compliance.*

Policy context



PAHO adopted in 2009 a regional policy on research for health, endorsed by Member States

Six interrelated objectives have been established:

- (a) Quality: to promote the generation of relevant, ethical, and high-quality research;
- (b) Governance: to strengthen research governance and promote the definition of research agendas;
- (c) Human resources: to improve competencies of and support for human resources involved in research;
- (d) Partnerships: to seek efficiencies and enhanced impact and appropriation of research through effective and strategic alliances, collaboration and the building of public trust, and engagement in research;
- (e) Standards: to foster best practices and enhanced standards for research;
- (f) Impact: to promote the dissemination and utilization of research findings;

Policy context

- WHO/PAHO supports trial registration: International Clinical trial registry platform (ICTRP)
- Two primary registries from LAC (Brazil and Cuba) and other registry are under development (Peru)
- BIREME/PAHO recommended journals indexed in Scielo and Lilacs to endorse trial registration: 56 journals from LAC publicly endorse TR in 2007
- Endorsement of trial registration and the CONSORT statement by specific journals (i.e Revista Brasileira de Fisioterapia, Cad Saude Publica, revista colombiana anestesiologia etc)
- The Buenos Aires Declaration on Ethics and Clinical Trials (2008)
- PAHO has an agreement with Equator network

Health research agendas



Countries that
have uploaded a
policy on
research for
health in HRWeb

Availability of research reporting guidelines in LAC

- EQUATOR Network Webpage in Spanish
- CONSORT, STROBE, PRISMA and TREND are available in Spanish



The screenshot shows the EQUATOR Network website interface. At the top right, there is a language selector set to "In English" and a login button labeled "Iniciar sesión". Below this is a search bar with the text "Buscar:" and a blue "Ir" button. The main header features the EQUATOR Network logo and the tagline "Enhancing the QUALITY and Transparency Of health Research" and "Mejoramos la calidad y la claridad de la investigación sanitaria". A navigation menu includes links for "Home", "Acerca de EQUATOR", "Centro de recursos", "Cursos y eventos", "Proyectos", "Contacto", and "Noticias". The main content area contains a welcome message: "Bienvenido al sitio web de EQUATOR Network, el centro de recursos para la presentación correcta de informes sobre estudios de investigación sanitaria". To the right of this message is the logo for the "Organización Panamericana de la Salud" (Pan American Health Organization), which is the "Oficina Regional de la Organización Mundial de la Salud" (Regional Office of the World Health Organization). Below the welcome message is a globe icon and a paragraph stating: "Es muy frecuente que los datos de una investigación válida se desvirtúen por la baja calidad de los informes." To the right of the globe is another paragraph: "EQUATOR Network es una iniciativa internacional cuyo objetivo es mejorar la confiabilidad y el valor de la bibliografía de investigación médica por medio de la promoción". On the far right, there is a box indicating that the page is a Spanish translation of the English site, with the URL www.equator-network.org. Below this is a "Directrices" (Guidelines) section with a book icon and the text "Biblioteca, presentación informes sanitarios".

Impact

- A systematic search of studies assessing the implementation of reporting guidelines in journals and trial registration in LAC was conducted (Pubmed, Cochrane, Lilacs)
- A number of studies conducted by PAHO were included

Journals context

Objective *: To determine to what extent LAC biomedical journals have endorse and implement clinical trial registration and reporting guidelines

Methods:

- We identified randomized controlled trials published in 2011 from journals indexed in LILACS;
- From the online author instructions we extracted information regarding endorsement of trial registration and of a number of major reporting guidelines (CONSORT, PRISMA, STROBE, STARD) and the EQUATOR Network.
- We check for compliance (Trial registration in the ICTRP and mention of using CONSORT) in published RCT of those journals

*Revez L. Endorsement of the clinical trial registration initiative and reporting guidelines by biomedical journals. Unpublished data.

Journals context

Results

- 477 controlled trials were identified by the search. A random sample of 240 were assessed and finally 101 RCT published in 56 journals (10 countries) were included
- 68% of journals mentioned the International Committee of Medical Journal Editors (ICMJE) and most provided a link
- Prospective trial registration was explicitly required by 20/56 journals (36%)
- Advice about reporting guidelines was less often provided CONSORT (7 journals; 13%), PRISMA (1 journal; 1.8%), STROBE (1 journal; 1.8%). The EQUATOR network was acknowledged by 2 journals (3.6%).

