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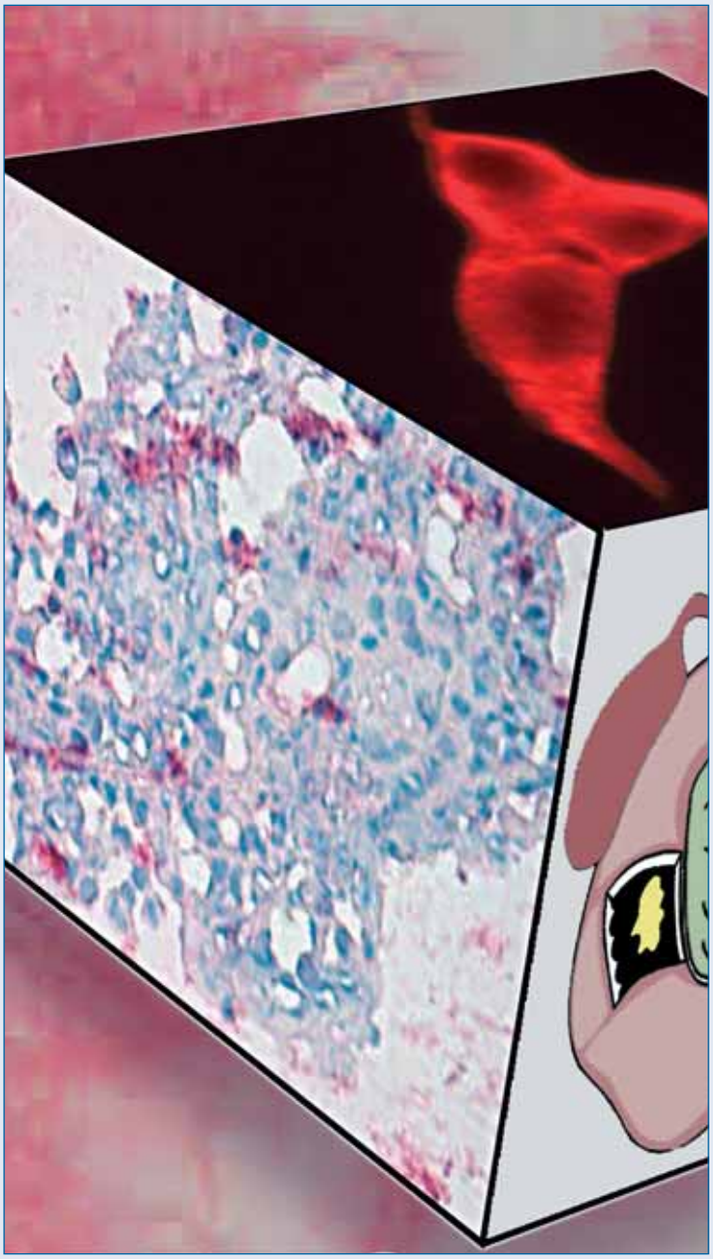

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Fifty Years Of Smoking Research

Sir Richard Doll*

The fiftieth anniversary of the first publication of the Journal of the World Medical Association also saw the fiftieth anniversary of the publication of the results of an epidemiological study[1] of the effects of something that many people at the time thought to be of little or no international importance, but which is now beginning to equate internationally with the big three: AIDS, Malaria and Tuberculosis. The study, which was continued for 50 years, was the first of a series of cohort studies of the effect of smoking, and was begun in October 1951 to test the validity of the conclusion that had been reached a year earlier[2] that cigarette smoking was "an important cause of carcinoma of the bronchus."

This conclusion had been based on the results of personal enquiries of 709 pairs of patients with and without lung cancer and had been tentatively supported, with varying degrees of strength, by seven other studies of a similar type in Germany, the Netherlands and the USA[3]. Few people, however, and no Government had taken the conclusion seriously. A new approach, by some different method of investigation, was evidently needed. In the UK this took the form of writing, with the help of the British Medical Association, to all doctors resident in the country and seeking details of their smoking habits, with the intention of following them for 5 years to see if knowledge of their habits would enable their risk of developing cancer of the lung to be predicted.

In the event, replies were received from over 34 000 male and 6000 female British doctors. Within 3 years the first results confirmed the predicted relationship. When, however, five years had passed and the study was planned to stop, other diseases began to be seen to be associated with smoking and observations were continued for 50 years, before the final results of the study were published earlier this year[4]. By then, other similar studies had been carried out in Canada, Germany, Japan, the Netherlands, Sweden and the USA. The associations observed with some 40 diseases had, for the most part, proved to be causal, and the epidemic of cigarette (or bidi) smoking, so much more hazardous than the smoking of pipes or cigars, had been shown to be a major cause of mortality in nearly all developed countries. In the extreme case of the UK, where the prevalence of cigarette smoking by young men had first became predominant, smoking was estimated to have been responsible in the mid 1970s for as much as 25% of all deaths (in men) from all causes[5]. For the regular cigarette smoker who persisted with the habit the average loss of expectation of life was 10 years and, of course, much more for the half of them who died prematurely as a result of their habit in middle age.

Fifty years, one might have thought, was more than enough for the lesson to have been learned and action taken internationally to counter the blandishments of the tobacco industry. But as smoking has been reduced in countries where the total effects first began to be seen, and a substantial proportion of smokers in them had abandoned the habit, the industry has turned its attention more and more to the billions of men and women in the developing countries, who have not yet had the bitter experience of seeing the worst effects amongst their own relatives and friends. That it will have a comparable effect in all countries is already clear, although the types of disease most affected will differ from country to country depending on the background distribution of disease – cancer of the lung everywhere, but chronic obstructive pulmonary disease, oesophagus cancer and stroke in China rather than myocardial infarction[6,7], and tuberculosis, most notably in some parts of India[8].

The lessons of fifty years are not, however, all depressing; for it is now clear that stopping smoking reduces the risk and can reduce it to a very large extent. In the study of British doctors who began smoking an average of 18 cigarettes a day at a mean age of 18 years, stopping around 50 years of age halved the risk, while stopping around 30 years of age almost eliminated it[4].

Editorial

The action of the World Health Organisation in seeking an International agreement to discourage the spread of smoking may be thought to have been unduly delayed, but it is welcome now and deserves the full support of the World Medical Association.

At the time of writing, this Framework Convention on Tobacco Control had already been signed by 168 of the 192 countries of the world and ratified by 24. It bans the promotion of the use of tobacco, prevents the industry from interfering in any legislation to improve public health, and inter alia requires the public to be fully informed about the hazards of smoking. If it succeeds it will have a major effect on mortality in the second half of the 21st century. It will, however, be possible to diminish seriously the 450 million deaths from smoking that are estimated to occur worldwide in the first half of the century if present smoking habits continue[5], only if there is intensive education to persuade current smokers to stop and to provide medical help for the many who are already heavily addicted.

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Public / Private Financing and Health Research

Financing of every aspect of health care has been of major concern at both national and international levels for decades. At the national level the more developed and sophisticated the society, the greater the political problem in seeking to meet the high expectations of the population. For the developing countries and relevant international bodies the concern is to ensure adequate support to finance health care for the major causes of morbidity and mortality, not only because of the threats to the individual citizen, but because of the impact of disease on the national economy.

Over the past two decades there has been a move to explore alternative methods of finance, notably the establishment of public/private financing partnerships. This applies to both countries with so-called nationalised health care systems such as the British National Health Service and other so-called "liberal" systems, in which, however, government regulation also plays a part even if only by regulating the activities of health care providers or insurance schemes.

Public/Private initiatives have been variously viewed with enthusiasm and scepticism. Nevertheless over the past few years there has been increasing experimentation with this concept, which has been encouraged by both the present and immediate-past Director Generals of the World Health Organisation. This is well illustrated by the Stop TB programme and the HIV/AIDS initiatives. In both cases partnerships involved both pharmaceutical and non-health related institutions. Collaboration included both funding of joint research initiatives and also facilitating the availability of measures to contain and reduce the incidence of specific diseases and also to provide appropriate treatment.

The recently announced potential breakthrough in anti-malarial treatment promises to add weight to the evidence of the value of public/private partnerships. In the World Medical Journal (WMJ(2004) **50** (2),p46), reference was made to the potential value of Artemisinin in the treatment of Malaria, one of the three great global scourges of morbidity and mortality. In a partnership involving several international funding sources (a non profit making organisation, a Generic drug manufacturer, scientists from various universities, a research Foundation and proprietary drug manufacturer), research has developed a new drug based on the structure of Artemesinin, which appears to be an even more effective anti-malarial than Artemesinin itself. Furthermore, this product, by avoiding the expensive and laborious extraction processes involved in extracting Artemesinin at present, the cost of treatment is likely to be one US dollar or less. This intensive research effort, made possible by the use of public/private partnership, will no doubt encourage the use of this financing mechanism for research relating to major international diseases. It is important to note that in the context of this initiative it is understood that any profits will be shared between one funder and the drug manufacturer, but that the profits will be re-deployed back into research. If the promise of the effectiveness of the new drug is confirmed in trials over the next two years, this promises to save a million lives a year in Africa alone.

The public/private financing mechanism is, of course, also being introduced at national levels in health care services. This is substantially in hospital development, but it is also emerging in funding treatment centres and other sectors of health care. Whilst there are marked divisions of opinion on the appropriateness of the application of this concept in this context, it is still too early to determine the outcome. One can only wait and see whether a similar success in the context of national healthcare provision occurs and how it will influence the debate.

Alan J. Rowe

Genetics Underlying Diabetes

Classification

Type I diabetes[1] is caused by an absolute lack of insulin, and its treatment is based on insulin replacement. Type I diabetes represents 15-20 % of cases of diabetes mellitus. The peak incidence is between 10-14 years of age. The incidence varies markedly from country to country (from about 3-40 cases/100.000/year) and is increasing in many countries. The average increase in European children under 15 years of age for example is 3-4 % each year.

Antigen targets for auto-immunity in pancreatic β-cells (islets of Langerhans) include glutanic acid decarboxylase and insulin. There are genetic and environmental influences – the major susceptibility is associated with human leucocyte antigen (HLA) class II immune response genes – but in more than 90 % of cases there is no family history of diabetes. Likely environmental triggers for type I diabetes in genetically susceptible individuals include toxins and viruses.

Type 2 diabetes[2] (which replaces the terms 'non-insulin-dependent' and 'maturity-onset' diabetes) is the commonest form of the disease, accounting for 85-95 % of all cases worldwide, and effecting 5-7 % of the world's population. The prevalence varies greatly throughout the world from less than 1 % in rural China to over 50 % in the Pima Indians of Arizona. Differences may result from the impact of the diabetogenic Westernised lifestyle (decrease in physical activity, lack of exercise; increased energy intake from excessive sugar, fats and 'junk' foods) on diverse genetic backgrounds – which may include 'Thrifty' genes that in evolutionary selection favour fat storage and/or build up of insulin resistance by the tissues.

It is estimated that the global prevalence of type 2 diabetes will have doubled by 2025, relative to 1995 figures, to a total of 270 million people. The greatest increases will be in the developing world, among economically productive adults aged 45-65 years.

Environmental risks for type 2 diabetes include obesity (which accounts for 90 % of acquired risk) and physical inactivity. Malnutrition in utero and infancy may predispose to type 2 diabetes in adult life by 'programming' pancreatic β-cell failure and the development of insulin resistance. Obesity, especially with abdominal and visceral fat accumulation, induces insulin resistance in the tissues and is associated with glucose toxicity and cardiovascular risk factors such as hypertension and dyslipidaemia. Potentially diabetogenic factors produced by adipose tissue include free fatty acids, which can interfere with glucose metabolism and therefore the action of insulin in liver and skeletal muscle.

Clinical presentations of type 2 diabetes include raised blood sugar, intercurrent urinary or genital tract infections – and as an incidental finding in 30 % of cases. In the UK fifty patients present with type 2 diabetes, and a further fifty don't know they are developing the disease (which can take several years). Hyperosmolar non-ketotic coma occurs, but ketoacidosis is rare unless precipitated by severe intercurrent illness, such as myocardial infarction or overwhelming infections.

Diabetic complications such as retinopathy, macular degeneration, nephropathy, neuropathy, coronary, cerebrovascular and peripheral vascular disease, in particular in the feet, are commonly found at diagnosis.

A new classification of diabetes was adopted in 1997 by the American Diabetes Association[3] and later in 1999 by a group of experts under the auspices of WHO[4]. This was based on aetiology rather than treatment. Type Ia (about 90 % of type I cases in Europe) is due to autoimmune destruction of the β-cells in the islets of Langerhans, and type Ib where these is no evidence of autoimmunity. Another diabetic subtype resembling type 2, but showing serological evidence of autoimmunity, is referred to as latent autoimmune diabetes in adults (LADA), comprising about 10-25 % of type 2 cases. There may be other forms of insulin-deficient diabetes. Modern techniques for hormone and receptor characterisation, together with molecular genetics, show diabetes to be a family of diseases. It is clear that people are affected by the immune process of the diabetic condition both before and beyond the stage of strict insulin dependence.

Genetic factors in diabetes

A striking feature of mature-onset diabetes is the strength of its genetic component, which is much greater than in type I diabetes – it is estimated to account for 40-80 % of total disease susceptibility. In identical twins type 2 diabetes is highly concordant (60-90 %), but in non-identical twins this is less so, at 17-37 %. The risk of developing type 2 diabetes increases strikingly if there is a family history of the disease, especially among the first-degree relatives.

Diabetogenic genes could influence either or both of the basic defects in type 2 diabetes, namely insulin resistance genetically expressed in the tissues or the inability of the pancreatic β-cells in the islets of Langerhans to secrete enough insulin. Candidate genes therefore include: (1) signalling mediators and enzymes on metabolic pathways (1 gene for each protein chain) that regulate the biological actions of insulin, and (2) components of the pancreatic β-cell energising secretion, together with mechanisms that ensure β-cell survival.

