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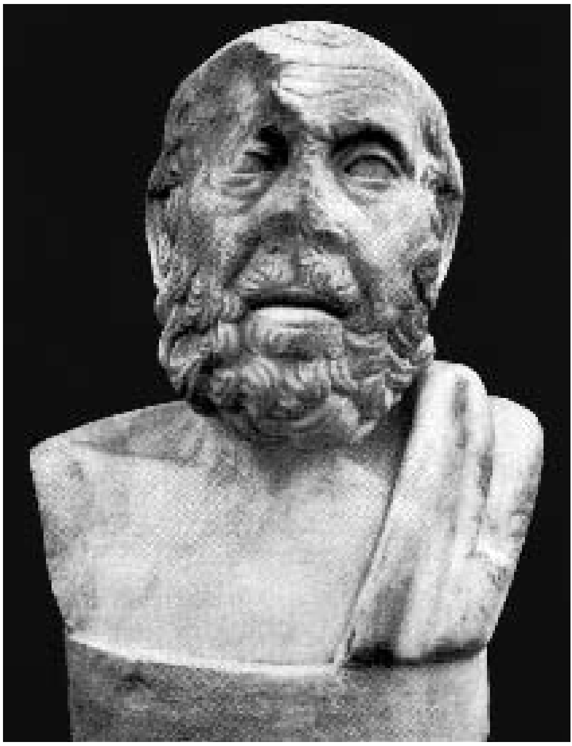
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HIPPOKRATES

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Editorial

The World Medical Journal 1954 – 2004 – yesterday, today and tomorrow

The issue is the first of the fiftieth volume of the World Medical Journal, which we celebrate with the appearance of a new style quarterly journal. Readers may not be aware that this journal was not the first ”house publication” of the WMA. Following the early meetings starting in 1945 which led to the setting up to the World Medical Association in 1947, a regular publication entitled ”The World Medical Association Bulletin” made its first appearance in 1950. It was printed in three languages, English, French and Spanish and appeared quarterly. The Bulletin of October 1953 was the last, being replaced by World Medical Journal in January 1954. According to the editorial of the first issue, it was renamed **”because it has become more important and deserves such a name. It also reduces the possibility of confusion with other bulletins, particularly those published by other international societies”. The editorial also comments that as ”an official organ for a medical organisation,** *(it)* **must reproduce the actions of that organisation”.** With the new style journal we intend to enlarge on this by reinstating the views from the desk of the Secretary General, including reporting on the activities of the Chief Officers. There will also be informative background articles on topical issues, some of which may be under consideration by Council and its committees.

Information about major problems and initiatives of National Medical Associations (NMAs) are not only of general interest to members but may also identify issues relevant to the medical profession in other parts of the world and facilitate exchange of experiences. Therefore a new section ”Regional and N M A News” will in future appear as a separate section of the Journal. It is appropiate that this new section opens with a contribution from Japan, providing an informative and thoughtful background for the Tokyo WMA General Assembly later this year.

Articles will be grouped in sections devoted to ”Medical Ethics & Human Rights”, and ”Medical Science, professional practice and education”. In these sections it is our aim not to duplicate the plethora of material already available in the journals dealing with scientific and technical matters for individual medical disciplines, but to address issues which relate to the aims of the WMA. At the same time we will try to reflect the comment in WMJ 1(1) **”While doctors are always interested in medical economic and social problems, they also want additional items, and these must be offered to arouse and maintain interest and support”.** This will of course not preclude useful reference to, and comment on, important epidemiological, preventive and therapeutic innovations and other issues, including WHO and other relevant international agencies’ initiatives and policies.

With the current trends in globalisation impacting on all parts of society, this cannot be disregarded by the medical profession, and increasingly individual physicians are recognising that these developments affect them directly or indirectly, both personally and in their individual medical practice. As a non-governmental organisation comprising a membership of national medical associations, the World Medical Association is in a unique position to influence international opinion, both in the interests of the medical profession and of society whom it serves. The WMJ therefore aims to inform the profession and hopefully engage its support for these WMA activities on its behalf.

We hope that these changes will enhance the value and interest of the Journal as it moves into its sixth decade and beyond. Meanwhile, during this year we will include some commentaries on the remarkable scientific and other changes which have taken place over the past 50 years. In this connection it is interesting to note that in 1954 the first issue of the Journal reported that the Council has discussed ”Ethical problems of Bacteriological warfare and experiments on humans", "preparation of the programme for the First World Congress on Medical education", "recommendations to WHO on the International Pharmacopoeia", and "seeking information from NMAs on Social Security". It also reported the WHO aid to six countries to produce antibiotics and insecticides – with special reference to the problem of malaria, and WHO's call for enhanced services to control Tuberculosis. Looking at the medical scene today one may well comment **"plus ça change, plus c'est la même chose!"**

Alan Rowe

A Rational Approach To Drug Design

"Essentially, health is another name for human harmony, harmony not only among our several parts, but also between ourselves and our environments."

Earle P. Scarlett

The future for delivery of healthcare

Technological advances, increased expectations for medicine, an ageing population and legal, ethical and economic factors coupled with a move towards "evidence-based" medicine are all driving the rapid change in the delivery of healthcare at the start of the new millennium.

In a fast-changing world, where increasing healthcare regulation co-exists with globalisation of business, we encounter on a daily basis, more diversity and more uncertainty.

At no other time in global history has healthcare, its benefits, its risks and its structure been so frequently and so widely discussed. From the man in the street through the pressure groups and governments, everyone is talking "healthcare". The language may vary, but the topics remain the same.

Both as producers and consumers as doctors, patients and healthcare providers, we face higher demands and higher expectations in targeted drug treatment.

Over the years, the pharmaceutical sector has had some notable successes. Antibiotics and vaccines mean that many infections our parents and grandparents feared are now little more than medical curiosities. Antihypertensives, cholesterol lowering agents and other cardiovascular drugs are making considerable in-roads into the morbidity and mortality arising from the epidemic of heart disease. In the area of osteoporosis, which often leaves sufferers disabled and debilitated, bisphosphonates are tackling the increasing problem of osteoporosis.

However, pharmacologists cannot rest on their laurels. There is a continuing need for new medicines. But, finding innovative, more effective and safer drugs is not easy. A recent editorial in Nature noted that some 99.9 % of drugs either fail during development in the laboratory or during clinical trials. This attrition rate means that the cost of bringing a drug to market is around US$ 800 million (Nature 2002). This wastage delays the launch of drugs that could potentially reduce the morbidity and mortality associated with cancers, heart disease, osteoporosis and other common conditions.

So for the last few years, pharmacologists advocated "rational drug discovery" and "rational drug design" as ways to reduce the attrition rate, lower development costs and advance drugs to market more rapidly. "Rational drugs discovery is a systematic process based on screening for a particular biological effect," explains Professor Philippe Van der Auwera, Lifecycle Leader Roche Basel. "Rational drug design uses our intimate knowledge of the target's molecular shape and structure to develop specific medicines." Both approaches offer powerful methods for discover of new medicines.

Track record

In some ways, of course, drug discovery has always been rational – at least within the prevailing intellectual culture. In the mid-eighteenth century, for example, the Reverend Edward Stone of Chipping Norton in Oxfordshire, England developed a new treatment for fever. As he explained later, the idea was a rational extrapolation of the prevailing scientific view that "remedies lie not far from their causes". Swamps and marshes, doctors believed, caused fevers and agues. Willow grows near swamps and marshes. Ergo, willow should cure fevers. The discovery that willow bark was an effective treatment for fever led, ultimately, to aspirin's development (Vane 2000) Although scientists no longer accept the logic, Stone's discovery was an example of rational drug discovery within the intellectual framework of the time.

Probably the first drug to emerge from a modern rational drug design programme was the angiotensin converting enzyme (ACE) inhibitor captopril. ACE is an enzyme that cleaves an inactive precursor to produce the protein angiotensin II. This controls blood pressure by action of the heart, blood vessels and kidneys. In the 1950s, Sergio Farreira, in Sao Paulo, found that the Brazilian pit viper's venom contains peptides that inhibit an enzyme that degrades another protein called bradykinin. Eventually, researchers recognised that ACE and the enzyme that degraded bradykinin were identical. One of the venom's peptides – teprotide – lowered blood pressure when given to humans. Researchers from Squibb identified teprotide's active site and developed specific inhibitors. Captopril was the first of the ACE inhibitors to reach the market (Landau 1999 p 186–187).

On the other hand, for scientists to recognise that an idea is ”rational”, it must link logically to other aspects of the current knowledge base. If not, scientists tend to dismiss or ignore the idea – however rational it seems in retrospect. For instance, DNA was first discovered as a constituent of the nucleus of living cells by the Swiss biochemist Frederick Miescher in 1869, but not until 1953 was its true nature as the unique substance of heredity identified. But the intellectual framework was not in place for other biologists to appreciate its importance before the pioneering work of James Watson, Francis Crick and Maurice Wilkins was awarded the Nobel Prize in 1962. This was based on their model building of the constituent DNA base pairs and Rosalind Franklin's X-ray diffraction patterns of the DNA double helix. Even today the properties of the genes remain elusive, despite our knowledge of the complete sequence of the human genome, in terms of embryonic growth, organ development and the phased switching on and off for gene sequences in human development.

Mendel's work lay unread for years, partly because his findings about inherited characteristics did not fit in the prevailing intellectual paradigms[4] (Sacks 1997 p. 158). Moreover the now well-accepted idea that viruses caused some cancers proved so controversial that one of the concept's pioneers was virtually ostracised by some of his colleagues[5] (Kevles 1997 p. 82–3).

Such examples are relatively rare, however. Rational drug discovery and computer-aided design are emerging as valuable means to develop new medicines. The explosion in the number of possible drug targets arising from, in part, genomics, gave the move towards rational drug discovery and design extra impetus.

Around 1,000 disease genes might be relevant for therapeutic development by big business. Not all these offer direct therapeutic targets. However, many disease genes are linked to between 5 and 10 physiological or pathological proteins that might offer alternative targets. Thus, the total number of possible drug targets might lie between 5,000 and 10,000. Drugs available in 1996 targeted just 483. In other words, there are at least 10 times as many molecular targets than the pharmaceutical sector currently exploits[6] (Drews 2000). Screening all these using conventional drug discovery techniques would prove impossible.

Fortunately, rational drug discovery through molecular biology offers powerful means to develop, prioritise and test medicines aimed at these targets. For example, during rational drug discovery, researchers systematically screen compounds against the target. The screening test depends on the disease and target. So researchers could use the strength of the drugs' binding to a particular receptor involved in blood pressure control for an antihypertensive, or an ability to inhibit osteoclasts when screening for a drug for osteoporosis. However, all screens need to be very sensitive – so that researchers do not miss a potential drug – and also specific, to avoid false leads.

Traditionally, screening was time consuming, especially when using biological screening systems such as cells or even animals. In some cases, researchers had no alternative but to test every possible drug on animals. However, recent technological advances, in particular, high throughput screening (HTS) and laboratory robotics dramatically increase productivity. Automated HTS can test some 10,000 possible drugs against the target each day, without using animals. Increasingly sophisticated computer programs can prioritise the hits for further development.

”At first, there is a disease and a ‘dream’, such as inhibiting osteoclasts to alleviate osteoporosis,” says Professor Van der Auwera. ”We then identify a potential molecular target, such as a receptor or enzyme, based on literature and pathophysiological research. If the target can be isolated, we clone it using genetic engineering. This allows us to build a specific and sensitive screening assay. But in many cases we don't know the target. So, we have to identify the gene's function and, if applicable, the gene product, the latter using so-called proteomic approaches. However, identifying what the product does in the body – a procedure called functional genomics – can be a real nightmare. But ultimately we are usually able to identify a target that we can produce in large quantities for high-throughput screening assays.”

For example, researchers developed ibandronate using a rat model that induced hypercalcemia (raised calcium levels in the blood) using retinoids. This example of rational drug discovery uses the rise in serum calcium levels as a marker for increased osteoclast activity. In this model, bisphosphonates and other drugs targeting the osteoclasts lead to lower calcium levels compared to controls. Recently, the target of a drug like ibandronate has been identified and could be used to better understand the interaction between the enzyme [fiarnesyl disphosphate (FPP) synthase] and its specific inhibitor. The enzyme activates essential intracellular signalling proteins (”intracellular hormones”) which regulate a variety of cell processes important for osteoclast function. When these signalling proteins are no longer activated, the osteoclast triggers its apoptosis (programmed cell death).

Gene expression

Rational drug design takes a different approach. A gene encodes a protein. But this protein is rarely the final biologically active form. Often the ”first generation” gene product undergoes considerable modification in the cell's cytoplasm. Enzymes in the cell may, for example, cleave the active protein from the precursor – as ACE does to form angiotensin II. In other cases, the cell adds sugars to the protein backbone. Moreover the allostery between the amino acids in the protein means that the protein folds into a complex three-dimensional shape, to achieve its biological effect.

Even a single acid change can dramatically alter the protein's three-dimensional shape and function. That is one reason why mutations and polymorphisms, which often subtly change the amino acid sequence, can so dramatically influence the risk of developing a particular disease.

So genetically encoded differences in the vitamin D receptor seem to influence patients' risk of developing osteoporosis[7] (for example, Tofteng 2002). The mutation alters vitamin D's ability to bind to its receptor. As vitamin D contributes to bone mineral density, the reduced binding ultimately weakens the skeleton.

Researchers can grow crystals of these proteins. By examining the way in which the crystal scatters X-rays, biologists can gain an insight into the protein's structure. A computer can integrate these X-ray results with the protein sequence to show the shape of, for example, a receptor or an enzyme. This allows researchers to home in on the active site and design drugs that fit specifically into the site-rather like a lock and key mechanism.

Nevertheless, validating targets can prove difficult, especially when the lead comes from genomic rather than clinical studies. ”Traditionally, we associate the target and the disease from clinical studies. So we knew from clinical and pathophysiological studies that, in comparison to osteoclasts (bone forming cells), overactive osteoclasts contribute to low bone mass,” Professor Van der Auwera comments. ”However, genomic studies link a gene to the disease. Discovering what the gene's product does can be difficult. Knockout animals, which are genetically engineered not to express the gene, are fashionable and in many cases allow us to better understand the link with the disease. Nevertheless, we often have to go to phase II or even phase III clinical studies to validate the target – which has an enormous failure rate! Nevertheless, as we hone our understanding of the gene's function, our failure rate is declining.”

