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*Title page: The Rigshospitalet, Copenhagen founded as King Frederik's Hospital in 1757 celebrates its 250 anniversary this year. It became the State Hospital in 1910 and is now integrated in the Copenhagen Hospital Corporation. With extensive resources and research activities it serves as the national specialist referral hospital for Denmark.*

*Below: The Headquarters of the Danish Medical Association which is hosting the General Assembly of the World Medical Association this year, has been located in this attractive building since 1948.*

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# Editorial

The second half of the 20th century and the beginning of this one have experienced unprecedented and ever increasing rapidity of technological development, scientific discovery, research and the production of innovative diagnostic tools and therapeutic agents. All have had enormous impact on medical practice, some have posed major ethical problems and – not to be disregarded – increased public expectations of scientific discoveries and their application in medicine, together with calls for, and the need of consequent changes in medical practice.

In parallel, the huge expansion in the availability and accessibility of information about medicine, medicines and medical research through the growth of communication via the mass media and IT development, has played a major role in changes taking place in the organisation and the conduct of medical practice. At the same time it has also, through the instant availability on information via the media (both TV and the web) supplied compelling information about the increasing instances of natural disasters and their consequences. The instant availability of information has also highlighted to a wider public the problems of disparity in the provision of health care in differing parts of the world. The impact of information about the incidence of infectious diseases and the reality of the role of poverty in disease, relayed through media readily accessible in the home, conveys an even more realistic and compelling image of catastrophes, diseases and poverty, than that previously available through the spoken or written word.

The impact of these developments has had substantial political, social and economic effects in both developed and developing countries, leading to consequent changes in medical practice and its organisation, as well as challenges to the nature of the role of physicians in health care.

These developments have had far reaching impacts on the medical profession, including effects on basic medical education, postgraduate education, licensing and regulation, continuing professional development and re-accreditation, not to mention the nature of health care and the delivery of medical care. All of this has been accompanied by the increasing burden of administrative, managerial functions and economic constraints.

On a number of occasions in these columns we have commented on these trends, the challenges which they are producing and the increasing need for the medical profession to address them. Indeed, some of the issues have already been addressed in various parts of the world (1) (2), and a Charter (3) endorsed by a number of organisations in at least 28 countries. *(see annex to paper on Professionalism in this issue)*.

At its next meeting in October, the WMA Council will be considering these issues and with this in mind , the current issue of WMJ is substantially devoted to a paper on the issue of Medical Professionalism, in particular the role of the National Medical Associations. As will be seen, this paper highlights important problems which should be considered urgently by individual physicians in whatever aspect of medical practice as well as NMA's.

The inclusion of this substantial paper has substantial constraints on the normal contents of the journal which we will include in the next issue. While this topic has already been addressed in some parts of the world, we hope that it will stimulate further debate and contribute to a clear affirmation of the qualities of medical professionalism in the 21st century.

*Alan J. Rowe*

(1) Royal College of Physicians "Doctors' in Society: Medical Professionalism in a changing World. Report of a Working Party of the Royal College of Physicians, London: RCP 2005 (2) Rosen R, Dewar S., On being a doctor Medical Professionalism in a changing world Kings Fund Publications 2004 (3) Medical Professional Project. Medical Professionalism in the new millennium. A physician charter. Ann. Intern. Med 2002 **136** (3) 243-246

# Professionalism and the Medical Association

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## Introduction

Medical professionalism, and an examination of exactly what it means to be a professional in today's society, have received significant attention in the medical, scientific and lay press over the past few years. The accelerated development of medical and communication technologies, improvements in access to medical information for the public and direct to consumer advertising, have all changed the way in which physicians and their patients interact. While at times this change has been positive (for example, through its empowerment of patients to make medical decisions on their own behalf), at other times the impact has been negative, with many physicians feeling pressured to prescribe medications or order tests they might not have otherwise chosen.

In some locations, the very nature of the medical system itself forces physicians to assume an entrepreneurial role and encourages them to aggressively promote their own medical services. These types of activity may be seen as being incompatible with the traditional role of the physician as an altruistic and selfless healer.

These changes and others have caused a broad re-examination of the nature and meaning of medical professionalism, what it means to be a physician in today's society and culture, and the dynamic of the doctor-patient relationship.

Traditionally, nearly all of the focus of the discussion and debate in the literature on medical professionalism has been centred on attempts at arriving at a definition of the concept of professionalism, the particular obligations of *individual* physicians and the "social contract" between medicine and society. In contrast, nearly no attention has been given to a consideration of medical professionalism from the point of view of organized medicine (1), in particular the National Medical Association (NMA).

The intent of this paper is to briefly review the current literature and thinking on medical professionalism, to highlight some of the various roles played by different medical organizations, and to examine the intersection between medical associations and professionalism. Finally, specific areas are proposed where representative medical associations might become involved in setting guidelines or developing policies in order to assist the collective profession, and by extension its individual members, maintain and enhance medical professionalism for the benefit of patients and the profession alike.

## Medical Professionalism: Where do we stand?

Over the past few years, several articles have been published that have helped to refocus the debate and discussion on medical professionalism (2-8). The reason for this renewed interest generally varies by situation and locality. Certainly in some instances, it has been triggered by high-profile medico-legal cases involving physician misconduct or clinical misadventures and a subsequent public perception that there exists a desire by the members of the profession to "protect their own" in these situations. In other cases, the technological revolution and resultant change in access to medical information have caused physicians and others to re-examine the nature of the physician-patient relationship and the interactions between these two parties. In still others, discussion has focused on the duty of physicians to society, and the need to establish an updated and modernized "social contract" between society and the medical profession.

While a simple definition of medical professionalism that satisfies everyone's requirements does not appear to exist, for the purposes of this document it will be defined generally as follows:

*Medical professionalism* describes the skills, attitudes, values and behaviours common to those undertaking the practice of medicine. It includes concepts such as the maintenance of competence for a unique body of knowledge and skill set, personal integrity, altruism, adherence to ethical codes of conduct, accountability, a dedication to self-regulation, and the exercise of discretionary judgment. Professionalism is also the moral understanding among medical practitioners that gives reality to what is commonly referred to as the social contract between medicine and society. This contract in return grants the medical profession a monopoly over the use of its knowledge base, the right to considerable autonomy in practice and the privilege of self-regulation.

In February of 2002, the Annals of Internal Medicine published an article entitled "Medical Professionalism in the New Millennium: A Physician Charter" (2) written by Canadian, European and American physicians. This document has engendered much discussion, and the reaction to the concepts it proposes has been both positive and negative. The essential premise of the Charter (2) is that professionalism is the basis of medicine's contract with society, which demands placing the interests of patients above those of the physician, setting and maintaining standards of competency and integrity and providing expert advice to society on matters of health. It lays out 3 fundamental principles (primacy of patient welfare, patient autonomy and social justice) and 10 professional responsibilities (commitments to: professional competence, honesty with patients, patient confidentiality, maintaining appropriate relations with patients, improving quality of

care, improving access to care, a just distribution of resources, scientific knowledge, managing conflicts of interest and professional responsibilities including self-regulation).

While several bodies and organizations have adopted this Charter (see Appendix 1 for a complete list), others have been equally quick to point out its shortcomings (9-10). However, few would be likely to argue that it has not had a positive effect in renewing and reinvigorating the debate and dialogue on the topic.

Recent developments in Britain are perhaps especially illustrative of much of the present public and professional discourse on this complex issue. They also serve to highlight the relatively large and diverse number of relevant groups and stakeholders with an interest in the issue, including physician representative bodies such as National Medical Associations. These developments have included, among others, the following:

- The King's Fund published a discussion paper in 2004 entitled "On being a doctor: Redefining medical professionalism for better patient care" (11). This document argues that the medical profession as a whole needs to demonstrate better its duty to serve patients' interests in order to show its ability to respond to changing public expectations. It notes that the "compact" between physicians, the health care system and patients has changed since the inception of the NHS in 1948, and suggests that a new compact is required that will show a higher level of responsiveness to patient interests and a focus on identifying professional standards that are more in tune with current values and expectations.
- Subsequently, the Royal College of Physicians published a working party report in December 2005 entitled "Doctors in society: Medical professionalism in a changing world." (12) The aim of this working party was "To define the nature and role of medical professionalism in modern society". They define medical professionalism as a set of values, behaviours and relationships that underpin the trust the public has in doctors. The values identified as being of particular importance are integrity, compassion, altruism, continuous improvement, excellence and working in partnership with other members of the health care team. They suggest that these values should form the basis for a new moral contract between the profession and society.
- In 2006, the British Department of Health released a report authored by the Chief Medical Officer, Sir Liam Donaldson, entitled "Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients" (13). This report is aimed particularly at the topic of regulation of the medical profession, which in Britain is performed under the auspices of the General Medical Council (GMC). It notes that in the early 1990's, a series of highly public medical scandals in the United Kingdom gave rise to mounting public concern.

  The report itself was commissioned following the fairly scathing report of the Shipman Inquiry, chaired by Dame Janet Smith (14), which was extremely critical of the GMC in arguing that its culture, membership, methods of operation and governance structures were too likely to support the interests of doctors rather than protect patients. The Donaldson report notes that the current global trend is a move away from pure self-regulation to regulation in partnership between the profession and the public. The report recommends a regular assessment of physicians' clinical skills, a reshaping of the role, structure and functions of the GMC and an extension of medical regulation to the local level to create a stronger interface with the health care system.

  For many in the medical profession, the Donaldson report represents much of the current angst with respect to the potential weakening or total loss of physician self-regulation, which for the majority of doctors is one of the key pillars of medical professionalism. There appears to be a concerning trend in many parts of the world whereby governments and others are challenging and eroding the concept of physician self-regulation (and indeed the self-regulation of other professions as well).
- The British Medical Association (BMA) released a report on "Regulation of the medical profession" in March 2007 (15). It is critical of both the Donaldson report and the resulting government White Paper, "Trust, Assurance and Safety: The regulation of health professionals in the 21st century" (16) which was published in February 2007. The government document contains a series of proposals that, according to the BMA, would add up to the loss of professionally-led medical regulation. These proposals include: removal of the adjudication function from the GMC, having GMC Council members appointed rather than elected , and a new composition of the GMC Council with 50:50 lay and medical members. The BMA argues that with a state owned medical system (the NHS), and an appointed regulatory body, physicians might find themselves compromised in their ability to use their clinical independence to ensure optimal patient management, thus diminishing their medical professionalism.

It is against this backdrop of recent publications and events, and ongoing developments in the United States, Europe, Canada, Australia, New Zealand, Hong Kong and elsewhere, that the roles of the various bodies and stakeholders in medicine and health care will be considered.

## Organisational roles: Who does what?

The number and types of organisations involved in educating, licensing, regulating and representing physicians vary significantly depending on the individual country or geographic region. In some locations, in spite of the obvious challenges and potentially significant conflicts of interest, the same body or organisation assumes several of these roles. In general, one or more organisations are involved in the following areas of activity:

1) Education: Educational standards and curriculum setting are required for undergraduate medical education (i.e. medical schools) and postgraduate medical education (i.e. internship and residency training). In some places the same organization will be involved in both, while in many places these roles are separated. As well, many countries have bodies that oversee and accredit continuing medical education (CME) initiatives that help to ensure that practicing physicians have access to educational resources throughout the life cycle of their careers. Educational organizations may also administer examinations to ensure the adequacy of the knowledge and clinical skills of the physician-in-training, and may grant certificates of general or specialty designations on successful completion of the training programme and examinations.

2) Licensing: After physicians have completed their training, most places require them to obtain a license for the practice of medicine, usually within a specific field or area of expertise. The requirements for licensure (and training background) may vary significantly by country or region. In some situations, extensive testing and examination requirements will also exist. In some countries, a separate license is required to practice in different parts of the country, with different standards in each region and no transportability of licensure.

3) Regulation: The licensed, practicing physician is generally held to a certain standard that they must meet in an ongoing fashion in order to continue to practice medicine. This standard, and the way in which it is enforced, may also vary significantly. The specific body involved in regulation may also vary both between and within countries

   Traditionally, as for many of the "learned professions", physicians have been held responsible for professionally-led self-regulation, which many see as a privilege that must be continually earned. In practice, this requires physicians to form organizations that will receive allegations of professional misconduct or clinical negligence, investigate the complaints, render a judgement and impose a penalty. This activity and process is generally separate from the legal or civil litigation systems of that country.

