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## Official Journal of The World Medical Association

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**Cover painting : A Skin-Slice with Love**

**Painter: Mr. LI Shih-Chiao, 1956**

**Oil on canvas 116.5\*91cm**

**Authorized by: A Skin-Slice with Love**

**Foundation**

**The painting represents a scene of skin-slice  
surgery carried out by Dr. David Landsborough  
in 1928. A child patient suffered from skin  
necrosis due to an incident. In order to avoid  
amputation operation, Mrs. Landsborough  
donated her skin voluntarily to save the child.**

**Background: Sea Erosion Trenches**

**Author: Lin Yu-Wei**

**Authorized by: Government Information  
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## Editorial

It is well recognised that the continuing growth of both knowledge and scientific advances and their applications in medicine, (not to mention the new question they pose) inevitably continue to raise both medico-social and ethical problems, These tend to be dealt with on a “case by case” basis as many of the statements and declarations of the adopted by the World Medical Association illustrate. While new specialties and particularly sub-specialties reflect advances in knowledge and techniques, there are circumstances in which a topic emerges which affects a wide number of medical specialties and other disciplines.

Such a topic is Gender Medicine which, notably in the past two decades and more particularly since 2001, has brought together a wide

number of disciplines. The 21<sup>st</sup> century has been marked not only by the development of Departments of Gender Medicine and international collaboration reflected in the Three World Conferences, but also Journals of Gender Medicine and increasing trends to incorporate this in both undergraduate and postgraduate training.

While the World Medical Journal does not normally publish research articles, we felt that this development merited the inclusion in this issue of a paper which illustrates both the breadth of the disciplines involved in Gender Medicine, and indicates some ethical problems which may arise.

*Péteris Apinis, Alan J. Rowe, Elmar Doppelfeld*

## Result of Regional Elections, the Members of WMA Council 2009 – 2010

Following nominations for Regional places on the World Medical Association Council 2009-2010, in accordance with the regulations, the following were elected automatically or unopposed:

**The American Medical Association, the British Medical Association, Canadian Medical Association, Ethiopian Medical Association, German Medical Association, Indian Medical Association, Japan Medical Association, the Russian Medical Society, the Uruguay Medical Association** and in the Asian Region, following the withdrawal by **the Indian Medical Association** in favour of the IMA, **the Israel Medical Association.**

Elections were necessary in the European and Pacific Regions with the following results :

**EUROPE** **The Danish, Norwegian and Royal Dutch Medical Associations** were elected, having received 28,854, 36,376 and 34,112 votes, respectively. **The Association Beige des Syndicates Medicales, the Czech Medical Association, the Association Medicale Francaise and the Consuelo General de Colegios Medicos de Espana,** received 599, 2,290, 21,668 and 5,454 respectively.

**PACIFIC** **The Australian and Korean Medical Associations** were elected having received 18,576 and 35,200 votes, respectively. In this Region **the Indonesian and Thailand Medical Associations** received 2,599 and 2,694 votes respectively.

### Final Composition of the Council For 2009-2010

Therefore, as a result of the regional election process, conducted in accordance with Chapter IV of the WMA Bylaws, the composition of the Council for the 2009-2010 is:

Constituent Member	Number of seat(s)
American Medical Association	3
Australian Medical Association	1
Brazilian Medical Association	2
British Medical Association	1
Canadian Medical Association	1
Danish Medical Association	1
Ethiopian Medical Association	1
German Medical Association	2
Indian Medical Association	2
Israel Medical Association	1
Japan Medical Association	3
Korean Medical Association	1
Norwegian Medical Association	1
Royal Dutch Medical Association	1
Russian Medical Society	1
Sindicato Médico del Uruguay	1
<b>TOTAL</b>	<b>23</b>

The President, President-Elect and Immediate Past-President of the WMA are ex-officio members of Council, with no voting privileges.

Elections for the following posts will be held as soon as the Council convenes for its 182<sup>nd</sup> Session in Tel Aviv, Israel on 13 May 2009:

Chairperson of Council; Vice-Chairperson of Council; Treasurer, and Committee Chairpersons for the Finance and Planning Committee, Medical Ethics Committee, Socio-Medical Affairs Committee.

# Declaration of Helsinki

## Ethical Principles for Medical Research Involving Human Subjects

*Adopted by the 18<sup>th</sup> WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:*

*29<sup>th</sup> WMA General Assembly, Tokyo, Japan, October 1975*

*35<sup>th</sup> WMA General Assembly, Venice, Italy, October 1983*

*41<sup>st</sup> WMA General Assembly, Hong Kong, September 1989*

*48<sup>th</sup> WMA General Assembly, Somerset West, Republic of South Africa, October 1996*

*52<sup>nd</sup> WMA General Assembly, Edinburgh, Scotland, October 2000*

*53<sup>th</sup> WMA General Assembly, Washington, United States, October 2002*

*(Note of Clarification on paragraph 29 added)*

*55<sup>th</sup> WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification on Paragraph 30 added)*

*WMA General Assembly, Seoul, Korea, October 2008*

### A. Introduction

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

### B. Principles for all Medical Research

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study



- access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
  16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
  17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
  18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
  19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
  20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
  21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
  22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
  23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
  24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
  25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
  26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
  27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.

28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.
- C. Additional Principles for Medical Research Combined With Medical Care**
31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:  
The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or  
Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

## The Return of Primary Care

30 years ago the World Health Organization crafted the Alma Ata Declaration, which has served as the core policy of the WHO since that time. According to the Alma Ata Declaration "Primary health care forms an integral part both of the country's

health system, of which it is the central function and main focus, and of the overall social and economic development of the community. Primary care brings health care as close as possible to where people live and work, and constitutes the first element of a continuing health care pro-

*cess. [...] Primary care should be sustained by integrated, functional and mutually supportive referral systems, leading to the progressive improvement of comprehensive health care for all, and giving priority to those most in need."*

Although this approach enjoyed nearly universal support in principle, in practice it has failed the poor countries of the world. Rather than serving as the driver of overall



health care approaches and the core of comprehensive systems, all too often primary care appears to have been assigned the status of a general ideology and one in which primary care was, in fact, an end in itself. The WHO has recognized that the narrow interpretation of the Alma Ata Declaration has resulted in its failure. Not only has it led to primary care becoming the substitute for systematic development of health systems in some countries, in other cases, it has been used as a defense by funders to curtail improvements already underway.

The results are evident in many poor countries around the world, where health care systems at best only marginally serve the population, often providing unfocused public health approaches and no real care for seriously ill patients. Certainly, it can and must be argued that the financial resources for health care are scarce and the lack of financial resources is and remains the number one problem. But there is also an interdependency between the reductionist approach to primary care and the resources for it. Primary care in the Alma Ata Declaration is not only the main building block for any health care system, it is also intended to represent the *minimum* level of care that must be delivered. Instead, it has been mischaracterized as the *maximum* level considered necessary to be financed and thus primary care in this context has become a dead-end road, a scenario without a future.

In countries where this is the case, patients and health professionals with the financial means have simply left. The emigration of thousands of professionals left the scars of a painful brain drain epidemic on already overburdened societies and health systems. International programme, often constructed around vertical programme to address single diseases like HIV/AIDS, malaria, river blindness or tuberculosis, rarely support comprehensive care approaches. Unfortunately patients in these poor countries tend to have the same, or an even a broader, spectrum of diseases than in affluent countries, yet there is no care available to them if their health needs do not match one of the vertical programs that may be available.

WHO has taken a big step forward to revive primary care and to ask for the full and accurate interpretation of the Alma Ata Declaration. Primary care as the core building block of a health system, as opposed to the end goal, can then be extended step-by-step by secondary and tertiary care, which is the process required if the full development of health systems is to have any chance to succeed. Health care systems require academic centres for basic and specialist medical education. They need treatment facilities for more difficult cases and severely ill patients. The requirements will differ from country to country and will take time to meet. But in any system of care, there must be a perspective and an objective for treatment that goes

beyond primary care in order to provide trust, hope and the impetus for development.

WHO is formally reaffirming its core policy though the Alma Ata declaration – and reading it in its full and proper context creates a new and different story in which primary care is returned as the starting position and the cornerstone for strengthening and maintaining real health care systems. However, when listening to the politicians at the Executive Board session of WHO, where this policy had to be reaffirmed, the crux of our future challenge became evident. While WHO was attempting to frame primary care as the core element of comprehensive health care systems, some of the politicians were promising to provide comprehensive primary care.

#### Sources

Alma Ata declaration:  
[www.who.int/hpr/NPH/docs/declaration\\_almaata.pdf](http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf)

WHO report EB124/8 “Primary health care, including health system strengthening”:  
[http://www.who.int/gb/ebwha/pdf\\_files/EB124/B124\\_8-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB124/B124_8-en.pdf)

Resolution EB124/8 on Primary Care:  
[http://www.who.int/gb/ebwha/pdf\\_files/EB124/B124\\_R8-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB124/B124_R8-en.pdf)

Resolution EB124/9 on Traditional Medicine:

[http://www.who.int/gb/ebwha/pdf\\_files/EB124/B124\\_R9-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB124/B124_R9-en.pdf)

*Otmar Kloiber, WMA Secretary General*

#### Primary Care at the 124<sup>th</sup> Session of the WHO Executive Board

Between annual World Health Assemblies the Executive Board serves as the most influential organ of the WHO. According to the WHO website, “The main functions of the Executive Board are to give effect to the decisions and policies of the Health Assembly, to advise it and generally to facilitate its work.”

The body, composed of 34 country representatives, read among other documents the WHO report EB124/8 “Primary health care, including health system strengthening”. In resolution (EB124/8) the Executive Board accepted the report reaffirming WHO’s commitment to primary care and connected it to health system strengthening efforts, emphasising the will for development.

In a side debate some delegates tried to introduce traditional medicine into the resolution. This effort failed, but a separate resolution (EB124/9) on traditional medicine opens the door for countries to include traditional medicine in primary care. Among other points the resolution urges member states, “to consider, where appropriate, including traditional medicine into their national health systems based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, efficacy and quality”.

While the resolution offers a chance for the proper evaluation of traditional medicine, it may, on the other hand, open the door for substituting traditional medicine for quality, proven medical care. After all, the “evidence” of what constitutes efficient, effective and safe will most likely be determined by those in power.



## Counterfeit Medicines

Counterfeit medicines are drugs manufactured below established standards of safety, quality and efficacy and therefore risk causing ill health and killing thousands of people every year. Experts estimate that 10 per cent of medicines around the world could be counterfeit. The phenomenon has grown in recent years due to counterfeiting methods becoming more sophisticated and to the increasing amount of merchandise crossing borders.

### Health impact of counterfeit medication

According to the WHO, a counterfeit medicine is “a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source“. Counterfeiting can apply to both brand name and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients or even poisoning ingredients.

Counterfeit medicines are a threat to the health of individuals and the public health.

The serious harm for individuals can be generated either by excessive activity of the principal active ingredient, by an insufficient dosage of active ingredient or by the toxicity of ingredients that should not be present in the medicine. Patients may also think they are protected against a disease or an undesired health event when in fact they are not.

Diluted or insufficiently-dosed medicines are a threat to public health as they contribute to drug resistance in populations, leading to increased infection rates, increased need for research and development of new drugs, and increased health care spending. On the other hand counterfeits interfere with the analysis of adverse events as they give the impression that the regular drug produced the adverse event.

They deprive the inventors and original producers of medicines or materials from

their reward, thus inhibiting further development. Even worse, they reduce the trust in medication and therefore in physicians and in consequence diminish adherence to treatment schemes.

### WMA activities on counterfeit

The World Medical Association, together with the partner organisations of WHPA, joined the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) led by WHO in 2006 to combat the global problem of counterfeit pharmaceuticals.

IMPACT brings together nearly two hundred countries, as well as organizations with expertise in enforcement, manufacturing, and patient advocacy, and has called attention to the public health and commercial impact of counterfeit medicines.

WHPA have developed a counterfeit medicines toolkit ‘BE AWARE’ to assist dentists, nurses, pharmacists and physicians to tackle counterfeit medicines in their daily practice. The toolkit shows some key steps that health professionals can take to identify and report counterfeit medicines, to help fight such criminal practices and make treatments safer (see box).

#### BE AWARE toolkit:

- **Be** observant and use WHPA visual inspection tool to identify counterfeit medicines.
- **Evaluate** your patient’s response to the medicine use.
- **Acquire** as much information
- **Where** was the product procured
- **Actively** inform your health professional colleagues if medicines have been confirmed as counterfeit
- **Remove** any suspect medicines from the pharmacy, clinic, hospital or consulting room
- **Educate** your colleagues, patients and the public

### Executive board meeting of WHO

At the last Executive board meeting of the WHO in January 2009 the report and draft resolution on counterfeit medical products were discussed and all member states stressed the importance of protecting public health against risks caused by counterfeit medications. However an intense debate started on the definition of counterfeits versus substandards of medicine. So far WHO has focused on counterfeits while largely ignoring the broader and more politically sensitive -category of substandard drugs. WHO’s recommendations are subject to the whims of member states. They find it easier to tackle counterfeits rather than substandard drugs because the latter are often manufactured by taxpaying firms within their borders.

On the other hand substandard drugs are difficult to combat. Identifying poor-quality batches requires widespread testing, which poor governments may be reluctant or unable to finance. Demanding manufacturer compliance requires both strict legal codes, which countries may lack, and rigorous enforcement, which many governments are unable or unwilling to perform. Ultimately, sustainable quality control requires each company to introduce good techniques and production ethics, which can take decades.

Nevertheless exporting countries are involved in the production and distribution of substandard medication as well. Their exported medicines do not necessarily meet the same standards as those for domestic products, except when the importing countries have less stringent requirements. No consensus was found during the meeting and therefore the WHO secretariat will do further reporting in order to address the public health dimensions of counterfeit and substandard medicines and an additional text will be submitted for further discussion at the World Health Assembly in May 2009.

#### Further links:

<http://www.whpa.org/pubs.htm>  
<http://www.who.int/impact/FinalBrochureWHA2008a.pdf>  
<http://www.who.int/impact/en/>

*Julia Seyer, WMA Medical Advisor*





## Health Sciences Online: the First Authoritative, Comprehensive, Free and Ad-Free Resource for the World's Physicians

*Introduction:* December 2008 marked the launch of Health Sciences Online ([www.hso.info](http://www.hso.info)) the only site with more than 50,000 courses, references, guidelines, and other expert-reviewed, high-quality, current, cost-free, and ad-free health sciences resources.

Free and accessible to anyone, the up-to-date, authoritative information is aimed primarily at physicians, other health care practitioners, and public health providers, enabling their training, continuing education, and delivery of effective treatments to patients. The information is delivered by search technology from Vivisimo, Inc., which allows users to easily see comprehensive search results and quickly find the answers they need with an intuitively navigated graphic interface. Through integration with Google Translator, users can search and read materials in 22 languages.

Former CDC Director Dr. Jeff Koplan calls Health Sciences Online (HSO) "a visionary undertaking" and the World Bank heralds it as "globally democratizing health science knowledge." HSO is expected by the World Health Organization (WHO) "to make a considerable contribution to the advancement of e-learning worldwide."

HSO is a portal that includes more than 50,000 world-class health-sciences resources, selected by our knowledgeable staff from already-existing, reliable, professional sources and resource collections. These include medical specialty societies, accredited continuing education organizations, governments, and universities such as Cambridge, Columbia, Harvard, Hopkins, McGill, MIT, Penn, Stanford, and Yale. Founding collaborators for this site include the World Medical Association, CDC, World Bank, the American College of Preventive Medicine, and the University

of British Columbia, and financial support has come from WHO, the NATO Science for Peace Program, the Canadian government, the Annenberg Physician Training Program, and many volunteers.

*Background:* Health sciences information and training are vital for health and socio-economic development, but excellent, free learning resources are difficult to find. In recent years, information and communication technologies, particularly the Internet, have been central to remedying this situation. But there are still significant hurdles to accessing online content. WHO notes that there is an enormous need to identify selective, current, accessible online educational and training resources to promote appropriate care and policies.

*Initiative details:* A portal to a virtual learning center with browse and search functions, providing free, online linkages to a comprehensive collection of top-quality courses and references in medicine, public health, pharmacy, dentistry, nursing, basic sciences, and other health sciences disciplines. These materials are donated, and typically hosted and maintained by our distinguished content partners, so materials are constantly updated.

Our Advisory Committee includes both distinguished visionaries in health sciences, and experienced practitioners in online health sciences education:

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"HSO is an incredible resource for health professionals all over the world. Open access to health information should literally save millions of lives and lead to important new discoveries," said Anne Margulies, Advisory Committee member and Executive Director of Open Course Ware at MIT.