Drug discovery

Against this background, the next generation of drugs for osteoporosis is likely, Professor Van der Auwera believes, to emerge from rational drug design and discovery. ”Molecular biology and genomics identified many targets that either reduce resorption or increase bone formation,” he says. ”However, ibandronate and the other anti-resorptive agents are now just about as effective as they can be. Any advances in anti-resorptive agents are likely to be relatively minor, such as enhancing safety, tolerability and convenience. The key objective today is finding a drug to stimulate anabolism, the formation for new bone.”

For example, Professor Van der Auwera notes that up to half the patients using current oral bisphosphonates may stop taking the treatment within a year, which precludes any reduction in the risk of sustaining a fracture. ”Treatment schedules such as a once a month tablet, instead of weekly (52 tablets) or daily (365 tablets) can make a huge difference to compliance”, he comments. ”Likewise for patients already taking lots of oral medication, a quarterly intravenous injection can allow them to benefit from a very effective medicine that they would not otherwise take.”

Professor Van der Auwera adds that in addition to optimising anti-resorptive agents, another key objective for researchers is to find drugs that stimulate the formation of new bone (anabolism). ”It is predictable that, at least for patients with the most severe bone loss, combination or sequential therapy with an anabolic drug, probably for a short period such as 6 months, and an anti-resorptive agent will become the rule. So we need ‘smart' treatment schedules allowing the patients to improve their quality of life without the constant reminder of their disease.”

In many ways, drug discovery has always been rational. But biologist's limited understanding of the body's complexities hindered attempts to develop targeted drugs. And traditionally time-consuming screening slowed the development of much needed medicines. Today, the genomics revolution has massively increased biologists' understanding of the nature of common diseases and identified a plethora of possible targets. Fortunately, rational drug design and development give researchers the power to identify and develop specific and selective drugs that target a single cell type or even a single gene product. The possibilities for new medicines tackling some of the commonest diseases seem endless.[8]

Modern pharmacological advances

Epilepsy

Around 30 % of patients diagnosed with epilepsy fail to respond to prescribed antiepileptic drugs and continue to have seizures. These refractory seizures are associated with increased mortality and psychosocial morbidity and pose an enormous human and financial burden. Notwithstanding the seriousness of the problem, remarkably little attention has been paid to the biological basis of refractory epilepsy. Workers in the field of epilepsy-those concerned with the basic science of resistance and the blood-brain barrier, and those with clinical experience of drug resistance in cancer are collaborating with a view to exploring parallels between the fields and suggesting further potentially profitable avenues for exploration on drug resistance in epilepsy.

Ageing

Social and medical developments during the past century have led to a dramatic increase in life expectancy. The study and understanding of the endocrine organismic changes associated with ageing are therefore matters of urgency. Basic scientific facets and clinical aspects relevant to age-related changes in the multiple endocrine systems have been discussed. The implications of therapeutic reconstitution with hormones in the elderly, could be very important in the future.

Mucus hypersecretion in respiratory disease

A number of chronic respiratory diseases including chronic bronchitis, asthma, cystic fibrosis and bronchiectasis are characterised by mucus hypersecretion and this excessive mucus production can lead to a pathological state with increased risk of infection, hospitalisation and morbidity. Despite a high and increasing prevalence and cost to healthcare services and society, this phenomenon has received little attention until recently, probably because of the difficulties inherent in studying its pathology. Basic scientists and clinicians need to discuss recent advances and their implications for the development of novel, rational therapies, particularly as a potential cure for CF is on the horizon.

Autism as a spectrum

Twin and family data convincingly indicate that the heritability for the underlying liability to autism exceeds 90 % and these studies point to a multi-factorial causation involving an interaction among a relatively small number of susceptibility genes. New techniques are now available for examining the neurobiology of autism and imaging studies have been used to explore the contributions of different brain regions. The most important practical question facing medical and psychological practitioners is how to help children with autism. Data on possible psychological or psychiatric interventions for rehabilitation of children with autism need to be thoroughly investigated in child patients in order to prove the link between MMR injections, inflammatory bowel disease and autism.

Design of new drugs

Biological modelling and oscillatory properties represent fundamental approaches to collating data on gene structure and function. Since cell signalling systems form a particularly complicated aspect of all cellular function and are extremely important both in the understanding of basic cellular processes and in the practical problems of selecting targets for drugs, much work has been devoted to integrating data on cell signalling into computer models. Building on these approaches, computerised models of intact cells and ultimately of whole organs can be developed. Not only do computer models aid understanding of the basic nature of biological systems, but they also help in the design of new drugs for specific diseases.

The intrinsic measurement of time in biological systems

The primary hallmark of biological clocks is their ability to entrain to environmental stimuli and the dominant, and therefore physiologically most important, entraining stimulus comes from environmental light cues. The classical view of the circadian system describes it as diverse physiological rhythms regulated by a centralised clock structure. Data coming from both vertebrate and invertebrate systems have challenged this view, demonstrating that the circadian timing system is dispersed throughout the animal and that possibly every cell contains a functional circadian clock. The mechanism of light signalling to the vertebrate clock, the connections between central and peripheral clocks, the genetics of the clock and clock proteins remain to be evaluated at the molecular level, for example pairs of enzymes working in harmony across membrane.

Calcium ion flux in smooth muscle

Ion channels play a crucial role in regulating diverse cell functions in both electrically excitable and non-excitable cells, and have been found in organisms ranging from viruses and bacteria to plants and mammals. An increasing number of diseases (”channellopathies”) are associated with dysfunction of ion channels. Control of calcium ion flux and compartmentalisation in terms of theoretical biology would be illuminated by

- the structure of channels and pores,
- computer simulations of channel function, and
- detailed data on potassium channels, chloride and calcium channels and ligand-gated ion channels.

Smooth muscle contraction is crucial to health as in, for example, blood vessels, the uterus, airways and bladder and its malfunction can lead to serious pathological conditions such as hypertension and pre-term labour. The calcium ion plays a central role in its function, increasing in concentration for contraction and decreasing for relaxation. The source of calcium is through entry across the surface membrane and release from the sarcoplasmic reticulum (SR). However, recent data have challenged the view that the SR is simply a source and sink of calcium ions. Indeed the SR probably also acts to limit contraction, via ion channel-based feedback mechanisms. There is a most important relationship between calcium release and inhibition and/or promotion of contraction, the control and modulation of the SR in smooth muscle, the extent to which the SR may vary between smooth muscles and therefore potential therapeutic implications.

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Ivan M. Gillibrand

Medical Ethics & Human Rights

Medicine, the Law and Medical Ethics in a Changing Society

Paula Kokkonen, LL.M., Director General, National Authority for Medico-legal Affairs, Finland

Address given at the Ceremonial Session of the World Medical Association, Helsinki 2003

First of all I wish to express my great pleasure for this opportunity to address such an influential audience as represented by this WMA General Assembly. You represent a profession which in well organised countries issues both birth and death certificates, thus controlling human life not only when people are patients, but also at the beginning of life and at its end. This fact leads to discussion of power, responsibility, liability, ethics, trust and control.

The medical profession has for a long time been in the forefront of discussions on Medical Ethics. You all know very well the history of the WMA, established in Paris in 1947 due to the acts that had been revealed during the Nuremberg trials.

Although I usually present myself as a lawyer who has sacrificed her life for medicine, I have tried to bridge the two disciplines - Law and Medicine - both at home and also "globally". Thus I thought that it may be worth while drawing your attention to the existence of the World Association for Medical Law. The purposes of this association are

– to encourage the study and discussion of problems concerning Medical Law and their possible solutions, in ways that are beneficial to humanity,
– to promote the study and discussion of new developments in medicine and related sciences,
– to address any matters that involve issues of Health Law.

The Association was founded in Gent, Belgium in 1967, that is twenty years later than the WMA. This is a very concrete sign that the Law usually follows behind the ethics. I hope that the gap will be less than twenty years today.

At the time when the Association was founded, "Medical Law" was the term used. The question as to whether we should use the term "Health Law" instead has recently been raised. This discussion reflects very well the developments in the health-care field. Modern health-care is a very complex teamwork of many actors and disciplines. This is also reflected in the legislation.

The development of science has created a world where we live much longer than did our ancestors. Many of us who live in the so-called developed countries have a curriculum of diseases each of which would have killed our ancestors. There are many actors interfering in the doctor-patient relationship. One of them is society, which often bears the major part, if not all of the costs of health care. In Democracies, the modern way to organise relationships between individuals and between citizens and society is to use legislation as well as agreements.

Earlier, Medical Law was very much involved in questions like setting limits for "the profession" (i. e. medical doctors), drafting legislation concerning patients with contagious diseases, involuntary care of the mentally ill etc. Then came the discussion of medical negligence, and slowly after that, of patients' rights. Patients were not any more considered as material, but they were individuals who had a say in their own treatment. By this time the scientific developments in medicine had been enormous. Patients could in many cases be offered the choice of their own preferred treatment from amongst a few alternatives. This again increased the demand for more information in order to allow patients to really make an informed choice.

The result of this, we can recognise in patient insurance schemes and legislation, and also legislation on patients' rights. The Patients' Rights movement can be seen as an reflection of the modern discussions strengthening human rights and consumer rights.

From Ethics to Law and Law to Ethics

In "western societies", a Law passed in Parliament reflects the stage of common agreement. Legislation thus consists of the ethical minimum.

The values documented and instructions commonly and voluntarily accepted by the members of a given association or profession are called ethical rules. The most well-known of them is, as this audience knows, the Hippocratic Oath, which focussed on the relations between doctors and doctors vis-a-vis their patients.

Ethical rules drafted lately by the WMA have, to my mind, approached legislation. They aim at giving concrete directives in anticipation of foreseeable conflicts. Like legislation, ethical rules are based on facts and values. Values are culturally bound and thus stand in relation to a given society and time. Ethical rules are often compromises that lie on sound ethical grounds but to which reservations can be made, and from which it is possible to deviate under special circumstances.

Ethical discussions in medicine focused first (with the Hippocratic Oath) on the characteristics of the doctor, and the point of departure was that a good doctors performs good deeds. Wider ethical discussion in medicine dates back to the Nuremberg trials and the event in Hiroshima. It was realised that ethical discussion in medicine and in medical research cannot be limited to the medical profession, but that society at large has the right to a dialogue.

Human dignity, autonomy and the right to self-determination have been the focus of the discussion since the Nuremberg trials. The above mentioned values have also been documented in many human rights texts such as the Universal Declaration of Human Rights (1948), International Covenants on Economic, Social and Cultural Rights and on Civil Rights (1966) and the European Convention on Human Rights (1959), as well as the Convention on Bioethics of the Council of Europe, which is the latest of them and entered into force on December 1st 1999.

The values expressed in the Human Rights documents mentioned above are appropriate for legislation as well. In fact they are included in many Constitutions - not to mention other legislation.

Why doesn't the system work in a satisfactory way although there are so many rules? One of the reasons is probably the fact that the good principles cannot easily be found from the sources mentioned earlier. Or if they are found they need interpretation, which is not very easy even for lawyers, not to speak of lay-people.

Medical Ethics or health-care ethics draws a great deal of attention

Most of the topics discussed in the sphere of medical ethics have been discussed during decades. To these topics belong the beginning of life as well as the end of it. We have been able to witness how insemination has been developed into assisted reproduction and surrogate motherhood. Mercy killing is not any more offered as a topic for scientific meetings, but euthanasia and terminal care, as well as assisted suicide are. Dialysis has been changed into transplantation, which has brought about a new type of scarcity discussion. This Discussion has escaped the cabinets where doctors used to take difficult decisions as to who was to get dialysis and live, and who was not. International declarations, as well as many Constitutions secure the right to health care. What does this mean in the era of priorities?

The Transplantation debate has reached the level where many countries have already forbidden the selling of human organs. International Declarations and Conventions also condemn buying and selling of organs. Yet there are actors who advocate in favour of commercial activities in this field, arguing that a poor person should not be denied the right to improve his/her standard of living by selling organs to those in need. The argumentation is that this would just be using financial incentives and commercial considerations to save lives.

Human cloning can be used for the development of tissue for transplantation, but "cloning" can also refer to a wide range of activities, from bringing into existence genetically identical individuals to pre-implantation diagnostics. Distinctions between various techniques need to be drawn, and their acceptability has to be discussed thoroughly.

When discussing ethics and legislation, it is useful to keep in mind that theoretical discussion may widen our perspectives and give new ideas. It may thus enrich our thinking and decision making, and will help us to recognise at least our own motives.

Lay-people very often think that legislation is an open process of fundamental thinking and great elegance, as the ideal would demand. The common truth is very different. Open, profound discussion is often either absent or takes place in very small circles.

Health-care is an area of great common interest. There has been, still is, and may be even a growing tendency to try to increase the sphere of health-care. There is a tendency to try to medicalise social problems and ask doctors to testify more and more in matters that are not medical, or to ask them to isolate people for reasons other than medical. In our society we are to discuss for whom we are designing health-care services, and what are the values of the population.

Pressure, routine generally accepted behaviour, and the atmosphere, may be used as an excuse to deviate even from the ethical principles accepted by ourselves. The most common excuse is, of course, that the patient does not really understand his/her own best interest. But this way of thinking brings us to a weak soil, both ethically and legally.

In health-care we need both legislation and ethical rules. The aim of both is to promote co-operation and minimise conflicts. As time passes our values may change, and the legislative process is often rather slow. In the meantime ethics may guide us and cast a light for the developing legislation. An example of ethical discussion leading to legislation is **The Finnish Law on the Status and Rights of a Patient.**

Finnish Law

Following a long-almost twenty years debate, the Law on the Status and Rights of a Patient was finally passed in the Finnish Parliament in 1992 and it entered into force on 1st March 1993, ten years ago.