   The rationale for self-regulation is that physicians, by virtue of their extensive educational requirements and their unique grasp of a complex body of medical knowledge, obtained through years of training and experience, are felt to be in the best situation to be able to judge their peers.

   The argument against self-regulation is that it may be perceived as being overly self-serving and that the majority of the members of a profession will inherently want to "protect their own", so that physicians who misbehave or under-perform clinically will not be properly censured or reprimanded by their peers. As a result, many countries have developed a system of regulation whereby lay members of the public participate actively in the process. In almost all cases, these public members make up a minority of the total membership of the regulatory bodies.

   Many regulatory bodies have also assumed the role of ensuring that physicians remain up-to-date in their clinical knowledge and skills. This "revalidation" activity varies significantly by country. In some situations, it is a matter of providing proof that a physician is participating in CME activities on a regular basis, while in others the practicing physician may be required to repeat in-depth testing and examination on a regular basis in order to maintain their license to practice. Where no evidence exists to link the particular standard of revalidation to quality of patient care and outcomes, this activity may understandably be of some concern to physicians.

4) Representation: In nearly every country, there exists an association or organization that represents the interests of physicians (as exists for most professions). Some countries may have one or more competing organizations of this type. Most commonly (although not always), this body takes the form of a National Medical Association, whose name generally consists of the name of the country followed by the Medical Association designation (for example, Chilean Medical Association, Indian Medical Association, Russian Medical Association and so on).

   Some have argued that the roots of modern representative medical associations date back to the formation of guilds in the 12th and 13th centuries (17). The features of guilds at that time included the power of association and self-regulation (including training), control over the means of production or workplace, control of the market and power over relations with the state. However, it may be more accurate to say that today's medical associations represent the concept of freedom of coalition that evolved following Napoleon's dissolution of the guilds and his introduction of a democratic system in the early 1800's.

   The type and degree of specific activity in today's medical association can vary. In many instances, they provide specific benefits to their members, including the ability to connect with a network of their peers. In some countries, the NMA is involved in advocacy activities on behalf of its membership. This can include lobbying governments for improved working conditions and health care system reform, and often includes lobbying on behalf of patients to improve the level and quality of the care they receive.

   In other countries, the NMA also acts as a bargaining body for its membership so that it negotiates contracts and fee structures on their behalf. In some situations, the association may actually have an official "union" designation. Other NMA's have also assumed various educational and regulatory roles.

Given the large number of roles undertaken by the NMA's of some countries, it is not surprising that conflicts occasionally arise in the course of their activities. For example, an association that is actively advocating on behalf of its membership might not be seen as being able to also assume a regulatory role that requires it on occasion to publicly censure some of its members, or

remove their license to practice medicine. In the case of those NMA's that negotiate contracts on behalf of their membership, some have questioned whether they can also be legitimately involved in setting standards of professional behaviour and codes of conduct.

The next section of this paper will explore the intersection between medical professionalism and the representative medical association.

## Professionalism and Medical Associations

The following quote probably best summarizes the concerns that most commonly arise at the intersection of representative medical associations and medical professionalism (1):

> " Medicine is, in essence, a moral enterprise, and its professional associations should therefore be built on ethically sound foundations. At the very least, when physicians form associations, such occasions should promote the interests of those they serve. This, sadly, has not always been the case, when economic, commercial, and political agendas so often take precedence over ethical obligations. The history of professional medical associations reflects a constant tension between self-interest and ethical ideals that has never been resolved."

Most would agree that representing the economic, commercial and political interests of physicians and organized medicine as a whole is a legitimate and important undertaking, and likely one best done by a body with democratic representation of the profession. In many cases (though certainly not all), this representation and the resultant advocacy also serve to further the cause of patients and improve the care that they receive.

The greater concern arises when the actions (or inactions) of an NMA appear to serve only their own self-interests. If individual physicians have an obligation to put the care of their patients above all else, should this obligation extend as well to their representative associations? If we are to say that altruism and integrity are key values for the medical professional, are they by extension key values for the professional's association as well?

The argument has been made (1) that:

> "…effacement of self-interest is the distinguishing feature of a true profession that sets it apart from other occupations….When physicians form associations, they should make this promise collectively…. Without such a commitment, they easily degenerate into self-serving trade associations, lobbies or unions….In a properly conceived professional association, physicians should associate to improve the care of the sick, to advance the health of the public, and to ensure that their fellow associates are faithful to that mission…Associations should be aware of the dangers of focussing attention on the economic concerns of their members at the expense of their more important public and professional responsibilities."

According to this argument, physician associations should make an active and considered decision: to represent the vested interests of their members, or of their patients, but in general probably not both, as the interests of the two groups will too often be mutually exclusive.

All professions are represented in some way by a body or organization that serves to further their particular needs and interests. Without this, that particular profession would soon disappear from the horizon as members of other more organized and more ably represented professions, slowly (or rapidly) eroded its place in the social order. It is patently impossible to make the argument that physicians do not require collective representation. Like all other professions, they will be legitimately concerned about their work environment and safety, educational and promotional opportunities, salary levels, and all the other things employed persons need to care about.

However, medicine is substantively different from most other professions, and the fundamental difference is its commitment to the welfare of the individual patient, and the tradition of placing the interests of this patient above those of the medical practitioner. How can we reconcile these competing principles? Can a medical association serve both its members and the patients they care for?

The 1991 President's Address to the Annual Meeting of the House of Delegates of the American Medical Association (AMA) (18) by Dr. John Ring provides some direction in this regard. The address states, inter alia:

> "The new AMA has chosen the right road for medicine: the course of professionalism, of patient advocacy, and of personal sacrifice. It is the way of helping doctors be better doctors – not necessarily richer, not necessarily more powerful, not necessarily more authoritative – but better doctors…
>
> The new AMA is a confluence of professionals whose clear agenda is the health of the American people. …We are a doctor's organization, working for the good of our patients, rather than a pressure group aiming for political power as a way to build organizational predominance, to create personal prestige, or to line our own pockets…
>
> Professionalism is our very identity as doctors. And the basic act of professionalism is a doctor looking after a patient: the doctor-patient relationship. We can accept nothing that threatens this relationship by trying to turn medicine into a mere trade, a dispassionate business venture, an impersonal public utility."

Dr. Ring goes on to describe a new AMA initiative examining the issue of access to care. Clearly, the interests of both patients and physicians are served by improving access to care. He uses this as a prototypical example of where the AMA should be focusing its efforts. From this, we understand that organized medicine has a legitimate claim at representing its own interests, and that this representation can and should be done by a representative medical association. However, these interests, like those of the individual physician, should not supersede or replace the interests of patients in the collective.

Perhaps the vision statement of the Canadian Medical Association (19) best captures the preferred approach. In describing its vision, it lists only two aims: "A healthy population and a vibrant medical profession." The promotion of both ideals can and should coexist in the same representative medical association. But the rank ordering of these priorities, which is clearly not random, should not change.

The next section will examine specific issues and areas where medical associations can set guidelines, policies and standards to advance the professionalism of the association and its members while also striving to serve the best interests of patients and society.

## Potential areas of activity

There are several potential areas where representative medical associations might become actively involved in promoting and enhancing professionalism within the association and for their membership. What follows is a discussion of some of these areas, recognizing that others are likely to exist as well.

**1) <u>Pandemic and disaster preparedness</u>**

Since the experience with the Severe Acute Respiratory Syndrome (SARS) epidemic of 2003, there has been much discussion in the medical literature regarding issues of professionalism and medical care during a crisis situation, be it pandemic or otherwise (20-23). Although it is generally accepted that physicians and other health care workers have a duty to provide care in such a situation, several important questions have been raised as part of the broader discussion. These include:

- What exactly is the obligation of health care providers during a pandemic? Is it to provide care to all those in need regardless of the level of personal risk?
- Do physicians and others have a right to refuse to provide care when their own health (or that of their family) is at risk?
- Is the provision of services during a pandemic based in whole or in part on the obligation of governments and others to provide reciprocal services to physicians? If this reciprocity is not honoured, are physicians then absolved of their obligations?

Clearly, these are questions not easily answered. While some have argued that physicians and other health care workers appear to have an absolute obligation to provide care regardless of the circumstances in which they find themselves (24, 25), others have argued that this obligation may vary depending on the particular situation and circumstances (26-28). There are clearly compelling arguments to be made on both sides. The professional obligations of physicians in this situation are also well set out in various codes of ethics and regulatory documents.

Traditionally, physicians have respected the principle of altruism, whereby, throughout history, they have set aside concern for their own health and well-being in order to serve their patients. While this has generally manifested itself primarily as long hours away from home and family, and a benign neglect of personal health issues, at times more drastic sacrifices have been required. During previous pandemics, physicians have served selflessly in the public interest, often at great risk to their own well-being (although it should be noted that there are also isolated historical exceptions of physicians who have fled from such situations; Galen and Sydenham both fled from patients with contagious epidemic diseases) (29).

Since the experience of SARS, the concepts of reciprocity and reciprocal obligations have received significant attention from physicians and others both in and outside of the health care field. During this crisis, many health care workers found themselves assuming great personal risk, sometimes with very little support and assistance from governments, hospitals, health districts and others. Several physicians and nurses contracted the virus, and some of these died as a result. It has become increasingly clear that more support will be expected during the next public health crisis, particularly in developed countries that have the necessary resources to provide this support.

As the University of Toronto Joint Centre for Bioethics report, "We stand on guard for thee" (30), states:

> "(The substantive value of) reciprocity requires that society support those who face a disproportionate burden in protecting the public good, and take steps to minimize burdens as much as possible. Measures to protect the public good are likely to impose a disproportionate burden on health care workers, patients and their families."

Some of these reciprocal obligations, which should be undertaken by governments, hospitals, and others, might include:

- Physicians and the associations that represent them should be more involved in planning and decision making at the local, national and international levels. In turn, physicians and the associations that represent them have an obligation to participate in these discussions.
- Physicians should be made aware of a clear plan for resource utilization, including:
  - clearly defined physician roles and expectations, especially for those practicing outside of their area of expertise;
  - vaccination/treatment plans – clarification of whether health care workers (and their families) will have preferential access based on the need to keep caregivers healthy and on the job;
  - triage plans, including how the triage model might be altered and plans to inform the public of such.
- Physicians and health care providers should have access to the best equipment needed and should be able to undergo extra training in its use if required.
- Physicians and health care providers should have access to up-to-date, real time information. They should be kept informed about developments locally and globally.
- Resources should be provided for back-up and relief of physicians and health care workers.

- Physicians and health care providers should receive financial compensation to cover expenses such as lost wages, lost group earnings, overhead, medical care, medications, rehabilitative therapy, and other relevant expenses in case of quarantine, clinic cancellations or illness.
- Families should receive financial compensation in the case of a physician family member who dies as a result of providing care during a health care crisis.
- Physicians should be given expanded liability coverage as required, particularly for those practicing outside of their area of expertise.
- Psychological and emotional counselling and support should be provided in a timely fashion for physicians, health care providers, their staff and family members.

It should be noted that meeting these reciprocal obligations might not be possible in less developed countries which lack sufficient resources to do so. For example, in countries with few resources and poor infrastructure, even providing soap for all health care workers might be difficult. In this case, situational reciprocity must be ensured; that is, health care workers should be provided with whatever resources are available in order to optimise patient care and the safety of the workers.

What NMA's can do on the issue of disaster and pandemic preparedness

National Medical Associations can develop guidelines on disaster and pandemic preparedness that will specifically outline for their membership exactly what is expected of them in such a situation, and what their professional obligations entail. They can also assist their members, and the public, by helping ensure that governments, hospitals and others understand and meet the reciprocal obligations (as outlined above) that will be critically important for ensuring the care and safety of patients and physicians alike during a pandemic or other public health emergency.

**2) Conscientious objection**

In this context, conscientious objection is a term generally used to refer to a situation where a physician or other health care worker refuses to provide treatment or therapy on the grounds that such provision would violate their strongly held moral principles. The concept originated during wartime tension between religious freedom and patriotic obligations (31) and was subsequently co-opted during the reproductive rights debates of the 1960 and '70s

The most common examples in the literature and in day-to-day medical practice continue to involve reproductive medicine: specifically, the provision of therapeutic abortion services and access to contraceptive devices and medication. More recently, the issue of access to post-coital contraception and abortifacient options has garnered much attention, from both the physician and pharmacist perspective, with reports of pharmacists refusing to dispense emergency contraception dating back to 1991 (32). The past several years have seen an increase in legislative initiatives, particularly in the United States under the current Republican administration, designed to protect health care providers who refuse to participate in specific reproductive procedures or practices (33).

