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Editorial

Sun City – A chance to influence change

The General Assembly of the World Medical Association takes place in South Africa in October. At a time when the continuing burden of disease, AIDS/HIV, Malaria, Tuberculosis etc., inadequate resources and under-funding of need is so great (despite the international response so far), it is thus appropriate that the Assembly is meeting in the African continent.

Although the agenda of the General Assembly will be much occupied with the necessary updating of WMA policy statements, including the International Code of Medical Ethics (see Council meeting report in WMJ 52(2)) and possibly adopting statements on other issues such as Obesity, Pandemic Influenza etc., no doubt other matters relating to major health issues including those of the African continent will be raised during the meeting.

The Scientific session will be devoted to “Health as an Investment” and “Advocacy”, providing an opportunity to examine aspects of these topics as diverse as Investment in Human Resources, Medical Research, Public-funded healthcare planning – not to mention the economic aspects of the topic. The presentation will consider the obligations of governments in the provision of basic health care, move on to aspects of Advocacy and finally address the Role of National Medical Associations in the topics addressed.

Looking round the world today, it is clear that health care is a major topic of discussion not only in developing countries. Developed countries, with health care – often long established and well developed – are also experiencing major problems although not to the same degree. It is not without significance that in considering the economics of health, both its promotion and care, governments are now trying to assess the value of investment in health and how the best value for this type of investment can achieved. This situation is not without its effect on physicians, as can be seen in the notes on news from the regions and national medical associations (p. 82). Disquiet is with lack of resources both financial and human, due not only to problems associated with the economy or productivity in both developing and developed countries. In developing countries it can be due to emergence of new diseases or inadequate control of old ones, or by armed conflict or social unrest.

In developed countries as well, governmental and healthcare system’s suggested or imposed changes, or dissatisfaction with the working conditions of health professionals, are increasingly provoking not only disquiet and demonstrations but, in some countries, even strikes.

In todays world of rapid change it is not to be unexpected that change will affect the medical profession. Indeed we have addressed this problem previously in these columns. However, it would appear that in some quarters the rapidity of change or the perceived inequity of conditions, are producing considerable reactions. Not infrequently the views being expressed are reflections of concern that proposed or imposed changes are not in the interest of the relevant population in general and patients in particular.

Faced with these trends, it is to be hoped that the discussions in South Africa will shine some light on the best ways in which National Medical Associations can act themselves and advise their members, both in there interest and that of the health of the people.

Alan Rowe
First steps towards selecting a new WHO Director General

WHO announces list of candidates

Following the tragic death of Dr. Lee Jong-wook, the WHO Executive decided to hasten the process of electing a successor. Nomination by Member States closed on 5th September and the list of thirteen nominations were announced and appear below. Amongst the formidable list of candidates are members and former members of WHO staff, and a former member of the WHO Executive committee.

It also should be noted that Dr. Lee Jong-wook had only completed 3 of his 5 years of office. While this might be thought to influence the decision in favour of an Asian candidate and normally other UN elections such as that of the UN Secretary General do not influence proposals, it may be that the possibility in the UN Security Council that the next UN Secretary General will be Asian may prove significant.

The 34 members of the Executive committee meeting in a special session on 6-8 November and make a nomination from a short list to the World Health Assembly on 9th November, who will then make the final decision and appoint the new Director General.

The list of candidates and the proposing Member State are:
- Dr. Kazem Behbehani (Kuwait)
- Dr Margaret Chan (China)
- Fr. Julio Frenck (Mexico)
- Mr David A. Gunnarsson (Iceland)
- Dr. Nay Htun (Myanmar)
- Dr. Karam Karam (Syrian Arab Republic)
- Dr. Bernard Kouschner (France)
- Dr. Pascoal Manuel Mocumbi (Mozambique)
- Dr. Shigaru Omi (Japan)
- Dr. Alfredo Palacio Gonzalez (Ecuador)
- Professor Pekka Puska (Finland)
- Ms Elena Saigado Médez (Spain)
- Professor Dr. Tomris Türmen (Turkey)

Medical Ethics and Human Rights

Safeguarding Global Research on Human Subjects

Dr. James Appleyard, FRCP, Past President of the World Medical Association.

The majority of research on human subjects is now being undertaken in the ‘developing’ nations. This change from the established centres of clinical research in the United States, Europe and Japan has been accelerating in the recent years because of relatively low costs and the increased availability of human subjects in the poorer countries.

Concerns have been raised about the vulnerability of local populations in the developing world and whether there are sufficient safeguards to protect them. Instances of alleged abuse have been highlighted in the medical literature as well as the World’s Press.

Physicians have a clear duty to look after the best interests of those who entrust themselves to their care. The WMA’s Declaration of Helsinki on the Ethical Principles of Medical Research involving Human subjects from its origin in 1964 has provided the source of guidance set for Physicians worldwide. The 2000 version of the Declaration states that “it is the duty of the physician to promote and safeguard the health of the people. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty”. The Declaration also recognizes that medical progress is based on research which ultimately must rest in part on experimentation involving human subjects, but that considerations related to the well being of the human subject should take precedence over the interests of science and society.

These duties and responsibilities of physicians to their patients cannot be subsumed by a research ethics committee or research team. Physicians by themselves or as members of national medical associations are unable to provide full protection to their patients and populations. They work as members of research teams in an increasingly complex environment. They should not work in an environment which breaches their ethical duties and obligations.

Awareness of these ethical issues had been heightened by Claude Bernard in France in the mid-nineteenth century. Personal, institutional and national codes of practice emerged over the next hundred years.

An expert group, bringing together the research community, industry and regulators was set up by the International Conference on the Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human use. (ICH) Their consolidated “guidance” on Good Clinical Practice in 1996 was gleaned from their participants. This has provided a uniform standard for the European Union (EU), Japan and the United States for designing, conducting, recording and reporting clinical trials on human subjects. (ICH.GCP) In the introduction, the Guidance states that “Compliance with this standard provides public assurance that their rights, safety and wellbeing of trial subjects are protected consistent with the principles that have their
receiving research support from the NIH did most of the research community appear to respect the basic underlying ethical principles of the Belmont Report, those of Respect for Persons, beneficence and justice. The first Director of OHRP Dr. Greg Koski emphasized the requirement for “shared goals and shared responsibilities” and the need to move from “a culture of compliance to a culture of conscience in human research”. His view underscores the need for the research community to internalize the principles of the Declaration of Helsinki and the Belmont Report into their “conscience” Dr. Melody Lin, the Deputy Director, emphasizes that the work of the OHRP depends on Trust (that is individual and institutional ‘conscience’), Education and Regulatory oversight – it is indeed getting this balance right that is the major challenge for Governments and the professions and the research community.

