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**Titlepage:** Great Ormond Street Hospital for Sick Children, London. This hospital was founded in 1852. the first Children's Hospital in Britain. From very modest beginnings it has developed into a world famous centre both for the treatment of childrens' diseases and for teaching and research into paediatric diseases. The photograph shows the entrance to the present main building. Photo by courtesy of GOS.

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## Editorial

## **Backward to the future?**

WHO has not only warned about the potential danger of a global pandemic of Avian Influenza but recently, in this connection, has also welcomed articles in Nature and in Science reporting possible means of containment of pandemics following work based on two model projections (1)(2)(3). These suggest both the use of the drug – Oseltamivir, and strict early individual and area quarantine as a possible means of avoiding a major pandemic.(see p. 79).

Turning to another area of concern namely, Multi-Resistant Stqphylococcus Aureus (MRSA), amongst the world wide activities to contain infections with MRSA, there has been a renewed emphasis on the basic principles of strict cleanliness-, hand-washing and scrubbing and non- touch techniques, as well as the use of detergents and bactericides. For years now there have been repeated warnings to physicians about the dangers of the development of antibiotic-resistance and the need to avoid over-prescribing of antibiotics, and their overuse and misuse. While there is still unfortunately a need to remind some physicians to discipline their use of antibiotics, the contributory factors of deregulation of antibiotics and their sale over the counter still exists in some jurisdictions, as well as the use of drugs in cosmetics and to increase food production.

Perhaps the time has come when we should return to basics – to the principles upon which our predecessors worked before the advent of antibiotics, a re-examination of the application of fundamental precautions and techniques which were common in the late 1940-1950s, became unfashionable in the present industrialised systems of healthcare, and have been forgotten or neglected in a new age of wonder drugs, technology and commercial pressures for rapid "through put" of patients in healthcare systems and public demands for immediate cure. We also hear calls for the revision of medical training, from a system geared to dealing with acute medicine to one capable of dealing with the huge increase of chronic disease morbidity, exacerbated by the increased longevity of mankind.

None of this is suggesting that we should not welcome and utilise the remarkable developments in medical science technology, the ability to discover new treatments.

It is, rather, an emphasis on the need to respect the basic principles of medical care and treatment, which include assessment of the need for sophisticated drugs when others will also achieve a cure, and to use medications and new technology with respect.

Coupled with all of this, there are calls for the re-humanisation of medical care. Is there a need to stress to those responsible for the administration and organisation of healthcare services, that these services are for human beings, each having a unique persona and physical needs? The healthcare services provided are provided to individual human beings – not simply to machines requiring servicing or repair.

Have we really reached the stage when the qualities which each individual personally possesses can be repaired by standard "spare part" technology taken as a package off the shelf? The opening paragraphs above address fundamental principles of medical care. Do we need to add to these the basic principles of humanity and care for others? We hear of many examples of selfless activity amongst physicians, but are we also hearing cries of despair at changing attitudes in physicians? Humanity and care for individuals are certainly qualities which have for generations been basic to the practice of medicine. Is there nevertheless a need today to re-emphasise this in basic medical training? Is there is a need to reject an enthusiastic unquestioning welcoming of the wonders of modern scientific and technological development in medicine without pause for thought? While an evidence-based approach to treatment deals with the tools available for treatment, is such a questioning approach applied to individual self analysis of each physicians' activity?

Editorial





## <u>Editorial</u>

We face a dilemma – how to deal with new medical discoveries and technological advances at a rate which has led to a belief that nothing is beyond the reach of a science today, and that it should be available to everyone immediately. Of course this is unrealistic but should we be reconsidering the need to go "back to basics", both in our daily practice and our approach to the wonders of

medical advances and how we apply them in the 21st century?

There is a need for physicians to renew their allegiance to Hippocratean principles, and to the Geneva Declaration.

- (1) WHO Statement 3rd August 2005
- (2 Nature on-line: accessed 31.09.05.
- (3) Science 2005, 309, 870.

Alan Rowe

## **Cardiovascular Research Advances** The developing human heart and its congenital malformations

During embryonic development, the great veins, atrial and ventricular chambers and arterial trunks are formed, and the process occurs by which the heart divides into its two distinct halves. Following this, further complexities kick in when the heart's outflow vessels form. An understanding of the way in which the heart normally develops is essential both to fully comprehend the nature and mechanisms which underlie congenital malformations, such as holes in the heart and transposition of the great arteries (Fallot's Tetralogy), and for subsequent corrective surgery to be successful. We now know that much of the early knowledge of embryonic heart development was incorrect, and that patients were dying following heart repair operations, because surgeons put their stitches into essential parts of the heart's conduction system of Purkinje fibres. In turn, in some malformations, the electrical physiological "wiring" is itself abnormal – so the ethical dilemma of where it is safe to cut and stitch, and avoid losing a life, becomes even more complex. The importance of such work is backed up by the falling death rates associated with heart repair. As many as one in four patients used to die during or after surgery 30 years ago, compared with about one in 50 today. While this is in part due to advances in cardiac diagnostics, surgery and intensive care, increased anatomical knowledge has undoubtedly contributed to safer and more successful surgery.

Congenital malformations, which present in a range of degrees of severity, affect as many as 1% of live births. They are also the prime cause of miscarriage in 2-3 times this number of embryos. Clarifying the structure of the congenitally malformed heart now underpins much research and several treatment approaches in this area worldwide, as well as laving the foundations for current research into sub-types of malformations and how these arise. In terms of refined diagnosis, three-dimensional ultrasound, echocardiography and computerised imaging methods are being utilised to find out more about the efficiency of heart valve function before and after surgery. Cardiovascular physiology can be investigated before, during and following birth. There is a strong focus now on exercise physiology in children with congenital heart disease. Strategies are being developed to improve the outcome of surgical repair of transposition of the great arteries. Indeed, the long-term outcome of congenital heart disease in adults is being studied in order to improve current management in childhood, and to further anticipate problems in adulthood.

There is a greater emphasis now on interventional cardiology, such as introducing stents, closing defects, and even inserting valves through a catheter – in some instances avoiding the need for open heart surgery. Atrioventricular septal defects (AVSDs) are a type of cardiac malformation, where the septum fails to develop properly - leading to septal defects between the chambers, with serious abnormalities of the atrioventricular valves. Digital imaging technology is being employed to improve the quality of surgical repair in this malformation. All of the operations carried out by the surgeon are filmed using a head camera. In a unbalanced AVSD in the child one ventricle is smaller than the other. What would be the best way to increase the size of the smaller ventricle? It was discovered that in these unbalanced ventricles there are often thick muscular bundles that are amenable to surgical division, which frees up the small chamber. Three-dimensional functional MRI reconstruction of these imbalanced defects are performed in order to determine the position of these muscular bundles before the operation is carried out. Dividing these muscle fibres means that the size of the right ventricular cavity, and hence efficient pumping action, can be significantly increased.

Computational fluid dynamics is used to improve the design of heart operations – and studying cerebral blood flow together with metabolic pathways during the course of open heart surgery aims to reduce subsequent brain damage. Pulmonary hypertension is also coming under the spotlight: severe pulmonary vascular disease prevents the surgical repair of congenital heart defects. Consequently more basic research is needed on the pathogenesis of this condition combined with clinical research on treatment strategies.

In adults with normally formed hearts, atherosclerosis is a major cause of morbidity and mortality, and reducing the burden of coronary arterial disease is a priority. The disease has its origins in childhood, and so risk factors which lead to atherosclerosis are being assessed with the intention of evolving strategies to prevent its onset.

## Heart attacks

Vascular smooth muscle cells and inflammatory cells comprise the atherosclerotic plaque, where a rupture causes arterial occlusion and heart attacks. Excessive accumulation of vascular smooth muscle



cells also promotes re-narrowing of arteries after re-vascularisation, such as intracoronary stenting and bypass grafts. The proliferation of such cells is therefore critical to understanding myocardial infarction disease processes. A major focus of research has been to identify the key regulatory pathways that control cell proliferation in atherosclerosis and re-stenosis. Why should cells in advanced human atherosclerotic plaques proliferate poorly, and therefore be unable to repair minor damage? It has now been determined how cells from in-stent narrowings bypass conventional cell cycle control. Similarly, how novel therapies such as brachytherapy (radiation therapy) achieve their effect is becoming increasingly clear. These studies have led to the design of antiproliferative agents that are disease-specific, which are currently being tested. Genetic profiling has identified new markers of disease, a prelude to rational drug design to target diseased tissues.

New studies have recently been funded to study the various processes of cell ageing, as exemplified by atherosclerosis, and to identify mechanisms that either halt or reverse the intrinsic biological cellular clock. Vascular smooth muscle cell death promotes instability of atherosclerotic plaques. Advanced disease plaques have lost the ability to protect themselves from cell death, being also particularly vulnerable to local scavenging inflammatory cells. Cholesterollowering drugs such as the statins have beneficial effect on these disease states.

#### Mechanisms of immune response triggered by endothelium

Although the latest immunosuppressant drugs have virtually eliminated the risk of acute rejection of heart transplants, the risk of chronic rejection in the form of a gradual hardening of the arteries remains. It was previously considered that graft rejection is triggered by "passenger leukocytes", donor white blood cells present in the graft, which migrate to the patient's lymph nodes and activate host T-cells that attack the graft and lead to rejection. Graft endothelial cells may be capable of activating host T-cells, which would explain why chronic rejection occurs long after the clearance of passenger leucocytes. Differences between subsets of CD4<sup>+</sup> and CD8<sup>+</sup> T-cells have been demonstrated in their ability to be activated by endothelial tissue. It may thus be possible to develop target agents for therapeutic intervention.

## Myocardial stem cell biology

Until recently, the heart was believed to lack regenerative capacity. However, there is mounting evidence that a population of progenitor cells within the heart is capable of producing mature cardiac myocytes in response to injury. The challenge is to understand why this healing process is so limited in the heart, which results in inadequate tissue response after large myocardial infarcts or global insults to the heart such as viral infection. What is the molecular basis for differentiation of adult cardiac myocytes derived from embryonic stem cells? The processes which inhibit complete myocardial regeneration need to be identified. Indeed, several approaches are possible for myocardial tissue engineering towards potential therapeutic strategies in both congenital and acquired cardiac disease.

## Tissue engineered vascular conduits

In surgery, both coronary artery and peripheral artery bypass procedures depend on the ready availability of adequate arteries or veins. Many patients lack suitable blood vessels for grafting, which limits their ability to benefit from surgical re-vascularisation. In collaboration with a biotechnology company research will begin with clinical trials utilising wholly autologous, engineered vascular conduits. Engineered vessels in the way will have no foreign proteins and will be "grown" in the laboratory from a small skin and vein biopsy donated by the patient. If successful, this will revolutionise vascular surgery and will provide proof in principle that similar engineering approaches for other tissues will be possible.

## Heart transplantation

The success of heart transplantation is primarily limited by the availability of suitable donors. Papworth Hospital, University of Cambridge, has pioneered approaches to in vivo donor organ resuscitation and evaluation, which have become the recognised "standard of care" both in the UK and North America. A surgical device will be tested which can perfuse explanted hearts with substrate-enhanced, warm, oxygenated blood and thereby resuscitate the organ outside the inflammatory milieu of the brain-dead donor. Moreover, in developing the resuscitation device, each heart will be fully evaluated in terms of its physiological, anatomical and biochemical performance, so as to provide an evidence-based assessment of transplant suitability.

## Vascular smooth muscle cell gene expression

At Addenbrooke's Hospital, Cambridge, an entirely novel gene has been identified and sequenced which is expressed in both smooth muscle and cardiac muscle. In terms of its chromosomal location it may turn out to be an important agent in excitations-contraction coupling and the regulation of myocardial contractility.

Also identified is a family of genes, containing some novel members, that regulate the transcription of smooth muscle specific genes.

## Vascular calcification

It has been established that vascular calcification is a regulated process involving both inhibitory and facilitative gene products. Apoptotic cell death, under certain circumstances, may lead to the precipitation of calcium salts and the initiation soft tissue calcification. With respect to the gene coding for matrix Gla protein, an important inhibitory protein in calcification, there is significant variability in the gene coding which may predispose some individuals to



develop either earlier or more pronounced calcification.

By adopting novel approaches to imaging the atherosclerotic process, pilot data suggest that in patients with symptomatic vascular disease, using functional MRI and CAT scans, visualisation of localised inflammatory activity may become feasible. The thin layer of cells which lines blood vessels, particularly vulnerable to build up of deposits at vessel junctions, is crucially important in normalising raised blood pressure. Dysfunction here is believed to be a key factor in atherosclerosis, and so mechanisms are being investigated and therapies evaluated aimed at restoring endothelial function.

## Arterial vessel wall injury

Early atheroma development in the arterial wall covers the impact of key genetic, inflammatory and dietary factors. The latter include the role of partially oxidised lipids and essential fatty acids. Such early mechanisms are linked with abnormalities in the function of vascular endothelial cells and with activation of fibrin and platelets triggering thrombotic complications, as for example in stroke and heart attacks. It is possible to identify patients with threatened myocardial infarction, to inhibit the thrombin and platelet aggregation mechanisms with the "clot-buster" group of drugs, and to diminish the risks of major cardiovascular complications, provided that the patient is seen early enough by the doctor. This now means that, in delivery of healthcare to heart patients, myocardial infarction and unstable anginal pain can be more accurately assessed for their frequency and clinical significance.

