Secretariat's Report to 42nd PAHO's Advisory Committee on Health Research - ACHR/CAIS

Rio de Janeiro, Brasil
14 April 2008

Dr. Luis Gabriel Cuervo
ACHR Secretary
Leader, PAHO/WHO Research Promotion & Development Team

Pan American Health Organization
Regional Office of the World Health Organization

ANEXO VI

Key Messages

- Recommendations from the Regional ACHR have been heard; action has been taken to address the new challenges while protecting achievements
- The preparation of PAHOs Research Policy is progressing according to the schedule agreed following the 41st ACHR. The policy is progressing as WHOs Health Research Strategy evolves; convergence
- Strong alignment with WHO ACHR; harmonization and cohesion are now regularly reported.
- ACHR members are active and have engaged in specific initiatives

Pan American Health Organization
Regional Office of the World Health Organization

This Presentation

- **Some background developments**
- **Committee Recommendations 40th and 41st ACHR/CAIS**
- **Progress Reports and achievements**
- **Questions, issues for debate**

Pan American Health Organization
Regional Office of the World Health Organization

Some background developments

Pan American Health Organization
Regional Office of the World Health Organization

2002 - 2006

Essential Public Health Functions

Mexico Ministerial Summit on Health Research

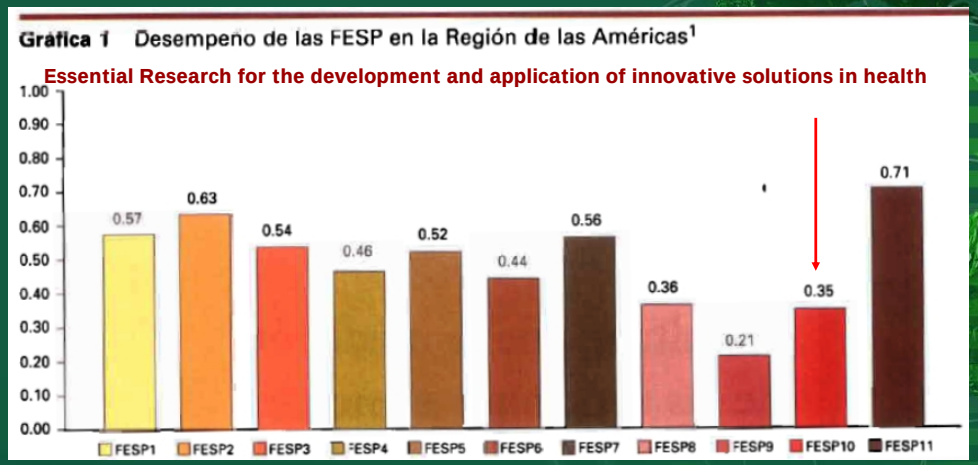
WHA Resolution on Health Research

Pan American Health Organization
Regional Office of the World Health Organization

Essential Public Health Funcitons

- EPHF 10: Essential Research for the development and the application of innovative solutions in public health
  - Indicators:
    - Development of public health research plans
    - Development of the institutional capacity in research
    - Assessment and technical support for public health research at the sub national levels

Pan American Health Organization
Regional Office of the World Health Organization



Source: PAHO, *Health in the Americas* 2002

Pan American Health Organization
Regional Office of the World Health Organization

Developments 2007 – 2008

- **Alignment of WHO and PAHO Strategic Plans (2008-2012)** and expected results for the next biennium.
- **IX IberoAmerican Conference of Ministers of Health** "*Social Cohesion & Health Protection*", Iquique, Chile:
  - **Ibero-American Ministerial Network for Education & Research for Public Health, RIMAIS. First meeting with countries March 2008**
- **Health Agenda for the Americas 2008-2017,** launched in Panama in June 2007

Pan American Health Organization
Regional Office of the World Health Organization

Health Agenda for the Americas
2008 -2017
Harnessing Knowledge, Science & Technology

- Agreed by Ministers of Health from Latin America & Caribbean, after broad consultation and involvement of other sectors; presented for the Assembly of the *Organization of American States,* Panama, 5 June 2007
- Impacts the 2008-2017 work plan of member countries

Pan American Health Organization
Regional Office of the World Health Organization

News and Public Information

Press Release

Health Agenda for the Americas Launched In Panama

PANAMA CITY, Panama, June 5, 2007 (PAHO)—The hemisphere's top health policy authorities have launched the Health Agenda for the Americas, setting out the health priorities the governments propose to tackle over the next decade. The plan was unveiled here before the opening of the 37th General Assembly of the Organization of American States (OAS).

Panamanian Health Minister Dr. Camilo Alleyne and PAHO Director Dr. Mirta Roses Periago.

Panamanian President Martín Torrijos, Panamanian Health Minister Dr. Camilo Alleyne, UN Secretary- General Ban Ki-moon and PAHO Director Dr. Mirta Roses, along with OAS Secretary General José Miguel Insulza signed the Health Agenda for the Americas.

PAHO's Dr. Roses said that launching the Health Agenda of the Americas represents a singleness of purpose around improving human life and enhancing understanding and harmony among peoples.

"The Health Agenda for the Americas will be a framework to orient the development of future health plans and the strategic plans of those organizations interested in cooperating in health with the countries of the Americas, including PAHO/WHO," she said.

Roses described the health plan as the product of a process of consultations at various levels, involving governments and civil society, to present "a platform that articulates the governments' sovereign and collective will, speaking to the world, to their citizens and to civil society while addressing the need for international cooperation and identifying what the health sector can contribute to development and what it needs from the other sectors."