The challenge is not only to promote these principles world wide but to ensure that there is a robust ethical research committee infrastructure globally to support the increase in research in developing countries necessary to correct the global imbalance of research. The WHO has estimated that 90% of the resources devoted to research and development on medical problems are applied to diseases causing less than 10% of the global suffering.

The WHO published Operational Guidelines for Ethics Committees reviewing Biomedical Research following an initiative by the Research and Training in Tropical Diseases (TDR), the World Bank and the United Nations DP in 2000. The Secretary General of WMA assisted in this development in the International Working Party, which was chaired by Francis P. Crawley from Belgium.

A strategic Initiative for Developing Capacity in Ethical review (SIDCER) was launched under the aegis of UNICEF / UNDP / World Bank / WHO TDR in 2001. This is a network of independently established regional forums for Ethical Review committees, health researchers and invited partner organisations including the WMA. It was designed to address the principle gaps and challenges in ethics encountered origin in the Declaration of Helsinki and that the Clinical Data are credible”.

Revelations that financial relationships and conflicts of interest had become ‘pervasive’ and were undermining public trust in the integrity of Science resulted in the call for greater transparency (honesty) within the US regulatory framework. The Office for Human Research Protections (OHRP) was set up in 2000 from the former Office for Protection from Research Risk (OPRR). It reports to the Assistant Secretary of Health and Human services.

The National Institutes of Health [NIH] is by far the largest human research funding agency worldwide. To carry out its research mission, nearly 10,000 universities, hospitals and other Research Institutions in the United States and internationally have formal assurances with OHRP to comply with the US regulations related to human subject protection.

Only when the NIH required documentation of some training in research ethics and human subject protection as a condition of
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in global health research. In Dr. Vichai Chokevivat (Thailand), its Chairman’s words “the network of regional forums create unique opportunities for professional development and learning with innovative approaches to cross cultural, cross national and cross regional understanding and mutual support”. Funding from different sources including the OHRP was channeled through the WHO/TDR. The regional fora are known by their acronyms – FERCAP (Forum for Ethical Review Committees in Asia and Western Pacific), the first to be set up; FLACEIS (For a Latino American de Comités de Ética en Investigación en Salud); PABIN (Pan African Bioethics Initiative), FECCIS (Forum for Ethical Committees in the Confederation of Independent States and FOCUS (Forum for Ethical Review Boards/Institutional Review Boards in Canada and the US).

The European Forum for Good Clinical Practice (EFGCP) had previously been set up under the pioneering guidance of Professor Joseph Hoet and has contributed to SIDCER’s work.

SIDCER’s vision was to establish systems and infrastructure for the accreditation of ethics in Health Research and develop a register of resources and data bases of ethics committees and institutional review boards within the countries who are members of the Regional Fora.

Members of the original WHO International Working Party are still very active in the Fora. Host governments to the Regional meetings are interested “stakeholders”. Progress has been made in influencing some of the governments in the newly independent states to adopt legislation respecting human rights and human dignity upon which the ethical principles in medical research on human subjects depend. Reports from the different participating countries are presented, shared and discussed at the Fora Training courses are also arranged.

When President of the WMA I was invited to give the Joseph Hoet Lecture at the EFGCP, to attend FECCIS and have since had the opportunity to participate in three of the five regional fora. Such conferences are both stimulating and enjoyable for the participants. Often there is a feeling of achievement when new recommendations are made to the constituent members.

However only three Medical Research Institutions have been accredited by SIDCER in 5 years – two of these in Taiwan. The research community in Taiwan have taken the ethical issues very seriously and have established their own Forum for Independent Review System in Taiwan – FIRST. National medical associations are not directly involved in the regional conferences and the most senior researchers from the countries are not invited regularly. The fora are therefore not always connected with those that influence and implement policy locally. Some training may ‘trickle down’ but there must be more effective ways to promote and support education in Research Ethics locally.

In addition to the WMA setting the ethical standards through the Declaration of Helsinki, the Association needs to support measures to implement it globally.

The Declaration itself has been the subject of a comprehensive study by Carlson, Boyd and Webb from Edinburgh University. They comment: “there is no doubt that the Declaration of Helsinki – still less than 2000 words in length – is one of the most succinct documents encapsulating the principles guiding research ethics in existence”.

The World Medical Association can only be effective in its promotion locally through its constituent national medical associations, who are the local custodians of the principles in the Declaration of Helsinki. The traditional ethical base within the national medical associations in the ‘developing’ countries needs to be strengthened and supported so they can contribute more actively to the development of research within their domain and the infrastructure of research ethics committees. This could be achieved through educational materials which can be easily accessed. The WMA has initiated two web based courses over the last three years on other topics; these on-line courses allow greater access. This can be complemented by materials available on CDs, as in the more remote areas access to the internet is at present difficult and disproportionately expensive.

A number of courses are already available in the USA and Europe. It would be possible for the WMA to develop with suitable partners web-based courses which could be integrated with Regional and National strategies. One potential partner could be the Collaborative Institutional Training Initiative (CITI) together with international funding agencies involved in planning research in the developing world, such as the Gates Foundation, the Welcome Trust, the pharmaceutical industry, non-governmental organizations, and national Governments themselves.

CITI was formed by a small group of physicians, bio-ethicists, institutional review board chairs and scientists from nine independent academic institutions in the USA, including the university of Miami, Dartmouth College, the University of Washington and the Children’s Hospital, Boston. The universities pooled their resources to meet the requirements of the US Department of Health and Human Services (DHHS) that all investigators and key personal in human subject research must complete training in human subject protection by October 1st 2000. The CITI programme has been devised by the multidisciplinary research community itself and is independent of any US National Regulatory Body.

