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40th ADVISORY COMMITTEE ON HEALTH RESEARCH (ACHR)

Montego Bay, Jamaica. - 29 April to 1 May 2007

Report to the Director

Pan American Health Organization
2007

CONTENTS_

Report to the Director on the 40th Meeting of the Advisory Committee on Health Research (ACHR), held from 29 April to 1 May 2007 in Montego Bay, Jamaica

1. Introduction

The Secretariat of the Advisory Committee on Health Research (ACHR) convened the 40th Meeting of the Committee at the request of the Director of the Pan American Health Organization (PAHO/WHO), Dr. Mirta Roses Periago, in order to examine the Organization's technical cooperation geared to promoting research as well as the projects of the Research Promotion and Development Unit (HSS/RC), and to define the work agenda of the ACHR and the way in which it will support the Organization.

It was agreed at the 2005 meeting of the ACHR that the Committee would be a permanent, dynamic forum that would encourage and generate debate about health research issues relevant to the decisions that the Director of PAHO must make. It was decided that that the Committee would meet periodically, remaining active between meetings and, when necessary, creating advisory groups to address specific issues.

The objectives of the 40th Meeting of the PAHO/WHO Advisory Committee on Health Research were to:

a) Promote and guarantee interaction and the exchange of information and knowledge among ACHR members in order to promote the dynamic of a permanent forum

b) Update the ACHR's information on the progress and implementation of technical cooperation projects and activities in health research within PAHO

c) Define the ACHR work agenda

This report summarizes the agenda,[1] presentations, and comments made during the 40th Meeting of the PAHO/WHO Advisory Committee on Health Research and the recommendations made in its final session.

2. Opening Session

2.1 *Opening Session*

2.1.1 Remarks of the PAHO/WHO Representative in Jamaica, Dr. Ernest Pate

[1] ACHR-40/2007.01. *Agenda. 40 Meeting of the Advisory Committee on Health Research (ACHR).* Montego Bay, Jamaica. 29 April to the 1st of May 2007. http://www.paho.org/English/DD/IKM/RC/ACHR-2007-40-01-AGENDA-English-Final.pdf

Dr. Ernest Pate, PAHO/WHO Representative in Jamaica, welcomed the participants to the meeting, thanked them for having elected Jamaica as the site of the meeting, and expressed his hope that their efforts would be very productive.

2.1.2 Remarks of the Director of the Pan American Health Organization (PAHO/WHO), Dr. Mirta Roses Periago

Dr. Mirta Roses Periago, Director of PAHO/WHO, opened with a brief outline of the Committee's history. She then summarized the main challenges to health and health systems in the Region, noting that three key events were currently under way:

a) The development of a Health Agenda for the Americas, which, if approved by the countries, will guide the technical cooperation of PAHO in the coming years;

b) The Pan American Sanitary Conference's adoption of a 5-year strategic plan; and

c) The commitment to attaining the Millennium Development Goals by 2015, stressing in this last point that there are poor people in our Region, not poor countries, emphasizing the burden that the lock of equity creates.

Dr. Roses identified a series of PAHO strengths and stated that this Organization can contribute to the development of health research systems by:

a) acting as an honest broker, facilitating cooperation and consensus between researchers and research users

b) promoting good practices among research institutions, decision-makers, international agencies, and other organizations; and

c) disseminating information on the work of WHO and public policies on research in the Region of the Americas.

2.1.3 Remarks of the Minister of Health of Jamaica, the Hon. Horace Dalley

The Hon. Horace Dalley, Minister of Health of Jamaica, presented an overview of health and health system challenges in Jamaica, noting moreover that PAHO has provided significant support to Jamaica, including assistance with:

- the vital statistics system;
- the community health program, which/that was expanded to the entire country;
- a study on deaths from traffic accidents, completed and widely used; and
- the country's malaria outbreak

The Minister of Health identified the need for relevant research in areas such as reemerging diseases. He also mentioned the importance of making official use of research findings and sources of scientific evidence.

2.1.4 Remarks of the outgoing Chairman of the ACHR, Dr. Víctor Penchaszadeh

Dr. Víctor Penchaszadeh, outgoing Chairman of the ACHR, reflected on the progress made in recent years with the revitalization of the ACHR.

Dr. Penchaszadeh noted the need to direct the Committee's focus to research on health determinants and systems rather than biomedical research and stressed the importance of having members from different disciplines. He discussed the growing privatization of health research financing in the Region and how the Organization can deal with this new phenomenon.

2.1.5 Dr. Roses' thanks to Dr. Penchaszadeh and introduction of the Committee's new Chairman, Dr. John Lavis

Dr. Roses thanked Dr. Penchaszadeh for his contributions and described his new role in PAHO's Representative Office in Argentina as Adviser on Research and Genetics. She then introduced Dr. John Lavis as the new Chairman of the PAHO/WHO ACHR.

Dr. Lavis thanked the Director for his appointment and commented on the Committee's mandate to promote research, identifying three transitions in its history:

a) The transition from being focused primarily on biomedical and secondarily on clinical research to being focused on the full range of biomedical, clinical, health policy and systems, and public health research;

b) The transition from being primarily focused on supporting investigator-driven research to being focused on investigator-driven and priority-driven research; and

c) The transition from being focused on research focus to being focused on both research and research use.

He expressed his hope of seeing a transition from a Committee of researchers to a Committee and invited guests drawn from both the research community and the research-user community. He suggested that the Committee function as a working collaboration among colleagues, with enough structure to ensure that the work gets done efficiently and enough flexibility to ensure that the Committee can identify new issues and find time to address them effectively. He also suggested that the Committee plan to continue its work between meetings by telephone and internet.

2.1.6 Presentation of the Agenda by Dr. Luis Gabriel Cuervo, Secretary of the ACHR and Manager of PAHO/WHO's Research Promotion and Development Unit

Dr. Luis Gabriel Cuervo, Manager of the Research Promotion and Development Unit (HSS/RC) of PAHO/WHO, which acts as the Committee's Secretariat, provided an overview of the meeting's objectives and Agenda (mentioned earlier), described the Committee, reviewed the recommendations of the 39th Meeting of the ACHR in Chile in 2005 and Committee activities since then, and introduced the Secretariat and its members, describing the ACHR's mission and vision.

2.1.7 Introduction of the Committee's Members and Guests and Opening of the Work Session

Dr. Lavis asked the Committee's Members and guests to introduce themselves.[2] Following the introductions, the Chairman noted that the guests are drawn from organizations and networks that can contribute to the promotion and use of research in the Region. He noted the remarkable array of skills and experience represented on the Committee.

2.2 *Presentations*

2.2.1 Technical Cooperation of the Research Promotion and Development Unit, by Dr. Luis Gabriel Cuervo

Dr. Cuervo's presentation addressed four main topics:

- The reorganization and evolution of HSS/RC and the technical cooperation in research
- Alignment with WHO research policy
- The search for efficient, harmonized work with research networks and initiatives
- The vision of a point in time rich in opportunities and options, which should lead to a decision on what paths to take

In his presentation, he discussed:

a) The immediate background: Essential Public Health Functions, the Ministerial Summit on Health Research in Mexico, the document on WHO's Role and Responsibilities in Health Research, and the reorganization of the Unit to respond to new challenges;

b) The role of research in PAHO: where research is conducted in PAHO; the role of the Areas, Units, Centers, and Representative Offices; the Research Grants Program; and PAHO's research inventory; and

c) HSS/RC's lines of work: research policy development; the strengthening of country capacities; and research management at PAHO.

As PAHO's research policy would be taken up on the second day of the meeting, Dr. Cuervo emphasized the issues of PAHO's research inventory[3] and the Research Grants Program,[4] which would be presented for consideration by the Committee the same day.

Finally, he concluded with a series of questions about the proposed lines of work, which would be answered by the members of the Committee during the course of the meeting.

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[2] *ACHR-40/2007.02 Ready of participants. 40 Meeting of the `Advisory Committee on Health Research` (ACHR). Montego Bay, Jamaica 29 April to 1ro of May 2007.* *http://www.paho.org/English/DD/IKM/RC/ACHR-40-02-Participants-AVM-1.pdf*

[3] *Registry of research of PAHO. Document framework. Summary. Executive.* jul. 2006. Report prepared by Dr. Ludovic Reveiz (version in Spanish only)

[4] *40/2007.08 Analysis RIS2000*. Area of Strengthening of Health Systems. Unit of Promotion and Development of Research. http://www.paho.org/English/DD/IKM/RC/ACHR-40-2007-08-RIS2000.pdf

The discussions that took place in the morning and part of the afternoon centered on issues related to the PAHO research registry, including questions on the Organization's publication and registration policy and on the desirability of restoring the Research Grants Program. The background documents for this discussion had been distributed earlier and are found in Annexes III and IV.

PAHO Research Inventory

The Committee members recognized that research inventories and registries can have many objectives, including that among others of informing the work of international agencies such as PAHO, strengthening clinical research, and identifying gaps in both capacity and research. Committee members also noted research inventories and registries can be very time-consuming to develop and maintain. The Committee agreed to establish a PAHO research inventory that would identify and describe the research carried out with PAHO participation in the Organization's various administrative divisions. The inventory will contain data about research proposals (including at a minimum the title, objectives, methods, researchers, and funders) and can be expanded to include data on publications stemming from the results, thus permitting greater visibility and dissemination of the research. The inventory will be useful for scientific, administrative, and management purposes and should be accessible to all stakeholders in the Region. Its objective should be to support PAHO governance, so that it can better invest in its cooperation responses.

Regional Participation in the International Clinical Trials Registry

The Committee discussed the initiative launched in response to the Ministerial Summit of Mexico and the resolutions of the World Health Assembly, which called for the creation of a platform with a single point of access to serve as a link between clinical trial registries. The Committee agreed about the importance of establishing clear objectives for any inventory or registry proposed (whether initiated by PAHO, a Member State, or both) and of starting with what is already under way and building from there. There was interest in Committee Secretariat's proposal to establish a regional portal and primary research registry, building on the experiences of entities such as BIREME in developing regional databases. There was also interest in the idea of developing a common platform to facilitate the creation of national registries--one that would guarantee compatibility and efficient data-sharing with the regional platform and reduce duplication of efforts in the countries.

The Committee members agreed about the importance of the Region participating in the International Clinical Trials Registry that is being developed and coordinated by the WHO Secretariat through coordinated regional activities.

The registry will contain data on clinical trial protocols and an identifier that will facilitate links between publications and other products related to each protocol. Although participation in the clinical trials registry will be voluntary, strategies are being put in place to make participation a condition for the publication, ethical approval, and funding of the protocols. Several publishers, including a regional one, have begun to make the registry of protocols a prerequisite for

publication. It was mentioned that some countries, such as Argentina, have begun developing clinical trials registries for national research, which could be linked with the international registry. A proposal from the Latin American Clinical Trials Registry (LATINREC) for Latin America is under consideration.

Concerning BIREME's involvement, it was noted that the LILACS database provides information about the institutions connected with the research.

The Committee members and the guests also recognized that any inventory or registry must contain appropriate information on sampling techniques.

They also noted that PAHO and other organizations could use the registry and inventory for periodic tracking of the research proposals, including those that do not end in a publication.

Research Grants Program

The members of the Committee offered a series of comments and suggestions for reestablishing the Research Grants Program:

a) The program could be valuable even if the grants remained small, because they provide a leveraging opportunity, even with other funders.

b) Some preparatory work needs to be cone on the PAHO research policy, from which the program objectives would follow. An effort should be made to identify what went wrong with unsuccessful proposals in the past to avoid repeating the same errors that led to high-capacity countries benefiting disproportionately from the program. Documentation should be obtained on the countries' priorities and their financial and human resource capacity to fund research that addresses these priorities and the gaps that only PAHO can address.

c) The objectives of the program must be cleared. The following suggestions were made:

- Develop national research capacity to address health system priorities in countries that currently exhibit the greatest weaknesses;

- Support the goal of funding research that addresses the countries' health system priorities;

- Emphasize the importance of a broad definition of health research that covers many domains that have health consequences

d) There is some interest in the idea of funding teams that bring together higher- and lower-capacity countries, provided that the process becomes simpler than that of many existing team grant competitions.

2.2.2 The Evidence-informed Policy Networks Program (EVIPNet) in the Americas, by Mrs. Sonya Corkum

Mrs. Sonya Corkum presented an overview of the Research Promotion and Development Unit's efforts to promote research use in the Region through Evidence-informed Policy Networks. Her presentation included the program's objectives and development status in the different regions of the world and the steps necessary for its implementation in the Region of the Americas. The document on which the presentation was based was distributed earlier and is found in Annex V.[5]

The members of the Committee suggested five elements needed in each country to promote research use:

a) The existence of an enduring climate that supports research use;

- Researchers who want to focus on linking research to action (and not just the publication of articles).
- People who promote research use in the areas in which health policies are established.

b) The production of different types of research that address priority health system issues in the countries; for example, systematic reviews and primary research on the impact of alternative strategies for attaining the Millennium Development Goals or qualitative research on the views and experiences of patients and key stakeholders.

c) The rapid dissemination of research on emerging topics on policymakers' agendas and on topics that research suggests should be on their agendas. Researchers should be trained and made aware of the needs and challenges confronting policymakers in order to help find solutions in areas such as:

- Presenting complex findings (e.g., relative risk);
- Integrating other types of information (e.g.,: financial implications); and
- Putting the findings in the context of local economic policy

d) Supporting and training for policymakers (and intermediaries) to acquire, assess, adapt, and apply research.

e) Developing partnerships between researchers and policymakers to ask and answer emerging policy questions, even when they are not urgent.

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[5] ACHR-40/2007.06 *EVIPNET:Evidence-Informed Policy Networks. Pan American Health Organization. In order to build bridges between research and the policies*. April 2007 http://www.paho.org/English/DD/IKM/RC/ACHR-40-2007-06-EVIPNe.pdf

The Committee members considered linking with the following initiatives: REACH-Policy, the IDRC/PAHO initiative, INDEPTH, and Equity Gauge to make it easier to obtain funding; it also considered working with existing networks that transcend regions (e.g.,: Mozambique could link with Brazil and Portugal).

During the discussions, the members of the Committee offered four recommendations concerning EVIPNet in the Americas:

a) PAHO should consider EVIPNet a tool for strengthening research and its use in health systems, which would require a commitment from the ministries of health.

b) PAHO needs a firm, ongoing commitment from the participating countries to help fund the initiative and guarantee its sustainability.

c) EVIPNet needs to engage the national science and technology councils, since they are the dominant providers of research evidence in many countries.

d) EVIPNet needs to build on regional strengths, such as BIREME.

The discussion also addressed other matters, such as setting up mechanisms for technical cooperation among countries, rethinking of the project in terms of subregional components, and the importance of submitting a transparent proposal that includes its potential and constraints.

Some constraints were noted, such as the language in which the majority of scientific publications are written and the need to include economic analysis for decision-making in health. Concerning the difficulties in accessing scientific information, BIREME's experience shows that the greatest problem at the present time is not access, which has improved thanks to the technology and agreements of recent decades, but the need to fine-tune the information.

Finally, it was pointed out that EVIPNet can be geared to health systems and that human resources should be strengthened throughout the cycle. Here, the emergence of observatories of human resources was mentioned, along with the idea of creating observatories of health research.

2.2.3 Health Research Policy in the Americas and the Proposal for Developing the Organization's Research Policy, by Dr. Delia Sánchez

Dr. Delia Sánchez presented:

a) The history of thought on research and the research policy of PAHO/WHO

b) The current international and regional context for developing a moved research policy aimed at strengthening the capacity of national health research systems

The proposal for developing PAHO's research policy should include components from the Organization's system and technical cooperation with the countries, as well as matrix containing a series of instruments with multiple functions. The majority of these instruments were discussed

by the Committee during this meeting. The document on which this presentation was based was distributed earlier and is found in Annex VI.[6]

Dr. Roses opened the discussion by describing the context for the development of a PAHO/WHO research policy. She noted that PAHO, as a specialized agency with a governing body comprised of member states, has normative and technical cooperation functions.

The normative function, including the development of a joint policy, can be exercised in three ways:

a) The values and principles that inspire or underpin the policy;

b) The global and regional context for the policy; and

c) What PAHO and its member states will do and with which partners. The policies inspire regional, subregional, and national plans of action, including plans for technical cooperation.

The Committee agreed that the background document, especially the last table, provided an excellent starting point for this work. In addition it agreed that a research policy needs a commitment to support research and its use at two levels: 1) what countries can do to support research at the national level; and 2) what PAHO can do to promote research and research use in the Region. Concerning the latter, the Committee agreed on the need for a study of PAHO's strengths and weaknesses and the opportunities and threats in the Region (i.e., a SWOT analysis), as proposed in the document, this study will be critical for addressing now PAHO's role as a regional intergovernmental agency helps or hinders its role as a promoter of research and research use and the resource implications of alternative positions. The Committee also agreed that it would be important to identify parts of the proposed policy that could be pilot-tested while the full policy is being developed.

a) The Committee members identified a number of domains where a deeper level of analysis is required—e.g., the role of the public sector in supporting research and where PAHO's comparative advantages in the field of research lie.

b) PAHO's comparative advantages in research (for example, capacity building, support for research, or both)

c) Research funding patterns in the Region (e.g., the role of countries like Spain or regions like the European Union, which are not considered in the document).

d) The stewardship of the Region's ministries of health in health research.

e) The importance of other types of non-biomedical research.

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[6] ACHRS-40/2007.05 *Overview of the situation of the policies of proposed research in the Americas and for the development of a policy in health research of the Organization http://www.paho.org/English/DD/IKM/RC/ACHR-2007-40-05-Policy.pdf*

f) The potential for technological developments that are not accessible to all the population as a factor to increase inequity.

The Committee members identified a number of specific issues that the research policy should address, inviting PAHO to consider:

a) The need to determine when it is best positioned to act as funder, commissioner, or producer of research or as an adviser about or facilitator of research (or both) in countries, recognizing that the former role has large resource implications. PAHO could undertake research in two ways: a) evaluating its own activities; and, b) collectively undertaking research that pertains directly to a group of countries.

b) The imperative that all research should be translatable to accessible technologies for all citizens, not just those who can afford the high prices typically associated with patented technologies. PAHO should also consider looking beyond access to technology and focus on technology, effectiveness and information (since much information is protected through intellectual property rights and trade agreements). Furthermore, PAHO should continue to assist policymakers in their relationships with health technology firms (e.g., the pharmaceutical industry) to protect the public interest, especially in emerging areas like molecular genetic technologies. Related to this, the Committee observed that PAHO might wish to promote or make use of research on the impact of regulations governing intellectual property, drugs, medical devices, and free trade on health research.

c) Implementation of strategies for strengthening national health research systems should be flexible and recognize the particular characteristics of each country. PAHO should provide countries with feedback on the bases of a good national health research system and on gaps in what has been done to date.

d) Research on the health workers' competencies in using of the results of scientific research.

e) Promotion of the development of structures and standards for ethical review and research practices that adhere to ethical guidelines.

Dr. Cuervo summarized PAHO's response through a regional consultation, when WHO requested contributions for its position paper *WHO's Role and Responsibilities in Health Research*.[7] The Unit will continue consulting with staff at WHO Headquarters to discover opportunities for synergy and determine where global efforts should be targeted for application in the Region.

The Committee underscored the importance of also consulting with international agencies, such as the Council for Health Research for Development (COHRED), the Global Forum for Health Research, and international networks such as the Campbell and Cochrane Collaborations, the International Clinical Epidemiology Network (INCLEN), and the International Network of

[7] WHO. CAIS 45/05.16 Rev. 1 *Position Paper on WHO's Role and Responsibilities in Health Research*.http://www.who.int/rpc/meetings/position_paper.pdf

Agencies for Health Technology Assessment (INAHTA). It emphasized that, when it is finished, the Health Agenda for the Americas could help inform the development of the research policy.

Finally, the Committee discussed a tentative timetable for developing the research policy, which could include two meetings of the Committee before the end of April 2008, when the research policy should be ready for broad discussion.

2.2.4 The Regional Health Research Data Initiative for the Region of the Americas (RHRDI), by Dr. Jaume Canela Soler

Dr. Canela briefly discussed the RHRDI initiative, whose purpose is to have basic information available on health sciences research in the Americas. His presentation covered the objectives, work methodology, and tentative timetable of activities. A document containing the details of the initiative was distributed earlier and can be found in Annex VIII.[8] Some members of the Committee raised questions about the inclusion of social indicators, compatibility with existing indicators, and coordination with BIREME.

2.2.5 Other Presentations

Dr. Ashok Patwari, Executive Director of INCLEN, and Dr. Sergio Muñoz, incoming Director of LatinCLEN, presented the global and regional activities of INCLEN and expressed their interest in supporting PAHO efforts to promote the use of research findings in the Region.

Dr. Zulma Ortiz, a member of the Committee, outlined the objectives and activities of the Cochrane Collaboration globally and in the Region, while Dr. Peter Tugwell, of the University of Ottawa, did the same for the Campbell Collaboration. While Cochrane has basically concentrated on issues connected with clinical decision-making, Campbell deals with public policy issues. Both presenters indicated their strong interest in supporting PAHO efforts to promote a summary of research on health priorities and challenges in the health systems.

The participants recognized the value of these collaborations and networks and underscored the importance of ensuring access to the information that they produce.

3. Health Research in Jamaica and the English-speaking Caribbean

The morning of the third day was devoted to presentations on health research in Jamaica and the English-speaking Caribbean.

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[8] *ACHR-40/2007.07 Regional Initiative of Health Research. IRDIS.* 40 Meeting of the `Advisory Committee on Health Research` (ACHR). Montego Bay, Jamaica. 29 April to the 1st one of May 2007 http://www.paho.org/English/DD/IKM/RC/ACHR-2007-40-07-IRDIS.pdf

Dr. Terrence Forrester, Director of the University of the West Indies Tropical Metabolism Unit, summarized the public health research situation in Jamaica, emphasizing the existing research on risk factors for cardiovascular disease and diabetes, which has led to the creation of prevention programs.

Prof. Archibald McDonald, Dean of the University of the West Indies School of Medicine, discussed biomedical research in Jamaica, with particular emphasis on the growing number of clinical trials conducted in the country.

Dr. Donald Simeon, Director of the Caribbean Health Research Council, described the health research situation in the Caribbean, its history, strengths, and weaknesses, as well as challenges.

The Committee thanked the speakers for identifying the challenges and opportunities for PAHO in its efforts to strengthen health information systems in the countries and in its support for research that addresses public health needs in the Region.

4. Presentation and Discussion of the Final Report

Dr. Lavis presented the summary and recommendations of the ACHR which had been discussed in depth, to the Committee. Some changes were introduced, and the two documents that served as the basis for this report were finally approved. The recommendations submitted below (item 6) are taken verbatim from the text approved by the Committee (English version).

This session also discussed the future work plan of the Committee, which indicated that it wished to work jointly to advise the Research Promotion and Development Unit on the preparatory work for the drafting of PAHO's research policy. Four members of the Committee expressed special interest in supporting this work: Drs. Izzy Gerstembluth, Moisés Goldbaum, Trudo Lemmens, and Rodrigo Salinas.

Other Committee members indicated their willingness to advise PAHO on particular initiatives: Dr. Zulma Ortiz, on the development of the research registries and inventories; Dr. Jorge Izquierdo, on the Research Grants Program; Dr. Fernando de la Hoz, on the development of health research indicators, and Dr. Ernesto Medina, on EVIPNet.

The Unit will contact the two Committee members who were unable to attend the meeting to determine their availability and desire to serve as advisers to some of these initiatives.

The Committee will provide this assistance by telephone and virtually. Also mentioned was the need for holding two Committee meetings with the participants physically present before April 2008, when the draft of the research policy should be ready for broader consultation.

5. Closing Session

The Chairman of the Committee thanked the attendees for their participation. He also thanked the members of the Secretariat, especially Dr. Luis Gabriel Cuervo, for his hard work on the preparations for the Meeting, and Drs. Mirta Roses and Pedro Brito for taking the time to attend all the sessions.

Dr. Mirta Roses noted that the work accomplished and the willingness to continue collaborating in the proposed tasks is a good indicator of the level of cooperation that will have to be achieved with other organizations and networks that promote research and research use. She confirmed her intention to promote a second meeting of the Committee in 2007 in order to maintain the excellent dynamic and momentum of the significant progress that has been made.

Dr. Campbell Forrester, Chief Medical Officer of Jamaica, thanked the participants and wished them a good journey home.

6. Recommendations of the Advisory Committee on Health Research to the Director of the Pan American Health Organization

a) Congratulate PAHO on its efforts to develop a research policy for the Organization and support the continuation of preparatory work on such a policy. The ACHR commits to supporting this work in order to ensure that a carefully considered draft of a research policy can be discussed by the Member States, interested parties in the countries, and international agencies as part of a broad consultative exercise that will take place in April 2008.

b) Provide through PAHO the leadership to promote regional initiatives that support the development and implementation of a PAHO research policy, including, for example, preparation of the regional meeting to discuss strengthening national health research systems. The meeting will be co-sponsored by the Council on Health for Development, the Ministry of Health of Brazil, and the Global Forum for Health Research, among others, and will take place in Rio de Janeiro, Brazil, in April 2008.

c) Support the continuation of preparatory work to establish a PAHO health research inventory that identifies and describes the research in which the Organization.

d) Continue work that enables the Member States to participate in the World Health

e) Organization's International Clinical Trials Registry Platform (ICTRP). This includes evaluating the development of tools and strategies that facilitate the adoption and use of registries in the Region.

f) The Committee supports the reestablishment of research grants, taking into consideration the following points:

- development of the PAHO research policy (from which the objectives will arise);
- documentation of the priorities of the countries, the existence of the financial and human resource capacity to conduct research that responds to these priorities, and the persistence of gaps that only PAHO could fill; ….
- an evaluation of the advantages and disadvantages of requiring a steering role of health ministries in countries where research will be carried out; and

- a study of the determinants of outcomes of grant applications.

g) The Committee supports the continuation of preparatory work to launch the Evidence-Informed Policy Network (EVIPNet) initiative in the Region as a promising mechanism to strengthen research and its use in health systems and health research. The Committee emphasizes the need for an ongoing commitment by the ministries of health of each country to provide the resources necessary to develop the EVIPNet as a component of health systems and health research, as well as the need to involve existing organizations, networks, and initiatives at the regional, subregional, and national levels.

Annex I

Pan American Health Organization
Regional Office of the World Health Organization

ACHR: 40/2007.01
Original: Spanish/English

40TH ADVISORY COMMITTEE ON HEALTH RESEARCH (ACHR)

MONTEGO BAY, JAMAICA. APRIL 29TH TO MAY1ST, 2007

AGENDA

Pan American Health Organization
2007

Created on 04/23/2007 6:01:00 PM

Organización Panamericana de la Salud

Oficina Regional de la Organización Mundial de la Salud

Dear Colleagues:

During the meeting of the Advisory Committee on Health Research (ACHR) we will hold an open discussion to critically analyze the Organization's technical cooperation for the promotion of health research, and the projects of the Research Promotion and Development Unit (RC). We will also define the ACHR's work agenda and how it will support the Organization's efforts.

We envision the ACHR as a lively permanent forum, promoting and generating debates addressing topics on health research relevant to PAHOs Director's decisions. It will meet periodically to evaluate and moderate its course, remaining active in between meetings, and generating, when deemed necessary, advisory groups on specific topics. As such, the forum would be facilitated and fed from the Organization by the Director and the Unit of Research Promotion and Development, and the generated debate will guide the Organization's response to the region's needs.

Objectives:

- Promote and ensure the interaction and exchange of information and knowledge between the members of the ACHR, to advance the dynamics within the permanent forum.
- Update the ACHR regarding the progress and development of projects and activities of technical cooperation in health research at PAHO.
- Define a work agenda for the ACHR.

Location:

Hotel Rose Hall Resort and County Club
Montego Bay, Jamaica
Telephone: 876-953-2650
Fax: 876-953-2617

Agenda

Sunday April 29th

08:00 a.m.- 08:30 a.m.	**Inaugural Session** Welcome and Opening Remarks by the PAHO/WHO Representative in Jamaica **Dr. Ernest Pate** Greetings by the Director of the Pan American Health Organization (PAHO) **Dr. Mirta Roses Periago** Brief Address and Declaration of Opening Meeting by the Minister of Health, Ministry of Health, Jamaica **Honorable Horace Dalley**
08:30 a.m.- 09:15 a.m.	**Induction** Address by the Retiring President of PAHO's Advisory Committee on Health Research (ACHR) **Dr. Víctor Penchaszadeh** Acknowledgment of exiting President, Dr. Víctor Penchaszadeh's contributions and announcement of ACHR's newly designated President **Dr. Mirta Roses Periago** Presentation of the Agenda by the Committee's Secretariat Unit Chief of Research Promotion and Development and ACHR's secretary **Dr. Luis Gabriel Cuervo**
09:15 a.m. - 10:00 a.m.	Presentation session and debate with the Committee's members and Meeting commencement **Designated President**
10:00 a.m. - 10:15 a.m.	*Coffee Break*

Agenda

10:15 a.m. – 11:15 p.m.	PAHO's technical cooperation in health research **Panel Coordinators**: ACHR's President	
Dr. Luis Gabriel Cuervo ACHR Secretary and Unit Chief of Research Promotion and Development PAHO		Overview of technical cooperation from the Unit of Research Promotion and Development [30 min.]
11:15 p.m. - 12: 30 p.m.	Debate and recommendations	
12:30 p.m. - 2:00 p.m.	*Lunch*	
2:00 p.m. – 05:30 p.m.	Continuation of the Panel on PAHO's technical cooperation in health research	
Ms. Sonya Corkum Advisor. Unit of Research Promotion and Development (HSS/RC), PAHO		EVIPNet in the Americas: Networks for evidence-based policies [30 min.]
2:30 p.m. – 3: 00 p.m.	Deliberations and recommendations	
3:00 p.m. – 3:15 p.m.	*Coffee Break*	
3:15 p.m. – 5: 00 p.m.	Continuation of the debate and recommendations	
5:00 p.m. – 5: 30 p.m.	Summary of the day's events by ACHR's President	

Monday April 30th

9:00 a.m. – 12:30 p.m.	Strategies to strengthen the Organization's processes, development and capacities in health research **Panel Coordinator**: ACHR's President.

Dra. Delia Sánchez Consultant. Unit of Research Promotion and Development (HSS/RC), PAHO	Overview of the research policy situation in the Americas and proposal for the development of the Organization's policy on health research [30 min.]

9:30 a.m. – 10:00 p.m.	Debate and recommendations
10:00 a.m. – 10:15 a.m.	*Coffee Break*
10:15 a.m. – 12: 15 p.m.	Continuation of the debate and recommendations
12:15 p.m. – 02:00 p.m.	*Lunch*
2:00 p.m. – 3:00 p.m.	Defining ACHR's work plan **Coordinator**: ACHR's President
3:00 p.m. – 3:15 p.m.	*Coffee Break*
3:15 p.m. – 5:00 p.m.	Continuation, definition of the work plan, its strategy and contents
5:00 p.m. – 5: 30 p.m.	Summary of the day's events by ACHR's President

Tuesday May 1st

9:00 p.m. – 10:30 p.m.	Panel: Research in Jamaica and the English-speaking Caribbean **Panel Coordinators**: Dr. Ernest Pate (PAHO/WHO Representative Jamaica), and ACHR's President

Dr. Terrence Forrester Director, Tropical Metabolism Research Unit, University of the West Indies	Public health research in Jamaica [15 min.]
Professor Archibald McDonald Dean, Faculty of Medical Sciences University of the West Indies	Biomedical Research in Jamaica [15 min.]
Dr. Donald Simeon Director Caribbean Health Research Council	Health research in the Caribbean [30 min.]

10:00 a.m. – 10:30 a.m.	Comments and debate
10:30 a.m. – 10:45 a.m.	*Coffee Break*
10:45 a.m. – 11:00 a.m.	Revision of the meeting's minutes and recommendations of the 40th meeting of the ACHR (ACHR's President and Secretary)
11:00 a.m. – 12:00 m.	Comments and recommendations for the final report
12.00 m. – 12.30 p.m.	**Closing Session** Address by the ACHR's President and its Secretariat **Dr. Mirta Roses Periago,** Director PAHO/WHO **Dr. Sheila Campbell Forrester,** Chief Medical Officer (Acting), Ministry of Health, Jamaica
12:30 p. m. – 2:00 p.m.	*Lunch*

Annex II

Pan American Health Organization
Regional Office of the World Health Organization

ACHR: 40/2007.02
Original: Spanish

40TH ADVISORY COMMITTEE ON HEALTH RESEARCH (ACHR)

MONTEGO BAY, JAMAICA. APRIL 29TH TO MAY1ST, 2007

List of Participants

Pan American Health Organization
2007

Created on 04/23/2007 11:27:00 AM

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Annex III

REGISTRO DE INVESTIGACIÓN DE LA OPS ORGANIZACIÓN PANAMERICANA DE LA SALUD. RIS-Millennium

Documento Marco

Elaborado por: Ludovic Reveiz

Versión Final

Bogotá, Julio de 2006.

TABLA DE CONTENIDO

RESUMEN EJECUTIVO

Introducción

Atendiendo la solicitud de la dirección de la Organización Panamericana de la Salud (OPS)**,** la Unidad de Promoción y Desarrollo de la Investigación se ha propuesto fortalecer el Comité de Revisión Ética de la OPS (PAHOERC) con el objetivo de contribuir a salvaguardar la dignidad, derechos, seguridad y bienestar de todos los y las participantes actuales y potenciales de la investigación en la que la OPS se encuentre involucrada, estableciendo los más altos estándares éticos y científicos a través de un proceso sistemático y documentado que permita producir investigación relevante y útil. De otra parte la Organización Mundial de la Salud ha propuesto el desarrollo de la Plataforma de Registro de Ensayos Clínicos que permita consultar los diferentes registros y el intercambio de información estandarizada (20 datos mínimos necesarios), así como la creación de un Número Universal de Referencia para Ensayos Clínicos que facilite referenciar los protocolos de los estudios cuando estos figuren en más de un registro. Adicionalmente, el Acta de Modernización de 1997 de la Food and Drug Administration de los Estados Unidos de Norteamérica (FDA) aseguró la creación de un registro de los ensayos clínicos por parte de los Institutos Nacionales de Salud (NIH), mandato gracias al cual fue creado el registro ClinicalTrials.gov. Todas las entidades que conducen experimentos clínicos de medicamentos que sean mercadeados en los Estados Unidos, deben divulgar información relativa al desarrollo del producto. Todas estas medidas buscan generar mecanismos de transparencia para la investigación científica y eliminar el sesgo de publicación y de resultados descrito ampliamente en la literatura científica.

Objetivo

El objetivo de la propuesta es el desarrollo de un Sistema de Registro de los protocolos de los estudios de investigación en los que esté involucrada la Organización Panamericana de la Salud y que sean evaluados por el Comité de Revisores de Ética de la OPS. Así mismo el mejoramiento de la gestión- decisión de los proyectos de investigación y de los sistemas de información que dependen del Comité de Revisión Ética de la OPS (PAHOERC), buscando la apropiada interrelación entre la Unidad de Promoción y Desarrollo de la Investigación y los diferentes actores comprometidos con la investigación.

Diseño Conceptual

El Registro de Investigación de la OPS se concibe como un mecanismo de cooperación entre los diferentes actores involucrados con el manejo de proyectos de investigación en los que se encuentra vinculada la OPS a través del PAHOERC. Su alcance trasciende sin embargo los procesos de este Comité, para permitir el acceso a información a los actores sociales, la comunidad científica y a aquellos que deben tomar las decisiones. Los participantes involucrados en el proceso de investigación de la OPS corresponden a los Investigadores e instituciones de investigación, las Unidades Técnicas, Representaciones y Centros en los países, los Centros Colaboradores PAHO/WHO los Centros Regionales y Subregionales, Institutos y Programas, la Unidad de Promoción y Desarrollo de la Investigación de la OPS, el Proceso de Revisión Ética así como el Área Legal y de Finanzas. La Unidad de Promoción y Desarrollo de la Investigación de la

OPS es responsable por el desarrollo, gerencia, difusión, coordinación y reporte del Registro de Estudios de la OPS.

La "unidad de intercambio" de información es el proyecto que ha sido enviado para evaluación al Comité y que en adelante tendrá un Número Único de Identificación de la OPS. De él dependerán en adelante varios procesos. El sistema busca hacer el seguimiento de cada proyecto de investigación enviado para revisión por parte del PAHOERC, registrando a través del tiempo, los procesos de aprobación por parte del Comité de Ética, de generación de la información con respecto al costo financiado, al estatus en que se encuentra y a su posterior finalización y reporte. Así mismo permitirá la búsqueda de parte de la información recolectada por la comunidad, y garantizará el acceso a toda la información y a la Memoria Institucional de las decisiones del PAHOERC a la OPS.

Diseño Operativo

La aplicación Web de apoyo a la operación de registro de estudios una vez desarrollada debe instalarse en un servidor de aplicaciones. Para hacer uso de la aplicación Web los usuarios externos tendrán que tener un computador con conexión a Internet y un navegador. Los usuarios internos con diferentes niveles de acceso permitido utilizarán la aplicación a través de la red local de la PAHO.

