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

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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.
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
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
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

*Reveiz 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.

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)
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.
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

* Hopewell S. Endorsement of the CONSORT Statement by high impact factor medical journals: a survey of journal editors or 'Instructions to Authors’
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
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