



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



28th PAN AMERICAN SANITARY CONFERENCE 64th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 17-21 September 2012

Provisional Agenda Item 4.9

CSP28/14, Rev. 1 (Eng.)

20 September 2012

ORIGINAL: SPANISH

BIOETHICS: TOWARDS THE INTEGRATION OF ETHICS IN HEALTH

Concept paper

Introduction

1. We are facing numerous and complex ethical controversies in medical care, research involving human participants, and the formulation and implementation of public health policy. Bioethics is the discipline that seeks to clarify ethical problems that arise in health.
2. The *Health Agenda for the Americas (2008-2017)*¹ underscored the importance of promoting bioethics: “Bioethics should be better disseminated and applied in the countries of the Americas to protect the quality of research, respect human dignity, safeguard cultural diversity, and assure the application of knowledge in health, as well as in public health decision-making.”(1).
3. This document aims to provide the Member States with up-to-date information on the work of the Pan American Health Organization (PAHO) in the area of bioethics and to demonstrate the importance of integrating ethical considerations into health policy, medical care, health-related research involving human beings, and the development and adoption of new technologies that impact on health.

Background

4. PAHO’s Regional Program on Bioethics was created in Santiago (Chile) in 1993 with the mission to cooperate with the Member States of the Organization and their public and private agencies in the conceptual, regulatory, and applied development of

¹ The *Health Agenda for the Americas (2008-2017)* was presented in Panama on 3 June 2007 and is a policy tool to guide the development of future national health plans and the strategic plans of all the organizations interested in cooperation in health with the countries of the Americas. Available from: http://www.paho.org/English/DD/PIN/Health_Agenda.pdf.

bioethics as it relates to health (2). The Program began its work in 1994 under an agreement between PAHO, the University of Chile, and the Chilean Government.

5. After evaluating the Regional Program on Bioethics in 2000 (3), the Directing Council resolved “To encourage Member States to incorporate the development of the capacity for bioethical analysis within the normative and stewardship functions of the ministries of health and to formulate public policies in health informed by bioethical principles, particularly with regard to research with human subjects”(4).

6. In 2011, the Regional Program on Bioethics was transferred to PAHO Headquarters, in Washington, D.C., and was incorporated into the Office of Gender, Diversity, and Human Rights (GDR). Ethical issues permeate all technical areas of PAHO’s work and GDR advises the Organization’s four technical areas and Member States on issues that cut across all areas of health-related work.

Situation Analysis

7. In its 17 years in operation, the Regional Program on Bioethics, with the continuous support of the Government of Chile, has produced a critical mass of people trained in bioethics, with an emphasis on research ethics. This emphasis is driven by the demand created by the provision in the *Declaration of Helsinki* of the World Medical Association (5) requiring that all research involving human subjects be approved by an independent ethics committee. Training in research ethics is necessary in order to perform an ethics review.

8. The emphasis on research ethics is also justified because research involving human participants involves the risk of exploitation.² Unlike medical treatment and public health activities, which seek the benefit of the patients or populations involved, the purpose of research is not the benefit of the participants. The objective of research involving human participants is the production of generalizable knowledge that benefits society. Research therefore poses the challenge of making sure that the participants are protected. The aim of research ethics is to determine the conditions in which it is ethically acceptable to use human beings for knowledge production. PAHO recently strengthened research ethics as part of its Policy on Research for Health (6). The ethics review processes for research involving human participants in which PAHO participates, which

² This risk is exacerbated when research is conducted with people in situations of vulnerability, as is the case of members of minority groups, communities, and peoples that experience discrimination and other violations of basic human rights. See the Universal Declaration of UNESCO on Bioethics and Human Rights, available from:
http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

are carried out by PAHO's Ethics Review Committee (PAHOERC), have been institutionalized and strengthened.³