## Cardiac specific gene targeting

A research group at the Edinburgh New Royal Infirmary under Dr. KAA Fox has examined the molecular genetics of key factors involved in hypertension. Important steps have been identified in the control of the renin-angiotensin cascade, regulating It is with great sadness that we report the death of Sir Richard Doll whose seminal work on Smoking and Lung Cancer was reflected on its fiftieth anniversary last year in his guest editorial in this journal (WMJ50 (3)).

## William Richard Shaboe DOLL d. 24 July 2005 aged 92

It is over fifty years since the young researcher who had served in a hospital ship during the second world war and had lost a kidney to tuberculosis, first demonstrated in collaboration with Austin Bradford Hill, the close link between smoking and lung cancer (and so many other diseases, notably coronary heart disease). Inevitably he was frustrated by the subsequent failure both of governments and so many victims of their smoking habit to follow his example and act on these findings, but, supported by a "powerful marriage" to Joan Faulkner, he devoted his painstaking epidemiological skills to an infinite range of diseases related to environmental, occupational and lifestyle factors.

His exact and exacting scientific work, underpinned by a strong humanitarian drive, made him an example and an inspiration to those who followed him. Showers of honours worldwide failed to spoil a truly modest man. Despite increasing frailty and the loss of his wife in 2001, he continued to the end to respond to requests for advice and support to those who shared his commitment to the prevention of preventable disease and suffering.

blood pressure and arterial vascular tone, and in gluccorticoid metabolism, covering susceptibility to atheroma and accelerated phase hypertension. It has been possible to mark renal juxtaglomerular cells genetically, which are critically involvend in the disease process.

This group of doctors has the largest singlecentre experience in Europe of survivors from out-of-hospital cardiac arrests. Specific brain enzyme markers can predict the risk of death and cognitive impairment amongst those surviving initial resuscitation Using MRI, the anatomical location and metabolic substrate for defects in mental function and memory loss have been defined. Related work examines the risk of the patient developing further arrhythmias. Thus, specific rehabilitation measures can now be targeted as survivors of cardiac arrest.

## Arrhythmias

According to Dr. AJ Cann, St. George's Hospital, fatal atrial fibrillation is a common rhythm disorder which requires investigation in a long series of studies. Examples include design and testing of pacemaker algorithms for control of atrial fibrillation and the development of implantable defibrillators. New medications and medical regimens are being discovered to treat paroxysmal, persistent and permanent atrial fibrillation. Mapping of atrial fibrillation at surgery is being carried out in order to identify areas which can be destroyed that will eliminate rhythm disturbance, together with the use of digital recordings to evaluate oscillatory mechanisms initiating atrial fibrillation.

Heart muscle disorders, such as hypertrophic obstructive cardiomyopathy (HOCM) and



dilated cardiomyopathy, generally occur in families. These disorders and other genetic cardiac conditions, which may cause sudden unexpected cardiac death, are being studied: the genetic basis and the phenotype-genotype correlations in HOCM; dilated cardiomyopathy genetics, arrhythmogenic dysplasia, Marfan syndrome, long QT syndrome, Brugada syndrome, sudden infant death syndrome (SIDS) and the conditions responsible for sudden death in professional athletes.

The latest techniques which can assess the cardiac electrical arrhythmogenic risk of patients suffering from heart disease incorporate several risk of patients suffering from heart disease incorporate several large databases taken from multi-centre clinical trials. Risk factors cover heart rate variability – frequency, time and non-linear methods; a new approach known as heart rate

turbulence; and spatial and temporal variability of the QT interval (QT dispersion).

## Outlook

Analysis of hospital records in Western Europe and America by computer has shown that many fatal diseases of Western culture, particularly heart attacks and strokes, can be brought on by a previous infection. Clinical technology should therefore be harnessed to identify patients at risk of cardiac disease progression, whether from the genetic point of view of inherited diseases associated with heart muscle and t he conduction system, sudden death in the young, HOCM, the ion channelopathies and arrhythmogenic right ventricular cardiomyopathy – or on the other hand the environmental approach via the strength of the immune reaction in fending off disease. The recognition of such patients at risk is important from an ethical point of view as effective treatments are available.

Ivan M. Gillibrand

#### **Further reading**

Institute of Child Health & Great Ormond Street Hospital for Children NHS Trust: "Leading The Way" Research Review 2003

British Heart Foundation 2003/04 Annual Report of the Medical Division Medical Director: Professor Sir Charles George www.bhf.org.uk

## **Comprehensive cover for modern medics** Dr Michael Saunders, Chief Executive of the Medical Defence Union

This article explores the trends in indemnity insurance worldwide, set against the UK scene and draws conclusions about the future arrangements for liability cover for physicians and other healthcare workers.

The number of multi-million pound medical negligence claims has been rising above the rate of inflation for some years and stories about such cases are a regular feature in the newspapers. Despite this, some UK doctors and dentists do not always know for certain whether compensation for harm suffered from proven clinical negligence will be available. Contractual indemnity insurance is in place throughout the United States, Australia and most of continental Europe but this has not yet happened in the United Kingdom.

This article investigates whether there is now irresistible momentum behind insurance being made compulsory for healthcare professionals

## Medical negligence trends

Set against the staggering number of National Health Service (NHS) consulta-

tions which take place in the UK – around 270 million every year<sup>1</sup> – the number of medical negligence claims is very small. The NHS Litigation Authority (NHSLA), which indemnifies NHS bodies, such as hospitals, paid out £502.9million in claims and legal costs in 2004-5, compared to £422.5million in 2003-4. In contrast, the number of clinical negligence claims against the NHS in 2004-5 fell to 5,609, compared with 6,251 in 2003-4<sup>2</sup>.

The Medical Defence Union (MDU) has revealed that the costs of medical negligence claims are rising well above the rate of inflation, although the trend seems to be for fewer claims to be made against members. Those we do see are generally well thought out and have a more realistic chance of succeeding. Last year the MDU, which has over 165,000 members, including over 50 per cent of UK doctors, paid seven patients more than £1million each for claims and legal costs against hospital doctor and GP members<sup>3</sup>. Ten years ago just one patient received more than £1million. The high cost of these cases reflects the severity of the injury and the amount of care the patient needs for the rest of his or her life.

It is difficult to draw conclusions in comparing the claims statistics in different countries because legal systems differ so greatly that this would be misleading. Suffice it to say that there is some evidence that there has been an increase in medical negligence claims in other countries. In the United States, for example, a study by the Joint Economic Committee of US Congress reported in May 2003 that, between 1994 and 2001, the average medical malpractice award increased 176 per cent to \$1million<sup>4</sup>.

## **Government action**

Some governments, such as that in Australia, have sought to tackle the high cost of clinical negligence cases by imposing a cap on the amount of damages that can be awarded. In the United States too, President Bush has stated his determination to reform the system and reduce the number of lawsuits, including a cap on non-economic damages.

Meanwhile, the UK Government is investigating ways to regulate the claims system. This may include an attempt to rein in socalled "claims farmers" which offer to assist in pursuing personally injury claims, usually in exchange for a share of any compensation recovered. In a speech to the Institute of



## **Guest Editorial**

Public Policy and Research (IPPR) on 26 May 2005 Lord Falconer, the Secretary of State for Constitutional Affairs and Lord Chancellor said: "The growth of claims farmers has fostered and encouraged the attitude that if you are injured, you should see if you can turn it into money. Our Compensation Bill will help with that by introducing regulation of claims farmers."

In addition, in the 2005 Queen's Speech at the opening of parliament a NHS Redress Bill was proposed with the aim of reducing long delays in bringing cases and the high legal costs in settling some claims. Although the details of the scheme have yet to be made available, it is likely to follow the outline of the scheme outlined in the Chief Medical Officer's consultation paper on reforming clinical negligence: 'Making Amends' in 20035. This also included a proposal for a scheme of no fault compensation. In 2002, such cases accounted for 5 per cent of the cases on the NHS's books but 60 per cent of the money paid out by the NHS to compensate patients.

## **Medical indemnity**

With the costs of claims rising so rapidly, it is vital that doctors are properly indemnified against the cost of a claim which could easily bankrupt them, while leaving a patient uncompensated.

In the past, some doctors have relied on discretionary indemnity – that is, they have paid a subscription to an organisation that gives them the right to seek assistance from that company and have that request fairly considered, but not the contractual right to receive help which comes with an insurance policy. No Company providing discretionary indemnity can give a guarantee that they will assist with clinical negligence claims. The decision to assist or not can only be made at the time the practitioner presents the indemnifier with the facts of the case for which he is seeking help.

The alternative – contractual indemnity insurance – is already a requirement for practising doctors and dentists in most developed countries in order to protect patients, amongst them, the US, France, Germany, Belgium, Holland and Spain.

Australia was the most recent country to convert in 2003 following a crisis in the medical indemnity market precipitated by the threatened failure of one of the biggest organisations that had offered discretionary indemnity, United Medical Protection (UMP). UMP was forced into provisional liquidation in 2001 by a combination of factors identified by the provisional liquidator (Deloitte) including multi-million dollar court payouts, and the collapse of its reinsurer HIH.

In the midst of the crisis, the Australian Federal Government stepped in to rescue UMP (which was allowed to resume trading in 2003) and put in place a new medical indemnity insurance framework, which included direct financial support to ensure that doctors in high-risk specialisms such as obstetrics and gynaecology, could afford premiums. The Government made it a requirement for all Australian doctors and dentists to have professional indemnity insurance on a claims-made basis, through an approved provider. Doctors and dentists are also required to buy a 'run-off' policy so that after the claims made policy has expired (for example because the insured has retired, is disabled or has died), incidents that have occurred during the term of the policy remain insured.

Launching the scheme the Australian government said the reason for the change was to ensure that doctors and dentists "will have access to contracts of insurance that are legally enforceable rather than discretionary arrangements that exist now which provide no certainty that claims will be met."

#### **Indemnity in the UK**

In the UK, concerns about discretionary indemnity were expressed as far back as 1979 in a judgment of the then Vice-Chancellor, Sir Robert Megarry:

'... When a person insures, I think that he is contracting for the certainty of payment in specified events, and not merely for the certainty of proper consideration being given to his claim that the discretion to make a payment in those events should be exercised in his favour. The certainty must be direct, and not at one remove.' <sup>6</sup>

Today, lawyers, architects and accountants working in private practice in the UK have to have professional indemnity insurance, as do health professionals such as chiropractors and the majority of osteopaths, but the same is not true of doctors and dentists. However, recent events have renewed focus on the insurance question.

In 2004, the Department of Health (DoH) issued a consultation, which proposed to make indemnity insurance compulsory for dentists. However after the consultation had closed, the DoH said there was a mistake in the wording and that discretionary indemnity would be equally acceptable. The Dentists Act 1984 (Amendment) Order 2005 makes "adequate and appropriate insurance" a requirement for all registered dentists and dental care professionals. However, in defining "adequate and appropriate insurance" the order states that as well as a contract of insurance, "an arrangement made for the purpose of indemnifying a person..." is acceptable. It is now up to the General Dental Council (GDC) to draw up rules specifying what type of insurance it considers will provide adequate and appropriate safeguards for dentists and their patients.

In the debate surrounding the DoH consultation and the insurance versus discretion question, discretionary-only providers suggest that discretion is more flexible and that the problem with insurance is the 'small print'. However, one of the major problems with discretion is that there isn't any print at all, no contract, any enforceable right to assistance. In contrast, an insurance policy should set out, in plain English, what is covered and what is excluded. If a healthcare professional is refused assistance under their insurance policy they may seek and be given a reason for that decision. He or she also has recourse to the Financial Ombudsman Service and the civil courts for assistance in challenging the decision. Doctors refused indemnity by a discretionary provider have none of these safeguards and only know if they will be assisted when they make the claim.

The Consumers' Association has said: "...the provision of clinical indemnity should be regulated to ensure that one only

## **Medical Ethics and Human Rights**



practitioners are assured that they have cover if something goes wrong, but also that consumers will be able to achieve redress and receive recompense in this event..."

Discretion only indemnifiers are unregulated. Only doctors who are insured have the kind of consumer guarantees that one would expect from a highly regulated industry. Insurers are authorised and regulated by the Financial Services Authority (FSA) which oversees the financial management of insurance companies in order to protect solvency margins, insure capital adequacy and reduce the risk of capital flight. It also sets standards for systems, sales and policyholder communications, claims handling and complaints procedures.

Both the UK General Dental Council and the General Optical Council, which has also been given the power to make rules specifying their indemnity requirements, have sought or will seek legal advice and no doubt will wish to consider whether an indemnity arrangement that gives healthcare professionals no contractual rights, and that is not legally enforceable, provides adequate and

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appropriate safeguards for healthcare professionals, and patients who sue for negligence.

### The need for insurance

As professional accountability increases, the likelihood also increases that non-medical healthcare professionals will be sued personally if a patient they are treating is harmed. Given that discretionary indemnity is no longer acceptable in Australia, in most other EU countries and most states in the USA, it is the MDU's view that discretionary indemnity does not provide the necessary safeguards for UK healthcare professionals and their patients and that all healthcare professionals should be required to hold professional indemnity insurance.

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Address for correspondence: Dr. Michael Saunders, The MDU, 302 Blackfriars Rd, London SE1 8PT The Medical Defence Union was founded in 1885 and was the first medical mutual professional assurance organisation in the world. It continued worldwide coverage for its members who, at various stages, have included members from other countries practising in many parts of the world until the year 2000, when only doctors and dentists practising in the UK and Ireland became eligible for membership. ED

- 1 Office of Health Economics Compendium of Health Statistics, London 2000, p36
- 2 NHSLA Report and Accounts 2005, London 2005
- 3 Medical Defence Union, London 2005
- 4 Liability For Medical Malpractice Issues And Evidence, Joint Economic Committee United States Congress, Washington 2003 (introduction)
- 5 Making amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS – A report by the Chief Medical Officer, London, July 2003
- 6 MDU Ltd v Department of Trade [1979] 2 WLR 686

about and include concepts such as compassion, caring and commitment (box 2).