Dentro de las opciones propuestas se contempla la adaptación de software existentes, el desarrollo de una nueva aplicación y el uso de programas disponibles en la Organización como son Sharepoint y Workflow. La solución Web puede desarrollarse utilizando alguna de las dos mayores tecnologías para el desarrollo de páginas activas con manejo de datos provenientes de una administrador de base de datos. Esto es en la plataforma de desarrollo .net de Microsoft o en la de J2EE de Sun. Cada uno de los usuarios tendrá un nivel de acceso que garantice la seguridad y confidencialidad de la información. Los usuarios que utilizan la aplicación son El administrador local (contraparte de investigador en PAHO), el Administrador Central (la Unidad de Promoción y Desarrollo de la Investigación), los investigadores, el comité de revisión ética y el público en general.

Resultados esperados

El registro de todos los protocolos de los proyectos en los que está involucrada la OPS así como de sus resultados permitirá el acceso a información no sesgada, facilitará una asignación equitativa y ordenada de los recursos, incrementará la confianza de la comunidad en la comunidad científica, será una herramienta para reducir la duplicación de esfuerzos y estudios, evidenciará la necesidad de investigación de enfermedad olvidadas, identificará investigaciones que midan desenlaces irrelevantes e incrementará la ética y transparencia en la investigación. Particularmente permitirá la generación de reportes para la Directora, las Unidades, Representaciones y Centros que caractericen la investigación realizada en cada país, el costo de la inversión. Así mismo se convierte en una herramienta para fortalecer la evaluación de los proyectos por parte del PAHOERC.

1. CONTEXTO

1.1 Definiciones

"*Investigación*" se refiere a un tipo de actividad diseñada para desarrollar o contribuir al conocimiento generalizable. El conocimiento generalizable consiste en teorías, principios o relaciones, o acumulación de la información sobre la que se basan, que puede ser corroborado por métodos científicos aceptados de observación e inferencia. En el presente contexto, "investigación" incluye los estudios biomédicos y de comportamiento relativos a la salud humana, incluyendo aquellos relacionados con la Salud Pública. Por lo general, el término "investigación" es acompañado por el adjetivo "biomédica" para indicar su relación con la salud (1).

´*Proyecto*´ en el contexto de este documento incluye todo tipo iniciativa de Cooperación Técnica, de investigación en salud que signifique una transferencia de fondos y/o recursos humanos o de otro tipo de la Organización Panamericana de la Salud, para ayudar, complementar o suplementar las actividades de cooperación técnica contenidas en el Programa Presupuestario Bienal aprobado. Incluye igualmente los proyectos de Cooperación Técnica entre los países y que la OPS financia como son Grants (2).

'*Protocolo'* se refiere a un documento escrito antes del inicio del proyecto, que describa el marco teórico, la justificación, los objetivos de un proyecto de investigación y detalla el diseño, la metodología, el análisis estadístico y ético, los detalles administrativos y la organización del proyecto.

´*Enmienda al protocolo*´ es una descripción escrita de un cambio o aclaración formal a un protocolo.

'*Patrocinador'* se define como un individuo, compañía, organización o institución que toma la responsabilidad del inicio, gestión y/o financiamiento de un proyecto. Patrocinadores (Sponsors): son los principales responsables del (1) diseño de la investigación (2) desarrollo del protocolo de proyecto, folleto de la investigación y materiales relacionados para describir los procedimientos que serán llevados a cabo, los desenlaces del estudio, la recolección de los datos y otros requerimientos del estudio (3) asegurar que el protocolo cumpla con las leyes y regulaciones nacionales e internacionales. El Patrocinador no conduce la investigación a menos de que sea el mismo investigador.

´ *Participante en la investigación*´ se refiere a un individuo que participa en un proyecto de investigación biomédica ya sea como receptor directo de una intervención (ej.: producto del estudio o procedimiento invasivo), como un control, o a través de la observación. El individuo puede ser una persona sana que voluntariamente participa en la investigación; o una persona con una condición no relacionada a la investigación en proceso que voluntariamente participa; o una persona (generalmente un paciente) cuya condición es relevante para el uso del producto estudiado o para las preguntas que están siendo investigadas.

´*Fuente de ayuda monetaria o Material*´ se refiere a la fundación, agencia, compañía o institución que provee la fuente de apoyo monetario o material para el financiamiento del proyecto/estudio.

´*Investigador*´ se refiere a un científico calificado que asume la responsabilidad científica y ética ya sea en nombre propio o en el de una organización/patrocinador/compañía, de la integridad ética y científica de un proyecto de investigación en un sitio específico o grupo de sitios. En algunas instancias, un

coordinador o un investigador principal, puede ser nombrado como líder responsable de un equipo de co-investigadores.

'*Investigador Principal'* se define como la persona responsable de la conducción general de un estudio o proyecto.

'*Administrador Local'* para el Registro de Estudios de Investigación de la OPS se define como la persona responsable en la OPS del proyecto/estudio de investigación, contraparte del investigador. Frecuentemente corresponde a un técnico de una unidad, representación o Centro en los países.

'*Administrador Central'* para el Registro de Estudios de Investigación de la OPS se define como la persona responsable en la Unidad de Promoción y Desarrollo de la Investigación de realizar los procesos administrativos relacionados con los proyectos/estudios de investigación en los que está involucrado el Comité de Revisores de Ética de la OPS.

'Ensayo clínico' se refiere a un estudio de investigación prospectivo controlado o no, que evalúa los efectos de una o más intervenciones de salud en humanos. Por ejemplo, un ensayo clínico puede investigar intervenciones relacionadas con uno o más de los siguientes aspectos: prevención, promoción en salud, tamizaje, diagnóstico, tratamiento, rehabilitación o financiamiento y organización en salud.

'*Intervención'* se refiere a un acto deliberado que se practica en un individuo o grupo de individuos. Las intervenciones relacionadas con la salud incluyen (pero no se limitan) el uso de fármacos, productos biológicos, cirugía, procedimientos, radiaciones, dispositivos, educación, apoyo y consejería, cambio de hábitos y comportamientos, diversas modalidades de medicina complementaria, y políticas económicas.

'*Registro'* de un estudio/proyecto involucra la asignación de un número único de identificación así como el registro y libre acceso del público tanto al protocolo como a los resultados de un estudio/proyecto.

´Solicitante´. Investigador calificado que asume la responsabilidad científica y ética de un proyecto de investigación, ya sea en nombre propio o en el de una organización/patrocinador solicitando la aprobación del Comité de ética a través de una solicitud formal.

´Requisitos´. En el contexto de las decisiones, los requisitos son elementos obligatorios que expresan y contemplan consideraciones éticas cuya implementación es considerada como indispensable y obligatoria por parte de los comités de ética para poder llevar a cabo la investigación.

´Decisión´ la respuesta (positiva, negativa o condicional) de un Comité de Ética a una solicitud después de la revisión, en la cual se emite la posición de Comité de Ética del estudio propuesto (3).

1.2 Directrices de la OPS

En la declaración de México sobre investigaciones sanitaria se solicitó la intervención de "los gobiernos nacionales para que se comprometan a financiar las necesarias investigaciones de salud que permitan contar con sistemas de salud dinámicos y reducir la inequidad y la injusticia social". Se anotó que la Comisión de Investigaciones Sanitarias para el Desarrollo recomendó en 1990 que los países en desarrollo invirtieran al menos el 2% del presupuesto nacional de salud en investigaciones y en el fortalecimiento de la capacidad de investigación, y que al menos el 5% de la ayuda para

proyectos y programas del sector de la salud procedente de los organismos de ayuda para el desarrollo se destinara a investigaciones y al fortalecimiento de la capacidad de investigación. La OMS debería por tanto considerar la posibilidad de asignar una parte de sus presupuestos previstos para los países al apoyo de las investigaciones sobre sistemas de salud de alta calidad (4).

Durante el 39 Comité Asesor de Investigaciones en Salud (CAIS) la Directora de la OPS destacó algunos aspectos que deberían concentrar la atención del Comité como son la alta prioridad en la agenda internacional que tiene la Salud y su vinculación con la investigación, como un factor importante ligado a la riqueza de recursos humanos. Así mismo enfatizó en la necesidad de que la OPS establezca puentes entre investigadores y gerentes de la salud, incluyendo identificar mecanismos apropiados para "empaquetar" el conocimiento y la información. Por último subrayó la capacidad de convocatoria e integración de la OPS y el rol rector que deben cumplir los ministerios de salud en relación con la investigación. Adicionalmente el documento plantea "la necesidad de un sistema en la OPS que permita consultar información sobre la investigación en la que OPS participa e invierte recursos, ya sea con objetivos gerenciales y programación técnica, o como fuente de conocimiento científico que apoya la excelencia técnica del personal de la OPS."(5)

Entre las recomendaciones a la 59 Asamblea Mundial de la salud, la OMS planteó la necesidad de que Director General que ..."establezca procedimientos y mecanismos estandarizados para la realización de investigaciones y el uso de sus resultados por la Organización, incluidos el registro de las propuestas de investigación en una base de datos de acceso público, el examen de las propuestas por expertos y la divulgación de los resultados.." (6)

En el informe final "El impacto de las publicaciones de la OPS en la toma de decisión en salud: presentado en Febrero de 2005 por la Unidad de Diseminación y Mercadeo

Área de Publicaciones se reconocieron tensiones y obstáculos en la relación entre los resultados de la investigación en salud en la Región y su uso en la toma de decisión; estos fueron sintetizados en cinco núcleos principales (7):

a. Definición de prioridades: desacuerdos en la fijación de la agenda de investigación entre los decisores y el sector académico.
b. Manejo del tiempo, tanto en la publicación de resultados como en la disponibilidad para absorber la oferta de información existente.
c. Lenguaje y formatos de resultados
d. Multiplicidad de resultados sobre el mismo problema
e. Producto final de la investigación: hallazgo versus decisión

Dentro de las recomendaciones generadas por el reporte para fomentar un mejor uso de los resultados de la investigación en la toma de decisión, los autores plantean algunas acciones entre las que se destacan "la colaboración y la comunicación desde etapas tempranas en la planificación de proyectos y sus resultados parciales puede ser un factor de solución. La OPS puede promover la publicación de productos intermedios, que den cuenta de resultados incluso fragmentarios de investigaciones en marcha, utilizando para ello distintos mecanismos, pero especialmente las redes electrónicas."…" La OPS puede apoyar la publicación orientada hacia la síntesis integradora de resultados, a fin de solucionar la tensión identificada en cuanto a la multiplicidad de resultados sobre un mismo problema."

1.3 La Plataforma de Registro de Ensayos Clínicos de la Organización Mundial de la Salud

La Plataforma de Registro de Ensayos Clínicos de la Organización Mundial de la Salud ha propuesto el desarrollo de un portal único que permita consultar los diferentes registros que permitan el intercambio de información estandarizada (20 datos mínimos necesarios) y la creación de un número único de identificación que facilite referenciar los protocolos de los estudios cuando estos figuren en más de un registro (8).

Entre los principales objetivos de la Plataforma de Registro de la OMS está el promover la asignación equitativa de recursos y fortalecer el desarrollo de estudios relevantes que aborden enfermedades desatendidas y que tengan impacto favorable en la salud y evitar la duplicación de trabajo. En la declaración de México sobre investigaciones sanitarias se resaltó la necesidad de realizar investigaciones y utilizar los resultados completos de los estudios para la promoción de la salud y la prevención y control de las enfermedades en base a la mejor evidencia científica disponible. Para ello es indispensable que la evidencia de todos los estudios, incluyendo los protocolos y los resultados se encuentren públicamente disponibles (4).

La implementación de la Plataforma de Registro ha tomado un periodo de tiempo adicional al previsto. Por ello algunos de los aspectos que se irán desarrollando tendrán que ser adaptados por el Registro de Investigación de la OPS en su debido momento.

1.4 Comité de Ética para la Investigación de la OPS

Atendiendo la solicitud de la dirección de la OPS**,** la Unidad de Promoción y Desarrollo de la Investigación se ha propuesto fortalecer el Comité Ético Revisor de la OPS (CRE-OPS) con el objetivo de contribuir a salvaguardar la dignidad, derechos, seguridad y bienestar de todos los y las participantes actuales y potenciales de la investigación en la que la OPS se encuentre involucrada, estableciendo los más altos estándares éticos y científicos a través de un proceso sistemático y documentado que permita producir investigación relevante y útil. (9).

Diversas guías internacionales incluyendo la Declaración de Helsinki, la Guías Éticas internacionales para Investigación Biomédica que Involucra humanos, del CIOMS y de la Organización Mundial de la Salud y las guías para Buena Práctica Clínica, de la International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) han establecido y desarrollado los estándares éticos y científicos para llevar a cabo investigación biomédica en humanos (1,3,10,11).

El CRE-OPS tiene como funciones asegurar la calidad de los proyectos en los que la Organización se encuentra involucrada, asegurar la protección de las consideraciones éticas en la investigación en salud, coordinar actividades educativas en temas relevantes de la investigación ética, así como constituir, organizar y mantener la Memoria Institucional de las decisiones, actividades y documentos.

- Participantes en el proceso de revisión ético de los proyectos de investigación

Para asegurar la calidad del proceso de revisión de las propuestas de investigación la Unidad de Promoción y Desarrollo de la Investigación ha sugerido la participación de los siguientes participantes:

1 **Secretariado (Secretariat)**: compuesto por un asistente administrativo, un coordinador del comité y el Jefe de la Unidad de Promoción y Desarrollo de la Investigación.

2 **Equipo de Tamizaje (PAHOERC Screening Team):** conformado por el Presidente del Comité de Revisión Ética de la OPS (PAHOERC), el Jefe de la Unidad de Promoción y Desarrollo de la Investigación. Y un miembro designado por el PAHOERC

3 **Comité de Revisión Ética de la OPS (PAHOERC):** Los miembros serán en general empleados de la OPS designados por la Directora de la OPS.

4 **Consejo de Revisores (Review Board):** compuesto por un grupo multidisciplinario de aproximadamente 30 expertos que realicen una revisión ética y metodológica detallada de los proyectos o reportes de investigación.

5 **Listado de Revisores Pares (Peer Reviewers list):** conformado por personas con experiencia en diferentes áreas de investigación, metodología, ética, ciencias sociales, bioestadística y políticas o economía de la salud.

Proceso de Revisión Ética

Una explicación detallada del proceso de revisión de los proyectos de investigación se encuentra en el (anexo 1 Conformación Comité Revisor de Ética).

a Los proyectos son enviados a la Unidad de Promoción y Desarrollo de la Investigación para evaluación por diferentes fuentes que incluyen entre otras las unidades técnicas, las Representaciones o Centros en los países.

b Revisión por parte de un asistente administrativo de que la documentación se encuentre completa, de acuerdo a una lista de chequeo previamente establecida (anexo 2: Listados de chequeo). De tratarse de un ensayo clínico debe presentar el número único Internacional de registro de ensayos clínicos, de acuerdo a la iniciativa de la Plataforma de Registro de ensayos clínicos de la OMS. Las aplicaciones incompletas serán devueltas a los remitentes.

c Generación de un Número Único de Identificación de la OPS y confirmación de recepción de los documentos.

d Evaluación por parte del Equipo de Tamizaje (PAHOERC Screening Team) para evaluar si el proyecto amerita revisión ética. Los documentos relacionados con esta decisión deben hacer parte de la Memoria Institucional.

e De requerir evaluación Ética, el protocolo del proyecto será asignado por parte del Secretariado a uno de los Miembros del Comité de Revisión Ética quien a su vez requerirá la evaluación de un miembro del Consejo de Revisores y de un Revisor Par.

f El miembro del Comité de Revisión Ética recogerá los comentarios de los otros revisores así como los suyos propios y los presentará en un formato estandarizado al Comité Revisor Ético. El Comité Revisor Ético decidirá si el protocolo del proyecto es:

- Aprobado
- Rechazado
- Aprobado con cambios y requiere nueva revisión
- Requiere mayos análisis por parte de un experto.

La decisión es comunicada al remitente.

1.5 Guías de la OPS para investigadores

La Organización Panamericana de la Salud ha dispuesto unas guías con el objetivo de capacitar a los investigadores para cumplir con los estándares de la OPS al entregar las propuestas para proyectos de investigación, informes parciales, informes finales y

resúmenes, y recomendaciones para políticas, cumpliendo con las normas bioéticas internacionales. Antes de ser evaluado por Comité de Revisión Ética de la OPS (PAHOERC), cualquier proyecto que involucre sujetos humanos está sujeto a revisión tanto por un comité de ética en el país donde se lleva a cabo la investigación. (11).

1.6 El Sistema de Información actual

En 1999, se publicó los resultados de una encuesta realizada en los Centros y Representaciones de la OPS, así como diversas recomendaciones. Particularmente se estableció que varias divisiones, Centros y Representaciones no tenían mecanismos y criterios establecidos para la revisión de los proyectos en los que la OPS estaba involucrada. Así mismo se encontró que no existía claridad de que todo proyecto en el cual esté involucrada la OPS debía tener una Revisión Ética por parte del PAHOERC. Se recomendó la necesidad de establecer una directiva que definiera claramente los objetivos, criterios y responsabilidades de las diversas agencias de la OPS en relación a la cooperación técnica en investigación en salud. (12).

Se concluyó que los proyectos de investigación en los que estuviera involucrada la OPS a través de sus diversas entidades, debían cumplir con los siguientes requisitos:

- Relevancia en relación con las Orientaciones programáticas y estratégicas de la organización
- Contribución de importancia en relación a la promoción de la Salud y a la resolución de las prioridades de salud pública.
- Justificación científica.
- Requisitos éticos para la investigación que involucre sujetos humanos
- Garantizar que los resultados obtenidos de la investigación se encuentren en el dominio público.

Las entrevistas y encuestas (12) evidenciaron una pobre comunicación entre las diferentes partes involucradas en la investigación y se sugirió que el Sistema de Información de la investigación (RIS) podría ser un agente importante de integración y comunicación entre las entidades. A pesar de sus limitaciones, la implantación del RIS ha sido de cierta utilidad para evaluar la investigación en la OPS:

- El Sistema de Información de la Investigación (RIS), fue diseñado utilizando Microsoft Access, para ser diligenciado en la Unidad de Promoción y Desarrollo de la Investigación, por una asistente administrativa. Algunos reportes finales son exportados periódicamente a la página de la Biblioteca Virtual en Salud http://www.bireme.br/bvs/E/ehome.htm. El RIS produce reportes actualizados cada vez que la Unidad RC los genera. Se realizaba una exportación de datos desde el RIS-2000 al RIS-Online, que también presupone reportes según solicitud RC y han dependido de la calidad de los datos ingresados al sistema.
- El número de campos que contiene el RIS 2000 es aproximadamente 200, indagando por datos personales e institucionales, detalles del proyecto, costos, datos administrativos de la OPS, fuentes de financiamiento, estatus de proyecto, desembolsos, etc.
- Los proyectos multicéntricos son considerados estudios independientes. Han sido registrados según desembolso, institución que recibe el desembolso y responsable.
- Durante la revisión efectuada al RIS en el mes de mayo de 2006, se encontró datos incompletos acerca de los proyectos, e inconsistencia al compararlos con las carpetas de archivo. Para resolver este inconveniente, el jefe de la Unidad de

Promoción y Desarrollo de la Investigación está actualmente actualizando los datos de los proyectos evaluados y que se encuentran en el archivo.

- Basados en la revisión de la documentación existente acerca de los proyectos concluidos y en curso, se encontró por parte del autor, la carencia de soporte formal de evaluación ética de algunos de los proyectos revisados, que lo requerían.
- No existe actualmente un formato o documento que certifique que el proyecto requiere o no de revisión por parte del PAHOERC. Algunos proyectos a pesar de involucrar sujetos humanos y de requerir de evaluación por parte del PAHOERC, no tienen dicha evaluación de soporte disponible en las carpetas evaluadas.
- El sistema actual no permite comparar de manera sencilla los protocolos de los proyectos con el reporte final de los resultados.
- El RIS no permite guardar sistemáticamente la memoria institucional relativa a las decisiones y recomendaciones del Comité de Revisión Ética.
- El sistema es tiene diferentes niveles de acceso; en el RIS OnLine se puede recuperar información públicamente en Internet. No se desarrollo en su momento la cultura ni se tuvo la contribución de toda la OPS. Los usuarios externos pueden tener acceso a los reportes a través de de la Librería Virtual en Salud. Esta página es sin embargo difícil de encontrar a partir de la página principal de la Librería Virtual para quien no la conozca.

Las necesidades que llevaron en 1999 a la creación del RIS en cierta medida siguen latentes:

- Algunas Áreas, Centros y Representaciones no tienen mecanismos y criterios establecidos para la revisión ética de los proyectos de investigación en los que la OPS esta involucrada.
- No existe claridad de que todo proyecto de investigación en el cual esté involucrada la OPS debe tener una Revisión Ética por parte del PAHOERC
- No es clara o consistente la definición de lo que es un proyecto de investigación.
- Se requiere mejorar la comunicación entre los diversos actores involucrados en la investigación.
- Facilitar el proceso de Revisión Ética de los proyectos presentados al PAHOERC por medio del Registro de Estudios de la OPS.

2. JUSTIFICACIÓN

2.1 Ética

Diversos eventos recientes han puesto en evidencia el daño que genera el no reporte de los datos de la investigación y los posibles conflictos de interés que pueden modificar la investigación biomédica en diferentes maneras (13-15). Así mismo algunos estudios han encontrado importantes discrepancias entre los protocolos y la publicación de los resultados. La posibilidad de comparar el protocolo de los estudios con el reporte final de los resultados se constituye en una medida eficaz para evaluar la conducción y el reporte de los resultados de la investigación científica (16,17).

Por tanto, el registro de los protocolos de los estudios de investigación así como de los resultados de los mismos se constituye en una obligación ética que se contrae con los participantes, los patrocinadores y los financiadores de la investigación. Cuando las

diferentes partes involucradas en la investigación consienten en participar o involucrarse en los estudios, lo hacen basados en el supuesto de que están contribuyendo al conocimiento científico global. Por lo tanto, no es ético conducir una investigación sin garantizar que una descripción válida de los estudios y de sus resultados esté disponible libremente.

Los participantes potenciales en los estudios de investigación, los proveedores de salud, los investigadores, los comités de investigación institucionales, los comités éticos independientes, las agencias reguladores gubernamentales y los patrocinadores deben tener acceso a información válida y confiable acerca de los estudios de investigación. La disponibilidad de información no sesgada acerca de todos los estudios de investigación iniciados contribuye al acceso abierto al conocimiento, lo que constituye un bien público.

2.2 Científica

El acceso público a la información contenida en el protocolo del ensayo clínico (tal y como ha sido aprobado por el comité de investigación institucional y el comité ético independiente) y a los resultados del estudio tiene un impacto crucial para monitorizar la exactitud y validez de la investigación (18,19).

Los protocolos y resultados de la investigación deben estar disponibles a la comunidad y poder ser verificados por los organismos de inspección, vigilancia y control para eliminar el sesgo de publicación y el reporte selectivo de los resultados y para proveer de información completa acerca del beneficio y daño de las intervenciones en salud.

El sesgo de publicación se refiere al sesgo que se introduce por el reporte selectivo de las publicaciones en los resultados de la investigación (20). Por ejemplo, se ha reconocido que se publican más frecuentemente o en menor lapso de tiempo -por parte de las revistas- o que se envía para publicación los manuscritos -por parte de los autores- los estudios que tienen resultados con efectos estadísticamente significativos, que son más interesantes o pertenecen a instituciones o patrocinadores reconocidos, o que son de mayor calidad metodológica. Esta tendencia es particularmente relevante cuando los resultados parecen significativos, porque los estudios negativos o neutros no son nunca publicados, llevando a que el personal en salud tome decisiones basadas únicamente en parte de la evidencia disponible.

Particularmente se ha sugerido que el registro de los protocolos de los estudios de investigación puede incidir en los siguientes aspectos:

- Minimizar los riesgos conocidos y el daño potencial que surgen de exposiciones innecesarias a intervenciones que ya han sido probadas;
- Acelerar la investigación al tener acceso al conocimiento de estudios previos;
- Identificar y disuadir la realización de investigación y la publicación de resultados redundantes.
- Identificar y disuadir el reporte selectivo de la investigación (sesgo de reporte/publicación);
- Optimizar la utilización de los recursos al identificar estudios en curso, disuadiendo la realización de investigación redundante.
- promover la equidad en el acceso a la información y facilitar el control social
- Proveer un medio para comparar el protocolo original aprobado por el comité de ética con el estudio llevado a cabo;

- Fortalecer las entidades de investigación y los investigadores por la disposición pública y visibilidad de sus actividades investigativas. En el mismo sentido el registro contribuye a la creación o consolidación de redes de investigación temáticas.

Estos elementos generan una necesidad muy grande de desarrollo de capacidades en la evaluación de protocolos, la evaluación crítica de la literatura médica y la interpretación de resultados de la investigación clínica de los países.

2.3 Organizacional

La Plataforma de Registro de ensayos clínicos de la Organización Mundial de la Salud considera que el registro de todos los experimentos clínicos de intervención es una responsabilidad ética, moral y científica. El objetivo esencial es asegurar que todos los experimentos clínicos que se inicien sean identificados y declarados públicamente antes de iniciar el reclutamiento de los pacientes (8). La OPS tendrá a su cargo implementar estrategias que conlleven a fomentar el uso y adherencia al registro de los estudios en la región de las Américas; así mismo deberá "liderar con ejemplo, implementando procedimientos y mecanismo estandarizados para la monitorización de la investigación que adelanta y apoya, adoptando el registro sistemático de sus estudios clínicos y promoviendo la divulgación y control de los resultados de investigación" (21). La visión en investigación de la Organización Panamericana de la Salud (OPS) considera primordial el fortalecimiento de los servicios de salud, la reducción de las inequidades y la marginación de la población. Pare ello, es esencial que toda la información relativa a la investigación científica, evidencia sobre la que se basan frecuentemente las decisiones en políticas y acciones en salud, se publique, se encuentre disponible y se garantice la transparencia, monitorización y utilización del conocimiento.

El registro sistemático de los protocolos de los estudios de investigación en una base diseñada para ello y de las decisiones del PAHOERC se constituye en un elemento de protección y seguridad para la Organización y sus empleados garantizando los más altos estándares éticos y científicos.

3. DISEÑO CONCEPTUAL

3.1 Características generales

3.1.1 Los principios básicos

El Registro de Investigación de la OPS se concibe como un mecanismo de cooperación entre los diferentes actores involucrados con el manejo de proyectos en la región que permite facilitar el intercambio de experiencias exitosas o no de proyectos de investigación, ligados al PAHOERC. Su alcance trasciende sin embargo los procesos de este Comité, para permitir el acceso a información a los actores sociales, la comunidad científica y a aquellos que deben tomar las decisiones. Adicionalmente, el registro de los protocolos de los proyectos no aceptados por el PAHOERC permite generar una cultura abierta que genere autocrítica y una memoria personal e institucional.

El Registro se concibe sobre la base de los siguientes Principios:

- Herramienta para fortalecimiento del Comité de Revisores de Ética de la OPS
- Herramienta para caracterizar la Investigación en la que la OPS está involucrada.

- Incrementar la comunicación entre los diferentes actores involucrados en la investigación
- Transparencia en la Investigación
- Participación Activa
- Beneficios compartidos en la Cooperación
- Generación de Memoria Institucional
- Descentralización del acceso a la información.
- Acceso a Información completa y actualizada para la Región

3.1.2 Objetivos generales

El objetivo de la propuesta es el desarrollo de un sistema de registro de los protocolos de los estudios de investigación en los que esté involucrada la Organización Panamericana de la Salud y que sean evaluados por el Comité de Revisores de Ética de la OPS. Así mismo el mejoramiento de la gestión- decisión de los proyectos de investigación y de los sistemas de información que dependen del PAHOERC, buscando la apropiada interrelación entre la Unidad de Promoción y Desarrollo de la Investigación y los diferentes actores comprometidos con la investigación.

3.1.3 Propósito

La Organización Panamericana de la Salud contará con un sistema de registro que permita recoger toda la información acerca de los protocolos y resultados de los estudios de investigación en los que se encuentre involucrada y que funcione a través de Internet permitiendo el acceso de la comunidad científica, los decidores en salud, los pacientes y la propia Organización.

3.1.4 Objetivos específicos del sistema de Registro de Estudios de la OPS

1. Registrar la totalidad de los protocolos de los estudios de investigación en los que la OPS esté involucrada. La fuente de alimentación del registro provendrá de los enviados para revisión por parte de las unidades técnicas, Representaciones y Centros de la Organización entre otros.
2. Registrar las actas y documentos de aprobación generados por el proceso de Revisión del PAHOERC.
3. Crear una biblioteca que contenga la Memoria Institucional del PAHOERC.
4. Registrar los reportes finales de los estudios de investigación en los que la OPS esté involucrada, ligado al protocolo inicial de los estudios de investigación.
5. Generar un sistema de búsqueda de la información para los usuarios internos y externos.
6. Permitir el acceso libre al público en general a información acerca de los protocolos de los estudios llevados en los que participa la OPS.
7. Generar un sistema de Reportes que permitan monitorizar y consultar la investigación que se realiza dentro de la Organización.
8. Generar un sistema que permita caracterizar y evaluar los estudios llevados a cabo en cada país
9. Asegurar la confidencialidad de la información de acuerdo a los niveles de acceso permitidos.
10. Capacitar a los actores involucrados y divulgar la iniciativa a los investigadores, unidades técnicas, representaciones y Centros para garantizar la alimentación directa de los protocolos.

11. Articular el registro nacional a la iniciativa de la Organización Mundial de la Salud
12. Facilitar la asignación eficiente de los recursos.
13. Propiciar la transferencia fluida de tecnología, especialmente bajo mecanismos de cooperación horizontal.
14. Impulsar la evaluación expost como medio para aprender de la experiencia y mejorar los proyectos futuros.
15. Hacer más fluida la comunicación entre las diferentes áreas y unidades de la Organización.
16. Proteger y promover la integridad y transparencia de la Organización.

3.1.5 Tipo de Proyectos a incluir en el Registro

En sus actividades de investigación, la Organización Panamericana de la Salud (OPS) trata de asegurar que cualquier proyecto en que está involucrada cumple con las normas éticas internacionales. Todas las investigaciones que sean financiadas por la OPS o en las que ésta participe de alguna forma tienen que llenar ciertos criterios y haber sido revisadas por un comité de ética local antes de ser revisadas por el Comité de Revisión Ética de la OPS (PAHOERC).

Por tanto cualquier proyecto sometido a la OPS debe contener lo siguiente:

A. Una descripción detallada de los procedimientos que se van a seguir para proteger a los sujetos humanos que participen en el estudio.
B. Una copia del formulario de consentimiento informado que se va a usar con los sujetos humanos que participen en el estudio.
C. La certificación firmada por el Comité de Ética local / institucional / ad hoc.
En línea con los principios promovidos por la Plataforma de Registro de Ensayos Clínicos de la OMS, la Unidad de Promoción y Desarrollo de la Investigación ha expresado la necesidad de registrar toda la información concerniente al protocolo y los resultados de todos los estudios de investigación en los que la OPS esté involucrada.

Riesgos:

Una dificultad particular que subyace, identificada en las entrevistas, es la definición de lo que es un proyecto de investigación. En ocasiones no puede ser del todo clara para quien define si los proyectos deben ser evaluados por el Comité de Revisores de Ética de la OPS. Adicionalmente algunos entrevistados desconocían la existencia de este Comité, de sus funciones, objetivos y alcance. Prueba de ello es que un número importante de proyectos de investigación son enviados por el área de PROCUREMENT para definir si requieren ser evaluados por el PAHOERC y no directamente por los Centros, Representaciones o unidades técnicas de la OPS. Este hecho es particularmente inquietante teniendo en cuenta que los encargados del área de PROCUREMENT no son especialistas en temas de investigación pero que detectan frecuentemente protocolos sin evaluación ética por parte de la Organización.

Por otra parte, parece evidente que un número importante de proyectos cuyo costo es menor de 15.000 dólares (el monto es mayor para Brasil) no es enviado a revisión por el PAHOERC, por parte de las diferentes fuentes.

Los estudios multicéntricos, es decir, aquellos realizados en varias instituciones o países tienen implícita una complejidad mayor, desde la perspectiva de la evaluación por parte del PAHOERC. Un único estudio o proyecto puede tener modificaciones particulares

realizadas por cada país o patrocinador, que puede derivar en varios protocolos para un solo proyecto.

Para asegurar el reporte completo de toda la investigación en la que OPS está involucrada es necesario generar mecanismos que garanticen que todos los proyectos de investigación sean evaluados por el PAHOERC.

Recomendación

- Reforzar y difundir los objetivos, roles, actividades, normal y alcance del Comité de Revisores de Ética a nivel Regional y Local, en la Unidades Técnicas, Representaciones y Centros.
- Coordinar actividades educativas dirigidas tanto a los miembros del PAHOERC como a aquellos empleados directamente involucrados con los procesos de investigación con el objetivo de fortalecer el conocimiento, la enseñanza y la discusión alrededor de las diferentes metodologías para la investigación y la evaluación ética.
- Monitorizar que se cumpla con el registro de los protocolos de los estudios científicos en el sistema para ser evaluados por el PAHOERC.

Aquellos estudios multicéntricos o multinacionales deberán ser incluidos sin excepción. De tener asignado un Número Universal de Referencia para Ensayos Clínicos por parte de la Organización Mundial de la Salud, este deberá ser comunicado al momento del registro.

3.1.6 Alcance del Registro

A) Participantes involucrados en el proceso de investigación de la OPS

- Los Investigadores e instituciones de investigación.
- Las Unidades Técnicas, Representaciones y Centros en los países (Ver Anexo 3: Organigrama Áreas y Unidades)
- Los Centros Colaboradores PAHO/WHO (Ver Anexo 4: Centros Colaboradores)
- Los Centros Regionales y Subregionales, Institutos y Programas (Ver Anexo 5: Centros regionales y Subregionales)
- La Unidad de Promoción y Desarrollo de la Investigación de la OPS
- Proceso de Revisión Ética integrado por el Comité de Revisores Ético (PAHOERC), el Secretariado, el Equipo de Tamizaje (PAHOERC Screening Team), el Consejo de Revisores (Review Board), los Revisores Pares (Peer Reviewers) y una secretaria administrativa.
- Procesos administrativos internos que incluyen al Área Legal y de Finanzas.

Recomendaciones

- Los proyectos de investigación de la OPS involucran una gran cantidad de actores a quienes es esencial integrar al proceso de desarrollo del Registro de estudios de la OPS. Para incentivar y garantizar el cumplimiento en el Registro completo de la información la Unidad de Promoción y Desarrollo de la Investigación debe considerar la posibilidad de generar un mecanismo gracias al cual el Área de Finanzas no pueda generar una aprobación de desembolso sin la confirmación de aprobación por parte del PAHOERC tanto para los proyectos que no requieren de aprobación por parte del Comité como para aquellos que han sido definitivamente aprobados.

- Difundir la importancia y relevancia ética, científica y organizacional del PAHOERC y del Registro de Estudios de la OPS.

B) Objetivos estratégicos y Factores Críticos de Éxito

- Caracterizar la investigación en la que la OPS está involucrada en cada país.
- Determinar la contribución financiera de la OPS en los proyectos de investigación en cada país.
- Generar mecanismos para la asignación eficaz de recursos, evitando la duplicación de esfuerzo en investigación.
- Asegurar la calidad ética y científica de los proyectos en los que la Organización se encuentra involucrada
- Organizar y mantener la Memoria Institucional de las decisiones, actividades y documentos relacionados con la investigación en la que la OPS se encuentra involucrada.

C) Idioma

La Organización Panamericana tiene como idiomas oficiales el español, el portugués, el francés y el inglés. Siguiendo la recomendación de la Plataforma de Registro de Ensayos Clínicos se sugiere que los campos de información sean completados en inglés para unificarla información. Sin embargo puede existir una interfaz en los 4 idiomas.

3.1.7 Responsables

- La Unidad de Promoción y Desarrollo de la Investigación de la OPS es responsable por el desarrollo, mantenimiento, difusión, coordinación y reporte del Registro de Estudios de la OPS. Para ello requiere de una asistente administrativo que cumpla la función de asegurar que los resultados de los procesos del PAHOERC sean apropiadamente incluidos dentro del Registro, verificar que la información del registro esté completa y actualizada, soportar a los Administradores Locales, Investigadores, PAHOERC y al departamento de finanzas, actualizar las convocatorias y listados de accesos a usuarios (administradores locales) y generar los reportes. La supervisión de estos procesos requiere de un profesional con experiencia en investigación, diseños de estudios epidemiológicos, experiencia con el registro de información en bases de datos y conocimiento del funcionamiento de los procesos de evaluación de proyectos por parte de un Comité de Ética.
- Los Administradores Locales son responsables de solicitar la Revisión Ética de todo proyecto de investigación utilizando el sistema de Registro de estudios de la OPS.
- El Área de finanzas (Procurement) es el encargado de solicitar la documentación de soporte de aprobación del proyecto por parte del PAHOERC o la no necesidad de Revisión Ética por parte del Equipo de Tamizaje (PAHOERC screening Team)
- Durante las entrevistas llevadas a cabo, se recomendó que El Comité de Revisores Ético genere mecanismos ágiles que permitan la aprobación de los proyectos en periodos de tiempo cortos que faciliten los procesos de investigación. Claramente es un punto crítico para quienes presentan proyectos de investigación y tienen cronogramas planeados, que el PAHOERC decida en el menor periodo de tiempo.