Courses have been developed covering Biomedical Research including Good Clinical Practice and Social and Behavioural Research with quality controls. An International Group has been formed within CITI which includes input from the Caribbean, SE Asia and the Middle East. Though the underlying ethical principles need to be the same worldwide, the local context and culture are important. International Courses are being developed on a pilot basis for individual countries. Research institutions in the poorer nations are already finding even the current more US-centric CITI courses helpful.

Such a collaborative approach would allow the creation of sound international educational materials leading to accreditation and continuing professional development with quality standards shared with those in the US, Europe and Japan. In short a truly glob-
al research ethics network. Enhanced training will give more confidence to those funding and sponsoring clinical research. Professions are the rightful custodians of their body of knowledge. In medicine this means a continuing duty to expand that knowledge base in the interest of patients with new therapies and new procedures and ensuring that the best evidence is available for effective management of disease and disorders internationally. A sound research ethics infrastructure should encourage a greater increase in the clinical research in the developing world necessary to reduce the overwhelming burden of disease due to AIDS, Malaria, and Tuberculosis in the poorer nations.

The WMA with other key stakeholders could build on their recognized standards of medical research ethics to influence their practical implementation and to reduce the serious research ‘gap’ between the rich and the poor nations. The resultant improvement in the health of the nations from quality research will have major economic benefits by enabling nations to prosper, rather than perpetuate their cycles of poverty and malnutrition.

It will be a long, hard and continuing process but one that could well make a major contribution to protection of patients in research worldwide.

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Medical Ethics and Human Rights

A European Perspective on the Clinical Research Ethical Review Procedure

Dr. Frank Wells, Co-chairman of EFGPC Ethics Working Party

A major challenge that exists for each of the, now 25, member states in the European Union is how to adopt a Directive whilst still retaining all the national characteristics within the particular field that is to be covered by that Directive*. On the other hand, the adoption of a European Directive can provide a good opportunity to alter, or even abandon, national characteristics that have become outdated or are inappropriate or irrelevant.

One such Directive, known as the Clinical Trials Directive, was introduced in 2001 (2001/EC), which required member states to adopt the principles of good clinical (research) practice where they had not already done so and, particularly, to establish research ethics committees. For some member states these had, in practice, been in operation for many years, but in others the ethical review procedure for clinical trials was vestigial and, for them, the implementation of this Directive presented a number of problems.

The European Forum for Good Clinical Practice (EFGCP) is a not-for-profit organisation, based in Brussels, which exists to promote, in its widest sense, and across the board, uniformly high standards for the conduct of clinical research. It is a confusing convention that, throughout the clinical research community, the word ‘research’ has been dropped from the phrase ‘good clinical research practice’, but that is what ‘good clinical practice’ (GCP) means, certainly in the context of this article.

One of the key features of the strategy of the European Forum for Good Clinical Practice (EFGCP) has always been to promote European values and principles in ethics across the EU member states and in international research. The standards against which this should be achieved were, by general agreement, set out by the Declaration of Helsinki of the World Medical Association, the International Conference on Harmonisation (ICH) process as it applied to good clinical practice (GCP) and, as far as Europe is concerned, were included within the Clinical Trials Directive. All these important policy documents included reference to the structure and function of independent ethics committees established to provide the ethical review of all clinical trial protocols.

EFGCP operates through conferences, workshops and working parties and it was the EFGCP Ethics Working Party that felt that the advent of the Clinical Trials Directive presented a golden opportunity to ascertain exactly how this extremely important Directive, which was drafted to ensure that clinical trials throughout Europe were all conducted to the same high standard having been subjected to a proper ethical review, had in practice been interpreted in each of the 25 member states. We felt that
reporting on the structure and function of research ethics committees in every member state was important, given that such a review had not been conducted previously by anyone else and that nobody seemed to know what was happening outside their own country in this regard.

We were particularly mindful that one of the functions of EFGCP is to observe the methods by which member states fulfill the various Directives of the European Commission that affect the conduct of clinical research to GCP standards. Thus it was in early 2005 that the EFGCP Ethics Working Party recognised that the ethical review processes in the various member states varied widely and that, in the context of multi-national research, it was not easy to be sure that ethical review had been consistent across the whole of Europe. The Working Party even wondered whether the differences between operational policies in the various member states might interfere with the aims of the Directives. Furthermore, whereas a sponsor could be reasonably confident that it understood the ethical review process that operated in the member states in which it regularly conducted research, it was sometimes difficult to gain access to the ethical review process in other member states in which it might wish to conduct research in the future.

A subgroup of the EFGCP Ethics Working Party was established, specifically to ascertain in detail exactly what were the structures and functions of research ethics committees across the 25 member states of the EU. The nine members of the subgroup came from eight different member states, which made it easy for us to share the work that had to be done. In practice, we acknowledged that Luxembourg relied wholly on Belgian legislation in this regard, and, because much clinical research emanates from, or is conducted within, Switzerland and Norway, we took a pragmatic decision to add these two countries to our project.

The differences we discovered were widespread. For example, roughly half the member states specify that an application should be made to an ethics committee by the sponsor, whereas the other half specify that it should be made by the chief investigator. Another example revealed the different methods by which a single opinion is obtained for a multi-site application within any given member state: some countries designate which committee out of several, whereas others only have one committee for the whole country anyway. The most striking differences arose in the areas of training for members of research ethics committees and of quality assurance, assessment and accreditation of such committees.

We were particularly interested in the independence of research ethics committees (RECs). For some time there has been concern within the research ethics community that the equivalent bodies to RECs in the USA are institutional review boards (IRBs) which, by definition, cannot be truly independent as they are based on specific, usually academic, institutions. In general, we found that RECs in Europe are constituted in such a way as to ensure that the independence of committees and of individual members is safeguarded, but there were some member states that clearly followed the institution-based model. However, where appropriate safeguards are in place, even institutional review boards can demonstrate that they operate independently; but such safeguards are not always there. It is therefore important that bodies such as the WMA and EFGCP strive to ensure that any committee conducting ethical reviews of research projects involving human subjects is truly independent in its constitution and in its decision-making processes.