9. The Regional Program on Bioethics has mainly strengthened the academic development of the discipline. The gap persists, however, between academics trained in bioethics and the decision-makers and health professionals who deal directly with issues that concern bioethics. The incorporation of bioethics into public policy-making in health is still a work in progress in the Region. Although they have people trained in research ethics, some Member States still do not have a legal and regulatory framework for research involving human participants,⁴ or guidelines and mechanisms to address the ethical problems that arise in health care.⁵

10. Moreover, new technologies and the complexity of contemporary societies are presenting us with more and increasingly complicated ethical problems. The situations created by new assisted reproduction techniques, the possibilities for genetic improvement, and access to technologies that artificially maintain and prolong life have shown us that ethical standards are not obvious and it is not a simple task to determine what ethical principles dictate in specific situations or how to apply them in practice. The diverse cultural, ethnic, linguistic, and religious values and traditions present in every society only compound this difficulty. Given the inevitable resource constraints, we are also confronted with the need to evaluate and prioritize interventions. It is already clear that mere intuition and good intentions will not suffice to ensure that activities in the health field are ethical. A sound, well-founded analysis is necessary in order to incorporate ethical considerations into the work in the health sphere.

11. The systematic integration of ethics in health requires conceptual clarity about bioethics as a discipline. Bioethics elucidates the ethical problems that arise in public health, health care, and health research. Bioethics is not an empirical discipline, because the empirical evidence that something occurs does not determine that it is ethically correct. As a normative discipline, bioethics examines what "ought to be," which often differs from what "is." Bioethics is not a code of precepts. Bioethics is a discipline consisting of analytic activity based on ethical principles and criteria that guide practice in the different areas related to health.

³ The standard operating procedures of PAHOERC are available from: http://new.paho.org/hq/dmdocuments/2009/074_ENG.pdf. More information on progress and the challenges ahead can be found in: Saenz C, Saxena A, Cuervo LC, Roses Periago M. Guatemala never again: progress and challenges in the protection of research subjects. *Rev Panam Salud Pública*. 2011; 29(5):380-381, Available from: <http://www.scielosp.org/pdf/rpsp/v29n5/a12v29n5.pdf>.

⁴ Except for the accepted norms set out in universal and regional human rights treaties.

⁵ The 2012 edition of the *International Compilation of Human Research Standards 2012*, prepared by the Office for Human Research Protections (OHRP) of the United States Department of Health and Human Services (HHS) is available from: <http://www.hhs.gov/ohrp/international/intlcompilation/intlcompil2012.doc.doc>.

12. Bioethical analysis is carried out in light of fundamental values such as respect for human beings and their capacity to decide for themselves on the basis of their values and beliefs, the well-being of individuals and populations, and fairness. The analysis should take into account specific contexts and actual situations, identifying all morally relevant aspects and striving for consistency. Even if a single individual is conducting the analysis, it should still follow the model of a pluralistic and inclusive dialogue that respects diversity and take the different viewpoints involved into consideration. As a deliberative exercise, ethical analysis does not always lead to a univocal response. It is possible that there is more than one ethically correct way to proceed.

13. Not all actions aimed at improving health are ethically acceptable. Moreover, public health practice is not ethically neutral; rather it implies value judgments about what is correct and what is fair. In order to integrate ethics in health, it is necessary to identify and analyze the ethical criteria and principles that are at stake; there may be several of these and they may be contradictory. It cannot simply be assumed that activities and policies aimed at improving health are ethically acceptable without first having examined them from the standpoint of bioethics. Similarly, it cannot simply be assumed that the laws suffice to clarify or resolve all ethical conflicts. The law plays a crucial role in establishing the minimum standards that should be respected. Legal requirements, however, are just one aspect of acting in an ethical manner: ethics frequently dictates actions that go beyond what the law requires. Indeed, it is neither possible nor desirable for the law to cover the entire spectrum of the moral life of individuals or societies.

14. History has shown, moreover, that the law may require actions that are not ethical and that certain ethical actions may not be legal. While this is usually not the case, it behooves us to keep in mind that just because the law requires something does not necessarily make it ethical. Ethics, as a discipline, allows for continual analysis and reflection on the law and on what should be required by law. Furthermore, ethics should inform law.