Journals context

Results

- Trial registration was reported in the abstract of 9 RCT (9%) and in 20% of manuscripts. Overall, prospective registration was done in 7 RCT (7%).
- 11/56 journals (20%) had at least one RCT reporting trial registration
- Only one journal (having more than 2 RCT) had all RCT registered
- CONSORT was mentioned in 3 RCT (3%)
- Many journals did not use electronic solutions for submission and peer review → difficult to standardized processes

Researchers context

Few studies were found; no study used CONSORT items:

- Six dental Brazilian journal: assessment focused on the Cochrane risk of bias domains; 8/43 were judged as having adequate sequence generation and allocation concealment
- Biomedical Chilean journals: assessment of methodological quality of the design and report of randomized clinical trials; used Jadad scale.

1. de Souza et al. A quantitative and qualitative evaluation of reports of clinical trials published in six Brazilian dental journals indexed in the Scientific Electronic Library Online (SciELO) (2010)

2. Manríquez M et al. Critical assessment of randomized controlled trials published in biomedical Chilean journals (2005)

Researchers context

*Objective**: To determine the prevalence of trial registration in randomized controlled trials (RCTs) from LAC researchers and assess methodological characteristics

Methods:

- We identified and assessed randomized controlled trials published in 2010 from LAC authors in PUBMED/LILACS;
- Data were independently extracted by two authors
- We also check in the International Clinical Trials Registry platform (ICTRP)

Revez L et al. Trial registration in Latin America and the Caribbean's: study of randomized trials published in 2010

Revez L et al. Characteristics of randomized trials published in Latin America and the Caribbean according to funding source

Researchers context

Results

Trial registration

- 526 RCTs from 19 countries were finally included (70% Brazil).
- 17% (89/526) of RCTs were registered in the ICTRP
- Only 4.0% were prospectively registered.
- 16% RCT were published in LAC journals; only 15% of them were registered
- Overall, registered RCTs were multinational, had larger sample size and longer follow-up, and reported more frequently information on funding, conflict of interests, and ethic issues
- 21% of publicly funded RCTs were registered compared to 36% of non-publicly funded RCTs (private, NGOs).

Researchers context

Results

Other characteristics

- 11% were coauthored by foreigners (most frequently from the USA, Canada and European countries)
- 92% reported an informed consent process and 95% approval by an ethics review committee
- Rate of unclear judgment on sequence generation and allocation concealment was 2/3 of trials
- Source of funding was not reported in 37% of RCTs. Public funding (34%), private (e.g. pharmaceutical company) (14%), and other (e.g. mixed, NGO) (15%).

