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Editorial

The business of manufacturing is usually good for the consumer and good for the economy. However, not all manufactured or produced goods are safe. One of the functions of government is to regulate the safety of products. When the negative effects upon the economy of putting a stop to a dangerous practice takes precedence over protecting the health of the population and the government takes no action, doctors have an obligation to step in. This issue was brought to light with a recent problem of melamine.

Melamine is an industrial chemical that is used to manufacture certain plastics. It was added to pet foods produced in China and to animal feed. Because it has high nitrogen content, it was used in China to increase the apparent protein content of foods when simple nutritional tests were done. Adding melamine to powdered milk changed the texture, thickness and flavor of the milk. Adding melamine was a common, though illegal practice in China.

The first reported incident of toxicity from melamine in pets came in 2007. In humans it was recently revealed that at least four infants have died, 13,000 hospitalized and about 50,000 affected by ingesting melamine-tainted powdered milk in China. Nephrolithiasis and renal dysfunction are the most common problems reported from excess melamine ingestion. Melamine has been found in powdered

baby milk and some dairy and candy products produced in China; it has also been found in eggs, probably as a result of its being added to animal feed.

Some of the revelations about melamine have come from Taiwan, which imports products from China. Because of political considerations, Taiwan is not a member of the World Health Organization. Since they share a common language, Taiwan can be an important source of information about health practices in China that might not otherwise be revealed.

Just as in the past, with issues such as alcohol use and smoking, doctors have led the battle to eliminate public health hazard in the face of economic forces to the contrary. In the coming years, the fight against alcohol abuse will take center stage. It remains to be seen if organizations such as the World Health Organization, which receives funding from businesses that profit from the sale of alcohol, will be effective leaders in this battle. Doctors, who put patients' well-being foremost and have no conflict of interest should be active in this effort and help lead this campaign.

A bad message. On the cover of "Times" 24th of November Barack Obama is smoking a cigarette.

*Pēteris Apinis, M.D.
Editor-in-Chief of the World Medical Journal*

Dr. Ron Davis, former Council Member of WMA, and recently Adviser, Immediate Past-President of the American Medical Association and strong supported of our work, passed away on November 6th, 2008.

We have lost a strong advocate for public health, a fantastic colleague, teacher and friend. He has been a skilled scholar, enlightening us with lectures and advice – last at our seminar in Seoul, just a couple of weeks ago.

Working with him until his last days, we will remember him for what he worked and stood for – Health for all people.

Our thoughts are with his family.



Financial Crisis may Hasten Move to Shift Responsibilities Away from Doctors



*Dr. Yoram Blachar,
President of the World Medical Association*

It is an honor and privilege for me to serve as the president of this auspicious organization that unites the world's doctors and represents us all. Advocating on behalf of doctors and patients around the world is a pinnacle any physician committed to the public service can aspire to and I am so fortunate to be able to realize my aspirations in this realm. I am extremely grateful to the members of the WMA who placed their trust with me and allowed me the privilege of serving this very vibrant and important organization.

The WMA has come a long way since its establishment in Paris in 1947. It has grown, evolved and flourished, and it has always remained true to its values and founding principles. (Incidentally, Israeli doctors have participated in the WMA since its establishment, initially as representatives of the Palestine Jewish Physician Association.) The need for an international organization to unite physicians around the globe existed in 1926 and continued to the era of the Second World War; this need was amplified by the horrendous experiences the world endured throughout that war. In light of the inconceivable events that occurred and the radical breach of any sort of humanitarian or ethical code, as revealed during the Nuremberg trials, it was evident that the first task of the WMA would be the formulation of an

ethical code for all the world's doctors. As the world became increasingly aware of the horrific use of human beings in experiments that held no regard for human life or basic human rights, it became the responsibility of physicians to assure we would never again take part in acts that do not benefit people. Out of this unthinkable past the Declaration of Helsinki was created and has since burgeoned to become one of the irrefutable cornerstones of physician conduct. The Declaration has withstood the test of time and scientific evolution because of our ability to modify and adapt it to developments in medicine and society.

Fundamental topics in medical ethics have been at the heart of the WMA's work and a core component of its activities from its inception. Many of the WMA's declarations – such as the Declaration of Tokyo, the Declaration of Malta, the Declaration of Madrid, and many others – have become the inalienable property of the medical community around the globe. Over time, with the surfacing of new dilemmas, physicians have been faced with new challenges in the fields of medicine and health. Consequently, discussions within the WMA have widened to include new ideas and changes in medicine worldwide. The field of medicine has undergone vast changes in the last century and these changes only accelerate as time passes. For example, penicillin was discovered less than 100 years ago and this discovery revolutionized the face of medicine. Today, it is difficult for us to conceive of a reality without antibiotics.

There have also been prominent changes in the quality of life. Most of the world has experienced a great improvement in its standard of living and in the quality of nutrition and hygiene. Alongside these changes have been social changes, such as the information revolution, electronic media and the internet, all of which have greatly increased the amount of information in the public domain. These changes have all contributed to a surge in patient em-

powerment and an ever evolving doctor-patient relationship. The accessibility of information and remarkable developments in medicine have brought both increased transparency and increased expectations.

However, economic factors increasingly infringe upon the aforementioned advances in medicine. Many countries cannot afford to pay for modern medicine so the populations of these countries do not benefit from some of the most basic advances. The outcome of this situation is evident in health indices and indicators. Additionally, it has become increasingly apparent that there is no country able to thoroughly fund medical care from its public budget, and, as a result, a new reality has been created in which different levels of medical care are provided, depending on the patient's economic standing. This is true even in countries with public health insurance. There is a growing trend of transferring the funding of medical services from the public account to the private pocket. Thus, whoever has the ability to privately purchase what the state does not provide will receive excellent, up to date, care and whoever does not, will receive a lower level of care in accordance with his or her ability to pay. This situation creates a conflict of the most basic medical, ethical principles with economic factors.

The new reality in which we find ourselves results in an emphasis on disparities in the access, timeliness, and level of medical care. Health disparity is a topic that has always existed but has become more critical with its effects becoming so profound, making it a topic worthy of being central to the agenda of the WMA. Health disparities are evident both in comparison among different countries as well as within different regions of a single country. It is sufficient to measure standard parameters of health quality – such as infant mortality rate, life expectancy, number of hospital beds in relation to the population, and number of modern technological devices – to realize that this phenomenon will soon become intolerable. The lower one's socio-economic status or educational level, the more extreme the phenomenon becomes. The topic of health disparities includes within it ethical aspects, principles of doctor-patient relationships, the definition of a physician's



role in society, and the issue of human rights. This crucial topic requires us to formulate an agenda. The WHO has recently declared that, "Health disparities costs lives." It is our responsibility as leaders in health to act on this crucial topic.

Recently, a global economic tsunami has invaded our safe havens. It would seem that the global outlook of a free economy completely subject to the vagaries of the market has not withstood the test of time and has collapsed. The impact of this crisis on the global level is still unclear, though it is clear that no national economy has been left unaffected. The vital question for us will be how this economic crisis, combined with the anticipated global recession, will affect the world's health systems. Especially in countries where health insurance is an integral component of employment conditions, the recent waves of layoffs will make it difficult to escape disastrous consequences. It is our duty both in our individual national organizations as well as on the level of an international medical association to be aware of these developments so as to moderate their destructive impact and shield the health care system as much as possible. These developments will force countries without public health insurance to understand that their health services cannot be controlled by bankrupting market forces and free economy, and social-welfare states will understand that the recent inclination of governments towards privatization threatens the equality and health of their citizens.

As members of the WMA we are also social leaders and, thus, we have the responsibility of addressing a wider scope of issues affecting health, one of which is the subject of armed conflict. Many areas of the world are involved in military conflict; some of these are more recent while others have roots so deep that all attempts to mediate between the extreme positions are unsuccessful. This reality claims the lives of many victims and leaves others with physical or mental impairments. Many organizations around the world, including the UN and the EU, are involved in attempts to tone down of the level of violence between the disputing countries. There are also humanitarian organizations manned by physicians – such as Doctors Without Borders,

the Taiwanese Tzu-Chi organization, and Physicians for Human Rights – that act as pacifying forces through the medical care they provide. The WMA is in a unique position in that it has both the ability and positioning to try to bring conflicting parties to the discussion table via encouragement and dialogue with our organization. One of the regions involved in an ongoing conflict is my own. The Arab-Israeli conflict has existed for many years. However, it is important to note that Israel does have peace agreements with two countries with which Israel had been at war for many years: Egypt and Jordan. There are full diplomatic relations between Israel and Egypt and between Israel and Jordan, as well as open borders. There is still much work to be done to achieve peace between Israel and other countries, such as Syria, Lebanon and especially the Palestinian Authority. I plan to make every effort to turn health and medicine on an organizational level into a bridging force so that maybe, as naïve as it sounds, the peace process in our region can be advanced as it so desperately needs to be. I plan on being instrumental in the inclusion of NMAs who are not yet members or active in the WMA, so as to allow a dialogue to begin under the auspices of the WMA, with the WMA mediating based on our common profession. This profession spans different nationalities, viewpoints, and is common to all doctors, whose purpose it is to bring help and healing.

There is another topic which concerns all of us as health leaders. The expected shortage of physicians will almost certainly change the face of medicine. This threat is real and tangible; even today the world lacks over 4 million health workers, according to WHO data. This shortage is not homogenous. There are areas, such as Africa, where the shortage is overwhelming, and other areas where the shortage is barely felt. The genuine solution to this shortage is to increase the number of physicians, install solid long-lasting retention plans for health care providers, and solve the problem of physician recruitment from poorer areas to areas where the shortage is less severe. The proposed solution of task shifting is not a real solution. Filling the positions of professionals with partially trained individuals is a temporary answer. It is extremely dangerous to view task shifting

as a genuine solution since this will only prevent us from finding a real solution. As long as task shifting is solely a temporary solution meant to fill a gap that would otherwise remain empty and provide some sort of answer to the world's critical need for medical care it is justified. However, while implementing task shifting we must work towards a lasting solution that deals with the root of the problem. We have a shared responsibility to act and convince policy makers of this need for real solutions.

Some of the previously mentioned topics of health discrepancies, privatization of health services, armed conflict, and shortage of health workers have already begun to be dealt with by the WMA, some of these topics have been awaiting our attention, and some of these topics have just emerged. Such is the way of the WMA, with each of its presidents "picking up the torch" and continuing some of the tasks of their predecessors, taking on new tasks, and leaving some tasks to be completed by their successors. I intend to continue the work of Dr. Snaedal, especially on the topics of task shifting and health disparities, both on the policy level of governments and NMAs as well as on the level of the practice of doctors, with every individual doctor taking a role in the battle against disparities in health. Additionally, I intend to make attempts to engage in medical diplomacy. Hopefully, these attempts will be successful in making a difference to those people living in areas of conflict.

The issues to be addressed are large and complex and this can not be the task of any one individual or even group of people. In order to bring about a lasting contribution that brings about true change, every member of the WMA must take part. Only by working together can we make a difference and inspire others to join us in working to fulfill our goals. It is not our responsibility to finish all the work that must be done, but we are not at liberty to shy away from it.

I conclude with a statement from Maimonides' Physician's Prayer, which reminds us all that the patient must come first. "May I never forget that the patient is a fellow creature/May I never consider him merely a vessel of disease."

Revising the Declaration of Helsinki



John R. Williams, Ph.D., Ethics Advisor, World Medical Association, Adjunct Professor, Department of Medicine, University of Ottawa, Canada

Introduction

On October 18, 2008 the WMA General Assembly, meeting in Seoul, South Korea, voted overwhelmingly to adopt a new version of the *Declaration of Helsinki* (DoH). The vote marked the end of an 18-month revision process that involved extensive consultation with stakeholders and careful consideration of their suggestions for changes. The final document is available for viewing on the WMA website: www.wma.net.

This article will describe the 18-month revision process, the main issues that were considered and the final resolution of these issues. It will conclude with some suggestions for future reviews of the DoH.

Why Revise the DoH

The DoH has been amended several times since its adoption in 1964. An extensive revision process was begun in 1997 and concluded with the approval of a new version by the WMA General Assembly in October 2000. Although the Assembly vote in favour of the new version was almost unanimous, it quickly became apparent that some of the paragraphs, especially #29 dealing

with the use of placebos in clinical trials and #30 on access to the benefits of research, were unclear and/or contentious. The addition of explanatory notes of clarification to these paragraphs in 2002 and 2004 did not resolve these difficulties. Another attempt was needed.

A second reason for revising the DoH was the changing environment of medical research. In response to widely publicized scandals involving the testing, approval and marketing of certain drugs that were later shown to be unsafe, there have been increased demands for greater transparency in medical research and stronger protection for research subjects. The DoH's statements on issues such as these required clarification and, perhaps, strengthening.

An additional reason for undertaking a revision was to see whether there were gaps that needed to be filled, for example, ethical principles for research on human materials and data. A final reason was to remove inconsistencies in terminology within the DoH as well as inconsistencies among the three official language versions.

Scope of the Revision

The 2000 version of the DoH was a major revision of the previous (1996) version and included a significant restructuring of the document. In contrast, the most recent revision was intended from the beginning to be relatively minor in scope. In initiating the revision process at its May 2007 meeting, the WMA Council wanted to "identify gaps in the content but avoid a complete re-opening of the document." There had been general approval and acceptance of the 2000 version, apart from paragraphs 29 and 30, and Council felt that the remainder of the document required at most some fine-tuning. As for the two controversial paragraphs, it seemed desirable to integrate the notes of clarification into the body of the document

but any substantive change to the 2000 positions would be unlikely to receive the 75% majority vote at the General Assembly that is required for adoption or amendment of an ethical statement.

Process

The previous revision took three and a half years, followed by a further four years developing the two notes of clarification. In contrast, the May 2007 Council meeting approved a one and a half year timetable for this revision. It was to be guided by a five-member workgroup and would include three rounds of stakeholder consultation.

The workgroup was made up of representatives from the National Medical Associations of Brazil, Germany, Japan, South Africa and Sweden. The chair was Dr. Eva Nilsson-Bågenholm of Sweden, who was also the chair of the WMA Medical Ethics Committee, and the coordinator was Professor John Williams from Canada, who had recently retired as WMA's Director of Ethics.

The first consultation took place from June to August 2007. It consisted of a request for suggested changes to the DoH that was sent by the WMA Secretariat to National Medical Associations and international research, medical, health and ethics organizations. National Medical Associations were asked to distribute the request for suggested changes to organizations in their own countries and to collate the responses for transmission to the workgroup.

39 responses were received in response to this request, some many pages in length. They were considered by the workgroup and subsequently by the WMA Medical Ethics Committee at its meeting in Copenhagen in October 2007. The Committee's recommendation, subsequently endorsed by the Council, was for the workgroup to prepare a draft revision of the DoH for further consultation with stakeholders and to report back to the Committee at its May 2008 meeting.

Following the Copenhagen meetings the workgroup completed its draft revision, which was distributed for comment to stakeholders in early November. This round of consultation elicited 46 responses, including some from NMAs that represented the consolidated comments of numerous national organizations. During the last week of February the comments were collated and a list of controversial issues was developed to serve as the agenda for a stakeholders' workshop in Helsinki, Finland in March. Immediately after the workshop, the workgroup met to decide what changes to the November 2007 consultation draft should be made in consideration of the written comments and the workshop discussion. A revised draft was prepared and discussed by the Medical Ethics Committee and Council at their May meetings, where several changes to the draft were made.

A third round of consultation, this time on the amended revised draft, took place during the summer of 2008. It included the posting of the draft and an electronic response form on the WMA website and stakeholder workshops in Cairo, Egypt and Sao Paulo, Brazil. The workgroup met in Sao Paulo immediately after that workshop and during the next two weeks it considered all the comments that had been received (80 submissions) and prepared its final draft for the October meetings of the Medical Ethics Committee, Council and General Assembly in Seoul.

Issues

From the three rounds of consultation the WMA received suggestions for changes to every paragraph of the DoH as well as for additional paragraphs on several topics. Some respondents felt that the document should be reorganized in a more logical order. Others wanted a preamble that would clarify the scope and status of the document, including whether it applied only to physicians or to all researchers. Still others asked for a fuller treatment of certain topics, for example, vulnerability, placebos or publication of research results. Terminology was another issue, for example, 'medical research'

vs. 'biomedical research', 'research subject' vs. 'research participant', 'method' vs. 'intervention', 'must' or 'should'. Conversely, with very few exceptions such as paragraphs 29 and 30, there was general agreement among respondents that the DoH's positions were basically correct and in no need of fundamental change.

Suggestions for additional topics included the following: conflict of interest; research involving human data, including access to this data; access to participation in research by previously excluded or underutilized populations (e.g., children and pregnant women); international research requirements; waiver of the consent requirement for some epidemiological studies; individual limits on participation in clinical trials; methodology in prevention trials; implications of research studies for public policy; responsibilities of editors; insurance coverage; consent for use of personal data in publications; consent for reuse of personal data in other studies; and access to the results of research.

Outcome

In evaluating these suggestions, the workgroup considered that its mandate required it to preserve the order and wording of the current (2004) version of the DoH except where clarification was needed or where significant gaps existed. Moreover, since the DoH is primarily a statement of ethical principles and not a handbook on how these principles should be applied, the workgroup did not consider it appropriate to make the document too detailed. Finally, the workgroup recognized that there is no consensus on a few of the issues treated in the DoH, especially placebo use and post-trial access, and did not make changes to the previous DoH position on these issues.

Although the workgroup decided against adding a preamble to the DoH, in the first two paragraphs it did specify more clearly the purpose, scope and intended readership of the document. It also added a sentence to the first paragraph cautioning against any interpretation of a paragraph that is incon-

sistent with the spirit and intention of the entire document (as had occurred with the 2002 Note of Clarification to paragraph 29).

The workgroup's final draft reinforces, in the face of considerable opposition, the DoH's longstanding principle of the priority of the individual research subject over all other interests. Far from discouraging medical research, however, this principle encourages access to research for both individuals and populations, especially those that are under-represented in research (an addition in new paragraph 5).

The workgroup was aware that in the 2004 version the paragraphs dealing with the research protocol and the responsibilities of research ethics committees went beyond statements of principle to include many details, but they decided not to delete any of these requirements because that might be interpreted as if the WMA no longer considers them to be important. Instead, these two paragraphs were reorganized to distinguish clearly between what should go in the protocol (new paragraph 14) and what is required of the research ethics committee (new paragraph 15).

