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Comments on the 1978 Belmont Report

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From the Editor

The development of regulation framework for human subject research

Bustos-Montero Daniel, MD[1,2]

From the moment the Nuremberg Code1 (1947) acceptance as the starting point for the regulation of human subject research, and its subsequent reinterpretation by the World Medical Association, known as the Declaration of Helsinki2 in 1964, several efforts have been made by different international organizations and by the countries in their individual management, in order to have a standardized regulatory framework which protects humans beings participating in research, at the time that promotes and allows this activity to be integrated as an engine for the development of health around the world.

These regulations were evolving in accordance with the demands of technological and innovative advances which required an extensive analysis in order to guarantee a real protection for people participating in research. Evidently, the diagnostic, preventive and therapeutic options which existed 50 years ago were very limited in comparison with the current ones, motivating a needed debate about how adequate these regulations are in the social context.

In this changing line, international organizations such as the World Health Organization, the Council for International Organizations of Medical Sciences (CIOMS), and the United Nations Educational, Scientific and Cultural Organization (UNESCO), among others, assumed a protagonist role by issuing guidelines and policies that resulted in a regulatory maturity in protecting human beings that participate in research.[3-7]

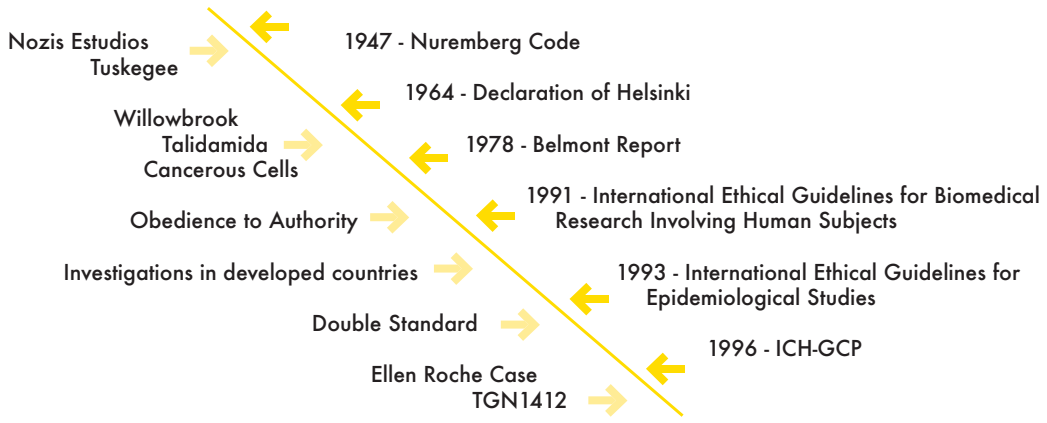
The regulatory evolution has been casuistic, in other words, according to the social debates generated regarding one or other conflict on the research ethics field, it has been necessary to adapt these norms to the demands of a society. Figure 1 shows the chronologic correlation of the different regulations issued by these organizations and the events that caused their enactment (Figure 1).

But, why is it important to regulate research? At the beginning, this was the question raised by all those involved in the matter, especially by the investigators that, with the development and better understanding of the topic, they led high-level discussions that have nurtured the current regulatory framework.

The justification of the need for research regulations has been stated in CIOMS Guideline 1 of the International Ethical Guidelines for Biomedical Research Involving Human Subjects, which indicates the following:

"The ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to the subjects of that research and are morally acceptable within the communities in which the research is carried out."

FIGURE 1. EVOLUTION OF THE REGULATIONS FOR HUMAN EXPERIMENTATION



Therefore, it is logical to think that in order for the regulations for research on human beings to achieve their objectives, they must fulfill three essential characteristics:

1.To have the capacity to adapt, allowing the analysis of a specific situation in the context of the society; hence, based on the results of this exercise, it can be applied later in an authorized form.

2.To be transcendent, in order words, it should avoid the unnecessary regulation of research; instead, it should be focused on the aspects that really have an impact to guide the development of this activity.

3.To have common sense, the most important characteristic of all human praxis.

Considering that that any activity which results in a change on the health condition of a human being will always bring an ethical conflict, there is no doubt that the international regulatory framework is far from being perfect; however, constitute the base to safeguard the dignity and well-being of the people who participate in an investigation.