Other less common issues sometimes referred to during a discussion of conscientious objection include euthanasia, physician assisted suicide, assisted reproductive technologies, assistance during executions and experimentation on human embryos (34).

A recent New England Journal of Medicine article has served to highlight the scope of the issue, at least in the United States (35). According to a survey of 1144 physicians, most physicians (63%) believe that it is ethically permissible for physicians to outline their moral beliefs and objections to their patients. The majority (86%) also agree that physicians must present all options regarding specific therapies and treatments to their patients – which of course means that a sizeable minority of 14% of physicians are not providing all the information required by their patients. In addition, 71% of physicians feel that a doctor has an obligation to refer a patient to another clinician to obtain a service to which the referring physician is morally opposed.

There are several possible advantages in allowing physicians to invoke the concept of conscientious objection as a reason for refusing to participate in certain procedures or therapies. It allows the physician to stay true to their morals and values; in general, society does not require professionals to forsake their morals upon entry into a particular profession. It allows medical professionals to exercise their independent judgement. And the right to refuse to participate in acts that conflict with personal, ethical, moral or religious convictions is generally accepted as an essential element of a free and democratic society (33).

There are also several possible downsides when physicians invoke the right of conscientious objection. This practice may limit access to care and consequently have a detrimental impact on the health of patients. It can serve to impose the values and personal morals of the physician on the patient. It may be in direct opposition with the obligation of the physician to provide care without discrimination. Furthermore, professional autonomy is not without its limits and the interests of the patients are generally held to take precedence over those of the physician. Finally, the practice can introduce elements of inefficiency, inequity and inconsistency into a medical system (36).

While there are clearly arguments to be made on both sides of the issue, some authors have particularly strongly held beliefs. In a recent article in the British Medical Journal, Savulescu (36) claims that:

> "A doctor's conscience has little place in the delivery of modern medical care. What should be provided is defined by the law and consideration of the just distribution of finite medical resources, which requires a reasonable conception of the patient's good and the patient's informed desires. If people are not prepared to offer legally permitted, efficient, and beneficial care because it conflicts with their values, they should not be doctors."

There seems to be general agreement in the medical and ethics literature, current Codes of Medical Ethics and legislative approaches on several issues. First, it would appear

that physicians and other health care providers have at least a limited right to refuse to participate in certain procedures or therapies if these are in opposition to their values and beliefs. However, one needs to distinguish this right from the right to refuse to refer a patient to a clinician who will provide these services. While there is some debate about this issue, the majority of the current literature, if not current policy and legislation, appears to support the obligation to refer (33, 36, 37, 38).

From the perspective of the National Medical Association, this issue would appear to provide fertile ground for policy development and professional guidance.

What NMA's can do on the issue of conscientious objection

It is suggested that policy development in this area should consider and address at least 6 aspects of the issue:

1) The concept of conscientious objection, its history and its current use should be carefully and comprehensively outlined.
2) In general terms, there appears to be agreement that physicians have a right to stay true to their personal values and morals and to exercise their independent professional judgement. They also have the right to inform their patients of such, but not in a way that is unduly coercive or argumentative.
3) Physicians should understand that they should not refuse to provide urgently needed care by using the concept of conscientious objection. A distinction must be made between an acute situation where immediate care is required to save a life or maintain health, as opposed to a less acute situation where there is time for a patient to seek medical services elsewhere.
4) Physicians should not obstruct, actively or passively, patients from receiving care from another clinician. Although health professionals may have a right to object, they do not have a right to obstruct (33).
5) Physicians should provide their patients with all the information they require regardless of the personal values of the physician. For patients to give valid informed consent, they have to be informed of the relevant alternatives and their risks and benefits in a reasonable, complete and unbiased way. This concept is one of the central tenets of modern medical ethics and cannot be undermined based on conscientious objection.
6) NMA's should address the issue of whether or not the conscientious objector has a duty to refer the patient to another clinician for services the objector will not provide. Clearly worded guidance in this area will be of benefit to patients and physicians alike.

While some NMA's may elect to include this information within the context of a related policy (for example, a policy on therapeutic abortion), because the concept of conscientious objection can apply in several different types of clinical situations, it is suggested that it is preferable to develop a separate policy that can be used in multiple circumstances.

### 3) Self-regulation

The general concept of self-regulation has been outlined above in the section on organizational roles. In some parts of the world, the term "self-governance" is used interchangeably with self-regulation, while in other areas the regulatory function is felt to be one part of the overall governance function. For ease of understanding, the term "self-regulation" will be used in this document.

It is fair to say that the vast majority of representative medical associations, if not all of them, support and encourage the concept of self-regulation of the medical profession. From a physician standpoint, it would not be advantageous to have their actions or clinical decisions evaluated by lay people and members of the public who are not likely to have the necessary training or experience to make those judgements. In addition, this is an area where individual physicians can demonstrate their collective sense of responsibility rather than through sometimes abstract principles or declarations.

From the standpoint of the general public, they need to have confidence that the regulation of physicians is fair, open and transparent and that physicians are held liable for any clinical or professional transgressions in a significant and meaningful way so that such transgressions will not be repeated in the future. They need to be confident that self-regulation does not mean self-protection. Some degree of public involvement in regulatory bodies is now generally well accepted, but physicians usually become concerned when consideration is given to having these organizations constituted with a public majority, meaning that decision making will then be outside the control of the profession.

According to the website of the College of Physicians and Surgeons of Ontario (39), the self-regulatory body for physicians practicing in this Canadian province, the relationship between the College, the profession and the public is as follows:

> "The College of Physicians and Surgeons of Ontario governs the practice of medicine in the public interest. It does not exist to protect the medical profession. The profession's interests are well represented by other bodies, including the Canadian Medical Association.
>
> The medical profession has been permitted by legislation to play a leading role in the protection of the public. It does this through the College. This is what is meant by „self-regulation." Self-regulation should never be confused with professional autonomy. The profession, through the College, is always accountable to the public."

It is not uncommon for there to be a somewhat strained relationship between representative medical associations and those organizations involved in physician self-regulation. While the public may see regulatory bodies as occasionally overly protective of physicians and not always acting in the best interests of the public, some physicians find them unnecessarily intrusive, interventionist and restrictive when it comes to regulating the day-to-day practice of medicine. However, in order to preserve the privilege of self-regulation, the medical profession must be clearly seen to be acting in the best interests of the public and not of the profession itself.

The concept of self-regulation of the medical profession presents a situation where representative medical associations may find themselves with a choice to make, between representing the desire of their membership for more freedom to practice medicine in a fully autonomous way with little "unnecessary" regulatory intrusion, versus supporting the public desire to strengthen the regulatory oversight of physicians and increase the transparency of the system. As suggested previously, and for reasons outlined above, the interests of the public and patients should take precedence in this type of situation.

What NMA's can do on the issue of self-regulation

This does not mean that NMA's should acquiesce to any and all demands of regulators and the public. It does mean that they should support, through policy, advocacy and action, legitimate efforts to improve the quality of medical care and outcomes through regulatory oversight of their physician members.

Unduly intrusive activities that have not been shown to improve the quality of patient care are not necessarily appropriate. Efforts at revalidation of physicians should not simply be exercises intended to reassure the public and legislators, but should truly strive to improve the quality of medical practice, and should be based on solid evidence demonstrating that the means used will be efficient and effective. It may be up to NMA's to help ensure that this evidence exists and is incorporated in a meaningful way.

NMA's should develop policy or position statements clarifying their support for self-regulation and outlining the importance of this concept to the maintenance of medical professionalism. They should assist their members in understanding that self-regulation cannot be perceived as being protective of physicians, but must maintain the support and confidence of the general public.

**4) Interactions between physicians and industry**

Perhaps nowhere in medicine today is the potential for conflict of interest greater than in the interaction between physicians and private industry. These industries can include pharmaceutical companies, medical device manufacturers and makers of other products like baby formulas. In short, any private interest whose income generation depends on physician prescription or approval of their product.

From a business standpoint, the model is fairly simple. In most businesses, the product is marketed directly to the public through means such as advertising and word of mouth campaigns. However, in medicine, the companies must go through the "middle man", the physician. The physician must prescribe a product, usually a medication, which is then purchased by the consumer, their patients. Sound and accepted business practice means that the companies will mount marketing and advertising campaigns to influence physician prescribing patterns in favour of their company, thereby increasing their income and market share.

The pharmaceutical industry has traditionally denied that they attempt to influence physician prescribing behaviour, instead insisting that their marketing efforts are simply intended to educate physicians on new products in order to ensure that their prescribing choices are well-informed and based on the latest available scientific literature. However, there is now much evidence to the contrary.

To start with, the information presented to physicians is usually extremely biased, often inaccurate, and intended to portray the target product in a favourable light. A Spanish study revealed that 44.5% of the information provided by pharmaceutical representatives to family physicians is factually erroneous and is biased towards their own products (40). An Argentinean study (41) concluded that 46% of references given in literature distributed by industry representatives did not concur with the claims made in the company's literature. A German study (42) found that 94% of the information in brochures for doctors had no basis in scientific evidence; while many brochures had cited publications that could not be found, the majority of information found in them did not accurately reflect the publications that they cited.

This mounting body of evidence hardly supports the industry argument that physician education is the true intent of its information dissemination. Clearly the purpose is instead to provide information in such a way that physicians will view the product in a more favourable light and be more likely to prescribe it to their patients.

Secondly, a significant number of former pharmaceutical representatives and industry insiders have recently come forward to reveal the internal machinations of the business. One states: "An unofficial, and more accurate, job description for a sales rep would be: Change the prescribing habits of physicians." (43). Another says: "It is my job to figure out what a physician's price is…everything is for sale and everything is an exchange" and "It's my job to constantly sway the doctors. Doctors are neither trained nor paid to negotiate. Most of the time they don't even realize that's what they're doing." Perhaps most concerning, this same former representative (43) went on to write:

> "The concept that reps provide necessary services to physicians and patients is a fiction. Pharmaceutical companies spend billions of dollars annually to ensure that physicians most susceptible to marketing prescribe the most expensive, most promoted drugs to the most people possible. If detailing were an educational service, it would be provided to all physicians, not just those who affect market share. Every piece of information provided is carefully crafted, not to assist doctors or patients, but to increase market share for targeted drugs."

Finally, an increasing number of studies are revealing that pharmaceutical marketing does impact physician prescribing habits (44-48). The old argument that "it just doesn't affect me" does not hold water anymore, nor does the assertion that "It may influence my colleagues, but it does not influence me".

Given the current lack of public funding for CME events and medical research, and the resulting reliance of these important activities on private industry funding, most physicians seem to be in agreement that banning all forms of contact between physi-

cians and industry is not feasible or perhaps even desirable. However, there is clearly a need to develop policies and guidelines in this area to help regulate the relationship in order to avoid the appearance or presence of real or perceived conflicts of interest.

The bodies setting these policies can vary and may include some or all of the following:- government and legislators, medical regulators, physician representative associations, medical specialty groups, and the industry itself. The argument is made here that these policies should be developed and led by the profession, should be clear and transparent and should ensure that any interactions taking place between physicians and industry will be only for the clear benefit of patients, not of for physicians or industry.

What NMA's can do on the issue of interactions between physicians and industry

National medical associations can and should develop clear and comprehensive policy in this area to ensure that their members do not find themselves in a position of conflict of interest. They should widely distribute these policies to their membership and others, and undertake educational initiatives to clarify their importance, intent and content. They should use their advocacy capabilities to help ensure that these physician-led guidelines become the accepted standard for all the other participants involved, including industry.

At a minimum, these guidelines should address the following topics:

- a clear explanation of the issue and the concept of conflicts of interest
- gifts to physicians, including social science literature on gift giving
- drug samples and their impact on prescribing behaviour and drug costs
- educational and promotional materials aimed at physicians
- CME events (including electronically-delivered CME) and sponsorship, including physician payment for participation
- physician participation and patient enrolment in industry-sponsored research trials, including physician payment for participation
- disclosure obligations for physicians submitting research or providing educational sessions
- physician participation as medical advisors or on advisory boards, and the distinction between these activities and marketing

-peer selling and direct physician promotion of individual products or companies

- how medical students and residents should approach the issue

Those NMA's without sufficient resources to develop their own policy in this area may wish to adopt the policy of other NMA's or of the World Medical Association (49).