EFGCP hopes that this report, which will be published in January 2007, will be of practical use to sponsors, investigators, regulators and those that have responsibility for setting research ethics committees up and subsequently approving them. The report could not have been produced without the invaluable help and co-operation provided by the many persons within the member states who have provided information that has been gathered together.

Finally, the development of the research ethical review process in Europe is inevitably in a state of flux. Recent entrants into the EU have clearly striven to achieve the requirements of the Directive and of its recent companion on GCP (2005/28/EC). New candidates for EU membership, notably Bulgaria and Romania, have yet to demonstrate their adoption of these Directives but no doubt they will. Even within well-established member states we found that the detail of how ethical review was actually being conducted was constantly changing. However, by referring to the relevant websites for the various countries, readers will be able to check for themselves the exact situation pertaining at any given time. The challenge of safeguarding research subjects is a highly responsible one for research ethics committees throughout the world. Our awareness of the importance of this challenge should go some way towards ensuring that the highest possible standards of clinical research practice are attained.

References

* A Directive is a form of European Legislative instrument which is binding as to the effect to be achieved but permits the Member State to choose the form and method of legislative implementation.

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Medical Ethics and Human Rights

Conference Report

8th World Congress of Bioethics, 4-9 August 2006, Beijing, China

John R. Williams, Ph. D, Head of Ethics Department, WMA

This biennial conference of the International Association of Bioethics attracted approximately 600 participants, including over 200 Chinese scholars and students. It was held concurrently with the 6th International Congress on Feminist Approaches to Bioethics and consisted of two days of pre-conference workshops and four days of plenary and simultaneous sessions.

There were five preconference workshops of which I was able to attend two which were all day sessions:

• “Ethics and human rights: Working together for global health” – this was organized by three Harvard University units. Their premise was that there has been relatively little communication or other interaction between these two academic and organizational fields and that this should be changed. The main presenter, Steven Marks, a human rights specialist at Harvard and editor of a recent book, Health and Human Rights: Basic International Documents (which includes 6 WMA statements). He described in some detail the similarities and differences between bioethics and human rights: both cover many of the same issues (which includes 6 WMA statements). He described in some detail the similarities and differences between bioethics and human rights: both cover many of the same issues, but bioethics deals with specific details of the implementation of rights. Both combine aspirations and current realities. The rest of the workshop was devoted to a free-ranging discussion of the topic from many points of view and ended with reactions to a proposed Harvard graduate programme on bioethics and human rights.

• “Ethical issues in AIDS vaccine research” – This was a tightly structured session with numerous formal presentations and relatively little opportunity for discussion. The presentations dealt with the following aspects of the topic: an update on AIDS vaccine research, which is not very promising; design issues in HIV/AIDS clinical trials, including standards of care (para. 30 of the Declaration of Helsinki was cited favourably); informed consent: from theory to practice (it was noted that the practice in China is far from adequate); risks and benefits to participants and communities; meaningful stakeholder consultation and community advisory boards; and vulnerable groups.

The three other pre-conference workshops dealt with public health ethics and control of emerging contagious diseases, stem-cell research, and human enhancement (physical, cognitive, life-extending, etc.).

The opening plenary session featured the following presentations:

• The British philosopher, Onora O’Neill, spoke on informed consent, the topic of her forthcoming book. She contended that the requirement that consent be explicit and specific, which is found in the Declaration of Helsinki and many laws and regulations, is impossible to fulfill. Her justification of consent procedures would see them not as securing individual autonomy, but as a way by which research subjects can waive standard obligations – such as obligations not to injure, coerce or deceive – in limited ways in particular circumstances.

• In his response, Dan Wikler of Harvard criticized her position and pointed out that context sensitive when context seems insensitive? She criticized a recent tendency in bioethics to downplay the concept of ‘vulnerability’.

Other plenary sessions dealt with health care reform in China, ethical lessons from Unit 731’s human experiments, access to life-saving drugs, and experiences and lessons in emergent public health issues: from SARS to avian flu.

Most of the conference timetable was devoted to 64 concurrent sessions on a wide variety of topics which, amongst others, included the following:

• “Medical professionalism” – this consisted of four short presentations on why professionalism cannot be assessed, professionalism in psychiatry, enhancing professionalism in Taiwan following the SARS outbreak, and fostering patient autonomy.

• “Sex ratio at birth imbalance” – this focussed on China but included comparisons with other countries where there is no such imbalance, the question being whether the ethics of pre-natal sex selection are universal or country-specific.

• “Ethical issues in pandemic avian influenza” – this included presentations on Chi-
Discussion Paper

Several other concurrent sessions focussed on China, including a Germany-China Forum on ethical and legal issues in end-of-life care, emerging health and environmental issues facing China, a France-China Forum on stem cell research, a Japan-China Forum on “Is human dignity or human right principle sustainable for a future Asian society?”, ethical issues in new rural cooperative medical care programs of Mainland China, and Confucianism and bioethics. None of the presentation abstracts mentioned the retrieval of organs from executed prisoners for transplantation although three of them discussed the sale of organs and compensation of donors.

The next World Congress of Bioethics will take place in Croatia in 2008.

FROM PATIENT TO SELF CARER:

A Discussion Paper on the Future of Self Care and its Implications for Physicians

David E. Webber Ph.D., General Secretaery Self Medication Industry. John R. Williams Ph.D., Head of Ethics Department, World Medical Association

(Clearly the selfcare aspect of healthcare, both in the context of self management of minor illness and the selfcare aspect of collaborative care by the affected individual in partnership with caring health professionals such as doctors and nurses etc., is important to both patient and health professionals. The following discussion paper is particularly timely also in the context of the global shortage of healthcare professionals, which is currently the focus of WHO’s decade of action. Comments on this will be welcomed in these columns – edit)

This discussion paper is the first product of a project that has been initiated by representatives of the World Medical Association (WMA) and the World Self-Medication Industry (WSMI), although it does not necessarily reflect the official policy of either organization. Its goal is to identify the potential impacts and implications for physicians of the increasing prevalence of self care. Following on from this, there will be an opportunity to consider ‘tools’ by which physicians may be better equipped to support and deal with patient self care.