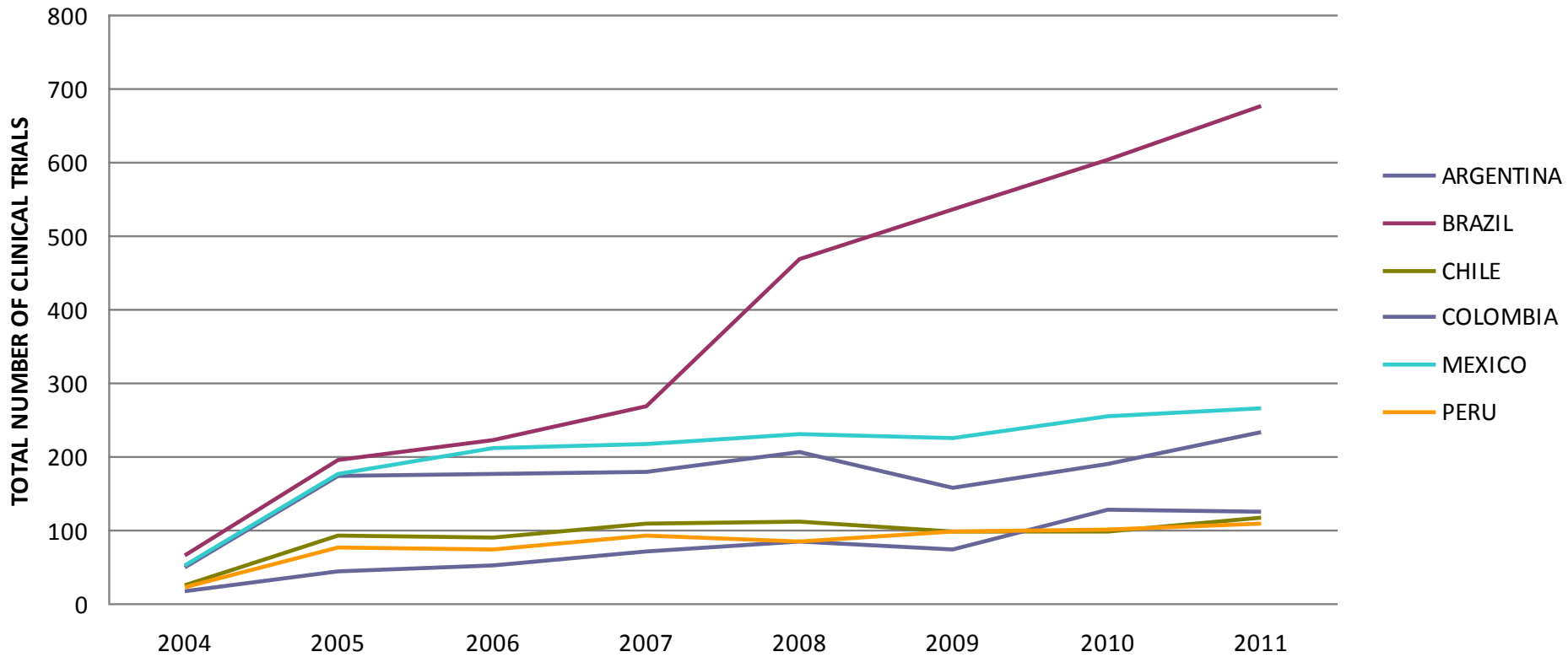
Researchers context

Results

Other characteristics

- RCTs covered the following specialty areas: dentistry (11%), gynecology-obstetrics (9%), anesthesia (6%), cardiology (6%), and infectious diseases (6%).
- The most frequent intervention types involved drugs (48.3%), followed by procedures (23.2%), behavior modification, education, counseling (10.1%), vaccines (3.1%), and devices (2.8%).
- Statistically significant differences between RCTs and funding source (public vs. private and others) were detected in the study setting, trial registration, and conflict of interest reporting

TOTAL NUMBER OF REGISTERED CLINICAL TRIALS IN LATIN AMERICA FROM 2004-2011



Ethic committees context

- PAHO mapped over 1200 ethic research committees in LAC
- Most committees do not use electronic software to perform evaluation processes (Brazil :)



Interpretation

- Challenges to implement policies at different levels
- Few studies that monitor or evaluate progress
- Progresses on overall and prospective trial registration from 2010 to 2011 were found
- Low endorsement of reporting guidelines in LAC journals as compared to other studies worldwide
- Room for improvement on research reporting quality
- Difference between journals and within RCT in the same journal

2. Potential solutions for improvement of health research literature

Challenges to improve health research literature report

Memorandum of understanding between EQUATOR Network Steering Group and PAHO:

- Collaborate in efforts to strengthen capacities in Member States and technical cooperation for Improving Research Reporting in Latin America and the Caribbean



Partnership: EQUATOR Network



The EQUATOR Network is an international initiative that seeks to enhance reliability and value of medical research literature by promoting transparent and accurate reporting of research studies. A leader in defining standards for health research reporting, they provide PAHO with an opportunity to help raise the level of publications and reports for research from the Americas and to promote adherence to international reporting standards in line with PAHO's policy.

EQUATOR's collaboration with PAHO will result in organized dialogues and workshops on best practices in reporting research which will be translated to better suit the audiences of the Americas. The collaboration will support and contribute towards institutional strengthening within PAHO Member States for better system-wide knowledge of reporting standards within national health research systems. Also, working jointly with PAHO's Knowledge Management and Communication unit, it will expand the dissemination of reporting guidelines and facilitate translation of key documents to PAHO official languages.

- [Press Release](#)
- [EQUATOR Network Website](#)
- [Equator Network in Spanish](#)

Last Updated on Wednesday, 07 March 2012 09:21

Challenges to improve health research literature report

Journals

- Identify and contact journal Editors and ethic review committees from LAC to promote the endorsement and implementation of clinical trial registration and reporting guidelines
- Contacting providers of web-based solutions for submission and peer review to promote clinical trial registration and reporting guidelines
- Training in research reporting for Editors, researchers, medical journalist etc

Ethic review committees

- Development of a free, standardized, open source software to manage approval processes by ethic review committees (four languages)
- Dissemination of reporting guidelines

Challenges to improve health research literature report

Researchers

- Dissemination of reporting guidelines
- Promoting research on health research reporting
- Monitoring the implementation

EQUATOR & reporting guidelines

- Creating regional 'EQUATOR' nodes supporting EQUATOR Network activities in Spanish, Portuguese and French
- Glossary of terms in Spanish and Portuguese (consensus) (Differences in terms for translation according to LAC country)
- Publishing new research reporting guidelines at the same time than the version in English

National level

- Developing WHO Primary registries in LAC countries
- Incorporating trial registration and research reporting in national policies, strategic plans and agendas

Thanks