Since medical research is conducted by other health professionals, e.g., nurses and dentists, as well as by scientists who are not health professionals, the role of physicians in such research, as described in old paragraph 15, needed clarification. The workgroup revised this paragraph (new #16) to separate and distinguish two issues: (1) who may conduct medical research – since medical research includes research on human materials and data, some of it can be done by individuals who are not members of a health profession, as long as they have the appropriate scientific training and qualifications; (2) what research requires supervision by a physician or other health professional – research on patients or healthy volunteers but not research on human materials or data.

A new paragraph 19 has been added that requires every clinical trial to be registered in a publicly accessible database before re-

cruitment of the first subject. The workgroup declined to elaborate on this principle since trial registries are still under development.

Another topic on which the previous version of the DoH goes into considerable detail is informed consent. Because of the great importance of this topic for research ethics, the workgroup did not omit any of the requirements in the previous version and even added some additional ones. It also distinguished more clearly the consent procedures for competent and incompetent research subjects.

One of the most difficult issues facing the workgroup was whether the requirements for research on human material and data should be the same as for other types of research on human subjects. It decided that the DoH should deal only with identifiable material or data and that consent for such research may sometimes be impossible or impractical to obtain or would pose a threat to the validity of the research. However, it is not up to researchers to decide this issue; they must justify their request for an exemption to the consent requirement to the research ethics committee (new paragraph 25).

As noted above, the most contentious issues during this revision process, as well as the previous one, were the use of placebos in clinical trials and access to the benefits of research once it is completed. The work-

group's first concern was to integrate the 2002 and 2004 notes of clarification on these paragraphs in the text of the DoH. It also wanted to preserve the substance of the previous version while clarifying the wording. Its proposed revision achieved both these objectives but did not resolve the deeply felt conflicting views on the two issues that were expressed in the written comments, at the stakeholders' workshops and, for the placebo issue, in the October 2008 meetings of the Medical Ethics Committee and General Assembly. The General Assembly adopted an amendment to the new paragraph 32 stating that "Extreme care must be taken to avoid abuse of this option", i.e., the use of placebos to determine the efficacy or safety of a new intervention where there is already a proven intervention. However, this did not satisfy all the delegates and the new version did not receive unanimous approval.

Conclusion

The DoH is regarded as "a living document" and will undoubtedly undergo further review and revision in the future. Although it is too early to determine the success of the latest revision, some lessons from this exercise may be valuable, not just for the WMA but for any organization engaged in policy review.

The three rounds of consultation were very useful both for soliciting input from those affected by the DoH's provisions and for

making the document known to a wider audience. By considering carefully the suggestions of the respondents and sending them each new draft, the WMA demonstrated that the DoH is not just an internal policy but rather a universal statement of medical research ethics.

Setting a tight deadline for the completion of a project such as this revision prevents it from being extended indefinitely. This is especially important for organizations such as the WMA whose policy making bodies meet just once a year.

In a short document such as the DoH, every word is important. In their discussions of the workgroup's drafts the WMA Medical Ethics Committee and Council wisely focussed on the principles and left it to the workgroup to come up with appropriate wording. The workgroup was able to do this efficiently through email exchanges.

Finally, since "the perfect is the enemy of the good," it is better to settle for incremental improvements than to try to achieve the absolute best. Both the structure and the wording of the revised DoH could undoubtedly be further improved but the workgroup felt, and the General Assembly agreed, that it is good enough for the time being, and is certainly an improvement over the previous version.

Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
 29th WMA General Assembly, Tokyo, Japan, October 1975
 35th WMA General Assembly, Venice, Italy, October 1983
 41st WMA General Assembly, Hong Kong, September 1989
 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
 53th WMA General Assembly, Washington, United States, October 2002
 (Note of Clarification on paragraph 29 added)
 55th WMA General Assembly, Tokyo, Japan, October 2004
 (Note of Clarification on Paragraph 30 added)
 WMA General Assembly, Seoul, Korea, October 2008

A. Introduction

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
 3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
 4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
 5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
 6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
 7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
 8. In medical practice and in medical research, most interventions involve risks and burdens.
 9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
 10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
- B. Principles for all Medical Research**
11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
 12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
 13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
 14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
 15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
 16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
 17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
 18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
 19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval by a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C. Additional Principles for Medical Research Combined With Medical Care

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
 - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
 - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy

or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.

35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

WMA General Assembly, Seoul 2008

More than 200 delegates from 42 National Medical Associations attended the 2008 General Assembly held at The Shilla, Seoul, in the Republic Korea from 15th -18th October 2008.

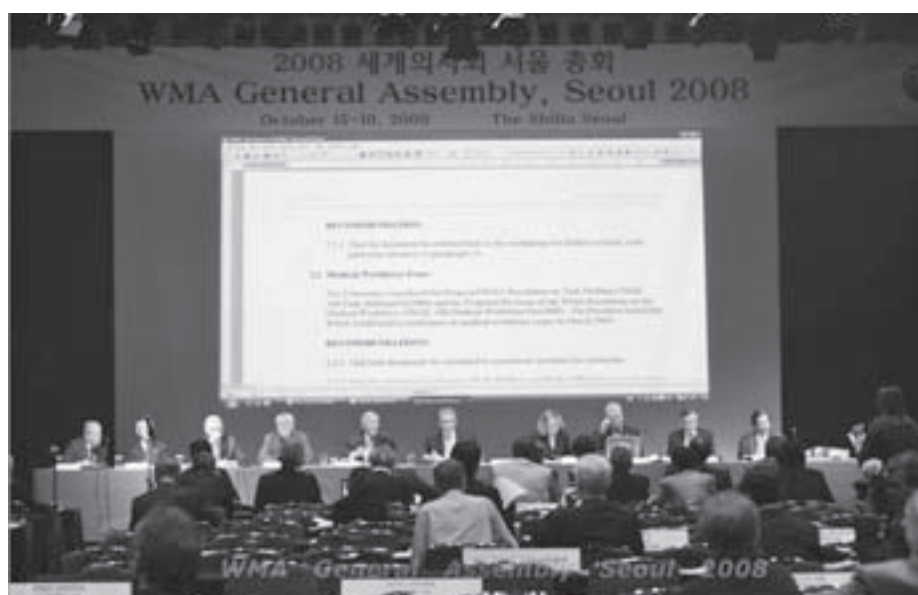
The four-day event, hosted by the Korean Medical Association in its centennial year, comprised three committee meetings, two Council meetings, the General Assembly, receptions, luncheon and evening seminars. During the event there were visits at various stages from the President and the Prime Minister of Korea, as well as the Minister for Health, Welfare and Family Affairs. The agenda for the formal meetings was one of the longest ever and inevitably the debates in committee, Council and Assembly were dominated by discussion on revisions to the Declaration of Helsinki.

When the Assembly met on the final day, under the brisk, but avuncular chairmanship of Dr. Edward Hill, it adopted a host of new and revised policies. In addition to the revised Declaration of Helsinki, there were documents on autonomy, on antimicrobial agents, mercury, sodium, the access of women to health, on capital punishment, nuclear weapons and anti-personnel mines, on the economic crisis, poppies and veterinary medicine.

Medical Ethics

The Assembly adopted three documents from the Medical Ethics Committee, which had been chaired by Dr. Eva Bågenholm. In addition to the revised Declaration of Helsinki, it adopted a new **Declaration on Professional Autonomy and Clinical Independence** and decided to name it the Declaration of Seoul. The document is a successor to the 1987 Declaration of Madrid, incorporating new issues based on

a document written by Dr. Jeff Blackmer from the Canadian Medical Association. The new policy states that unreasonable restraints on physicians' clinical independence imposed by governments and administrators are not in the best interests of patients and can damage the trust which is an essential component of the patient-physician relationship. However the document adds that physicians recognize they must take into account the structure of the health system and available resources. It declares that the central element of professional autonomy and clinical independence is the assurance that individual physicians have the freedom to





exercise their professional judgment in the care and treatment of their patients without undue influence by outside parties or individuals. Patients expected their physicians to be free to make clinically appropriate recommendations. Hospital administrators and third-party payers may consider physician professional autonomy to be incompatible with prudent management of health care costs. However, the restraints that administrators and third-party payers attempted to place on clinical independence might not be in the best interests of patients.

In a press statement, Dr. Edward Hill said: "In this new Declaration we are reaffirming the importance of professional autonomy and clinical independence. We see this not only as an essential component of high quality medical care and therefore a benefit to the patient that must be preserved, but also as an essential principle of medical professionalism."

The Assembly also adopted revisions to the **WMA Statement on Physician Participation in Capital Punishment**, which was first adopted in 1981 and then amended in 2000. The revised document urges NMA members to lobby actively their national governments and legislators against any participation of physicians in capital punishment. The Statement states that it is un-

ethical for physicians to participate in capital punishment in any way, including the planning and instruction and/or training of people to perform executions.

Socio-Medical Affairs

No fewer than eight policy documents emanating from the Socio-Medical Affairs Committee, chaired by Dr. J.L. Gomes do Amaral, were adopted by the Assembly.

The **Statement on Antimicrobial Drugs** updates Association policy adopted in 1996 following revisions prepared by the American Medical Association. The new Statement declares that antimicrobial agents should be available only through a prescription provided by licensed and qualified health care or veterinary professionals. It warns that the global increase in resistance to antimicrobial drugs has created a multifaceted public health problem of crisis proportions with significant economic and human implications. It also says that the use of antimicrobial agents as feed additives for animals should be strictly restricted to those antimicrobials that do not have a human public health impact. The Statement contains a warning that there is substantial misuse and overuse of antimicrobial agents, inappropriate prescribing, and poor

compliance with antimicrobial regimens by patients. The Association plans to continue to work with George Mason University in Virginia, USA to monitor and develop this issue.

Three new Statements were adopted. The **Statement on Reducing the Global Burden of Mercury**, initiated by the American Medical Association and based on work by Dr. Peter Orris, Professor of Occupational and Environmental Medicine at the University of Illinois, Chicago Medical Centre. The Statement calls for the phasing out of mercury use in the health care sector. It says hospitals and medical facilities should switch to non-mercury equivalents. This would involve eliminating mercury-containing products such as thermometers, sphygmomanometers, gastrointestinal tubes, batteries, lamps, electrical supplies, thermostats, pressure gauges, and other laboratory reagents and devices. The Statement urges physicians to counsel patients about fish consumption in order to emphasise those fish high in omega 3 fatty acids for their value to heart and brain health and low in mercury contamination. This was particularly necessary for children and women of childbearing age.

A new **Statement on Reducing Dietary Sodium Intake** calls for a fifty per cent reduction in the sodium content of processed foods, fast food products and restaurant meals over the next decade. Citing overwhelming evidence that excessive sodium/salt intake is a risk factor for the worsening of hypertension and cardiovascular diseases, it urges physicians to advise patients on how to reduce sodium/salt intake, including reducing the amount of salt used in cooking at home.

A new Statement was also adopted on **Collaboration between Human and Veterinary Medicine** encouraging NMAs to engage in a dialogue with their veterinary counterparts to discuss strategies for enhancing collaboration between human and veterinary medical professions within their own countries.

The revised Resolution on **The Prohibition of Access of Women to Health Care and the Prohibition of Practice by Female Doctors** supports the rights of women and children to full and adequate medical care, especially where religious and cultural restrictions hinder access to such medical care. It urges NMAs to condemn violations of the basic human rights of women and children. It says that for years women and girls worldwide have been suffering increasing violations of their human rights, including restrictions to access to employment, education and health care. In many countries female doctors and nurses have been prevented from exercising their profession, leading to female patients and their children not having access to health care. Finally the Resolution urges NMAs to increase the effective participation of women in the medical profession.

The Assembly also adopted a **Resolution on Poppies for Medicine Project for Afghanistan**, which supports calls for investigating the controlled production of opium for medical purposes in Afghanistan. The Resolution urges governments to support a scientific pilot project to investigate whether certain areas of Afghanistan could provide the right conditions for the strictly controlled production of morphine and di-morphine for medical purposes.

The Assembly adopted the revised **Statement on Nuclear Weapons**, asking NMAs to urge their respective governments to work towards the elimination of nuclear weapons, and a **Resolution Supporting the Ottawa Convention on Prohibition of the Use, Stockpiling, Production and Transfer of Anti-Personnel Mines and on their Destruction**.

Finally the Assembly adopted an emergency Resolution from Council on **The Economic Crisis: Implications for Health** urging NMAs to work with their governments to initiate programmes for families and individuals needing medical and psychological support because of the current economic crisis and to preserve at least the current expenditure on health.

New work groups were set up on stem cell research, conflict of interest, the placebo issue and the development of Associate Members' meetings. Dr. G. Dumont was re-elected Chair of the Associates Committee.

Applications for membership were accepted from no less than eight national medical associations - Albania, Angola, Cote d'Ivoire, Cyprus, Mali, Senegal, Poland and Ukraine, bringing the total number of NMA members to 94.

In relation to **future General Assemblies**, it was agreed that next year's scientific session in Mumbai, India should be on 'Multi-Drug Resistant Tuberculosis and Lessons Learned from this Epidemic' and that the scientific session in Vancouver in 2010 should be 'Health and the Environment'.

It was agreed that the 2011 General Assembly should be held in Uruguay and the 2012 Assembly in Thailand.

Presidential addresses

During the Assembly, **Dr. Yoram Blachar**, President of the Israeli Medical Association, was installed as President for 2008/9. In his inaugural address he issued a plea for action to shield the world's health care systems as much as possible from the aftershock of the global financial turmoil and the economic recession. He said the WMA and National Medical Associations must act to moderate the destructive impact of the financial crisis. He spoke about the intolerable phenomenon of health disparities. They had always existed both among and within countries, but the gaps were widening. The WMA and individual physicians had a role to play in combating this problem.

He said that doctors as social leaders had a responsibility to address a wider scope of issues affecting health, such as armed conflict. The WMA had a unique opportunity, with both ability and positioning to try to bring conflicting parties to the discussion table by encouragement and dialogue within its organization. In his own region of the Middle



East, he said he would use his Presidency to make every effort to turn health and medicine on an organizational level to a bridging force and to advance the peace process the region so desperately needed.

Dr. Jon Snaedal, in his valedictory address as President for 2007/8 warned that the global economic crisis could lead to health authorities saving costs by shifting tasks away from doctors to other health professionals. He said that the WMA was now discussing this whole issue with the World Health Organisation and with the other health professions. Unity among the health professions would result in more effective changes. He announced that the WMA would be organising a meeting in Iceland next March, to look in further detail at human resources for health, task shifting and interprofessional relations.

Dr. Dana Hanson, a dermatologist from New Brunswick in Canada, was elected unopposed as President for 2009/10, the first Canadian to be elected President. Dr. Hanson, a former president of the Canadian Medical Association, has practiced as a dermatologist in Fredericton, the capital of New Brunswick, since 1980. He said he planned to focus his Presidency on advocacy, both for patients and physicians, and on

health and the environment. The last Canadian President of the WMA was Dr. Arthur Peart, secretary general of the Canadian Medical Association, in 1971, although it is not thought he was elected to the post.

In an **Open session** at the conclusion of the Assembly, Michael Maves, Executive Vice President of the American Medical Association, spoke about the work on task shifting in the US, which in America, he said, was called scope of practice. What the AMA and other medical organisations were trying to do was restrict inappropriate expansion of scope of practice by allied health personnel through legislative activities, regulatory activities and judicial advocacy. He said they were trying to put together a campaign to highlight for the public those characteristics that distinguished physicians from other health personnel.

In addition to the formal business of the Assembly, there were three important fringe events.

At an evening seminar, the launch was announced of the **WMA Physicians Leadership Course**, a global, annual programme to enhance physician leadership skills in advocating for health care reform and achieving improved patient care. Nominated through their NMAs, 32 top physician leaders representing 20 countries are to be selected by the WMA to participate in the high-level training conducted by INSEAD, one of the world's leading and largest graduate business schools. The six-day intensive curriculum will focus on proficiency in decision-making, participation in public debate and preparation to serve as spokespersons on key

health care policy issues. The Course was developed from a pilot programme created last year and is sponsored by a grant from the Pfizer Medical Partnerships Initiative.

The seminar heard a welcome speech by Dr. Yank D. Coble Jr., Past President of the WMA, and presentations by Dr. Robert Miglani, Senior Director, Pfizer, and Dr. Ruth Collins-Nakai, Alumni of 1st INSEAD Leadership Course, who reviewed content and participants ratings.

A lunchtime event was held to launch a **new speaking book**, designed to explain the rights and responsibilities of people entering into clinical trials in Africa. The book is aimed at patients and their relatives who do not read and write sufficiently well to understand what a clinical trial is for and how it works. The project has been developed by Books of Hope together with the World Medical Association, the Steve Biko Centre of Bioethics, the South African Medical Association and funded by Pfizer. It is planned to distribute 4,500 books in South Africa and three other Sub-Saharan countries before the end of 2008.

A second lunchtime symposium was held on **smoking cessation** under the title 'The Critical Role of Physicians in Helping Smokers Quit'. With tobacco use projected to cause one billion premature deaths in the 21st century, speakers spoke about the importance of the global health community fighting to reduce the tobacco death toll by implementing the Framework Convention on Tobacco Control (FCTC), whose provisions call for countries to take strong action against to-

bacco use. The symposium, supported by an unrestricted educational grant from GlaxoSmithKline Consumer Healthcare, heard presentations from Dr. Il Suh, Dean of Yonsei University College of Medicine, Korea, on the success story of an anti-smoking campaign in a developing country with high prevalence of cigarette smoking, Dr. Ron Davis, Immediate past president of the American Medical Association, on physician intervention and how to make a difference, and Dr. Chi Pang We, Professor at the National Health Research Institutes, in Taiwan on overcoming barriers to smoking cessation.

The all-day **Scientific Session** on the topic of 'Health and Human Rights' included presentations on Health and Human Rights from the Social Perspective, Health and Human Rights from the Environmental Perspective and Medical Ethics and Human Rights Advocacy.