But it would be a big mistake if we forget that the regulations, by themselves, will never achieve their objectives; it is essential the commitment and moral and ethical awareness of all the healthcare professionals related with this topic. ❖

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Antibiotics in the XXI century

Vega Silvio, MD MSC [1,2]

The expectations created by the discovery of the antimicrobials in the early 20th century, first by Paul Erlich and then by Alexander Fleming, have been vanishing gradually with time. The fact is that these tools- some created in their own micro-organisms- turned into weapons against the death they caused. At that time, severe infection was equal to death.

The decrease of morbidity and mortality during the warlike conflicts, demonstrated the great help these wonderful substances provided, which had the potential to keep away all germs that were invincible at that time. Around the middle of the century, the sulfonamides and penicillins were already widely trusted, while the tetracyclines, streptomycin and chloramphenicol –products that were extensively used for human and animal infections- were added to the arsenal.

A subsequent increase in the development on antimicrobials was seen on the horizon: in the 50's erythromycin and vancomycin; in the 60's gentamicin, ampicillin, cephalothin and amikacin; in the 70's cephalexin, carbenicillin, cefoxitin and cefaclor; in the 80's cefotaxime, moxalactam, imipenem, aztreonam and the combination of penicillins with anti-betalactamases like calvulanic- amoxicillin acid. During this decade however, there has been a progressive decrease in the appearance of antimicrobials, the number of labs working in this type of research has lessened, and less substances are being developed.

The substances that were once believed to be magical were losing their efficiency because they showed a resistance to the antimicrobials.

A resistance phenomenon to penicillin was first seen soon after its therapeutic potential was discovered; however, it was taken more as a biological curiosity, and the impact that it could cause in the clinical field was not considered: it could make the valuable substance useless. Accordingly, together with the increase in the discovery of antimicrobials, there was an increase of germs that became resistant to them. They appeared as follow: Staphylococcus that are resistant to penicillin (PRSA), Staphylococcus that are resistant to meticilines (SARM), Escherichia coli that are resistant to ampicillin and to chloramphenicol, multi-resistant Pseudomonas, Klebsiella that produces extended-spectrum betalactemases (ESBL), Enterococci that are resistant to vancomicine (VRE), Enterobacteria that are resistant to quinolones and Acinetobacter pan-resistant. Currently, there isn't an antibiotic for which a resistant mechanism has not been observed.

Apparently, the resistance phenomenon is multi-causal; it could be due to a spontaneous aparition of resistant strains caused by a simple random mutation, as well as the selection of resistant strains as a result of misuse and abuse of antimicrobials.

The scene is terrifying. In the first part of this century, we observed an increase in the number of deaths caused by infections that originated from a massive increment of bacterial resistance to the available antibiotics, in addition to a continuous decrease in the development of new antimicrobials.

Consequently, at the dawn of this new century, the magical antimicrobial substances that once bloomed are now nearing extinction and it is necessary to join forces to save them.

The approach to neutralize this phenomenon should then be interdisciplinary and multifocal; starting byeducating medical and allied health providers, as well as the general public, so they can understand the situation, and be prepared to cooperate by using these substances more rationally. Regular hand washing, hygiene and observance of sterilization norms should be the essential core of every medical procedure.

Among the multiple action plans suggested by the experts, it can be mentioned the following: Establishing monitoring programs to detect new resistant strains in early stages, as well as improving the quality of the detection systems in order to ensure that all bases are being covered.

To design guidelines for treatment at a regional level based on the local epidemiology, which would facilitate the creation of a more accurate empirical therapy. To implement preventive measures like immunization and isolation when necessary.

We live in the information, technology and communication era which allows us to be alert to future events. ❖

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Refractory Hypertension Management

Cerezo César, MD [1]

The assessment of patients with refractory hypertension should focused mainly on confirming a real resistance to the treatment, as well as investigating the possible causes, and providing evidence of lesions on the target organ.

Refractory hypertension treatment is intended to modify lifestyle aspects, and obtain an efficient pharmacological regimen.

Arterial hypertension is defined as resistant or refractory when a therapeutic regimen including changes in lifestyle and an antihypertensive treatment with 3 or more drugs (including a diuretic) at adequate doses is not enough to control systolic and diastolic blood pressure (BP) below 140/90 mmHg. However, recent data consider refractory hypertension patients as those who need four or more drugs to keep their blood pressure under control. [1]

Various evidence shows that refractory hypertension is a clinical problem of large magnitude, even though its real incidence is unknown. Furthermore, patients with refractory hypertension show a worse prognosis when compared with those whose BP is more easily controlled, because of the poor control over time and the association with cardiovascular (CVS) risk factors. The positive effects of an efficient regimen of pharmacological treatment have been revealed in many studies.