The discussion paper is structured as follows:

• Introduction – purpose, scope, definitions;
• Section 1 – Current trends regarding self care (social, economic, technological, etc.);
• Section 2 – Implications for physicians;
• Conclusion;
• Select bibliography.

Introduction

The topic of this project is very broad. Moreover, there has been relatively little attention paid to it by health professionals, policy makers, academics and industry. Although it would benefit from a well-funded, large-scale study, the scope of this project is much more modest. It will review some of the recent developments on the subject of self care and identify the major factors that are likely to have an impact on physicians. The general approach of the project is deliberately towards a broader, over-arching view that will be useful in guiding future activities, rather than an expert focused study.

The basic methodology of the project will be to pull together and synthesise available information rather than undertake original research. Since it is likely that ‘gaps’ in

na’s planning, the WHO’s project, and different scenarios for distributing scarce resources such as Tamiflu. Dan Wikler made an interesting observation that during the 1918-19 influenza pandemic, the annual number of deaths from TB in the U.S.A. decreased by almost the same amount as the increase in deaths from the ‘flu.

• “Ethical Lessons from Unit 731’s Human Experiments” — Takashi Tsuchiya from Osaka gave a detailed account of the Japanese biological weapons programme in Manchuria and elsewhere. He noted that following W.W. II the U.S. did not investigate medical crimes of the Japanese but sought the data to use against the U.S.S.R. The Soviets did conduct some trials but both the Japanese and the Americans covered up the atrocities. The first Japanese exposure was in 1981 but only in the 1990s did the crimes become known outside Japan. The Japanese medical profession considers the subject taboo.

• Another session on “Professionalism in Medicine” was chaired by David Rothman of Columbia University. He dealt with the current challenges to professionalism, including conflicts of interest, weak self-regulation, medical errors, lack of civic engagement, patient use of the Internet and overwork. There were two presentations of surveys of American physicians’ attitudes towards professional and ethical issues and one on professionalism among Chinese physicians.

• “From SARS to Avian Flu in China” — a presentation by Guang Zeng, Chief Epidemiologist, Center for Disease Prevention and Control. SARS caused Chinese politicians to become concerned with public health for the first time and to begin to overcome the tradition of secrecy and cover-up with regard to health-related problems. There is a better surveillance and reporting system now, although decentralization poses obstacles.

• “Bioethics Without Borders” — this consisted of presentations on the ethics activities of the WMA, WHO, UNESCO and the European Commission.
knowledge will be identified that will lead to the possibility of commissioning research; such opportunities will be considered as they arise.

The following working definitions of key terms are proposed for the purposes of the project:

**Health** – An indicator of physical, mental, emotional and/or spiritual well-being, characterized in part by an absence of illness (a subjective experience) and disease (a pathological abnormality) that enable one to pursue major life goals and to function in personal, social and work contexts.

**Wellness** – Another term for health that emphasizes measures, such as a healthy diet, exercise and self-care decisions, that promote health and prevent illness. This includes reducing the risk of chronic disease, preventing injuries, enhancing environmental and safety hazards from home and workplace, and eliminating unnecessary trips to the hospital.

**Health care** – Any activity that has as its primary objective the improvement, maintenance or support of physical, mental, emotional and spiritual well-being, as characterized by the absence of illness and disease.

**Self care** – The care taken by individuals towards their own health and well-being, including the care extended to their family members and others.

In practice self care includes the actions people take to stay fit and maintain good physical and mental health; meet social and psychological needs; prevent illness or accidents; avoid unnecessary risks; care and self medicate for minor ailments and long-term conditions; and maintain health and well being after an acute illness or discharge from hospital.

This is a substantial and broad set of activities that may be further detailed; today’s understanding of self care involves:

- Healthy choices that encourage the maintenance of health and the prevention of illness, including good nutrition and appropriate levels of physical activity;
- Avoidance of risk factors such as unsafe sex, tobacco smoking and environmental hazards;
- Self recognition of symptoms, screening and assessing these in partnership with a healthcare professional, when necessary;
- Self management that includes being able to handle the symptoms of disease either alone or in partnership with healthcare professionals or other people with the same condition;
- Self treatment involving responsible use of medication, both OTC and prescription (but specifically excluding ‘self prescription’).

In practice, the definition and understanding of self care have evolved significantly over the last 25 years and are likely to evolve still further.

**The future** – The horizon for this report is 3-10 years. Further than that it becomes extremely difficult to predict and plan, given the rapid pace of technological and social change.

**Section 1 – Current trends regarding self care**

• **What is self care?**

Self care is the care taken by individuals towards their own health and well being, including the care extended to their family members and others.

In practice, self care includes the actions people take to stay fit and maintain good physical and mental health; meet social and psychological needs; prevent illness or accidents; avoid unnecessary risks; care and self medicate for minor ailments and long-term conditions; and maintain health and well being after an acute illness or discharge from hospital.

This is a substantial and broad set of activities that may be further detailed; today’s understanding of self care involves:

- Healthy choices that encourage the maintenance of health and the prevention of illness, including good nutrition and appropriate levels of physical activity;
- Avoidance of risk factors such as unsafe sex, tobacco smoking and environmental hazards;
- Self recognition of symptoms, screening and assessing these in partnership with a healthcare professional, when necessary;
- Self management that includes being able to handle the symptoms of disease either alone or in partnership with healthcare professionals or other people with the same condition;
- Self treatment involving responsible use of medication, both OTC and prescription.

More recently this definition has been expanded to include a focus on risk factors and risk factor avoidance (WHO 2002) and a more explicit and better defined expression of the role of physical activity (beyond ‘sporting activity, leisure, etc.’) in maintaining health.

Another important understanding today is that self care may be exercised alone (e.g. treating a mild headache) or in collaboration with professional care. In other words, self care presents an important opportunity for the healthcare professional in a supporting role, guiding and advising the self care manager. For the present discussion this role (sometimes called ‘collaborative care’) should be underlined: self care should not mean absence of healthcare professional involvement.

Of course, seeking professional care can also be the result of a self-determined self care decision-making process. In effect the role of the patient in symptom recognition and even minor ailment diagnosis is also expanding. In future, self care may more
explicitly involve family and friends, as well as community-level activities.