And our reviews\* have been strong, calling HSO "the internet at its finest... a bonanza... a boon... an incredibly worthwhile enterprise... a model of what Health 2.0 and Science 2.0 can be... one of the most altruistic and honorable health service resources on the planet". We believe that HSO has succeeded because our vision of a democratization of health sciences knowledge has tremendous appeal to a wide variety of supporters. This ranges from an endocrinologist who donated \$50,000 because "HSO will



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and even degrees, and encourage interested collaborators to contact us.

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[\\*http://www.altsearchengines.com/2008/12/26/hope-for-the-future-health-sciences-online/](http://www.altsearchengines.com/2008/12/26/hope-for-the-future-health-sciences-online/)

[\\*http://sandsurf.medbrains.net/2008/12/health-sciences-online/](http://sandsurf.medbrains.net/2008/12/health-sciences-online/)

*Erica Frank,*

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## Social Determinants of Health as a Driving Force Towards Health Equity

In August 2008, the Commission on Social Determinants of Health, chaired by Professor Sir Michael Marmot of the University College of London, published its final report “Closing the gap in a generation – Health equity through action on the social determinants of health”. The report is the result of global collaboration of policy-makers, researchers and civil society, led by Commissioners with extensive political, academic and advocacy experience. The purpose of the Commission, launched by the late WHO Director general Dr. Lee Jong-Wook, was to provide guidance to Member States and WHO’s programmes by gathering evidence on social determinants and ways to overcome inequities. In this comprehensive 200-page report, the Commission addresses global health through social determinants, i.e. the structural determinants and conditions of daily life responsible for a major part of health inequities between and within countries, and proposes a new global agenda for health equity. The global agenda includes three overarching recommendations:

### 1. Improve daily conditions

This recommendation puts major emphasis on early child development and education for girls and boys, improvement of living and working conditions and creating social protection policy supportive of all.

### 2. Tackle the inequitable distribution of power, money, and resources

This proposal places responsibility for action on health equity – including equity between women and men – at the highest level of gov-

ernment policy, with the support of a strong public sector and effective governance.

### 3. Measure and understand the problem and assess the impact of action

Under this recommendation, national and global health equity surveillance systems should be established to conduct routine monitoring of health inequity and the social determinants of health. This requires investment in research, training of policy-makers and health

#### Lack of emphasis on health professionals as key players to achieve health equity

On the occasion of the 124<sup>th</sup> session of WHO Executive Board (January 2009), the World Medical Association – on behalf of the World Health Professions Alliance (WHPA) – presented a statement on this report, with a focus on the health workforce. In this statement, the WHPA welcomed the recommendation directed at national governments and donors to “increase investment in medical and health personnel”, but regrets that the report in general does not give more attention to health professionals as key players in addressing the social determinants of health and the inequalities health professionals face in their daily work. Concerning more specifically the recommendation to address the health human resources brain-drain, the WHPA recalls the key message of its Joint Health Professions Statement on Task Shifting<sup>1</sup> and insists on the importance of developing positive practice environments in the health sector as a retention strategy.

practitioners, and public understanding of the social determinants of health.

### Developing a health mainstreaming strategy

The holistic approach taken in the report places health equity at the core of the matter, calling for global and coherent principles of action in order to achieve the health-related Millennium Development Goals (MDGs). The Commission supports the implementation of “health mainstreaming”, a strategy originally designed by the United Nations in 1985<sup>1</sup> to advance equality between women and men worldwide. Since then, the concept has been developed and used in other areas of discriminations and in the environmental field. Applied to health, such a strategy aims to make health matters an integral dimension of the design, implementation and evaluation of policies and programmes in all political, economic and societal spheres, with the ultimate goal of achieving health equality. At the national level, favouring this horizontal approach, rather than a sectoral one, leverages the full decision-making spectrum – from design through monitoring – to assess the health impact for the population of any decision planned. This strategy helps raise awareness of the intrinsic value of health, from social, economic and human rights perspectives, and its potential to promote social cohesion and well-being. It can also stimulate reflections on the overall health system and its relation to the other national policies and structures in place.

Similar to gender-mainstreaming, the success of a health mainstreaming strategy relies on the political will of decision-makers, on

<sup>1</sup> Third World Conference on Women, Nairobi, 1985

the involvement of the actors concerned, and, of course, on financial means. Although the report of the Commission on Social Determinants of Health has been applauded for its comprehensive analysis and data, as well as for its ambitious recommendations, it remains to be seen whether the Member States

will have the political will and the means to “lead global action on the social determinants of health with the aim of achieving health equity”<sup>2</sup>. For now, during its last session (January 2009) the countries members

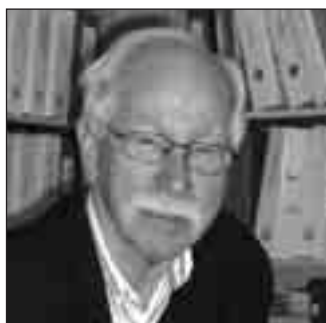
2 Closing the gap in a generation', intro, p.1

of the Executive Board of the World Health Organisation were humbly invited “to note” the report ...

The report can be downloaded from WHO website: [http://www.who.int/social\\_determinants/en/](http://www.who.int/social_determinants/en/)

Clarisse Delorme, WMA Advocacy Advisor

## The Avicenna Directories – a new tool in quality assurance of medical education



David Gordon, Leif Christensen, Hans Karle and Theanne Walters Avicenna Directories, University of Copenhagen

The creation of the Avicenna Directories – the global directories of education institutions for health professions – is a project in progress.

### Introduction

Early in its history, the World Health Organisation (WHO) developed a Directory of Medical Schools, the first edition being published in 1953 [1]. It was intended, at that time, that the Directory of Medical Schools would be followed by comparable directories of schools of dentistry and of veterinary medicine. The data were gathered through questionnaires to the institutions themselves. The medicine-centred approach, which would not be appropriate in the 21st century, was clear: the introduction stated “The physician is the key figure in any health or medical programme”.

The WHO World Directory of Medical Schools appeared in successive editions until the last, seventh, edition published in 2000 [2]. Successive editions have varied in style and content. Most have included, for each country, a summary of salient informa-

tion about the system of medical education and regulation of medical practice in the country. The sixth edition (1988) included information on admissions and on the curriculum for each school, where available, but this feature is not found in earlier or later editions. Notably, each edition soon fell out of date, because of the rapid evolution of medical education, because of the inevitable time-lag between collection of data and publication in book form, and because of the lack of effective mechanisms for updating information.

### New Directories

In designing such an important resource, modern electronic data collection and data management give an opportunity for collection of wide-ranging information, in particular statistical data about institutions and their programmes and about quality assurance. Web-based methods allow timely updating and verification of such information. Thus, directories can be created that are more accurate, more up-to-date and more comprehensive – both in the range of disciplines covered, and in the amount of

information on each institution. It is also important to extend the range of the directories beyond medicine, because the provision of health care, and the prevention of ill-health, is the remit of the entire team of health workers: medicine, pharmacy, public health, dentistry and so on.

In 2007, WHO and the University of Copenhagen agreed that the University would develop new global directories of higher education institutions for health professionals, on the principles of:

- Comprehensive coverage
- Improved high-quality detailed information – and
- Improved usability

Comprehensive coverage includes both the range of health professions, as above, and coverage of all schools that meet the following criteria:

- Recognition by the national government
- Regular admissions of students for face to face education
- Schools with national admission in the country concerned



- Schools with at least one campus in the country concerned and
- Schools with administrative and legal structures in the country concerned.

Improved information includes information on management, ownership, accreditation, educational programme and admissions for each school, and improved usability includes information that can be readily accessed, searched and downloaded.

These principles were set out in a Memorandum of Understanding (MoU) between WHO and the University of Copenhagen signed in August 2007. The MoU established a Steering Board jointly between the University and WHO, to be assisted by an Advisory Committee of interested stakeholders, and provides that the University will be assisted by the World Federation for Medical Education (WFME [3]) in development of the new directories: the Avicenna directories.

### Why Avicenna?

Avicenna – Abu Ali al-Hussain Ibn Abdallah Ibn Sina – was a polymath, and the leading physician and philosopher of his age [4]. His life (ca. 980 – 1037 CE) and career was in and around modern-day Iran and Uzbekistan, but his outlook was international. His most important medical writing was *The Canon of Medicine* [5], in which he integrated his own learning with sources as disparate as classical Greece, Galen and early Indian medicine: the *Canon* was widely translated, for example into Chinese and Latin, and remained an important textbook for centuries.

Three principles in Avicenna's career and writing are particularly inspiring for the Avicenna Directories: his willingness to gather and synthesise worthwhile knowledge from the entire known world; the emphasis on the practical application of medical principles (it was not enough to know medicine, the need was to apply knowledge to heal the sick); and the preservation and dissemination of learning to take medicine forward. These principles are as true now as a thousand years ago – therefore the choice.

Within the detailed aims of the MoU establishing the Avicenna directories, these three principles associated with Avicenna remain: the collection of information from world-wide sources; the synthesis of that data into a useful and applicable form; and dissemination to all who need the information.

### Progress since July 2007

The offices of WFME are situated within the University of Copenhagen, and the Avicenna secretariat is based with WFME. The team that has been created is international and includes experts in medical and social science and in the work of standard-setting authorities, as well as IT and database expertise. There is regular discussion with colleagues within the University of Copenhagen, with WHO, and with an international network of interested advisors. In addition, the Advisory Committee for the project had its first meeting in 2008.

One early task was to place data from the seventh edition of the WHO World Directory of Medical Schools, with updates received by WHO to the end of 2007, on the Avicenna website [6]. These data are still being updated on request. Regulatory agencies and other interested parties are increasingly using the Avicenna website for this information. One outcome is a steady stream of enquires (between 5 – 20 each week) about inclusion of medical schools in the database, and an increasing number of hits on the Avicenna website, currently about 2.500 each month.

### Current and future issues

For the time being, the only academic discipline represented in the database on the Avicenna website is medicine. In order to expand the Directories, so that the other professions are presented as soon as is practicable, discussions have begun with other partners in the Avicenna project. Thus far, this has included the International Pharmaceutical Federation (FIP) and the World Federation of Public Health Associations (WFPHA), to plan the development of

Directories of schools of pharmacy, and of public health, in the Avicenna project.

The MoU between WHO and the University sets out the need for information to be gathered from reliable sources, using a variety of tools, and explicitly mentions a questionnaire based approach, as was also the case for entries for individual medical schools in all editions of the WHO World Directory. The Avicenna team have no doubt that this remains the most important approach. It ensures that all schools in a given academic discipline are asked identical questions and can provide their own response: it is comprehensive and allows a uniform and standardised approach to the checking and validation of data. The use, as a primary source, of information from places other than the institution itself would be unequal and would require inappropriate interpretation by the Avicenna team itself.

The development of a questionnaire to produce reliable and valid data is a considerable technical task [7, 8] and has taken many months, with extensive consultation. A draft version was piloted the last three months of 2008 by 20 medical schools, representing a world-wide range of many different types of school. In the light of these pilot responses, and comments received, a final version of the questionnaire for general use has been developed. The questionnaire is web-based, and will – where possible – be completed on line, and is in a format that, once the information is validated, can be downloaded into the Avicenna database.

The validation process will extract relevant answers from the questionnaire response from each school, and verify these with the proper national validating authority.

It would logistically not be possible to survey all the medical schools in the world, or all the schools in any discipline, at a single time. Studies will therefore begin with data collection from a group of countries that represent about one quarter of all the world's medical schools. The remaining medical schools will be surveyed in successive waves. Allowing time for valida-

tion of information, and for transfer to the website, a complete Avicenna Directory for medicine is expected to be available by early 2010. The completion of Avicenna Directories for the next two subjects, pharmacy and public health, depends on the continuing development of plans with the relevant partners, FIP and WFPHA.

Updating of information according to requests will be on a continuing basis. In addition, it is planned to survey all institutions every three years, on a rolling programme, so that information is never long out-of-date.

It is clearly desirable for the Avicenna Directories to include relevant information at a national and regional level about the system of education for health professionals, processes

for evaluation of educational institutions and their programmes, the licensing framework for these professions and so on.

### Concluding remarks

The Avicenna project will create an up-to-date, easily accessible, and comprehensive electronic world list of education institutions for the health professions.

There will be detailed information by country on each educational institution, about the programmes of study and the resources in each school, about quality assurance, and contact details – useful for everyone world-wide concerned with education for the health professions, whether as a student, a teacher, a regulator or other health authority.

<http://avicenna.ku.dk>

### References

- 1 World Health Organization. World directory of medical schools, 1st edn. Geneva: WHO, 1953.
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## National Health Service (England). Next Stage Review – “*high quality care for all?*”



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### Blair's Plan

On the eve of the 1997 election, Tony Blair, the soon-to-be Prime Minister, famously told voters they had ‘24 hours to save the NHS’ (National Health Service). With Labour’s subsequent victory much was expected from a government that had purposefully positioned itself as ‘the party of the NHS’. A series of pledges and initiatives followed. but it was with the publication of the ‘NHS

Plan<sup>1</sup> in 2000 that a watershed moment in modern NHS reform came to pass which was to set the direction of health policy for the coming decade. At its core the NHS Plan articulated a desire to increase capacity, improve access and forge a new, more responsive NHS. By promoting the value of a more mixed supply side and encouraging an increased challenge to the medical profession’s power, the NHS Plan ushered in a period of ‘constructive discomfort’<sup>2</sup> based on a belief that improvements in the NHS would require a certain amount of creative tension in order to overcome what was regarded as a degree of both complacency and inertia in the system.

In setting out a series of strategies designed to reform the NHS – modernising its infrastructure, setting national standards, enabling ‘patient choice’, employing market incentives and a growing role for the private sector in delivering NHS care – the Gov-

ernment matched these ambitions with a five-year spending plan to bring the NHS budget up to European levels by 2008 comprising year-on-year rises in UK spending from £65.4bn in 2002 to £100.6bn in 2007, more than 7% in real terms annually. Alongside this health reform agenda, the United Kingdom was also witnessing a process of devolution, with each of its four home nations slowly evidencing divergent policy across a range of areas. The NHS was (and remains) at the vanguard of this process.

### Brown's Vision

With a change of Prime Minister in the summer of 2007 it was not clear whether the direction of travel would alter, particularly the recent emphasis on market-based reform. Some commentators anticipated a step-change given the new Prime Minister Gordon Brown’s documented reservations concerning the extent to which the market could play a role in healthcare and medicine<sup>3</sup>. The launch of the NHS Next Stage Review in the months after Brown took charge was regarded as an early signal that change was perhaps on the horizon. The 12-month review, led by the eminent surgeon Professor (now Lord) Darzi, was to take stock of the

<sup>1</sup> Department of Health (2000) The NHS Plan: a plan for investment, a plan for reform, London: DH.

<sup>2</sup> Stevens, S (2004) ‘Reform strategies for the English NHS’, Health Affairs, vol 23, no 3:37-44.

<sup>3</sup> Brown, G. (2004) A modern agenda for prosperity and social reform, London: Social Market Foundation.

reform agenda in the English NHS and propose a vision for the next 10 years.

The review's findings were published in June 2008 in 'High Quality Care for All'<sup>4</sup> and the vision it comprises is structured around four broad themes:

- 'high-quality care for patients and the public' – an NHS that works in partnership to prevent ill health, providing care that is personal, effective and safe
- 'quality at the heart of everything' – high-quality care throughout the NHS
- 'freedom to focus on quality' – fostering clinical leadership and putting frontline staff in control
- 'high-quality work in the NHS' – supporting staff through education and training to deliver high-quality care.

A further substantive element of the report established proposals for an NHS constitution for England, with the aim of formally setting out for the first time the purpose, principles and values of the NHS as well as the rights and responsibilities of patients, the public and NHS staff<sup>5</sup>. The concept of a constitution has received cautious support from a range of stakeholders, including the BMA<sup>6</sup>.

Amongst other headline proposals was the undertaking to offer extended choice in primary and community care with improved access and a wider range of providers, primarily by way of a pledge to create 150 new GP-led health centres (or 'polyclinics'). This has so far proved to be perhaps the most controversial proposal with much concern amongst the medical profession, in particular general practitioners, that these plans were not only ill-thought through with no thorough assessment of any real local need for the new centres, but that they would act to divert resources away from existing gen-

eral practice and primary care services, destabilising local health economies and well-established care pathways. Moreover, the view that these plans might offer the private sector another opportunity to increase its role in delivering NHS care further fuelled fears about the ongoing commercialisation of the NHS.