Many studies to date have attempted to locate and identify genes that predispose to type 2 diabetes, such as glycogen synthase

and its tandem repeat DNA polymorphisms, protein phosphatase and its regulatory subunits, coding regions for messenger RNA, and calpain – one of the proteolytic enzymes. It is now clear that no single major locus explains the inheritance of type 2 diabetes, and the disease is caused by the interaction of multiple genes operating in unison with environmental factors. The strongest evidence to date for a type 2 diabetes susceptibility gene is for a locus designated 'NIDDMI' on the short arm of chromosome 2, which accounts for as much as 30 % of the genetic susceptibility among Mexican-American sibling pairs.

'Thrifty' genes

During the course of human evolution, have some genes been rendered detrimental by progressive selection? Major stressors have been periodic food shortages, famine, and the resulting depletion of the body's energy stores. Some animals may be able to cope with this by hibernating through winter but in the case of humans, it was first suggested by Neel[5] (1962) that the evolutionary response could have been the selection of 'thrifty' genes which favour energy storage as triglyceride in adipose tissue. Candidate thrifty genes could include those involved with insulin resistance in the liver (regulating blood glucose levels) and in skeletal muscle (regulating protein synthesis). Such genes could promote substrate uptake into adipose tissue. Expression of the genes would be selected in populations living in extreme or precarious environments – indeed, such a selection process would have operated throughout human history.

So, at the present day, humans are poorly adapted from a tree-dwelling existence in the jungle to a modern environment of the 'concrete jungle' in cities. In the 21st century humans are forced to adapt to the novel stresses, in evolutionary terms, of overnutrition from 'junk' foods containing excessive sugar, fats and salt from an early age (even in utero), and lack of exercise. Such factors could explain the pandemic of obesity in the last 20 years among societies that have adopted a Western-type lifestyle.

Obesity

Total body adiposity, a central fat distribution, together with a duration and time-course of developing obesity, are all established risk factors for clinical diabetes in both sexes. Indeed, having a body-mass index (BMI) of >35 kg/m^2 increases the risk of developing diabetes over a 10-year period by a staggering 80-fold, as compared with slim individuals with a BMI <22 kg/m^2. Lifestyle factors such as diet and exercise account for 90 % of this excess susceptibility to type 2 diabetes, of which obesity is the most important. Biochemical factors promoting obesity include ageing, circulating free fatty acids, expressive glucose, and the action of local hormones in the tissues (cytokines). Genetic control of the central metabolic pathways into (a) protein synthesis, (b) free fatty acid utilisation from glucose via acetyl coenzyme A, or (c) synthesis of cholesterol and arterial plaque, all contribute to an increasing prevalence of diabetes.

Ivan M. Gillibrand

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Migration of health workers: Critical issues in the global debate

The following article deals with a major issue affecting all health professionals, but more notably doctors and nurses.

Unlike many resource problems, this one has major ethical and moral aspects, which need to be addressed by all concerned, including the professionals, both individually and collectively.

Orvill Adams*

The World Health Organization at the 57th World Health Assembly debated extensively the international migration of health personnel.[1] The existence of an important public health issue that had to be addressed was never in question. How to reverse current trends, and reduce adverse effects of migration of health personnel on service delivery ,was at the heart of the discourse.

The subsequent resolution recognized that action needed to be taken by all involved both in sending and receiving countries. The critical role played by health workers in tackling health problems, and the potential negative impact of migration on the delivery of health services is explicitly stated. Member States are urged to develop strategies, frame and implement policies, use government to government agreements and to do all of this with a view to strengthening health systems.

* Director Dpt. Health Service Provision, W.H.O. Geneva

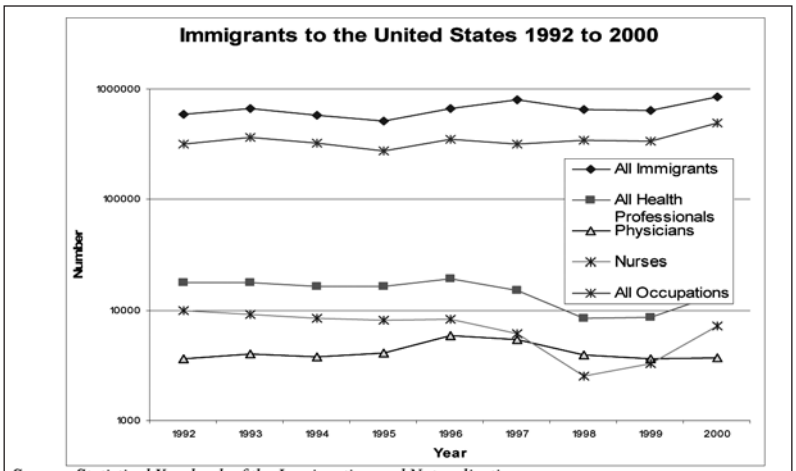
The need to engage a large and diverse number of stakeholders in tackling the issues of international migration of health workers is the focus of the resolution, which calls on the Director General of WHO to work with international organizations to monitor the changing situation, conduct research, and seek options to address identified problems arising from migration of health personnel.

The debate and the resulting resolution are far reaching, in that they acknowledge that to reverse and/or slow down trends, it is necessary to look at the workings of country health systems, and the labour market for different types of health workers. It also reinforces the notion that there are fair and unfair practices in international recruitment of health personnel.

The Commonwealth Code of Practice for the International Recruitment of Health Workers is noted, and the Director General is requested "to explore additional measures that might assist in developing fair practices in international recruitment of health personnel, including the feasibility, cost, and appropriateness of an international instrument." Also "to develop, in consultation with Member States and all relevant partners, including development agencies, a code of practice[2] on the international recruitment of health personnel, especially from developing countries, and to report on progress to the Fifty-eighth World Health Assembly."

Why this debate at this time

Over the past five years there has been a growing recognition of an impending if not an actual crisis, in health worker migration. The plight of nurses has been the primary focus, and organizations such the International Council of Nurses, the World Health Organization, the Commonwealth Secretariat, the World Bank, the Royal College of Nursing in the United Kingdom and others have undertaken surveys and commissioned studies that have described mobility trends, identified "pull" and "push" factors, and the policies and strategies being used by different countries.



Source: Statistical Yearbook of the Immigration and Naturalization Service 2001; Bureau of Citizenship and Immigration Services

Fig. 1 Trends in migration of professionals to the U.S.

While there are significant challenges in measuring migration flows due to differences in definitions of categories of health workers, in what constitutes the migration, and the lack of timeliness of data collection[3], there is growing agreement that the trend is rising. Stilwell et al.[4] argue that "The number of people migrating has never been higher than it is now and the majority of migrants are highly skilled."

Figure 1 shows that between 1992 and 2002 the trend in health professional migration is similar to that of other migrants to the United States of America. Data for other countries show similar trends. *Figure 2* uses data from the United Kingdom (and corroborates the trend in the US) to demonstrate that the trend in the movement of nurses is much more pronounced that that of physicians.

Aitken et al. refer to countries that receive migrating health workers as "host countries" and countries that send or export health workers as "source countries".

They recognize, however, that countries can be host and source countries at the same time.

The study examined six host countries, the United States of America, the United Kingdom, Ireland, Canada, Australia and New Zealand. They found that "each country's health workforce planning bodies project a sizeable increase in national requirements for nurses within the decade."[5] The authors suggest that the demands of these six countries are enough to deplete the sup-

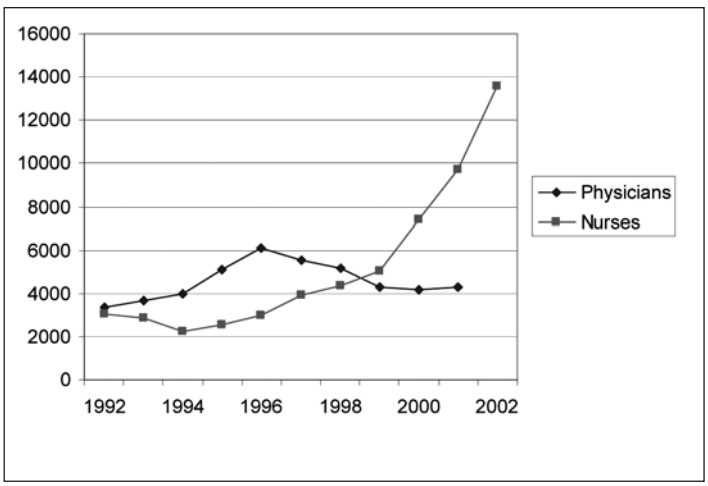


Fig. 2. Trend in migration of physicans and nurses to the UK

Table 1. Number of South African-born workers practising a medical profession in certain OECD member countries in 2001

Countries	Practitioners (1)	Nurses and midwives	Other health professionals (2)	Total
Australia	1114	1085	1297	3496
Canada	1345	330	685	2360
New Zealand	555	423	618	1596
United Kingdom	3282	2923 (3)	2451	8999
United States	2282	2083	2591	6956
Total	8921	6844	7642	23 407

1. Doctors, dentists, veterinarians and other diagnostic practitioners.
2. Including assistants.
3. Possibly including some assistant nurses.
Source: OECD, Trends in International Migration- ISBN 92-64-01944-8

ply of qualified nurses throughout the developing world.

There has not been as much focus on the migration of physicians. A study released in 2002[6] finds that within the OECD countries there is a reliance on foreign physicians. The percentage of the workforce from other countries, ranged from a low of 1.9% in Austria to 21.3% (1998) in Australia, 23% (2001), 25 % (1998) in Canada and 31% (2001) and 34.5% (2000) in the United Kingdom and New Zealand respectively.

The OECD conducted a case study of international mobility of health workers from South Africa. The study found that in the year 2001, 23,407 South African-born workers were practising a medical profession in the five OECD countries shown in Table 1. The report states that South African health workers are appreciated for their professional and language skills.

A recent report by Physicians for Human Rights states that “By one measure, about 50% of graduate physicians emigrate within 4.5 years and 75% within 9.5 years. Further, during the 1990s, 1,200 physicians were trained in Zimbabwe; only 360 were still practising in the country in 2001”.[7] Ethiopia is said to have lost one third of its physicians during the period 1988 to 2001.

Internal migration

International migration compounds internal migration from the public to the private sector. The Report of the Physicians for Human Rights above states that “Zambia's public sector has retained only 50 of the 600 physicians that have been trained in the country’s medical school from approximately 1978 to 1999”.[8] Awases et al[9] in a study of migration of health professionals in the six African countries of Cameroon, Ghana, Senegal, South Africa, Uganda and Zimbabwe found that internal migration is a large and growing problem for the public health sector.

This concern is highlighted by the following example from South Africa “In 1998, 52.7% of all general practitioners and 76% of all specialists worked in the South African private health sector. By 1999, 73% of general practitioners were estimated to be working in the private sector in South Africa, despite the fact that this sector catered for less than 20% of the population”.[10] The movement from the private to the public sector is often accompanied by movement from the rural to urban areas, resulting in increased inequities in the delivery of health services.

Factors affecting the movement of health workers

The migration of health workers is affected by personal and external or environmental factors. These include political and socio-economic differences between countries, as well as formal and informal information networks for migrants and prospective migrants. Authors [11,12,13] have identified “pull” and “push” factors. Poor working conditions, low wages, economic instability, health and safety concerns are some of the "push" factors. Opportunities to earn higher wages, to have better working conditions, access to education and career advancement, are among the “pull” factors. These factors are interrelated and will take on different degrees of importance in the decision of the prospective migrant depending on age, economic and social position in their country.

It is important to note that the relative importance of the "push and pull" factors differ across countries. An unpublished WHO African Regional Office study of six countries found that health workers, when asked if they had an intention to migrate, responded with the proportions of those saying yes ranging from 26% in Uganda to 68% in Zimbabwe. The four

top factors affecting their decisions were their expectations for better management of health services, continuing education and training opportunities, conducive working environment and better and realistic remuneration for their work. Prospective migrants from Ghana gave more weight, for example, to better management of health services and to a conducive working environment than did health workers interviewed in the other countries.

Ethical recruitment

Aggressive recruitment of health workers has attracted a lot of international attention and some of the practices have been viewed as unethical and unfair. This notion of unethical and unfair includes the impact of the practices on the individual health worker as well as their impact on the health systems from which the health worker is recruited. The ICN describes aggressive recruitment campaigns as "focussing on large numbers of recruits, sometimes significantly depleting a given health facility or contracting an important number of newly graduated nurses from a given educational institute…. Nurses may be employed under false pretences or misled as to the conditions of work and possible remuneration and benefits."[14]

The aggressive recruitment of health workers from vulnerable health systems has resulted in a call for ethical recruitment practices. These practices are voluntary and have not yet proven to be very effective. The codes can be put into three categories based on the source of their development. In the first, the Department of Health in England has developed two instruments, one in 1999 and the other in 2001. The codes are aimed at protecting vulnerable developing countries from the recruitment of nurses unless there is an agreement between England and the respective country. Ireland developed a similar instrument in 2001.

The second category is that of multiple governments. The Commonwealth code of practice for international recruitment of health professionals was developed by the Commonwealth Secretariat at the instigation of the member countries.

In the third category are non-governmental membership organizations The International Council of Nurses, the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians, the Royal College of Nursing in England, and a group of independent sector employers have also developed and adopted statements that can be said to be in support of ethical recruitment practices.

Willett and Martineau, after conducting an analysis of the above instruments, concluded that "it is currently far from clear whether codes of practice or other such instruments – on ethical international recruitment of health professionals-will actually succeed in protecting developing countries health systems."[15] The authors call for more focus on the ethical recruitment objective of existing or new codes. Improved data collection systems on international recruitment to facilitate monitoring of the implementation of the codes and more sustained external pressure to apply the code are also required.

Conclusion

The recruitment, retention and migration of health workers requires concerted efforts by a mix of nationally based and international stakeholders. The factors determining why health workers choose to move or stay are complex. There are no simple solutions. More evidence is needed and this requires the active and willing participation of governments, employers and professional bodies at national and international levels. Health systems have to be strengthened to provide better conditions and opportunities to practice one's career while getting fulfilment from being able to practice one's profession. All interested parties-, governmental, non-governmental, health care providing agencies and the health care professionals themselves – will have to address the moral and ethical issues underlying the problems of recruitment and migration.