Medicine has also had the advantage of having ethical codes for over two and a half thousand years which most doctors regard as being binding.

As a profession we are also regulated. For many doctors, this regulation which includes consideration of the concept of self-development, learning and working to

## Professor Vivienne Nathansen Director of Professional Activities, British Medical Association

**Conference of experts on biological weapons** 

The following presentation was given on behalf of the WMA at the Conference of Experts on Biological Weapons in Geneva

#### 11<sup>th</sup> June 2005.

The World Medical Association was set up following the Nuremburg trials to deal with the issue, amongst others, of abuse of medical expertise. (Box 1) In the concept of the current conference it could even be shown that some of the abuses were dual use of medicine. The WMA was also set up because doctors' recognised a need for international standards which were codified and formalised. Such standards offer benefits to individuals, and help them to resist imprecations to become involved in ethically unacceptable practices. When we consider common medical standards, it is important to look at issues such as the core values that bind doctors together. These values are what being a doctor is all

## Box 1 What is the WMA?

- Established in 1948
- An association of associations
- National Medical Associations
- Independent and representative
- Members from all parts of the world (but not all countries)
- Bound by common standards



## WMA

## **Box 2 Common medical standards**

- Core values
- Binding ethical codes
- Professional regualtion partly or wholly self regulation
- · Continuing education/professional development

externally agreed standards, will be wholly by other members of their profession, that is a peer group. Increasingly such regulation is only partly self-regulation and includes input from lawyers, parliamentarians, patients and many others.

Being a professional includes a commitment to common standards, but also includes the concept of regulation or licensing.

For most doctors throughout the modern world, being employed depends upon having a licence, and that licence itself is likely to be in part dependent upon understanding educational achievement and in part upon adherence to ethical and other norms and observation of ethical standards is therefore a routine part of medical practice. (Box 3)

Ethical codes have been established to raise the standards of medical practice to a high common norm. Whilst they do not guarantee the end of abuse by individuals, or indeed of observance of ethical principles by individuals, we believe they have contributed significantly to a decrease in the incidence of such abuse.

There are, of course, many ethical codes surrounding medicine. While the Hippocratic Oath has been around for more than two and a half thousand years, there are many other codes established by the World Medical Association. These include the Declaration of Geneva and the International Code of Medical Ethics, established in 1948 effectively as a modern re-statement of the principles in the Hippocratic Oath. Other codes include the Declaration of Tokyo on the treatment of prisoners, the Declaration of Helsinki on Research Ethics, and the Declaration of Washington on Biological Weapons. The key to all of these codes and many others is that the World Medical Association has significant experience in crafting codes and promoting those to doctor members of its member associations around the world.

Where do these codes fit in the network of guidance available doctors? As set out in box 4. there are many different areas of control of medical practice and these laws vary from country to country. However, ethical codes and professional guidance can effectively become customary law within a country because the majority of practitioners will practice according to those codes and guidance. Courts do not accept ignorance of the Geneva code as an excuse for breaching well accepted principles.

How does the World Medical Association go about writing a code? The first thing to say is that although historically these were written by doctors for doctors with little external advice, based upon Judaeo-Christian ethics and setting doctors apart from other professionals, this is gradually being changed. Increasingly they are written with a medical view but as codes by health professionals for all health professionals and with input from many stakeholders, including patients. This has particularly been the case in relation to the revision of the Declaration of Helsinki on research ethics, where patients and research subjects had a major role to play in informing the debate.

Because ethical codes are about the framework of limits set by society with the professions that serve it, it is important to recognise that there has to be multi-cultural, multi-professional input, but the key to the code being useful remains getting "buyin" from those will have to follow it.

Why then did the World Medical Association write a Declaration on Biological Weapons (box 5). The simple answer was that a number of different associations had been doing work on biological weapons and related issues for some time. The British Medical

## **Box 3 Ethical codes**

- Post Nuremberg
- Code by doctors for doctors
- · General adherence even if not formally sworn
- Set of principles
- Interpretation required

## **Box 4 Control of Medical Practice**

- Statute Law
- Judicial Decisions
- Customary Law
- Ethical Codes
- Professional guidance



## **Box 5: The WMA Declaration of Washington on biological weapons**

## A. Introduction

- 1. The World Medical Association recognizes the growing threat that biological weapons might be used to cause devastating epidemics that could spread internationally. All countries are potentially at risk. The release of organisms causing smallpox. plague, anthrax or other diseases could prove catastrophic in terms of the resulting illnesses and deaths compounded by the panic such outbreaks would generate. At the same time, there is a growing potential for production of new microbial agents, as expertise in biotechnology grows and methods for genetic manipulation of organisms become simpler. These developments are of special concern to medical and public health professionals because it is they who best know the potential human suffering caused by epidemic disease and it is they who will bear primary responsibility for dealing with the victims of biological weapons. Thus, the World Medical Association believes that medical associations and all who are concerned with health care bear a special responsibility to lead in educating the public and policy makers about the implications of biological weapons and to mobilize universal support for condemning research, development, or use of such weapons as morally and ethically unacceptable.
- 2. Unlike the use of nuclear, chemical, and conventional weapons, the consequences of a biological attack are likely to be insidious. Their impact might continue with secondary and tertiary transmission of the agent, weeks or months after the initial epidemic. The consequences of a successful biological attack, especially if the infection were readily communicable, could far exceed those of a chemical or even a nuclear event. Given the ease of travel and increasing globalization, an outbreak anywhere in the world could be a threat to all nations.

- 3. A great many severe, acute illnesses occurring over a short span of time would almost certainly overwhelm the capacities of most health systems in both the developing and industrialized world. Health services throughout the world are struggling to meet the demands created by HIV/AIDS and antimicrobial-resistant organisms, the problems created by civil strife, refugees and crowded, unsanitary urban environments as well as the increased health needs of aging populations. Coping over a short period of time with large numbers of desperately ill persons could overwhelm entire health systems.
- 4. Actions can be taken to diminish the risk of biological weapons as well as the potentially harmful consequences of serious epidemics whatever their origin. International collaboration is needed to build a universal consensus that condemns the development, production, or use of biological weapons. Programs of surveillance are needed in all countries for the early detection, identification, and response to serious epidemic disease; health education and training is needed for professionals, civic leaders, and the public alike; and collaborative programs of research are needed to improve disease diagnosis, prevention, and treatment.
- 5. The proliferation of technology and scientific progress in biochemistry, biotechnology, and the life sciences provides the opportunity to create novel pathogens and diseases and simplified production methods for bioweapons. The technology is relatively inexpensive and, because production is similar to that used in biological facilities such as vaccine manufacturing, it is easy to obtain. Capacity to produce and effectively disperse biological weapons exists globally, allowing extremists (acting collectively or individually) to threaten governments and endanger peoples around the world. Nonproliferation and arms control measures can diminish but cannot completely eliminate the threat of

biological weapons. Thus, there is a need for the creation of and adherence to a globally accepted ethos that rejects the development and use of biological weapons.

## B. Strengthening public health and disease surveillanceCE systems

- 6. A critical component in dealing with epidemic disease is a strong public health infrastructure. Investment in public health systems will enhance capacity to detect and to contain expeditiously, rare or unusual disease outbreaks, whether deliberately induced or naturally occurring. Core public health functions (disease surveillance and supporting laboratory services) are needed as a foundation for detection, investigation, and response to all epidemic threats. A more effective global surveillance program will improve response to naturally occurring infectious diseases and will permit earlier detection and characterization of new or emerging diseases.
- 7. It is especially important that physicians be alert to the occurrence of cases or clusters of unusual infectious diseases, to seek help from infectious disease specialists in diagnosis, and to report cases promptly to public health authorities. Because any physician may see only one or a few cases and may not recognize that an outbreak is occurring, cooperation between primary care physicians and public health authorities is especially important.
- 8. Public health officials, dealing with an epidemic, will require the cooperation of emergency management agencies, law enforcement officials, healthcare facilities, and a variety of community service organizations. For these different groups to work together effectively, advance planning will be important. In addition to developing surveillance activities for early detection and reporting, public health efforts should be directed toward educating primary caregivers and public health staff about potential agents that might be used, building laboratory capacity for rapid identification of biological agents, provi-



ding medical and hospital services as well as vaccines and drugs to control the epidemic.

# C. Enhancement of medical preparedness and response capacity

- 9. The first indication that a biological weapon may have been disseminated is likely to be the appearance of patients in the offices of practicing physicians, especially those in acute care settings. Physicians thus play a critical role in early detection of an outbreak and must be prepared to recognize and deal with diseases resulting from the use of biological weapons as well as other infectious disease agents and to promptly report suspicious illnesses and diseases to public health officials.
- 10. In the course of an epidemic, physicians will be directly involved with mass patient care, with mass immunization and antibiotic prophylaxis, with providing information to the public, and in a variety of hospital and community efforts to control the epidemic. Thus, physicians should participate with local and national health authorities to develop and implement disaster preparedness and response plans for intentional and natural infectious disease outbreaks.

# **D.** Bioweapons research and medical ethics

11. Rapid advances in microbiology, molecular biology, and genetic engineering have created extraordinary opportunities for biomedical research and hold great promise for improving human health and the quality of life. Better and more rapid diagnostic tools, novel vaccines, and therapeutic drugs can be foreseen. At the same time, there is concern about the possible misuse of research for the development of more potent biological weapons and the spread of new infectious diseases. It may be difficult to distinguish legitimate biomedical research from research by unscrupulous scientists with the malign purpose of producing more effective biological weapons.

- 12. All who participate in biomedical research have a moral and ethical obligation to consider the implications of possible malicious use of their findings. Through deliberate or inadvertent means, genetic modification of microorganisms could create organisms that are more virulent, are antibiotic-resistant, or have greater stability in the environment. Genetic modification of microorganisms could alter their immunogenicity, allowing them to evade natural- and vaccine-induced immunity. Advances in genetic engineering and gene therapy may allow modification of the immune response system of the target population to increase or decrease susceptibility to a pathogen or disrupt the functioning of normal host genes.
- 13. Research specifically for the purposes of creating biological weapons is to be condemned. As scientists and humanitarians, physicians have a societal responsibility to decry scientific research for the development and use of biological weapons and to express abhorrence for the use of biotechnology and information technologies for potentially harmful purposes.
- 14. Physicians and medical organizations have important societal roles in demanding a global prohibition on biological weapons and stigmatizing their use, guarding against unethical and illicit research, and mitigating civilian harm from use of biological weapons.

## **E. Recommendations**

- 15. That the World Medical Association and National Medical Associations worldwide take an active role in promoting an international ethos condemning the development, production, or use of toxins and biological agents that have no justification for prophylactic, protective, or other peaceful purposes.
- That the World Medical Association, National Medical Associations and healthcare workers worldwide promote, with

the World Health Organization, the United Nations, and other appropriate entities, the establishment of an international consortium of medical and public health leaders to monitor the threat of biological weapons, to identify actions likely to prevent bioweapons proliferation, and to develop a coordinated plan for monitoring the worldwide emergence of infectious diseases. This plan should address: (a) international monitoring and reporting systems so as to enhance the surveillance and control of infectious disease outbreaks throughout the world; (b) the development of an effective verification protocol under the UN Biological and Toxin Weapons Convention; (c) education of physicians and public health workers about emerging infectious diseases and potential biological weapons; (d) laboratory capacity to identify biological pathogens; (e) availability of appropriate vaccines and pharmaceuticals; and (f) financial, technical, and research needs to reduce the risk of use of biological weapons and other major infectious disease threats.

- 17. That the World Medical Association urge physicians to be alert to the occurrence of unexplained illnesses and deaths in the community and knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations.
- 18. That the World Medical Association encourage physicians, National Medical Associations and other medical societies to participate with local, national, and international health authorities in developing and implementing disaster preparedness and response protocols for acts of bioterrorism and natural infectious disease outbreaks. These protocols should be used as the basis for physician and public education.
- 19. That the World Medical Association urge all who participate in biomedical research to consider the implications and possible applications of their work and to weigh carefully in the balance the pursuit of scientific knowledge with their ethical responsibilities to society.



Association for example wrote book length reports in 1999 and 2004, but first published on weapons control issues in the 1890s. The American Medical Association had started the drafting work on the Washington Declaration before the Anthrax attacks, and followed it up by organising the scientific session at the 2002 General Assembly on Natural and Deliberately Inflicted Biological Events.

The key is that doctors see disease and are engaged in trying to control, manage and reduce the impact of epidemics. In terms of biological weapons doctors would like to see principles of public health applied, including both primary and secondary prevention, to decrease the likely incidence or prevalence of such biological attacks and also to manage the seriousness of such attacks including reducing the spread of disease.

If codes have something to offer, then the question is what makes them effective? The World Medical Association believes that making codes work needs to follow a simple set of rules. These include making them relevant, simple and clear. Similarly ensuring that the code is taught and understood by those who will have to follow it and ensuring that you engage those who must use it or follow its principle so that they understand, are aware of and are compliant with that code on a voluntary basis

The key to effectiveness is getting those who should be bound to it, to understand, value and internalise it as well as getting society itself to recognise the important place that the code plays.