### The same, but different

Ultimately in looking beyond the detail contained in "High Quality Care for All", it is clear that the mainstays of previous English reform – improving access, patient choice, a diversity of provision linked to market incentives – will continue to feature heavily. Nevertheless, the report does provide a shift in focus and with it a change in language and approach. Key to this new focus is the central desire to target improvements in quality (rather than the previous targeting of capacity). Furthermore, the 'quality agenda' is articulated by way of a commitment to have future reform 'locally-led, patient-centred and clinically-driven'. Importantly for the medical profession in developing this theme, the review built on an earlier recognition that NHS staff 'had been ignored, that their values had not been fully recognised, and that they had not been given credit for improvements that had been made'<sup>7</sup>. The vision for the future is therefore one that aims to nurture a 'new professionalism' with a much greater emphasis on clinical leadership in delivering improvements in the NHS. The vast scope of the report does not lend itself to a brief analysis and so what follows is an overview of two of the fundamental elements of the vision it espouses, the 'quest for quality' and 'clinical leadership', and some of the questions they raise.

### Darzi's Quest

#### Quality

In wishing to steer the NHS away from a centrally driven performance management regime, Lord Darzi's report seeks to enable a future where all change is based on the best

available evidence, with the aim of improving the quality of care that patients receive always paramount. The 'quest for quality' he sets out is supported by a host of initiatives including a new set of national quality indicators for acute services, a new quality framework for community services and the development of a wider range of local quality metrics. All providers working for or on behalf of the NHS will, by 2010, be required to publish 'Quality Accounts' detailing the quality of their services based on measures of patient safety, patient experience and the effectiveness of care (mortality, complication or survival rates and patient-reported outcome measures).

To further incentivise change in this area the review also proposes payments to hospitals conditional on the quality of care they deliver. As a result, by 2010-11 a proportion of annual hospital trust income will be dependant on meeting service quality requirements. This will be driven by two particular initiatives. The first will link hospital tariff payments to patient-reported outcome measures and indicators, such as hospital acquired infection rates. The second will see the introduction of a 'best practice tariff' through which payments for a range of procedures that are currently evidencing significant unexplained variation in practice will be based not on average cost, but rather on best practice (which notably in most cases will be at a lower cost than the average).

Clearly, these initiatives require the NHS to expand the scope and volume of data it collects. However, the NHS's ability to produce reliable, comparable data has historically been the subject of much criticism and the initiatives' success will therefore depend heavily on a significant improvement in the quality of data production itself, rather than simply using existing datasets differently. In addressing this shortcoming one cannot ignore the related cost implications. A report to the Department of Health in 2007 suggested that the cost of collecting data on patient-reported outcome measures for elective surgery ranged from £3 to £11 per patient (Browne et al 2007). If such figures were ap-

<sup>4</sup> Department of Health (2008) High Quality Care for All, London:DH.

<sup>5</sup> The 'NHS Constitution for England' was formally published on 21st January 2009. see <http://www.dh.gov.uk/en/Healthcare/NHSConstitution/index.htm>

<sup>6</sup> British Medical Association (2008) An NHS Constitution for England, London:BMA. ([www.bma.org.uk](http://www.bma.org.uk))

<sup>7</sup> Department of Health (2007) Our NHS, Our Future, NHS Next Stage Review: interim report, London:DH.

plied to high-volume procedures, the total cost would approximate to many hundreds of thousands of pounds per procedure type. It is noteworthy that "High Quality Care for All" contains few details of costings for these and the other proposals it contains.

Interestingly, as these examples demonstrate, despite the report's focus on localism and its determination to avoid a culture of imposed targets, there remains a critical role for the centre with large elements of the quality agenda set at the national level. Further to this, the report also proposes that the National Institute for Clinical Excellence (NICE) has its remit expanded to set and approve more national quality standards, whilst a new 'National Quality Board' will provide strategic oversight and leadership on quality issues. It remains to be seen how successfully these national and local level initiatives will interface and where tensions may arise, how the old charge of a 'top-down' approach will be avoided.

Nevertheless, the focus on quality is to be welcomed. Robust and reliable quality measures should provide a solid, evidence-based platform for service improvement and will hopefully provide a currency that clinicians can both identify with and engage in when reviewing clinical practice and looking at service redesign. For patients, the routine production of outcome data promises to increase their ability to make informed choices about their care and with the inclusion of patient experience indicators, the NHS should become ever more responsive to patients' needs. However, whether patients can truly become the empowered users of this information remains open to question. Past experience suggests that those patients who might most benefit from a more detailed picture of the care available to them often do not have the necessary understanding or expertise to make use of data to this end. Consequently, such patients will require support in relating to the quality markers and making informed choices on this basis thus raising again the issue of where the necessary resource can be found to enable this.

### Clinical Leadership

As noted above what is striking about the outcome of the NHS Next Stage Review is the unprecedented emphasis it places on the role that clinicians have to play in leading change in the NHS. Where previous reform, imposed from above, often acted to disenfranchise NHS staff, the vision for the future places the medical profession (and other health professions) at the heart of the process, seeking to engage them in its planning, implementation and delivery. The review contends that where change is led by clinicians and based on evidence of improved quality of care, staff who work in the NHS respond better to it and patients and the public are more likely to support it.

To enable this new approach the review proposes a series of initiatives aimed at developing clinical leadership skills across the medical profession. These range from reviewing undergraduate curricula for medical students to ensure that they reflect the skills required for leadership; establishing Clinical Leadership Fellowships to provide protected time for clinicians to develop their leadership skills; and establishing a 'Clinical Management for Quality' programme for clinicians managing services, especially clinical directors and primary care professionals running practice-based commissioning groups. Much of this centres on developing leadership at a local level but in wishing to promote the concept of leadership further an NHS Leadership Council, chaired by the NHS Chief Executive, has also been created that will act to nurture the next generation of NHS leaders.

This investment in new programmes of clinical leadership is welcome but it will be some time before a proper assessment can be made as to whether clinicians on the ground identify and engage with the process in a meaningful way. There will no doubt be some initial scepticism amongst those who question how meaningful the new opportunities are. The true test of success will be how these undertakings are taken forward at the local level where doctors and their colleagues should undoubtedly be central to

the leadership of the organisations in which they work.

### What next?

Many concerns remain about the general direction of travel that reform over the last decade has taken, in particular the growing commercialisation of the NHS and the potential for market reforms to foster competition rather than collaboration and engender fragmentation not integration. There is also doubt as to whether the ambitious programme of reform has begun to deliver substantial benefit to patients.<sup>8</sup> As with recent past policy, the Next Stage Review suffers from its own grand scale. Whilst promising no new reorganisations and offering the hope of stability within the service, the vision encompasses a wide range of significant changes – in primary care, in community care, in acute care, in funding, in measurement, in reporting, in training and education. Does the 'quality agenda' provide enough of a cohesive focus to ensure that such expected widespread change will be successful? More worryingly, it is not at all clear that many of the proposals have an adequate evidence-base or have been sufficiently tested in terms of cost or possible unintended consequences.

Now, in early 2009, some 6 months or so on from the launch of High Quality Care for All, there are early signs that the NHS in England is pursuing many of the policy challenges it sets out. But perhaps now even bigger challenges lie ahead. Given the current economic climate the Treasury has already warned that overall public spending growth will be cut from the 1.9 per cent real terms growth rate enjoyed for 2008-09 so that it will be reduced to just 1.2 % a year from 2011 onwards. We might predict that the NHS will see growth close to zero when allocated its share of public funds. The question is, following on from the exceptional levels of funding the NHS has experienced in recent years can Lord Darzi's vision be delivered on a shoe-string?

<sup>8</sup> Audit Commission (2008). *Is the treatment working? Progress with the NHS system reform programme*, London: Audit Commission.

## Gender Aspects in Cardiovascular Drug Therapy



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### Introduction

In recent times sex differences in cardiovascular disease have gained increased attention. We are learning that the mortality of acute myocardial infarction in young women is higher than in age-matched men and stroke is increasingly frequent in young women. Systolic heart failure has a more severe clinical course and outcome in men. Diastolic heart failure predominates in women. Additional important sex differences are found in diabetes, hypertension, in the anti-coagulation system, in cardiovascular metabolism and arrhythmia. Women and men differ in many aspects and particularly in metabolic ones. This includes handling of drugs and drug effects. A large number of major studies in cardiovascular therapy included mainly men. Therefore we have less data on the mechanisms and side effects in women compared with men.

### Drug metabolism

FDA data shows that sex differences in bioavailability are found in about 30 % of all submitted drugs. Lower body mass and

higher lipid levels in total body composition in women account for differences in drug exposure. Dosing adapted to weight would at least partially correct for these differences. Weight adapted dosing recommendations exist for digoxin, for some anti-arrhythmic drugs, for heparin and some thrombolytic drugs. These recommendations are, however, not always respected [1]. Increased bleeding in women with fixed dosage of thrombolytic or GPIIb/3a inhibitors underscores the relevance of dose-adaptation. In addition to pure weight, the higher lipid content of the female body is of relevance. Consequently, lipid soluble substances have a greater distribution volume in women. Gastrointestinal function

is also affected by sex hormones leading to shorter mean transit times in women [2].

Some drug metabolising enzymes are differently expressed in women and men. The activity of gastric alcohol dehydrogenase is much lower in women than in men. Sex differences in the expression of cytochrome P450 isoenzymes also affect metabolism of numerous substances. Sex differences with clinical relevance are mainly shown for CYP1A2, CYP2B6, CYP2E1 und CYP3A4 (Tab. 1) [3]. CYP2E1 metabolises anaesthetic drugs such as halothane, isoflurane, as well as ethanol. Activity is about 30% lower in women compared to men. CYP3A4 makes up for 30% of total hepatic CYP activity and contributes to the metabolism of more than 50% of drugs. It is involved in the metabolism of endogenous and exogenous steroids, and of drugs like erythromycin, methylprednisolone, methadone, tacrolimus, diltiazem, nifedipin, triacelam, cyclosporine and verapamil. Women have a 20-50% higher activity of this enzyme than men. Accordingly CYP3A4 substrates are metabolised faster in women [3].

Renal function in general is higher in men than in women. This is only partially explained by differences in body weight. Accordingly, renal drug clearance in general is lower in women than in men. In fact, digoxin displays a 12-14% lower clearance rate in women than in men. This difference additionally increases with age [4].

### Pharmacodynamics

#### Digitalis

In 1997 the digitalis study group reported the positive effects of digitalis on heart

**Table 1.**  
*Sex differences in Cytochrome P450 Isoenzymes*

Isoenzyme	Sex differences	Drugs with cardiovascular interaction
CYP1A2	Lower activity in females, influenced by hormones	Caffeine, paracetamol
CYP2C9	No sex differences	Warfarin
CYP2C19	Controversial data	Omeprazole, diazepam
CYP2D6	Higher activity in males	Propranolol, metoprolol
CYP2E1	Higher activity in males	Halothane, isoflourane
CYP3A4	Higher activity in females	Tacrolimus, diltiazem, nifedipine, triazolam, cyclosporine, verapamil



failure. Thereafter, these study results were adopted as recommendations by numerous guidelines. There was no sex specific analysis. However, in 2002 a retrospective gender specific analysis was undertaken and demonstrated that digitalis is associated with a significantly higher mortality in women compared with men. In the original study, a modest survival benefit could be detected in men, while the opposite was true for women; nonetheless, as the study population consisted of a combined study group with a 3:1 male:female ratio the opposing effects on survival counterbalanced each other allowing for no survival difference detection in the mixed population [5]. In the following year it was shown that higher digitalis serum levels were associated with increased mortality in men [4], whereas serum levels in the lower normal range were associated with better survival. Similar trends were reported in women. Lower drug elimination, higher blood levels and an increased mortality associated with drug levels in the upper normal range explain the unfavourable survival difference reported in women (Fig. 1).

**Beta blockers**

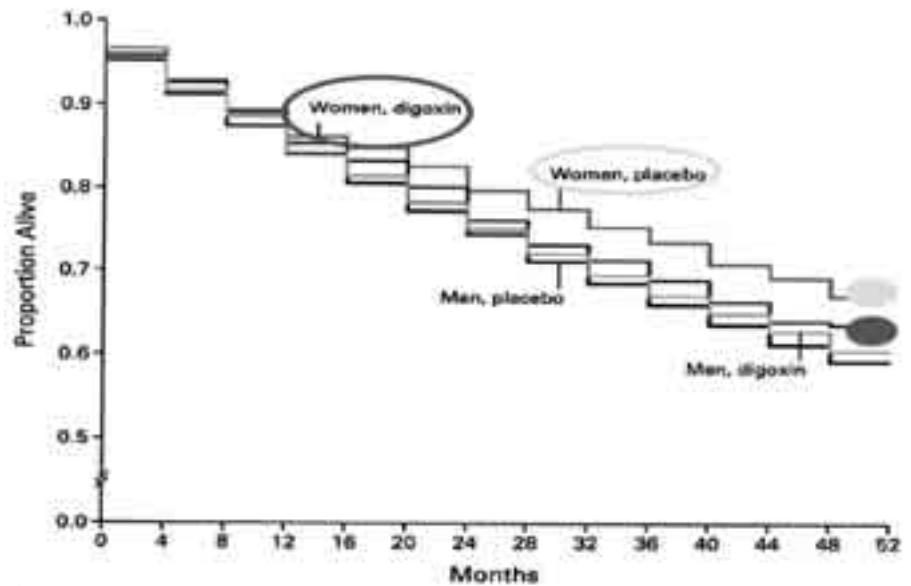
Beta blockers are frequently associated with higher drug exposure in women. The beta<sub>1</sub> selective blocker metoprolol is primarily metabolised by CYP2D6 which has a lower activity in women. In addition women have a lower distribution volume for metoprolol. Thus, plasma concentrations are higher in women than in men. Moreover, oral contraceptives can interact with metoprolol [6] and further increase its plasma levels. Other beta blockers, like propranolol for example, reach plasma levels that are up to 80% higher in women compared to men [7]. Accordingly women show stronger beta blocker side effects, a stronger decrease in heart rate and systolic blood pressure. Positive effects are similar in women and men [8, 9] (Fig. 2).

**ACE inhibitors**

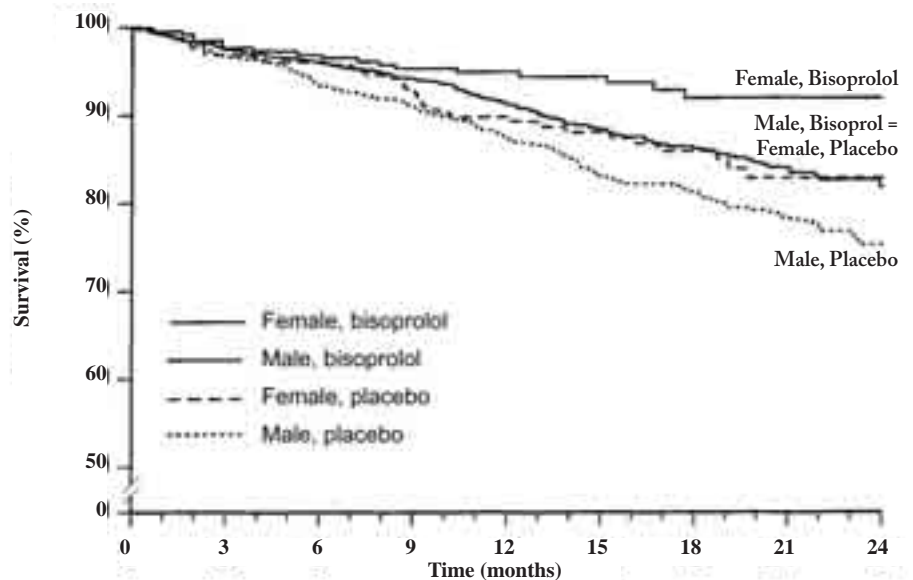
In the early multicenter randomised trials with Ace inhibitors (ACEI), benefit was more frequently found in men in comparison to women. In Consensus 1 and solvd, mortal-

ity reduction in women was below 5 % while reaching 30-40 % in men [10]. Since mainly men were included in these studies, the combined analysis of both cohorts showed a beneficial effect. Side effects in all these studies were more frequent in women. Later, ACEI

study such as AIRE and HOPE documented a significant benefit for women [11]. This was particularly the case for the secondary prevention of cardiovascular events in high risk patients. In contrast, the recently published 2nd Australian National Blood Pressure Study



**Figure 1** Digitalis therapy for heart insufficiency: survival rates in female and male study populations with digitalis and placebo [5]. Female patients on digitalis display a significantly worse survival rate compared to the placebo group.



**Figure 2** Survival rates with beta-blocker therapy for systolic insufficiency. Sex-specific survival curves from the bisoprolol study [9]: female patients have better outcomes than male patients, irrespective of therapeutic regimen. Effects of the beta-blocker therapy are similar in both groups.