Source: www.paho.org

Main topics Health Agenda

- Systematic use of research evidence
- Better understanding of health determinants and the means to address them
- Broader scope and identification of appropriate technologies
- Bioethics approach
- Equity and distribution of the benefits of progress
- Public engagement, appropriation, demands for knowledge, and confidence in research
- Rational use of resources
- Continuous improvement; monitoring & evaluation

Pan American Health Organization
Regional Office of the World Health Organization

Developments 2007 – 2008

- **Alignment of WHO and PAHO Strategic Plans (2008-2012)** and expected results for the next biennium.
- **IX IberoAmerican Conference of Ministers of Health** "*Social Cohesion & Health Protection*", Iquique, Chile:
  - **Ibero-American Ministerial Network for Education & Research for Public Health, RIMAIS. First meeting with countries March 2008**
- **Health Agenda for the Americas 2008-2017,** launched in Panama in June 2007
- **Bamako Ministerial Summit 2008 "Research for Health"**: consultations with Regional offices. PAHO consultation took place in February 2008. Consultation with Member States will precede WHA

Pan American Health Organization
Regional Office of the World Health Organization

Committee Recommendations and Secretariat's Response

May 2007

Pan American Health Organization
Regional Office of the World Health Organization

Recommendations ACHR May 2007 (Tab 9)

- Engagement of the ACHR with the process for the preparation of a PAHOs Policy for Research and its consultation
- Leadership to promote regional initiatives that promote the strengthening of national health research systems and the development and implementation of PAHOs research policy

Pan American Health Organization
Regional Office of the World Health Organization

Recommendations ACHR May 2007 (2)

- Implement a PAHO research inventory:
  - Characterizing and monitoring research
  - Leading by example
- Implement a strategy to bolster the use of scientific evidence in health policy building on existing resources, opening opportunities for local contributions, and based on local needs and context (EVIPNet Americas)

Pan American Health Organization
Regional Office of the World Health Organization

Committee Recommendations and Secretariat's Response

November 2007

Pan American Health Organization
Regional Office of the World Health Organization

Recommendations ACHR Nov 2007

(Tab 8)

- Accelerate the development of PAHOs Research Policy aligning it with WHOs Research Strategy to make them synergic and complementary
- Secretariat to conduct a needs assessment leading to a capacity building strategy for EVIPNet, building on existing resources and partnerships; mobilize resources to further develop EVIPNet in the Americas (Tab 5 & 6)

Pan American Health Organization
Regional Office of the World Health Organization

Recommendations ACHR Nov 2007 (2)

- Continue the collaborative work, advocacy, and technical cooperation leading towards the establishment of a regional clinical research registry, a regional portal, and facilitating the establishment of registers that meet the WHO standards. (Reference document 6)
  - Promote trial registration as a requirement for ethics review approval
  - Assess impact of promoting transparent research and the means of harmonizing it with intellectual property rights and trade secret laws

Pan American Health Organization
Regional Office of the World Health Organization

Recommendations ACHR Nov 2007 (3)

- Action plan to standardize the developments of guidelines that are evidence based and aligned with the Organization's needs, building on the lessons learned from WHO. (Reference document 5)
- Nurture a climate to promote the systematic use of research evidence in PAHO; make research an integral part of the work of the organization
- Success stories of using accepted approaches including the use of information specialists

Pan American Health Organization
Regional Office of the World Health Organization

PAHO Research Inventory

- Create a PAHO Research Inventory to support PAHO research governance
- It needs to have clear objectives

Pan American Health Organization
Regional Office of the World Health Organization

Project Statement

To enhance PAHO's research governance, impact and visibility, we will establish a working electronic research inventory and tracking system rolled out throughout PAHO in 2008

Goal

To enable appropriate governance of PAHOs research, maximize its impact, and improve research management.

Pan American Health Organization
Regional Office of the World Health Organization

Objective 1

- **To have an operational digital tracking system by the end of 2008 that allows the monitoring, characterization, and integration of PAHOs research into routine research management processes, such as those involving the Ethics Review Committee.**
  - The database tested and ready to be used and deployed
  - An executive report presented to the ACHR (with input from the system) characterizing research being done in PAHO
  - Automated reports delivered to selected parties

Pan American Health Organization
Regional Office of the World Health Organization

Objective 2

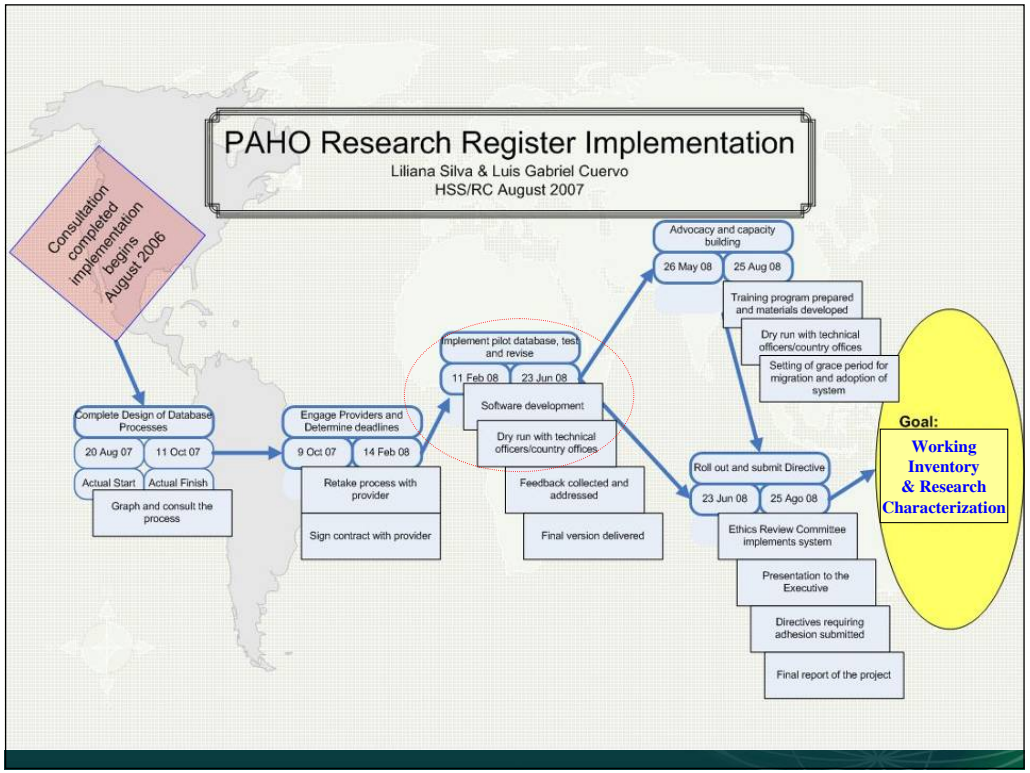
- **To deliver by December 2008 a Directive that requires compulsory research registration within PAHO, and to offer the tools that allow compliance with this requirement**
  - A directive approved and published

