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WMA SANTIAGO GENERAL ASSEMBLY – REPORTS

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Editorial



Editorial

2005 – a Lesson: “Humanity’s need for Care”

The editorial in the September issue was entitled “Backwards to the future?”. As this year draws to its close it is natural to look back over the past 12 months and to consider where we are and where we are going.

Internationally there has been much activity in the health field tackling long standing disease problems, as such HIV/AIDS and Malaria. Preventive policies such as basic immunisation, the provision of impregnated mosquito nets continue to reduce morbidity and save many lives, when the resources available permit their use and provision. Despite the efforts to eliminate poliomyelitis major efforts are still needed to deal with the threat of sudden outbreaks requiring rapid large scale immunisation programmes, and the declaration by WHO of Tuberculosis in Africa as an emergency, both highlight the need for constant vigilance and continuing action. At the same time the underlying problem of poverty in many parts of the underdeveloped, the developing and even the so-called developed world, appear as far as ever from solution although the global summit meetings may assist.

All this has been complicated by natural disasters, such as those arising in Southeast Asia, Pakistan and even in such a highly developed and affluent country as the USA, and made sudden demands on health care resources both in terms of materials and skilled personnel.

Attention has been focused not only on the global shortage of healthcare personnel but also on training and retention of physician policies in the face of developments such as the “skills drain” phenomenon. Health Services Reform remains a high priority in many countries and, both at national and international levels, continues to exercise those responsible – health professionals, administrators and politicians – as to how to proceed, at what cost and at what speed change can or should be effected.

All of the above are having major impacts on many health professionals, including the physicians. Long standing traditions of practice are being abandoned in the efforts to meet the huge demands both of deprived populations and of those in more fortunate circumstances, in a rapidly changing society where speed of access to knowledge and scientific developments are leading to new expectations.

Positive developments, increasing scientific knowledge, proven healthcare reform policies are of course to be welcomed, and the physicians, like others, should be prepared to adapt their professional style of practice appropriately – points we have sought to emphasise in these columns. The changes are, however, often very radical. Reform of the basic medical curriculum, the changing role of individual health professionals and professional working practices are not easy to adapt to the speed which some politicians consider possible. Adequate consultation and co-operation on all sides is essential to achieve them.

One thing however remains constant regardless of the problems and issues mentioned above, it is the continuing need for care and relief of humanity’s sick and suffering. This, the medical profession clearly responded to the crises of the past year. Through the many challenges which it will continue to face, this must remain at the centre of all its activity in the future.

Alan Rowe

Editorial note: Please accept our apologies that unfortunately, due to technical problems, it has not been possible to include all the reports of the Santiago WMA meeting in this issue. The rest will appear in the next issue.



Medical Ethics and Human Rights

Sponsorship Guidelines

This issue was discussed during the meeting of the WMA Ethics Committee in Santiago. We feel it to be of sufficient general interest to include in the Journal. (The following report is based on notes kindly provided by Dr. Appleyard to whom we are most grateful. Edit.)

Dr. Bagenholm introduced the issue of the acceptance by the WMA of commercial sponsorship funding. She indicated that the current financial situation for the WMA was difficult in that membership dues did not cover the WMA's expenses. Some member organisations had approached her with their concerns that the WMA had become dependent on financial sponsorship from the pharmaceutical industry for many of its activities. Posing the question as to why such industries want to sponsor our activities, she said they became involved so that they could influence us. If the WMA was thought to be influenced by the pharmaceutical industry, it would lose its credibility. Dr. Bagenholm, recognized that there were guidelines agreed by the Council for such sponsorship, but felt that they needed to be revisited to consider whether it is ethical to receive sponsorship, from the pharmaceutical industry and what would be the financial implications. The delegate from Denmark agreed that the ethical and financial aspects should be reconsidered and suggested a small group comprising the Chair of Ethics and the Chair of Finance and Planning be set up who could receive information about how NMAs are coping with these problems in their own countries. (This was subsequently approved by Council.) He felt that the WMA mission was to foster the independence of the profession and set the highest possible ethical standards for physicians worldwide. Ethics and Human Rights were fundamental to our profession. National Medical Associations founded the WMA with these issues foremost in their minds

and we are only as strong as the individual components of the 'chain' of our membership associations.

Jon Snaedal, (Iceland) Icelandic Medical Association and former chair of Ethics agreed that the WMA needed to be financially 'autonomous' and should not rely on other sources of finance. If we were seen to be influenced by our Sponsors the WMA would cease to be respected.

Dr. Johnson (UK) agreed that the ideal would be that the WMA was self funding. With the cost of all the activities at International level with all our partners this was not possible and he asked what was the evidence of the WMA being influenced by the current sponsors Dr. Kgnosi Letlape, President Elect, told the meeting that there were different issues in different countries, In South Africa the main influence on the Profession was that of Government and he felt that Industry was much more understanding of the importance of the independence of the Profession. Without their partnership and support, the Association would not be able to function the way it does as an advocate for its members. Ms. Wapner (Israel) said that where there were matters of ethics and finance, ethics was preeminent. She recognized the concerns raised. Any change in standards should apply to all

NMAs and financial relationships with all outside organisations needed to be considered Dr. Appleyard (Immediate Past President) made the point that in any 'relationship' there was potential for 'influence' both ways, The WMA was not a passive partner and we should never compromise our own internationally accepted ethical standards, we should rather use any partnership 'platform' to promote them. Dr. H Miyazaki (Japan) emphasised the importance of transparency in all our financial arrangements Dr. Kloiber, the Secretary General, said that specific guidance had been developed for sponsorship by commercial, governmental and charitable partnerships for specific projects or pieces of work which were consistent with existing WMA policies. He was advised by the Sponsorship Advisory Committee, which reviewed all potential developments. Dr. Kloiber said that he personally had been one of the greatest critics of commercial sponsorship. In response to the question about how much existing sponsors had attempted to 'influence' the WMA, he said he had not experienced any attempt to influence the association whatsoever. Dr. Kloiber felt that a Work Group could identify the concerns expressed and review the existing guidelines

The committee agreed unanimously to recommend "That Council establish a Work Group consisting of the Chairs of the Medical Ethics and Finance and Planning Committees, to review the WMA Corporate Relationship Guidelines". This was subsequently AGREED by Council. ■

Enhancing the WMA Declarations on Human Rights

V. Nathanson

The WMA was founded in 1947 to attempt to ensure that never again would doctors be complicit in human rights abuses. The "big three" WMA declarations – Geneva, Helsinki and Tokyo – aim to raise ethical standards globally, and to protect the rights of the vulnerable. Despite these carefully

drafted words stories of medical involvement in human rights abuses still emerge. Current draft amendments to the Declarations of Tokyo and Geneva and to the Regulations in Times of Armed Conflict are the latest attempt to fortify this global consensus.



The sad fact is that prisoners *are* subjected to human rights abuses – both torture and cruel inhuman and degrading treatment in very many countries. Involvement by doctors, when it occurs, is often a part of the process; doctors resuscitate the torture survivor so that he or she can be tortured again. They certify fitness for harsh interrogations and for frankly abusive practices. They falsify death certificates or other key parts of medical and legal records. At the same time other doctors are putting themselves at risk in decrying the torturers, documenting abuse, giving evidence in courts, opposing systematic and episodic practices that put people at risk of abuse and using medical knowledge and expertise to protect the vulnerable and challenge the abusers.

Allegations have emerged from a variety of sources about the abuse of prisoners in Abu Ghraib and in Guantanamo Bay.¹ While no cases have been brought against doctors there are stories in circulation of doctor involvement that would, if true, amount to serious ethical failures. While these are not the only places where such medical abuses are alleged they are important as they highlight apparent weaknesses in current WMA policy. The BMA has led a WMA Council working group that has prepared amendments to existing policy that will, we believe, strengthen the appropriate prohibitions.²

One issue that has arisen in relation to these allegations as well as to those from some other countries, is that medical records are being provided to interrogators to aid in targeting of harsh interrogation or torture. Although the Declaration of Tokyo is read by most people as disallowing this practice, it does not currently say so explicitly. In too many countries physicians' notes, recorded to help their patients and to inform other health care workers about their findings and treatment plans, are instead used to undermine the safety and security of the individual. Some physicians appear willing to hand over such notes, or even to help the prison authorities use medical information to devise a programme that will undermine the mental or physical health of a detainee. They argue that as the code is silent on the prohibition, it does not in fact exist.³

For that reason an amendment has been suggested to make this prohibition explicit. This will not only strengthen the hand of those doctors who refuse to hand over records to prison authorities, but it may also help doctors who work for agencies visiting prisons and detention centres as part of the checks and balances system of international regulation, including the Red Cross, the UNHCHR, Amnesty International and MSF. This specific amendment has also been repeated in the Regulations in Times of Armed Conflict, to make doubly certain that this prohibition exists regardless of current political and security circumstances.

The carefully constructed language of WMA declarations and regulations can also become obscure over time as common language usage changes. This is why the suggestions for amendments include removing the concept that physicians' consciences should be their guides and its replacement with a requirement to adhere to international conventions on human rights, international humanitarian law and WMA declarations on medical ethics. The international laws are easily found; they are the Geneva Conventions and associated protocols of which the ICRC acts as guardian. "The other laws and conventions are available online from the UN or the WMA itself." All are clear; torture is prohibited, and we each have an absolute right not to be subjected to such treatment.

So are these changes a response to as yet unproven allegations about Abu Ghraib and Guantanamo Bay? No; not only to these,

but also to similar allegations to similar abuses in many places

Many associations reading these changes may wonder if they are necessary. I believe that they are; the number of reports Amnesty and others can produce of medical involvement in abuse makes change and reinforcement of high norms essential. They give us, as doctors, a chance to rededicate ourselves to stopping abuse by doctors, or medical complicity. They give us a chance to applaud those colleagues who stick their heads above the parapet, putting themselves at risk by adhering to the highest standards. They give us an opportunity to condemn those we think unworthy of their medical licences. They can act as a call to arms for all of us to defend vulnerable people around the world. In short; they are an opportunity for the WMA to reassert its core reason for existing.

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1 See, for example, Lewis NA. Red Cross finds detainee abuse in Guantanamo. *New York Times*, Nov 30, 2004: A1. Okie S. Glimpses of Guantanamo – medical ethics and the war on terror. *NEJM* 353:24 15 Dec 05.

2 See WMA paper MEC/Misc/Dec2005

3 Bloche G, Marks J. When Doctors go to War. *NEJM* 352:3-6 6 Jan 05

4 <http://www.icrc.org/Web/Eng/siteeng0.nsf/html/genevaconventions>.

5 <http://www.wma.net>. ■

Nurses and Physicians Welcome Libyan Court's Decision to Reverse Death Sentences

The International Council of Nurses and the World Medical Association have welcomed the decision of Libya's Supreme Court to reverse the death sentences and order a retrial for five Bulgarian nurses and a Palestinian doctor, accused of deliberately infecting more than 400 children with AIDS. The supreme court has quashed the sentences and accepted the appeal against the lower court ruling on both substance and procedure. Prosecutors agreed with defence lawyers that there were "irregularities" in the arrests and interrogations of the accused. Expert evidence that the cause was probably poor hygiene at the hospital appeared to have been ignored. Indeed, infections were believed to have occurred before the accused started work at the hospital, and continued after their arrests.

ICN and WMA call for a speedy retrial that will consider the evidence presented by international experts and liberate the health professionals.



Medical Science, Professional Practice and Education

Health Care System Reform in Japan

Hideki Miyazaki, MD, Ph.D
Vice President, Japan Medical Association
Presented at WMA Scientific Session, Santiago

Japan is experiencing a lowering of the birth rate and an aging of the population. In 1985, population from 0 to 4-year-old accounted for 6.2% of the total population. In 2004, the figure declined to 4.5%. On the other hand, the elderly over 65 years old accounted for 10.3% of the total population in 1985 and increased to 19.5% in 2004. As this indicates, the population structure is rapidly changing. In the current year, 2005, population aged 4 years old or below is 4.5% of the total population, and this figure is estimated to decrease to 3.6% in 2025. People aged 65 years or over, however, account for 19.9% of the total population in the current year, 2005, and this is estimated to increase to 28.7% in 2025. These trends of declining birth rate and aging population are expected to continue at an even more accelerated rate in the future. This situation, combined with the deteriorated financial basis of the nation, is calling for social security reform. Health care system reform is currently underway to keep the system sustainable in the future, supported by balanced economic and fiscal foundation.

The government proposes a basic policy plan for health care system reform. It is necessary to radically change all parts of the health care system, while taking into account changes in the medical environment, the rapidly declining birth rate and aging population, and the current stagnant economy, as well as advances in medical technologies and shifts in the public's attitude. It is also essential to reform the health care system, health care delivery system, medical fee programme, and the health insurance system. In other words, a health system that meets the demands of the changing environment is required. In addition to the basic points for reform, the government also proposes the following improvement. They are, the importance of respecting the patients' point of view, pro-

motion of disclosure of health information, reestablishment of safe and assured health care, provision of quality and efficient health care, establishment of a health care delivery system of high quality and efficiency, separation of roles between medical institutions for more focused and efficient medical services, ensuring necessary health services in communities, cultivation of human resource in health care and improvement of their quality, improvement of the structural basis for health care, and the improvement of the foundation for health care to support lives in the 21st century.

