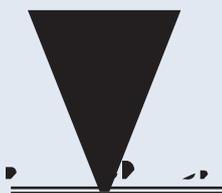


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Deutscher Ärzte-Verlag GmbH, Dieselstr. 2, P. O. Box 40 02 65, 50832 Köln/Germany, Phone (0 22 34) 70 11-0, Fax (0 22 34) 70 11-2 55, Postal Cheque Account: Köln 192 50-506, Bank: Commerzbank Köln No. 1 500 057, Deutsche Apotheker- und Ärztebank, 50670 Köln, No. 015 13330.

At present rate-card No. 3 a is valid.

The magazine is published quarterly. Subscriptions will be accepted by Deutscher Ärzte-Verlag or the World Medical Association.

Subscription fee €22,80 per annum (incl. 7 % MwSt.). For members of the World Medical Association and for Associate members the subscription fee is settled by the membership or associate payment. Details of Associate Membership may be found at the World Medical

Association

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

Printed by  
Deutscher Ärzte-Verlag  
Köln — Germany

ISSN: 0049-8122

## 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<sup>1</sup> 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<sup>2</sup>

<sup>4</sup>. 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 become 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<sup>5</sup>. 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<sup>6,7</sup>, and tuberculosis, most notably in some parts of India<sup>8</sup>.

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<sup>4</sup>.

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 pre-

sent smoking habits continue<sup>5</sup>, 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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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

## Classification

*Type 1* diabetes<sup>1</sup> 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  $\beta$ -cells (islets of Langerhans) include glutamic 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<sup>2</sup> (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 affecting 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  $\beta$ -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<sup>3</sup> and later in 1999 by a group of experts under the auspices of WHO<sup>4</sup>. 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  $\beta$ -cells in the islets of Langerhans, and type Ib where there 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  $\beta$ -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

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 'NIDDM1' 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<sup>5</sup> (1962) that the evolutionary re-'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 muscle 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  $>35 \text{ kg/m}^2$  increases the risk of developing diabetes over a 10-year period by a staggering 80-fold, as compared with slim individuals with a BMI  $<22 \text{ kg/m}^2$

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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<sup>2</sup> 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 as 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.

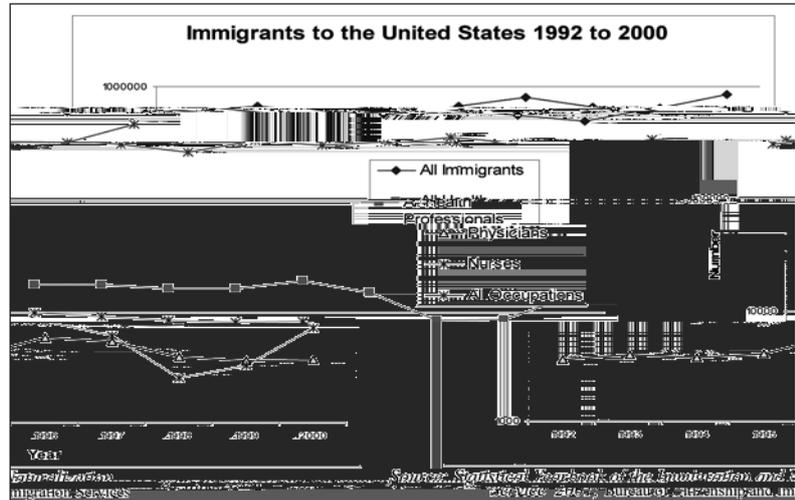


Fig. 1 Trends in migration of professionals to the U.S.

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<sup>3</sup>, there is growing agreement that the trend is rising. Stilwell et al.<sup>4</sup> 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 than 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.”<sup>5</sup> The authors suggest that the demands of these six countries are enough to deplete the sup-

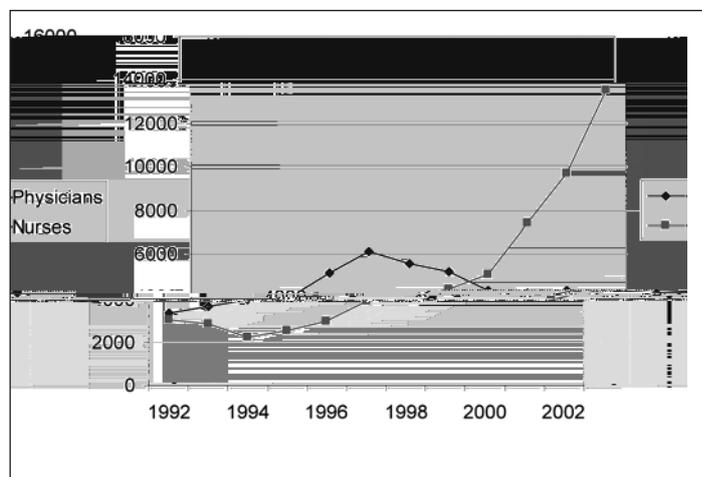


Fig. 2. Trend in migration of physicians and nurses to the UK

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<sup>6</sup> 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".<sup>7</sup> 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".<sup>8</sup> Awases et al<sup>9</sup> 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".<sup>10</sup> 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<sup>11,12,13</sup> 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.”<sup>14</sup>