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Biomedical Research In Europe

New International Legal Instruments

Elmar Doppelfeld

Biomedical research as part of science has ,since the end of the 2nd World War, traditionally been performed in an international context, which includes exchange of results, errors and benefits. Some aspects of this scientific sector are subject to some regulation by specific provisions within legislation covering broader frameworks, such as those covering the use of personal data for medical epidemiological research. For decades there have been no international legally binding instruments covering the entire area of biomedical research on humans. Nevertheless, most medical researchers followed the Declaration of Helsinki (1964) as amended in Tokyo 1975 and subsequent later amendments.(3) The International Ethical Guidelines of CIOMS played a similar role addressing researchers in medicine and other disciplines (5).

Research is becoming more and more complex with respect to the aims, the methods used, and involving researchers coming from both medical and non-medical scientific disciplines. Research entails the risk of violations of human rights and basic ethical principles. Therefore States are more and more disposed to regulate this sector by national legislation and no longer leave it to professional standards established by the professions and codes of ethics alone. This new thinking was in part prompted by the developments in in-vitro-fertilisation techniques. Taking into account these and other developments in biology and medicine, the Council of Europe decided to establish a special Steering Committee on Bioethics (CDBI), for consideration of ethical and legal questions linked to these new research practices and their application in humans. As a result, one remarks more and more national and international efforts to implement legally binding instruments regulating research on humans. Regarding the transborder flow of research, it has been recognised that there is a need to base national legislation on international legal provisions.

The following two examples illustrate the importance of these developments to the medical profession, its national and its international organisations.

Directive 2001/20/EC

In 2001 the European Union adopted the "Directive 2001/20/EC" (4) on good clinical practice in research on drugs for human use within Member States. In implementing the provisions of this directive in national legislation (which was required at the latest by 1st of May 2004), Member States are allowed to deviate to some extent if the intentions of this European law are not altered. The directive covers the whole field of drug research in the course of which it also introduces changes in the meaning of some terms used by the medical profession in this field. In contrast to the traditional understanding, the directive defines (Art.2) "sponsor" as an "individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial." The sponsor, understood in that sense e.g. as interpreted by the new German drug law of 5 August 2004, has in addition to other obligations, to negotiate with the ethics committees and the competent national authority. Members of the medical profession are no longer the only partners of an ethics committee established at their medical association or their Faculty of Medicine. This is also introduced in the new definition of an investigator. In future, the function of an investigator or of a principal investigator in drug research is no longer restricted to physicians. The directive definition states "investigator": a doctor or a person following a profession agreed in the Member States, for investigations because of the scientific background and the experience in patient care it requires." The Member States as already mentioned, have some freedom of interpretation. The new German drug legislation uses this right by prescribing that an investigator, a principal investigator or a coordinating investigator should be a duly qualified physician. Any exception to this basic principle has to be justified to the ethics committee.

The status and the rights of ethics committees are widened. The directive obliges the Member States to establish a system of ethics committees (Art 6), leaving all specific details to national law. Germany decided to maintain the well proven system of ethics committees in the Faculties of Medicine and the Medical Associations within the States ("Bundesländer"). In the future, drug research on humans may only be started following the favourable opinion of an ethics committee and "inasmuch as the competent authority of the Member State concerned has not informed the sponsor of any grounds of non-acceptance" (Art. 9). In this

way, in incorporating the provisions of the directive into the new German drug law, the vote of an ethics committees has changed its character from that of advice to the researcher to a legally binding decision. Fearing for good reasons some kind of liability coming from this new status of the vote, Medical Associations in Germany discussed refusing the duty to maintain their ethics committees for the new purpose imposed by the Federal Drug Legislation, although technically these professional bodies and institutions are bound by Lande law.

There are a number of other implications for change in carrying out drug research in this EU Directive. These cannot be outlined in this short communication which only aims to highlight key issues. The directive calls for detailed study and, bearing in mind the global nature of drug research,will merit study by the relevant sector of the profession outside Europe.

Protocol "Biomedical Research" of the Council of Europe

The "Convention on Human Rights and Biomedicine"(2) of the Council of Europe, opened for signature in Oviedo on 4 April 1997 and has been signed by more than 30 and ratified by 18 Member States. It outlines the basic principles for the protection of human rights and dignity with regard to the application of biology and medicine in humans. This convention, also known as "Convention of Oviedo" permits regulation in special fields such as organ transplantation or biomedical research in human in additional protocols in accordance with the principles of the convention itself. Only States which have signed and ratified the convention are admitted to sign and to ratify these additional protocols. By signing and ratifying the Convention and additional protocols, Member States implement these international treaties into their national legislation, normally giving them by this procedure a high position in the internal hierarchy of legal provisions.

On 30 June 2004 the Committee of Ministers of the Council of Europe adopted the additional protocol concerning biomedical research (1). It is planned to open it for signature on 18 October 2004 in Oslo. This protocol respecting the principles laid down in the Convention of Oviedo addresses medical as well as non medical researchers, who carry out biomedical research in humans. As there is no restriction of this type of research to physicians, the term "physician" or the term "doctor" does not appear.

The protocol covers various types of research. Research on healthy volunteers without a potential direct benefit for the person concerned and aimed to achieve basic knowledge, e.g. in human physiology, is included, as well as research linked to clinical care. Attention is given to special conditions such as pregnancy, or the situation of persons deprived of liberty. Research on the latter group is in some Member States of the Council of Europe permitted, in others it is strictly prohibited. This situation shows the difficulty, as in many other fields, to find a legal solution which satisfies all the different views. Usually such problems are left to national legislation. The additional protocol sets the conditions under which such a derogation can be used.

Research with potential direct benefit for the person concerned in emergency situations and on persons not able to consent is widely accepted and is also addressed in the protocol. In contrast, research on persons not able to consent – e.g. minors, victims of traffic injuries, persons suffering from dementia such as Alzheimers disease – without the potential direct benefit for the participant concerned but with an expected benefit for the group, entails major legal problems in some Member States. The protocol requires that the State concerned should provide a legal clarification of the conditions to be respected for that research, in first line: minimal risk and minimal burden. Leaving the special legal position of ethics committees to the internal legislation of the Member States, the protocol prescribes precisely how to fulfil the basic condition of informed consent of participants in research and the duties of representatives of persons not able to consent. There are precisely elaborated chapters on how to inform the participants and how to inform the ethics committees. The list of items to be used for the application to seek an ethics committee's assessment should serve as a tool for the harmonisation of research in humans in the Member States of the Council of Europe.

In addition to the scientific quality of the project, legal aspects and ethical considerations, the ethics committee has for example to know something on contracts between researchers and participants, financial remuneration or other awards for both parties, how to offer to the individual findings relevant for his or her health, publication of results and safeguarding that any necessary healthcare is not delayed for research reasons. The protocol allows the use of placebo only under the classic conditions: no methods of proven effectiveness exist or the withdrawal or withholding of such methods does not present an unacceptable risk or burden. In contrast to the Declaration of Helsinki 2000, scientific reasons as such are not accepted as justification for the use of placebo.

It should be stressed that the protection of the rights of the participants is the leading aim of the protocol, in the same way providing the necessary framework for research of a high scientific level in accordance with accepted principles of ethics and human rights.

Details of that new international legal provision can be found in the text itself.

Final considerations

The new international legal instruments for biomedical research in humans as a basis for legislation in the Member States of the EU and in the 45 Member States of the Council of Europe, (representing about 800 millions of habitants) will replace as tools of first legal choice traditional and without any doubt, proven regulations coming from other groups such as the World Medical Association or Medical Associations in the States concerned. In any case of conflict, the national or international legal provisions prevail over regulations coming from a non-legal source. In a State which, for example, has adopted the additional protocol on biomedical research, the use of

placebo is only permitted under the conditions of that protocol. A physician who follows the wider provisions of the Declaration of Helsinki, using placebos also for scientific reasons as the only justification, could be found guilty by a court. On the other hand, if non-legal provisions give a range more narrow as compared to the research protocol, the researcher may always decide to stick to legal provisions as justification.

Nevertheless, the recommendations of the NGOs mentioned will not become worthless in the future. Legislation may adopt them as an auxiliary tool for regulation inasmuch they are in accordance with national and international legally binding instruments. They may as recommendations or principles given by the profession be of assistance, for example to physicians, in deciding whether or not to perform research under the legal conditions of the country in which they are living. Members of the profession should respect these recommendations and principles in decision making, but they must follow the legal frame given for research.

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UN Standard Minimum Rules for the Treatment of Prisoners

Following a recent decision of the Board of the Norwegian Medical Association, the President, Dr. Hans Kristian Bakkem, has written in the following terms to all national medical associations seeking their support in actions to ensure the full implementation of the UN Minimum Rules for the Treatment of Prisoners.

“With reference to recent disclosure of episodes of torture and other degrading treatment of prisoners in Iraqi prisons:

Recalling UN Standard Minimum Rules for the Treatment of Prisoners which state:

“At every institution there shall be available the services of at least one qualified medical officer who should have some knowledge of psychiatry. The medical services should be organised in close relationship to the general health administration of the community or nation. They shall include a psychiatric service for the diagnosis and, in proper cases, the treatment of states of mental abnormality.” The Norwegian Medical Association (NMA) is concerned about prisoners' health not only in Iraq but also in other countries, where international regulations are being violated. The Norwegian Medical Association would emphasise physicians' ethical obligation to speak out against torture and/or other degrading treatment in prisons, whenever disclosed.

Governments, as well as penal authorities should accept physicians’ obligations in this respect. They should also inform and encourage their physicians to speak out regarding inhuman and/or other degrading treatment.

The Norwegian Medical Association encourages all National Medical Associations to call upon their governments to organise prison health care according to the international regulations mentioned above.” *[June 2004]*

Medical Associations and Global Health Emergencies – The Canadian Experience

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Introduction

In a world that seems characterized by an increasing number of natural disasters, terrorist threats and an array of new diseases that can travel around the globe at jet speed, all nations, now more than ever before, need to be adequately prepared to respond to an emergency situation. During a large-scale health emergency such as an emerging infectious disease outbreak, while public health is often the first line of defense the resources of the entire health system will be called upon to respond to the crisis. In 2003 both the resources and the resourcefulness of Canada's public and acute care health systems were put to the test when Severe Acute Respiratory Syndrome (SARS) entered the country. While SARS brought out the best in Canadians' commitment to one another, it also turned a bright, sometimes uncomfortable spotlight on the ability of Canada's health care system to respond to a crisis.

During the SARS crisis, the critical role played by physicians and their professional associations quickly became apparent. This paper will briefly review the course and impact of SARS in Canada; outline the role of the Canadian Medical Association (CMA) during and after the crisis; review the evolution of public health policy in Canada post-SARS; and reflect on the role of the World Medical Association (WMA) in preparing for future health emergencies. A companion article that addresses the role of the CMA and lessons learned during the SARS outbreak can be found in Business Briefings: Global Healthcare – Advanced Medical Technologies 2004, prepared for the WMA[i].

The Course of SARS in Canada

On February 23, 2003 SARS entered Canada. In the manner of many emerging infectious diseases it entered quietly and initially went unrecognized. Canada's first SARS death occurred before the WHO issued its initial global alert on March 12th. By the time Canada's SARS outbreak was declared over at the beginning of July 2003, 44 people had died. Overall 438 SARS cases, 251 probable and 187 suspect, were reported in Canada during the period of the outbreak and tens of thousands of individuals, including hundreds of health care workers, were quarantined.

The entire health system, from preventive public health through acute care to long-term care, was severely disrupted in Toronto, one of Canada's most populated and medically advanced cities. Local public health authorities in the Greater Toronto Area (GTA) as well as their provincial counterparts, diverted almost all of their resources to respond to the crisis. Many public health professionals from outside the GTA volunteered weeks of service to assist in the response, sometimes leaving local public health units elsewhere in the country with significant human resource gaps in their own ongoing programs.

Acute care services were also adversely affected as stringent infection-control and screening measures were put into place to control the spread of SARS. Institutions closed their doors, limiting access to emergency departments, clinics and physicians' offices. Intensive care units were full and surgeries were cancelled. Front-line health care professionals involved in critical care were stretched to their physical and mental limits. Remarkably, others found themselves underutilized due to the impact of the infection-control measures on their practice settings. "Feast and famine" co-existed.

Although the GTA bore the brunt of the impact of SARS, the entire province of Ontario and indeed all of Canada was affected. Business suffered. The tourism industry was severely impacted. The disruption that SARS caused continues to reverberate through the health care systems and economies of Canada.

The Role of the Canadian Medical Association

Front line physicians played a critical role in the health emergency, both in terms of the public health and laboratory response, and in their community and institutional acute care roles. During the outbreak physicians were engaged in identifying and tracking down the emergence, cause and modes of transmission of a new disease, and caring for patients in an environment of shifting and evolving clinical knowledge. They collaborated with researchers and scientists to determine optimum therapy and clinical best practice guidelines. And through all of this clinicians dealt with the personal stress, anxiety and burnout associated with a desperate race to control and contain the unknown, in a context of human resources inadequate to function optimally even in normal circumstances.

The CMA's primary goal was to support physicians during the crisis. It became apparent very early in the outbreak that governments did not have the ability to communicate in real time with front line clinicians across the country. CMA and its provincial counterpart, the Ontario Medical Association (OMA) moved quickly to plug this gap.

CMA activated its national electronic communication networks to alert physicians to crucial information such as public health management guidelines, about SARS. A dedicated website, e-mail and fax broadcasts to physicians, coupled with the support and assistance of provincial divisions and national speciality affiliates, meant that over 90% of physicians in Canada had access to relevant expert information about SARS as it became available. The OMA was critical to ensuring the flow of information to clinicians in Ontario, Canada's most affected province. The association used its web site, fax and e-mail networks as well as

personal telephone calls when necessary to ensure that clinicians received pertinent information that was clear, consistent, and relevant. During the early days of the outbreak the OMA communicated with its membership every 24 to 48 hours and its web site was updated frequently.