However, the government is pushing policies to "contain health costs" to "ensure appropriate health costs" because of worsening national finances. It is trying to introduce the total budget system of health care costs as well as controlling the increasing costs to suppress the growth of social security costs lower than the economic growth.

What is needed for health care from the general public is improved quality and safety of health care. From the government's point of view, however, it is containment of health costs. The problem may be how well the medical profession can meet these needs. The Japan Medical Association (JMA) advocates that it is fundamentally necessary to ensure the health insurance system which permits every citizen to equally receive health services with an insurance card, anytime and anywhere, which may be most characteristic of Japan's health system.

The JMA considers that all the people have a right to lead a healthy life, and enhancement of social security for this purpose is an obligation of the government. Health care is an asset for the public good, and development of the foundation of the health care system is the responsibility of the nation. The government should not fit

health care to the economy. The economy should be fitted to health care. To secure quality health care and provide safe health services, financial resources to cover the health costs are necessary. We maintain that the policies to contain health costs surely lead to lowered quality of health care and may block the promotion of safer medical services.

In relation to the health status of Japan, according to the report by WHO, Japan retains the longest average life expectancy in the world. As for the health care costs, when total health care costs are compared with GDP, Japan has the 17th lowest health care cost among the OECD countries. Furthermore, in comparison with other countries for health achievement, Japan ranked No. 1 in life expectancy and in overall rating of health achievement. Japan's health insurance system is an excellent system with high performance at low cost.

Looking at the trends of national health care expenditure and life expectancy, the growth of expenditure and average life expectancy for females, is in proportion. Of course, there are other factors such as advances in medical technologies and increase disease in the elderly. However, the increase in expenditure is obviously linked and corresponds with the growth of average life expectancy. The containment of health expenditure could, therefore, shorten life expectancy.

The financial resources of Japan's health costs consist of public expenditure (taxes), premium from employers and the insured, and patient cost sharing. From 1990 to 2002, the percentage of public expenditure showed little changes. As for the premiums, the burden on the employers decreased, while the percentage of patient cost sharing increased. This is because of the increase in the patient's co-payment for medical services from 20% to 30% after April 2003 and the establishment of the fixed amount of payment by the elderly which started in October 2002. In Japan, a limit is set for patients' co-payment at 72,300 yen (approximately 650 US dollars) for the general public, except for low-income earners. However, the government



has been taking policies to increase the costs to be paid by the patient in the past few years. It is contrary to the principles of insurance when you consider that the insured who pays the premiums to be covered by the insurance has to pay extra costs to receive health services.

There is a large gap between the employee's pension insurance rate and the health insurance rate. This partly accounts for the deficit of the health costs. The health insurance rate has hardly changed since 1980. In 2003, the employee's pension insurance rate dropped because premiums were charged for total remuneration, including bonuses. The insurance rate up to the year 2018 has been set by law. However, there is no policy to increase the health insurance rate further and when compared with the employee's pension, it is undervalued. The health insurance rate, if increased, will help to secure resources for the health costs.

Japan's national contribution ratio which is the ratio of tax burden and social security burden has been showing around 37% for the past 18 years which is very low. In the government's policy, the rate should be suppressed below 50% at the highest, but it is already at a low level, compared with other developed countries.

The comparison of the ratio of national health expenditures to GDP, and the breakdown of public and private spending in major countries, suggests that health costs in Japan need an increase of 1 to 2% of public spending to GDP when compared with Sweden, France, and Germany. From this point of view, the government should allocate more of its money on health care areas.

I have just explained the current situation in Japan. The problem in the health care system reform to be discussed here is that the number of insurers in Japan is extraordinarily large when compared with health care insurance systems of other countries. In the Revised Health Insurance Act enacted 2 years ago, integration and unification of different kinds of insurances is one of the items to be studied in the future.

In 2004, the number of insurers managed by the national government is 1, while those managed by health insurance soci-

eties is 1,674 and those managed by seamen's insurance is 1. As for the mutual aid insurance, the number of insurers managed by the national government employees mutual aid associations is 23; those managed by local government employees mutual aid associations is 54; those managed by private school teachers & employees mutual aid is 1. As for national health insurance, the number of insurers managed by municipalities is 3,224 and those managed by associations is 166. The total number of insurers is 5,144 with the total of insured persons being 94,248,000.

Currently there is a discussion to integrate and reorganize the insurers in each prefecture, and it is suggested firstly to integrate those managed by municipalities and by national government.

The Japan Medical Association is proposing basic policies for the health care system reform.

We firstly and strongly advocate for maintaining the universal health insurance system. We are also suggesting the creation of new Medical Insurance System for the Elderly to address public concerns. The system with the national government as insurer would cover only those aged 75 years and older. However, the system will be managed by the local government after a certain period of time. We are proposing for the financial sources of this system special; 10% of the contribution from the patient, 10% from insurance premiums, with consideration for low-income earners, and 80% from public expenses and national mutual assistance such as consumption tax and cigarettes tax. If a health insurance system is seen as a part of social security system, it is necessary to increase public funding or tax to meet its need for financial sources.

Compared to other in major countries, the price of cigarettes is the lowest for Japan and it is necessary to discuss various related matters including a consumption tax scheme and a proposal for an earmarked tax for health care.

A rise in cigarette prices may be the most efficient measures to cut the number of smokers. We are proposing to utilize the

increased tax for financial resources for health care.

Health care should not be regulated by age. This is natural when you think about characteristics of the elderly and their potential diseases. The Medical Insurance System for the Elderly will be based on self-help, and mutual and public assistance. The health insurance system in Japan provides benefits in kind sufficiently to meet people's needs for health care. In Japan, the Long-term Care Insurance System was established for those aged over 40 years of age in 2000, which provides cash benefits to support long-term or nursing care. The fund comes from the premiums and public spending. The level of nursing care required is divided into 5 levels, each having a set quota. We distinguish between a long-term or nursing care and medical care. And necessary arrangements are being made between the two areas of care. Therefore, the Long-term Care Insurance System, which provides cash benefits, and the health insurance system cannot be integrated. Control of the growth rate of health costs based on the economic indicators such as GDP should not be permitted because it disturbs necessary and safe health care.

To enhance the level of health services for the elderly, it is important to promote preventative measures against lifestyle-related diseases to keep the elderly healthy. Co-payment by patients should be decreased and should not exceed the current level. The government should extend the retirement age of workers to 65 years of age. All retired employees should join the National Health Insurance which provides benefits which will be covered by patients' co-payment, premiums and mutual assistance between employee's health insurance systems.

The government managed health insurance system has been enlarged by the Social Insurance Agency and been establishing and managing hospitals. Retired bureaucrats of the Health, Labour and Welfare Ministry have been obtaining jobs at these hospitals. A reform is going to abolish these hospitals.

As for the health care delivery system, in a comparison of the average number of visits per person per year in major countries, it is



21 higher times in Japan, the highest figure. However, health cost per one visit in Japan compared with other countries in 63 US dollars, which is very low. To sum it up, it can be said that health cost in Japan is very low.

In an international comparison of the health care delivery system in 1998, the number of beds per 1,000 people was high at 13.1 in Japan, while the number of physicians per 100 beds was low at 12.5. Furthermore, the number of nursing staff per 100 beds was also low at 43.5, with the longest average number of hospital stays being 31.8. The rate of outpatient visits stand at 16.0. This reveals the facts that in Japan the people

have many opportunities to visit any kind of medical institutions under the universal health insurance, the period of hospital stay is long, and a patient is attended by a small number of physicians and nursing staff.

To shorten the hospital stay, we are trying to review the organizational problems related to the inpatient settings, health care delivery system, and the revision of the medical fees. The Japan Medical Association is making its utmost efforts to maintain the universal health insurance which Japan is proud of, to provide necessary and safer health care services for all the nation of Japan. ■

care in the world, despite our significant delivery and systems problems.

But for others, it barely functions, if at all. For instance, there are almost 46 million Americans who have no health insurance. That's about 15 percent of our population – a national disgrace.

The employer-based system of health insurance is showing signs of weakness.

More than 80 percent of the uninsured – 36 million of them – work or are members of working families. They hold down jobs and draw a paycheck. For them, living without health insurance has terrible consequences for health and economic well-being. They live sicker and die younger. Often, they delay seeking help until they are suffering from a more advanced stage of disease – when treatment is often more expensive – and less effective.

But it takes a toll on more than the individual. It extracts a heavy cost on our society in terms of reduced employment and productivity, and the flood of uninsured into emergency departments and free clinics has a price tag, too.

In 2004, American taxpayers spent 35 billion U.S. dollars from uncompensated, publicly-funded care. That's \$4 million per hour every day. And this number doesn't take into account the additional billions of dollars spent on privately given care, including uncompensated care by physicians.

Managed Care Concentration

So the question is, how do we in the United States repair our system? It is flawed, and fails to give coverage to enough people.

One of the most severe issues, not only with those who have no health insurance, but for all American patients, is continuity of care – the patient-physician relationship. That relationship has been under siege in recent decades in the U.S.

In my practice, I've seen some of my patients for many years. I know their medical histories. I can follow up on old problems or see subtle changes that a stranger

The U.S. Health System: A Question of Access

Presented at the World Medical Association Scientific Session, Santiago
J. Edward Hill, MD, President American Medical Association

I am delighted to be here today on behalf of the American Medical Association. My visit with you continues a decades-long tradition of mutual friendship and support. And our friendship, now and in the future, is even more vital than it has been in the past. Together, we face potential pandemics and terrorist threats. Public health challenges from tsunamis, hurricanes, earthquakes and floods. We are subject to economic and political decisions made far away that have immediate impact in our communities – that affect access to care and quality of care for our patients. More than others, perhaps, we recognize that disease and discord, that epidemics and terrorists, alike, respect no boundaries.

We also know that knowledge and our mutual caring for our patients know no boundaries, either. No boundaries and no limits. In such a world, cooperation among our associations and within the WMA is more important than ever. I shine like a beacon – a model for ethical behavior for all other professions and associations. Today, as we discuss the strengths and weaknesses of our nations' health care systems, we can learn from each other. Identify the best prac-

tices – and the worst pitfalls. And steer ourselves toward a better, healthier world tomorrow.

The Uninsured

This is something the American Medical Association is trying to deal with in my homeland, the United States.

There, medical care is financed and delivered through both public and private means. Persons over the age of 65 are covered under the Medicare program, administered by our national federal government. The economically disadvantaged are eligible for Medicaid, administered on the state level with partial federal funding.

Most American workers get their health insurance through their employers, a practice that started during World War II, when wages were controlled. Health insurance emerged as a way to enhance benefits for workers who couldn't get salary increases.

For some people, this patchwork system works well. For those with access, the U.S. offers what I believe is the highest quality



might not. In these circumstances, a patient feels comfortable – and is better able to ask questions and communicate.

This patient-physician relationship is the cornerstone of medicine. A healthy and continuous relationship with a physician can lower costs by getting a patient access to the health care system at an earlier stage of a disease.

But with the spread of privately run managed care in the U.S., this continuity has been disrupted. Patients often move from physician to physician – when their employers change health plans – or when their physician decides not to contract with a given insurer.

Perhaps it is because with some of the more abusive insurers – physicians are paid less to see more patients and work longer hours.

It is clear that a more competitive insurance landscape would help protect the quality of medical care – and ultimately lower costs for consumers.

What we have structured is a cost-based care system – while we should be offering a care-based cost system. We need to put decisions about health care coverage – back where they belong: in the hands of patients – and their physicians.

In the United States, a handful of giant health insurance companies dominate the market. It makes it difficult for an individual physician to negotiate patient care issues with what are essentially monopolies.

Managed care organizations have consolidated at a record pace in the United States, with more than 350 mergers and acquisitions in one five-year span.

The AMA is working to redress this imbalance.

We believe regulators should start looking more closely at the behavior of the health insurance industry. Also that physicians should be able to negotiate more effectively with large health insurance companies. Because when the health care market landscape is dominated by just a few giant companies, it forces physicians to accept unfair

contracts which can have serious implications for patient care.

Single-Payer Not the Answer

Some would argue that the solution to the problem of the uninsured would be to adopt a single-payer national health insurance plan. Most of you in this room practice under such a system, in one form or another.

Proponents of such a system are passionate and vocal. But we at the American Medical Association respectfully disagree. We believe a single-payer system in the United States would:

- Require physicians to negotiate a binding fee schedule;
- Discourage hospital expansions and capital purchases;
- Eliminate the health insurance industry, eliminating institutional memory and hundreds of thousands of jobs;
- Force employers to transfer money earmarked for health benefits to a national health insurance program.
- And discourage the innovation that has driven medical advances and innovations in the United States over the past century.

To us, this runs counter to freedom, choice, and private enterprise, qualities ingrained in the American psyche, and which fuel American society.

Such a system would be exponentially more difficult to manage in the United States than it is almost elsewhere, because we have a “melting pot” society with a remarkably diverse and diffuse character. It makes our country especially resistant to one-size-fits-all solutions imposed from above.