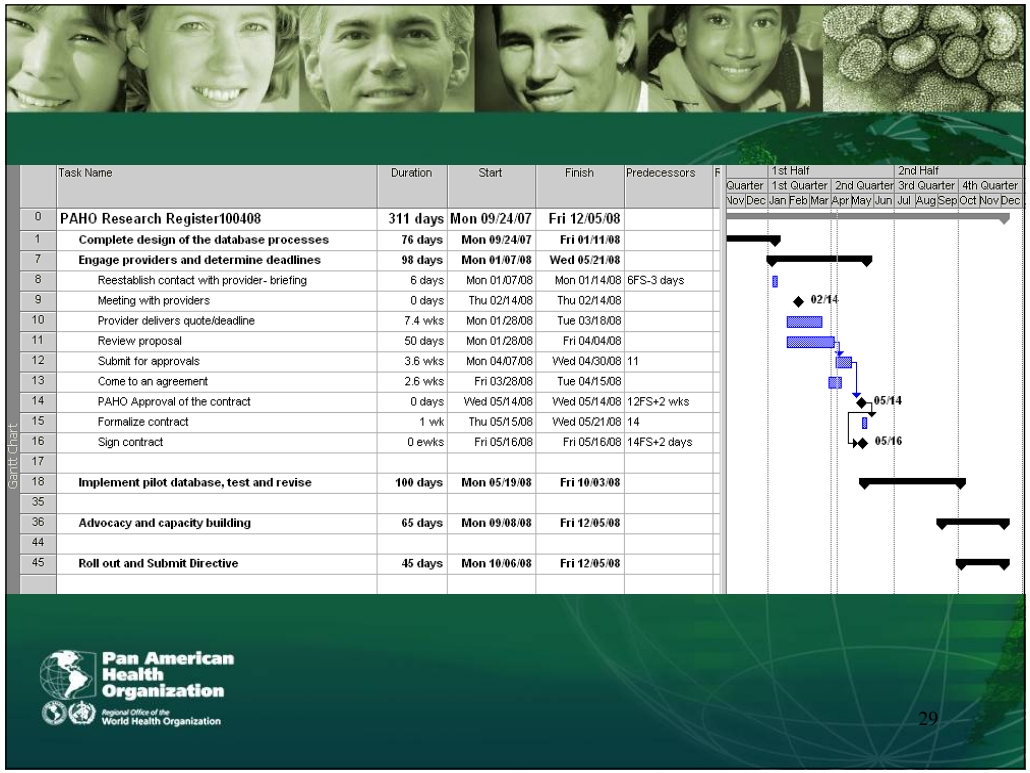
Pan American Health Organization
Regional Office of the World Health Organization

What we have done so far…

- A strategy was developed for the implementation of the system. It addresses the needs of parties governing and developing research in PAHO
- Identified and selection of tools and providers; software is being prepared to match our technical specifications and needs
- A project coordinator is following on the implementation of the system and providing strategic guidance.
- Implementation is going to plan and a functional system is expected to be delivered in 2008

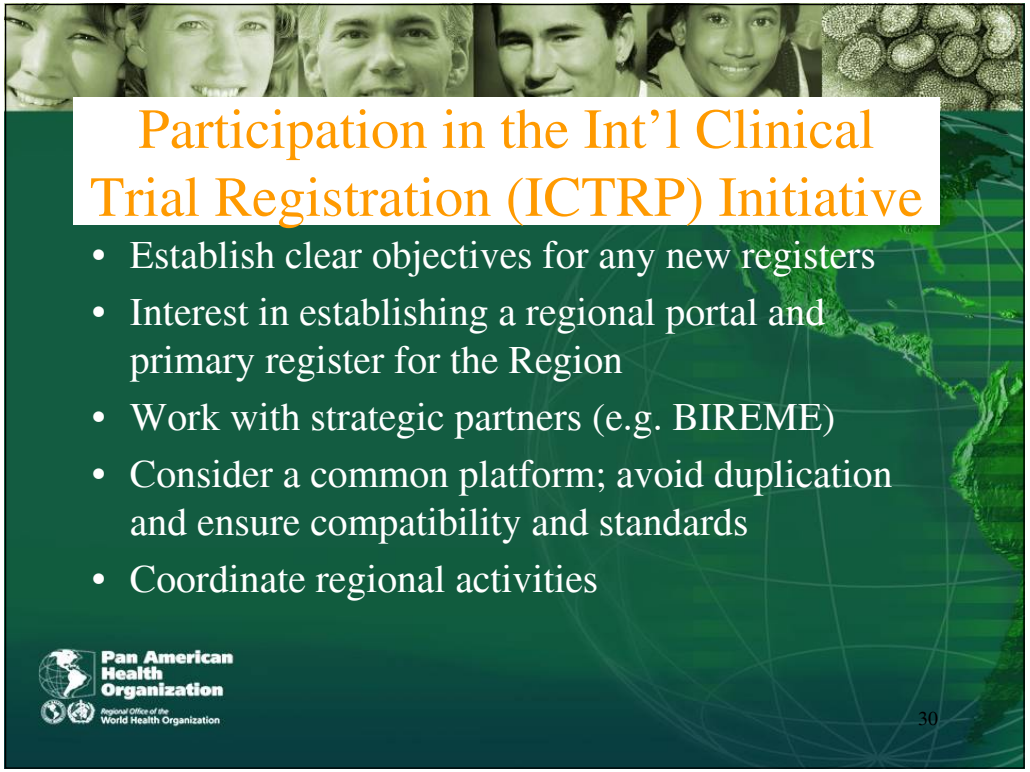
Pan American Health Organization
Regional Office of the World Health Organization