3.1.8 Marco legal

El Acta de Modernización de 1997 de la Food and Drug Administration de los Estados Unidos de Norteamérica (FDA) aseguró la creación de un registro de los ensayos clínicos por parte de los Institutos Nacionales de Salud (NIH), mandato gracias al cual fue creado el registro ClinicalTrials.gov. Todas las entidades que conducen experimentos clínicos de medicamentos que sean mercadeados en los Estados Unidos, deben divulgar información relativa al desarrollo del producto.

A pesar de que ClinicalTrials.gov es una herramienta valiosa para que la comunidad y los agentes relacionados con la salud accedan a información acerca de los experimentos clínicos en curso, tiene aún algunas limitaciones importantes: aplica únicamente a enfermedades serias o potencialmente mortales, no existe un mecanismo que asegure el cumplimiento por parte de todas las entidades, no permite la divulgación de los resultados de los estudios y los datos requeridos no son siempre completados de la mejor forma. Por ello, diversos grupos han solicitado la imposición de un mandato de obligatoriedad que incluya todo tipo de experimento clínico y que permita acceder a mayor información del protocolo de los estudios.

Cada país tiene sus propias regulaciones al respecto y no existe un consenso alrededor del tema, más aún teniendo en cuenta la controversia relativa a la protección de la propiedad intelectual y las patentes. En la actualidad no existe un mandato de ley que obligue a declarar públicamente el protocolo de los estudios (experimentos clínicos o no). Estos son presentados para ser evaluados por los Comités de Ética e Investigación de las instituciones y de requerirlo a las entidades regulatorias de cada país.

Debido a ello, y a menos que sea un requisito para aplicar poder realizar investigación en la OPS, la visualización del protocolo completo en el Registro de la OPS, debería contar con la anuencia de los investigadores. Los investigadores deberán tener claro que al ingresar sus datos al sistema, alguna de la información será de acceso público (ver datos de búsqueda) y que la visualización del texto completo del protocolo puede ser opcional.

3.2 Modelo General del Sistema de Registro

El Registro de Estudios de la OPS se basa en la adhesión de los diferentes actores, con sujeción a unas normas establecidas para el registro de la información d acuerdo a las diferentes etapas que conlleva la realización de un proyecto de investigación. Por la naturaleza del sistema, serán miembros de acuerdo a su rol, quienes requieran realizar un proyecto de investigación en el que la OPS está involucrada. Para que el sistema sea operativo y eficaz, debe garantizar en la práctica el cumplimiento de las siguientes condiciones:

- Abierta, fluida y democrática.
- Interfase sencilla, ágil y de fácil acceso.
- Claridad en la información requerida.
- Eficacia en la Atención a los usuarios según las posibilidades tecnológicas.
- Ágil y sencilla en la búsqueda de información
- Segura en garantizar el almacenamiento de los datos y confidencialidad de los datos que así lo requieran.

De esta forma, la red no será:

- Un grupo cerrado de intercambio de información
- Un archivo de información de dudosa utilidad
- Un gran archivo de información interesante que se queda guardada y sin uso para activar procesos
- Un proceso burocrático más, que no beneficie a cada uno de los actores involucrados

3.2.1 Organización del Registro

La "unidad de intercambio" de información es el proyecto que ha sido enviado para evaluación al Comité y que en adelante tendrá un Número Único de Identificación de la OPS. De él dependerán en adelante varios procesos que son descritas en el Anexo 6 Descripción de los procesos del Registro**.** El sistema busca hacer el seguimiento de cada proyecto de investigación enviado para revisión por parte del PAHOERC, siguiendo a través del tiempo, los procesos de aprobación por parte del Comité de Ética, de generación de la información con respecto al costo financiado, al estatus en que se encuentra y a su posterior finalización y reporte.

No es conveniente introducir mucha inflexibilidad al sistema con exigencias rigurosas, pero sí se hace necesario un filtro que se apoye en requisitos mínimos, los cuales podrán ir afinándose sobre la marcha. Algunos de estos requisitos mínimos se basan en aquellos sugeridos por la Plataforma de Registro de Ensayos Clínicos de la OMS y registros existentes como son Clinicaltrials.gov y el Registro Latinoamericano de Ensayos Clínicos (LATINREC- www.latinrec.org). El registro de estudios de la OPS, no pretende ser un registro primario de experimentos clínicos que alimente a la Plataforma de Registros de la OMS, en la medida en que esta no es una función que le competa y que existen alternativas en la región que suplen esta necesidad. Sin embargo la OPS debe garantizar que los experimentos clínicos en los que está involucrada tengan un número único de identificación asignado por la Plataforma de Registro de la OMS y que este quede registrado en su sistema de Registro.

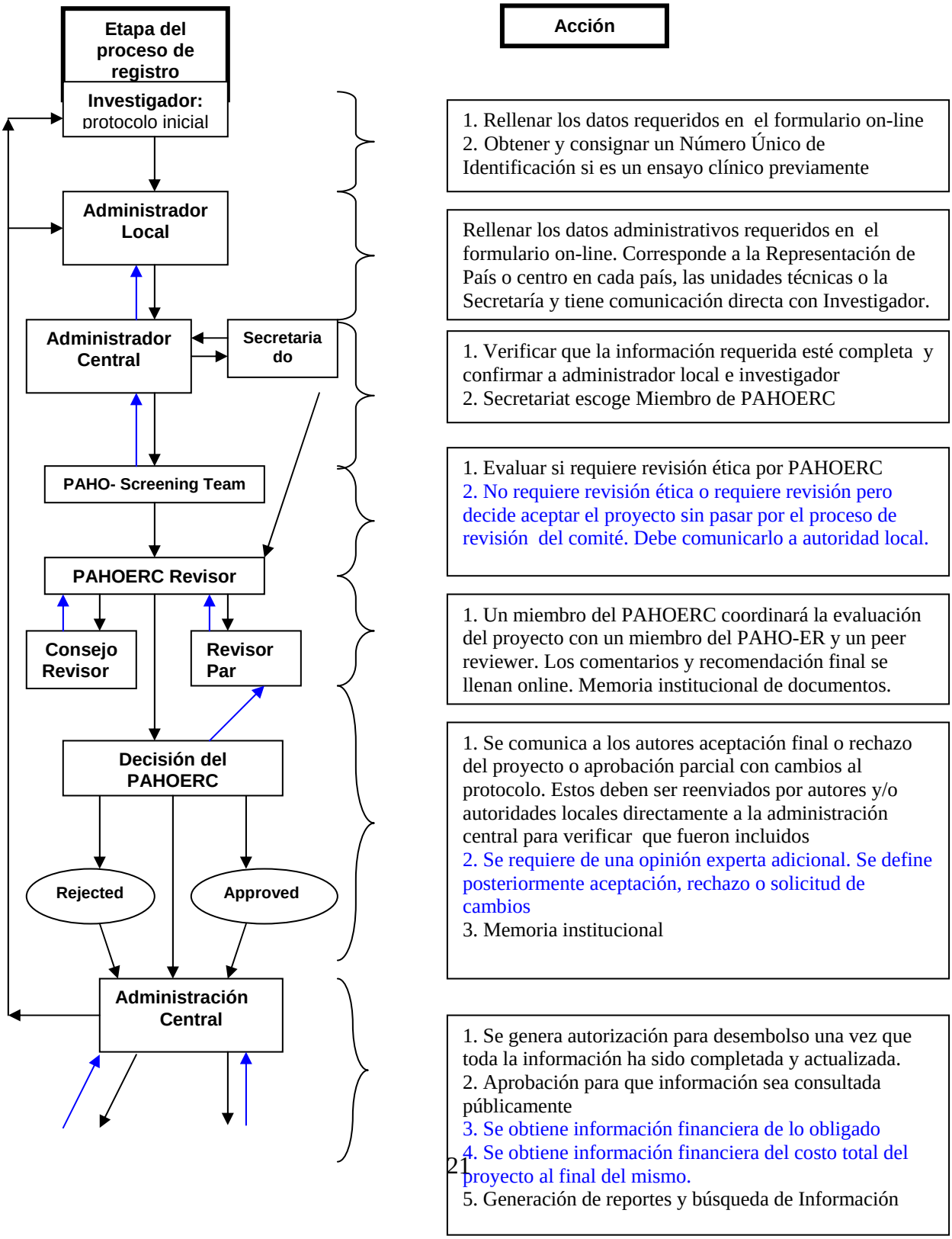
El sistema de registro no soporta todos los procesos de aprobación por parte del PAHOERC, sin embargo recoge las decisiones esenciales. La decisión de no incluir los procesos del PAHOERC se basó en que esto incrementaría la complejidad y número de actores en el sistema. Adicionalmente el PAHOERC se encuentra en un proceso de reorganización y fortalecimiento el cual probablemente requiera de ajustes y evaluación; un sistema rígido de información podría interferir negativamente en este proceso de reorganización.

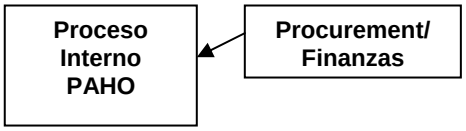
Una vez que el PAHOERC haya fortalecido y probado sus procesos de evaluación de protocolos de los estudios de investigación, se recomienda desarrollar herramientas probadas dentro de la OPS como es el Workflow, que permite realizar el seguimiento de la aprobación de un proyecto por parte de los diferentes actores involucrados. Las decisiones finales seguirán alimentando el Registro de Investigación de la OPS. El PAHOERC seguirá recibiendo los documentos para evaluación de los protocolos de los proyectos a partir del Registro de estudios de la OPS.

Las diferentes etapas por las que pasa un proyecto deben ser seguidas utilizando un sistema de "tracking". Esto permite que los Administradores Centrales y Locales puedan hacer un seguimiento del estudio.

Una descripción general de los procesos en los que está involucrado el sistema de Registro se describe a continuación:

Diagrama1. Proceso General de Registro de protocolos de la OPS





3.2.2 Partes involucradas en el Registro

Cada parte involucrada en el Registro tiene unos roles y niveles de acceso diferentes:

Roles

- La Unidad de Promoción y Desarrollo de la Investigación de la OPS deberá:
  - Promover el sostenimiento del Registro
  - Coordinar la integración del proceso del PAHOERC con los del Registro
  - Determinar las personas responsables de la administración Central
  - Monitorizar el cumplimiento de todas las partes
  - Difundir y la necesidad de Registrar
  - Coordinar con el Área de finanzas el desembolso de los proyectos cuando se cumplan los requisitos.
  - Utilizar la información generada por el Registro en los reportes de la Organización.
- El Administrador Central

El Administrador Central es la persona responsable en la Unidad de Promoción y Desarrollo de la Investigación de realizar los procesos administrativos relacionados con los proyectos/estudios de investigación en los que está involucrado el Comité de Revisores de Ética de la OPS. Tendrá a su cargo las siguientes funciones:

- Aseguramiento de la calidad de la información
- Ingresar la información administrativa relativa al PAHOERC.
- Actualizar las convocatorias en las que puede participar los investigadores
- Monitorizar el cumplimiento de los demás actores
- Actualizar el listado de administradores locales
- Cumplir las funciones de Administrador Local en caso de requerirse
- Generar los reportes para la Unidad de Promoción y Desarrollo de la Investigación de la OPS.
- Los Administradores Locales

El Administrador Local es cualquier persona que pertenezca a la OPS y sea contraparte del investigador para el desarrollo del proyecto de investigación. Tendrá las siguientes el compromiso de realizar las siguientes funciones:

- Ingresar la información administrativa del proceso
- Iniciar un registro para invitar al investigador a ingresar la información
- Validar la información enviada por el investigador
- Proveer los datos relativos al financiamiento del proyecto por parte de la OPS al momento de ser aprobado y al final del estudio.
- Determinar el estatus del proyecto
- Actualizar las convocatorias en las que puede participar los investigadores.
- Aseguramiento de la calidad de la información

- Los Investigadores

El investigador cumplirá las siguientes las actividades dentro del registro:

- Ingresar los datos y documentos solicitados para presentar el proyecto al PAHOERC
- Realizar los cambios sugeridos por el PAHOERC
- Solicitar las enmiendas al protocolo.
- Presentar el reporte final del proyecto

3.2.3 Procesos del Registro

El proceso detallado del funcionamiento del registro se encuentra en el Anexo Documento de Soporte Técnico.

La solicitud para la revisión de un proyecto por parte del PAHOERC puede darse de dos formas diferentes:

a. El administrador local invita al investigador al crear un nuevo proyecto y enviar el Número Único de Identificación del estudio.
b. Atendiendo una convocatoria, el investigador da inicio al proceso momento en el cual se genera el crea Número Único de Identificación de OPS del estudio.

3.2.4 Requisitos de Información de los usuarios

Una descripción gráfica de cada una de las pantallas del sistema y de su contenido se encuentra disponible en archivo electrónico anexo con el contenido de esta propuesta y temporalmente en la dirección electrónica http://itandem.net/registro_estudios_paho

Para una descripción detallada remitirse al Anexo Documento de Soporte Técnico.

3.2.5 Condiciones del proponente para garantizar un adecuado desarrollo en la ejecución de la proyecto

Las siguientes son las condiciones que debe cumplir el proponente para garantizar un adecuado desarrollo en la ejecución del proyecto

a. Hacer la instalación del software en la máquina servidora
b. Capacitar a los usuarios del sistema en el manejo del nuevo aplicativo.
c. El proponente debe contemplar como parte del tiempo de duración del proyecto, un periodo para realizar a partir de la descripción de los servicios de usuario final y de administración del sistema, las especificaciones detallas de la aplicación (Definición de tablas, parámetros generales del sistema, revisión de entradas, salidas, procesos, condiciones, salida detallada de reportes, consultas, etc)
d. La implantación de la solución en su parte técnica estará a cargo del proveedor.
e. El proveedor debe presentar un cronograma de las actividades mayores (especificaciones, ajustes, pruebas, correcciones, piloto, conversión) y el tiempo de ejecución, en donde se pueda ver con exactitud la duración estimada del proyecto total.

Documentación:

La siguiente es la documentación mínima que debe entregarse con la solución informática:

- Descripción de la aplicación, que hace y como opera.
- Descripción de las estructuras de información y diccionario de datos.

- Diagrama entidad - relación de las principales estructuras de información que utiliza la solución y descripción de cada una de ellas en términos de los datos que almacena.

3.2.6 Niveles de Acceso de los Usuarios

Los usuarios que utilizan la aplicación son El administrador local, el administrador central, los investigadores, el comité de revisión ética y el público en general. Los servicios a los que pueden tener acceso están descritos en la Tabla 1

Tabla 1. Descripción a los servicios a los que tienen acceso los usuarios

Tipo de usuario	Servicios a los que tiene acceso
Administrador Central	a. Acceso a la Memoria Institucional b. Acceso a todos los protocolos y documentos relacionados con cada proyecto c. Acceso a todos los reportes d. Acceso a toda la información contenida por el registro e. Acceso a los servicios descritos correspondientes a sus funciones f. Resultado de la Búsqueda sencilla y avanzada g. Acceso a actualizaciones como listado de administradores locales y convocatorias.
Administrador Local	a. Acceso a todos los protocolos y documentos relacionados con los proyectos con los que esté involucrado c. Acceso a todos los reportes b. Acceso a los servicios descritos correspondientes a sus funciones f. Resultado de la Búsqueda sencilla y avanzada g. Acceso a actualizaciones de convocatorias.
Investigador	a. Resultado de la Búsqueda sencilla y avanzada. Solo puede acceder a los protocolos a los que los investigadores han dado permiso público de acceso. b. Reportes a los que el administrador central dé acceso público c. Acceso a su propio proyecto a través del número de identificación único, su ID y su Password. d. Acceso a los servicios correspondientes al ingreso de la información y documentos por parte del Investigador.
PAHOERC	a. Acceso a la Memoria Institucional b. Acceso a todos los protocolos y documentos relacionados con cada proyecto c. Acceso a todos los reportes
Público en general (Anónimo)	a. Resultado de la Búsqueda Sencilla y avanzada. Solo puede acceder a los protocolos a los que los investigadores han dado permiso público de acceso.

	b. Reportes a los que el administrador central dé acceso público

3.2.7 Mantenimiento de la solución informática

En este tipo de aplicaciones es importante hacer un trabajo exhaustivo en el proceso de especificaciones detalladas y pruebas, para tener una solución de apoyo al trabajo que no requiera ajustes en un tiempo corto. Tomarse el tiempo en hacer pruebas con algunos de los diferentes niveles de usuarios puede verse recompensado en un mantenimiento ocasional de la solución informática.

El tipo de ajustes que puede requerir la solución es en orden de dificultad el siguiente:

- Generar nuevos reportes y consultas
- Generar nuevas salidas de información
- Modificar procesos debido a que se requieren nuevos servicios de información
- Modificar estructuras de información

Se puede capacitar a lo usuarios para que generen nuevos reportes y consultas con un producto como "Crystal Reports 10 STANDARD" cuyo costo en el mercado es de aproximadamente 200 dólares. Por otra parte, se debe garantizar la entrega completa de la documentación por parte del equipo que desarrolle la aplicación, tal como se describe previamente.

Para otros ajustes es conveniente acudir al desarrollador de la solución ya que se tiene que modificar la lógica de la aplicación y eventualmente crear nuevas estructuras de información.

3.2.8 Seguridad de la solución informática

La seguridad se entiende como el proceso que permite proteger los componentes de la aplicación de manera que sólo puedan ser utilizados por las personas a quienes se les otorgaron permisos, después de verificar sus identidades y los permisos que se les concedieron.

Los servicios de información de la aplicación no deben estar disponibles para todos los usuarios. El acceso a la aplicación debe verificarse por un proceso de autenticación que verifica que el usuario que intenta entrar a la aplicación si es quien dice ser. Esto se debe hacer con un mecanismo de número de identificación y de clave.

Luego se pasa al proceso de autorización en dónde según el tipo de usuario que entró al sistema se le concede la utilización de algún recurso de la aplicación, en este caso uno o varios servicios de información, y se niega el acceso a otros.

- En cualquier comunicación o publicación en cualquier forma y en cualquier soporte (con inclusión de Internet) del protocolo o los resultados de un estudio se dejará constancia de que sólo compromete a su autor y que no representa la opinión de la Organización panamericana de la Salud Comunidad y que ésta no es responsable del uso que pueda hacerse de los datos que figuran en el Sistema de Información.

4. RESULTADOS ESPERADOS E INDICADORES

4.1 Resultados relacionados con la generación de conocimiento y/o nuevos desarrollos tecnológicos

La OPS no tiene en el momento un registro sistematizado formal que integre toda la información relativa a los protocolos de los ensayos clínicos evaluados por el PAHOERC. Así mismo tanto la comunidad como los diversos actores del campo de salud no tienen acceso a información relativa al tipo de investigación clínica realizada en la OPS que permita establecer prioridades y evaluar políticas de investigación. El Registro de estudios de la OPS contribuirá con el acceso gratuito tanto al registro de la información por parte de los investigadores o los patrocinadores así como a la búsqueda de la misma por parte de la comunidad y de los actores del sector salud.

Así mismo, el PAHOERC se encuentra en un proceso de renovación y fortalecimiento que requiere a su vez organizar la información de los protocolos que evalúa y conservar una Memoria Institucional. Adicionalmente, el sistema garantizará que los investigadores que presenten protocolos de experimentos clínicos provean el número de identificación Único suministrador por la la Plataforma de Registro de la OMS. Este proyecto contribuirá con el acceso gratuito tanto al registro de la información por parte de los investigadores como los patrocinadores así como a la búsqueda de la misma por parte de la comunidad y de los actores del sector salud.

Tabla 2. Generación de nuevo conocimiento

Resultado/Producto esperado	Indicador	Beneficiario	Supuesto
Conocimiento de la caracterización y evaluación de los proyectos realizados en la Región, así como la descripción de su metodología.	Publicación periódica de reportes. Sistema de Información.	Pacientes, Organización Panamericana de la Salud, comunidad científica, proveedores de cuidados en salud, pacientes, Instituciones participantes, Entes locales de salud, Sociedad en general.	- Todos los Proyectos de Investigación fueron ingresados. - Todos los Administrador locales conocen las actividades, procesos y definiciones del PAHOERC. - Conocimiento del funcionamiento y acceso al Registro de Investigación de la OPS
Descripción de los resultados de los proyectos en los que la OPS está involucrada.	Publicación periódica de reportes. Sistema de Información.	Pacientes, Organización Panamericana de la Salud Comunidad científica nacional e internacional, proveedores de cuidados en salud, pacientes, Instituciones participantes, Entes locales de salud, Sociedad en general.	- Difusión del Registro a la comunidad. - Una persona de la unidad de promoción para la Investigación de la OPS va a generar periódicamente los reported.
Disminución del sesgo	Sistema de	Pacientes,	- Visibilidad del

de publicación, del reporte de los resultados y de las múltiples publicaciones.	Información, Publicación periódica de Reportes	Organización Panamericana de la Salud Comunidad científica nacional e internacional, Editores de Revistas biomédicas, proveedores de cuidados en salud, Instituciones participantes, Entes locales de salud, Sociedad en general.	Registro de Investigación de la OPS. - Enlace con otros registros existentes
Capacidades técnicas del PAHOERC en la evaluación de los protocolos y resultados de la investigación clínica experimental para verificar su consistencia.	Sistema de Información.	Organización Panamericana de la Salud, Fuentes de Financiamiento.	- Parte de las funciones del PAHOERC son comparar los protocolos y los resultados de los proyectos en forma sistemática.
Implementación de procedimientos y mecanismos estandarizados para la monitorización de la investigación que adelanta y apoya, Promoción de la divulgación y control de los resultados de investigación	Sistema de Información, Reportes Periódicos	Organización Panamericana de la Salud.	- La Unidad de Promoción de la Investigación hace seguimiento a los proyectos contenidos en el registro.

4.2 Resultados conducentes al fortalecimiento de la capacidad científica

El registro de todos los protocolos de los proyectos en los que está involucrada la OPS así como de sus resultados permitirá el acceso a información no sesgada, facilitará una asignación equitativa y ordenada de los recursos, incrementará la confianza de la comunidad en la comunidad científica, será una herramienta para reducir la duplicación de esfuerzos y estudios, evidenciará la necesidad de investigación de enfermedad olvidadas, identificará investigaciones que midan desenlaces irrelevantes e incrementará la ética y transparencia en la investigación.

Tabla 3. Fortalecimiento de la comunidad científica

Resultado/Producto esperado	Indicador	Beneficiario	Supuesto
Aplicación de conocimientos y habilidades de todos los procesos de investigación clínica y epidemiológica.	- Acceso a los protocolos de investigación. - Retroalimentación de comentarios acerca de los protocolos.	Investigadores.	- Visibilidad del Registro en la comunidad científica. - Los Investigadores tienen acceso a los protocolos de los colegas permitiendo

	- Número de contactos solicitando información acerca de un estudio		evaluar, comparar y mejorar sus propios proyectos.
Desarrollo regional para el reporte del protocolo y de los resultados de los estudios.	Proyectos registrados	Red de investigadores y comités de ética médica.	- Difusión del Registro en los Comités de Ética de la región. - Se asimila la experiencia de la OPS
Visibilidad de investigadores Latinoamericanos en la WEB	- Publicación de Reporte, registros bases de datos de acceso universal. - Número de accesos de usuarios externos al registro por Unidad de Tiempo -Número de accesos externos por País	Patrocinadores e investigadores, comunidades científica.	Visibilidad del Registro en a región.
Fortalecimiento del PAHOERC	- Registros bases de datos de acceso universal. - Utilización del Registro por parte de los miembros de PAHOERC. - Número de accesos a la Memoria Institucional por Unidad de Tiempo	Organización Panamericana de la Salud	- Los miembros del PAHOERC se identifican con el Registro

4.3 Resultados dirigidos a la apropiación social del conocimiento.

El registro será de acceso público y por tanto todos los actores del sistema de salud tendrán la oportunidad de consultar, estudiar y evaluar los protocolos de investigación existentes en la región. Teniendo en cuenta que el conocimiento científico se construye basado en el conocimiento previo, esto tendrá un impacto positivo en la generación de conocimiento e ideas de los investigadores, así como de los clínicos y estudiantes de áreas de la salud.

Desafortunadamente varios de los proyectos que se llevan a cabo no han sido diseñados teniendo en cuenta todo el conocimiento porque éste no está públicamente disponible. La falta de oportunidad para compartir el conocimiento es un obstáculo en la creación de nuevo conocimiento. Si adicionalmente los resultados no son nunca publicados o el estudio es abandonado, este conocimiento nunca se comparte. Estos aspectos generan que varios grupos de investigación trabajen simultáneamente pero en forma aislada y solo con parte de la evidencia disponible. Así mismo, y más importante aún la comunidad participantes de los estudios puede verse sometida en ocasiones a riesgos innecesarios. Por encima de todo, la investigación en humanos se justifica en la medida en que el conocimiento que emerja de ella sea puesto a disposición de la misma

comunidad para el bien común. El registro prospectivo de los protocolos y resultados de los estudios de investigación puede asegurar que todos los estudios que se lleven a cabo sean reportados.

Por otra parte el acceso de la comunidad en general a la información concerniente a los protocolos de investigación permitirá incrementar su conocimiento en los estudios en que participan.

Tabla 4. Apropiación social del conocimiento

Resultado/Producto esperado	Indicador	Beneficiario	Supuestos
Conocimiento del sesgo de publicación y sesgo de desenlace.	Comparación del protocolo y de los resultados por parte del PAHOERC	Organización Panamericana de la Salud, Comunidad científica.	Conociendo la experiencia del Registro de Investigación de la OPS la comunidad solicita experiencias similares en otros Organismos o instituciones.
Registro de publicación de los proyectos	Publicación, bases de datos	Comunidad científica, Ligas de usuarios y consumidores	El Registro se convierte en una fuente de búsqueda de proyectos realizados y en curso.
Verificación de que la información de los protocolos de los estudios esté acorde con los resultados del reporte final.	Calidad de la información	Comunidad científica y pacientes.	La comunidad científica y la Sociedad en general evalúan la información que genera el Registro.

5. RECURSOS Y PRESUPUESTO

5.1 Equipo de Trabajo de la OPS

Fase Desarrollo, Prueba e Implantación

La gestión integral del proyecto, desde el comienzo hasta el final, estará a cargo de un equipo básico formado por el Director de la Unidad de promoción a la Investigación, un Profesional y un funcionario técnico con experiencia en el tema quienes coordinarán la labor de diversos equipos funcionales (por ejemplo, asuntos financieros, recursos humanos y presupuesto) familiarizados con estas cuestiones en todos los destinos y niveles de la Organización.

Se recomienda que la Sra América Valdés forme parte de este equipo, teniendo en cuenta su conocimiento y experiencia en el sistema de información previo (RIS 2000) y por su participación activa en el desarrollo de la propuesta actual. Su dedicación horaria

a esta actividad será de ¼ de tiempo y reportará al Jefe de la Unidad de Promoción de la Investigación.

Se requiere de un empleado profesional, con experiencia reconocida en Investigación, conocimiento del funcionamiento de los Comités de Ética para la evaluación de proyectos y conocimientos en sistemas de información para que sea la contraparte (Usuario experto) de la empresa que desarrolle la Aplicación. Su función es la de asegurar que todas las especificaciones han sido alcanzadas, adaptar posibles limitaciones no tenidas en cuenta durante el desarrollo de la propuesta, probar e implementar el sistema y certificar los criterios de aceptación. Así mismo se encargará de realizar la difusión del proyecto en la Organización. En el marco de los procesos de gestión de la OPS se informará periódicamente sobre los progresos técnicos del proyecto, sus correspondientes gastos.
Su dedicación horaria será de 1/3 a 1/2 tiempo y reportará al Jefe de la Unidad de Promoción de la Investigación.

El equipo de la Unidad de Promoción para la Investigación definirá las características operacionales para el buen funcionamiento del PAHOERC y el establecimiento de mecanismo de difusión en las oficinas de países, las oficinas regionales y la Sede de las actividades de los mismos. Como se mencionó anteriormente, la aceptación de los procesos del PAHOERC está íntimamente ligada a la del Registro.

Capacitación

Seguimiento

Se requiere de un empleado profesional, con experiencia reconocida en Investigación, conocimiento del funcionamiento de los Comités de Ética para la evaluación de proyectos y conocimientos en sistemas de información. En la fase de seguimiento, evaluará los datos contenidos en el Registro, generará reportes para contribuir con la toma de decisiones por parte de la Organización y participará activamente en la difusión y visibilidad del Registro. Su dedicación horaria a esta actividad será aproximadamente de ¼ de tiempo y reportará al Jefe de la Unidad de Promoción de la Investigación.

5.2 Presupuesto

El costo general del desarrollo de proyecto se estima en unos US$ 30.000 dólares, para la fase de desarrollo, pruebas, implantación y capacitación de los usuarios. Se prevé que las mayores necesidades de financiación se darán para el costo de desarrollo de la Aplicación. El costo no tiene en cuenta el recurso humano requerido por parte de la OPS para el acompañamiento como usuario, durante esta fase de desarrollo.
Se prevé que el los gastos se efectuarán en el bienio 2006-2007 para completar el proyecto.
Si el proyecto es realizado por empresas que tienen actualmente un software adaptable en el mercado, el precio estimado es de US$ de acuerdo a cotizaciones solicitadas a las empresas ScholarOne y Highwire Press.

6. CRONOGRAMA Y PLANES DE TRABAJO PARA LA IMPLANTACIÓN DEL REGISTRO

6.1 Cronograma

Búsqueda de soluciones

- Formulación de solicitudes de información a posibles proveedores.
- Solicitud oficial de presentación de propuestas de solución
- Análisis de las diferentes soluciones disponibles de acuerdo a:
  - Los costos (con inclusión de los correspondientes a la aplicación, licencias de programas informáticos, Pruebas, Implantación, Capacitación de los Usuarios, Mantenimiento, pago por Registro)
  - Comparación de Adaptación versus desarrollo de la Aplicación
  - la negociación de contratos de prestación de apoyo en materia de programas informáticos y ejecución para crear asociaciones que no sólo contribuyan al logro de metas inmediatas, sino que también permitan establecer relaciones sostenibles y mutuamente beneficiosas, en especial con respecto al mantenimiento y mejoramiento de los sistemas.
  - Las políticas de seguridad de la Organización.

Ejecución

- Plan operacional detallado para la ejecución del proyecto.
- Gestión de la ejecución y realización Pruebas Implantación.
- Capacitación para la utilización del nuevo sistema; establecimiento del sistema
- Aseguramiento del apoyo y del mantenimiento permanente del sistema.

Fases del Proyecto

Fase 1: Convocatoria: 2 a 4 semanas
Fase 2: Selección Equipo OPS: 2 semanas
Fase 3: Selección Proponente de la Convocatoria: 2 semanas
Fase 4: Desarrollo de la Aplicación: 12 a 14 semanas
- o Plataforma de seguridad (encriptación)
- o Plataforma de gestión de usuarios
- o Desarrollo de la aplicación
- o Documentación

Prueba de Aplicación: 3 semanas
Implantación de la aplicación: 2 a 4 semanas (dependiendo si es interna o externa)
Fase 5: Capacitación de los Usuarios: 2 a 4 semanas
Fase 6 Difusión del Registro: 2 a 3 semanas

Tabla 5. Cronograma

Tiempo (semanas) / Actividad	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Desarrollo de la Aplicación																				
Prueba de la Aplicación																				
Implantación de la Aplicación																				

Capacitación de los Usuarios																				
Difusión del Registro																				

6.2 Pruebas

La especificación detallada de la solución informática debe ser validada por los usuarios de la misma. Para esto se debe escoger un representante por cada tipo de puesto (Administradores, investigadores, comité de ética), que participe de esta actividad y la valide.

El equipo de desarrollo y el grupo usuario o el representante de este deben definir cuáles son los componentes o servicios de información que requerirían un proceso de pilotaje (Simulación del servicio con alguna herramienta de programación) antes de hacer el desarrollo definitivo.

La estrategia de hacer pilotos para los servicios más complejos de especificar presenta la ventaja de reducir el periodo de pruebas después del desarrollo y agiliza la implantación.

Durante la etapa de pruebas se debe considerar los siguientes puntos en la especificación del entorno:

- Entorno tecnológico: hardware, software y comunicaciones.
- Restricciones técnicas del entorno.
- Requisitos de operación y seguridad del entorno de pruebas.
- Herramientas de prueba relacionadas con la extracción de juegos de ensayo, análisis de resultados, utilidades de gestión del entorno, etc.
- Planificación de capacidades previstas, o la información que estime oportuno el departamento técnico para efectuar dicha planificación.
- Procedimientos de promoción de elementos entre entornos (desarrollo, pruebas, explotación, etc.).
- Procedimientos de emergencia y de recuperación, así como de vuelta atrás.

Participantes

- Equipo del Proyecto en OPS
- Diseñadores de la aplicación
- Equipo de Soporte Técnico (ITS)
- Equipo de Seguridad (ITS)
- Usuarios Expertos

6.3 Implantación

Revisión de la Interfaz de Usuario

Se evalúa el diseño detallado del comportamiento de la interfaz del usuario a partir de la especificación de la misma, obtenida en el proceso de análisis, y de acuerdo con el entorno tecnológico definido. Para la implantación se debe volver a reunir el grupo de

usuarios, con un representante por puesto de trabajo, establecer un plan de simulación con todo el proceso del registro de estudios y efectuar la operación completa apoyándose en la solución informática. En particular se debe prestar atención al funcionamiento de la interfaz de usuario, la navegación entre ventanas, los elementos que forman cada interfaz, sus características (que deben ser consistentes con los atributos con los que están relacionadas), su disposición, y cómo se gestionan los eventos relacionados con los objetos.

Presentar luego las observaciones y posibles correcciones de funcionamiento si se observan discrepancias frente a la especificación detallada para proceder a los ajustes y nuevas pruebas.

Cuando se terminen las pruebas a satisfacción del usuario, se debe dejar vacío el repositorio de datos para comenzar la operación del sistema. Es fundamental en este proceso la participación del grupo de usuarios. El tiempo estimado para esta parte del proyecto de desarrollo es de **mes y medio**.

Participantes

- Jefe de Proyecto
- Equipo Unidad Promoción de la Investigación
- Usuarios expertos
- Equipo de Soporte Técnico (ITS)

Revisión de Subsistemas de Diseño e Interfaces

Se debe evaluar los subsistemas que participan en la aplicación, los actores que intervienen en el mismo y los mensajes que intercambian los objetos de un subsistema con otro.

6.4 Capacitación de los usuarios

- El sistema debe ser intuitivo y amigable facilitando la implantación del sistema y la capacitación de los usuarios. Los investigadores deben poder ingresar la información requerida intuitivamente y si ayuda adicional. Se recomienda sin embargo que el Registro tenga una descripción de ayuda de los campos y acciones.

- Es aconsejable que la persona encargada de cumplir las funciones de Administrador Central sea ser invitada a participar en las fases de Pruebas e Implantación de la Aplicación. Así mismo algunos miembros del PAHOERC pueden hacer parte de esta actividad para tener en cuenta su retroalimentación y adicionalmente para que se conviertan en difusores del funcionamiento del registro. Se requiere organizar algunas sesiones prácticas con el equipo que desarrolla la aplicación.

- Se recomienda utilizar la tecnología de “Elluminate” para realizar la capacitación de los Administradores Locales. Así mismo es aconsejable que la Unidad de Promoción para la Investigación de la OPS solicitar definir los responsables locales en las Representaciones de País, Centros, Unidades Técnicas o cualquier otro representante de la Organización que pueda cumplir la función de Administrador Local.

- Cualquier sistema en nuevo que entra en funcionamiento posee cierta inercia o resistencia por parte de los usuarios. Por esta razón, al implementar El Registro de Investigación de la OPS es necesario considerar la tendencia natural de las personas de resistirse al cambio. Para minimizar el impacto de la inercia, es recomendable hacer todos los esfuerzos posibles para que el usuario se sienta parte integrante del proyecto y centrar su atención en los beneficios que pueden esperar del nuevo sistema. Un sistema de registro intuitivo y amigable, acorde con desarrollos similares a los existentes en el mercado facilita el aprendizaje por parte de los usuarios. Se debe tener en cuenta que la mayor parte de los Administradores locales se encuentran en cada uno de los países que representa la organización. Por otra parte, los investigadores se enfrentarán con la necesidad de suministrar la información en el momento de conocer el Registro de investigación de la OPS. En los últimos años la comunidad científica Panamericana ha tenido acceso a sistemas similares al planteado en esta propuesta al momento de solicitar financiación a los Organismos de Ciencia y Tecnología en sus países, o de enviar sus manuscritos para publicación a las revistas biomédicas.
- La capacitación de los usuarios se debe llevar a cabo en las siguientes etapas (22):

a- Al iniciar los esfuerzos para el desarrollo del sistema se precisa generar expectativas entre los usuarios de que se está trabajando sobre un nuevo sistema, destacando los beneficios esperados, características y el programa del sistema propuesto.

b- Durante el desarrollo del sistema impartir un conocimiento del funcionamiento general de la aplicación que anticipe la llegada al nuevo sistema.

c. Durante la fase de implementación buscar familiarizar al usuario con el funcionamiento detallado del sistema.
d. Asegurarse de que los usuarios están aprovechando las opciones del sistema y que reciban los beneficios que esperaban del mismo, después de un período inicial de operación.
e. Revisar periódicamente la aplicación para asegurar que el sistema funciona de acuerdo a las especificaciones y que los usuarios no requieren de otros procesos para resolver sus problemas.