In all legislative work, the history and cultural tradition of a country, as well as previously existing legislation and administrative systems and structures, have to be taken into consideration. Legislation may be described as a safety net. If you are going to mend the net, you have to know where the holes are. Thus I do not offer our law as a global solution applicable to all societies and problems a patient may ever experience in the field of health-care.

Our law regulates, *inter alia*, the patients' right to good health care, to medical care and related treatment when needed; the right of access to treatment, to be informed and of self-determination; the status of minor patients; emergency treatment; powers of the representatives of the patient in certain situations, and a new complaint procedure. It also establishes a Patient Ombudsman institution.

Right to care

Every person who stays in Finland permanently is entitled, without discrimination, to the health and medical care required by his/her state of health, within the limits of resources available to health care at the time in question.

This provision has drawn much attention now that the discussion concerning the division of scarce resources has once again surfaced. It was originally designed with the notion in mind that society has the right to limit how much and what kind of care it provides for its citizens. (There had at that time been cases of Finnish citizens demanding that they be sent abroad at society's expense for treatment which was not available in Finland.)

The care has to be of good quality, the patients' dignity must not be violated and her/his individual needs and culture have to be taken into account as far as possible. These provisions sound perhaps like mere declarations, but they are still important. They can be especially important in cases where psychiatric care is required, since mental patients and their relatives are, at least according to our Finnish experience, very often not capable of defending their own rights.

Patient's right to be informed

The right to information is closely connected to the right of self-determination, because the latter cannot be exercised without the former.

How much information and in which form it is given to patients, seems to vary between countries. The right to information has during the last quarter of the century, been increasingly emphasised in Finland. Yet, judging from the patients' complaints the situation is far from satisfactory. The law specifies that various alternative methods of treatment and their effects have to be explained to the patient. It is noteworthy that the law also gives the patient the right not to know, and the "therapeutic exception" – the withholding of information from the patient in certain cases. The information to be given should be tailored to the individual patient and interpreters should be used if needed.

Patients' right to self-determination

With the provision of health care, a mutual understanding between patient and caregiver must exist. If the patient refuses a certain treatment or measure s/he has to be treated according to the possibilities provided by another medically acceptable way, in mutual understanding. There had been cases in which, for example, a terminal cancer patient had refused radiation because of side effects. This led to a discussion in which the patient was threatened with deportation.

There are also provisions in the law according to which a legal representative etc. can interpret the patient's will. It is, however, to be emphasised that it is the patient's will which is decisive and not the representatives. If the patient's will cannot be assessed, that patient has to be given the treatment that can be considered to be in accordance with his/her personal interests.

Emergency treatment

A patient has to be given treatment necessary to ward off a hazard imperilling her/his life or health even if it is not possible to assess the patient's will because of unconsciousness or other reason. However, if the patient has previously steadfastly and competently expressed her/his will concerning the treatment given to her/him, s/he must not be given treatment that is against her/his will.

The latter part of this section is aimed at guaranteeing the patient's right to self-determination. For instance, the patient's right to draft a valid „living will“ is based on this provision, as is the right of an adult Jehovah's Witness to refuse a blood transfusion even after losing consciousness – both are topics constantly debated in health care.

Complaints

A patient who is not satisfied with the health care or medical care and related treatment received by her/him, has the right to make a complaint on the matter to the director responsible for the health care unit in question. A decision on the complaint must be given within a reasonable time after the making of a complaint.

Making a complaint does not restrict the right of a patient to appeal to the authorities controlling health care or related treatment received by her/him.

If, once the complaint has been dealt with it becomes obvious that the care or treatment of the patient my cause liability for patient injury, indemnification liability, taking legal action, cancelling or restricting the right of vocational practice of health care staff, or taking disciplinary proceedings, the patient shall be advised as to how the matter can be initiated **through** a competent authority or organ.

When investigating a complaint, special attention is paid to patient safety, the equality of citizens, and good service to consumers of health services.

Patient Ombudsman

A Patient Ombudsman, who may also be common for two or more units, has to be appointed for health care units. The tasks are to advise patients on issues concerning the application of the Law on Patients' rights, to help patients in complaints and liability questions, to inform patients of their rights, and to act also for the promotion and implementation of patients' rights.

There are hundreds of Patient Ombudsmen in Finland. The National Authority of Medico-legal affairs has organised symposia for them at the State level, and the Provincial Boards at the provincial level.

Ethics and Law

The Law on Patients' Rights is our attempt in Finnish society to try to clarify and to strengthen a few of those rights of patients which in everyday clinical practice, seem to have caused insecurity, and have resulted in varying interpretations and complaints to supervising authorities. We have tried to keep in mind that the rights of the healthcare personnel and the patients ought not to conflict but should be seen as complementary.

It is obvious that we need both Ethical Rules and Law. Nowadays they seem to be in interaction. Health care professionals are very conscious about the situation. Professional organisations, both domestic and international, draft Ethical Rules with the aim of improving quality control of the work of their members. Yet society also drafts legislation, as it wants to control the professions and the work of professionals, and to guide them.

The training and curricula of health care professions are under reflection. I want to inform you that there is a world-wide project under the UNESCO Chair of Medical Ethics, Professor Amnon Carmi, to draft a universal curriculum for teaching medical ethics. The project involves more than 50 universities in different parts of the world and 124 professors. The aim is to collect some 20-30 booklets dealing with living cases, offering from two to three ethical solutions. The approach is multicultural and aims at showing that ethics cannot be taught by just giving information. Students have to be involved in discussions and trained in decision making.

New challenges are ethics, behavioural sciences, genetics and information technology. The two latter disciplines offer powerful tools to be used in health care for the benefit of humanity, but they also carry risks if they are used irresponsibly. A more comprehensive approach than today's strictly biomedical one towards patients is a "must" for health care professionals in the future, if they want to be trustworthy. It is clear from statements made in public speeches that ethics is widely being introduced into the curricula. In addition to the ethical and the biological, other aspects of human life are also being discussed. This will no doubt bring "added value" to the well being of the people.

Helsinki and the Declaration of Helsinki

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The 55th General Assembly of the WMA[1] took place in Helsinki on September 2003, a long-waited meeting which it was hoped would have allowed the controversies that arose from the latest version of the Declaration of Helsinki to settle. A final agreement in the town where the Declaration had been established for the first time in 1964 would give a symbolical value to the event. This paper sets out a personal view of the twists and turns of the ethical discussion concerning the most recent version.

The 6th edition of the Declaration of Helsinki[2] was adopted in Edinburgh on October 7, 2000. During the debates, several delegates had asked that the adoption of this new version be postponed. They were expecting many criticism from researchers and sponsors, but their warnings were soon swept away, it being said that the credibility of the WMA would be compromised if the revision (already announced for a long time) would be delayed after so many years of preparatory work.

Nevertheless those who had argued for a time of further reflection had been right: suddenly some members of the WMA raised serious objections to the previous unanimously adopted version. The United States especially had rebukes from their rearguard – read the FDA[3]. The sources of irritation were paragraphs 29 and 30, respectively concerning the use of placebo, and the participants' right of access to the best-proven treatment identified by the study.

The opponents of paragraph 29 considered that studies controlled by placebo were essential for a reliable statistical assessment of the results of the trial. This is moreover the reason why the FDA recommends systematic control, because the methodology of the scientific study is otherwise worthless, and if worthless, the research projects do not receive subsidies. By following paragraph 29, institutions, including universities, have taken the risk of a negative response from their Institutional Review Board[4], from the NIH[5] and obviously from the FDA. Therefore several scientific projects involving human subjects have been interrupted and others not even started. In the circumstances the protests are understandable.

The opponents of paragraph 30 emphasised the very poor functioning of the healthcare systems in poorly resourced nations where most experimentation involving human beings is carried out. This paragraph would oblige the pharmaceutical companies to provide the participants with the best-proven treatment identified at the end of the study. From the drug industry's point of view this cannot be afforded.

The academic authorities and spokespersons of the pharmaceutical industry insisted very firmly that the Declaration of Helsinki should be amended. They would otherwise seriously be thinking of not referring anymore to the strong mandatory character of the Declaration of Helsinki. Such a boycott would mean a loss of prestige for the WMA whose Declaration of Helsinki is its pride. Basically nobody intended to undermine the moral leadership of the WMA regarding research, and certainly not the developing countries.

In order to avert an imminent crisis the WMA organised a conference in Pretoria on March 2001, in collaboration with the EFGCP[6] and the University of Pretoria School of Health Systems and Public Health, which had the appearance of an emergency sitting. Representatives of the pharmaceutical industry, of the FDA and of the NIH were numerous. In contrast the attendance of developing countries was on the other hand very sparse, possibly because they were financially too weak to be represented.

The only agreement that could be reached in Pretoria was that the Declaration of Helsinki had to remain the most important guideline in the field of research. The few countries which could hardly accept the paragraphs 29 and 30 would just have to come to terms with it. However these "few" countries were clearly the richer countries who persisted in protesting and asking for revision. A revision of the declaration hardly a few months after its adoption was politically not feasible, as it would have undoubtedly led to the view that the WMA had bowed to the financial interests of the rich countries.

To get out of the deadlock, the Council of the WMA has simply attributed this important difference of opinion to difficulties in interpretation of the controversial paragraphs, which could be easily resolved by adding notes of clarification and through amendments if necessary. The United States agreed with the proposal that the declaration would not be rewritten, but paragraphs 29 and 30 would be examined closely. The situation was defused!

A working group would examine whether paragraph 29 was really an obstacle to reliable scientific research and also consider the financial implications of paragraph 30. It was felt advisable to involve in the discussions external representatives respected for their moral authority and expertise. Thus the CIOMS[7] took part in the debates despite engaging in rewriting its own "ethical guidelines for biomedical research"[8].

The working group decided to add a note of clarification to paragraph 29 rather than rewrite it. The note of clarification was adopted by the 160th the Council of the WMA, October 7, 2001, and is now an integral part of the Declaration of Helsinki.

The unchanged paragraph 29 and its added note of clarification read as follows:

"Paragraph 29:

The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic and therapeutic methods. This doesn't exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists."

"Note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proved therapy is available, under the following circumstances:

– Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
– Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review."

Commentators judged that rather than throw light on the paragraph, this note of clarification by reintroducing the use of placebo, certainly on well-defined conditions, made it meaningless. Some claim that this would finally be of benefit to scientific research; while others considered that the ethical implications for poor countries didn't get enough attention.

Paragraph 30:

"At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."

This paragraph needs to be read with paragraph 19.

Paragraph 19:

„Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.“

Both paragraphs deal with the sensitive subject of experimentation on human beings in developing countries. Without these paragraphs, the protection of participants is virtually non-existent.

The supporters of an unchanged paragraph 30 recalled that the Declaration of Helsinki adopted in 1964 was directly inspired by the Nuremberg Code. This Code refers to the mandatory safeguard of participants' rights, especially for the most vulnerable. Other international authorities such as the CIOMS and the EGE[9-10] also favoured the protection of population groups involved in clinical research.

The dispute about paragraph 30 showed a gap between North and South, between wealthy nations and poor nations. The resource-poor nations consider that they have a right to the best-proven treatment identified by the study. In practice however, the experimental treatments usual cease at the end of the study. The group in question for whom the only available treatment is that in the investigation, is then left on its own, with no-one concerned about them.[11] The developing countries invoke paragraph 30 specifically to prevent conduct which, in their view, is unethical. Paragraph 30 is their last defence.

The resource-rich countries say that these people would not anyway have access to some treatments. The pharmaceutical companies are not inclined in these conditions to engage in heavy financial commitments. Companies are not humanitarian aid organisations, but are, fully prepared to sustain research knowing that they will profit from some of it allthough they don't intent to set up and pay the cost of effective healthcare systems for under-resourced countries. The companies are not satisfied with paragraphs 19 and 30, taking a less absolute approach to the right of participants to the best treatment and its cost. An ethical declaration is not a law and it is ultimately only mandatory to do one's best to observe it. Often the researcher is not able to decide which is the best treatment at the end of the research, the results of which must be compared with others before knowing which treatment is best; it can take decades before a medicine becomes available on the market.

Those who have ever heard the plea of representatives of developing countries recall how distressing their message is. With dignity, they make a distinction between their frustrations and the harm done to them without anger, but resigned to the misfortune of having to cope with a poor health care system and a cruel lack of technology, pharmaceuticals and basic welfare. For many this means utmost poverty and reliance on charity to survive. They don't have Social Security (= the Heath Service) based on solidarity as in the wealthier countries and frequently mentioned in the WMA.

Virtually everyone is convinced that these well founded concerns are justified and that many things need to be done for developing countries, but by whom it is to be done appears much less clear. For the rich countries, this large-scale problem can't be solved by the Declaration of Helsinki but by the local authorities. But the response is that this is another debate (in which the term "corruption" often appears), and in which the economically weak are reduced to silence. It rests with the poorer countries to interpret paragraph 30 correctly. Its aim is not to make drugs available to the population of the Third World but to protect that population from possible exploitation in clinical trials.

In this period of growing commercialisation and globalisation, the poorer countries wonder anxiously, what will be left of paragraph 30, their only glimmer of hope, after its classification by the wealthy countries.

The General Assembly promised to continue working on the problem meanwhile leaving the paragraph unchanged – hopefully for not too long, think those countries which remember well where they buried the hatchet in May 2001. Certainly the debate will continue …

No-one questions the Declaration of Helsinki as being an authoritative reference document. Its implications are ethically binding on everyone involved in scientific clinical research, including both the investigator as sponsor on the study, and the members of ethic committees. It is therefore satisfying that the Declaration of Helsinki is often referred to in both European and national law. In March 2001 in Pretoria, the draft European directive 2001/20/EC on "the approximation of the laws, regulations and administrative provisions of the Members States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" was presented. The Assembly was very keen that the directive should refer to the Declaration of Helsinki which would give it the force of law, at least in the Members States of the European Union.

The Directive was published on May 1, 2001[12], and refers to the Declaration of Helsinki in its preamble. But one is amazed to discover that it refers to the obsolete version of 1996 and not to that of 2000. Thus the last revised version with its hindering prescriptions regarding to drug industry is considerably weakened.