	Task Name	Duration	Start	Finish	Predecessors
0	PAHO Research Register100408	311 days	Mon 09/24/07	Fri 12/05/08	
1	Complete design of the database processes	76 days	Mon 09/24/07	Fri 01/11/08	
7	Engage providers and determine deadlines	98 days	Mon 01/07/08	Wed 05/21/08	
8	Reestablish contact with provider- briefing	6 days	Mon 01/07/08	Mon 01/14/08	6FS-3 days
9	Meeting with providers	0 days	Thu 02/14/08	Thu 02/14/08	
10	Provider delivers quote/deadline	7.4 wks	Mon 01/28/08	Tue 03/18/08	
11	Review proposal	50 days	Mon 01/28/08	Fri 04/04/08	
12	Submit for approvals	3.6 wks	Mon 04/07/08	Wed 04/30/08	11
13	Come to an agreement	2.6 wks	Fri 03/28/08	Tue 04/15/08	
14	PAHO Approval of the contract	0 days	Wed 05/14/08	Wed 05/14/08	12FS+2 wks
15	Formalize contract	1 wk	Thu 05/15/08	Wed 05/21/08	14
16	Sign contract	0 ewks	Fri 05/16/08	Fri 05/16/08	14FS+2 days
17					
18	Implement pilot database, test and revise	100 days	Mon 05/19/08	Fri 10/03/08	
35					
36	Advocacy and capacity building	65 days	Mon 09/08/08	Fri 12/05/08	
44					
45	Roll out and Submit Directive	45 days	Mon 10/06/08	Fri 12/05/08	

Pan American Health Organization
Regional Office of the World Health Organization



Participation in the Int'l Clinical Trial Registration (ICTRP) Initiative

- Establish clear objectives for any new registers
- Interest in establishing a regional portal and primary register for the Region
- Work with strategic partners (e.g. BIREME)
- Consider a common platform; avoid duplication and ensure compatibility and standards
- Coordinate regional activities

Pan American Health Organization
Regional Office of the World Health Organization

Registry Network

Primary Registries

The ICTRP accepts data into the Search Portal from registries that meet specific criteria. The registries that currently meet these criteria are listed in the table below. Within the framework of the ICTRP, these registries are referred to as Primary Registries.

Australian New Zealand Clinical Trials Registry (ANZCTR)	View Profile	Go to Website
Chinese Clinical Trial Register (ChiCTR)	View Profile	Go to Website
Clinical Trials Registry - India (CTRI)	View Profile	Go to Website
ISRCTN.org	View Profile	Go to Website
The Netherlands National Trial Register (NTR)	View Profile	Go to Website
Sri Lanka Clinical Trials Registry (SLCTR)	View Profile	Go to Website

World Health Organization

INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM
SEARCH PORTAL

Home | Advanced Search | ICTRP website | Disclaimer | Search tips | Resources | Contact us

Exact phrase match | Search | Search tips

Welcome

- The Search Portal is a web site that enables users to search a central database that contains the trial registration data sets provided by Primary Registers.
- When a user finds a trial on the Search Portal that they are interested in, they can learn more about the trial by clicking on a link that will take them to the relevant record in the source register.
- New users are advised to read the Search Tips before commencing their search.
- The Search Portal is not a clinical trials register.
- No attempt is made to identify and tag trials that may have been registered on more than one register.

Data Sources

- Australian New Zealand Clinical Trials Registry, last data file imported on **8 April 2008**
- ClinicalTrials.gov, last data file imported on **8 April 2008**
- ISRCTN, last data file imported on **8 April 2008**

Copyright - World Health Organization

World Health Organization

INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM
SEARCH PORTAL

Home | Simple Search | ICTRP website | Disclaimer | Advanced Search Tips | Resources | Contact u

ields can be left blank. Click on the field name hyperlink for an explanation of each search field

ook for trials with the exact phrase or contains

Example: liver cancer OR breast cancer NOT genetic — in the Title , AND

Example: liver cancer OR breast cancer NOT genetic — in the Condition , AND

Example: paxil OR paroxetine — in the Intervention , AND

Register is: ALL

Recruitment status is: Recruiting

Primary sponsor is or contains

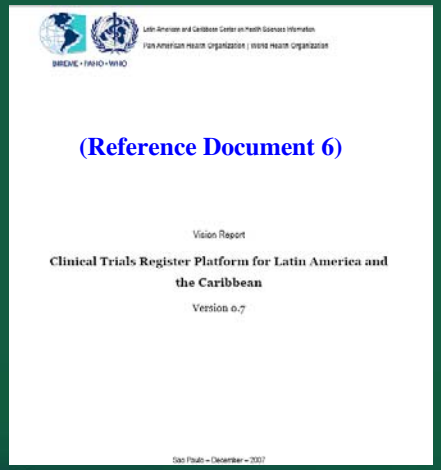
Secondary ID is or contains

Countries of recruitment are: Afghanistan, Albania, Algeria, American Samo — Add, Clear

Date of registration is between DD/MM/YYYY and DD/MM/YYYY

Sort by: Date of Registration — Search, Clear, Search Tips

ICTRP in the Americas


BIREME • PAHO • WHO

(Reference Document 6)

Vision Report

Clinical Trials Register Platform for Latin America and the Caribbean

Version 0.7

São Paulo – December – 2007

- Work with existing and developing registers to implement ICTRP Standards
- Technical cooperation
- Joint development and consultation (São Paulo, Oct 2007)
- Bireme reaches agreement with Editors to request trial registration
- Advocacy activities and engagement of IRBs/ERC
- Advancement of the scientific debate focusing on outcome reports