- The self care continuum

The fact that the majority of symptoms and complaints are treated by self care has been described as an “iceberg” (Verbrugge & Ascione 1987). The small part of the iceberg that is above the water represents the cases seen by health professionals and the large unseen part under the water represents cases treated via different self care practices. Overall, an estimated 70% to 95% of all illnesses are managed without the intervention of a physician (Dean 1981, Coons & McGhan 1988, Segal & Goldstein 1989, Vulcovic & Nichter 1997).

In terms of episodes and hours, most health care in daily life is self-evidently self care. If, for illustrative purposes, a person has 3 hours contact with a healthcare professional each year, they in reality undertake self care for the remaining 8757 hours of the year. They do this by using the advice given by professionals during the 3 hours contact, or by using knowledge and skills gained from a variety of sources. There are many opportunities to improve on this self care, and physicians can play a leading role in supporting and encouraging more appropriate self care across the whole spectrum of care, to the advantage of healthcare professionals and particularly to people themselves.

An alternative visualisation is of health care on a continuum (see Fig. 1) ranging from 100% self care (e.g. brushing teeth regularly) to 100% professional care (e.g. neurosurgery). In between these two extremes is shared care where individuals or families partner with practitioners in the care of the individual; practitioners include physicians, nurses, allied health professionals, social workers and pharmacists. This is a more useful image than the iceberg since it shows that supporting self care has always been part of good practice, especially for allied health professionals, nurses and pharmacists. Further, it shows that the dividing lines between self care, collaborative care and professional care are not necessarily fixed, but can depend on a variety of individual and social factors.

- The (re)-emergence of self care

At a simplistic level it is a fact that throughout most of human history, self care was the norm and the only available form of health care for the majority of the population. With the industrialisation of societies and the increase in knowledge and specialisation of the last 300 years has come the development of – and wider access to – medical professional help. But fundamentally, self care is not a new invention so much as the previous norm.

Today self care is being positively driven by a number of powerful forces and trends. These include the following:

- Many developing countries are starting to experience the disease transitions that come with improved economic performance. This includes a shift away from communicable diseases such as TB and malaria to non-communicable diseases. Today’s reality is that, globally, the greatest causes of avoidable death in the world are not HIV/AIDS or TB but cardiovascular disease, cancer and respiratory diseases. If disease burden is considered, neuropsychiatric disorders and injuries should be added to this list. (World Health Report 2005). The epidemiological shift in disease patterns from acute to chronic morbidity results in the need to move from ‘curative’ to ‘chronic’ care. Self care is particularly important for patients living with chronic diseases and the term ‘self management’ is sometimes used here.

- Improved scientific and medical understanding of the causes of health and illness shows where self care can most appropriately be deployed (WHO 2002). Increased knowledge about the effects of lifestyles on health is playing a part. As expressed by one set of authors: ”It is estimated that by 2020 two-thirds of the global burden of disease will be attributable to chronic non-communicable diseases, most of them strongly associated with diet. The nutrition transition towards refined foods, foods of animal origin and increased fats plays a major role in the current global epidemics of obesity, diabetes and cardiovascular diseases, among other non-communicable conditions. Sedentary lifestyles and the use of tobacco are also significant risk factors” (Chopra et al 2002).

- Putting this another way, increasingly the fundamental causes of disease are being understood and it is seen that many represent a failure of prevention rather than an inevitability of life.

Figure 1. The healthcare continuum
Although controversial, there is now a good body of evidence to show that people with better health habits survive longer, and in such persons, disability is postponed and compressed into fewer years at the end of life (Vita et al 1998). With ageing populations this has substantial implications on the design of health care systems of the future, and for the self care sector. A new balance between disease prevention + wellness management vs. downstream disease treatment needs to be struck.

- Society is ever-changing. People around the world are better educated and want more information, choice and control over their lives and this is no different for health. The public’s attitude to looking after their own health is beginning to change. There is a shift towards independence and a range of personalised options for provider agencies. Surveys in many countries consistently indicate that many patients and the public have the increasing sense that health, and healthcare in general, is something with rights attached to it and want more support for self care.

- There is an increasing amount of information available to people on all aspects of self care and self medication, in printed form in books and articles, and through the Internet. Some of this is of high quality; some of lesser quality.

- As part of the consumer movement, groups representing patients have become more prominent in recent years. For example, the International Alliance of Patient’s Organisations (IAPO) has been formed and has expanded rapidly. IAPO has produced a ‘Declaration on Patient-Centred Healthcare’ that includes patient information and involvement in health policy as key principles (IAPO 2006). Patient-focused organisations such as the Picker Institute are publishing studies on topics such as ‘patient-centred medical professionalism’ (Askham & Chisholm 2006).

- Economic constraints, always a major consideration in much of the world, are increasingly a key factor in the most developed countries as the cost of technologies (medicines and other high-tech interventions) continues to rise. Governments and payers are looking afresh at all means of containing health care costs. Encouraging people to take more responsibility for their own health through self care is seen as an important potential opportunity to achieve a double effect of better health at lower cost.

In summary, a complex mix of drivers has combined to give impetus to the movement for self care. At the same time, there are substantial hurdles or barriers to be overcome before self care can make its full contribution to human health.

- The case for encouraging self care

The potential opportunity in self care is well expressed in the UK Department of Health’s publication: “Self Care – A Real Choice” (2005):

Research shows that supporting self care can improve health outcomes, increase patient satisfaction and help in deploying the biggest collaborative resource available to the NHS [National Health Service] and social care – patients and the public. Helping people self care represents an exciting opportunity and challenge for the NHS and social care services to empower patients to take more control over their lives.

Many individual peer-reviewed studies have shown that there are a variety of potential benefits that can be achieved by encouraging self care. Some examples are as follows:

- Reduction in general practitioner consultations. Professors Blenkinsopp and Noyce from Keele and Manchester Universities in the UK collected data on GP consultations for 12 ailments: constipation, cough, diarrhoea, dyspepsia, earache, hay fever, headache, head lice, nasal symptoms, sore throat, temperature and vaginal thrush. The proportion of GP consultations for these ailments was 8.9% representing about 11 consultations per GP per week. Almost 40% of consultations for these ailments were transferred to pharmacy management, with the implication that future recurrence could be similarly managed without the need for further consultation (Blenkinsopp & Noyce 2002).

