

# World Medical Journal



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- Declaration of Helsinki
- Strong Tobacco Policy
- Model of Colombian Social Security in Health

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# World Medical Association Officers, Chairpersons and Officials

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515 North State Street  
60654 Chicago, Illinois  
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Plot 8, 41-43 circular rd., P.O. Box  
29874  
Kampala  
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Israel

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Tokyo 113-8621  
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14 rue des Tiennes  
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WMA Treasurer  
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(Wegelystrasse)  
10623 Berlin  
Germany

[www.wma.net](http://www.wma.net)

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## Official Journal of the World Medical Association

**Editor in Chief**

Dr. Pēteris Apinis  
Latvian Medical Association  
Skolas iela 3, Riga, Latvia  
Phone +371 67 220 661  
[peteris@arstubiembra.lv](mailto:peteris@arstubiembra.lv)  
[editorin-chief@wma.net](mailto:editorin-chief@wma.net)

**Co-Editor**

Prof. Dr. med. Elmar Doppelfeld  
Deutscher Ärzte-Verlag  
Dieselstr. 2, D-50859 Köln, Germany

**Assistant Editor**

Velta Pozņaka  
[wmj-editor@wma.net](mailto:wmj-editor@wma.net)

**Journal design and  
cover design by**

Pēteris Gricenko

**Layout and Artwork**

The Latvian Medical Publisher  
"Medicīnas apgāds",  
President Dr. Maija Šetlere,  
Katrīnas iela 2, Riga, Latvia

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**Producer**

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## The Globalization and the Role of Medical Professional Associations



*Pēteris Apinis*

The globalization in more narrow sense is presence of international contacts as well as dependence of people and groups of people on international activities. International contacts have been taking place throughout the history of the world. Since ancient times trade, migration and wars have been bringing together people from different origins. The notion "citizen of the world" belongs to Diogenes of Sinope, an ancient Greek philosopher who lived in 4<sup>th</sup> century BC.

The term "globalization" and the concept of global development emerged in the 80-ties and was first broadly used in 1981 by J. Mcleen and later expanded by R. Robertson in 1983. More detailed research of globalization as a process or phenomenon started in 90-ties. R. Robertson's "Globalization", was published in 1992, while M. Waters's fundamental work "Globalization" came out in 1995.

**The main achievements of XX century – computers and space exploration, globalization and communication, antibiotics and hormone replacement therapy in medicine**

The XX century brought to humankind huge changes and astonishing events, wars, epidemics, discoveries, development, and both human reasoning and insanity. There was more news in the human world than in the whole millennium before. New matters, that were crucial for the formation of new culture and new world, emerged.

Globalization is essential here. A human life became completely different, particularly the volume of received information increased dramatically. One of the main cornerstones of globalization was the development of new means of communication. On the other hand this brought along dependence on information and its carriers and changed the way people communicated.

**Globalization in XXI century means different economic situations**

Today the world is divided into two parts: the economically developed one and the other that suffers from stagnation. In addition, the developed countries declare that they are trying to eliminate the gap while in reality they often do everything to deepen the gap. In the context of globalization processes the world economy is concentrated in three regions (Eastern Asia, North America, Western Europe). Meanwhile the interests of the developed countries determine the way science and technologies move towards absolute privatization, decentralization and liberalization.

Globalization is also characterized by unbalanced demographics – Asian numerous

dominance and African poverty. At the same time there is economic growth in China, India, Nigeria etc. That sooner or later will lead to shift of economic centres.

The social strategy in the most of the world is wavering between free market economy and restricted social market economy that is supplemented by moderate protectionism. Big companies more and more actively become participants of co-operating networks while middle-sized and small ones are subjected to huge management changes and market demands. At the same time the gap between socially integrated groups of population and those socially outcast is continuously increasing, unemployment rates grow and they move towards developed countries. In the sphere of health care and medicine prevention, diagnostics, treatment and rehabilitation both concerning quantity and quality are determined by financial capacities. Inhabitants of poor countries suffer from diseases hardly imaginable for an European doctor as they are caused by insufficient nutrition or even hunger.

**Globalization means speed. Information is spreading fast, so are diseases, however, particularly fast travel people who spread the diseases**

Not so long ago in the XIX century an epidemic of flu was travelling at speed of a horse carriage while today it is taken around by airlines. Any flight to a distant destination is shorter than any period of incubation of any infectious disease.

Distribution of diseases in the age of globalization is determined by changes in people's lifestyles, growth of population and the process of urbanization, as well as migration of peoples caused by wars or natural or human-inspired catastrophes and particularly migration as a result of economic problems. Travelling is also an important factor when spread of diseases is concerned, as travellers contact rain forests or other wild habitats

that serve as reserve for insects and other animals that carry infections.

The third influence of globalization is the one of medicine that happens through international drug companies that develop and produce medications and provide international schemes and guidelines. The consequence of this is increased antibacterial resistance that is also based on uncontrolled use of pesticides in agriculture and uncontrolled use of antibacterial substances in animal and fish farming.

As the fourth aspect that essentially influences human health and medicine I would name uncontrolled use of chemicals in households, washing the linen and dishes, car wash, machine oils, biotechnologies, which results in chemicals being washed away into oceans where after being absorbed by plancton they return to dining tables of people through prawns, fish and crayfish.

Human health is essentially influenced by the harm done to nature by people. Deforestation, irrigation, genetical crops have caused changes both in human bodies and recarriers of illnesses. Moreover, serious changes have taken place in human behaviour, overexcessive amounts of medicine, narcotics, alcohol; traditional family patterns and sexual culture have changed a lot.

## Globalization as loss of geographical segmentation concerning food

Similarly to people goods and food travel long distances. Today all food supplies have become global – people consume more and more international food and the role of locally grown and processed food has lost its significance. This means that seafood is consumed worldwide, tropical fruit is mostly consumed in Northern countries in Scandinavia, South-eastern Asian poultry can be found anywhere in the world as well as lamb from New Zealand and South American beef. Globalization has brought along un-

justified schemes of nutrition, meals that are easy to cook, but that do not contain necessary ingredients and is referred to as *junk food* – different kinds of *macburgers*, chips, *French fries*, *hotdogs*.

The world tends to repeat mistakes once made in the USA. If we observe the tendency to obesity of the whole nation in the USA in the end of XX century, we can predict that illness number one worldwide in XXI century will be obesity carrying along diabetes and cardio-vascular diseases. Germans (along with other Central Europeans) have bread and sausage with beer for lunch while Americans help themselves on big burger and cola. In the evening football match on TV is supplemented by chips in Germany but Americans enjoy their French fries with American football.

## Globalization as changes in ideology and lifestyle. Tobacco as an example

A classical example of globalization is smoking. Bradford Hill in 1951 discovered that smoking causes lung cancer. It was a stunning discovery at that time as almost every male adult in Europe was smoking. During the war tobacco served as consolation in all entrenchments; even if it did not help to relax, it could serve as a pastime. In those times it was difficult to prove that smoking caused lung cancer because it was common among both the ill and the healthy. In 1947. the Council of British Medical Research asked Bradford Hill, Richard Doll, Edward Kenneway and Percy Stock to find out whether smoking could be the reason for the shocking increase of death rate 15 times during the last 25 years. Since 1951 it has been proven that smoking is a threat to human life. Already in 70-ties doctors started to fight the calamity of smoking while in 80-ties and 90-ties both in USA and Western Europe merciless fight against smoking started. Major Tobacco companies lost millions in courts, lost their advertising facilities, started pay-

ing huge taxes. It seemed that smoking was going to lose the battle. However, the result was opposite. Tobacco companies felt threatened and started fighting desperately to win new markets. They best succeeded in Eastern Europe, South Asia, North Africa and Latin America. Tobacco companies entered developing countries using excellent marketing strategies, attractive advertising, exact political approach and friendly attitude to mass media. As a result number of smokers in the world increased three times.

## Globalization today is an economic strategy that proposes unrestricted free trade and free market economy

In the end of XX century globalization came on the stage with a patented economic prescription for any situation – privatization above all. The state lost its position of manufacturer and employer becoming a judge, surveyor and dictator of the rules of the game.

The process of globalization along with expansion of market economy caused not only political changes in the map of the world but also economic fluctuations. The market of raw materials was redivided, this process brought along the collapse of the Soviet Union and Yugoslavia, a number of new independent countries emerged. Any economics has faced serious problems during the last twenty years yet the most significant crisis touched Mexico (1995), Taiwan, Korea (1997), Thailand (1998), Brazil (2000), Argentina (2002), Baltic states (2008), Greece (2009). In all mentioned countries the economic difficulties brought along social and health problems, besides in Mexico and Thailand children's health was severely affected (they had to work and missed school and medical examination), while in Argentina – the elderly (the collapse of pension system, bankruptcy of social homes).

Economic crises in individual and national level show as depression, alcoholism, family

unstability, diseases determined by stress, increased death rate from cardio-vascular diseases, more suicides and lethal accidents. There is even a new term in the world literature – the losses of transitional period.

Market took over everywhere including medicine, however, the state should have taken the best possible control of this market. The role of the patient had changed – the patient was not anymore a grateful subject of help but a customer, who buys services offered by a doctor, nurse, rehabilitation specialist, laboratory assistant. Consumer philosophy became a part of health care. There are two axioms in consumer philosophy: “more medicine is better health” and “expensive medicine is better than cheap medicine”. This leads to get served as royal customers not ill people. So the result is that a person who suffers from an illness is treated as a broken car. the situation when those who are able to pay.

## Medicine, if it has enough funds is able to extend any individual's life essentially

This means that any individual is entitled to significant amount of common funds to prolong their individual life which causes catastrophic lack of money in medical sector not depending on how rich the country is. Any resource (professional medical knowledge, intuition, experience, working hours, premises, equipment, medications, money) that is invested in health care, specific prevention issues, diagnostics, treatment and rehabilitation, prolongs an individual's lifespan and improves the quality of life. This is where the main paradox of medicine appears – the more money is invested in health care, the longer people live (and as it was mentioned before agree with their chronic illness), the more resources will be required for health care.

All the countries that have reached this stage of economic development face rapidly

growing discontentment with the health care system and financial regulation of health care.

The proportion of medical expenses in the big money purse of the world or global economy has been increasing during last thirty years. In the world as whole the growth of funding medicine is 3–5% per year, which is significantly more than total global gross product. Consequently, rules of globalization are dictated by economic interest and market. Where big money is present, business interests emerge.

Commerce has entered the medical world through spirit of market competition, privatization, rivalry, information technologies, circulation of information, mass media and other routines of globalization, which can be seen in different ways in major capitalist countries, Eastern Europe, as well as South America and even Africa.

## The biggest player in the arena of global medicine – the BIG PHARMA. Medication companies have set their new goals to reach every person on the planet and make them take medications every day

Pharmacy business is ranked as the third or sixth by significance in the world depending on methodology of accounting.

Moreover, pharmacy business is the significant player in advertising market, direct and indirect advertising expenses are higher than those on cars, travelling and fashion goods in total. There are 5 billion USD (30–35% of all expenses) spent on pharmacy marketing.

The global pharmacy market is explicitly heterogeneous. 89% of funds spent on medicine go to 11% people. More than 80% of the world population only use folk-medicine and do not receive contemporary medications.

In Europe 2/3 of total medications are prescribed to people who are older than 66. Polypharmacy dominates in treatment of the elderly – on average 6 (2.7–9.3) medications. All the side effects elderly patients face stand out against the background of a number of medications. More than 50% of elderly patients suffer from side effects as a result of combination of polypharmacy and disturbances of kidney function. The biggest problem is the situation that there is no monitoring of medication for elderly people.

In the XXI century massive use of medications has reduced the role of other ways of treatment (including rehabilitation). In the XIX century as well as the most of XX century in Europe there was equal proportion regarding surgery, treatment using medications, physical therapy and psychotherapy.

In the end of XX century the role of surgery became less important because of the pharmacy business (e. g. stomach resection disappeared, number of appendectomies decreased), physical therapy significantly lost its weight, and psychotherapy lost a lot of its position, while Eastern and non-traditional methods of treatment came in. Consumption of medications rose exponentially.

There is an opinion that pharmacy companies invest their assets and profit in the world's biggest news agencies. As a result the big pharmacy business on the earth has merged with the big media. The industry of pharmacy supports the *journalism of sickness*.

In 2001 we had type C hepatitis,

- in 2003 there was Bovine spongiform encephalopathy or Creutzfeldt-Jakob disease,
- in 2005 – SARS,
- in 2007 – Bird flu,
- in 2009 – Swine flu.

Looking back, we can see that every two years a new reason to spend money is invented. It is easy to compare: every year half a million people die of common flu.

Bird flu took 250 lives in the period of 10 years, but what fantastic profit it gave to BIG PHARMA! Half a million against 25 a year. Newspaper headlines inform about bird migration that spreads bird flu. Birds usually travel from North to South while flu spreads from East to West!

Pharmacy companies try to supply everybody with everyday pills. One of the most obvious examples is the presumption that contraception pills is a must for every woman every day while those in menopause have to take hormones regularly at least to prevent osteoporosis. This guarantees two milliard pills a day and this where the big business starts. Pharmacy companies do not strive to create new medications that could treat malaria or infectious diseases; they actively develop antidepressants, new ways to reduce blood lipids, blood pressure, try to find Viagra for women in order to gain their interest from market.

An analogous situation: in the sphere of transportation most funds go to develop aviation while most of the world's population inhabiting India, China, countries of Indochina mostly travels by rickshaw or bicycle. So pharmacy as a part of medical treatment becomes similar to aviation as a part of transportation. **The market structure changes, medications leave chemist's stores and go to supermarkets or internet stores.**

The traditional model of medical treatment (a medical professional – a patient who needs help) is threatened; self treatment is on the rise.

Medications leave for drugstores and to escape the Swine flu every second British citizen buys a thermometer and Tamiflu.

In the age of globalization the roles of doctor and pharmacist are taken over by internet. Internet drugstores advertise their benefits – no visit to a doctor is required, no prescription, time and money are saved as they say that the prices are lower. Today there are

drugstore systems that function as cartel all around the world.

## **Serious changes concerning morbidity**

The doctor of the XXI century is much more than ever involved in the treatment process of incurable patients suffering from chronic illnesses. Most of those who would be considered sentenced to death today have become survivors, however, chronically ill. They are people who will have to agree with their illness that is incurable in therapeutic or surgical way until the end of their lives. Accordingly the frequency of different types of illnesses has changed: today's patient as a rule is a chronic one while acuities are exceptional.

A typical patient, for example, is a 65-year-old lady. Her diagnosis is the third stage of adiposity accompanied by 2<sup>nd</sup> type diabetes mellitus, hypertension, cardiovascular inability, as well as breathing inability. Excessive weight has caused pain in knee and hip joints. She has been prescribed eight to twelve different medications to treat every separate illness.

Polypragmasia is a problem of XXI century. If there are more than three types of pills, one can be almost 100% sure that there will be confusion about which are to be taken three times a day by one pill and which four times a day by two pills. It is even worse if several doctors have been visited; and every of them did their duty giving a prescription.

## **Task shifting and global migration of medical workers in XXI century are consequences of the globalisation of medicine**

Even in the beginning of XX century nobody could imagine a Riva Rocci device or a fonendoscope in the hands of a non-medical person. Not longer than ten years ago nobody could imagine ultrasound diagnostic device operated by someone whose

qualifications are not adequate. However, the costs of educating a doctor are becoming higher and higher, doctor's work costs more and more, while as a result of the aging of population has caused lack of doctors. It is cheaper to produce "substitute doctors" – functional specialists, optometrists, logopedes, ergotherapists, technical orthopaedists. In many countries a nurse has a right to give prescriptions.

At the same time emigration waves of medical workers travel the world. At least 70% of Philipinian nurses work abroad. The most typical brain exporters are India, Pakistan, Malaysia, Philippines as well as Eastern European countries. Doctors and nurses from Eastern Europe are enticed by massive advertising campaigns carried out by Professional recruiting companies. An opposite tendency is medical tourism. The expansion of hospitals, that is becoming more and more fashionable, ensures that new medical centres emerge in developing countries. For instance, in Thailand and India the most Professional doctors get concentrated in medical institutions belonging to foreigners, working with foreign patients.

As a result of globalisation doctors can find any education materials on the Internet in a few minutes; materials of almost all medical congresses are available on the world wide web. Exactly the same way possibilities to contact and consult anyone are widely available as well as telemedicine.

## **Globalisation in medicine in XXI century is often referred to as a global crisis in health care. Psychological pressure is applied to medical workers widely exposing negations in mass media**

Health care expenses have been increasing both absolutely and relatively related to national gross product in civilized countries. At the same time it means longer lifespan. Everybody wants to live longer not depending on



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being a labourer, doctor, journalist or politician. The last two wish to get it free of charge.

It is quite typical that politicians when they talk about medicine not being competent enough try to promote e-health, expensive Technologies and premises but trying avoid to pay the medical professionals.

The World Wide Web also answers the question about the people who are loudly campaigning against doctors – they are middle-aged people who are practically healthy, however, in this economically complex situation suffer from stress, emotional disturbances and as a result from vegetative disorders. They complain about palpitation, frequent colds, dizziness etc. and they wish to be cured by a doctor immediately. This group of people are frequent visitors at quack doctors and healers, and they consume a lot of food supplements.

They feel they have paid their taxes, however they do not get in return attention or financial value for that as most of the money goes to elderly chronic patients. They have no idea that after some time they will belong to the category themselves. This unfair situation in financing the health care is the key factor that ruins reputation of doctors – someone who is still young and pays taxes does not know that at some point life starts turning down. So everybody declaring now that they do not need this kind of doctors and health care sooner or later will face the situation when they do.

On the other hand – those who form opinions of humankind, country or just locality as a rule are not chronic patients or elderly people who are receiving more health care than they are actually paying for.

## **The Professional prestige of doctors (hospitals, whole medicine) is falling in XXI century**

The significance of doctor's profession has decreased, the role of bureaucracy has swol-

len, the profession has lost its autonomy. World wide research results show that a doctor (variously in different countries and specialities) has to spend 50–75% of their working time making written or digital reports.

Is the decrease of medical professions prestige reasonable? Doctors work better and more professionally, which is proved by lengthening the lifespan in the entire civilized world. New technologies are applied in doctors' work, which means fast and precise diagnostics, atraumatic operations and safe application of narcosis. Every year new medications – safer and more effective – are developed while there is a new qualitative improvement in pharmacy every decade. Cancer is not any more one hundred percent lethal not to mention infectious diseases that have been threatening people for centuries.

Firstly, the problem is caused by qualitative changes in lifestyle, economic formation, attitude to health issues simultaneously changing opinions regarding fundamental principles. For instance, in the beginning of XX century the notion *diet* meant enough of "proper food" as patients lacked food or had food that was not nutritional enough. In the beginning of XXI century diet means necessity of "less food".

In the beginning of XX century prescription of sustaining regime meant warmed room and lying in bed. In the beginning of XXI century active movements, swimming in a pool, running, and ways of toughening the body are considered sustaining. There are also changes in procedure of diagnostics – a conversation between doctor and patient, inspection and auscultation have been replaced by megacomputers that carry out visual diagnostics and complicated machines that make analyses.

Today doctor's opinion is substituted by results of proved research that are part of evidence based medicine.

The patient today is much more educated, which is ensured by extensive flow of information coming from pharmacy companies. As a result quite often patients know more about newest medications than overloaded doctors who do not have enough time to surf the internet.