The Member States of the European Union have to transpose the directive into their national legislation for May 1, 2004. Although the directive refers to the version of the Declaration of Helsinki of 1996, we hope that national legislators will take into account the last stance of the WMA thus avoiding (by way of parody!) that someone consults an invalidated version of the Highway Code to determine his way of driving! The time has come both for WMA and for the pharmaceutical industry to decide on driving either on the left or on the right, in other words, to choose in favour of the rich or the poor.

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Editorial note:

Following the September 2003 Council meeting in Helsinki (see WMJ 49 (5/6), 71), the working group on the Helsinki Declaration has continued its work and following the many comments, discussions and consultations, and will present a report to the WMA Council meeting in May 2004.

Linking moral progress to medical progress: New opportunities for the Declaration of Helsinki[1]

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Summary

- Progress in science and medicine is essential for human advancement.
- Ethical values are essential in directing the application of scientific and medical advances.
- Moral progress requires that the benefits of progress be shared more widely and more equitably throughout the world.
- Scientific and medical progress should be inextricably linked to moral progress.

Introduction

The Declaration of Helsinki has played a seminal role in promoting protection of research subjects from abuse and exploitation. However, as medical advances have benefited only a small proportion of the world's population it cannot be claimed that moral progress has matched scientific progress. Given the limited value of progress for humankind as a whole if its benefits are not widely shared, it is essential that scientific progress be coupled to moral progress in research and in access to health care. We have previously argued that moral progress will require more than new or refashioned declarations, as it is people with the will and the capacity to implement the content of declarations that are the key factor. The recent focus on the future of the Declaration of Helsinki at the 2003 World Medical Association (WMA) General Assembly scientific meeting provides an opportunity to consider the potential for making moral progress through visionary modifications to this Declaration.

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[1] Based on a presentation at the WMA General Assembly in Helsinki in September 2003

Discussion

Moral progress in research on human subjects since the infamous Nazi human experiments, is evident in many activities. These include the development of many codes, guidelines and procedures for research ethics that aim to protect research subjects from harm and exploitation, and the increasing attention being paid by scientists and others to the requirements for ethical research. Expansion of international collaborative research has prompted generous funding from the US National Institutes of Health's Fogarty International Centre for promotion of capacity building in research ethics in developing countries.[1]

However, there is a wide gap between scientific/medical progress and moral progress in medical research and practice. This is starkly evident from widening disparities in health, longevity and health care and in the expenditure on medical research. Indeed questions must be raised about the moral credibility of a medical research endeavour in which 90 % of US$ 73 billion is spent on diseases that cause 10 % global burden of disease (10 : 90 gap),[ii] and only 16 of the 1393 new drugs marketed from 1975-1999 were for tropical diseases or tuberculosis.[iii] Dealing with such moral challenges requires that in addition to preserving and enhancing commitment to long-standing values in research ethics (Box 2), several new values be built into the research endeavour (Box 3).

Box 2. Long-standing ethical values in research ethics

- Do not harm
  - Minimisation of risk
- Protection of the vulnerable
- Respect for dignity of patients/subjects
  - Informed consent
  - Protection of confidentiality
  - Freedom to withdraw
- Justice
  - Compensation for injury
  - Appropriate remuneration for participation

Box 3. Newer ethical values in research ethics

- Justice
- Fair access to participation in research studies
- Fairness in distribution of harms/benefits - long term as well as short-term
- Non-Exploitation of the vulnerable
- Coupling the research endeavour to improvements in health care through partnerships and improves overall standards of care in research
- Relevance of research to local needs - the importance of context
  - Narrowing the 10 : 90 gap by reshaping the research agenda
  - Cultural and linguistic sensitivity in obtaining informed consent
  - Solidarity and interdependence - acknowledging and facing global threats
  - Addressing deteriorating global health
  - Focusing on re-emerging and new infectious diseases
  - Global health information equity

In evaluating the research enterprise and possible future changes to the Declaration of Helsinki from a moral perspective, a critical question that could be asked is what the priorities of the World Medical Association (WMA) and its Declaration should be. That is, whose agenda should the WMA be addressing through the Declaration? Choices include the pharmaceutical industry; medical associations in North America and Europe; the US Federal Drug Administration; researchers in privileged countries; the health of those who already have the prospect of long lives; the health of those dying prematurely from preventable diseases, or the health of all people at a global level.

Given the widening disparities in health globally,[iv] and the presumption that the health of all people globally is the concern of the WMA, it is suggested that incorporation of new ethical values in research (Box 3) into the Declaration of Helsinki could enhance the "moral capital" of the Declaration. This in turn may lead to reduction in disparities in health and medical research.

Suggested Changes to the Declaration of Helsinki

An appropriate preamble to the declaration could sensitise research workers to imbalance in the research agenda.

"Spectacular developments in science, technology and medical practice have transformed health care and improved the lives of many. Despite such progress millions of people live in degrading poverty with little access to health care and are denied even basic medical treatments. Because improving the potential for good health for a greater proportion of the world's population is one of the most pressing moral problems of our time, research should increasingly be directed towards diseases that afflict poor and marginalised people. Those undertaking research in developing countries should also have some understanding of and be sensitive to the social, economic and political milieu that frames the context in which such research is undertaken. Lessons learned from research should be made more equitably available world wide and used to improve relationships between host and sponsoring countries, as part of the endeavour to improve health globally."

The declaration states that medical research involving human subjects must conform to generally accepted scientific principles, and be based on a thorough knowledge of the scientific literature. An accompanying statement should indicate that all such research should conform to accepted ethical principles, be based on a thorough knowledge of the research ethics literature, and that medical research involving human subjects should be conducted by scientifically qualified persons with knowledge of research ethics.

It should also be explicitly stated that exploitation of subjects, or their use as means to the ends of others, must be avoided by ensuring that the research is of relevance to the individuals participating in the research as well as to their communities. The balance of benefits and burdens of research should be fairly distributed with due consideration of the benefits that could accrue to sponsors in the long term, and to ensuring that studies are not done with the intention of spending as little as possible on care of research subjects and the communities in which they live, when large profits may result from the research.

Care should be taken that research does not inappropriately deflect local human or material resources away from the health care system in the host country towards research projects, thus more deeply entrenching existing disparities. Priors evaluation by a local committee or governing body should include consideration of whether study findings can, and will be incorporated into the local health care system.

Informed consent should be obtained in the language spoken by the research subject and with insight into, and respect for the subject's culture.

At the conclusion of the study, every patient should receive interventions identified as beneficial by the study, or access to other appropriate care. This is particularly important for patients with serious conditions for whom cessation of the study intervention could have severe consequences. Research in developing countries should be linked to a broader notion of standard of care, to capacity building in health care, and to economic and educational empowerment that could benefit delivery of health care specifically, and progress generally, in the host country. Some of these issues are being addressed in an expanding discourse on research ethics and much remains to be done.[v, vi, vii, viii, ix]

Conclusions

Disparities in global health pose the greatest potential security risk to the lives of all people in the world.[x] We are challenged to recognise this risk and to take appropriate action. To paraphrase Virchow "health is political and population health is politics writ large". Research is also political and it does not take place in a vacuum.

Scientific progress must be coupled to moral progress, and in particular in relation to social justice. The Helsinki Declaration has the potential to stimulate moral progress in research. Such progress, if made, will be reflected in reductions in health inequity, and in improvements in population health.

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World Medical Association

”Getting it Right for our Children”

Presidential Address of Dr. James Appleyard to the General Assembly of the World Medical Association, Helsinki, September 2004

”The level of civilisation attained by any society will be determined by the attention it has paid to the welfare of its children.” Professor Billy Andrews (1964)

The continuing challenge facing the World Medical Association is to maintain and promote the professional values that underpin medical practice world-wide. At the 90th birthday celebrations of our hosts the Finnish Medical Association entitled ”pro humanitate”, the Emeritus Archbishop of Helsinki encouraged physicians to reaffirm our shared values so that they became ”internalised” as our professional conscience. Our conscience should become our compass in the everyday practice of medicine and for our role as leaders and teachers in the field of healthcare.

The Hippocratic tradition recognises our responsibility to respect the individual ”rights” of those who entrust themselves to our care. This respect for our patients, nurtured by our profession in the patient/physician relationship, is fundamental for the survival and development of communities and nations.

The standards we set in our WMA Declarations are important safeguards for our patients. The Declarations of Geneva(1), Helsinki (2) and Tokyo (3) in particular reestablished ourselves as a trustworthy ethical profession after the horrors of World War 2. More recently we have established essential standards for the care of children world-wide in the Declaration of Ottawa on the ”Right of a Child to healthcare”(4)

Children are a country’s most valuable resource. Poverty and the denial of children’s rights have devastating effects on our childrens’ survival. The World Health Organisation's Commission on Macro-economics and Health has recognised that substantially improved health outcomes are a pre-requisite if developing countries are to break out of the cycle of poverty.(5) Healthy children become healthy, more productive adults and remain healthier in their old age.

A study of the "Value of Children" was conducted in nine countries comparing parents' motivation for child bearing.(6) It was found that in less developed countries where children were conceived to be "used" for economic reasons, there was a relatively high fertility rate. In more affluent countries where children were conceived as loved individuals in what was termed their "psychological value", there was a lower fertility rate. With improvement in health and education, less children will die and less children will be conceived.

Table 1 – Under 5-year mortality – Top 10

Country	Value	Rank	Gross National Income per capita US$
Sweden	3	1	25,400
Singapore	4	2	24,740
Norway	4		35,530
Iceland	4		28,880
Denmark	4		31,090
Slovenia	5	6	9,780
Monaco			n/a
Malta			9,120
Luxembourg	5		41,770
Korea	5		9,4000

Table 2 – Under 5-year mortality – 10 nations with highest rates per 1,000 births

Country	Value	Gross National Income per capita US$
Sierra Leone	316	140
Niger	265	170
Angola	260	500
Afghanistan	257	250
Liberia	235	490
Mali	231	210
Somalia	225	120
Ginea Bissan	211	160
Congo	205	700
Zambia	202	320

UNICEF publish international comparative tables of the under five mortality rate per 1,000 births.(7) This is a remarkably sensitive indicator of how individual nations "value" their children. Top of the list with the lowest mortality rate is Sweden, which has only around 3 children dying under five year of age per 1,000 births (Table 1). Bottom of the world list is Sierra Leone with 316 children per 1,000 dying under the age of five years (Table 2). That country is "sacrificing" nearly one third of its young children. The difference between the top and bottom nations is 100 fold. This differential reflects that widening gap between the "rich" and "poor" nations which is unsustainable for clear humanitarian, health and economic reasons.

Just how sensitive this "index" is to the "political" factors of a nation can be seen in table 3. With a very similar birth rate and gross national income per capita to Tanzania, Uganda has "saved" the lives of some 50,000 children under five in 2001 as compared to the rate in 1990. Neighbouring Tanzania however made no real progress. Likewise over the same ten year period, the devastating deterioration in the survival of children under five in Iraq contrasts dramatically with neighbouring Iran. The additional loss of around 20,000 children under five in Zimbabwe as compared to ten years ago will have very serious consequences for the future of that country.

Though the difference in the Gross National Income per capita in US$ between the top and bottom ten nations in the UNICEF list is enormous, the correlation between how rich a country is and how much it invests in its children is variable. For instance Cuba has had half the gross national income per capita of Iraq but they are ranked 42nd, whereas Iraq has fallen to 162nd of the 195 nations in the world which are recognised by the WHO (Table 4). Slovenia (6th) has an under five mortality rate of only 5 with a GNI of 9,780 US$, which is significantly above the United Kingdom (31st) with a GNI of well over twice as much!

Table 3 – Selected countries – under 5-year Mortality ranking and GNI

Country	Value	Rank	Gross National Income per capita US$
Japan	5	11	35,990
Greece	5		11,780
Germany	5		23,700
Finland	5		23,940
Czech	5		5,270
Austria	5		23,940
Switzerland	5		36,970
Spain	5		14,860
San Marino	6	19	n/a
Portugal	6		10.670
Israel	6	24	16,710
United Kingdom	7	31	24,230
United States	8	34	34,870
Cuba	9	42	1,170
Kuwait	10	43	18,070
Occ. Palestine	24	80	1,350
China	39	110	890
Iran	42	114	1,750
Zimbabwe	123	156	480
Iraq	133	162	2,170

The major causes of the under 5 mortality world-wide are diarrhoea, malnutrition, malaria, measles, HIV/AIDS and Pulmonary Tuberculosis. Each of these conditions is easily preventable and treated. Indeed the World Bank has estimated that if the burden of infectious disease were lifted from the developing world, the gap between the richest 20 and poorest 20 nations would largely be bridged.(17)

So what action can national medical associations take to effect change? Their members are involved in and affected by all aspects of these problems. There needs to be both the central political will to make changes as well as an effective local infrastructure in which changes can be made. This requires advocacy with professional and allied partners, and the setting of priorities for action.

Table 4 – Rate of progress

Country	Gross National Income per capita US$	Under 5 mortality per 1,000 births 1990	Under 5 mortality per 1,000 births 2001	Annual births 1000's in 2001	Change
Tanzania	270	163	165	1,393	2,786 +
Uganda	280	165	124	1,222	50,000 +
Zimbabwe	480	80	123	459	20,000 –
South Africa	2,900	60	71	1,105	12,155 –
Iran	1,750	72	42	1592	47,600 +
Iraq	2170	50	133	823	66,840 –
Occ. Palestine	1350	40	24	132	2,112 +
Israel	16,710	12	6	126	756 +
Afghanistan	250	260	257	1,078	3,234 +
Rwanda	220	178	183	320	1,600 –
Russian Federation	1,750	21	21	1,230	– 0 –
Romania	1,170	32	21	233	2,330 +

Water and Sanitation

About 1,2 billion people world-wide lack access to safe drinking water and 2,4 billion lack adequate sanitation, giving rise to diseases such as diarrhoea, cholera and trachoma. In poor countries it has been estimated that at any one time, about half the urban population is suffering from one or more of the diseases associated with the lack of water and proper sanitation.(8) The incidence of diarrhoea can be reduced by nearly a quarter and the number of deaths by close to 2/3rds, through improvements in safe water supply with sanitation and hygiene. The cost of realising universal access to health, water sanitation and education, was estimated by the United Nations and the World Bank in 1995 to be an additional 70–80 billion dollars per year. The World leaders can and must afford this. The Ugandan Medical Association has made "sanitation" their theme for the coming year.(9) The Japan Medical Association is leading the WMA's current initiative on key issues concerning water world-wide.