15. Human rights have been set out in binding legal instruments that protect individuals and groups from actions that interfere with their basic freedoms and human dignity. These instruments, such as treaties and conventions, are therefore relevant to health and have been successfully incorporated into PAHO's work (7). They are suitable for dealing with cases in which governments have failed to comply with their specific obligations under the law. Clearly, human rights are ethically justified and codify certain basic bioethical values, such as respect for people and fairness. These human right instruments therefore provide a legal framework for the work in bioethics. The fact that this framework exists, however, does not obviate the need for ongoing deliberation and ethical analysis in the countless complex situations that we are confronted with in relation to health (8).

16. Bioethics should not be invoked only after ethical principles have been infringed upon and we find ourselves before an ethically questionable situation that we must resolve. Bioethics should be integrated into the everyday work of health professionals and policy-makers to ensure that public health policies are informed by bioethical principles, as the Directing Council recommended in 2000 (4).

17. In order to determine whether a policy or public health intervention is ethical, it is necessary to evaluate whether there is evidence that: (a) the intervention is effective in achieving the proposed objectives; (b) the public health benefits of the intervention outweigh any harm and burdens that might result from it; (c) the public health objective cannot be achieved in a different way that would impose a lesser burden on the population; (d) the intervention is going to result in the least possible burden or adverse effects; and (e) the burdens and benefits will be distributed fairly and, if possible, previous social injustices will be minimized. In addition, in view of the ethical imperative to treat people with respect, fair procedures should be used, such as a public deliberation to determine what the community in question would consider less burdensome (9, 10).

18. The Member States have made progress in the development of normative and regulatory frameworks for research involving human participants that are informed by universal guidelines and declarations (5, 11), and most have established procedures for ethics review by independent committees. These processes should be completed and strengthened in order to consolidate the progress made in research ethics. Progress in other areas of bioethics should be added to these accomplishments, namely, clinical ethics and public health ethics. In the case of clinical ethics, the guidelines are not as specific in spelling out what the principles require as they are in the case of research involving human subjects. The deliberative work of clinical ethics committees should be supplemented by the adoption of mechanisms that ensure effective respect for ethical principles in the clinical setting.

19. In order to consolidate and promote the progress made, it is essential to explain the role of bioethics to a wide audience by specifying its applications in different areas of health-related work, strengthen capacity in all areas of bioethics, and ensure that the political commitment exists to integrate ethics in health.

Proposal

20. PAHO's Regional Program on Bioethics provides technical cooperation to the Member States in the three areas of bioethics: research ethics, clinical ethics, and public health ethics. Public health ethics deserves special attention because it is the most recently developed area of bioethics as a discipline and because of the ubiquitous nature of public health actions and the consideration of the social determinants of health. The

Regional Program on Bioethics proposes that the Bureau and the Member States prioritize efforts to ensure respect for ethical principles in public health interventions.

21. Several approaches are proposed in order to incorporate ethics solidly and systematically into the different areas of health, including the following:

- (a) Strengthen capacity in bioethics:
 - emphasizing the application of bioethical analysis;
 - prioritizing decision-makers and governmental health agency staff;
 - continually identifying and evaluating existing capabilities in order to target training activities to the specific needs of the Region to improve their effectiveness;
 - establishing and strengthening national and regional networks in order to develop a common agenda that integrates the different efforts underway to ensure efficient progress.
- (b) Support countries through:
 - the formulation and implementation of policies, plans, programs, and regulations in areas pertaining to bioethics;
 - the incorporation of bioethics into the formulation and implementation of policies, plans, programs, and regulations in the different areas of health, in order to ensure that the resulting policies, plans, programs, and regulations are ethically sound.