Pan American Health Organization
Regional Office of the World Health Organization

http://regional.bvsalud.org:8070/reddes/documentacao-dos-projetos/clinical-trials-1/draft-reports/vision-report-0.7/vision-report-0-7-pdf/

Evidence Informed Policy Networks

(Progress report Tuesday 15 April at 14:00)

- Creating a climate that supports research use
- Address priority health systems issues using a range of research methods
- Laying bridges between policy and research
- Getting policy makers to have a thoughtful (and systematic) use of evidence
- Deliver evidence just on time and in a helpful and useful format

Pan American Health Organization
Regional Office of the World Health Organization

EVIPNet Recommendations

(Progress report Tuesday at 14:00)

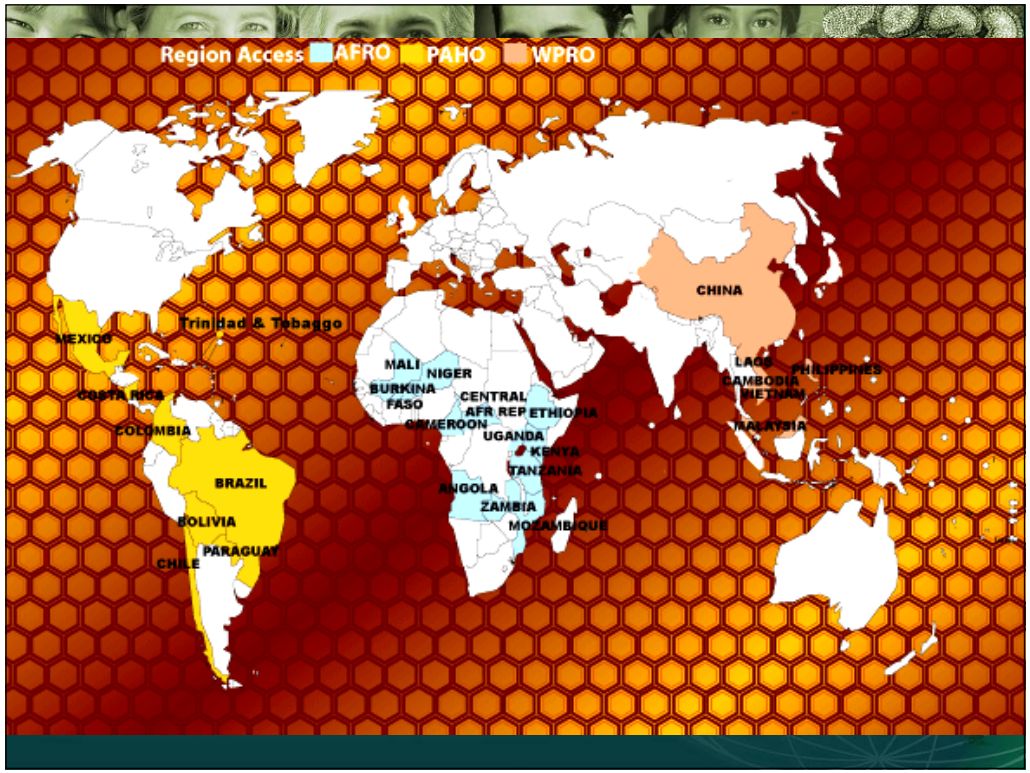
- Use as a tool, get health authorities to engage and commit to it.
- Get firm and ongoing country commitment
- Engage national science & technology associations
- Build on existing resources and strengths (e.g. BIREME)
- Consider sub-regional approaches
- Engage with human resources initiatives

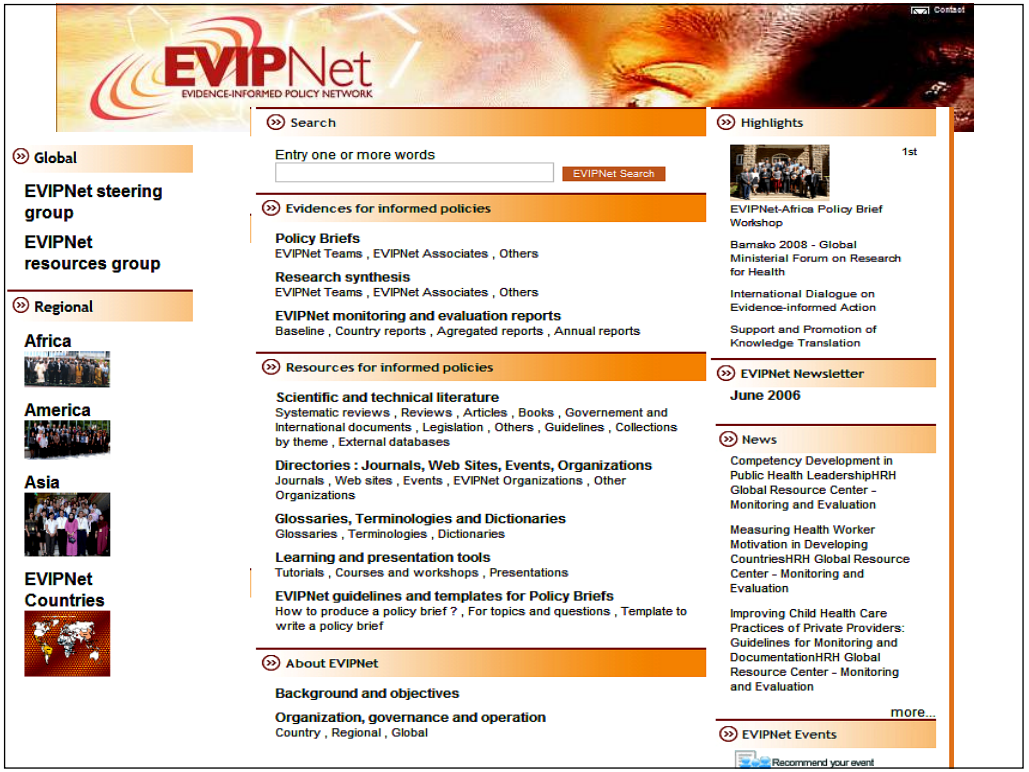
Pan American Health Organization
Regional Office of the World Health Organization