The AMA believes that by implementing a single-payer system, the United States would be trading one set of problems for another.

- We would see long, detrimental waits for care and the rationing of care.
- We would be slow to adopt new technology and maintain facilities.

- We would be bound by price controls, which eventually drive up costs;
- And it would create a gigantic bureaucracy that interferes with clinical decision making.

Would a single-payer system save us money? We don’t think so. We believe that such a conclusion is rooted in faulty and incomplete comparisons of administrative costs between the United States and countries that offer a single-payer system.

It has long been recognized that public insurance imposes a variety of costs on patients, including excessive wait times, a proliferation of short visits, and lack of access to certain services and procedures.

In June 2003, the Chairman of the British Medical Association characterized the U.K.’s single-payer health care system as:

“The stifling of innovation by excessive, intrusive audit ... the shackling of doctors by prescribing guidelines, referral guidelines and protocols ... the suffocation of professional responsibility by target-setting and production-line values that leave little room for the professional judgment of individual doctors or the needs of individual patients.” So say a physician with long, first-hand experience with a single-payer health system.

We have to recognize that nothing worthwhile – comes without a price. The fact is that effective prices play a role in the provision of, and access to, services in any health care system, not just market-based systems.

In the final analysis, consumers clearly pay, in one way or another – regardless of the system.

Any system that offers access to care without direct charges to consumers generates demand for care that exceeds what can be delivered. Ultimately, there is no guarantee that even medically urgent services will be available when needed.

The AMA has a viable solution – one that does not limit the universe of choices and that does not dictate a single-payer system as the only path toward universal health coverage.



AMA Plan for the Uninsured

The AMA has long advocated that every American should have health insurance and thus access to medical care. We've been working with other major players on the American health care scene to raise the profile of this issue – and to remind the public of its urgency. We believe the country will seriously address this issue eventually.

As Winston Churchill once said, "Americans can always be counted on to do the right thing ... after they have exhausted all other possibilities".

The American Medical Association believe we have a plan that would expand health insurance coverage in our country. We think it's the right thing to do.

The plan is simple:

- Give people money to buy their own health care coverage.
- Give wealthy people less money. Give more to poor people.

The AMA plan has three pillars – tax credits, individual ownership and selection of plans, and regulatory reform.

The most central point to understand – is the system of tax credits. Under the AMA plan, all workers would get a tax credit large enough to ensure they could purchase affordable coverage. The tax credit would be inversely related to income. This means that the people with the lowest incomes – those most likely to be uninsured – would get the biggest subsidy. The tax credits would be refundable, so families that owe little or no taxes would still get a credit. Finally, the credits would be available in advance, so that families who can't afford monthly premiums don't have to wait for a year-end refund to buy coverage.

What's more, Americans could choose and purchase a health care plan that fits their needs.

At present, of those companies that offer health care coverage only one in six offers a choice of more than one plan. Under the AMA insurance proposal, employees could choose to get coverage through their employers or not.

This would empower people. Allow them to do what federal government employees, including members of our U.S. Congress, can do today. That is to choose from a wide array of plans. This in turn, would create competition and vibrant health insurance markets.

Finally, our plans for regulatory reform would also bring sanity and reason to the current maze of market regulations for health insurance.

Currently, some regulations aimed at protecting high-risk individuals have the unintended consequence of a driving up the number of people who are insured.

We aim to create a more sensible regulatory system. A system that gives incentives to patients to purchase coverage before they get sick. And that gives incentives to insurers to cover high-risk individuals. Overall, our plan to expand health care coverage and choice – would get 94 percent of Americans covered. This is just one example of how we could improve market regulations for health insurance and get more people covered in the process.

These kind of market-based approaches for reform in the United States are already showing promise. The removal of some mandates, for example, has made possible a new kind of plan that combines high deductible insurance with health savings accounts – HSAs. These accounts allow consumers to use tax free dollars to pay for out of pocket health care costs, or to roll those dollars over. Nationwide, more than one million people have already signed up for HSAs. And the best part is that the statistics show that about one-third of them were previously uninsured. [U.S. Chamber of Commerce].

Can groups like families of the developmentally and mentally disabled benefit from these kinds of market-driven reforms, too? We think so. That's why we endorse the concept of a tax-exempt medical trust to provide for the long-term health care needs of disabled family members. And we think this concept should be linked to our overall plan to finance health care for all Americans. [H-165.893]

There's no reason that anyone should be left out of the picture (when it comes to creating a system driven by choice), that has the potential to increase quality of life and reduce costs for all patients.

The AMA's plan of action is a good one. If enacted nationally, it could give more than 94 percent of Americans health coverage.

It is an idea with powerful support. During the most recent U.S. presidential campaign, the candidates from both major political parties endorsed the general concept of using tax credits for individuals to purchase health care coverage. However, given current government budget challenges, we know it's unlikely that our plan will be enacted nationally soon. That's way we are willing to support an incremental approach. For example, we would like to see pilot programs on local government levels to try out our reforms. Such pilot programs could focus on particularly vulnerable populations such as a low-income people, children, or the chronically ill. Pilot programs have the added benefit of allowing policy-makers to guide future decisions through actual data an experience and letting them see how the AMA plan could work on a national scale.

An editorial from one of America's leading newspaper, The Detroit News said, "The AMA is offering a credible blueprint for fundamental health care reform. It deserves a hearing in Congress." We agree.

But we know that this won't be easy. That's why our leadership is bringing our ideas to a group called the Search for Common Ground. This group has all the major players and associations in health care – employers, health plans, physicians and many more. The one thing we have in common is that we're all frustrated that 45 million Americans are uninsured and 10 to 15 million more are underinsured. The mission of this group? To cover as many people as possible as soon as possible through non-governmental solutions. Together, we can get coverage for the millions of Americans who lack it and we can maintain the integrity and quality of American medicine in the process.

Conclusion

One thing is certain – whatever insurance plan we arrive at will be a uniquely American system, with uniquely American characteristics. Yet perhaps we can show the world a different approach to providing health coverage to everyone in our communities – and our countries.

We have a motto in the American Medical Association that goes like this:

“Together we are stronger.”

It sounds self-evident, but it is a powerful idea.

Working together – in meetings just like this – we all become stronger.

Our profession becomes stronger. We learn from each other. We find out more about what works in medicine – and what doesn't. And we reinforce the foundation of science, ethics, caring and compassion that supports all we do. Through our work our patients are better off. No matter what our health care system. No matter what our country. The commitment of the world's physician to their patients is one thing that doesn't need reform. ■

WMA

WMA Assembly Ceremonial Session, Santiago 2005

The ceremony was opened by the President, Dr. Yank D. Coble Jr., who warmly thanked the Chilean Medical Association and its leaders for the excellent arrangements and the warmth and hospitality which had been shown to the participants. He then called on Dr. Juan Luis Castro, President of the Chilean Medical Association, to address the Assembly.

Dr. Castro in welcoming the Assembly, said that the Chilean Medical Association was a voluntary organisation with 20000 members. Speaking about the problems of the profession in Chile, he referred both to the need to improve salaries (stating that on qualification earnings were about \$ 300 and after five years might reach \$30000), but stressed that a major problem was that of lawsuits and liability. He mentioned that these resulted in about 180 trials a year and spoke of the pioneering experience in Latin America of creating the Foundation for Legal Assistance (FALMED) to manage lawsuits against the physicians and avoid increases in insurance costs. Another important achievement was the restoration of ethical defence for the Association. At a time when many countries were undergoing

processes of health reform, Chile was no exception. There, physicians are witnessing changes which will impact greatly on the medical profession and its relations with patients.

Thanking him Dr. Coble then introduced Dr. Pedro Garcia, the Chilean Minister of Health, who addressed the Assembly. He welcomed delegates and referred to the importance of the profession meeting to discuss problems. As a doctor himself and as a politician he was, of course, interested in the challenges facing society. Referring to the complexity of the geography of Chile he said this posed many problems for health care, but there was a long history of health care in the country and they still looked to physicians to keep up with new developments in scientific knowledge and health care. In his view it was there was need for politicians and physicians to work together to solve these problems and he was therefore particularly delighted that the WMA had chosen to meet in Chile. He congratulated all the bodies responsible for the organisation of the meeting, in particular, the Chilean Medical Association. He pointed out that 80% of Chilean doctors were mem-

bers of the CMA, of which he had been one for many years. He hoped that delegates would be able to get some idea of the Chilean Health Reforms and also that they would see something of the country during their visit. He would be happy to respond to any questions and he closed by wishing the WMA a very successful conference.

Dr. Blachar, the Chair of Council, paid a tribute to Dr. Yank Coble for his outstanding services during his Presidential term of office and invested him with the Past President's medal following which Dr. Coble gave his valedictory address (*This will appear in WMJ 52 (1)*)

Dr. Blachar then introduced the new President Dr. Kgosi Letlape and invited him to take the oath of office. Following this, Dr. Blachar invested him with the President's Badge of Office and invited him to address the meeting (*see Inaugural Presidential Address p. 94*).

Dr. Blachar after thanking the speakers for their addresses and once again the members of the Chilean Medical Association for inviting the WMA to hold its General Assembly in Santiago, adjourned the meeting. ■



WMA General Assembly, Santiago 2005

Inaugural Presidential Address

Dr. T. K. S. Letlape

Honourable Minister of Health Dr. Pedro Garcia, Dr. Castro, the President of the Chilean Medical Association, Honoured Guests, Ladies and Gentlemen

Thank you for the privilege you have given me to serve as President of the World Medical Association. I assume this role on behalf of all physicians on earth, but please indulge me as I single out particularly my brothers and sisters of Africa.

I would firstly like to congratulate Dr. Yank Coble on an extraordinary Presidency. Through his Presidential initiative of "Caring Physicians of the World", he has managed to re-establish the fundamental values of medicine—caring, ethics and science. Together with the book on caring physicians, he has succeeded in making us feel good about being doctors again—so Yank, thank you again for your leadership, dedication and commitment to our profession. I find it a humbling experience to follow him as President and hope that I will be able to rise to the occasion.

An old Israeli saying states that you have to look back to where you have come from, to better see where you are heading. Looking back over the last few years, it is gratifying to note that the WMA has unquestionably grown into the representative voice of physicians. The World Health Organization, World Bank and other UN agencies turn to the WMA if they need to hear the views of physicians. Through our alliance with the International Council of Nurses, International Pharmaceutical Federation and the World Dental Federation we have also been able to make major breakthroughs in the field of public health.

Within the WMA there have also been very positive developments. Our role as the custodians of medical ethics has been reinforced by the successful revision of the Declaration of Helsinki and the launch of the WMA Ethics Manual. The impact of the manual has been immediate and very

significant. From its publication in January this year, it has now already been distributed worldwide and translated into at least 12 languages.

The WMA's recent contributions in health related human rights have also been welcomed by my compatriots from Africa. We cannot encourage the WMA enough to help physicians to be involved as the advocates and protectors of patients and the vulnerable groups in society. It will be part of my Presidential plan to help push forward our health-related human rights agenda.



I see the future role of the WMA as more and more that of social leaders, in addition to our role as the leaders of the health care teams. I would like to tell you three stories from the North, South and East to illustrate this point.

In the East we currently have an outbreak of avian flu. You will remember that in 2003 the world endured the SARS epidemic, where hundreds of patients died in China, Taiwan, Singapore and Canada. At the Time the WMA argued strongly for the establishment of a global surveillance and response network which would include

front line physicians. In addition, the WMA called for Taiwan to be included in the WHO surveillance and response network, as they are a separate health entity, not receiving any funding or assistance from China. Here we are in 2005, with avian flu posing as a possible disaster of a proportion we have not seen since the Spanish Flu epidemic in 1918, when millions died. Yet we do not have a fully functional network where the physicians and medical associations are directly linked to WHO. The gap in the global public health network, Taiwan, a country with 23 million citizens, has not been yet addressed. If avian flu is transmitted from China to Taiwan, as had happened with SARS, there are still no formal channels open between WHO and Taiwan to exchange technical data and provide help. Clearly we need to be more vocal and active as social leaders to make sure that all measures can be taken to include all the peoples of the world in preparing for health disasters.

The UN Commanding Officer in Rwanda General Dallaire said that after shaking hands with the devil in Rwanda he knows there is a God. Noting that SARS never came to Africa in 2003 I have also come to know fully that God is there for all of us.

I offer you another story from my own continent. Last year the fundamentalist governor of Nigeria's Kano State halted all polio immunisation efforts because of alleged and unsubstantiated claims that it was part of a plot to sterilize Muslim girls. By the time he relented, polio had spread to 12 African countries that had previously been freed of the disease, thereby dramatically setting back global eradication efforts and forcing the rest of the world to continue vaccination programmes—another classic example of where politics ruled over health imperatives. Where were we, the physicians of the world, in preventing this kind of disaster? We can and should prevent this from happening again!