Doctors who work too hard but do not get rewarded neither financially nor morally come to frustration regarding the medical system and their job. TV and press abuse and slander doctors that results in decreasing self-confidence, patients do not trust doctors and mutual co-operation regarding the process of treatment becomes ineffective. The doctors' frustration influences heavily the quality of health care.

## **The only protection comes through Professional medical associations or chambers**

Doctors elect their representatives who are entitled to protect their interests. At the same time electors are not always satisfied with the protection they receive. Associations cannot cope with their duties because government, the ministry, patients, journalists and ordinary doctors oppose them.

The tasks of National medical associations are:

- protection of doctors' professional, economic and legal interests;
- promotion of prestige and respect of doctor's profession as a free profession;
- perfection of doctors' ethical code and catering for professional ethics;
- facilitation of postgraduate education;
- improvement of professional skills and perfection of professional knowledge;
- assessment of professional qualifications of foreign doctors and dentists;
- improvement of health care organization;
- facilitation of improvement of the health of society;
- certification and licensing;
- co-operation regarding legislation etc.

Professional medical associations in different countries function differently and they reach their objectives by different means. The new issues imposed by globalization require serious financial way of dealing with them instead of just public activities.

Contemporary medical non-governmental organizations are non-profit organizations in reality are non-profit organizations that have thousands of shareholders thus being transparent business structures. Mostly they do not depend on the budget of the state, functioning on finance obtained in other ways.

National medical associations are financed by membership fees, income from certification and licensing, publishing books and magazines, creating other mass media, income from post-graduate education, organizing of conferences and congresses, incomes from international funds of environmental and public health, income from international projects of health care over the borders, donations and gifts, and different kind of co-operation between pharmacy and food companies etc.

## **The role of non-governmental medical associations in the area of public and environmental health is continuously increasing**

Only 7% of world's population are concerned about environmental health while only 1% are ready to act in benefit of it. Amazingly, the most interested people in environmental issues are clinical doctors. National medical associations can be considered as the most influential power regarding public and environmental health, in some countries it is the only power. For example, in some Eastern European countries National medical associations in reality function as Green parties.

Public health is a science that is continuously developing. Public health is based on

science, that is why only science performed by doctors promotes health and quality life.

The main function of a medical association is to serve as medium between doctors and the government trying to explain doctors' ideas to politicians.

It is true that politicians love saying that doctors are interested in people being ill and that is why doctors are not promoting public health issues. The real truth is quite opposite – all around the world doctors are those who promote public health because our profession due to its humanity is constantly searching not only for solutions in individual's health but also in health of entire humankind. This driving force has been and still is obliged to work in the frames of the system determined by legislation and state structure.

The crucial health issues that are to be solved by National medical associations in XXI century are:

- controlling tobacco consumption, active fighting against children and young people smoking. Prevention of children and pregnant women from active and passive smoking. Banning tobacco advertising in mass media available to children.
- reducing of alcohol consumption in society. World wide fighting against alcohol consumption by young people until age of 21. Banning alcohol advertising in mass media available to children.
- fighting against spreading of narcotics.
- elimination of trans fatty acids from people's food. Initially reach legislative restrictions of not more than 2% trans fatty acids from the whole amount of fat in any product.
- eliminating sugary drinks from schools or any places where children gather together. Banning sugary drinks advertising in mass media available to children.
- reducing the salt (NaCl) consumption in food, reaching in average 5g daily;
- active fighting of sedentary lifestyle, popularizing the principle – sports at least half

an hour at least 5 times daily. The balance of calories organized in a way that people can reduce the weight while the world can fight the epidemic of obesity. Sports as means of prevention and treatment of illnesses.

- more fruit and vegetables in everyday food (5 times a day), popularization of fiber-rich food.
- popularization of breast-feeding, education of young mothers and pregnant women (The best progress in reducing infant mortality is reachable by educating women).
- fighting for clean air and water worldwide, fighting against global warming.
- fighting against charlatanism and quack doctors;
- popularization of healthy workplaces;
- promotion of prevention diabetes, cardiovascular diseases, obesity and other non-contagious illnesses;
- promotion of prevention HIV/AIDS and carrying out interpretive activities;
- cancer prevention, especially breast and cervical cancer prevention;
- reducing of antibacterial resistance and polypragmasia etc.

Working to improve public health, national medical associations can obtain publicity and recognition, which empowers them to solve their main tasks – protection of doctors' rights, forwarding ethical issues.

## **The most significant goal on the earth is clean air and clean water as well as reducing toxic and not tested chemicals in everyday life**

The most important issue for every person is clean air and clean water, unpolluted environment. Air pollution is mostly caused by fossil fuels, road traffic and volcanoes.

Usually when we talk about clean water we mean clear and clean drinking water. Every



year 1.5 million children die of diarrhea that is mostly caused by polluted water.

Regarding chemical pollution today's world could be characterized being in the state of chemical war. The largest catastrophe of the world last year was toxic red sludge spill in a Hungarian aluminum plant. Nobody ever expected chemical catastrophes. Nobody ever expected radiological catastrophes – neither Chernobyl nor Fukushima.

Every rich country tries to get rid of their chemical or nuclear waste preferably burying them in another country or sinking in the sea.

During the last 60 years 70,000 new chemicals have been introduced. 15,000 chemicals that are used in everyday life have not been tested and there is no information about their toxicity. In more than 90% cases there is no information, what their impact on children's health is.

An average woman during their lifetime feeds into her body about 80 kilograms of different chemicals using cosmetics to

nourish their face and body skin. . At least 200 different compounds used in cosmetics have harmful or as minimum negative effect on one's health. Human tissues and parts of body have become a target for toxic substances. Pollution heavily influences human health and functioning – liver, kidneys, intestines, nervous system, skin and immune system. The most sensitive parts of human body are reproductive system and immune system; they suffer from pollution the most

Today's reality is the fact that most of the food we consume comes from supermarket chains; it is no more grown in our farm fields, gardens or cattle-sheds.

Today every animal that is grown by methods of intensive breeding gets antibiotics, hormones and other stuff added to their food aiming to speed up the process of growth and prevent any disease.

The shop counter exposes genetically modified food (grain, root vegetables, soy). Even if we do not buy them directly, we consume it through animal food or as ingredients of complex foodstuff.

## **In XXI century there is a rapid upsurge of science for health and life**

Prognosticating progress of science is a complicated issue. In the 70-ties of XX century scientists predicted that human genome could be read at the end of XXI century, but it was done almost a whole century earlier.

The most significant achievements and discoveries of XXI century will be connected with sciences about life. The competition in the sphere of biomedical and genome technologies is going to be tough and expensive, comparable to space investigation race in XX century. Last century was the one of the spaceship, nuclear power station, Internet and mobile phone. At the same time people discovered that environment has changed not bringing along longer lifespan and better health. In XXI century medicine will be significantly driven by science.

**We are living in a perspective era. There is a lot to do for us.**

*Dr. Pēteris Apinis,  
Editor-in-Chief of World Medical Journal,  
President of Latvian Medical Association*

## **EU Health Ministers Need to Agree on Strong Tobacco Policy and Stop 650,000 Europeans from Dying Each Year**

Europe pays a hefty price for its slow action on tobacco, both in economic costs and harm to its citizens' health and well-being (1). Today, EU Health Ministers will meet to agree a common position on the revised, smarter Tobacco Products Directive (TPD) (2)

"A majority of Europeans support tobacco control policies (3). They deserve a strong commitment both from the EU Health Ministers and the outgoing and upcoming rotating presidencies of the EU – Ireland and Lithuania respectively.

They should make sure that tobacco products are not presented in a way that manipulates people, in particular children and youth, to pick up a smoking habit," said Monika Kosińska, Secretary General of the European Public Health Alliance (EPHA).

This week five committees of the European Parliament (4) are giving their non-binding opinions on the revision of the TPD in a disappointing affair that widely prioritises the interests of the tobacco industry (5) at the expense of people's health.

If European policy-makers keep on basing their decisions on arguments by the tobacco lobby, the final Directive will resemble a tobacco industry report. Additionally, if the approval of the tobacco legislation does not occur by the end of the year, it would put its adoption dangerously close to the next European Parliament's elections, putting the hard-fought political process back to square one.

In a letter (6) co-signed this week, nine public health organisations stress that the current political procedure around an

**updated TPD represents a window of opportunity to better control the marketing of an addictive product that kills half of its users when used as intended.** Some of the letter's signatories spell out why Health Ministers, Members of the European Parliament and national authorities should take this piece of legislation seriously:

**"Tobacco kills over 650,000 Europeans each year. It is 1,800 people each day, the equivalent of three jumbo jets crashing each day in the EU.** This is unacceptable. We need a bold new TPD so that our children are not taken hostage by the tobacco industry," said Francis Grogna Secretary General of the European Network for Smoking and Tobacco Prevention (ENSP).

"The revision of the TPD is aimed at preventing new generations from lighting up by reducing the attractiveness of tobacco, especially to children and young women. It is very disquieting that **even if all EU Member States are committed to the WHO Framework Convention on Tobacco Control (FCTC), some of them still protect the tobacco industry,** in what amounts, to put it mildly, to an unethical practice," said by Professor Aurelijus Veryga, President of the Lithuanian National Tobacco and Alcohol Control Coalition.

"A strong European legislation preventing the uptake of **smoking and making tobacco less accessible and glamorous is essential to protect EU citizens from the hazards of smoking. Smoking causes Chronic Obstructive Pulmonary Disease (COPD), an irreversible chronic disease that is not curable and reduces one's life expectancy of more than 10 years and one's ability to contribute to EU economy.** EU leaders must show they care by adopting the proposed tobacco products directive," said Catherine Hartmann, Secretary General of the European COPD Coalition.

"The Standing Committee of European Doctors (CPME) warmly welcomes the

presidencies' commitment to **ensuring that the TPD revision results in a meaningful legal framework to reduce tobacco-related harm.** European doctors call on decision-makers to keep health at the heart of the negotiations," Dr. Katrín Fjeldsted, President of the CPME.

**"The EU faces a tobacco epidemic.** Tobacco is a lifestyle factor that causes huge number of premature and preventable deaths every year. Therefore, the EU's transposition of the FCTC is a crucial element to preserve the health of people living in Europe," said Professor V. Grabauskas, President of the Health Forum.

(1) **The estimated annual cost of tobacco** to the European economy is of more than half a trillion euros, or about 4.6% of the EU's GDP. Furthermore, close to 13 million people in the 27 countries of the EU suffer from smoking-related diseases, with devastating effects on economies, societies, and healthcare systems – Study on liability and health costs of smoking produced for the European Commission (DG SANCO, 2012).

(2) The revision addresses the following main issues: (a) how to regulate products which do not contain tobacco, for example electronic cigarettes; (b) labelling and packaging of tobacco products; (c) additives, such as flavourings; (d) internet sales of tobacco products; (e) and racking and tracing of these products.

(3) Attitudes of Europeans Towards Tobacco, Report: Special Eurobarometer 385 (May 2012)

(4) The TPD is subject to co-decision procedure and therefore needs to be approved by both co-legislators: the Council of the EU representing the Member States (in this case the Employment, Social Policy, Health and Consumer Affairs Council –EPSCO-) and the European Parliament (EP). As regards the EP procedure,

five Committees (IMCO, INTA, AGRI, JURI, ITRE) are giving this week their non-binding opinion to the leading Environment, Public Health and Food Safety (ENVI) Committee. After the final ENVI vote in July, the EP Plenary will discuss the proposal in September and vote it in October. Following the Plenary vote, the EP will have the mandate to reach an agreement with EPSCO in the few months before the end of this year.

(5) Tobacco companies claim that large pictorial warnings and standardised packaging of tobacco products will increase smuggling, that tobacco product regulation endangers European jobs, or that labelling and packaging measures are ineffective. There is strong evidence that these statements are not just false but intentionally aimed at preventing or delaying implementation of effective measures to reduce smoking prevalence. Tobacco Products Directive: fact not fiction (by the Smoke Free Partnership).

(6) Public Health NGOs call for an updated EU Tobacco Products Directive

*For more information, please contact:*

*Birgit Beger*

*CPME Secretary General*

*E-mail: secretariat@cpme.eu*

*www.cpme.eu*

## The European Union and Tobacco Legislation: Revision of the Tobacco Products Directive – Opportunity to be Seized



*Peteris Ancans*

The European Union and tobacco legislation: revision of the Tobacco Products Directive – opportunity to be seized

There are some products on the market that always cause controversy when discussed and even more – when regulated. However, there is only one – tobacco – ‘legally available consumer product which kills people when it is used entirely as intended.’ [1] This is the same product – regarded in regulatory circles – that would probably not be placed on the market if introduced today due to the proven health risks. Governments across the world have tried to tighten tobacco control policies to improve public health, and the European Union (EU), an economic and political partnership between 28 European countries, is no exception. Although the proposal from the European Commission regarding the revision of the Tobacco Products Directive has the interests of public health at heart, the discussions in two co-legislator institutions – the

Council of the EU (the EU Council) and the European Parliament – show inconsistent willingness to legislate in favour of the health of European citizens for fear of economic effects. Nevertheless, there is still a chance for health community in the EU to push further in support of common sense and public health.

The situation in the EU is considered unsatisfactory by the public health community. Many EU Member States are ‘significant offenders as key exporters of the tobacco problem to the rest of the world,’ and ‘many EU countries are now falling behind best practice in the WHO Framework Convention on Tobacco Control (FCTC) implementation.’ [2] It is the only international treaty devoted solely to tobacco control under the auspices of the WHO. [3] Measures taken to reduce smoking have made a difference; however, tobacco use remains the leading preventable cause of death in the EU, and around 700 000 people die from tobacco-related diseases each year. The number of smokers has dropped but is still high – around 28% population-wide, and even higher for young people aged 15–24 at 29% in 2012. [4]

Eleven years after an agreement on the first Tobacco Products Directive in 2001, the European Commission tabled a proposal to revise the Directive (COM(2012)788) in December 2012. ‘From a broader perspective, the revision will contribute to the overall aim of the EU to promote the well-being of its people [...], as keeping people healthy and active longer, and helping people to prevent avoidable diseases and premature death, will have a positive impact on productivity and competitiveness.’ [5] However, taking into account that 70% of

smokers start before the age of 18 and 94% before the age of 25 years in Europe [6] the focus of the revised Directive is on children and youth. In essence – its aim is to prevent young people from starting to smoke. To achieve this, the Commission proposes to make pictorial warnings mandatory, to increase the size of combined text and pictorial warnings on both sides of a pack to 75%, to ban slim cigarettes and to prohibit characterising flavours such as vanilla or menthol. The proposal suggests tobacco should smell and taste like tobacco, and most importantly – should be packaged in a way that accurately informs consumers of its risks, while making the product less attractive to children and young people. Moreover, the Commission proposal establishes measures such as security features on packs, which are designed to reduce counterfeiting of tobacco, along with tracking and tracing features to better control the supply chain. Furthermore, the proposal regulates those products which do not necessarily contain tobacco, but are closely linked to smoking, for instance, nicotine containing products. In brief, the proposal of the Commission favours public health interests by trying to deter young people from starting to smoke.

According to the EU legislative procedure there are several steps before the proposal from the European Commission can come into force. There are two co-legislators – the EU Council and the European Parliament. Agreement first has to be reached separately in the EU Council among Member State governments and in the European Parliament among parliamentarians elected by Europeans every 5 years. Afterwards both institutions as co-legislators have to reach an agreement between themselves by compromising. Both have made an effort and it seems they would like to get an agreement by the end of 2013 before the elections of the Parliament next year.

The EU Council, where governments of all EU Member States are represented, has



managed to reach 'a general approach' on the Directive under the Irish Presidency after heavy and intense discussions during the first half of 2013. The Council's position, described by the Minister for Health of Ireland, Dr. James Reilly, as 'a remarkable achievement for the Irish Presidency,' [7] was forged in a number of meetings among representatives mostly from the Ministries of Health (Health Attachés) in Brussels and was officially finalised during the Council of Health Ministers in Luxembourg on 21 June.

The agreement, however, was a compromise between Member States as not all 27 (Croatia joined later on 1 July) could support the proposal as put forward by the European Commission. Therefore, substantial changes were introduced to the initial Commission's proposal. Although the EU Council accepted a ban on characterising flavours, it could not reach agreement on the ban on slim cigarettes, and that provision was removed. The size of combined picture and text health warnings was also reduced from 75% to 65%. Regarding nicotine containing products, such as electronic cigarettes, Member States maintained the Commission's principle. These products should be regulated depending on their nicotine content – as consumer products but with health warnings if nicotine levels fall below a certain threshold; and only as medicinal products if they contain nicotine above this threshold. Nevertheless, Member States maintained the option of allowing individual Member States to go further than EU legislation. For example, individual Member States could introduce plain standardised packaging like in Australia on a national level under the approach adopted by the EU Council. It should be stressed, however, that the agreement between the Health Ministers on 21 June was not unanimous. It was a result of intense discussion process led by the pro-health Irish Presidency that had to reach a compromise which took into account the differing positions of all Member States.

The position of the EU Council regarding this Directive is prepared in discussions among Member States' representatives, whereas the position of the European Parliament, the other co-legislator, is adopted in debates among Members of the European Parliament (MEPs) that take place in Committees, and a final vote – in a plenary session. The plenary vote by 766 elected members from all 28 Member States for the Directive is scheduled for early September. The Directive is steered through the European Parliament [8] and discussed in several Committees. After votes in five opinion Committees, the sixth – lead Committee – Environment, Public Health and Food Safety (ENVI), voted on its position on 10 July. The ENVI Committee not only accepted a ban on characterising flavours but also voted for the prohibition of slim cigarettes, a different position than that of the EU Council. Although plain standardised packaging, initially suggested by MEP Linda McAvan, was not approved, the size of health warnings was kept at the level of 75% as proposed by the Commission. Regarding electronic cigarettes, the ENVI Committee voted in favour of their regulation as medicinal products regardless of nicotine content, thus eliminating the thresholds limits proposed by the Commission. The position of the ENVI Committee will be a basis for the vote in the plenary session in September during which the position of the Parliament shall be approved.

At times the process both in the EU Council and the European Parliament was anything but smooth. There are several Member States who do not support the new measures proposed by the Commission and continue to object to some aspects of the Directive or delay the legislative process. The Irish Presidency diligently managed to carve out a compromise that at the same time unfortunately involved weakening some aspects of the Commission's proposal. However, it was not enough to sway Poland, Czech Republic, Bulgaria and Romania which voted

against the particular compromise proposal during the Ministerial meeting on 21 June. For example, Poland wished to have the possibility to keep menthol cigarettes, and the Czech Republic objected generally to the proposal.

Although there were four Member States that voted openly against the compromise, some presume that there are more which are working in silent opposition and making it harder for the EU Presidencies to reach agreement on the Directive. Media reports have documented reluctance to support the Directive also in several other Member States.

It seems unclear and controversial especially as Europeans of all Member States ask for more decisive action and a majority of them support strong tobacco control policies. A Eurobarometer published in 2012 [9] shows, for instance, that 76% of the EU population supports putting pictorial warnings on all packages of tobacco products and 57% support a ban on logos, colours and promotional elements on packs – which means there might be a support for plain standardised packaging like in Australia.