(ACEIs compared with diuretics) showed a significant reduction of cardiovascular events with in men on ACEIs, but not in women [12].

**Angiotensin receptor blockers, Aldosterone antagonists and diuretics**

These drugs are effective in women and men. The large studies LIFE, ELITE, VALHEFT, VALUE, VALIANT and OPTIMAAL did not show any sex differences. 20-30 % of women were generally included in these studies [10]. Aldosterone antagonists are nowadays used in add-on strategies in the treatment of heart failure showing equal effectiveness in women and men. The most prominent side effect of these drugs is a painful gynecomasty that affects only men [13]. Diuretics are more frequently used in women even though they have more unwanted side effects, such as hyponatremia and hypokalemia [11].

**Acetyl salicylic acid, thrombolytics and anticoagulation**

Recently, surprising results were observed. In a long term study with approx. 40,000 women the reduction of primary cardiovascular events, i.e. myocardial infarction (MI) or cardiovascular death, by Aspirin was not statistically significant [14]. However, primary prevention of stroke was achieved. This is opposite to the effects in men showing inhibition of a primary MI, but not a primary stroke by Aspirin. Reasons for these differences are yet unclear.

A recent study (Crusade) documented that percutaneous coronary interventions and subsequent antithrombotic therapy lead to bleeding more frequently in women compared with men [15]. Detailed analysis showed that the substances are more frequently overdosed in women compared with men and that particularly older women are affected. However, even after adaptation of dosage to body mass and serum creatinine levels, women suffered from bleeding more frequently than men. Thus, pharmacody-

namic as well as pharmacokinetic effects may play a role in these substances [16].

**Antiarrhythmic drugs**

Women exhibit severe arrhythmia more frequently on QT-prolonging therapy than men [17, 18]. Women have a longer corrected QT-time than men and a greater QT prolongation on drugs that inhibit potassium inward channels. This enables the generation of arrhythmia. A number of drugs have been identified that prolong repolarisation by blocking potassium channels. These are more frequently associated with arrhythmia in women than in men. The group does not only include anti-arrhythmid drugs, but also gastrointestinal drugs, antipsychotics, antihistamines and antibiotics [19].

**Reasons for sex differences in drug effects**

Most drug development in the cardiovascular field is undertaken in young male mice. Reasons for this include the greater lethality of myocardial infarction or heart failure in male mice allowing for easier detection of pharmaceutical effects. Young male mice often have more severe outcome than female mice with myocardial infarction (MI) or heart failure for yet unknown reasons. In addition, the greater biological variability in females due to their cycling makes it more difficult to detect effects and more female animals are needed for breeding than males. Lethality of male mice

after MI in general is about 60%, whereas it's only 20% in female mice. Consequently, a drug that improves mortality by 30% has a major effect in male mice. This same drug may have no effect or a very small, non significant effect on female mice. Unfortunately, this substance, which is only effective in male mice, is then frequently developed into a drug that is used to treat women as well as men. Similar relations are found in heart failure. Of about 20 transgenic animal models that exhibit heart failure, 18 exhibit a more severe phenotype in males and only 2 a more severe phenotype in females. Frequently male mice are dying whereas female mice don't exhibit a phenotype. Again, drugs are then developed to treat the disease of male mice and are eventually sold for female and male patients [11].

**Measures**

Are there any measures that can be undertaken to improve this situation? The Institute for Gender in Medicine aims at establishing a database collecting all relevant data on sex differences in drug therapy that will be publicly accessible. This database will be based on very systematic literature searches using standardised text mining procedures. Further, medical quality circles are rising that are considering gender aspects. The International Society of Gender Medicine is involved in analysing sex differences in drug effects and side effects. Most importantly a number of Universities in Europe have started to develop curricula for Gender Medicine including

**Table 2.**  
*Sex differences in cardiovascular drug therapy*

Drug	Sex differences	Reference
Beta-blocker	Higher plasma levels, in some cases higher effect on female patients	10
ACE inhibitor	More side-effects in women	10
Angiotensin Receptor Blocker		
Digitalis	Higher lethality in female patients, most likely due to dosage	4,5
Diuretics	No reliable data on sex differences	11
Acetylsalicylic Acid	Sex differences in primary prevention of Myocardial infarction and stroke	14
Glycoprotein IIb/IIIa Antagonists	More bleeding in women, most likely due to dosage	15
Antiarrhythmic Agents	More severe arrhythmia with QT-prolonging drugs	17,18,19

Gender differences in pharmacotherapy. This will hopefully increase awareness of patients and doctors and lead to better treatment of women and men.

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*The following article is reprinted below in its complete form as unfortunately part of it was omitted in WMJ(54)4. ED*

## Building a Consensus in Regenerative Medicine

Louis M. Guenin is Lecturer on Ethics in Science, Department of Microbiology and Molecular Genetics, Harvard Medical School. His recent book *The Morality of Embryo Use (Cambridge University Press, 2008)* explores ethical and metaphysical issues pertaining to embryonic stem cell research and the formation of consensus across diverse views. He has served as co-chair of the Ethics Committee, International Society for Stem Cell Research.

On occasion, discretionary actions preclude transfer of extracorporeal embryos into the womb. Such actions constitute an overlooked

and crucial ground for the moral justification of embryo use in regenerative medicine.

In the first instance, we encounter the situation, which often arises with fertility patients, in which the one person in the world who, together with the coprogenitor, is empowered to decide about intrauterine transfer of an embryo formed from her oocyte decides that neither does she wish to bear the embryo, nor does she wish to give it to anyone else. Whereupon she and the coprogenitor may decide to donate the embryo to medical research and therapy. In the second case, embryos may originate in

research from cells donated to medicine for that purpose.

If progenitors, while fully-informed and acting of their own volition, donate an embryo, either before or after the embryo's creation, on the condition that the embryo shall be used in medical research and therapy, and may never be transferred into a uterus, such embryo constitutes what I have called an "epidosemryo."<sup>1</sup> I have taken this name from the Greek *epidosis* for a citizen's beneficence to the common weal.

As a moral justification for the use of epidosemryos in accordance with donor instructions, I have offered the "argument

<sup>1</sup> "Morals and Primordials," *Science* 292: 1659-1660 (2001).



from nonenablement.”<sup>2</sup> This proceeds as follows. A woman does not have a duty to undergo a transfer into her of an embryo lying outside her. There does not obtain a duty of intrauterine embryo transfer into oneself. We, most of us, regard the decision to undergo such a medical procedure as reserved to a woman’s autonomous discretion. A separate question is whether a woman and the coprogenitor lie under a duty to surrender for adoption any embryo that she declines to bear. Imposition of such a duty would likely present such adverse incentives and consequences for fertility patients, including compelled remote parenthood, that we are hard pressed to find any moral view that would support such imposition. For reasons developed in the full account of this argument, the decision whether to surrender an embryo for adoption also lies within progenitor discretion.

Suppose, then, that a woman forbids intrauterine transfer of an embryo. She, with the coprogenitor, donates to medicine either an epidosembryo created during her fertility treatment, or an epidosembryo that will be created by a scientist from their donated cells. This decision is final. The epidosembryo has left progenitor control. A distinction now obtains between the developmental potential of this epidosembryo, lying in a petri dish where it will remain, and an embryo that lies in a uterus, however it got there. In consequence of the prohibition on intrauterine transfer, the epidosembryo will not complete gastrulation. If not earlier sacrificed, the epidosembryo will begin to disintegrate by about day 10. During its remaining life, it cannot acquire any morally significant property that it does not already possess. To put the matter in language that I owe to Richard Hare,<sup>3</sup> no possible person corresponds to an epidosembryo. We also know that no embryo is sentient. It can neither form preferences nor adopt ends. Nothing that we might do concerning it can cause it discomfort or frustrate it. We

cannot gain anything—neither for it nor for any other being—by classifying it as a person for purposes of the duty not to harm. By forgoing its use in research, we could only assure that the epidosembryo dies in vain. Scientists maintain the reasonable, though not certain, belief that embryo experimentation could contribute to the relief of human suffering. Use of donated embryos remains crucial in research even as techniques develop for reprogramming somatic cells into pluripotent or specialized cells. Embryonic stem cell research has been the fountainhead of emerging knowledge of reprogramming, and the embryonic stem cell remains the gold standard of pluripotency. In this situation, the duty of mutual aid—the duty, recognized across moral views, to aid those in need when one may do so without imposing an unreasonable burden—bids us undertake such research. Hence not only is it permissible to use epidosembryos in medicine, but to do so will help to fulfill a collective duty.

According to this argument, the permissibility and virtuousness of epidosembryo use rests on the autonomous decisions of people from whose cells such embryos originate. The moral analysis flows entirely from what it is that they decide. Developmental potential matters, but it is human decisions that determine its situation-dependent extent. If it is permissible for progenitors to donate epidosembryos, then it is permissible for recipient scientists to use the donations as instructed.

Some discussants seem to suppose that the justification of embryonic stem cell research lies in the circumstance that the embryos donated were created with procreative intent. The argument from nonenablement does not invoke procreative intent. The argument applies to any donated embryo, whether left over from an attempt at pregnancy, or created in experiment. The use of surplus embryos and the nonprocreative formation of embryos by fertilization, non-reprocloning, and parthenogenesis rest on one and the same moral ground.

The argument from nonenablement is a consensus argument insofar as it does not invoke any premise peculiar to one or another moral or religious view. The bounded developmental potential of an embryo in the dish is a biological circumstance. The duty of beneficence and respect for the discretion of persons to elect whether they shall undergo medical procedures are common to all leading moral and religious views. Some form of the Golden Rule is found in virtually every major moral and religious view since Confucius.

In this analysis, I accord a wide berth to religious views across diverse cultures, provided only that when moral verdicts are urged on religious grounds, support for them can be given on the basis of reasonable non-religious premises. As we all know, many religious believers condemn the sacrifice of embryonic lives in aid of other lives. Hence a further task presents itself. It remains to be shown, if it can be, that if the argument from nonenablement is introduced in the course of sympathetically reinterpreting one or more views presumptively opposed to all embryo use, such views will issue in approval for epidosembryo use. I illustrate how that task may be accomplished as to the most influential presumptively contrary view, the magisterium of the Roman Catholic Church.

In condemning all manner of embryo destruction, the Catholic magisterium speaks consistently. Just as it condemns destruction of embryos as research subjects, it condemns the practice of assisted reproduction because that practice brings about destruction of surplus embryos. (Other discussants who approve *in vitro* fertilization as practiced, but oppose embryo use in research fall into inconsistency: they condone destruction of surplus embryos as waste, but condemn sacrifice of surplus embryos for beneficent ends.) On what ground does the magisterium’s condemnation of embryo sacrifice rest?

One will often hear it asserted that an embryo is a person and that killing a person

<sup>2</sup> *The Morality of Embryo Use* (Cambridge University Press, 2008).

<sup>3</sup> Richard M. Hare, *Essays on Bioethics* (Oxford: Clarendon Press, 1993).



is murder. To say that a being is a person is to recite the conclusion that the being falls within the category of beings protected by the duty not to harm. It remains to ask what reasoning supports that conclusion. Conceding that the Bible does not assert personhood of an extracorporeal embryo—in antiquity, people did not even know that there existed oocytes, hence never thought about embryos outside the body—the magisterium allows that personhood of an embryo is a philosophical question.<sup>4</sup> Concerning this, the magisterium's argument in chief is the following: fertilization creates a new genome, therefore fertilization creates a person. This argument's premise is true—fertilization produces a new genome—but the conclusion doesn't follow. To identify a person with a genome is to practice genetic reductionism with a vengeance. That view contradicts the bedrock belief that a person is a *corpore et anima unus*, a union of body and soul. On pain of internal contradiction, the argument cannot stand.

A defender of zygotic personhood might plead that precisely because embryos cannot form preferences, it is our obligation to act according to their advantage, hence to classify them as persons. But we cannot foster any advantage of epidosembryos. Entry into the only kind of environment by which they could attain the ability to experience benefit has been forbidden by the only persons in the world empowered to decide such matters. It is from this recognition that the argument from nonenablement builds a *prima facie* justification within Catholicism, as within other views, for epidosembryo use. Is there a countervailing argument?

One argument is that if we do not know whether an embryo is a person in God's eyes, we should exercise caution and act as if it were. But from within a view holding that divine will is the arbiter of morality, suppose that we could have a conversation with God. We report that in 1998, we dis-

covered how to culture human embryonic stem cells. We describe hopes of relieving human suffering by using embryos that will never enter a womb. Is it plausible that He would tell us that He regards such embryos as persons in the sense that He includes them in a universe of beings that He never wishes us to use as means? I do not know of a tenable argument according to which an all-merciful and omniscient God would assert that preference. He would know that unenabled embryos would never become sentient if not used in research.

An objection peculiar to nonreprocloning might be this. An oocyte is created for a purpose, namely to issue in offspring, and it is wrong to divert an oocyte to any other purpose. This objection presupposes with Aristotle that everything has a fixed purpose and that we know what it is. After Darwin, that notion has lost its grip on our thought. We have learned from the history of medicine how mistaken we humans have often been in inferring purposes of various cells and structures of the body. Our forbears would have said that bones are what hold us up; today we think of the marrow as a blood factory. We think it appropriate to transfer marrow from one patient to another. We know that many cells perform multiple functions, and we are learning to redirect proteins and cellular processes to serve chosen ends. It seems arbitrary to say that an oocyte can or should serve only one purpose. Such a rule would seem puzzling insofar as every human female possesses from birth a quarter million or more oocytes.

Turning to public policy, we observe that there obtains no practical scheme by which a government may fund use of embryonic derivatives without complicity in their derivation. Downstream demand induces supply, and complicity transmits through the channel of inducement. Our collective deliberations would benefit from moral reasoning generally overlooked in the policy arena. That is the reasoning adduced in the argument from nonenablement beginning with the premises that intrauterine embryo

transfer is discretionary and that when progenitors forbid such transfer, developmental potential is permissibly bounded. The key to assuring that legislation endorses morally permissible activity is what it says about progenitors. Progenitors possess unique power: each is the only person in the world (with the coprogenitor) privileged to decide what will happen to an embryo. It is because a progenitor-donor decides that an embryo will never enter a uterus that a donee may experiment on it.

Hence the most compelling justification for a donee in performing experiments, and for a legislature in endorsing experiments, consists in the donee's fidelity to permissible donative instructions bounding potential. This brings us to the following public policy:

The government shall support biomedical research using human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine transfer.

This policy wears its moral justification on its sleeve. That attribute avails for public discussion. There the policy may be described as one that assures that the scope of the publicly-supported is congruent with the scope of the morally permissible.

There arise various other ethical questions about embryo use, including fair compensation to oocyte contributors, and the formation of hybrids and chimeras. In the foregoing, we have canvassed a ground for consensus on the most fundamental question.

<sup>4</sup> Sacred Congregation for the Doctrine of the Faith, *Declaration on Procured Abortion* (Vatican City: The Holy See, 1974), and *Donum Vitae* (Vatican City: The Holy See, 1987).

## Barriers to Smoking Cessation: Are they really insurmountable?



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### Introduction

One of the most widespread beliefs in the medical community is that smoking is a habit of personal choice, and quitting does not require professional help [1]. To quit or not is solely determined by the smoker's will power [1,2]. These beliefs by majority of physicians are also shared by smokers [3], and have evolved to form the stumbling block in our efforts to mitigate one of the most harmful and most preventable health issues worldwide: cigarette smoking.

In forming these beliefs, or mis-beliefs, physicians failed to recognise two important aspects of evidence: (A) "Smoking is a chronic addictive disease" [4,5], and as a highly addictive disease, medical assistance is not just highly desirable, but absolutely necessary [2]. (B) Smokers take their physician's advice to heart [2,6,7]. Physicians, by wearing the white gown with the aura of authority, have the magic to break the inertia or the disinterest of smokers [8]. Doctors did not realise that not only it is their job as care givers, but also they had the unique magic touch in motivating smokers to quit. Asian patients visit their doctors 14 times a year [9], providing numerous opportunities and perfect moments for repeated interventions.