In terms of this Conference of Experts on Biological Weapons and the concept of codes, there are a number of questions to ask which raise problems in writing these codes. The first of these is "what is a scientist?". The answer is that there are many types of scientist, including life scientists, natural scientists, pure scientists, biologists, physics, chemists and so on who are key players in reducing the risk of bio-warfare and bio-terrorism. This makes the sciences more difficult to regulate than medicine which has the advantage of being a relatively cohesive profession wherever you are in the world. The second problem is that regulation and licensing of scientists is at a much earlier stage than it is in medicine, where regulation has existed for one and a half centuries in many countries. The question that has to be addressed is whether licensing and regulation will be of different groups of scientists separately and apart, or whether there will be a cohesive all-scientist programme.

The third point is whether employment standards are adequate as an alternative to a code. The World Medical Association believes that employment standards are useful, but those employment standards work best when they embody concepts such as adherence to a code of ethics as a prerequisite for continuing employment.

There are already a plethora of codes of conduct and practice around the world which can in their own way undermine the development of a new code unless it is seen as being over arching and having real professional value and support.

The final problem that we see is the absence of a single international body representing scientists. There is a plethora of representative bodies, both national and international, within the sciences. The key factor here is to create a new international body which can over arch in all these areas and get input and "buy-in" to an emerging code from all specialities and subspecialties.

Finally – what can the World Medical Association do to help in this process? The first simple answer is that we can help write a code based upon our significant expertise in doing just that. The second way in which the World Medical Association can and will help, is to publicise and engage with medical researchers and their colleagues to spread the message and achieve engagement from the scientific community.

The third thing that the World Medical Association can do is use its links with other professional groups such as the World Health Professionals Alliance to get further publicity for, and "buy in" to, an emerging code.

The final thing that the World Medical Association can do is to offer reassurance to scientists. Codes are far from being the end of freedom. They are a part of the responsibility that scientists have to the society which they serve. They are a framework which helps to ensure that scientists keep within the limits that society would wish and expect to have in place and they will contribute to all of our overall safety.

The WMA looks forward to continuing the debate.

# AMA position on Physician participation in Guantanamo Interrogations

Dr J. Edward Hill, President of the American Medical Association, speaking at the BMA Annual Representative Meeting made the following points concerning the position of the AMA on allegations of physician participation in Guantanamo Interrogations e.g articles in the New England Journal of Medicine (7 July) New York Times (June 24) and earlier report in the Press etc.

The American Medical Association Code of Medical Ethics clearly prohibits any form of physician participation in torture. Any physician involvement in torture compromises te integrity of the medical profession.

The AMA defines torture as the use of "cruel, inhumane and degrading treatments or punishments during imprisonment or detainment". The AMA CODE specifies that "participation in torture includes, but is not limited to, providing, or with-holding any services, substances or knowledge, to facilitate the practice of torture". "Physicians should provide support for victims of torture and whenever possible, strive to change sit-



uations in which torture is practised or the potential for torture is great."

The confidentiality of medical records and patient-physician communications should be protected, when that confidentiality is violated, trust in undermined and patients may not provide full and accurate information to their physicians (AMA Policy E-5 05). This applies even to patients who are prisoners or detainees.

As the leading voice of the American Medical Profession, the AMA calls on all physicians to stand together in opposing torture, physician participation in torture, and breaches of patient confidentiality.

Dr. Hill also referred to AMA meetings with the US Department of Defence to express concern over published reports alleging physician participation in coercive interrogations in Guantanamo Prison Camp. DOD officials assured the AMA that aggressive investigation of these complaints was taking place but disputed whether military physicians were involved in any unethical misconduct. Further conversations with DOD Officials had subsequently taken place, detailing AMA concerns about the allegations. In June 2005 a document outlining the ethical principles for all health personnel of the Armed Forces was sent to the AMA.

At the June meeting of the House of Delegates of the AMA, the house reaffirmed its support of the ethical medical treatment of prisoners of war and said it would "encourage medical schools to include ethics training on the issue of medical treatment of prisoners of war and detainees".

The AMA is working with colleagues from the British, Icelandic, French and Danish Medical associations to study the Declarations of Geneva and Tokyo to determine whether additional provisions are necessary to provide guidance to physicians and address violations by physicians in conflict settings.

The AMA policy that "physician participation in torture and/or abuse of prisoners is unethical and unacceptable has been communicated to the media, public and the Pentagon itself, and the AMA will continue both to monitor the situation and to advocate that all physicians honour these ethical principles.

## From the Secretary General's Desk

# The Bologna Process – not well done, but well intended?

In the Middle Ages studying was a fairly international activity. Many of the universities were in southern Europe and persons seeking education had to travel a long way to find their teachers. However, the power of the titles academicians earned at that time was not questioned. Once bestowed the title remained with the person.

Nowadays students may travel much faster, but to take their degrees and credits from one country to another takes not only longer than any journey across Europe in the Middle Ages, it is also very cumbersome and sometimes even very expensive. Universities, claiming their independence, often do not care about the interests of their migrating students, and governments find it difficult to compare degrees and to properly recognize them.

Moreover, many students feel unprepared for university studies and many drop out early without acquiring a degree. One of the most unknown international mega-projects is the so-called Bologna Process. In 1999, twentynine European Ministers of Education meeting in Bologna, agreed to install a uniform system of University degrees and credits with two major aims:

- To facilitate migration by awarding easily understandable and comparable credits and degrees and
- To provide two study cycles for all disciplines/fields, each ending with a degree giving access to the labour market.

This step was unprecedented: The Ministers of Education met and decided to take common action to provide easier migration across Europe, not only in the European Union, which had at that time 15 member states. And of course, such changes had to be mandatory for all studies, all disciplines/ fields, all Universities and Colleges. In the future there should be two degrees a European Bachelor to be reached after 3 or 4 years of undergraduate education, and a European master to be reached after another 1 to 2 years of graduate studies. (The doctorate degree was later added to this system as an additional third degree.)

However the Ministers of Education took this decision on their own: Experts from the different disciplines were obviously not involved, students and representatives of the professions were not heard. In consequence, the result is a reform which looks nice on first sight, but which raises many doubts on further examination.

Interestingly, in medicine the Bologna process was widely ignored and this for a good reason. For the last thirty years many efforts have been made to unify the traditionally bi-phasic medical undergraduate education. The formerly separated basic and clinical sciences were combined into one study cycle in order to expose the student to a medical setting from the very beginning of medical education. Of course, this cycle has precisely one end product, the physician. There is no half-way product – this was never intended nor would it have



been meaningful. Splitting this up again just doesn't make sense!

Confusion in the medical field is complete. Some countries decided to split the medical studies in accordance with the Bologna process, so that the Bachelor degree defines more or less only the theoretically educated physician, and the Masters degree the completion of internship. Other countries want to introduce just a mock Bachelor – an intermediate degree without any meaning and without any use. Most countries have not decided what to do with medicine, while other countries are certain that they will not include medicine in the Bologna process.

One thing is clear: better comparability of equal and qualifying degrees remains far

away, the new situation actually appears to be more difficult than before the Bologna process.

Academic studies at public universities in many of the European countries are offered more or less free of tuition fees. This is a huge burden for governments, most of which are in financial troubles. But the promise always is repeated: "Education will remain free". However, the small print in the political programmes reads rather differently. A closer look reveals that in the future, studies may be free only up to the first professional degree, and thanks to Bologna, in all countries this will now be after three to four years instead of four to six years as it was previously.

#### WMA

# The Significance of the Scientific Session of WMA General Assembly, Tokyo 2004

Nobuya Hashimoto, MD Vice-Chairperson, WMA Council Executive Board Member, JMA

The Scientific Session of the WMA General Assembly Tokyo held from October 6 to 9, 2004 gave direction to resolving a variety of issues that directly confront global health care today. As a person involved in planning this session from the JMA side and as an executive board member from the host NMA responsible for this event, I wish to review the significance of the Scientific Session (and WMA General Assembly), and make a few suggestions.

The Scientific Session provided a forum through which the overall state of medical and health care in the 21<sup>st</sup> century was reviewed through two themes – "Advanced Medical Technology and Medical Ethics" (Theme I) and "Progress in Information Technology and Health Care" (Theme II). Progress made in science and technology has greatly changed the environment around us today and has also affected medical and health care. Subsequently, it has also pro-

duced a variety of unforeseen problems that inevitably accompany the progress made by humanity and which are unavoidable. Thus, I believe a consensus was reached on how the issues that were discussed at the Scientific Session should be addressed. In summary, we, physicians, should secure the patient's safety based on a relationship of physicianpatient trust and do our utmost best to provide high quality medical care. The themes that were addressed at the Scientific Session dealt with problems that health care related personnel have never had to face in the past. Therefore, there are no exemplar models that may provide the answers. However, the outcome of the day and a half of active discussions, was a shared recognition of the need for a code of behaviour for our profession by the participants from 42 countries. Thus, I hope that what was discussed at the Scientific Session will contribute to more effective discussions at the WMA.

The essential points of the Scientific Session were summarised as follows. The achievements of advanced medical technology and information technology (IT) based on the knowledge of past generations are indeed wonderful, and no one will deny this fact. But these achievements are not shared at large within the global community. As pointed out by Dr. Takaku, we must not forget the view that the benefits that are derived from this new technology should be shared equally and globally. In the advanced countries, concern regarding advanced medical technology and progress in IT has been increasing. As emphasized by JMA president, Dr. Uematsu, society as a whole must recognise that advanced medical technology should guarantee the safety and happiness of humanity, and that a system which enables only a handful of people to benefit from costly advanced medical technology should be reformed. As Dr. Sakurai has explained, in Japan the JMA has lobbied the Japanese government to enable medical insurance to cover advanced medical technology under the guidance of the JMA. This is, of course, related to national financial issues, but it is the duty of medical associations to protect the public health by lobbying the government to prevent fiscal initiatives from dominating medical and health care issues. To achieve this, physicians must have the ability to foresee future developments in medical technology.

As Dr. Haddad has pointed out, we should constantly bear in mind that future developments in science and technology should supplement the knowledge and experience that physicians have accumulated through traditional methods and they should not replace them. If we lose sight of this basic concept, then physicians become merely the subcontractors of electronic engineers.

The need for common ethical guidelines for advanced medical technology was pointed out; and at the 2002 WMA General Assembly in Washington the Japanese Medical Association's draft proposal on Medical Ethics and Advanced Medical Technology was adopted as a WMA Declaration. This declaration is a general statement on advanced medical technology and medical ethics, and there is a continued



need to review this issue from many different perspectives. For example, Japan has achieved the world's highest life expectancy with low health costs. But to sustain this feat, it has become essential to secure financial resources. In advanced countries, improving the financial foundations needed to secure the health level of its population has become a major problem, and there is wide scope for discussion.

In the area of medical technology and advanced IT, Dr. Kim pointed out the inevitable transformation of health care due to IT and genomics. But, as Dr. Uematsu has advocated, the goals that we physicians should aim for are to practice holistic medicine and to provide safe and high quality medical care. It is to be expected that medical costs will rise when quality medical care is provided. But, its quality should not be lowered as a means of containing health costs. However, financial resources for medical and health care are limited. Therefore, how these resources are allocated is a major issue which should be reviewed by the WMA.

Certainly, as Dr. Groth has pointed out, more than 90 percent of advanced technology is currently developed by less than 10 percent of the countries in the world (advanced countries). Of course, it is a fact that the social and financial foundations of advanced and developing countries differ greatly. However, it is also a fact that physicians in developing countries should do their ultimate best within the respective environment of the country.

Progress in IT technology will continue to influence developments in medical care. As noted by Dr. Kaihara, obtaining correct information will promote physician-patient relations and will help realize better medical care. Thus, balancing IT and medical care is one of the goals before us to attain. But, again, as stated by attorney, Dr. Higuchi, medical information must ultimately function under the principle that it will be used to provide the best treatment for patients and allow society at large to benefit from it. As pointed out by Dr. Takaku, that is the difficulty of resolving specific issues such as the need to protect individual gene related data. By whom, and

## WORLD MEDICAL ASSOCIATION

The General Assembly and Scientific Meeting of the World Medical Association will take place in the Hyatt Regency Hotel, Santiago,

Chile, on the 12–15 October 2005.

The Scientific Meeting on "Health System Reform and Access to

Medicine" will be held on Thursday 13th October, preceded an

#### Associates meeting.

The General Assembly Ceremonial Session will be on the morning of the Friday 14th October and the rest of the General Assembly will take place on Saturday, the 15th October;

how such issues will be resolved should be carefully addressed with the co-operation of physicians on a global scale through the WMA General Assembly meetings, rather than under the leadership of individual country governments and their financial concerns. Therefore, the WMA should be willing to provide a forum to discuss these issues as needed. As Dr. Haddad has indicated, WMA is also duty bound to alert each country about the responsibility not to leave our future generations with the burden of dealing with the destruction of the natural environment and environmental pollution caused by national greed.

These are my personal views on the important issues of CME and professional autonomy that are being debated in Japan today, based on the discussions that took place at the Scientific Session. Against a background of extensive mass media coverage about medical errors and publicity about distrust of medical care, CME for physicians is a vital issue that must be addressed to enable physicians to provide high quality medical care. Moreover, physicians voluntarily undertake CME, and this is where professional autonomy becomes important. Therefore, I would like to emphasise the need for voluntary discipline by physicians through reaffirmation of the WMA Declaration of Madrid on Professional Autonomy and Self-Regulation.

The following observations and proposals are made in the light of the opportunities

which were presented at the Tokyo General Assembly.