However, it seems that the public administrations of these countries are keeping their 'eyes shut' to public opinion and scientific medical evidence. Moreover, their attention to the voice of the tobacco industry along with their disproportionate focus on alleged disastrous economic effects of the tobacco regulation, sheds doubts on their compliance with Article 5.3 of the WHO FCTC. This Article requires all Parties, 'when setting and implementing their public health policies with respect to tobacco control', to '[...] act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.' [10]. As surprising it could be it appears that there might be Member States who only partly care about the health of their citizens and especially the health of a

new generation putting other, for instance, economic interests as first priority. By doing so they prevent other EU Member States from reaching the agreement that would bring maximum benefit to the health of all Europeans.

Unfortunately, the same can be said about a number of Members of the European Parliament (MEPs) who voted to weaken the legislative proposal and ignored public health aspects. In June four opinion Committees – on legal affairs, agriculture, international trade, and industry – voted to water down the Directive significantly. A fifth Committee, dealing with consumer affairs, had a more balanced approach. Despite the fierce opposition, the ENVI Committee adopted a health focused report, strengthening several measures in the proposal. The Rapporteur Linda McAvan will now have to face the plenary session in early September where it is assumed that the strong health position of the ENVI Committee might be watered down as lobbying is expected to intensify from the side of the tobacco industry and their allies.

The EU Council is waiting for the position of the European Parliament to start negotiations towards a final agreement among both institutions. There are a number of European countries who support the strongest possible tobacco legislation to help safeguard their citizens' health. As the decision has to be made together with other Member States and in negotiations with the European Parliament afterwards, the outcome is unclear. The new Lithuanian Presidency of the EU Council that took over from Ireland on 1 July seems to be aware of the tense situation. Minister for Health of Lithuania, Dr. Vytenis Povilas Andriukaitis, in a passionate speech in the ENVI Committee on 11 July, thanked ENVI for their vote the day before and added: 'I know that the negotiations on Tobacco Products [Directive] are difficult because of influential tobacco industry lobbying but many non-governmental

organizations at the EU and a big part of the voters support those measures on tobacco control or even stricter regulation. The WHO FCTC also obliges us to implement more active tobacco control measures.' [11].

As outcome is still unclear, health care professionals in Europe play a crucial role in reminding their politicians of the importance of health both at national and EU level. Their engagement in promoting a sound Tobacco Products Directive by contacting their national public administration or their MEPs could help to achieve healthier Europe.

Hippocrates said – 'wherever the art of medicine is loved, there is also a love of humanity.' This is why physicians enjoy the trust of people – they possess knowledge and they also care to use it when needed. Hippocrates also noted that time is of importance, but sometimes an opportunity matters the most. This might be one of those opportunities to make an impact and reach the agreement that supports strong public health interests in the EU that might have an effect outside Europe as well.

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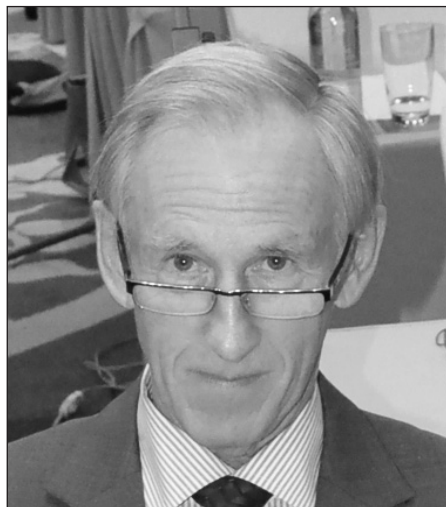
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Peteris Ancans  
Advisor to the Smoke Free Partnership  
Former Health Attaché of Latvia  
to the European Union

*SFP is a partnership between the European Respiratory Society, Cancer Research UK, the European Heart Network, Action on Smoking and Health UK, and the Irish Cancer Society. SFP aims to promote tobacco control advocacy and policy research at EU and national levels in collaboration with other EU health organisations and EU tobacco control networks.*

## Declaration of Helsinki

Stakeholders Meeting in Washington, DC



*Nigel Duncan*

Important progress in revising the Declaration of Helsinki was achieved at the final WMA stakeholders meeting held in Washington DC on August 26. As a result, a final draft document was developed to be sent to the WMA's Medical Ethics Committee and then the Council in Fortaleza, Brazil, for forwarding to the WMA General Assembly for adoption. The one-day Washington meeting, hosted by the American Medical Association at the Hay-Adams Hotel opposite the White House, was originally intended to be a routine meeting of the WMA workgroup set up in 2011 to progress the revision of the Declaration of Helsinki. However, following a decision taken at the Council meeting in Bali in April, the meeting was extended to include interested national medical associations and stakeholders and as a result more than 70 people attended the gathering in the US capital.

An impressive line-up of outside experts and leading figures from 13 NMAs spent the day discussing the draft revised Decla-

ration paragraph by paragraph, line by line suggesting further changes and alternative wording.

The meeting was opened by Dr. Ardis D. Hoven, President of the American Medical Association. She welcomed people to Washington, reminding them that their drive towards reaching the goal of a revised Declaration of Helsinki was coinciding with the 50<sup>th</sup> anniversary celebrations in Washington that week of the Poor People's March in the city and the 'I Have a Dream' speech by Martin Luther King.

Dr. Mukesh Haikerwal, Chair of the WMA, said that the Declaration of Helsinki was a seminal document that guided the way physicians worked and the way that ethics were protected. He said that Dr. Cecil Wilson, President of the WMA, was to have addressed the meeting, but because of illness could not attend. So Dr. Haikerwal read the words he would have spoken.

Dr. Wilson declared: "Physicians are most credible when we speak from a platform based on ethics and principle. As physicians we must have moral authority and speak and act with moral authority. That means we must speak out on broad public health issues. Doing that makes our message more credible and more effective when we advocate on matters of public policy."

He said that those physicians from around the world who came together to form the World Medical Association in 1947 understood that an organization was needed to become the authoritative voice on global standards for medical ethics and professional conduct, rather than focusing solely on protecting the interests of the profession. They recognized the importance of endeavoring to achieve the highest possible stan-

dards of medical care, ethics and health-related human rights for all people.

"There is perhaps no clearer example of addressing ethics in medicine than the Declaration of Helsinki that advises physicians on doing medical research on human subjects.

Today we benefit from truly astounding advances in development of medications and devices that save lives and relieve suffering. This would not be possible without research involving human subjects. Fortunately the public in general accepts the importance of research, and in fact many volunteer to participate out of a desire to help others. That participation is dependent on having trust in those who conduct research.

It is important to have an international standard for research in a world where studies on human subjects increasingly involve multiple countries. The Declaration of Helsinki is that key international standard, the loadstone, the North Star if you will, that guides physicians, governments and industry in this area of advice on doing medical research on human subjects. And adherence to its principles is critical to preserving the trust of those who are subjects, our patients – and those who conduct research."

Dr. Wilson's speech reminded the meeting that the Declaration, adopted in 1964, had had multiple revisions and the current process begun in 2011 was based on being thorough, transparent and reflecting of diverse viewpoints. To that end the WMA had held expert conferences to receive insights and recommendations from ethics scholars, academicians, practicing physicians, government officials and those engaged in sponsoring clinical research. These had been held in different parts of the world, including the Netherlands, South Africa, Japan and now Washington, D.C.

The speech concluded: "To reiterate points made earlier, medical progress is dependent on research that ultimately includes studies



involving human subjects. The Declaration of Helsinki provides the roadmap for trust and duty, essential to the success of research. The revisions being considered are important and will preserve and strengthen that roadmap.”

Dr. Raman Parsa-Parsi, Chair of the WMA Workgroup, reminded the meeting about how the workgroup was set up with a mandate to develop a draft revised version of the Declaration to be sent to the WMA's Medical Ethics Committee for approval and then to the General Assembly for adoption. He said that during the public consultation that took place in the summer 129 submissions had been received from 36 different countries or regions.

He added: “We were extremely delighted with this response to the public consultation both for the broad range of respondents as well as the carefully thought out comments. All of the submissions were carefully reviewed and considered in the development of a new draft version.”

Professor Urban Wiesing, one of the two ethical experts on the workgroup, said that the group had received suggestions from 150 public comments, 50 expert presentations and numerous articles. He detailed the changes that had been proposed before the public consultation, saying that they were based on the document being more readable, providing more protection for participants and with more precise post study arrangements.

He outlined why some of the suggested changes that had been proposed would not be appropriate.

He said the placebo issue was still controversial, adding: “I am afraid that no guidelines will ever be able to end this controversy.” The workgroup proposal in the draft did not change the ethical principles from the 2008 version, but set up a new paradigm that was more comprehensive and more systematic because it addressed not only

the controls but any control of less than the best intervention. The workgroup did not change the section from the draft for public comment.

Also receiving much comment was the section on research ethics committees. Prof. Wiesing said that many commenters requested more details for the committees. The same was true for the section on informed consent, but he said: “We received so many suggestions to mention this and this and this. We decided not to adopt further changes to maintain the character and length of the Declaration.”

The same problem was confronted with vulnerable groups. “We received many suggestions by commentators to mention this or another vulnerable group, at least a dozen. The question was always which one shall we take? Lists are never comprehensive. We decided not to mention specific vulnerable groups but rather to provide a general definition and general regulation.”

Many commentators had also suggested that the Declaration should address all professions involved in bio-medical research and not only physicians. However, he said that the mandate of the WMA was to represent national medical associations.

Dr. Jeff Blackmer, the second ethical expert on the workgroup, explained the reasoning behind the revisions that had been incorporated in the revised draft Declaration. Much of the new wording had been introduced for the purposes of clarification and consistency, such as using the word ‘groups’ rather than ‘populations’ or ‘communities’. The section on informed consent had been amended in several areas to use the word ‘must’ rather than ‘should’ to increase the level of obligation on physicians. In addition the document had been amended to clarify the meaning of the word ‘competence’.

He referred to the issue of the well-being of the individual research subject having

to take precedence over all other interests. The new draft changed that to read: “While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the health, well-being, safety, rights and best interests of the individual research subjects.” This was one of the more substantive changes made to the document as a result of the consultation.

Other parts of the Declaration that had prompted considerable comment included physicians combining medical research with clinical care, compensation for injury, privacy and confidentiality, post-study provisions, trial registration and publication of results and unproven interventions in clinical practice.

The workgroup also changed “appropriate caution must be exercised in the conduct of medical research that may harm the environment” to “medical research should be conducted in a manner that minimizes possible harm to the environment.” This provided increased specificity around minimization of harm.

Under measures to minimize risks, the work group added that “the risks must be continuously monitored, assessed and documented by the researcher.”

Ambassador Jimmy Kolker, Acting Head of the Office of Global Affairs in the Office of the Secretary of the US Department of Health and Human Services, said the Declaration had been an important source of ethical guidance in the conduct of clinical research throughout the world for nearly half a century. It was highly respected as a source of fundamental principles and widely-held values.

“We support your efforts to maintain the currency and relevance of the DoH through periodic updates to address new ethical challenges and make adjustments to reflect new research practices and directions. We commend the WMA for the integrity and transparency of its consultative and deliberative process.”

erative processes to revise the Declaration and for giving due consideration to the perspectives of a wide variety of stakeholders and interest parties.”

However, the HHS did have concerns about several paragraphs. One of its general concerns related to the prescribing of specific procedural steps in a statement of ethical principles.

“This presents a tension between the Declaration and the mandatory procedures that countries have in place to protect human research participants. Such conflicts can diminish the impact of the Declaration as a source of fundamental guidance. Procedural details should not be mandated; the Declaration should allow for more flexibility in how the principle or safeguard is implemented. The use of the word “must” can also establish an ethical standard that may be impossible to achieve. Establishing an unachievable standard as a global norm may inhibit ethical and scientifically sound research.”

He said that the word “must” should be used only in the articulation of an ethical principle. However, there were a number of instances in the revised draft in which the word “must” was used regarding a process or procedure.

Ambassador Kolker specifically raised concerns about paragraph 10 which, as currently written, stated that researches need only “consider” the laws of their countries and appeared to assert the Declaration’s primacy over national laws.

“Ethical norms and standards and national laws and regulations are both important, but they are not equivalent. Researchers are required to follow national laws and regulations, but their duty to follow ethical principles is a matter of medical ethics.”

He suggested a new wording to address this concern – that “physicians must follow the ethical, legal and regulatory requirements for

research involving human subjects in their own countries as well as the ethical principles underlying this Declaration and other applicable international norms and standards. No national or international legal or regulatory requirement should reduce or eliminate any of the fundamental protections for research subjects set forth in this Declaration”.

With regard to paragraph 15 on compensation he agreed with its intent that at a minimum researchers had an ethical obligation to ensure that individuals received treatment if they were harmed as a result of participation in research. However, compensation for harms or costs of long term care was a more complex issue and guaranteeing that injured participants received compensation was a standard that might not be achievable in many countries.

He said that the responsibility for determining compensation for research injuries varied among countries. For example, in the US injured parties could seek remedy in a court of law through the country’s tort system, but there was no guarantee that they would receive compensation. There was recognition that this current approach might not be sufficient and there had been calls for further study to determine whether a research-specific national system of compensation was needed. For these reasons he recommended that “must” be changed to “should”.

During the discussion that followed, the meeting heard interventions from speakers from many organisations, including the Council for International Organisations of Medical Sciences, the National Institutes of Health and the World Health Organisation, proposing different wording for various parts of the document.

Representatives from several National Medical Associations also spoke, including Dr. Antoine Mbutuku, President of the Congolese NMA. He said that for the African continent facing a lot of problems in relation to human research, the Declaration

was a very important document. It was seen in many African countries as the fundamental document on which the countries based their own regulations to protect people.

He emphasised that there should not be double standards and that the same standards should be applied in the north as in the south for placebo control trials. It was necessary in less developed countries to allow placebo controlled trials and not to have too many barriers.

Dr. Mbutuku also referred to the idea of fair benefit, suggesting that this was questionable. It might be that participants in a trial were seen from the north as a vulnerable group when they were not regarded as such in the south.

Roopa Dhatt, President of the International Federation of Medical Students Association, spoke about the special attention that must be given to the storage of personal information on digital platforms. This information must be encrypted to ensure the privacy of the research subjects and only available to the responsible of the study.

She said that consideration of social media was applicable to digital platform use. Every day, more patients’ data was being stored on digital platforms. These digital platforms existed in hospitals, schools, research institutions and many others. Any access to the platforms was a breach of privacy and violation of the rights of research subjects. The system must be encrypted to ensure that only those responsible for the research were accessing that data.

She added that while the argument for including details was valid for many aspects of the document, in the opinion of the IFSMA, digital platforms were a reality of medical research and care. Yet often the principles of confidentiality, privacy and consent were not implemented in the case of digital data, especially when looking beyond clinical trials and health systems research.

As for social media, she said that while it might not be necessary to explicitly include it in the Declaration, it was still an area that required consideration in the areas of medical research.

Dr. Blackmer, summing up the day's discussion, said that many of the points raised had already been made during the previous expert conferences. Other points raised had received conflicting views. They had not heard complete consensus on any single topic. Not surprisingly the paragraphs of the Declaration that had engendered the most focus and discussion during the day were those on which the workgroup had spent the most time and those upon which

they had received the most input from stakeholders.

Dr. Otmar Kloiber, Secretary General of the WMA, thanked the participants at the meeting for a useful discussion: "We hope that this gives another emphasis to the question of research and research ethics. We still think this is very necessary even after 50 years. There are always some things that we have to repeat and express more precisely and more openly or to say more provocatively."

He said the WMA had always tried with the Declaration of Helsinki to 'set new standards, to reach out to a new age, to drive

the environment, to be better, to be more ethical and to be more responsible'.

Following the open discussion, the WMA workgroup convened to consider the points raised. Some further amendments were made to the revised Declaration and it was decided that the draft document should be sent to the Medical Ethics Committee for further debate and approval in Fortaleza, Brazil, in October. The document would then go to the WMA Council for forwarding to the General Assembly for adoption on October 19.

Mr. Nigel Duncan,  
Public Relations Consultant, WMA

## The Helsinki Statement on Health in all Policies

The 8<sup>th</sup> Global Conference on Health Promotion, Helsinki, Finland, 10–14 June 2013

### Building on our heritage, looking to our future

The 8<sup>th</sup> Global Conference on Health Promotion was held in Helsinki, Finland from 10–14 June 2013. The meeting builds upon a rich heritage of ideas, actions and evidence originally inspired by the *Alma Ata Declaration on Primary Health Care* (1978) and the *Ottawa Charter for Health Promotion* (1986). These identified intersectoral action and healthy public policy as central elements for the promotion of health, the achievement of health equity, and the realization of health as a human right. Subsequent WHO global health promotion conferences<sup>1</sup> cemented key principles for health promotion action. These principles have been reinforced in the 2011 *Rio Political Declaration on Social Determinants of Health*, the 2011 *Political Declaration of the UN High-level Meeting of the General Assembly on the Prevention and Control of Non-commu-*

*nicable Diseases*, and the 2012 Rio+20 Outcome Document (*the Future We Want*). They are also reflected in many other WHO frameworks, strategies and resolutions, and contribute to the formulation of the post-2015 development goals.

The 8<sup>th</sup> Global Conference on Health Promotion (8GCHP) was held in Helsinki, Finland, from 10 to 14 June 2013. The conference was co-organized by the World Health Organization (WHO) and the Ministry of Social Affairs and Health of Finland (MSAH).

The plenary sessions and the press briefings were broadcasted live on the Internet and may be viewed as recordings here: [www.healthpromotion2013.org/media-healthpromotion2013/videos](http://www.healthpromotion2013.org/media-healthpromotion2013/videos)

The presentations may be viewed here: [www.slideshare.net/stmslide](http://www.slideshare.net/stmslide)

Further information: [healthpromotion@who.int](mailto:healthpromotion@who.int)

1 Subsequent conferences were held in Adelaide (1988); Sundsvall (1991); Jakarta (1997); Mexico City (2000); Bangkok (2005); Nairobi (2009).

### Health for All is a major societal goal of governments, and the cornerstone of sustainable development

We, the participants of this conference

Affirm our commitment to equity in health and recognize that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condi-

tion. We recognize that governments have a responsibility for the health of their people and that equity in health is an expression of social justice. We know that good health enhances quality of life, increases capacity for learning, strengthens families and commu-



nities and improves workforce productivity. Likewise, action aimed at promoting equity significantly contributes to health, poverty reduction, social inclusion and security.

Health inequities between and within countries are politically, socially and economically unacceptable, as well as unfair and avoidable. Policies made in all sectors can have a profound effect on population health and health equity. In our interconnected world, health is shaped by many powerful forces, especially demographic change, rapid urbanization, climate change and globalization. While some diseases are disappearing as living conditions improve, many diseases of poverty still persist in developing countries. In many countries lifestyles and living and working environments are influenced by unrestrained marketing and subject to unsustainable production and consumption patterns. The health of the people is not only a health sector responsibility, it also embraces wider political issues such as trade and foreign policy. Tackling this requires political will to engage the whole of government in health.

Health in All Policies is an approach to public policies across sectors that systematically takes into account the health implications of decisions, seeks synergies, and avoids harmful health impacts in order to improve population health and health equity. It improves accountability of policy-makers for health impacts at all levels of policy-making. It includes an emphasis on the consequences of public policies on health systems, determinants of health and well-being.

We recognize that governments have a range of priorities in which health and equity do not automatically gain precedence over other policy objectives. We call on them to ensure that health considerations are transparently taken into account in policy-making, and to open up opportunities for co-benefits across sectors and society at large.