In Northern Europe over the last year, physicians have expressed their severe dissatisfaction with the new trend of rationing of care, ever increasing paper work, work hours and diminishing remuneration. This led to protest actions in France, Germany

and Belgium. As governments find it difficult to fund health care services (from the patients' own money), rationing has increasingly been used to balance accounts. This has placed great pressure on the patient-physician relationship and physician autonomy. In September Belgian doctors protested against a proposed new government policy, whereby the Ministry of Health could intervene whenever the country's health insurance budget goes into deficit, effectively being able to exclude financial benefits for certain types of diagnosis or treatment. What is in fact happening is that health care is being dumped down to the lowest common denominator of cost. Even more importantly, rationing is slowly destroying the art and professional practice of medicine, the patient-physician relationship and patient access to all treatment options. Physicians are expected to act as administrative clerks and accountants and their professional role downgraded to select the least expensive, not the best available, treatment for their patients.

This trend of political considerations denying our patients the best possible health care services is unacceptable. We cannot allow politics to stand in the way of effective handling of epidemics or disasters affecting both national and international levels. It highlights the fact that physicians need to become more effective in shaping the health policy environment, rather than be shaped by it.

As I mentioned before, the last WMA Presidency very effectively re-affirmed the fundamental values of medicine. During my term as President, I would like to place the focus on patient-centred medical care. As physicians we can draw encouragement from the fact that patients still regard us as the most trusted source of health information, but as communicators we can do much better. Patients are overawed with the information they can now source from the internet, but recent reports show that physicians still don't communicate effectively enough with their patients. During my term I hope that we can revisit our policy on patient information and communication and develop a training manual on the subject, as we have done so successfully for ethics and human rights. We must remem-

ber always that our responsibilities come before our rights.

We have two themes in the vision of the World Medical Association, these are ethics and access. Whilst we have been in the forefront on ethics, there is still a lot to be done on access. We have collective responsibility globally to ensure access to basic healthcare for all citizens of the world. The Millennium Development Goals are being rolled back and those that are needing help are not necessarily receiving it. Globally, healthcare is being under-funded and physician autonomy is interfered with, thus undermining patients' rights. Doctors need to work together with civil society to create a safer world that can fund health care appropriately.

I come from South Africa, the epicentre of the HIV and AIDS epidemic. Therefore I would like to close with an impassioned plea for the WMA and all its members to fully take on the responsibility of combating HIV. This is still a growing disease, where the role physicians can and should play has not been optimized. This is especially true for our role in prevention. So far only a limited number of full scale prevention efforts have been developed with effectively target "at risk" populations, the infrastructure of health systems, societal attitudes and individual beliefs and motivations.

Remember, prevention in HIV and AIDS is ABCD, the four letters of the alphabet collectively and in the proper sequence; selec-

tive application of the alphabet is hazardous to the health of the people.

We need to ensure that our doctors are trained appropriately to fulfil the role that they play as leaders and healers. Medical schools train them to be great healers; we need to find a way to appropriately train them to be great leaders too. We need a programme to assist National Medical Associations to get doctors to be good leaders as well. I will dedicate my years as president to realise this objective as a follow-on to caring physicians, so that we can emulate those caring physicians and truly put our patients first.

There are three things to remember:

1. Health is political even for doctors but we will be non-partisan and engage others, as opposed to confronting them.
2. Health is a foundation for peace not a bridge, for as we saw in the aftermath of Katrina, bridges were swept away but the foundations remained.
3. A quote from Nelson Mandela: "After climbing a great hill, one finds that there are many more hills to climb."

Having seen the hills and mountains of Chile, I wonder if Mr. Mandela ever lived in Chile!

I would like to end by thanking our hosts, the Chilean Medical Association for their unforgettable warmth and hospitality during this Assembly. We are inviting you all to our Assembly in South Africa next year where we will try to emulate them. ■

171th WMA Council Session

(We are particularly indebted to Dr. Appleyard for his background notes on this meeting. Ed.)

The 171th Council meeting took place in Santiago, Chile on 14th October 2005.

The meeting was opened by the Chairman, Dr. Blachar who called on the Secretary General to give his report.

Secretary General's Report

Dr. Otmar Kloiber thanked the President, Dr. Yank Coble, for his dedication and for the 'added value' he had given to the Association through the "Caring Physicians of the World" initiative. The resulting book provides insight into how our physician



colleagues throughout the world serve their patients under conditions that are often hard to accept. The initiative had also supported conferences in different parts of the world. Dr. Kloiber also *thanked all NMAs* for their response to the disaster caused by the Tsunami and mentioned that money was still being collected. He expressed his gratitude to specific NMAs for their support, in particular for the staff time provided by the AMA, in particular to Sharon Ostrowski and Robin Menes, to the BMA, which through Dr. Vivienne Nathanson provided support for Work Groups, the Canadian Medical Association and Dr. Bill Thould for the Business Development Group, the German Medical Association especially for Dr. Parsa-Parsi's secondment, Ms Leah Wapner and the Israeli Medical Association, also to the Norwegian Medical Association for the online courses.

Turning to *restructuring of WMA Office Team*, he reported that since the last meeting of Council Ms. Emma Viaud, a member of Staff, had left the office. Dr. Parsi had been seconded to the office for three months and had, among other items, worked on the development of the TB Course, Outreach to Arab Countries, and on the Regional Office for Africa in SAMA.

The *Prison Medical Course* had now been translated into Spanish and is available on a CD-Rom.

Dr. Kloiber appealed to all NMAs to *assist the Office* in Ferney Voltaire by making available secondments for one of their staff to work at the WMA for three months until another member of staff has been employed. It was felt that this could provide a valuable educational opportunity for NMAs' junior medical staff.

Dr. Kloiber thanked Johnson and Johnson for their continuing support of the Ethics Unit and the production of the Ethics Manual and to the South African, Australian and Norwegian MA's for their work on the TB project.

Following the successful completion of the implementation of the *Istanbul Project* in five nations with the ICRT, the work will be extended to other countries through a further grant from the *European Commission*.

Dr. Kloiber reported that the FDI had now joined *the World Health Professions Alliance*. At a very successful WHPA Reception on Patient Safety held at the same time as the World Health Assembly. Sir Liam Donaldson, Chairman of the World Alliance for Patient Safety, gave the keynote address. A joint seminar will be held next year on three topics, the Reporting of Medical Errors, Counterfeit Medicines and on Human Resources for Health.

Turning to *finance and organisation*, Dr. Kloiber told Council that his first priority following his appointment was to ensure sound financial governance. In this he had had great support from Mr Adi Hallmayr and Dr. Karsten Vilmar, the Treasurer Emeritus. He had had to apply the brakes to give an emergency stop to expenditure. Stating that his main concern was to know how much of the WMA could be used for advocacy he commented that the WMA had established a high reputation internationally and its opinion was increasingly being sought for its professional expertise.

Concerning *Forced Sterilizations*, since the last Council meeting Dr. Kloiber had been in correspondence with the Slovak Medical Association about allegations that some Physicians in Slovakia had been involved in forced sterilisations (an illegal practice in that country). The Slovak Medical Association had investigated these allegations with the Slovakian Government. The Board of the Slovakian Medical Association had written, stating that the allegations could not be confirmed and that none of the members of the Slovakian Medical Association had been involved.

Dr. Kloiber reported that since the last Council Session he had *attended meetings* of the AMA, BMA, Norwegian MA and Cuban Medical Association. He valued these personal contacts and by participating in the meetings had a greater understanding of local issues. Further visits to other NMAs will be undertaken next year.

Dues

The Revision of the Dues system as proposed by the Treasure Emeritus was considered. Dr. Plested (AMA) asked if the full implica-

tions of the proposed changes had been explored and whether some NMAs would use this schedule as an opportunity to reduce their dues. Dr. Kloiber replied that he anticipated that the changes would be cost neutral. The NMA's from poorer nations would be able to receive more votes in proportion to their subscriptions and become more involved in the activities of the WMA. The lower cost would encourage non members from poorer nations to join. He emphasised that there would be no change in the dues paid by the larger and richer NMA's, who provide 85% of the WMA's dues revenue.

After Dr. Johnson (BMA) agreed that the recommendations had to be taken as a 'package', the revised dues system was AGREED.

Sponsorship

Dr. Plested (AMA) proposed that the specification for new Sponsorship projects should be reassessed to ensure robust projections for anticipated Income and Expenditure. He moved a motion, seconded by Dr. Nelson (USA), 'that the Secretary General work within the existing guidelines to maximise non-dues income'. This was AGREED.

Medical Ethics Committee Report

This was presented by the Chairman, Dr. Bagenholm.

Minor Revisions of Declarations etc.

The Declaration of Lisbon, as revised, was approved.

It was agreed that a work group be convened by the AMA with the BMA to integrate NMA comments on the 'Statement of Ethical Issues concerning patients with Mental Illness', which was re-classified as requiring major revision.

Major Revisions of Declarations etc.

It was **resolved** that all the Documents classified as requiring major revisions be referred to NMA's for comment.

Concerning the Policy Review of the *Declarations of Geneva, of Tokyo*, and the *Regulations in Times of Armed Conflict*, Dr. Nathanson gave an oral report on her pro-

posals to amend these statements. It was AGREED that the proposals of the BMAs convened Work Group be circulated to NMA's.

Sponsorship Guidelines

Dr. Bagenholm reported on the discussion within her committee on the principle of accepting sponsorship. It was AGREED that Council establish a Working Group of the Chairs of Ethics and of Finance and Planning Committees, to review the WMA's Corporate relationship Guidelines (*see page 86 for fuller account of the discussion*).

Socio-Medical Affairs Committee Report

Dr. Haddad in presenting his report, introduced for the first time a Consent Calendar for the Recommendations of his Committee. This procedure involves the presentation of all the Recommendations from the Committee together as one recommendation, with the option that any member of Council could request the withdrawal of any specific recommendation, for further debate.

The report was for the first time presented as a consent calendar, which meant that all recommendations that were not challenged (extracted) were then voted for en bloc and approved.

Dr. Plested suggested the extraction of para 2.2.1, the Proposed Statement on Reducing the Global impact of Alcohol. This enabled him to speak in favour of the document emphasising the point made within it of the necessity for a Strategic Framework similar to the one on Tobacco, following this the statement was agreed unanimously (*the Alcohol Statement will appear in the next issue of WMJ*).

Skills Drain

The BMA had prepared two background papers on the Healthcare Skills Drain from Developing Countries. These will be distributed to NMA's for information.

Finance and Planning Committee

Dr. John Nelson presented his report of the meeting of the committee. All the recom-

mendations were adopted without further debate including the revised dues structure. (*see also Dues above*)

Other Business

Recommendations on Business Development and on Non-dues income were agreed (see above!).

Disaster Planning

It was AGREED that a Work Group be established to consider the preventive measures and contingencies necessary for Disaster Planning including the possible Asian Flu pandemic. The Canadian, South African, German and American MA's will contribute to this.

Preventing Chronic Diseases

Dr. Appleyard (IPP) referred to his report to Council in May concerning the WHO initiative on Preventing Chronic Diseases and stressed the importance of the major financial burden this would place on developing countries. WHO was launching the initiative at the end of October and it would be appropriate for the WMA to identify itself with this important preventive venture. In view of the time constraints he suggested a special Council Resolution:

„The WMA (Council) welcomes the WHO Report on “Preventing Chronic Diseases, a vital investment, and recommends that all NMA's work with health professional organisations, interested stakeholders and their Governments, to

prevent and relieve the increasing burden of chronic disease.

This was formally proposed by Dr. Haddad and seconded by Dr. Wu.

Dr. Kloiber raised concerns about the financial impact saying that he had no capacity to attend the launch later in the month.

After further debate to which Dr. Appleyard replied, reading out for translation purposes a brief background paper he had prepared, the Council Resolution was AGREED nem con, with the caveat that there would be no additional cost incurred.

(full WHO report is accessible at www.who.int/chp/chronic_disease_report/overview_en.pdf)

Executive Committee

Dr. John Nelson raised a question about the composition of the Executive Committee, expressing concern at the exclusion of the three Presidents as non-voting members. Presidents were elected from the General Assembly representing all the NMAs, not just those larger NMA's who had 'bought' seats on the Council with their larger declared membership. Dr. Kloiber said that he was bound by the last decision of Council that only the voting members of Council would be included on the executive. These had been specified as the Chair of Council, Deputy Chair, and the Chair of the three Committees. The Executive committee had already decided to revisit the issue again. ■

The World Medical Association Resolution on Avian Influenza

Adopted by the WMA General Assembly, Santiago 2005

The World Medical Association recognizes the potential global morbidity and mortality as a result of the H5N1 strain of avian flu. This possibility increases with every passing day as more countries find infected birds in their territories. The WMA will work with member NMAs, the

WHO and other stakeholders to track the progress of the disease and propose the necessary measures to minimize its impact on the global human population. The WMA also urges governments to engage with NMAs to prepare for the possibility of a pandemic.



The World Medical Association Statement on Genetics and Medicine

Adopted by the WMA General Assembly, Santiago 2005

Preamble

1. In recent years, the field of genetics has undergone rapid change and development. The areas of gene therapy and genetic engineering and the development of new technology have presented possibilities inconceivable only decades ago.
2. The Human Genome Project opened new spheres of research. Its applications also proved useful to clinical care by allowing physicians to utilize knowledge of the human genome in order to diagnose future disease, as well as to individualize drug therapy (pharmacogenomics).
3. Because of this, genetics has become an integral part of primary care medicine. Whereas at one time, medical genetics was devoted to the study of relatively rare genetic disorders, the Human Genome Project has established a genetic contribution to a variety of common diseases. It is therefore incumbent upon all physicians to have a working knowledge of the field.
4. Genetics is an area of medicine with enormous medical, social, ethical and legal implications. The WMA has developed this statement in order to address some of these concerns and provide guidance to physicians. These guidelines should be updated in accordance with developments in the field of genetics.