This review is focused on the detection and treatment of patients with resistant hypertension.

Assessment of a patient with refractory hypertension.

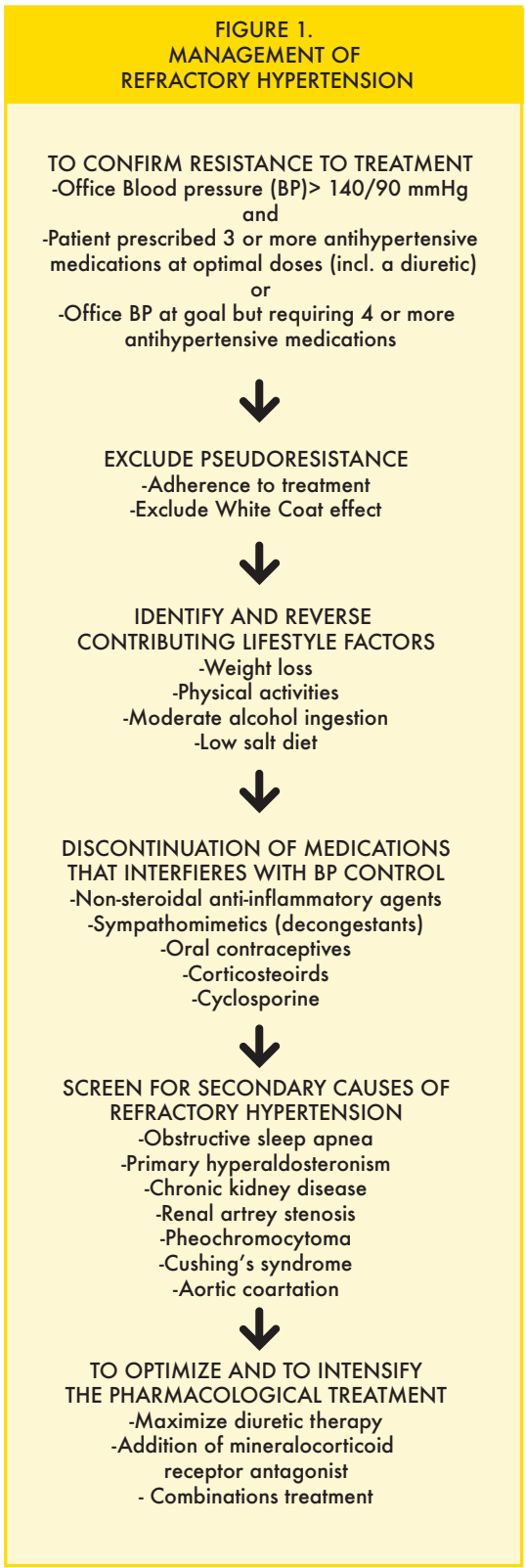
Generally speaking, the failure to control BP is caused by the constant elevation of systolic BP. Older age, left ventricular hypertrophy (LVH), and obesity, as well as chronic renal disease (CKD) or diabetes are predictive factors for resistance to treatment.

The identification of patients with refractory hypertension should be focused on the confirmation of a real resistance to the treatment, the identification of possible causes that contribute to the resistance, including secondary causes of hypertension, and the demonstration of organic injury (Figure1)[1].

A precise evaluation of treatment adherence and a reliable BP measurement are essential to rule out the existence of pseudo-resistant hypertension.

A complete medical history allows for an in depth study of the duration, severity and evolution of the hypertension, as well as a better understanding of the current treatment,

FIGURE 1.
MANAGEMENT OF
REFRACTORY HYPERTENSION



the degree of therapeutic adherence and the response of the patient to previous drug treatments, including side effects. In addition, possible secondary effects of hypertension should be evaluated, such as sleep apnea syndrome, renal artery stenosis or pheochromocytoma (Figure 1).[1]

A reliable measurement of BP is essential to precisely diagnose refractory hypertension. It is known that this group of patients shows an important frequency of white coat hypertension[7], this requires a reliable evaluation of BP through a 24-hour ambulatory BP monitoring, especially for those patients whose BP values are constantly high during doctor's appointments in comparison with values on ambulatory monitoring and do not show organic damage [1]. Additionally, high BP values during ambulatory monitoring offers a more accurately predict a future CVS than those shown during doctor's appointments.