- Dr. Martin Lipsky of Northwestern University Medical School in Chicago and colleagues showed in a study that availability of over-the-counter clotrimazole for the treatment of candidal vaginitis led to a 15% decline in the number of vaginitis visits. The decrease in physician visits resulted in approximately $45 million in direct cost savings and another $18.75 million in indirect savings by reducing time lost from work (Lipsky et al 2000).

- In Canada, a study by Mullet showed that people’s intent to use emergency services decreased from 30.5% to 13.4% after advice from a health support line. Compliance with self care advice was 84%. Some patients still visited doctors for reassurance that they had done the right thing but self-reported doctor visits were reduced (Mullet 2000).

- In Shanghai China, Fu et al. evaluated the effectiveness of a chronic disease self-management programme in the form of a lay-lead teaching course and guidebook. The study found that, compared with controls, patients who received this had significant improvement in amount of exercise undertaken, cognitive symptom management, self-efficacy in symptom management, and self-efficacy in disease management (Fu et al. 2003).

- In the UK, emergency hormonal contraception (EHC) became available over the counter from pharmacies in 2001 for women aged 16 and over. This change was welcomed by emergency physicians and there were anecdotal reports of fewer requests for EHC at accident and emergency departments. Kerins et al (2004) undertook a study to see if these anecdotal reports were true, reviewing patient records from two emergency departments. They showed a 52% reduction in the number of women attending for EHC between 2000 and 2001.

- In a project commencing in 1995, Healthwise, a US based non-profit organization, initiated the Healthy Communities Project: distributing
143,000 copies of a handbook on 180 common ailments and how to care for them, plus a telephone nurse advice helpline. Three years after the programme launch, an estimated $7.5 to 21.5 million was saved in unnecessary health care costs. More recently a similar initiative reported a reduction in unnecessary visits to the doctor of 23% and of 15% in unnecessary visits to emergency room services, and 16% of employees saving a sick day from work (see http://www.healthwise.org/a_communities.aspx).

- A workplace health education programme aimed at reducing unnecessary outpatient visits was designed by Lorig et al. A total of 5,200 employees attended a presentation, received self-help books, and completed self-administered questionnaires. The study found that a minimal cost, self-care workplace intervention can reduce outpatient visits by important magnitudes – up to 17% or 2.0 visits per household per year (Lorig et al 1985).

Based on these and other studies the potential benefits may be summarised as:

- Reducing time spent in seeing a general practice physician for minor or trivial ailments, giving physicians more time for more important cases.
- Reduction in the number of unnecessary visits to accident and emergency departments, again saving the time of these hard-pressed services.
- Increased motivation for patients and for healthy people in maintaining or improving their well being.

It is important to emphasise that none of these examples excludes healthcare professionals; indeed their full involvement helps ensure the success of self care schemes. An important point must, however, be made. In many poor countries the reality is of obligatory self care due to the absence of basic healthcare facilities. Obligatory self care is prevalent in the least developed countries and can be most unfortunate when it is a forced substitute for essential medical interventions. On the other hand, in many developed countries, the reverse is true – insufficient self care and over-dependency on the health care system gives a major opportunity to encourage self care in these countries. In both situations there are significant questions about the appropriate levels of self care for a country, given the particular circumstances, and around approaches for integrating self care into the mainstream health care systems.

Section 2 – Implications for physicians

Every person has the right to health education that will assist him/her in making informed choices about personal health and about the available health services. The education should include information about healthy lifestyles and about methods of prevention and early detection of illnesses. The personal responsibility of everybody for his/her own health should be stressed. Physicians have an obligation to participate actively in educational efforts (WMA Declaration of Lisbon on the Rights of the Patient).

As described above, self care is already widely practised in many parts of the world and this is likely to increase.

Physicians and medical associations may be sceptical of some of the claims of self care advocates, especially regarding the financial savings that can result from the expansion of self care (e.g., the reduction in hospital admissions). For one thing, these advocates may underestimate the role of uncertainty in symptom analysis, especially when the analysis is performed by someone with no medical training. It is often only after an examination by a physician that it is evident that the patient’s condition is self-limiting and can be dealt with by self care. Conversely, attempts to provide self care for some conditions can result in serious, and costly, complications because a physician was not consulted in time.

Nevertheless, physicians and medical associations should welcome the self care movement. There are both ethical and practical reasons for this:

- Physician support of appropriate self care is in keeping with the shift to shared decision making in the patient-physician relationship that has been occurring in many parts of the world during the past half-century. This shift is reflected in the policy statements of the World Medical Association. For example, the Declaration of Lisbon on the Rights of the Patient states, “The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions.”

- Although self care deprives physicians of certain functions that they are accustomed to perform, it also frees them from routine, relatively unskilled, tasks and allows them to focus on more interesting and challenging ones. This is especially appropriate in areas where there is a shortage of physicians.

Physician involvement in self care is nothing new. They have always encouraged patients to adopt practices that are conducive to good health, e.g., a balanced diet, moderate exercise and, more recently, abstinence from tobacco, and most of the medications prescribed by physicians are administered by the patients themselves or their family members. The current self care movement requires an evolution, rather than a revolution, in the role of the physician. The principal elements of this evolving role are the following:

- Learning about self care – Just as physicians have to maintain their clinical knowledge and skills, so also do they need to be aware of developments in patient expectations and requirements for self care, as well as the resources available for this purpose. Whereas at one time physicians had a virtual monopoly on medical knowledge, now there are many other sources – the Internet, the media (articles and advertisements), WHO, governments, patient organizations, pharmacies, health food stores, etc. Much valuable information is available from these sources, but there is a great deal of misinformation as well. Physicians need to have some familiarity with these sources in order to direct
patients towards those that are reputable and away from the others.

- Listening to patients – Patients differ greatly in their understanding of and capacity for self care. Some will ask for a physician’s help in learning how to care for themselves while others will expect the physician to take care of them. Only by careful questioning and listening to their answers can the physician know the extent to which they are able to exercise self care.