In the past, many prominent declarations and statements have been drafted and adopted by the WMA Council and General Assembly, which have been used as guidelines by NMAs in resolving different issues, and I pay sincere homage to the efforts of the WMA to produce these invaluable statements.

In particular, the Declaration of Geneva, Declaration of Helsinki, Declaration of Madrid on Professional Autonomy and Self-Regulation are some of the many very distinguished statements that have been produced so far. They have served as the golden rule for physicians throughout the world during both under and postgraduate education. Their principles remain immutable in both the East and the West.

Despite this fact, the WMA has repeatedly revised these historical declarations beginning with the Declaration of Helsinki. The Physician's Oath in the Declaration of Geneva embodied the Hippocratic Oath, the Declaration of Helsinki had incidently the effect of applying some of the principles of the Nuremburg Code to the ethical principles for medical research involving human subjects, and the Declaration of Madrid provided the principles governing the complex physician-patient relationship and defined the attitude of the physician about professional autonomy and self-regulation.



The basic principles that are inherent in these declarations are important and they represent WMA's recognition of their significance in adopting them at that time. Therefore, they are also invaluable historical assets. To revise them unnecessarily may be to ignore the intent of those who originally drafted them. Moreover, it may also obliterate their significance as historical assets of the time. There is also concern that the original text will eventually disappear with repeated revisions.

The revisions of WMA declarations have hitherto been limited to unavoidable circumstances. But I would like to propose that in future, when there is a need for a declaration to reflect present-day medical and health care issues, a new and separate declaration be proposed, discussed, and adopted.

I would like to see the WMA Council spend its valuable time discussing current and

important issues rather than revising past documents. There is a backlog of many significant issues that we must discuss. Disclosure of medical information and protection of personal information, the spread of advanced medicine and soaring medical expenses, policies to control medical costs and improve quality of medical care, and the specialist and the general practitioner are just some of the many issues at hand that the WMA should address.

As a global professional organisation for physicians, the WMA must contribute to providing high quality medical care, based on professional medical ethics against a background of changing social conditions and public awareness. Therefore, it must be vigilant in its efforts to resolve the many issues at hand.

In conclusion, I look forward to WMA's further growth and development.

## Medical Science, Professional Practice and Education

## **Current Problems in Medical Education**

#### Hans Karle

#### President World Federation of Medical Education (WFME)

A prerequisite for progress towards the United Nations (UN) Millennium Development Goals (MDG), relevant for the health care sector, will be adjustments in the capacity of the professional health workforce worldwide<sup>1</sup>. This requirement will have considerable implications for medical education and education and training of other health professions in many parts of the world. The World Health Organisation (WHO) decision to launch a decade dedicated to human resources for health (HRH), starting with the World Health Dav and the World Health Report in 2006, is a clear indication of the fact that we are challenged by tremendous problems of ensuring the necessary HRH basis for sustainability and efficiency of health care systems. HRH is the central asset of health systems' development.

A new Strategic Partnership to Improve Medical Education and ultimately health professions education in general, formed jointly in 2004 by the World Health Organization and the World Federation for Medical Education<sup>2</sup>, is based on the rather simple concept (unfortunately not always recognised by all stakeholders) that quality medical education is of fundamental significance for quality health care.

The actual situation is that medical education is facing huge quantitative and qualitative problems worldwide. They are to a certain extent interrelated. The former are foremost determined by insufficient planning of production and distribution of medical doctors and their uncontrolled migration; the latter by insufficient leadership, conservatism and lack of incentives at the institutional level. For both, lack of or not using proper priorities of resources is a critical factor.

Focus is presently put on negative effects of migration of doctors. What from ancient times has traditionally been considered an advantage for the medical profession has now become a threat to health care systems in the developing world. In earlier periods, mobility was mostly a temporary phenomenon resulting in the achievement or delivery of expertise, whereas the present trend is a (unfortunately unclosed) circular movement in a chain reaction with the end result of the developing world being deprived of medical doctors. The mechanisms behind this traffic are, on one side, insufficient capacity of the educational system in some rich countries, the major sinners (USA, Canada and UK) benefiting from brain-gain without providing the necessary investments in health professionals education. On the other side, insufficient postgraduate training possibilities and the unattractive working and remunerative conditions for medical doctors in the poor countries, lead to external brain-drain and subsequently to increased in-country migration from rural areas to the big cities. Evidently, this pattern has catastrophic consequences for the health care systems, especially in Sub-Saharan Africa. The density of doctors in some parts of Africa is below 1 per 100,000 compared to 160-350 (in a few countries up to 550) per 100,000 in the Western world.

The existence of a vicious circle is underpinned by the fact that the underdeveloped countries are loosing some of the best qualified doctors and thereby part of the foundation for their training institutions.

The problem of migration, which is in fact even more complicated by the existence of active recruitment by some countries, and also by deliberate brain-export by other countries, have already been discussed extensively. In 2004, a World Health Assembly resolution<sup>3</sup> emphasised the critical situation and follow-up is planned, e.g. at the upcoming UN General Assembly Special Session (UNGASS) on migration. Some initiatives to remedy the critical situation have been taken, but the fundamental



causes have so far not been tackled. A recent proposal to obtain solutions points to the need for internationally adopted standards or norms for numbers of doctors in the developed part of the world and also for effective compensation to the developing countries<sup>4</sup>. Discussion at high political levels like the G8 Forum has included the HRH area in their considerations for support. It is generally agreed that capacity building regarding HRH is needed in many countries in Sub-Saharan Africa. This will require better data on the situation country-wise, evaluation of the existing training capacity and the needed conditions for expansion, and probably the establishment of new institutions in some countries as well as direct support from institutions in other Regions. The latter could include twinning arrangements between universities and hospitals and teleeducation programmes.

Facing the present HRH capacity problems, many authorities seem to be looking for a reduction of the training programmes in medical schools below the present norm of 5-7 years for graduate and 3.5-4 years for postgraduate medical curricula, which would enable higher production rates. The medical profession should resist such a development without thorough analysis of consequences. A curriculum programme below 5 years is generally not compatible with production of a medical doctor. Health workers coming out of such programmes must have other designations than "medical doctor", and instead of shortening the curriculum, a more realistic approach would be to consider the role of medical doctors and their relationship to the function and education of other health professions, including perhaps new cadres.

On the qualitative side, the problems are closely related to the mushrooming of new medical schools. Over the last decade, there has been an increase in number of about 100 per year. At the moment, there are no clear data regarding the overall number of medical schools. It is also becoming an issue of concern that this question depends on how we define a medical school. In this respect, some of the new schools have been established without adequate resources and often without sufficient clinical training facilities. A transition from a situation with largely public financed medical schools to an increasing private enterprise (in some cases even with for-profit purposes), adds to the problem of ensuring quality. Medical education like other types of higher education has now become a trade commodity which not only invites the establishment of diploma mills without proper training activities, but which also has led to off-shore satellites from some highly estimated medical schools, looking for opportunities to stabilise their economy by attracting affluent students more than thinking about quality education.

However, on the qualitative side of the coin there are also positive trends. Medical education is gradually being directed into an evidence-based educational activity with many valuable innovations as far as curricular design, teaching- and learning methods and assessment are concerned. More focus on social accountability, introduction of integrated curricula and community orientation as well as more reliable examination systems are examples of this development.

With respect to mutual integration of basic sciences and integration between basic and clinical sciences in education and assessments, medical education is now threatened by the European Bologna Declaration and Process, which tends to influence higher education principles also beyond Europe. This process, which otherwise includes important and valuable qualitative elements. requires a two-cvcle model of independent bachelor- and master-degrees. Although several stakeholders<sup>5</sup> have criticised such a development in medicine, arguing that current attempts to create integrated curricula will be invalidated, there is still major concern in many countries and institutions.

On the positive side could be added broad international consensus about the use of standards in medical education and the attention to quality assurance and accreditation of medical education institutions and programmes. The WFME Global Standards Programme for Quality Improvement, which received broad international endorsement at the World Conference on Medical Education in 2003<sup>6</sup> is now being implemented in all Regions of the world. The Trilogy of WFME Standards<sup>7</sup> are being used in institutional self-evaluation and peer reviews as basis for reforms (in the near future to be supported by a new WFME Advisor function) and are also being incorporated in National and Regional standards and accreditation procedures of both well-established and new accreditation systems. In most parts of the world there is a growing awareness of the need for effective, but transparent accreditation systems. Recently, the WHO/WFME Partnership has developed Guidelines for accreditation<sup>8</sup>. This development will most likely result in a Register of accredited medical schools based on quality indicators. The plans for developments of the WHO Directory of Medical Schools9 are in accordance with this.

The ongoing focus on outcome-based curricular design might be seen as a germ to the creation of new problems. While everybody would agree that attempts to use outcome definition is a valuable lighthouse in curricular planning, too narrow and shorttermed specification of the outcome of the educational process (which already seems to be the case in some medical schools). will have the risk of spoiling the fundamentals of academic medicine. Medical education should not only be determined by the endeavour to achieve a number of concrete practical competencies, but should foremost foster understanding and methodological capabilities.

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- **Development of new vaccines**

A number of new vaccines with major potential for controlling infectious diseases are at advanced stages of development. Among the illnesses targeted are rotavirus diarrhoea, pneumococcal disease, and cervical cancer (as caused by human papillomavirus), which together kill more than a million people each year, most of them in developing countries. In addition to these efforts against diseases of global importance, progress is being made on a vaccine for the regional menace posed by meningococcal meningitis serogroup A, which causes frequent epidemics and high rates of death and disability in African countries south of the Sahara.

These advanced candidate vaccines are the focus of the information provided below. However, it should be noted that continuing, intensive efforts are under way to develop effective vaccines for AIDS, malaria, dengue, leishmaniasis, and shigella dysentery, among others.

Vaccine development proceeds through discovery, process engineering, toxicology and animal studies to human Phase I, II, and III trials. The process can take more than 10 years, depending on the disease. The human trials focus initially on safety, 9. World Directory of Medical Schools. Seventh Edition. World Health Organization, Geneva, 2000 and www.who.int.

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involving small groups of people (I); then progress to moderate-sized "target" populations (persons close to the age and other characteristics for whom the vaccine is intended) to determine both safety and the stimulation of immune response (II); and finally to large target populations to establish whether a vaccine actually prevents a disease as intended (efficacy) (III).

## The current situation of a number of new vaccines in development:

#### Rotavirus

Acute diarrhoea is responsible for nearly 1.9 million deaths per year in children under age five. Rotavirus is responsible for as much as one quarter of these casualties, almost all of which occur in developing countries.

#### Status of vaccine development:

RotaRix, a vaccine developed by GlaxoSmithKline (GSK), showed an efficacy rate against severe rotavirus diarrhoea of 87% in a clinical study of 1986 infants in Venezuela, Brazil, and Mexico, and is now licensed in Mexico, the Dominican Republic, and Kuwait, although currently used only in the private market. A Phase III trial of over 60 000 infants was carried out in Latin America in 2003–2004, and efficacy results are expected soon. Phase III trials also are under way in South Africa and Bangladesh.

RotaTeq, a vaccine developed by Merck, protected more than 95% of recipients from severe rotavirus diarrhoea in a clinical trial of 1,946 infants in Finland. A Phase III trial of more than 70,000 infants in the United States and European countries has been carried out to investigate safety, and a subset of that group was followed to determine efficacy. The results of these studies are expected by mid 2005. Trials in Asia and Africa – where different strains of the virus may predominate – are likely to start this year but may not be completed for several years.

Rotavirus vaccines in earlier stages of development include two vaccines sponsored by the United States National Institutes of Health; a neonatal vaccine developed by an Indian-US consortium; and an Australian neonatal vaccine.

*Challenges:* A vaccine must be effective against numerous rotavirus strains (serotypes), including those prominent in developing countries. Large, stringent safe-ty trials are necessary because an earlier, unrelated rotavirus vaccine appeared to cause, in rare cases, a serious complication. Candidate vaccines, since they are live, oral vaccines, must be shown not to interfere with oral polio vaccine; and must be shown to be safe in HIV-infected children. Price is also likely to be an issue.

*Prospects:* Rotavirus vaccines will be ready for use in some additional countries by 2006, but information on their effectiveness in Africa and Asia will not be available until 2008. They are expected to be ready for widespread use in immunization programmes in Africa and Asia by 2009.

#### Pneumococcal disease

Acute lower respiratory infections are responsible for two million deaths per year and a large proportion of these are pneumococcal disease. A recent study (Cutts F. et al., The Lancet 2005) in The Gambia indicates that more than one third of these deaths might be caused by the bacterium *Streptococcus pneumoniae*. Most victims are children in developing countries.



Pneumonia deaths far outnumber deaths from meningitis. Nonetheless, in non-epidemic situations, *Streptococcus pneumoniae* is the main cause of meningitis fatalities in sub-Saharan Africa; of those who develop pneumococcal meningitis, 40–75% either die or are permanently disabled. Children infected with HIV/AIDS are 20–40 times more likely to contract pneumococcal disease than children without HIV/AIDS.