One notable absentee from the meeting in Seoul was Dr. Mukesh Haikerwal, Chair of the Finance and Planning Committee, who was recovering at home in Australia after being the victim of a street attack in his home city of Melbourne. He had suffered serious head injuries and was now recuperating. Delegates sent their good wishes to Dr. Haikerwal and in support the meeting reaffirmed the WMA's 2003 Statement on Violence and Health.

Nigel Duncan

The full texts of all the Declarations, Statments and Resolutions my be accessed on the WMA website wma@wma.net

Resolution on the Economic Crisis: Implications for Health

Adopted by the WMA General Assembly, Seoul, Korea, October 2008

The current global economic crisis is affecting individuals as well as national and global economies and will have implications for health. Individuals face uncertainties about their future and psychological consequences are beginning to emerge. Governments facing economic downturns have to respond by cutting down na-

tional expenses. There is a risk that expenditure on health care will decrease nominally and proportionally in the coming years. Experience has shown that this response can have serious consequences on the health of individuals and on their contribution to the national economy. Any savings will therefore be reduced.

The WMA therefore urges NMAs to work with their governments to:

- Initiate programs for families and individuals needing medical and psychological support because of the current economic crisis.
- Preserve at least the current expenditure on health.

Declaration of Seoul on Professional Autonomy and Clinical Independence

Adopted by the WMA General Assembly, Seoul, Korea, October 2008

The World Medical Association, having explored the importance of professional autonomy and physician clinical independence, hereby adopts the following principles:

- The central element of professional autonomy and clinical independence is the assurance that individual physicians have the freedom to exercise their professional judgment in the care and treatment of their patients without undue influence by outside parties or individuals.
- Medicine is a highly complex art and science. Through lengthy training and experience, physicians become medical experts and healers. Whereas patients have the right to decide to a large extent which medical interventions they will undergo, they expect their physicians to be free to make clinically appropriate recommendations.
- Although physicians recognize that they must take into account the structure of the health system and available resources, unreasonable restraints on clinical independence imposed by governments and administrators are not in the best interests of patients, not least because they can damage the trust which is an essential component of the patient-physician relationship.
- Hospital administrators and third-party payers may consider physician professional autonomy to be incompatible with prudent management of health care costs. However, the restraints that administrators and third-party payers attempt to place on clinical independence may not be in the best interests of patients. Furthermore, restraints on the ability of physicians to refuse demands by patients or their families for inappropriate medical services are not in the best interests of either patients or society.
- The World Medical Association reaffirms the importance of professional autonomy and clinical independence not only as an essential component of high quality medical care and therefore a benefit to the patient that must be preserved, but also as an essential principle of medical professionalism. The World Medical Association therefore re-dedicates itself to maintaining and assuring the continuation of professional autonomy and clinical independence in the care of patients.

New Speaking Book on Clinical Trials Aimed at African Populations with low Literacy Level

A new speaking book, designed to explain the rights and responsibilities of people entering into clinical trials, has been launched for use in Africa.

The book to be launched at the World Medical Association's General Assembly in Seoul, South Korea, is aimed at patients and their relatives who do not read and write sufficiently well to understand what a clinical trial is for and how it works.

The 'speaking book' has an audio component that corresponds to text and illustrations in the book. A simple button on the book begins a conversation on rights, roles and responsibilities of patients in relation to their potential participation in a clinical trial. The book can be used by patients, social workers and community based health workers involved in clinical trials.

The project has been developed by Books of Hope together with the World Medical Association, the Steve Biko Centre of Bioethics, the South African Medical Association and funded by Pfizer.

Dr. Kgosi Letlape, Chair of the South African Medical Association, said: 'Animation and cartoons help to break down the barriers of communication and most people feel comfortable with educational material presented in this form. If you cannot understand the words, you can get the meaning from the pictures.'

Dr. Edward Hill, Chair of Council, WMA, said: 'More than ever it is necessary to do research, with, in and – most important – for poor populations. I applaud the production of the speaking book, because it means paying more attention to the poorer communities of this world instead of abandoning them or just ignoring their needs.'

It is planned to distribute 4,500 books in South Africa and three other Sub-Saharan countries before the end of 2008. Following the launch, the book will be presented to internal and external organizations with the aim of assessing additional international need.

Pfizer's vice president Dr. Jack Watters, said: 'It is absolutely crucial that all people involved in clinical research – whether as a health professional, an ethics committee member or as a patient – have the necessary knowledge and/or skills to play their role. That effort is significantly supported by this book.'

179th Council meeting

(Part 2) [continued from WMJ54 (3)]

Finance and Planning Committee

The committee was opened by the Chair, Dr. Haikerwal, who commented that the Executive had met monthly, following which the minutes of the last meeting were adopted.

Finance

The reports on membership dues and the oral report on dues areas were received.

The pre-audited financial statement for 2007 was presented by Mr. Halmayr; he indicated that improvement over the 2006-7 position was sustained and referred to the increase in staff which had now returned to its normal level, commenting that in relation to the Advocacy adviser the generous assistance of the AMA had reduced the cost. He further said that the costs of the Council meeting in Berlin, despite the increased size of the council, were less than the benchmark set for meetings not held in Divonne. The committee received a report from the Business Development Group including a report on the development of the Web Portal and the Secretary General expressed his special thanks to the CMA for their work on this.

Business Development Group

The committee received a report from the Business Development Group on the Seoul General Assembly.

Future meetings

The committee received reports on future plans for meetings as follows:

2008 General Assembly:

The committee heard a report on the forthcoming **General Assembly in Seoul** outlining the scientific programme on Health and

Human Rights, which was considered to be very exciting.

182nd Council:

2009 General Assembly in Mumbai, India, on which Dr. Desai gave a presentation & film. The IMA proposal that the Scientific Session be Multi Drug Resistant Tuberculosis was recommended to and **approved** by Council

2010 General Assembly, Vancouver, Canada. The CMA proposed the Scientific Session to be on Human Health and the Environment which was recommended to and **approved by Council**.

Indications were given of offers to host the General Assembly from Uruguay in 2011 and from Australia in 2012.

WMA Office

The Secretary General gave an oral report on necessary renovation and possible renting/selling of part of the office space surplus to needs following which there was a general discussion. It was made clear the appropriate expert advice would be sought which would be passed to the Executive committee and Chair of Council.

Conduct of business

During a discussion of the conduct of business introduced by Dr. Waikerwal, he reported to council a number of points had been made which could improve the conduct of business.

Membership

The following applications for membership of the WMA were recommended and later **approved by Council** to be forwarded to the General Assembly

- **Ukrainian Medical Association**
- **National Order of Physicians of Côte d'Ivoire**
- **National Order of Physicians of Senegal**
- **National Order of Physicians of Mali**
- **Cyprus Medical Association (pending legal approval of the statutes)**

The Secretary reported on the Albanian Order of Physicians whose statutes conformed with the requirements and from whom an application would be received for the next meeting.

The committee received a report on the Associate Membership and the Chair of Council reported that Drs. Ishii and Johnson had agreed to undertake a thorough analysis of the associate membership and report to the next meeting of the committee.

WMJ

The committee had an oral report from the new Editor of the WMJ Dr. Peteris Apinis, explaining his new presentation and the changed design. He again encouraged NMAs to write about themselves, called for cooperation with those responsible for national association publications and also sought cooperation with regional medical association organisations such as Confermel etc. Speaking of design and layout he had introduced pictures of countries relating to the country to be presented each issue. The key words for policy were "Informative" and "Interdisciplinary"

Dr. Kloiber reported that the Business Group had recommended and discussed the content and development of the WMJ and provided its guidance. It suggested that there would be value in exploring the niche for this publication and considered that a full scientific peer reviewed publication was not the preferred option for the WMJ. Dr. Kloiber thanked Dr. Apinis, Dr. Rowe and Professor Doppelfeld for their work on the Journal.

The committee received the report of the Press Officer, Nigel Duncan who requested

member associations to mention the WMA in their Press releases when appropriate to increase the visibility of the WMA.

Socio-Medical Affairs Committee

The Chairman Dr. J.L Gomes do Amaral opened the meeting, welcomed a new member. The minutes of the Copenhagen meeting were considered and approved.

Antimicrobial Drugs

The committee recommended that a revision of the Statement on Antimicrobial Drugs, a recommendation subsequently **adopted and approved by council**.

Continuous Quality Assurance

The revision of a Continuous Quality Assurance statement provoked considerable discussion. This arose from concerns in the AMA relating to governmental interpretation of medical research and what constitutes "evidence". The committee recommended to council that the document be referred back to NMAs with an explanation of the new concerns. The recommendation was subsequently **accepted by Council**.

Access of Women to Healthcare

Following interventions from the BMA, Canada and the AMA, a number of amendments were suggested and the amended document recommended to council who approved **its adoption and forwarding to the General Assembly**.

Dietary Sodium

The AMA moved the adoption of this document. The Indian Medical Association questioned whether reducing sodium increased the risk of cardiovascular disease, referring to a literature review of 450 papers and proposed that in the light of this, a working group be established to review the proposed document. It was pointed out that the paragraph referred to uses the words "can have an effect". Numerous other

speakers observed that the proposal agrees with other bodies which have made such recommendations and did not refer to a direct link. The Japanese Medical Association commented that while there was no direct link with all cardiovascular disease, there was one with hypertension and thus with apoplexy.

The motion to refer to a working group was lost.

A motion to recommend approval to council for forwarding the document to the General Assembly was agreed and subsequently **adopted by Council**.

Resolution on Task Shifting

The President referred to the press release at the Addis Ababa conference. The concept of Task shifting had positive and negative aspects, it moves tasks which were initially complicated and have become simplified. Now however, we are dealing with task shifting determined by other authorities, with governments and legislation moving tasks to other professions and lay persons. His article on the Kampala meeting in March "Human Resources for Health" was in the May WMJ (see WMJ54 (2), 34-35) which the council had before them and addressed the problems facing 55 countries, mostly in Africa. The Executive on the previous day had recommended that council should adopt a statement based on the World Health Professions' Joint Statement at the Kampala meeting. Dr. Blachar (President-elect) said the proposal was that the WMA council endorse the WHPA Kampala document and recommends that WMA engage in further study of this issue. Responding to a question as to whether actions taken by the executive require endorsement by the council. The Secretary General observed that this was a special situation. Normally strategy was determined by council and passed to others. In Kampala, action had to be taken on the spot in the WHPA of which WHO was a member. We don't have a policy on Task Shifting and therefore endorsement

of the action taken by an organisation of which WMA is a member was necessary.

Dr. Snaedel (President) observed that this was a problem also affecting other health professionals. It was important that the council should make a statement on this occasion. This was a problem for the health professions. Dr. Letlape (Immediate Past President) commended the Executive. What we had here was a new cadre of health worker. He also had a concern about nomenclature. The President commented that the wording was correct, namely "task shifting" and that Dr. Letlape was raising a South African issue.

The President-elect felt that the WHPA document should be endorsed. We were not concerned about losing work, but work was being placed elsewhere due to the shortage of health personnel.

Dr. Vilmar (Germany) considered that we should think of the relationship between Task shifting and Quality. In our daily work as Health Professionals we delegate tasks to others e.g. ECGs to technicians. Delegation of other tasks could be disastrous. However we now have other professions claiming more prerogatives. We must work with other Health Professions to ensure safety and quality. However, to ensure quality and safety, diagnosis must remain with Physicians.

Dr. Call'och supported the Executive's action. Some time we must produce a supplementary motion to extend the WHPA statement to ensure safety and quality. Task shifting in French is translated as Task Transferring. In France protocols are now being written for doctors transferring technical tasks (including drug substitution) to other professions.

A comment from Bolivia sought assistance to deal with the problem of inadequately trained Cuban doctors. The Chair commented that we had to consider the effects of task shifting not only in relation to a phy-

sician shortage, but also in relation to other health professionals

Dr. Letlape proposed a two part decision. First that the executive action be endorsed – this was **agreed**. Secondly, that a study be undertaken. It was observed that the issues raised by task shifting clearly had major medical workforce implications, on which a work group already existed. It was finally agreed to recommend that this group undertake the study to define the issues and recommend long term viable solutions. Council later **endorsed this recommendation**

Global Problem of Mercury

A Statement on the Global Burden of Mercury was recommended for approval by council and forwarding to the General Assembly. This recommendation was **adopted by Council**.

Poppies for Medicine

In connection with the proposed motion it was pointed out that the Standing Committee of Doctors had recommended the project.

The proposal was recommended for approval and referral to General Assembly by council and later **adopted by Council**.

Action on classification of 1998 policies.

- The following recommendation were made and **adopted** by council:
- Declaration on Nuclear Weapons to be **reaffirmed with minor revisions**
- Resolution on Medical Workforce to undergo **major revision**
- Resolution on Improved Investment in Health Care to undergo a **major revision**
- Resolution on the Hague Appeal for Peace to be **rescinded and archived**
- Resolution supporting the Ottawa Convention of Anti-Personnel Landmines and their destruction to undergo a **major revision**
- Resolution on Medical Care for Refugees to be **reaffirmed with minor revisions**.

Health and the Environment.

Dr. Hansen said that a document was being prepared by CMA on “Health and Environment” a topic which we should be addressing, rather than “climate change”. Firm facts are needed. It is possible to address effects such as those of Mercury (as in the WMA document) and the CMA has some projects in mind. They would try to make the document relate to physicians. Advocacy and research are important in this area – such advocacy would fit into Advocacy for patients. This work would prepare the way for a General Assembly which was proposed to be held in Canada in 2010. He suggested a task Force with a mandate to look at Health and the Environment, using expertise as necessary.

The Chair of Council called for nominations for a force to develop policy on Environment and Health to which Canada, France, Korea, UK and Switzerland responded. As the UN policy conference would take place in Copenhagen on 2009 Denmark also offered to join the group.

Dr. Wilks (Chair of Standing Committee of European Doctors) reported that as the EU was doing work on Climate change and the CPME is developing policy. This will be shared with WMA.

Drug Prescription

A resolution on Drug Prescription was introduced to the committee. In presenting this, a plea was made that prescribing should only be done by physicians and based on the clinical history and diagnosis – information which is private and cannot be shared - which implied that physicians with the scientific and human training were required. Advocacy only thinks of Safety of the patient whereas the Pharmaceutical Industry tends to separate this form of medical practice.

In a general debate it was suggested that this trend was part of Task Shifting. In its current form however, the motion would

make WMA a laughing stock. This motion was relevant to the 20th century, but not the 21st where many other professionals were trained to prescribe drugs. It was pointed out that in the UK nurses and pharmacists were able to prescribe drugs. While expressing sympathy with the Spanish, it was pointed out that prescribing by a physician was not necessary on every occasion e.g. OTCs. The motion needed substantial rephrasing. The President reported that the Annual meeting of the Pharmacists were already working on this issue. WMA is waiting see the guidelines on this topic in relation to physicians and pharmacists.

The Spanish replying to the debate agreed that work on this topic should start at once and said that patients need guarantees. In Spain the European Society of Patients support prescribing by Physicians only. He spoke of the problem of Adverse Drug Reactions and patients tending to take drugs blindly e.g. OTC preparations. Physicians were not superior, but should be at the head of prescribing.

After agreeing that the work should be done by a working group, it was agreed that a new working group should be set up, with a remit to examine the draft proposal, as well as the authority to prescribe, and report back to the committee. This recommendation was later **accepted by Council**.

Human and Veterinary Medicine

Following the presentation of a proposed Statement on this issue by the American Medical Association the committee recommended and the **council approved** the document being sent to NMAs for comment.

Advocacy Advisory Group

It was reported that the mandate of the group had been clarified, namely that it would produce an advocacy plan for the year, including a strategy highlighting areas for NMAs.

Dr. Alan J. Rowe

The WMA Caring Physicians of the World Initiative



Yank D. Coble, MD, Chair, WMA Caring Physicians of the World Initiative

"The most important thing is caring, so do it first, for the caring Physician best inspires hope and trust." Sir William Osler

Caring, Ethics and Science are the three fundamental and enduring traditions that unite medical professionals and their patients around the world. Because of these universal traditions, we find global similarity in physicians' and patients' desires and concerns, despite the enormously disparate environments and circumstances in which physicians care for patients.

The **Caring Physicians of the World Initiative (CPWI)** was designed to restore enthusiasm and optimism in medicine, through medical and social leadership based on the enduring traditions of the medical profession: Caring, Ethics and Science. The initiative was conceived in Helsinki, Finland at the 2003 General Assembly of the World Medical Association.



Otmar Kloiber, MD, Secretary General, World Medical Association

The World Medical Association (WMA) represents physicians around the world and provides a global forum for physicians to communicate, cooperate and promote high standards and professionalism. The WMA is a federation of National Medical Associations (NMAs) representing over eight million physicians in more than 90 countries around the world. It was founded in 1947 with the mission to "serve humanity by endeavoring to achieve the highest international standards in medical education, medical science, medical care, and medical ethics, and health care for all the people of the world". This unique partnership of physicians enhances the health and quality of life for people all over the world.

As part of its work to achieve high standards in medicine, the WMA conducted a survey of physicians in over 40 countries around the globe in 2003. Survey results revealed physicians' concerns about access to quality safe medical care, appropriate professional autonomy to provide that care, and adequate

resources and facilities to deliver care. Physicians were also seriously concerned about the regulatory, legal, political, and other barriers to providing care, as well as governmental attitudes regarding **medical care as an expense**, rather than an **investment** with positive return. To a large degree, physicians across the world felt marginalized, threatened, and demeaned. They requested that the WMA provide increased information on health systems and facilitate greater exchange of experience between physicians throughout the world. Physicians requested vigorous communication of the professional values of the medical and health professions and the well-documented value in relieving distress, despair, disease, disability, and premature death, and the extraordinary return on investment in medical care and public health. Physicians also felt they needed to enhance their own knowledge and skills in leadership and advocacy for patients, public health, and the medical profession.

The WMA resolved to address these global concerns in 2004, and formed a partnership with an experienced sponsor, Pfizer, Inc. They developed the **Caring Physicians of the World Initiative (CPWI)**, chaired by WMA President-elect Yank D. Coble, MD. Through this initiative, the WMA would unite NMAs around the world, implementing a multipart program to address the identified global concerns of physicians.