Throughout the crisis, the CMA maintained close liaison with Health Canada, federal, provincial and territorial public health authorities and relevant national medical organizations, notably the Canadian Infectious Disease Society and the Canadian Association of Emergency Physicians. The CMA also co-ordinated regular meetings of non-physician national health professional organizations, including the Canadian Nurses Association and the Canadian Public Health Association, to facilitate rapid information-sharing among all health care providers.

Facilitating communications, reviewing information, and providing the clinician perspective on government directives became a key activity for medical associations during the SARS outbreak. The CMA also ensured that the physicians' voice was heard at Federal decision-making tables during the crisis. It must be noted that while governments eventually welcomed this assistance, the valuable role that professional associations can play during a crisis had not been considered in their emergency planning and was not uniformly embraced or recognized as the outbreak unfolded.

Evolution of Canadian Public Health Policy Post SARS

As the crisis subsided, a number of national and provincial committees were set up to examine the country's response to SARS. In June 2003, *Answering the Wake-Up Call: CMA's Public Health Action Plan*[ii] was submitted to the National Advisory Committee on SARS and Public Health (Naylor Committee) established by the Federal Minister of Health to report on learnings from the SARS outbreak. The CMA has a long tradition of participating in the development of health policy in Canada. It has always been a very vocal advocate for a strong and effective health system and had repeatedly called for governments to enhance public health capacity and strengthen the public health infrastructure.

The CMA's action plan focused on three key areas: legislative reform, capacity enhancement and communications. Key recommendations included:

- A national public health agency led by a chief public health officer
- Increased funding to strengthen the public health infrastructure and increase capacity
- A real-time communication and coordination initiative for front line clinicians.

Similar recommendations were also made in the CMA submission[iii] to the Canadian Senate Standing Committee on Social Affairs, Science and Technology's (Kirby Committee) study of the governance and infrastructure of the public health system in Canada and its response during public health emergencies.

SARS was indeed a wake up call to the deteriorating condition of Canada's public health system and to the country's ability to respond to a health emergency from a health care system perspective. Both national and provincial inquiries pointed out many systemic deficiencies in the response to SARS. Lack of surge capacity in the clinical and public health systems; difficulties with timely information sharing among levels of government; lack of co-ordinated business processes across institutions and jurisdictions for outbreak management and emergency response; inadequacies in institutional outbreak management protocols, infection control, and infectious disease surveillance; and weak links between public health and the personal health services system, including primary care, institutions, and home care were some of the problems cited.[iv]

There has been a consistency in the recommendations of the main inquiries into the impact of SARS on the health care system and these recommendations reflect those made by the CMA. All inquiries have stressed the need for a coordinated collaborative framework among different levels of government. This coordination of activity should be integral to the core functions of public health and is essential to an effective response during times of crisis. The rules for a seamless public health system must be sorted out in advance of a health emergency in a spirit of partnership and shared commitment to health. Both the Naylor and Kirby reports called for the establishment of a national public health agency in Canada with authority to provide leadership and action on public health matters such as national disease outbreaks and emergencies. It was further recommended that a Chief Public Health Officer of Canada head up the Agency and serve as the national voice for public health particularly during health emergencies.

The need for new funding to shore up the public health infrastructure in Canada was also widely recognized. In addition, the importance of disease surveillance and dissemination of information to clinical and public health information systems and relevant stakeholders was raised in provincial and national reports.

Governments wasted no time in responding to the lessons learned from SARS. In September 2003 the Canadian Conference of Federal/Provincial/Territorial Ministers of Health acknowledged the need to work together to improve public health infrastructure, and increase institutional, provincial, territorial and federal capacity. They also agreed to work collaboratively on such issues as clarifying roles and responsibilities of the differing jurisdictions when responding to public health threats; ensuring the adequacy of health human resources; strengthening capacity to respond to regional and national public health emergencies; and enhancing national surveillance and information infrastructure.[v]

In the fall of 2003 the federal government accepted many of the recommendations of the Naylor report and appointed the first ever Minister of State for Public Health. It committed itself to the establishment of a national public health agency and a chief public health officer. The 2004 Federal budget directed new investment to public health in Canada. Details of the new Public Health Agency for Canada were announced in May 2004 as was the creation of six National Collaborating Centres for Public Health.

While SARS in Canada was an undeniably tragic chapter in Canada's history it did serve to bring attention to the plight of the public health system and has spurred the federal and provincial governments to strengthen public health systems and capacity to be better prepared in the future.

The lessons learned from SARS in Canada and the steps being taken to improve the public health system and its emergency preparedness and response capabilities may be of value to others as they assess their own state of readiness.

World Medical Association

The World Medical Association has recognized the critical role of physicians during a health emergency. Physicians are often the first point of contact with the emergence of new diseases, and therefore are in a position to aid in all elements of diagnosis, treatment of affected patients and prevention of disease. At its September 2003 General Assembly, the WMA adopted a Resolution on SARS that: "strongly encouraged the World Health Organisation to enhance its emergency response protocol to provide for the early, ongoing and meaningful engagement and involvement of the medical community globally."

In the aftermath of SARS, the WMA and the CMA have worked closely together to examine the lessons learnt for physicians and medical associations. A discussion paper, *SARS in Canada*,[vi] informed the deliberations of the WMA Socio-Medical Affairs Committee on implications of the SARS experience for physicians in Canada. Key among them is the need for:

- a co-ordinated system to notify acute care facilities and front line health care professionals of global health alerts and ensure real time communication of critical information to physicians;
- cross training to boost surge capacity by equipping health professionals with the knowledge and skills that can be called upon in times of health emergency;
- rapid distribution of supplies of protective equipment to health professionals and their patients to reduce anxiety and the spread of infectious disease
- the incorporation of physicians with key expertise into the health emergency decision-making process so that the impact of directives on clinical settings and patient care is understood.

These implications apply, in general terms, in all countries of the world, no matter the type, structure or capacity of the health care system.

In May 2004 the WMA Council adopted a resolution on health emergency communication and co-ordination which includes recommendations for physicians, national medical associations, national governments and the WHO. The resolution seeks to improve physician reporting of suspicious illness; disaster preparedness and response protocols for infectious disease outbreaks; coordination of stockpiles of supplies; and international co-operation on emergency communication.

Conclusion

A dispassionate assessment of the experience with the SARS outbreak of 2003 clearly indicates that the global medical community and the global public health community must strive to build mechanisms together, and also with governments, to closely link the clinical, public health and government responses to emerging infectious diseases, and bridge communications between these communities.

The WMA will seek, in partnership with the WHO and others, to develop a Health Information Communication initiative that meaningfully does just this, both in times of global health emergencies, and also in times of routine health system operations.

i Avaliable at: http://www.touchbriefings.com/cdps/cditem.cfm?NID=950&CID=5&CFID=1688258&CFTOKEN=90

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iii Available on the CMA website at http://www.cma.ca/index.cfm/ci_id/40463/la_id/1.htm

iv Learning from SARS: Renewal of Public Health in Canada; A Report of the National Advisory Committee on SARS and Public Health, Health Canada, October 2003; http://www.hc–sc.gc.ca/english/protection/warnings/sars/ learning.html

v News Release, Conference of Federal/Provincial/Territorial Ministers of Health, Halifax, Nova Scotia - September 4, 2003, http://www.hc-sc.gc.ca/english/media/releases/ 2003/2003_67.htm

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Patient Safety – the collaboration between the health professions in Japan

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People in Japan especially health professionals, have been sorely troubled by the inability to come up with effective measures to curb the increasing number of medical errors in this country. Although statistics on all medical errors that have occurred in Japan have not been compiled, the number of civil cases in this area has doubled during the past decade from 442 incidents in 1993 to 896 in 2002. The increase in the overall number of errors cannot be debated if it is focused only on the number of civil suits, but it is a reality that national public interest has become focused on reducing the number of medical errors.

Several extremely serious medical errors have been widely reported in Japan in recent years, notably medication and dosage mistakes, patient mix-ups, inadequately trained physicians conducting unfamiliar surgical operations, and other errors stemming from negligence of basic precau-

tionary measures that have caused patient deaths and other serious consequences. The majority of those involved have been indicted as criminal case defendants. Many of these errors have occurred at large university and major city hospitals that are equipped with the latest equipment and facilities and where there is a team of physicians, nurses, pharmacists and other health personnel working conjointly. The main cause of medical errors at these hospitals appears to be a lack of communication and misinformation.

In the wake of a medical error stemming from a patient mix-up involving a medical team at a major university hospital in January 1999, the Ministry of Health, Labour and Welfare created a committee of specialists to review measures aimed at preventing the reoccurrence of medical errors. In March 2000, the MHLW organized a liaison meeting of representatives from medical associations, pharmacist associations, nurses associations, hospital associations, and other health organizations aimed at raising the awareness about the importance of all health-related organizations to implement patient safety protection countermeasures.

Prior to this, the JMA had established its own committee on medical safety countermeasures in 1997 with the goal of creating a framework for medical error prevention countermeasures. This committee consisted of JMA members, members from the Japan Pharmaceutical Association and the Japanese Nursing Association to ensure the participation of not only physicians but also health professions representing all aspects of the health care sector in providing recommendations on how to improve patient safety. According to the committee's 1998 report, the major factor in preventing medical errors and realizing patient safety was to create an atmosphere at the health care site where all health professions could freely voice their opinions and hold constructive discussions outside the confines of established authority. To achieve this change in awareness successfully, upper management and the physicians themselves must take the initiative in promoting this change.

Presently, many hospitals in Japan have established committees consisted of a variety of professions dedicated to preventing medical errors. They are responsible for discussing and recommending measures to prevent the reoccurrence of actual medical errors as well as compiling reports on errors that did not harm patients. What is important about these measures is not the quantity of data collected for x-number of cases, but rather how many errors were prevented as a result of the lessons that were learned from past experiences. It is the health professions from all walks of the health sector that are in direct contact with the problems at the actual health site who can identify truly beneficial information from the lessons that are extracted from the enormous amount of data that is available.

In addition to medical associations, each health organization has conducted significant recommendations and activities to realize patient safety in medicine. For example, the Japan Pharmaceutical Association has focused its efforts on preventing errors related to dispensing drug prescriptions and the Japanese Nursing Association has published accident prevention guidelines. Needless to say, health care activities are not carried out by one health profession. They requires the mutual collaboration of all health professions. Patient safety countermeasures require the collective effort of the entire health care team and they must be based on shared knowledge and an awareness that go beyond the confines of each profession.

Members of a health care team are colleagues that have been brought together by a mutual goal – the task of saving the life of a patient. Therefore, they must engage in wholehearted discussions, mutually assist each other and collectively face the many dangers that threaten the safety of patients.

WMA

How does the world treat our children?

Violence and child health

Presentation given by Dr. Appleyard, President of the World Medical Association, to the Scientific Conference of the Dominican Medical & Dental Society 16 July 2004

Violence is a leading public health problem. As a profession we need to have a fundamental re-think of the role we physicians can play both to mitigate the effects of the current epidemic of violence and to develop strategies to prevent violence in the longer term.

The World Medical Association was founded after the turbulence, terror and torture of World War II in 1947, to unite physicians worldwide in a shared mission founded on traditional Hippocratic principles. These have been enshrined in the Declaration of Geneva, which commits members of the profession to “consecrate their lives in the service of humanity and that the health of each patient will be their first consideration”. Further work on repairing the damage resulting from some doctors' conduct during that War was undertaken to establish the Declaration of Helsinki which defines the ethical principles underlying clinical research. Later, after wide consultation, the Declaration of Tokyo was forged which states that doctors “shall not countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures.” More recently, the Declaration of Ottawa on the Right of a Child to Health Care encouraged physicians to “eradicate all forms of child abuse”.

After the end of the ‘Cold War’, a ‘peace dividend’ never materialized. Expenditure on arms decreased in the early 1990s, but the savings were not allocated to children’s needs. A decade of ethnic conflict and civil wars ensued, characterised by deliberate violence against children on a vast scale.

Children have become targets as well as perpetrators of violence, perpetuating the

cycle of violence into the next generation. During these conflicts, children have been maimed, killed, uprooted from their homes, orphaned, exploited and sexually abused. They have been abducted and recruited as soldiers. During conflict, a country's food production is compromised, malnutrition ensues with a life-long effect, and with the disintegration of the local 'infrastructure' health services disappear and mortality rates rise. These are clearly reflected in UNICEF league tables of under-5 mortality rates per 1,000 live births. Those countries riven by conflict and thrown into poverty have the highest rates of childhood mortality. An enormous sacrifice, which those countries cannot afford to bear.

An estimated 300,000 children are actively involved in armed conflicts. AIDS follows in the wake of such conflicts, leaving large numbers of orphans and by killing teachers, health workers and public servants undermines the stability of the country. Immunization programmes disintegrate, leaving a further burden of disability and death for the poorer countries to bear. Thus, Angola has the highest polio infection rate in all Africa and the Democratic Republic of the Congo has had a ten-fold increase in polio since 1999.

The epidemic of violence perpetuates poverty giving a further twist to the vicious cycle of poverty, poor health and death to more poverty, more ill health and more deaths.

Violence becomes endemic in communities and is continued in such institutionalised cultural practices as female genital mutilation affecting 2 million children and women worldwide. Rape and domestic violence also cause a 5% loss of healthy life years.

"The 20th century was one of the most violent periods in human history. An estimated 191 million people lost their lives directly or indirectly, as a result of armed conflict and well over half were civilians" (Rummel R J 1994). The risk factors are well known.

- Lack of the democratic process and denial of the rights of the individual
- Social inequity with unequal access to wealth and health
- Control of natural resources by a single group
- Rapid demographic change (Carnegie Commission)

To prevent violence nations must;

- reduce poverty and ensure that developmental assistance in the form of social and health care reaches those who need it
- reduce inequity
- reduce access to arms
- abide by international treaties.

Physicians are very much involved in the first action and by their example will encourage others to seek the 2nd, 3rd, and 4th.

The costs of violence have been calculated in Latin America. It costs Colombia and El Salvador 25% of their gross national budgets, Brazil and Venezuela about 11% and Mexico 1.3%

If those countries are to emerge from poverty, their internal conflicts must cease through the example of their neighbours.