It is necessary to carry out a general physical assessment to reveal the possible secondary effects of hypertension and organ involvement. It should include an ophthalmoscopic screening to assess the existence and seriousness of renopathy, as well as the exploration of carotid and abdominal bruits and femoral and radial pulses to evaluate renal artery stenosis and aortic coarctation or aortoiliac disease, respectively.

Likewise, a complete biochemical assessment should be conducted. It should include routine metabolic profile test, urine analysis and renin and aldosterone determination in plasma or plasmatic renin activity to detect primary hyperaldosteronism.[1] Urine collection over 24 hours would be useful to determine dietary electrolytic supply (mainly of sodium),

creatinine clearance, albumin excretion and metanefrines quantification.

Refractory Hypertension Treatment

An appropiatetreatment of refractory hypertension suggests modifying lifestyle factors that contribute to treatment resistance, treating secondary causes of hypertension and including efficient regimens based on a combination of antihypertensive medicines.

Changes in lifestyle, which include weight loss [2] regular exercise [3], a high-fiber low-fat and low-salt diet[4,5] treatment of obstructive sleep apnea and a moderate alcohol consumption, should be encouraged as an everyday habit. The pharmacologic regimen should be simplified as much as possible, encouraging the use of a combination of long-acting medicines aiming to decrease the quantity of coated tablets prescribed and the use of once a day doses. [7]

Medication that could hinder the control of BP, primarily NSAID, should be avoided in patients with refractory hypertension, or at least, be prescribed in effective low dosages starting with a decreasing routine until its discontinued as soon as possible, with a strict control of the PB numbers during the period they are being used.[1]

Treatment resistance has been partially associated with the lack or incorrect use of diuretic treatment. In most patients, the use of long-lasting thiazide diuretics will be effective most of the time; since these people have an inappropriate increase of volume. In a comparative study between daily doses of hydrochlorothiazide 50 mg and chlorthalidone 25mg, the last one produced a greater PB reduction in the 24 hours ambulatory records[8]. For patients with underlying CRF, loop diuretics are needed to efficiently control volume and BP.

Since there is a high incidence of primary hyperaldosteronism in patients with refractory hypertension, it has been shown that mineralocorticoid receptor antagonists provide an important antihypertensive benefit when associated with polytherapy regimes, even with low dosages of spironolactone.

Although there is little information confirming the effectiveness of a treatment that constantly combines 3 or more medications, intuitively, it seems more appropriate to combine medications with different mechanisms of action, for example, an angiotensin converter enzyme inhibitor (ACE) or an angiotensin receptor II antagonist (ARB), a calcium antagonist and a tiazidic diuretic. [1,9] Medicine combination in fixed dosages can provide potential advantages in comparison with the same drugs used in monotherapy, some of which include the increase of effectiveness, a lower incidence of side effects and more patient adherence to the treatment due to the use of only one coated tablet once a day. [7,10]

However, refractory hypertension, as specific sub-group, is still not well researched. More information is needed in order to better identify and treat these patients. It is necessary to analyze the efficacy of different combinations of medications, including new treatment plans. In this respect, different data about the efficacy of a new vasodilator, drusentan, a type-A selective endothelin receptor antagonist has been published.[11] Renal sympathetic hyperactivity is associated with hypertension and its development, as well as with CRF

and heart failure. A recent study shows that catheter-based renal denervation achieves important decreases and maintains BP numbers in a cohort of resistant hypertensive patients, without any serious adverse symptoms [12].

Conclusion

The results of recent studies have shown individual aspects of refractory arterial hypertension, but the resistance underlying mechanisms to treatment, which most of which in all probability are genetic mechanisms, have not been studied in-depth. Even though different drug treatments and lifestyle changes have shown they provide benefits to refractory hypertension patients, more data is necessary to identify and treat this group of patients, as well as to increase the evidence on the efficacy of specific treatment plans that would lead to stronger treatment guidelines.❖

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Frequency of Cancer in Latin America and the Caribbean

Ortiz-Barboza Adolfo, MD MPH [1]

Cancer Worldwide

Cancer is one of the major problems in public health that mankind faces nowadays. In its 2007 World Health Statistics report [1], of the World Health Organization (WHO) classified cancer as the main cause of death worldwide in 2010 and through the next few decades, exceeding the deaths caused by ischemic cardiopathy and cerebrovascular disease.