Policies designed to enable people to lead healthy lives face opposition from many sides. Often they are challenged by the interests of powerful economic forces that resist regulation. Business interests and market power can affect the ability of governments and health systems to promote and protect health and respond to health needs. *Health in All Policies* is a practical response to these challenges. It can provide a framework for regulation and practical tools that combine health, social and equity goals with economic development, and manage conflicts of interest transparently. These can support relationships with all sectors, including the private sector, to contribute positively to public health outcomes.

We see *Health in All Policies* as a constituent part of countries' contribution to achieving the United Nations *Millennium Development Goals* and it must remain a key consideration in the drafting of the post-2015 Development Agenda.

### We, the participants of this conference

- Prioritize health and equity as a core responsibility of governments to its peoples.
- Affirm the compelling and urgent need for effective policy coherence for health and well-being.
- Recognize that this will require political will, courage and strategic foresight.

**We call on governments** to fulfil their obligations to their peoples' health and well-being by taking the following actions:

- Commit to health and health equity as a political priority by adopting the principles of Health in All Policies and taking action on the social determinants of health.
- Ensure effective structures, processes and resources that enable implementation of the Health in All Policies approach across governments at all levels and between governments.
- Strengthen the capacity of Ministries of Health to engage other sectors of gov-

ernment through leadership, partnership, advocacy and mediation to achieve improved health outcomes.

- Build institutional capacity and skills that enable the implementation of Health in All Policies and provide evidence on the determinants of health and inequity and on effective responses.
- Adopt transparent audit and accountability mechanisms for health and equity impacts that build trust across government and between governments and their people.
- Establish conflict of interest measures that include effective safeguards to protect policies from distortion by commercial and vested interests and influence.
- Include communities, social movements and civil society in the development, implementation and monitoring of Health in All Policies, building health literacy in the population.

### We call on WHO to

- Support Member States to put Health in All Policies into practice.
- Strengthen its own capacity in Health in All Policies.
- Use the Health in All Policies approach in working with United Nations agencies and other partners on the unfinished Millennium Development Goals agenda and the post-2015 Development Agenda.
- Urge the United Nations family, other international organizations, multilateral development banks and development agencies to achieve coherence and synergy in their work with Member States to enable implementation of Health in All Policies.

### We, the participants of this conference

- Commit ourselves to communicate the key messages of this Helsinki Statement to our governments, institutions and communities.

## Advancing The Global Health Agenda: the Role for Medical Women

Keynote speech at 29<sup>th</sup> Medical Women International Association Congress, Seoul, Korea – 1–3 August, 2013



*Margaret Mungherera*

The world has made tremendous strides in improving health and there are many success stories all over the world. Global maternal deaths have dropped nearly 50% since 1990. And in October 2012 we celebrated the first ever International Day of the Girl Child. Yet economic, social and political barriers still exist for women and girls. For instance, 287,000 expectant mothers die every year, that is 800 women every day. In addition, more than 200 million women want but do not have the tools they need to plan their families.

Many countries will not be meeting the targets set and there are several discussions ongoing at various levels. There are for instance growing consensus that Non Communicable Diseases (NCDs) and Universal Health Care should be additional goals. There is also talk about introducing Sustainable Development Goals.

The stumbling goals to attainment of goals differ in the different countries. Generally the most important challenges are:

- Political will and commitment
- Ineffective leadership – within and outside Health Sector
- Poor prioritization – resource allocation
- Weak health systems – especially Human Resource for Health
- Limited high impact solutions
- Sustainable interventions – impact
- Social mobilization – prevention, rights
- Inter-sectoral and intra-sectoral collaboration
- Low literacy levels

Medical women can play an important role in addressing the above issues in their countries. However, as individuals, the impact is likely to be minimal. However, as organized groups, medical women can make a difference.

Indeed it will take a critical mass of strong professional and influential medical women who are strategically positioned and actively engaged in setting national and global policy agenda. It will require women who are focused and committed to improving access to, and quality of health care, in line with national and global goals and standards for health and development. This requires more support from Medical Women International Association (MWIA) as regards:

- Encouraging mentoring programs aimed at enabling medical students and young women doctors become leaders.
- Training materials on advocacy, negotiation, communication, etc
- Advocacy for gender training of all health professionals – pre-service and in-service (CPD)
- More active participation and visibility in on-going global level discussions eg. Post MDG
- Capacity assessment of medical women associations vis a vis the MDGs.
- Capacity building opportunities. Eg. – sharing information and training manuals, promoting joint projects, and even

twinning between the stronger and the weaker associations.

- Identification of medical women who have had extensive experience and encourage them to take up leadership roles at national, regional and global levels.
- Emphasis should also be placed on grooming the next generation of women leaders – medical students and young women doctors should receive mentorship.

All the above strategies will require MWIA to form new alliances and partnerships at global level with likeminded organizations.

The World Medical Association's efforts are aimed at that all the people in the world have access to health care and therefore subscribed to the MDGs. Therefore both WMA and MWIA have a common interest, one that needs alliances and partnerships.

During my own term as WMA President which begins in October this year, I plan to focus on the following key areas which I strongly feel many countries especially the low and middle income ones urgently need to address in order to achieve the MDGs. These are:

1. Engendering the Health Sector
2. The Human Resource for Health crisis
3. Integrating Mental Health into general health services
4. NCDs
5. Preventive Medicine
6. The One Health approach.

The areas identified are also key areas for MWIA. In conclusion, I look forward to strengthened collaboration between the 2 organizations. Thank you for listening.

*Dr. Margaret Mungherera,  
President Elect,  
World Medical Association*

## The Chicago Department of Public Health and Healthy Chicago



Janis Sayer



Raed Mansour



Erica Salem



Bechara Choucair

### Background

The Chicago Department of Public Health (CDPH), like many of the more than 2000 local public health agencies (LPHAs) in the United States, has faced numerous challenges in ensuring the public health of its residents [1]. Public health is responsible for three core functions – assessment, policy development and assurance – and a LPHA's strength lies in its capacity to provide essential public health services within these areas [2]. Confronted by funding cuts, limited resources and workforce shortages, LPHAs must re-think the way they conduct business.

In 2011, 57% of LPHAs (serving 65% of the U.S. population) surveyed by the National Association of County and City Health Officials (NACCHO) reported having reduced or eliminated service [3]. Since the most recent recession began in 2008, NACCHO reports that 39,600 local public health positions have been lost due to lay-offs and attrition [4].

Like other health departments, CDPH has been forced to change its service array. Established in 1835, the CDPH has a long history of service delivery. Many services and programs were initiated in response to the emergence of new public health threats (such as HIV and West Nile Virus). Un-

til recently, a large portion of CDPH resources was directed towards clinical services. While not core to public health, these primary health care services were initially needed to fill gaps in care in the 1970's. In 2011, and in response to significant growth in community based primary care capacity, the Department transitioned its several primary care centers to Federally Qualified Health Centers that were better positioned to deliver this care.

Budget cuts have necessitated that public health concentrate efforts to those at the core of the public health mission. LPHAs have also sought out opportunities to increase their impact in the midst of declining resources. In Chicago, these challenges presented an opportunity to envision public health in a new way. With a commitment to strategically prioritizing efforts and capitalizing on opportunities to achieve the greatest public health impact, Chicago's public health system remains vital.

### Healthy Chicago

The challenges facing LPHAs in general and CDPH specifically require that public health efforts be both strategic and focused. In Chicago, the Healthy Chicago public health agenda provides that focus.

The Healthy Chicago agenda, released in August 2011, serves as a blueprint for city-wide public health action. The Agenda contains 16 health outcome targets, 12 priority areas, and 193 related policy, program and public awareness strategies. The Agenda not only presents concrete actions for community health improvement, it also provides a roadmap for partners and other stakeholders to contribute to a healthier Chicago [5].



### Key Elements of Healthy Chicago

Of Healthy Chicago's many features, three have proven essential to the successes achieved to date. The first has been the shift from programmatic interventions to policy solutions, which hold greater promise for sustainable change. Policy changes make healthy choices practical and available for



everyone, and can create a large and lasting impact with little time and few resources. The second critical element has been the move to maximize and leverage partnerships. The third element is the utilization of innovative technology, which has provided new avenues for carrying out our essential services, maximized resources and facilitated improved communication and information sharing.

## Focus on Policy Solutions

One of the best examples of this shift concerns efforts to reduce tobacco use. Prior to the development of Healthy Chicago, CDPH's tobacco prevention resources were directed almost exclusively towards smoking prevention and cessation efforts. Prevention programming was directed towards about 500 of the City's 400,000 public school students annually, while counseling and nicotine replacement therapy was provided to a few hundred adults each year. While these services undoubtedly affected some proportion of the limited number of persons reached, it was clear that more could be done. Thus, efforts were re-directed towards policy solutions. Within the first 18 months following the release of Healthy Chicago, smoke-free policies were enacted at five hospitals, four institutions of higher learning, six behavioral health agencies, four public housing developments (currently nearly 1000 individual units of public housing), and more than 3,200 units of multi-unit private housing. Legislatively, tobacco enforcement laws were strengthened, fines for illegal sales doubled, and tobacco vending machines were prohibited.

Opportunities for policy change also abound in the area of obesity prevention. For example, in collaboration with CDPH, in late 2011, the Chicago Park District converted all of their snack vending machines to 100% healthy options. In April 2013, in a multi-departmental effort, all snack and beverage vending machines on City of

Chicago owned or operated property began offering healthier options. Under this new policy, at least 75% of offerings must meet specified nutritional standards. Public schools have also implemented healthy vending policies. Policy changes within the City's Department of Transportation have dramatically increased opportunities for active transportation, with over 200 miles of on-street bikeways, including almost 35 miles of new barrier and buffer protected bike lanes; a bike-sharing program and the development of a Pedestrian Plan.

Policy solutions have also been implemented in the area of maternal and child health. One way to help improve outcomes for infants is by breastfeeding. Rather than promoting breastfeeding solely through education, Chicago's efforts have focused on influencing the breastfeeding support policies of its 19 labor and delivery hospitals, thus increasing the likelihood that new mothers will choose to breastfeed. With federal support and in partnership with the not-for-profit the Consortium to Lower Obesity in Chicago Children, 15 Chicago hospitals with Labor and Delivery services have committed to support breastfeeding and are currently working towards the World Health Organization's Baby-Friendly designation which requires hospitals to implement a breast-feeding policy. The initiative has been shown to dramatically increase breastfeeding among its patients.

## Leveraging Partnerships

A second contributor to the success of Healthy Chicago is the priority placed on partnerships. The complexity of the challenges facing public health necessitates collaborative responses that draw upon and leverage the expertise and resources of public, private, and community-based partners.

The City's work to eliminate food deserts has been strengthened through such partnerships. Last year, CDPH and the Chi-

cago Department of Business Affairs and Consumer Protection worked together to pass a mobile produce cart ordinance, in essence creating a new class of vending. Subsequently, CDPH and the City's Department of Housing and Economic Development partnered with Neighbor Capital, LCC, to establish the "Neighborhood Cart" system to increase access to fresh produce and to create jobs for the unemployed and underemployed. By providing training and then leasing their carts, the partnership provides an opportunity for meaningful employment while promoting healthy foods in underserved communities. A partnership with Streetwise, a community organization serving homeless persons, ensures these opportunities are presented first to those at risk of homelessness. Over 60 people have enrolled in classes to enter the program, 41 have completed job training, and 33 individuals have been placed in employment. By the end of the year, a total of 30 carts will be operating in Chicago's low food access neighborhoods.

Other partnerships have focused on increasing physical activity. One example is the Healthy Chicago PlayStreets initiative. With support from Blue Cross Blue Shield of Illinois, and in partnership with three citywide and several community-based organizations, CDPH launched Healthy Chicago PlayStreets to provide children and adults with safe, supervised outdoor spaces for structured and unstructured play and physical activity. Sixty community-based events were held in 2012 where either a lack of park space or concerns about community violence were limiting the ability of residents to be physically active, and close to 50 will be conducted by the end of 2013.

Partnerships have also proven critical in re-focusing CDPH's efforts on core public health services. In 2012, CDPH partnered with the Cook County Health & Hospital System (CCHHS) to better align Tuberculosis (TB) services. CDPH transitioned responsibility for the clinical care of TB



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cases to the CCHHS, which has a core focus on health care service delivery. CDPH retained the core services of TB surveillance and prevention. And as previously noted, CDPH partnered with seven FQHCs to provide primary care. In making this transition, CDPH retained its public health presence in these centers and continues to provide services such as HIV and Sexually Transmitted Disease (STD) screening and treatment, and women and children's health services such as the Women, Infant and Children's (WIC) supplemental food and nutrition program.

## The Role of Technology in Healthy Chicago

The policy and partnerships that have to date been the hallmarks of Healthy Chicago efforts are strongly complemented by a changing role in technology. There are many ways LPHAs can use technology to support public health's mission. In Chicago, leadership has facilitated communication with the public through increased transparency and liberating data through the Internet. This liberated data, commonly known as online open data portals, provides an opportunity for CDPH to collaborate with nonprofits and civic volunteers to not only make sense of the data, but also to make it useful. And as Internet usage moves more towards mobile and smartphone use, opportunities arise to reach a wider audience. With increased mobile usage, a demand for useful health related applications usually follows. Supporting all of these technological innovations is CDPH's social media strategy. All of these advancements in information technology and social networking are used to drive our Healthy Chicago agenda.

## Social Media

In public health, offline strategies are used to support online strategies and vice versa. Choosing the channel on which a LPHA

should operate depends on where residents are having their conversations. For CDPH, Twitter (<https://twitter.com/ChicagoPublicHealth>) and Facebook (<https://www.facebook.com/ChicagoPublicHealth>) are the two most frequently used social media channels. CDPH's social media strategy does not exist to replace other communication channels. Rather, CDPH's social media channels complement and support all of the communication channels. CDPH's social media channels are supportive of the Department's website, which serves as the information hub. Social media employs two-way symmetric conversations as well as one-way symmetric conversations[6]. To obtain resident feedback on initiatives is a great opportunity to either confirm strategies are on target or possibly modify an approach. Sometimes, CDPH will engage with residents that may never have interacted with the department before on social media, thus increasing trust and comfort level to interact with CDPH, which is especially important with vulnerable populations. Social media channels also serve to frame messages so that all residents easily comprehend them.

Social media performance metrics are calculated to guide goals and objectives to ensure that they are in line with the Healthy Chicago agenda. They also help give CDPH a glimpse into who the influencers, key opinion and knowledge leaders are, as well as ongoing health conversations in general, through hashtag analysis. Tapping into these social media resources aids in building and solidifying necessary partnerships within CDPH's Healthy Chicago agenda.

## Data Portal

The City of Chicago has established an open data portal for many reasons, including for increased government transparency. The data portal has provided an abundance of information to the public, such as the locations of condom distribution centers,

clinics and immunization sites; food inspection results; and birth, death, and disease data (<https://data.cityofchicago.org>). Not only does making this data readily available to the public help to facilitate positive relationships with residents, it has also freed up limited resources by reducing the number of data requests.

## Applications

A unique opportunity also arises by making data readily available – application development thrives. Civic programmers lend their unique talents by taking open data and visualizing complex data sets into applications they develop, usually through web applications. The concentration of application development lies in using HTML5 applications that removes barriers of needing unique iOS or Android coding skills and isolating groups of people that may or may not be on either of these platforms. The effect is to reach a wider population, which achieves almost universal access when no operating system is favored over another.

The Chicago Flu Shot App ([http://www.cityofchicago.org/city/en/depts/cdp/iframe/scc\\_app.html](http://www.cityofchicago.org/city/en/depts/cdp/iframe/scc_app.html)) and Back to School Immunization App (<http://backtoschool.cdphapps.org>) are examples. Vaccination locations, which are listed in the data portal, were formatted onto a map with an address finder that finds nearby vaccination clinics or mobile immunization vehicles based on a resident's location. These maps can be used on smartphones or on computers making vaccination locations easier to find. Ultimately, applications like these make information relevant to the user. Removing barriers to adoption of technology is also accomplished since these types of web applications do not need to be downloaded. The only requirement to use the application is the entry of the URL into any web browser.

When LPHA utilize apps such as these, public health work can be performed with



greater efficiency despite diminished resources. By working with civic programmers, relationships are forged with residents that volunteer their own skills for the greater good of their communities, thus, building stronger relationships with the communities overall.

The CDPH found that many residents are tweeting about their food poisoning symptoms and restaurant experiences on Twitter. However, most food poisoning cases go unreported, and most times, it is because residents do not know that they can report this to the city. The Smart Chicago Collaborative, in partnership with local civic developers and the Chicago Department of Public Health, launched Foodborne Chicago, an innovative application that scans Twitter for mentions of food poisoning in Chicago (<http://foodbornechicago.org>).

This web app enabled CDPH to connect with Chicago residents on Twitter through @foodbornechi and encourage them to report details of their food poisoning to the CDPH Food Protection Division. Residents also get to see the inspection results of their report through an online service called 311 Service Tracker Chicago. In order to determine if a tweet is relevant to "food poisoning," the web app has to classify tweets by sifting through Chicago's 50,000 tweets/day as relevant or noise. This classification is done via machine learning. In this process, a mathematical, natural language model was built using existing tweets and human classifiers to learn which tweets may be food poisoning incidents.

FoodBorneChi has the capability of serving as a sentinel for outbreaks. As the app gets smarter, it presents Tweets that are more likely to be food poisoning cases, increasing the chance of reporting by affected residents. If the app shows one location generating several complaints, a faster investigation response can prevent more people from being affected. This "real-time"

digital syndromic surveillance complements traditional methods of public health surveillance and in the future, may be applied to increase response times to natural disasters and flu outbreaks.

## Big Data

Big data is a large and complex collection of data, that when presented without any visualization or within a stand-alone spreadsheet, makes little sense. CDPH, along with several informatics researchers, collaborated to make sense out of de-identified electronic health record data of one million Chicagoan inpatient and outpatient visits from 2006 through 2011. This serves to provide information regarding resident health and illness events, behaviors and disparities.

A website was created, Chicago Health Atlas, that brings together many data sets to make sense of diseases and healthcare delivery within the city as well as within the 77 neighborhoods in Chicago. Included in the data are demographics, vital signs, encounter types, diagnoses, medications and lab tests (<http://www.chicagohelthatlas.org>). The result is a website that can be used to see prevalence of specific diseases, health trends and outcomes within different neighborhoods and can provide focus in improving the public's health.

## Conclusion

By providing a focus for local public health efforts, the Healthy Chicago agenda has provided CDPH the opportunity to maximize the use of limited resources, strengthen its use of policy development as a public health tool, and establish a significant network of partners who share the Department's public health mission. CDPH's adoption of new technology has not only served to promote the work of Chicago's public health community and Healthy Chicago, it has in it-

self, provided a new means to efficiently address a wide-ranging number of public health goals. Further, the adoption of new technology created new partnerships and strengthened existing partnerships within the technology community.

The changing political and economic climate requires all LPHAs to focus on core public health issues and to do so in ways that have significant results. LPHAs cannot singlehandedly create healthy communities, nor can they rely solely on traditional interventions. Innovative efforts through partnerships, policy, and technology can provide significant and sustainable impact with fewer resources. LPHAs must develop, pilot, and share new interventions with others as we work to keep our communities healthy.