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 Phy4wed asrvhy4wai(ta.-.5368brf Tw(categories basedi In-.1(

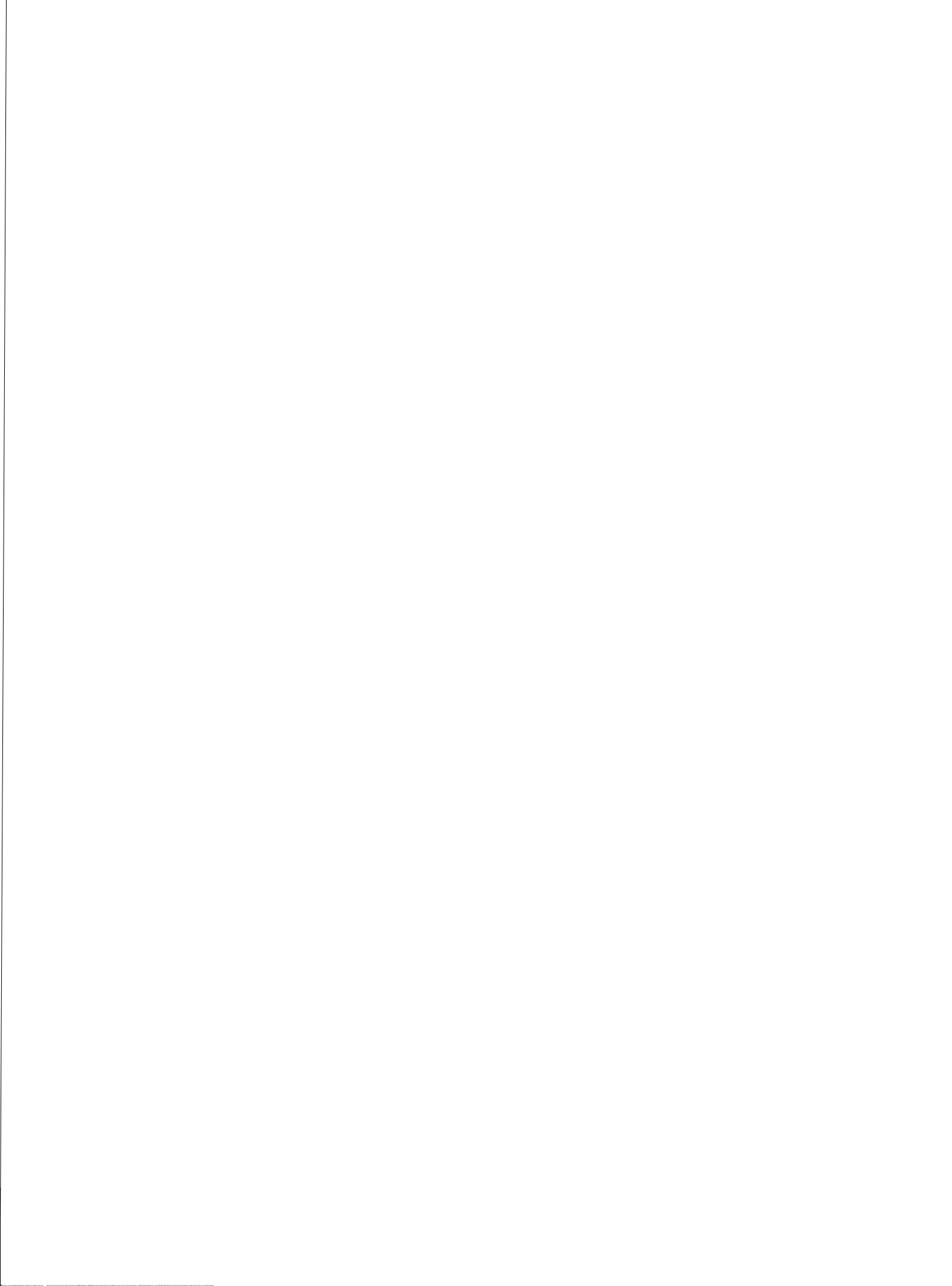
Biomedical research as part of science has, since the end of the 2nd World War, traditionally been performed in an international context, which includes exchange of results, errors and benefits. Some aspects of this scientific sector are subject to some regulation by specific provisions within legislation 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.<sup>(3)</sup> The International Ethical Guidelines of CIOMS

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



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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<sup>1</sup>.

## 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

involved in a variety of roles, including: providing direct patient care, participating in public health activities, and providing support to the health system. The Canadian Medical Association (CMA) 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

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**

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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.

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*



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 con-





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 Wcw-9acareng prysiciansTjT\*0.027 Tw(ahimself h



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

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.

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/](http://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](mailto:seoanem@who.int)



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



*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



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