Physician representative associations should also give careful consideration to developing stringent internal policy for governing relationships between the organization and third parties. This will serve to set an example for the membership and ensure that the association itself is able to avoid situations of conflict of interest (a lesson learned painfully by the American Medical Association during a brief sponsorship deal with Sunbeam in the 1990's).

## 5) Interprofessionalism

Traditionally, and until relatively recently, health care had been delivered in what can best be described as a multidisciplinary model of teamwork. In this model, each member of the health care team fulfilled a certain well-defined and predetermined role with little or no overlap between the activities of the team members. Ultimate decision-making authority rested nearly always with the physician.

More recently, this model has evolved into one of interdisciplinary team care (or "interprofessionalism") whereby the members of the team work collaboratively together to help ensure optimum patient care and outcomes. In this model, there may be some overlap between the roles and responsibilities of the team members, based on what is in the best interests of the individual patient at that particular point in time. For example, a speech and language pathologist might prescribe a specific dysphagia diet based on their clinical assessment, or a pharmacist might renew a prescription without consulting the physician. Unfortunately, studies have shown that even in this model the provision of health services is still often fraught with interprofessional conflict, dissension and misunderstandings (50).

In the current context of limited health human resources, and particularly limited physician resources, it makes inherent sense to take full advantage of the abilities of each member of the health care team. These members can include, but are not limited to, physicians, physician assistants, nurses, nurse practitioners, pharmacists, occupational and physical therapists, psychologists, speech and language pathologists, social workers and dieticians.

In general terms, the move towards interprofessionalism has particularly impacted on the role and responsibilities of the physician, as many of the expanded roles of team members have been into areas traditionally occupied by the physician on the team. While physicians have by and large accepted and sometimes actively embraced such changes, particularly where they have been shown to impact positively on patient care and outcomes (although it should be noted that such an impact has not been conclusively proven) (51), they have also shown well-placed concern when warranted. Although physicians have been often criticized as "defending their turf" or being unwilling to relinquish complete control over patient care, there are justifiable reasons to approach interprofessionalism with caution. It should also be noted that the assumption of traditional physician duties by other professions is not a new concept, as witnessed by the undertaking of surgery by barbers and the medical treatment of patients by apothecaries.

It is at times unclear as to who has ultimate responsibility for patient care. If everyone is responsible, then no one is truly responsible. In addition, when physicians provide direct medical care and there is a mishap, then medico-legal liability, once established, is usually fairly straightforward. In an interprofessional model of care, the

physician may not be constantly aware of services or recommendations being provided by other team members, yet the patient and their lawyers may expect the physician to assume ultimate liability for this care if harm occurs. Where individual liability ends and group liability begins might not always be clear.

Different professions may have different Codes of Ethics with different values, standards and priorities. As a recent example, while the American Psychiatric Association (52) has clearly stated that sharing clinical knowledge for the purpose of using this information to torture or gain admissions from terrorism suspects is unprofessional and unacceptable behaviour, the American Psychological Association has elected not to take this stance (53, 54). When competing principles of various team members occur during patient care, how are we to determine which one will win out?

There are professional divisions based on demographics, gender composition, class of origin of members, educational attainment, status and relative size and source of primary income; these have all been cited as obstacles to the development of interdisciplinary collaboration in the health field (51). Medicine is a long-established and fairly large profession whose members come mostly from a well-educated, small, upper class and earn a high income. Thus, it is argued that:

> "The raw power of medicine, combined with a high degree of professional self-confidence developed by doctors and consciousness of these differences in prestige among other occupational groups, contributes to a degree of mutual wariness and defensiveness as each occupation attempts to defend its own territory. For most of the twentieth century the health division of labour has been organised and hierarchically structured around the dominant profession of medicine. However, over recent decades medicine's claims to autonomy and dominance have been increasingly challenged by non-medical groups." (51)

Interdisciplinary relationships are also often political. Different occupational groups attempt to establish clear professional demarcations and demand that their expertise be recognized. They construct their own distinct codes and standards and advance what they deem to be their own ethical theories (for example, "medical ethics" versus "nursing ethics") (55).

Different professions may use different standards to judge the acuity of a case or situation. When other professionals then apply their own frames of reference to make sense of a situation, they may differ intensely over the priority the case is assigned (51). This may be a source of significant conflict amongst team members.

Professional differences may also have been reinforced by various court decisions. For example, decisions by the English courts in the early twentieth century emphasized the responsibility of medical practitioners and the subservient nature of nurses (56). Although more recent court decisions have not been quite as harsh, there are those who feel that the earlier approach still has some influence on attitudes to the responsibilities of those offering care to patients (51).

Unfortunately, relationships between health care professionals remain fraught with organizational, status and value differences (55). An Australian survey of hospital admissions reported that problems with professional interactions were the most common cause of preventable disability or death in the intensive care unit, and were twice as common as those due to poor medical skill (57).

There is a significant body of work on the topic of interprofessional education and training at the medical school and undergraduate level (58 - 61) but relatively little guidance when it comes to educating postgraduate trainees or practicing physicians. While tomorrow's physicians may be well equipped to work in collaborative practice models, today's physicians may require extra guidance and training in this area, as many of the skills and concepts required are not necessarily inherently known.

What NMA's can do on the issue of interprofessionalism

In spite of the many challenges of interprofessionalism and interdisciplinary models of care, it is clearly a concept that is becoming firmly entrenched in today's patient care settings. In order to optimise patient care and outcomes, physicians must be able to work collaboratively with a wide variety of health professionals in different settings. Representative medical associations can assist their members (as well as their patients and other health care professionals) by developing policy and guidance in this complex area. Such policy should ideally include:

- a review and definition of the concept of interprofessionalism with attention given to both the medical and non-medical literature
- a clarification of the relevant medico-legal liability issues, including the need for all team members (and not just physicians) to carry liability insurance; this may need to be done in partnership with local and/or national medical malpractice insurance carriers where appropriate
- an approach towards education in this area for medical students, postgraduate medical trainees and physicians in practice, as well as other health care professionals who will be working in the team setting
- an integrated or separate policy or document outlining the issue of scopes of practice for the various health care professions, including the fact that roles and scopes must be in keeping with the relevant training and expertise and should not exceed the capabilities of a given field (for example, professionals not trained to provide a diagnosis should not be licensed to do so; this is not in keeping with clinical or ethical standards and is a potential threat to patient care and well-being)
- a clarification on potentially competing ethical principles and Codes of Ethics to ensure that physicians understand their individual obligations in this regard

**6) Clinical practice guidelines (CPGs)**

Clinical practice guidelines or CPG's, are systematically developed statements that aim to help physicians and patients reach

the best possible health care decisions (62). While they have been in existence for a long time, recent years have seen an explosion in their numbers. They go beyond systematic reviews of the literature by recommending what should and should not be done in specific clinical circumstances.

Generally, CPG's are developed by a group of writers with representatives from clinical medicine, research, and epidemiology, among other disciplines. The body or organization sponsoring their development may vary significantly, from an uninterested third party (rare), to a medical society or association (more common) to a disease specific organization (perhaps increasingly common). The funding for each type of group may also vary, with differing degrees of private and public sponsorship. Private sponsorship usually comes from parties with a vested interest in the outcome of the process, particularly the pharmaceutical industry (and less commonly the insurance industry). Pharmaceutical companies can benefit from the outcome of a CPG either through the recommendation of a specific therapeutic agent or a lowering of the threshold required before the use of an agent. Sometimes the source of financial sponsorship is made transparent, but it is not uncommon for it to remain relatively anonymous (or hidden).

Not only the process itself, but also the actual participants in the process, may also be subject to potential conflicts of interest. This has been the focus of much debate in the medical and scientific literature as of late (63-65). Two recent publications have helped to outline the scope of this problem. One study (66) notes that 87% of authors of CPG's had some form of interaction with the pharmaceutical industry. Fifty eight percent had received financial support to perform research and 38% had served as employees or consultants for a pharmaceutical company. Only 2 published CPG's out of 44 examined made declarations regarding the personal financial interactions of individual authors with drug companies. Another report (67) on more than 200 CPG's from various countries deposited in 2004 with the United States National Guideline Clearinghouse found that more than one third of the authors declared finan-

**Table 1 – Summary of potential areas of NMA activity**

| Potential area of activity | What NMA's can do |
|---|---|
| 1) Pandemic and disaster preparedness | – develop guidelines on disaster and pandemic preparedness that will specifically outline for their membership exactly what is expected of them in such a situation, and what their professional obligations entail<br>– assist their members, and the public, by helping ensure that governments, hospitals and others understand and meet the reciprocal obligations that will be critically important for ensuring the care and safety of patients and physicians alike during a pandemic or other public health emergency |
| 2) Conscientious objection | – outline the concept of conscientious objection, its history and its current use<br>– assist members to understand that they should not refuse to provide urgently needed care by using the concept of conscientious objection<br>– assist members to understand that they should not obstruct, actively or passively, patients from receiving care from another clinician<br>– address the issue of whether or not the conscientious objector has a duty to refer the patient to another clinician for services the objector will not provide |
| 3) Physician self regulation | – support, through policy, advocacy and action, legitimate efforts to improve the quality of medical care and outcomes through regulatory oversight of their physician members<br>– help ensure that efforts at revalidation of physicians are not simply exercises intended to reassure the public and legislators, but truly strive to improve the quality of medical practice, and are be based on solid evidence demonstrating that the means used will be efficient and effective<br>– develop policy or position statements clarifying their support for self-regulation and outlining the importance of this concept to the maintenance of medical professionalism<br>– assist their members in understanding that self-regulation cannot be perceived as being protective of physicians, but must maintain the support and confidence of the general public. |
| 4) Physician-industry interactions | – develop clear and comprehensive policy in this area to ensure that their members do not find themselves in a position of conflict of interest<br>– widely distribute these policies to their membership and others, and undertake educational initiatives to clarify their importance, intent and content<br>– use their advocacy capabilities to help ensure that these physician-led guidelines become the accepted standard for all the other participants involved, including industry<br>– give careful consideration to developing stringent internal policy for governing relationships between the organization and third parties |

| Potential area of activity | What NMA's can do |
|---|---|
| 5) Interprofessionalism | – develop policy and guidance in this complex area, including:<br>– a review and definition of the concept of interprofessionalism<br>– a clarification of the relevant medico-legal liability issues<br>– an approach towards education in this area for medical students, postgraduate medical trainees and physicians in practice, as well as other health care professionals who will be working in the team setting<br>– an integrated or separate policy or document outlining the issue of scopes of practice for the various health care professions<br>– a clarification on potentially competing ethical principles and Codes of Ethics to ensure that physicians understand their individual obligations in this regard |
| 6) Clinical practice guidelines | – provide physicians with access to recent, high quality, unbiased CPG's by:<br>– actively screening guidelines for their membership<br>– providing a quality rating for each guideline<br>– organizing the many thousands of CPG's into areas of clinical content and relevancy<br>– selecting the most appropriate and relevant guidelines for use by their members<br>– providing a clearinghouse for the screened and selected CPG's with membership access on its website or other location |
| 7) Organizational ethics | – develop thoughtful and well-articulated mission, vision and values statements that are produced with input from association staff<br>– develop internal organizational policies and codes which address specific ethical and professional issues<br>– make efforts to promote the above policies and documents<br>– measure and evaluate the impact of these policies, and keep them updated in an ongoing fashion<br>– ensure that the physician membership of the association is aware of these internal policies |

cial links to relevant drug companies with nearly 70% of panels being involved, and almost half of the CPG's providing no information about conflicts of interest.

It is increasingly clear that the problem of conflicts of interest in the development of CPG's is widespread and under-reported. While there are those who argue that it is not possible to develop CPG's without using authors linked to industry, since these authors are experts in the field and are sought both by the companies and the bodies producing the CPG's, some organizations have taken steps to remedy this situation. Various guidelines have been developed to ensure that any possible conflicts are declared to all those involved in the process of CPG development and that those with conflicts are given reduced or modified roles. For example, since 1999 the National Institute for Health and Clinical Excellence (NICE) has provided guidance on appropriate clinical practice within Britain's National Health Service. NICE has taken steps to avoid situations arising from potential conflicts of interest, requiring members of its advisory bodies to declare financial and other interests. If a conflict is identified, the individual will be required to step down and not take part in the decision-making process (68).

Other criticisms of CPG's have included the fact that some leave little room for deviation in the case of individual patients whose needs may differ, that they may present physicians with difficult medico-legal situations if CPG's are held to be the standard of care, and that they may provide reasons for insurers to deny coverage.