With regards to its incidence, in the publication by the International Agency for Research on Cancer (IARC) World Cancer Report 2008 22, the WHO emphasized the fact that globally, cancer incidences would duplicate in the last 30 years of the 20th century, and according to their calculations, it will duplicate again in the 2000-2020 period, and it will triple in the year 2030. Maybe what is worrisome is that nowadays half of the cancer cases are registered in developing countries and over 70% of deaths are registered in those same areas.

The main types of cancers that affect people worldwide are lung, prostate, breast and colon, especially in developed countries. Other type of cancers such as, liver, stomach and cervix are more frequent in developing countries.

In June 2010, the IARC presented GLOBACAN 2008 3, an online data base, which estimates the number of new cases (incidence) and the number of deaths caused by cancer which were registered in 2008 worldwide. It was estimated that in 2008 12.7 million new cancer cases were diagnosed, and 7.6 million people died due to cancer around the world.

Addtionally, 2008 Globocan showed that a high proportion of new cases and deaths are ocurring in developing countries. 56% of new cases and 63% of deaths occured in underdeveloped countries.

The types of cancers which are more frequently diagnosed in the world are lung cancer (a total of 12.7%), breast cancer (a total of 10.9%) and colorectal cancer (9.7%). The types of cancers which cause the most deaths are lung (18.2%), stomach (9.7) and liver (a total of 9.2%).

Considering the current situation, it is necessary to review the specific information about the frequency of cancer in Latin America and the Caribbean, according to the latest official, globally update, data.

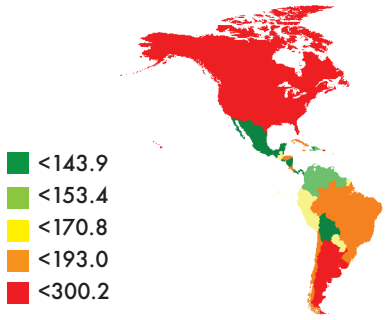
Cancer in Latin America and the Caribbean

According to GLOBACAN 2008 database, the population in Latin America and the Caribbean in 2008 was calculated to be 576.1 million (50.6% women and 49.4%), including a total of 31 countries (10 in the Caribbean and 21 on the continental shelf).

In that same year, it was estimated that 906,000 new cancer cases were diagnosed in that region,

MAP AND FIGURE 1.

Estimated age-standardised incidence rate per 100.000
All cancers excl. non-melanoma skin cancer: both sexes, all ages.



Source: Globocan 2008 (IARC)-9.5.2011

and a total of 542,100 deaths caused by cancer were registered. Table 1 shows in detail the number of new cases by country, crude rate, incidence adjusted rate and accumulated risk by all types of cancer in both sexes (excluding non-melanoma skin cancer) in descendent order, according to the adjusted rate of incident. Figure 1 shows the map of America continent.