We can do more to undo the harm of terror and torture which are the hallmarks of the oppressive regime, by exposing the practice of torture. Physicians are in a dangerous but crucial position to identify the victims and document their injuries so that the perpetrators can be brought to justice.

It is a gradual process. Torture is undertaken in intense secrecy, though it instills fear from the knowledge that it is taking place. Once brought to the light of day with the naming and shaming of the perpetrators, the will of the people will prevail. That is why the WMA is partnering in the International Council for the Rehabilitation of Torture Victims in pilot projects in five countries to promote the Istanbul Protocol, which provides guidance on the identification of the injuries of torture victims so that they can be documented and the perpetrators brought to justice.

In my view, as a profession we need to do more. We must also tackle the root causes of child abuse, instill in societies non-violent means of resolving disputes, and we must start in childhood.

The chastisement of children promotes a culture of violence; this is exacerbated by the severer forms of child abuse. Idi Amin was a prime example of how devastating the long term consequences can be. I smacked my own children on a very few occasions. Each time it was a failure by me as their father to manage an annoying provocative act. No one can be perfect, but we can change our way of thinking and learn nurturing ways of bringing up our children. The case against chastising children is overwhelming. Under UK law, reasonable chastisement is allowed. Not to allow chastisement is more reasonable. Like the introduction of seat belts in the UK, change of behaviour comes over time. The important message is that the community agrees that it does not condone violence towards children or adults. In this way communities and the world will be much safer places for their children and the future of the world.

Dr James Appleyard

UNICEF in highlighting the plight of thousands of children abducted by the rebel Lord's Resistance Army in Northern Uganda has said that the plight of these children as child soldiers and sex slaves is being forgotten. UNICEF Executive Director Carol Bellamy is quoted as saying, "The world may be awakening to the emergency in Sudan, but it has all but forgotten the tragedy of neighbouring Uganda, where in the past two years some 12,000 boys and girls have been abducted by the LRA" (UN Office for the Coordination of Humanitarian Affairs, 27 July 2004).

In WMJ50(1) we published a preliminary note that a course on Ethics and Human Rights for Prison Doctors was being developed by the Norwegian Medical Association and the WMA. This course is now accessible on the WMA website and his article sets out in some detail the motivation for the course, its content and how doctors can participate.

A new online course for prison doctors

Dr. Bjørn Oscar Hoftvedt, Head of Department of Professional Affairs, Norwegian Medical Association

Introduction

Medical services in prison should be available to prisoners and organised to the same quality and standards available to persons in the community at large. A prison doctor is responsible for the prisoners' physical and mental health, and if necessary a prisoner should have access to specialised health care outside the custodial setting.

The doctor's duty to secure that the prisoner receives appropriate health care can, however, come into conflict with the interests of the prison administration. Referring a patient to a specialist service can be expensive, particularly when the patient needs a guard or other security measures 24 hours a day. For economical reasons many prison directors could try to put pressure on the doctor to refrain from referring patients to clinics outside the prison.

Prison doctors can be called upon to examine whether a prisoner is fit for isolation or other forms of special punishment. They can also be ordered to give medical treatment to prisoners who have been tortured. Situations like these can cause difficult dilemmas for the doctor. On the one hand, he/she should comply with the same ethical rules and human rights standards that are applicable to all patients outside the prison. On the other hand, the prison doctor is a part of the correctional system. Regardless of the organisational structure, it can be difficult to defend the rights of the prisoners.

The prison doctors therefore should have the knowledge and skills needed to identify situations where they are in danger of violating medical ethics and human rights, and how they should deal with such situations. Educational programmes on ethics and human rights for prison doctors are not, however a priority in most countries. The Norwegian Medical Association, in co-operation with the World Medical Association, has therefore developed an Internet course on ethics and human rights for doctors and other health personnel working in prisons.

Structure of the course

The course is interactive, using cases and real-life material on which the student can reflect. Each module ends with a multiple choice test and there are also exercises and open questions on which the doctor is required to comment. When the doctor has finished all the modules and completed the tests and the evaluations, he can receive a diploma and earn 12 hours/points in post-graduate and continuing education.

Accreditation

The Norwegian Medical Association has accredited the course, but we have also applied for accreditation from the European Accreditation Council for Continuing Medical Education. The course is free of charge. The World Medical Association is the main distributor of the programme.

How to access the course

The course can be accessed via the World Medical Association's website: www.wma.net or directly on http://lupin-nma.net. Those wishing to get an impression of the course can log on as a guest.

Doctors and others who wish to take the course must register and are required to answer all the exercises and tests and complete the evaluation form which appears at the end of each module.

Content

The course consists of twelve modules:

1. International statements on human rights, medical ethics and international humanitarian law

Jim Welsh, Amnesty International, London, UK.

This module discusses the general principles underlying the body of law and ethics relevant to the work of prison doctors and how it can assist doctors in structuring their work with prisoners. The module also outlines the main differences between human rights standards, medical ethics and humanitarian law.

2. Patient confidentiality and informed consent

Ann Sommerville, Head of Ethics, British Medical Association, Visiting Professor of Medical Ethics, Queen Mary College, University of London.

Regardless of where they are employed, doctors have ethical duties to treat all patients with respect. Seeking patient consent and co-operation is part of this. Prisoners are entitled to the same respect as other patients, from the time of their admission and throughout their period of detention.

Having completed this module, the doctor should understand when consent is needed from prisoners as from other patients, have knowledge of the prisoners' right to confidentiality, be able to assess when non-medical staff have a right to look at prisoners' medical records, and identify situations in which doctors can breach confidentiality.

3. The prison doctor's responsibility to report abuses of human rights

Jim Welsh, Amnesty International, London, UK.

Incarceration and lack of power, as well as prisoners' relative deprivation, contribute to making them vulnerable to abuses. They represent a population whose rights are

inherently at risk - from staff, from other inmates and from the prison environment. This chapter focuses on situations in which doctors are obliged to take action and what actions are possible. It also suggests sources of support and cites standards which can be used to support action.

4. Dual loyalties

Bjørn Oscar Hoftvedt MD, The Norwegian Medical Association, and Hernan Reyes, Medical Division, International Committee of the Red Cross.

The interests of the penitentiary or correctional system are clearly security and control, and not primarily the prisoners' health. In many prison systems, doctors are obliged by the prison rules to see every prisoner before he or she can be punished for breaking some prison rule and sent to the punishment cell. Should the doctor declare a prisoner as fit for punishment, or monitor prisoners in solitary confinement fit for the continuation of the punishment? There are often no clear solutions to such dilemmas. After completing this module the doctor should be able to identify situations where medical independence can be violated and be acquainted with international codes and declarations that ensure medical independence.

5. Hunger strike

Hernan Reyes, Medical Division, International Committee of the Red Cross.

A hunger strike is a way of fasting that involves some form of protest. It is usually undertaken by prisoners or other persons in a custodial setting. There are different types of hunger strikes, some of which involve complex situations and conflicts. Prison doctors need to know about the clinical situations and physiology of fasting, but also have to be aware of the ethical issues at stake. This chapter discusses these issues and presents the medical and ethical guidelines relating to hunger strikes of which all doctors should be aware.

The module concentrates on the definitions of hunger strike and how to analyse the hunger striker's motives. The doctor should be acquainted with Ethies and human rights the doctor's role and be able to counsel a person on a hunger strike.

6. Health services for female prisoners

Ingrid Lycke Ellingsen, Member Committee for Prevention of Torture, Council of Europe.

Female prisoners serve their sentences under the same conditions as men, enjoy the same rights and incur the same obligations. They belong, however, to the category of especially vulnerable prisoners - a fact which poses challenges for prison management as well as for health care personnel working in the prisons.

The main points in this module are the international instruments which give the doctor authority within the prison context to seek ways to protect female prisoners. It also deals with signs to look for which may indicate the specific problems women will experience in a prison setting, the importance of clinical assessment on admission and during imprisonment and appropriate management and treatment proposals.

7. Health care for vulnerable groups

Rosemary Wool, International Council for Prison Medical Services.

The very nature of imprisonment inevitably increases the vulnerability of any person entering prison custody. There is no way to escape the close proximity of fellow prisoners or the culture of the prison community, which has its own hierarchical structures and its own value system. Within the prison community there are some groups of prisoners (adolescents, HIV-infected, homosexuals, etc.) who are particularly vulnerable to physical and/or mental abuse.

By the end of this module the prison doctor will have learnt the important role of the doctor in the management of vulnerable prisoners, the main vulnerability factors of each category of prisoner mentioned, and ways of reducing the risk of physical and mental harm and deterioration of health.

8. Care of the mentally ill in prison

Dusica Lecic-Tosevski, MD, Professor of Psychiatry, Institute of Mental Health School of Medicine, University of Belgrade Serbia and Montenegro, and Vladimir Jovic, MD, Psychiatrist and Psychotherapist, Psychiatric Service "Median", Belgrade, Serbia and Montenegro.

The high level of psychiatric morbidity in the prison population means that doctors providing health care within prisons come into frequent contact with mental health problems, often of considerable severity. In most respects, care of the mentally ill in prisons is no different from such care in other areas of the mental health services. However, it does differ in some ways. It occurs in an environment of compulsion and coercion. The modern concept of mental health care focuses on therapy and rehabilitation rather than control and containment. This is not easy to achieve in prisons, where dual loyalties and responsibilities are dominant. There is no doubt, however, that doctors should consider the care of mentally disordered offenders as their primary function. The goals to reduce symptoms and improve function are not in conflict with prevention of recidivism (social function). Prevention and rehabilitation of mental disorders should not be neglected in prison settings.

9. Violence in Prisons: The Role of the Medical Professional

James McManus, Professor of Criminal Justice at Glasgow Caledonian University.

Violence is endemic in prisons. Indeed, the very act of depriving someone of his or her liberty is an act of violence, but one which almost all societies accept as legitimate in certain circumstances. Not surprisingly, however, the generally accepted legitimacy of imprisonment does not in itself always prevent the inherent violence of the act from setting a general tone of violence in penal institutions.

In this module the prison doctor will be able to understand the different kinds of violence which can arise in this arena, develop strategies for medical responses to each of the categories of violence in prisons, and consider his/her contribution to strategies for violence reduction.

10. Medical signs of torture and other degrading treatment

Sverre Varvin, PhD, Senior Consultant Psychiatrist, Researcher, National

Knowledge Centre for Trauma and Violence, University of Oslo, and Önder Ozkalipci, MD, Human Rights Foundation of Turkey.

Trauma affects the mind and body and gives symptoms and signs that originate in a disturbance in the mind-body organisation. Mental trauma is an experience of overwhelming fear and helplessness. Habitual ways of coping break down, and the person must use desperate and primitive means to survive, both mentally and physically. Repeated or prolonged traumatic experiences strain the capacities, exhaust the individual and commonly may lead to severe and prolonged after-effects.

After going through this section the learner should understand and be able to diagnose psychic trauma and set up a treatment plan for the traumatised person.

11. Research involving members of the prison population

Julian Sheather, Ethics Adviser, British Medical Association.

As a general principle, prison inmates have exactly the same rights to consent and to refuse involvement in research projects as the general population. Prisoners are also entitled to benefit from research and innovative treatment in the same way as individuals in the community. They have the right to act altruistically through involvement in research projects which, while carrying only minimal risk, might benefit others in the same category without directly benefiting themselves.

This module particularly explores what rights prisoners have to consent or refuse involvement in research programmes, and to what extent, if any, these differ from the rights of the general population; how to assess the various ethical considerations that apply when designing research using prison populations; and the factors that need to be taken into account when assessing the fairness of procedures for recruiting prison participants into research programmes.

12. Capital punishment

Vivienne Nathanson, MD, Director of Professional Activities at the British Medical Association, Professor, School of Health, University of Durham.

Capital punishment has been removed from the statute books in many countries. Of those that retain it within their legislative framework, only a minority continue to use it. A very small number of countries use capital punishment extensively. The purpose of this section is not to consider the moral and ethical issues covering its availability and appropriateness as a sanction, but the issues that surround its use, and in particular the roles that may be played by doctors.

Doctors working in prisons should be able to identify the areas in which they might be asked to become involved, and the ethical dilemmas relating to treatment decisions. Capital punishment is not a uniform system, and the dilemmas will therefore differ, depending upon the legislation.

From the Secretary General's Desk, August 2004

As the WMA approaches its 55th General Assembly, scheduled to take place in Tokyo during October 2004, the organization celebrates its long and fruitful partnership with the Japan Medical Association. This association joined the WMA in its early years and ever since has made a formidable contribution in every sense of the word. Not only have the physicians from Japan been able to help build cultural bridges between other nations and Japan, but they have also managed to produce great leaders. The legendary Dr. Takeo Takemi was a hugely influential leader in Japan and one of the trusted advisers of the Emperor of Japan. He also served as the President of the WMA and managed to make a great impact on how the medical profession and its ethical codes evolved. Another JMA leader who made a huge contribution to international medicine was Dr. Eitaka Tsuboi. During his reign as JMA President, he managed to help defend the profession's clinical autonomy and ethics in a time of rapid change and globalization. As WMA President, he represented the organization with great honour throughout the world, including cross-sectoral interchanges such as the World Economic Forum in Davos. During 2004, another great leader emerged when Dr. Harano Uematsu, long-time President of the Osaka Medical Association, was elected as the new JMA President. He will be welcoming some 200 medical leaders from all over the world to Tokyo this October. As two organizations with an ever-growing influence, the WMA and JMA will facilitate the international debate on a wide-ranging spectrum of issues, from the ethics of research to the management of human resources for health. In addition, the JMA was one of the initiators of the policy debate on the link between water resources and public health, and the WMA will most probably adopt its first policy statement on the important links between water and health. It will again be a privilege to welcome the Emperor and Empress as well as the Prime Minister of Japan to the General Assembly, a great honour for all the international participants present.