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Janis Sayer, MSW;  
Raed Mansour, MS;  
Erica Salem, MPH;  
Bechara Choucair, MD

Chicago Department of Public Health,  
E-mail: [Bechara.Choucair@cityofchicago.org](mailto:Bechara.Choucair@cityofchicago.org)

## American Medical Association Inaugurates New President



*Cecil Wilson, MD, WMA President; Ardis D. Hoven, MD, AMA President; Otmar Kloiber, MD, WMA Secretary General*

Ardis Dee Hoven, M.D., an internal medicine and infectious disease specialist from Lexington, Ky., became the 168<sup>th</sup> president of the American Medical Association (AMA) on June 18, 2013. In her inaugural address, Dr. Hoven emphasized the tremendous power physicians have to change the course of history. (Watch or read the entire address (<http://www.ama-assn.org/ama/pub/news/speeches/2013-06-18-hoven-inaugural-address.page>))

"The collective voice—the voice of America's physicians," Dr. Hoven said, "has the power to make a difference."

Reflecting upon her decades of inspirational efforts to improve access to care for the uninsured and advance care for patients with HIV/AIDS, Dr. Hoven pointed to the opportunity presented to physicians as they live through a time of unprecedented change.

"I say we are lucky," she told the assembly. "Because the great thing about living through history is we don't have to just witness it. We can shape it."

She called on physicians to face today's challenges head on. By working together, she said, physicians can make strides in such areas as combating the nation's epidemic of chronic diseases, fostering innovation in medical education and creating a practice environment in which physicians can thrive. Reminding physicians of the century and a half of history in which organized medicine has won resounding victories for the health of the nation, Dr. Hoven encouraged physicians to stand together and leverage the power of organized medicine. "Today we stand at a crossroads in the history of health care in this great nation," she said. "Let's never forget the future of American health care is in our hands."

Dr. Hoven has been a member of the AMA Board of Trustees since 2005, serving as its secretary for 2008–2009, chair for 2010–2011 and immediate past chair for 2011–2012. Dr. Hoven is the third female president in the organization's history.

Prior to her election to the board, Dr. Hoven served as a member and chair of the

AMA Council on Medical Service. She was a member of the Utilization Review and Accreditation Commission for six years and served on its executive committee. Additional activities have included service on the AMA Foundation board of directors, the Group Practice Advisory Council of the AMA and an appointment to the Practicing Physicians Advisory Commission. Currently Dr. Hoven serves as the AMA representative on the Board of Directors of the National Quality Forum and the Quality Alliance Steering Committee.

Dr. Hoven's involvement at the state level in Kentucky has been extensive. She was president of the Kentucky Medical Association from 1993 to 1994 and served as a delegate to the AMA from Kentucky prior to her election to the AMA Board of Trustees. She has also been actively involved in medical staff issues at her local hospital where she has held a variety of positions including president of the medical staff, member of the board of directors and president of the hospital foundation board.

Born in Cincinnati, Ohio, Dr. Hoven received her undergraduate degree in microbiology and then her medical degree from the University of Kentucky, Lexington. She completed her internal medicine and infectious disease training at the University of North Carolina, Chapel Hill.

Board-certified in internal medicine and infectious disease, Dr. Hoven is a fellow of the American College of Physicians and the Infectious Disease Society of America. She has been the recipient of many awards, including the University of Kentucky College of Medicine Distinguished Alumnus Award and the Kentucky Medical Association Distinguished Service Award. In 2013 Dr. Hoven was named one of Modern Healthcare Magazine's Top 25 Women in Healthcare.

## Model of Colombian Social Security in Health



*Cesar Prieto Avila*

As a result of the campaign in the year 1938 the Colombian Medical Federation (FMC) managed to establish the Ministry of Hygiene, actually the Ministry of Health. In the same year it also participated in setting up the Committee for Pharmaceutical Specialities and Medical Board which resulted in the emergence of medical specialities and the Colombian Association of Scientific Societies (ACSC).

Act 90 of 1946 stipulated the establishment of compulsory social insurance and in 1948 the Colombian Institute of Social Insurance (ICSS) was founded. The Institute started as a private facility to insure workers in the private sector receiving contributions to the following amount – 50% from employers, 25% from workers and 25% from the State. Workers in the public sector covered by the social welfare were excluded, so that all social benefits to the employees and workers of the private sector equalled the compulsory social insurance through the ICSS and the public benefits of the sector were in charge of the National Fund of Social

Welfare – CAJANAL – and the departmental and municipal funds. To embrace all health services, there were included hospitals receiving contributions from the national Government for the operations performed and caring for the unemployed or low income people by means that was known as subsidy to clinics, private or religious or civil organizations, receiving particular patients or offering services to people of high income not covered by other systems.

In 1973 by Decree No 1935 the Government unilaterally changed the economic framework of the ICSS and forgave the debt that had since then started, but it retained all its power of management and administrative control. In 1977 Decree No 1650 was passed stipulating reorganization of the ICSS and the establishment of the ISS – Instituto de Seguros.

Until 1990 health care in Colombia was under a completely vertical framework of the National Health System, supervised by the Ministry of Health that developed policies and concentrated most of the resources. The four-tier system consisted of the national level represented by the Ministry of Health and the supervised establishments and decentralized institutions; the sectional level, embracing 33 sectional health services working under the direction of Head of Health Services and a sectional meeting that operated in each capital of the Departments and technically depended on the Ministry of Health; the regional level comprised 107 regional units and generally followed the directions of the level II regional hospital; and the fourth level consisting of local units and functioning under the jurisdiction of the municipalities and level I care, without involvement in the decision making of the respective municipality on health care issues.

Health care was based on a model of progressive complexity according to the technical and scientific capacity of level I or the primary level, offering basic health services of first aid, emergency, general dental medical care and sanitation; institutions offering this care level were the local hospitals and health posts and centres; level II or the secondary level, having greater technical and scientific possibilities at its disposal and including level I, offered outpatient and hospital care in the basic medical fields: Internal Medicine, General Surgery, Paediatrics, Gynaecology and Obstetrics, Surgery and Anaesthesiology division as well; level III or the tertiary level included the activities of the two lower levels, as well as hospitalization and different specialities and medical subspecialties with high complexity diagnostic and therapeutic procedures in a clinical laboratory, diagnostic imaging, endoscopy, medical and pathological anatomy; much of it served as a basis for higher medical education.

Social security establishments, such as the ISS, funds of compensation, etc., and the private sector functioned within the framework of the national system, even though they had autonomy in their internal organization. This system, known as subsidy to the offer, implied that all the entities from the public sector as well as foundations and private institutions that provided health care and who had contracts or agreements with the State to serve low income people, received resources, requested by these entities at the end of the year, from the annual budget. The Central Government assessed the costs and coverage for the following period and the execution depended on the income of the nation and was included in its annual budget. In many cases this system resulted in hospitals receiving resources not for their performance, but





due to their political orientation or the directors' capacity of reaching the decision-making level at the head of the Department of Health Care or the Ministry of Health.

There were three sectors in health care. The first was Social Security represented on the one hand by a monopoly for the private sector: ICSS that covered only workers but, at the end of the 1970's, included the family medicine program and the Compensation Family Funds, representing the families of workers in the private sector and on the other hand there was a system of public welfare for the workers and employees in the public sector, with the National Fund (CAJANAL) for the sector and the majority of entities created its own welfare system, e.g. such institutions as the Congress, Ecopetrol, workers of ports, railways, public universities, etc., as well as the armed forces and at the departmental and local levels established funds for medical employees. Each entity had its governing bodies and their boards of Directors had representation in the national Government.

The second sector was that of welfare responsible of care for the population without affiliation to social security or welfare funds. The service network was formed by 906 hospitals, 3705 centres and health posts and some foundations receiving official contributions. It was supervised by the Ministry of Health and addressed issues at national level, while the sectional level was in charge of the Departments and the local level – of municipalities.

The third sector was private embracing pre-paid medical entities, insurance companies and institutions and professional groups offering health services under the prepayment of fees or by direct payment as private entities, but under the surveillance and control of the Ministry of Health through the National Superintendence of Health, a semi-centralized entity.

At that time according to the data released by the Ministry of Health 34% of the population were not covered by any health system, i.e. the system-wide coverage was 66% of the Colombians.

Act 10 of 1990 reorganized the national health system, establishing that "...the provision of the health services, at all levels, is a public service in charge of the nation, free basic services for all inhabitants managed in partnership with local authorities and locally decentralized...". Moreover, it provided that "...the National Health System consists both of the entity set public and private health sector, as well as, in the relevant institutions of other sectors that influence health risk factors..."

This law reassigned the responsibility for the provision of health services, it fractured the vertical frame, made it more horizontal by totally decentralizing it, thus:

- the municipalities were to provide the direction and provisions of health services at the primary care level that included local hospitals, centres and health posts;
- the Departments were to provide the direction and delivery of health services at the second and third levels of care that included regional, specialized and university hospitals.

The responsibility of the managing bodies was transferred to the regional and local levels – the respective Governor, each Department or Mayor of each municipality, through their respective Secretaries of Health, as the search for resources at the local level, reordered the offer of services to decentralize the competences to the municipalities and Departments. The only institution remaining at the Central level was the National Cancer Institute.

## Social State Enterprises (ESE)

The enactment of Act 10 of 1990 introduced structural, more radical transforma-

tion in the Law of Public Health, concerning both the Health Promoting Companies (EPS), Instituto de Seguros Sociales (ISS), Caja Nacional de Prevision Social (Cajanal), the Fund of Social Welfare of the Ministry of Communications – Caprecom – etc., the institutions, health providers – IPS, and all the network hospitals. The Law provided provisions for receiving resources drawn from the State: located Prosecutor, ceded income, transfers, etc., to all territorial entities to carry out the institutional transformations necessary for the provision of health services as stipulated in Article 6 of this Law and, in particular, providing legal status and an administrative structure of health units.

Act 60 of 1993 already carried out the constitutional reform of 1991, Social State Enterprises (ESE) were established which was a "special category of public entity, decentralized, with legal personality, its own patrimony and administrative autonomy, created and organized by law or by the departmental assemblies and municipal councils". The objective of that "will be the provision of health services, understood as public service by the State and as an integral part of the General Social security health system".

This situation, caused by the major system change as it was suspension of the subsidy offer to transform it into a demand subsidy, created not only problems for the Colombian population to create the provision of subsidized health but the financial difficulty and the collapse in the provision of the health services in public hospitals.

Summary of the effect of this legislation: Act 10/ 1990 and Act 60/ 1993 and its regulatory decrees requiring administrative processes and billing services to public entities without training, without technology, without accompaniment that very few could meet, producing the greatest crisis of the system of institutions providing health services, providing system-wide entities pri-

vate technology on silver tray-staff trained, without labour or performance loads the new methods of recruitment of human talent, etc. that public institutions could not provide.

The most dire consequence of the reform of the system for involvement in the economies of scale of the neoliberal thought, “tuning of the central power”, was the loss of financial support from the State’s hospitals and the obligation to all public entities to have health care programs, retain a high percentage of their income for self-management without information and registration systems, no studies of costs, without training administrative personnel, invoicing, marketing etc., but with high labour costs and pension loads, low budgets for the maintenance of buildings for many years, all circumstances that made the public entities to remain with a minimum option to compete with the private Institutions Providers of Services (IPS) for the sale of health services, led to complete financial crisis in hospitals, to have a minimum percentage of the total of the hiring by private EPS, which implemented the construction and adaptation of its own clinics IPS and with legalistic manoeuvres achieved vertical integration by means of which hire private EPS with their own IPS insurers and round off the business.

As coup de grace there was the rancid neoliberal strain of the 1991 Constitutional Reform that by approving two articles allowed the health system, called the General System of Social Security in Health (SGSSS), lead the country to the brink of collapse in the social area: Article 480 deprived the Colombians the right to health as a FUNDAMENTAL right and an INDIVIDUAL right and transformed it into the right to buy health care according to the capacity of payment and Article 49 suppressed the State of its obligation to be responsible for the public health, words that do not appear in the constitutional text as there is only the term “sanitation”.

## LAW 100 of 1993

On the basis of the Constitutional reform, in 1993 Law 100 was passed establishing the General Social Security System, consisting of three branches: health, pensions and occupational hazards but, in a decision completely harmful to the majority of Colombians and transcendental, delivered the management of these branches to individuals, national and multinational private capital.

Health developed the mandatory Plan of Health (POS) according to which all Colombians had to be affiliated to the health system. But what we have seen is that it is taking the country to a crisis in health care, into bankruptcy and closure of many hospitals in the network, to the disappearance of all public Social Security health care entities, income earned from the provision of the health service to the economy of scale, the law of supply and demand but, the most disastrous, to circumvent the surveillance and control of the system and accountability by the State for public health.

There were established the National Council of Social Security in Health (CNSSS) with the power of advisory entity, unless its decisions were enforced by the Government, which was under the “dictates” of the compulsory National Health Plan and some Territorial Councils of Social Security in Health (CTSSS) for Departments with much less decision-making role; on the other hand the National Superintendence of Health in a single office in Bogota, without regional delegations and without legal or logistical tools to exercise their theoretical role of surveillance and control, especially for the EPS, and private IPS was centralized.

All the public EPS ceased to exist and finally there was the liquidation of the ISS, the only insurance company that regulated the entire system to introduce, now yes, “wild

capitalism” in terms of Social Security in our country.

It developed the process in three different regimens:

- contributory – for persons with the ability to pay the entities to join public and private insurance companies that are called Providers of Health (EPS);
- subsidized – for the population of strata 0 and I without the ability to pay that theoretically would receive a subsidy from the State; surrendered the administration and management institutions to public and private managers subsidized regime ARS. By Law 1122 of 2007 the name was changed to the regime subsidized EPS-S, but with the same vices of the ARS;
- customs-related or UBN (unsatisfied basic needs) – for the population in poverty and misery that even do not have access to the subsidy, until then it could access a subsidy, a term absurd as it is an important part of the population not affiliated to anything.

What is even worse that the process envisaged three types of patients and three medicines: the contributory regime had free choice of doctors and clinics, no more problem of access to specialized medicine and technology and the best hotel service in private clinics. Those of the subsidized regime had all kinds of geographic barriers to access the same benefits, less limited by the attention on the part of auxiliary staff or basic drugs that could only be those listed in an arbitrary manner in the “Vademecum of the POS” and concerning those whom no one wanted to attend as there was no answer who should do it, turning attention to hospitals in the network that had hired the care for patients of the subsidized regime, but to attend the related tort-produced “billing surplus” that the State did not recognize, and paying less leading to deepening of the financial crisis and putting at risk the survival of public hospitals.



Another fundamental aspect that must be analyzed concerns drugs in general, but especially generic drugs in Colombia, and there is a very serious problem of marketing and the POS drug supply and the situation posed by the recovery by the EPS and the risk of the shot cost for patients after signing of the terrible FTA with the United States and with the European Union that is even more harmful than that of the USA.

Figures for the recovery of drugs not in POS of the EPS to the Fosyga spent \$58 billion pesos in 2003 rose to 628 billion in 2007, according to these, 507 billion correspond to the contributory scheme; for the closing of the year 2008 the forecast was that recovery via guardianship and the technical-scientific committees of the EPS, the figure would reach \$ 1 billion 139 million pesos, these data mean that in two years, by the year 2010, all the Fosyga and health system resources would not be enough to pay for medicines not POS regains. One of the causes of morbidity and mortality in the country, more than the epidemiological transition, a profile of structural heterogeneity predominate while the diseases of poverty are unequally combined with the diseases of development, and in which the expression of the inequities of social and health care that have characterized the Colombian Health System for long is very strong. The topical problems of today are high and early deaths homicides and violence, though predominantly affecting young males, begins to appear more strongly in other age groups; the persistence of inequalities between regions, between urban and rural areas and genders; the deterioration in the living conditions has deepened in recent years and the high vulnerability of young people, women and rural inhabitants.

This latest health reform in Colombia in the 1990s failed to overcome the chronic inequalities and exclusions from the Colombian Health System. Executed in the period of transition, the universality in the

assurance and approval of benefits plans are promises unfulfilled and impossible to realize in the midst of policy adjustment, co-modification of health services, and deepening of the neo-liberal social policies. A big question is posed which has proven to be the main achievement of Law 100/93, what was the assurance of the poor people as the official figures show that for the year 2006, 56% and 63% of the population of deciles 1 and 2 respectively, was not insured, the total coverage of the health system in that same year was 64%; but as regards the alleged coverage of the subsidized regime another fallacy was used, called "partial subsidies" which were those vertical subsidies given to a person who did not have coverage in case of disease, as they called them traders of "high-cost" health (cancer, AIDS, heart problems that require procedures of high complexity, etc.) only for that person and for the respective medical problem, implying support at any time to the same person for other health problems that appear and less for the other members of the family. These subsidies added, they inflate the number of patients allegedly "covered by the system".

Today the population, especially the poorest, spends more on health and the subsidized regime affiliates receive from the plan of benefits 30% fewer services than the contributory scheme. For the population not insured, "linked", inequities are larger, and the poor becoming poorer have decreased the use of services and those who have most increased spending in health care have fewer opportunities and the levels of poverty and misery have expanded dramatically and the social gap between them and the rich increases; increase in absolute numbers reveals that more than 50% of the Colombians are out of the health system in the 15 years of implementation of Law 100 of 1993 and its regulatory decrees.

Comprehensive addressing of the transformation of the health situation of the country requires acting in double perspective,

the construction of a model of alternative development and, in this context, a new system of health, both aimed at resizing the social policy and equity, placing them, instead of economic growth, as the axes of the development agenda. Equity and social policy understood as equality of opportunity for all and the guarantee of universal rights, to deploy capabilities and individual freedoms that materialize the plural projects of good life of human groups, and not as welfare, residual and subsidiary actions, economic growth and financial sustainability criterion.

The results of the current health system, based on the cumulative evidence of the poor health situation of the population with a high percentage of Colombians that never out of it, the inequalities between regions of the country, the collapse of the hospital network, the decrease in the coverage of the system, the resurgence of priority of health problems increased and all this in the midst of increase of progressive resources both public and private. The system caused crisis due to structural reasons and not implementation because it was built based on inequalities and therefore is self-destructive.

Numerous studies revealing the crisis of the general system in all aspects, including the most critical, its inability to respond decently and humanely to the needs of citizens in health or, perhaps better, its great capacity for nugatory rights, even to the services specified in the compulsory Health Plan have been published in the 'private' contract that supposedly governs the relationship between the citizens and the insurance companies in the contributory scheme, or between the State and the corresponding EPS in the subsidized regime.

The same studies that confirm the growth of spending on health as a result of the Reformation (National Health Accounts) show that spending grew only between 1993 and 1997 and then declined steadily until the year 2003. Health expenditure increased

from 6.2% to 9.6% of the GDP between 1993 and 1997 and fell from the 9.6% to 7.8 % between 1997 and 2003. It also shows an increase of the expenditure per capita of 257 thousand pesos in 1993 to 403 thousand in 1997 and a fall to 320 thousand pesos in 2003. In addition, the expenditure per capita grew significantly in the population covered by the contributory scheme and did not grow for the poor population.

It also shows increase of specific care spending of 10.6% between 1993 and 2003 (less than the population growth in the same period), and reveals a fall of per capita expenditure in the resources actually allocated to health care. This is the worst outcome to demonstrate a reform. Moreover, the per capita annual expenditure spent on outpatient services fell unceasingly since 1995 when it reached 178,000 pesos to 130,000 in 2003, and made the situation very serious and demonstrated the greatest failure regarding the real access to early diagnosis and treatment needs.