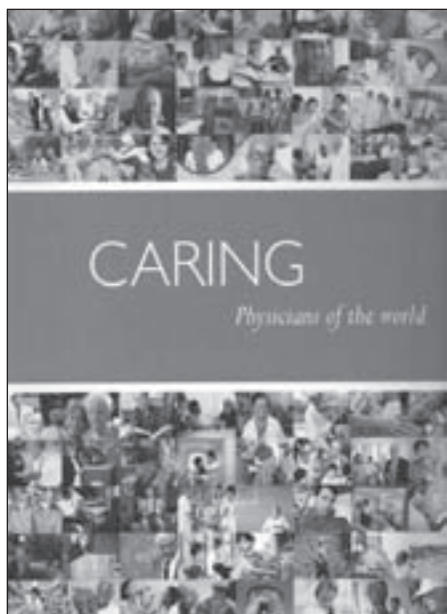
Phase I of the CPW Initiative: Connecting

The goal of Phase 1 was to connect with NMAs around the world, enhancing global communication. The WMA reached out to NMAs and regional associations such as the Medical Association of Southeast Asian Nations (MASEAN) and the Medical Confederation of Latin America and the Caribbean (CONFEMEL), building relationships and increasing participation and leadership in the World Health Organization (WHO) and World Health Professions Alliance (WHPA). WMA officers visited Africa, Europe, Latin America, the Middle East and North America, and made multiple visits to India and China. These outreach visits by WMA officers enabled

them to learn more directly about circumstances, needs, and desires, and to obtain support and increase advocacy for the values of the medical profession.

Phase II of the CPW Initiative: Inspiring

The goal of Phase II was to inspire, building enthusiasm and optimism for the medical profession, by showcasing exemplary physicians from around the world in a compilation of **"Caring Physicians of the World."** This publication featured 65 physicians from 58 countries: heroes and social leaders who were nominated by their NMAs as exemplifying the enduring traditions of caring, ethics, and science.



Plans for the book were announced at the WMA General Assembly in Tokyo, 2004. NMAs nominated over 200 physicians; 65 physicians were interviewed, photographed on site, and memorialized in the publication. The book was presented at the 2005 WMA General Assembly in Santiago, Chile and the regional conference of CONFEMEL. Subsequently, the message of the Caring Physicians of the World was communicated to NMAs, medical schools and specialty societies, government, media, businesses, philanthropies, and multiple other public and private associations and organi-

zations around the world. In May 2006 the Caring Physicians of the World Book and Initiative were featured at a luncheon reception of over 200 Ministers of Health and other health and medical leaders following the opening sessions of the 2004 World Health Assembly. The preface, describing the relevance, importance and power of caring, ethics and science.

Phase III of the CPW Initiative: Collaborating

The goal of Phase III was to improve collaboration, forming regional partnerships in areas around the world, to enhance communication, collegiality, and advocacy for patients, public health, and the medical profession. With WMA officers' participation, and the Pfizer partnership and support, Dr. Otmar Kloiber, Secretary General of the WMA, and host NMAs organized highly successful regional meetings in Johannesburg, Prague, Santiago, Tokyo, Bangkok, Shanghai, and Amelia Island, Florida. These regional meetings focused on effective ways to address the primary issues for patients, physicians, and public health. During these meetings it emerged that there was a growing desire for improving physicians' advocacy and leadership skills.

Phase IV of the CPW Initiative: Developing

The goal of Phase IV was to address the emergent need for development of physicians' advocacy and leadership skills. Throughout 2006 and 2007 the WMA, in collaboration with INSEAD and again with the partnership of Pfizer, Inc., developed the **WMA/CPW Leadership Course**. The program was designed to develop the skills and knowledge needed for medical and social leadership, enhancing the abilities of medical professionals to advocate



WMA/CPW Leadership Course 2007

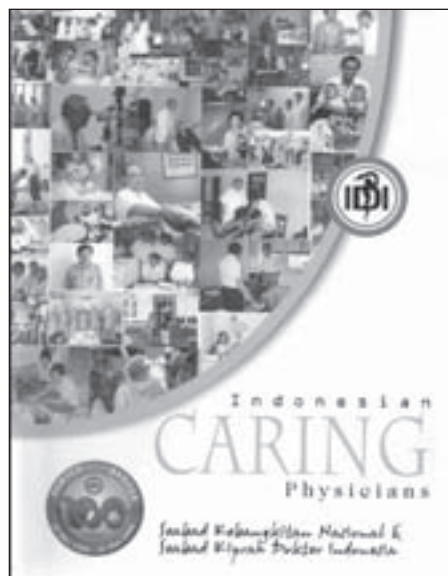
more effectively for medical care, education, research, ethics, and the medical profession.

The first course was held from 2-9 December, 2007, at INSEAD in Fontainebleau, France. Thirty three colleagues, selected by their NMAs in 22 countries, participated in the course. Feedback from this inaugural course has been extraordinarily positive, as has the increased communication between the "Alumni" of the course. The next course is planned for INSEAD, Fontainebleau, 1-6 December, 2008. INSEAD Singapore is under consideration as the site for the course in 2009.

Phase V of the CPW Initiative: Applying and Achieving

Phase V is an enduring phase in which WMA will explore application of the CPW principles and achievement of the CPWI goals. One of the first examples of **CPWI Application** can be found in Indonesia.

Two Indonesian Medical Association (IMA) leaders, Dr. Fachmi Idris and Dr. Taufik Jaaman, participated in the December 2007 WMA/CPW Leadership Course. They proposed an Indonesian Caring Physicians Initiative for their IMA Centennial Annual meeting in May 2008. They began planning, and by early 2008 had the support of the President of the Indonesian Republic, collaboration of the Minister of Health, and additional support.



The IMA created a video documentary of 100 years of Indonesian history, and a new book, *Indonesian Caring Physicians*, edited by Dr. Taufik Jaaman. This book profiles 112 Indonesian physicians, nominated as heroes and social leaders, exemplifying the enduring medical traditions of caring, ethics, and science. The publication includes messages from the Indonesian President, and the Minister of Health, and the WMA. Both books, the *Caring Physicians of the World* and the *Indonesian Caring Physicians*, were presented to the Indonesian President and Minister of Health at the IMA Centennial Anniversary at a large event held at the President's Palace, May 28, 2008, and to the faculty and students of the Indonesian University School of Medicine by IMA and WMA officers with presentation addresses. The opening of the IMA Centennial Meeting and exposition featured the ICP book, video, and initiative.

The WMA is proud of the growth and achievements of the CPW Initiative. However much remains to be accomplished in, by and for the medical profession. Global threats of communicable and non-communicable disease persist despite unparalleled progress in biomedical science, public health and medical care. Barriers to care flourish, created by ineffective, inefficient, and sometimes even corrupt governments. The pub-



Ceremonial Event at the Presidential Palace. (L-R) Dr. Fachmi Idris, President of Indonesian Medical Association; Dr. Siti Fadilah Supari, Health Minister of Indonesian Republic; Dr. Susilo Bambang Yudhoyono, President of Indonesian Republic; Dr Yank Coble, Past President of WMA

lic is confused by terms such as providers instead of professionals, customers instead of patients, health care instead of medical care, the pollution of scientific information by media, and distortion by legal and regulatory systems. They are understandably distrustful. However there is good reason to be optimistic: the justifiable enthusiasm physicians have for the value and values of their profession, and the ability to be useful. The CPW Initiative has helped to clarify the assertion of physicians around the world that effective leadership, hard work, a clear definition of responsibilities and rights as a profession, and a mission beyond self, will result in significant and measurable success.

- The CPWI has a **focus on Patients:** working to inspire hope and trust, as well as to reduce disease, despair, disability and premature death.
- The CPWI has a **focus on Rights:** promoting the right of all patients to choose physicians providing care based on a singular ethical commitment to them, using the best available science, in a caring manner. To provide this level of care, physicians require the right to appropriate autonomy, self regulation and advocacy for patient health.
- The CPWI has a **focus on Responsibility:** endorsing ethical and science-based



*Presentation of the Caring Physicians of the World. Dr. Fachmi Idris, President of Indonesian Medical Association, presents the book of *Caring Physicians of the World* to Susilo Bambang Yudhoyono, President of Indonesian Republic*

care, and social leadership in advocacy for patient care and public health.

- Finally, the CPWI has a **focus on the Value of Medicine:** both economic and humanitarian. The Economic Value represents the positive financial return of investment in medical care and biomedical research. The Humanitarian Value represents the immeasurable worth of reducing disease, despair, disability and premature death.

The goal of the CPWI is to restore enthusiasm and optimism in the field of medicine, through medical and social leadership based on the enduring traditions of the medical profession: Caring, Ethics and Science. The CPW Initiative exemplifies the triad of medical traditions, Caring, Ethics and Science, emphasizing that caring physicians of the world are committed to and effective at medical and social leadership. The CPWI mission is to help physicians throughout the world, despite the diversity and adversity of circumstances, to communicate Caring and Compassion, with the best Science and highest Ethics, in every professional interaction.

Building a Consensus in Regenerative Medicine



Louis M. Guenin, Department of Microbiology and Molecular Genetics, Harvard Medical School

On occasion, discretionary actions preclude transfer of extracorporeal embryos into the womb. Such actions constitute an overlooked and crucial ground for the moral justification of embryo use in regenerative medicine.

In the first instance, we encounter the situation, which often arises with fertility patients, in which the one person in the world who, together with the co-progenitor, is empowered to decide about intrauterine transfer of an embryo formed from her oocyte decides that neither does she wish to bear the embryo, nor does she wish to give it to anyone else. Whereupon she and the co-progenitor may decide to donate the embryo to medical research and therapy. In the second case, embryos may originate in research from cells donated to medicine for that purpose.

If progenitors, while fully-informed and acting of their own volition, donate an embryo, either before or after the embryo's creation, on the condition that the embryo shall be used in medical research and therapy, and may never be transferred into a uterus, such embryo constitutes what I have called an "epidosembryo." I have taken this

name from the Greek *epidosis* for a citizen's beneficence to the common weal.

As a moral justification for the use of epidosembryos in accordance with donor instructions, I have offered the "argument from nonenableness." This proceeds as follows. A woman does not have a duty to undergo a transfer into her of an embryo lying outside her. There does not obtain a duty of intrauterine embryo transfer into oneself. We, most of us, regard the decision to undergo such a medical procedure as reserved to a woman's autonomous discretion. A separate question is whether a woman and the co-progenitor lie under a duty to surrender for adoption any embryo that she declines to bear. Imposition of such a duty would likely present such adverse incentives and consequences for fertility patients, including compelled remote parenthood, that we are hard pressed to find any moral view that would support such imposition. For reasons developed in the full account of this argument, the decision whether to surrender an embryo for adoption also lies within progenitor discretion.

Suppose, then, that a woman forbids intrauterine transfer of an embryo. She, with the co-progenitor, donates to medicine either an epidosembryo created during her fertility treatment, or an epidosembryo that will be created by a scientist from their donated cells. This decision is final. The epidosembryo has left progenitor control. A distinction now obtains between the developmental potential of this epidosembryo, lying in a petri dish where it will remain, and an embryo that lies in a uterus, however it got there. In consequence of the prohibition on intrauterine transfer, the epidosembryo will not complete gastrulation. If not earlier sacrificed, the epidosembryo will begin to disintegrate by about day 10. During its remaining life, it cannot acquire any morally significant property that it does not already possess. To put the matter in language that I owe to Richard Hare, no possible person

corresponds to an epidosembryo. We also know that no embryo is sentient. It can neither form preferences nor adopt ends. Nothing that we might do concerning it can cause it discomfort or frustrate it. We cannot gain anything – neither for it nor for any other being – by classifying it as a person for purposes of the duty not to harm. By forgoing its use in research, we could only assure that the epidosembryo dies in vain. Scientists maintain the reasonable, though not certain, belief that embryo experimentation could contribute to the relief of human suffering. Use of donated embryos remains crucial in research even as techniques develop for reprogramming somatic cells into pluripotent or specialized cells. Embryonic stem cell research has been the fountainhead of emerging knowledge of reprogramming, and the embryonic stem cell remains the gold standard of pluripotency. In this situation, the duty of mutual aid – the duty, recognized across moral views, to aid those in need when one may do so without imposing an unreasonable burden – bids us undertake such research. Hence not only is it permissible to use epidosembryos in medicine, but to do so will help to fulfil a collective duty.

According to this argument, the permissibility and virtuousness of epidosembryo use rests on the autonomous decisions of people from whose cells such embryos originate. The moral analysis flows entirely from what it is that they decide. Developmental potential matters, but it is human decisions that determine its situation-dependent extent. If it is permissible for progenitors to donate epidosembryos, then it is permissible for recipient scientists to use the donations as instructed.

Some discussants seem to suppose that the justification of embryonic stem cell research lies in the circumstance that the embryos donated were created with procreative intent. The argument from nonenableness does not invoke procreative intent. The argument applies to any donated embryo, whether left over from an attempt at pregnancy, or created in experiment. The use of surplus embryos and the nonprocreative

formation of embryos by fertilization, non-reprocloning, and parthenogenesis rest on one and the same moral ground.

The argument from nonenableness is a consensus argument insofar as it does not invoke any premise peculiar to one or another moral or religious view. The bounded developmental potential of an embryo in the dish is a biological circumstance. The duty of beneficence and respect for the discretion of persons to elect whether they shall undergo medical procedures are common to all leading moral and religious views. Some form of the Golden Rule is found in virtually every major moral and religious view since Confucius.

In this analysis, I accord a wide berth to religious views across diverse cultures, provided only that when moral verdicts are urged on religious grounds, support for them can be given on the basis of reasonable nonreligious premises. As we all know, many religious believers condemn the sacrifice of embryonic lives in aid of other lives. Hence a further task presents itself. It remains to be shown, if it can be, that if the argument from nonenableness is introduced in the course of sympathetically reinterpreting one or more views presumptively opposed to all embryo use, such views will issue in approval for epidosembryo use. I illustrate how that task may be accomplished as to the most influential presumptively contrary view, the magisterium of the Roman Catholic Church.

In condemning all manner of embryo destruction, the Catholic magisterium speaks consistently. Just as it condemns destruction of embryos as research subjects, it condemns the practice of assisted reproduction because that practice brings about destruction of surplus embryos. (Other discussants who approve *in vitro* fertilization as practiced, but oppose embryo use in research fall into inconsistency: they condone destruction of surplus embryos as waste, but condemn sacrifice of surplus embryos for beneficent ends.) On what ground does the magisterium's

condemnation of embryo sacrifice rest?

One will often hear it asserted that an embryo is a person and that killing a person is murder. To say that a being is a person is to recite the conclusion that the being falls within the category of beings protected by the duty not to harm. It remains to ask what reasoning supports that conclusion. Conceding that the Bible does not assert personhood of an extracorporeal embryo – in antiquity, people did not even know that there existed oocytes, hence never thought about embryos outside the body – the magisterium allows that personhood of an embryo is a philosophical question. Concerning this, the magisterium's argument in chief is the following: fertilization creates a new genome, therefore fertilization creates a person. This argument's premise is true – fertilization produces a new genome – but the conclusion doesn't follow. To identify a person with a genome is to practice genetic reductionism with a vengeance. That view contradicts the bedrock belief that a person is a *corpore et anima unus*, a union of body and soul. On pain of internal contradiction, the argument cannot stand.

A defender of zygotic personhood might plead that precisely because embryos cannot form preferences, it is our obligation to act according to their advantage, hence to classify them as persons. But we cannot foster any advantage of epidosembryos. Entry into the only kind of environment by which they could attain the ability to experience benefit has been forbidden by the only persons in the world empowered to decide such matters. It is from this recognition that the argument from nonenableness builds a *prima facie* justification within Catholicism, as within other views, for epidosembryo use. Is there a countervailing argument?

One argument is that if we do not know whether an embryo is a person in God's eyes, we should exercise caution and act as if it were. But from within a view holding that divine will is the arbiter of morality, suppose that we could have a conversation

with God. We report that in 1998, we discovered how to culture human embryonic stem cells. We describe hopes of relieving human suffering by using embryos that will never enter a womb. Is it plausible that He would tell us that He regards such embryos as persons in the sense that He includes them in a universe of beings that He never wishes us to use as means? I do not know of a tenable argument according to which an all-merciful and omniscient God would assert that preference. He would know that unenabled embryos would never become sentient if not used in research.

An objection peculiar to nonreprocloning might be this. An oocyte is created for a purpose, namely to issue in offspring, and it is wrong to divert an oocyte to any other purpose. This objection presupposes with Aristotle that everything has a fixed purpose and that we know what it is. After Darwin, that notion has lost its grip on our thought. We have learned from the history of medicine how mistaken we humans have often been in inferring purposes of various cells and structures of the body. Our forbears would have said that bones are what hold us up; today we think of the marrow as a blood factory. We think it appropriate to transfer marrow from one patient to another. We know that many cells perform multiple functions, and we are learning to redirect proteins and cellular processes to serve chosen ends. It seems arbitrary to say that an oocyte can or should serve only one purpose. Such a rule would seem puzzling insofar as every human female possesses from birth a quarter million or more oocytes.

Turning to public policy, we observe that there obtains no practical scheme by which a government may fund use of embryonic derivatives without complicity in their derivation. Downstream demand induces supply, and complicity transmits through the channel of inducement. Our collective deliberations would benefit from moral reasoning generally overlooked in the policy arena. That is the reasoning adduced in the argument from nonenableness beginning

with the premises that intrauterine embryo transfer is discretionary and that when progenitors forbid such transfer, developmental potential is permissibly bounded. The key to assuring that legislation endorses morally permissible activity is what it says about progenitors. Progenitors possess unique power: each is the only person in the world (with the co-progenitor) privileged to decide what will happen to an embryo. It is because a progenitor-donor decides that an embryo will never enter a uterus that a donee may experiment on it.

Hence the most compelling justification for a donee in performing experiments, and for a legislature in endorsing experiments, consists in the donee's fidelity to permissible donative instructions bounding potential. This brings us to the following public policy:

The government shall support biomedical research using human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine transfer.

This policy wears its moral justification on its sleeve. That attribute avails for public discussion. There the policy may be described as one that assures that the scope of the publicly-supported is congruent with the scope of the morally permissible.

There arise various other ethical questions about embryo use, including fair compensation to oocyte contributors, and the formation of hybrids and chimeras. In the foregoing, we have canvassed a ground for consensus on the most fundamental question.