Tokyo was the site where one of the landmark policies of the WMA, the famous Declaration of Tokyo, was adopted. In 1975, the WMA General Assembly developed and adopted this Declaration to provide guidelines for physicians to detect, treat and help prevent the torture and abuse of detainees or prisoners. The importance of this policy document has always been valued by partners such as the Red Cross, who perform prison visits throughout the world and know how vulnerable prisoners are to torture and abuse. But in the last few months, with much being written in the press about the possible involvement of physicians in the torture and abuse of detainees in different countries, the impact

and importance of this policy has been emphasized even more. The Declaration states in no uncertain terms that physicians should in no way facilitate, condone or participate in the practice of torture or other forms of cruel, inhuman and degrading procedures of prisoners and detainees. This ethical obligation applies to all physicians in all situations, including armed conflict and strife. It is evident that physicians working in prisons have a greater challenge to deal with these realities, and for this reason the WMA, in collaboration with the Norwegian Medical Association, have developed a training manual to help bolster knowledge of the subject of the prevention of torture and abuse. This distance learning course will be launched during September 2004 and will hopefully provide a much - needed resource for prison personnel world-wide.

Lastly, the General Assembly in Tokyo will mark the change of guard of the WMA Presidency. Dr. Jim Appleyard, a paediatrician and seasoned medical politician from Britain, will hand over the reins to Dr. Yank Coble, a Past President of the American Medical Association. Dr. Appleyard has served the WMA and the medical profession with great distinction. His Presidential theme, the protection and development of children's rights to health care, was timely, appropriate and well received both by members and world bodies such as the World Health Organization. His successor, Dr. Coble, plans to launch a "Caring Physicians" campaign during his term. As the classic example of a caring physician himself, he will visit the six regions of the WMA promoting and highlighting the fundamental values of medicine - science, care and ethics. For the first time, the President will have his own website and end the year with the publication of a book depicting role model physicians from all over the world. Truly an Assembly and Presidency to look forward to.

Mental and substance abuse disorders

Mental disorders are widespread, disabling and often go untreated

Geneva – Up to half of all people with serious mental disorders in the United States and several European Countries are not receiving treatment, and the situation is even worse in some developing countries, according to major studies by the World Health Organization.

The findings from the first of a series of WHO World Mental Health Surveys are published in the current issue of *the Journal of the American Medical Association* (JAMA)[1]. They clearly show the high prevalence and burden of mental disorders globally which, despite available treatments, remain largely untreated.

The first WHO World Mental Health Survey report includes data from 14 countries (six less developed, eight developed) on the prevalence, severity, and treatment of mental disorders from 60,463 face-to-face interviews with adult individuals representing the general population. The Surveys were conducted from 2001–2003 in the Americas (Colombia, Mexico, United States), Europe (Belgium, France, Germany, Italy, Netherlands, Spain, Ukraine), the Middle East and Africa (Lebanon, Nigeria), and Asia (Japan, separate surveys in Beijing and Shanghai in the People's Republic of China). The six countries classified as less developed by the World Bank are China, Colombia, Lebanon, Mexico, Nigeria, and Ukraine.

All surveys used a structured diagnostic interview to assess disorders and treatment. Disorders considered included anxiety disorders, mood disorders, disorders that share a feature of problems with impulse control, and substance abuse disorders.

The researchers found that the prevalence of having any mental disorders in the prior year varied widely from 4.3% in Shanghai to 26.4% in the United States.

“Between 33.1% (Colombia) and 80.9% (Nigeria) of 12-month cases were mild,” the researchers report. “Serious disorders were associated with substantial role disability [inability to carry out usual activities] 35.5% to 50.3% of serious cases in developed countries and 76.3% to 85.4% in less-developed countries received no treatment in the 12 months before the interview.”

“The fact that many people with subthreshold disorders are treated while many with serious disorders are not shows that unmet need for treatment among serious cases is not merely a matter of limited treatment resources, but that misallocation of treatment resources is also involved”, the authors, Drs Ronald C. Kessler and T. Bedirhan Ustün on behalf of the 28 country network, concluded.

“To the extent that early intervention can prevent progression, early treatment might be cost effective. A new focus on development and evaluation of secondary prevention programs for the early treatment of mild cases is needed to guide rationalization of treatment resource allocation,” the authors conclude.

Dr. Benadetto Saraceno, Director of the WHO Department of Mental Health and Substance Abuse, commended the study as “conclusive evidence on indicating the global burden of disease due to mental and substance abuse disorders” and “good insight into the treatment gap that exists all over the world largely because of stigma and under-recognition of mental and substance abuse disorders.”

1. JAMA 2004; 291: 2581-2590. Available at www.jama.ama-assn.org/cgi/reprint/291/21/2581. Please see Jama paper for list of authors and for funding information.

The Health Academy: a first step towards a virtual school to promote public health world-wide

Philippe Stroot, WHO Geneva

The Health Academy is a WHO initiative to create a global health and technology network. Its uniqueness lies in its capacity to provides health information to the general public for the purpose of health improvement. It provides guidance in terms easily understood by people from all walks of life and all age groups, taking into consideration their individual cultural sensitivities.

Health is a universal value that transcends cultures and classes and is considered by the World Health Organization (WHO) to be at the heart of human development. The opportunity to enjoy the highest attainable standard of health has been enshrined in the World Health Organization's Constitution for more than half a century. Yet today, an intolerable burden of illness still afflicts a large part of the world population. For millions of people around the world, particularly those who live in the poorest segments of society, the reality today is one of rampant disease aggravated by poverty and lack of knowledge. On the other hand, it is quite obvious that development, economic growth, stability, human dignity and the fulfilment of human rights will only be achieved when people are given the opportunity to live healthy lives.

Since health-care is increasingly expensive, the key to break the cycle of disease and poverty has to be health promotion and prevention. But the question is how to do it effectively? How to help people prevent disease and fully benefit from the care they need? WHO believes that one solution could be the efficient harnessing of modern technology to convey electronic information on health to all levels of society. In the last half of the twentieth century, advances in technology and telecommunications, while bringing human beings closer in one sense, have also contributed to the ever-widening gap between prosperity and poverty and between health and sickness. New drugs and vaccines are being developed and new disease prevention and control mechanisms envisaged. Technological advance has been unbelievable. But who really benefits from this progress?

Bridging the digital divide

Information, and its corollary, knowledge, can indeed either divide or unite, depending on its use. It gives the means to either correct social inequities or create them, enhance sustainable development or deplete valuable and irreplaceable resources. The Health Academy's aim is to reach the poorest of the poor all over the world and give them the knowledge they need to protect and improve their health. It will bring information, technology and health together, in the form of e-learning, to create awareness and convey pertinent basic health knowledge in a language that everyone can understand. This is expected to help improving the quality of life and promoting more positive attitudes, eventually leading to a more productive society of individuals. It will also contribute to bridging the digital divide, which is obviously linked to the social and economic inequalities that exist in the world today.

WHO's conviction is that information technology must be used in the field of education, for the schoolchild, undergraduate, and postgraduate, providing the knowledge of health specialists for all citizens of the world, particularly in the field of health and specifically in educating future health professionals. Research is providing insights into diseases that were not known before. To keep abreast of the latest knowledge on physiology, pathology, and genetics is an enormous task. It is essential that doctors' and health professionals' skills and competence be maintained and validated. One major advantage of communication technologies is that materials can be instantly updated and disseminated. Textbooks take time to prepare and publish, and are costly to distribute.

By making health information accessible, WHO believes that people will attain a safe, healthy, and productive lifestyle. It should also stimulate a dialogue between the public, medical professionals and policy-makers. The Health Academy especially takes into consideration individual cultural sensitivities. With its globally spread educational networks, it will eventually be able to connect people from different nationalities and cultures. Such an enhanced global interaction will lead to an exchange of knowledge and cultural customs that can engender a global society that is rich in its diversity and united in its humanity.

Carefully validated health content and state of the art technology

WHO's rich information resources and expertise in health issues, as well as its world-wide access to health information in all countries, is the main source of validated health content for the Health Academy. As the main partner in this new initiative, Cisco Systems Inc. is providing and developing the e-learning methodology, which goes far beyond simple distance learning. Its essential feature is its interactivity, which allows the learner to construct from first principles the very essence of what is being taught and to consolidate vital relationships between each building block. This approach helps to develop critical thinking and enhances concentration capacities. The curriculum is exciting to both educators and students, as it is a truly interactive mix of different media technologies. E-learning courses will cover major health issues including tobacco use, blood infections, food safety, nutrition, physical activity, rational use of medicines, personal hygiene, etc.

The portal concept has been developed and two pilot studies were carried out, one in Egypt and the other in Jordan. They were directed at 12 to 18-year old students in 20 schools in each of the two countries. Based on the evaluation of this experience, the

Health Academy will be expanded to other countries and regions of the world, with a view to eventually reach the entire population of our planet. Two major dimensions will be taken into account in order to achieve the overall vision: the health condition dimension and the cultural dimension. On this basis, the following regional clusters may be identified: Latin and Central America, North America and Western Europe, the Arab World and the Middle-East countries, Central and Eastern Europe, Sub-Saharan Africa, the Indian subcontinent, Japan and South East Asia, and Oceania.

An initiative with limitless possibilities

By following these e-learning courses, young people will rapidly learn the modern technological skills to acquire new knowledge. They will develop new attitudes and healthier behaviours and promote good health messages in their family and community. Improved mental and physical health will facilitate clarity of mind and emotional stability. This in turn will enable students to take empowering, life-changing steps in all aspects of their lives. As a result, individuals, families, communities and nations will become healthier and more able to partake in global society.

The educational process will not stop at the participating users enrolled in the courses. Once the Health Academy is established, the equipment and courses provided within the education system can be used in the evenings by the parents and the general public under the guidance of mentors. This could have important benefits in improving the teacher-parent relationships as well as educating people of all age groups in the use of the computer, accessing Internet and in the subjects selected. In addition, the Health Academy may be extended to community Internet centres and other points of access. As such, it is hoped that health development will become entrenched in the society at large.

The Health Academy has developed completely four courses in English. Because the pilot study was carried out in two Middle Eastern countries, these courses are also available in Arabic. All courses will eventually become available in the six United Nations official languages.

"The Health Academy provides unprecedented opportunities for effective health promotion through people-centred partnerships" said Dr LEE Jong-wook, Director-General of WHO, at the launch of this new initiative last December. "It is more than just education; it is a means to influence attitudes and behaviour towards a healthier lifestyle, which in turn may help reduce gaps between prosperity and poverty and health and sickness."

The launch generated a lot of interest worldwide. Government offices, medical institutions, educational and health organizations, universities and individuals from all parts of the world contacted the Health Academy to request more information or to propose collaboration, suggesting to expand it to specific regions, countries and languages. This high level of expectation meets the very aim of the Health Academy, which is to become a virtual school of public health disseminating validated knowledge and information to the entire global community.

Further information: contact Philippe Stroot,Information and External Relations, WHO, 20 avenue Appia, 1211 Geneva 27, Switzerland, tel 41 22 791 4316 e-mail strootp@who.int.

The WHO Framework Convention on Tobacco Control on track to become law by the end of the year

The Treaty closed for signature with nearly 90% of countries having signed and over half the ratifications needed for its entry into force having been received

Geneva, 2 July 2004 – The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) closed for signature this week, with nearly 90% of countries having signed and over half of the required ratifications, keeping the Convention on track to become binding international law by the end of 2004. The WHO FCTC has become one of the most rapidly embraced United Nations conventions, with 168 WHO Member States and the European Community (EC) signing, and 23 countries ratifying, accepting, approving or acceding to the Convention, just one year after it opened for signature in Geneva.

WHO is now helping countries prepare for the moment when the WHO FCTC reaches 40 ratifications and it comes into force. An important step in this process included a five-day Intergovernmental Working Group in Geneva, chaired by Brazilian Ambassador Luiz Felipe de Seixas Corrêa, Chair also of the last three rounds negotiations that led to the accepted text of the WHO FCTC. The rapid response to the WHO FCTC demonstrates the increasing commitment worldwide to control the tobacco epidemic, which continues to expand at alarming rates, especially among people in less-developed countries.

"Although we have good reason to be confident, a relentless effort will still be needed for the foreseeable future. Current projections show a rise of 31% in tobacco-related deaths during the next twenty years, which will double the current death toll, bringing it to almost ten million a year," said WHO Director-General Dr. LEE Jong-wook to countries attending the Intergovernmental Working Group. "When the Treaty comes into force, national and local activities aimed at reversing these trends will be enormously strengthened. The result will be improved public health and reduced poverty."

WHO has urged countries that have signed to ratify the Treaty as soon as possible. "The sooner the 40 ratifications are in place, the sooner effective and coordinated actions within the Framework Convention

at country level can begin. Countries can rely on WHO for continued support," said Dr. Catherine Le Galès-Camus, Assistant Director-General, Noncommunicable Diseases and Mental Health, at WHO.

The WHO FCTC, adopted unanimously by all WHO Member States in May 2003, is the first public health treaty negotiated under the auspices of WHO. It was designed to become a tool to manage what has become the single biggest preventable cause of death. There are currently an estimated 1.3 billion smokers worldwide. Half of them, some 650 million people, are expected to die prematurely of a tobacco-related disease.

Note

The WHO FCTC has, as of 30 June 2004, 168 signatories (including the European Community) and 23 ratifications or the equivalent. The Parties to the WHO FCTC as of 30 June 2004 are Bangladesh. Brunei Darussalam, Cook Islands, Fiji, Hungary, Iceland, India, Japan, Kenya, Maldives, Malta, Mauritius, Mexico, Mongolia, Myanmar, Nauru, New Zealand, Norway, Palau, Seychelles, Singapore, Slovakia and Sri Lanka.*

The WHO FCTC has provisions that set international standards on tobacco price and tax increases, tobacco advertising and sponsorship, labelling, illicit trade and second-hand smoke. The Treaty will enter into force and become law for the countries that are parties to it 90 days after the 40th ratification or equivalent instrument. Seventeen more Parties are needed for the entry into force of the Treaty.

During the Intergovernmental Working Group from 21 to 25 June in Geneva, delegates elaborated proposals on different procedural, institutional, financial and budgetary issues that will be presented to the WHO FCTC Conference of the Parties for its consideration and adoption. The Conference of the Parties (COP), formed by all Parties to the Treaty, will take place during the year following the entry into force of the WHO FCTC.