### Individual physicians' view and WMA organisational policy position

In a survey conducted by Harris International polling agency of both physicians and smokers in 16 countries [3], the majority of physicians ranked smoking as the most harmful behaviour globally, outranking obesity, inactivity, or poor diet. [The 16 countries surveyed included 11 countries from Europe (France, Germany, Greece, Italy, Netherlands, Poland, Spain, Sweden, Switzerland [physician survey only], Turkey, and UK), one from Central America (Mexico), two from North America (Canada and USA), and two from East Asia (Japan and South Korea). Globally, a total of 3760 smokers and 2836 physicians were surveyed [3]]. However, when physicians were asked as to whether they wanted to help the smokers to quit, the majority indicated they had more important things to do and had no time for smoking cessation. This contradictory phenomenon was observed worldwide, in North America, in Europe and in Asia. In addition, this dilemma faced by the individuals was quite different in respect of their organisational position. As far back as in 1988, the World Medical Association (WMA) adopted a policy statement [10] urging all national medical associations to establish a policy position opposing smoking and the use

of tobacco products, and publicise the anti-smoking policy so adopted. In other words, physicians worldwide and their national organisations are fully aware of the harm from consuming tobacco, but individual physicians do not behave accordingly, despite their strong belief to the contrary. Obviously, there is a large the perceptual gap and the gap is universally observed, and physicians are not behaving as they should. Why? It is because there are barriers that seem insurmountable. What are the barriers, and can existing barriers be overcome? That is the current challenge faced by physicians. The following is a summary of the ten most prevalent barriers to cessation and, by proposing solutions to overcome them, these perceived barriers could be solved and these seeming "barriers" would just become myths.

### Barriers to cessation

The followings are the ten barriers to cessation perceived by physicians. The proposed solutions, when internalised by physicians, would eliminate them:

**(1) No time:** The most common reason for physicians not to engage in smoking cessation is lack of time [11,12]. Surveys found contradictory statements by physicians: On the one hand three quarters of physicians indicate the most harmful behaviour was smoking, among the four most commonly cited behaviours: smoking, inactivity, obesity and poor dietary habits. On the other hand, 75% of physicians worldwide indicate such feelings as "I have more important things to do" as I do not have time for cessation based on survey [3]. Smoking cessation takes time.

**Solution:** Not every doctor has to become a cessation specialist. There should be cessation specialists available. If the individual doctor believes cessation is important, we all agree that it takes very little time to refer to the cessation team available in most hospitals. This may take from 30 seconds to 5-10 minutes, and most doctors should have the time to do this. In fact, "ask, advise and refer (2A's + R)" is all we need. It takes 30 seconds



to intervene. Let us tell all physicians to remember 2As + R in smoking cessation.

**(2) No skills:** Whether the doctors realise or not, the reality is that smoking cessation was rarely taught in the medical school years and the majority of physicians did not receive much training after medical schools [3]. Doctors are not interested in smoking cessation and therefore not motivated to learn as a new skill.

- **Solution:** As much as not every doctor needs to become a cessation specialist, the attitude toward smoking cessation will be more important than the technical skill of cessation per se. The skill to refer can be learned relatively easy, as long as the doctor's attitude is positively favourable. Whether the doctor is committed to the importance of smoking hazards, his body language will be fully revealed in making the referral.

**(3) No money:** Smoking cessation is very time consuming for the doctors, and yet few health insurances would reimburse such services, including many Asian countries. To view smoking cessation as free services is not placing its value in the right spot or making it a sustaining effort

- **Solution:** The reward for successful cessation could be far more precious and long lasting than financial terms. Cessation gives the smoker a new and healthy life for him and his family that money cannot buy. Of the tens of thousands of patients a doctor has treated in his long career, few patients would remember the contribution by the doctor after ten or fifteen years. One exception is the smoker who was talked into quitting and succeeded in quitting. Most smokers are so grateful that they will remember the turning point when decisive action was taken by the doctor.

**(4) No interest from smokers [12,14]:** Smoking patients visit the doctors for medical complaints such as diabetes or hypertension and not for smoking. It is just natural for patients to be more concerned with their chief complaints than other issues.

- **Solution 1:** The most important reason for smokers to quit worldwide has been health concerns, and most smokers are not interested in quitting because they feel fine health-wise. The self reported health of smokers showed that majority felt they were in excellent health [15]. However, this is deceptive feeling, as within the next ten years, those who feel good or average had doubled their mortality risks of their non-smoking counterparts. The evidence is against the smokers.

- **Solution 2:** On the website of Philip Morris [16], the international tobacco giant advised smokers that tobacco company agrees with the overwhelming medical and scientific consensus that cigarette smoking is "addictive", making it very difficult to quit and "cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases, like lung cancer, than non-smokers [2]. There is no safe cigarette." Let smokers find out these statements from the manufactures of cigarettes.

- **Solution 3:** The advice from tobacco manufacturer: "The best thing to do for smokers is to quit." (Philip Morris website) Even the manufactures asked the user not to use their products. What an irony!

**(5) No more:** Doctors feel as long as they had advised smoking patients once, that would be sufficient and do not need more than that. They are concerned that "nagging" or repeated reminding, would scare away patients.

- **Solution:** The global survey [3] revealed that when physicians were interviewed, 75% of them indicated they discussed smoking with their smoking patients, but when smokers were interviewed only 20% recalled such encounters. This discrepancy reflects a major communication gap between the doctors and the smokers. Part of the solution to bridge the gap is for the doctors to repeat the message in every visit, and not limited to one visit.

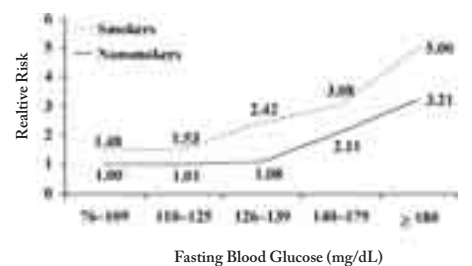
**(6) No connection:** Smoking cessation is not connected with the chief complaints clinics by the patients, and to bring up smoking seems to be an entirely different subject. When pressed for time, it is difficult to initiate a new conversation on a different issue.

- **Solution:** As patients are interested in the progress of diabetes or hypertension, they are interested in following their blood glucose and blood pressure. For this, the glucose equivalent of smoking and blood pressure equivalent of smoking will help doctor to talk to their patients. Smoking cessation is equivalent to a reduction of 40 mg/dl of fasting blood glucose [17] or to a reduction of 40 mmHg of systolic blood pressure [18] (shown in the accompanying figures). While some medications might be able to achieve such a significant drop in blood sugar or blood pressure, but they are effective only during the time when medications are taken, and most medications have short term and long term side effects. Smoking cessation provides a life long reduction of these parameters.

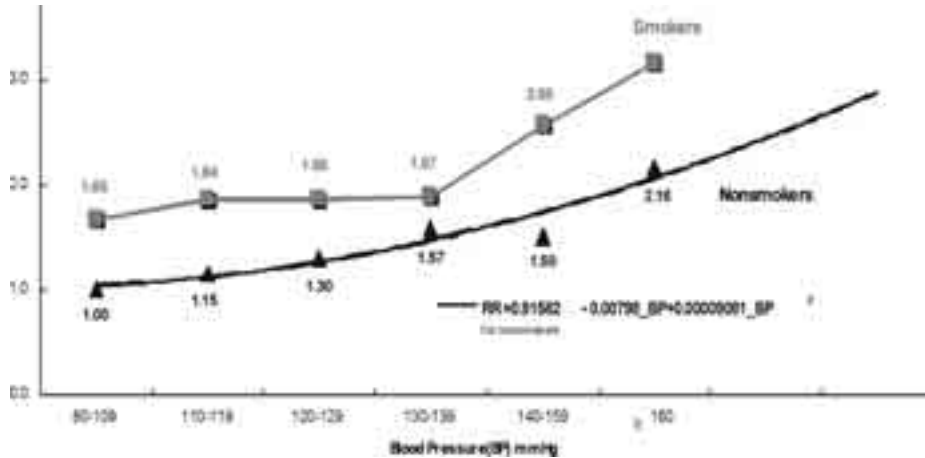
Results showed that the addition of smoking was equivalent to an increase of mortality risk approximating a 41 mg/dL increase in blood pressure [17].

Results showed that the addition of smoking was equivalent to an increase of mortality risk approximating a 40 mmHg increase in blood pressure [18].

**(7) No alternative:** Cigarettes acted as the best friend, with intimate contact 20 times a day (one pack) 365 days a year. Such an intimate contact was more than any member



**Figure 1.** Comparison of relative risks between smokers and non-smokers by fasting blood glucose for all cause mortality.



**Figure 2.** Comparison of relative risks between smokers and non-smokers by systolic blood pressure for all cause mortality.

of his family. How could someone separate relationship with such a best friend without any alternative? For a young man to say goodbye to his girl friend of more than ten years will be extremely difficult. Even if he decided to do so, he would miss her day and night, struggling emotionally. He wished, at any moment, to see her and make up again.

• **Solution:** The only way to separate with his girl friend successfully is to cultivate another girl friend before separation is to take effect. The analogy in this case for separating with cigarettes is to cultivate the love for physical activity: walking, running, sports, climbing or going to the gym. In comparing and analysing the caloric expenditure between smokers and non-smokers, we found, as shown in the table, that ex-smokers had twice the levels of exercise as smokers. This implied that either through picking up exercise the smokers quit smoking or smokers start to exercise after quitting.

**Table 1.**  
Exercise levels by smoking status in Taiwan [19].

	>750 Kcal/Week	>1,000 Kcal/Week	>2,000 Kcal/Week
Non-smoker	19.6%	14.3%	4.5%
Smoker	15.1%	11.1%	4.4%
Ex-Smoker	31.8%	25.4%	11.6%

Ex-smokers **doubled** their activity levels

**(8) No effect:** Cessation treatment is not fail-proof, having only one or two successes in ten attempts, even with the availability of the most recent medication like Varenicline [20]. In other words, failure is the rule and success from quitting attempts is an exception or a miracle.

• **Solution:** The success rate noted above is defined as one year from treatment. The rate quitting within 2-3 months of treatment was nearly 60% [21]. What happened after that and why the decline? One reason was the lack of intensive follow up after the first few weeks when intensive care was invariably provided. The quitters were very vulnerable and should be given all the TLC (Tender Loving Care) from the health care team and from their friends and families, particularly when they were struggling to quit.

**(9) No reminder:** During clinical encounters with smoking patients, physicians focused on the medical problem and in many instances failed to note the smoking status of the patients. This is also true for inpatient care.

• **Solution 1:** The entire medical group, including the hospital administrator and medical director, should all agree with the importance of this issue and set up a series of support system. For reminder, a red tag, a computer prompt, or smoking status being included as part of the vital signs can all be instituted. A cessation

team should be available and referral can be conveniently made and intensive follow up will be carried out. .

• **Solution 2:** Tobacco company stated in their website that “second-hand smoke from cigarettes causes disease, including lung cancer and heart disease, in non-smoking adults, as well as causes conditions in children such as asthma, respiratory infections, cough, wheeze, otitis media (middle ear infection) and Sudden Infant Death Syndrome” [22]. This should be posted in the examining room and in the corridor.

**(10) No environmental support:** With limited legal restrictions on second hand smoking, low cigarette price, or no reimbursement for cessation services, the hostile environment will be barriers for cessation services.

• **Solution:**

▪ Physicians become advocates of tobacco control in the society and let the public know their stance. Examples of issues include:

- ♦ Increase in cigarette price [23].
  - This has been proven to curb youth smoking. Smoking rates will decrease, first among the poorer smokers and then followed by the rest, if the increase is sufficiently large. For 10% increase in price, there will be a 8% reduction in youth smoking and 4% reduction in adult smoking rates [24].
  - Experience in France showed a reduction of 1.5 million smokers in 2 years after the price increase [25].
  - The added revenue can be tapped for mounting more tobacco control programs [26].

♦ Smoke free home when there are small children or pregnant women at home

• This has been proven to reduce heart attacks and emergency visits

♦ Free cessation services for all smokers
 

- With tax increase, it is just natural to return the money to the smokers, so that next increase will be supported by them.



- Physicians become more involved with national policy setting on tobacco control.
  - ♦ This has the policy statement of World Medical Association.
- Medical societies issue position statement on smoking and smoking cessation
- Hospitals become exemplary institution in tobacco control by setting up “No smoking policy for the hospitals” and by voicing out loud on the hazards of smoking and the availability of cessation inside the hospitals. Inpatients are more open for cessation, as they suffer from more serious medical conditions.

Physicians who share similar concerns on tobacco control form alliances for tobacco control. They can make their views known to the public, such as tax increases or reimbursement for cessation services.

Unless we do things differently, quickly and effectively, this coming 21<sup>st</sup> century will see 1 billion deaths from tobacco [23]. Just imagine every single day, the number people dying from tobacco is equivalent to 5 times the number of deaths occurred in 9/11 tragedies in 2001. In other words, 9/11 is happening every 5 hours. Among all the care and “treatment” offered by a physician, including counselling, doing a physical, giving out prescriptions, or ordering lab tests, there is nothing more important and could have more health impact than helping smokers quit. Most everyday interventions are “band-aid relief” for symptoms to make patients happier, but helping smokers quit is to make them “healthier”. While making them happier is important, physicians should focus on more important goal, “Healthier”.

## Conclusion

In summary, the physicians’ attitude toward smoking is the turning point, rather than the skill. Making smokers quit will be the most rewarding activities for physicians. Ask, advise and refer (2A’s + R), and it takes only 30 seconds to intervene. Overcom-

ing 10 excuses, by changing ten No’s to ten Yeses, will make the seemingly difficult task one of the most valuable and meaningful work physicians could offer the patients. In addition, physicians need to stand up and be visible in position against smoking. With this, public respect toward physicians will be greatly furthered.

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## Ocular Risk Standards and Medical Ethics. A Development on Occupational Radiation Exposure in an Epidemiological Study



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Epidemiological investigations in occupational health accept the ideals of free inquiry and pursuit of knowledge. The goal of occupational health science, after all, is to explain and to predict natural phenomena of occupational exposure. However, epidemiologists in occupational health also cherish values of improving the public's health of workers through application of scientific knowledge to the different hazards of the working environment. These dual professional obligations sometimes give rise to medical moral problems [1, 2, 3].

Many occupations are necessarily associated with exposure of a worker to ionizing radiation in the course of their activities. From Ukrainian uranium miners and oil drillers to interventional radiologists and airline crews, the population associated with this exposure is diverse and has varied specific job parameters. Occasionally, workers can receive a significant radiation dose as a result of efforts to mitigate an accidental occurrence, wherein radioactive substances are accidentally released into uncontrolled environments [2, 4]. These situations often create a

higher exposure than would otherwise be allowable. There are also cumulative exposures from unique activities, such as space flights, which are treated as exceptional cases. Thus, the permissible radiation load is different for the general population, radiological workers and extraordinary occupational activities. The timeframes associated with allowable exposure also vary with the population in question allowable exposure e.g. determining permissible doses for the visual system, for which radiogenic cataract can serve as a dose-limiting expression of the damage.

In the effort to be illustrated in guidelines, several determining parameters are given differing weights depending on the particular activity. In the early hours of April 26, 1986, Reactor Number Four of the Chernobyl Nuclear Power Plant (ChNPP) underwent a power excursion during a turbine rundown experiment, resulting in a steam explosion that spewed radioactive materials into the environment. It is estimated that at least 4% of the fuel inventory was ejected as well as all the noble gases and most of the volatile isotopes. To deal with the accident, workers, conscripts,

and army reservists were assigned to clean up and perform maintenance duties in the weeks and months following the disaster. The so-called "Liquidators" (those who would remediate or eliminate, "ліквідувати", the damage) numbered more than 250,000 during the period of activity considered in this publication (April 26, 1986 – December 31, 1987).

In 1996, ten years after the event, a cohort epidemiological study of radiation-exposed Chernobyl Liquidators was initiated [5]. The programme is a joint effort by scientists and ophthalmologists of Ukraine and the United States, known as the Ukrainian/American Chernobyl Ocular Study (UACOS) [3]. Two major objectives are to: 1) address whether or not ocular disease such as radiation cataracts data are compatible with a high dose threshold, and 2) define the magnitude of the dose-response association for radiogenic cataracts among Liquidators. The first two rounds of ophthalmologic exams of 8,607 subjects at approximately 12 and 14 years post-radiation exposure permit us to draw conclusions regarding the relative sensitivity of the human lens to radiation injury that are pertinent to current guidelines for ocular protection of radiation exposed individuals [6].

We should indicate that development of the National System for Ethical Review in Ukraine was done as a part of joint efforts in Eastern Europe and Central Asia [7]. In the case of cataracts, the considerations are not straightforward. Irrespective of job description, cataracts generally appear in the last decade(s) of individuals' working life-time and, more often than not, the subject is unaware of their presence.

Before the examination we settled legal and ethical considerations of the epidemiological investigation which included the secured consent in epidemiological medical research in the USA and in Ukraine. Confidentiality and privacy aspects and protection of human rights in epidemiologic research were considered.