Human Resources and Bioethics in Palliative Care as an Example of Human Resource and Bioethics Development in Kazakhstan

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Introduction

Kazakhstan is an independent republic located in the central Asian steppe. Covering 2.7 million square kilometres (about the size of the 15 states constituting the European Union up to 2004), the country is the largest of the former Soviet republics after Russia. Kazakhstan has a long border with Russia to the north, adjoins China to the east, and Kyrgyzstan, Uzbekistan and Turkmenistan to the south. Kazakhstan is a land-locked country which borders on two large inland seas: the Aral Sea and the Caspian Sea. The terrain stretches across steppes and deserts to the high mountains in the south east including the Tian Shan and Altai ranges. The capital, formerly Almaty (previously Alma-Ata), was moved in December 1997 to Astana (Aqmola) in the north.

When Kazakhstan became independent in 1991, it faced many of the same challenges as other countries from the former Soviet Union, including an oversized and inpatient-oriented system of health facilities, a drop of health financing in the early years of transition and many other challenges that



Maksut K. Kulzhanov

are the similar to world health care problems such as human resource development and bioethics. While the country has embarked on several major health reforms in the second half of the 1990s, these often lacked consistency and clear directions. In the wake of the economic upswing fuelled by oil revenues in recent years, Kazakhstan in 2004 embarked on a comprehensive national health reform programme for the period 2005-2010.

Human resources in health care system and public health

Kazakhstan has a high level of public sector employment. In the mid-1990s, the country had one of the highest levels of government employment in the world, when health per-

sonnel accounted for about 40% of government employees (WB 1996b). The number of active personnel is difficult to ascertain, as there is no accurate and comprehensive information system on the actual number of active health care workers. In addition, health care workers who have moved to the private sector, such as many dentists and pharmacists, are not counted in public figures.

The area of human resources in the health sector is mainly related through the Law on the Health System of 4th June 2003. According to this law, the Ministry of Health is responsible for:

- developing an overall human resources policy in the health sector;
- approving forms and training programmes for medical specialties, and developing and approving typical staffing and staffing standards of health organizations;
- conducting the attestation of managers of health organizations and health departments;
- defining standards for the training of specialists with higher and postgraduate education, for continuous education and the retraining of health professionals.

Oblast health departments are responsible for:

- ensuring the provision of human resources in health organizations and assessing the expertise of health workers;
- planning the training and retraining of medical specialists;
- ensuring the continuous education and retraining of medical and pharmaceutical specialists.

Health care personnel per 10 000 population, 1990-2007

	1990	2000	2001	2002	2003	2004	2005	2006	2007
Physicians (PP)	39.6	33.0	34.6	36.1	36.5	36.3	36.5	37.6	36.8
Dentists (PP)	2.6	2.1	2.3	2.7	2.8	2.9	2.7	2.9	2.9
Nurses (PP)		44.7	46.5	48.9	49.1	50.0	51.1	54.2	
Midwives (PP)		5.2	5.5	5.4	5.4	5.5	5.5	5.7	

Note: PP: physical persons

In 2007, there were 57, 387 medical doctors working in Kazakhstan's health system, equivalent to a ratio of 3.68 physicians (physical persons) per 1000 population, which was close to EU-15 and CIS averages (WHO 2007a).

The decline in the ratio of health care workers to population since 1990 is due to a number of factors, including a shift to the private sector, health care workers leaving the health sector, the outmigration of ethnic Russians, and the dismissal of health personnel.

There is a huge gap between rural and urban areas. Primary health care facilities are facing problems in recruiting qualified staff, especially in remote and rural areas. This is in large part due to an insufficient number of new graduates. Enrolment to medical schools financed by state grants or credits has increased annually by about 10% since 1999, but the need in human resources is still high (President of Kazakhstan 2004). Kazakhstan is facing a serious problem with the ageing of health personnel and the understaffing of health facilities, in particular in rural areas.

There is also an urgent need for certain categories of health professionals, such as specialists in health management or health economics. The lack of properly trained managers translates into poor management and inefficient use of resources. Often, the manager of a health facility has a number of simultaneous functions: acting as manager, administrator and chief physician (President of Kazakhstan 2004).

Kazakhstan has inherited the Soviet system of training and retraining of health professionals and there have hardly been any changes in this area in the years since independence (President of Kazakhstan 2004), although it should be noted that there has been signifi-

cant postgraduate training in family medicine and priority programmes including mother and child health and tuberculosis.

Overall, the quality of training and retraining remains poor, which is partly due to an underdeveloped regulatory system with regard to university entry and the quality of medical and pharmaceutical teaching, but also to years of underinvestment in educational buildings and facilities. The limited funds allocated to medical training in the public sector do not allow the purchase of up-to-date technical equipment or visual aids (President of Kazakhstan 2004).

In addition to state-funded students, universities try to attract additional funds by accepting medical students who pay for the tuition themselves. The number of students paying for their studies has increased in recent years.

The Concept for the Educational Development of Kazakhstan until 2015 envisaged changes to the training of all professionals with higher education that also have an impact on medical education. In line with this concept, new obligatory standards for medical and pharmaceutical education were introduced in 2003 that place greater emphasis on continuity between different educational levels.

Kazakhstan had nine medical schools (three of which were private), 26 nursing colleges, an Institute of Continuing Training, a national School of Public Health, and 65 research enterprises. The Kazakhstan School of Public Health was established by the Ministry of Health together with the WHO Regional Office for Europe in 1997.

There are four streams in medical education. Physicians are trained for six years and

specialize in their sixth year. Paediatricians are trained in an entirely separate course. Sanitary-epidemiological service physicians are trained for five years in separate faculties. Dentists are also trained in a separate five-year course.

A one year internship based on six major specialties (residency), which in similar form existed in the Soviet period, has recently been reintroduced to improve the quality of medical graduates. Following the internship, physicians can specialize in more than 80 specialties with a training duration of 2-4 years.

A family practice specialty was introduced in 1995 as a four-month short course at the postgraduate medical institute and other short courses are being mounted at approved sites. Training in general practice (both for undergraduates and for practicing physicians) has been supported with both technical assistance and funding from USAID, the United Kingdom Department for International Development and the World Bank. In 2005, the government spent 2% of the total health care budget on the training of general practitioners and health managers.

Further education is conducted at the Postgraduate Medical Institute or at one of the medical research institutes. Physicians must do a short retraining course every five years and clinical lecturers every three years. This requirement has faltered, however, with budget cuts and the difficulties of taking leave from employment.

A postgraduate course in public health commenced in 1997 at the Kazakhstan School of Public Health in Almaty. Management courses are also available at the Kazakhstan Institute of Management, Economics and Strategic Research and at the Centre for Medical and Economic Research. The number of new physicians graduating has continued to rise during the 1990s although there are few available jobs. Unemployment is said to be a problem among new medical graduates, and this is likely to continue, given the unwillingness of new graduates to work in rural areas.

Nursing education consists 2 years basic training, followed by one year of specialization in general medicine, emergency care, obstetrics, or management. However, the curricula are outdated and fail to reflect the requirements of health service provision and many nurses are poorly trained.

At present, nursing education is being reformed with the aim of upgrading it to postgraduate level, strengthening the status of nurses as an independent health profession, and providing continuing education. More attention is also paid to the training and retraining of managerial and administrative staff, including nurse managers, in line with the increased importance of primary health care, where most nurse specialists are expected to work in the future. At Almaty Medical College for example, a 4-year training programme for nurse managers has been introduced.

Feldshers receive nurse/midwife training with additional training in diagnosis and prescribing. They carry out clinical responsibilities that are mid-way between doctors and nurses. In rural areas, *feldshers* work in effect as primary care physicians.

In the former Soviet Union, the health sector was not regarded as productive compared to other sectors such as mining. Therefore, wages for health care personnel were set below the workforce average. Despite repeated increases in the salaries for health care workers in Kazakhstan, with an increase by 20% in 2004 alone, the official average salary in the health sector in 2004 was only half the national average for all sectors combined (President of Kazakhstan 2004). At present, the remuneration of health workers is regulated through the Government decree No. 41 on the System of Labour Remuneration of Public Employees who are not Civil Servants of 11th January 2002. Health workers are remunerated according to seniority and qualification, with no regard to outcomes or the quality of services provided.

The prestige and financial reimbursement of nurses continues to be very low. While

the official salary of physicians is not much higher than that of nurses, they can gain various official bonus payments and informal 'under-the-table' payments from patients. Physicians might also be appointed to more than one position, with a respective increase in income. The skill mix of health care workers is being adjusted in many European countries with the aim of increasing the number of trained nurses in relation to the number of doctors (Rechel, Dubois et al. 2006). In Kazakhstan, doctors often perform tasks that in western European countries would be performed by nurses, while nurses perform many tasks that elsewhere would be performed by auxiliary or support staff. The difference in Kazakhstan is that the salary differential is not as large and that nurses receive far less training than doctors.

Human resource development for successful palliative care

One of the developing fields in public health in the country is palliative care. There are a lot of problems that need to be decided at the different managerial levels including human resource development issues and bioethics.

Palliative care in Kazakhstan has developed since 1990s. Such figures as morbidity rate increasing, high mortality rate from oncological diseases, high rate of people with IV stage of tumour are evidence about necessity of this service in Kazakhstan. Six palliative care centres have been established in Kazakhstan. All of them get financial support from governmental budget. By patient and physicians' opinion palliative care service is a very important and helpful part in oncological service providing, and during last ten years Kazakhstan achieves real positive results in organization of this care.

At the same time there are a lot of challenges in this field. By medical experts' opinion only in Almaty already today there should be a minimum of four palliative care centres to satisfy population needs in this service. Moreover, if today most of the patients in the palliative care centres (80%) are with

oncological diseases, and only 20% of them with internal diseases, so in near future patients with such diseases as tuberculosis and HIV/AIDS will also need palliative care. This will lead to another big challenge for palliative care - human resources development. Currently there is lack of specialists in general oncology that should provide services as in oncological clinics, so in palliative care centres; lack of trained specialists in palliative care; psychologists and social workers. There is lack of unified training programs in palliative medicine to prepare qualified professionals.

Kazakhstan School of Public Health has conducted a study on palliative care needs assessment in Kazakhstan including human resource development aspects. Results of the survey explored the necessity of palliative care development in the country for the growing number of patients of both genders and different ages. Due to study conducted among medical workers and population in 10 cities (10 different oblasts) of Kazakhstan demonstrated following results. 24.5% of medical workers ($n=357$) noted about different problems in palliative care including lack of professionals with good knowledge of palliative care concept. Only 49.9% of respondents have regularly training. Other problem is emotional aspects of palliative care. 65.0% of population in different ages ($n=453$) noted that they have a relative who has needed palliative care service. 60.3% of them know where to receive palliative care service and got it, 39.7% are not. Only 38.4% of respondents have had emotional support from palliative care clinics staff. Emotional support was provided by medical workers in 37.6% and social workers in 13.8% cases. 21.6% of medical workers noted that they have positions for workers who may provide emotional and social support, 13.7% of medical workers noted that they have social workers and 13.1% - volunteers from religion organizations.

This shows another challenge - the problem regarding the training and retraining of specialists on palliative care in new concept, organization and management issues. To-

day there are no separate training courses on palliative care provision, on quality of services in palliative care for patients and their families to reduce the gap in professional development and this is an option to improve the situation.

Thus, there are a lot of problems regarding the organization and management of palliative care in the country, including the provision of medical, psychological and social services for patients and their families. Palliative care is in a transition stage in Kazakhstan. Decisions regarding these issues would further the development of this service. It is necessary to work on modern organizational, economic, and managerial mechanisms and standards to establish appropriate centres. Also, it is important to work on workforce development to provide qualitative palliative care. One of the main expected results following the study would be curriculum development for specialists of palliative care services.

Bioethics

Health care is an extremely complex and complicated field. Ethics is integral to health care: to its clinical practice, governmental and organizational policy development, payment system, legislation development, and finally to the national economy. Bioethics principles broadly integrated with its directions starting from research and continuing by national policy and economics of the country. Bioethics in Kazakhstan is in a developing stage. The Medical Society started to introduce modern international bioethics concepts, approaches and instruments. At the present time there are a few committees that could revise the ethical issues of research. One of them, the Institu-

tional Research Board, is located in the Kazakh National Medical University in Almaty. This Board works in line with international requirements. The Ministry of Health plans to develop a similar committee at the national level and this process is in progress. There is still a big challenge in the development of the legislation base in this field. The Kazakhstan School of Public Health in collaboration with international experts has developed a curriculum on bioethics for researchers. This course has been conducted during the last five years and helped to form a critical mass of health professionals who are capable of developing and implementing the bioethics concepts in the country.

In respect of public health research among elderly people it is necessary to remember that bioethics principles help correctly and in-depth to collect data on pertinent information. In particular in this direction such principles as "respect for human persons", "human control of life", "culture, behaviour, and interpersonal relationships", "justice", and "allocation of resources" are very important. In research with the elderly it is necessary to keep in mind that elderly people are more vulnerable in the psychological and social spheres. Confidentiality, honesty, autonomy are very important components in ethical research among the elderly population. During the planning of such research the investigator needs to think about such points as the value of conducted research and the results of the research, the climate or the environment of conducting the study, issues of the influence of culture and country policy to planning research, the prevention of potential conflicts of interest between clients and professionals and the compensation strategy for the research.

Another important approach to ethical research among the elderly is equitable distribution of benefits and burdens during the study. It is necessary to understand the formal and material principles of justice and the possibility for establishing (saving) balance of justice with other principles of bioethics such as mercy, beneficence, nonmaleficence, allocation of scarce resources and the fair opportunity principles.

Also very important are such aspects in conducting research among the elderly as differences between the definitions of "right to the life", "quality of life", "right to health care" and "resource allocation" according to ethics positions, and also the contrast between "allocation of resources" with "implicit and explicit rationing".

Thus, conducting research among the elderly, the study of the peculiarities of ageing, health status, quality of life, and providing health, prevention, psychological and social services become more actual for all countries in the world, and that is why such research should be conducted to modern requirements and held due to bioethics principles.

References

- Highlights on health in Kazakhstan. World Health Organization, 2006.*
- Kulzhanov M, Rechel B. Kazakhstan: Health system review. Health System in transition, 2007; 9(7): 1-158.*
- Kulzhanov M., Yegeubaeva S., Dosmailova A. Palliative care in Kazakhstan: Current Status and Perspectives for Development. Journal of Central Asian Health Services Research, 2007; 6(4): 35-40.*
- Schick I.C., Porter R., Chaiken M. Domains and Core Competencies in Ethics*

Georgian Health Care System in the Time of Armed Conflict (Georgian – Russian War of August 2008)

Prof. Gia Lobzhanidze – President of Georgian Medical Association
Dr. Levan Labauri – Secretary General of Georgian Medical Association

In August, 2008, during an armed conflict between Georgia and Russia, the infrastructure of the Georgian Healthcare system was severely damaged, including a loss of hu-

man resources. During the war, Georgian health professionals continued working in special teams, organizing specialists groups to deal with the critical situation. Emergency medical centers were entirely overloaded. Health system and personnel losses have not yet been definitively assessed however there are trends and medical perspectives of the disaster that can be discussed.

At the beginning of the war, medical institutions located in the conflict region were able to support entirely the flow of the injured military personnel and civilians. From the conflict zone, patients were taken to the Tkhviavi and Nikozi medical centres. Mobile military hospitals were also effective and saved many lives. After receiving emergency medical support in the above-mentioned centres or mobile hospitals, patients were transported to Gori Central Hospital and Gori City Hospital, where patients received qualified medical aid. When needed, patients were taken directly to various (mostly Tbilisi) clinical settings. Civilians, particularly those injured during war in areas far beyond the conflict zone, were concentrated in local medical centers by geographical principle. The system of the medical support described above worked well in the first days of the war. Later, Russian military forces attacked medical centres and the medical support strategy had to be changed.

Results from the Georgian Hospitals showed that the number of injured and killed civilians was many times more than the number of military casualties. As from the military-medical experience, the ratio of bullet-related injuries to missile-related injuries was 43/57; in the Georgian-Russian war the ratio was 7/93. It means, that the gunshot wounds from automatic weapon were not observed during the military operations. The first flow of wounded was received by the Gori Hospital on August 09, 2008. The Chief Surgeon reported that the absolute majority of injuries were missile wounds, fragment



wounds and blast injuries. There was no case of bullet-related (automatic weapon) wounds among the 65 patients admitted on this day. The absolute majority of the patients were peaceful civilian population. In all cases life stress events have severe consequences such as acute stress disorder and PTSD symptoms.

On August 8, 2008 Gori emergency medical centre was bombed just after that mobile military hospital, Tkhviavi and Nikozi medical centres' infrastructure were also paralyzed and destroyed. In the next phase, when Gori was bombed, the Gori military hospital was also practically paralyzed. Because of high level of risk, medical staff was evacuated. This effectively broke the second circle of medical aid. Although the medical staff was evacuated several times, doctors returned repeatedly to work in this high-risk zone. The Gori Hospital provided emergency medical service to Russian soldiers as well. Excellent work by the ambulance cars must also be mentioned. Both, Gori and Tbilisi emergency aid systems were working hard and the coordinated work of this circle saved lots of lives. During the war emergency aid vehicles have driven up to 2000 times from Tbilisi to Gori and back, in order to transport all the patients. During the transportation none of the patients have died.

The Georgian Medical Association has trying to inform doctors in other countries about the situation since the beginning of the war. We are very grateful to the World Medical Association, which reacted promptly. On 11th September 2008,



the WMA Secretary General, Dr. Otmar Kloiber, issued a press release on behalf of the WMA calling on both parties of the conflict to respect the professional independence of physicians. The WMA reiterated the principle in its policy on Regulations in Armed Conflict that physicians must be granted access to patients, medical facilities and equipment and the protection needed to carry out their professional activities freely. Shortly after receiving the message from WMA, the Georgia Medical Association received supporting letters from Germany, Belgium, Austria, Great Britain, Hong-Kong, Estonia, Finland, Ireland, and other countries' medical organizations. The letters included suggestions for helping injured people. We have also received thousands of letters of condolence from our foreign colleagues.