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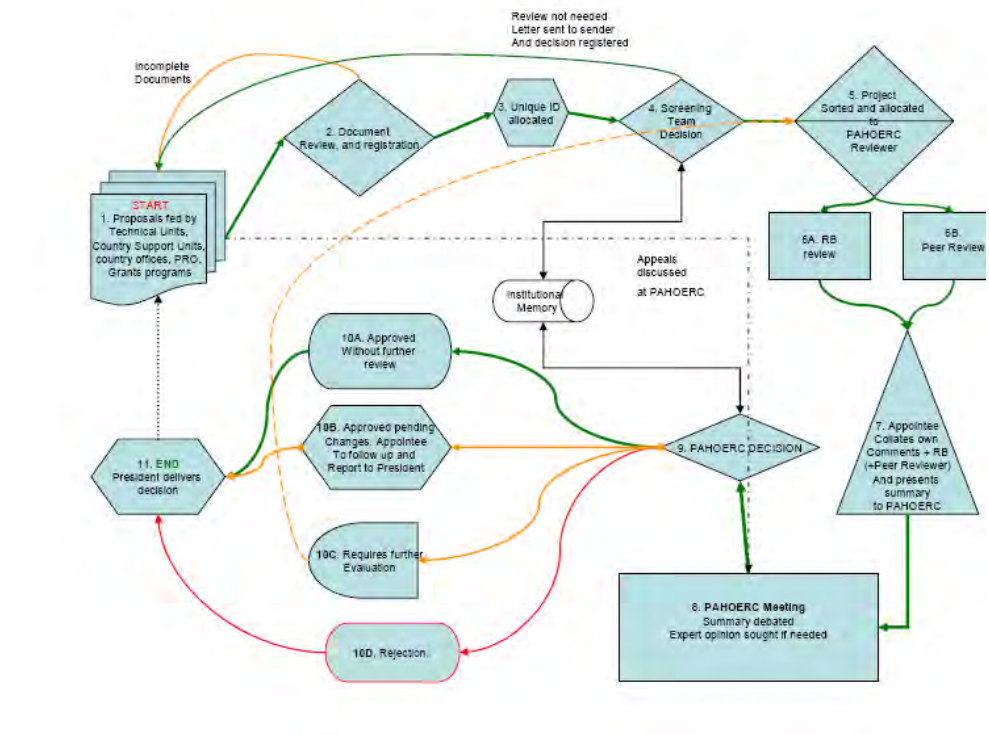
8. ANEXOS

Anexo 1: Conformación Comité Revisor de Ética.

(Documento completo en archive adjunto)

Graph of Review Decision Processes



Anexo 2: Listados de chequeo

Check List - Proyecto Multicéntrico

Ronda / Año 1/2002 -	Nombre IP
Proyecto remitido por Unidad/División Técnica (con memorándum) Quién es la Unidad Técnica que lo presenta. Quién(es) son los asesores de PAHO a cargo del proyecto.	☒
Centros Colaboradores de PAHO/WHO Participan centros colaboradores de PAHO/WHO?	☒ -

Indicar qué centros colaboradores participan en el proyecto	
Centros/Países que se involucran en el proyecto Existen centros involucrados en el proyecto? Qué países participan en el proyecto?	 ☒
Protocolo Hoja Resumen 20 Páginas	 ☐ ☒
Duración del Proyecto (18 Meses)	☒
Contrapartida (Matching) Cantidad solicitada a PAHO Monto del aporte externo (contrapartida)	
Documentos Eticos Certificación local Consentimiento informado Procedimientos éticos descritos en el protocolo	 ☐ ☐ ☒
Certificación Local	☐ -
9) Curriculum Vitae CV de los investigadores principales	 ☒ =
Comentarios	

Check List Proyectos de Capacitación

Ronda / Año 2003	Nombre IP
Formulario 1 a) Hoja Resumen de la Investigación b) Resumen de la Capacitación Propuesta	 a) ☐ b) ☐
Formulario 2 a) Cronograma para el Proyecto b) Cronograma para la Capacitación en el Exterior	 ☐ ☐
Formulario 3 Presupuesto	 ☐
Formulario 4 a) Certificación local	 a) ☐

b) Consentimiento informado c) Procedimientos éticos descritos en el protocolo	b) ☐ c) ☐
Formulario 5 IP Curriculum Vitae	☐
Formulario 5 Tutor Curriculum Vitae	☐
Formulario 6 a) Datos de la Institución Auspiciadora b) Certificación de la institución Académica	☐ ☐
Formulario 7 a) Descripción de la Capacitación en el Exterior b) Certificación de la Institución Laboral	☑ ☑
¿Protocolo satisfactorio?	

Check List Cartas Acuerdos

Ronda / Año 2006	LOA No.
Formulario 1 a) Hoja Resumen de la Investigación	a) ☐
Formulario 2 a) Cronograma para el Proyecto	☐
Formulario 3 Presupuesto	☐
Formulario 4 a) Certificación local b) Consentimiento informado c) Procedimientos éticos descritos en el protocolo	a) ☐ b) ☐ c) ☐
¿Protocolo satisfactorio?	

Check List - PAHO/NIH Fellowships

Year 2002 _____

Proposal	
Protocol	
Eight-page research proposal	☒
Abstract (250 words or less)	☒
Statement of the Problem	☒
Objectives	☒
Methodology	☒
Justification and use of results	☒
Current phase of the research and findings up to now	☒
Bibliography	☒
Priority Areas	☒
Biomedical, clinical, epidemiological and behavioral studies on:	
Emerging infectious diseases, including drug resistance	
Chronic diseases, particularly cardiovascular and cancer disease, prevalent in Latin American and Caribbean countries	
Aging related conditions	
Diseases of immunological, genetic, or endocrine origin of relevance to public health	
Diseases associated with nutritional deficiencies	
The impact of environmental risks on human health	
Training	☒
NIH institute where applicant wishes to work	☒
Describe how the postgraduate will contribute to enrich the PI's scientific background and improve his/her technical skills	
Timetable / (Not to exceed one-year training)	☐

Principal Investigator	
Affiliated with academic/research institution	☒
Citizen/permanent resident of LA or C country	☒
Doctoral Degree (PhD) in Public Health, Behavioral, Biomedical, or Social Science (or equivalent in Health Sciences: MD, DDS, DMV)	☒
Involved in the development of a research project in the institution	☒
Fluent in English	☒
Eligible for the J-1 Visa	☒
Live and Work outside USA when applying	☒
Brief curriculum vitae containing:	☒
Date and place of birth	
Nationality and country of residence	
Academic degrees	
Current position, tasks, and research area	
Two-year research experience or teaching experience	
Recent relevant publications (last 5 years)	
Institution	
Academic/research institution (Public or Private non-profit) in LA or the C	☒
Has received grants for research projects in the area where candidate is working	☐
Signed Certification including:	
Name, address, institution's website and name of institutional representative	☐
And that the candidate is currently involved in the research/teaching activities of the institution;	☒
How the fellowship will benefit the research institution activities and the professional development of the candidate	☐
And the institutions commitment to reincorporate the researcher at the end of the fellowship	☐
	☐
¿Protocol Suitable? / Comments	☐

Check List Proyectos de Tesis

Ronda II - Año 2003	Nombre:
Formulario 1 a) Hoja Resumen de la Investigación	☒
Formulario 2 a) Cronograma para el Proyecto	☒
Formulario 3 Presupuesto	☒

Formulario 4 a) Certificación local b) Consentimiento informado c) Procedimientos éticos descritos en el protocolo	 ☒ ☒ ☐
Formulario 5 IP Curriculum Vitae	 ☒
Formulario 5 Tutor Curriculum Vitae	 ☒
Formulario 6 a) Datos de la Institución Académica b) Certificación de la Institución Académica	 ☒ ☒
Formulario 7 a) Datos de la Institución Laboral b) Certificación de la Institución Laboral	 ☐ ☐
¿Protocolo satisfactorio?	

Anexo 3: Organigrama OPS

1. OFFICE OF THE DIRECTOR PAHO Country Office in Argentina PAHO Country Office in Belize PAHO Country Office in Bolivia Caribbean Program Coordination, CPC, Barbados PAHO Country Office in Brazil PAHO's technical representative in Canada: Canadian Society for International Health (CSIH), Canada PAHO/Country Office in Chile PAHO/Country Office in Colombia PAHO Country Office in Costa Rica PAHO Country Office in Ecuador PAHO Country Office in El Salvador PAHO Country Office in Guatemala PAHO Country Office in Honduras PAHO Country Office in Nicaragua PAHO Country Office in Paraguay PAHO Country Office in Peru El Paso Field Office - US-Mexico Border PAHO Country Office in Uruguay PAHO Country Office in Venezuela 2. OFFICE OF THE DEPUTY DIRECTOR (DD) 2.1 Emergency Preparedness and Disaster Relief (PED) 2.2 Information and Knowledge Management (IKM)

2.2.1 Latin American and Caribbean Center on Health Sciences Information (BIREME)
2.2.2 Bioethics Unit (IKM/BI)
2.2.3 Research Promotion and Development Unit (IKM/RC)
2.2.4 Information and Knowledge Operations (IKM/KO)
2.3 Publications (PUB)
2.4 Public Information (PIN)
2.5 Legal Affairs (LEG)
2.6 Health Analysis and Information Systems (AIS)
3. OFFICE OF THE ASSISTANT DIRECTOR (AD)
3.1 Family and Community Health (FCH)
3.1.1 Child and Adolescent Health Unit (FCH/CA)
3.1.2 Women and Maternal Health Unit (FCH/WM)
3.1.3 Latin American Center for Perinatology and Human Development (CLAP)
3.1.4 Nutrition Unit (FCH/NU)
3.1.5 Immunizations Unit (FCH/IM)
3.1.6 HIV/AIDS Unit (FCH/AI)
3.1.7 Caribbean Food and Nutrition Institute (CFNI)
3.2 Disease Prevention and Control (DPC)
3.2.1 Communicable Diseases Unit (DPC/CD)
3.2.2 Non-Communicable Diseases Unit (DPC/NC)
3.2.3 Veterinary Public Health Unit (DPC/VP)
3.2.4 Pan American Institute for Food Protection and Zoonoses (INPPAZ)
3.2.5 Pan American Foot-and-Mouth Disease Center (PANAFTOSA)
3.2.6 Caribbean Epidemiology Center (CAREC)
3.3 Sustainable Development and Environmental Health (SDE)
3.3.1 Local and Urban Development Unit (SDE/LU)
3.3.2 Risk Assessment and Management Unit (SDE/RA)
3.3.3 Healthy Setting Unit (SDE/HS)
3.3.4 Pan American Center for Sanitary Engineering and Environmental Sciences (CEPIS)
3.3.5 Institute of Nutrition of Central America and Panama (INCAP)
3.4 Technology and Health Services Delivery (THS)
3.4.1 Health Services Organization Unit (THS/OS)
3.4.2 Mental Health and Specialized Programs (THS/MH)
3.4.3 Essential Medicines, Vaccines and Health Technologies Unit (THS/EV)
4. OFFICE OF THE DIRECTOR OF ADMINISTRATION (AM)
Unit of Country Administrative Support (AM/CAS)
4.1 Human Resources Management (HRM)
4.2 Financial Management and Reporting (FMR)
4.3 General Services and Procurement (GSP)
4.4. Information Technology Services (ITS)
5. OFFICE OF THE DIRECTOR OF PROGRAM MANAGEMENT (DPM)
5.1. Strategic Alliances and Partnerships (SAP)
5.2. Governance and Policy (GPP)
5.2.1 Policy and Governance Unit (GPP/PG)
Gender and Health Unit (GPP/GH)
5.3. Planning, Program Budget and Project Support (PPS)
5.3.1 Program Budget Unit (PPS/PB)
5.3.2 Project Support Unit (PPS/PS)

5.4.	Strategic Health Development (SHD)
5.4.1	Human Resources Development Unit (SHD/HR)
5.4.2	Health Policies and Systems Unit (SHD/HP)

Anexo 4: Centros Colaboradores

Ver archivo anexo en Excel.

Anexo 5: Centros regionales y Sub-regionales

a. Latin American and Caribbean Center on Health Sciences Information (BIREME)
b. Caribbean Epidemiology Center (CAREC)
c. Pan American Center for Sanitary Engineering and Environmental Sciences (CEPIS)
d. Caribbean Food and Nutrition Institute (CFNI)
e. Centro Latinoamericano de Perinatología y Desarrollo Humano (CLAP)
f. Institute of Nutrition of Central America and Panama (INCAP)
g. Pan American Foot-and-Mouth Disease Center (PANAFTOSA),

Anexo 6: Descripción de los procesos del Registro

Ver archivo anexo en PDF

Anexo 7: Listado de Personas Entrevistadas

Nombre	**Departamento**	**Actividad**
Luis Gabriel Cuervo	Unidad de Promoción y Desarrollo de la Investigación	Entrevista, sesiones de trabajo
América Valdés	Unidad de Promoción y Desarrollo de la Investigación	Entrevista, sesiones de trabajo
Tania Pereyra	Unidad de Promoción y Desarrollo de la Investigación	Entrevista
Rebeca de los Rios	Unidad de Promoción y Desarrollo de la Investigación	Entrevista
François Fortier	Unidad de Promoción y Desarrollo de la Investigación	Entrevista
Patrica Ramos	Procurement Services Unit	Entrevista
Lucimar Coser canon	Country Support unit	Entrevista
Ana Leone	Programa de Publicaciones	Entrevista, sesión práctica software Revista Panamericana de Salud Pública
María Teresa Villén	Technical Planning, Program Budget and Association Project	Entrevista, sesion práctica Workflow

	Support	
Hernán Rosemberg	Technical Planning, Program Budget and Association Project Support	Entrevista
Roberto Rodriguez	Unidad de Promoción y Desarrollo de la Investigación	Entrevista
Roberto Samayoa	Procurement Services Unit	Entrevista
Marlo Libel		Entrevista
Henry Méndez	Information Technology Services (ITS)	
Charles Anstrom	Information Technology Services (ITS)	Entrevista, sesion práctica Workflow, sharepoint.
Mirta del Granado	Unidad Ténica	Entrevista
Henry Muñoz	Information Technology Services (ITS)	Entrevista
Daniel Purcallas	Representación de País	Correo electrónico
Henry Méndez	Information Technology Services (ITS)	Correo electrónico
Guillermo Troya	Representación de País	Correo electrónico
Julie Morrison	HighWire Press (http://benchpress.highwire.org/)	Entrevista, contacto correo electrónico
Enrique Hernández	Itandem.net	Entrevista, sesión práctica
Mike Wiley	Focus Technology Consulting	Entrevista Virtual
Lori Barber	Client Development Manager. Scholarone	Entrevista, sessión práctica
Ramón Granados	Representación	No se logró entrevista
Jacques Girard	Representación	No se logró entrevista
Edmundo Granda	Representación	No se logró entrevista
Germán Perdomo	Representación	No se logró entrevista
Marcelo D´Agostino		Correo Electrónico
Jeannie Kent	Staff development	Correo electrónico
Ana Kaul	Staff development	Correo electrónico
Zaida Yadón	Regional Adviser Communicable Disease Unit	Correo electrónico
D'Alessio, Ms. Rosario		No se logró entrevista
Lucía Jimenez		No se logró entrevista
Ana Kaul	Capacitación	Entrevista

Annex IV

Organización Panamericana de la Salud

Oficina Regional de la Organización Mundial de la Salud

CAIS 40/2007.08
ACHR 40/2007.08
Original: Spanish / English

40th ADVISORY COMMITTEE ON HEALTH RESEARCH (ACHR)

Montego Bay, Jamaica, 29th April to May 1st, 2007

Analysis RIS2000

Pan American Health Organization
2007

Summary of Findings:

Analysis of the PAHO Research Grant Program,

1985 – 2005

Table of Contents

Introduction

Part of the role of the Unit for Research Promotion and Development of the Pan American Health Organization (HSS/RC) is to support and evaluate the development of health research in order to strengthen, within a framework of international cooperation, the institutional capacities of the member countries (see table 1).

From 1985 until 2005 HSS/RC coordinated the Research Grant Program (RGP) o *Programa de Subvenciones de Investigación* (PSI), in Spanish. This document provides a primary analysis towards identifying details regarding the distribution and financing of the RGP. The objective of this study is to synthesize previous reports and, using available administrative data, describe the grants, and their application/use. Additionally, it could serve as a basis for a more in depth evaluation of the RGP's long term impact in the region.

The RGP was formally established by the **Directive 01-85**, which in February of that year determined the norms for the program.[1] The program was placed under the coordination of the Research Promotion and Development Unit (then known as the DRC Unit), two years after the creation of the Grants Fund with USD $1.27 million dollars made available.[2] This **Directive** also identified 11 priority areas and themes, which were modified to 15 in 1988 (when different modalities for the projects were also established) and were later reduced to 5, in 1994. Finally, in the 2000 report to the Advisory Committee on Health Research (ACHR) various modalities were identified – including:

1. grants focused on increasing opportunities for training and educating researchers, including:
   - grants for theses (masters or doctorate)
   - grants for training for public health researchers
2. grants emphasizing general knowledge, including:
   - promotion and support of collaborative multi-centric projects
   - promotion of research projects through regional research competitions[3]

Of the 35 member countries, 30 have participated in one or more of the aforementioned categories supported by the RGP. The themes and priority areas have been modified various times throughout the 21 years.

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[1] XXVII Meeting of the Advisory Committee on Health Research. Evaluation of the PAHO/WHO Research Grants Program for the period of 1985-1988. Washington, DC 5-8 September, 1989: pg.1

[2] XXV Meeting of the Advisory Committee on Health Research, Report to the Director. Washington, DC 21-25 April 1986: pg. 7.

[3] Health Research Coordination. Division of Health and Human Development. *XXXV Meeting of the Advisory Committee on Health Research. Havana, Cuba. 17-19 July 2000. PAHO Research Grants Program Report*. Washington, DC. April, 2000. pg. 2.

This program was implemented without interruption until 2005, when it was halted. An existing perception of the program argued that the funds, originally designated to build capacities and a critical mass of researchers to contribute to the development of research in public health, were not reaching the places with the greatest need; instead, the program favored countries where such capacities were already firmly established. In other words, the system for managing the program has not been modified to accommodate change, making it necessary to pause and evaluate it. This study will determine whether this perception is well-founded.

Table 1: List of Member, Associate and Observer Countries

CENTRAL AMERICA		CARIBBEAN (SPANISH)		ANDEAN REGION		SOUTHERN CONE	
BLZ	Belize	CUB	Cuba	BOL	Bolivia	ARG	Argentina
COR	Costa Rica	DOM	Dominica	COL	Colombia	BRA	Brazil
ELS	El Salvador	DOR	Dominican Republic	ECU	Ecuador	CHI	Chile
GUT	Guatemala	HAI	Haiti	PER	Peru	PAR	Paraguay
HON	Honduras	PUR	Puerto Rico †	VEN	Venezuela	URU	Uruguay
NIC	Nicaragua						
PAN	Panama						

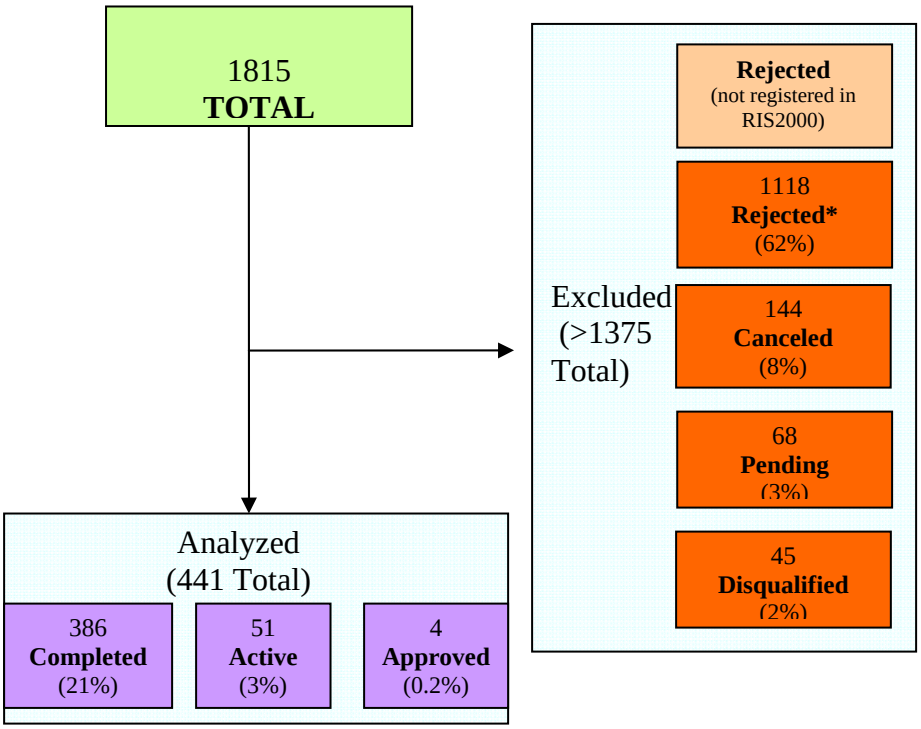
EUROPE		NORTH AMERICA		CARIBBEAN (ENGLISH)	
FRA	France*	CAN	Canada	ANI	Antigua and Barbuda
NET	Holland*	MEX	Mexico	BAH	Bahamas
UNK	United Kingdom	USA	United States	BAR	Barbados
SPA	Spain**			GRA	Grenada
POR	Portugal**			GUY	Guyana
				JAM	Jamaica
				SAL	Santa Lucia
				SAV	San Vicente & Grenadines
				SCN	St. Kitts and Nevis
				SUR	Suriname
				TRT	Trinidad and Tobago

* participating country
** observer country
† associated member

Materials and Methods

The *Pan American Health Organization Research Information System* (RIS 2000) database, available on Microsoft Access and managed by HSS/RC, was used to carry out this study. The database registers a total of 1,815 projects, of which 437 (24%) correspond to completed projects (386; 88%) or active projects (51; 12%). Many of the remaining 1,378 projects did not advance to the next round, but it is important to note that not all the rejected projects were registered in the database. Additionally, there are 4 approved projects identified as pending, awaiting commencement or financing. The remaining projects were classified as such:

Figure 1: Analyzed Projects



*The data regarding the rejected projects are not reliable. Not all the rejected projects were registered in the *RIS2000* database.

Explanations documenting how the registry was developed or what criteria were used to categorize the information in the database are not available. Before carrying out the analysis the database was updated and organized, so that the electronic information matched the available hard copies. The following eight variables were considered when planning the analysis:

1. country where projected is registered
2. project identification code
3. date project was received by PAHO
4. date project is begun
5. total cost of the project
6. project duration
7. gender of the registered principal investigator
8. sponsoring institution

The study was guided to answer the following questions:

1. How were the projects distributed?
2. How were the funds distributed?
3. How long did the projects last, on average?
4. What was the distribution of institutions that participate in more than one project?

5. How was the gender of principal researchers distributed?

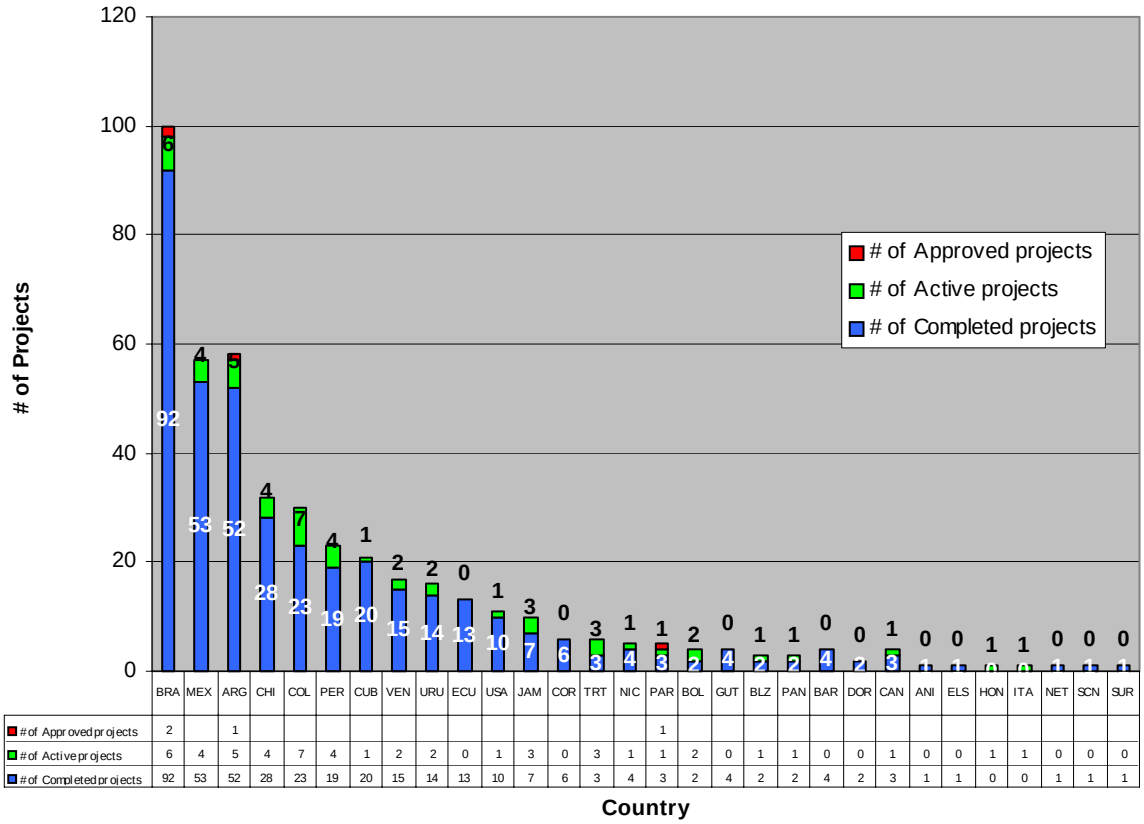
Ideally, the analysis would have included classifying the projects by theme or categories (thesis, training, etc.); however, it was impossible to do so since the database did not contain this information. Additionally, the database did not register whether the researchers went on to publish their work, or if there were any mechanisms available for the dissemination or implementation of the conclusions produced by their projects.

SPSS version 15.0 for Windows was used to carry out the analysis of univariate and bivariate distributions.

Results

The following information analyzes the completed (386), active (51) and approved (4) projects.

Figure 2: Distribution of Projects by Country



	BRA	MEX	ARG	CHI	COL	PER	CUB	VEN	URU	ECU	USA	JAM	COR	TRT	NIC	PAR	BOL	GUT	BLZ	PAN	BAR	DOR	CAN	ANI	ELS	HON	ITA	NET	SCN	SUR
# of Approved projects	2		1													1														
# of Active projects	6	4	5	4	7	4	1	2	2	0	1	3	0	3	1	1	2	0	1	1	0	0	1	0	0	1	1	0	0	0
# of Completed projects	92	53	52	28	23	19	20	15	14	13	10	7	6	3	4	3	2	4	2	2	4	2	3	1	1	0	0	1	1	1

Approved Projects

Approved projects refer to those that have been approved by PAHO's Ethical Research Committee, but were not yet begun when this study was carried out; as a result, their completion is not definite. These projects represent two in Brazil, one in Paraguay and one in Argentina.

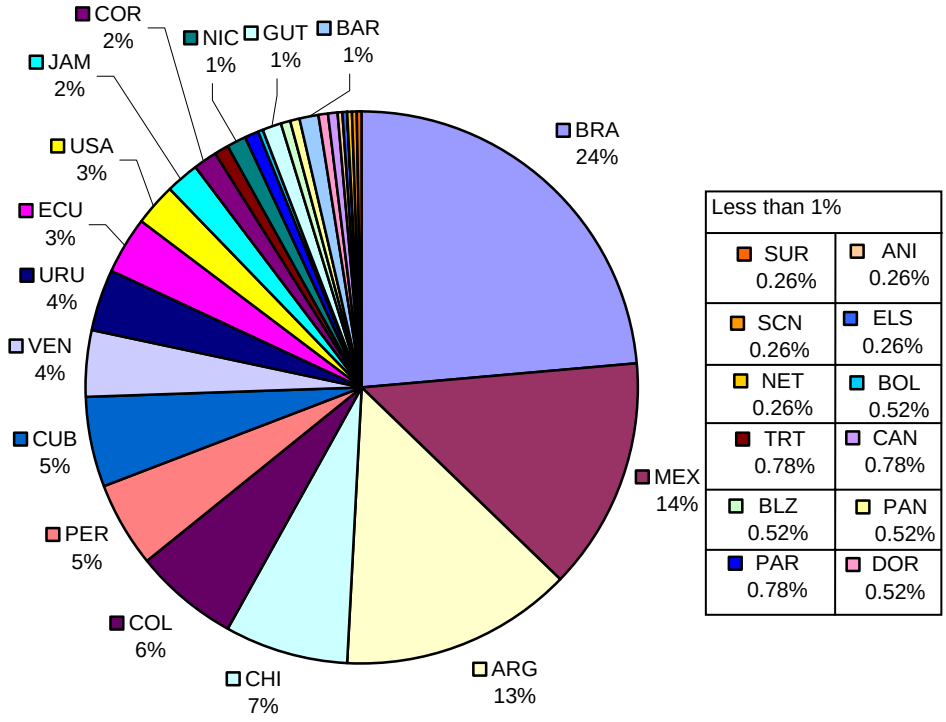
Active Projects

These projects have already commenced. The category includes those that have already collected data but have not submitted a final report. The 51 active projects are distributed throughout 20 countries, as illustrated by Figure 2, noting the four of these projects are taking place in priority countries: two in Bolivia, one in Nicaragua, and one in Honduras.

Completed Projects

The 386 complete projects were performed between January 1st, 1985 and March 30th, 2005 (see figure 3). Nearly half of the projects took place in three countries: Brazil, Mexico, and Argentina. Seventy-five percent of the projects were executed in seven member countries: the aforementioned three, Chile, Colombia, Peru and Cuba.

Figure 3: Distribution of Completed Projects by Country

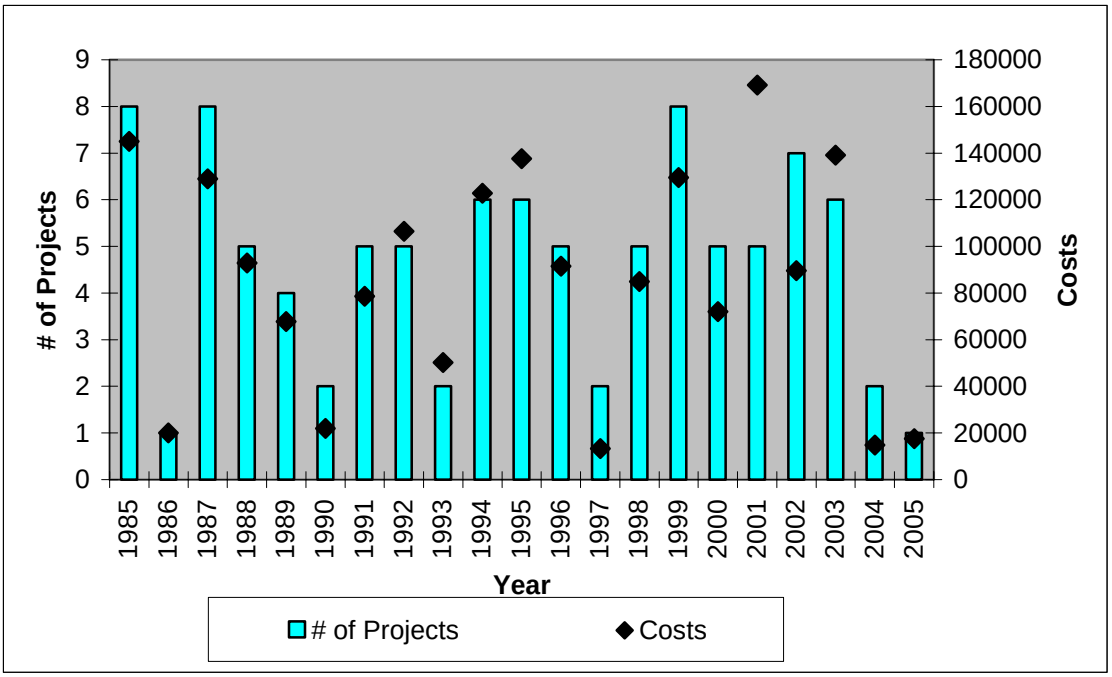


Distribution by Country

Brazil

Brazil has produced the greatest number of projects: 97 (22%) in the past 21 years since RGP was established. Of these 97, 6 are still active, and 2 have been approved. Figure 4 illustrates the association between the number of projects and the amount of funds allotted by year.

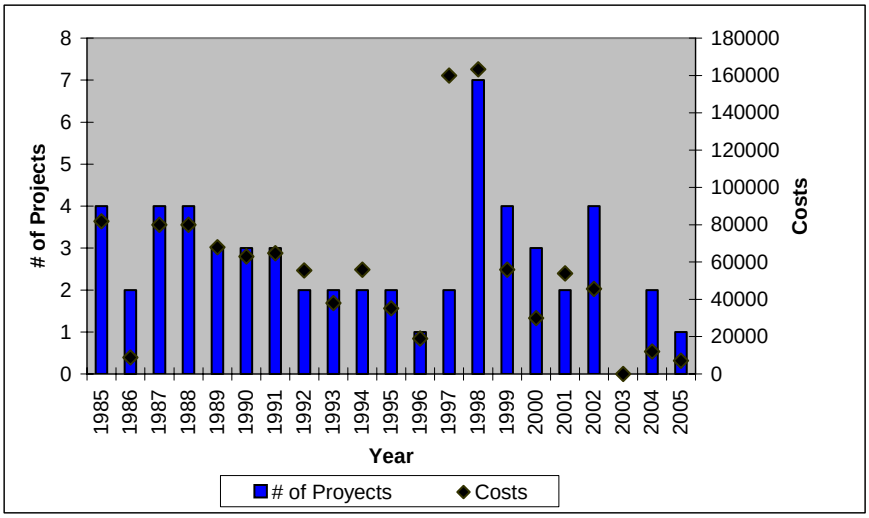
Figure 4: Association between Projects and Funds in Brazil



Mexico

Mexico is the second largest receiver of funds from the RGP with 57 projects (53 completed and 4 active), representing a 13% of the total number of projects analyzed. In actuality, the number of projects performed in Mexico equals those performed in Argentina. In terms of funds, however, Mexico has received a larger amount, totaling USD $ 1,177,559.

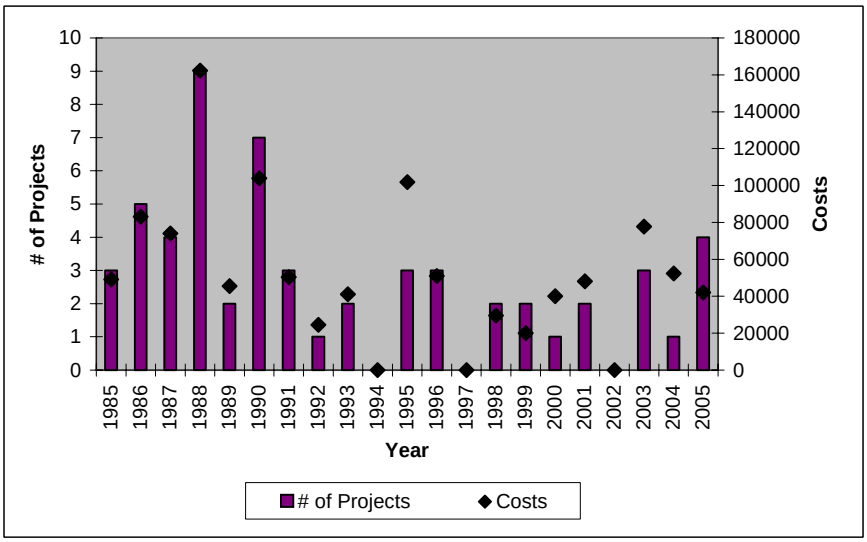
Figure 5: Distribution of Projects by Year and Cost in Mexico



Argentina

In 1988, Argentina produced the largest number of projects with 9 selected from the pool of applicants. In total Argentina received USD $ 1,096,566 in 21 years, with 52 completed projects, 5 remain active and 1 has been approved.