* *edit: The number of countries which have ratified or taken equivalent action had risen to 30 (August 2004)*

Countries that have not signed at this date wishing to become party to the Treaty can do so by means of accession. For signatories of the Treaty, there is no deadline for ratification (equivalent).

For the current status and full text of the WHO FCTC, please visit:

www.who.int/tobacco/areas/framework/signing_ceremony/countrylist/en/

For further information, please contact Marta Seoane, Communications Officer, Tobacco Free Initiative, WHO Geneva, Tel.: +41 22 791 2489, mobile: +41 79475 5551, e-mail: seoanem@who.int

Herbal medicines

Medicinal Plants – Guidelines to Promote Patient Safety and Plant Conservation for a US$ 60 Billion Industry

WHO issues new recommendations for Ginseng, Echinacea and other medicinal plants

Geneva: The World Health Organization has released guidelines for good agricultural and collection practices for medicinal plants – an industry estimated to be worth more than US$ 60 billion. The guidelines are intended for national governments to ensure that production of herbal medicines is of good quality, safe, sustainable and poses no threat to either people or the environment.

Herbal medicines could be the natural answer to some ailments and can often be readily available. For these reasons, they are growing in popularity in wealthy countries and their use remains widespread in developing regions.

However, reports of patients experiencing negative health consequences caused by the use of herbal medicines are on the rise. One of the major causes of adverse events is directly linked to the poor quality of herbal medicines, including raw medicinal plant materials, and to the wrong identification of plant species. Cultivating, collecting and classifying plants correctly are therefore of the utmost importance for the quality and safety of products.

In addition to patient safety issues, there is the risk that a growing herbal market and its great commercial benefit might pose a threat to biodiversity through over-harvesting of the raw materials for herbal medicines and other natural health care products. If not controlled, these practices may lead to the extinction of endangered species and the destruction of natural habitats and resources.

The *WHO guidelines on good agricultural and collection practices (GACP)* for medicinal plants are an important initial step to ensure good quality, safe herbal medicines and ecologically sound cultivation practices for future generations. In an easy-to-understand style they cover the spectrum of cultivation and collection activities, including site selection, climate and soil considerations and identification of seeds and plants. Guidance is also given on the main post-harvest operations and includes legal components such as national and regional laws on quality standards, patent status and benefit sharing.

Background facts

The safety and quality of raw medicinal plant materials and finished products depend on intrinsic (genetic) or external (environment collection methods, cultivation, harvest, post-harvest processing, transport and storage practices) factors. Inadvertent contamination by microbial or chemical agents during any of the production stages can also lead to deterioration in safety and quality. Medicinal plants collected in the wild may be contaminated by other species or plant parts through

misidentification, accidental contamination or intentional adulteration, all of which may have unsafe consequences.

Adverse reactions due to substitution of incorrect plant:

Digitalis: Cases of serious cardiac arrhythmias were reported in the USA in 1997 following the accidental substitution of plantain, to be used as a dietary supplement, with *Digitalis lanata*, generally used for heart conditions. Subsequent investigations were reported to reveal that large quantities of the misidentified plantain had been shipped to more than 150 manufacturers, distributors and retailers over a two-year period.

Podophyllum: Fourteen cases of *Podophyllum* poisoning have been reported from Hong Kong Special Administrative Region of China, following the inadvertent use of the roots *Podophyllum hexandrum* instead of the *Gentiana* and *Clematis* species for the antiviral qualities. It is reported that this accidental substitution arose because of the apparent similarity in the morphology of the roots.

Aconitum: Cases of cardiotoxicity resulting from the ingestion of *Aconitum* species used in complementary medicine for acute infections and panic attacks have been reported from Hong Kong, China. *Aconitum* rootstocks are processed by soaking or boiling them in water in order to hydrolyse the aconite alkaloids into their less toxic, aconine derivatives. Toxicity can, however, result when such processes are mismanaged. In the United Kingdom, the internal use of aconite is restricted to prescription only.

Endangered medicinal plants:

The wild types of the popular medicinal plant ginseng *(Panax ginseng)*, used to address digestive conditions resulting from nervous disorders, is currently reported to be rapidly declining due to increasing demand and collection.

Wild Amercian ginseng, goldenseal, echinacea, black cohosh, slippery elm and kava kava top the "at-risk list" of endangered species of medicinal plants.

Cultivation has replaced wild collection for the supply of some essential drugs used in modern medicine. The Madagascar rosy periwinkle, *Catharanthus roseus*, is widely cultivated in Spain and the United States for its properties which are considered useful in treating childhood leukaemia and Hodgkin's disease.

A traditional medicine for which demand is greater than the potential for supply is the African Pygeum tree *(Prunus africana)*. The bark is a very popular natural remedy for prostate disorders in some European countries such as Spain – but it is harvested from wild trees growing in the mountain forests of continental Africa and in Madagascar and is unsustainable under current practices. While the bark *can* be harvested sustainably, harvesters either cut too much, which results in the death of the trees, or they fell whole trees. The International Centre for Research in Agroforestry (ICRAF) and others are working to establish sustainable sources of *Prunus africana* through conservation of wild tree populations and assistance to smallholders to grow the tree – something that will also help increase farmers' incomes. ICRAF is also working on a breeding programme to select varieties which will take less time to reach harvestable age.

Devil's Claw, *Harpagophytum procumbens*, is another popular remedy that is unsustainably harvested and may become extinct in the wild under current practices. It has been used as a tonic, as a treatment for arthritis and rheumatism, to reduce fever, ease sore muscles, and reduce cholesterol, and externally the ointment is used to treat sores, boils, and ulcers. It is also used to cleanse the lymph system and to remove toxins from the blood.

Devil's Claw is produced in southern Africa, and Namibia is the biggest exporter in the region. Just under 200 tonnes were exported from Namibia between January and August 2000. Between 10,000 and 15,000 harvesters rely on sales from its collection as their only source of cash. However, current prices are not a true reflection of the real value of their work; indeed, over the last 24 years the price has dropped by as much as 85%. In 1998, a sustainably harvested Devil's Claw project was set up on a resettlement farm in Namibia and has rapidly expanded. The following year, 10,210 kg of certified organic Devil's Claw was produced, providing local people with a sustainable product at a guaranteed and fair price. This could be the way forward, provided that users of Devil's Claw demand that suppliers stock only certified products.

Humanitarian aid

Dire Health Consequences for Millions of People in Darfur, Sudan, and Calls for Intensified Health Response

Geneva – The World Health Organization has warned of dire health consequences for millions of people in Darfur, Sudan. A significant increase in disease and death is inevitable without a rapid increase in external help. The catastrophe can only be prevented through an urgent scaling up of the current international response.

Greater Darfur is comprised of three States with a population of 6.7 million. The humanitarian crisis has displaced more than 1.2 million people from their villages and homes and Iffected two million in total. In at least one instance, the child mortality rate rose to three times higher than the international threshold for a humanitarian emergency (two deaths per 10,000 under-five children per day).

On 3 June, Ministers and senior officials from donor nations met in Geneva to intensify their response to the crisis in Darfur. Bold and decisive action is needed now. WHO estimates that a humanitarian crisis can only be prevented through a rapid scaling up in the responses, especially during the next three months, WHO now seeks

US$ 7.6 million for the health response in Darfur as part of US$ 30 million needed for health work throughout Sudan, to help the Government coordinate the response of the health sector and tackle disease outbreaks, improve sanitation, respond to public health needs and improve access to medical care.

The deepening Darfur crisis

"Death and disease spiral upwards when there is inadequate food, unsafe water, improper sanitation and shelter, widespread violence, lack of public health inputs like vaccinations and insufficient access to medical care. These are the realities of the current crisis in Darfur," said WHO Director-General LEE Jong-wook. "The world must not stand by as conflict is compounded by rising rates of death that could be prevented through concerted action."

In October 2003, the United Nations warned of an imminent humanitarian crisis in Darfur and appealed for extra resources. After a long delay, funds are now being pledged.

Subsequently, needs have increased. During April 2004, the number of affected people rose to two million, with at least 1.2 million internally displaced and 100,000 refugees in Chad. Reports suggest continuing increases in levels of malnutrition (doubling each week in some settings), diarrhoea, measles and death. WHO has, so far, been promised a total of US$ 3.9 million for its response.

Dr Hussein Gezairy, WHO Regional Director for the Eastern Mediterranean Region, stated that, "Delivering much-needed aid is an immense challenge in Darfur because people are scattered over a vast land area, and communications have been badly disrupted. Accessing those in need requires intense collaboration by all. A massive scale-up in international commitment, action and effective ground presence is needed now to save precious lives."

The UN and non-governmental organisations have faced many challenges in their efforts to scale up action in Darfur during the past few months. The immediate priority now is to save lives and mitigate the overall risk, exacerbated by the onslaught of the rainy season, to the health of the affected populations. This will require skilled public health staff properly equipped to tackle disease, initiate immunization campaigns, ensure water quality and proper sanitation and make sure that priority surgical and medical care is available where it is needed. The Ministry of Health, WHO and partners have identified needs and priorities, and are together working to deploy Sudanese physicians and surgeons to Darfur hospitals and health centres urgently, in coordination with the UN system as well as NGOs.

In the short term, there is an urgent need for skilled and experienced international senior public health specialists, together with surgeons, physicians, nurses and logisticians, to work in Darfur under the direction of the Government of Sudan and WHO. They need equipment and supplies in order to be effective.

WHO welcomed recent assurances from the Government of Sudan that permits for humanitarian workers to travel from Khartoum to Darfur would be issued within 48 hours, and that movement of relief supplies will be facilitated.

A call to action

Now the misery of Darfur is becoming apparent to all the world's leaders. WHO reiterated its call for action to counter this human suffering. The UN system and NGOs need sustained and committed financial and political backing to counter what can only be described as a disaster.

Some recent actions for health in the Darfur crises

WHO has had staff in Darfur since the end of 2003 and provides regular assessments of people's health situation and needs. WHO helps coordinate and oversee international support for public health in Darfur.

- Disease Surveillance and Preparation for Outbreaks: an early warning system for cholera, dysentery, and malaria, is run by 52 trained surveillance officers, with pre-placement of outbreak response materials in the three States.
- Measles Vaccination Campaign: the Ministry of Health, UNICEF, WHO and partners are making final preparations for a massive measles vaccination campaign covering more than two million children in Darfur. This will supplement the measles care being undertaken by NGOs, targeting children between the ages of nine months and 15 years. As part of the campaign, children will receive vital Vitamin A supplements and vaccination against poliomyelitis.
- Environmental Health: 172 environmental health workers have been trained and equipped to ensure that vector control, waste disposal measures and health promotion are in place for 310,000 people in four locations: El Mashtel, Abu Shouk and Kaalma, and Geneina.

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Drug Costs in Europe

While there is universal concern about the cost of medicines, it is interesting to note the report in Euro Observer* that in Denmark while drug prices have fallen by about 20% since 1995, public sector prescription drug costs continue to rise. Costs in 2003 showed a 5.7% rise over the previous year. This is attributed to "rising drug consumption due to demographic developments and the introduction of new drugs on the market."

In the same newsletter, it is reported that in Finland, generic substitution, which was introduced into the Social Insurance System (Kela) in April 2003, produced a

saving of € 39.7 (US$47.6) million in the first six months. While prescribing physicians can refuse to authorise "substitution", during this period only 0.4% were not allowed by the prescriber. The savings are continuing, with combined savings of approximately € 48.6 (US$58.3) million between October 2003 and March 2004.**

* Euro Observer 2004, 6 (2).

** see also Kela website, www.kela.fi/research, consulted on 02.08.04

The politics of health care – tackling health care problems Canadian style

Because Canada is a federation of one federal, three territorial and ten provincial governments, political jockeying at different levels is a well-established part of Canadian life. At no time is this more abundantly clear than when health care is involved.

In fact, health care issues dominate Canadian political life to such an extent that they were the overriding theme of most political advertising and debate during the June 2004 federal election.

These diverging views and opinions can place an organization like the Canadian Medical Association (CMA) in the no-man's land between competing political interests and visions. And although life in no-man's land can be difficult, it also presents powerful opportunities to affect political outcomes.

In Canada, these opportunities have never been greater.

First, after a strident election the political gods conspired on June 28 to give Canada its first minority federal government in 25 years. This means the new Liberal government will have to attract allies because it holds only 135 of the 308 seats in Canada's House of Commons. (The CMA takes a neutral stance in all federal elections and supports no political party before or during an election campaign. Although it raises health care issues, it never supports a particular political party during a campaign.)

Second, from this new minority position Prime Minister Paul Martin must deal with a restive group of provincial and territorial politicians who appear more ready than ever to challenge the federal government on health care funding.

Combine these two facts, says Dr. Sunil Patel, who was the CMA's president during the federal election, and the health care debate in Canada is approaching a crucial juncture. He thinks Canada's physicians are ideally placed to affect the outcome.

It is notable, he says, that Canada's new federal minister of health, Ujjal Dosanjh, chose the CMA's 2004 annual meeting in August as the venue for his first major speech – exactly one month before the provincial premiers and federal prime minister hold an extraordinary "First Ministers" meeting dealing solely with health care.

"It will be interesting to see what messages the federal government chooses to deliver at our meeting," said Dr. Patel, whose term ended during the 2004 annual meeting. "A lot of people, and not just doctors, will be watching this closely."

He was right. Delegates were addressed by Premier Dalton McGuinty of Ontario, (which, with a population of 11 million people is Canada's biggest province) as well as by Mr. Dosanjh and Roy Romanow, who led a 2002 federal royal commission on health care. Their comments dominated Canadian media reports while the Aug. 16-18 CMA meeting was taking place.

The health care issues confronting Canada's politicians are both considerable and controversial. For example:

• How much should each level of government spend to provide health care? The current annual bill is C$120 billion for everything from physicians' fees to drug costs and dentists' bills. Governments are responsible for about 70 percent of the total, and the provinces and territories claim they have been left with too large a share to pay because of deficit-cutting efforts at the federal level.