It should be noted at this point that "linked" are not simply "not insured" as it is claimed in the studies, at least not as it was implied by the National Health System before the year 1993. Linked are a construction of the system, most of which have been excluded intentionally from the benefits of the system by the focus mechanism (Benefits System or SISBEN) At the time when systematically the hospitals cut their care resources it is logical to find advantages of affiliates to the subsidized regime with respect to those who had been left intentionally at the gates of health services. Therefore, we cannot prove that members of the subsidized regime are well or much better provided, what happens is that the linked are really excluded, except a few exceptions as in the district capital, Bogota, and the Valle del Cauca that are investing in this group significant resources pursuing policies of their own.

Summarizing, we can point out that one of the many goals Law 100/ 1993 was not

able to meet and could not meet because the very structure of the Law was based on inequality and made it self-destructive was the idealistic "universal coverage" according to which there would be health care for all by the year 2000 and then as an electoral strategy of the current Government which set its deadline in 2005 there was passed the famous Law 1122/07 or "Amendments to Act 100" which lowered the "universal" coverage at levels I, II and III of the SISBEN and so spent the highest percentage of the money of the health sector to increase that coverage at the level of municipalities at the expense of the subsidy to the offer and the possibility of maintaining of level II care hospitals functioning and financially stable to meet their objectives of providing health care of specialized medicine and advanced technology to the most vulnerable part of the departments for the uninsured poor whereupon health care moved towards total collapse.

The official sector has a network of public hospitals monitored by the departments, by the Ministry of Social Protection, the National Superintendence of Health; each private EPS has its own vertically integrated network, adverse selection, the constraint of professional practice, the labour abuse, de-professionalization of medicine and the delabourization of unregulated by the departments health workers not integrated in the surveillance systems, morbidity and mortality committees that are only monitored by the National Superintendence of Health entity that is located in the capital with a single office and only 100 employees to cover the entire country.

Finally, it is necessary to point out that Social Security is the best way to ensure the health of Colombians and when asking about the current occurrences, it is not questioning social security, or even the delegation of public service to private actors, what is in question is the absolute lack of capacity of the system to address and regulate the system, the deviation

from the objectives of a universal system with equal benefits plan for all Colombians, the vulnerability of the majority of workers in the country without formal employment contract, the road taken from the assistance and the political patronage in the subsidized regime which disclaims employers and leaves without rights workers managing many EPS under the two regimes (especially the ownerless), where administrators steal or simply dispose with total irresponsibility of money earmarked for the health of Colombians and there is development towards de-professionalization of medicine and delabourization of the medical profession.

The everyday positive account of the system is contrary to what happens to the citizens, the majority of whom do not find a decent and humane response to their health needs in the current operation of the SGSSS.

All this leads us to conclude that if nothing is done, Colombia will become the only country with no public Social Security in which all health assurance will remain in private hands and where there is private monopoly in assuring the health of Colombians in less than 15 years if implementing the "Colombian model" which is nothing to be proud of because instead of being an advanced model it is totally regressive from the social point of view, excellent in financial returns but without meeting any social function of equity and universality.

*Cesar Prieto Avila M.D.*

*President Colegio Medico del Valle del Cauca  
Vicepresident Federacion Medica Colombiana*

*E-mail: colmedvalle@gmail.com*



# World Medical Journal



## Myanmar Medical Association (MMA)

Founded in 1949, MMA is the only professional organization of qualified medical doctors in the Republic of the Union (ROU) of Myanmar. It is a registered, non-political, non-governmental, non-profitable organization and operates with its own budget, generated from its activities and membership fees. MMA has its own policy, constitution, bylaws and regulations.

### Member Strength of MMA

Over 18,000 of 33,000 registered doctors are MMA members, out of which over 8,000 doctors are not involved in Public Service (non-service personnel); they are medical practitioners (General Practitioners) in the community.

### MMA Offices

Under MMA, 83 medical association offices are located all over the country in major cities (townships and districts) of the states and regions, covering nearly the whole population, except in a few areas where communications is encumbered, the population density is low and the doctor community is small.

There are 33 clinical and non-clinical specialist societies, and the General Practitioners (GP) society is the biggest, strongest and most active among the other societies.

### Leadership

Organization leaders are elected (at all levels every two years) by democratic voting, a system based on meritocracy and all members enjoying equal rights. MMA has been sharing responsibilities and working together for the global aims of philanthropy and altruism with true professionalism.

### Vision

MMA vision is to be instrumental in promoting the health of the people by enhancing the professionalism of the members and striving to work together, sharing responsibilities and experiences, with strong commitment towards quality health care.

### Mission

MMA mission is volunteer spirit on non-profit basis, democratic leadership, sharing responsibilities with equity and unity among the members, private-public partnership approach to other health alliances,

working together for quality healthcare for all.

### Main Functions

1. Education and Training towards the CME accreditation.
2. Clinical and Public Health Research with ethical and professional needs and standard.
3. Community healthcare including public health projects, health promotion including reproductive health.
4. Maintain high professional and ethical standard among the members.
5. Collaboration and coordination with medical societies in the region as well as outside the region.
6. Partnership approach to allied medical societies, INGOs, NGOs within the country.
7. Encourage and support total capacity building of the association at all levels with professional aspiration.



*On the left, Professor Pe Thet Khin, Minister for Health, receiving the souvenir from Professor Kyaw Myint Naing, President of Myanmar Medical Association, on the right, at the Inaugural Ceremony of the 59<sup>th</sup> Myanmar Medical Conference (22 January 2013) held in Mawlamyaing, the fourth largest city of Myanmar.*

## Activities in 2012–2013

1. Annual Meeting together with Annual Academic Conference every January. In 2013 the 59<sup>th</sup> Conference was held in Mawlamyaing, the fourth largest city of the ROU of Myanmar.
2. The 19<sup>th</sup> Surgeons Conference was held in November 2013 at Mandalay, the third largest city of the ROU of Myanmar.
3. The 10<sup>th</sup> O&G Conference was held in February 2013 at Yangon, the second largest city of the ROU of Myanmar.
4. The 21<sup>st</sup> ENT Conference was held in January 2013 at Yangon.
5. The 21<sup>st</sup> Eye Conference was held in November 2012 at Yangon.
6. The 14<sup>th</sup> General Practitioners Scientific Conference was held in November 2012 at Lashio, Northern Shan State.
7. The 9<sup>th</sup> Rehabilitation Medicine Conference was held in October 2012 at Yangon.
8. The 2<sup>nd</sup> International Pain Seminar was organized by the ROU of Myanmar and was held in January 2013 at Yangon.
9. There are 3 academic projects, and 18 public health related projects funded by various International donor agencies including Myanmar Medical Association itself, covering 80 townships in the ROU of Myanmar.
10. Support Group for Elderly Doctors (SGED), care about doctors over the

age of 70 with sickness support, social visits, regular medical check-ups, social gatherings, support in cataract operations, and at funeral.

11. Lady Doctors Section organized to pay homage to the elderly doctors residing in Yangon every December of the year (the recent data: 340 doctors over 75 years of age).
12. Emergency Ambulance Service has been established and initiated and has an appreciable performance in Yangon by Myanmar Medical Association with charity support.

*Dr. Khine Soe Win, Executive Director,  
Myanmar Medical Association*

## Ethical Principles of the Management of Incidental Findings in Research



*Dirk Lanzerath*

Incidental findings and chance findings encounter in many areas of medical investigations in diagnosis and research. But due to the refinement of new technologies in the context of medical research they appear more frequently in modern clinical studies and biomedical research projects. In general, the term “incidental finding” can

be considered to refer to an unexpected medical (clinically uncertain or possibly relevant) finding, whose presence was not previously suspected, and which was not specifically sought for during the research procedure. Whereas “chance findings” are in fact, fairly probable due to the large scale nature of a specific research process like in medical genetics. Those findings are not really “incidental” [cf. Lanzerath et al 2013]. In particular the introduction of imaging techniques (e.g. PET, MRT) to investigate function and dysfunction of the human brain produces incidental findings and has initiated a vital ethical and legal debate on the question to which extent investigators – including doctors engaged in research – need to inform about these kinds of findings and how they should deal in general with pathological, or potentially pathological, findings arising within the context of a research project that are of no direct relevance to the research question in hand. Although data on this subject remain limited, empirical studies have shown that incidental findings are widespread (up to 8%) within brain imaging studies [Morris et al.

2009]. At the time of writing, no common guidelines or laws are available to researchers in Europe that regulate this very specific issue of the management of incidental findings. Only general provision concerning the researcher-participant-relationships and in particular those on data protection are applicable here and create a pattern “that gives rights to data subjects (those to whom the personal data in question relates) and imposes duties upon data controllers (those who control the processing of those data)” [Townend 2013]. Only some professional medical associations [e.g. GFHEV 2013] or groups of researchers [e.g. Wolf et al. 2008 or Heinemann et al. 2013] published specific proposals and statements concerning the management of incidental or chance findings in research.

Against this background the question arises as to how ethical principles and rules established over past decades should be specified and supplemented in order to create ethically acceptable conditions for medical research. Some even suggest that the normative obligations between researchers and research subjects on the one hand, and doctors and patients on the other, must be fundamentally re-evaluated. This view indicates that medical ethics and research ethics

differ more widely in the normative sense than hitherto assumed. Others consider this appraisal too far-reaching, and assume that the updating of established medical and research ethics will lead to an adequate solution [Heinrichs 2013]. Most of those involved are, however, in agreement that binding ethical and legal standards – e.g. included in professional law – should be established in order to ensure equal clarity for researchers and research subjects in terms of the normative auspices under which the relevant techniques within medical research are applied.

## Information, Autonomy, and Knowledge

The management of incidental findings touches upon certain fundamental ethical principles that exert a reciprocal influence on each other in both other areas of medical care and medical research. The most prominent of these are the right to informational self-determination, and the associated right of a research subject to receive comprehensive information prior to the performance of the study. This latter right includes entitlement to an adequate explanation concerning the aim of the research, the data to be gathered, and the techniques to be used in order to ensure that research subjects are in a position to provide informed consent. In the sense intended here, however, this right also includes the entitlement to receive information regarding the possible consequences of research participation. These possible consequences include any incidental findings, or indeed chance findings, that may be detected during analysis of the data. Thus first and foremost, we may speak of a basic obligation to provide information that data with this potential are to be generated. However, the question of how comprehensive this information may and needs to be clarified. For example in the field of whole genome sequencing many data will be available even those which cannot be interpreted for the moment. But the investi-

gator has the duty to explain and to specify which kind of data will be analyzed and can or cannot be disclosed to the state of the art.

Rights pertaining to the principle of the autonomy of the research subject include not only the right to know, but also the right not to know. No individual may be forced to (want to) know all that can be detected in someone's brain or discovered about someone's genetic constitution [Oviedo Convention, Council of Europe, Article 10]. Although knowledge of this kind may be of benefit to the individual in terms of life planning, it may also prove very burdensome. For instance, awareness of a particular genetic predisposition may be associated with serious disadvantages, and may result in discrimination or stigmatisation in day-to-day life (e.g. insurance cover, occupational status). Therefore this right not to know has become an established ethical principle, which is also reflected by several legal regulations. However, this should not to be confused with simple ignorance of certain possibilities; what is meant here is an enlightened desire not to know. If I am the person who will be affected, then I must know in advance what I am letting myself in for if I do not wish to gain a particular kind of knowledge. In other words, not wanting to know does not obviate the need for elucidation; rather the consequences of not wanting to know must be elucidated in advance. The decisive point is that this right necessitates a limitation of elucidation, i.e. it respects the wishes of individuals not to be so informed.

## Non-maleficence versus Solidarity

Two further principles are of importance in the ethical appraisal of strategies for dealing with incidental findings and of the criterionology that is to be elaborated for this purpose. Medical intervention should not cause harm (*primum nil nocere*). This has been developed as a basic ethical principle

in medicine initiated already in the Hippocratic tradition, as even though therapeutic interventions often result in damage to health, they are necessary to prevent or remedy even greater harm. Clearly the principle of non-maleficence must be applied more stringently in medical research than in day-to-day medical practice, since healing a research subject is not the main purpose of research, and even healing in general is only one of its aims. Therefore, there is no justification for causing detriment, not even temporarily, such as can and must pertain to direct curative treatment. Scientific enquiry may only expose research subjects to risks that are not disproportionate to the potential benefits of the research [Oviedo Convention, Council of Europe, Article 16]. A common tendency exists among medical professionals to consider the principle of non-maleficence as being restricted to instances of physical harm. However, the spoken word can also cause considerable distress, for instance in the course of a consultation to explain findings or test results.

Evaluation of specific and problematic incidental findings arising within a research setting cannot be evaluated according to criteria applied within a clearly defined diagnostic and therapeutic context. The relationship that exists between a physician and a patient is typically of a diagnostic/therapeutic nature which includes specific legal implications. In the research context, however, the ethical principles of solidarity and common good must be taken into account to justify that human subjects will be involved as research subjects in research projects. In Anglo-Saxon bioethics, such principles are frequently subsumed under the principle of justice. The performance and success of medical research are by no means guaranteed under all circumstances. Firstly, they require enormous amounts of money, and secondly they are contingent upon the research being attractive to individual researchers and scientific institutions, as well as the preparedness of people to act as research subjects. In many cases, these

latter individuals are healthy volunteers in no need of medical treatment. Although the improvement of treatments and medicines through scientific endeavour may be regarded as conferring a high degree of social benefit, this consideration does not override the ethically justified rights of research subjects. It must also be borne in mind that social benefits including the increase of knowledge do not accrue on the basis of any single study – which may in any case fail to generate significant data – but rather from the fact that this study is part of a general and international body of biomedical research. On this basis, it may be legitimate – under appropriate circumstances and with appropriate deference to the principles of research ethics – to engage healthy volunteers for testing purposes and expose them to some risks, if the anticipated benefit cannot otherwise be achieved. It is then the task of Research Ethics Committees to determine, on a case to case basis, whether the design and implementation of a given medical study infringes upon the rights of research subjects. The risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. This process also involves scrutiny of whether the proposed procedures with respect to incidental findings are in accordance with existing laws and guidelines for research ethics.

## Criteriaological Considerations

Such general ethical principles do not, however, suffice as a criteriology for dealing with incidental findings within the research setting; they only provide a set of boundary conditions. To establish the degree to which researchers are obliged to provide information concerning incidental findings, these findings should first be categorised according to their information content, since this represents a means of assessing possible benefits or detriment for research subjects. Questions of relevance in relation to information content are:

- Reliability of knowledge: What can become known on the basis of the information that has been obtained?
- Transferring medical knowledge into personal knowledge: How might the knowledge of a finding affect a person's life planning?
- Concernment of person involved, offspring or relatives: Who is affected by the communication of findings?
- Therapeutic value of the knowledge: Can the prognosticated disorder be treated by preventative, therapeutic, or palliative means?
- Pathogenic significance of the knowledge: How serious is the prognosticated disease?
- Prognostic value of the knowledge: What is the likelihood that a condition will manifest itself?

These questions categorize the different incidental findings to constitute a framework for recommendations for a criteriology for use in communications with research subjects in medical studies. [Lanzerath et al. 2013] Incidental findings are categorised according to the respective degree of obligation to provide information, and with respect to the physician's duty of care, and the rights of the research subject to self-determination and to know or not to know. The physician's duty of care includes the offer of information of relevance to the current or future state of health. But the investigator has to take account that the research subject might exercise his or her right not to know, i.e. that a research subject does not want to receive such information about a finding.

Nevertheless, two potential conflict scenarios remain. In the first case, the researcher is of the opinion that the incidental genetic finding is of major significance to the research subject that its disclosure would be of considerable benefit to them, but the research subject has declared in advance that he or she does not wish to be told (conflict between the right not to know and duty of

care). In the second case, the researcher considers the benefits of imparting information to be questionable, or that the information is based on unreliable data, but the research subject wants to know more ("tell me everything you did find"); however, the knowledge may cause him or her unnecessary disquiet. These conflicts cannot be resolved through the presently proposed categorisation process, and must instead be clarified ahead of study participation. Whether the right to self-determination or the duty of care should take precedence in such cases, and whether research subjects who insist upon not being informed about incidental findings (even if these are of great potential benefit) should be excluded from studies, are matters of heated debate [cf. Lanzerath et al. 2013].

## Conclusion

Even if researchers – including doctors engaged in research – implement the proposed normative categorisation of incidental findings in order to determine their degree of obligation in terms of disclosure, they may nevertheless find it difficult in individual cases to make a reliable assignment. A dilemma emerges from the experience that many incidental findings are of "unclear significance". The research subject faces an unclear risk-benefit ratio when it is unclear how this certain kind of knowledge can be applied, in particular in the field of human genetics. The involved subject decides on what kind of risk he or she is ready to take. But this can be done only on a basis of categorized types of data and information. Raw data do not automatically correlate with "information"; generating and compiling reliable information emerges from a prior interpretive and hermeneutic approach. Therefore it must devolve upon the specialist associations to formulate the proposed categorisation in more detail, so that even in the case of multi-centre studies, clearer criteria for the protection of the research subject, which are oriented on the



ethics of research practice, are generally available. At the same time, there is a strong need to specify the “counselling capacities” (i.e. their skill in imparting information in an appropriately empathic manner) of those entrusted with the task of provide and disclose information to research subjects. Unfortunately, competency for this task cannot be assured in all cases.

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*Priv.-Doz. Dr. Dirk Lanzerath  
Geschäftsführer / Executive Officer  
Deutsches Referenzzentrum für Ethik  
in den Biowissenschaften (DRZE)  
German Reference Centre for  
Ethics in the Life Sciences  
Universität Bonn / University of Bonn  
E-mail: lanzerath@drze.de*

## Experience in Treating Patients in Sylvinite-Halite Mines of Soligorsk in the Republic of Belarus

The Belarusian Medical Academy of Postgraduate Education in Minsk, Belarus, has developed speleotherapy as one of the perspective drug-free methods in the treatment of bronchial asthma (BA), chronic obstructive pulmonary disease (COPD), allergic processes (rhinitis, pollinosis, dermatitis) which allows to prevent the development of those diseases at the early stages of their development, and it does not have any significant side effects.

The Republican Clinic of Speleotherapy (RCS) in Soligorsk has opened a unique subsurface speleo complex, constructed in the rock salt (halite) massif and the potassium (sylvinite) layer.

34 thousand patients have been treated there during the 23 years of its functioning. The treatment efficiency is high. Positive results have been achieved in 97.6% of the cases.

The world practice has accumulated experience in the application of the speleotherapy method for treating diseases of respiratory

organs, which testifies to the high effectiveness without the risk of developing side reactions due to the microclimate of salt mines.

The RCS in Soligorsk carries out the specialized treatment with the speleotherapy method by using the subsurface space, existing in different mining and geological layers.

The uniqueness of the RCS subsurface speleo complex manifests in the following:

1. It is in the rock salt (halite) massif and the potassium (sylvinite) layer, providing the possibility of placing the patients in different therapeutic environment depending on the form of the disease and individual reaction of the organism to the speleo environment [Figure 1].
2. The subsurface departments are built according to the scientifically-based project [Figure 2].
3. Special air intake labyrinths ensure the air flow to the therapeutic area and also individually to each ward.

4. The physico-chemical properties of the microclimate in Soligorsk salt mines significantly differ from those in other speleo complexes. The sylvinite layer near the halite layer of the salt exceeds the potassium chloride content in the air 20 times in comparison with other similar mines.

The specific therapeutic effect of the speleo environment is achieved due to the stable microclimate, the optimal ionic composition, the presence of fine salt aerosol in it, the absence of allergens and pathogenic microflora.