22. In order to carry out these tasks, PAHO proposes to strengthen coordination between the Regional Program on Bioethics, the Ethics and Health Unit of the World Health Organization (WHO), the Collaborating Centers for bioethics in the Region, and the UNESCO Bioethics Programme.⁶ PAHO/WHO concurs with UNESCO on the importance of having independent, multidisciplinary and pluralistic bioethics commissions in place to serve as advisory bodies, provide information for decision-making, and lead public debates on topics related to bioethics. PAHO proposes to join forces with UNESCO to support national bioethics commissions.⁷

⁶ The PAHO/WHO Collaborating Centers on Bioethics in the Americas are the University of Miami, the Mailman School of Public Health (Columbia University) and the University of Toronto.

⁷ UNESCO and WHO have agreed that UNESCO will provide the support necessary for the establishment of national bioethics commissions and that WHO will provide cooperation on technical matters.

Action by the Pan American Sanitary Conference

23. The Conference is invited to review the attached concept paper, provide comments, and make recommendations for the sound and systematic incorporation of ethical considerations into the different areas of health-related work. It is also requested to consider approving the proposed resolution included in Annex A.

References

1. Pan American Health Organization. Health Agenda for the Americas 2008-2017 [Internet]. Presented by the Ministers of Health of the Americas in Panama City, in the framework of the XXXVII General Assembly of the Organization of American States; June 2007. Washington (DC), US. Washington (DC): PAHO; 2007 [cited 2012 Apr 3]. Available from: http://www.paho.org/English/DD/PIN/Health_Agenda.pdf
2. Pan American Health Organization. Establishment of the Regional Program on Bioethics [Internet]. 37th Directing Council of PAHO, 45th Session of the Regional Committee of WHO for the Americas; 1993 Sep 28-Oct 1; Washington (DC), US. Washington (DC): PAHO; 1993: (Resolution CD37.R9) [cited 2012 Apr 3]. Available from: http://www.paho.org/english/gov/cd/ftcd_37.htm.
3. Pan American Health Organization. Evaluation of the regional program on bioethics [Internet]. 42nd Directing Council of PAHO, 52nd Session of the Regional Committee of WHO for the Americas; 2000 Sep 27-29. Washington (DC), US. Washington (DC): PAHO; 2000 (Document CD42/9) [cited 2012 April 3]. Available from: http://www.paho.org/english/gov/cd/cd42_09-e.pdf.
4. Pan American Health Organization Directing Council. Regional Program on Bioethics [Internet]. 42nd Directing Council of PAHO, 52nd Session of the Regional Committee of WHO for the Americas; 2000 Sep 27-29. Washington (DC), United States. Washington (DC): PAHO; 2000 (Resolution CD42.R6) [cited 2012 Apr 3]. Available from: www.paho.org/english/gov/cd/cd42_fr-e.pdf
5. World Medical Association. Declaration of Helsinki [Internet]. Ethical Principles for Medical Research Involving Human Subjects. October, 2008 [cited 2012 Apr 3]. Available from: <http://www.wma.net/en/30publications/10policies/b3/>.
6. Pan American Health Organization. Policy on Research for Health [Internet]. 49th Directing Council of PAHO, 61st Session of the Regional Committee of WHO for

- the Americas; 2009 Sep 28-Oct 2. Washington (DC), US. Washington (DC): PAHO; 2009 (Document CD49/10). [cited 2012 Apr 3]. Available from: <http://new.paho.org/hq/dmdocuments/2009/CD49-10-e.pdf>
7. Pan American Health Organization. Health and Human Rights [Internet]. 50th Directing Council of PAHO, 62nd Session of the Regional Committee of WHO for the Americas; 2010 Sep 27-Oct 1. Washington (DC), US. Washington (DC): PAHO; 2010 (Document CD50/12) [cited 2012 Apr 3]. Available from: www.un.org/disabilities/documents/paho_mh_resolution.pdf.
 8. World Health Organization. Guidance on ethics of tuberculosis prevention, care and control [Internet]. Ginebra, Suiza: 2010 [cited 2012 Apr 3]. Available from: http://whqlibdoc.who.int/publications/2010/9789241500531_eng.pdf.
 9. Childress JF, Faden RR, Gaare RD, et al. Public health ethics: mapping the terrain. *J Law Med Ethics*. 2002;30(2):170–181.
 10. Kass N. An ethics framework for public health. *Am J Public Health*. 2001;91(11):1776–1782.
 11. Council for International Organizations of Medical Sciences. International ethical guidelines for biomedical research involving human subjects – Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). Geneva, Switzerland: CIOMS; 2002 [cited 2012 Apr 3]. Available from: http://www.cioms.ch/publications/layout_guide2002.pdf.