Status of vaccine development: A sevenvalent conjugate vaccine called Prevnar is designed to act against seven strains of pneumococcal disease. It has been developed by Wyeth and is licensed in the United States and several other countries, but does not include two serotypes (types 1 and 5) that cause a high percentage of pneumococcal illness in developing countries. (Conjugate vaccines, which have proved to be highly effective, are made by linking purified polysaccharides - complex sugars - from the coat of a disease-causing bacterium to a protein "carrier.") In the United States, use of this vaccine has led to a dramatic decline in rates of pneumococcal disease, not only in immunized children, but also in the un-immunized population through reduced transmission. Wyeth has now completed evaluation of a nine-valent conjugate vaccine, including serotypes 1 and 5. A Phase III trial of the vaccine involving 40,000 people was completed in South Africa in 2002, and a Phase III trial with 17,437 subjects was concluded in the Gambia in 2004. In the South African trial, the vaccine offered a rate of protection against invasive disease caused by the relevant serotypes of 83% in HIV-uninfected children and 65% in HIV-infected children. Results just released from The Gambia trial show the vaccine was 77% effective in preventing infections caused by the relevant serotypes; that it resulted in 37% fewer cases of pneumonia (as confirmed by chest X-ray) as compared with a control group; and that recipients experienced a 16% reduction in overall mortality. A vaccine containing these nine serotypes with or without additional serotypes is expected to be submitted for licensure within the next three to four years.

In addition, two 11-valent vaccines for pneumococcal disease – developed by two

different pharmaceutical firms – are undergoing evaluation.

Challenges: It can be difficult to establish the extent of pneumococcal disease as developing countries often lack the clinical and laboratory facilities, the expertise, and the resources to do so. As a result, public health decision-makers are often unaware of the prevalence of the disease and of the toll it exacts in death and disability. Because of the scarcity of data from developing countries, there is concern over whether the seven- and nine-valent vaccines contain the serotypes appropriate for all countries. Concerns remain - although results to date are encouraging - that prevention of some serotypes of pneumococcal disease may lead to increased incidence of other serotypes. The price of the vaccine, although still to be set for developing countries, may be too high for them to afford without special financing arrangements.

*Prospects:* A vaccine providing effective protection against pneumococcal disease for young children in developing countries may be ready for use in 2008–2009, and could be introduced in such countries provided adequate supply and financial help are arranged.

#### Human Papillomavirus (HPV)

Sexually transmitted HPV is the major cause of cervical cancer, the most common cause of cancer deaths among women in developing countries. About 500,000 cases occur each year, 80% of them in developing countries. Cervical cancer kills some 240,000 women annually.

Status of vaccine development: Phase III trials are under way of two commercial vaccines, each given in three doses. One, developed by Merck, covers four types of HPV, including the cancer-causing types 16 and 18 and types 6 and 11 for non-cancerous genital warts. The multi-year Merck trial, with an enrolment of over 25 000 women, is expected to conclude this year. The second vaccine, developed by GSK, covers HPV types 16 and 18 alone. The GSK trial began in 2004, has an enrolment of about 30000 women, and is still under way.

Results of a Phase II trial on a monovalent type 16 vaccine were published by Merck

in 2002. GSK published Phase II results of its bivalent type 16 and 18 vaccine in 2004. Both studies indicate that the candidate vaccines are well-tolerated; that they are highly immunogenic (produce antibodies); that they are greater than 90% effective in protecting against the relevant viral infections; and that they offer virtually complete protection against persistent infections by the target viruses.

Challenges: HPV types 16 and 18 cause 70% of HPV cervical cancers, but the vaccines in development will not cover the 30% of cancers attributed to other HPV types. Because these other types are numerous, significantly expanding vaccine coverage against them may present technical challenges for manufacturers. The duration of the immunity conferred by the vaccines is not yet known, but studies are planned that will look at this question. Because HPV is spread by sexual contact, and the high-risk years for infection are roughly from ages 18 to 25, the best subjects for vaccination will likely be pre-adolescents or adolescents, unlike for traditional vaccination programmes, which are aimed mostly at infants and pregnant women. Access to the vaccines is likely to be an issue in developing countries due to limited resources for the implementation of vaccination programmes.

*Prospects:* Both vaccines may be licensed within one or two years in the United States and Europe. Discussions are ongoing about collecting the necessary data for introducing the vaccines into developing countries. Their systematic use in developing countries may well depend on local epidemiology, acceptability, financial resources, and the feasibility of vaccinating adolescents.

#### Meningococcal meningitis A (Men A)

The African "meningitis belt" – which includes all or part of 21 countries stretching south of the Sahara desert from Senegal to Ethiopia – is the site of frequent epidemics, usually caused by serogroup A meningitis. Over the past decade more than 700,000 cases have been reported. Roughly 10–20% of persons infected die, and one out of five survivors is likely to suffer from a permanent disability such as hearing loss,



mental retardation, or paralysis. The rate of meningitis epidemics in the region has increased in recent years.

Status of vaccine development: Polysaccharide vaccines (vaccines made from complex sugars taken from the outer coats of the Men bacterium) are currently in use, but are not very effective at protecting young children, do not create long-lasting immunity, and do not confer a "herd effect" – that is, do not prevent spread of the disease in nonvaccinated people through reduction of the carriage of the infectious agent by vaccinated people during epidemics. Because of these shortcomings, immunization with polysaccharide vaccines is usually undertaken only after the onset of an epidemic.

To provide greater and more efficient protection, a public-private effort called the Meningitis Vaccine Project (MVP) is developing a Men A conjugate vaccine. This vaccine is intended to have long-lasting effect, to create immunity in infants, and to allow protection to be conferred in advance through mass immunization programmes. Toxicology studies and animal studies have been successfully completed, and the animal studies suggest the conjugate vaccine is highly immunogenic – that is, stimulates high levels of antibodies against Men A infection. Phase I trials will begin in May 2005 in India.

Other conjugate vaccines, including a tetravalent vaccine covering serogroups A, C, Y, and W135, are being developed by the private sector; and a tetravalent vaccine has recently been licensed by Sanofi-Pasteur in the United States.

*Challenges:* Clinical development of the Men A conjugate vaccine must still be carried out – it must be shown to be safe and effective in humans in Phase I, II, and III trials. In addition, other meningococcal meningitis strains are circulating in Africa which will not be controlled by a vaccine for serogroup A. One strain, referred to as W135, has recently caused epidemics in Burkina Faso and has become more prevalent, although its long-term potential as an epidemic agent is not known.

*Prospects:* A low-priced conjugate vaccine for Men A may be ready for widespread use in the African meningitis belt by 2008 or 2009, thanks to an innovative arrangement for development and production. The vaccine was designed by the Center for Biological Evaluation and Research of the United States Food and Drug Administration. The technology was then transferred without intellectual property charges to the Serum Institute of India, which carries out production at the lower costs prevailing in a developing country. The Serum Institute uses raw materials (group A polysaccharides) supplied by SynCo Bio Partners of the Netherlands. The arrangement is expected to keep costs as low as US\$ 0.40 per dose, making the vaccine affordable for lowincome countries. Much of this vaccinedevelopment project was underwritten by a US\$ 70 million grant from the Bill & Melinda Gates Foundation.

## WHO Initiative for Vaccine Research (IVR)

The WHO Initiative for Vaccine Research was established in 2001 to streamline the various vaccine research and development projects being carried out by different departments of WHO (including the Special Programme for Research and Training in Tropical Diseases: TDR) and UNAIDS. IVR also provides leadership, priority setting, and coordination among efforts worldwide to develop vaccines against neglected diseases, particularly diseases endemic in developing countries. In addition to collaboration within WHO. IVR works in close association with international organizations, philanthropic organizations, academic medical institutions, and private- and public-sector partners active in the research and development of vaccines.

## **Robots on the Hospital Wards**

In a pilot scheme Remote Presence (RP6) Robots are being tried out in a trial conducted in a General Surgery Ward and Accident and Emergency Department in St. Mary's Hospital, London and for training purposes, in the Academic and Clinical Skills Unit at Imperial College, London.

The robots are controlled with a joystick from a remote site and, via the machine and using wireless technology, permit the doctor to see the patient, ask questions and read patient notes, view x-rays and test results from the *console*. The patient can see the doctor's image on the robot's face.

Parv Sains, Surgical Specialist registrar and Research Fellow, who leads the project, said benefits include allowing patients direct access *(for consultation)* to experts worldwide and to the doctor who performed their surgery even if they cannot be physically at the patient's bedside.

Dr. Sains said:

"Our robots certainly would never replace all doctors on ward rounds, but they are a communication tool with allows doctors to have direct contact with their patient if they are unable to get to them."

The RP6 was developed by In Touch Health, a US robotics company. Trials of the robots are taking also place in the UAA (3) and in Strassbourg (1).

The robot runs on a wireless system with the doctor at another location. It is controlled by a secure internet connection, the doctor (controller) and patient are able to have a real time two way audiovisual interaction, with the controller in full command of the robot's movements.

This first trial in the United Kingdom is the latest strand in pioneering integration of robots into healthcare Professor Sir Ara surgeon at St. Mary's Hospital, who is the head of Imperial's Division of Surgery, Anaesthetics and Intensive care.

Professor Darzi added "This revolutionary concept which opens new avenues for telemedicine research an integrates technology with healthcare at the grass roots level, increasing the interface between patients, clinicians and teaching staff."



## **Detection Of Faulty Genes In Breast Cancer**

Four genes on chromosome 8 have been discovered by Professor Caldas and his researchers at Cambridge University which appear in breast cancer tumours but not in normal tissue. During the 1990s defects in the breast cancer tumour suppressor genes were established as the major cause of hereditary or familial breast cancer. Now mutations of genes within tumours have been discovered linking cancer to the environmental and non-hereditary forms of breast cancer. Nevertheless scientists are still puzzling over why these genes are so rarely mutated in sporadic forms of the disease, which represent the vast majority of cases.

#### **Aggressive tumours**

Why should breast cancer, in terms of its metastasis, be so aggressive in its attack on other organs when its cells are transported round the body? The disease is known to be triggered by faulty genes, and now we have the technology to isolate rogue gene mutations in tumours from hundreds of other genes which are also present. Making multiple copies of gene sequences could lead ultimately to sensitive diagnostic tests for cancer and treatments that work far more effectively.

According to Professor Tony Kouzarides of Cancer Research UK, a protein binding on the BRCA2 breast cancer gene, in a region deleted in cancer, might itself be involved in the cancer process. Such a gene, known as EMSY, has been mapped to a large region on chromosome 11, at q13.5, which is amplified in many breast cancers. An antibody has been raised against EMSY which could mean further diagnostic progress, but to date the gene hasn't been persuaded to over-express itself or been knocked out by a new technique known as RNA interference. However it has been shown to be involved in DNA repair and in transcriptional control. A search of BRCA2's lengthy DNA sequence could reveal similarities to other known genes,

which would provide clues as to its function. It turned out that there was a similarity between a small region of BRCA2 and a transcription factor. Such a finding is clinically important, because it is known that this sequence in BRCA2 is deleted in patients with familial breast cancer. Mapping studies confirmed that the function of the EMSY gene lay in the binding of methylated chromatin in the chromosome, which links EMSY to specific signals recognised by the nuclear transcription machinery.

#### EMSY as a cancer gene

Professor David Huntsman's group in Vancouver have analysed very large numbers of tumour samples. EMSY was amplified in 13% of breast cancers and 17% of ovarian cancers – another particularly aggressive tumour – with a clinical profile that perfectly mirrored deletions of BRCA2 in hereditary cancers. It was found that breasts cancer patients, in whose tumours EMSY was amplified, lived on average for a further 6.4 years, compared with 14 years otherwise, which suggests that EMSY has the potential when cloned up to be a very useful prognostic marker.

Ivan M. Gillibrand

## IAEA Programme of Action for Cancer Therapy (PACT) Building Capacity for Radiation Therapy in Developing Countries

Werner Burkart, G. Gellert, M.D. Rosenthal, Massoud Samiei, Susan Snyder and Bhadrasain Vikram

#### Abstract

World Health Organization (WHO) data predict a growing cancer epidemic, especially in the developing world. In 2003, WHO issued a global call to action to address increasing cancer needs. The International Atomic Energy Agency (IAEA) answered this call in June, 2004, and established the Programme of Action for Cancer Therapy (PACT). The IAEA has long standing experience in developing countries with the delivery of technical assistance related to cancer detection and treatment through nuclear technologies. PACT is designed to respond to the needs of developing countries by addressing the technical, human resource, legal, and regulatory needs to establish, improve, or expand radiotherapy programs in the context of sound national cancer control strategies. PACT invites organisations sharing this interest in advancing cancer control in developing nations to partner with the IAEA and others in a global effort to respond immediately and effectively to the WHO call to action.

#### **Cancer in the Developing** World

Cancer is a global problem today, and its prevalence will increase dramatically over the next decade, especially in the developing world. According to the World Health Organization (WHO), 12.5% of all deaths world-wide are currently caused by cancer, a greater percentage than caused by HIV/AIDS, tuberculosis, and malaria com-



bined. (1) And while cancer is often viewed as primarily a disease affecting the advanced industrialized states, where it is already the second leading cause of death, it is among the three leading causes of death for adults in the developing world. (1)

Based on recent incidence and mortality data, in 2000, there were 10.1 million new cancer cases, 6.2 million deaths and 22.4 million persons living with cancer. (2) This represents an increase of 19% in incidence and 18% in mortality since 1990. The International Agency for Research on Cancer (IARC) data predict that cancer rates could further increase by 50% from 10 million new cases in 2000 to 15 million new cases by 2020. (1) The largest rates of increase of new cases are foreseen to occur in developing countries, where governments are least prepared to address the growing cancer burden. (1) This dramatic increase will result, in part, from changing demographics with steadily aging populations in developing countries, as well as current trends in smoking prevalence and the growing adoption of unhealthy lifestyles and behaviours. (2)

Cancer varies between developing and developed nations in both incidence and site. Cancers associated with infectious agents, including cancers of the stomach, uterine cervix, and liver, impact more heavily on populations in developing countries. (2) The developed world has a higher incidence of colorectal and prostate cancers. The differences are attributable to many factors, including tobacco use and diet. (2) Up to 25 percent of malignancies in the developing world are caused by infectious agents, while in developed countries these malignancies account for only about 8 percent. (2) This difference is especially large for cervical cancer. In developed countries, early detection has led to impressive cure rates, to such that among cancer deaths, the death rate from cervical cancer is more than 4 times higher in the developing world than it is in developed countries.