## Characteristics of the speleo environment:

- The optimal gas composition of the air according to the content of oxygen (20, 80–20, 90 by volume) and according to the content of CO<sub>2</sub> (0.031–0.047 by volume); 0.35 mg/m<sup>3</sup>
- The total microbial contamination of the air is 42–102 colonies in m<sup>3</sup>.



- The following factors also apply to the subsurface environment.
- The shielding effect of the rock mass from the effects of radio frequency electromagnetic fields; the psycho-emotional readaptation due to the strange conditions in the underground.

Materials and methods

The RCS treats about 2000 people a year average. The twice increased hospital capacity in 2012 has increased the number of patients to 4000 respectively.

78 treatment courses of speleotherapy have been performed during the period 2009–2013, lasting for not less than 12–18 beds/days. 11407 patients have been treated during this period. 6896(61%) of them were women, 4421 (39%) were men [Figure 3a]. The number of grown-ups was 9424(82.6%), children and teenagers – 1983 (17.4%) [Figure 3b].

Of all the patients treated in the RCS 58% were 18–50 years old, it means the most active working age. The average length of the treatment is 17.4 days, the average amount of speleo manipulations for one patient – 15.7. The speleo manipulations are performed in the day time and in the evening and at night for 5 and 12 hours, during the above period 8924 (77.4%) patients with BA, 1540 (12%) patients with COPD and chronic bronchitis, 1095 (4.8%) patients with allergic rhinitis have been treated [Figure 4]. The positive effect is observed after speleotherapy among the patients with allergic skin disease etiology. The method of research: computer spirometer was used in this work.

Results and Discussion

Speleo environment reduces allergic disposition of the body, reduces inflammatory changes in the bronchi, helps to improve the rheological properties of sputum and

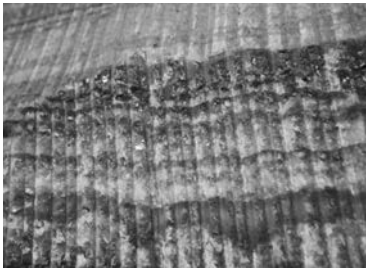


Figure 1. The structure of salt

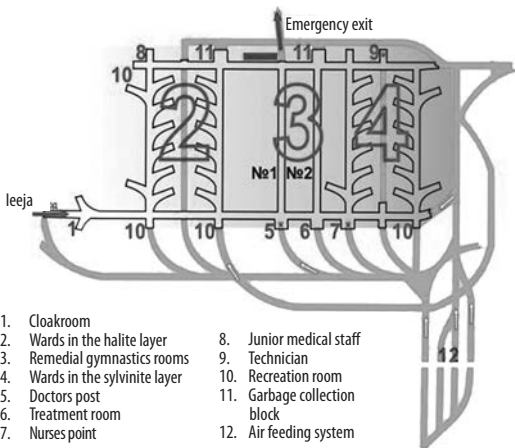


Figure 2. The subsurface speleocomplex

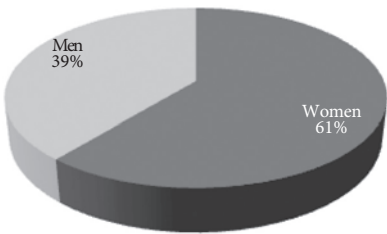


Figure 3a. The structure of the patients by gender (2009–2013)

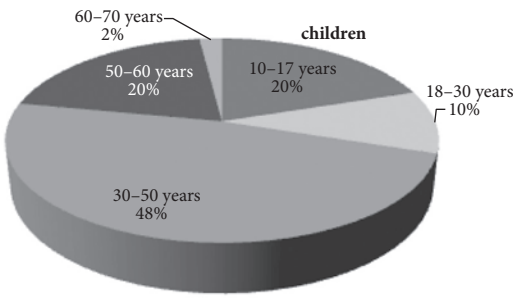
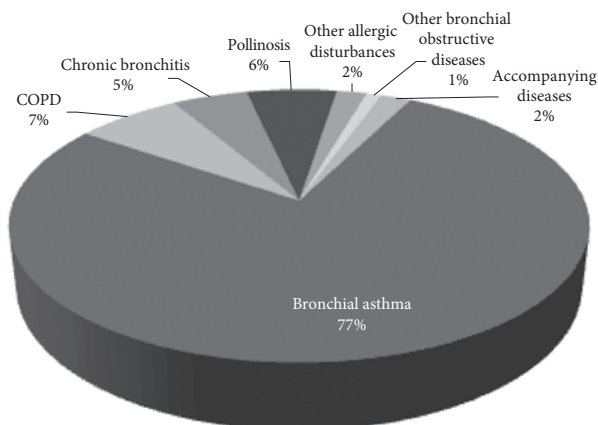
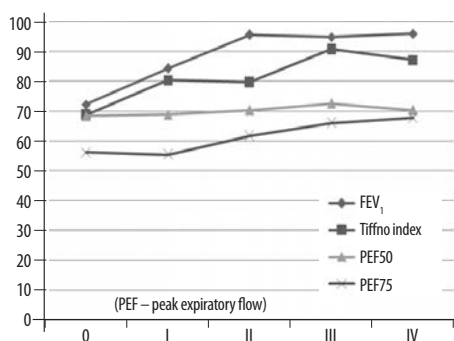


Figure 3b. The structure of the patients by age

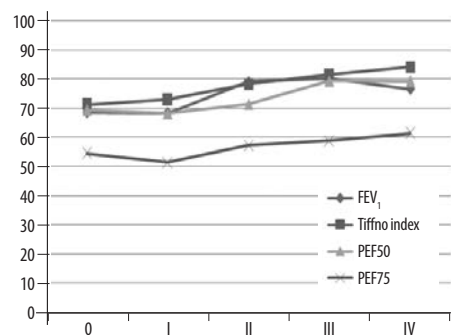
Medical indications to treatment	Medical contraindications
<ul style="list-style-type: none"><li>• Bronchial asthma, all forms of light and average course;</li><li>• RI(respiratory insufficiency) of 1<sup>st</sup> degree;</li><li>• COPD, light and average course of RI;</li><li>• Chronic bronchitis;</li><li>• Pollinoses (before and during the pollen season);</li><li>• Allergic rhinitis;</li><li>• Allergic urticaria.</li></ul>	<ul style="list-style-type: none"><li>• Acute diseases;</li><li>• Chronic diseases in the acute stage or in the case of heavy clinical course;</li><li>• Asthma;</li><li>• Respiratory diseases with respiratory insufficiency of 2<sup>nd</sup>–3<sup>rd</sup> degree;</li><li>• Malignant neoplasms of all localizations;</li><li>• Blood circulation system diseases with cases of cardiac insufficiency;</li><li>• Mental insanity;</li><li>• Tuberculosis of various localization.</li></ul>



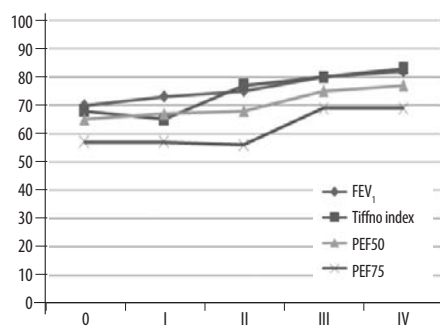
**Figure 4.** The structure of the patients according to nosology



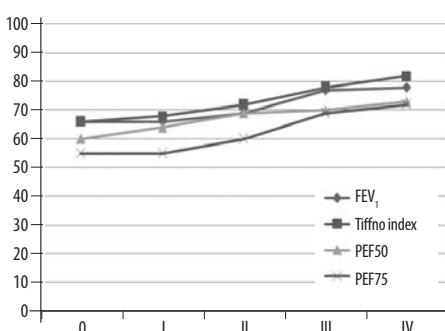
**Figure 5.** The dynamics of the Function of Internal Respiration parameters in patients with controlled BA of allergic form



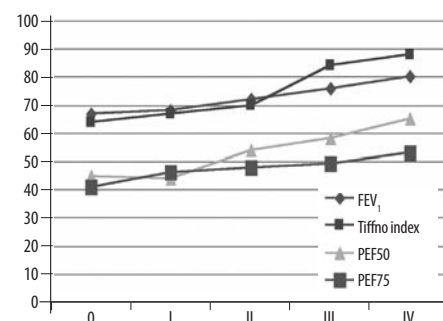
**Figure 6.** The dynamics of the Function of Internal Respiration parameters in patients with partly controlled BA of allergic form



**Figure 7.** The dynamics of the Function of Internal Respiration parameters in patients with controlled BA of mixed form



**Figure 8.** The dynamics of the Function of Internal Respiration parameters in patients with partly controlled BA of the mixed form



**Figure 9.** The dynamics of the Function of Internal Respiration parameters in patients with COPD

bronchial drainage function, has antibacterial action, mild immunomodulatory effect, which explains the wide list of indications for speleotherapy [Figure 5].

Considering the information above, at the RCS research has been performed focusing on the influence of speleo treatment in the course of allergic rhinitis, BA and COPD. It was aimed at the development of various methods of treatment, defining the modes of speleo influence, duration and multiplicity of speleotherapy courses depending on the nosology and the severity of the disease. The effectiveness of the method for patients with different clinical forms of the disease and severity was assessed by the severity of the dynamics of the main functional parameters and immunological criteria. The study revealed significant differences in the dynamics of the functional parameters in patients with different forms and levels of BA. During the speleotherapy a statistically significant increase in the basic forced expiratory volume in the first second ( $FEV_1$ ) was observed in patients with controlled BA allergic form by the end of the 2<sup>nd</sup> week of the treatment and it was  $19.3 \pm 8.4\%$ . In the following days, significant increase of the indicator was not observed [Figure 5].

A slower dynamics of the Function of Internal Respiration was observed in patients with partly controlled allergic BA. The dy-

namics of the main indicators of respiratory function was observed throughout the treatment, but statistically significant it was in the second week of speleo influence, reaching the level of  $FEV_1$   $12.8 \pm 4.2\%$ . Significant differences in the dynamics of the Function of Internal Respiration in patients with the mixed form of BA, depending on the level of control, have not been identified [Figure 6].

A statistically significant increase in  $FEV_1$  in patients with controlled BA of the mixed form was observed during the third week of the treatment and amounted to  $11.9 \pm 4.4\%$  [Figure 7].

Partly controlled BA of the mixed form was characterized by a gradual increase in the values of the basic functional parameters, reaching a statistically significant level during the third week of speleotherapy –  $12.5 \pm 3.8\%$  in terms of  $FEV_1$  [Figure 8].

The revealed changes in the level of the investigated Ig were treated as the stabilization of defense mechanisms at a lower functional level by minimizing immune stimulation. The identified functional and immunological changes in patients with light and moderate course of COPD had no relationship to the severity of the disease and therefore were joined into one observation group. During speleotherapy a statistically

significant dynamics of the main indicators of the Function of Internal Respiration was observed in these patients during the third week of the treatment [Figure 9].

During speleotherapy a statistically significant increase in the basic of  $FEV_1$  at the end of the third week of the treatment was  $16.7 \pm 4.7\%$ , which continued during the fourth week, but had no statistical significance in comparison with the levels achieved during the third week.

## Conclusions

1. The subsurface departments of speleotherapy based in Soligorsk sylvinites-halite mines are unique in the structure of salt and they are constructed according a specially designed project.
2. Speleotherapy in Soligorsk sylvinites-halite salt mines has a positive effect on the course of allergic rhinitis, BA, COPD, resulting in the possibility of its use in the prevention of progression of these diseases.
3. It is appropriate to use differential treatments of speleotherapy from 12 to 18 beds/days; it depends on the level of control and forms of BA, severity of the course of COPD.
4. A more rapid and significant therapeutic effect of speleotherapy is achieved among patients with the controlled course of the disease.

5. According to our observations, the effectiveness of the treatment is 97% and it manifests as improving the quality of life of patients, long-term stable remission of the disease, reducing the frequency of asthma attacks, improving the performance of the respiratory function, reducing pill burden.

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P. A. Levchenko, Y. A. Lapteva  
State-owned enterprise The Republican  
Clinic of Speleotherapy  
Soligorsk, Belarus

## Basic Wellness Features and Some Related Actions Propensive for Active and Healthy Ageing

*The current global financial crisis inevitably alters the quality of life of many individuals, mainly (but not exclusively) its fourth – after Guelphi – dimension: the economic one (a deeply intricate component). Under these conditions, we can only hope that the holistic and idealistic definition of health, adopted by the World Health Organization (WHO) more than 65*

*years ago, will maintain its contemporaneity and applicability – from before the recession – at least in the more developed countries/economies. This work presents a synthetic overview of the main issues related to the notion of quality of life: the presence/absence of risk factors, (especially) the ones associated to the “civilization pathology”, wellness, current thinking/*

*paradigm (integrating the medical and social models) of the WHO regarding human functioning, (di)stress – including its relationship to premature/pathologic ageing – respectively, active prophylactic (relaxing, fitness/“mise en forme” anti-stress, maintenance, rejuvenation/anti-ageing/gero-prophylaxis) balnear therapy courses.*



## Background. The WHO definition of health. Connected concepts

"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (1).

This definition was formulated almost seven decades ago and it included a "wishful thinking" dimension, representing, conceptually, the option for the main strategic target of general human progress and of sustainable (peaceful) development: to ensure the quality of life (QoL). Nowadays, this forward-looking strategic option is not obsolete, but on the contrary, it proves to be modern and desirable.

Effective *physical well-being* entails:

- the absence of medical disorders or/and of physical overwork/strain
- the absence/alleviation of disease risk factors (e.g., those for vascular pathology, that may lead to strokes/lesional attacks to virtually any organ – brain, heart, etc. – relatively easy to avoid, modify or eliminate: sedentary life, obesity, smoking, dyslipidemia, diabetes, hypertension, cardiac dysrhythmia, hyperfibrinogenemia) (2)

Moreover, an optimal/complete state of physical well-being requires not only the mere absence of illness risk factors and/or physical distress, but also a state of moderate physical performance – fitness.

**Fitness** is defined as "good health or physical condition, especially as the result of exercise and proper nutrition or the extent to which an organism is adapted to or able to produce offspring, in a particular environment" (3).

The definition of physical fitness also indicates to the indissoluble relationship of health with physical exercise and nutrition – major "poles" of the "lifestyle" notion, a comprehensive concept that includes

many positive and negative factors (e.g., sedentary life – a negative factor, of course, and a central pathogenic item of the "civilization pathology" (4).

Effective *mental well-being* entails:

- the absence of psychological and/or cognitive disorders and/or absence of psychic distress
- the absence/alleviation of specific risk factors (dissatisfaction, suppression, denial, low self-esteem)

A simple, quick, orientative modality to assess the cognitive function, frequently used in clinical settings, is the Mini-Mental State Evaluation (MMSE) (5).

Effective *social well-being* entails not merely the lack of poverty, but also (constant) decent living from an economic point of view. Furthermore, certain social conditions should be met: leading one's life in a democratic/constitutional state with a valid system of laws and regulations that are effectively enforced in a civilized society, engaged in "sustainable development", characterized by tolerance and cohesion, adhering to the principles of non-discrimination and inclusion, with increased consideration for the individuals with special needs (including morbid obesity or frail elderly, for example) and at the same time, based on fair competition and professional performance – "knowledge-based society".

The current understanding of health as physical, mental and social well-being is based on two fundamental, strategic, complementary concepts, which were brought forth and intensively promoted by the developed contemporary societies:

- *Quality of Life (QoL)*
- *Wellness ("well tempered hedonism").*

The major determinants of the QoL are physical and functional performance, psychological well-being, social interactions and the economic status (6).

The Flanagan Quality of Life Scale is a commonly used instrument for QoL assesment.

The concept of "wellness" – antonym to the word "illness", according to the Oxford English Dictionary (cited by 7), generally designates an adequate balance of "body, mind, and spirit", leading to a harmonious interaction with the "constantly changing total environment" (8).

An adequate physical, cognitive and spiritual interaction with one's environment (in all its dimensions: physical, familial, professional, social, economic, political, cultural, etc.) leads, in turn, to a state/feeling of general well-being, which represents far more than the mere absence of illness. Consequently, wellness may be defined as "an integrated method of functioning, which is oriented toward maximizing the potential of which the individual is capable" (7).

*"When we learn how to diagnose high-level wellness through objective measures, we shall probably find that a substantial amount of creative expression, altruism, and love in daily life is essential for the approach to a high state of well-being. Through the development and application of these values in daily life, we will achieve self-confidence and faith in ourselves. This in turn will bring growth of self, development toward fuller maturity, and a balanced wellness of body, mind, and spirit."* (8)

(Di)stress is a concept of paramount importance, related to the QoL and wellness. In a very general sense, at least for the biomedical field, the term **stress**, introduced since the first half of the last century by the endocrinologist Hans Selye who has "fathered" the stress research, is translated as pressure/strain/tension. It must be underlined from the beginning that both, the lack of stress (such as a sedentary life or social marginalization) as well as the excess/overload are equal sources of pathogenic stress (**distress**).

Historically, the first clinical preliminary/collateral observations in connection to this

subject were noted at the end of the 19<sup>th</sup> century by one of the most celebrated and contributive nurses Florence Nightingale (*"Notes on nursing: What it is and what it is not"* – cited by 9), but the Austrian-Hungarian endocrinologist Hans Selye was the first to develop the theory of "general adaptation syndrome"/"diseases of adaptation" (10) as a bio-physio-psychological paradigm to understand the concept of stress (initially, during the interwar period, he had formulated it as "the alarm reaction") (11).

According to this paradigm, the general adaptation syndrome is triggered by any event that affects (to a lesser or more often larger extent) the equilibrium state of an organism – called stressor (10). The initial response to distress is coordinated by the hypothalamic-pituitary axis, a system which will "gear the body for defence" (10). Within the reactivity to stress, the link between the brain – as an initiator – and the immune system [immune-neuro-endocrine interactions (12)] involves the neuro-endocrine system as a whole (12, 13).

Stress is one of the six major representative situations/biological phenomena characterized by duality, where the physiological/the functional is intertwined with the pathological, listed here in the alphabetical order:

- ageing (through genetic program/a major risk factor for old age polipathology)
- hyperthermia (reactional or therapeutic – fever versus pathological – burns, insolation)
- inflammation (reactional versus pathological)
- neuroplasticity (learning versus pathological reorganization)
- pain (reactional – a physiological, bioprotective alarm response to nociceptive stimuli versus pathological, neuropathic pain)
- stress (eustress – a vital stimulus for the antientropic behaviour of the organism versus distress – pathogenic stress) (4)

From a medical and biological point of view, the psychological distress influences the hy-

pothalamic-pituitary-adrenal axis (which is connected and modulated by suprathalamic, including centers), leading to the release (as a neuro-endocrine mechanism of the "adaptation syndrome") of a large number of hormones: CRH (corticotropin-releasing hormone – from the paraventricular nucleus of the hypothalamus), somatotrophins (from the anterior pituitary): ACTH (adrenocorticotrophic hormone), GH (growth hormone), PRL (prolactin), hormones from the posterior pituitary: ADH (antidiuretic hormone), respectively catecholamines (epinephrine and norepinephrine, from the adrenal medulla), cortisol (from the adrenal cortex), insuline (from pancreas), as well as neurotransmitters (serotonine, GABA – gamma-aminobutyric acid) and neuromodulators (endorphins, enkephalins), resulting in a series of alterations of humoral parameters and/or organ functions (14).

All these changes induced by distress make one prone to "organic body damage" (15), generate major risk factors for psychosomatic syndromes and diseases.