Malnutrition

More than half the deaths of children in the world under the age of five are associated with malnutrition. The number of malnourished children in sub-Saharan Africa has increased over the last ten years. Malnutrition is a cause as well as a consequence of poverty. Despite the high profile and the work of a large number of non-governmental organisations, the essential infrastructure has not been properly developed to relieve this totally preventable burden.

Armed Conflict

More children have suffered from armed conflicts and violence in the last ten years than in any other comparable period in history.(8) Ethnic conflicts and civil wars have come in the wake of the "cold war". Conflicts killed 2 million children in the '90s. They left large numbers of children disabled and psychologically scarred. Violence breeds violence! Children have been displaced, placed in unsanitary conditions with poor or absent social infrastructure, and with no system of justice. There are 35 million displaced persons and refugees worldwide, 80 % are women and children. This is a severe indictment on the responsibilities of some nations' leaders and the ineffectiveness of the United Nations to resolve international conflicts.

Abuse, Neglect and Exploitation

In the wake of armed conflict, poverty and a culture of violence, children are increasingly becoming victims of abuse, neglect and exploitation. It has been estimated that there may be as many as 35 million child victims of child prostitution, sex tourism and child "slavery". One form of gross breach of human rights affecting young girls is female genital mutilation. The WMA believe that this practice is completely unethical.(18) Yet in the UK where the practice is outlawed, it is widely alleged that FGM continues to be practised in private hospitals.(10) Girls are also being sent abroad to those countries where the operation is allowed. Physicians have a duty to do all in their power to expose unethical practice and try and prevent all forms of child abuse.

Smoking

More than five million children alive today will die prematurely of smoking related diseases.(11) Recent studies have revealed that in Bangladesh as a result of marketing by the tobacco industry, family members are spending money on cigarettes rather than on food for their children, even to the extent of causing malnutrition.(12) It is crucial that the tobacco "epidemic" that has swept the western world causing such a toll of respiratory, cardio-vascular and neurological disease, is not inflicted on the poor nations already bearing an intolerable and financially overwhelming burden of disease by the marketing practices of a selfish and unscrupulous tobacco industry. Cigarette Companies spend more then US$ 11,22 billion on promoting their products. It is well known that children are more susceptible to cigarette advertising than adults. To quote Philip Morris: ”Today’s teenager is tomorrows regular customer, and the overwhelming majority of smokers first begin to smoke in their teens. The smoking pattern of teenagers is particularly important to Philip Morris.” National medical associations need to advocate in the strongest possible terms for their country to sign up to the UN Framework Convention on Tobacco Control (13) which will provide their fellow citizens with some protection from the predicted tobacco epidemic.

HIV/AIDS

The HIV/AIDS pandemic is a global disaster. There are 10.4 AIDS orphans, 95 % of whom live in Sub-Saharan Africa. In children under five years, it has been predicted that the virus will cause 2/3rds of deaths in Botswana and half the deaths in Zimbabwe and South Africa. In Uganda of the 100,000 people suitable for anti-retroviral therapy, only 10,000 can be afforded the treatment.(14)

Medicines, Resources and Responsibilities

The affordability of medications is a key issue in the battle against infectious diseases in poor nations. The development of life saving drugs is however largely subject to market forces. Those nations with the highest burden of disease have the smallest financial market. Indeed only 10 % of the global health research is devoted to conditions that account for 90 % of the global disease burden – the so called 10/90 dis-equilibrium. Of the 1393 new chemical entities developed between 1975 and 1999, only 1/3rd were truly ”breakthrough” drugs and only 16 were for tropical diseases, TB and AIDS. All these 16 drugs were developed with ”public sector” support.(15)

There are seriously disabling and life threatening diseases, mainly affecting the poor in developing countries, that may be considered as ”neglected diseases”, where treatment options are inadequate or simply do not exist. These include Malaria – causing over a million deaths – and Tuberculosis, over 2 million deaths each year, HIV/AIDS which result in some 3 million deaths each year, and visceral Leishmaniasis which affects some 12 million people world-wide. In Africa, Asia and America 146 million are affected by Trachoma and in 6 million this has caused blindness. Likewise Onchocercosis affects 18 million with nearly a third of a million blinded. The agencies active in the field of drugs for the ”neglected diseases” include the WHO/World Bank’s Tropical Disease Research Unit, the Global Alliances for ”TB” and ”Vaccines and Immunisations”, Medicines for Malaria and the International AIDS Vaccine Initiative. But all these entities with the few others involved only have a combined budget of around 100 million dollars a year.(15) It is only a fraction of the reported cost of up to US$ 800 million that it takes the pharmaceutical industry to develop a single new drug. In order to restore a proper balance to the current 10/90 dis-equilibrium, it is essential that Governments of all nations, global industries, academia, universities and the non-government organisations involved, urgently start focusing on these neglected diseases. National medical associations need to encourage and foster academic partnerships between universities and academic centres in the rich and poor countries which could provide a valuable research network world-wide.(16)

The modern pestilences due to HIV, Ebola Virus and more recently SARS have arisen in the aftermath of conflict and/or in areas of great poverty. When faced with a greater risk of dying and the serious financial consequences of the SARS epidemic, it was remarkable that in the ”rich” world the combined resourcefulness of humans and human resources were mobilised, commercial competition set aside and the causative organism of SARS, its genetic sequence, likely mode of transmission and some possible therapeutic agents identified within a very short time. If the same energy could be sustained to resolve the burden of infectious diseases in the poor countries, great strides would be made in relieving the widening inequalities in the health and wealth of nations.

Future Progress

There are clear and well trodden paths to progress. These require children to be at the centre of each nation’s thoughts for their future, and governments need to examine the impact of all their policies on the health of children. The World Medical Association has built on the foundations of the UN Declaration of the Rights of the Child in the WMA Declaration of Ottawa on the Right of a Child to Healthcare.(4) National Medical Associations with others need to use these standards as a measurement of progress to achieve improved healthcare for, and the health of children.

The World Summit for Children’s ”Plan of Action” in 1990 called on Government to prepare their own national programmes, in order to implement their World Summit commitments on children. It is the will to incorporate the needs of children into each nation’s mainstream developmental thinking together with a robust local infrastructure that will produce results. Local communities often struggle to meet the needs of children without a fair share of the country’s resources. In the 1990s, the World Health Organisation’s 20/20 initiative was based on the premise that an average of 20 % of the national budget in developing countries and 20 % of the Official Developmental Assistance (ODA), would be sufficient to achieve universal access to basic social and health services. Most countries continue to seriously under invest in these basic social and health services for children, with only 12–14 % of the national budget and only 11 % of the ODA being allocated to these basic services.

Developing countries spent on average more on defence than on either basic education or basic healthcare.(8) Levels of defence spending by developed countries were about 10 times the level of spending allocated to international development. Yet the increasing gap between the rich and poor nations has been shown to foster violence and terrorism and to promote conflict. This vicious circle can and must be broken.(17)

Physicians individually and collectively through their national medical associations, are strong advocates for the health needs of their local communities and nations. Medical students and young doctors in the rich countries need to experience the health facilities of the ”poor” countries first hand as an elective and as part of their postgraduate training. Such experience will change their lives. In turn their work and their advocacy will change the lives of those currently overwhelmed by the burden of disease. The final thought I leave with them is a quote from Nelson Mandella and Graca Machel:

”We cannot waste our precious children. Not another one. Not another day. It is long past the time for us to act on their behalf.”

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Medical Science, Professional Practice and Education

Orthopaedic Surgeons Are Failing To Prevent Osteoporotic Fractures

A multinational study of orthopaedic surgeons has found that in as much as 95 % of cases, orthopaedists fail to investigate osteoporosis as a cause of the fracture and are inconsistent in offering specific treatment or referrals.

Full results of the study co-sponsored by the Bone and Joint Decade and the International Osteoporosis Foundation (IOF), were presented by Dr Karsten Dreinhöfer, Ulm University Hospital, Germany on October 15th during the first global 24-hour eLecture conference on musculoskeletal disorders, organised by the Bone and Joint Decade for the medical community and in recognition of World Osteoporosis Day, October 20th.

Until recently, the only fractures considered to be osteoporotic in nature were spinal wedge, hip and wrist fractures as these caused the majority of problems for patients and hospitals. ”However, it is now clear that fractures of the pelvis, ankle, knee and shoulder, as well as fractures of the clavicle should all be treated as osteoporotic fractures,” said Dr Karsten Dreinhöfer.

”All orthopaedic surgeons who treat middle-aged and elderly patients with fractures have a duty to consider and institute mechanisms for preventing future fractures. This can be done by instituting protocols for the screening, identification and treatment of those who have sustained a fracture”, he said.

Studies show that 50 % of women and 30 % of men will experience an osteoporotic fracture in their lifetime and a prior fracture increases the risk of subsequent fracture as much as five-fold. Osteoporotic fractures are associated with increased morbidity and mortality: 50 % of hip fracture patients will have long-term disability, and 25 % will require long-time nursing home care. With the population ageing world-wide, the number of fragility fractures is expected to increase dramatically over the next few years.

A multinational survey involving 3,500 orthopaedic surgeons from France, Germany, Italy, Spain, the UK and New Zealand was conducted earlier in 2003 to determine the scope of the problem and areas for improvement. The results revealed striking examples of ineffective care of osteoporosis:

- Fifty percent of orthopaedic surgeons practising today received little or no training in osteoporosis.
- Only roughly one in four orthopaedic surgeons in France and the UK feel knowledgeable about managing the disease in their patients.
- Only in Germany are the majority of fracture patients referred for a bone density test; in the UK, this figure is as low as 16 %.
- Only half of the orthopaedic surgeons in Southern Europe know about the importance of external risk factors for hip fractures (cataracts, poor lighting, pathway obstacles, poor balance).
- In four of the countries surveyed, more than half of the surgeons have not heard about their national osteoporosis patient society.

”Since orthopaedic surgeons are often the first and only physicians to see fracture patients, they are in a unique position to identify untreated cases of osteoporosis, and as such reduce the risk of subsequent fracture,” said Professor Olof Johnell, International Osteoporosis Foundation, who led the development of guidelines for orthopaedic surgeons to identify and treat osteoporosis. He cautioned, ”It is important to act at the time of fracture. It is the responsibility of orthopaedic surgeons to investigate whether osteoporosis is the underlying cause.”

Osteoporosis is a condition that affects people of all ethnic and cultural groups from around the world. Although there is no cure for osteoporosis, there are treatments and lifestyle changes such as regular exercise that can stop further bone loss and reduce the risk of fractures. For example, a recent study in China by Professor Kai Ming Chan, shows that regular tai chi chuan exercises can delay bone loss in postmenopausal women.

Background

The Bone and Joint Action Week, October 12–20th 2003

As a highlight of the Bone and Joint Decade Action Week, leading authorities in the musculoskeletal field presented a 24-hour series of eLectures via webcast. Subjects ranged from prevention, to state-of-the-art treatment and from how to best teach musculoskeletal disorders to the best biological approaches.

The Action Week was a major driving force for prevention and advocacy and included: World Arthritis Day (Oct 12th), World Spine Day (Oct 16th), World Trauma Day (Oct 17th) and World Osteoporosis Day (Oct 20th).

Launched in January 2000, the Bone and Joint Decade is an NGO, headquartered in Sweden. Its mission is to advance understanding of musculoskeletal disorders world-wide through research, and to improve the quality of life for those affected by these disorders. The Bone and Joint Decade is supported by National Action Networks, professional medical societies, patient advocacy groups, governments, industry and researchers who are to effect change. The Bone and Joint Decade is delighted to have the personal and active support of Kofi Annan, Secretary-General of the UN, the WHO and the World Bank.

The Bone and Joint Decade encompasses diseases associated with musculoskeletal disorders such as joint diseases, osteoporosis, osteoarthritis, rheumatoid arthritis, low back pain, spinal disorders, severe trauma to the extremities, crippling diseases and deformities in children.

For more information and a copy of the osteoporosis guidelines, see: The Bone & Joint Decade: http://www.boneandjointdecade.org and: International Osteoporosis Foundation: http://www.osteofound.org.

Relationship Based Health Care in Six Countries

A comparative study of patient and physicians' perceptions world-wide

The following is an abstract summary of this study carried out and presented at the Helsinki General Assembly, September 2003 by Dr. Mike Mcgee, WMA, Fellow in Humanities 2003 The full text can be obtained from the author*

Context of study

A number of forces have transformed the practice of medicine in the past two decades. Evidence suggests that these forces are impacting on both patients and physicians and on their relationship with each other.

Objectives

To simultaneously survey patients' and physicians' perceptions of their relationship with each other in six countries on four continents.

Design and Setting

Patients and physicians were simultaneously studied in six countries using nationally representative telephone surveys between July 22, 2002 and October 13, 2002. 2506 interviews were conducted on patients (63 % response rate) and 1201 interviews were conducted on physicians (58 % response rate) using a random digit dialing (RDD) methodology.

Participants

Patients had to be at least 21 years of age. Physicians had to be general practitioners and in practice for five or more years.

Main Outcome Measures

Relative importance of patient-physician relationships compared to other critical relationships in society. Type of relationship as defined by patients and physicians. Levels of patient empowerment and self-management of care. Actual and ideal performance ratings in 5 dimensions in the humanistic domain (compassion, trust, understanding, patience, listening) and 5 dimensions in the access domain (access to physician, time with physician, appointment scheduling, choice of treatment, choice of specialists).