Tobacco use, a leading cause of cancer, stroke, chronic lung, and cardiovascular disease, is also on the increase in the devel-

oping world. In the 20<sup>th</sup> century, approximately 100 million people died from tobacco-related diseases, including cancer. (3) Almost half of all men in developing countries now smoke, and the tendency of youth around the world to start smoking at younger and younger ages is alarming. (4)

The data are unequivocal: a cancer epidemic is emerging in the developing world. Action to stem the increase, manage the growing burden of morbidity, and reduce the suffering caused by cancer in the developing world should begin immediately. Indeed, the World Health Organization has called for action from all sectors, public and private, in a global effort against cancer.

#### The International Atomic Energy Agency and Promotion of Human Health and Development

The International Atomic Energy Agency (IAEA) is highly regarded for its successful long-term effort in safeguarding nuclear material and preventing nuclear proliferation. The IAEA is less well known for advancing development in the areas of agriculture, nutrition, water, and health. Since its inception, the IAEA has had a dual mandate: containing the spread of nuclear weapons while advancing the peaceful application of nuclear sciences and technology. Over the past five decades, nuclear applications have expanded to become an almost ubiquitous factor in daily life, especially in the developed world. Around the globe, nuclear technologies are used widely to support industrial applications and to combat disease, poverty, hunger and a shortage of drinking water.

Radiation medicine, including the diagnosis and treatment of cancer, is an area where the IAEA has excelled in the past 50 years. The IAEA is the only international organisation with the specific mandate to "accelerate and enlarge" (5) the use of nuclear and radiation techniques for the prevention, diagnosis, and treatment of health problems. Nuclear techniques play a major role in modern medicine. They are important tools for the diagnosis and treatment of many diseases and are indispensable in fighting cancer, where radiation therapy plays a fundamental role. Alone or in combination with surgery and/or chemotherapy, radiation therapy is recommended for the majority of cancer patients, although this can vary by country or region.

The IAEA has solid technical and managerial experience in working in developing countries over the past 30 years to develop and deploy essential elements of sound cancer management programmes. Since 1980, the IAEA has delivered to developing countries some \$150 million worth of cancerrelated assistance under its Technical Cooperation programme. This assistance has involved over a 100 countries and has enabled many of them to establish for the first time safe and effective radiotherapy capabilities. (Figure 1 – World Map showing IAEA assistance in RT transfer)

However, in order to meet the ever growing needs placed on developing countries by the burgeoning cancer epidemic, much more needs to be done. More staff needs to be trained, diagnostic and treatment technology needs to be in place, and at least hundreds of millions of additional dollars need to be raised over the next 10 years. Although it is anticipated that the IAEA's support for cancer programmes will remain significant, at about \$15 million per year, the resources available to the IAEA fall well short of what is needed to meet the growing needs of developing countries.

#### Programme of Action for Cancer Therapy (PACT)

In the light of rapidly increasing rates of cancer in the developing world, in June, 2004, the IAEA launched a Programme of Action for Cancer Therapy (PACT). This new programme offers a crucial element in the global response to the growing cancer burden. Radiotherapy is a mature, robust and cost-effective technology that can, depending on stage of presentation, cure many cancer patients and relieve many others' suffering. Currently, radiotherapy is not available to most cancer patients in the developing world.

PACT is designed to respond to the needs of developing countries by addressing the technical, human resource, legal, and regulatory needs to establish, improve, or expand radiotherapy programmes in the context of sound national cancer control strategies. PACT will develop a systematic, global, sustainable and accountable programme to prevent and treat cancer and





relieve the pain and suffering of cancer patients throughout the developing world.

Specifically PACT will: (a) build an international, public-private coalition of interested parties committed to addressing the challenge of cancer in developing countries in all of its aspects; and (b) mobilize resources from foundations, charitable trusts, industry and others in the public and private sectors for the benefit of cancer patients. PACT will build partnerships among countries, with other UN institutions such as WHO and IARC, and other international stakeholders. In addition to securing resources for radiotherapy centres, PACT will respond to the most frequent problems encountered by developing countries in building effective cancer control infrastructure. In order to assist countries in the analysis of options and to put in place cancer therapy programmes appropriate to their needs: PACT will:

 Increase capacity within ministries of health and other health sector institutions, to formulate policies and set priorities for investments in radiotherapy. According to WHO, "many policy makers do not attach enough importance to the provision of good radiotherapy. Although it has a strong clinical background, its role has not been understood as well as other cancer treatment modalities such as surgery and chemotherapy."(6)

- Provide training, management skills and other resources that will help institutions leverage the initial investments in trained staff and equipment towards safe, effective, and sustainable operations.
- Promote the development and implementation of effective, well balanced national strategies for cancer control, including generation of surveillance data to ascertain local cancer disease burdens, care needs, and outcomes.
- Enhance technical, legal and administrative capabilities to establish and implement regulatory systems, including those appropriate for radiation protection, safety and security.

Specifically, PACT will meet the needs of developing countries because it will:

- Strengthen national programmes for cancer control.
- Enable health sector institutions to design and support the implementation of policies and projects for the sound application of radiation therapy.
- Establish radiotherapy centres in each developing country appropriate to its

needs and national cancer control strategy, taking into account economic and demographic factors.

- Establish centres of excellence for radiation therapy that will serve as training sites for regions served by PACT.
- Review the status of radiation protection, safety, and security arrangements at national and local levels, and, as needed, help nations put in place the technical, legal, and regulatory capacities appropriate to take best advantage of radiation therapy.
- Promote strategic partnerships between countries in cancer therapy and in their national research, education, and regulatory systems at the sub-regional and regional levels; between national and international organizations; and between the public and private sectors that are both South-South as well as North-South.

Most importantly, the investment of significant resources to advance cancer prevention and therapy in developing countries will save untold lives and relieve suffering.

## **Call To Collaboration**

PACT invites organisations sharing this interest in advancing cancer care in developing nations to partner with the IAEA and others in a global effort to respond immediately and effectively to the WHO call to action. PACT seeks organisations with pertinent developing world experience and capability in cancer control, including, but not limited to radiation oncology, cancer screening and diagnosis, cancer prevention programmes, fundraising, programme impact evaluation and outcomes research. Interested parties should contact PACT at PACT@iaea.org to learn more, or volunteer support.

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A Global Strategy for Radiotherapy: A WHO Consultation, Clinical Oncology

### <u>WHO</u>

## WHO declares TB an emergency in Africa and Calls for "urgent and extraordinary actions" to halt worsening epidemic

The World Health Organization (WHO) Regional Committee for Africa comprising health ministers from 46 Member States has declared tuberculosis an emergency in the African region - a response to an epidemic that has more than quadrupled the annual number of new TB cases in most African countries since 1990 and is continuing to rise across the continent, killing more than half a million people every year.

The declaration was made in a resolution adopted today at the end of the Committee's fifty-fifth session in Maputo, Mozambique. The resolution urges Member States in the African Region to commit more human and financial resources to strengthen DOTS programmes and scale up collaborative interventions to fight the co-epidemic of TB and HIV. These and other measures recommended by the Committee encompass those laid out in a "blueprint" developed by the global Stop TB Partnership, which calls for US \$2.2 billion in new funding for TB control in Africa during 2006-2007.

"Despite commendable efforts by countries and partners to control tuberculosis, impact on incidence has not been significant and the epidemic has now reached unprecedented proportions," said WHO Regional Director for Africa, Dr. Luis Gomes Sambo. "Urgent and extraordinary actions must be taken, or else the situation will only get worse and the TB targets in the Abuja Declaration and the Millennium Development Goals will not be achieved."

In the late 1970s and early 1980s, African countries like Tanzania, Mozambique and Malawi were among the first to apply what became the global TB control strategy now known as DOTS. But in the past 15 years, TB incidence rates have soared in the region - to as high as four-fold in Malawi and five-fold in Kenya, to cite some typical examples -due largely to the link with HIV/AIDS, poverty and weak health systems. Although countries have made efforts to treat the rising tide of TB cases, they are still being outpaced by the epidemic.

"It is tragic that this disease has not been brought under control, because I am living proof that TB can be effectively treated and cured," said Nobel laureate Archbishop Desmond Tutu, who along with former South African President Nelson Mandela is a survivor of the disease. "The problem is huge and medical authorities cannot overcome it alone, they need help. A full course of TB drugs that costs 15 dollars will save the lives of TB patients - and in the case of people who are co-infected with HIV, extend their lives by precious years until ARVs become more widely available in Africa."

Among the constraints to fighting the epidemic cited in the Maputo meeting is the inadequate financial support currently available for TB control. A large majority of African countries that provided financial data to WHO in 2003 reported funding gaps, including eight of the nine countries with the highest TB burden.

But more financial resources alone will not solve the TB problem. Dedicated efforts must also be made to strengthen health systems and respond to the crisis of health workforce attrition in the region. The specific actions called for by the Regional Committee to address the TB emergency are:

- improve the quantity and quality of staff involved in TB control;
- rapidly improve TB case detection and treatment success rates with expanded DOTS coverage at national and district levels;
- reduce the combined TB patient default and transfer out rates to 10% or less;
- scale up interventions to manage TB and HIV together, including increased access to anti-retroviral therapy for TB patients who are co-infected with HIV, and to chemoprophylaxis against TB for people with HIV;
- expand national TB partnerships, publicprivate collaboration and community participation in TB control activities.

In the other four WHO regions of the world, TB trends are either stable or in decline and are on track to reach the MDG targets of halving TB prevalence and deaths by 2015.

## **Models of Disease**

**Geneva 3 August 2005 – Statement** The World Health Organization welcomes the pandemic influenza response modelling papers published in the journals Science

and Nature 3<sup>rd</sup> August 2005. This is work done by expert scientists using two different sets of assumptions. The models provide additonal information which will help WHO and public health officials in our Member States to improve pandemic influenza preparedness planning.

Both papers suggest that a combination of early, targeted use of antiviral medicines and social distancing (measures such as can-



celling mass gatherings and closing schools) can stop a pandemic, or at least slow its spread. There would be significant practical challenges to implementing such measures, but the enormous social trauma and human suffering that an influenza pandemic could inflict creates an obligation to thoroughly explore all proposals to limit this damage. Several countries have already purchased stockpiles of antiviral drugs and WHO has taken steps to establish an international stockpile. National and international stockpiles of antiviral drugs may be an essential component of comprehensive international pandemic preparedness, that also includes vaccine development and disease surveillance. If we have a chance to reduce the scale of a pandemic with antivirals and other public health measures, the success of these interventions will depend on effective disease surveillance and early reporting in riskprone countries. Before any stockpile can be used effectively, both must be strengthened.

## Indonesia launches country's largest-ever immunization campaign to tackle expanding polio epidemic

To combat Indonesia's largest recorded polio epidemic, which now threatens a broad swath of countries across Asia, on 30 August, 24 million children were to be immunized during the country's largestever mass immunization campaign.

Since March, 225 children have been paralysed, due to a poliovirus imported into the country earlier this year. Initially restricted to two provinces on Java island (Banten and West Java provinces), the outbreak is geographically expanding, recently infecting the country's capital Jakarta, as well as Sumatra and Central Java.

"In addition to paralysing children throughout Java and southern Sumatra, the outbreak continues to expand, and there is great risk that it could spread into neighbouring countries," confirmed Dr David Heymann, Representative for Polio Eradication at the World Health Organization (WHO), who recently returned from Jakarta. "As with other infectious diseases, the poliovirus does not respect borders. The Government of Indonesia has assured the polio partners that it is fully engaged and committed to stopping this outbreak, and to doing everything it can to prevent further international spread of the virus."

The polio eradication partnership is urgently scaling-up both technical and financial assistance to the Indonesia authorities. Leading the civil society sector charge is Rotary International, which has raised more than US\$600 million for polio eradication since 1985.

"We are more than ever committed to the attainment of a polio-free world," commented Frank J Devlyn, Chairman, The Rotary Foundation. "Concerned Rotarians are mobilising across Asia. Rotarians from Malaysia, Thailand and Singapore are joining their fellow Rotary members in Indonesia in supporting these important activities."

"Reaching every, single child requires a massive communication effort, in highlighting to parents the dangers of the current polio outbreak and of the need to immunize every child," said Alan Court, Director of UNICEF's Programme Division. "This is our best chance to protect Indonesia's children, safeguard vulnerable children across the region, and keep a polio-free world within our sight."

The campaign on 30 August will be followed by additional immunization rounds on 27 September and early November.

## **Partnerships Working for Health Forum**

In announcing a WHO Forum on Partnership, WHO states that the proposed theme will be "Making Partnerships work for Health", with subsidiary illustrative themes of "Preventing Chronic Diseases", "Human Resources for Health" and "Making every mother and child count" – the theme of this year's World Health report and World Health Day.

"Human resources for Health" is the subject of the World Health report and World Health Day in 2006, which will also mark the beginning of a decade of action on this theme. The WHO, which, for the first time has offered open consultation encouraging broad participation on the 2006 World Health report theme via e-mails and the web, stresses that the WHO workforce is crucial to scaling up health interventions to meet the MDG health goals. Pointing out that a common problem is overall health workforce shortage, it says that this is aggravated by in-balanced distribution between urban and rural areas. This all leads to low productivity and is made worse by inadequate investment and pre-service training, work overload, inadequate remuneration and negative working conditions.