EVIPNet Global

- Coordination between regions and joint developments; collaboration between Regions and HQ at its best. Cross fertilization
- Consolidation of the Steering Group, Support Group and Secretariat, and development of Regional Steering Groups in Asia and Africa
- Development of a joint portal and one stop shop for evidence (with Bireme and HQ); integration of networks and resources.
- Evaluation strategy
- Funding for proposals from Africa and Asia

Pan American Health Organization
Regional Office of the World Health Organization





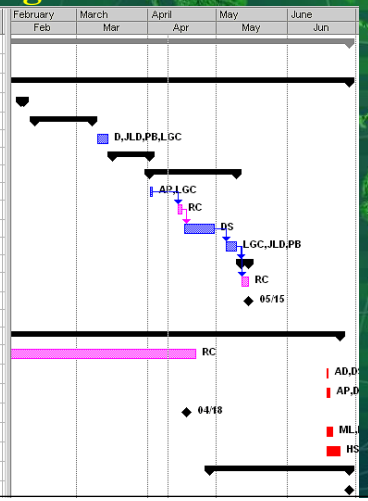
Evidence Portal

PAHO Research Policy

(Presented earlier)

Minutes previous meetings: Tab 8 & 9

	Task Name	Duration	Start	Finish
0	Policy Development	475 days?	Mon 09/04/06	Fri 06/27/08
1	Data and information gathering	270 days?	Mon 09/04/06	Fri 09/14/07
5	Writing documents	304 days	Tue 05/01/07	Fri 06/27/08
13	Consultations	1 day	Wed 02/06/08	Wed 02/06/08
15	Draft policy writing	19 days	Tue 02/12/08	Fri 03/07/08
20	Approval by Director (AD, Area Managers)	5 days	Mon 03/10/08	Fri 03/14/08
21	Draft policy translated	12 days	Mon 03/17/08	Tue 04/01/08
24	Draft policy consulted	28 days	Wed 04/02/08	Fri 05/09/08
25	Draft policy sent out to ACHR & Director	1 day	Wed 04/02/08	Wed 04/02/08
26	ACHR/CAIS discusses policy	2 days	Mon 04/14/08	Tue 04/15/08
27	Policy edited	9 days	Thu 04/17/08	Tue 04/29/08
28	Edited policy sent to Director and ACHR	5 days	Mon 05/05/08	Fri 05/09/08
29	Policy submitted to the Executive Committee	3 days	Mon 05/12/08	Thu 05/15/08
30	Policy prepared for the Executive Comn	3 days	Mon 05/12/08	Wed 05/14/08
31	Document submitted to the Exec Committee	0 days	Thu 05/15/08	Thu 05/15/08
32				
33	*Further consultations (external and internal)*	285 days	Tue 05/22/07	Mon 06/23/08
34	*ACHR continuous*	240 days	Tue 05/22/07	Mon 04/21/08
35	*PAHO area managers*	1 day	Wed 06/18/08	Wed 06/18/08
36	*governments and civil society and ACH*	1.5 days	Wed 06/18/08	Thu 06/19/08
37	*govenments and civil society consulted*	0 days	Fri 04/18/08	Fri 04/18/08
38	*PWRs*	3 days	Wed 06/18/08	Fri 06/20/08
39	*internal (HSS)*	4 days	Wed 06/18/08	Mon 06/23/08
40	*Approvals*	45 days	Mon 04/28/08	Fri 06/27/08
41	*Director approval*	0 days	Fri 06/27/08	Fri 06/27/08



Corporate Activities

- ACHR: Advisory Committee on Health Research
- PAHOERC: PAHO Ethics Committee
- PAHO/WHO Collaborating Centers
- Tools for dissemination and communication

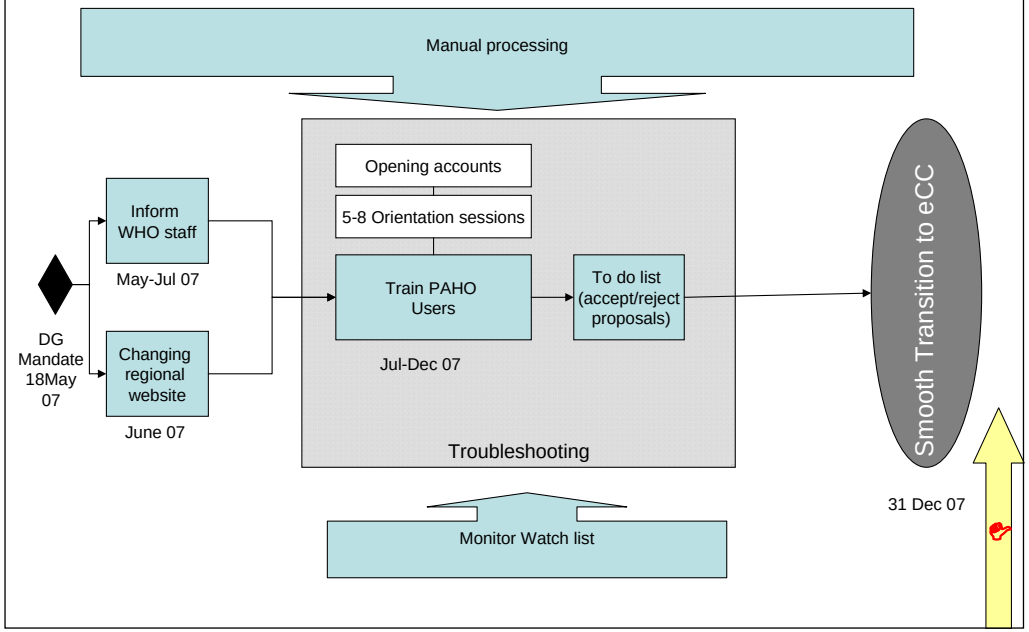
Pan American Health Organization
Regional Office of the World Health Organization