The ophthalmic examinations were conducted in six cities – Dnipropetrovsk, Donetsk,

Kharkiv, Kyiv, Poltava and Slavutych – located in five Ukrainian regions (oblasts) proximal to Chernobyl. The database collection and analysis were done at the SI “Institute for Occupational Health of AMS of Ukraine” (responsible organization), and the ophthalmology data quality control and education of the ophthalmologists performed in the National Medical Academy for Post-Graduate Education. The SI “Scientific Center for Radiation Medicine of AMS of Ukraine” was responsible for the dosimetry part of these studies.

Annual human subjects’ reviews and bio-ethical approval were provided by the Institutional Review Boards of Columbia University, Health Sciences Division (New York), the Institute for Occupational Health (Kyiv) and New York University School of Medicine (New York) from the 1992.

To complicate matters, lens changes appear with age in a specific manner and the rate of development (worsening) varies among individuals. Until recently, the presence of a potential background level of cataract was not considered a problem because it was believed that radiation cataracts were a deterministic response and therefore required a dose threshold to be exceeded if the radiation was to be considered cataractogenic.

The data indicate that radiation cataractogenesis has a dose threshold much lower than the current radiation protection guidelines specify. For highly fractionated or protracted exposures the ICRP assumed the dose-effect threshold was 5 Gy for “detectable opacities” and >8 Gy for “visual impairment” [8]. The NCRP, following UNSCEAR, indicated a cataract threshold dose of 4 Gy for fractionated low-LET exposures, therefore recommended dose limits to the eye were 2 Gy-Equivalent in a year or 4 Gy-Eq over a career for space activities [9]. These dose values are incompatible with the findings of the present study, which involves predominantly protracted exposures; our formal threshold analyses are statistically inconsistent with a cumulative-dose threshold less 700 mGy.

However, accumulated data suggest that a real threshold does not yet exist. In allowing for such a possibility, standards in special conditions, such as the astronaut corps, were based on the concept of “clinical relevance,” i.e. induced lens changes might be acceptable if an individual does not suffer from visual decrements by their presence. This is one more medical moral question. This position is fraught with a host of problems, not least of which is the variegated distribution and pleomorphism of early lens changes. However, perhaps the most problematic to such considerations is a recent follow-up of the Chernobyl Liquidators, which clearly shows that if a threshold exists it is at least of an order of magnitude lower than presently thought and is likely not to exist at all (for Lens – 200 mGy). Under such circumstances, the potential to develop cataracts occupies the same stochastic realm as cancer.

The problem was discussed on the National Committee of Radiation Protection of Population of Ukraine under the “Verkhovna Rada” (Parliament of Ukraine) in August 2008 and our proposal to decrease the threshold for lens was adopted. The last publication of the ICRP indicates that this question must be discussed and the target group created. The ethical issue then appears: “How many excess cataracts in a particular age we are willing to accept?” Although there are other cataract-specific aspects which must also be considered, philosophically and ethically the acceptance of a certain damage is the main issue.

Once decisions have been made regarding permissible exposures, the bioethical issue becomes one of the informed consent. How should the actual health risk be framed, so that the individual can make a judgment as to whether or not the added risk to cataract development is personally acceptable? Clearly, occupational activity that leads to compromised visual acuity could easily constitute a trigger to change an individual’s environment in order to minimize the exposure. However, what of clinically detectable, but not “clinically relevant” lens changes characterize a radiogenic damage?

What provision should be made to deal with the individual? Is simply informing the patient of the finding without further action an appropriate response? Should a worker be educated on realities of the only proven method to deal with visually debilitating cataracts, namely, eye surgery? Or, should a worker quit his/her job?

These are only some of ethical issues to be examined and although, in this case, they apply to cataract as the medical ethical judgment, they are similarly to a problem of other work-related pathologies.

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## Medical Ethics in the Present Scenario: Revisiting the Basics and Recognizing Emerging Concerns



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Medical ethics can be defined as principles of proper professional conduct concerning the rights and duties of patients, doctors and fellow practitioners, as well as physician's action in the care of patients and in relation with their families.

With the explosion of scientific knowledge, introduction of newer medical technologies of investigation and treatment, as well as an increasing level of consciousness of the public, the importance of Medical Ethics has evolved tremendously over the years. The question of medical ethics and its discussion became very relevant and urgent in contemporary times owing to the practice of medicine increasingly becoming more and more legalistic. Consumer laws also embraced medical practice which became more defensive with doctors taking recourse to writing many investigations.

The relation between the doctor and the patient, which was essentially based on mutual respect and trust, came to be based more on evidence and documentation.

Medical practice in India is governed by the regulations of the Medical Council of India which is the apex medical regulatory body of the country, legally endowed not only with regulatory powers, but also with the authority to discipline errant doctors as well. Being the statutory authority to register doctors, it can punish them also with deregistration for a certain time or permanently. This is a function no court of law does, but only the Medical Council. In the contemporary scenario, the ethical role of the Medical Council has also increased greatly. Basically, ethics are the moral requirements of medical practice. It has various areas. We will try to highlight few of them.

### **Doctor - Patient Relationship:**

The doctor has to be careful at all times so as to be able to earn the trust and respect of patients. And to be able to do so, he has not only to be professional and competent, but has to be compassionate and caring and well versed in codes of ethics and the laws governing this sphere as well. Truthfulness is the first ethical principle a doctor has to follow and also it is the first expectation of the patient.

A doctor's attitude towards the patient is of vital importance. When a person chooses the medical profession the die is cast. He or she is then expected to behave in a certain way, uphold certain value systems, follow an exemplary and disciplined conduct both in public and private life, be transparent in all dealings including financial ones and be aware at all times that once the profession of medicine has been chosen, it will be necessary to have a mentality of service towards the people, towards the patient.

### **Patient Autonomy:**

The patient has the right not only to choose the modality of treatment, but also the doc-

tor who would be treating him. Thus, doctor must explain the details of treatment, diagnostic procedures, surgical procedural details and others, if any.

Only in emergencies, a doctor should know what has to be done and why. In such situation, proper documentation is important which doctor must bear in mind. Doctors otherwise should always respect the patient's right of autonomy and never fail to inform about the various treatment modalities available and the details of the management plan chosen for the patient in a particular case. Even in ward settings these principles must be adhered to.

### **Confidentiality:**

Preserving confidentiality is another area of a doctor-patient relationship, a doctor is bound by his code of honour (read ethics code) not to divulge this information to anyone at anytime except possibly in a court of law and that too in camera. A patient's trust of his doctor (and respect too) greatly depends on this. It also involves not divulging medical secrets of wives to husbands and vice versa. The principles of ethics demand that the patient and the patient alone must be told fully about the diagnosis.

### **Communication with the patient:**

This is another central aspect of doctor-patient relations.

### **Informed Consent:**

A patient's acceptance is required in writing, but it has to be obtained after informing the patient regarding invasive procedures, dangerous drugs (such as in Chemotherapy), anaesthesia and surgery to be undertaken. Even at the stage of investigation, where invasive procedures, endoscopic procedures, biopsy etc. are required then it is also necessary to obtain informed consent. It is a legal requirement and not only an ethical requirement alone. Consent from nearest relatives, children or legal guardians have to be obtained if legal consent from the patient is unobtainable owing to patient's condition.

The doctor must never forget that a patient has the right to withhold consent.

A doctor must also know what are the **patient's rights** and what are the **doctor's rights** i.e. the respective rights of the patient and the service provider. There are many authorities who have charted out these rights of the patient. Mostly, these are matters of ethical principles, but in USA and some countries these have the sanctity of law. Whether such rights are within the realm of law or morality (ethics), the doctor must be well conversant with them.

There should be no discrimination on the basis of race, religion, language, colour and culture. The doctors must also ensure that in all treatment decisions there is participation of the patient.

No doctor can refuse to attend to a patient if called in an emergency; however, in non-emergency situations, in routine practice, a doctor has every right to refuse to see a patient. A Doctor's function within rules and at certain times only they may be available for consultation.

A doctor may have to take certain tough decisions at the end stage of the patient's life, specially, death declaration of patients, on life support systems which should depend to a large extent on the relevant laws of the country. These are called **end of life decisions**. One aspect of it concerns euthanasia. In India, euthanasia is not allowed. But for every medical action there is a code of ethical conduct which is based on commonsense, cultural practices, social codes and even law. For not following these self regulatory codes, a doctor can be accused of misconduct or infamous conduct which may attract various censures, penalties, fines, etc as per the laws set by the regulatory authorities, government, employers and courts.

**Medical negligence** is one part of the sphere of ethics which every doctor is afraid of and is a very serious matter. Civil and criminal negligence is the broader indexing of all negligence.

If a doctor, without required and recognized competence performs a procedure on a patient for which the doctor has no legal sanction and competence, he is bound to be committing an act of medical negligence, whether something untoward occurred to the patient or not. This could be **act of commission** by a medical doctor.

Negligence can be by an **act of omission**, the doctor has not done a particular act he was required to do, or by forgetting it or not having the competence. To avoid malpractice and negligence suits, it is essential that the doctors follow a disciplined scientific approach and maintain self regulation.

Doctors need to be firm to refuse the lure of unethical gratification and withstand the inappropriate promotion practices of the pharmaceutical industry. Similarly, working in private practice brings many ethical dilemmas before the doctor. Management pressure on the doctors to perform in terms of more patients, more investigations, more operations, more revenue can create an unhealthy atmosphere and pose serious ethical problems. The doctors should be strong enough to withstand these pressures and insist of working in a professional atmosphere only.

The tremendous development of scientific knowledge and treatment techniques in the last two-three decades have brought many new ethical problems for the doctors. But, this field is so vast that it is not possible to cover the entire sphere of these newly emerging ethical concerns in medical practice in the scope of one single article.

Genetic screening, gene therapy, sex determination of the foetus and female foeticide, organ transplantation and donation all deserve special attention owing to newer laws of the land. In India, where female foeticide abuse is not insubstantial, has quite strict laws regarding these (Prenatal sex determination test act 1994 PNDT act). Similarly, in India, the whole spectrum of organ donation and transplantation is covered by the Transplantation of human organ act, 1994.

Such screenings have to be kept confidential; as such genetic information can be used to discriminate individuals by employers, insurers and even by spouses and relatives. Doctors must ensure that such test results are kept strictly confidential and disclosure should be only done in a manner prescribed by law. Doctors should not attempt genetic counselling unless they are trained and usually such counselling should be confined to one's own speciality. Breach of laid down law, professional protocols, need of maintaining confidentiality can be considered as serious ethical infamous conduct.

Drug trials, animal experimentation, stem cell research, everywhere newer ethical issues are cropping up which are subject and situation specific. In India, the Indian Council of Medical Research and also the Drug Controller of India have laid down legal and ethical guidelines for medical research and doctor should strictly follow these guidelines. Those who are in the field of medical research should scrupulously follow the principles of the Helsinki Declaration. No doctor should undertake drug trials or clinical research unless these are specifically approved.

Ethical issues are emerging in the treatment of patients suffering from HIV/AIDS. Refusal to treat, stigmatization, and unfair resource allocation are some of the most unethical practices that a doctor can indulge in. Ethical issues also crop up in instances where notification or partner tracing are required to be done.

With the development of medical science, with newer treatment and diagnostic modalities, newer ethical issues are cropping up everyday and they are likely to continue to do so in the foreseeable future as well. It is the legal, moral and ethical duty of all doctors to keep track of these newly emerging medical issues. Ethical practice is the bedrock where the reputation and respect of a medical practitioner is based. We must never lose sight of this.

## The Continuing Medical Education Program of the Japan Medical Association



Masami ISHII, MD, Executive Board Member of JMA, Council Member of WMA

### 1. Introduction

In 1987 the Japan Medical Association (JMA) initiated systematized continuing medical education (CME) programs to provide systematic support to the broad-based, effective engagement of physicians in CME under the philosophy of professional autonomy based on self-regulation.

### 2. School Education System in Japan

The compulsory education in Japan consists of nine years from elementary school to junior high school. After compulsory education, students must undergo a three-year high school education and then complete a university medical course to be eligible for qualification as physicians. The university medical education comprises six years, including basic and clinical education. The courses up to this point are under the supervision of the Ministry of Education, Culture, Sports, Science and Technology. There are presently 80 medical colleges and university medical departments in Japan, admitting approximately 7,500 students every year. In response to the shortage of physicians,

the annual admission capacity is expected to increase gradually. After the six-year medical education program, students must pass the National Examination for Medical Practitioners, be registered with the Ministry of Health, Labour and Welfare, and complete two years of postgraduate training. While this postgraduate training was voluntary in the past, it was made compulsory in 2004. With this education, new physicians are trained and allowed to perform medical acts in Japan.

### 3. CME Program of JMA

#### (1) Basic Policy

The CME Promotion Committee of the JMA has been established to promote and support the CME of members. Local associations also have similar committees for physicians in respective regions, and the JMA is working in close cooperation with these committees. The CME Committee of each local association supports the teaching of members with programs incorporating regional policies and characteristics. The content of learning covers not only medical science but also various fundamental issues physicians must understand in their daily practice, such as medical ethics. Respecting the self-determination of physicians, the CME activities undertaken by individual physicians are evaluated on the principle of self-reporting, and no penalty is imposed on physicians who fail to report. "The CME Certificate" is awarded to physicians who declare that they have completed 10 credit units or more in a year. Physicians achieving this certificate in three successive years are granted "the Certificate of Recognition for Completion of CME."

#### (2) Curricula

The curricula sets the goals and outlines the learning directions of the physicians. The

study topics in the curricula are divided into basic healthcare topics and medical topics.

#### 1) Basic Healthcare Topics

These include about 100 basic healthcare topics that all physicians should know, irrespective of the fields in which they specialize. Examples of such topics are medical ethics, laws, welfare, social security, and health economics. This part of the curriculum is intended for the acquisition of broad knowledge related to healthcare.

#### 2) Medical Topics

These are the learning of medical science, comprising the two parts covering "important matters in medical practice" and "important diseases," respectively. The former part, "important matters in medical practice," assesses the attainment of knowledge, skills, and attitudes related to the important matters in the process of medical practice. The latter part, "important diseases," is a curriculum that assesses the attainment of sufficient knowledge and treatment skills for diseases commonly seen in daily practice and diseases of clinical importance.

The JMA recommends the following ways of utilizing these curricula.

The CME Committee of a local medical association may plan a CME workshop, featuring some of the themes in the curricula.

The curricula may be used in self-directed home learning and group learning.

It is recommended to select study topics referring to the curriculum of experience-based learning in hospital-clinic collaboration.

#### (3) Main Learning Media

Main learning media tools include the Journal of JMA published in Japanese by the JMA. The Journal, produced by the Editorial Committee of the JMA, is published in twelve regular issues and two special issues

every year. The JMA CME Courses refer collectively to the CME courses supported by collaborating companies, reflecting the diversification of learning media. These courses are also planned by the Editorial Committee.

The JMA website allows visitors to search and read papers in the Journal of JMA, to search titles in the video library, to view video-streamed medical TV programs, and to view Internet-based CME courses.

In addition, journals and websites of local medical associations are also used as learning media.

#### **(4) Learning Methods**

Learners may obtain credit units defined as follows.

A learner attending a lecture meeting or a workshop receives a certificate (card, sticker, etc.) from the host organization and submits it with the declaration to acquire 3-5 credit units. In the case of experience-based learning (learning in hospital-clinic or clinic-clinic collaboration), the learner submits the theme, the name of facility, and other details with the report form, and receives five credit units. Some professional achievements may be recognized as credit units. A learner making an academic presentation or publishing a paper attaches the records of presentation title, author name, etc. to the declaration and receives 3-10 credit units. Home learning, such as sending an answer to a question in the Journal of JMA via mail or the Internet or answering the self-assessment in the Internet-based CME courses, is worth one credit unit each time.

#### **(5) Self-declaration Practice**

The acquisition of credit units is based on the principle of self-reporting. Some local medical associations collect declarations from the members send them to the JMA. The report form is distributed as a supplement to the March issue of the Journal of JMA every year. A person making a decla-

ration fills in the report form, attaches the certificates of attendance to seminars and other events and records of achievements, and submits the completed form to the county, city, or ward medical association or the university medical association to which he or she belongs by the end of April every year. The submitted declaration forms are sent to the JMA via prefectural medical associations and processed and managed by computer.

#### **(6) Interchangeability of Credit Units**

The certificates of attendance obtained from the participation in the JMA CME Courses are interchangeable with the credit units needed for the renewal of specialist certification in several specialty societies. In the CME system of JMA, attendance of a lecture meeting or other events of a specialty society is counted as three credit units. As of 2008, arrangement for credit interchangeability has been made with the specialist physician/certificate physician systems of 27 specialty societies

#### **(7) Awarding of "the CME Certificate" and "the Certificate of Recognition for Completion of CME"**

"The CME Certificate" is awarded to physicians submitting the CME declaration and documented (by certificates of attendance, records, etc.) to have achieved ten credit units or more in a year. Physicians achieving this certificate in three successive years are granted "the Certificate of Recognition for Completion of CME".