Results

The patient-physician relationship ranked second in importance only to family relationships in all countries studied. Physicians were the leading source of health information, the most trusted source, and the source most likely to instigate positive behavioural change in patients in all countries studied. All countries agree that authoritarian paternalistic relationships between physicians and patients are relatively uncommon today. These relationships are being replaced by mutual partnerships or advisor models. Patients and physicians in all countries foresee future movement toward partnership and team based models. Compared to 10 years ago, most patients in all countries believe they ask more questions, make more choices, actively evaluate benefit and risk, and take better care of their own health. Patients' confidence in managing their own health is very high in all countries except Japan. Physician confidence in patients self-management is lower than patients scoring in five of the six countries. In general, all cohorts rate physician humanistic performance higher than access performance. Physicians in all countries rate their ideal humanistic performance higher than do patients. In contrast, physicians in the United Kingdom and Germany rate their ideal access performance lower than the patients' expectation for ideal access performance. In actual performance both in humanistic and access domains, physicians score themselves higher than do patients in 8 of the 10 dimensions. Patients and physicians scoring of opportunities for improvement is relatively well aligned in five of the six countries studied. The greatest variance in opportunity scores between patient and physician exists in the United Kingdom in both humanistic domain (17 % difference) and access domain (26 % difference) and in Germany access domain (19 % difference), with patients seeing more opportunity than do physicians.

Conclusions

The findings indicate a fundamental shift in the patient-physician relationship away from an authoritarian and paternalistic model and toward partnership and team based approaches. Patients are significantly more confident and empowered than they were ten years ago. Physician confidence in patient self-management is more modest. Patients possess high confidence in physicians but also demonstrate higher expectations for ideal physician performance and higher expectations for improvement along five dimensions of humanistic care and five dimensions of access to care. The ability to align expectations of patients and physicians, and meet commonly held objectives, will be increasingly important in assuring the future health of this critically important societal relationship.

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World Health Organisation

More Research, More Resources Needed To Control Expanding Global Diseases

Dr. Lee Jong-wook, WHO Director General in his introduction to the **World Health Report 2003,** writes „Today's global health situation raises urgent questions about justice. In some parts of the world there is a continued expectation of longer and more comfortable life, while in many others there is despair over the failure to control disease although the means to do so exist.

This contrast is starkly evident in lack of access to HIV/AIDS treatment, which led me, earlier this year, to declare a global health emergency. WHO decided to take this rare measure after evaluating the global situation and finding that only 5 % of those in the developing world who require antiretrovirals (ARVs) are getting them. In sub-Saharan Africa, only 50,000 of the 4 million people in need have access to ARVs. This spells catastrophe, not only for the societies hardest hit but for the world as a whole. Our first step to respond to this crisis must be to reach ”3 by 5” – 3 million people in developing countries on antiretrovirals by 2005. Major disparities also exist in areas such as child mortality. Of the more than 10 million children under 5 years old who die every year, almost all are in developing countries.

A world marked by such inequities is in very serious trouble. We have to find ways to unite our strengths as a global community to shape a healthier future. This report on the world's health, my first since taking office, gives some initial indications of how to do it.

The message (running through the report) is that progress in health, including rapid and sustainable expansion of emergency treatments, depends on viable national and local health systems. Scaling up ARV therapy in resource-poor settings has to be done in such a way as to strengthen health systems based on primary health care. In most countries, there will be only small and short-lived advances towards acceptable standards of health without the development of health care systems which are strong enough to respond the current challenges.

To lend impetus to this process WHO is now making results in countries its main objective. Effective action to improve population health is possible in every country but it takes local knowledge and strength to turn that possibility into reality. We have learnt this through successes such as controlling the SARS epidemic and major advances in the polio eradication campaign, and we have learnt it through setbacks as well, such as continuing rise of AIDS, TB and malaria. All of these lessons have prepared us for the task ahead.

Twenty-five years ago, the Declaration of Alma-Ata challenged the world to embrace the principles of primary health care as the way to overcome gross health inequalities between and within countries. ”Health for all” became the slogan for a movement. It was not just an ideal but an organizing principle: everybody needs and is entitled to the highest possible standard of health. The principles defined at that time remain indispensable for a coherent vision of global health. Turning that vision into reality calls for clarity both on the possibilities and on the obstacles that have slowed and in some cases reversed progress towards meeting the health needs of all people. This entails working with countries – especially those most in need – not only to confront health crises, but to construct sustainable and equitable health systems.

I urge the global health community to set its sights on bold objectives. All countries of the world have pledged to reach the Millenium Development Goals set at the United Nations Summit in 2000. These include ambitious targets for nutrition, maternal and child health, infectious disease control, and access to essential medicines. With this support we have a real opportunity now to make progress that will mean longer, healthier lives for millions for people, turn despair into realistic hope, and lay the foundations for improved health for generations to come.

To reach our goals, increased resource commitments and intensified collaboration among partners will be required. The [...] report describes the challenges we face and points the way for a united response from WHO and the global health community.“

Geneva
October 2003

World Health Organisation

Poverty

Health And Finance Ministers Address Need For World-wide Increase In Health Investment

Geneva – Ministers of Health, Finance and Planning from 40 developing countries came together with development partners at WHO headquarters from 29 to 30 October to address the need to significantly increase investments in health. This is the first time that the World Health Organisation has hosted a meeting so widely attended by non-health officials, underlining the urgency of building national capacity to absorb increased health funding.

”This meeting signifies real political commitment from the highest levels of government and donor representatives. Let us capitalize on this unique opportunity to regognize health as a critical investment and together develop a common understanding of how countries and their partners can transform these commitments into immediate actions. We must choose to make equitable and efficient health investments a reality,” said WHO Director-General Dr Lee Jong-wook.

This meeting comes nearly two years after the launch of the 2001 Report of the Commission on Macroeconomics and Health (CMH), which recommends that by 2007, donors should increase assistance for health to US$ 27 billion. The Commission also calls for more budgetary resources for public health from both developed and developing countries, and more political and organisational effort than has been seen in the past decades to achieve real improvements in health.

Two years on, the world still has not shown determination in increase investment in health to the levels needed to measurably impact major diseases that affect the world’s poor. A recent study* has shown that the total development assistance for health from major selected sources increased by US$ 1.6 billion, from an average of US$ 6.1 billion (1997–1999) to US$ 7.7 billion (2001). Most of the increase in funding was allocated to fighting HIV/AIDS in sub-Saharan Africa. Although these recent increases in assistance for health are encouraging, they still fall short of meeting real needs.

”On taking office, I declared the target of ‘3 by 5’ – to have 3 million people with AIDS in developing countries on treatment with antiretrovirals by the end of 2005. Only 300,000 are on treatment at the moment. To achieve ‘3 by 5’ and other health priorities we need considerably more funds than those currently available. If we don’t increase resources for health and target these resources to activities that will have the greatest impact, we stand to lose millions of men, women and children to disease. This also means trapping individuals and families in poverty and disillusionment,” said Dr Lee.

During the meeting, the combined work of countries, WHO and partners was to develop concrete plans for increased health investment in countries. Continued global leadership and follow-up from the development community, combined with inter-ministerial collaboration is needed: first, to increase resources for health from domestic resources, debt relief and development assistance for health, and second to eliminate health system and institutional constraints, enabling greater absorption of increased resources. This will be critical for pursuing country action to reach the ‘3 by 5’ and other health targets.

”We need country-specific blueprints for making real increases in health investment. Developing countries and their partners need to collectively and quickly do much more, for health and global stability. This meeting can identify ways to make this happen,” added Dr Lee.

National Macroeconomics and Health activities are ongoing in the countries participating in the Consultation: From Africa: Angola, Botswana, Congo, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Nigeria, Rwanda, Senegal, South Africa, Uganda, United Republic of Tanzania. From the Americans: Argentina, Brazil, Mexico, Nicaragua, Peru and the Caribbean Community including Haiti. From the Eastern Mediterranean: Djibouti, Iran (Islamic Republic of), Jordan, Pakistan, Sudan, Yemen. From Europe: Azerbaijan and Estonia. From South East Asia: Bangladesh, Bhutan, India, Indonesia, Myanmar, Nepal, Sri Lanka and Thailand. From the Western Pacific: Cambodia, China, Philippines and Viet Nam.

* Development
Assistance for health (DAH): Recent Trends and resource Allocation Dr. Catherine Michaud, Senior Reserach Associate, Harvard Center for Population and Development Studies

WHO welcomes new initiative to cut the price of AIDS medicines

Geneva – The World Health Organisation has welcomed a new initiative to further cut the price of AIDS medicines in developing countries. WHO also underlined the importance of speedy delivery and distribution, as well as effective treatment and care to ensure equitable access to treatment around the world.

In New York, the William J. Clinton Foundation announced that it had reached agreement with some manufacturers to cut the price of AIDS medicines in half.

”Providing AIDS treatment to those who most urgently need it in poor countries is the most urgent health challenge the world faces,” said the WHO Director-General, Dr LEE Jong-wook. ”WHO welcomes this Clinton Foundation initiative and all private and public sector efforts that will both reduce the price of AIDS medicines and ensure their availability to the people who most urgently need them.”

WHO and its partners are fully committed to delivering antiretroviral therapy to three million people in developing countries by the end of 2005, the ”3 by 5” target. To do this, WHO is leading emergency response teams to assist developing countries in increasing the availability of treatment for people with AIDS, developing simplified treatment guidelines, building an AIDS drugs and diagnostics facility, and ensuring the widespread availability of training for health staff and volunteers.

”Further price reductions are vital for countries to be able to provide treatment to those who need it,” said Dr Paulo Teixeira, Director of the HIV/AIDS Department at WHO. ”But lower price medicines alone will not deliver treatment. Improving the ability of countries to deliver the medicines, building stronger health systems and training more health workers are also vital if we are to reach the ‘3 by 5’ target.”

Maternal mortality

Maternal Deaths Disproportionately High In Developing Countries

African women are 175 times more likely to die in childbirth than women in developed regions of the world

Geneva – New findings on maternal mortality by **WHO, UNICEF** and **UNFPA** show that a woman living in Sub-Saharan Africa has a 1 in 16 chance of dying in pregnancy or childbirth. This compares with a 1 in 2,800 risk for a woman from a developed region. These findings are contained in a new global report on maternal mortality released online by the three agencies at.
www.who.int/........

Of the estimated 529,000 maternal deaths in 2000, 95 % occurred in Africa and Asia, while only 4 % (22,000) occurred in Latin America and the Caribbean, and less than one percent (2,500) in the more developed regions of the world.

Experience from successful maternal health programs let show that much of this death and suffering could be avoided if all women had the assistance of a skilled health worker during pregnancy and delivery, and access to emergency medical care when complications arise.

”Many women deliver their children alone or with family members or other untrained attendants who lack the skills to deal with complications during delivery,” said Dr LEE Jong-wook, Director-General of WHO. ”Skilled attendants are vital because they can recognise and prevent medical crises and provide or refer for life-saving care when complications arise. They also provide mothers with basic information about care for themselves and their children before and after giving birth.”

Reducing maternal mortality is a key factor in ensuring that all children, especially in the world’s poorest countries, survive and thrive through adolescence.

”These new estimates indicate an unacceptably high number of women dying in childbirth and an urgent need for increased access to emergency obstetric care, especially in sub-Saharan Africa,” said UNICEF Executive Director Carol Bellamy. ”The widespread provision of emergency obstetric care is essential if we want to reduce maternal deaths.”

The maternal mortality ratio, was estimated to be 400 per 100,000 live births globally in 2000. By region, it was highest in Africa (830), followed by Asia – excluding Japan (330), Oceania – excluding Australia and New Zealand (240), Latin America and the Caribbean (190) and the developed countries (20).

Worldwide, 13 developing countries accounted for 70 % of all maternal deaths. The highest number occurred in India where 136,000 women died, followed by Nigeria where there were 37,000 deaths.

In 2000, world leaders agreed to reduce maternal mortality by three-quarters by 2015, as part of the Millenium Development Goals (MDGs). Tracking progress remains difficult, except where comprehensive registration of deaths, including causes of death, exists. For this reason, the use of indicators such as the proportion of women who have a skilled attendant at delivery is essential to track change.

The use of skilled attendants at delivery in developing countries increased between

WHO/UNICEF/UNFPA Estimates of number of maternal deaths, lifetime risk and maternal mortality ratio, by MDG regions, for the year 2000

MDG region	**Number of maternal deaths***	**Lifetime risk of maternal deaths: 1 in:**	**Maternal mortality ratio** (maternal deaths per 100,000 livebirths)
World	529,000	74	**400**
Developed regions [2]	2,500	2,800	**20**
Europe	1,700	2,400	**24**
Developing regions	527,000	61	**440**
Africa	251,000	20	**830**
Northern Africa	4,600	210	**130**
Sub-Saharan Africa	247,000	16	**920**
Latin America and the Caribbean	22,000	160	**190**
Asia	253,000	94	**330**
Eastern Asia	11,000	840	**55**
South-central Asia	207,000	46	**520**
South-eastern Asia	25,000	140	**210**
Western Asia	9,800	120	**19**
Oceania	530	83	**240**

* includes Canada, United States of America, Japan, Australia and New Zealand.

1990 and 2000 from 42 to 52 %, suggesting a potential decrease in maternal deaths. Findings show the greatest improvements in South East Asia and Northern Africa and the slowest change in sub-Saharan Africa, which went from 40 % in 1990 to 43 % in 2000.

Most maternal deaths and disability occur as the result of one or more of three delays: a delay in recognising complications; a delay in reaching a medical facility; or a delay in receiving good quality care. Efforts to address these delays are essential in order to save the lives of mothers and babies.

Education on family planning and the provision of family planning services of high quality can also make a difference.

As the focal agencies within the United Nations systems for the health of women and children, WHO, UNICEF and UNFPA pledge to enhance – both individually and jointly in collaboration with their partners – their efforts in assisting countries strengthen their maternal health programs.

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WMA Secretary General

From the Secretary General’s Desk

It is fascinating to look back on the history of the World Medical Association (WMA) in this historic 50th edition of the World Medical Journal (WMJ). The roots of the WMA are described in an article of the British Medical Journal on October 5, 1946, where it was reported that physician’s leaders had met to discuss the establishment of the World Medical Association (WMA). This Association would ”promote closer ties between National Medical Associations, study the problems which confront the medical profession throughout the world, organise the exchange of information and establish relations with the World Health Organisation and present the views of the profession”.