Administration of PAHO/WHO Collaborating Centers

Plan to improve the document management system and processing

Pan American Health Organization
Regional Office of the World Health Organization

WHO Collaborating Centers: AMRO Transition to Automated Electronic Processing system (June – December 2007)



Unified website + regional info

Pan American Health Organization
Regional Office of the World Health Organization

Strengthening and harmonization of the Guideline Development Process

Pan American Health Organization
Regional Office of the World Health Organization

Background information

- New approach to the production, use and dissemination of scientific evidence has progressed during recent years transforming the field; change has been fast and the Organization needs to catch up with it.
- Practice guidelines have been developed to improve the process of health care and health outcomes. They are intended to decrease unjustified variations, and optimize resource utilization.
- Failure to use the best current knowledge can harm people and bring the Organization into disrepute.

Pan American Health Organization
Regional Office of the World Health Organization

Mexico Declaration

- *All major stakeholders* to strengthen or to establish activities to communicate, improve access to, and promote the use of reliable, relevant, unbiased, and timely health information.

Response to Mexico

- *WHO Guidelines now follow a standardized and tested process. The Organization has been praised for its response to the evaluation, is leading by example by transforming processes and habits.*

Pan American Health Organization
Regional Office of the World Health Organization

Wake up call

Use of evidence in WHO recommendations

Andrew D Oxman, John N Lavis, Atle Fretheim

Summary

Background WHO regulations, dating back to 1951, emphasise the role of expert opinion in the development of recommendations. However, the organisation's guidelines, approved in 2003, emphasise the use of systematic reviews for evidence of effects, processes that allow for the explicit incorporation of other types of information (including values), and evidence-informed dissemination and implementation strategies. We examined the use of evidence, particularly evidence of effects, in recommendations developed by WHO departments.

Methods We interviewed department directors (or their delegates) at WHO headquarters in Geneva, Switzerland, and reviewed a sample of the recommendation-containing reports that were discussed in the interviews (as well as related background documentation). Two individuals independently analysed the interviews and reviewed key features of the reports and background documentation.

Findings Systematic reviews and concise summaries of findings are rarely used for developing recommendations. Instead, processes usually rely heavily on experts in a particular specialty, rather than representatives of those who will have to live with the recommendations or on experts in particular methodological areas.

Interpretation Progress in the development, adaptation, dissemination, and implementation of recommendations for member states will need leadership, the resources necessary for WHO to undertake these processes in a transparent and defensible way, and close attention to the current and emerging research literature related to these processes.

Lancet 2007; 369: 1883–89

Published Online May 9, 2007
DOI:10.1016/S0140-6736(07)60675-8

See Comment page 1842

Norwegian Knowledge Centre for the Health Services, PO Box 7004, St Olavs plass, N-0130 Oslo, Norway (A D Oxman MD, A Fretheim MD); and Department of Clinical Epidemiology and Biostatistics and Department of Political Science, and Member of the Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Canada (J N Lavis MD)

Correspondence to: Dr Andy Oxman oxman@online.no

Leading by example: a culture change at WHO

Published Online May 9, 2007
DOI:10.1016/S0140-6736(07)60676-X
See Articles page 1883

To quote Iain Chalmers, "Because professionals sometimes do more harm than good when they intervene in the lives of other people, their policies and practices should be informed by rigorous, transparent, up-to-date evaluations."[1] One of the major functions of WHO is the selection of policies and practices for the promotion of health, and the organisation issues nearly 200 recommendations and policy-guidance documents every year. However, WHO's own practices might be less than optimum, as reported in today's *Lancet* by Andrew Oxman and colleagues.[2]

After surveying WHO staff and assessing documents, Oxman and colleagues report several problems with current practice at WHO. Scientific evidence is often not used systematically in the development of recommendations, and the needs of

Pan American Health Organization
Regional Office of the World Health Organization

WHO's response

WHO signals strong commitment to evidence

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". Well-implemented high-quality guidelines for member states can realise this aim through the equitable sharing of best practice in a locally-appropriate form. However, despite a decision by WHO in 2000 to make guidelines evidence-based, and the publication of internal guidance in 2003 to standardise procedures, the quality of the 200 recommendations produced by WHO each year has been inconsistent. On May 9, *The Lancet* published Andy Oxman and colleagues' investigation into how WHO recommendations are formulated, which identified shortcomings in both process and products. Thus, WHO's response, to create a Guidelines Review Committee, is swift, unequivocal, and welcome.

The Guidelines Review Committee will be a crucial mechanism to advise staff on guideline development. It will seek to strengthen the capacity of all WHO staff to produce good guidelines. In otherwords, the Committee is not only about quality assurance, it is about triggering an institution-wide change in culture and behaviour. The changes will, in time, extend to WHO's most vulnerable outposts—its regional offices. And they will feed into the creation of a WHO-wide research strategy to be presented to the World Health Assembly in 2009.

The creation of a Guidelines Review Committee is good news for WHO, and provides an example of transparency to the UN, and of accountability to its stakeholders. The World Health Assembly, convening in Geneva this week, can take pride in these actions, but must recognise that the synthesis, implementation, and evaluation of science-based guidelines will require considerable resources if the commitment is to be sustained as a core activity. Establishing the Guidelines Review Committee confirms new Director-General Margaret Chan's commitment to "decisions based on evidence" and her own vision to make WHO "absolutely authoritative in our guidance...to use health as a lever for making this world a better place for all humanity". ■ *The Lancet*

For use of evidence in WHO recommendations see DOI:10.1016/S0140-6736(07)60675-8 and DOI:10.1016/S0140-6736(07)60676-X

For World Report on Margaret Chan see *Lancet* 2006; 368: 1757–58

Favorable Impact

WHO Rapid Advice Guidelines for pharmacological management of sporadic human infection with avian influenza A (H5N1) virus