Many Georgian physicians indicated that their Russian colleagues had no wish to communicate. The Georgian Medical Association called on the medical profession of Georgia to unite their effort and strongly follow to the WMA policy statements. The Georgian Medical Association confirms the death of 4 healthcare professionals during the war: 1. Goga Abramishvili – the Trauma Surgeon from Gori hospital; 2. Marina Gogiashvili – nurse of emergency aid; 3. Leri Lagurashvili – military doctor; 4. S.B. – military doctor. One physician (Zurab Begiashvili) is still missing. The Georgian Medical Association also attempted to identify injured health



workers. We have collected information about 18 of them. Most injured doctors were taken to Tbilisi hospitals for further treatment. Through the initiative of Georgian Medical Association, a special fund was created to help and support medical staff harmed by the war. GMA representatives personally met with injured physicians and received the alarming news that nearly each of them claims that medical staff and hospitals were attacked directly and intentionally.

During the war, the medical infrastructure was seriously harmed. In such a situation, the main public health threat is the spread of infectious diseases. There was a high risk of this in the conflict zone because there were no medical staff and facilities available there. There was also no possibility of maintaining sanitary conditions in the collective living places of refugees. As from the WHO release, "in South-Ossetia people are in need of water, food and medical support, although no communicable

disease outbreaks". WHO also stated that there have been no reported outbreaks of communicable diseases in areas affected by the conflict.

The Georgian healthcare system has endured the first wave of crisis, and although there are some losses, the system keeps operating. In the next stage, some problems may emerge and our main objective is to anticipate what they will be and develop strategies and solutions to overcoming them.

Alcohol use in Norway



Guri Spilhaug, MD, Head of Unit for Primary Health Care and Psychiatry. Norwegian Medical Association

The consumption of alcohol in Norway has been relatively low for the last 150 years. The drinking pattern has been dominated by week-end drinking – relatively few drinking occasions, but drinking to intoxication (binge drinking). Lately the pattern has changed towards more continental habits, however, heavy drinking during week-ends still continues. More people drink alcohol, especially women, they drink more when they drink and they drink more often than before. Many people also seem to use more alcohol in work related situations. It is an important issue to prevent alcohol abuse in Norwegian workplaces and also to make sure employees with abuse problems get help.



Arne Johannesen, MD, Head of section, Dep. for Service Development. South-East Regional Health Board

Measured as pure alcohol each person 15 years or older drank an average of 5.66 litres in 2000, and in 2007 this had increased to 6.60 litres. The data of quantity of alcoholic beverages consumed during the last year shows that men consume on average 2.5 times more than women. The alcohol consumption decreases by age, while it seems to increase with income and education. People who live in the Oslo area consume more alcohol than people living in small towns and rural areas. The popularity of wine and beer has shown a strong increase over time while liquor consumption has decreased. A key element in Norwegian alcohol policy has been to remove the private profit motive from sales of wine, spirits and strong beer.

The business became subject to a special Vinmonopol (Wine and Spirits Monopoly) Act on 19 June 1931, removing alcohol from the scope of the regular Joint Stock Companies Act. Directors and the president are appointed by the government. The board is also bound to observe directives issued by the Ministry of Health and Social Affairs. After the private interests had been gradually bought out, Vinmonopolet became wholly state-owned in 1939.

Vinmonopolet has the exclusive right to retail wine, spirits and strong beer in Norway. Vinmonopolet purchases the products from importers holding the required licence and who have signed a purchase agreement with Vinmonopolet.

Norwegian alcohol policy has changed in recent times. Keywords are cuts in alcohol taxation, an expanding hospitality sector – especially restaurants and bars – and increasing numbers of Vinmonopol outlets. The development in the EU and Nordic area is also feeding this growth along with growing public disaffection with traditional alcohol policy mechanisms. Higher import quotas and lower taxation on alcohol in other Nordic countries made Norway's stance increasingly untenable.

The Norwegian Institute for Alcohol and Drug Research (SIRUS) is an independent research institute with the purpose of research concerning the use and abuse of intoxicants and other addictive substances, with a particular stress on questions relating

to social studies. The institute monitors both consumption and the consequences of such and has played an important role in the policy formation on alcohol in Norway. Alcohol is a risk factor to more than 60 different illnesses, like for example cancer, heart and vascular diseases and psychiatric conditions. We also know that violence, traffic and other accidents and self-harm are related to use of alcohol. In Norway the amount of patients hospitalised because of alcohol intoxication was doubled from 1999 to 2003. More research on alcohol use and alcohol related health problems is necessary to increase our knowledge about risks and treatment. Prior to the Drug Reform in Norway in 2004, treatment for addiction was primarily a social service, and it was the social services in the municipalities who referred patients to drug treatment. The Drug Reform made specialised treatment a health service and doctors obtained the right to refer patients

to treatment. As a consequence the number of referrals has risen. General practitioners account for a large portion of this increase, while there are small changes in the number of referrals from social services.

The Norwegian Medical Association has watched the increase in alcohol consumption with growing concern, and in 2004 the organisation wrote a report about addiction and health problems. The report concludes with several recommendations, amongst these are to increase doctors' and other health workers' knowledge about alcohol addiction and alcohol related health problems, and how to discover it. It is important to employ more brief interventions that can help to reduce the risk of alcohol problems among persons with high-risk consumption. Such intervention usually consists of ascertaining alcohol consumption and a motivational interview or conversation. These

interventions are not frequently used today. There is also a lack of routines for follow-up after detection of alcohol problems.

The Norwegian Medical Association recommends to maintain a restrictive alcohol policy in Norway, where price and access are the main factors to influence alcohol consumption. From a public health perspective it is important to keep the total consumption of alcohol in the country low. Doctors, and especially the general practitioners have a special responsibility to inform about the dangers of risk drinking and resulting health problems.

This year the Norwegian Medical Association has established an expert group to write the organisation's strategy document on alcohol policy.

Challenges in Health Care Unite the Medical Associations



Heikki Pälve MD, Ph.D., CEO, Finnish Medical Association, Specialist in Anaesthesia and Intensive Care, Special Competency in Emergency care

The developed countries all face the same challenges to their health care system. Because of the advanced treatment pos-

sibilities offered by modern medicine and increasing health demand of the citizens, which is partially a result of an ageing population, health care providers are faced with budgetary pressures. There are several different ways how the authorities have tried to diminish these problems.

The health care systems in nearly every developed economy are on the move away from current organisational models in a quest for cost-effectiveness. As a result the autonomy of doctors is often restricted and task shifting is considered as one possible solution to the lack of resources. Legislative action is taken to cut down the health care expenses. Gate keeping roles for doctors are often also proposed to cut down the demand of hospital care, but simultaneously doctors are often expected to treat their patients not according to the best proven therapeutic or diagnostic method. Doctors and their organisations all over the world have to work in a very stormy environment facing constant system changes. The case

is no different in Finland and the situation requires increasing involvement and action from the Finnish Medical Association. It seems that Finland is the world in miniature size and we are facing all these challenges at the same time.

The Finnish health care system

In Finland, the health care system is financed mainly through taxation and run by the municipalities, which are responsible for providing the services. The treatment results of many diseases are globally on top level and all the citizens have equal access to health care regardless of their wealth.

The satisfaction of the population with the system is very high and the total health care spending represents only eight percent of the GDP, which can be considered to be cheap. Even though it is difficult to measure the total effectiveness of health care, the international comparisons that have been made have proven that the Finnish system is cost-effective. In spite of this the representatives of local and central government judge Finnish health care as expensive. Therefore many major

changes to the system are either ongoing or being prepared.

New legislation to salvage primary care

Primary care, which in Finland is organised in the municipal health centres, has increasing difficulties to attract doctors. The situation is especially difficult in rural areas, but problems occur even in major cities that have their own medical faculties. The current law separates primary and specialist care into two different organizations.

This total division of primary and specialist care and lack of coordination between them is one reason for increased spending in health care. Therefore the Finnish government is preparing new legislation that would cover both specialist and primary care and increase their joint organisation as well. The bill would increase the freedom of the patient to choose between different doctors and hospitals, which is not a right that the patients in Finland enjoy at the moment. Another aim is to increase competition and cost control to achieve savings. There is an increasing tendency to encourage private entrepreneurship on the health market. Currently municipalities spend only 3% of their health care resources to buy services from the private sector. The public sector is thus managed practically in a monopolistic manner. However, people use the private sector in an increasing frequency since it can offer care without undue delay and the patient can choose the doctor freely and see a specialist directly without turning to a general practitioner first.

Until now it has been politically impossible to liberate the services, which has led towards different methods of rationing the care. Because the local officials hold the purse strings of service production in a monopolistic manner, the central government has already earlier taken legislative action to increase pressure on the local level. In 2005 a treatment guarantee law was introduced. It requires the local authorities to see to it that necessary treatment in hospitals has to

be given within six months from the moment the need has been diagnosed.

The Finnish Medical Association has as one of its basic values the enhancement the best for the patient. Therefore the FMA has advocated strongly both for the treatment guarantee and the free choice of the doctor, as well as the possibility of patients to travel abroad for their treatment when and if necessary. The latter choice is included in a new framework law proposal that is under preparation in the European Union to unify patient care within the borders of the EU. It is expected to raise some opposition from the governments of EU Member States, who want to keep the grip on their citizens' rights and possibilities to choose between different caregivers in order to safeguard their own health care budgets.

Non-doctors as managers

Finnish doctors have traditionally finished their professional careers as leading administrators in hospitals and health centres. Their experience of the health care system as a whole together with accumulated managerial experience and education has made them highly capable to fill these positions. Even though the international comparisons have shown that the Finnish system is run very cost-effectively, doctors are now being charged for being responsible to the cost increases during the last decade and therefore judged to be bad managers.

If doctors are considered unfit leaders it serves as a good excuse to actively diminish the role of the medical profession in running the system. Process management is preferred instead of professional management, and being a doctor is turning out to be a disadvantage instead of being a virtue. Key indicators used to measure the success in health care – such as time spent and number of patients met – are secondary to its real goals and effects. This mechanistic view of measuring the “health industry” rarely takes into account real health benefits to the patients and their level of satisfaction with the system or their treatment results. It

also totally ignores the central tasks of our profession: always comfort, often alleviate and when possible heal.

When we lose medical professionalism in the management of health care we also lose valuable insight how to develop patient care and how to advance medicine in the best possible way. Undoubtedly this trend will first worsen the working conditions of doctors and as a result of that also patient care.

Forcing the doctors to step aside from their administrative role has already led into serious problems in Finland, especially in the health centres. Doctors feel their voice is not heard when primary care work is reorganised. In many cases they have sought new positions elsewhere and even whole municipalities have lost their all doctors in a very short time. The FMA tries actively to lobby the local politicians and administrators to understand the importance of professional experience and leadership when meddling with the structures in order to contain costs.

Helsinki University Hospital, by far the biggest hospital in the country, is in the middle of serious crises at the moment. A new CEO was appointed to the hospital and he introduced a new managerial leadership model into the hospital leaving doctors out of the organisation's strategy work and top leader positions. This was justified by arguing that doctors are not educated and experienced leaders. It resulted in an open conflict, which made front page news. In the end the united doctors' front got their opinion approved, setting a good example to the profession in the country and worldwide: united we are strong and able to defend our possibilities to treat the patients.

In Finland there was a special educational program for doctors on health care management, but it has been abolished recently. No new program has been introduced even though it was promised. This has led into mistrust between the profession and the government and increasing numbers of doctors are moving from the public sector to

the private sector and occupational health, thus leaving the health centres and hospitals in resource crises. It is important that educational programs for doctors in health care management exist. Doctors should be encouraged to participate in these courses and make use of the qualifications accordingly when seeking positions. There is certainly a need for international cooperation in this area as well and the FMA welcomes the efforts of the World Medical Association with its INSEAD training program which will take place for the second time in France in December 2008.

Working time

Other current topics related to the organisation of medical services in Finland are the questions of working time and on-call work. The European Union is at the moment trying to renew the framework legislation that regulates the maximum daily and weekly working hours of most employees, including doctors. The FMA understands well the risks for patient safety that are caused by excessively long working hours. At the same time it is clear that emergency care requires doctors to be on call when needed and they also must be properly remunerated for the inconvenience caused by these abnormal hours of work. The proposed ceilings to the maximum weekly working hours are not a major problem in Finland. However the attempt to limit the active daily working hours will affect the on-call work in hospitals substantially and require a much higher number of doctors.

Task shifting

The Finnish government has promised to propose a bill on task shifting later this year. The aim is to give restricted right to some 200 nurses to prescribe. According to the government this is justified because it allows the patients to get their medication easier. The Finnish Medical Association feels that prescriptions are a part of the treatment decisions that should be restricted to medical profession only and sees any attempt to change this as a substantial violation of the

autonomy of the medical profession. Doctors have the knowledge, training and competence to diagnose and determine the best and most effective medication. They also know how to take into consideration the overall condition and possible other illnesses of the patient, as well as eventual interactions between different drugs. Therefore the responsibility of the pharmacotherapy must always lie on the profession and individual professionals that are responsible of the patient's treatment as a whole. It is certain that the debate in the parliament about this issue will be vivid, but the political pressure is unfortunately towards the medically unacceptable result.

In Finland there is one working-age doctor for every 300 inhabitants. In our system it is therefore not plausible that nurses are needed for prescribing. Even if there was a problem it could not be solved by training some 200 nurses trained to prescribe, as has been suggested. It is evident that the real reasons for these changes differ from the ones that have been expressed in public. Factors like cost-containment have been stated to play a role. Unfortunately it is probable that this policy will increase the medication costs even though the salary of prescribers would be lower. Savings are not easily attained since the more there are prescribers the more there will be prescriptions – but not necessarily more health. Especially antimicrobial resistance may easily increase and lead into more dangerous and costly infections.

The lack of human resources (physicians) and immaterial resources (time) should not be used to justify shifting the therapeutic decision upon other non-medical professions. Health care is teamwork. The patient's integral health care requires a multidisciplinary effort by all health professions, taking into consideration each other's field of competence. Other health professionals may considerably help the workload of the doctor in their quest for the best of the patient. However, in low-income countries that suffer from an extreme shortage of doctors, it is understandable that some tasks – such

as the practical delivery of drugs – may be partially delegated to other health professionals, but even in those cases always in a clearly defined manner.

Clinical autonomy

A physician should always act in the best interests of the patient. Respecting the will of the patient must however not result in avoiding responsibility. A physician must support the decision-making of the patient by providing factual, evidence-based information in a clearly understandable manner. The patient must always be able to trust the honesty and professionalism of the physician. This trust from the patients and the support of colleagues are the cornerstones of our everyday work. They must be supplemented by an agreement with society that results in a health care system which gives us the necessary clinical autonomy.

A Finnish patient was recently let down by the false promises of a quack. Later, the patient was quoted in a newspaper saying 'I trusted him like a doctor'. This trust that we now enjoy from the patients, from colleagues and from the society at large must be regained and reinforced every day. The only way to do that is to always act for the best interest of the patient in an ethical way.

Our profession faces major challenges today. The patients have been empowered into demanding customers, the politicians like to see us as any other group of workers and not as highly trained experts in medicine who can and should bear the responsibility of medical care in every health care organisation. We must insist that organisations based on medical expertise require medical experts to lead them. For all of us, there is much work to be done. Like the doctors in the Helsinki University Hospital, the National Medical Associations should face these challenges united and prepared. Together we are strong and can best serve our members and their patients. That is why there is an increasing need for WMA and regional co-operation of the NMAs.

Colegio Medico de Mexico

Dr. Federico Marin, President Elect 2009- 2011

I would like to talk about “*México Mágico*”. Let me preface by saying that Mexico is a Country of many contrasts; we have lived, as was described by a Latin American writer, in the Country of the “perfect dictatorial state”. It only lasted 77 years, until the year 2000. Then, after the treacherous murder of the “official” candidate to the presidency, the ruling party lost control, and thanks to their last president the system changed bringing us to the dawn of a new era, the beginning of a democracy. It is said that we are living in the midst of a political system that does not seem to end, and one that has not yet been established. Theoretically, we live in a democracy, in a republic, “The United States of Mexico”. It consists of 32 states and one Federal District, (Mexico City) with the geography of a horn, the “Cornucopia”, but with the opening to the north that just so happens to be to the USA. The truth is that the northern states of Mexico, mainly agricultural and with cheap labor, (they have many labor plants) have exported their production to the United States, hence their wealth. And since NAFTA was created, their growth has been 10 times as much as that of the southern states, thus, one-third of the northernmost part of the country, close to the USA, are the rich estates. The central part is where the Capitol is, as well as most of the Government offices; and the southernmost part is where the poorer states are located and civilization seems to have stalled. (We cannot but wonder if it ever arrived.) But then again the contrasts; Cancun is almost at the tip, or the southernmost part of the country, as are Oaxaca and Chiapas with their natural wonders and if that were not enough, all the Mayan Culture. A paradox one might think?

This is a country where official data shows that half the population is below the poverty line. (The Mexican population in 2008 is 106,600,000). 13.8% of the population is incapable of even buying their own food. In contrast, the wealth is in a small group

of families, comprising less than 5%. We are still wondering how it is possible that the World Bank defined our Country as a rich Country, with high income. Perhaps we should tell the World Bank to go and ask the 13.8% people who are starving. The Mexican Constitution was signed on February 5, 1917. Within its 136 Sections, it talks about the right to food, housing, health and education for all. That has not yet been the realized and nobody knows who is supposed to foot the bill. Still, feudal lords rule each in their own reign, doing and deciding for others, on their own free will and for their own benefit. We could say that health is the hostage to the lords and they use it as ransom. We are a country with huge proven oil reserves, but with the lack of technology to produce or refine gasoline, the gas is burned right in its extraction site, and then we import gas from other countries.

The Health System

National Social Security, *IMSS*, *ISSSTE*, *PEMEX* (equivalent to Medicare and Medicaid in the United States), serve 58.7 million people, except that their inventories, materials and physicians, are roughly at a 50% capacity to achieve this. Waiting time for a doctor appointment is more than two hours and surgical procedures are deferred up to 6 months.

Around 20 million people are not protected by any kind of system (“out-of-pocket”). The

other 22 million people are in a prepaid system, or so they say, but again, I doubt it. The government insurance policy called “*Seguro Popular*”, (Popular Insurance or Popular Security) was established in a way to cope with the text. Suffice it to say that “reality” did not read the terms and conditions of the contract. With the same health institutions, the government is trying to provide Social Services – in exchange for payment – as a way of insurance. We, the physicians, never agreed, but we were never asked either.