Subsequently the WMA was formally established on September 18, 1947, and has grown into a formidable organisation. What I find most appealing of the work of National Medical Associations and the WMA is its dual purpose – serving the profession, but always making sure that the best interest of the patient remains our first consideration. This is one reason why medical leaders are often, as it should be, gifted social leaders. As the WMJ turns a new page and embarks on a new style, format and list of contents, we stand on the shoulders of these medical and social giants of the past and present to build an even greater WMA, the global representative body for physicians. We congratulate and wish Dr. Alan Rowe, our new WMJ Editor-in-Chief and his team all of the very best in this worthy endeavour.

Much has been done to promote the medical profession since the WMA General Assembly last met in Helsinki during September 2003:

Working against torture

The WMA, in partnership with the International Council for the Rehabilitation of Torture Victims (IRCT), has developed a successful project to help train physicians in the detection, documentation and treatment of torture victims, using the so-called ”Istanbul Protocol”. Funded by the European Union, the partnership has now completed the first phase of establishing links and building training centres in five pilot countries (Georgia, Morocco, Mexico, Uganda and Sri Lanka). One of the highlights over the last few months has been the determined efforts by Dr. Yoram Blachar, WMA Chair of Council (and President of the Israel Medical Association) to help establish these centres as he undertook the trip to Sri Lanka on behalf of the WMA;

Fight against SARS

The Canadian Medical Association was particularly effective in helping their members understand and combat the SARS virus when it hit that country during 2003. Building on the CMA example and following a resolution by the WMA General Assembly, the CMA and WMA are now preparing a new policy on NMA preparedness for epidemics. The WMA has been negotiating with WHO to develop a more effective communication channel and network to provide information and resources to NMAs and their members in times of epidemics such as SARS or the current Avian Flu;

Russian Medical Society (RMS) comes of age

It took the WMA four years of persistent and often difficult negotiations to identify and help develop a National Medical Association in Russia. When the Russian Medical Society was admitted as member to the WMA in 2002, it was a historic moment, long overdue. In this process, Dr Leonid Mikhailov, RMS Secretary General, deserves credit for his committed efforts to forge together medical groups in Russia and build links with the international community. Russia has such vast intellectual riches that a world body simply cannot afford to grow without the Russian medical leadership. During February 2004, this was strengthened even more when one of the fathers of Russian medicine, Prof. Valerie Pokrovsky, was elected as President of the RMS for the next year. Prof. Pokrovsky is also the President of the prestigious Academy of Russian Medicine and is thus in a very good position to further strengthen the uniting role of the RMS in the Russian medical profession;

Advocacy at the WHO

Never before in the history of the WMA have there been a stronger links and more collaborative work between the WMA and WHO. During the annual meetings of WHO, WMA leaders regularly present the views of the profession in a concise and forthright manner. Most recently the Chair of Council, Dr Blachar represented the WMA views on health promotion and healthy lifestyles at the WHO Executive Board Meeting during January 2004. Other examples of collaboration over the last 6 years include:

- The WMA has been a forceful partner and supporter of the Framework Convention on Tobacco Control
- Leadership of health professional groups in the World No Tobacco Day 1999
- Development of a policy on safe injections as part of the Safe Injection Global Network
- Development of a policy on Violence and Health
- Survey on Human Resources for Health
- Inclusion of the WMA in the Global Alert and Response Network for the combat of communicable diseases and now the development of a more comprehensive network to respond more rapidly and effectively against diseases such as SARS.

Even though it is reassuring that progress has been made, much still needs to be done. The WMA has as one of its stated objectives that every nation in the world should be represented in its membership. This ideal has not yet been achieved. Furthermore, the WMA Council has set some priorities for action over the next few years. The organisation will focus on medical ethics, health related human rights, the development of a database of physician and NMA information, and to be the foremost central advocate for the medical profession, especially at the level of WHO and other United Nations agencies. At the Secretariat, we are very excited about this growth of enthusiasm and energy in the organisation, and hope that all physicians and NMAs will unite and help build the WMA into a truly world class association. We owe this to our dual constituencies, our patients and our colleagues in the medical profession, the noblest profession on earth.

Regional and NMA News

Social Security is a National Security Issue

Eitaka Tsuboi, MD President, Japan Medical Association

The time for government intervention is when the national security of its citizens is threatened. That is why the national populace pays taxes to enable their national leaders to deal with national crises. If the Japanese government does not adequately address national security or the social security of its people, our country may undergo the experience of total national dysfunction.

To rescue Japan from this kind of crisis situation, it is vitally important for the government to pursue a national policy that will provide Japanese citizens with a sense of security. Fostering a national sense of security, removes apprehensions about the future and creates an atmosphere of social pace. A sense of security must be restored, in other words, national security must be definitely promised.

This must be regarded as a national task that is a segment of the overall national security strategy without diminishing social security as a safety net. The ultimate goal of social security is employment, i. e., the ability of individual citizens to contribute confidently to building society and the economy in good mental and physical health through gainful employment. What supports employment is health care, long-term care, education, pension, employment insurance and livelihood protection – components of the social security system.

The ability to work is developed through education, while national securityprotects our lives through health care. Employment insurance provides assistance in the unfortunate event we become unemployed. Livelihood insurance provides assistance when we experience permanent unemployment. Pension is remuneration for yielding our job to a younger person. Pensions help us maintain our livelihood in our twilight years as we prepare for death. Long-term care helps us through our final stage of life. The social security system is our common social capital that supports the cycle of transitions in our lives. The government has an obligation to permanently enhance this common social capital.

Social security is a dynamic system that is constantly evolving to enable us to live and work in prosperity. In terms of the health care sector, social security has evolved in tandem with the era of infectious diseases in the aftermath of the war, followed by the era of lifestyle related diseases, the current era of medical care for the elderly and the future era of preventive medical care. Japan has become a nation with the world's longest life expectancy and the lowest infant mortality rate. Although individual issues remain, the fact that the entire nation functions quietly on a system that guarantees these living standards for its people has raised Japan's national worth and has contributed to high quality human resources.

This social security system is a paramount task that maintains and strengthens national stability. As common social capital, social security must be strategically invested to achieve the combined components of health care, long-term care, pension, education, employment and others. Based on this fundamental recognition of the social security system, those of us who have been entrusted with the country's health care must fulfil the following three responsibilities.

1) Recognise that the universal national health insurance is national security. Strongly demand that the government substantiate, improve and strengthen the national health insurance system.
2) Secure that individual rights of citizens to have access to physicians at all time and in all areas throughout the country, in order to guarantee the equality of life.
3) Individual payments of medical expenses are required under the prevent system. However they should be limited to a 20 % maximum of the medical cost. In future, individual payments should be completely abolished.

Physicians should continue to advocate this responsibility while enduring the criticism and disapproval of market principle supporters.

Substantiating, improving and strengthening health care is a welcome means of maintaining and increasing the health of the national populace. But as we pursue the benefits that are derived from this process and those stemming from the introduction of advanced medical technology, there is always the risk that medical ethics will be abandoned.

At the time of my inauguration as the 52nd president of the WMA in Edinburgh, 2000, I discussed the subject of ”channelling the abundant benefits of advanced medical technology”. The JMA submitted a proposed declaration on this issue, and ”the WMA Declaration on Medical Ethics and Advanced Medical Technology” was adopted by the WMA General Assembly, Washington 2002.

A scientific session on the theme, ”Advanced Medical Technology and Medical Ethics” and ”The Internet and Health Care”, is planned for the WMA General Assembly, Tokyo 2004, and many successful developments are anticipated. It is hoped that the medical profession, which has been entrusted with the control of advanced medical technology and cutting-edge information technology in the 21st century, will raise its awareness about its responsibility of overseeing humanity’s health based on a code of medical ethics that is the essence of all medical practice.

I look forward to the contribution of your wisdom and the participation of all WMA member associations of the WMA Tokyo General Assembly.

Health Reform in Germany ”sustaining or diluting social insurance?”

Dr. Otmar Kloiber, German Medical Association

The German Health Care System (social insurance system) has been financed on the basis of contributions linked to wages and salaries. For many years now Co-payments have also been a feature of the system but these were only *set at a symbolic level.*

In a major reform act the government coalition with support of the opposition Christian Democrats have introduced multiple changes in the Statutory Health Insurance (Gesetzliche Krankenversicherung). The changes are of considerable concern to German doctors but will be of interest to others whose health care systems are based on this type of social insurance.

The major aim is the reduction of expenditure. As the financing of the SHI is based on contributions linked to wages and salaries, increasing cost for health insurance is being seen as an economic burden to the export orientated German industry. The following note indicates some of the major concerns about the changes in the SHI.

Co-payments

Co-payments have existed for many years but only on a symbolic level. Now they have been raised significantly and can in some instances reach 100 %, including prescribed ”Over-the-Counter”-Drugs (OTC), transportation costs, and many remedies including glasses. For hospital stays the co-payment has been raised from 9 Euros for a maximum of 14 days per year, to 10 Euros for 28 days per year. A 10 Euro co-payment is required for the first consultation with a physician in each quarter. If another physician is consulted without referral by a General practitioner, an additional co-payment is applied. It is thought that this will reduce the common ”doctor hopping” in Germany.

A limit of 2 % of annual income has been set on the yearly sum of co-payments for which participants are responsible. If co-payments exceed this value the excess is covered. For serious chronically ill patients (needing at least one physician consultation per quarter) the capping operates a 1 % of income. Certain exceptions much more rigid than in the past may however be set in the future.

Whilst in the past Pharmacists income depended in part on a percentage payment based on the cost of drugs, this has been replaced by a fixed pharmacy charge of 8.10 Euro. Whereas this has resulted in an increase in price for low-cost prescribed drugs, it has reduced the cost of the higher priced ones.

The introduction of these co-payments is highly criticised by consumer organisations and unions. Due to unclear wording in the law and lack of regulations at the time of implementation, many problems and arguments occurred.

Sick funds may provide some relief to their members by offering the use of internet pharmacies, which was previously prohibited, or of enrolment in a primary care model in which the insured would agree always to consult a GP first.

Definition of Basket

A common body of the sick funds, physicians and hospitals, will define the services and treatment that can be rendered under SHI. In the past this covered only ambulatory treatment, but now also includes the hospital sector. The decisions have to be based on evidence, thus giving Health Technology Assessment and EBM a strong boost. In addition a patients’ representative has been installed (Bundesbeand is to be heard before decisions will be taken). Furthermore the self-government of sick funds and providers has to introduce a new institute for quality matters. (The initial plan to copy the British National Institute for Clinical Excellence was not followed.)

Selective contracting – new provider types

While until now contracts between the sick funds and the ambulatory physicians only existed as group contracts negotiated between the ”umbrella” organisations of the sick funds and the association of the office based physicians (Kassenärztliche Vereinigung – KV) (a statutory body with obligatory membership), sick funds are now permitted to make contracts with physicians and groups of physicians directly on a limited basis. One percent of the budget for ambulatory treatment is to be set aside for such new types of contracts, whose number is planned to be increased in the future. At the same time new types of ambulatory institutions owned by third parties will be eligible to provide ambulatory treatments. Hospital emergency rooms, which in the past have been strictly limited to use for emergency cases, will also be eligible to provide ambulatory services.

Commentary:

The reform brings back some of the birth defects of the SHI, namely the high burden for the sick and a market (financial interest) driven system for the relations between sick funds and physicians.

In the beginning of the SHI, the sick funds only paid compensation for lost income. Over time it became more and more evident that it is better to care for the medical treatment in a comprehensive way, including financial protection. Access to care is limited by high co-payments. However, while one might correctly argue that contributing an extra 1 or 2 % of income is not very much, it hits especially the seriously ill patients. Often they already have only a very small income because of their disease or handicap. 1 or 2 % percent may be above what they can afford - just the money they can’t decide about. Taking this away may have effects on compliance.

In the beginning of the SHI it took more than 30 years to understand that selective contracting of physicians leads to a suppression of the provider side by powerful sick funds. Finally after years of strikes and fights the situation was resolved, as it was ordered by government and later by law, that contracts could only be made with the trade union of ambulatory physicians. The union was later transformed into a statutory body with obligatory membership for all physicians who wished to treat patients insured under SHI in ambulatory settings. Also, in order to avoid Sick Funds circumventing this mutual bargaining, they were not permitted to have their own establishment for ambulatory treatment or to contract with third parties. This gave enormous stability and prevented competition for prices.

The new regulation shifts the provision of ambulatory care towards a commodity business, as it will put financial considerations before medical ones. The same is true for permitting third parties e. g. commercial entities, to open ambulatory treatment facilities competing with established specialists and GPs.

Although there have never been formally mandated patient representatives in Germany, the patient’s voice has always been effective. If not, public movements resulted in change, and the courts decided very often in favour of patients and continuously extended benefits for patients. The underlying notion was that neither sick funds nor providers in their contractual relationship should be able to deprive patients of benefits. Now, with a formally installed patient representative included in the procedures, the argument that decisions were taken without participation of patients may no longer be applicable. This may lead to more effective limitation of the basket than in the past. Indeed the introduction of a patient representative may in the end do just this: limiting patient claims. In the context of the overall aim of the reform, namely limiting health care expenditure, this of course would be a success but at what cost to be principle of equity in providing for the needs of the sick

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The South African Medical Association’s work on the HIV/Aids front

The South African Medical Association (SAMA) has for years been the association taking doctors forward and into the future. As an Association with many social responsibilities, we have dedicated ourselves to fighting the HIV/Aids scourge.

In July 2001, SAMA criticised the government for their lack of direction in rolling out an HIV programme, and called on government to provide antiretroviral treatment (ART) to South Africans in the public sector. SAMA Chairperson, Dr Kgosi Letlape, said South Africa was the only country in the world where there was no policy for the treatment of HIV.