Holger J Schünemann, Suzanne R Hill, Meetali Kakad, Richard Bellamy, Timothy M Uyeki, Frederick G Hayden, Yazdan Yazdanpanah, John Beigel, Tawee Chotpitayasunondh, Chris Del Mar, Jeremy Farrar, Tran Tinh Hien, Bülent Özbay, Norio Sugaya, Keiji Fukuda, Nikki Shindo, Lauren Stockman, Gunn E Vist, Alice Croisier, Azim Nagjdaliyev, Cathy Roth, Gail Thomson, Howard Zucker, Andrew D Oxman, for the WHO Rapid Advice Guideline Panel on Avian Influenza

Recent spread of avian influenza A (H5N1) virus to poultry and wild birds has increased the threat of human infections with H5N1 virus worldwide. Despite international agreement to stockpile antivirals, evidence-based guidelines for their use do not exist. WHO assembled an international multidisciplinary panel to develop rapid advice for the pharmacological management of human H5N1 virus infection in the current pandemic alert period. A transparent methodological guideline process on the basis of the Grading Recommendations, Assessment, Development and Evaluation (GRADE) approach was used to develop evidence-based guidelines. Our development of specific recommendations for treatment and chemoprophylaxis of sporadic H5N1 infection resulted from the benefits, harms, burden, and cost of interventions in several patient and exposure groups. Overall, the quality of the underlying evidence for all recommendations was rated as very low because it was based on small case series of H5N1 patients, on extrapolation from preclinical studies, and high quality studies of seasonal influenza. A strong recommendation to treat H5N1 patients with oseltamivir was made in part because of the severity of the disease. Similarly, strong recommendations were made to use neuraminidase inhibitors as chemoprophylaxis in high-risk exposure populations. Emergence of other novel influenza A viral subtypes with pandemic potential, or changes in the pathogenicity of H5N1 virus strains, will require an update of these guidelines and WHO will be monitoring this closely.

Lancet Infect Dis 2007; 7: 21–31

Italian National Cancer Institute Regina Elena, INFORMA Unit, Department of Epidemiology, Istituto Regina Elena, Rome, Italy (Prof H J Schünemann MD); Health Technology and Pharmaceuticals, WHO, Geneva, Switzerland (S R Hill MD, H Zucker MD); Norwegian Knowledge Centre for the Health Services, Oslo, Norway (M Kakad MD, G E Vist PhD, A D Oxman MD); Department of Infection and Travel Medicine, James Cook University Hospital, Middlesbrough, UK

Introduction Methods

Transparent Development of the WHO Rapid Advice Guidelines

Holger J. Schünemann*, Suzanne R. Hill, Meetali Kakad, Gunn E. Vist, Richard Bellamy, Lauren Stockman, Torbjørn Fosen Wisløff, Chris Del Mar, Frederick Hayden, Timothy M. Uyeki, Jeremy Farrar, Yazdan Yazdanpanah, Howard Zucker, John Beigel, Tawee Chotpitayasunondh, Tran Tinh Hien, Bülent Özbay, Norio Sugaya, Andrew D. Oxman

Summary

Emerging health problems require rapid advice. We describe the development and pilot testing of a systematic, transparent approach used by the World Health Organization (WHO) to develop rapid advice guidelines in response to requests from member states confronted with uncertainty about the pharmacological management of avian influenza A (H5N1) virus infection. We first searched for systematic reviews of randomized trials of treatment and prevention of seasonal influenza and for non-trial evidence on H5N1 infection, including case reports and animal and in vitro studies. A panel of clinical experts, clinicians with experience in treating patients with H5N1, influenza

Clinical practice guidelines generally, and some WHO guidelines specifically, have been criticized for not being based on the best available evidence, for being exposed to undue influence by industry and experts who participate in guideline panels, and for not adhering to guidelines for preparing guidelines [1–7]. Guidance that is not informed by the best available evidence or by statements that the available evidence is of low quality can harm patients, waste limited resources, and hinder research to address important uncertainties [8].

While there is broad agreement that rigorous and transparent methods should be used [9–12], rigorous development of guidelines can take two years or more [13,14]. This timeframe is not practical for providing rapid advice, for example for emerging infectious diseases such as avian influenza (H5N1 infection) or severe acute respiratory syndrome (SARS). Indeed, one of the most frequently cited weaknesses in guideline development is the length of time that it takes to develop a guideline [15]. Organizations including the National Centre for Health and Clinical Excellence in the United Kingdom and the National Institutes of Health in the United States are investigating ways of streamlining guidelines development processes [16,17].

Funding: This guideline project was funded by the World Health Organization.

Holger J. Schünemann is with the Italian National Cancer Institute Regina Elena, Department of Epidemiology, Rome, Italy. Suzanne R. Hill and

Citation: Schünemann HJ, Hill SR, Kakad M, Vist GE, Bellamy R, et al. (2007) Transparent development of the WHO Rapid Advice Guidelines. PLoS Med 4(5): e119. doi:10.1371/journal.pmed.0040119

Copyright: This is an open-access article distributed under the terms of the Creative Commons Public Domain declaration which stipulates that, once placed in the public domain, this work may be freely reproduced, distributed, transmitted, modified, built upon, or otherwise used by anyone for any lawful purpose.

Pan American Health Organization
Regional Office of the World Health Organization

PAHOs Research Ethics Review Committee (PAHOERC)

Quality assurance

Education & advocacy

Institutional memory

Pan American Health Organization
Regional Office of the World Health Organization

Key Messages

- Recommendations from the Regional ACHR have been heard; action has been taken to address the new challenges while protecting achievements
- The preparation of PAHOs Research Policy is progressing according to the schedule agreed following the 41st ACHR. The policy is progressing as WHOs Health Research Strategy evolves
- Strong alignment with WHO ACHR; harmonization and cohesion
- ACHR members are active and have engaged in specific initiatives

Pan American Health Organization
Regional Office of the World Health Organization