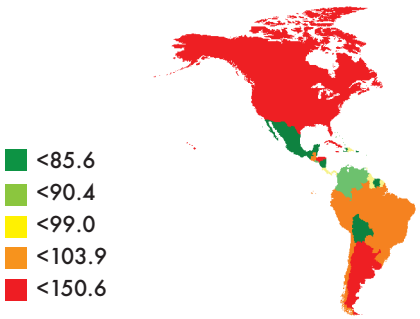
ALL CANCERS EXCL. NON-MELANOMA SKIN CANCER: BOTH SEXES - INCIDENCE, ALL AGES

POPULATION	NUMBERS	CRUDE RATE	ASR(W)	CUMULATIVE RISK
United States of America	1437199	461.1	300.2	29.90
Canada	166142	499.5	296.6	29.44
Uruguay	14584	435.4	280.3	28.13
France, Martinique	1550	384.3	234.9	24.44
Barbados	758	297.0	207.9	21.93
Argentina	104859	262.9	206.2	20.97
France, Guadeloupe	1409	303.9	196.9	21.09
Puerto Rico	12756	321.7	194.0	19.62
Cuba	31503	281.2	193.0	19.43
Jamaica	5063	187.0	187.8	19.95
Honduras	8923	121.9	180.5	18.32
Chile	36047	214.5	176.7	18.21
Costa Rica	7653	169.3	176.3	17.27
Brazil	320955	167.	171.3	17.58
French Guyana	260	118.1	170.8	18.62
Paraguay	7957	127.6	166.3	17.09
Ecuador	20167	149.6	160.5	15.67
Peru	39305	136.3	157.1	15.52
Bahamas	511	151.3	156.4	18.13
Guatemala	14155	103.4	154.0	15.32
Trinidad and Tobago	2080	156.0	153.4	16.15
Venezuela	36961	131.4	152.6	15.64
Dominican Republic	13063	131.3	151.7	16.15
Colombia	58534	130.0	150.2	15.29
Guyana	1079	141.3	150.2	15.41
Suriname	676	131.2	144.5	15.14
Panama	4630	136.2	143.9	14.73
Nicaragua	5591	98.7	140.2	14.46
El Salvador	7782	126.9	135.9	13.65
Haiti	8414	85.2	133.8	14.53
Mexico	127604	117.5	128.4	13.42
Bolivia	8689	89.6	121.6	12.59
Belize	226	75.2	115.0	12.70

Crude and age-standardised rates per 100,000 • Cumulative risk [0-74], percent, GLOBOCAN 2008,
International Agency for Research on Cancer • http://globocan.iarc.fr/ • 9/5/2011

MAP AND FIGURE 2.

Estimated age-standardised mortality rate per 100.000
All cancers excl. non-melanoma skin cancer: both sexes, all ages



Source: Globocan 2008 (IARC)-9.5.2011

Table 2 shows the same information as the previous table but it includes the mortality data by cancer type, except non-melanoma skin cancer. Figure 2 shows the corresponding map.

The cancers with the most incidences and the highest mortality rate in Latin America and the Caribbean are prostate, breast, lung, cervix and stomach cancers.

ALL CANCERS EXCL. NON-MELANOMA SKIN CANCER: BOTH SEXES - MORTALITY, ALL AGES

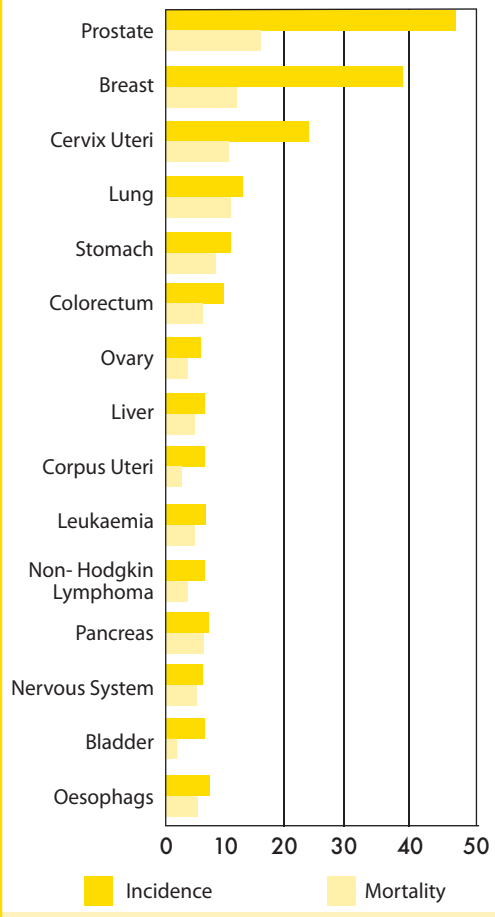
POPULATION	NUMBERS	CRUDE RATE	ASR(W)	CUMULATIVE RISK
Uruguay	8644	258.1	150.6	15.80
Cuba	21211	189.3	121.6	12.13
Honduras	5723	78.2	117.3	12.07
Barbados	456	178.7	116.4	11.97
Canada	72493	218.0	113.3	11.81
Jamaica	3151	116.4	110.9	11.91
Argentina	60500	151.7	110.8	11.66
United States of America	565644	181.5	104.1	11.19
Chile	22123	131.7	103.9	10.83
Ecuador	13280	98.5	103.1	9.99
Brazil	190014	99.0	100.4	10.50
Guatemala	9120	66.6	99.9	10.07
Paraguay	4788	76.8	99.8	10.32
Peru	24828	86.1	99.3	9.92
Trinidad and Tobago	1358	101.8	99.0	10.39
French Guyana	142	64.5	95.9	10.61
Costa Rica	4256	94.2	95.6	9.22
Panama	2982	87.7	90.9	9.01
Guyana	653	85.5	90.7	9.43
Dominican Republic	7952	79.9	90.6	9.46
Bahamas	296	87.7	90.4	10.27
France, Martinique	698	173.1	89.6	8.73
Venezuela	21249	75.6	88.5	9.19
Colombia	34016	75.6	88.2	9.19
France, Guadeloupe	717	154.7	86.5	9.06
El Salvador	5047	82.3	85.9	8.84
Nicaragua	3345	59.0	85.6	8.92
Haiti	5360	54.3	85.5	8.66
Suriname	376	73.0	79.3	8.39
Mexico	77708	71.6	77.6	8.21
Puerto Rico	5301	133.7	75.5	7.72
Belize	147	48.9	75.3	7.73
Bolivia	5245	54.1	74.8	8.03