An interim working group has already been formed to explore workforce problems facing leaders, which call for long term strategies and high level commitment.

The Forum, to be held on 26-28 October, will involve UN organisations, NGO's, professional and research institutions, as well as private sector entities.



## **Concerted Action to Achieve The Millennium Development Goals**

**Geneva** – The World Health Organization has joined the United Nations in supporting the mean message of the *Millennium Development Goals Report 2005*: Despite uneven progress towards achieving the global development goals, they are still achievable with determination, renewed commitment and immediate concerted action from global leaders.

Progress on the health-related Millennium Development Goals (MDGs) is mixed and if current trends continue, most poor countries will not meet these goals. However, investing in proven solutions can still turn the tide and help to achieve the goals.

"We have the means to achieve those goals. We have the technology. What we need are the resources and the political will", said Dr LEE Jong-wook, WHO Director-General. "We cannot wait any longer to do what we have promised to achieve in the coming decade."

No region of the developing world is currently on track to meet the child mortality target of reducing by two-thirds the mortality rate of children under the age of five. For maternal mortality, evidence indicates that declines have been limited to countries with lower levels of mortality; countries with high maternal mortality are experiencing stagnation or even reversals.

Data on coverage of some health interventions are more hopeful. For example, the proportion of women who have a skilled medical person with them during delivery has increased rapidly in some regions – especially in Asia, albeit from a low baseline; use of insecticide-treated bednets has risen; and coverage of effective tuberculosis treatment has expanded.

In June 2005, WHO launched its own MDG report, *Health in the Millennium Development Goals*, which looks beyond the target-by-target information and identifies trends, successes and failures which are currently affecting the health sector as a whole.

In September 2000, 189 world leaders signed the Millennium Declaration, and made a commitment to achieve the Millennium Development Goals by 2015. Three of the eight goals relate directly to health: to reduce maternal mortality by three-quarters, child mortality by two-thirds and combat HIV/AIDS, malaria and other diseases. Health is an essential component of three further targets: to halve the proportion of people who suffer from hunger, improve access to safe drinking water and sanitation and ensure affordable, safe access to essential drugs.

## New Bangkok charter for health promotion adopted to address rapidly changing global health issues

The 6<sup>th</sup> Global Conference on Health Promotion. Thailand, 7-11 August, adopted a new Bangkok Charter for Health Promotion. It identifies major challenges, actions and the commitments needed to address the determinants of health in a globalized world by engaging the many actors and stakeholders critical to achieving health for all.

The Charter highlights the changing context of global health and the challenges faced in achieving its aims, including the growing double burden of communicable and chronic diseases which include heart disease, stroke, cancer and diabetes. There is also the need to address and harness the health effects of globalization such as widening inequities, rapid urbanization and the degradation of environments.

The Bangkok Charter gives new direction to Health Promotion by calling for policy coherence, investment and partnering across governments, international organizations, civil society and the private sector to work towards four key commitments. These include ensuring that health promotion is central to the global development agenda, that it is a core responsibility of all governments and part of good corporate practice, as well as a focus of community and civil society initiatives.

"The Bangkok Charter for Health Promotion will be the product of many organizations, networks, groups and individuals in many countries. It will urge all stakeholders to work together in a worldwide partnership to fulfill its commitments and carry out its strategies," said Dr. LEE Jong-wook, Director-General of the World Health Organization in his opening address to the conference. "The action you take in the light of this Charter can radically



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improve the prospects for health in communities and countries around the world."

The Charter was developed through an open consultation process involving participants from a wide range of groups and organizations around the globe. The discussion was concluded at the conference this week, attended by 700 participants from more than 100 countries including leading Health Promotion experts, government policy makers, non-governmental organizations, health specialists and representatives from the private sector.

The Ottawa Charter of 1986 established the core principles of Health Promotion which seek to identify and positively affect the root causes, or determinants, of health. These are social and economic factors that determine health status such as income, education, profession, working conditions, mental status, which in turn can affect risk factors such as smoking, alcohol consumption, eating habits and physical inactivity.

Health Promotion works to enable people to increase control over their health and its determinants by developing personal skills, embracing community action, and fostering appropriate public policies, health services and supportive environments. Health Promotion is currently guiding global, national and community health policies, thereby contributing to reducing health risks. The WHO Framework Convention on Tobacco Control and The WHO Global Strategy on Diet, Physical Activity and Health represent just two examples of such activity.

Nevertheless major inequities persist globally, particularly in the developing world. Speaking at the Bangkok conference, Professor Sir Michael Marmot, Chair of WHO's Commission on the Social Determinants of Health, identified a fundamental concern: "It is not inevitable that there should be a spread of life expectancy of 48 years among countries and 20 years or more within countries. A burgeoning volume of research identifies social factors at the root of much of these inequalities in health." The challenge of the Bangkok Charter has been to determine how best to respond to the many global changes and trends that are critically affecting health and well-being and how to evolve Health Promotion strategies to address these inequalities and to be more relevant to the demands of the new millennium.

The conference has also examined many issues pertaining to these challenges. Discussion ranged from trade agreements and public health to the regulation of products harmful to health, and from the health experience of marginalized groups to the role of private sector foundations. The conference proved a valuable forum for disseminating results and lessons learnt of the effectiveness of Health Promotion and how to evolve these to better address ongoing inequalities. Speaking at the opening ceremony of the conference, the Prime Minister of Thailand, H. E. Pol. Lt. Col. Dr. Thaksin Shinawatra, noted, "It is clear that good health is a key to progress. In those societies where people are healthy, such communities are sure to progress in many ways. Building health has thus become a priority on national and global agendas."

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## **EU Project Targets Killer Viruses**

A new project targeting the increasing resistance of some viruses to drugs is being funded with the help of nine million euros under the Life Sciences, Genomics and Biotechnology for Health area of the EU's Framework Programme.

The VIRGIL (Vigilance against Viral Resistance) project brings together experts from 55 organisations in 12 European countries to examine the problems being faced in treating certain diseases. Many of these problems have been caused by heavy use of antivirals in treating viruses and this is resulting in a growing number of mutations in viruses that are becoming increasingly resistant to drugs.

VIRGIL draws on the experience of the top academic researchers within Europe as well as the pharmaceutical industry, clinicians and public health authorities to help save lives by overcoming the problems associated with viral drug resistance.

"Acute and chronic viral infections represent a major public health problem in Europe and are responsible for a major socio-economical burden", says Howard Thomas, Professor of Medicine at Imperial College. "The development of new antiviral drugs and new diagnostic tools in the past decade has played a major role in the improvement of patient care and treatment of viral diseases to extend the quality and duration of human life. However, their increased use - and sometimes misuse - in medicine have brought about viral drug resistance. This has led to treatment failure and increased costs for health care and society."

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"As there is no global programme to develop strategies for the surveillance and containment of viral resistance to antiviral agents, there is a clear need to implement a European programme to optimise patients care and to minimise emergence and spread of antiviral drug resistance. The overall objective of the VIRGIL Network of Excellence is to set up the first-ever European Vigilance Network capable of addressing current and emerging antiviral drug resistance developments that will allow for the management of this critical problem in Europe."

Initially, VIRGIL will be looking into drug resistance in the treatment of three major diseases – hepatitis B and C and influenza.

Research shows that more than 520 million people around the world are chronically infected by hepatitis viruses (B or C). In addition, new strains of influenza cause up to 500,000 deaths every year worldwide. However, it is intended to broaden the viral scope later in the project, to treat further diseases VIRGIL is being built around seven "research and technological platforms" all centred around the patients. Two of them will test and monitor antiviral drug resistance in patients with the aim of improving and standardising the management of viral resistance on a global level. Other platforms will look to find the reasons for the increasing drug resistance with particular focus on patient-related factors.

The project will also investigate how drugs, pharmacology, innovation and technology can be brought together to anticipate ways which will beat drug resistance.

"Viral resistance is becoming a major health problem", says Claire Horton, FP6UK's National Contact Point for Life Sciences, Genomics and Biotechnology for Health. "The VIRGIL project complements a 30 million Euro EU research investment into antimicrobial drug resistance over the past two years to address this growing problem."

information on the VIRGIL project visit http://www.virgil-net.org.

## Developments in Kazakhstan (Kazakhstan Medical Association)

The Kazakhstan Medical Association (KzMA) established in 1990, continues its development not only by its representation on relevant governmental commissions, influencing draft health legislation, state programmes and projects in health and other professional activities, but also by its strong interest and action in the ethics of biomedical research. It participated in the Central and Independent States (CIS) Ethics Commission in 2001, suggesting the need for a Forum for Ethics Committees in the CIS which was subsequently adopted, and holding an international conference on "Qualitative Ethical Practice in Biomedical Research" in 2002. This led to a further initiative, the Second International Conference in 2005 on "Bioethical Problems in Health in the Twenty-first century". The out-

come of this conference was a Resolution recommending that the Kazakhstan government and other relevant institutions should institute the development of educational programmes on ethics and the establishment of an Ethics and Bioethics committees. It further considered it necessary to support cooperation on issues relating to the ethics of science and bioethics with international organisations such as the UNESCO, World Health Organization, the Council of Europe and other Non-governmental organisations such as the World Medical Association and European Forum of Good Clinical Practice etc. The KzMA has developed a draft Regulation on National Committees for Bioethics, which has been submitted to the government.

## Family Medicine recruitment in Canada

The Canadian Medical Association reports that after a period during which there has been a fall - off in the number of new graduates choosing Family Medicine as a career choice, the latest figures indicate some increase. In the first quarter of this year the residency match indicated that 28% of graduating students from English language medical schools made family medicine their first choice in 2005. Whilst this is far from the 35% level achieved in 1997 it is an improvement. It shows an improvement on the low of 24% two years ago. Dr. Gutkin Chief Executive of the College of Family Physicians of Canada said "Public survey after public survey reinforces the fact that patients value having a family doctor very highly and that Canadians see the shortage of FPs as one of the nation's main health system problems".

Recent polls indicate that more than three million Canadians do not have a family physician.



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## **TCRC receives WHO Certificate of Appreciation**

The Tobacco Control Resource Centre (TCRC) run by the British Medical Association and supported by the European Community and the World Health Organisation has been awarded a Certificate of Appreciation by the World Health Organisation, in recognition of its outstanding contribution to Tobacco Control.

The TCRC is well known not only to NMAs in the European Region but to NMAs worldwide, both for its assistance to NMAs individually and its international seminars lectures and research. TCRC has produced a range of important publications, in particular "Doctors and Tobacco – medicine's big challenge" (now translated into nine languages) and "Doctors and Tobacco: The Masterclass" which includes the reports "Smoking and reproductive life", "Smoke free World: doctors' notes on clean air laws" and "Towards smoke-free public places".

The TCRC is based in the BMA Office in Edinburgh e-mail: tcrc@bma.org.uk

## Bomb explodes outside NMA building

During the bomb incidents in London in July, a bomb exploded in a bus immediately outside the headquarters building of the British Medical Association, killing 13 people and injuring many more. Hospital doctors and GPs who were in the building, led by the Deputy Chairman of Council and the Deputy Chairman of the General Practice Committee, converted the building into an effective and efficient casualty unit for emergency care. Staff and doctors joined together to comfort the injured, create makeshift stretchers and move the dead and injured to the safety of the building.

The Chairman of Council who is also member of WMA Council, commented

"I want to pay a huge tribute to BMA staff and doctors, who pulled together to help the victims of this atrocious terrorist act. I believe that without the skills of our doctors on the scene the death rate would have been significantly higher.

It is also a tribute to the organisation which I am honoured to lead, that within a day plans were made to keep services to members functioning even though only a handful of BMA staff and members were able to get into our HQ for the next ten days".

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Review

## **Information Products Catalogue 2003, 2004** (WHO Regional Office for Europe, Copenhagen p. 47 + CD ROM)

It is unique in these columns to review a catalogue, but on this occasion the contents could be so useful to those working in any field of Healthcare provision, no matter in which part of the world, that this review is particularly justified.

The second publication by the WHO European Regional Office of the second Information Products Catalogue is a remarkable document which could easily be overlooked by those who could benefit from it. It provides bibliographic data, including descriptions of the material available, categorised to reflect the WHO global database for 130 publications issued in 2003/2004. But even more commendably, the full text of each publication is available in the CD ROM which is attached to the catalogue. The scatter of topics is vast. The ready availability of the full material of papers or books in fields as variable as Chronic Disease control, Communicable Diseases and their control, Environmental and Public Health, Epidemiology and Statistics, Health Manpower and Planning, Mental Health, Parasitic Diseases and their control, Smoking and Health (to mention but a few of the diverse topics covered by the 18 broad categories under which the 130 reports and books are classified) is indicative of their potential value.

Anyone with an interest in any one of these areas would be well advised to look at this catalogue and, if they so wish, access immediately any relevant documents whose full text is available in the CD ROM provided with the Catalogue.

## Walter Burkart

It is with great regret that we report the death of Walter Burkart who was for many years the Co-Editor of the World Medical Journal. A multi-linguist, his comments on the international scene were clear and penetrating. In his activities he was particularly interested in psychiatry and in the provision of further medical education. The earlier part of his career was as Editor and Bonn correspondent of The Hamburg Advertiser and later among many other activities Publisher of the Social Press Service "Bonn Social Politics" Later he joined the editorial staff in the scientific division – of the German Medical Journal (Deutsches Ärzteblatt) He was a good friend and colleague to all who knew and worked with him.

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