Major Issues:

Genetic Testing

5. The identification of disease-related genes has led to an increase in the number of available genetic tests that detect disease or an individual's risk of disease. As the number and types of such tests and the diseases they detect increases, there is concern about the reliability and limitations of such tests, as well as the implica-

tions of testing and disclosure. The ability of physicians to interpret test results and counsel their patients has also been challenged by the proliferation of knowledge.

6. Genetic testing may be undergone prior to marriage or childbearing to detect the presence of carrier genes that might affect the health of future offspring. Physicians should actively inform those from populations with high incidence of certain genetic diseases about the possibility of premarital and pre-pregnancy testing, and genetic counseling should be made available to those individuals or couples who are considering such testing.
7. Genetic counseling and testing during pregnancy should be offered as an option. In cases where no medical intervention is possible following diagnosis, this should be explained to the couple prior to their decision to test.
8. In recent years, with the advent of IVF, genetic testing has been extended to pre-implantation genetic diagnosis of embryos (PGD). This can be a useful tool in cases where a couple has a high chance of conceiving a child with genetic disease.
9. Since the purpose of medicine is to treat, in cases where no sickness or disability is involved genetic screening should not be employed as a means of producing children with pre-determined characteristics. For example, genetic screening should not be used to enable sex selection unless there is a gender-based illness involved. Similarly, physicians should not countenance the use of such screening to promote non-health related personal attributes.
10. Genetic testing should be done only with informed consent of the individual or his/her legal guardian. Genetic testing for predisposition to disease should be performed only on consenting adults, unless

there is treatment available for the condition and the test results would facilitate earlier instigation of this treatment.

11. Valid consent to genetic testing should include the following factors:
 - a. The limitations of genetic testing, including the fact that the presence of a specific gene may denote predisposition to disease rather than the disease itself and does not definitively predict the likelihood of developing a certain disease, particularly in multi-factorial disorders.
 - b. The fact that a disease may manifest itself in one of several forms and in varying degrees
 - c. Information about the nature and predictability of information received from the tests.
 - d. The benefits of testing including the relief of uncertainty and the ability to make informed choices, including the possible need to increase or reduce regular screenings and checkups, and to implement risk reduction measures
 - e. The implications of a positive result and the prevention, screening and/or treatment possibilities.
 - f. The possible implications for the family members of the patient involved.
12. In the case of a positive test result that may have implications for third parties such as close relatives, the individual tested should be encouraged to discuss the results of the test with such third parties. In cases where not disclosing the results involves a direct and imminent threat to the life or health of an individual, the physician may reveal the results to such third parties, but should usually discuss this with the patient first. If the physician has access to an ethics committee, it is

preferable to consult such a committee prior to revealing results to third parties.

Genetic Counseling

13. Genetic counseling is generally offered prior to marriage or conception, in order to predict the likelihood of conceiving an affected child, during pregnancy, in order to determine the condition of the fetus, or to an adult, in order to determine susceptibility to a certain disease.
14. Individuals at higher risk for conceiving a child with a specific disease should be offered genetic counseling prior to conception or during pregnancy. In addition, adults at higher risk for various diseases such as cancer, mental illness or neurodegenerative diseases in which the risk can be tested for, should be made aware of the availability of genetic counseling.
15. Because of the scientific complexity involved in genetic testing as well as the practical and emotional implications of the results, the WMA sees great importance in educating and training medical students and physicians in genetic counseling, particularly counseling related to pre-symptomatic diagnosis of disease. Independent genetic counselors also have an important role to play. The WMA acknowledges that there can be very complex situations requiring the involvement of medical genetics specialists.
16. In all cases where genetic counseling is offered, it should be non-directive and protect the individual's right not to be tested.
17. In cases of counseling prior to or during pregnancy, the prospective parents should be given information to provide the basis for an informed decision regarding child-bearing, but should not be influenced by the physicians' personal views in this matter and physicians should be careful not to substitute their own moral judgment for that of the prospective parents. In cases where a physician is morally opposed to contraception or abortion, he/she may

choose not to provide these services but should alert prospective parents that a potential genetic problem exists and make note of the option of contraception or abortion as well as treatment alternatives, relevant genetic tests, and the availability of genetic counseling.

Confidentiality of results

18. Like all medical records, the results of genetic testing should be kept strictly confidential, and should not be revealed to outside parties without the consent of the individual tested. Third parties to whom results may in certain circumstances be released are identified in paragraph 12.
19. Physicians should support the passage of laws guaranteeing that no individual shall be discriminated against on the basis of genetic makeup in the fields of human rights, employment and insurance.

Gene therapy and genetic research

20. Gene therapy represents a combination of techniques used to correct defective genes that cause disease, especially in the fields of oncology, hematology and immune disorders. Gene therapy is not yet an active current therapy but is still in a stage of clinical investigation. However, with the continued development of this field, it should proceed according to the following guidelines:
 - a. Gene therapy performed in a research context should conform to the requirements of the Declaration of Helsinki while therapy performed in a treatment context should conform to standards of medical practice and professional responsibility.
 - b. Informed consent should always be obtained from the patient undergoing the therapy. This informed consent should include disclosure of the risks of gene therapy, including the fact that the patient may have to undergo multiple rounds of gene therapy, the risk of an immune response, and the potential

problems arising from the use of viral vectors.

- c. Gene therapy should only be undertaken after a careful analysis of the risks and benefits involved and an evaluation of the perceived effectiveness of the therapy, as compared to the risks, side effects, availability and effectiveness of other treatments.

21. It is currently possible to undertake screening of an embryo in order to provide stem cell or other therapies for an existing sibling with a genetic disorder. This may be considered acceptable medical practice where no evidence exists that the embryo is being created exclusively for this purpose.
22. Genetic discoveries should be shared as much as possible between countries, so as to benefit humankind and reduce duplication of research and the risk inherent in research in this area.
23. In the case of genetic research performed on large, defined population groups, efforts should be made to avoid potential stigmatization.

Cloning

24. Recent developments in science have led to the cloning of a mammal and raise the possibility of such cloning techniques being used in humans.
25. Cloning includes both therapeutic cloning, namely the cloning of individual stem cells in order to produce a healthy copy of a diseased tissue or organ for transplant, and reproductive cloning, namely the cloning of an existing mammal to produce a duplicate of such mammal. The WMA currently opposes reproductive cloning, and in many countries it is considered to pose more of an ethical problem than therapeutic cloning.
26. Physicians should act in accordance with the codes of medical ethics in their countries regarding the use of cloning and be mindful of the law governing this activity.



The World Medical Association Statement on Drug Substitution

Adopted by the WMA General Assembly, Santiago 2005

Introduction

1. The prescription of a drug represents the culmination of a careful deliberative process between physician and patient aimed at the prevention, amelioration or cure of a disease or problem. This deliberative process requires that the physician evaluate a variety of scientific and other data including costs and make an individualized choice of therapy for the patient. Sometimes, however, a pharmacist is required to substitute a different drug for the one prescribed by the physician. The World Medical Association has serious concerns about this practice.
2. Drug substitution can take two forms: generic substitution and therapeutic substitution.
3. In generic substitution, a generic drug is substituted for a brand name drug. However, both drugs have the same active chemical ingredient, same dosage strength, and same dosage form.
4. Therapeutic substitution occurs when a pharmacist substitutes a chemically different drug for the drug that the physician prescribed. The drug substituted by the pharmacist belongs to the same pharmacologic class and/or to the same therapeutic class. However since the two drugs have different chemical structures, adverse outcomes for the patient can occur.
5. The respective roles of physicians and pharmacists in serving the patient's need for optimal drug therapy are outlined in the WMA Statement on the Working Relationship between Physicians and Pharmacists in Medicinal Therapy.
6. The physician should be assured by national regulatory authorities of the bioequivalence and the chemical and therapeutic equivalence of prescription drug products from both multiple and single sources. Quality assurance procedures should be in place to ensure their lot-to-lot bioequivalence and their chemical and therapeutic equivalence.
7. Many considerations should be addressed before prescribing the drug of choice for a particular indication in any given patient. Drug therapy should be individualized based on a complete clinical patient history, current physical findings, all relevant laboratory data, and psychosocial factors. Once these primary considerations are met, the physician should then consider comparative costs of similar drug products available to best serve the patient's needs. The physician should select the type and quantity of drug product that he or she considers to be in the best medical and financial interest of the patient.
8. Once the patient gives his or her consent to the drug selected, that drug should not be changed without the consent of the patient and his or her physician. Failure to follow this principle can result in harm to patients. On behalf of patients and physicians alike, National Medical Associations should do everything possible to ensure the implementation of the following recommendations:
9. Physicians should become familiar with specific laws and/or regulations governing drug substitution where they practise.
10. Pharmacists should be required to dispense the exact chemical, dose, and dosage form prescribed by the physician. Once medication has been prescribed and begun, no drug substitution should be made without the prescribing physician's permission.
11. If substitution of a drug product occurs, the physician should carefully monitor and adjust the dose to ensure therapeutic equivalence of the drug products.
12. If drug substitution leads to serious adverse drug reaction or therapeutic failure, the physician should document this finding and report it to appropriate drug regulatory authorities.
13. National Medical Associations should regularly monitor drug substitution issues and keep their members advised on developments that have special relevance for patient care. Collection and evaluation of information reports on significant developments in this area is encouraged.
14. Appropriate drug regulatory bodies should evaluate and ensure the bioequivalence and the chemical and therapeutic equivalence of all similar drug products, whether generic or brand-name, in order to ensure safe and effective treatment.
15. National Medical Associations should oppose any action to restrict the freedom and the responsibility of the physician to prescribe in the best medical and financial interest of the patient.
16. National Medical Associations should urge national regulatory authorities to declare therapeutic substitution illegal, unless such substitution has the immediate prior consent of the prescribing physician.

Recommendations

9. Physicians should become familiar with specific laws and/or regulations governing drug substitution where they practise.

The World Medical Association Statement on Medical Liability Reform

Adopted by the WMA General Assembly, Santiago 2005

1. A culture of litigation is growing around the world that is adversely affecting the practice of medicine and eroding the availability and quality of health care services. Some National Medical Associations report a medical liability crisis whereby the lawsuit culture is increasing health care costs, restraining access to health care services, and hindering efforts to improve patient safety and quality. In other countries, medical liability claims are less rampant, but National Medical Associations in those countries should be alert to the issues and circumstances that could result in an increase in the frequency and severity of medical liability claims brought against physicians.
2. Medical liability claims have greatly increased health care costs, diverting scarce health care resources to the legal system and away from direct patient care, research, and physician training. The lawsuit culture has also blurred the distinction between negligence and unavoidable adverse outcomes, often resulting in a random determination of the standard of care. This has led to the broad perception that anyone can sue for almost anything, betting on a chance to win a big award. Such a culture breeds cynicism and distrust in both the medical and legal systems with damaging consequences to the patient-physician relationship.
3. In adopting this Statement, the World Medical Association makes an urgent call to all National Medical Associations to demand the establishment of a reliable system of medical justice in their respective countries. Legal systems should ensure that patients are protected against harmful practices, physicians are protected against unmeritorious lawsuits, and “standard of care” determinations are consistent and reliable, so that all parties know where they stand.
4. In this Statement the World Medical Association wishes to inform National Medical Associations of some of the facts and issues related to medical liability claims. The laws and legal systems in each country, as well as the social traditions and the economic conditions of the country, will affect the relevance of some portions of this Statement to each National Medical Association but do not detract from the fundamental importance of such a Statement.
5. An increase in the frequency and severity of medical liability claims may result, in part, from one or more of the following circumstances:
 - a. Increases in medical knowledge and medical technology that have enabled physicians to accomplish medical feats that were not possible in the past, but that involve considerable risks in many instances.
 - b. Pressures on physicians by private managed care organizations or government-managed health care systems to limit the costs of medical care.
 - c. Confusing the right to access to health care, which is attainable, with the right to achieve and maintain health, which cannot be guaranteed.
 - d. The role of the media in fostering mistrust of physicians by questioning their ability, knowledge, behaviour, and management of patients, and by prompting patients to submit complaints against physicians.
6. A distinction must be made between harm caused by medical negligence and an untoward result occurring in the course of medical care and treatment that is not the fault of the physician.
 - a. Injury caused by negligence is the direct result of the physician's failure to conform to the standard of care for treatment of the patient's condition, or the physician's lack of skill in providing care to the patient.
 - b. An untoward result is an injury occurring in the course of medical treatment that was not the result of any lack of skill or knowledge on the part of the treating physician, and for which the physician should not bear any liability.
7. Compensation for patients suffering a medical injury should be determined differently for medical liability claims than for the untoward results that occur during medical care and treatment, unless there is an alternative system in place such as a no-fault system or alternate resolution system.
 - a. Where an untoward result occurs without fault on the part of the physician, each country must determine if the patient should be compensated for the injuries suffered, and if so, the source from which the funds will be paid. The economic conditions of the country will determine if such solidarity funds are available to compensate the patient without being at the expense of the physician.
 - b. The laws of each jurisdiction should provide the procedures for deciding