Medical Schools

Legally there are 106 schools of medicine. Every year, before starting any specialization, an evaluation examination is required. Some 25,000 new physicians attempt it, but fewer than 5,000 are admitted. That means that we have a surplus of 20,000 general practitioners every year. With this number of schools, one can imagine how many associations, councils, colleges, boards, etc., exist. We have talked about the atomization of physicians, meaning that the authorities, by allowing this, have created such confusion that the possibility of doing anything in an orderly manner is quite minimized.

The challenge is to convince physicians to move to where they are needed. Southern states have a minimum of medical services, while, on the other hand, in the capitol and in the big cities, there is “top of the line” medical services, with excellent hospitals for those who can afford it. The health system is supported mainly by residents as a labor force. Depending on the health system



needs, the number of physicians admitted by the evaluation examination may increase or decrease.

According to the Mexican Constitution, no person can be obligated, forced or restricted from the free exercise of work or employment; therefore, by law, good fellowship is not stimulated, promoted or enforced. The Secretary of Education has 638 medical specialties. Currently, the *COLEGIO MÉDICO DE MÉXICO* is certifying, providing continuing medical education, and trying to return dignity to physicians. This dignity was lost when third parties or third payers, interested in belittling the profession, intervened with the purpose of having technicians who are easily and rapidly trained, as opposed to educated

specialists who undertake years of formal education and training.

Our meetings take place in different states with the idea of visiting the whole country, presenting new programs and setting new goals, and to try to negotiate with the different departments in the government, who demonstrate unlawful management. In trying to make them modify their performance – though it is a day by day battle – we finally seem to be making progress with the new government administration (democratic government?). Now we seem to have reached a meeting place for negotiations. Our comments on health issues have been accepted and are beginning to influence the health programs, the pharmaceutical industry and other health issues.



XLV General Meeting, in Monterrey, Nuevo Leon, Mexico, November 18, 2007 Doctors. From the left: Reynaldo Cantu Mata, Former President 2005-2007; Eduardo Tello, Current President 2007-2009; Federico Marin President elect 2009-2011

The Medical Association of Malta

*Gordon Caruana Dingli, MD LRCP Edin
LRCS Edin LRCP&S Glasg, FRCS Edin
FRCS RCP&S Glasg, Secretary General,
Medical Association of Malta*

The Medical Association of Malta (MAM) was established in 1955. MAM represents all the different medical specialties in Malta with a membership of around seven hundred doctors. MAM is both a medical association and a trade union; in fact it is one of the oldest and most prestigious trade unions in Malta.

The founder President of MAM is the Honourable Dr. Vincent Tabone, an ophthalmic surgeon and Emeritus President of Malta.

The council of the Medical Association of Malta is elected every three years and is completely voluntary and unpaid with only part-time secretarial support.

MAM aims to unite all medical practitioners and to safeguard their interests, providing advice and assistance in their mutual relations and with the State and other authorities and organizations and provides

spokesmen for any member seeking assistance.

MAM promotes the ethical, scientific, professional, cultural, social and economic interests of its members to lead to the highest possible standards of education, ethics and patient care.

MAM works with other national and international partners and organizations to further its aims. Its local affiliations are with the Federation of Professional Associations and the Confederation of Malta Trade Unions (CMTU). On the international scene, MAM is affiliated with the World Medical Association (WMA), European Forum of Medical Associations and WHO (EFMA), Permanent Working Group of European Junior Doctors (PWG), European Union of Family Doctors (UEMO), Commonwealth Medical Association (CMA), European Union of Medical Specialists (UEMS) and the Standing Committee of European Doctors (CP).

In 2007 the Medical Association of Malta negotiated a new agreement with the Health Division of the Malta Government which

improved working conditions for hospital doctors. The new agreement promoted flexible working times by introducing sessions and also entrenched postgraduate training.

In Malta the medical profession faces several challenges, foremost of which is the 'brain drain' where locally trained doctors are emigrating to other European countries for financial benefits and for better career prospects. This new agreement will serve to retain local graduates by improving training, working conditions and career prospects.

MAM is also conscious of the physical and mental stresses of working in the profession leading to early 'burn out'. This problem will be approached by improving health care services for practicing doctors.

On the other hand there are exciting new prospects for the medical profession in Malta. A brand new 'state of the art' hospital has recently been commissioned and there are several new developments especially in postgraduate training. There are plans to make Malta an international training centre and also to encourage medical tourism.

MAM strives to improve the standard of health care in Malta to provide the highest possible levels of patient care.

Albanian Order of Physicians – Progress and Strategy of Development

Dr. Din Abazaj, President

Dr. Shaqir Krasta, General Secretary

The Order of Physicians of Albania was created in 1994, by a law of Parliament, during the first years after changes in the socio-economic and political system of Albania, as a new body without any precedent in Albanian medical practice. This entity began its activities in the circumstances of a very difficult transition in all sectors of Albanian social life.

The foundation of the Order of Physicians was a very important step for Albanian medicine as an independent link of professional self-regulation and effective support within the framework of the reforms in health care.

Until 2000, the Order was completely dependent on the Ministry of Health; the activity and competencies of the Order was very restricted. During this year a new Law No. 1615 date 01.06.2000 "On the Order of Physicians in the Republic of Albania" was promulgated, which considered it a "Public Entity". From this time the Order began to develop, raise and enforce institutional capacities and functioning as an effective, independent, professional body.

During the last few years of the activity the challenges of the Order had been oriented to:

- **Firstly**, raising of capacity and institutional effectiveness,
- **Secondly**, raising of public credibility, among the membership and in partnership with counterparts in the country and abroad.
- **Thirdly**, the construction and consolidation of systems and processes for the good functioning of all the Order's structures.

The Order of Physicians is a regulatory body of medical professions and its main

mission is to offer support and encourage high standards for formation and continuing education of doctors. On the other hand, it is engaged to guarantee the application of these standards in the defence of the public and patients from medical malpractice and transgressions of the Code of Medical Ethics.

The Order has concentrated its efforts on:

- Registration of doctors
- Fitness to medical practice
- Managing of financial sustainability
- Public involvement
- Public relations and communication
- International relations

The National Council of the Order had approved the Code of Deontology and Medical Ethics as a central document for professional standards, to be applied compulsorily by every physician during medical practice.

The establishment of the National and Regional Register of physician's membership and creation of the website (www.umsh.org) were important challenges of these years. The register was constructed as a database and is open to the public and it contains some data, which belongs only to the Order, regarding the Continuous Medical Education for doctors, needed for the periodical revalidation of health professionals.

Closely associated with the National Council is the National Disciplinary Judgment Commission, which deals with the doctors who avoid the fitness to practice and other commissions.

A very important issue for the Order has been public communication and the examination of public and patients complaints.

The Order of Physicians of Albania is a young body without experience and tradition. These conditions have led to the ex-

pansion of relations and collaboration with similar bodies and international organisations. Today the Order has relations with a number of European medical associations and is a member of IAMRA, GIPEF, EFMA, ZEVA, COMEM, etc.

The expansion of international relations has been directed to the integration of Albanian medicine with European medicine.

The priority challenges to the future activity of the Order are:

- **Firstly**: enforcement and improvement of activities related to raising the credibility of the Order and consolidation of it as an independent public entity,
- **Secondly**: invigoration of all the Order's branches for monitoring and control of daily medical practice standards related to the protection of the public and patients from medical malpractice.

The long term Strategy of Order of Physicians has been directed to the support of Health policy reform in Albania.

15 years after the changing of the political and social regime in Albania the health system still encounters a lot of difficulties related to:

- very limited technical capacities to develop policies, strategies and national plans,
- institutional and individual professional accreditation has not yet been applied. Albania does not currently enjoy either experience or tradition in this sector.
- lack of the decentralisation of competencies from government authorities to health organisations, institutions and public entities and, as result, the orders and professional organisations are not playing the role which belongs to them for exercising their competencies, authority and commitment regarding Continuous Medical Education, and the accrediting and licensing of professionals.
- lack of experience in monitoring and controlling the activities of private practice,
- lack of necessary structures for monitoring and controlling the quality of health care,

- lack of many diagnostic equipment and curative services.
- lack of credibility and public dissatisfaction of the quality of medical services delivered.
- one of the more acute problems is the unequal distribution of medical staff. Many communities are left uncovered by the health service. As result of free movement and the migration toward big cities, physicians abandoned their working places in remote rural areas, which make the planning of the needs for health services very difficult.
- insufficiency in the financing the health system.
- little experience and weak capacities in the field of health management.

Taking into consideration the above-mentioned problems, health reform in Albania has concentrated on an ambitious strategy that introduces challenges to be faced, such as:

- Strengthening the technical capacity of the Ministry of Health in drafting policies, strategies or national plans for health system development, avoiding the traditional role of direct management of health services,
- Improving the stimulating policies for private health service, as well as the strengthening of legislation, standards, and monitoring structures in order to protect the public from abuses and harmful medical practices.
- Placing the patient in the centre of the health system as a fundamental condition for quality service and development.
- Decentralization of health system with the final aim of its autonomy, as the optimal solution for good management and the safeguarding of system integrity.
- Establishing of a national system of human health resources, capable of achieving its mission.
- Extension of financial basic resources, increase of the financial and cost-effectiveness of their use through increasing public funds for health, enlargement and strengthening of health insurance schemes, improvement of contracting mechanisms.

- Strengthening of managerial capacity of health institutions through creation of models for their management. Establishing of the profession of health managers.
- Preserving and improving public health by adapting it to the economic, social and epidemiological changes in the country.
- Strengthening and perfecting of primary health care service by considering it as the main pillar of health services.
- Creating the model of an autonomous hospital aiming at the improvement of health care quality.
- Improvement of dental and pharmaceutical service with the aim to standardise, strengthen and monitor structures.

To face and realize all these challenges Albania needs the setting up of necessary structures in the sectors of Health Insurance Policies, Mental health, Health Management, Quality Control, Accreditation, Licensing, Monitoring. CME, Standardization and Maintenance of medical equipment and others.

The human resources in the health care system today in Albania are limited. The ratio of physicians to population is 1.36 per 1000 inhabitants (among the lowest ratios in Europe). The ratio of mid-qualified staff is 3.7 per 1000 inhabitants.

For resolving these issues, the reform is concentrated in developing a medium term and long term plan for human resources in the health system, improving the geographical distribution of medical staff by applying the principles of the labour market, establishing a Centre of CME and allocating the necessary funds, establishing the School of Public Health in order to create a functional training system for physicians and medical staff. On the other hand, it is important to strengthen the role of the family doctor. Albania possesses an insufficient number of family doctors – 0.5 per 1000 inhabitants. The specialty of family medicine was introduced only recently and is still the most discriminated and low-esteem specialty. It is very important to strengthen the category of family doctors by improving their tech-

nical abilities and the infrastructure of Primary health care.

The reform in Albanian medical services should include also:

- Strengthening the patient's role in assessing the level of health service and development of health policies,
- Encouraging the establishment of autonomous health services (PHC and hospitals), financed by the health insurance scheme.
- Establishing the School of Public Health and institutionalising Continuous Medical Education.
- Changing the image of family doctors through improvement of clinical practice and a new philosophy of dealing with the individual and community issues.
- The new Government has decided to rise the percentage of GDP for medical services from 2.4 today to 3.5 during 2007-2008.
- Organising of health promotion focusing on improvement of life style, prevention of road accidents, drugs, alcohol, tobacco, etc.
- Improve population access by primary, secondary and tertiary health services.
- Improving the primary health care infrastructures.
- Encouraging and supporting the enlargement process of private practice in delivering health care in the primary and hospital services.
- Improving legislation to harmonise the reform in medical service.
- Privatised the curative dental service completely and apply the health insurance scheme cover people of 0-18 years of age.
- Improving the pharmaceutical legislation based upon EU experience.
- Strengthening the monitoring capacities in manufacturing, storage and marketing of drugs.
- Strengthen the structures, collaboration and the role of public entities such as the Order of Physicians and Dentists of Albania, the Order of Pharmacists, the Order of Nurses and professional associations of the medical specialties.

International Hospital Federation

Eric De Roodenbeke, Director General of the International Hospital Federation.

The International Hospital Federation is the successor to the International Hospital Association, which was established in 1929 after the first International Hospital Congress in Atlantic City, USA. The Association ceased to function during the Second World War, but was revived under its new title – International Hospital Federation (IHF) – in 1947. The IHF is an international non-governmental organisation, supported by members from over 100 countries. As the worldwide body for hospitals and healthcare organisations it develops and maintains a spirit of co-operation and communication among them, with the primary goal of improving patient safety and promoting health in underserved communities.

The IHF vision is to become a world leader in facilitating the exchange of knowledge and experience in health sector management, with its main goals being:

- To improve patient care quality around the globe, through the dissemination of evidence-based information.
- To collect, collate, publish and facilitate the exchange of information and ideas on best practice in hospital and health care management.
- To assist in the creation of environments that support organisations in the promotion and delivery of health care.
- To foster international partnerships that promote interaction among public and private hospitals and health care organisations, the community and commercial entities.
- To promote and protect the dignity, safety and welfare of patients.

The vision is promoted through events, publications, networking and projects in line with its mission and values. These activities prioritize information on leadership

and management of hospitals and health services.

The IHF publishes the journals *World Hospitals and Health Services* and *Building Quality in Health Care* launched in October 2007 in collaboration with The Methodist Hospital (Texas, USA); the yearbook *International Hospital Federation Reference Book*

IHF events which are organized and located to ensure its presence in all regions of the world include the Biennial World Hospital Congress, Pan-Regional Conferences. IHF events also provide both a forum and meeting place for public and corporate actors.

The IHF engages in a myriad of activities which have as their objectives prioritization of information on leadership and management of hospitals and health services. Examples of such activities include:

- Development of a Training Manual for Tuberculosis (TB) and MultiDrug Resistant-Tuberculosis (MDR-TB) Control for Hospital/Clinic/Health Facility Managers.
- Assessment and preparation of a report on water usage within hospitals and healthcare facilities, for which aspects of waste management and control of infectious diseases were points of focus.
- Inter-professional collaborative project involving conduct of and preparation of a report on smoking policies and practices in hospitals and health services in selected African countries.
- Technical Assistance Programmes to Ministry of Health (Kuwait), to review recent initiatives undertaken to improve the country's health care.
- Collaboration with the International Association for Infant Food Manufacturers (IFM) to develop a concept paper for a safety training programme for feeding practices in hospitals.

The IHF through its membership and communications activities acts as a bridge be-

tween members in order to facilitate and support cross-fertilization of knowledge and experience in management and leadership of health organizations. Through these activities, the IHF supports the creation of new national hospital associations.

The IHF has official relations with the World Health Organization and also maintains good working relationships with a number of other international organizations, such as:

- the International Council of Nurses;
- the World Medical Association;
- the Hospital Committee of the European Community;
- the World Dental Federation;
- the International Pharmaceutical Federation;
- the Global Health Workforce Alliance;
- World Alliance for Patient Safety of WHO.

IHF secretariat is engaged in questioning all of its national members to better reflect their priority areas of concern. This review will lead to the organization of the first-ever global retreat of health-care organization representative top decision-makers, in May 2009. Such a forum will energize solutions and enhance advocacy capacities both at global and national level. It will also be of major importance to clarify the dialogue IHF will undertake at global level with major health organizations. Today hospitals are trying to find opportunities to grow and/or sustain their activities. The hospital sector is going to change dramatically in the coming years. It is more than ever important to think ahead relying on a better understanding of how the future is shaping up. Innovative solutions emerge locally but they can be scaled up through a bottom up - top-down process, thereby making the global level a necessary step to accelerate responsiveness.

IHF is the key to this process because it is the link between the hospital sector, the health care professions and the international organizations.

The International Council of Nurses

Dr. Hiroko Minami

The International Council of Nurses (ICN) is the world's first and widest reaching forum for health professionals. As a federation of 131 national nurses' associations, ICN represents more than 13 million nurses working around the globe. Our mission is to represent and advance the nursing profession worldwide, and influence health policy. Our vision is to lead our societies toward better health. All ICN activity is guided by three strategic goals and five core values. The goals are:

- to bring nursing together worldwide;
- to advance nurses and nursing worldwide;
- to influence health policy.

Five core values form the basis of all ICN decisions: Visionary Leadership, Inclusiveness, Flexibility, Partnership and Achievement. As a federation of nursing organisations – professional associations, regulatory bodies, and unions – ICN's work encompasses professional practice, regulation and socio-economic welfare.

Professional Practice

In professional practice ICN's current focus is in three main areas. The first, leadership, focuses on developing nursing leadership skills – to make the nursing voice heard at the policy level, to improve working environments and, most importantly, to support quality care for patients, families and communities. As a specific example, ICN is developing nursing skills in the area of disaster preparedness, and lobbying international institutions to integrate disaster preparedness, response and recovery into their aid programmes.

A second focus is the development of a specific language to describe nursing practice. Called the International Classification of Nursing Practice or ICNP®, it is used to document and describe nursing practice across geographic areas, languages and time. A third focus of ICN's work in professional practice

is the importance of strong linkages with national, regional and international nursing and non-nursing organisations. Building positive relationships internationally helps position ICN, nurses and nursing for now and the future. ICN works with a wide range of partners, including United Nations agencies, the World Health Organization (WHO) and the International Labour Organisation. We also work with a variety of other intergovernmental agencies, non-government organisations and industry.

Regulation

Turning to ICN's second pillar, regulation, ICN has long recognised that setting and enforcing standards for nursing education and practice is a major responsibility of organised nursing. ICN has established an Observatory that identifies future trends and issues that require consideration and action. We have produced guidance documents, fact sheets and monographs on issues as diverse as mutual recognition agreements, professional regulation, competencies and a model nursing act. ICN brings the global regulatory community together via a forum for Regulators and 'triad' meetings bringing together NNAs, regulators and Government Chief Nurses. We are currently undertaking a major research study that will facilitate communication and understanding between nurse regulators. This study in addition to conducting a comparative analysis of legislation also identifies regulatory best practices.