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



28th PAN AMERICAN SANITARY CONFERENCE

64th SESSION OF THE REGIONAL COMMITTEE

Washington, D.C., USA, 17-21 September 2012

CSP28/14, Rev. 1 (Eng.)
Annex A
ORIGINAL: SPANISH

PROPOSED RESOLUTION

BIOETHICS: TOWARDS THE INTEGRATION OF ETHICS IN HEALTH

THE 28th PAN AMERICAN SANITARY CONFERENCE,

Having reviewed the concept paper *Bioethics: Towards the Integration of Ethics in Health* (Document CSP28/14, Rev. 1);

Taking into account that in the Health Agenda for the Americas (2008-2017), the ministers and secretaries of health underscored the importance of better disseminating and applying bioethics in the countries of the Americas;

Aware of the ethical controversies in the areas of medical care, research involving human participants, and the formulation and implementation of public health policies, and that new technologies and the diversity of contemporary societies increase the complexity of these ethical controversies;

Recognizing that bioethics is the discipline that seeks to clarify the ethical problems that arise in relation to health;

Taking into account that since 1994, PAHO's Regional Program on Bioethics has cooperated with the Member States in the conceptual, normative, and applied development of bioethics;

Observing that the Directing Council has encouraged the Member States to boost their capacity for bioethical analysis and to develop health policies based on bioethical principles,

RESOLVES:

1. To endorse the concept paper *Bioethics: Towards the Integration of Ethics in Health*.
2. To urge the Member States to:
 - (a) strengthen the technical capacity of the health authorities in the area of bioethical analysis;
 - (b) support and promote the incorporation of bioethical analysis into the formulation and implementation of policies and plans, and into decision-making on health;
 - (c) support and promote the formulation of national policies and normative and regulatory documents on bioethical issues;
 - (d) promote the dissemination of information on bioethics among civil society organizations and other social actors, clarifying the applications of bioethics in different areas of work in the health sphere;
 - (e) strengthen communications activities at the national level in order to build support for the incorporation of bioethics into health-related work;
 - (f) foster collaboration with academic institutions in order to develop training programs in bioethics, with an emphasis on public health ethics;
 - (g) support PAHO's technical cooperation for the integration of bioethics into different areas of health-related work.
3. To request the Director to:
 - (a) continue to strengthen the technical cooperation that the Regional Program on Bioethics provides to the Member States;
 - (b) promote the development of regional networks and encourage collaboration with academic institutions for the incorporation of bioethics into health-related work;
 - (c) promote the development and dissemination of guidelines and tools that guide and galvanize the work in different areas of bioethics;
 - (d) promote the inclusion of bioethical analysis in the different areas of PAHO's technical cooperation;

- (e) continue to support and promote PAHO's ethics review of research involving human subjects in which it participates;
- (f) advocate the mobilization of national and international resources to support efforts to integrate ethics into health-related activities.