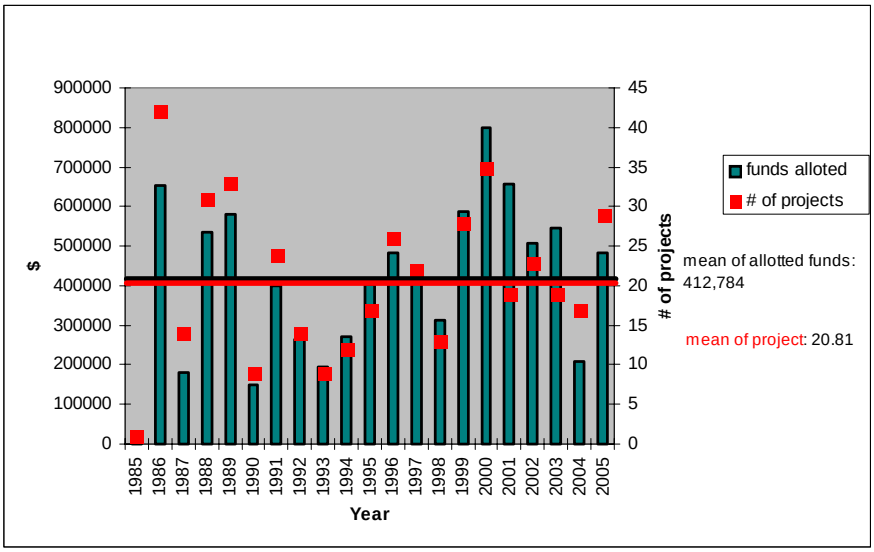
Figure 6: Distribution of Projects by Year and Cost in Argentina



Yearly Distribution of Funds

In the 21 years that the RGP was operating, a total of USD$ 8,668,458 were dispensed, to approved, active, and completed projects. The average number of projects per year was 21; while the average amount of funds distributed per year was USD $412,784.

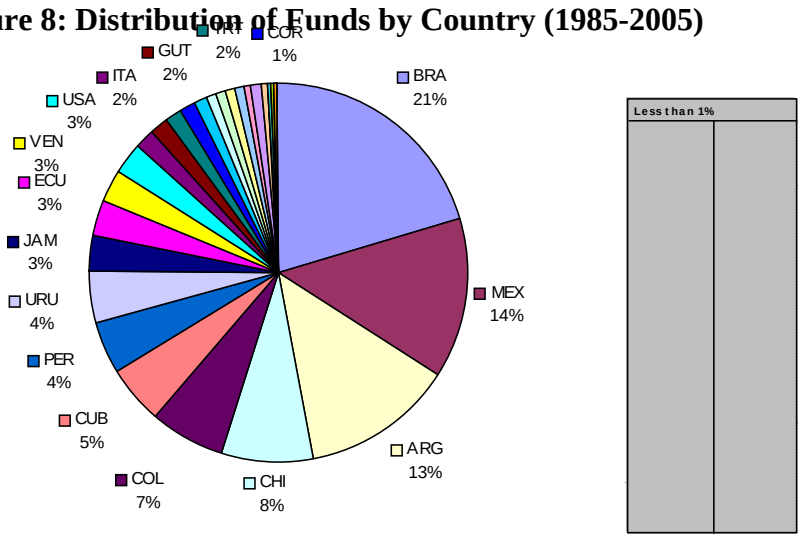
Figure 7: Distribution of Projects and Funds per Year



Distribution of Funds by Country

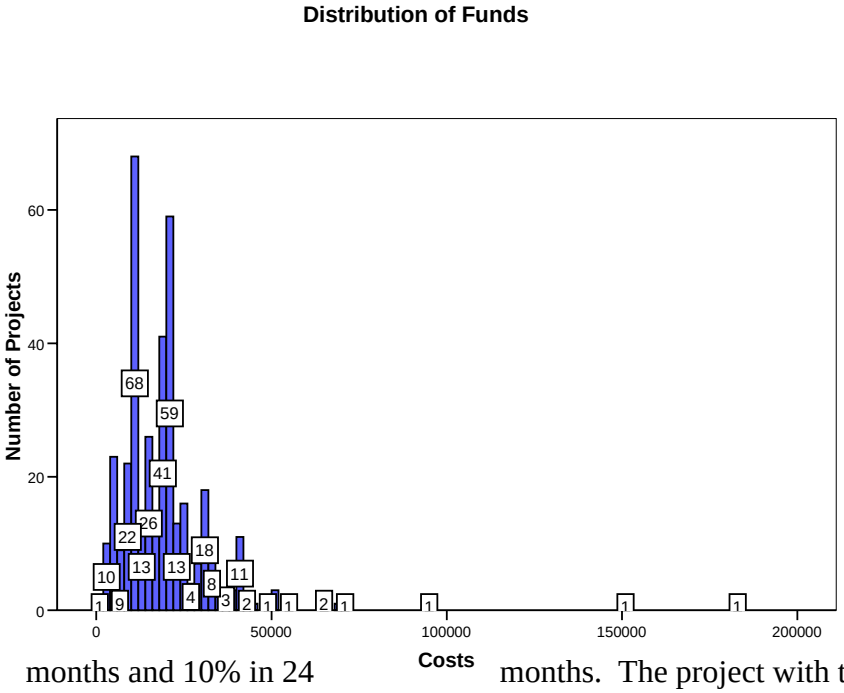
Of the USD $8,668,458 allotted, Brazil received the largest amount of funds (21%), followed by Mexico (14%) and Argentina (13%) as illustrated by Figure 8.

Figure 8: Distribution of Funds by Country (1985-2005)



The range of total costs for the projects spread between USD $1,800 to USD $182,000. The amount most frequently allotted (mode) was of USD $10,000, which was distributed to 68 projects. The mean amount allotted was USD $19,457, while the median was of USD $18,569.

Figure 9: Spread of Allotted Amounts (in dollars)

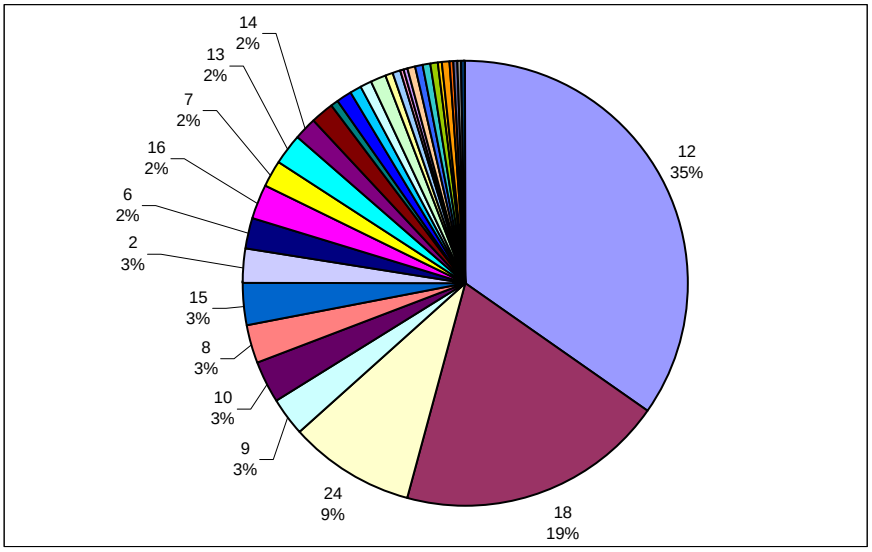


Duration

A third of the projects (34%) were completed within 12 months of their start day; 22% finished within 18 months and 10% in 24 months. The project with the shortest duration was

completed in 2 months and the longest was realized in 48 months. Figure 10 illustrates the distribution of projects according to their duration.

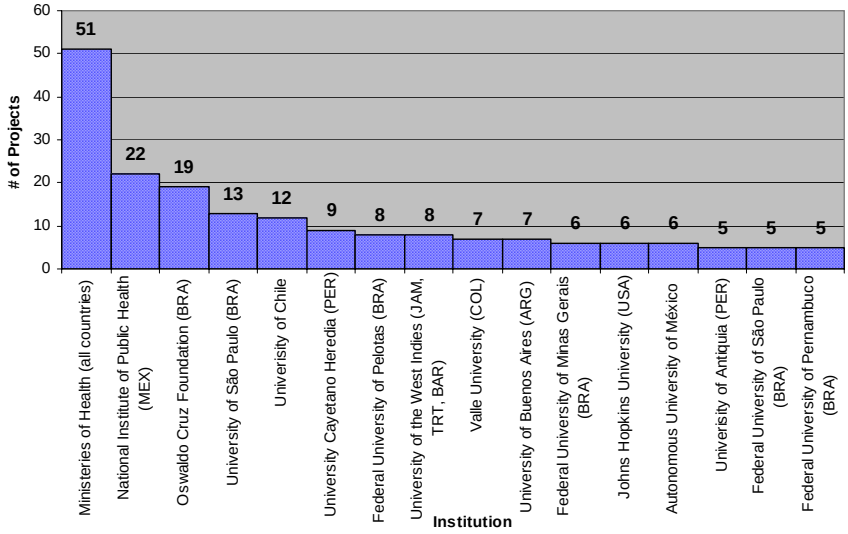
Figure 10: Distribution of Project Duration (in months)



Sponsoring Institutions

The Health Ministries in all the countries have contributed with a number of projects, 51 total: the National Institute of Public Health in Mexico sponsored the greatest number of projects, with 22; in Brazil, the Oswaldo Cruz Foundation (FIOCRUZ) backed 19 projects. Universities and other academic centers were also frequent supporters of RGP projects. Many Brazilian universities were among the 20 most frequent sponsors, including the Universities of São Paulo, Pelotas, Minas Gerais, and the Federal Universities of São Paulo and Pernambuco

Figure 11: Most Frequent Sponsoring Institutions



Distribution by Gender

The balance of distribution by gender has been relatively equal, with 41% of the principal researchers identified as females and 54% identified as male. Five percent of the registry information regarding the gender of the principal investigator was missing and could not be recovered by other means.

Figure 12: Distribution of Funds by Gender and Year

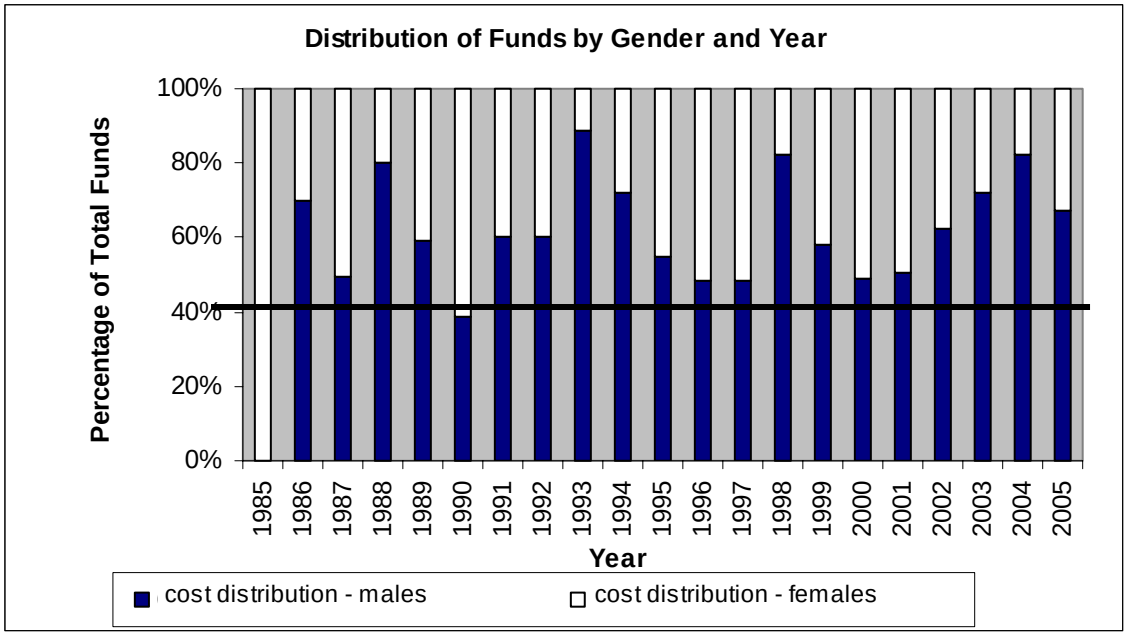
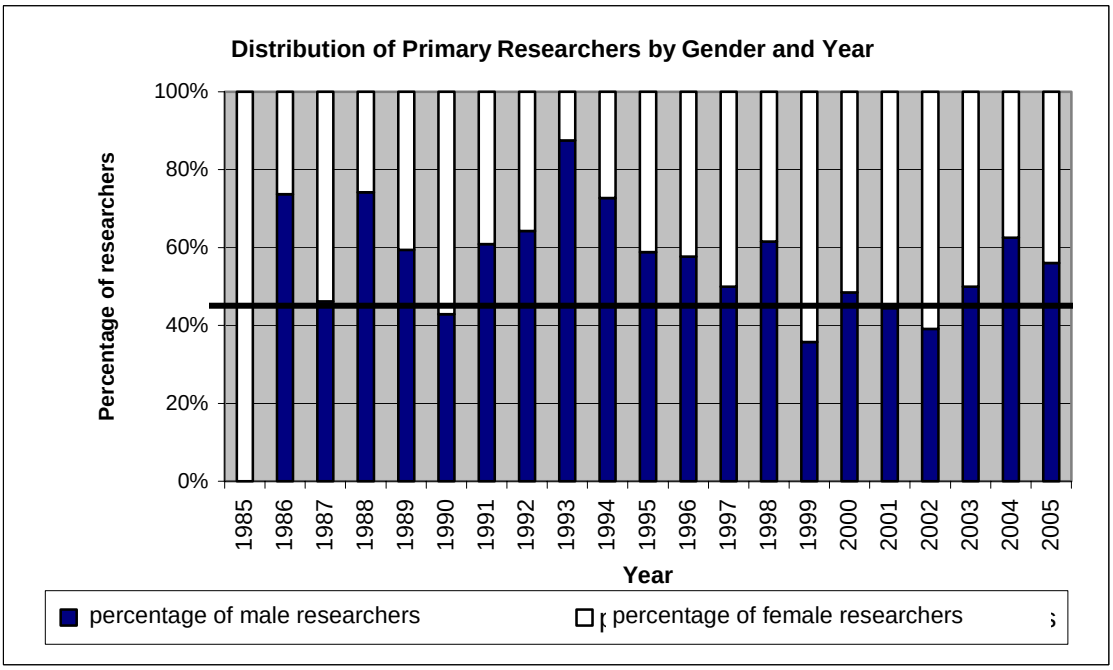


Figure 13: Distribution of Primary Researchers by Gender and Year



Internacional Multicentric Projects

The RGP financed 9 multicentric projects: each followed the same protocol, but was carried out in different countries. The following list describes these projects in more detail:

Table 2: List of Multicentric Projects

Project Title	Date	Contributing Countries
Research on Health Profiles	1986-1987	Argentina, Mexico, Brazil, Cuba, Paraguay, Suriname, Uruguay
Attitudes and Cultural Norms regarding Violence in Select Cities of the Region of the Americas.	1996	Brazil, Chile, Colombia, Costa Rica, El Salvador, Venezuela
Health, Well-being and Aging in Latin America and the Caribbean (SABE)	1998-1999	Argentina, Chile, United States, Mexico, Cuba, Brazil, Uruguay
Inequities of the State of Health, Access and Spending on Healthcare.	2000	Bolivia, Brazil, Colombia, Peru
Comparative Gender Analysis of Dietary and Exercise Behavior in the Caribbean.	2000-2001	Belize, Trinidad y Tobago, Jamaica, St. Kitts and Nevis
Nutritional State of Adolescents during Pregnancy and Lactation	2001	Guatemala, Dominican Republic, Uruguay
Costs of Medical Attention for Diseases Attributed to Tobacco Consumption	2002	Brazil, Chile, México, Colombia
Forging a Strategy to Prevent Early Childhood Malnutrition through Improving Complementary Feeding and Access to Fortified Foods.	2002-2003	United States, México, Brazil, Jamaica, Panama
Gender, Alcohol, Culture and Harm.	2004-2005	Canada, Belize, Nicaragua, Peru

Conclusions

This study illustrates the general distribution of the projects of the RGP of the PAHO to present some of the tendencies of the program. The following recommendations are based on the observations gathered from the analysis.

1. The study corroborates the perception that the grants awarded by the RPG favor experienced institutions and researchers. Another common perception of the program is that it has been important to strengthening institutions and capacities.

Yet, in order to substantiate these beliefs it would be necessary to perform a more in depth study to incorporate qualitative aspects, such as: the perceived effect of the projects on research, the consolidation of research in participating centers, the perceived impact on the career of the researchers, the dissemination and use of the obtained results, the immediate use and acknowledgment of results in politics and practices. We propose that the Organization lead such an investigation.

2. While such an evaluation takes place, it would be best to continue the program with important changes. First, to promote a more equitable distribution, a process to identify priority themes and guide the RGP towards the needs and priorities outlined by the member countries must be instituted. At the same time this process will define if the RGP is proposed as an instrument to generate capacities or to advance strategic investigation in public health. Second, this process will also promote the development of strategic alliances between countries, for example, through international multicentric projects that involve countries with different levels of development, focused on strengthening the systems and capacity for research in public health. Finally, if necessary, the implementation of a quota or qualification system, which would favor projects oriented towards developing research in areas with the greatest need and potentially having the largest impact, could be considered.

3. This evaluation also allowed for the identification of certain characteristics of the registry system (RIS2000) that can be improved or considered in the development of a new database which will respond to current needs.

i. It is necessary to increase the quality of the registry and create incentives for the comprehensive inclusion of information. It would be ideal to have access to data which would allow for an analysis according to the project's topic specifically in reference to priority areas and modalities delineated by the Organization. These categories might include information on the following:

    a. Identify the modality of the project as either training, education (i.e. masters or doctoral thesis), multicentric project, or regional research competition

    b. define and identify themes and categorization of each project

    c. further information regarding the sponsoring institution (i.e. whether it is public or private, etc.)

ii. In reference to the classification of a project's status, it is be important to have a system of structured categorization system that allows for the addition of details such as the reasons why a project is rejected, cancelled or disqualified.

The authors recognize that the evolution of health research in the region is of great importance. Bettering the infrastructure, organization and follow-up of the Research Grants Program is fundamental for furthering research in the region of the Americas.

Authors

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Annex V

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EVIPNet

Pan American Health Organization
2007

EVIPNet: Evidence-Informed Policy Networks
Pan American Health Organization

Bridging the gap between research and policy

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Introduction

Research evidence should be the basis of good decision-making when addressing important health policy or system issues such as extending health coverage, insurance schemes, human resource distribution, provision of diagnostic and therapeutic options, updating and implementing recommendations and guidelines, financing or the millennium development goals such as maternal and child health, HIV/ AIDS control, malaria and other diseases. This is especially important in low and middle income countries which have limited resources yet a disproportionate amount of health issues. Despite the general recognition of the merit of research evidence, the access and application of high quality research results is limited. There are many reasons for this gap: either the evidence is of poor quality, not relevant to the issues faced by local health officials; not available in time of need or in a user-friendly format or perhaps not valued as an important element to the decision-making process.

The Pan American Health Organization is providing leadership in increasing the availability and use of high quality research within Latin American and Caribbean countries through a program called EVIPNet (Evidence Informed Policy Networks). This program is being organized by the Research Promotion and Development Unit (the Unit), which is part of the Health Systems Strengthening Area. PAHO recognizes that if we are to succeed in promoting better decision-making on important health issues, a collective effort among many countries is needed to realize improvements in the production and use of research evidence.

2. The rationale for EVIPNet

During the Ministerial Summit in Mexico City, Ministers of Health from low and middle income countries stressed that more attention needs to be given to bridging the gap between research, policy and practice. Therefore, the 58th World Health Assembly subsequently endorsed a resolution from the Ministerial Summit that called for “establishing or strengthening mechanisms to transfer knowledge in support of evidence-based public health care delivery systems and evidence-based health-related policies” in May of 2005. This resulted in the development and launching of EVIPNet in Asia (2005) and Africa (2006).

In Latin America countries have expressed the need for technical cooperation to help strengthen their health research systems. Furthermore, the report on Public Health in the Americas (PAHO, 2002) ranked research as one of the least developed essential public health functions. Both this need and the expressed interest from countries are important factors in launching an initiative to increase the use of research.

3. What is EVIPNet

EVIPNet is an innovative mechanism designed to improve health and reduce health inequities by increasing decision and policy makers' access and use of high quality evidence. This will occur through creating mechanisms to capture readily available knowledge, its dissemination, sharing and application of such knowledge to influence policy and decision making. Ultimately, EVIPNet represents a partnership between policy-makers and researchers to support the access and use of the best quality research evidence at the local and global level.

The concept and theoretical framework for EVIPNet is based upon the lessons learned and research on how to maximize the likelihood that research evidence is used to shape policy and practice. Please see Appendix I for an overview of EVIPNet: how it works, its implementation and history in Asia and Africa.

4. EVIPNet in the Americas

PAHO, in its role as regional office for the Americas of the WHO, is organizing the launch of EVIPNet in selected countries within its jurisdiction during 2007. To ensure the successful planning and implementation phases of the initiative, PAHO is building on the lessons learned during the launch of EVIPNet in Asia and Africa. Those relevant for the Americas include:

- Each country must define its priority areas for EVIPNet implementation. This varies from country to country and depends upon the particular health needs of each country as well as the existing infrastructure.

- Each country must have an EVIPNet champion. A person or group of persons devoted to the successful implementation of EVIPNet is of paramount importance. These individual(s) provide ongoing leadership and direction over the implementation phase of EVIPNet (regardless of the country's political cycle).

- The deployment of EVIPNet requires a strong Secretariat and active strategic planning that monitors and adjusts to a changing environment and the invidividual needs of countries.

EVIPNet Americas will be introduced in stages. In the first stage, efforts will target a selected group of pilot countries that have already expressed interest and sought technical cooperation to strengthen the use of evidence among their policy makers. Other countries will be invited to develop applications during the second stage. It is anticipated that the second round of countries will work with and learn from the first grouping of countries. Please see Appendix II for an overview of the timeline for EVIPNet implementation.

4.1 Country selection

The pilot countries were chosen according to the following criteria:

- Countries that are priorities for PAHO.
- Expression of interest: Countries that have indicated their will to participate in the implementation of EVIPNet.
- Synergies with the existing Country Cooperation Strategy
- Capacity: research strength, links to policy.
- Commitment of funding.
- Policy and government stability.
- Regional distribution

Based on the above criteria the following countries were invited to be part of the first round of EVIPNet:

- Bolivia
- Brazil
- Costa Rica
- Chile
- Mexico/El Paso
- Paraguay
- Puerto Rico
- Trinidad & Tobago
- Colombia

We have received positive response from 6/10 countries. The Ministries of Health from Brazil, Paraguay, Trinidad and Tobago, and Bolivia have yet to respond to our invitation. We recognize that the countries chosen have varying capacity issues, resources and experience in using research to inform decision-making. We hope to capitalize on these differences by facilitating partnerships (Costa Rica, Brazil and Chile have already signed a technical cooperation agreement on research) and supporting countries where ever their starting point may be.

4.2 Launching EVIPNet in the Americas

The first goal will be to build a strong foundation for EVIPNet namely in the following areas:

- Building in-country stakeholder ownership
- Developing initial communication tools
- Introducing EVIPNet to country teams

- Developing a governance model for EVIPNet Americas
- Securing funding
- Establishing evaluation protocols
- Ensuring a strong secretariat

4.2.1 Building In-Country Stakeholder Ownership

Over the next few months PAHO will meet individually and collectively with representatives or delegates from each of the selected pilot countries. The meetings will be designed to discuss expectations, ideas and strategies for the planning and implementation phases of the network, building on in-country capacity and infrastructures. The active support and involvement of PAHO representatives (PWRs) is of paramount importance to the success of this initiative, therefore they will be involved in this preparatory phase through regular face-to-face and virtual meetings. Through the PWRs, the Unit will identify country champions for EVIPNet; an element that has proven critical in advancing EVIPNet in Asian and African countries to date.

4.2.2 Developing initial communication tools

It will be critical to develop appropriate communication tools that will effectively market and promote the concept for EVIPNet thereby supporting the above activities related to building in-country support. To this end, the Unit has developed a brochure designed specifically for PWRs which covers such topics as the concept, the planning and implementation phase expectations and considerations based on lessons learned from Asia and Africa. A modified version of the brochure will also be created for funders and also general use. The Unit has designed a common restricted access web site (on Share Point platform) where PWRs and others can access key EVIPNet documents. In the coming months a web portal will be developed for all EVIPNet countries worldwide which will serve as a one-stop access point for communication among teams (both through a bulletin board and real-time connection) and linkages to key databases.

4.2.3 Introducing EVIPNet to country teams

Building on the launching processes for EVIPNet Asia and Africa, PAHO will hold an invitational workshop in Washington on July 2 and 3, 2007 for potential county team leaders. At this meeting we will present the concept for EVIPNet, share experiences from existing EVIPNet countries and discuss strategies for developing planning phase applications of intent. Teams will be expected to submit applications by October 2007 (see Appendix II for the detailed schedule).

4.2.4 Developing a governance model for EVIPNet Americas

Recognizing that for EVIPNet to succeed it will require country commitment. To that end, at the July meeting we will also discuss possible methods to maximize intra-country ownership such as appropriate governance models, communication channels, and funding sources. EVIPNet Asia and Africa are also working towards configuring teams within their region into collective networks. It is expected that representatives from each of the three regional networks will form a global EVIPNet network and provide ongoing strategic direction of EVIPNet internationally. WHO through WPRO, AFRO and PAHO, as well as headquarters, will provide facilitation and secretariat support.

4.2.5 Securing funding

In order to kick start EVIPNet dedicated funding will be required to support the various activities listed in this paper in addition to providing seed funding to teams during the planning phase. PAHO in coordination with Geneva WHO office is actively seeking support from various foundations and appropriate donor countries. We will also investigate the likelihood of in-country support where possible which should also help to maximize country support and sustainability over time.

4.2.6 Establishing evaluation protocols

We recognize that EVIPNet is an experiment onto itself. Although the concept is based on evidence of what works in reducing the gap between research and policy and practice it is important to evaluate the impact of implementing EVIPNet. Expected results could include short term process measures such as use of the services by decision-makers, number of searches for evidence, number of consultations, any change in the linkage and exchange among creators and users of evidence, and the degree of interest in training workshops. More medium and longer term outcomes could be the degree to which evidence helped inform policies and health system management, organization or functioning, and any change in decision-makers awareness, knowledge and attitudes towards evidence. An international team has already been established and the initial protocol has been developed. Funding of the study, obtaining team commitment to providing information and launching the evaluation are the next steps. A PhD student from McMaster University in Canada will assist with establishing and maintaining an evidence base for EVIPNet in the Americas.

4.2.7 Ensuring a strong secretariat

It is the dedication of people that will be the key driving force behind EVIPNet. We have already discussed the importance of identifying the right champions within countries, obtaining buy in from Ministry's of Health, and tapping into the expertise of PWRs. A strong core secretariat team based at PAHO, supported by technical experts already involved in EVIPNet as well as those affiliated with initiatives and organizations that can play a supportive role is also key. PAHO is committed to providing leadership for EVIPNet as part of its strategic vision.

SUMMARY

The need for promoting the use of health research in low and middle income countries, specifically those in Latin America and the Caribbean is great. The resources required to have significant impact are fortunately within our collective ability. What is needed is demonstrated leadership from a variety of individuals, groups and countries to join forces to work together towards long term change. EVIPNet has already proven to be a successful model to do just that.

Appendix I
EVIPNet Overview

How EVIPNet Works

The implementation of EVIPNet is shaped by each country, based on its own particular needs and realities in order to strengthen the links between policy-makers, health system managers and researchers. The long term goal is to develop a sustainable mechanism to promote the access and use of research evidence by integrating systematized evidence with other necessary health information.

In addition, EVIPNet will contribute to improving the relationship between the producers and users of evidence through training opportunities and will build capacity of decision- and policy-makers to access and apply evidence. The overall objective of EVIPNet is to decrease the gap between research and health decision and policymaking by improving the standards in evidence-informed decision making through the collection and dissemination of high quality evidence and through strengthening local and international partnerships.

How EVIPNet is Implemented

One of the main principles of EVIPNet is that it must include representatives from it core target audiences. Therefore the implementation effort should actively involve policy makers and researchers under the leadership of the Minister of Health or equivalent high ranking officer. The participation of civil society is encouraged and each country should decide on the best approach for such involvement (as team members, advisors, etc.).

Teams can function regionally within a country, nationally or assist other countries in the region. They are expected to have the flexibility to respond to current and emerging health issues based on the needs within their jurisdiction and be in a position to work with a variety of user groups. Key to the EVIPNet concept is the two stage process in which teams are brought together to develop their concept for how they will carry out work to support decision-making within their region/country (called the Planning Phase) and then the actual conducting of the work (called the Implementation Phase). Also it is essential that teams are comprised of both policy makers and researchers and that a governance model reflects the equal role of both groups in advancing evidence-informed decision-making.

EVIPNet teams once up and running are expected to focus on all, or at least the majority, of the following objectives:

- Enhance linkages between and among the producers and users of evidence.
- Acquire, assess, and adapt systematic reviews and other types of evidence relevant to the needs of decision-makers.
- Commission and/or update systematic reviews of health research

(especially local research), or communicate the need for specific reviews to groups that are involved in knowledge synthesis.

- Commission or communicate the need for new health research when gaps are identified and assist with the setting of research agendas for more policy-relevant research.
- Design, implement and promote strategies to enhance the uptake of evidence by decision and policy-makers and those who seek to influence them.
- Provide training opportunities to develop the capacity of decision and policy-makers to access and apply evidence.
- Provide decision and policy-makers 'one-stop shopping' for high quality evidence.
- Partner with existing organizations engaged in any of the above functions.

EVIPNet Launch in Asia

The World Health Organization officially launched EVIPNet is its Western Pacific Region in June 2005 in Kuala Lumpur, Malaysia. Five countries (China, Laos PDR, Malaysia, Philippines and Vietnam) were invited to submit letters of intent to become a network (three regions in China; Beijing, Shandong and Sichuan provinces formed separate teams). The letters of intent were reviewed by an international panel of experts who have extensive experience in the research to policy field. Funds were awarded for the planning phase in the fall of 2005. Over the following eight month period applicants further developed their teams, created partnerships with key stakeholders (such as government departments, research institutions, civil society groups); conducted priority setting consultations to determine early areas of focus; and crafted the concept for their approach to EVIPNet resulting in a 5 year plan with corresponding goals, objectives, outcomes and budget. These plans were again reviewed by the international panel in October 2006 with modest funds for selected first year activities released in December 2006.

EVIPNet Launch in Africa

The concept and theoretical framework for EVIPNet is based on what has been learned from the research on guiding principles in maximizing the likelihood that research evidence is used in shaping policy and practice. However, the field of knowledge translation is still very much in the developmental phase and therefore it is critical that a process and outcome evaluation process of EVIPNet is included as a promising approach to strengthening the use of research. Such was the case with the launch of EVIPNet in Africa. WHO learned from what worked and what could be improved from the launch in Asia and adjusted the way in which it launched the program in Brazzaville Congo in March 2006. Seven countries were invited to develop applications of intent; they are Burkina Faso,

Cameroon, Centrafrique, Ethiopia, Mozambique, Niger and Zambia. As with Asia an international review panel assessed each team's application and provided comments on strengths and areas for improvement. Another critical element of the EVIPNet concept is that the goal of the initiative is not to merely fund the strongest teams but to build overall capacity for promoting the use of research in countries regardless of their current ability and resources. WHO is firmly committed to 'not leaving any teams behind' and therefore in addition to providing initial funding support has actively worked with various teams to help understand their needs and resources and to further develop their concept for EVIPNet and necessary support to increase their in-country expertise.

African teams were awarded modest planning phase funds in November 2006 and are now undertaking activities such as developing their teams, fostering partnerships with stakeholders, establishing priorities and creating the concept for 5 years of EVIPNet work.

Appendix II
EVIPNet Americas Timeline

Timetable	
January/February 2007	Selection of potential countries to be invited to submit Applications of Intent (AOIs); preparation of budget; organize planning workshops/meetings
March – June, 2007	Planning workshops with PWRs and resource group – virtual meeting out of Washington
March – July 2007	Planning of country workshop launch & collaborating with local representatives
July, 2007	Country workshop to launch EVIPNet Americas – Washington DC
July – Sept, 2007	Creation of AOIs by teams
October 1, 2007	Submission of AOIs will be due **October 1, 2007.**
October and November, 2007	Review process for planning phase AOIs
December 1, 2007	Synthesize reviewers' comments; decide on results and communicate to teams by **December 1**
December – June, 2008	Planning Phase
July 1, 2008	**Implementation Phase** Application Deadline
July – September 2008	Review process for implementation phase applications
October 1, 2008	Notification of decision for the **Implementation Phase** and awarding of funds.

Annex VI

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Montego Bay, Jamaica. April 29th to May 1st, 2007

An overview of health research policy in the Americas and a proposal for PAHO/WHO's research policy[1]

Pan American Health Organization
2007

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An overview of health research policy in the Americas and a proposal for PAHO/WHO's research policy

Abstract: A literature search on health research policy was carried out in order to propose a model for the development of the Pan American Health Organization (PAHO/WHO) research policy. Emphasis was placed on documents produced by the World Health Organization (WHO), PAHO/WHO and Latin American and Caribbean countries. Results of this search are presented and a research policy is proposed for the Organization, which may respond to the directives of its Governing Bodies and the challenges posed by PAHO/WHO's own structure, the diversity of contexts in the Region and the state of the art of knowledge on the development of Health Research Systems.

1 Background

Some key events in global and regional research policies development are presented next.

1.1 Global health research policies

The importance of health research as an instrument for equitable development has gained ground at the global level since 1990. On that year, the **Commission on Health Research for Development,** an initiative independent of international agencies and created on 1987, published its final report, presented at the Nobel Conference in Stockholm, Sweden[2]. Among the Commissions' findings is the concept of the "10/90 gap", meaning that only 10% of funds invested in health research respond to the problems of 90% of the world population. In its report the Commission proposed a series of measures to increase national health research capacity, including increasing the priority assigned to health research in national development plans, acknowledging research as a useful tool for health development and increasing collaboration amongst scientists from different places in the world. Recommendations to advance this vision were:

a) To promote Essential National Health Research (ENHR)

b) To stimulate international partnerships for health research for development

c) To mobilize larger funding for health research

d) To set up a forum for the review and advocacy of these concepts and strategies

The **Task Force on Health Research for Developmen**t was established in 1991, with the mission of advancing the Commission's recommendations and to support country level activities. This Task Force developed the Essential National Health Research (ENHR) strategy. In 1993 the **Council on Health Research for Development (COHRED)** was created as an international mechanism to facilitate the implementation of ENHR.

[2] Commission on Health Research for Development. Health research: essential link to equity in development. Oxford: Oxford University; 1990

In 1998 the **Global Forum for Health Research** was established as an independent foundation based in Switzerland. Its mission includes: to change priorities regarding how health research resources are presently used, to promote the direction of new resources to research on neglected areas, as well as to promote research on neglected areas to reduce the burden of disease and disability.[3] The Global Forum's main activities include original research on health research funding and the yearly organization of a Health Research Forum which sheds light on the problems and achievements of health research in developing countries.

At the **World Health Organization (WHO),** in 1990 a paper entitled "The role of health research in the Health for All by the year 2000 Strategy" was included in the technical discussions of the 43rd World Health Assembly, stressing the importance of research for the conformation of health systems. Still, it would be wrong to ignore previous history, from the creation on May 1959 of the Advisory Committee on Medical Research (ACMR) which became the Advisory Committee on Health Research (ACHR) in 1986, or the existence within the Organization of important research related initiatives, such as the **Special Programme for Research, Development and Training in Human Reproduction (HRP),** created in 1972 and which from 1988 had UNDP, UNFPA and the World Bank as co-sponsors, or the **Special Programme for Research and Training in Tropical Diseases (TDR)**, with co-sponsorship by UNICEF, UNDP and the World Bank.

On the year 2000 the **Alliance for Health Policy and Systems Research (AHPSR)** was set up. It is based at WHO but has independent funding and the mission to advance this field of research.

On 2003 Tikki Pang et al, in an author's paper bearing the institutional weight of their location within WHO, proposed a conceptual framework for the analysis of health research systems and identified their main functions.[4]. The four functions identified are: System stewardship, Funding, Creation and sustainability of resources and Knowledge production and utilization.