While National Medical Associations have not been traditionally involved in the actual development of CPG's, there may well be an important role for them to play in the process of ensuring the highest standards of care based on the use of recent, high quality, unbiased CPG's by practicing clinicians. There are some good examples of NMA's who have become involved in this area.

The American Medical Association, together with the Agency for Healthcare Research and Quality and the American Association of Health Plans, initially assisted in the development of the National Guideline Clearinghouse in the United States (www.guideline.gov). The National Guideline Clearinghouse is a comprehensive database of evidence-based clinical practice guidelines and related documents. Its mission is "to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use" (69).

The Canadian Medical Association, on its website at www.cma.ca, provides its membership with access to a service called CMA Infobase. This site provides access to CPG's which are produced or endorsed in Canada by a national, provincial/territorial or regional medical or health organization, professional society, government agency or expert panel. In addition, the CMA and one of its provincial divisions, the Ontario Medical Association, have combined with

the Ontario Ministry of Health and Long Term Care to form the Guidelines Advisory Committee (GAC) (70). For selected topics relevant to clinicians, patients and the health care system, the GAC identifies, rates and endorses the best available guideline (71). The GAC uses the Appraisal of Guidelines, Research and Evaluation (AGREE) tool to assess the quality of CPG's. The AGREE tool was created and validated for physicians to use in rating guidelines according to their process of development by identifying the factors that are considered important in judging their quality (72). On the CMA website, a rating of the quality of the guideline development process for those guidelines that have been reviewed by the GAC is included.

What NMA's can do on the issue of clinical practice guidelines

Providing physicians with access to recent, high quality, unbiased CPG's will enhance medical professionalism by increasing the quality of patient care and outcomes and ensuring that patients everywhere receive the same high standard of care. Although it is probably not reasonable to expect NMA's to participate in the production of the guidelines themselves, given the relative intensity of resources required to do so, they can assist in the process by:

- actively screening guidelines for their membership using a validated tool such as AGREE
- providing a quality rating for each guideline based on a validated tool such as AGREE
- organizing the many thousands of CPG's into areas of clinical content and relevancy
- selecting the most appropriate and relevant guidelines for use by their members (for example, there are over 300 English CPG's on the management of high cholesterol, and NMA's could review these and choose the highest quality 2 or 3 CPG's)
- providing a clearinghouse for the screened and selected CPG's with membership access on its website or other location (which also provides a direct benefit of membership in the association)

**7) Organizational ethics and professionalism**

Organizational ethics has been defined as "the articulation and application of the consistent values and moral positions of an organization by which it is defined, both internally and externally" (73). It is generally articulated via values statements, mission and vision statements, organizational codes of ethics, policies addressing specific ethical issues, and especially through its effects on the attitudes and activities of everyone associated with the organization.

This represents in many cases a relatively new approach to the consideration of ethics in organizations, particularly healthcare organizations. With the Enron scandal (74) and other recent developments in the business world and elsewhere, organizational ethics have become increasingly important both in practice and to reassure stakeholders and others that an ethics framework is in place.

While the medical literature in this area focuses on healthcare organizations such as hospitals, health care districts and health maintenance organizations (HMO's) (74-76), the general principles of this approach can be applied to representative medical associations as well. While these associations serve an important role in helping to guide their individual member physicians in professional and ethical standards, as outlined in previous sections of this paper, having robust internal policies will also help to set a high standard of behavior and provide an example of professionalism from within the organization.

There are four important strategies that can be used to help build a solid ethics infrastructure in a medical organization (77). These include:

1) Conducting a formal process to clarify and articulate the organization's values and link them to the mission and vision statements. This should include building the mission, vision and values statements into the introduction of the strategic plan, involving all employees in the design of the mission, vision and values statements, using facilitated group approaches to discuss these statements and using team building strategies to enhance organizational values.

2) Facilitating communication and learning about ethics and professionalism. Specific strategies include:

a. placing mission and vision statements in highly visible locations throughout the organization

b. offering training programmes that encourage interaction about the organization's values

c. using role playing, case studies and lunchtime educational sessions to facilitate communication about ethics and professionalism

d. engaging employees in values clarification techniques

3) Creating structures that encourage and support the culture. These structures should be multiple, interconnected and diffused throughout the organization, and ideally should include an ethics infrastructure with sufficient dedicated staff and resources.

4) Creating processes to monitor and offer feedback on ethical performance. Specific strategies include:

a. using ethics and professionalism audits

b. examining processes and/or outcomes of ethical decision making

c. regular evaluation of the organization's mission, vision and values statements

The American Medical Association has published a document entitled "Organizational ethics in healthcare: toward a model for ethical decision-making by provider organizations" (78). While the document specifically notes that its focus is on organizations that provide health care to individual patients, and not other organizations such as associations of health care professionals, several of the principles reviewed are of relevance. For example, the document discusses in some detail the prioritization of competing principles to help

organizations understand that patient health is their ultimate priority, regardless of other competing considerations. The paper also provides an overview of various sources of organizational ethics for provider organizations, including business ethics, professional accountability and law and social context.

What NMA's can do on the issue of organizational ethics

It is very important that a representative medical association exhibit strong organizational ethics. Not only does this assist with ensuring the proper prioritisation of association objectives and strategies, it also helps demonstrate to the physician membership the importance the organization places on ethics and professionalism. An NMA cannot expect its membership to respect and follow the ethical codes and policies it produces without first setting the same high standards for the NMA itself. Associations can do this by:

- developing thoughtful and well-articulated mission, vision and values statements that are produced with input from association staff and physicians
- developing internal organizational policies and codes which address specific ethical and professional issues (for example, harassment in the workplace, individual and organizational conflict of interest, and professional interactions with outside third parties)
- making efforts to promote the above policies and documents, including them both during orientation of new staff, and in an ongoing manner through retreats and educational sessions
- measuring and evaluating the impact of these policies, and keeping them updated in an ongoing fashion
- ensuring that the physician membership of the association is aware of these internal policies via mailings, journals and websites

## Summary

In many respects, medical professionalism is currently at a crossroads. The nature of the physician-patient relationship continues to evolve, as physicians struggle to redefine their role in an ever-changing society that is in the midst of a technological revolution. Threats to medical self-regulation and evolving physician scopes of practice have caused many practicing doctors to question whether the profession itself will ever be the same.

At the same time, change often represents opportunity. Many have seized this chance to try to redefine the concept of medical professionalism and refocus attention on the sanctity of the physician-patient relationship. New social contracts have been devised to help physicians understand how to balance their competing priorities and roles. Task forces have been formed, reports have been written and hands have been wrung. Whether all this activity will have a lasting impact remains to be seen.

Representative physician organizations are in a unique position. They serve in many instances as the public face of the profession, and help make known and understood the views of physicians on important matters. They also have the opportunity to be standard-setters for the profession, to help shape and mould the ongoing evolution and development of medical professionalism. While the literature to date focuses with near exclusivity on the roles and obligations of individual physicians, there is much that medical associations can do, both internally and externally, to advance and promote the concept. Whether this is done in isolation from, or together with, other relevant medical and non-medical bodies will vary depending on individual circumstances.

The objective of this paper has been to examine medical professionalism through the lens of the representative medical association rather than the individual clinician. Through providing both general and specific, concrete suggestions and examples of current and future potential activities which might be undertaken, it is hoped that it will add in a positive and constructive way to the preservation of what most doctors consider to be at the core of medicine: the role of the physician as healer and professional.

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# Appendix 1

Organizations that have endorsed the Physician Charter:

Accreditation Council for Graduate Medical Education
Administrators of Internal Medicine
Alliance for Academic Internal Medicine
American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology
American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology–Head and Neck Surgery
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Board of Medical Specialties
American Board of Allergy and Immunology
American Board of Anesthesiology
American Board of Colon and Rectal Surgery
American Board of Dermatology
American Board of Emergency Medicine
American Board of Family Practice
American Board of Internal Medicine
American Board of Medical Genetics
American Board of Neurological Surgery
American Board of Nuclear Medicine
American Board of Obstetrics and Gynecology
American Board of Ophthalmology
American Board of Orthopedic Surgery
American Board of Otolaryngology
American Board of Pathology
American Board of Pediatrics
American Board of Physical Medicine and Rehabilitation
American Board of Plastic Surgery
American Board of Preventive Medicine
American Board of Psychiatry and Neurology
American Board of Radiology
American Board of Surgery
American Board of Thoracic Surgery
American Board of Urology
ABIM Foundation
American College of Dentists
American College of Medical Genetics
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Radiology
American College of Surgeons
ACP Foundation
American Orthopaedic Association
American Osteopathic Association
American Psychiatric Association
American Society of Anesthesiologists

American Society of Clinical Pathologists
American Society of Plastic Surgeons
American Urological Association
Association of Academic Physiatrists
Association of American Medical Colleges
Association of Physicians of Ireland
Association of Physicians of Malta
Association of Professors of Medicine
Association of Program Directors in Internal Medicine
Association of Subspecialty Professors
Austrian Society of Internal Medicine
Belgian Society of Internal Medicine
Clerkship Directors in Internal Medicine
Chinese Medical Doctors Association
College of Physicians and Surgeons of British Columbia
Council of Deans, Association of Canadian Medical Colleges
Council of Medical Specialty Societies
Czech Society of Internal Medicine
Danish Society of Internal Medicine
Estonian Society of Internal Medicine
European Federation of Internal Medicine
Federation of Royal Colleges of Physicians of United Kingdom
Federation of State Medical Boards
Finnish Society of Internal Medicine
French Society of Internal Medicine
German Society of Internal Medicine
Hellenic Society of Internal Medicine
Hungarian Society of Internal Medicine
Icelandic Society of Internal Medicine
Israeli Society of Internal Medicine
Italian Society of Internal Medicine
Latvian Society of Internal Medicine
Lithuanian Society of Internal Medicine
Luxembourg Society of Internal Medicine
Medical Council of Canada
Ministero della Salute
Netherlands Society of Internal Medicine
North American Society of Radiologists
Polish Society of Internal Medicine
Portuguese Society of Internal Medicine
Residency Review Committee for Internal Medicine
Royal Australasian College of Physicians and Surgeons
Royal College of Physicians of Edinburgh
Royal College of Physicians of Ireland
Royal College of Physicians of London
Royal College of Physicians and Surgeons of Canada
Slovak Society of Internal Medicine
Slovenian Society of Internal Medicine
Society of Neurological Surgeons ociety of Nuclear Medicine
Society of Thoracic Surgeons
Spanish Society of Internal Medicine
Swedish Society of Internal Medicine
Swiss Society of Internal Medicine
Turkish Society of Internal Medicine

# The Ethics of Stem Cell Research

**Dr. John Williams**

**(from WMA Ethical issues of the month)**

During the past decade a great deal of scientific research activity has been devoted to human stem cells. Considerable progress has been made in deriving and replicating cell lines and in understanding cell biology. The ultimate goal of this activity is to develop therapeutic applications of this knowledge, but it is still uncertain how successful this quest will be.

From the outset stem cell research has raised ethical issues over and above those associated with other types of medical research. The principal cause of ethical uncertainty and conflict has been the use of human embryos as the source of stem cells for research. Despite claims that adult stem cells may be equally suitable for therapeutic purposes, there is a strong consensus among scientists working in this field that embryo stem cells are better suited for research purposes. However, since the derivation of these cells requires the destruction of the embryo, the question arises whether or not such research is fundamentally unethical.

Proponents of embryo stem cell research are not insensitive to the special ethical status of the human embryo and there has been substantial agreement on certain limitations to such research. Ethical guidelines and national legislation generally prohibit the creation of embryos for research, allowing research only on embryos created but no longer wanted for reproductive purposes. The consent process for the donation of embryos for research is usually very rigorous. Some countries restrict the embryonic cell lines that their researchers are allowed to use to ones that have been derived in accordance with strict ethical requirements. The introduction of human stem cells into animals is either forbidden or severely limited.