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION

CSP28/14, Rev. 1 (Eng.)
Annex B

**Report on the Financial and Administrative Implications for
the Secretariat of the Proposed Resolutions**

<p>1. Agenda item: 4.9: Bioethics: Towards the Integration of Ethics in Health</p>
<p>2. Linkage to Program and Budget:</p> <p>(a) Area of work: Gender, Diversity, and Human Rights/Regional Program on Bioethics</p> <p>(b) Expected result:</p> <p><i>Strategic Objective II:</i> To strengthen leadership, governance, and the evidence base of health systems.</p> <p><i>RER 11.4:</i> Member States supported through technical cooperation for facilitating the generation and transfer of knowledge in priority areas, including public health and health systems research, and ensuring that the products meet WHO ethical standards.</p> <p><i>Strategic Objective 7:</i> To address the underlying social and economic determinants of health through policies and programs that enhance health equity and integrate pro-poor, gender-responsive, and human rights-based approaches.</p> <p><i>RER 7.4:</i> Ethics- and human rights-based approaches to health promoted within PAHO/WHO and at national, regional and global levels.</p>
<p>3. Financial implications:</p> <p>(a) Total estimated cost for implementation over the life cycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities):</p> <p>As a concept paper, the proposed resolution does not specify a life cycle. However, the activities included in the proposed resolution should continue beyond the current biennium</p> <p>(b) Estimated cost for the biennium 2013-2014 (estimated to the nearest US\$ 10,000; including staff and activities):</p> <p>\$540,000</p> <p>The estimate available is \$300,000 for work on bioethics in the biennium 2012-2013: \$10,000 in regular funds, \$184,000 from the Spanish Agency for International Development Cooperation (AECID), \$10,000 in the Country Office budgets, and \$96,000 approved for support for the PAHO Ethics Review Committee (PAHOERC).</p> <p>In order to fully implement the resolution, it will be necessary to mobilize an estimated \$240,000 more per biennium, or \$60,000 per year at the regional level and \$60,000 per year at the country level.</p>

(c) Of the estimated cost noted in (b), what can be subsumed under existing programmed activities?:

\$300,000

4. Administrative implications:

(a) Indicate the levels of the Organization at which the work will be undertaken:

Regional, subregional, and national.

(b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):

Not applicable.

(c) Time frames (indicate broad time frames for the implementation and evaluation):

2012-2017



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the

WORLD HEALTH ORGANIZATION

CSP28/14, Rev. 1 (Eng.)
 Annex C

**ANALYTICAL FORM TO LINK THE AGENDA ITEMS
 WITH THE INSTITUTIONAL MANDATES**

1. Agenda item: 4.9: Bioethics: Towards the Integration of Ethics in Health

2. Responsible unit: Gender, Diversity, and Human Rights/Program Regional of Bioethics

3. Preparing officer: Carla Saenz, Bioethics Regional Adviser

4. List of collaborating centers and national institutions linked to this agenda item:

- University of Miami
- Mailman School of Public Health (University of Columbia)
- University of Toronto

5. Link between agenda item and Health Agenda for the Americas 2008-2017:

Area of action (g): Harnessing knowledge, science and technology.

Item 68: Bioethics should be better disseminated and applied in the countries of the Americas to protect the quality of research, respect human dignity, safeguard the cultural diversity, and assure the application of knowledge in health, as well as in public health decision-making.

6. Link between agenda item and Strategic Plan 2008-2012:

Strategic Objective 11: To strengthen leadership, governance, and the evidence base of health systems.

RER 11.4, Indicator 11.4.2

Strategic Objective 7: To address the underlying social and economic determinants of health through policies and programs that enhance health equity and integrate pro-poor, gender-responsive, and human rights-based approaches.

RER 7.4, Indicator 7.4.2

7. Best practices in this area and examples from countries within the Region of the Americas:

- Mexico offers an example of optimal incorporation of bioethics in priority-setting for health; an illustration of the process for determining coverage of the pneumococcal vaccine is found in: Daniels N, Valencia-Mendoza A, Gelpi A, Hernandez Ávila M, Bertozzi S. The art of public health: pneumococcal vaccine coverage in Mexico. *The Lancet* 2010; 375(979):114-115.
- Many national bioethics commissions and other advisory or regulatory bodies (some focused on research ethics) also serve as examples of progress in the work of bioethics in the region.

8. Financial implications of this agenda item:

\$540,000 per biennium, which entails a \$120,000 increase per year (\$60,000 at the regional level, \$60,000 at the country level) over the funding currently available.

- - -