Some more recent key events have been the publication in 2004 of the World Report on Knowledge for Better Health: Strengthening Health Research Systems[5] and the Ministerial Summit on Health Research, which took place in Mexico City on 2004.[6]

Some of the main recommendations of the World Report on Knowledge for Better Health include:

1. To strengthen the capacity of individuals and institutions, together with the promotion of a favorable environment

2. To pay attention to capacity retention, not just its creation

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[3] Global Forum for Health Research. Mission. [en línea] [fecha de acceso 9 de abril 2007] URL disponible en: http://www.globalforumhealth.org/Site/001__Who%20we%20are/002__Mission.php

[4] Pang T, Sadana R, Hanney S, et al. Knowledge for better health: a conceptual framework and foundation for health research systems. [en línea] Bull World Health Organization 2003 [fecha de acceso 17 de abril de 2007] 81(11): 815-820. URL disponible en: http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0042-96862003001100008&lng=es&nrm=iso&tlng=en

[5] WHO. World Report on knowledge for better health. [en línea] [fecha de acceso 17 de abril de 2007] Geneva: WHO; 2004. URL disponible en http://www.who.int/rpc/meetings/wr2004/en/index13.html

[6] Ministerial Summit on Health Research. Identify challenges, inform actions, correct inequities: report. México; 2004. [en línea] [fecha de acceso 17 de abril de 2007] Geneva: WHO; 2005. URL disponible en: http://www.who.int/rpc/summit/en/index.html

3 To strengthen capacity not just on the technical aspects of research

4 To assign greater importance to health research financing

5 To pay attention to a long term approach based on research systems

In 2005 WHO published its knowledge management strategy[7], based on five strategic directions:

1 To improve access to world health information

2 To translate knowledge into policies and action

3 To share and reapply knowledge derived from experience

4 To enhance cyber health in countries and

5 To facilitate a favorable environment for an efficacious use of knowledge

By 2006 the paper entitled "Research for health: a position paper on WHO's role and responsibilities in health research"[8] was published. It identified the following WHO roles and responsibilities:

1 promoting the messages that research is fundamental to generating knowledge to improve health outcomes and that evidence must inform the design and implementation of health programmes as well as all attempts to reform and strengthen health systems;

2 advocating for increased funding (from governments in low- and middle-income countries and from donors) for neglected areas of health research;

3 influencing the global health research agenda and advocating for research and research-translation efforts to address the most pressing health needs in Member States;

4 fostering communication among the main organizations devoted to health research for development and other key stakeholders;

5 building consensus among governments, funders, researchers, NGOs, civil society, and industry around global health research priorities, policies, and strategies;

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[7] WHO. World Health Organization knowledge management strategy. Geneva: WHO; 2005. (WHO/EIP/KMS/2005.1)

[8] WHO. Research for health: a position paper on WHO's role and responsibilities in health research. [en línea] [fecha de acceso 17 de abril de 2007] Geneva: WHO; 2006. (ACHR45/05.16 Rev. 1) URL disponible en: http://www.who.int/rpc/meetings##osition_paper.pdf

6 *creating, sustaining, and participating in national, regional, and global partnerships, including public-private partnerships, that aim to identify knowledge gaps, establish research priorities, initiate new research to generate such knowledge, and accelerate product development;*

7 *setting norms and standards for health research, including its ethical oversight, and developing "best practices" guidelines;*

8 *performing and supporting research in priority areas where the Organization has a comparative advantage;*

9 *taking a leadership role in addressing potentially controversial and/or neglected research issues that have an impact on health such as those associated with intellectual property rights, sexual and reproductive health, equitable access to the benefits of research, social determinants of health, human resources, patient safety, and public access to information on clinical trials;*

10 *assisting Member States in developing capacity to conduct health research, identify health research priorities, evaluate research results, translate knowledge, solve health-related problems by using evidence to inform policy, assess the impact of interventions and programmes in terms of outcomes and sustainability for development and equity goals, and communicate lessons learned;*

11 *gathering, synthesizing, and disseminating research results and ensuring that all users of health research have access to reliable, relevant, and timely information;*

12 *building public trust in and support for health research."*

This paper was submitted to the 59th World Health Assembly on May 2006, which discussed it and agreed to postpone its discussion till the Executive Board meeting of January 2007[9]. On February 2007, during the 120th meeting of WHO's Executive Board[10], a recommendation was made to the 60th World Health Assembly to adopt a resolution on the issue, including exhorting "the health research community, other international organizations, the private sector, civil society and other interested parties" to ""provide their support to all health research, particularly research on communicable

[9] Asamblea Mundial de la Salud, 59, Ginebra, Suiza, 2006. Actas resumidas de las sesiones 4ª y 5 de la Comisión B. [en línea] [fecha de acceso 9 de abril de 2007] Geneva: WHO, 2006. (WHO WHA59/2006/REC/3). URL disponible en http://www.who.int/gb/s/s_wha59.html#Resolutions

[10] Reunión del Consejo Ejecutivo de la OMS, 120, Ginebra, Suiza, 22-30 enero. 2007. [en línea] [fecha de acceso 17 de abril de 2007] Ginebra: OMS; 2007. (WHO EB120.R15). URL disponible en: http://www.who.int/gb/s/s_eb120.html

diseases and on poverty and health equity, with community participation and in accordance with each country's priorities, and to continue supporting those activities that promote the use of research results as the foundation of policies and practice and to inform public opinion". The proposed resolution includes a series of requests for action to the General Director, directed particularly to the strengthening of a research culture and the utilization of research results within the Organization.

The coming into office of a new Director General on January 2007 has stressed the importance of research as a source of evidence for action. Addressing the Organization's Executive Board 19 days after taking her new position, Dr. Chan said: *"I have identified six issues that can guide the way we approach our work in the coming years. Two address fundamental health needs: for health development and health security. Two are strategic: we need to strengthen health systems, and we need better evidence to shape our strategies and measure our results. The last two are operational: our reliance on partners, especially those with an implementation role in countries, and our need to perform well as an organization, across all programmes and at all three levels."*[11].

There are now other global actors who are particularly important; many of them donor agencies, international organizations, governmental and non-governmental organizations, that have great impact on the global health research agenda setting.

1.2 Health research policies in the American region

PAHO/WHO assigned an important role to research from an early stage, including the creation of the Research Coordination Office (today HSS/RC) in 1961 and the Research Advisory Committee on 1962. Both were considered at the 43rd Executive Committee meeting.

The first PAHO/WHO research policy statement was presented in the Director's Report to the XVI Pan American Sanitary Conference. It made the following definition: "PAHO/WHO research policy consists in collaborating with the countries of the Americas in developing the resources needed to solve the most urgent health problems of the population" It stated the need to study "biological and environmental factors, communication systems, institutions and cultural patterns , as well as the physical environment where health systems function."

In 1983 the paper called "PAHO/WHO research policy"[12] proposed an update of that policy, which was rewritten as follows: "PAHO/WHO research policy has the objective of promoting the identification of knowledge gaps that hinder the solution of national health problems and to cooperate with the countries of the Americas in developing, in a coordinated fashion, research activities to fill those gaps."

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[11] Reunión del Consejo Ejecutivo de la OMS, 120, Ginebra, Suiza, 22 enero 2007. Discurso de la Dra. Margaret Chan. [en línea] [fecha de acceso 11 de abril de 2007] Ginebra: OMS; 2007. URL disponible en: http://www.who.int/dg/speeches/2007/eb120_opening/en/index.html

[12] Reunión del Comité Asesor sobre Investigaciones Médicas de OPS, XXII, México, México, 7-9 julio de 1983. Política de la OPS en materia de investigaciones. [en línea] [fecha de acceso 17 de abril de 2007] Washington: OPS; 1983. (PAHO/ACMR/22/8.2) URL disponible en: http://hist.library.paho.org/Spanish/CAIS/27657.pdf

It is worth noting that the Region, apart from considering health research as a necessary input for health care or decision making, has a tradition of analysis of scientific production (and health research in particular) as a research object in itself.

Juan César García[13] analyzed research institutions in Latin America in 1880-1930 and showed a predominance of tropical disease research, with a prevalence of institutes devoted to Bacteriology research. He identified the rise of basic science research , particularly clinical research from the 1940's and of Social Medicine from 1960. García described an opposition between scientific ideas prevailing among the North and Latin American academic communities and the ideological differences underlying this. García also analyzed in 1984 the participation of social sciences in health in Latin America [14] and reflected on the creation and dissemination of ideas by PAHO/WHO, besides launching a line of work on bibliographic analysis as an approximation to the understanding of research trends in the Region[15], which was later followed by Alberto Pellegrini[16].

In the year 2000 Alberto Pellegrini, also from PAHO/WHO, analyzed the organization of scientific activity for health in the Region.[17]. He pointed out that several indicators had improved in the 90's in comparison with the 80's. Among these improvements he cites the increase in research and development expenditure, which rose by 56% from 1990 to 1996, though the research and development per capita expenditure in the region was of only 0.5% of GDP, with a strong concentration in Brazil (60% of the total), Argentina (12.5%) and Mexico (10%). A large part of this increase was due to clinical trials by large multinational companies and another to funding by multilateral agencies such as the World Bank or the Inter American Development Bank (IDB). He showed a rise in the number of researchers during the same period, also concentrated in Brazil and Argentina. The author pointed out to a similar increase in the production of scientific literature.

In that work Pellegrini criticized the prevailing risk approach and the fundamental responsibility of individuals due to life styles and behavior and proposed that research pay attention to the social context in the determination of the health- disease process.

He also identified some key problems in capacity development and retention of human resources for research and in the dissemination and utilization of research results, problems that did not appear as such in the policy papers we have quoted before. It is interesting to note that WHO papers take up these concerns five years later and stress them as challenges to the technical cooperation strategy in health research.

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[13] García JC. Historia de las instituciones de investigación en salud en América Latina: 1880-1930 En: García JC. Pensamiento social en salud en América Latina. México: Interamericana; 1994.

[14] García JC. Ciencias sociales en salud en América Latina: JC García entrevista a JC García. En: García JC. Pensamiento social en salud en América Latina. México: Interamericana; 1994.

[15] García JC. Nuevas tendencias en la investigación biomédica en América Latina. En: García JC. Pensamiento social en salud en América Latina. México: Interamericana; 1994.

[16] Pellegrini Filho A, Goldbaum M, Silvi J. Production of scientific articles about health in six Latin American countries: 1973-1992. Rev Panam Salud Pública. [online] Aug 1997 [cited 2007 April 20]; 2(2):121-34. URL available from: http://www.scielosp.org/pdf/rpsp/v2n2/v2n2a5.pdf
Spanish. Erratum in: Rev Panam Salud Publica Mar 1997; 1(3):212.

[17] Pellegrini Filho, A. Ciencia en pro de la salud: notas sobre la organización científica para el desarrollo de la salud en América Latina y el Caribe. Washington: OPS; 2000. (Publicación Científica y Técnica; 578).

On the other hand, faced with the challenge to Stewardship of Public Health posed in the context of health sector reforms, PAHO/WHO proposed in 2000 the Public Health in the Americas initiative", aimed at the definition and measurement of the Essential Public Health Functions (EPHF)[18]. This initiative, coordinated by the Health Systems and Services Division, developed instruments to measure the performance of EPHF in collaboration with the Centers for Disease Control and Prevention of the United States of America (CDC) and the Latin American Health Systems Research Center (CLAISS, from its name in Spanish). 11 EPHF were identified, among which No 10 "Research, development and implementation of innovative solutions in public health" is stressed due to its relevance in this case, but pointing out to the fact that most functions include an important research component, such as function No 1: "Monitoring and analysis of the population health status", No 2: "Public health surveillance, research and control of risks and damage to public health", No 7: "Evaluation and promotion of equitable access of the population to necessary health services" and No 9: "Quality assurance of individual and collective health services"

1.3 Other important actors in research cooperation in Latin America

In the past 20 years we may notice an increase in bilateral cooperation at the expense of multilateral cooperation. Health research cooperation has not been alien to this phenomenon.

There are numerous national external health cooperation agencies, which play a more or less important role on research. Due to their relevance in Latin America and the differences in their approaches, three are mentioned here: the Center for Disease Control and Prevention , depending on the Dpt. of Health and Human Services of the US, the International Development Research Center (IDRC) of Canada, and Sweden's Sida/SAREC.

The CDC has numerous institutes, but the bulk of its activities in Latin America is centered on epidemiological and laboratory studies of communicable diseases and chronic diseases to a lesser degree. It has provided training to a large number of researchers in basic disciplines and Epidemiology and has a strong link to the epidemiological surveillance network of the whole Region, acting often as reference laboratory.

The International Development Research Center has a long tradition of support of health research in Latin America. Throughout its history it has changed the definition of its priorities and areas of action, including the disappearance of Health as an area, but keeping some of its contents in more comprehensive approaches. It is characterized by having introduced innovative approaches in the conceptualization of health research. Among other important contributions mention should be made

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[18] Muñoz F, López-Acuña D, Halverson P, Macedo C Guerra de, Hanna W, Larrieu M et al. Las funciones esenciales de la salud pública: un tema emergente en las reformas del sector de la salud. Rev Panam Salud Publica. [en línea]. Ago 2000 [fecha de acceso 20 de abril de 2007]; 8(1-2): 126-134. URL disponible en: http://www.scielosp.org/pdf/rpsp/v8n1-2/3012.pdf

to the production of training manuals on Health Systems Research[19] when that discipline was starting to develop. It also funded work on the determination of priorities of research needs in collective health in Latin America [20], with the collaboration of PAHO/WHO and COHRED.

Sida/SAREC, the Swedish agency specialized in research cooperation, has an interesting experience in strengthening research capacity and knowledge access in Bolivia and Nicaragua.[21] Its approach to cooperation makes it particularly interesting, since it develops long term commitments to the strengthening of the set of capacities needed in a research system. It has offered training at the Masters, PhD and post-doctoral levels to scientists of the before mentioned countries, but in recent years it has become aware of the need to provide training at, and strengthen the institutional level, in order to create what it calls sustainable research environments.

1.4 Some key concepts regarding health policy research in the recent literature:

Health Research Systems:

While some years ago the idea was that training of researchers was an adequate and sufficient instrument for the development of research capacity in a country, we now see the need to understand and act on the system as a whole.

Pang et al.[22] define a National Health Research System as "the people, institutions, and activities whose primary purpose in relation to research is to generate high-quality knowledge that can be used to promote, restore, and/or maintain the health status of populations; it should include the mechanisms adopted to encourage the utilization of research. The definition includes all actors involved in knowledge generation, research synthesis, and using research results in the public and private sectors." The most important thing of this definition is its systemic approach, which presents a challenge to cooperation strategies in health research. It becomes ever more accepted that the objective of cooperation should be to strengthen research systems as such, so that action focused on only one of its functions would not fulfill its objective.

Knowledge translation, utilization and brokerage

Though there is consensus in admitting the systemic approach to National Health Research Systems, most recent literature is concentrated on one system component: knowledge translation and its utilization for policy-making.

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[19] Corlien M, Varkevisser, IP, Brownlee A. Designing and conducting health systems research projects. Ottawa: IDRC/WHO; 1991.

[20] Sánchez D, Gómez S, Basan R. Editores. Desafíos a la investigación en salud colectiva en América Latina. Montevideo: GEOPS; 1996.

[21] Boeren AD, Alberts T, Alveteg T, Thulstrup EW, Trojer L. Sida/SAREC Bilateral Research Cooperation: lessons learned. [on line] [cited on 2007 April 20] Stockholm: Sida; 2006. (Sida Evaluation; 06/17). URL available from: http://www.oecd.org/dataoecd/26/30/38081758.pdf

[22] Pang et al, op cit

The knowledge translation concept is complex. The Canadian Institute of Health Research defines it as "the exchange, synthesis and ethically-sound application of knowledge - within a complex system of interactions among researchers and users"[23]

An associate concept is that of knowledge management, which also has several definitions, amongst them the one used by the Association of State and Territorial Health Officials[24], which defines it as "an organization or community's planned approach to collecting, evaluating, cataloging, integrating, sharing, improving, and generating value from its intellectual and information-based assets."

In a WHO Bulletin editorial written by Nuyens and Lansang[25], the authors warn about a series of lessons learnt from different knowledge translation initiatives. These are: a- the utmost importance of context, b- the importance of continuity, c- the need to take complexity into consideration, d- consideration to all involved actors, e- the weakest link is capacity development.

Another concept appearing in the literature is that of knowledge broker.[26] It is based on the fact that knowledge creation and policy making are different activities and that what is needed is the creation of an interactive process between knowledge producers and users (not just transfer of research results).

The region has not ignored this discussion. In 2001 a paper was presented at the XXXVI ACHR meeting in Kingston, Jamaica[27], analyzing some of the main instruments available for scientific evidence based policy making, including the Virtual Health Library (BVS, from its name in Spanish), the Cochrane Collaboration, the Campbell Collaboration and the Health Equity Observatory, and the DECIDES (Democratization of Knowledge and Information for the Right to Health) project was discussed. A draft of this project had been presented at the XXXV ACHR meeting in La Habana the previous year[28]. The project was based on three basic components, using the Virtual Health Library as technological platform and virtual space: an Interactive Health Research Agenda, a Researchers Exchange Network, and the Solidary Cities project, which aimed at facilitating access to information for citizens and decision makers. This project was never implemented.

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[23] Canadian Institute of Health Research (CIHR). The CIHR Knowledge Translation Strategy 2004-2009: innovation in Action. [online]. Ottawa: CIHR; 2004 [cited 2007 April 20]. URL available from: http://www.cihr-irsc.gc.ca/e/26574.htlm

[24] Association of State and Territorial Health Officials. Knowledge management for better health. ASTHO report [online] 2005 Jan [cited 2007 April 20] 13(3) URL available from: http://www.astho.org/pubs/FallA###HOReport2005.pdf

[25] Nuyens Y, Lansang MA. Knowledge translation: linking the past to the future. Bull World Health Organ [online] 2006 Aug [cited 2007 April 20] 84 (8): 590. URL available from: http://www.scielosp.org/pdf/bwho/v84n8/v84n8a02.pdf

[26] Lomas J. The in-between world of knowledge brokering. BMJ [online] 2007 Jan [cited 2007 April 20] 334:129-132 , http://www.bmj.co###cgi/content/full/334/7585/129- Lomas J, Culyer T, McCutcheon C, McAuley L, Law S. Conceptualizing and Combining Evidence for Health System Guidance: final report. [online] [cited 2007 April 20] Ottawa**:** Canadian Health Services Research Foundation; 2005. URL available from: http://www.chsrf.ca/other_##cuments/pdf/evidence_e.pd##

[27] OPS.Programa de Coordinación de Investigaciones. Editor. Estrategias para la utilización de información científica en la toma de decisiones en pro de la equidad en salud. XXXVI Reunión del CAIS, 9-11 junio 2001, Kingston, Jamaica. [en línea] [fecha de acceso 20 de abril de 2007]. Washington: OPS; 2001 URL disponible en: http://www.paho.or##Spanish/HDP/HDR/CAIS-01-07.pdf (CAIS; 36/2001.7)

[28] OPS.Programa de Coordinación de Investigaciones. Editor. Democratizando la información y el conocimiento para el derecho a la salud: DECIDES. XXXV Reunión del CAIS, 17-19 julio 2000, La Habana, Cuba. [en línea] [fecha de acceso 20 de abril de 2007] Washington: OPS; 2000. URL disponible en: http://www.paho.org/S##nish/HDP/HDR/CAIS-00-05.pdf (CAIS; 35/2000.5)

The launch of the EVIPNet initiative by WHO falls within this movement that stresses access to and utilization of knowledge for policy making, as well as the use of virtual space and the creation of networks as the suitable instrument to share and build knowledge.

The use of evidence by civil society has been assessed by the Overseas Development Institute (ODI)[29]. According to the authors of this evaluation civil society organizations use evidence to influence agenda setting, to influence policy definition, their implementation, monitoring and evaluation, but the crucial issue is the political context where they move. Due to methodological reasons (extrapolating to communities information obtained from individuals), the strong context dependency and different interpretations of definitions, are authors who have expressed doubts about the limitations of the "Evidence based Public Health" concept[30].

Health research and research for health

The dichotomy between health research and research for health is often presented. Nevertheless, the 43rd World Health Assembly[31] defined Health Research in the following manner: "A process to systematically obtain knowledge and technologies that may be used to improve the health of individuals and groups. It provides basic information on health and disease status of the population, it endeavors to develop instruments for the prevention, cure and relief of the effects of diseases and it is committed to planning better approaches for individual and community health services".

This definition includes both the study object and its final use and attention should be paid to the fact that it does not speak of the health of "individuals or groups" but of "individuals and groups". Hence it would not acknowledge as health research that whose ultimate goal is not to serve society, which is something we may agree with, but leaves us in a taxonomically complex situation regarding some types of health research which, though hard to classify as basic research, have limited application or more frequently, one that is distant in time.

Perhaps as an answer to this difficulty the concept of "Research for Public Health" has arisen, which not denying the place for health research in general, identifies that which has direct impact on the health of population in the short (or medium) time and which encompasses different problems and disciplinary approaches.

2- A review of available information on National Health Research Systems

Objective: To identify the main components of National Health Research Systems in the Latin American and Caribbean countries, as well as existing papers on health research policy.

Methodology: Between October 2006 and March 2007 a literature search was carried out in the PubMed, LILACS and Google Scholar data bases with the following headings: "Health research

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[29] Pollard A, Court J. How civil society organizations' use evidence to influence policy processes: a literature review. [online] [cited 2007 April 20] London: ODI; July 2005. (Working Paper; 249) URL available from: http://www.globalpolicy.org/ngos/intro/general/2005/07evidence.pdf

[30] Kemm J. The limitations of "evidence-based" public health. Journal Evaluation Clinical Practice 2006 Jun; 12(3):319-324.

[31] Asamblea Mundial de la Salud, 43, 16 de mayo de 1990, Ginebra, Suiza. Informe de discusiones técnicas: documento A 43. Ginebra: OMS; 1990.

priorities", "Science and technology policy", "Health research" and "Science and technology" and their Spanish and Portuguese translation, plus the name of each country in Latin America and the Caribbean. Web pages of the Ministries of Health, Ministries of Science and Technology (when they existed), and National Science and Technology agencies of the countries as well as the Ibero American Network of Science and Technology (RICYT) web page were accessed.

Only official documents were selected, understanding that as those recognized as official policy by States, except for the case of El Salvador, where only a paper originated at the University of El Salvador could be retrieved. 64 documents were retrieved using this criterion, including descriptions of the Science, technology and innovation systems, Science and Technology policy papers or Health research policy papers. These corresponded to 16 countries in Latin America and the Caribbean region as a whole.

Agencies involved in the different functions of Health Research Systems were identified, focusing our analysis at this time particularly in the stewardship function to the detriment of the identification of knowledge producers.

An analysis was made of the science, technology and innovation policy papers as well as those on health research priorities(when found) in order to identify the research areas and subjects that countries regard as most relevant.

Results: Taking into consideration the four basic functions of National Health Research Systems, there follows a description of information presently available and the gaps that should be covered in the short term:

2.1 Stewardship

It may be said in general terms that there are two main Health Research Stewardship models in the region. While most English speaking Caribbean countries have adopted the British model of Medical Research Councils, Latin American countries developed during the 60's science and technology agencies where health research was included. Although some Ministries of Health in Latin America have areas (Divisions or Departments) devoted to research, as well as research institutions directly related to them and with different degrees of autonomy, in most cases health research has taken place at Universities, independent from the needs and priorities of Ministries.

Table No1 shows a summary of the agencies performing the stewardship function in research in general and in health research in those Latin American countries for which information could be retrieved.

Table N°1
Map of scientific research and health research stewardship actors in Latin American countries

Argentina	Ministerio de Educación, Ciencia y Tecnología- Secretaría de Ciencia, Tecnología e Innovación Productiva (SECYT) Consejo nacional de Investigaciones Científicas y Técnicas (CONICET) Ministerio de Salud: Comisión Nacional de Programas de Investigación Sanitaria (CONAPRIS), con integración de CONICET
Bolivia	According to the new legislation: Comisión Interministerial de Ciencia, Tecnología e Innovación Secretaría Nacional de Ciencia, Tecnología e Innovación Consejo Nacional de Ciencia y Tecnología Consejos Departamentales de Ciencia y Tecnología Previously: Consejo Nacional de Ciencia y Tecnología (CONACYT) Viceministro de Educación superior, Ciencia y Tecnología: Div. Gral. de Ciencia y Tecnología
Brazil	Conselho Nacional de Pesquisa (CNPq) Ministerio da Saúde: Secretaría de Ciencia y Tecnología
Chile	Comisión Nacional de Investigación científica y tecnológica (CONICYT): Fondo de Fomento al Desarrollo Científico y Tecnológico (Fondef) Ministerio de Salud y CONICYT: Fondo Nacional de Investigación y Desarrollo en Salud (FONIS)
Colombia	Instituto Colombiano para el Desarrollo de la Ciencia y la Tecnología, Francisco José de Caldas – Colciencias
Costa Rica	Ministerio de Ciencia y Tecnología (MICIT) Consejo Nacional de Investigación Científica y Tecnológica (CONICIT) Ministerio de Salud: Consejo Nacional de Investigación en Salud (CONIS) Consejo Nacional de Rectores Academia Nacional de Ciencia
Cuba	Ministerio de Ciencia, Tecnología y Medio ambiente Ministerio de Salud Pública : Dirección de Ciencia y Tecnología
Ecuador	Secretaría Nacional de Ciencia y Tecnología (SENACYT) Fundación para la Ciencia y Tecnología (FUNDACYT)
Guatemala	Sistema Nacional de Ciencia y Tecnología (SINCYT) : o Consejo Nacional de Ciencia y Tecnología (CONCYT) o Secretaría Nacional de Ciencia y Tecnología (SENACYT) o Comisiones Técnicas Sectoriales
Mexico	Secretaría de Salud Consejo Nacional de Ciencia y Tecnología (CONACYT)

Panama	Secretaría Nacional de Ciencia, Tecnología e Innovación (SENACYT) 13 Comisiones nacionales sectoriales Fondo Nacional para el Desarrollo de la Ciencia, Tecnología e Innovación Instituto Conmemorativo Gorgas de Estudios en Salud
Paraguay	Consejo Nacional de Ciencia y Tecnología (CONACYT) Instituto de Investigación en Ciencias de la Salud
Peru	Sistema Nacional de Ciencia, Tecnología e Innovación Tecnológica (SINACIT) Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica (CONCYTEC)
Uruguay	Ministerio de Educación y Cultura: Secretaría de Ciencia, Tecnología e Innovación. Consejo Nacional de Ciencia, Tecnología e Innovación (CONICYT)
Venezuela	Sistema Nacional de Ciencia, Tecnología e Innovación: Ministerio de Ciencia y Tecnología

In Argentina[32], six priority areas were identified (plus an item called "others"). These include:

a) Research on health systems, policies and programs, with emphasis on health service and medical care quality;
b) Research on sociocultural determinants of Health-Disease
c) Research on social inclusion policies for people with disabilities
d) Research on innovation and technological development of drugs, food and medical technology
e) Research on the development and production of biologicals and
f) Research in the field of communicable diseases.

Brazil's National Health Research Priorities[33] include 24 research sub-agendas, comprising: Health of indigenous populations, Mental health, Violence, accidents and trauma, Health of the black population, Non communicable diseases, Older adult health, Health in childhood and adolescence, Women's health, Health of people with special needs, Food and nutrition, Bioethics and research ethics, Clinical research, Productive health complexes, Technology assessment and health economics, Epidemiology, Demography and health, Oral health, Health promotion, Communicable diseases, Health communication and information, Labor management and health education, Health policies and systems, Health, environment labor and biosafety and Pharmaceutical care.

[32] Programa Transversal Integrador del Sistema Nacional de Innovación (PROTIS). Plan estratégico nacional de ciencia, tecnología e innovación "bicentenario" 2006-2010. [en línea] [fecha de acceso 20 de abril de 2007] Buenos Aires: SECYT; 2006. URL disponible en: http://www.secyt.gov.ar/plan_bicen###nario/documentos##inales/plan_bicentenario_publicacion.pdf

[33] Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Agenda nacional de prioridades de pesquisa em saúde. [em línea] [fecha de acceso 23 de abril de 2007] Brasília: Ministério da Saúde; 2005. (Série B. Textos básicos em saúde). URL disponible en: http://portal.saude.gov.br/portal/arquivos/pdf/AGENDA.pdf

In Chile, FONIS[34] finances projects on health technology assessment, health management, primary health care, labor and environmental health and others defined in its general guidelines, while FONDECYT[35] finances projects in basic research according to their academic quality, regardless of their discipline.

Choosing to identify wide areas, Peru[36] includes Communicable diseases (tropical and endemic); Traditional medicine; Food and nutrition, Mother and child health and Occupational and mental health as its research priorities.

The Intersectoral Fund for Health Research and Social Security in Mexico[37] identified the following priority areas in 2006: Avian influenza; Malignant neoplasms; Health technology development; Infectious and parasitic diseases; Chronic diseases; Reproductive and perinatal health, Nutritional disorders; Psychiatric and neurological disorders; Vulnerable groups and Health systems, health economics and social security.

Priorities identified by the University of El Salvador[38] include: Health policy and reform; Health systems and services; Health promotion and prevention of communicable and non communicable diseases; Environmental health; Food and nutrition security; Drug surveillance, drug quality control, control in drug use and management; Reproductive and family health; Oral health; Family and community violence; Women, gender and health; Socioepidemiology; New, emergent and re-emergent diseases, diagnosis and prevention.

The Caribbean Health Research Council (CHRC) identified the following priorities[39]: Environmental health, Health systems strengthening, Chronic non communicable diseases, Mental health, Family health, Prevention and control of communicable diseases, Food and nutrition and Human resources development.

2.2 Financing

There is information available on science and technology and research and development funding in the RICYT data base. As far as our objectives are concerned, this information has two limitations: it does not identify health research funding as such and although it covers a large number of countries, it does not include the English speaking ones. Information is provided by each Science

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[34] Chile. Comisión Nacional de Investigación Científica y Tecnológica. Fondo Nacional de Investigación y Desarrollo en Salud. FONIS [fecha de acceso 23 de abril de 2007] URL disponible: http://www.conicyt.cl/index.php?option=com_content&task=view&id=12&Itemid=27

[35] Chile: Comisión Nacional de Investigación Científica y Tecnológica CONICYT Fondo de fomento al desarrollo scientific y tecnologico FONDEF [fecha de acceso 23 de abril de 2007] URL disponible: http://www.CONICYTfondef.htm

[36] Perú. Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica. Plan nacional de ciencia, tecnología e innovación para la competitividad y el desarrollo humano: PNCTI 2006-2021. [en línea] [fecha de acceso 23 de abril de 2007] Lima: CONCYTEC, 2006. URL disponible en: http://ap.concytec.gob.pe/planctei/index.htm

[37] México. Consejo Nacional de Ciencia y Tecnología. Fondo Sectorial de Investigación en Salud y Seguridad Social SSA/IMSS/ISSSTE-CONACYT. [en línea] [fecha de acceso 23 de abril de 2007] URL disponible en: http://www.conacyt.mx/Fondos/Sectoriales/SSA/SSA_ConvocatoriaCerrada.html

[38] Cedillos R. Centro de Investigación y Desarrollo en Salud: CENSALUD: biotecnologías al servicio de El Salvador. [en línea] [fecha de acceso 23 de abril de 2007] El Salvador: Universidad de El Salvador; 2005. URL disponible en: http://www.conacyt.gob.sv/CentrodeInvesyDesSaludESCyT-08-11-2003.doc

[39] Caribbean Health Research Council. Research Grants. [online] [cited 2007 April 23] URL available from: http://www.chrc-caribbean.org/Downloads/Grants_home.html

and Technology Agency followed the Organization for Economic Cooperation and Development (OECD) consensual methodology, which allows for comparisons between countries.

A second source of information are the Financial Flows in Health Research Studies carried out by the Global Forum for Health Research, which have the advantage of analyzing the sum of funds from different origins, but in the case of our region they are available for a limited number of countries.

At the global level, the Global Forum for Health Research information allows us to know the growth in the amount of money available for health research between 1998 and 2003, the participation of different regions and the distance between what is invested by a limited number of countries and the desirable goal of 2% of the national health expenditure[40]. It shows that the Latin American and Caribbean participation in global health research spending is lower than its corresponding proportion by number of inhabitants.

If we add that this small percentage of global expenditure is concentrated mainly in three countries (Brazil, Argentina and Mexico, which are above the 2% of health expenses suggested in the goal) we see the limited economic resources of most health research systems in the Region. Besides the challenge to increase this amount, there is that of making a more socially efficient use of existing funding.

2.3 Creation and sustenance of resources

Based upon the RICYT data base again, we have information on the number of scientists available in those countries that participate in the network. Due to the definition used, they are people with academic training that allows them to carry out research (Masters and PhDs), not active researchers, and we can not identify those active in health research. The Regional Initiative of Health Research Data (IRDIS, from its name in Spanish), proposed by the Research Promotion and Development Unit, aims to carry out the consultations and agreements needed to make available basic standardized data on National Health Research Systems for the whole Region, including indicators of human resources that may be useful to the countries and to PAHO/WHO's analytic work.

Another source with great potential is the CVLaC data base, but it is presently underutilized and functioning in a limited number of countries. We should hope that with its extension to the remaining countries in the Region it will be possible to have a more suitable instrument for the analysis of human resources devoted to health research.

There is an ever growing consensus on the need to create and strengthen institutional resources, not just individuals. Nevertheless, we know very little about the strategies used in our Region to create work environments that favor knowledge production and the retention of researchers, despite the existence of some institutions that have demonstrated to be successful in this, such as the Oswaldo Cruz Foundation in Brazil or the National Institute of Public Health in Mexico, for instance.

The capacity of Science, Technology and Innovation agencies and of Ministries of Health to

[40] De Francisco A, Maitlen S. Editor. Monitoring financial flows for health research 2006: the changing landscape of health research for development. [online] [cited 2007 April 23] Geneva: Global Forum for Health Research; 2006. URL available from: http://www.globalforumhealth.org/filesupld/monitoring_financial_flows_06/Financial%20Flows%202006.pdf

perform the stewardship function on National Health Research Systems has been little explored and deserves further study. This includes not only the capacity to set research priorities, but to create a favorable environment for research production, including ethical review of research projects that conform to internationally accepted standards.

2.4 Research production and utilization

Analysis of literature production is a line of work that PAHO/WHO has carried out for several decades, though admitting that it has limitations such as publication bias.

As may be seen in Table No 2, between 1990 and 2004 there was an increase in the total number of articles published in Medline, but the participation of Latin America and the Caribbean , though it doubled in percentages (it went from 1.15% of the world total in 1990 to 2.24% in 2004), remains very small. The same has happened with publications indexed in ISI (Table No 3)

Table N°2: Publications indexed in MEDLINE by region and year. Number and percentage of total

Region	Year			
	1990	1995	2000	2004
Latin America and the Caribbean*	4.358 (1,15%)	5.231 (1,31%)	8.584 (1,98%)	13.522 (2,24%)
Ibero America#*	9.518 (2,52%)	12.975 (3,25%)	19.429 (4,04%)	28.036 (4,65%)
World Total	376.710	398.851	479.731	601.644

Source: RICYT En: http://www.ricyt.edu.ar

*By Latin America and the Caribbean we understand all countries south of the United States of America and all Caribbean countries, regardless of their official language.

** By Ibero America we understand all Spanish and Portuguese speaking countries in the Region, plus Spain and Portugal

Table Nº 3 Publications indexed in ISI by region and year. Number and percentage of total

Region	Year			
	1990	1995	2000	2004
Latin America and the Caribbean	11.046 (1,61%)	17.072 (1,98%)	28.657 (2,90%)	36.745 (3,30%)
Ibero América	22.465 (3,27%)	36.636 (4,26%)	55.661 (5,63%)	72.478 (6,52%)
Total	685.171	858.970	988.156	1:111.565

Source: RICYT En: http://www.ricyt.edu.ar

Publications indexed in the LILACS data base have also increased during this period. Since there has been an increase in the number of publications included in the base it is difficult to determine if in this case the increase is due to greater production or greater inclusion of what is produced.

The Health Research System function of promoting the utilization of research for decision making in health policies and production of new products (drugs, vaccines, devices, etc.) is not well studied and there are no established methodologies to measure it. Health Policy and Systems Research is a relatively new field of knowledge that should be strengthened in order to answer many of these questions.

The Virtual Health Library (BVS) has been an instrument used by PAHO/WHO in order to allow access to scientific knowledge in the Region. Through it access is granted not only to international, regional and national literature bases, but to valuable sources of secondary research, such as the systematic reviews included in the Cochrane Collaboration base.

As for access to full text scientific literature, BIREME's SciELO project grants access to a selected number of Latin American scientific journals and just a small number of countries in the Region have free access to international scientific journals through the HINARI program. The others must acquire access through the payment to commercial providers.

Only two countries (Argentina and Brazil) have technology assessment agencies that are members of the International Network of Health Technology Assessment Agencies (INAHTA), which shows the weakness of this practice in the Region. In spite of that, there is a small number of centers participating in the Iberoamerican Cochrane Collaboration and they might become important elements in the strengthening of the use of research for decision making, if properly supported. The coming launch of the EvipNet initiative in the region is aimed at the same objective

3. Role of research in PAHO/WHO's activities and cooperation, a policy and strategy proposal

The Research Promotion & Development Unit has the following lines of work, which are in line with WHO's health research policies, with the orientation given by the Advisory Committee on Health Research, and its history and mandates from the Directing Bodies:

a) Define a research policy for the Organization, as well as the instruments and tools for its implementation and monitoring.
b) Provide technical cooperation to the countries to strengthen national heath research systems so that they respond to each country knowledge needs, and subsequently, to the Region's as a whole.
c) Knowledge management in PAHO/WHO: lead PAHO/WHOs research stewardship and support the Organization as a whole in the delivery of technical cooperation based on values and informed by the best available evidence.

To support this functions, the Research Promotion & Development Unit (HSS/RC) must become a space for study and reflection about research at the global, and especially, regional level.

PAHO/WHO's technical cooperation is based in its capacity to generate, use and disseminate knowledge. For this the Areas and Units not just undertake and fund original research; they rely on Centers which have as a main function the production and dissemination of knowledge in specific areas, and with the support of numerous Collaborating Centers. Given the multiplicity of players and processes, it is particularly relevant to have the global perspective and a stewardship role for research at PAHO/WHO, and this is a key role of HSS/RC

Given the increased ease with which it is possible to find out what has been done and the conclusions of a research piece, there is a clear perception of the need to avoid unnecessary duplications, address knowledge gaps, and use current knowledge to solve health problems affecting

people in the Americas. This raises the need to establish knowledge dissemination and systematization, and knowledge translation into health policies and programs, into a key component of technical cooperation.