Hence, gastroduodenal ulcer disease, irritable bowel syndrome, arterial hypertension, some forms of cardiac ischemia and/or ischemic strokes, diabetes mellitus, amenorrhea, etc. can be considered as such conditions. These add to a long list of disorders also related to distress/overload that alter the QoL and/or the work capacity/professional performance: neurovegetative dystonias (including spasmophilic phenomena, thermoregulation disorders, nycthemeral rhythm alterations with, in a vicious circle, disturbances of the circadian hormonal secretion biorhythms), neurastenic/neurotic syndromes, deconditioning syndromes, etc.

On the basis of the extremely tight and intricate morph-functional immune-neuro-endocrine connections/feedbacks most of the substances released by stress alter the functionality of the immune system. A specific example is serotonine that seems to act, in this context, directly on the lym-

phocytes with repressive effects on some morph-functional changes which normally take place before their blastic transformation (Rozman, cited by 14). In addition, it is currently recognized that mental distress, repeatedly present in everyday life, produces in time, in both, experimental and clinical situations, an activity decrease of NK (natural killer) lymphocytes, a decline in interferon production, a lowering of IgA (immunoglobulin A) serum titers and consequently leads to the alteration of endogenous antineoplastic surveillance, as well as to reduction of the organism's resistance to infections (14). In this respect, an example of a disease that may also be considered psychosomatic disorder is the chronic fatigue syndrome.

Psychic (di)stress – including the one induced by chronic/neuropathic pain – results in lowering of the mass of cortical-thalamic gray matter (and/or medullary neuron apoptosis – observed in rats with such sufferance) by an excitotoxic mechanism leading to functional overload atrophy – "overuse atrophy", associated with destructive, inflammatory phenomena (16). The (di)stress of intense lumbar chronic pain can diminish the brain volume by 11% in one year, more precisely by 1.3 cm<sup>3</sup> of gray matter – equivalent to 10-20 years of normal ageing. This fact highlights the psychosomatic link – "the mind-body connection" – manifested in both, eustress and distress. The latter, especially when prolonged/chronic, affects the high complexity levels of the organization of living structures, the molecular genotype including. Chronic distress appears to be an accelerator of telomere shortening; telomeres are intimate markers of ageing, but they are closely related with longevity, as well as with various pathological conditions. At an intimate level, chronic stress induces cumulative lesional phenomena, with repercussions extending to the DNA level. These have micro- and macro- metabolic consequences – including an increased risk of developing obesity in the second half of life – and on the processes of replication/

ageing/longevity, as well as the oncogenic skidding (17), all primarily by:

- oxidative stress (including unbalanced diet, quantitatively and/or qualitatively)
- increased telomeric activity/metabolism – with accelerated shortening
- reduction of telomerase activity

A clinical study showed that healthy, premenopausal women who reported the highest levels of perceived stress had shorter telomeres by the equivalent of at least one decade of additional ageing, in comparison to those who reported low levels of stress (18).

To date, there are around 200 genes, among which over 150 recently identified, considered to interfere (whose mutations affect telomere length) with the telomere metabolism/length: 2/3 shorten and 1/3 lengthen them; they are generically called “clock” genes, as they control – in a complex and sometimes, apparently controversial/dialectical way – ageing and, respectively, longevity.

There is a definite connection between stress and ageing: by accelerated telomere shortening – linked with longevity but also with illness, especially cancer, through telomere length/metabolism.

It has been documented that mental distress is associated with premature mortality and increased risk of coronary heart disease, elevated blood pressure, type 2 diabetes (19), and disability, while positive affective states are protective (20, 21), though the pathways leading to these effects remain still poorly understood. Low levels of stress are associated with lower heart rates, lower cortisol, lower plasma fibrinogen levels and smaller fibrinogen stress responses; inversely, high levels of psychological stress are associated with accelerated heart rates, higher cortisol levels (increasing the risk for arterial hypertension and type 2 diabetes), higher plasma fibrinogen (leading to an elevated risk of atherosclerosis and ischemic heart disease)

and intense acute phase response (APR) (20, 21).

## The QoL of the elderly in the contemporary society

Starting, especially with the last quarter of the past century, there is an international trend towards connecting and integrating healthcare/medical assistance with social care/social solidarity endeavors. As a result, there emerged the modern idea of providing and maintaining an adequate QoL for all society members, including the elderly. The first decade of this millennium was dedicated by the WHO, among other subjects, to the QoL.

As a corollary to these contemporary concepts and realities, in 2001, after more than 20 years from its precedent model (The International Classification of Impairments, Disabilities and Handicaps – ICIDH) (22), and following almost a decade of preparation, the WHO published The International Classification of Functioning, Disability and Health (ICF-DH) (23).

ICF-DH is an universal, trans-cultural system, taking into account not only the medical/health aspects, but also the social ones and, thus, it holds a large applicability from healthcare-related activities (prophylaxis, medical therapy, rehabilitation, biostatistics, research, medical management/health strategies) to the ones related to social care and social policy, environment adjustment and protection, advocacy – to increase the QoL and/or legislative measures (including those related to protection of the individuals with special needs, social reinsertion, professional/vocational reorientation, etc.).

In conclusion, ICF-DH is designed to allow through its implementation the syncretic and integrative analysis and monitoring of health and well-being states at an individual level through the use of core sets, as well as at a population (“macro”) level, by compar-

ing the results of various disability pattern analysis, between (groups of) statuses from different pathologic entities.

Statistical reports show that the average life expectancy of Europeans has increased over the last few decades (approximately by 0.25 years annually) while their number of healthy life years (HLY – the lifespan spent in good health) has remained unchanged (24, 25). Thus, it can be inferred that the average lifespan spent in poor health has been increasing. The European Union (EU) takes on a significant challenge – to increase the number of HLY by two years by 2020. Maintaining a good QoL in elderly, from the point of view of physical well-being, entails effective prevention, early detection (using appropriate assessment tools) and timely medical treatment of all disorders that may lead to functional and/or cognitive decline.

To optimize the social and psychological well-being of the ageing individual, active and independent living should be promoted and extended for as long as possible, social inclusion should be maximized (e.g., by including the elderly in adequate group activities at the community level) and assistance with daily living should be provided for those with functional and/or cognitive impairments. To achieve these goals, education/counseling of the patients, community and healthcare workers may prove helpful; for example:

- patient and caretaker education/counseling (information leaflets; e-learning)
- qualification courses on the management of the elderly, for general practitioners and specialist doctors
- courses on the psychology of elderly care
- teaching courses for community care volunteers
- qualification courses for nurses/creating of management teams for elderly home and/or community care, etc.

However, the current global financial crisis inevitably alters the quality of life of many

individuals, especially of the elderly, mainly (but not exclusively) its fourth dimension: the economic one. Under these conditions, we can only hope that the holistic and idealistic definition of health, adopted by the WHO more than 65 years ago, will maintain its contemporaneity and applicability – from before the recession – at least in the more developed countries/economies.

The number of employment opportunities for people with disabilities tends to decrease during the economic crisis, leading to unwanted increase in the number of individuals receiving disability benefits. Moreover, the ageing phenomenon in the European population brings about a need for elderly people to remain professionally active up to an older age in order to avoid a decline of productivity coupled with the accumulation of the financial burden of pensions (24).

## The contribution of Physical and Rehabilitation Medicine (PRM) to QoL/wellness, active and healthy ageing

It is clear that the medical field contributes only partly to the QoL/wellness through its three types of chrono-interventional measures:

- primary prophylaxis (elimination or mitigation of risk factors)
- secondary prophylaxis – medical therapy (aimed at preventing complications, relapses and/or chronicization)
- tertiary prophylaxis – medical rehabilitation (aimed at diminishing dysfunction/chronic disability/invalidity)
- PRM is particularly concerned with the enhancement of the QoL and a large array of tools is available, applicable in order to improve the functional capacity and related to QoL:
- balneotherapy, climatotherapy, health tourism
- physical medicine/physiatry, including kinesiology

- assistive technologies and devices
- rehabilitative care/nursing (RC/N)

The great importance of anti-stress/relaxation, active prophylactic, “mise en forme”/maintenance, rejuvenation/anti-ageing balneotherapy courses in modern society has already been revealed by the above discussion. Regardless of how healthy individuals will be after “the new revolution in regenerative medicine”, there will remain some fundamental human behavioral traits whose optimization will continue to be essentially necessary.

The main types of methodological sequences used in anti-stress/wellness balneotherapy courses are the following:

- techniques, possibly combined of extrinsic and especially intrinsic relaxation
- kinetic prophylaxis, mainly targeting: general optimization of the muscle and joint function – possibly with some analytical loco-regional accents (e.g., muscle and posture rebalance of the cervical region, associated with contracture relaxation in the middle trapezius muscles for office workers, requiring for several hours a day monotonous position of the head – working at the computer with the eyes focused on the screen or excessive TV watching), increasing the physical endurance, and possibly – if required and no contraindications present – programs to improve the somatic image, “body former”/aesthetics of the body
- for the overall objectives of relaxation and maintenance/“mise en forme”, stated above, the following are recommended: land therapy, recreational occupational therapy and various types and forms of massage – appropriately, individually prescribed
- various procedures of physiotherapy, including water-based, and climatotherapy, exploiting in a professional manner the natural physical/chemical therapeutic agents
- nutritional education and assistance
- individual and group psychotherapy

- health education
- biotrophic treatment (rejuvenation/“anti-ageing”) general and/or cosmetic (for the presenescent and elderly)
- alternative procedural sequences, such as: chromotherapy, aromatherapy, and/or melotherapy may be used in a complementary way

It is possible and advisable to combine these sequences with recreational activities, like cultural events, tourism and/or sports.

It should also be underlined in this context, the particular value of sanogenous natural factors such as: the sedative climate of the hills, the lack of pollution, including the phonic one and the aesthetic valences of the landscape.

All the above recommend balnear resorts – true “ecologic niches” – as optimal areas for carrying out anti-(di)stress, active prophylactic/rest, fitness/“mise en forme”/wellness, maintenance/, rejuvenation (anti-ageing) therapy courses.

The main Romanian climatic health resorts appropriate for this purpose are: Călimănești-Căciulata-Cozia, Olănești, Govora, Felix, Herculane, Eforie Nord, Mangalia, Techirghiol, Covasna, Sovata, Slănic-Moldova, Sinaia, and respectively Otopeni – the clinical premises of the National Institute of Gerontology and Geriatrics “Ana Aslan”, Bucharest.

In recent years a modern concept is emerging, based inclusively on the experience and many contributions in the field of the Romanian medical school: complex “gerontoprophyllaxis” by physiatric, balnear, hygienic-behavioral and pharmacological means. The subject is quite vast, exceeding the current approach framework. This concept is extended, incorporating the sustained efforts to fight on daily basis the distress. Specifically, it involves daily, dynamic exercises – tailored based on regular, individual clinical and functional assessment of the exercise





capacity, such as running (jogging) and/or cycling, coupled with a balanced diet (without excesses and avoiding highly processed aliments) and taking once or twice a year, a course of anti-(di)stress balneotherapy, lasting for 10–14 days.

Corollary of this current synthesis on such an important subject matter – the strategic attention of the European Commission (EC) is to be underlined when considering “Frailty in old age, a public health concern at EU level” and, accordingly, supporting the “European Innovation Partnership on Active and Healthy Ageing” (EIP-AHA) – with the involvement of members of the Action Group on Frailty and Functional Decline and respectively of the I<sup>2</sup>FRESCO project on integrated interventions for frailty prevention in older people/patients (the Comité Permanent/Standing Committee of the European Doctors (CPME), including in this field, very contributive, specifically by the sustained activity of its Working Group on Active and Healthy Ageing).

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*Prof. Onose G, MD, PhD, MSc<sup>1,2</sup>,  
Univ. Assist. Haras MA, MD, PhD<sup>1,2</sup>,  
Prof. Sinescu CJ, MD, PhD<sup>1,2</sup>,  
Univ. Assist. Daia CO, MD, PhD<sup>1,2</sup>,  
Andone I, MD, Postgrad<sup>3</sup>,  
Onose VL, MD<sup>3</sup>,  
Assist. Prof. Capisizu A, MD, PhD<sup>4,4</sup>,  
Assoc. Prof. Grigorean VT, MD, PhD<sup>4,2</sup>,  
Assist. Prof. Ciobotaru C, MD, PhD<sup>5,6</sup>,  
Sandu AM, MD, PhD<sup>2</sup>,  
Assist. Prof. Blendea CD, MD, PhD<sup>7,8</sup>*

*1 (State) University of Medicine  
and Pharmacy “Carol Davila”, Bucharest.  
2 Teaching Emergency Hospital  
“Bagdasar-Arseni”, Bucharest.  
3 Metrorex, the Medical Service, Bucharest.  
4 St. Luke Hospital for Chronic Diseases,  
Bucharest.  
5 Ovidius University, Constanta.  
6 County Teaching Hospital, Constanta.  
7 Titu Maiorescu University, Bucharest.  
8 County Teaching Hospital, Ilfov.*

*E-mail: geluonose@clicknet.ro*

## Activities of Environment Caucus in the WMA

The Environment Caucus was organized with the purpose of exchanging opinions among WMA members and related bodies regarding WMA's future activities related with "health and the Environment", when the working group devoted to the topic completed its term as of the Council Meeting in April 2011. Since its first gathering at the 191<sup>st</sup> Council meeting in April 2012 (Prague, Czech Republic), about 15 constituent members have participated in the caucus held in conjunction with WMA Council Session and General Assembly.

Prof. Vivienne Nathanson of the BMA and Prof. Peter Orris of the University of Illinois have been contributing as advisors and myself is the coordinator. Ms Clarisse Delorme from WMA secretariat provides us support.

The main activity of the Environment Caucus is to share global trends and conferences information regarding environment, to identify common topics of interest and to discuss follow-up measures. It aims to share the various wisdom and experience of each member and observer and to encourage free exchange of opinions by adopting such an informal setting.

Major themes discussed at the Environmental Caucus with regards to the direction of future WMA activities include the role of physicians and of constituent members in greenhouse gas reduction, promoting research on the health co-benefits of countering climate change and expansion of green hospitals and clinics.

The Environment Caucus also monitors how each member is utilizing the environment-related policies adopted by WMA and studies ways of encouraging their utilization. As a part of such efforts, a survey of member NMAs was conducted in 2012. According to the survey results, members agreed that WMA must continue to take an active stance in tackling environmental problems. A wide majority stated that they use WMA's environment-related policies in developing their own policies or in raising awareness among their members. Constituent members expressed the opinion that WMA must continue to place top priority on climate change issues and provide guidance on environmental issues to medical professionals. The WMA is also expected to set the example by making WMA meetings greener.

Based on such feedback, the Environment Caucus plans to diversify the direction of

WMA's activities on Environment and as a first step, to focus on promoting and encouraging the increase of green hospitals in each country. Furthermore, the Caucus would like to work on a WMA policy on pollution or environmental degradation from energy sources by collecting data and conducting discussions.

Korea, an active participant in the Environment Caucus, established the Korea Society for Green Hospital last June as the focal point of information exchange and cooperation for growth of green hospitals. This Society also plans to collaborate with international organizations such as the WMA in the future.

To strengthen the network for Environment Caucus' activity, a green page is established on the WMA website devoted to environmental issues, so that environment-related activities of WMA and each constituent members can be posted and various information can be shared. We encourage all members to actively use this section on WMA website and also eagerly seek your participation and advice in the future activities of the Environment Caucus.

*Dong Chun Shin, MD, PhD  
Prof. Dept. of Preventive Medicine  
Yonsei Univ. College of Medicine  
Chair, Executive Committee  
of International Relations  
Korean Medical Association*

## UN Climate Change Summit

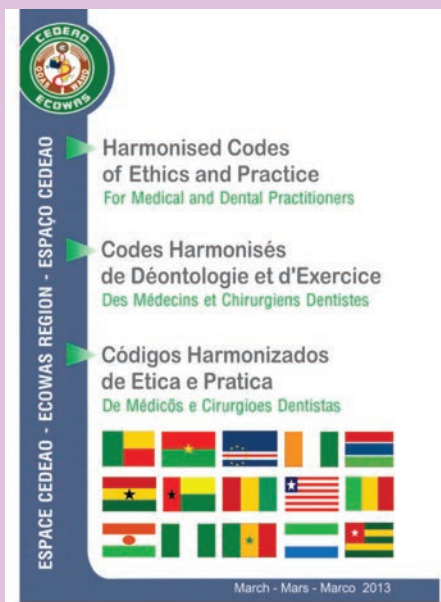
**(<http://www.cop19.gov.pl>) will take place 11–22 November 2013, in Warsaw**

The WMA together with other health and medical organizations are working on the preparation of a second Climate and Health Summit in parallel to the official conference. This will provide an opportunity to share progress on the development and implementation of strategies to build resilience to the impact of climate change on health.

Global Climate & Health Summit that will take place on the 16<sup>th</sup> of November, in parallel to the official Conference Climate Change Conference.

The Summit is co-organised by a range of organizations working on health and environmental matters, under the auspices of WHO. The WMA is one of the organizers of the event. Prof. V. Nathanson (BMA), who is co-chairing the Environment Caucus together with Dr. DC Shin, will represent WMA at the meeting.

More information: <http://www.climateandhealthalliance.org/summit/summit-programme>



In the West African Region regulated by the Economic Community of West African States (ECOWAS), medical integration is evolving favourably. (15 countries, 03 languages – population # 300 million) Recently, April 3, 2015, the Assembly of Health Ministers adopted in Praia (Cape Verde) more documents to improve the effective integration;

- The Harmonised Codes of Conduct and Exercise doctors and dentists (applicable in 2015).
- The Training Curricula General Medicine
- The Curricula harmonized degrees (medical specialties)

In Côte d'Ivoire, after a dozen years of civil-military crisis marked by an episode of armed conflict in 2011, the National Order of Physicians of Côte d'Ivoire (ONMCI) decided to write a **“white paper”** on the Rights and Duties of Physicians face to violence, in period crisis and armed conflicts in the exercise of profession.

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## Medical West African Region

This book recalls the summary:

1. "Respecting and protecting health care in armed conflicts and in areas not covered by international humanitarian law situations" – technical specifications ICRC – International Humanitarian Law in relation to The Geneva Conventions of 12 August 1949 and their Additional Protocols developed June 8, 1977, with the duties and expectations of physicians.
2. The general guidelines of the World Medical Association (WMA) in crisis and armed conflicts.
3. The Code of Conduct (WMA): Duties of physicians in crisis and armed conflicts.
4. The position of the World Medical Association Statement on Violence in the Health Sector on the part of patients and people close.

The characteristic of this book (A5) which will be freely available to the Physicians is that it contains several testimonials from doctors and family doctors victims of these sad events in the life of the Nation. Particular emphasis was placed on the prevention of violence by reactivating Security Observatory of Physicians in the course of their professional practice; structure that will be responsible for identifying all the verbal and physical abuse, by making available medical Corps as a whole inspired questionnaire of our colleagues from the College of Physicians of France fighting this unfortunate phenomenon in their country.

The West African region is unfortunately not preserved by other episodes of crises



and armed conflicts which is why the National Order of Physicians of Côte d'Ivoire (ONMCI) will make this book available to the West African Health Organization (WAHO) for translation in English and Portuguese for the 15 countries of the region.

*Dr. AKA Kroo Florent*  
President of National Council of the Order  
Physicians in Côte d'Ivoire