• What role should privately owned for-profit facilities play in the delivery of health care? This is supposed to be strictly controlled under federal legislation, but lengthening waiting lists within the public system are causing concern. The key question: Is the existing system sustainable?

The CMA has responded with a multi-pronged effort to publicize problems and potential solutions.

For example, the Association's 137th annual meeting was held in Toronto Aug. 16-18, and it kicked off with a one-hour "strategic session" on health care waiting times, chaired by Dr. David Naylor, dean of medicine at the University of Toronto. The next day Dr. Dana Hanson, the CMA's past president, released results of a year-long study of personnel problems facing Canada's health care professions. However, although a maximum of only 260 physician delegates attend the CMA's General Council, the real audience is much larger because many reporters attend the meeting.

Dr. Patel says it was easy to choose this year's accessibility-to-care theme. "The federal election proved that it is Canadians' major concern," he said, "and we already knew that it is the issue that worries doctors most."

The CMA, which launched a major campaign promoting the need for better access to care in February, commits significant resources to public opinion polling, and those results play a major role in its advocacy efforts.

Waiting lists are a case in point.

The CMA is trying to convince Canadian governments at all levels that the country has a shortage of health care personnel. To support its arguments, it polled 1500 adults in February 2004 and learned:

• Barely one in ten Canadians (14 percent) now believes that the country has an adequate supply of physicians, a significant decline since 1999 (35 percent).

• Concern about access to advanced diagnostic procedures has risen significantly.

When asked if they had to wait "longer than you thought was reasonable" for these procedures in the past year, 31 percent answered affirmatively, compared with only 14 percent in 1999.

The CMA, which represents 58 000 practising physicians, residents and medical students, responded with a National Health Access Campaign. "We are making a simple argument," Dr. Patel told reporters during the campaign launch. "Accessibility is the currency of the health care system, and if people lose faith in that currency – in their ability to get care when they need it – Canada's medicare system won't survive. We want to ensure its survival."

The same message was delivered via a CMA "Election Tool Kit" prepared for the 2004 federal election. It outlined the major challenges facing health care and provided questions physicians could ask their local candidates.

Finally, a major report on the personnel issues facing medicine was released during the 2004 annual meeting. It called for Canada to rely less on doctors imported from other countries – international medical graduates account for about 24 percent of Canada's doctors, and the country has faced charges of poaching, particularly from South Africa. The report proposed that enrolment at Canada's 16 medical schools be increased to 2,500 spaces per year (currently 2,200).

Although problems dogging the health care system account for much of the CMA's advocacy efforts, it also takes concerted action on specific medical issues. For instance, when SARS struck Canada in 2003, the CMA compiled a list of physicians who were willing to help out their hard-pressed colleagues in Toronto – the epicentre of the epidemic in North America.

And it remains an impassioned critic of smoking. In March the CMA sent letters to all major cities that host conventions announcing that it will no longer hold annual meetings in cities that allow smoking in indoor public places such as restaurants. More than 100 Canadian cities have already announced such bans.

Patrick Sullivan

Senior Manager, Member Communications, CMA

Personal View

Card Games – lessons on high stake gambling from the German Health Care System

Otmar Kloiber

In 1994 a chip-based electronic patient card replaced a paper-based voucher granting access to medical care under statutory health insurance for 70 million people. High expectations in the new tool came to a quick end when the state data protection officers pointed out that the chip must not to be used for any other purpose than identification. As the law only permitted storage of ID data, any other use would require legislation.

This decision today looks like an act of wise prescience as the main effect of the patient card has been an excessive "doctor-hopping", accompanied by a variety of fraudulent uses. The old card turned out to be completely unsafe: it can easily be copied, has no crypto-functions for confidential or private information and practically it cannot be revoked. Fraudulent use produces an estimated damage of more than 1 billion Euro a year.

There is no doubt that telematics in medicine ("e-health") will help to provide better medicine and to provide medicine in better way. However, estimates of how much money could be saved by using telematics (they range between 300 and 500 thousand Euro per year for the introduction of the electronic prescriptions alone) are rather speculative. Nevertheless, the government introduced an intelligent mandatory "Health Card" in legislation last year as part of over 400 pages of amendments to the Social Code which were adopted. The intelligent cards as described in the law will obligatorily carry electronic prescriptions, as they should give "room" for a medication history, emergency information and an electronic patient record.

Currently there is no card with all these anticipated functions on the market and in use. On the other hand, nobody seems to doubt that they are technically possible. During the parliamentary procedure the proposal was passed without opposition. From the medical community two things were criticised: first, the time frame set by law for the introduction of the Health Card was unrealistic; second, there was no mention of financing the Health Card implementation in the Law.

The countrywide introduction of the Health Card for virtually all people living in Germany by January 1, 2006 appeared to most experts and leaders of the health care system completely unrealistic. As with all things in the statutory health care system the realization of the project has to be done by the self-governing institutions of the sick funds and the providers. Usually they regulate their interaction by contracts, without influence from the government. For the introduction of the Health Card into the Social Security system, the government introduced an amendment into the law. This enabled the government to withdraw the implementation from the self-governing bodies, if it decided that they are unable to carry out this task. While the self-governing bodies claimed that the time frame was unrealistic, the government claimed that the self-governing bodies are simply unable to do the job.

Obviously to augment the tension, the government did not introduce any indication as to how to finance the introduction of the Health Card. This is a tricky situation as the investment, that may amount to 1.6 billion Euro, would substantially fall on the providers who had to purchase card readers, new software, DSL or ISDN – lines, equipment, and the health professional card. However, the return on investment would almost exclusively go to the sick funds.

With this constellation of an unrealistic time frame and a potential financial dispute, the Ministry increased the chances of failure. This appears to be deliberate as the Ministry had always suggested giving the whole project to the IT-service industry. The idea of the Ministry is that IT-service companies would provide the whole system for health telematics at their own cost, and make a charge for each transaction that will be made with the system. Of course the IT-industry looks for more. With the introduction of the Health Card and the telematic infrastructure, they are looking towards taking over the whole financial management of the health care system. The game is not about the small change for telematics, it is about the ownership of the process.

This of course would lead to a totally new health care system. Currently the law does not permit the government to interfere with the financing of the health care system. Financing has to be regulated between sick funds and providers only. Taking the health card introduction away from the self-governing bodies on the grounds of incompetence as proposed would allow the government indirectly to contract the transaction steering to the IT-industry, thus gaining influence over the cash flow in the health care system, which by law has to be strictly separated from the government. The seriousness of the Ministry's intention may be indicated by the fact that several employees of different IT companies are working in the ministry full time – paid by the industry.

Deus ex machina

Sometimes relief comes from a side one does not expect. Earlier the Ministry of Transport contracted a toll collection system out to the IT-Industry. The system would collect road fees from those lorries using the German Autobahn. Instead of choosing an established technique, the German Government contracted a highly sophisticated model that would allow the contractors not only to collect the toll for the government but also to offer hauler services, such as fleet management and cargo dispatch. But unlike the technologically simpler models already in use in other countries, the German "Toll Collect" system was not more than an idea.

The introduction of the toll collect system became a complete disaster. Its failure led to major deficits in toll collection and also to the realisation that the IT-industry does not always deliver what they promise, and that the commercialisation of state functions may not always be the best way to go. Every politician now has to be aware that such a liaison with the industry may be his political end if it fails – and the possibility of failure is a real, one.

The simple sociological principle that two counterparts will unify if they are disturbed by a third one worked for the self-government in the health care system. In a very short time since the beginning of this year, a common institution was set up and the financing of the whole system is about to be agreed. That is more than could have been expected in such a short time. However, a previous apparently academic dispute about the way an electronic prescription should travel resurfaced: As government and providers assume that the health card would be a good place to carry the e-prescription, the sick funds wish to have a server-based push and pull system. The nearly religious way sick funds make this a dogma can only be explained by their wish to provide these prescription servers and have direct control over the doctors' prescriptions as means of a concurrent review. But again the cards are not open and the game continues.

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The views expressed in this article are those of the author and not those of the WMJ or the WMA.

Review

Double Standards in Medical Research in Developing Countries

Ruth Macklin
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Ruth Macklin, Professor of Bioethics at Albert Einstein College of Medicine in New York, has been for many years both an active participant-observer in, and a widely-published analyst of, the debates over standards for research on human beings in developing countries. In this book she reviews the principal ethical issues that have been addressed in these debates, analyses the responses that have been provided by organizations such as the WMA, and offers her own proposals for resolving the issues.

As the title of the book indicates, the author's principal concern is whether it is ethically acceptable to have standards in research ethics for developing countries that differ significantly from those in industrialized countries. She poses four questions to illustrate this concern:

1. How can biomedical research be designed and conducted so as to contribute to the health needs of developing countries and at the same time contain adequate protections for the rights and welfare of the human subjects recruited for these studies?
2. If a particular study may not be conducted in the sponsoring country for ethical reasons, is it acceptable to carry out an identical study in a developing country, and, if so, with what justification?
3. When completed research yields successful products or other beneficial interventions, what obligations, if any, do the sponsors have to the community or country where the research was conducted?
4. Should the provisions of international ethical guidelines for research, such as the Declaration of Helsinki, be interpreted and applied in the same way in resource-poor countries as they are in wealthier countries? (p. 14).

In responding to these questions, Macklin analyses and evaluates the different answers provided in such recent documents as the

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2000 *Declaration of Helsinki* (with its 2002 Note of Clarification), the 2000 UNAIDS document, *Ethical Considerations in HIV Preventive Vaccine Research*, the 2001 National Bioethics Advisory Commission (USA) report, *Ethical and Policy Issues in International Research*, the 2002 Nuffield Council on Bioethics (U.K.) report, *The Ethics of Research Related to Healthcare in Developing Countries*, the 2002 Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, and related policy documents from the USA National Institutes of Health, and the Food and Drug Administration, and the U.K. Medical Research Council, as well as comments on earlier versions of some of these documents and articles in medical and bioethical journals.

The two articles in the 2000 version of the *Declaration of Helsinki* that have generated the most controversy, paras 29 and 30, are given particular scrutiny by Macklin. The requirement of para. 29, that an experimental treatment be tested against the best current one, where such exists, has been modified or rejected in most, if not all, of the more recent documents listed above. Macklin criticizes these documents for deferring to pragmatic considerations, such as the extra cost of comparing an experimental drug to an existing one instead of a placebo, rather than focusing on ethical principles such as justice and how they can be achieved. She also has harsh words for the WMA's Note of Clarification to para. 29: "A major problem is that the clarification fails to clarify. …it provides no criteria for the 'compelling reasons' that could justify departure from the principle… [and therefore] it would allow participants in research to be subject to predictable serious or irreversible harm" (p. 48). Like many critics of the Note of Clarification, Macklin does not pay sufficient attention to its last sentence, "All other provisions of the Declaration of Helsinki must be adhered to…"

Para. 30 of the Declaration of Helsinki has likewise proved extremely challenging in the development of subsequent documents. Its requirement that participants in research studies should be among the beneficiaries of the study if the study succeeds has been widely contested, both on principle and on pragmatic grounds. Macklin cites the National Institutes of Health and the Food and Drug Administration of the USA as the strongest critics of para. 30, and a related but somewhat broader CIOMS Guideline that "any product developed will be made reasonably available to that population or community."

Macklin accuses those who reject the principles embodied in paras. 29 and 30 of the Declaration of Helsinki of legitimizing an unacceptable double standard in research, since there are stricter rules for placebo-controlled trials and much easier access to new drugs in wealthy countries than in poor ones. Against those who claim that medical research should not be used as a tool to fight world poverty, Macklin suggests that the ethical principle of justice and various international human rights statements require efforts on the part of the powerful and wealthy, whether governments or corporations, to lessen international disparities wherever they exist, including the treatment of human research subjects. However, she acknowledges that there are irreconcilable differences regarding the extent of this obligation and how it can best be fulfilled.

The appropriateness of double standards arises in discussions of other issues in research ethics besides those dealt with in paras. 29 and 30 of the Declaration of Helsinki. Macklin rejects the suggestion that promising the best current treatment and/or access to the benefits of a research study would constitute undue inducement to potential research subjects in developing countries and thereby compromise their ability to give informed consent to participation in the study. As to whether the standard requirements for informed consent in developed countries can be relaxed elsewhere, for example, by allowing a potential research subject's husband or a community leader to consent on behalf of others, Macklin favours universal application of the basic principles of research ethics, such as the requirement of individual consent, but flexibility in the processes by which the principles are applied, e.g., written vs. oral consent.

Besides addressing the substance of the various research ethics documents, Macklin raises issues concerning their nature. Should they be pragmatic or aspirational, descriptive or prescriptive? In her view they should be both pragmatic and aspirational but prescriptive rather than descriptive: "Since ethics is about what *ought* to be, rather than simply what is, the answer … is easy. The difficulty, however, is to craft guidelines that are usefully prescriptive without being hopelessly aspirational" (p. 30). As to whether it is possible to harmonize the various international statements, she is pessimistic because of the radically different interests of the parties concerned, including protection of research subjects, addressing international inequalities, promotion of research and maximizing commercial profits. Moreover, none of the organizations that have produced these documents has unquestioned authority in the area of research ethics.

Although she does not hesitate to state her own views on the various issues she treats, Macklin consistently provides thorough and accurate summaries of all the positions on the issues, including those she criticises. In addition, she analyses with care the principal concepts in the debate on double standards, including 'double standard' itself, 'standard of care', 'equity'/'equality', and 'exploitation', and criticizes their use as jargon or slogans. She does not hesitate to suggest practical solutions for overcoming double standards in research, such as:

1. differential pricing and financing of essential drugs;
2. negotiations followed by prior agreements before research is initiated;
3. collaborative efforts among international agencies and the creation of public-private partnerships; and
4. manufacture of generic copies of patented drugs in developing countries and sale of such drugs to other poor countries (p. 165).

Through the adoption of such measures, Macklin concludes, "Maintaining the same ethical standards for research will not thwart the research enterprise, but can help to ensure that judgments made at some future time will not condemn the current era as one that accepted and even endorsed double standards of research ethics" (p. 260).

John R. Williams