Although these certificates of completion and certificates of recognition do not signify any qualification, the proof of participation in CME as indicated by the declaration rate provides a yardstick for measuring the attitude of a physician towards CME. The physician may display these certificates in the clinic, for example, as a means of building a trust relationship with patients.

## **4. Conclusion**

The medical care system of Japan faces a crisis as a result of the government's policy of cutting expenditure and curtailing social security measures. In this difficult situation, the JMA is doing everything in its power to enrich community health, ensure patient safety and build a reliable foundation for social security. The CME program is one of the most reliable means of improving the quality and skills of individual physicians, and the importance of CME is will undoubtedly increase in the future.

In addition, the JMA has been engaged in international affairs through participation in WMA and continuing interactions with the medical associations of various countries to exchange opinions regarding world healthcare problems. The enrichment of community health in Japan is directly linked to Japan's contribution to the health of people in the world. From this perspective, the JMA is committed to continue its efforts to improve the health standard of the world from the standpoint of patients. The JMA intends to compile records of successful solutions of various problems of community health and share these experiences with the physicians of the world, so that it may be of help to physicians working in various environments.



## The FDI World Dental Federation and the growing realisation of oral health worldwide



*Dr. Tin Chun Wong, FDI Treasurer*

Despite oral diseases being some of the most common and most widespread in populations around the world there has been, and remains in many countries, surprisingly little attention paid to them. This may be a reflection of their often chronic and low grade nature, except for episodes of acute pain manifested as toothache, or that other diseases and conditions steal the limelight due to their more dramatic or life threatening potential.

As part of its role, and enshrined in its Mission Statement, the FDI World Dental Federation has the vision of optimal oral health for all and strives through its activities to achieve this goal. This article, by Dr. Tin Chun Wong, Treasurer of the FDI and based on her presentation to the World Assembly in Seoul – Oral Health and Human Rights – describes the work of the FDI and its importance in relation to oral health and human rights, and in turn the importance of oral health within the context of general health.

### The FDI

Founded in 1900 in Paris, France the Fédération Dentaire Internationale (FDI)

was the brainchild of Dr. Charles Godon, Dean of the Ecole Dentaire de Paris who has planned three International Dental Congresses in that city in the years 1889, 1893 and 1900. With a founding group of five other colleagues, on the morning of 15 August 1900 the Federation was born. Little could those dentists have imagined that over a century later the organisation would represent 135 countries, 190 national dental associations and special interest groups and through them effectively speak for over one million dentists and dental care professionals worldwide.

### The FDI's mission

As a federation of National Dental Associations the FDI's main roles are to bring together the world of dentistry, to represent the dental profession of the world and to stimulate and facilitate the exchange of information across all borders with the aim of optimal oral health for all peoples. It has four main areas of activity:

#### *The voice of dentistry*

To be the worldwide, authoritative and independent voice of the dental profession.

This it achieves by producing position statements on various aspects of dentistry and oral health, providing authoritative information for governments, the media and other organisations, and holding the Annual World Dental Parliament as part of its Congresses. The FDI develops and disseminates policies, standards and information related to all aspects of oral health care around the world. FDI Policy Statements lay out the profession's views on various issues related to oral health, oral health policies and the dental profession.

#### *Optimal oral health*

*To promote optimal oral and general health for all peoples*

Being an advocate for oral health at the WHO, UN and in a variety of other fora, the Federation also runs projects through its Dental Development Fund (see below).

#### *Member support*

*To promote the interests of the Member Associations and their members*

With its headquarters in the Geneva area, the FDI gives support and promotion to its constituent associations across a variety of project areas including sponsorship, oral health campaigns and expert advice networks.

#### *Information transfer*

*To advance and promote the ethics, art, science and practice of dentistry*

This aim is achieved through a range of activities including the Federation's three main publications and website ([www.fdi-worlddental.org](http://www.fdi-worlddental.org)) as well as its Annual World Dental Congress (AWDC). This encompasses an extensive scientific programme with international speakers, as well as those from the host country or region, focusing on the latest scientific topics affecting the dental profession globally. Recent venues have included China, Dubai and Sweden, with Singapore and Brazil in 2009 and 2010 respectively. Congresses also provide the opportunity for meetings of the Practice Committee, Science Committee and other specialist groupings whose ongoing projects produce position papers, papers for publication and fora for discussion and development.

### Advocacy Activities

As well as its Policy Statements the Federation's involvement in global health extends to the promotion of general health, with oral health as an integral component as one of the elements of a healthy lifestyle and a productive society. Oral health inequalities are addressed through the implementation of effective oral health policies. The FDI is a member of the World Health Professions Alliance, together with the International





Council of Nurses, International Pharmaceutical Federation and World Medical Association. It is also active in tobacco control since use of tobacco has both direct impact on oral health, such as oral cancer, as well as on general health issues. Tobacco cessation advice is effectively given by members of the oral health care team, which the FDI promotes as an active role.

### Development Projects

The FDI promotes and supports global oral health development for deprived communities and populations in various ways.

#### *Projects at grassroots level*

These are carried out in co-operation with FDI member associations and non-governmental organisations and supported through grants from the FDI's World Dental Development Fund. Projects have been established in Latin America, Asia and Africa.

#### *Support in developing appropriate policies*

The FDI supports governments and other organisations in the formulation of comprehensive oral health policies and helps in their implementation.

#### *Global partnerships to improve oral health*

Working in close partnership with the WHO, other UN agencies, health professions and organisations the Federation collaborates to improve oral health worldwide. Active involvement with FDI's corporate partners is another way of engaging broadly in promoting better oral health. The Live. Learn. Laugh programme, created as a unique partnership with a corporate partner, aims to increase oral health education and promotion in countries throughout the world.

### Education Programmes

#### *Continuing Dental Education*

Together with its member associations, the FDI participates in and supports continu-

ing dental education programmes in many regions. The organisation is currently involved with more than 20 continuing dental education programmes each year.

As mentioned above, the AWDC plays an important role in the advancement of dentistry. In addition to the scientific element, the programme also features speciality workshops and forums on oral health promotion, the World Dental Exhibition – a showcase of state-of-the-art advanced dental technology, equipment and products and the World Dental Parliament, a gathering of about 350 representatives from FDI member associations to establish the organisation's strategic direction and adopt policy statements that influence the world of dentistry.

### Communications

The Federation produces a series of reputable publications on topics related to oral health through its publishing division, FDI World Dental Press, based in the United Kingdom.

#### *The International Dental Journal (IDJ)*

The renowned *IDJ* has been FDI's flagship publication for nearly 60 years. It features peer-reviewed, scientific papers relevant to international oral health issues in addition to practical and informative articles aimed at clinicians. Published six times a year, *IDJ* is the FDI's main scientific publication. It is available in print and online ([www.idj.org](http://www.idj.org)).

#### *Developing Dentistry*

This biannual journal is the worldwide voice of oral health development. It offers a positive, forward-looking approach to dental development and tries to provoke discussions and debates around these topics by featuring papers from around the world.

*Developing Dentistry* is distributed free of charge.

#### *Worldental Communiqué*

This newsletter provides FDI member associations and other dental and health related groups with updates of our organisation. It is published six times a year.

#### *Annual Report*

Provides members, partners and other interested parties with an overview of the FDI's recent achievements and an outlook of the organisation's future. It includes messages from the organisation's President, Executive Director and Chairman of the Finance Committee, in addition to financial statements and reports on the FDI's activities.

#### *Website*

The website features information about the FDI as a federation of member associations a world renowned section on scientific guidelines for the dental profession, details about FDI development and public health activities and information about Annual World Dental Congresses and continuing education programmes.

### Oral health worldwide

It is now widely held that good oral health is a basic human right and should not be regarded as a privilege of a minority. The FDI believes strongly in this and indeed this emerged as the declaration of the April 2004 Nairobi Conference for Oral Health in the African Region, organised by the Federation. This was the first conference on oral health on the African continent and was supported by WHO.

There is a strong association between oral health and socio-economic status so that poor oral health is often a feature of low societal position also leading to a similarly strong association between oral health and inequalities.

There are two main oral diseases; dental decay and gum disease. Both are mediated by dental plaque which is formed of micro-



organisms that colonise tooth surfaces. Decay, or caries, is essentially a gradual process of demineralisation with calcium being removed from the outer enamel surface of the teeth by acid attack from the plaque bacteria. The process is driven primarily by sugars and carbohydrates in the diet which are then metabolised by the micro-organisms which create acidic by-products and toxins.

Gum disease is similarly promoted by the toxins from bacterial plaque that grows around the gum margins. In its early stages it causes inflammation of the gingivae (gingivitis) but can progress to destroy the supporting tissues of the teeth, the periodontium (periodontitis).

In an ideal world, removal of dental plaque in an efficient way and on a regular basis would prevent or limit the extent of both of these conditions. In the real world however this is either not possible at all, or only in part depending on a wide range of factors.

### Prevention rather than cure

Because the conditions are preventable, the FDI is a strong supporter of the two main methods of prevention and this runs throughout its activities and programmes. Periodontal disease prevention, reliant on effective and thorough removal of plaque, relies on good oral hygiene through tooth-brushing, flossing and other mechanical means such as the miswak, as well as chemical adjuncts such as appropriate mouth rinses and on occasion other anti-microbial agents.

As far as caries is concerned there are two approaches to prevention. One is dietary modification to reduce the frequency and quantity of refined carbohydrates consumed combined with good oral hygiene. However, this necessarily involves not only motivation from the patient but also the resources of time, finance and equipment to achieve it. It is in these situations in which inequalities impact so heavily on oral health. Another approach is the use of fluoride as an agent to help strengthen the tooth enamel

against the acid attack from the plaque. The incorporation of fluoride into the outer surface of the enamel makes it chemically more resistant to acid meaning that it can sustain an attack for longer, enabling it to survive intact for longer and until the saliva can restore the pH balance in the mouth allow remineralisation to take place from the calcium in the saliva.

### Fluoride advocacy

Currently only 20 % of the global population benefits from fluoride as a form of caries prevention. The FDI, working with other stakeholders, recommends to governments and other international organisations ways of increasing this availability on a population and individual basis.

Community fluoridation schemes are particularly effective as public health measures and none more so than water fluoridation. This is one of the great achievements in public health in the last century and is an inexpensive and cost effective way of reducing caries rates that benefits all members of society, preventing or reducing the pain, disruption to life suffering and hardship caused by caries; especially for children. This universal access to fluoride is a central part of the basic human right to oral health as noted above.

Fluoride in toothpaste is also a valuable preventive tool. Moves to provide affordable fluoride toothpaste in less advantaged countries are increasing in pressure as are discussions to convince governments that taxes and duties on fluoride toothpaste should be reduced or abolished so as to increase its affordability and spread its health gain.

### Oral health and general health

There is increasing evidence of the connection between poor oral health and other systemic health problems. In particular there are links between periodontal disease and both premature births and low-weight births. Diabetes is another condition strongly associated with periodontal disease

and there is a growing body of research suggesting links with heart disease and stroke.

Although not fully explained, the mediation of bacterial plaque is never far away from the centre of suspicion and it may be that the micro-organisms cause problems either through the production of their toxins escaping into the blood stream or that they somehow alter the host immunological response. The net effect however has been to create a framework in which it makes perfect sense for oral disease prevention to operate in tandem with general disease prevention. The days of perceiving the mouth as being separate from the rest of the body are numbered.

This concept found particularly strong backing in 2007 at the World Health Assembly (WHA) where, thanks to the work of the FDI and others over a long period of time, the WHA passed a resolution which calls for oral health to be integrated into chronic disease prevention programmes. Whilst perhaps not seeming to be earth shattering in its extent, the recognition of this is a major breakthrough and means that the FDI's member associations can use the resolution in advocacy for oral health programmes throughout the world, citing to governments the WHA's acknowledgment of the importance of this health measure.

### Working at many levels

The Federation's long history and its ability to attract the best of the profession means that it can work at many levels. Recent innovations have included the development of a *Dental Ethics Manual* which has found considerable popularity and is currently being translated into the FDI's main languages French, German, Spanish and Japanese.

The manual includes FDI Guidelines for dentists against torture, again strengthening the Federation's stand on human rights. Through this means the organisation is aiming towards better integration of ethics into dental curricula around the world to help guide an influence the dental care professionals of tomorrow.

## The Brazilian Medical Association (AMB): purpose and actions



*Dr. José Luiz Gomes do Amaral, President of Brazilian Medical Association*

The Brazilian Medical Association (AMB) ([www.amb.org.br](http://www.amb.org.br)) was founded in 1951 with a mission to ensure the dignity of the medical profession and quality health care for the Brazilian people. It consists of 27 State medical associations and 396 regional associations. In addition, 53 Medical Societies compose its Scientific Council, representing all specialties accredited in Brazil. The AMB is a member of the Council of the World Medical Association and is the founder of the Portuguese Language Medical Community.

In 2000, the AMB launched a team to elaborate medical guidelines based on scientific evidence in order to standardize procedures and assist physicians in making clinical diagnostic and treatment decisions. Each of the specialty societies affiliated with AMB is responsible for the substantive content and written elaboration of their guidelines. So far, more than 300 guidelines have been developed. They are available on the website: [www.projetodiretrizes.org.br](http://www.projetodiretrizes.org.br).

The AMB collaborates with the Ministry of Education and House of Representatives to fight for the quality of medical education.

In pursuit of scientific improvement and professional validation since 1958, the AMB grants specialization certificates to physicians who pass strict oral and practical evaluations. Through its National Commission of Credit, the AMB records credits earned and updates physicians' certificates.

The Continuing Medical Education Program (EMC) is freely accessible to all Brazilian physicians and includes distance learning.

Through the Parliamentary Affairs Commission, the AMB actively participates in the development of legislation that affects the health profession and health system.

The AMB has three key channels of communication: the *Jornal da Associação Médica Brasileira* (the AMB's journal), which is published every two months tracking developments in medical politics; the *Revista da Associação Médica Brasileira* (the AMB's magazine), which gathers scientific articles from renowned physicians throughout the country; and its website – [www.amb.org.br](http://www.amb.org.br).

The Brazilian Hierarchical Classification of Medical Procedures (CBHPM), developed and continually reviewed by the AMB, the Federal Council of Medicine and Specialty Societies, includes all scientifically accepted medical procedures and serves as a critical reference in the provision of quality health care. The present CBHPM was designed based on technical criteria. The AMB also participates on a Commission created to elaborate a proposed Plan of Position, Career and Salaries within the Public Health System, enabling medical entities to negotiate their implementation with States and municipal districts.

### Information about Brazil

Brazil has 190 million inhabitants and occupies an area of 8,514,876.599 km<sup>2</sup>, equal 47% of South American continent. There are 331,000 active physicians (1 doctor per 600 inhabitants).

Brazil has a public health system available to everyone, as well as a supplementary health insurance system that benefits approximately 40 million citizens. The public health system is structured with three levels: federal, state and municipal. It is financed by taxes and social contributions paid by the population.

In 2006, the federal government spent R\$ 40.78 billions (US\$ 22.45 billions). State and municipal sectors spent, respectively, R\$ 18.69 (US\$ 10.2) and R\$ 19.44 (US\$ 10.7) billions, in total R\$ 78.91 (US\$ 43.4) billions were invested in public health. The private sector invested R\$ 87.54 (US\$ 48.2) billions, including health insurance, direct disbursement and medicines. Summarizing both private and public investments, the Brazilian health system received R\$ 166.45 (US\$ 91.6) billions (around R\$ 892 per inhabitant – US\$ 491).

According to the Brazilian Institute of Statistics, the main diseases in the country are: circulatory system, cancer, diabetes, respiratory diseases and AIDS.

The fertility rate among Brazilian women is 1.95 child per woman. In 1960, this rate was 6.3 children per woman; in 1980, it was 4.4; and in 2000, it was 2.3. The ratio of males to females in Brazil is 48.8 (93 million) males to 51.2% (97 million) females.