Crude and age-standardised rates per 100,000 • Cumulative risk [0-74], percent, GLOBOCAN 2008, International Agency for Research on Cancer • http://globocan.iarc.fr/ • 9/5/2011

It is worthwhile pointing out that it is possible to carry out a screening in some areas for at least two (breast and cervix) of the five most important types of cancers in the region, with proven benefits. The same benefits occur with malignant colon lesions which is the sixth leading type of cancer.

Additionally, for the other three types of cancer, it is possible to develop strategies related to the early diagnose of the lesions. For all cancer types, general education for the public is being taken into consideration as a preventive measure.

INCIDENCE AND MORTALITY IN THE MAIN KINDS OF CANCER IN LATINOAMERICA AND THE CARIBBEAN



ASR (W) rate per 100,000

The incidence and mortality adjusted rates for the 15 most important types of cancer, for both sexes, in Latin America and the Caribbean are detailed in Figure 3.

To conclude, it is important to mention the projections of new cases and deaths calculated in this region for the next few years: an increment of 20% by 2015 and 40% by 2020 has been estimated for the numbers of incidents and death. This is especially important since there is a tendency for both frequency measurements to increase.

Some of the reasons which explain this important increase in the frequency of cancer in this area are the infectious diseases control (epidemiologic transition) and the changes in the population structures, characterized by a gradual and continuous ageing (demographic transition).

Even though the numbers are worrisome, nowadays cancer is the only non-transmissible chronic disease that can be cured if it is detected in early stages. Additionally, whose innovations in early, appropriate and efficient diagnostic gives hope to a population that is exposed to a great risk. ❖

1. Medical Manager, Oncology and Transplant Franchise Pfizer Central America and the Caribbean

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Comments on the 1978 Belmont Report [1,2]

Bustos-Montero Daniel, MD[1,2]

In 1974, after it became publicly known the way the U.S. Department of Health had carried out a study about the natural progression of untreated syphilis (known as the Tuskegee study), American society complained about the ethical violations this studied represented.

Knowing that this was not an isolated case, on the contrary, there were previous cases which leaded to the enactment of the Declaration of Helsinki in 1964, and besides the cases mentioned by Dr. Henry Beecher in his article Ethics and Clinical Research -published in the New England Journal of Medicine in 1966-, the U.S. Congress decided to create National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Its specific objective: to identify the basic ethical principles that research using human being as subjects should follow in order for it to be considered lawful.

The Commission report, and two appendixes which consisted of the materials the Commission gathered, were presented for the first time in 1978. However, it wasn't until April 18th 1979 that the report and its conclusions were officially published. It was named after the Conference Center where the document was drafted a year before: The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research".

Although this report introduced many relevant concepts in regards to ethics in research, it is known for the discussion it presented about three principles and the way they should be applied:

PRINCIPLE	GUIDELINE
Respect for Persons	Informed Consent
Beneficence	Risk-benefit Value
Justice	Subject Selection

The principles and guidelines that are derived from this report are still very important for the regulations of investigations on human subjects. Although it does not consider all the aspects related to the participation of human beings in research, it has exceeded the initial context limitations and it has been adopted in clinical practice and health care.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research existed under this name from 1974 to 1978; it was replaced later by a series of government institutions in the field of public bioethics. Its main successor is the National Bioethics Advisory Commission created in 1996 by President Bill Clinton; this commission remains functional to the present day.❖

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Reading Suggestions

WORLD HEALTH ORGANIZATION 2011 WORLD HEALTH STATISTICS.

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