A year later SAMA praised government for the provision of Nevirapine for the prevention of mother-to-child transmission of HIV. Dr Anant Chetty, then Chairperson of SAMA’s Human Rights, Law and Ethics Committee, emphasising that doctors need not be afraid to prescribe HIV/Aids drugs, said ”Doctor’s ethical and moral rights are protected in our constitution, their clinical independence is fully supported by the Health Professions Council of SA and internationally by world health organisations.”

Yet, still adamant that a treatment programme was necessary, SAMA met with the Minister of Health in August 2002. In discussions with the Minister, Dr Manto Tshabalala-Msimang, SAMA re-cemented its views that an HIV/Aids treatment policy that includes the provision of ART was essential to slow down the impact of HIV/Aids in South Africa. Following the unsuccessful meeting with the Department of Health, SAMA continued to persevere in its efforts to facilitate treatment for people living with Aids, irrespective of the government’s position of not providing ART. After the meeting Letlape stated, ”We have not changed our position, and neither has the Department of Health. But both parties are committed to further dialogue, and we will continue urging the department to review its stance on making ART available in the public sector. Unfortunately time is not on our side. We would like to see the implementation of pilot projects for

HIV/Aids treatment in all provinces as a matter of urgency, and will pursue all possibilities towards facilitating treatment through efforts with other organisations."

Meanwhile, SAMA joined forces with the Treatment Action Campaign and the Nelson Mandela Foundation to strengthen its position in the fight against the disease.

SAMA has over the years used all means necessary to inform its members, and patients, on the right to treatment of HIV. SAMA has reiterated the profession's commitment to the alleviation of the HIV pandemic by all means possible, and affirmed its strong support for the fundamental rights of medical practitioners to clinical independence and autonomy. This includes the right to treat patients without undue influence, pressure or victimisation from employers or government institutions.

The Association then adopted a set of guidelines, "HIV Human Rights and Ethical Guidelines" which informed members how to deal with the management of HIV. Members were kept informed of rulings by the Labour Court regarding HIV through our Human Rights, Law and Ethics Unit, and adopted a document on "Doctors' and Patients' Rights and Responsibilities". What makes this document unique, is that it translates the human rights found in the South African Constitution into real-life situations affecting doctors and patients. A second distinctive feature is the inclusion of responsibilities or duties. For example, every doctor has the right to life, which includes the right not to be placed in disproportional life-threatening situations. But every doctor has the duty to protect life, within the confines of patient autonomy and decision-making power. On the other hand, patients have the right to have their lives protected by means of the benefits of medicine when available, and when they so wish. However, patients also have the duty to ensure that their illness or incapacity does not endanger the lives of others.

SAMA has always stressed the fact that its members were fighting the pandemic in their everyday work. "Medical practitioners are under an ethical duty to act in the best interest of their patients, who form an exceptionally vulnerable group in South Africa society," said Dr Chetty.

Doctors' clinical independence came under fire with the von Mollendorff case. Dr Thys von Mollendorff was dismissed for treating HIV-positive patients. SAMA worked closely with the Greater Nelspruit Intervention Programme (GRIP) and the Aids Law Project to see that the case was concluded for the positive. Letlape referred to the dismissal of Dr von Mollendorff as an example in which doctors' responsibility to their patients was severely disrupted, which was in direct contrast with the rights of individuals which are entrenched in the constitution. He emphasised that urgent discussion with government was needed to look at the principle of interference in the profession's obligations and duties on a broad scale. "We need guidelines and rules to stimulate and nurture private public interface," Letlape said.

SAMA continued to reiterate the profession's right to clinical independence and autonomy. Letlape referred to the 38th World Medical Assembly (WMA) in 1986 when the WMA unambiguously denounced political interference in health care delivery. "Physicians must have the professional freedom to care for their patients without interference. The exercise of the physician's professional judgement and discretion in making clinical and ethical decisions in the care and treatment of patients must be preserved and protected." The Association made it clear that it would continue to assist and support doctors who acted in the best interest of patients and their rights to access to health care.

Later Amnesty International (A.I.) urged the Minister of Health to put a stop to the harassment of health care professionals and other service providers in Mpumalanga Province, to end discrimination against women in need and to uphold professional ethics. A.I.'s involvement in this issue started in November 2001 when renewed action was taken against Dr von Mollendorff for his involvement in GRIP, which offered counselling and treatment to rape survivors. According to A.I., its correspondence with the relevant authorities requesting information on the issue remained unanswered.

As part of awareness campaigns the Junior Doctors' Association of SA (Judasa), an affiliate group of SAMA, created the Black Armband Campaign to show solidarity with HIV/Aids victims. Judasa emphasised that their campaign was not an attack on government, but rather an offer to assist in any government action aimed at fighting the HIV/Aids pandemic. As part of the campaign, junior doctors intended to keep thorough records of patients they saw dying of HIV. The records would then be sent to the relevant authorities, to share with government what junior doctors' experienced in dealing with the HIV/Aids pandemic every day.

Awareness campaigns continued with SAMA closely watching the development of the country's HIV/Aids programme.

On December 1, 2002 SAMA launched the Tshepang Treatment Programme, named after baby Tshepang who had been savagely raped and was put back together by caring doctors.

Nearly a year later the Association's dream came true – supplying ART to people living with HIV. On December 1, 2003, World Aids Day, SAMA launched an ART treatment programme at the GF Jooste Hospital in the Western Cape. The Association plans to gather more financial support from the role-players in the industry, and eventually have two treatment sites in every province.

SAMA's Foundation for Professional Development (FPD), the educational arm of SAMA, has developed an HIV management course for doctors and other health personnel. To date they have trained 3,500 health care professionals in South Africa, and also train health workers in Africa.

SAMA's motto is "Uniting doctors for the health of the nation," and we plan to do just so. KL/TS

Norwegian Medical Association

Health care for prisoners: human rights and ethical dilemmas for doctors working in prison - a web-based course for health care personnel working in prison

In 2001 the Norwegian Medical Association took the initiative to develop a web-based course on Human rights and ethics for prison doctors. Various associations and organisations have contributed to this course, and World Medical Association will be the main provider.

Doctors working in prisons face problems that are different from the problems encountered by doctors working with the ordinary population. Prison doctors must be able to provide adequate health care in the special environments to be found in prisons, and ensure that this practice does not conflict with international human rights and ethical standards.

In many countries education of prison doctors is a priority area. Many doctors do not even have access to international conventions and rules regulating the health care service for prisoners. We are aware that many doctors know about human rights violations, but do not know how to deal with them in an adequate way. We hope this course will contribute to meeting some of the needs for more knowledge and skills in human rights and medical ethics felt by many prison doctors.

The objectives of the course are to present relevant international statements regulating medical treatment of prisoners, and to raise prison doctor's awareness of their role in various areas of conflicting interests between the prisoner (patient) and the prison administration, e. g. during hunger strikes; the patient's right to confidentiality; certifying prisoners for special punishment etc.

The course will be accessible to everyone with an Internet connection. Doctors and other health personnel working in prison can take the course at their own pace and whenever they want. Participants do not have to complete the whole course in one go. The course is divided into lessons and the system remembers which lessons the participant has completed.

No course fee will be charged for those who wish to complete the course. When it is finished we will apply for approval at European Accreditation Council for CME.

This course is sponsored by The Norwegian Ministry of Foreign Affairs. The authors and editors have contributed without receiving any fees.

A preliminary version of the course is accessible at **http://www.lupin-nma.net/b.m.**

U.K.

New report details the impact of smoking on sexual, reproductive and child health

A new report from the British Medical Association presents a disturbing picture of the effects of smoking on sexual, reproductive and child health - and demands national and international action to tackle the issue. *Smoking and Reproductive Life,* a joint publication of the BMA board of Science and Education and the BMA-funded Tobacco Control Resource Centre, is the first focused overview of its kind.

The picture that emerges is disturbing. Smoking harms sexual and reproductive health in both men and women. Its damaging effects are seen throughout reproductive life - from puberty, through young adulthood and into middle age. Smoking can compromise the capacity to have a family, and parental smoking can have long-term and serious consequences for child health. Exposure to second-hand smoke is a risk during pregnancy, and harms infants and children.

The peer-reviewed report draws together material from more than 200 reference sources, including expert evaluations by the US Surgeon General and the World Health Organisation, as well as more recent original research. Among the effects linked to active smoking are impotence, sperm damage, delayed conception, infertility. increased risk of ectopic pregnancy and miscarriage. damage to the foetus, low birthweight, placental complications, premature birth. Smoking is also a cause of early menopause, and increases the risk of malignant cervical cancer up to three fold.

The effects of passive smoking are also highlighted. Non-smoking women exposed to other people's tobacco smoke during pregnancy have lighter babies. and are at increased risk of having a low birth-weight baby. Even relatively low-level exposure has a significant effect. In children, secondhand smoke is a cause of cot death, and increases the risk of respiratory illness and middle ear infection. It can cause asthma, and exacerbates attacks in those already affected.

The good news is that giving up smoking reduces or eliminates many of the risks to reproductive life and health. In contrast to much of the excess risk of death associated with smoking, much of the bürden of smoking on reproductive life falls in younger adults, before age 40. In coming years. this bürden looks set to increase: smoking rates look set to triple among women in the next generation, and more than half the world's children are exposed to secondhand smoke.

The report frames smoking as an important consideration in sexual, reproductive and child health. It makes recommendations to reduce the burden of sexual, reproductive and childhood ill health caused by tobacco. including recommendations for research, healthcare professionals and public policy.

The full report is available from the Tobacco Control Resource Centre website:

http://www.tobacco-control.org. For further information, contact: tcrc@bma.org.uk.

Reviews

Fiji and India

Licensing and Regulation

The WHO Bulletin WHO Bull. 82/2 reports concern that legislative delays are slowing down the progress of continuing medical education in India. ”The Medical Council has been campaigning for CME to be made compulsory” and has ”proposed a draft amendment to a law that would standardise medical practice across the country while making sure that it is up to date with the latest medical developments”.

The Fiji Medical Association is seeking revision of the Medical Act and is also encountering problems in generating political will to provide legislative time. The key issues are to bring the licensing requirements into line with global trends in 2004, to introduce obligatory CME as a condition for renewal of registration and to update professional disciplinary procedures. The Fiji Medical Association has also joined the Fiji Human Rights Commission to become actively involved in assessment of treatment of persons in custody.

Book Review

Medical Ethics Today: The BMA’s handbook of ethics and law (2nd edition). British Medical Association Ethics Department. Pp. xxv, 882, London, BMJ Books, 2004, £ 60.00

In 1993 the BMA published *Medical Ethics Today: Its Practice and Philosophy,* which was the fifth in a series of handbooks on ethics dating back to 1980. Now, a decade later, a revised version of the 1993 edition has appeared. Its greatly increased bulk, more than twice that of its predecessor, is largely due to the addition of legal issues that were formerly treated in a separate BMA publication, *Rights and Responsibilities* of Doctors. Indeed, the title of the present volume is somewhat inaccurate, since the law receives at least as much consideration as does ethics.

Unlike the 1993 edition, the authorship and status of this book is unclear. The front cover assigns authorship to the BMA Ethics Department whereas on p. xxiii the book is referred to as a publication from the BMA’s Medical Ethics Committee. The text frequently speaks in the name of the BMA (”In the BMA’s view …,”, ”the BMA believes …,”, ”BMA advice is that …,” etc.) but it is seldom evident what type of approval any particular statement has received within the BMA.

The book comprises an introduction and 21 chapters on topics ranging from the doctor-patient relationship to public health and from assisted reproduction to responsibilities after a patient’s death. Each chapter includes a statement of relevant principles, detailed treatments of the chapter subtopics with summaries of the main points, abstracts of pertinent legal cases, and extensive endnotes. The chapters are generally quite comprehensive in their treatment of the issues, as least insofar as they affect doctors in the UK. There are very few citations of publications from other countries.

Like the 1993 edition, the aim of this book is to produce a working tool for doctors rather than a philosophical treatise: ”Since doctors tend to need a quick and workable solution for an immediate case, the guidance focuses on practical responses to these common questions, but this process inevitably brings in reference to philosophy and law” (p. 2). For many issues the practical response is relatively unproblematic, since the legislators, the courts or the General Medical Council have already reached a conclusion and the book states categorically that ”it is … necessary to ensure that the action proposed is not contrary to law or to guidance issued by the GMC” (p. 10).

Other issues are not so clear-cut because the law and the GMC are silent or inconclusive. However, as with the unproblematic issues, the book encourages doctors to look for external advice rather than deciding on their own how to deal with the situation. The guidance provided by the book on these issues is derived from previous BMA statements, reports from various organisations, the ethics and legal literature, and especially standards of good clinical practice. Indeed, much of the guidance is neither ethical nor legal but rather descriptive of social and organisational factors that doctors need to take into account in their everyday practice. And when the guidance is specifically ethical, it is sometimes formulated in prescriptive terms without any ethical reasoning, for example, ”doctors with a conscientious objection to providing contraceptive advice or treatment have an ethical duty to refer their patients promptly to another practitioner or family planning service” (p. 233).

Where ethical dilemmas occur for which there is no explicit legal or regulatory requirement, the book recommends that the BMA Ethics Department and/or the medical indemnity bodies be consulted. However, in these circumstances the book frequently also recommends that doctors seek legal advice. The reader is entitled to question the value of this approach, since legal opinions can and do differ greatly, especially when the law is unclear, and seeking such advice is both time-consuming and costly. Clinical ethics committees, which in other countries have proved useful for dealing with ethical dilemmas, are mentioned only in connection with assisted reproduction.

Despite the book’s massive size, there are several topics that would have merited more extensive treatment. These include allocation/rationing of health care resources, particularly the role of the individual doctor; the participation of doctors in medical research, including their qualifications, compensation and responsibility for ethical committee review; the relationship of doctors and commercial organisations, especially pharmaceutical companies; multicultural health care; and ethics education in medical schools.

Doctors in the UK will find this book to be a useful reference for a great variety of clinical, professional and public policy issues. Since so much of the book is devoted to British law, however, it has limited applicability in other countries.

A CD-ROM version of the book, with a handy search feature, is included at no extra cost or can be purchased separately. Updates on the issues covered in the book are to be provided on the BMA Ethics web site.

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