Socio-Economic Welfare

In much of the world the socio-economic welfare of nurses is inadequate. Unsafe and undesirable working conditions contribute to what is probably the greatest challenge to nursing and health today – the shortage of nurses worldwide. In 2004 ICN and the Florence Nightingale International Foundation undertook the first **systematic investigation of the nursing workforce to establish a global picture of the actual situation**

and the potential solutions. This global analysis has identified the policy and practice issues and solutions that should be considered by all sectors in addressing the supply and utilisation of nurses.

One of the solutions is the promotion of positive practice environments which support nurses' professional identity through meaningful work, autonomy, control over practice, input into decision making and strong leadership. ICN is working with other health professions on a campaign for positive practice environments.

We are also working with other health professions in the fight against counterfeit medicines – a growing global threat. This is an area in which nurses are well positioned to monitor drug effects and side effects. Nurses also have a key role in educating the public about the dangers of buying medicines through the Internet or on the streets from unauthorized sources. ICN also works in the area of HIV/AIDS care to protect nurses from the danger of occupational exposure to HIV and to address the particular needs of health care workers. ICN has established HIV and TB Wellness Centres of Excellence in sub-Saharan Africa which deliver comprehensive HIV and TB treatment, health services and training for all infected health workers and their families.

The health of women and girls is of particular concern to ICN because of the discrimination they suffer on the basis of their gender. ICN's Girl Child Education Fund is helping the orphaned daughters of nurses return to school. The education of girls and women has a direct result on poverty reduction, lower maternal and infant mortality rates, improved health and nutrition, higher productivity and increased likelihood that the next generation will in turn be educated. The successes ICN has known since its founding in 1899 are a product of the combined efforts of the nurses of every country, every continent. Our members, the national nursing associations, represent the strength of ICN and nursing and are vital to health and progress in every society.

The International Association of Medical Colleges (IAOMC)



James Appleyard MD FRCP, Hon. Secretary to the Board of Trustees, IAOMC

A few nations train a surplus of doctors. But most governments maintain a shortfall in medical manpower. The incomes of physicians varies substantially throughout the world. Thus we are now witnessing an ever-accelerating global migration of physicians, some of whom are poorly trained. This underlines the urgent need for transparent global medical accreditation standards with a transparent process applied by qualified medical educators to help insure compliance world-wide.

Accreditation's objective is to enhance medical education and thus medical practice. Indeed the future of medicine as a profession depends on our teaching tomorrow's doctors with the developing medical knowledge, skills, and ethics to an agreed standard as the basis for their lifetime of learning

The greatest assurance of maximum quality in medical education requires an impartial, external, open and transparent, non-political, global, accreditor. There are real and potential difficulties when governments control medical standards through their political processes. According to the Founda-

tion for the Advancement in Medical Education and Research (FAIMER) directory of international organizations involved in accreditation of medical standards, there are about 92 nations who claim there is an accreditation process for their nations medical school(s). (*see: <http://www.faimer.org/orgs.html>*).

Many nations however have no adequate mechanisms to maintain or improve their standards of medical education. Few of the existing national accrediting organizations are open and transparent. Transparency, Peer Oversight and Accreditation encourage improvement and diminish the opportunities for corruption. (*see examples at: <http://www.iaomc.org/databank1.htm#3>*). In times past some governments have not been candid with their citizens.

The IAOMC was founded as an independent agency and specifically designed to resolve these issues. (*see: <http://www.iaomc.org/beginning.htm>*). Global standards have been developed after public hearings were held. *see: <http://www.iaomc.org/minutes1.htm>*. and take into account the World Federation of Medical Education's (WFME) Trilogy of Global Standards.

IAOMC has an independent body of site visitors whose qualifications can be obtained from its website; <http://www.iaomc.org/svp.htm>. Members elect their own Chair and Secretary. An independent panel of regulators will accompany the site visitor as observers. Because of the distances, communication is electronic and via Skype. Between meetings Board members vote by email and the results are posted. *see: <http://www.iaomc.org/minutes3.htm>*.

Medical Ethics provides the foundation of the trust between patients and their physicians. The IAOMC has established an

standing Ethics Committee whose report forms the basis for the standards that medical schools are expected to maintain. *see: <http://www.iaomc.org/ec.htm>*. Ethical education with openness are central in preventing any corruption

The Board of Trustees are being assisted in their appreciation of the complexity of each nation or region's medical education/practice, through their Advisory Council. For details *see: <http://www.iaomc.org/council1.htm#1>*. There are three sections: 1. Experienced, expert, medical administrators or educators, 2. Senior government regulators/ Administrators or Medical Board members and, 3. Distinguished Representatives of Countries, Regions, or Organizations. Each section elects its own Chair and Secretary. To insure each section is heard its Chair has a permanent voting seat on the Board of Trustees. The Board of Trustees elects the Associations Officers. *see: <http://www.iaomc.org/officers.htm#1>*

Within Associations of Physicians and Medical Academic Institutions there should be an obligation to inculcate the values and attitudes required for preserving the medical professions standards and our 'social contract' with society across generations.

All medical associations or individuals who accept this professional responsibility, are invited, without regard for nationality, race, gender, religion, or age to become a part of the International Association of Medical Colleges The challenges that the IAOMC have set itself are as important as they are enormous.

But it is in the long term interest of all medical academic and representational institutions to develop and maintain their academic standards and independence. Joining together in the independent international association of medical colleges will further their aims of professionalism and academic excellence.

The Standing Committee of European Doctors (CPME)



Lisette Tiddens – Engwirda, CPME Secretary General

The CPME represents all, about 2 million, medical doctors in the EU. It is an international, not-for-profit association under Belgian Law composed of the National Medical Associations of the European Union and of the European Economic Area (30 members). It also has associated members (those countries that are currently negotiating with the EU), observers and 9 associated organisations (specialised European medical associations and the WMA). CPME aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all citizens of Europe. Linked to the activities from the EU, the CPME is also active in the area of promotion of public health, the relationship between patients and doctors and the free movement of patients and doctors within the European Union. The CPME formulates its policies both in answer to developments in Europe, as well as by taking the lead in matters regarding the profession and patient care.

To achieve its goals, the CPME co-operates closely and where possible proactively with the Institutions of the European Union.

The CPME offers broad expertise in matters related to medicine and the medical profession in its contacts with the European Parliament, the European Commission and relevant special European Agencies such as, for example, the EMEA (the European Medicines Agency) and the ECDC (the European Centre for Disease Control).

The Standing Committee of European Doctors is directed by a Board (each country has 1 Board member) that is elected by the General Assembly (in which each country has 1 head of delegation) for two years. The President and the Executive Committee are elected from the Board members also for a period of two years.

The CPME develops its policies in 4 sub-committees:

- Medical training, continuing professional development and quality improvement
- Medical ethics and professional codes
- Organisation of health care, social security and health economics
- Public health, prevention and environment

Experts from each national member organisation, associate members and associated organisations, as well as observers participate in these meetings.

Current Activities

The CPME is active in a very wide range of issues. The following are some examples:

Provision of health services: patients' and professional's mobility

The CPME supports the free movement of patients and health professionals within the EU. High quality of care and free movement of patients and professionals are intertwined topics that should all be addressed within a Community framework.

CPME policy states that patients should have the right to receive safe and high-quality care all over the Union. For this they need to be provided with a solid legal basis and the required information in order to make informed choices.

Therefore the recently published proposal for a Directive on Patients rights, that is based on existing European Court of Justice rulings, is welcomed by the CPME although a reaction in detail is still being prepared

It is the CPME position that health services have specific characteristics that should be recognised and protected. As they deal with citizens' lives and well-being, health services need stricter controls and regulation than most other services. It is essential that the Member States take responsibility for guaranteeing the quality and equal availability of healthcare for their citizens in all circumstances. Recently the CPME organised a Round Table discussion (under the auspices of the MEP Karas and together with the Council of European Dentists) on the proposed directive on patients' rights. At this occasion the CPME President Dr. M. Wilks warmly welcomed the draft Directive on behalf of European Doctors. He pointed out that the aim of the CPME as it is defined is very much linked to the core topic of the directive.

He underlined that all the topics reflected in the draft directive, especially in article 5, which deals with quality, safety and information are core issues for the CPME.

Patient safety

The CPME has been an initiating and central partner in setting patient safety on the EU agenda. The official launch took place in April 2005 with the Patient Safety Conference organised under the auspices of the Luxembourg Presidency of the EU, the European Commission and the CPME together with a large number of other relevant EU stakeholders. The Luxembourg Declaration on Patient Safety set a number of principles and objectives that marked a roadmap for the years to come.

The work on this issue is now continued in:

- The Patient Safety Working Group of the High Level Group that is the counsel of the European Commission on the drafting of European Recommendations on Patient Safety.
- The CPME has also been partner of European-wide projects on patient safety, such as the SIMPATIE (Safety IMprovement for PATients In Europe) project which published its final report in December 2007; has participated in the advisory council of the MARQUIS (Methods of Assessing Response to QUality Improvement Strategies) project and is partner of the new EUNetPaS (European Union NETwork for Patient Safety) Project, which gathers all member states' and a number of stakeholders that are active at EU level.

eHealth

In October 2007, the CPME adopted a policy document on Electronic Health Records. The CPME strongly values the use of eHealth technology as a support-tool for the physician in his or her work. However there are considerable differences within the EU regarding the approach physicians adopt towards eHealth. Because of these differences, the CPME has set out some essential principles for the use and development of eHealth systems. It is obvious however that further study and development is needed in order to be able to establish commonalities and solutions. Electronic health records should be a support-tool in the provision of optimal care that is based on face to face contact and trust between the patient and the physician. For the CPME it is clear that the bottom line needs to be that eHealth technology must be to help support the quality of care and patient safety provided by healthcare professionals, in full respect of current ethical and legal principles. eHealth will continue to be a developing topic within the CPME. The organisation will keep a keen eye on eHealth developments and will continue to deliver opinions to European Commission proposals, from both practical and ethical points of view.

Pharmaceuticals

In December 2005, the Pharma Forum was launched by the European Commissioners for Health and Enterprise. It was a follow up to the "G-10 Medicines Group". The CPME was invited to take part as a full member and thus sits around the very large table with all Member States, the European Commission, and 9 other EU stakeholders. The CPME has representatives in the 3 working groups of the Forum, which deal with information to patients, pricing and relative effectiveness. The CPME is often encouraged to deliver its views on a number of pharmaceutical issues such as pharmacovigilance, rare diseases or clinical trials.

EU Platform on Diet, Physical Activity and Health

As one of the founding members of the EU Platform on Diet, Physical Activity and Health, the CPME has been very vocal in the area of for example nutrition, physical activity, and food labelling. This Platform has been established by the EU in order to co-ordinate partners that could help find solutions for the growing obesity problem in Europe. Every year, every Platform member issues commitments on the issue. CPME commitments are available on the EU Platform on Diet, Physical Activity and Health, EUROPA website.

Alcohol

The CPME is a founding member of the Alcohol & Health Forum which was officially launched in June 2007. The CPME is a signatory of the charter. The CPME is member of the Task Force on Youth-Specific aspects of Alcohol and the Task Force on Marketing Communication. The CPME adopted a policy on alcohol which expressed its support to the EU and Member States in reducing alcohol related harm.

Working Time

The CPME, together with the PWG and FEMS is lobbying the European Parlia-

ment and is having close contacts with Member States on the current Revision of the European Working Time Directive. The CPME policy defends the codification of the ECJ rulings stating that the inactive part of on call time is to be considered to be working time.

Education and training: CPD

The CPME and the other European Medical Organizations plus relevant EU stakeholders organised a Conference on "Continuing Professional Development – Improving Patient Safety" in December 2006, under the auspices of the Finnish EU Presidency and the European Commission. A Consensus Statement was adopted declaring: "In addition to contributing to improvements in the care of individual patients, CPD also plays an important part in improving the quality of healthcare systems".

Teaching of medical ethics and of medical values are issues that are currently debated within the organisation

Relationship with stakeholders: Patients, a privileged stakeholder

As of course the patient is the most important partner for physicians, the CPME is in close contact with the EPF (European Patient Forum) and has developed a Framework Statement of Collaboration with them.

A similar exercise has been done with both the Pharmaceutical industry and the Medical Devices Industry.

Over the years, the CPME has developed close relations with all the relevant EU stakeholders, including nurses, dentists, pharmacists, public health organisations, institutions, and patient organisations. As this article is meant to give you an introduction to CPME, I was only able to give a short impression of the organisation and its activities. However you can find all our policies and more on the CPME website www.cpme.eu

The Swedish Medical Association

*Dr Eva Nilsson Bågenholm, MD, President of the Swedish Medical Association
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The Swedish Medical Association has a long tradition of international engagement in the area of human rights and ethics. Dr Eva Nilsson Bågenholm, current president of the Swedish Medical Association and also chairperson of the WMA Medical Ethics Committee (MEC), has been actively involved in the work of updating the Helsinki declaration during the last year. In this process the Swedish Medical Association has arranged a high level conference for Swedish stakeholders in order to make the Swedish updating comments solid and well thought-out. In pursuit of highest possible standards of ethical behaviour and care by physicians, the Swedish Medical Association feels a strong responsibility to promote WMA ethical policies.

The role and the structure of the SMA

The Swedish Medical Association is the union and the professional organisation for physicians in Sweden. Important issues dealt with include doctors' work environment, salaries, working hours, medical training and research. The SMA also has key role to play by influencing the development of healthcare in Sweden. Over 90 per cent of the physicians in Sweden belong to the SMA. All members of the SMA are also registered at a local branch in the area where they work. The membership moreover includes signing up for at least one national professional association, such as the association for general practitioners, for hospital doctors, for private practitioners or the national association for junior doctors.

Most members are also members in one of the 50 specialist associations, a number which reflects the amount of specialties that are recognized by the National board of Health and Welfare, the regulatory body of Swedish physicians.

The SMA enters into collective agreements with the employers organisations on behalf of its members in areas such as general employment conditions, which includes salaries, working hours, holidays, sick leave, parental leave and pensions. Members can get help with salary negotiations, and up-to-date salary statistics, legal assistance on disciplinary matters, such as negligence claims or probation, and on general matters of healthcare, tax and labour law. The SMA can also give peer support for doctors undergoing a personal crisis.

The Ethic Committee of the Swedish Medical association (EAR)

The EAR handles ethical questions in relation to the medical profession, as well as the ethical questions that are related to marketing in connection with medical practice. Another task of the EAR is to review the legislation that is linked to the professional responsibility of the medical profession. The committee also works for strengthening and developing the awareness of medical-ethical questions within the medical profession. One intermediate goal in this work is for example to collect and spread knowledge about national and international ethical policies and to put ethics on the agenda in the daily clinical work situation.

International engagement

The aim of the international engagement of the SMA is to protect and to develop human rights, professional ethics, conditions of the medical profession, patient's rights and a good quality healthcare for everybody. In order to pursue these goals the SMA is a member of CPME, Comité Permanent des Médecins Européens, Standing committee of European Doctors, which represent all medical doctors in the EU. SMA is also a member of the UEMS, the European Union of Medical Specialists and UEMO, the union of general practitioners in Europe. Already in 1947 the Swedish Medi-



Dr. Eva Nilsson Bågenholm, MD, President of the Swedish Medical Association

cal Association started its international engagement by being one of the founders of the World Medical Association.

The Swedish health care system

In Sweden 21 county councils and regions are responsible for supplying their citizens with health care services. This includes hospital care, primary care and psychiatric care. A county council tax supplemented by a state grant is the main mean of financing the health care system. In addition to that small user fees are paid at the point of use. Each county council and region is governed by a political assembly. Within the framework of national legislation and varying health care policy initiatives from the national government, the county councils and regions have substantial decision-making powers and obligations towards their citizens. The Swedish health care system is a decentralized system.

Structural changes in the Swedish Primary Care system

Swedish primary care is in the process of changing. Recently two green books are proposing to introduce a national system that gives each citizen the possibility to choose her/his provider of primary care. There is a plan of introducing the possibility of privately owned healthcare enterprises in order to increase the competition and thereby give a wider choice to the citizens.

New Doctors Orchestra plans to produce 'The Magic Flute' in 2010

The search is on for more musical doctors as yet another worldwide doctors' orchestra has been established. German doctor, conductor and concert pianist Wolfgang Ellenberger from Buchen has founded the Philharmonic Doctors Orchestra (PDO) and is planning to produce an entire opera, Mozart's 'Magic Flute' in the autumn of 2010.

His ambitious project follows on the success of the European Doctors Orchestra (www.EuropeanDoctorsOrchestra.com) which was founded in November 2004 by Miki Pohl in London. Their concerts in London, Bucharest, Budapest and Berlin have been overbooked and led to the orchestra producing several DVDs of their successful recitals. The orchestra's founder Miki Pohl said that the web site www.DoctorsTalents.com was largely responsible for finding doctors for the orchestra. This was followed by the establishment earlier this year of the World Doctors Orchestra (www.World-Doctors-Orchestra.org) with 80 musical doctors from 20 countries from all over the world.

Now Dr. Ellenberger is setting up the Philharmonic Doctors Orchestra and is looking for more musical doctors to perform. Together with conductors Callista Janzing and Otmar Desch, he plans to perform the entire opera of 'The Magic Flute' in 2010 after just four practice sessions.

Callista Janzing has studied with Sergiu Celibidache and is working as a coach with musicians and orchestras. Dr. Desch is a general practitioner and has been a conductor in the theatre of Stendal in Germany for the last five years where he also performed his new musical 'The Call of Dalai Lama'.

Dr. Ellenberger said that the new orchestra is open to a range of health professionals – medical doctors, dentists, veterinarians, pharmacists, psychotherapists and spiritual

healers – from all countries. Interested doctors can register on the website ([www. PDO.name](http://www PDO.name)) and the first practice session is planned for spring 2009 in Germany.

The target is to end up with a full orchestra, choir, soloists, conductors, director, stage and costume designers. Many of the roles will be covered by two singers.

The venue for the performances is still being negotiated, but there are hopes that it might be a significant festival theatre.

Money raised from the productions will go to charity and members of the orchestra and cast will have to cover their own travel and expenses, and play without a fee.

Already Dr. Ellenberger is planning the next phase of his musical developments. He has a vision of extending the web site (DoctorsTalents.com) into a building which could house permanent exhibitions, a library of literary doctors, piano classes and other events. One possibility is having a paying membership of doctors from all over the world.

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