\* Currency values converted on September 15<sup>th</sup>, 2008

*Communication Department of AMB*

## Healthcare in Singapore and the Singapore Medical Association

*Dr. Wong Chiang Yin, President of the 49<sup>th</sup> SMA Council, Hospital Administrator, a Public Health Physician*

*Dr. Lee Hsien Chieh, a Public Health Trainee at Changi General Hospital under the Singapore Health Services Group*

### Singapore Healthcare System

Singapore, a city-state with a land area of 707.1 square kilometres [1], is located 137 kilometres north of the equator at the southern tip of the Malay Peninsula. The Republic has a total population size of 4.59 million [1] and a population density of 6489 persons per square kilometre [1]. As of 31 December 2007, there were a total of 7348 registered medical practitioners, out of which 2781 (37.6%) were trained specialists in 35 recognised specialties [2]. The doctor-to-population ratio is 1:620 [2], and there are about 2.6 hospital beds per 1000 total population [3].

Primary healthcare is easily accessible through an extensive network of 2000 private medical practitioners' clinics, which provide 80% of primary healthcare services, as well as 18 government polyclinics, which provide the remaining 20% [3]. In contrast, the public sector accounts for 80% of tertiary hospital care *vis-à-vis* 7 public hospitals and 6 national specialty centres, with 16 private hospitals accounting for the remaining 20% [3]. Patients are free to choose their healthcare providers within this dual healthcare delivery model. The average length of stay in acute care hospitals is 4.7 days [3], and the average waiting time for elective surgery is one week [4].

In 2007, the Life Expectancy at Birth was 80.6 years (78.2 years for males; 82.9 years for females) [1]. Total Fertility Rate was 1.29 per female, while Infant Mortality Rate was 2.1 per 1,000 live-births [1]. The Crude Birth Rate was 10.3 per 1,000 popu-

lation and Crude Death Rate was 4.5 per 1,000 population [1].

### Healthcare Financing

Singapore's healthcare financing framework is formed by the "3M" system – Medisave, Medishield and Medifund. Medisave is a state-run compulsory medical savings scheme introduced in 1984, under which every working employee contributes 6.5 % to 9.0 % [3] of his monthly income to a personal Medisave account. The savings can be withdrawn either to pay his own hospital bills, or those of his immediate family members.

Medishield is a medical insurance scheme introduced in 1990 to help members cover medical expenses and protect against financial ruin from major illnesses. Premiums for Medishield can be paid for by savings under the Medisave account. Medishield covers almost 80 % of the Singaporean population today [3].

Medifund is an endowment fund set up in 1993 for needy patients who have exhausted all other means and cannot afford their medical expenses. Starting with an initial capital of S\$200 million in 1993 [3], additional capital injections are made during budget surpluses. Only the interest income from the capital sum, which currently stands at S\$1.66 billion [3] is utilised. Medifund ensures that no Singaporean is denied access to the healthcare system due to an inability to pay.

In 2005, Singapore spent a total of S\$7.6 billion, the equivalent of 3.8% Gross Domestic Product (GDP) on healthcare. The amount of government healthcare expenditure made up S\$1.8 billion (0.9% of GDP) [3].



### Singapore Medical Association

The Singapore Medical Association (SMA) is the national body for the medical profession. It is a voluntary NGO with 4917 members, or about 64% of all registered medical practitioners in Singapore (as at 31<sup>st</sup> August 2008). The membership make-up reflects the medical profession in Singapore with approximately 30 % who are general practitioners, 31 % who are specialists and the remainder being doctors-in-training. This makes the SMA the largest voluntary organisation for doctors in both the private and public sectors in Singapore.

The SMA was formed in 1959 when the Malayan Branch of the British Medical Association split to form the Malaysian Medical Association and the SMA. Some of the core activities of the SMA include promoting ethics and professionalism, publishing the monthly Singapore Medical Journal and SMA Newsletter, dealing with professional practice issues and organising medical talks/workshops for doctors. The SMA is also the secretariat for Medical Associations in South East Asian Nations (MASEAN), as well as a member of the World Medical Association and Confederation of Medical Associations in Asia and Oceania (CMAAO).

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## The Macedonian Medical Association



*Jovan Tofoski, Prof. Dr. Sci. Med, President of the MMA*

The Macedonian Medical Association - MMA, in Macedonian language *Makedonsko lekarsko drustvo* - MLD, was founded as an Association of doctors, dentists and pharmacists (then it joined only 123 doctors and dentists and 96 pharmacists). Today it gathers around 5000 doctors in all the branches of medicine, of whom 3025 are specialists in various fields while there are 2106 general practitioners of whom 35 % are family doctors. The doctors in the MMA are formed in 70 specialists and sub-specialist associations, as well as 20 local associations in the large towns of Macedonia.

In the course of its existence and its continuous growth and development the Macedonian Medical Association has, among other things, held sixteen congresses for all doctors and more than sixty-five congresses of its specialized branches, and all the papers submitted and edited, numbering 12 077 in all, have been published in special Proceedings or supplements of the Macedonian Medical Review (*Makedonski Medicinski Pregled*). In the period in question the regular professional meetings of the associations, which are held on average four times a year, with at least three subjects apiece, have reached an

overall total of more than 12 800 meetings with that a great number of various courses, workshops, seminars and other forms of continuous and higher education of the members have also been organized. Within the framework of the MMA the medical journal Macedonian Medical Review has been coming out for sixty-three years now with a total of 5196 papers reviewed and published in Macedonian and abstracts in the English language.

The Macedonian Medical Association was preceded of the Medical Faculty (1947) and many of its members later became professors in the Faculty. The MMA also took the initiative of forming, from among its own ranks, the Macedonian Chamber of Medicine as a separate institution (1992).

During the period of its activity the MMA has managed to accomplish an enormous amount of work and activities, which has up to the present, been carried out on an entirely voluntary basis. This shows of the enormous enthusiasm of generations of doctors-members of the MMA, in their efforts to offer the Macedonian public health protection which is wide-ranging and of as high quality as possible, by the application of good medical practice and high ethical standards.

Throughout its existence the MMA has not only followed, but also been an active par-

ticipant, initiator and consultant in the creation and improvement of the laws affecting the sphere of health service provision in the country. Its proposals and conclusions have frequently been influential in the passing of specific legislation. There have also been occasions where these have been rejected only for it to be recognised later that such rejections have had a negative effect in practice.

Throughout its long continuous activity and fruitful and successful work the Macedonian Medical Association has established itself as one of the pillars of health protection in Macedonia, as an exceptionally important factor in the development of medicine in the country, and as one of the key elements in the improvement and raising of the standards of the health protection of the population.

At the same time the Macedonian Medical Association established its identity and gained recognition as an extremely significant segment in the overall social development of the Republic of Macedonia and as a relevant factor in the development of medical profession and science in Macedonia.

There has so far been a high level of cooperation on the part of the MMA with the Faculty of Medicine, the Macedonian Chamber of Medicine and the Ministry of Health.

As a recognition of all its worthy and visible services the Macedonian Medical Association, on its 60<sup>th</sup> Jubilee, has received



*Delegates of General Assembly of MMA.*

the highest state honour, the 11<sup>th</sup> October Award.

The basic task of the MMA is to contribute to more efficient, rational and high-quality health protection for the population and to reconciling those health needs with the real possibilities of the society.

Continuing medical education, continuing medical development and professional guidelines are key factors in high quality and rational health protection, therefore the Educational Centre has been established for the regulation, promotion, organizing, monitoring and evaluation of CME and CPR. The MMA with financial support of Ministry of Health produced and distributed free of charge to all doctors GUIDELINES FOR

PRACTICING EVIDENCE BASED MEDICINE (4500 pages), in printed and electronic form.

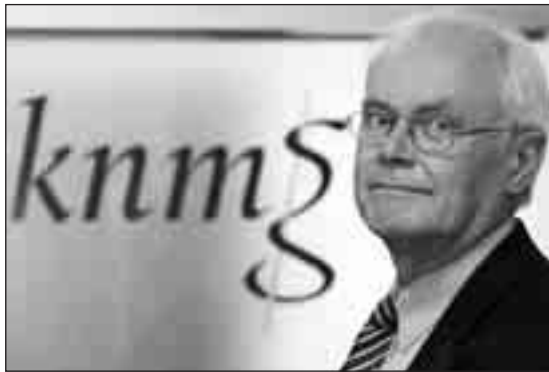
The MMA has a clear stand that more profound education in ethics is an integral part of CME. Besides the textbook on ethics for our colleagues, the MMA translated in (2005) the Medical Ethics Manual (WMA) into the Macedonian and Albanian languages and it was distributed to all individual doctors in Macedonia. The Manual is also available in pdf form on the web site of the MMA [www.mld.org.mk](http://www.mld.org.mk)

Work on patients rights, doctors rights and patients safety are very high on the agenda of the MMA, especially fostering and promotion of good medical practice and high

ethical standards, as well as harmonization of the Macedonian health service provision with that of the EU and membership of Europe, which presupposes the acceptance of appropriate standards.

The Macedonian Medical Association makes a continuous effort to a positive change in the social status of doctors and an equitable and worthy recognition of the medical profession, protection of the respect and the dignity of medical profession and fighting for the freedom and independence of the medical profession and the provision of the best medical services available for the patients, in a system of increasingly state controlled health management in the country.

## The Royal Dutch Medical Association (KNMG)



*Prof. Dr. A.C. Nieuwenhuijzen Kruseman, President. Mr. Paul Rijkse, General Manager*

The Royal Dutch Medical Association (KNMG) is the professional organisation for physicians of The Netherlands. It was established in 1849. Since 1<sup>st</sup> January 1999 the KNMG has become a federation of medical practitioners' professional associations. The federation consists of the National Association of Salaried Doctors (LAD), the National Association of General Practitioners (LHV), the Dutch Association for Occupational Health (NVAB), the Dutch Association for Nursing Home Physicians (NVVA), the Dutch Association of Insur-

ance Medicine (NvVG), the Dutch Order of Medical Specialists (Orde van Medisch Specialisten) and a group of individual KNMG members and students.

The main objectives of the KNMG are to improve the quality of medical care and healthcare in general. This is achieved by proactively responding to technological and social developments, by developing policy, lobbying and influencing stakeholders and by providing services to our members. We work in close collaboration with other stake-

holders, e.g. government, politics, health care insurance companies, patient organisations, and other organisations in healthcare. The goal is to promote the medical and associated sciences, and achieve high quality healthcare. Our policies cover the full range from public health issues, medical ethics, science, health law to medical education.

Another important task of the KNMG is the legal system concerning the postgraduate training and registration of specialists. Legislative boards issue rules on specialist training, recognition of trainers, hospitals etc., specialist registration and the recertification of specialists. The registration committees carry out legislation regarding the tasks mentioned above in the interest of the public.

### KNMG activities in 2009

1. A campaign on medical professionalism. In 2009 a national campaign will be launched, aimed at all physicians. The main goal is to support doctors in their professional conduct: good quality, earning trust of their patients and accountability.
2. Promoting quality of healthcare, safety and transparency of medical practice and professional integrity, through the establishment of guidelines and advice and influencing government and politics.

Activities are:

- Development of a quality framework: the quality and patient safety requirements any doctor in The Netherlands should meet;
- Contribute to educational modernisation of the training of medical specialists and the curriculum in accordance with the CanMEDs model;
- Contribute to the modernisation of the Individual Health Care Professionals Act (Wet BIG). This Act is concerned with the quality of care and protection provided to patients, and provides a register of health care professionals (the BIG-register). The BIG-register registers pharmacists, physicians, physiotherapists, health care psychologists, psychotherapists, dentists, midwives and nurses. Only those listed in this register may carry the legally protected titles belonging to these professions;
- Monitoring Health Insurance Act: under the new Health Insurance Act, all residents of the Netherlands are obliged to take out a health insurance. The system is a private health insurance with social

conditions. The system is operated by private health insurance companies; the insurers are obliged to accept every resident in their area of activity. A system of risk equalisation enables the acceptance obligation and prevents direct or indirect risk selection.

- Contribute to strengthening patients and patient organisations. Especially in the fields of quality, safety and legal complaints.
  - Activities related to “end of life” care: implementing the Directive palliative sedation, research on decisions of physicians concerning the final stage of life.
3. The KNMG studies trends and influences legislation in relevant areas where professional values and responsibilities are of major significance.
  - Monitoring, and if possible, influencing developments on health insurances and the Exceptional Medical Expenses Act (AWBZ) which is a national insurance scheme for long-term care. This is intended to provide for insured with chronic and continuous care. This involves con-

siderable financial consequences, such as care for disabled people with congenital, physical or mental disorders;

- Commenting on reports from government advisory boards;
- ICT in healthcare, Electronic Medical Record (EPD). This is a plan for a nationwide system which is intended to facilitate the exchange of patient information. Data from different healthcare information systems will be brought together in the EPD. KNMG is involved in the development and implementation of the EPD, lobbying etc.

#### 4. International activities:

The KNMG is an active member in the Standing Committee des Médecins Européens (CPME) and the World Medical Association (WMA). The CPME is involved in influencing policy at European level and this is of great importance, because the practice of doctors is increasingly a European dimension.

## The Fiji Medical Association



*Dr. Ifereimi Waqainabete, Hon. President, of the Fiji Medical Association*

The Fiji Medical Association (FMA) is a professional association, established under the Fiji medical and dental practitioner act of 1978 and is financed by its members through an annual subscription of \$260.00. The Act itself specifies that “membership of FMA shall be open to every person who is

registered in Part II of the Medical Registrar”, however, membership is voluntary and open to any medical practitioner registered in Part II of the Register, maintained by the Fiji Medical Council.

FMA is recognized by Fiji’s civil service administrative body (Fiji Public Service Commission) as the collective voice of doctors in the Civil Service. FMA has a considerable role in the medical profession, (within the guidelines of the ACT) and appoints 3 of the 7 members of the Fiji Medical Council. FMA is also represented on all various advisory bodies which deal with health issues including: National Advisory Council on AIDS (NACA), Non Communicable Disease (NCD) Taskforce, Mental Health Services Planning, National Research Ethics Committee, Fiji School of Medicine

Council, and the Tobacco Act monitoring task force. The FMA is also included with other NGOs in such bodies as the summit working Groups monitoring the National Development Plans implementation.

The operational functions of FMA are guided by its constitution which in turn is overseen by an Executive council whose members are elected during our annual general meeting. The FMA annual general meeting is usually held during our annual Medical Scientific conference which encompasses all specialties and includes overseas and local speakers. During the year the FMA also keeps members informed through:

- The Fiji Medical Association Journal (FMAJ) which is released every four months
- The Fiji Medical Association Newsletter namely Medmail, which is released every two months and by Email

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# The World Medical and Health Games

In the beautiful Spanish city, Alicante will take part the World Medical and Health Games. So, don't waste time and join Spain from July 4<sup>th</sup> to 11<sup>th</sup> to celebrate all together the 30<sup>th</sup> edition of the World Medical and Health Games!

Since their creation in 1978, the WMHG have claimed to have "The Olympic Spirit" as it was intended by the Baron Pierre De Coubertin: Beauty of sport and abundance of effort.

These are the values that still guide us today in the organisation of this event: every sports enthusiast that enrolls in the Games agrees to honour the following motto : "In the World Medical and Health Games, we agree to face each other in our sporting challenges with the willingness to try our chances, in a spirit of friendship, with respect for our counterparts and for sporting and indeed professional ethics, hoping to revive a spirit of "fair-play" even beyond our performance, a spirit that might act as an example for more important international competitions. "

54 countries have already participated in the Games since their creation: South Africa, Algeria, Germany, Argentina, Australia, Austria, Belgium, Bosnia, Brazil, Cameroon, Canada, Chile, Colom-

bia, Korea, Croatia, Denmark, Spain, Estonia, The United States, Finland, France, Georgia, Greece, Hungary, India, Iran, Ireland, Israel, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Morocco, Mexico, Moldavia, Norway, The Netherlands, Pakistan, Poland, Portugal, The Republic of Slovakia, The Czech Republic, The United Kingdom, Slovenia, Sweden, Tunisia, Turkey, The Ukraine, Uruguay, Venezuela, Yugoslavia

### Sports in the Programme

Athletics, Badminton, Basket-Ball, Beach-Volley, Cycling, Chess, Fencing, 11-a-side Football, 11-a-side Senior Football and 6-a-side Football, Power Lifting, Golf, Judo, Squash Rackets, Swimming, Windsurfing, Tennis, Table Tennis, Pistol Shooting, Rifle Shooting, Clay Pigeon Shooting, Triathlon, Sailing, Volley-Ball, Mountain Biking.

### The Age Categories

The date of reference that is taken into consideration is the date on which the Games are scheduled to begin, therefore 4th July 2009.

A – under 35 years; B – from 35 to 45 years ; C – from 45 to 55 years; D – from 55 to 65 years; E – over 65 years; F – Students: all those registered as students, without consideration of age Students will not be able to be part of the classifications in categories A, B, C, D or E. There are no age categories for collective sports, golf and chess.

[www.medigames.com](http://www.medigames.com)

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