The ethical issues of stem cell research have been widely discussed by medical associations and scientific organizations, including the following:

- In 2006 the WMA Assembly adopted a *Statement on Assisted Reproductive Technologies* that deals in part with stem cell research:
  - Due to the special nature of human embryos, research should be carefully controlled and should be limited to areas in which the use of alternative materials will not provide an adequate alternative.
  - Views, and legislation, differ on whether embryos may be created specifically for, or in the course of, research. Physicians should act in accordance with national legislation and local ethical advice.
  - Cell nuclear replacement may also be used to develop embryonic stem cells for research and ultimately, it is hoped, for therapy for many serious diseases. Views on the acceptability of such research differ and physicians wishing to participate in such research should ensure that they are acting in accordance with national laws and local ethical guidance.
- The WMA is currently considering a *Proposed Statement on Stem Cell Research* for possible adoption at its October 2007 Assembly in Copenhagen.
- In 2003 the American Medical Association adopted a policy on *Cloning-for-Biomedical-Research* that reads in part: „While the pluralism of moral visions that underlie this debate must be respected, physicians collectively must continue to be guided by their paramount obligation to the welfare of their patients. In this light, cloning-for-

biomedical-research is consistent with medical ethics. Every physician remains free to decide whether to participate in stem cell research or to use its products."

- The Australian Medical Association has expressed support for embryonic stem cell research.
- The British Medical Association is likewise in favour of embryonic stem cell research: „The BMA supports the use of carefully controlled research, including research using human embryos where necessary for the development of tissue for transplantation and the development of methods of therapy for mitochondrial diseases."
- The International Society for Stem Cell Research website includes a number of ethics-related documents, such as The *Ethics of Human Embryonic Stem Cell Research.*
- The U.S. National Institutes of Health website provides a useful set of resources on this topic: Bioethics Resources on the Web – Stem Cell Research.

# Ethics and Human Rights news

## Presumed Consent for removal of organs from dead patients

While "presumed consent" for the removal of organs from dead patients for transplant purposes exists in a number of countries, this does not apply in the United Kingdom. The U.K Chief Medical Officer, Sir Liam Donaldson, in his annual report (1) has raised the issue again. Commenting that in the UK it is estimated that of the total 7234 on the UK waiting list for transplants one person dies each day, he proposes that in view of the shortage of donated organs the principle of "presumed consent" should be introduced. This would mean that organs "donated" for transplant would at least double to meet present demands. He further suggest that those wishing to "opt out" of donation in the event of their death should be specifically registered (a system which in a number of countries is implemented in so – called "hard" and "soft" ways – see below).

The report comments on the experience of other countries. Acknowledging "there have been concerns that such an approach would be viewed as totalitarian" the report continues "However, as long as the option to voluntarily opt out from the system is both available and easily accessible and strict measures are applied to protect vulnerable groups, the experience shows that such a system can command public confidence."

In the "hard" version presumed consent allows organs to be removed unless the individual had formally registered an objection during his lifetime and no account would be taken of the views of relatives.

In the "soft" version presumed consent would permit removal of organs unless:

- the person had registered an objection during their lifetime;
- it is clear form information provided by the relatives that the individual had expressed an objection to donation but had not officially registered this;
- it is clear that removal of organs would cause major distress to the relatives.

"On the State of the Public Health: Annual report of the Chief Medical Officer 2007" HMSO com 7093

## UK Human Fertilisation and Embryology Authority (HFEA) issues statement on licensing of human-animal hybrids.

The UK HFEA, following a detailed and comprehensive consultation on the licensing of human animal hybrids and chimera research which involved both scientists and the wider public issued a statement on its decision taken at its recent meeting.

"Having looked at all the evidence, the Authority has decided that there is no fundamental reason to prevent cytoplasmic hybrid research. However, public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and is likely to lead to scientific or medical advancements. It continues "This is not a total green light to cytoplasmic hybrid research, but recognition that his area of research can, with caution and careful scrutiny, be permitted. Individual research teams should be able to undertake research projects involving the creation of cytoplasmic hybrid embryos if they can demonstrate, to the satisfaction of the HFEA licence committee, that their planned research project is both necessary and desirable and meets the standards required by the HFEA for any embryo research."

The authority indicated that its licence committee will now look at the details of the two research application referred to it earlier this year and hope to have a decision in November.

Currently Stem Cell Nuclear Transfer using animal eggs is permitted in some countries, often under special conditions, whereas in other its is specifically forbidden.

www.hfea.gov.uk/en/1581.html *accessed 11/09/2007*

## Medical Ethics and Human Rights

# HIV and Human Rights Handbook

A new Handbook on HIV and Human Rights was launched by the Office of the High Commissioner for Human Rights OHCR) and the Joint UN Programme on HIV/AIDS (UNAIDS) at the Eighth International Congress on AIDS in Asia and the Pacific held in Sri Lanka 19-23 August 2007. This is intended to help national human rights institutions to include HIV in their human rights mandates, providing an overview of the role of human rights in responding to the HIV epidemic. It includes suggestions for activities which could be carried out by national human rights institutions in their existing work and collaborating with national AIDS programmes. UNAIDS Executive Director Peter Piot is reported as saying that " This is a critical time for national human rights institutions to engage in the AIDS response. W e has learned that we will not succeed unless we address discrimination, gender inequality and other human rights abuses that drive the epidemic".

UN Human Rights Commissioner for Human Rights Louise Arbour referred to the Handbook as" an essential guide for nationals institutions in their efforts to ensure that States are held accountable for protecting the rights of people living with HIV.

In 2006, countries committed themselves to achieve universal access to HIV prevention, treatment, care and support by 2010.As they scale up their efforts towards this goal it is essential that they deal with the stigma, discrimination and gender inequality that have been identified as major obstacles to universal access.

*Copies of the Handbook are available from OHCR and UNAIDS*
*UN press release and OHCHR media release 27/28.08.07*

# WMA CPD course in Medical Ethics-Fundamentals in Medical Ethics

**The World Medical Association, in cooperation with the Norwegian Medical Association has developed a web-based continuing professional development course on Medical Ethics.**

**Working through the course should enable participants to:**
**– understand the role of ethics in medicine;**
**– recognise ethical issues when the arise in practice;**
**– deal with these issues in a systematic manner**

**The course, which is now online has been accredited by the Norwegian Medical Association with 8 hours/points in post-graduate and continuing education. On completion of the course, the tests and evaluation an accreditation/certificate will be issued if desired.**

**Further details of the WMA courses are accessible through the WMA website www.wma.net. More courses and versions of existing courses are being developed.**

***Current courses:***
**– Doctors working in Prison: human rights and ethical dilemmas.**
**– Fundamentals of Medical Ethics**

## Tobacco Control – new guideline

# Report on Progress made in the Second Session of the Conference of the Parties, WHO Framework Convention on Tobacco Control, Bangkok, Thailand, 30. June – 6. July 2007

**Dr. Song Lih Huang, MD, MSc.**

**Secretary General**

**Taiwan International Medical Alliance**

Each year tobacco use causes approximately 5 million deaths worldwide. Because of the increasing prevalence of tobacco use in many developing countries, it is estimated that by the year 2030, the death toll will increase to 10 million per year, with 70% coming from middle- and low-income countries. Although deaths associated with tobacco use are preventable, it would take society an extraordinary effort for the prevention to be effective. In view of the cross-border nature of tobacco trade, and the vast differences among governments on the concept and practice of tobacco control, it was recognized in the late 1990s that a global health treaty could help individual countries to strengthen legislative and regulatory measures

The WHO Framework Convention on Tobacco Control (FCTC) was adopted unanimously by the 56th World Health Assembly on 21 May 2003, and the FCTC entered into force in February 2005 after 40 countries had ratified it. Two Conferences of the Parties (COP) have been held, the first in February 2006 (Geneva) and the second in 30 June – 6 July, 2007 (Bangkok). At the second COP, the parties:

**adopted a guideline on protection from exposure to tobacco smoke (Article 8 of FCTC); *see also annex.***

- set up an international negotiating body to prepare a protocol on illicit trade with a timetable which envisages its readiness for adoption at the fourth COP in 2010;
- agreed to ask the secretariat to work on guidelines on Article 11 (packaging and labeling of tobacco products) and Article 13 (regulations on domestic and cross-border tobacco advertising, promotion and sponsorship) with the aim of adopting these guidelines at the third COP in 2008;
- agreed to work on guidelines on Article 5.3 (protection from tobacco industry interference), Article 12 (education, communication, training and public awareness) and Article 14 (cessation);
- agreed to continue with work on Article 9 and 10 (product testing, measurement and disclosure) and 17 (economically viable alternative activities); and
- agreed to set aside funding for all these activities.

The official documents about FCTC and COP can be found on WHO websites (http://www.who.int/tobacco/framework/en and http://www.who.int/gb/fctc/). Useful information is also available at the Framework Convention Alliance website (http://www.fctc.org/).

It was quite remarkable to be able to make such progress during any international meeting, reflecting the fact that most countries have begun to realize the magnitude of damage done by tobacco use. However, the challenges for medical professionals in each country still lie ahead. Three types of effort will require medical professionals to take actions in order to save millions of lives.

First, not all countries have ratified the FCTC. There are currently 148 parties (including the European Community) to the FCTC. Understandably, several African countries which rely on the exportation of tobacco leaves as their major revenue will certainly need to find ways for alternative agricultural or other income-generating activities before the governments will comply with the goals of reducing world tobacco consumption. On the other hand, almost all industrialized countries have ratified the FCTC, with the notable exceptions of USA and Russia. The health professionals in these countries have to exert their utmost influence on the government to give priority to the health of people both domestic and abroad.

Secondly, the FCTC and its associated agreements are instruments meant to assist individual government in the legislative and implementation processes towards tobacco control. Take "the guideline for the protection from exposure to tobacco smoke" for example. This guideline will be helpful to people exposed to secondhand smoke only if the governments are willing and able to make effective laws or policies to restrict smoking in public places. The health professionals in each country should try to convince law makers of the necessity, urgency, and feasibility of taking effective measures, citing the international health treaty and the examples of successes from many countries with various cultural characteristics. The FCTC has been very helpful in moving countries forward in tobacco control as the international treaty makes the issue more prominent on the political agenda and health professionals should take advantage of this.

The third challenge is for medical professionals of the rich countries which benefit from the tobacco industry. One of the major issues during the third COP was Article 13 (Tobacco advertising, promotion and sponsorship). As the barriers to international trade are diminishing, cross-border advertising and promotion are becoming more difficult to regulate. This is particularly so in developing countries which have limited resources and capability for monitoring and law enforcement. Another formidable challenge for these countries is the need to enact strong legislation controlling foreign com-

panies, and facing the possibility of dire consequences involving international trade arbitration. Cross-border advertising and promotion do not come out of thin air. They are sophisticated products of tobacco companies (often based in rich countries) with the sole purpose of addicting boys and girls of less privileged countries. Medical professionals in rich countries have the moral duty to try to limit the political power of the tobacco industry. It is an act that can protect the future lives and fortunes of people.

As stated above, agreements made at the second COP will continue to be worked on, and hopefully will yield meaningful results in the third and fourth COPs. The adopted guideline has started to serve the purpose of protecting people from exposure to tobacco smoke, and the protocols being developed now promise to help countries deal with illicit trade and advertisement/promotion which are hard to control by any single country. The progress on this international health treaty is to be celebrated, but it awaits the effort of each country to consolidate the benefits of FCTC. ***Medical professionals should stay involved and play more active roles in this regard.***

**Annex 1 (Extract from Guidelines on protection from tobacco smoke)**

**The following extracts from this document set out the objectives and main principles upon which the Guidelines on implementing Article 8 of the FCTC adopted by the 2nd FCTC COP at the Bangkok meeting, are based.**

**"Purpose of the guidelines**

1 Consistent with other provisions of the WHO Framework Convention and the intentions of the Conference of Parties (COP), these guidelines are intended to assist Parties (*to the convention*) in meeting their obligations under Article 8. They draw on the best available evidence and the experiences of Parties that have successfully implemented effective measures to reduce exposure to tobacco smoke.
2 The guidelines contain agreed upon statements of principles and definitions of relevant terms, as well as agreed upon recommendations for the steps required to satisfy the obligations of the Convention. In addition, the guidelines identify the measures necessary to achieve effective protection the hazards of second-hand tobacco smoke. Parties are encouraged to use these guidelines not only to fulfil their legal duties under the Convention, but also to follow best practices in protecting public health.

**Objectives of the guidelines**

These guidelines have two related objectives. The first is to assist Parties in meeting their obligations under Article 8 of the WHO Framework Convention, in a manner consistent with the scientific evidence regarding exposure to second hand tobacco smoke and the best practice worldwide in the implementation of smoke-free measures, in order to establish a high standard of health. The second objective is to identify key elements and legislation necessary to effectively protect people from exposure to tobacco smoke, as required by Article 8.