<p>liability for medical liability claims and for determining the amount of compensation owed to the patient in those cases where negligence is proven.</p> <p>8. National Medical Associations should consider some or all of the following activities in an effort to provide fair and equitable treatment for both physicians and patients:</p> <ul style="list-style-type: none">a. Establish public education programs on the risks inherent in some of the new advances in treatment modalities and surgery, and professional education programs on the need for obtaining the patient's informed consent to such treatment and surgery.b. Implement public advocacy programs to demonstrate the problems in medicine and health care delivery resulting from strict cost containment limitations.c. Enhance the level and quality of medical education for all physicians, including improved clinical training experiences.d. Develop and participate in programs for physicians to improve the quality of medical care and treatment.e. Develop appropriate policy positions on remedial training for physicians	<p>found to be deficient in knowledge or skills, including policy positions on limiting the physician's medical practice until the deficiencies are corrected.</p> <ul style="list-style-type: none">f. Inform the public and government of the dangers that various manifestations of defensive medicine may pose (the multiplication of medical acts or, on the contrary, the abstention of the physicians, the disaffection of young physicians for certain higher risk specialties or the reluctance by physicians or hospitals to treat higher-risk patients).g. Educate the public on the possible occurrence of injuries during medical treatment that are not the result of physician negligence, and establish simple procedures to allow patients to receive explanations in the case of adverse events and to be informed of the steps that must be taken to obtain compensation, if available.h. Advocate for legal protection for physicians when patients are injured by untoward results not caused by any negligence, and participate in decisions relating to the advisability of providing compensation for	<p>patients injured during medical treatment without any negligence.</p> <ul style="list-style-type: none">i. Participate in the development of the laws and procedures applicable to medical liability claims.j. Develop active opposition to meritless or frivolous claims and to contingency billing by lawyers.k. Explore innovative alternative dispute resolution procedures for handling medical liability claims, such as arbitration, rather than court proceedings.l. Encourage self-insurance by physicians against medical liability claims, paid by the practitioners themselves or by the employer if the physician is employed.m. Encourage the development of voluntary, confidential, and legally protected systems for reporting untoward outcomes or medical errors for the purpose of analysis and for making recommendations on reducing untoward outcomes and improving patient safety and health care quality.n. Advocate against the increasing criminalization or penal liability of medical acts by the courts.
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General Assembly Associates' Meeting, Santiago 2005

Dr. G Dumont was re-elected Chair and the minutes of the meeting in Tokyo 2004 were approved.

Arising from the minutes, Dr. Kloiber, the Secretary General, reported that, following last year's resolution in connection with forced sterilisation of women in the Slovak Republic, he had written to the Slovak

Medical Association. The Slovak Ministry of Health had investigated the allegation with the Medical Association. The allegations were found to have no foundation. The Slovak Medical Association had written to WMA stating that no member of the SMA had been involved in this practice which was illegal in the Slovak Republic.

The Secretary General, reporting on the total numbers of Associate Members commented that he was reviewing the role of Associate Members in the future, pointing out that the International Dental Federation's associate members played a more proactive role. Responding to a proposal by Dr. Montgomery, the longest serving member present at the meeting, that the meeting be disbanded, Dr. Appleyard opposing this, said that the Associate's meeting had produced some helpful statements, citing the two which were on the agenda as examples. Junior doctors were keen to form a group within WMA

and he referred to IFMSA members being eligible for free associate membership of WMA for three years after graduation. Dr. Kloiber confirming this, pointed out that resolutions of the Associates' meeting were sent to the General Assembly, although Council tended to consider them first.

After an extensive debate it was agreed that the Secretary General would report back on his deliberation.

Dr. Montgomery proposed, seconded by Dr. Nelson, that Assembly business be consid-

ered next on the agenda. Although this was opposed by Dr. Fransblau, the motion was adopted by a large majority.

The meeting then elected Drs. Montgomery and Smoak as representatives at the General Assembly.

The meeting then considered a resolution on Medical Assistance in Air Travel submitted by the late Dr. Odenbach, presented on his behalf by Dr. Kloiber. This was supported by Dr. Montgomery. Dr. Appleyard felt that the issue of liability in circumstances where

humanitarian help was offered was important and proposed that the motion be referred to Council in the first instance. The proposal was seconded by Dr. Montgomery and the Resolution was adopted.

A second proposed Resolution on Child Safety in Air travel, was introduced by Dr. Kloiber, expressing concern that adequate safety systems for babies and small children had not been implemented. After some discussion the Resolution was passed unanimously. ■

Beyond statements and resolutions – Working at the WMA Secretariat in Ferney-Voltaire

Dr. Ramin Parsa-Parsi, MD, MPH, German Medical Association

The author of the following note spent three months in the WMA Office this year and writes about the experience and what it offers.

The voice of the World Medical Association is considered as the opinion of millions of physicians from every region of the world. Its function has always been to constitute a free, open forum for the frank discussion of matters related to medical ethics, medical education, and socio-medical affairs. With its declarations and statements it has contributed significantly to national and international debates. Approved by its General Assembly, WMA documents guide national medical associations, health care, governments, non-governmental organisations and United Nations agencies.

The World Medical Association has also, however, always been involved in many other activities beyond statements and resolutions. A number of global projects and programmes are continuously initiated, supported or conducted by the WMA. These activities might not be as visible and well known to the health care community and the general public.

Who is doing all the work?

People might assume that a few tens of highly specialized staff members work inexorably in the high-tech offices of a large WMA headquarters. The WMA must surely work with heavy administration and staff budgets?

In truth, for reasons of economy, and in order to operate within the vicinity of Geneva-based international organizations like the WHO and other UN agencies, the International Red Cross and international associations, the WMA Secretariat was transferred in 1975 from New York to its present location in Ferney-Voltaire, France close to Geneva.

Membership of the World Medical Association is voluntary and its budget is funded from membership fees from national medical associations. Hence, funds are limited and vary significantly. The WMA has been a marvel in managing projects, programmes and its meetings and assemblies with extremely small budgets. Its Secretariat operates with a small permanent

staff only, but manages to accomplish an impressive amount of work.

The WMA would certainly be interested to commit itself to even more projects and activities. However, more manpower would be necessary. One way to increase capacities at WMA is its programme for health care professionals to spend three to six months at the WMA Secretariat in Ferney-Voltaire. National medical associations may use this opportunity to send a staff-member for a short-term "training" at the WMA Secretariat.

There is certainly no better way to get to know the work of the WMA and experience the job environment of a truly international organization.

It is a win-win-situation

Fellows are able to dive into „hands on“ work from the very first day. Apart from some routine work which clearly helps to understand the every-day work of an international organization, Fellows have the chance to take on the management of individual projects. Fellows routinely interact with senior health care experts from the various health care organisations and work self-responsibly and independently.

For example, this summer the WMA started a project to develop an online course for physicians on multi-drug-resistant tubercu-



losis (MDR-TB). The WMA had previously developed a similar programme for physicians in prisons. This training course is being developed to train physicians to more effectively diagnose, prevent and treat MDR-TB. The WMA is collaborating with the South African Medical Association and its Foundation for Professional Development on this project. The WMA is also collaborating with the WHO and several national medical associations in order to produce a state-of-the-art and universally accessible product. The Norwegian Medical Association is transforming the material into the online format and the German Medical Association is helping with logistic support. The management and the coordination of the entire project is performed by WMA staff. Although the coordination of all stakeholders and international experts can be challenging, helping to make this project happen is a truly exciting and rewarding task. The final product will be an important contribution to the global fight against MDR-TB.

For another project the WMA collaborates with the International Rehabilitation Council for Torture Victims (IRCT) on a European Union sponsored project. Using the "Istanbul Protocol" as a manual, physicians are trained in effective investigation and documentation of torture and other cruel, inhuman or degrading treatment or punishment. The training seminars were completed in five pilot countries: Morocco, Mexico, Uganda, Sri Lanka and Georgia. WMA experts participated in coordination and evaluation meetings and attended preparatory missions and training seminars. The WMA particularly fostered the identification process with national medical associations and used its special expertise in medical ethics during seminars. Also, the collaboration with other organizations, local authorities and consultants has been helpful and important in the process. The continuation of the project with a new phase is projected to run over a three-year period and will most probably start by January 2006. The new project will include a consolidation of activities in the five current project countries and initiate activities in five new countries. Furthermore it will support capacity-building activities for

rehabilitation centres and strengthen the collaboration between centres and local human rights organizations. The IRCT and the WMA have a formal partnership in this project with shared responsibilities. The collaboration has been extremely good. Regular contact and discussions on key issues helped ensuring a coordinated and efficient process.

Applications are welcome

Being involved in the work of various different projects, fellows will experience the entire spectrum of health care services and systems. Furthermore, regular communication with representatives of national medical associations, including new and future WMA members, helps understanding the differences and similarities of physician organizations worldwide. Also helping to prepare Council meetings and the Annual

General Assembly is indeed rewarding. In short: Working at the WMA Secretariat is a unique experience.

National Medical Associations who are interested in the fellowship programme may contact the WMA Secretariat in Ferney-Voltaire. Interested parties may also contact previous fellows for more detailed information.

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From the Secretary General's desk

"Don't forget the others"

While currently the whole world seems to worry about the prisoners in Guantánamo Bay those incarcerated in the other prisons of Cuba seem to be forgotten. Men and women asking for nothing but freedom, who are not involved in terrorism, war or oppression, are being held as prisoners of conscience permanently or repeatedly, some for decades. Many of them have not survived the special treatment by the Cuban government and others possibly will die.

While for many of us Cuba may be seen as a cheap Caribbean holiday resort, for those living there the paradise may have some dark spots. For more than forty years Cuba has been under communist dictatorship. What has been overcome in most of the former communist countries in Europe, terror, intimidation, oppression, and prosecution

of those who want freedom, still lives in Cuba.

The "Cuban Spring 2003" stands for an aggressive "cleaning-up" campaign which the communists carried out in Cuba: As far as it is known in the free world, 75 persons were sentenced to long prison terms of up to 28 years. The way they are treated is similar for totalitarian regimes. Methods include imprisonment far away from their families, placement together with violent criminals, intimidation of family members and reduced allowances for visits. Left without sufficient food some lose weight rapidly, and food and medicine brought by relatives has been taken away.

The World Medical Association has repeatedly remembered the fate of Cuban Physicians. They are outstanding col-



leagues fighting for the freedom of the Cuban People and for the freedom of medicine in their country. What they currently get is hell on earth. Six of them are known to us, they and their families and friends deserve our attention as examples of all those who pay a high price in the struggle for freedom. The following information has been compiled from various sources:

Dr. OSCAR ELÍAS BISCET, 44 years old, a specialist in internal medicine, is the president of the unofficial Lawton Human Rights Foundation. He has been detained more than two dozen times, charged with 'insult to the symbols of the homeland,' 'public disorder,' and 'incitement to commit an offence'. Dr. Biscet has been kept in special punishment cells for refusing to carry out disciplinary measures. Before Spring 2003 when Dr. Biscet was arrested last, he had already been in prison for 3 years. Now in December 2005 it adds up to 6 years.

To discourage visits by his family he was temporarily imprisoned in Prison Kilo 8 in the province of Pinar del Rio, sharing a cell with twelve other prisoners. He has been sentenced to 25 years in prison.

DR. MARCELO CANO RODRÍGUEZ, 41 years old, is National Coordinator of the unofficial Cuban Independent Medical Association, an association of medical professionals around the island. For not respecting the prison rules for criminals Dr. Cano has not been allowed to see the sun for 10 months. Dr. Cano has been sentenced to 18 years in prison.

DR. JOSÉ LUIS GARCÍA PANEQUE, aged 39, is a plastic surgeon and a member of the Cuban Independent Medical Association. He has worked as a journalist, as director of the independent news agency Libertad and member of the independent Journalists' Society. Dr. Paneque's weight has dropped from 86 to 48 kg and he is presently in the infirmary of "Las Mangas" Prison in Bayamo. His health continues to be critical. His wife is currently being threatened with imminent mob attacks against their home. Dr. Paneque was sentenced to 24 years in prison.

DR. LUIS MILÁN FERNÁNDEZ, 36 year old, is a member of the Cuban Medical Association. In June 2001 he and his wife, Lisandra Lafitta, also a doctor, signed a document called 'Manifiesto 2001,' calling among other measures for recognition of fundamental freedoms in Cuba. Together with other health professionals they carried out a one-day hunger strike to call attention to the medical situation of detainees and other issues. Although without emotional or mental problems, he is now confined with mental patients in the psychiatric ward of the Prison of Boniato, in the province of Santiago de Cuba. Dr. Milán Fernández, had been sentenced to 13 years in prison.