In the draft proposal for the Health Agenda for the Americas[41], the Organization visualizes research as one of its key areas. The preliminary version of this document –still under review, states in its item *c)* "Harnessing Knowledge, Science, and Technology":

> *"The countries should systematically evaluate the status of knowledge and incorporate it into the process of selecting interventions using effectiveness criteria. This function requires the capacity to integrate, synthesize, and use knowledge in decision making.*
>
> *Research must be strengthened in order to better understand the relationship between health determinants and their consequences, and to identify entities that can be partners or can be influenced through public policy. Traditional medicine and indigenous knowledge that can contribute to the well-being of populations should be taken advantage of. Efforts should be made to develop the capacity for research and the use of knowledge at local levels.*
>
> *Bioethics must be better disseminated and applied in the countries of the Americas to protect the quality of research, respect human dignity, safeguard cultural diversity and the application of knowledge in health, and ensure equitable access to scientific advances: tools, technologies, pharmaceutical products, vaccines, etc.*
>
> *All people should benefit from progress and have access to health information and education. The countries need to strengthen: their capacity for and level of scientific dissemination; public confidence in research; and the quality of knowledge that supports health actions. Ministries of health must strengthen their capacity for information and knowledge management, and their partnerships with those who generate that knowledge.…*
>
> *… Health surveillance should be strengthened at the local, national, regional, and global levels. The capacity of local health teams should be strengthened in order to carry out analytical epidemiological processes that generate scientific data for health planning and for the monitoring and evaluation of interventions. Decision-making in health should be evidence-based, taking into account available scientific knowledge that is systematically and transparently summarized. Furthermore, health information should be standardized to facilitate comparisons among and within countries, and in order to monitor and evaluate achievement of health goals."*

In the event of its approval by member countries, these components of the Agenda will constitute the basis for the mandate on research policy for PAHO/WHO until 2017.

Considering the broad range of tasks that the Organization undertakes and their enmeshment with research, a proposal is made for a work strategy based on cooperation with the different technical units, building partnerships with global initiatives and programs, and constituting and developing

[41] Reunión del Comité Ejecutivo de la OPS, 139, Washington, Estados Unidos, 29 septiembre 2006. Agenda de salud para las Américas 2008-2017: propuesta para discusión regional. [en línea] [fecha de acceso 23 de abril de 2007] Washington: OPS; 2006. CE1139/5. URL disponible en: http://www.paho.org/spanish/gov/ce/C##39-05-s.pdf

networks, under the understanding that these will strengthen the capacities of each participating party and exert a multiplying effect on the cooperation activities.

The diagram below presents a schematic view of the proposed strategy.

STRATEGIES FOR THE IMPLEMENTATION OF A RESEARCH POLICY IN PAHO/WHO	
A- Define the Organization's research policy, the instruments and tools for its implementation and monitoring.	
Context of research policies	Map the global, regional and national health research policies context.
Determine the Region's production and use of knowledge	Use different existing secondary sources (e.g. RICyT; BIREME BVS; ISI, etc.) Make basic data on health research available (vg. IRDIS)
Determine country needs and their capacity to address them	Support countries in the definition or updating of information about their needs of research for health. (E.g. Collaboration with COHRED). Define with the countries the solutions that will allow research to respond to their needs (vg. EVIPNet). Identify locally and regionally available resources.
Establish the demands for research cooperation	Assessment with the PAHO/WHO Representations Validation using other sources (e.g. Health Research Governing Organizations)
B. Technical cooperation to strengthen national health research systems, so that these address their knowledge needs, and those of the region as a whole.	
Strengthen health research stewardship	1 Strengthen the capacities of the health authority to determine research priorities. Work with country cooperation initiatives and other relevant parties (e.g. EVIPNet, COHRED, and IberoAmerican Network for Education & Research). 2 Strengthen National Science & Technology Organizations / Medical Research Councils (e.g. Networks, BVS, ScienTI, and RICYT) 3 Retrieve, analyze and summarize information on the structure and performance of national health research systems 4 Strengthen capacities to review research in humans, especially in bioethics and legal aspects (e.g. FLACEIS, PAHO/WHO Progam of Bioethics, UNESCO's Bioethics Network, Harvard School of Public Health, Collaborating Centers, etc.)

Funding	1 Retrieve, analyze and provide information of the situation of investment for health research (e.g. GFHR) 2 Fund strategic public health research for the region (e.g. PAHO/WHO Grants Program) 3 Facilitate access to funds for research in the countries 4 Advocate to increase funding for health research
Generation of resources	1 Human resources for health research: incorporating research into the debate on Human Resources for Health; grants for research in various modalities (Grants Program), support networks of researchers and policy mak rs (e.g. SCIENTI, RICyT, LatINCLEN, Cochrane, ALAMES, FLACSO, Networks of Research en Health Systems and Services). Interaction with universities, where human resources are being trained, and with international cooperation programs and agencies (e.g. IDRC, GHRI, Fogarty International, Fiocruz, INSP, AHPSR). 2 Support continuous education in health research, especially on policy and health systems (ditto) 3 Support training on research ethics (e.g. Bioethics Program, UNESCO's Bioethics Network, FLACEISS, Harvard School of Public Health, WHO-ERC, PAHOERC) 4 Strengthening of the skills to produce syntheses and systematic reviews of scientific literature to inform public health policy and evidence based guidelines (e.g. LatINCLEN, Campbell Collaboration, Cochrane Collaboration, health technology assessment units, GIN, AGREE, HRPS, INAHTA)
Producing and using research	1 Capacity building among researchers in successfully writing and funding research proposals. (e.g. BIREME, Ibero American Cochrane Network) 2 Increased access to evidence: VHL and VHL Science & Health (BIREME) 3 Support initiatives to promote the use of research knowledge (e.g. EVIPNet; James Lind Library; BIREME) 4 Democratizing knowledge: strategies to promote access and use of scientific information by lay people. Piloting developments.
C. Research Management and Stewardship in PAHO/WHO	

Assessment of health research scenarios, development of a vision for research in PAHO/WHO, identification of opportunities and threats.	1 Advisory Committee on Health Research 2 Strategic alliances and participation in events
Strengthen the situational analysis for research in the Americas	1 International Clinical Trials Register Portal ICTRP – (e.g. BIREME, WHO, WAME, FLACEIS, Register Network). 2 Assessment of secondary sources and the generation of health research indicators (e.g. IRDIS, REDES/RICyT, Grants Program)
Strengthen systematic approaches to the use and delivery of knowledge	1 Develop search, synthesis and systematic review skills (e.g. Agreements with the Iberoamerican Cochrane Network, the Canadian and US Cochrane Centers; CRICS) 2 Health research information dissemination activities (e.g. List servers, DECTs, Virtual Health Libraries, SharePoint sites, Websites, GIFT, Cochrane Library)
Develop instruments to assess the resources and results of research undertaken by PAHO/WHO	1 Implementation of PAHOs Research and Ethics Committee's Registers. Dissemination of the information obtained from such registers. 2 Surveys in areas, units and centers. 3 Evaluation of the Research Grants Program
Strengthening of the Organization's research ethics standards	PAHO's Ethics Review Committee: Activities leading towards quality assurance, advocacy, education and an institutional memory (e.g. Agreements with WHO-ERC, Harvard School of Public Health, Bioethics Program; FLACEIS, University of Chile, TDR)
Defining PAHO's research agenda	Assist the areas, units and centers at PAHO/WHO in the identification of their existing lines of research and the definition of their research priorities

Alignment between technical cooperation and Collaborating Centers and reference centers in the Region.	1 Strengthening the work of Collaborating Centers 2 Integrating the work plan for Collaborating Centers and the Strategic Plan of units, centers and areas 3 Strengthen communications with Collaborating Centers (dedicated focal points; targeted communications, electronic tracking systems, advocacy, exploring new collaboration strategies)

4. The need for more information to support PAHO/WHO research policy. A proposal to undertake a survey with key informants in the Organization

The review of available information has allowed the identification of some key knowledge gaps concerning the provision of appropriate technical cooperation. They are:

a The function of different national actors involved in stewardship of National Health Research Systems

b What research PAHO/WHO carries out and funds through its different Areas, Units, Centers and Country offices, as well as their priority setting mechanisms

c What are the countries' demands for cooperation in health research and PAHO/WHO's response to these demands

In order to start bridging this knowledge gap, a survey directed to those responsible for Areas, Units, Centers and Country Offices has been developed and is presented as an annex.

We understand that due to the characteristics of its insertion in all countries, the Organization may be a qualified informant on these issues. We understand this does not contradict the National Health Research Systems concept, which includes all actors, stewards, funders, producers and users of knowledge. Neither does it substitute in-depth studies that may be carried out in the future at the country level.

Once it has been discussed and approved with the changes the ACHR members deem necessary, it will be sent through e-mail to those responsible for Areas, Units, Centers and Country offices (7 technical areas, 17 units, 7 centers and 29 country offices). Responses are expected within a month since the time when the survey is sent. Qualitative analysis of information will be performed, identifying those cooperation modalities that have been requested and used most frequently in the health research field. Information on national priorities and its supporting documents will be used to complete the information obtained so far and to elaborate a dossier on each country's Health Research System.

We hope this survey will yield better understanding of the way National Health Research Systems work, their strengths and weaknesses and the demands that these systems, embedded in diverse contexts and with different resources, pose to PAHO/WHO, in order to adjust the design of a policy and strategy in health research cooperation that acknowledges diversity and responds to it, contributing to the improvement of the health of the people of the Americas, and to a more equitable development in general.

Annex VII

Research for Health

A Position Paper on WHO's Role and Responsibilities in Health Research

ACHR45/05.16 Rev.1

16 May 2006

Contents

Executive Summary

In response to a resolution by the 58th World Health Assembly, this paper seeks to clarify WHO's current and future roles and responsibilities in health research both within the Organization itself and among the multiple constituencies and partners with which it interacts.

WHO's Constitution states that "the extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health" and that "in order to achieve its objectives, the functions of the Organization shall be … to promote and conduct research in the field of health". Article 1.1 of the 1948 agreement between UNESCO and WHO gives WHO the primary responsibility for "the encouragement of research…in the fields of health and medicine."

In line with its mandate in health research, WHO has developed technical strengths and competencies across the entire spectrum of scientific enquiry, from setting priorities to formulating policies and guidelines, and from developing interventions to implementing and evaluating programmes. WHO's research activities are spread across different departments and programmes, between headquarters, regions, and countries, and through diverse institutional arrangements, partnerships, and collaborations.

In light of continued inequities in global health, the persistence of the "10/90" gap (less than 10% of global health research resources spent on health problems affecting 90% of the world's population), the existence of much larger research programmes outside of WHO, and the changing research environment, WHO's programme of action for the period 2006-2015 (its General Programme of Work-GPW) envisages a reorientation of its mission, vision, and responsibilities in the area of health research. The 11th GPW[1] states that "shaping the research agenda for health and stimulating the generation, translation and dissemination of valuable knowledge", "articulating ethical and evidence-based policy positions" and "setting norms and standards, and promoting and monitoring their implementation" are among the Organization's core functions.

WHO's research emphasis

WHO has a long tradition of being engaged in research strongly related to health issues of the poor and disadvantaged. Through its flagship research programmes (TDR, HRP, IVR), its dedicated research centres (IARC, WHO Kobe Centre), its collaborations with key partners (AHPSR, GFHR, COHRED), and its many and varied networks, the Organization has played an important role in identifying neglected areas and, where possible, in filling some of the gaps left by academia, the private sector, and other actors in health research.

The Organization has an equally long tradition in helping to build research capacity in low- and middle-income countries. By providing technical support and assistance and through the designation of collaborating centres, WHO has facilitated and improved health research governance and capabilities, introduced the concept of a national health research system, and promoted solidarity between and within regions and subregions. These activities have been instrumental in creating networks of research centres and scientists who can engage in global research, as well as serve the needs of their countries.

[1] Currently in draft form-to be discussed at the 59th World Health Assembly, May 2006.

Among its other objectives, WHO's work is in particular invested in research synthesis and the translation of knowledge into practice. Even though a technical department may not have the resources to produce, fund, or implement health research, it must in the very least have the capability to find, synthesize, analyze, and interpret research results. Communication and knowledge sharing are integral components of the Organization's research activities. Thus, technical departments must also be able to develop policy briefs, documents and other materials to effectively communicate research results to different target audiences.

WHO's roles and responsibilities in health research

In addition to its specific roles and responsibilities as a producer, capacity builder, user, and communicator, several unique comparative advantages point to other key roles WHO has to play in global health research. Among WHO's comparative advantages in health research are its position within the United Nations system, its role as the world's leading technical support agency in health, its mandate in health research, its ability to draw on and convene the best scientific expertise globally across all key disciplines, its cost-effectiveness in conducting research, its credibility and the fact that it is respected by all stakeholders, and its direct links to Ministries of Health and direct reach into national health-care systems. Therefore, depending on the research activity, WHO may act as an advocate, a catalyst, a consensus builder, a convenor, a setter of norms, and/or a steward.

In brief, WHO's roles and responsibilities in health research include:

- promoting the messages that research is fundamental to generating knowledge to improve health outcomes and that evidence must inform the design and implementation of health programmes as well as all attempts to reform and strengthen health systems;
- advocating for increased funding (from governments in low- and middle-income countries and from donors) for neglected areas of health research;
- influencing the global health research agenda and advocating for research and research-translation efforts to address the most pressing health needs in Member States;
- fostering communication among the main organizations devoted to health research for development and other key stakeholders;
- building consensus among governments, funders, researchers, NGOs, civil society, and industry around global health research priorities, policies, and strategies;
- creating, sustaining, and participating in national, regional, and global partnerships, including public-private partnerships, that aim to identify knowledge gaps, establish research priorities, initiate new research to generate such knowledge, and accelerate product development;
- setting norms and standards for health research, including its ethical oversight, and developing "best practices" guidelines;
- performing and supporting research in priority areas where the Organization has a comparative advantage;
- taking a leadership role in addressing potentially controversial and/or neglected research issues that have an impact on health such as those associated with

intellectual property rights, sexual and reproductive health, equitable access to the benefits of research, social determinants of health, human resources, patient safety, and public access to information on clinical trials;

- assisting Member States in developing capacity to conduct health research, identify health research priorities, evaluate research results, translate knowledge, solve health-related problems by using evidence to inform policy, assess the impact of interventions and programmes in terms of outcomes and sustainability for development and equity goals, and communicate lessons learned;
- gathering, synthesizing, and disseminating research results and ensuring that all users of health research have access to reliable, relevant, and timely information;
- building public trust in and support for health research.

Room for improvement

Despite significant contributions in many aspects of research, some aspects of WHO's involvement in health research could be further strengthened, especially in the way research is managed and used within the Organization. The present Position Paper calls for a stronger research culture at WHO, more evidence-based evaluations, standardized and transparent administrative procedures, better coordination of research activities between programmes, departments, regions, and countries, and increased and more sustainable funding for research. It also argues that more needs to be done to convince governments of the benefits of investing in health research.

Accomplishing these broad objectives and tackling the diverse issues will require the formulation of a comprehensive WHO strategy for health research. Because time and resource constraints limited the focus of this paper to WHO headquarters, the first step is a complete mapping and assessment of WHO's research activities, functions, and mechanisms across all levels of the Organization. The mapping must extend to all WHO's collaborating centres, dedicated research centres and partnerships that are involved in research.

Deciding what specific actions to take will largely depend on the answers to several crucial questions related to WHO's overall goals and framework, areas of research activity, and supporting and collaborative mechanisms.

The strategy must also address the following issues:

- WHO's staff capacity to implement the recommended changes;
- the structural changes and/or new mechanisms needed to improve the coordination and streamlining of research activities, to avoid duplication, and to communicate lessons learned across WHO; and
- the mechanisms that will be used to evaluate the activities and to monitor progress in the medium to long term.

The actions that have been proposed in this paper will be invaluable for WHO's own work, its support to Member States, and its interactions with partners, as well as for achieving the objectives of the 11th General Programme of Work (2006-2015).

1. Background

In May 2005 the 58th World Health Assembly requested the Director General "to undertake an assessment of WHO's internal resources, expertise, and activities in the area of health research, with a view to developing a position paper on WHO's role and responsibilities in the area of health research, and to report through the Executive Board to the next World Health Assembly" (WHA 58/34).

In response to this request, this paper seeks to clarify WHO's roles and responsibilities in health research both within the Organization and among the multiple constituencies and partners with which it interacts. It also considers how WHO needs to evolve to strengthen it's capacity to help meet global health challenges and lead the world towards improved health.

It is important to note at the outset that this document and the initial, independent report of WHO's research activities that has informed it[2] have largely focussed on WHO headquarters — on its major research programmes and initiatives (HRP, TDR, IVR) and on departments involved in research or in the use of the results of research. A complete mapping and assessment of research activities across the entire Organization that includes regions, countries, dedicated research centres, collaborating centres, and partnerships would have required more time and resources.

The Position Paper was developed under the guidance of the Inter-Cluster Research Group (ICRG). The following departments, representing all clusters, participated as members of the ICRG: CDS/TDR, EIP/RPC, EIP/KMS, FCH/CAH, FCH/IVR, FCH/RHR, HTM/HIV, HTP/PSM, HTM/STB, HTP/PSM, NMH/VIP, SDE/ETH (see Annex 5 for abbreviations and acronyms). The Group worked in close collaboration with relevant programmes and departments within WHO, as well as with the Advisory Committee on Health Research (ACHR). It has also relied on documents prepared for the WHO Eleventh General Programme of Work for 2006-2015, other relevant documents and articles, and structured interviews with department directors. A draft of the Position Paper was widely circulated and comments received were incorporated during the preparation of the final draft.

2. Contemporary issues in global health research

Unprecedented advances in scientific knowledge in the past 50 years complemented by appropriately directed research and development efforts have led to medicines, vaccines, diagnostics, and medical devices that have dramatically improved health worldwide. With the genomics and proteomics revolutions well underway, even more impressive research-driven innovations may be on the horizon. The need for new interventions to fight both communicable and non-communicable diseases is great: a vaccine for AIDS or pandemic influenza, a new treatment for tuberculosis or dengue, cures for cancer, heart disease, and diabetes, and better methods to prevent and diagnosis sexually transmitted infections are just a few examples of the many contributions biomedicine has yet to make to global health.

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[2] Kabir ZN, Holmgren J. Overview of research activities at the World Health Organization, report to the Swedish International Development Cooperation Agency (SIDA), December 2005. http://www.sida.se/sida/jsp/sida.jsp?d=118&a=23350.

Expanding health research agenda

But advances in biomedicine alone will not be sufficient to improve global health. New knowledge is required in all fields of health research, including operational, behavioural, economics, social sciences, and health systems and policy research. Such research often requires the use of qualitative as well as quantitative research methodologies. Some of the most urgent research questions relate to strengthening health systems: how to develop a sustainable health financing system that is responsive to the needs of the poor; how to train and sustain an adequate number of health workers to deliver health services; how to achieve universal access to safe, effective, and affordable interventions; how to develop a sustainable and reliable health information system; how to "scale-up" interventions; and how to better integrate "intervention-oriented" programmes within the broader health system?

Because the social and cultural determinants of health (gender, income, education, ability, conflict, violence, ethnicity, etc) have a significant impact on health outcomes, equity, and access to care, they have acquired a more prominent position on the global health research agenda. The health effects of globalization and climate change are among the multisectoral and cross-cutting topics that are being studied, as are responses to outbreaks of emerging diseases and to emergency health situations arising from natural and man-made disasters.

Improving research management and utilization

Ethics, intellectual property rights, systematic reviews and syntheses, public registration of clinical trials, and access to information are among the contemporary issues that concern the conduct of research.

Given that the development and implementation of evidence-based health-care policy and practice depends on research that addresses the need of the local population, all countries, including the least developed, need some capacity for analysis and research. Strengthening research capacity will allow for more research in and by low- and middle-income countries.

Research aimed at understanding policy-making processes and learning how to translate knowledge into practice more effectively has been receiving more attention from researchers in recent years. A participatory approach — collaborating with policy-makers in setting research questions and priorities — has been shown to improve the uptake of research results.

Linking health research to development

Several landmark events have raised awareness that improving population health in developing countries contributes to poverty reduction, that research is fundamental to achieving global health and development goals, and that health research needs increased investment. The 1990 report of the Commission on Health Research for Development drew attention to the “10/90 gap”— that less than 10% of global health research resources were being spent on health problems affecting 90% of the world’s population. This report was followed by the Ad Hoc Committee on Health Research Relating to Future Intervention Options in 1996 and the International Conference on Health Research for Development in 2000.

In 2004, WHO published the World Report on Knowledge for Better Health, which focused on research to strengthen health systems, and it co-sponsored a Ministerial Summit on Health Research with Mexico’s Ministry of Health. This was the first-ever

gathering of ministers held to discuss the role of health research in improving health globally. The main outcome of the meeting, the Mexico Statement on Health Research, defines an action agenda to help attain the key objectives. For example, it includes a call for the establishment and implementation of national health research agendas and the investment of 2% of national health expenditures into research and research capacity strengthening, as was suggested in 1990 by the Commission on Health Research for Development.

At the same time, the number of researchers and agencies undertaking and/or advocating for research on topics of relevance to health and development has been rising, as have overall levels of funding. These developments have been spearheaded by national and intergovernmental entities, in particular the USA's National Institutes of Health and the European Union; by foundations, most notably the Bill & Melinda Gates Foundation and the Wellcome Trust; and by industry. The work of groups like the International Clinical Epidemiology Network (INCLEN), the Council on Health Research for Development (COHRED), and the Global Forum for Health Research (GFHR) has been complemented by several public-private partnerships. These include, among others, Drugs for Neglected Diseases (DNDi), the European and Developing Countries Clinical Trials Partnership (EDCTP), the Global Alliance for TB Drug Development (GATB), the Accelerated Development and Introduction Plans of the Global Alliance for Vaccines and Immunization (GAVI), Malaria Vaccine Initiative (MVI) and the Medicines for Malaria Venture (MMV).

Although billions of dollars have been earmarked for global health research and development and significant progress has been made, the knowledge gaps are still greatest in areas of health where most of the people affected are poor and marginalized.

Leading the way

In light of continued inequities in health, the persistence of the “10/90” gap in the funding of research, the existence of much larger research programmes outside of WHO, and the changing research environment, WHO’s new General Programme of Work (GPW), a progamme of action for the period 2006-2015, envisages a reorientation of its mission, vision, and responsibilities in the area of health research. The 11th GPW states that "shaping the research agenda for health and stimulating the generation, translation and dissemination of valuable knowledge", "articulating ethical and evidence-based policy positions" and "setting norms and standards, and promoting and monitoring their implementation" are among the Organization’s core functions. In addition to ensuring access to essential services, harnessing knowledge, science and technology, and building well-financed and equitable health systems, the GPW has also placed security, human rights, poverty, social determinants, the environment, the workforce, and governance on the global health agenda.

The GPW acknowledges that meeting these challenges will depend in part on the generation and utilization of tools and information arising from research, especially in least-developed countries. Also required are leadership, commitment, adequate funding, and equitable, effective, and innovative partnerships.

3. Overview of WHO’s research activities

WHO’s Constitution states that "the extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health" and that "in order to achieve its objectives, the functions of the Organization shall be … to

promote and conduct research in the field of health". Article 1.1 of the 1948 agreement between UNESCO and WHO gives WHO the primary responsibility for "the encouragement of research…in the fields of health and medicine."

As a result of its mandate in health research, WHO has developed technical strengths and competencies across the entire spectrum of scientific enquiry, from setting priorities to formulating policies and guidelines, and from developing interventions to implementing and evaluating programmes. WHO's research activities are spread across different departments and programmes, between headquarters, regions, and countries, and through diverse institutional arrangements, partnerships and collaborations. See Annex 1 for selected historical milestones of WHO's involvement in health research and Annex 2 for examples of WHO-led research projects that have had a significant impact on public health. The Organization's current research activities include:

- two co-sponsored special programmes — HRP, which concentrates on human sexual and reproductive health research, and TDR, which focuses on tropical disease research, and one initiative — IVR, which is dedicated to vaccine research. All three are solely devoted to research;
- an alliance/partnership housed within WHO, AHPSR, focuses on health policy and systems research.
- 34 technical departments at WHO headquarters engaged in research activities, especially operational and epidemiological research;
- two partnerships housed within WHO — Roll Back Malaria and Stop TB — that actively support and coordinate a broad range of research activities;
- an alliance, the World Alliance on Patient Safety, and the Commission on Social Determinants in Health, housed within WHO, addresses research issues in their respective fields.
- several public-private partnerships play important roles in global health research. WHO's role in these groups ranges from host and collaborator to participant and sponsor;
- two specialized centres located outside Geneva—the International Agency for Research on Cancer (IARC) in Lyon, France and the Centre for Health Development in Kobe, Japan; and
- 368 (of 920) WHO Collaborating Centres as of May, 2006 that are involved in a wide range of research activities.

Annex 3 provides brief descriptive details about some of these entities.

Internal resources and expertise

Selected quantitative and qualitative data related to WHO's internal resources and expertise for the year 2004 (e.g. funding, projects, regional distribution, balance between different areas of research etc.) were obtained during an initial assessment of WHO's activities in this area[3]. Highlights include the following:

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[3] Kabir ZN, Holmgren J. Overview of research activities at the World Health Organization, report to the Swedish International Development Cooperation Agency (SIDA), December 2005. http://www.sida.se/sida/jsp/sida.jsp?d=118&a=23350.

- Annual spending on research was approximately $56 million (i.e. approximately 3.7% of the overall budget of the Organization) with more than 90% of this coming from extra-budgetary sources;
- Of approximately 600 research projects, 30% were based at AFRO, 17% at headquarters, 16% in AMRO, 12% in EURO, 10% in SEARO, 8% in WPRO, and 7% in EMRO;
- Major types of activities included coordinating research, performing research, and providing professional and financial support and technical expertise;
- For identification of research priorities, the most important determining factors were the current magnitude of the problem, implications for development of policy, and projected cost-effectiveness of interventions and expected results;
- For assessment of research proposals, the most important deciding factors were scientific merit, public health relevance of research topic, and policy implications.

4. Defining WHO's research emphasis

Each special programme, department, and WHO-linked institution places a different emphasis on types of research, institutional arrangements, and relationships with public and private partners. Governance, management, and funding mechanisms also vary. IARC, TDR, and HRP, for example, have independent governance structures and their programme of work is determined by their own governing councils. One common principle the Organization aspires to is that an ethical review committee within the WHO Secretariat examines all research proposals involving human subjects receiving any form of contribution from the Organization. The following four principles, which are shared across a diverse range research activities, define WHO's research emphasis.

Focussing on the poor and disadvantaged

Since its inception and in line with its mandate, WHO has been mostly engaged in research that is relevant to improving the health of the world's most marginalized populations. This is indeed a core element of WHO's research agenda and should remain an important criterion to make choices between the different roles of WHO and to identify priorities within each role. Through its flagship research programmes (TDR and HRP), its collaborations with key partners, and its many and varied networks, the Organization has played an important role in identifying neglected areas and, where possible, in filling some of the gaps left by academia, the private sector, and other actors in health research.

WHO should continue to strengthen its associated research programmes (in sexual and reproductive health, tropical diseases, vaccines, and health systems research) in areas where they have a comparative advantage. WHO should also perform a monitoring function in relation to the resources devoted to particular research areas. Given that research priorities are often influenced by strong financial interests, it is essential that WHO represents the needs of the poor and disadvantaged when it comes to setting the global research agenda. Where multiple and somewhat disparate initiatives and organizations are engaged in research activities (e.g. public-private partnerships for neglected diseases, health systems and health policy research) WHO and its programmes should try to be a unifying force, and bring coherence, understanding,

harmonization, and rationale to the multiple stakeholders and donors involved in such research.

Strengthening research capacity and collaborative networks

WHO has an equally long and important tradition of strengthening research capacity and research institutions in low- and middle-income countries. Its special programmes, departments, and partnerships carry out a range of country support and technical assistance activities. The designation of collaborating centres also contributes to strengthening national capacity. Through its work in this area, WHO has improved health research governance and introduced the concept of a national health research system. It has played a key role in supporting Member States as they set their own research priorities and agendas, and in helping them to develop infrastructure, such as Institutional Review Boards for conducting ethical review before research involving human subjects is undertaken, developing sound protocols for research that involves human subjects, laboratory expertise, etc.

These activities have also been instrumental in promoting solidarity and in creating networks of research centres and scientists within regions and subregions who can engage in global research, as well as serve the needs of their countries. Networks of WHO collaborating centres are an important channel to facilitate the exchange of information, experience, and expertise between developing countries.

Research synthesis and knowledge translation

Among its other objectives, WHO's work is in particular invested in research synthesis and the translation of knowledge into practice. Even though a technical department may not have the resources to produce, fund, or implement health research, it must in the very least have the capability to find, synthesize, analyze, and interpret research results. Adhering to the following five principles will help to ensure the translation of highly promising research into clinical applications and effective policies:[4]

- Good intentions are not enough to protect patients from unintended harm;
- Systematic reviews of research should inform decisions in health care;
- Biased under-reporting of research is unethical and should be condemned;
- More robust, high quality research is needed, and research should be undertaken for the right reasons; and
- New research should begin and end with systematic reviews of other relevant research.

WHO can encourage the adoption of these principles throughout the health research community by applying them to its own research activities and by linking researchers with decision-makers. It can also use its unique position as the United Nations specialized agency for health to bring about needed change. One recent example is WHO's leadership in setting up a meta-register of controlled clinical trials.

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[4] The five principles that should be used to guide decisions about health research were presented by Sir Iain Chalmers at the Ministerial Summit on Health Research, held in Mexico City in November 2004.

Communication, dissemination, and access to knowledge

Communicating and sharing knowledge are integral components of the Organization's research activities. As a promoter and disseminator of knowledge derived from scientific research, WHO accelerates the development of evidence-based policies and practices. Thus, in addition to research synthesis, technical departments must also be able to develop policy briefs, documents and other materials to effectively communicate results to different target audiences.

WHO disseminates research results and helps improve access to information through the WHO Bulletin and numerous other publications and reports, as well as through initiatives like BIREME (Latin American & Caribbean Center on Health Sciences Information), HINARI (Health Inter-Network Access to Research Initiative), RHL (Reproductive Health Library), and the planned Global Health Library (see Annex 4 for examples of publications and tools). Some initiatives like HEN (Health Evidence Network) and the European Observatory on Health Systems and Policies also facilitate the utilization of knowledge by providing evidence-based briefs to policy-makers.

5. WHO's comparative advantages in health research

Understanding WHO's comparative advantages further clarifies WHO's role in health research, the functions it is best equipped to perform, and how it can best work with its partners and collaborating centres to address major public health problems and improve health. Its comparative advantages include:

- its position within the United Nations system;
- its role as the world's leading technical support agency in health;
- its mandate in health research
- its experience in research and research capacity strengthening;
- its ability to draw on and convene the best scientific expertise globally across all key disciplines;
- its cost-effectiveness in conducting research;
- its independence and impartiality;
- its credibility and the fact that it is respected by all stakeholders; and
- its direct link to Ministries of Health and direct reach into national health-care systems.

An appreciation of some of the comparative *disadvantages* may also be helpful:

- its relatively small role as a major funder and supporter of health research;
- its having to deal with foci of "anti-research" culture within the Organization;
- its bias towards research activities favoured by extrabudgetary funding sources;
- its patchy and uneven distribution, within the Organization, of research expertise.

6. WHO's roles and responsibilities in health research

In addition to its specific roles and responsibilities as a producer, user, and capacity builder (see section 4), the Organization's unique comparative advantages point to other key roles it plays in global health research. Depending on the research activity, WHO may act as an advocate, a catalyst, a communicator, a consensus builder, a convenor, a setter of norms, and/or a steward.

In brief, WHO's roles and responsibilities in health research include:

- promoting the messages that research is fundamental to generating knowledge to improve health outcomes and that evidence must inform the design and implementation of health programmes as well as all attempts to reform and strengthen health systems and health policies;
- advocating for increased funding (from governments in low- and middle-income countries and from donors) for neglected areas of health research;
- influencing the global health research agenda and advocating for research and research-translation efforts to address the most pressing health needs in Member States;
- fostering communication among the main organizations devoted to health research for development and other key stakeholders;
- building consensus among governments, funders, researchers, NGOs, civil society, and industry around global health research priorities, policies, and strategies;
- creating, sustaining, and participating in national, regional, and global partnerships, including public-private partnerships, that aim to identify knowledge gaps, establish research priorities, initiate new research to generate such knowledge, and accelerate product development;
- setting norms and standards for health research, including its ethical oversight, and developing "best practices" guidelines;
- performing and supporting research in priority areas where the Organization has a comparative advantage;
- taking a leadership role in addressing potentially controversial and/or neglected research issues that have an impact on health such as those associated with intellectual property rights, sexual and reproductive health, equitable access to the benefits of research, social determinants of health, human resources, patient safety, and public access to information on clinical trials;
- assisting Member States in developing capacity to conduct health research, identify health research priorities, evaluate research results, translate knowledge, solve health-related problems by using evidence to inform policy, assess the impact of interventions and programmes in terms of outcomes and sustainability for development and equity goals, and communicate lessons learned;
- gathering, synthesizing, and disseminating research results and ensuring that all users of health research have access to reliable, relevant, and timely information;
- building public trust in and support for health research.

7. Room for improvement

Despite significant contributions in many areas of research (see Annex 2), some aspects of WHO's involvement in health research could be further strengthened, especially in the way research is managed and used within the Organization. Several of the proposals put forward in this section are based on some of the principles and expectations of Member States that were spelt out in the 58th World Health Assembly's resolution on health research (WHA 58/34).

Stronger research culture at WHO

Embedding research and an appreciation of research issues throughout all levels of the Organization would encourage innovation, promote the conduct and use of research, and increase capacity to manage complexity. It would also strengthen the ties between policy and programme development, on the one hand, and research, on the other. A stronger research culture could be promoted by integrating research activities as part of work plans, recognising research activities in PMDS (Performance Management and Development System), rewarding outstanding research, and encouraging knowledge exchange. For example, staff could be encouraged to affiliate with an academic institution in order to pursue a research degree or sabbatical leave linked to WHO work (which may involve flexibility regarding paid or unpaid leave) or to supervise research students.

More evidence-based evaluations

Perhaps the most effective way for WHO to gain support among Member States, funders, potential partners, and the public for its mandate in health research would be to lead the generation of a substantial body of evidence from evaluation studies showing how research has led to improved health outcomes. Evaluations of interventions that did not have the desired results and detailed assessments of research following major health emergencies (SARS, avian influenza, the Asian tsunami, etc) would also be valuable. Where appropriate, these evaluations and assessments should be done as a joint effort between the people who needed the evidence, those who conducted the research, and those who sought to make it accessible. Relating research funding to health outcomes will provide evidence to convince governments that money spent on research contributes significantly to the health of the nation and is an essential complement to that spent on health care.

Need for standardized procedures

Given its position as the world's leading health agency, WHO must ensure that all its research projects are informed by appropriate review of existing evidence (including systematic review), conducted in accordance with established ethical guidelines, and accompanied by an active dissemination strategy. It must also demonstrate that soundly based and well-targeted research is used to inform decisions in all areas of its work. A few WHO programmes — in particular TDR, HRP, and IVR — have transparent, accepted and well-established mechanisms for assessing research applications, prioritizing research, funding research through scientific expert committees, etc. But across the Organization as a whole, there is a need to develop standardized and streamlined administrative procedures related to the conduct of research and the use of research results. This includes the registration of research proposals in a publicly accessible database, the setting of priorities for research undertaken by the Organization, the funding of research, the peer review of proposals, the dissemination of

results, and the use of research in the development of guidelines and recommendations. In addition, WHO should assess the role and mandate of the Advisory Committee for Health Research and provide more clarity on how members are selected and how its advice is acted on.

Better coordination and communication

WHO's current research agenda operates over an extremely broad range of topics and over wide geographical areas. While this is to be applauded, the delineation of research responsibilities between each level of the Organization (i.e. headquarters, regions, countries) is very unclear. Such differentiation is important because some research, such as product R&D, needs to remain global, while other types, such as health systems research, are best undertaken at a local level. Improving coordination of research activities and communications between headquarters, regions, and countries, across departments, and among partners and collaborating centres should result in more effective collaborations, more efficient use of resources, and less duplication of work. The WHO Secretariat should investigate the need to develop a management system to steer research activities, not only between different departments, regions, and countries, but also with its other institutional relationships (other health related UN-agencies, public-private partnerships, collaborating centres etc).

Increased and more sustainable funding

Because only a small percentage of its regular budget gets allocated to research, WHO's research activities are highly dependent on largely unpredictable extra-budgetary income. The increasing dependence on voluntary funds to support research and the decreasing number of donors severely challenges the Organization's ability to fulfil its research functions in an independent manner. Funding agencies or research institutions may not be aware or appreciative of the role and capacity of WHO in research and are therefore reluctant to engage in collaborating with the Organization in areas relevant to its mission, mandate, interest, and priorities. Some development assistance agencies and foundations even exclude research from their funding agreements. The WHO Secretariat should allocate more of it budget explicitly to priority research activities.