Underlying considerations
The development of these guidelines has been influenced by the following fundamental considerations.

a) The duty to protect from tobacco smoke, embodied in the text of Article 8, is grounded in fundamental human rights and freedoms. Given the dangers of breathing second-hand tobacco smoke, the duty to protect from tobacco smoke is implicit in, inter alia, the right to life and the right to the highest attainable standard of health, as recognized by many international legal instruments (including the Constitution of the World Health Organisation, the Convention on the Rights of the Child, the Convention on the elimination of all forms of Discrimination Against Women and the Covenant on Economic, Social and Cultural Rights), as formally incorporated into the Preamble of the WHO Framework Convention and as recognized in the constitutions of many nations.
b) The duty to protect individuals from tobacco smoke corresponds to an obligation by governments to enact legislation to protect individuals against threats to their fundamental rights and freedoms. This obligation extends to all persons, and not merely to certain populations.
c) Several Authoritative scientific bodies have determined that second-hand tobacco smoke is a carcinogen. Some Parties to the Framework Convention (for example Finland and Germany) have classified second-hand tobacco smoke as a carcinogen and included the prevention of exposure to it at work in their health and safety legislation. In addition to the requirements of Article 8 therefore, Parties may be obligated to address the hazard of exposure to tobacco smoke in accordance with their existing workplace laws or other laws governing exposure to harmful substances, including carcinogens.

**Statement of Principles (shortened version edited by Dr. Song Lhi)***

**Principle 1**

6. Effective measures to provide protection from exposure to tobacco smoke require the total elimination of smoking and tobacco smoke in a particular space or environment in order to create a 100% smoke-free environment laws. There is no safe level of exposure to tobacco smoke, and approaches other than 100% smoke-free environment laws, including ventilation, air filtration and the use of designated smoking areas (whether with separate ventilation systems or not), have repeatedly been shown to be ineffective.

**Principle 2**

7. All people should be protected from exposure to tobacco smoke. All indoor workplaces and indoor public places should be smoke-free.

**Principle 3**

8. Legislation is necessary to protect people from exposure to tobacco smoke. Voluntary smoke-free policies have repeatedly been shown to be ineffective.

**Principle 4**

9. Good planning and adequate resources are essential for successful implementation and enforcement of smoke-free legislation.

**Principle 5**

10. Civil society has a central role in building support for and ensuring compliance with smoke-free measures, and should be included as an active partner.

**Principle 6**

11. The implementation of smoke-free legislation, its enforcement and its impact should all be monitored and evaluated. This should include monitoring and responding to tobacco industry activities.

**Principle 7**

12. The protection of people from exposure to tobacco smoke should be strengthened and expanded, if necessary; such action may include new or amended legislation, improved enforcement and other measures to reflect new scientific evidence and case-study experiences.

## WHO proposes global agenda on transplantation

# New world observatory launched with Spain

GENEVA – At the second Global Consultation on Transplantation the World Health Organization presented countries and other stakeholders with a blueprint for updated global guiding principles on cell, tissue and organ donation and transplantation.

Those principles aim to address a number of problems: the global shortage of human materials – particularly organs – for transplantation; the growing phenomenon of 'transplant tourism' partly caused by that shortage; quality, safety and efficacy issues related to transplantation procedures; traceability and accountability of human materials crossing borders.

Stakeholders agreed to the creation of a Global Forum on Transplantation to be spearheaded by WHO, to assist and support developing countries initiating transplantation programmes and to work towards a unified global coding system for cells, tissues and organs.

A central theme of the discussions was WHO's concern over increasing cases of commercial exploitation of human materials.

"Human organs are not spare parts," said Dr. Howard Zucker, WHO Assistant Director-General of Health Technology and Pharmaceuticals. "No one can put a price on an organ which is going to save someone's life."

"Non-existent or lax laws on organ donation and transplantation encourage commercialism and transplant tourism," said Dr. Luc Noel, in charge of transplantation at WHO. "If all countries agree on a common approach, and stop commercial exploitation, then access will be more equitable and we will have fewer health tragedies."

Transplantation is increasingly seen as the best solution to end-stage organ failure. End-stage kidney disease, for instance, can only be repaired with a kidney transplant. Without it, the patient will die or require dialysis for years, which is an expensive procedure and often out of reach of poorer patients. Transplantation is the only option for some liver conditions, such as severe cirrhosis or liver cancer, and a number of serious heart conditions.

Recent estimates communicated to WHO by 98 countries show that the most sought after organ is the kidney. Sixty-six thousand kidneys were transplanted in 2005 representing a mere 10 % of the estimated need. In the same year, 21 000 livers and 6 000 hearts were transplanted. Both kidney and liver transplants are on the rise but demand is also increasing and remains unmatched.

Reports on 'transplant tourism' show that it makes up an estimated 10 % of global transplantation practices. The phenomenon has been increasing since the mid-1990's, coinciding with greater acceptance of the therapeutic benefits of transplantation and with progress in the efficacy of the medicines – immuno-suppressants – used to prevent the body's rejection of a transplanted organ.

The principles put forward by WHO underscore that the person – whether recipient of an organ or a donor – must be the main concern both as patient and as human being; that commercial exploitation of organs denies equitable access and can be harmful to both donors and recipients; that organ donation from live donors poses numerous health risks which can be avoided by promoting donation from deceased donors; and that quality, safety, efficacy and transparency are essential if society is to reap the benefits transplantation can offer as a therapy.

"Live donations are not without risk, whether the organ is paid for or not. The donor must receive proper medical follow-up but this is often lacking when he or she is seen as a means to making a profit," added Dr. Luc Noel. "Donations from deceased persons eliminate the problem of donor safety and can help reduce organ trafficking."

WHO action on transplantation will be aided by a global observatory set up in Madrid under the auspices of the Government of Spain. The observatory, which is linked to the WHO Global Knowledge Base, will provide an interface for health authorities and the general public to access data on donation and transplanta-

tion practices, legal frameworks and obstacles to equitable access.

## Background

Figures collected by WHO and collated by the global observatory come from questionnaires answered by 98 countries representing just under 5.5 billion people, that is, about 82 % of the world's population. The countries were distributed in the following manner: 41 from the European region; 21 from North and South America; 13 from the Western Pacific region; 12 from the Eastern Mediterranean; eight from South East Asia; and three from Africa.

In 2005, 66 000 kidney transplants were performed, 60 % of which in industrialized countries. Seventy-five per cent of the more than 21 000 liver transplants and 6 000 heart transplants were performed in industrialized and emerging economies.

**Observatory link:**
http://www.transplant-observatory.org
Username: rticx\carmona
Password: Omsmc789

**Global Knowledge Base link:**
http://www.who.int/transplantation/knowledgebase/en/

## Medical Injuries

# WHO launches "Nine patient safety solutions" to save lives and avoid harm

WASHINGTON/GENEVA – The World Health Organization has launched ''Nine patient safety solutions" to help reduce the toll of health care-related harm affecting millions of patients worldwide.

''Recognizing that health care errors affect one in every 10 patients around the world, the WHO's World Alliance for Patient Safety and the Collaborating Centre have packaged nine effective solutions to reduce such errors," said WHO Director-General Dr Margaret Chan. ''Implementing these solutions is a way to improve patient safety."

The most important knowledge in the field of patient safety is how to prevent harm from happening to patients during treatment and care. The nine solutions are based on interventions and actions that have reduced problems related to patient safety in some countries.

Sir Liam Donaldson, Chair of the Alliance and Chief Medical Officer for England, said: ''Patient safety is now recognized as a priority by health systems around the world. The Patient Safety Solutions programme of work is addressing several vital areas of risk to patients. Clear and succinct actions contained in the nine solutions have proved to be useful in reducing the unacceptably high numbers of medical injuries around the world."

The nine solutions are now being made available in an accessible form for use and adaptation by WHO Member States to redesign patient care processes and make them safer. They come under the headings of: Look-Alike; Sound-Alike medication names; patient identification; communication during patient hand-overs; performance of correct procedure at correct body site; control of concentrated electrolyte solutions; assuring medication accuracy at transitions in care; avoiding catheter and tubing misconnections; single use of injection devices; and improved hand hygiene to prevent health care-associated infection.

The Patient Safety Solutions, a core programme of the WHO World Alliance for Patient Safety, brings attention to patient safety and best practices that can reduce risks to patients. It ensures that interventions and actions that have solved patient safety problems in one part of the world are made widely available in a form that is accessible and understandable to all. The Joint Commission on Accreditation of Healthcare Organizations and Joint Commission International were officially designated as a WHO Collaborating Centre on Patient Safety (Solutions) in 2005.

In the past 12 months, the WHO Collaborating Centre on Patient Safety (Solutions) has brought together more than 50 recognized leaders and experts in patient safety from around the world to identify and adapt the nine solutions to different needs. An international field review of the solutions was conducted to gather feedback from leading patient safety entities, accrediting bodies, ministries of health, international health professional organizations and other experts.

''These solutions offer to WHO Member States a major new resource to assist their hospitals in avoiding preventable deaths and injuries," says Dr Dennis S. O'Leary, president of the Joint Commission. „Countries around the world now face both the opportunity and the challenge to translate these solutions into tangible actions that actually save lives."

The patient Safety Solutions focus on the following challenges:

1. **Look-Alike, Sound-Alike Medication Names**
2. **Patient Identification**
3. **Communication During Patient Hand-Overs**
4. **Performance of Correct Procedure at Correct Body Site**
5. **Control of Concentrated Electrolyte Solutions**
6. **Assuring Medication Accuracy at transitions in Care**
7. **Avoiding Catheter and Tubing Mis-Connections**
8. **Single Use of Injection Devices**
9. **Improved Hand Hygiene to Prevent Health Care-Associated Infection.**

For more Information or to view the complete Patient Safety Solutions, please go to:

*www.jointcommissioninternational.org/solutions*

## H5N1 Avian `Flu

# WHO and manufactorers move ahead with plans for H5N1 influenza global vaccine stockpile

The World Health Organization has announced that it is working with vaccine manufacturers to move ahead on plans to create a global stockpile of vaccine for the H5N1 avian influenza virus.

The announcement follows a request by the World Health Assembly in May for WHO to establish an international stockpile of H5N1 vaccine.

WHO also welcomed the announcement by GlaxoSmithKline that it will contribute to the H5N1 global vaccine stockpile. Omninvest of Hungary, Baxter and Sanofi Pasteur have also indicated their willingness to make some of their H5N1 vaccine available.

''This is another significant step towards creating a global resource to help the world and especially to help developing countries in case of a major outbreak of H5N1 avian influenza,'' said Dr Margaret Chan, WHO Director-General.

''WHO welcomes this contribution from the vaccines industry and is also working with countries to develop capacity for the production of influenza vaccines.''

Further work is needed on detailed operational planning for the stockpile, including how and under which conditions it will be deployed, as well as regulatory aspects of the vaccine.

As well as developing a stockpile of H5N1 vaccine, other measures being taken by WHO to prepare for a potential influenza pandemic include:

- rapid containment plans to stop a pandemic using public health measures (isolation, quarantine of contacts, personal hygiene and social distancing) and antivirals;
- assistance to countries to increase vaccine production capacity, including research and promoting the transfer of technology to developing countries.

# WHO releases findings from research project on travel and blood clots

### Risk of VTE is higher after travel of more than four hours but is still relatively low

GENEVA – The World Health Organization released results from Phase 1 of the World Health Organization research into global hazards of travel project. Findings indicate that the risk of developing venous thromboembolism (VTE) approximately doubles after travel lasting four hours or more. However, the study points out that even with this increased risk, the absolute risk of developing VTE, if seated and immobile for more than four hours, remains relatively low at about 1 in 6000.

The two most common manifestations of VTE are deep vein thrombosis (DVT) and pulmonary embolism.

The study showed that plane, train, bus or automobile passengers are at higher risk of VTE when they remain seated and immobile on journeys of more than four hours. This is due to a stagnation of blood in the veins caused by prolonged immobility, which can promote blood clot formation in veins.

One study within the project examining flights in particular, found that those taking multiple flights over a short period of time are also at higher risk. This is because the risk of VTE does not go away completely after a flight is over, and the risk remains elevated for about four weeks.

The report showed that a number of other factors increase the risk of VTE during travel, including obesity, being very tall or very short (taller than 1.9 meters or shorter than 1.6 meters), use of oral contraceptives, and inherited blood disorders leading to increased clotting tendency.