ALFREDO MANUEL PULIDO LÓPEZ, aged 45, graduated in 1983 in the specialty of Stomatology, and Dentistry. He practiced until 1998, when he was fired from his job for joining the Christian Liberation Movement. In 2001 he joined the unofficial news agency El Mayor in Camagüey for which he worked as journalist. Incarcerated in the Maximum Security Prison Kilo 7 his health is rapidly deteriorating. He is not only suffering from severe migraine, but has also experienced several hypoglycemic episodes. Instead of providing treatment he has been threatened that he gets a psychi-

atric evaluation to find out the sources of his headaches. Dr. Pulido López has been sentenced to 14 years in prison.

RICARDO ENRIQUE SILVA GUAL, 32, physician and member of the Christian Liberation Movement like Dr. Pulido López. Dr. Siva Gual suffering from glaucoma. Dr. Silva Gual has been sentenced to 10 years in prison.

Sources:

Coalition of Cuban-American Women/LAIDA CARRO.
Joseito76@aol.com.

Human rights first
<http://action.humanrightsfirst.org/campaign/Biscet>

Amnesty International
<http://web.amnesty.org/library/Index/ENGAMR250022005>

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Medicina Cubana
http://medicinacubana.blogspot.com/2005_09_01_medicinacubana_archive.html

For further information monitor our website: www.wma.net ■

WHO

FAO/OIE/WB/WHO Meeting on Avian Influenza and Human Pandemic Influenza

Closing remarks of Dr. LEE Jong Wook, D.G., WHO

Geneva, Switzerland, 9 November 2005. "Thank you for making this a remarkable and productive meeting. The world has been watching and listening as, over these three days, the scale of the challenges has emerged. The international solidarity to confront these threats is clear. The urgency of acting now is felt by us all. Precise recommendations for action have emerged. Equally, precise offers of help and support

have been put forward, by both developing and industrialized countries.

I will now review the central points that have come out of the meeting. Next I will outline an integrated programme of action which responds to the issues raised.

1. Minimizing the threat at source to both animal and human populations through rapid reduction of the viral burden of



H5N1 is essential. This entails timely notification of outbreaks in birds, poultry culling and vaccination as indicated, including „backyard“ flocks, and provision of appropriate compensation for farmers.

2. “Early warning” and surveillance systems for animal and human influenza are critical to effective response. The current window of opportunity to intervene is measured in days. Transparent and immediate reporting is essential.
3. The introduction of avian infection with H5N1 to other countries is predicted, following the patterns of migratory birds, and as a result of production systems and market practices. Other strains of avian flu are also an ongoing and emerging threat and must be monitored. Strengthened veterinary services are a crucial aspect of detection and response. Open sharing of virus samples is essential. Quality assured animal vaccines produced to international standards should be used in healthy poultry when appropriate.
4. At present many governments are not ready to cope with outbreaks, still less a pandemic. Preparedness is vital in every country, in every Region. Integrated country plans will build on and strengthen existing systems and mechanisms. They will be comprehensive, costed, and evaluated. Response mechanisms should be rehearsed through simulation exercises. These plans will include protection of vulnerable groups such as children, refugees and displaced populations.
5. Resources needed to slow down or contain the emergence of a pandemic are insufficient. Supplies of antiviral drugs currently do not meet potential demand. Issues remain of equitable access to medicines and deployment of stockpiles.
6. A universal non-specific pandemic vaccine may be the ultimate protective solution for human influenza. „Smart“ solutions are being investigated. Issues of technology transfer, resolution of licensing and regulatory obstacles, sustained

use of good manufacturing practices and pre-qualification are under discussion. Predictable, increased orders for seasonal flu vaccine will support greater manufacturing capacity, including in developing countries.

7. Communications. The recent series of high-level meetings on avian influenza and human pandemic influenza have successfully created a shared agenda. The public needs clear, regular, reliable information. Civil society, nongovernmental organizations and other community groups must be involved.
8. A rich array of resources is potentially available to support government and institutional efforts. Countries that have successfully controlled outbreaks of avian influenza are prepared to help others.
9. Mechanisms for donor support are in place. There is broad commitment to minimize transaction costs of international support through alignment and harmonization. International support to country plans should supplement national resources, as well as existing donor resources, and should target resource-poor countries.
10. Investments are urgently needed at national level – potentially reaching 1 billion dollars over the next three years. An additional 35 million dollars is needed immediately to support high priority actions by technical agencies at the global level over the next six months.

The 10 points I have outlined need detailed and concrete actions. This meeting has identified a series of integrated actions that will start straight away.

1. Support the development of integrated national plans for avian influenza control and human pandemic influenza preparedness and response.
2. Assist countries in aggressive control of avian influenza in birds, and deepen the understanding of the role of wild birds in virus transmission.

3. Nominate „rapid response“ teams of experts to support epidemiological field investigations.

4. Strengthen country and regional capacity in surveillance, laboratory diagnosis, and alert and response systems.
5. Expand the network of influenza laboratories, with regional collaborative systems for access to reference laboratories.
6. Establish and integrate multi-country networks for the control or prevention of animal trans-boundary diseases, and regional support units as established in the Global Framework for the Progressive Control of Trans-boundary Animal Diseases.
7. Expand the global antiviral stockpile, and prepare standard operating practices for its rapid deployment to achieve early containment.
8. Assess the needs and strengthen veterinary infrastructure in line with OIE standards.
9. Map out a global strategy and work plan for coordinating antiviral and influenza vaccine research and development, and for increasing production capacity and equitable access.
10. Put forward proposals to the WHO Executive Board at its 117th meeting for immediate voluntary compliance with relevant articles of the International Health Regulations 2005.
11. Finalize detailed costing of country plans and the regional and global requirements to support them, in preparation for the January pledging meeting to be hosted by the Government of China.
12. Finalize a coordination framework building on existing mechanisms at the country level, and at the global level, building on international best practices.

This is a challenging agenda which will require all our best efforts.” ■

Massive international effort stops polio epidemic across 10 West and Central African countries

Public health experts have confirmed that a polio epidemic in ten countries in west and central Africa – Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Côte d'Ivoire, Ghana, Guinea, Mali and Togo – has been successfully stopped. The epidemic has paralysed nearly 200 children for life since mid-2003, but no new cases have been reported in these countries since early June. At the same time, polio eradication efforts are intensifying in Nigeria, where extensive disease transmission continues, as part of a mass polio campaign across 28 African countries beginning today.

Emergency efforts to stop the epidemic had been launched under the auspices of the African Union (AU), and largely underwritten through US\$ 135 million in emergency funding from the European Commission (EC), Canada and Sweden. The ten countries, which had previously been polio-free, participated in a series of mass immunisation drives across 23 countries, reaching as many as 100 million children with multiple doses of polio vaccine over the last 18 months.

Speaking on behalf of donors, European Commissioner for Development and Humanitarian Aid, Mr Louis Michel, said: „The reversal of these epidemics is precisely what EC development objectives are all about. Such a rapid return on development investment is good for Africa, good for donors, and most importantly, good for the children of Africa.“

Experts cautioned, however, that ongoing disease transmission in remaining endemic areas continues to pose a risk of more outbreaks across the region. To minimise this risk, 28 African countries – including the ten countries which have stopped their epidemics – today launched the first element of a ‘maintenance’ programme to sustain this progress, with an additional series of synchronized immunisation activities to reach more than 100 million children with polio vaccine in November and December.

The ‘maintenance’ programme is part of a four-pronged strategy to protect the US\$ 4

billion invested globally since the 1988 launch of the Global Polio Eradication Initiative. The other elements of the strategy include: strengthening routine immunisation at country level in close collaboration with the Global Alliance for Vaccines and Immunisation (GAVI) and through the new Global Immunisation Vision and Strategy (GIVS); increasing surveillance sensitivity and outbreak response capacity, and increasing both the number and quality of polio campaigns in the remaining endemic areas, particularly in Nigeria.

The Nigerian government has signalled strong commitments to further strengthening its polio eradication programme. With virus now beaten back to the north of the country, efforts are focusing on re-deploying support staff to the northern states during the upcoming immunisation campaigns. To succeed, however, Nigeria needs the ongoing support of the international community to ensure every child is reached throughout the country with polio vaccine.

Key to success is ensuring the necessary funds continue to be made available. A US\$ 200 million funding gap for 2006 must urgently be filled, US\$ 75 million of which is needed by December, to ensure activities in the first quarter of next year can proceed. Underlining the urgency of closing the funding gap, late arrival of funds may compromise the quality of the immunisation campaigns in some countries.

To support Nigeria and west and central Africa in polio eradication efforts, Rotary International is also gearing up its support to the region. „Rotary club members from across North America, Europe and Asia are joining fellow Rotarians in Africa to participate in the polio campaigns,“ commented Carl-Wilhelm Stenhammar, President of Rotary International. „At Rotary, we are committed to doing everything we can to support Africa in their polio eradication efforts.“ Rotary International and its 1.2 million volunteers worldwide have been integral to the global eradicate of polio.

Collectively, Rotarians have committed well over US\$ 600 million to the effort, and contributed countless volunteer hours during immunization campaigns.

The polio eradication coalition includes governments of countries affected by polio; private sector foundations (e.g. United Nations Foundation, Bill & Melinda Gates Foundation); development banks (e.g. the World Bank); donor governments (e.g. Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Luxembourg, Malaysia, Monaco, the Netherlands, New Zealand, Norway, Oman, Portugal, Qatar, the Russian Federation, Spain, Sweden, United Arab Emirates, the United Kingdom and the United States of America); the European Commission; humanitarian and nongovernmental organizations (e.g. the International Red Cross and Red Crescent societies) and corporate partners (e.g. Sanofi Pasteur, De Beers, Wyeth). Volunteers in developing countries also play a key role; 20 million have participated in mass immunization campaigns.

Since 1988, global eradication efforts have reduced the number of polio cases by more than 99%, from 350,000 annually to 1,469 cases in 2005 (as of 1 November). Six countries remain polio endemic (Nigeria, India, Pakistan, Afghanistan, Niger and Egypt), however poliovirus continues to spread to previously polio-free countries. In total, 11 previously polio-free countries have been re-infected in late 2004 and 2005 (Somalia, Indonesia, Yemen, Angola, Ethiopia, Chad, Sudan, Mali, Eritrea, Cameroon and Nepal).

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and other relevant persons in society have been able to meet and discuss issues during a two day meeting. The enlargement of the European Community to 25 has introduced new considerations into the discussions. This year the meeting was held in the Budapest, capital of one of the new members of the EU, the topic for discussion was "Living Longer but Healthier Lives" exploring how to achieve health gains in the Elderly of the

European Union. At these meetings the Senior and Junior Europe and Medicine Prizes are awarded.

Finally, at a meeting organised by WMA and the Caring Physicians of the World Network, leaders of national medical associations in the European Region of the World Medical Association met in Prague in November to discuss two major issues. Presentations were given by WHO and other experts on the two topics of discussion. The first was on the "Skills Drain" among physicians and what actions NMAs can take. The second topic was Human Avian Influenza when the meeting considered what actions can be done by NMAs in collaboration with other institutions to prepare for a potential pandemic. The presentations and discussions were both lively and productive. ■

Latin America and the Caribbean

Under the aegis of the Caring Physicians of the World Initiative, members of the General Assembly of CONFERMEL met with representatives of WMA to discuss issues of importance to the medical profession, Health Policy and reform of the Health Sector, the new role of physicians in society and how NMAs can meet the emerging needs of their members at a meeting held on 10th October prior to the WMA Assembly. A manifesto was issued in the name of the 12 countries present, Argentina, Bolivia, Brasil, Costa Rica Ecuador, Honduras, Mexico, Nicaragua, Panama, Peru, Venezuela and Uruguay. It referred to the difficult situation in these countries such as poverty and unfairness which

continue, despite some advances in growth indices. In particular reference was made to the consequent nutritional deficiencies, lack of sanitation, drinking water and the high prevalence of malaria, dengue AIDS and tuberculosis. Concern was expressed that the processes of reform and modernisation of the health sector in these countries promoted privatisation of the public sector, deepening the inequities without substantial improvement in the quality of life and excluding large segments of the population from health care.

Pointing out that reform and modernisation of the Health sector needs the participation of representative organisations of health professionals attention was drawn to the

lack of priority given by governments in resource allocation to the health care systems which among others affects quality of care and the rights of physicians and other health personnel. The manifesto denounced the indiscriminate creation of medical schools without social necessity, and the creation of non-medical careers permitting the illegal practice of medicine.

Expressing concern about inequitable commercial agreements relating to intellectual property and pharmaceuticals which limit access of citizens to drugs, and disregarding WTO agreements, the manifesto ends by reiterating the professional organisations' commitment to the supervision of the quality of medical care and the autoregulation of the profession through obligatory membership of a college in accordance with national legislation. ■

Korean Medical Association

Activity Report of the KMA Medical Team in to quake-affected areas in Pakistan

(Extract from this interesting report. Ed.)

"The 2nd KEMAT team arrived in Abbottabad in the morning of October 22 and took over all the tasks from the 1 team without any reservation. As many physicians have joined the 2nd team, mostly composed by staff of Asian Medical Center in Seoul, the camp was full of energy and vibrancy. Lawmaker Mr. Seok Hyun Lee, the Chairperson of Health and Welfare Committee of Korean National Assembly, also joined this team and supported all the commitment and hard work of all the Korean medical teams and rescue teams dis-

patched to the quake-hit-areas taking a field assessment from Abbottabad via Balakot to Muzaffarabad. Over ten Korean NGO's are taking part in voluntary medical work in Patika, Balakot, Muzaffarabad, Batagram and Abbottabad.