…at country level

Governments in many countries still need to be persuaded that health research is an essential input to health development and that investment in health research will benefit health policy. WHO should advise governments on how to organise for and fund health research in and by countries, not solely for the sake of national health services but also for the sake of linking up with international research and providing quality based higher education in health-related professions. While some ministries of health have their own institutions doing research, health research is also undertaken by universities, which are often linked to the ministries of higher education, and by national science councils and medical research institutes, which are often associated with ministries of science and technology. Therefore, WHO country representatives must extend their focus beyond ministries of health. To help a country develop a research agenda relevant to the health needs of the population and translate research into policies and programmes, country representatives should act as knowledge brokers. They should bring together researchers, policy-makers, and other users of research results and they should foster intersectoral dialogue among ministries of health, science and technology, education, health, housing, environment, finance, trade etc.

8. Towards a strategy for health research

Accomplishing the broad objectives and tackling the diverse issues mentioned in this Position Paper require the formulation of a comprehensive strategy. The first step is a complete mapping and assessment of WHO's research activities, functions, and mechanisms across all levels of the Organization — headquarters, regions, and countries. The mapping must extend to all WHO collaborating centres, dedicated research centres and partnerships that are involved in research.

Deciding what specific actions to take will largely depend on the answers to several crucial questions.

Overall goals and framework

- What is the role of WHO in setting global health research priorities?
- Does WHO's research structure need to be adapted to address the research issues in the various action points contained in the Eleventh GPW? (e.g. What is WHO's role in research on health-related human rights?, or on the social determinants of health?, or on strengthening health systems governance and leadership?)
- How can WHO ensure that efforts to strengthen research capacity are being undertaken in low-income countries?
- Should the decision made in 1959 to establish ACHR as an independent body from the Secretariat be reviewed? Is there a need to create a new structure in the Secretariat to give research a more prominent role inside the Organization and help mainstream a research "culture"? What could be the role of institutional partners, such as the World Bank, UNDP, UNICEF, and UNFPA, which have been so successful in the establishment and management of TDR and HRP?

Areas of research activity

- How can already successful programmes (TDR, HRP, IVR, IARC, etc.) be maintained and expanded at the same time as embracing new areas (e.g. research policy, health policy and health systems research, setting norms and standards) that will require new technical expertise and substantial financial support?
- What is the most effective and efficient way to apply an overall set of research principles to all WHO departments? Should each department, or each area of work, consider the need for a research component using pre-established guidance on what research it should engage in?

Supporting and collaborative mechanisms

- What structural changes and/or new mechanisms, if any, are needed to improve the coordination of research activities?
- What is the best strategy to facilitate the exchange of views and consultative processes between country offices, regional offices, and headquarters?
- How can WHO enhance the role of collaborating centres, as well as expand institutional linkages with major research institutions and with research centres that are emerging in developing countries?

- WHO/private sector collaborative ventures are expanding and experience is accumulating on approaches that achieve the highest impact. What are the policy, legal, and administrative implications of these diverse relationships?
- What linkages should WHO establish with "non-traditional partners" such as research institutions dealing with issues like social determinants or ethics?

The strategy must also address the following issues:

- WHO's staff capacity to implement the recommended changes outlined in the present Position Paper;
- any structural changes and/or new mechanisms needed to improve the coordination and streamlining of research activities, to avoid duplication, and to communicate lessons learned across WHO; and
- the mechanisms that will be used to evaluate the activities and to monitor progress in the medium to long term.

The actions that have been proposed in this paper will be invaluable for WHO's own work, its support to Member States, and its interactions with partners, as well as for achieving the objectives of the 11th General Programme of Work (2006-2015).

ANNEX 1 Selected historical milestones of WHO's involvement in health research

Year	Initiative/activity
1959	Establishment of the Advisory Committee on Medical Research (ACMR)
1965	Establishment of the International Agency for Research on Cancer (IARC) in Lyon, France
1972	Establishment of the Special Programme of Research, Development and Research Training in Human Reproduction (HRP)
1975	Establishment of the UNDP/World Bank/WHO co-sponsorship of Special Programme for Research and Training for Tropical Diseases (TDR)
1976	Concept of ACMR extended to all WHO regions
1986	ACMR became ACHR (Advisory Committee on Health Research)
1988	UNDP/ UNFPA/ WHO/World Bank co-sponsorship of Special Programme for Research, Development and Research Training in Human Reproduction approved by the World Health Assembly (WHA Resolution WHA 41.9)
1996	WHO Centre for Health Development established in Kobe, Japan
1996	Report from the Ad Hoc Committee on Health Research relating to future intervention options for investing in health research and development
1996	WHO becomes a signatory to the establishment of the International Vaccine Institute in Seoul, Korea
1997	ACHR report on a research policy agenda for science and technology to support global health development
1998	Following Ad Hoc Committee report (1996), WHO plays an important role in the establishment of the Global Forum for Health Research and provides in-kind support by hosting its secretariat within WHO headquarters
1999	Review of WHO's research strategy (Research strategy and mechanisms for cooperation, Document EB104/2, 104th session of the Executive Board)
1999	Creation of the Department of Research Policy and Cooperation
1999	Working through TDR, WHO incubates and spins off the first not-for-profit public private partnership for the development of new drugs, MMV
2000	WHO co-organized the International Conference on Health Research for Development in Bangkok, Thailand
2000	Alliance for Health Policy and Systems Research established and based in WHO headquarters
2000	Establishment of the Initiative for Vaccine Research (IVR)

2001	Release of the report from the Commission on Macroeconomics and Health: Macroeconomics and Health: investing in health for economic development.
2002	ACHR report on genomics and world health
2003	Establishment of the Department of Knowledge Management and Sharing
2004	Consolidation and strengthening of the WHO Research Ethics Review Committee (ERC)
2004	Release of the World Report on Knowledge for Better Health, which focuses on strengthening health systems
2004	World Health Report 2004 on HIV/AIDS devotes Chapter 5 to the topic of sharing research and knowledge
2004	WHO convened the first ever Ministerial Summit on Health Research in Mexico; endorsement of the Mexico Statement on Health Research by the 52 Member States attending the summit
2005	Resolutions on health research based on the Mexico Statement adopted by the 115th session of the Executive Board (document EB115/30) and the 58th World Health Assembly (document WHA58/34)
2005	Establishment of the secretariat for an International Clinical Trials Registry Platform (launched planned in 2006)
2005	Launch of EVIPNet (Evidence-informed Policy Networks) to strengthen national mechanism linking research evidence to health policy development

ANNEX 2 Some examples of WHO-led research impact

Impact area	Description
Development of several new contraceptives	Several long-acting contraceptives have been developed through HRP-sponsored research and subsequently produced, marketed, and distributed through a public-private partnership. Among these is the injectable contraceptive Cyclofem, for which commercialization is managed by the Concept Foundation.
Promotion of emergency contraception	International multicentre studies were carried out with the support of HRP and demonstrated the greater effectiveness and safety of high-dose levonorgestrel compared to the Yuzpe regimen for emergency contraception. An International Consortium for Emergency Contraception was formed to facilitate the registration and introduction of emergency contraception in countries. Currently, more than 100 countries have at least one registered emergency contraception product. It is estimated that the availability of this option has significantly reduced the numbers of unplanned pregnancies and of induced abortions.
Antenatal care	Routine antenatal care (ANC) is considered the cornerstone of preventive maternal and perinatal health. A detailed analytical review established that all necessary interventions can be optimally provided over four visits only. This model was tested and validated in a multicentre cluster-randomized trial. The new model is as effective as the standard Western ANC model and reduces costs significantly, making it particularly appropriate for resource constrained health systems. So far 16 countries have initiated implementation of the new model.
Development of new drugs for tropical infectious diseases	Nine new drugs for tropical diseases have been developed through TDR-initiated public-private partnerships. This represents over half of the new drugs registered for tropical disease use in the last 25 years. Perhaps the most significant of these are: ivermectin for onchocerciasis, praziquantel for schistosomiasis, eflornithine for African trypanosomiasis, and liposomal amphotericin B and miltefosine for leishmaniasis. A significant number of post-regulatory studies to inform the optimal use of drugs have also been undertaken e.g. Coartem for malaria.
Development and evaluation of diagnostics for tropical infectious diseases	Point-of-care diagnostics tests are being developed and evaluated for a range of diseases. The recent validation of several point-of-care tests for syphilis and enabling public sector procurement and use has had a significant impact on the potential for combating congenital syphilis in resource-poor settings.

Methodologies, strategies, and policies in tropical diseases	Several new approaches that have had a significant impact on controlling disease have been promoted and established as policy through appropriately directed multicentre studies. These include the use of insecticide-treated bednets and artemisinin combination therapy for malaria control, the use of community-directed ivermectin treatment for the control of onchocerciasis, the use of multidrug therapy for the control of leprosy, and the use of fumigant canisters for vector control of Chagas' disease. Increasing emphasis is being placed on studies to assist integrated approaches to disease control, taking into account social, economic, and behavioural issues.
Development of new technologies and devices	Many exploratory development projects are partnered and assisted by WHO. This can be at the basic or advanced level of development. One innovative project promoted by IVR that is likely to deliver practical results in a short time is the development of disposable cartridge jet injectors for safe, needle-free immunization. This technology holds the potential of eliminating the use of sharp objects from immunization programmes and of facilitating safe waste disposal.
Development of new vaccines	The Meningitis Vaccine Project (MVP) is a joint initiative between WHO and the Program for Appropriate Technology in Health (PATH). MVP, in collaboration with a number of stakeholders including industry, is developing a meningitis A conjugate vaccine for the African meningitis belt based on a price that reflects a cost-of-product calculation plus margin. Funded by the Bill and Melinda Gates Foundation, the strategy developed by MVP builds on the transfer of technology to manufacturers in developing countries.
Operational and epidemiological research	StopTB's projects to support community TB care, public-private DOTS, and TB/HIV collaborative interventions are examples of operational and epidemiological research in the context of a disease control programme.
Management of childhood illness	Research on diarrhoeal diseases including oral rehydration therapy and on management of pneumonia has been led and supported by WHO. This has resulted in a major expansion of the body of knowledge of effective measures and to their translation into guidelines and programmes at the country level.
Development of new tools for monitoring and evaluating child growth	Nutrition for Health and Development has coordinated the collection of data on child growth from 6 countries and these have been used to construct the WHO child growth standards which are a tool for assessing the growth of children from birth to 5 years of age.

Management of health research	The HRSA (Health Research System Analysis) initiative is working with countries to develop core indicators, tool kits, and methodologies to monitor key functions of health research systems.
Dissemination of research	The HINARI project has allowed full-text, free access to more than 2400 journals in more than 100 developing countries; WHO Bulletin impact factor increased from 1.5 in 1999 to 2.4 in 2003 (60%); the Health Evidence Network (HEN) and European Observatory for Health Systems and Policies in EURO prepares short policy briefs and in-depth analyses (based on research evidence) for policy-makers; the planned international clinical trials registry platform will increase access to and transparency of clinical research. EVIPNet (Evidence-informed Policy Networks) in countries aims to strengthen linkages between researchers and policy makers.
Research capacity strengthening	Both TDR and HRP have invested heavily in research capacity strengthening through a variety of strategies including research training and institutional development, and increasing the participation of developing country researchers in the formulation and implementation of their research agendas.

ANNEX 3 Overview of current research activities

I. Special Programmes and Research Initiatives

a) Special Programme of Research, Development and Research Training in Human Reproduction

The Special Programme of Research, Development and Research Training in Human Reproduction (HRP) was established by WHO in 1972 to coordinate, promote, conduct, and evaluate international research in human reproduction. In 1988, the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), and The World Bank joined WHO as co-sponsors of the Programme. As the main instrument within the United Nations system for coordinating the global research effort in the field of sexual and reproductive health, the Programme brings together health-care providers, policy-makers, scientists, clinicians, and consumer and community representatives to identify and address priorities for research aimed at improving sexual and reproductive health. HRP research helps people lead healthy sexual and reproductive lives by strengthening the capacities of countries to provide quality information and services that enable people to protect their own sexual and reproductive health and that of their partners. HRP supports and coordinates research on a global scale, synthesizes research through systematic reviews of literature, builds research capacity in low-income countries, and develops dissemination tools to make efficient use of ever-increasing research information.

b) Special Programme for Research and Training in Tropical Diseases

The Special Programme for Research and Training in Tropical Diseases (TDR) is an independent global programme of scientific collaboration. Established in 1975 and co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank, and WHO, it aims to help coordinate, support, and influence global efforts to combat a portfolio of major diseases of the poor and disadvantaged. One of its two objectives is to improve existing interventions and develop new approaches for preventing, diagnosing, treating, and controlling neglected infectious diseases. Interventions must be applicable, acceptable, and affordable in the developing countries where such diseases are endemic, and be able to be readily integrated into the health services of these countries. This research increasingly extends into research to evaluate tools and provide evidence for policy, and implementation research linked to control programmes to inform and develop strategies for improving accessibility to interventions in resource-poor settings. TDR’s second objective is to strengthen the capacity of developing countries to undertake the research required for developing and implementing these new and improved disease control approaches.

c) Initiative for Vaccine Research

The Initiative for Vaccine Research (IVR) was introduced by WHO's Director-General in 1999 and conceived jointly by the Health Technology and Pharmaceuticals Cluster (HTP), the Communicable Diseases Cluster (CDS), and UNAIDS. It aims to reinforce linkages between vaccine research and development and other components of immunization. Now housed within the Family and Community Health Cluster (FCH) in the Immunization, Vaccines and Biologicals Department, its roles are to provide a source of guidance and vision for vaccine R&D efforts worldwide, to contribute directly to a global research agenda with other partners, to advocate for R&D for priority vaccines, technologies, and vaccination strategies, to facilitate and coordinate clinical trials, to

ensure proper scientific and ethical standards, to provide normative guidance, standards, and reagents, to strengthen vaccine research capacity in developing countries, to facilitate technology transfer, to address the issues of access and introduction of new vaccines, and to encourage partnerships.

d) Alliance for Health Policy and Systems Research (AHPSR)

The aim of the Alliance is to promote the generation, dissemination, and use of knowledge to enhance health system performance. Its objectives are to stimulate the generation and synthesis of knowledge, encompassing evidence, tools, and methods; to facilitate the development of capacity for the generation, dissemination and use of knowledge among researchers, policy-makers and other stakeholders; and to promote the dissemination and use of knowledge to improve the performance of health systems. It does so through a variety of strategies including monitoring and publicizing the global progress of health policy and systems research (HPSR); synthesizing, disseminating, and funding research on priority areas; encouraging the attainment of a critical mass of researchers in the field of HPSR; promoting policy-relevant research and evidence-based decision making, including approaches that achieve effective interaction between key actors; ensuring widespread access to HPSR knowledge through effective communications strategies; and monitoring and evaluating progress in the Alliance partnership and secretariat.

II. Research within WHO departments

Research is a part of all 34 technical departments at WHO headquarters. Types of research include surveillance, secondary research, community-based intervention studies, clinical trials, economic studies, and health systems research.

A few examples of departments involved in research activities include:

a) Child and Adolescent Health and Development (CAH): www.who.int/child-adolescent-health/OVERVIEW/CHILD_HEALTH/child_overview.htm

b) Protection of the Human Environment (PHE): www.who.int/phe/en/

c) Stop TB (STB): www.who.int/tb/en/

d) Roll Back Malaria (RBM): www.who.int/malaria

d) Research Policy and Cooperation (RPC): www.who.int/rpc

e) Knowledge Management and Sharing (KMS): www.who.int/kms

f) Ethics, Trade, Human Rights and Health Law (ETH): www.who.int/eth

g) Medicines Policy and Standards (PSM): www.who.int/medicines/about/psm_contact

h) Violence and Injuries Prevention (VIP): www.who.int/violence_injury_prevention

III. WHO Specialized Centres involved in research

a) International Agency for Research on Cancer in Lyon, France

Founded in 1965, the mission of the International Agency for Research on Cancer (IARC) is to coordinate and conduct research on the causes of human cancer and mechanisms of carcinogenesis, and to develop scientific strategies for cancer control. IARC is involved in both epidemiological and laboratory research and the dissemination of scientific information through publications, meetings, courses, and fellowships. The Agency is directly involved in the implementation of control measures but only when necessary in order to assess the effectiveness of the mechanisms of carcinogenicity, or

when the experimental intervention is needed to permit identification of causes. IARC is part of WHO but it has its own governing council and scientific advisory board, and it is independently funded.

b) Centre for Health Development in Kobe, Japan

The WHO Centre for Health Development was established in 1996 as an integral part of WHO under the authority of the WHO Director-General, following the invitation from the Kobe Group. The Centre is directed to concentrate on issues relating to health development, with particular emphasis on health-care delivery and urbanization, delineating the place of health systems in society, determining the links between population, economy, environment and health, and assessing health needs from development perspectives. Its research activities improve scientific knowledge on the interrelatedness of social, cultural, economic, demographic, epidemiologic, and environmental factors and their effects on health development. The WHO Kobe Centre is positioned as a point of conversion of multidisciplinary discussion on the broad determinants of health. It also drives policy development and implementation by reviewing and effectively communicating existing research knowledge.

IV. WHO Collaborating Centres

An entire institution, or a department or laboratory within an institution, or a group of facilities for reference, research or training belonging to different institutions, may be designated as a "WHO Collaborating Centre". These centres play a strategic role in helping the Organization meet two major needs: they contribute to implementing WHO's programme priorities, in close coordination with the units concerned in WHO's six regional offices and at headquarters; and they strengthen institutional capacity in countries and regions.

Within this context, WHO collaborating centres may carry out one or several of the following functions:

- collection and dissemination of information;
- standardization of terminology and nomenclature, of technology, of diagnostic, therapeutic and prophylactic substances, and of methods and procedures;
- development, application and evaluation of appropriate technology;
- provision of reference substances and of services such as quality assurance;
- participation in collaborative research developed under WHO's leadership, including the planning, conduct, monitoring and evaluation of research, and the promotion of the application of its results;
- education and training, including research training;
- coordination of activities carried out by several institutions on a given subject;
- provision of information and advice on scientific, technical, and policy issues.

A database on WHO collaborating centres is being developed as a tool for enhancing communication and collaboration among institutions, networks and WHO and its constituents. This would help in evaluating how collaborating centres are chosen, renewed, and decommissioned, as well as how they report and respond to WHO research priorities.

ANNEX 4 Research publications and research tools

I. Research Publications

- By placing research findings and policy-relevant discussions side by side, the Bulletin of the World Health Organization aims to give public health policy and practice guidance based on the best evidence available, while also encouraging closer links between scientific investigation and the art of helping populations to lead healthier lives.
- The Eastern Mediterranean Health Journal aims to be a forum for the publication of research papers on a diverse range of medical topics and for the presentation of new initiatives in public health with special reference to the Eastern Mediterranean region.
- The Pan American Journal of Public Health communicates original research findings relevant to health problems in the Western Hemisphere. Articles are selected on the basis of their capacity to further scientific and technical understanding of diseases and the best ways to prevent and manage them.
- For more than seven decades, the Weekly Epidemiological Record has served as an essential instrument for the collation and dissemination of epidemiological data useful in disease surveillance on a global level. Priority is given to diseases or risk factors known to threaten international health.
- Launched in 1987, WHO Drug Information communicates pharmaceutical information that is either developed and issued by WHO or transmitted to WHO by research and regulatory agencies throughout the world. The journal also includes regular presentations of newly proposed and recommended International Non-proprietary Names (INN) for pharmaceutical substances.

II. Research Tools

- WHOLIS—WHO's library database available on the Internet—indexes all WHO publications from 1948 onwards and articles from WHO-produced journals and technical documents from 1985 to the present. An on-site card catalogue provides access to the pre-1986 technical documents.
- WHOSIS is a guide to epidemiological and statistical information available from WHO. Most WHO technical programmes develop health-related epidemiological and statistical information that they make available on the WHO website.
- WHODAS II is a family of international classifications, including i) international statistical classification of diseases, ii) international classification of functioning, disability and health, and ii) disability assessment schedule.
- Geographical information tools include i) communicable disease surveillance and response (public health mapping), ii) evidence and information for health policy (GIS), iii) global health atlas, and iv) PAHO/AMRO's SIG-Epi.

ANNEX 5 List of acronyms

ACHR	Advisory Committee on Health Research
ACMR	Advisory Committee on Medical Research
AFRO	WHO Regional Office for Africa
AHPSR	Alliance for Health Policy and Systems Research
AMRO	WHO Regional Office for the Americas
BIREME	Latin American & Caribbean Center on Health Sciences Information
CAH	Child and Adolescent Health and Development
CDS	Communicable Diseases cluster
COHRED	Council for Health Research and Development
DNDi	Drugs for Neglected Diseases Initiative
EDCTP	European-Developing Countries Clinical Trials Partnership
EIP	Evidence and Information for Policy
EMRO	WHO Regional Office for the Eastern Mediterranean
ERC	WHO Research Ethics Review Committee
ETH	Ethics, Trade, Human Rights and Health
EURO	WHO Regional Office for Europe
EVIPNet	Evidence-Informed Policy Networks
FCH	Family and Community Health cluster
GATB	Global Alliance for TB Drug Development
GAVI	Global Alliance for Vaccines and Immunization
GFHR	Global Forum for Health Research
GPW	WHO's General Programme of Work
HEN	Health Evidence Network
HINARI	Health Inter-Network Access to Research Initiative
HIV	HIV/AIDS department
HRP	UNDP/ UNFPA/ WHO/World Bank Special Programme for Research, Development and Research Training in Human Reproduction
HRSA	Health Research System Analysis
HTM	HIV/AIDS, TB and Malaria cluster
HTP	Health Technology and Pharmaceuticals cluster
IARC	International Agency for Research on Cancer
ICRG	Inter-cluster Research Group
INCLEN	International Clinical Epidemiology Network
INN	International Non-Proprietary Names
IVR	Initiative for Vaccine Research
KMS	Knowledge Management and Sharing
MDG's	Millennium Development Goals
MMV	Medicines for Malaria Venture
MVI	Malaria Vaccine Initiative
MVP	Meningitis Vaccine Project
NMH	Noncommunicable Diseases and Mental Health cluster
PATH	Program for Appropriate Technology in Health
PHE	Protection of the Human Environment
PMDS	Performance Management and Development System
PSM	Medicines Policies and Standards
RBM	Roll Back Malaria
RHL	Reproductive Health Library
RHR	Reproductive Health and Research
RPC	Research Policy and Cooperation

SDE	Sustainable Development and Healthy Environments cluster
SEARO	WHO Regional Office for South-East Asia
STB	Stop TB
TDR	UNDP/World Bank/WHO Special Programme for Research and Training for Tropical Diseases
UNDP	United Nations Development Program
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations population Fund
UNICEF	United Nations Children's Fund
VIP	Violence and Injuries Prevention
WPRO	WHO Regional Office for the Western Pacific

Annex VIII

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Regional Health Research Data Initiative
RHRDI

Pan American Health Organization
2007

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Regional Health Research Data Initiative: RCHDI

Pan American Health Organization

Health Systems Strengthening Area

Research Promotion and Development Unit

April 2007

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1. SUMMARY

The RHRDI is the proposal developed by HSS/RC for the Regional Health Research Data Initiative for the Region of the Americas, with the purpose of ensuring the availability of standardized information on health sciences research in the Hemisphere.

The objective of this document is to report on the proposal to develop the RHRDI and implement it in the Region of the Americas through the support and leadership of the Pan American Health Organization (PAHO). The launch of RHRDI in the Americas is built upon PAHO's experience with the development and harmonization of indicators, consultations with other organizations (such as the OAS and OECD) and related initiatives, and experiences in the countries of the Region. This document provides the background, objectives, expected results, components, current planning phase, development phase, the documentation consulted for RHRDI, together with the Annexes.

2. BACKGROUND

In 1995, the Pan American Health Organization (PAHO) launched a Regional Core Health Data and Country Profiles Initiative (RCHDI), which continues to function to this day and whose primary mission is to ensure the availability of the basic or essential health information on the Region of the Americas (AR) needed for the Organization and the countries that comprise it.

At the same time, following the example of the RCHDI, the Organization has implemented two initiatives for improving the available data and indicators in immunization and gender, areas that are highly relevant for PAHO. It is important to note that these two initiatives enjoy the support of the Interprogrammatic Advisory Group on Core Data and Health Situation Analysis whose role is to monitor the various processes of the RCHDI, with input from representatives of the different units and areas at Headquarters, as well as the Representative Offices in the countries. This reflects the horizontal relations and collaboration among the various structures within PAHO to ensure the availability of the basic relevant health information. It also reflects the support for ensuring the availability of information on specific themes (immunization and gender).

Within this context, it is important to mention the efforts of the World Health Organization, headquartered in Geneva, to develop a series of health indicators that will be useful worldwide; in 2005, the results of this effort were published within the framework of Health Information Systems (HIS). Other WHO regions are also launching their own initiatives, following the example of PAHO, which at one point was consulted about the RCHDI for these purposes. It is recognized that the "know-do" gap" is growing and that ensuring that the available knowledge is systematically considered in health policy-making and health interventions is an important challenge. Closing that gap is essential in research.

At the current time, information on health sector research is not reflected in PAHO's RCHDI. Thus, it is necessary to develop a specific mechanism to respond to information needs in health research. Following PAHO's conceptual and legislative framework to make progress toward improving the health of nations, and bearing in mind that the 10th Essential Public Health

Function refers to research, the *Regional Health Research Data Initiative (RHRDI)* is presented below.

Furthermore, the existing projects and literature on this subject should be reviewed and included, especially from the initiatives that are being advanced globally (WHO, COHRED) and regionally (BIREME, ScienTI, REDES/RICyT) to ensure the availability of baseline data.

3. OBJECTIVES

PAHO's RHRDI has the following objectives:

3.1 General objective:

Coordinate the processes leading to the identification and adoption by the Member States of a common set of indicators of the capacities, resources, processes, products or outcomes, priorities, and policies for public health research.

3.2 Specific objectives:

1. Conduct a systematic review of the development of indicators and standards; identify current regional and global initiatives, indicators, and information sources
2. Examine the indicators and agree on definitions and standards of measurement
3. Convene representatives from the different regional initiatives and reach agreement on the contributions, roles, and responsibilities of every project and initiative in meeting the general objective
4. Prepare a proposal for evaluating and monitoring the initiative
5. Set up an executive board to coordinate the RHRDI proposal and establish the mechanisms for coordination and linkage with other relevant initiatives
6. Devise the strategy for disseminating indicators, baseline data, and trends with respect to public health research capacities and processes

4. EXPECTED RESULTS

ER1. By the end of 2008, planning for the RHRDI will have been completed at PAHO Headquarters in Washington and in the countries.

ER2. By the end of 2009, the pilot phase in the proposed countries and its evaluation will have been completed.

RE3. In 2010, consolidation of the RHRDI will have begun and its deployment undertaken with the considerations incorporated in the pilot phase, with gradual implementation in all countries and territories in the Region of the Americas.

5. COMPONENTS OF THE RHRDI

5.1. Database with Health Research Indicators

An electronic tool will be available for multidimensional consultations of the RHRDI indicators specified by countries. IKM and ITS at PAHO Headquarters will provide assistance in the planning of this tool, which will take the form of a table generator.

5.2. Health Research Indicator System

The database will be constructed according to the Health Research Indicator System (HRIS), comprised of the following categories:

A. SOCIODEMOGRAPHIC
B. STRUCTURAL
C. PROCESS
D. RESULTS
E. IMPACT AND RELEVANCE

The data will be updated annually with the most recent information available. This information will be compiled in an annual joint effort between the Member States and the Pan American Health Organization (PAHO) through its Representative Offices and technical areas and units, coordinated by HSS/RC

5.3. Glossary of Health Research Indicators

For each indicator in the five categories mentioned, all the available information will be provided in the technical description (see Annex 1). The detailed list of indicators is found in Annex 2.

5.4. Pamphlet of Health Research Indicators

A biennial pamphlet of health research indicators will be published. It will contain a selection of the health research indicators found in the electronic database.

6. RHRDI PLANNING PHASE

The specifics of the RHRDI will be determined in 2007 and 2008. The RHRDI Secretariat (see further on) will be located in HSS/RC at PAHO.

The first steps that have been taken are: (1) A review of the information currently available; (2) Preparation of this document; and (3) The initial discussions with professionals at PAHO Headquarters (mainly HSS/RC) and the OAS.

The following action should be taken in the coming months: (1) Incorporation of suggested changes in the initial proposal, (2) Meeting to present the proposal to HSS/RC and HSS; (3) Presentation of the proposal at the 2007 meeting of the ACHR; and (4) Creation of an

interprogrammatic advisory group within PAHO/WHO to monitor the production of the document, an activity involving professional staff from HSS, IKM, ITS, BIREME, and other designated units; (5) Integration of the different projects, with the participation of the Representative Offices, ministries, ONCyTs, national planning offices, and networks such as ScienTI and RICyT; and (6) Presentation of the final proposal in the fourth quarter 2008.

6.1 Role of the RHRDI Secretariat

PAHO/WHO serves as the RHRDI Secretariat, ensuring effective and efficient planning. At PAHO, the Research Promotion and Development Unit (HSS/RC) of the Health Systems Strengthening Area serves as the RHRDI's technical secretariat

The RHRDI Secretariat plays a key role in the development and implementation of this proposal, as it will provide general support for the planning, implementation, and evaluation of this project.

The main activities of the RHRDI Secretariat during this process include, but are not limited to:

- ✓ Collaborating closely with the PAHO/WHO Representative Offices, the country support team, and the staff members who will be involved in the RHRDI
- ✓ Coordinating the evaluation of applications with experts to ensure the uniformity of the evaluation process
- ✓ Providing support for the RHRDI team and identifying opportunities for capacity building
- ✓ Promoting relevant resources (journal articles, tools, networks, databases) for this work
- ✓ Enlisting the participation of the key actors to maximize the viability and effective implementation of the proposals (for example, technical experts, financing agencies, and representatives of society)

The RHRDI Secretariat will also promote interaction with potential financing agencies that can support this initiative. During this period, a budget linked to the timetable and resources for the work will be drawn up.

7. RHRDI DEVELOPMENT PHASE

The development phase of the RHRDI will begin in 2009 with a pilot project, with definitive implementation beginning in 2010. Expected Results (ER) 2 and 3 refer to this phase. The pilot project will be carried out in countries selected on the basis of the recommendations made by the interprogrammatic group in 2007 and 2008. Obviously, the RHRDI Secretariat in HSS/RC will perform timely monitoring of this phase as well (see Annex 3).

8. INITIAL DOCUMENTATION

- http://cohred.org/cohred/Home.action
- Core Health Data: http://www.paho.org/english/dd/ais/coredata.htm
- Pan American Health Organization. 10-Year Evaluation of the Regional Core Health Data Initiative. Washington, D.C.: PAHO; 1 October 2004. (Document CD45/14)

- Pan American Health Organization. Health Indicators: Basic Elements for the Health Situation Analysis. Epidemiological Bulletin PAHO, 2001; 22 (4): 1-5.
- Pan American Health Organization. Collection and Utilization of Core Health Data. Washington, DC: PAHO; 14 July 1997 (Document CD40/19 and Resolution CD40.R10).
- http://hsc.unm.edu/lasm/Spanish/summary.shtml
- http://ec.europa.eu/health/ph_information/indicators/docs/longlist_en.pdf
- Pellegrini Filho A, Goldbaum M, Silvi J. Production of scientific articles about health in six Latin American countries, 1973-1992. Rev Panam Salud Publica. 1997 Jan;1(1):23-34. Spanish. Erratum in: Rev Panam Salud Publica 1997 Mar;1(3):212.
- "Assessment of Health Research Systems: Critical Review of Pragmatic Agreement Current Indicators", produced for the Council on Health Research for Development (COHRED) as a basic document for the meeting of the Working Group on *Indicators for the self-evaluation of health research systems in developing countries*. Geneva, May 2003.
- Cuervo LG, Valdés A, Clark ML. The international registry of clinical trials. Rev Panam Salud Publica. 2006 Jun; 19(6):365-70.
- Pérez Andrés C, López-Cozar ED, Jiménez Contreras E. The Revista Espanola de Salud Publica in the Social Science Citation Index of Thomson Scientific. Rev Esp Salud Publica. 2006 Jul-Aug; 80(4):293-302.
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- Delgado López-Cozar E, Ruíz-Pérez R, Jiménez-Contreras E. Medline criteria for scientific journal selection. Methodology and indicators. Application to Spanish medical journals paying special attention to public health. Rev Esp Salud Publica. 2006 Sep-Oct; 80(5):521-51.
- European Commission. Community Research. Study on the Economic and Technical Evolution of the Scientific Publication Markets in Europe. Final Report – January 2006.
- Manual FRASCATI.
- Typed text: "Acceso y uso de la información científica en salud en la Región de las Américas" for Salud de las Américas 2007. PAHO/WHO 2007.
- OECD Factbook 2006: Economic, Environmental and Social Statistics. OECD 2006.
- Documents from REDES, RICyT, EVIPNet, SCIELO, BIREME.

ANNEXES

Annex 1. Technical Description

Instructions for Technical Specifications

1. Font: Arial, size: 12
2. Paragraphs: 1.5 spaces
3. Please consider the number of words indicated (max. 200 words a piece)
4. Please send in Spanish and English

Technical Specifications

1. Name of the Indicator
2. Definitions and Basic Concepts
3. Unit of Measure
4. Type*:* Indicate whether they are rates, ratios, or absolute numbers.
5. Interpretation: Describe significance of what the indicator in question measures according to its values.
6. **Use**
7. Limitations of the indicator: Mention the characteristic limitations of the indicator and the difficulties obtaining the necessary data.
8. Calculation method and data necessary for determining the indicator*:* Indicate the formula used to calculate the indicator with its components, or alternatives for its estimation.
9. Available Categories*:* Indicate the disaggregations used to better interpret the indicator/datum (sex, age group, rural/urban).
10. **Data sources:** PAHO/WHO, United Nations, World Bank, Countries (Ministry of Health, Statistics Institute, etc.)

Annex 2. Potential list of indicators: preliminary version

Obviously, the indicators should be proposed once the review of the literature and existing initiatives has been conducted, based on the suggestions of both the ACHR and the Interprogrammatic Group in charge of this phase. The technical description in Annex 1 should be completed for each indicator, including the information sources and their definitions; for example, there should be a definition of "investigator" or of what should be included under "science and technology expenditure". This is the starting point, not the end.

A. SOCIODEMOGRAPHIC

A.1 - Population
A.2 - Proportion of urban population
A.3 - Annual population growth rate
A.4 - Crude birth rate
A.5 - Crude mortality rate
A.6 - Estimated total death rate, adjusted by age
A.7 - Life expectancy at birth
A.8 - Literacy rate

A.9 - Gross domestic product (GDP) per capita, international $ (PPP adjustment)
A10 – Annual national health expenditure as a percentage of GDP
A.11 –Income ration 20% highest/ 20% lowest
A.12 - Infant mortality rate
A.13 - Reported maternal mortality rate
A.14 - Proportion of the population with sustainable access to improved water supply sources
A.15 - Proportion of the population with access to improved sanitation services
A.16 - Physicians per 10,000 population
A.17 - Nurses per 10,000 population
A.18 - Hospital beds per 1,000 population

B. STRUCTURAL (this section will also include indicators of human resources for research, with a breakdown by training, location, and research area)

B.1 - Number of research centers
B.2 - Number of health science research centers
B.3 - Number of investigators
B.4 - Number of health science investigators
B.5 - Science and technology expenditure
B.6 - Proportion of health sciences expenditure in total science and technology expenditure.
B.7 - Science and technology expenditure in relation to GDP
B.8 – Per capita science and technology expenditure

C. PROCESS

C.1 - Total number of grants and fellowships requested
C.2 - Proportion of grants and aid requested in the health sciences
C.3. Total number of grants and aid received
C.4 - Proportion of grants and aid received in the health sciences
C.5 - Number of scientific conventions held
C.6 - Proportion of scientific conventions in the health sciences in total scientific conventions.
C.7. - Number of scientific communications
C.8 - Proportion of scientific communications in the health sciences in total of scientific communications.

D. RESULTS

D.1 - Publications in *Science Citation Index* (SCI)
D.2 - Publications in *Science Citation Index* (SCI) for the health sector
D.3 - Publications in *Chemical Abstracts*
D.4 - Publications in *Biosis*
D.5 - Publications in *MEDLINE*
D.6 - Publications in regional indexes
D.7 - Publications in SCI per inhabitant
D.8 - Publications in SCI per 100 investigators
D.9 - Publications in SCI in terms of GDP
D.10 - Publications in SCI in terms of R&D expenditure

D.11 - Publications in unindexed health sciences journals
D.12. - Patent requests in the health sciences
D.13 - Patents awarded in the health sciences

E. IMPACT AND RELEVANCE

E.1 - Impact Factor of the health sciences publications in the SCI
E.2 - Total number of citations of the health sciences publications in the SCI
E.3 – Award-winning publications in the health sector
E.4 - Publications with a social, public health, or medical impact

Annex 3. Preliminary RHRDI timetable

2007-2008	**RHRDI Planning Phase**
2009	**RHRDI Pilot Implementation Phase**
2010 on	**RHRDI Consolidation Phase**