''The study does confirm that there is an increased risk of venous thromboembolism during travel where the passenger is seated and immobile for over four hours, whether in a plane, train, bus or car. However, it is important to remember that the risk of developing VTE when travelling remains relatively low,'' says Dr Catherine Le Galès-Camus, WHO Assistant Director-General for Noncommunicable Disease and Mental Health.

This study did not investigate effective preventive measures against DVT and VTE. However, experts recognize that blood circulation can be promoted by exercising the calf muscles with up-and-down movements of the feet at the ankle joints. Moving feet in this manner encourages blood flow in the calf muscle veins, thus reducing blood stagnation. People should also avoid wearing tight clothing during travel, as such garments may promote blood stagnation.

Phase I of the research project concludes that there is a need for travellers to be given appropriate information regarding the risk of VTE by transport authorities, airlines, and medical professionals. Further studies will be needed to identify effective preventive measures. This will comprise Phase II of the project, which requires additional funding before it can begin.

Individuals with questions regarding prevention of VTE should consult their physicians before travelling.

**Background to the WRIGHT project:**

In 2000, following the death from pulmonary embolism of a young English woman who returned on a long-haul flight from Australia. Media and public attention was focused on the risk of thrombosis in long-haul travellers. In the same year, a report from the Select Committee on Science and Technology of the United Kingdom House of Lords recommended research into the risk of DVT. Following a consultation of experts convened by WHO in March 2001, the WRIGHT project was initiated. Phase 1 was funded by the UK Government (Department for Transport and Department of Health) and the European Commission.

The objectives of Phase I were to confirm whether the risk of VTE is increased by air travel and to determine the magnitude of risk.The studies were conducted under the auspices of WHO and performed by an international collaboration of researchers from the Universities of Leiden, Amsterdam, Leicester, Newcastle, Aberdeen and Lausanne.

There were five studies:

- a population-based case control study to investigate the risk factors of VTE;
- two retrospective cohort studies among employees of international organizations and Dutch commercial pilots to investigate the actual risk of VTE related to air travel; and
- two pathophysiological studies to investigate the influence of immobility on VTE related to travel and the influence, if any, of low oxygen and low pressure in the cabin of aircraft on VTE related to travel.

# Safe blood for mothers

## New WHO survey on blood safety and donation

GENEVA — On the occasion of World Blood Donor Day, the theme of which this year is Safe blood for safe motherhood, the World Health Organization launched a new initiative to improve the availability and use of safe blood to save the lives of women during and after childbirth. The initiative is the beginning of a broader blood safety agenda (redefined in Ottawa) aiming to work towards universal access to safe blood transfusion in support of the Millennium Development Goals.

On 14 June, WHO also released data collected from 172 countries on trends in blood donation, access and testing.

Globally, more than 500 000 women die each year during pregnancy, childbirth or in the postpartum period – 99% of them in the developing world – an estimated 25% of those deaths are caused by severe bleeding during childbirth, making this the most common cause of maternal mortality.

Severe bleeding during delivery or after childbirth contributes to around 34% of maternal deaths in Africa, 31% in Asia and 21% in Latin America and the Caribbean. As pregnant women are one of the main groups of patients requiring blood transfusion in developing countries, together with children they are particularly vulnerable to blood shortages and to HIV, hepatitis B and hepatitis C infections through unsafe blood.

‘‘If current trends continue, the world will fail to meet target 5 of the Millennium Development Goals to reduce maternal mortality,‘‘ said Dr Margaret Chan, WHO Director-General. ‘‘We must do everything we can to improve the chances of women during and after childbirth.‘‘

Blood transfusion has been identified as one of the eight key life-saving interventions in healthcare facilities providing emergency obstetric care. Timely, appropriate and safe blood transfusion during and after labour and delivery can make the difference between life and death for many women and their newborns.

The Global Initiative on Safe Blood for Safe Motherhood aims to improve access to safe blood to manage pregnancy-related complications as part of a comprehensive approach to maternal care. This includes good antenatal care, prevention and timely treatment of anaemia, assessment of the need for transfusion and safe blood transfusion given only when really required. WHO will strengthen the capacity of blood banks and district hospitals for improving maternal health through the provision of technical support in the areas of voluntary blood donation, safe blood collection, quality assured testing and best clinical practices. WHO will train clinicians, nurses, technicians and other key health personnel at district level facilities through its regional networks across the world.

The lack of access to safe blood for women reflects the general situation in developing countries. Developing countries are home to more than 80% of the world’s population, yet they currently represent only 45% of the global blood supply.

Out of 80 countries that have donation rates of less than 1% of the population (fewer than 10 donations per thousand people), 79

are in developing regions; it is generally recommended that 1-3% of the population give blood to meet a country's needs.

The WHO survey, conducted in 172 countries covering 95% of the world's population and based on 2004 data, shows that some progress has been made since the beginning of the millennium towards ensuring a safer, more adequate supply of blood. One of the survey's indicators was the implementation of voluntary, unpaid blood donation, which remains a mainstay of WHO recommendations to ensure a safe and sufficient blood supply.

In 2004, 50 countries had achieved 100% voluntary unpaid blood donation, compared with 39 countries in 2002. Three of the 11 new countries achieving this are categorized as least developed. More and more countries are moving towards voluntary blood donation. In 2002, 63 countries were collecting less than 25% of their blood from voluntary unpaid donors. By 2004, this had fallen to 46 countries.

Testing of blood for major infections such as HIV/AIDS, hepatitis B and C is also increasing, although in many countries there are few indicators showing if the testing is carried out according to quality assured procedures. Out of 40 countries in sub-Saharan Africa, 28 countries have yet to establish national quality systems. Worldwide, the highest rate of infection is found among donors who give blood for money or other form of payments. 41 of 148 countries (28%) that provided data on screening for transfusion-transmissible infections were not able to screen the donated blood for one or more of the markers.

On 9-11 June, Ottawa was the venue for a global consultation organized by WHO with the collaboration and support of the Government of Canada and the Canadian and French blood services. Around 100 experts in transfusion called on governments, international agencies and non-governmental organizations to work together towards universal access to safe blood transfusion by 2015 in support of the Millennium Development Goals to reduce maternal and child mortality and prevent the transmission of HIV, hepatitis and other life-threatening infections through unsafe blood and blood products.

## Background to World Blood Donor Day

While most countries celebrated World Blood Donor Day on 14 June, this year's main event was hosted by the Government of Canada. Festivities took place in Ottawa, in the presence of the Canadian Minister of Health and guests from WHO and other international partners.

WHO works with partners internationally and in countries to promote better blood collection practices, 100% voluntary, unpaid blood donation policies, quality assured blood testing and rational use of blood.

WHO, the International Federation of the Red Cross and Red Crescent Societies, the International Society of Blood Transfusion and the International Federation of Blood Donor Organizations joined forces in 2004 to celebrate for the first time World Blood Donor Day — a tribute to voluntary, unpaid blood donors who altruistically give of themselves to improve and save lives. In 2005 the World Health Assembly voted a resolution to make World Blood Donor Day an annual event. Since then, the Day has become a vehicle to launch national and regional awareness and advocacy campaigns to encourage blood donation and safer practices in blood transfusion.

Blood safety data are collected biennially by WHO through a comprehensive survey addressed to national governments.

Highlights of the data available on: *http://www.who.intienity/worldblooddonorday/resources/Data.xls*

# Improved meningitis vaccine for Africa could signal eventual end to deadly scourge

### Successful Vaccine Trial Promises Long-Term, Low-Cost Protection From Epidemics in Africa

GENEVA – The Meningitis Vaccine Project (MVP) has released new data on the performance of a meningitis vaccine in West African children, suggesting that the new vaccine – expected to sell initially for 40 US cents a dose – will be much more effective in protecting African children and their communities than any vaccine currently on the market in the region.

MVP, a partnership between the World Health Organization and the Seattle-based nonprofit, PATH, is collaborating with a vaccine producer, Serum Institute of India Limited (SIIL), to produce the new vaccine against serogroup A Neisseria meningitidis (meningococcus). The preliminary results of their study, a Phase 2 vaccine trial, reveal that the vaccine could eventually slash the incidence of epidemics in the "meningitis belt," as 21 affected nations of sub-Saharan Africa are collectively known. The vaccine is expected to block infection by the serogroup A meningococcus, and therefore extend protection to the entire population, including the unvaccinated, a phenomenon know as "herd immunity."

"When it becomes part of the public health arsenal, this vaccine will make a real difference in Africa," said Dr. F. Marc LaForce, MVP director. "The vaccine will allow elimination of the meningococcal epidemics that have afflicted the continent for more than 100 years."

The new meningococcal conjugate vaccine trial, in 12- to 23-month-olds in Mali and The Gambia, shows that the vaccine was safe, and that it produced antibody levels almost 20 times higher than those obtained with the marketed polysaccharide (un-conjugated) vaccine. This means that protection from serogroup A meningococcal meningitis is expected to last for several years.

''This important study brings real hope that the lives of thousands of children, teenagers, and young adults will be saved by immunization and that widespread suffering, sickness and socioeconomic disruption can be avoided," said Dr. Margaret Chan, Director-General of the World Health Organization.

"Elimination of these epidemics with wide use of the meningococcal A conjugate vaccine is now a likely possibility over the next few years," said LaForce. "People between the ages of 1 and 29 years of age will be protected by receiving a single dose in large mass vaccination campaigns. The large campaigns are expected to create herd immunity, and eventually, elimination of the disease."

As a result of the encouraging preliminary findings of this Phase 2 clinical study, SIIL and MVP will proceed with a Phase 2/3 study where the vaccine will be tested in 2- to 29-year-olds—the population that will be mostly targeted by mass vaccination campaigns. Testing will take place in Mali, The Gambia, and at least one other African country. An additional clinical study is planned for this summer in India, where the vaccine will be licensed.

"Serum Institute of India is dedicated to developing safe, effective, and affordable products for the poorest countries in the world," said Dr. Cyrus Poonawalla, Chairman of SIIL. "These results confirm and extend the observations made last year in our Phase 1 study in India. The new conjugate vaccine has an excellent safety profile in young children, and it is immunologically superior to the polysaccharide vaccine."

A conjugate vaccine joins (or "conjugates") sugars from the meningococcal bacterium with a protein, which in turn stimulates immune cells. These cells then produce antibodies to meningitis, protecting the individual from infection. A total of 600 toddlers participated in the Phase 2 study. They were enrolled at two clinical sites in Africa: Center for Vaccine Development (CVD)-Mali and the Medical Research Council (MRC) Laboratories in The Gambia. Dr. Brown Okoko, principal investigator at the MRC site in Basse, said, "The clinical teams at MRC and CVD-Mali identify with the vision, mission, and mandate of the Meningitis Vaccine Project. We are all highly motivated and very proud to be able to contribute to the development of a vaccine that is critically needed in Africa."

Dr. Samba Sow, principal investigator at CVD-Mali, said, "Some of the families who participated in the study have lost several members of their family to meningococcal meningitis. Those who have not been directly affected know the terrible impact that the disease has on the community. There is a lot of support for the clinical study and the new vaccine in the Bamako community."

iGATE Clinical Research International, a contract research company in Mumbai, India, is providing data management services.

"The plans for the future are quite ambitious," said LaForce. "With the successful completion of the Phase 2 study, and once funding is secured, we plan to do a demonstration study next year in a hyperendemic country where we will take the vaccine to public-health scale by immunizing the entire population between the ages of 1 and 29. If all continues to go well in testing and during the demonstration study, the new vaccine, which will be priced at about 40 cents per dose, could be introduced in Africa within the next two to three years."

Meningitis is one of the world's most dreaded infectious diseases. Even with antibiotic treatment, at least 10 percent of patients die, with up to 20 percent left with permanent problems, such as mental retardation, deafness, epilepsy, or necrosis leading to limb amputation.

The most prominent groups of meningococci are A, B, C, Y, and W135. While groups A, B, and C are responsible for the majority of cases worldwide, group A causes deadly, explosive epidemics every 8 to 10 years predominantly in what is known as the African "meningitis belt," an area that stretches from Senegal and The Gambia in the West to Ethiopia in the East. The belt has an at-risk population of about 430 million. The largest epidemic wave ever recorded in history swept across the entire region in 1996–1997, causing over 250,000 cases and 25,000 deaths. Africa has been relatively spared in recent years, but last year's 41,526 reported cases and the 47,925 cases reported from 1 January to 6 May 2007 bring the fear that a new epidemic wave may have begun in sub-Saharan Africa.