Cases of scabies are continuously on the rise and many people, especially children, are still in need of long-term medical attention after being amputated. Dr. Irfan Khatkhat, general surgeon of Ayub Medical Complex and coordinator of voluntary medical

work said that they need medical equipment such as DERMATOSE or MESHER to take care of these patients. Drugs for anesthesia are also needed. Moreover, mental shocks they are going through also should be brought under delicate treatment.

Operation Rooms of Ayub Medical Complex, once shut down of additional collapse are now functioning little by little. The 2nd KEMAT conducted five major surgeries including skin graft for open fractures, K-Wire Reconstruction Operation and PROSTALAC at operation rooms in cooperation of Pakistani doctors.

In Balakot mobile clinic, considerable numbers of patients are suffering from diarrhea and de-hydration. Scabies is a major concern here, too. The 2nd team has treated total 2,810 patients (2,485 at Ayuh Medical Center, and 325 in Balakot mobile clinic).



Replacing the tasks of the 2nd team, the 3rd KEMAT team, composed of six doctors, five nurses, one pharmacist, one policeman and two administrative staff, arrived in Abbottabad on October 29. The 3rd team specially is composed by the staff of National Police Hospital.

Due to the huge difference of temperatures between day and night, the number of patients coming down with the ART (Acute Respiratory Infections) continues to increase. At Ayub Medical Complex, quake-related emergency patients have decreased prominently, compared to the situation of two weeks ago and more and more patients with chronic diseases come to see a doctor and want to get medicines for their diseases. However patients in need of minor surgery dressing, cast and suturing still an average 70–80 people a day.

More equipment and efforts are necessary to be put prevention of epidemics. Although KEMAT is carrying out some prevention steps using a smoke disinfectant, more organized projects should be urgently arranged and carried out.

In Balakot mobile clinic, cases of diarrhea skin diseases like scabies, and ARI are still topping the list and many patients needing to get their dressing renewed, or need to get care after amputation keep visiting the mobile clinic.

The 3rd team has treated 3,395 patients all together (2,353 at Ayub Medical Complex and 1,040 at mobile clinic in Balakot), making the total number of patients through the activities of KEMAT is 7,505 approximately.

Ending its voluntary medical works, the KEMAT donated medicines (anti-scabies drugs, antibiotics, fluids, etc.) and medical supplies left from their activities to the Ayub Medical Complex and some medicines to the Good Samaritan Hospital run by Korean missionaries in Pakistan.

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Letters to the Editor

Saving the Lives of Siamese Twins

Sir,

First let me introduce myself: I am a Paediatric Surgeon, former Head of the Department of Surgery of the main Lisboa's Children's Hospital and also a former President of the WMA (more than 20 years ago – 1981/1983).

Secondly I would like to congratulate you and your co-workers for the excellent quality of the "World Medical Journal", which I read always with great interest.

Finally I have to make a short comment on your article "Saving the lives of Siamese Twins" [WMJ 51(2) 30-31, 2005].

My experience started in 1978 and stems from 7, fully and personally operated pairs, with 9 survivors and 5 deaths (in one pair one child was already dead on arrival, another died of "malignant hyperthermia" after separation had already been performed, and the remaining one patient dying 1 month post-operatively, with peritonitis due to a leak in an intestinal anastomoses). Lisboa and its Hospital D. Estefania, are not as fashionable and well-known worldwide, as the Hospital for Sick Children, (GOS), in London...!

My longest operation, with "total" reconstruction of omphaloischipagus twins (boys, of which one had to remain a girl, due to only one existing penis) took 13.30 hours, because, taking into account the training I received in England (GOS and Alder Hey), I was able to conduct the whole operation, in both twins, from "top to bottom" (and not having, at my side, several sub-specialist, working in succession, in the American Style). Also skin expanders proved unnecessary, after adequate iliac osteotomies.

The 7 survivors lead totally normal lives, and the 2 latest ones have only minor problems and lead also, practically, normal lives. The liver is usually the least problem, with no significant haemorrhagic danger, as normally a reasonable noticeable demarcation exists between the 2 individual seg-

ments. The most difficult problem, for a good functional and aesthetic outcome, is associated with the urinary tract, followed by the intestines. Osteotomies in the iliac bones usually do away with the need to use previously insert skin expanders.

In my opinion liver transplantation is not a primary factor in the treatment of Siamese twins, and its progress, no matter how desirable it certainly is, will not benefit these children (at least directly). Good anaesthesia and intensive care (including nurses), are the real issues, apart from surgery itself. No matter how well a surgeon works, if anaesthesia and intensive care are not also as good, the result may be disastrous. In fact, the only really inoperable Siamese twins are those with a "common heart", and in which, the existing heart and major vessels, cannot be useful for any of them (so malformed they are...).

As Horsley once said, "A beautiful operation that ends with the death of the patient is not satisfactory surgery".

Finally I believe it is completely wrong and a real pity, to abort Siamese twins, found at routine echographies (as well as some apparently major malformations), as modern Paediatric Surgery is able to correct them (allowing those human beings, to lead normal, useful and happy lives). That should, I feel, be the main message to promote!

Unfortunately abortion is what we find in the "so-called" developed countries. Most operated Siamese twins come from developing countries, where echography is not currently available and the diagnosis is made only after birth!

Yours sincerely

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Advancing Surgical Standards – Stem Cells

Sir,

With regards to your article about ‘Spray-on Skin Grafts’. I think this technique and other similar techniques involving the culture of skin stem cells still has a long way to go before they can be used for burns involving the full thickness of the skin. I am not familiar with the technology used at East Grinstead but I suspect it may have been rather over hyped. Just this week there has been an article in the Lancet from a French group using foetal skin cells which grow rapidly and are incorporated into a collagen matrix which have been used successfully in a small number of patients but

it is really a biological dressing which is replaced by host tissue. The use of cultured skin cells obviously is attractive particularly now that the stem cells of the skin can now be identified and grown quite rapidly but this still provided a very thin layer which would not be adequate to replace a full thickness burn following excision of the scar.

However, this is an important area of development and many groups around the world are working on the culture of cells of the skin and particularly the stem cells of the epidermis and without question in due course successful clinical applications will be devel-

oped that would allow permanent replacement without scarring. This then would be perhaps suitable in reconstruction of the face.

Yours sincerely

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Review

Éthique de la recherche et des soins dans les pays en développement

Ethics of Research and Treatment in Developing Countries

François and Emmanuel Hirsch, editors
Collection Espace éthique
Paris, Librairie Vuibert, 2005
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ISBN 2 7117 7278 0

When the World Medical Association undertook the latest revision of the *Declaration of Helsinki* in 1997, it encountered issues in the application of ethics to medical research in developing countries that had not arisen previously. The most controversial articles in the 2000 version of the *Declaration* are precisely those that address these issues, namely, paragraph 29 that deals with the comparator to be used in a clinical trial, and paragraphs 19 and 30 that specify the obligations of researchers and research sponsors to those who serve as research subjects.

These same issues have been considered in other international statements on research ethics such as the 2001 National Bioethics Advisory Commission (U.S.A.) report,

Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries, the 2002 Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, the 2002 Nuffield Council (U.K.) report, *The Ethics of Research Related to Healthcare in Developing Countries* and its 2005 follow-up discussion paper with the same title, and the 2003 European Group on Ethics in Science and New Technologies *Opinion #17 on the Ethical Aspects of Clinical Research in Developing Countries*. As the 2005 Nuffield Council discussion paper explains, these documents do not agree on many of the key issues in research in developing countries.

In October 2002, a conference was held in Paris to discuss these issues with particular reference to the francophone countries of Africa. The proceedings of this conference are the subject of this review. Many of the contributors are African and they do not hesitate to criticise the dominant ‘Western’ par-

adigm of medical research as it is applied in their countries.

Two sets of essays set out the context for the presentations that follow. The first deals with the principles of human rights and medical research, and the second describes the methodology of clinical trials and related ethical issues.

The major part of the book consists of seven substantial essays on African approaches to biomedical research, each of which points out shortcomings in the application of ‘Western’ research methodology in Africa. According to Godfrey B. Tangwa, this methodology is based on a worldview that is quite alien to Africans, for whom “metaphysical concepts, ethics, customs, laws and taboos form a unique ensemble...” (p. 57). Whereas Western approaches display an excess of epistemological confidence, bordering on arrogance and often resulting in imprudence, “the principal value underlying African worldviews and concepts is its epistemological humility and respectful prudence...” (p. 60). Certain



ethical principles of great importance in Western society, such as the confidentiality of personal information, must be applied differently in Africa where the family and the community, not the autonomous individual, are the fundamental social units. The widespread suspicion of Western researchers and the revelations of racist medical research in apartheid-era South Africa, have provided fertile ground for the spread of conspiracy theories regarding the origin and treatment of diseases such as HIV/AIDS. The rationing of medical treatment by ability to pay rather than by need is contrary to the African view of healthcare as a service, not a commodity. To illustrate the Western attitude to Africa, Tangwa provides a case study of a medical researcher in Cameroon who developed a promising approach to a vaccine for HIV but was unable to get funding from any of the Western research agencies because it did not fit their paradigm of medical research.

An important concept in both medical research and medical treatment is 'quality'. In his article, Jean-Godefroy Bidima raises many questions regarding how this concept applies in Africa – quality of what, quality for whom, and how should it be measured (pp. 80-83). He goes on to discuss why the Western concept of informed consent is inapplicable in much of Africa: "In certain African cultures one does not express a refusal to someone in authority. One expresses a refusal by not carrying out an order that has been given, but formally one agrees in order that the authority *does not lose face*. The caregiver is an authority, and when a sick African gives consent, what does that signify? An agreement or simple politeness?" (p. 85)

The African understanding of clinical trials ('essais thérapeutiques') is explored by Assétou Ismaëla Derme in relation to proposed treatments for malaria. As with other ailments, malaria is considered to be not just a physical affliction but a result of upsetting the relationships of natural and supernatural forces. Healing therefore requires spiritual as well as physical measures. Research on the prevention and treatment of malaria is complicated by the multiple local terms used for the different phases of this illness. Researchers must take all

these factors into account when undertaking projects in Africa.

In the Ivory Coast, according to Lazare Marcelin Poame, the concept of free and informed consent to medical research or treatment is largely unknown. Physicians are the experts and the patient is expected, and expects, to follow their orders. Moreover, busy physicians simply do not have the time required to present all their patients with the information necessary for informed consent. Where consent is sought, it is usually from the family rather than the individual patient. Despite all these obstacles, Poame believes that the practice of informed consent is achievable in the Ivory Coast and offers concrete suggestions for moving in this direction.

A French social scientist, Christophe Perrey, reports on a research project on informed consent conducted in the Ivory Coast in which 57 women were interviewed about their understanding of clinical trials, including the meaning of placebo. Despite explanations, it turned out that none of the women could explain what a placebo is and they all were convinced that they had received the experimental drug. Other challenges to informed consent were different understandings and terminology for the symptoms and causes of diseases, the difficulty of getting spousal consent for a woman's participation in the trial, and rumours about toxicity of the proposed intervention. If the principle of informed consent is to be implemented in such settings, much more work is needed on its pedagogy.

In May 2002 the French National Agency for AIDS Research published a *Charter of Ethics for Research in Developing Countries* that addresses many of the issues raised at this conference. In presenting the *Charter*, Brigitte Bazin noted some of the difficulties in its implementation, including the absence of ethics regulations and committees in many developing countries, the lack of resources for those ethics committees that do exist, and the inability of non-profit agencies to provide continuing care to participants in research as required by the *Declaration of Helsinki*.

In the final contribution from Africa, Patrice Emmanuel Mbo Abenoyap provides a perspective on these issues from African theology. Africans live simultaneously in two worlds: the visible one of humans and finite creatures and the invisible one of energies and powers. In the former, individuals are subordinate to the community; in the latter, they are subordinate to supernatural forces. Both relationships challenge the Western concept of individual autonomy and the related principle of informed consent. Moreover, the fact that one's family is often the only source of funds for one's medical treatment entails that the family has a legitimate role to play in the consent process.

To complete the list of issues that need to be considered in relation to the ethics of research in developing countries, the editors included as an annex a summary of discussions that took place in Paris in January 2001 and that presumably inspired the conference that led to this book. The additional issues mentioned include the following: the right to health, global disparities, lack of democracy in some developing countries, the needs of migrants, corruption (a two-way process, involving corrupters as well as corruptees), taboos, and learning from developing countries.

None of the issues, problems and challenges raised in this book admits of easy answers. However, they must first be recognized, and the authors have provided a valuable service in pointing out both theoretical and practical difficulties in the application of international standards of research ethics in developing countries. The suggestions they make for improving the situation are worthy of further consideration, but as the authors would be the first to admit, much more needs to be done. All those responsible for international research ethics should follow the example of the editors of this book in seeking meaningful involvement of developing country representatives in both the review of policies and in the design and implementation of research studies.

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