- Encouraging and teaching patients how to care for themselves and when to seek expert advice – Self care is vastly more complex than it was a few decades ago when its main form was taking medication as prescribed by a physician. Nowadays there are multiple regimes of pharmaceutical products, medical devices, monitors and exercises available for a great variety of conditions, both acute and chronic. The choice of the most appropriate regime for a particular patient and instruction for its use can be a significant task for a physician, especially when there are intellectual, linguistic or cultural barriers. Self-medication is an important aspect of self care. The World Medical Association Statement on Self-Medication (www.wma.net/e/policy/s7.htm) provides guidance to physicians and patients on the following topics: the distinction between prescription and non-prescription medication and potential interactions between the two; the roles and responsibilities of patients, physicians, drug manufacturers, pharmacists and governments; and the promotion and marketing of self-medication products.

- Monitoring patient self care – In order to provide optimal care, physicians need to know what self care measures, such as non-prescription medication and health foods, are being used by the patient. If they are inappropriate, the physician should so inform the patient.

- Developing and maintaining skill in motivating behaviour change in patients – Many self care measures, for example, smoking cessation and dieting, require significant will power on the part of physicians to overcome long-established habits or addictions. There is a large body of evidence-based literature on how physicians can best assist such behaviour changes (www.tcs.org/tobacco/cessation/biblio/medical_01.pdf), and familiarity with this literature is an important step in developing the skill required to help patients with this aspect of self care. Also important for patient motivation is physician role modelling of healthy behaviour.

- Collaborating with other health professionals (nurses, pharmacists, social workers, etc.) – Just as self care requires collaboration between patients and physicians, so too are other health professionals involved. For various reasons, patients receive more education in self care from these others than they do from physicians, but physicians need to know what patients are being told and whether they are following the advice they receive from these sources. Ideally self care will be part of collaborative care involving good communication among all those who deal with the patient.

For self care to enter the mainstream of medical practice, certain system changes are required:

- As noted above, education and advice regarding self care can be very time consuming, and many physician remuneration plans do not provide adequate compensation for this work, even though it can provide significant cost savings to health care systems. Medical associations should develop evidence-based arguments to convince the appropriate funding authorities to correct this imbalance.

- Medical school curricula need to prepare future physicians to deal with self care, which will include instruction in the knowledge and skills listed above. Continuing medical education programmes on this subject should also be developed.

- Medical associations should collaborate with patient self help and support groups to develop programs and resources that promote a proper balance between self care and professional care.

Conclusion

As stated at the beginning of this document, its purpose is to identify the potential impacts and implications for physicians of the increasing prevalence of self care. The WMA and WSMI welcome comments on this paper, including suggestions for next steps. Please send your comments by email to Dr. David Webber, Director-General, WSMI, dwebber@wsmi.org and Dr. John Williams, Director of Ethics, WMA, williams@wma.net.

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WHO

Medicines, money and motivated health workers are key to universal access to HIV/AIDS prevention, treatment and care and support

A “borderless society for health” necessary to make greater inroads: WHO Acting Director-General

18 AUGUST 2006 | TORONTO – Dr. Anders Nordström, Acting Director-General of the World Health Organization told delegates at the XVIth International AIDS Conference that “drastic measures” were required to ensure there are enough health workers available to deliver universal access to HIV/AIDS prevention, treatment, care and support by 2010. He also welcomed the broad consensus at the conference that a comprehensive response to HIV/AIDS was essential. Speaking at the closing session, Dr Nordström stressed that

“money, medicines and a motivated, skilled workforce” were key to delivering universal access.

He underscored that the funds available for HIV/AIDS globally were growing, but so were the needs. “Worldwide, resources for HIV/AIDS have increased to over US$ 8 billion a year, but estimated need in low- and middle-income countries is US$ 15 billion this year, and that will grow to US$ 22 billion in 2008. “That widening gap must be filled, and commitment sustained. It calls
Dr Nordström praised recent initiatives aimed at providing sustainable financing mechanisms, such as the UNITAID initiative of France, Brazil, Chile, Norway and the United Kingdom, which uses a levy on airline taxes to channel new money to HIV work. He also noted that new potential mechanisms – such as advance market commitments – could provide incentives for research and development into new medicines and vaccines. He stressed that developed countries, including the G8, must live up to their financial and political HIV/AIDS commitments, and that national governments must also spend more on health domestically, and make HIV/AIDS a funding priority.

Medicines – access to drugs remains critical

Dr Nordström noted that “3 by 5” – the WHO and UNAIDS initiative to expand access to antiretroviral treatment to 3 million people in low- and middle-income countries by the end of 2005 – had influenced the HIV/AIDS landscape. He paid tribute to Dr Lee Jong-Wook, WHO’s former Director-General, and his role in forcing a shift in approach and attitude to access to treatment. “This is demonstrated through a ten-fold increase in people on treatment in sub-Saharan Africa,” he said. “But the challenges in that region also illustrate what still needs to be done. Seventy per cent of the global unmet need for treatment is in Africa.”

He stressed that drug pricing was still an issue – to ensure that both first-line and second-line treatments were affordable. “There is growing momentum for innovation, research and addressing intellectual property issues to ensure maximum access to new products that save lives. We need ideas to turn into new drugs and diagnostics that strengthen our ability to safely treat infants and children as well as adults. We also need a vaccine and a microbicide.”

“Universal access must include access to a skilled and motivated health worker,” said Dr Nordström. “No improvement in financing or medical products can make a lasting difference in people’s lives until the crisis in the health workforce is solved.”

WHO's contribution to achieving universal access to HIV prevention, treatment, care and support focuses on five strategic directions: scaling up HIV testing and counselling; maximizing the health sector’s role in prevention; scaling up treatment, care and support; strengthening health systems and investing in strategic information.

Without health workers, universal access not possible

He called for “drastic measures” to urgently strengthen the workforce. WHO’s new ‘Treat, Train, Retain’ plan, launched at the conference, (see below) also demonstrates how ensuring prevention and treatment for health workers in a supportive work environment can help improve working conditions, and critically, keep staff healthy and motivated.

A health system also depends on stronger information and surveillance systems, logistics and distribution systems – all areas that WHO is helping national governments to address, he said.

Dr Nordström asked delegates to make universal access possible through “a borderless society for health. One that embraces all who can make a difference, from political leaders, scientists, health workers to young people, persons living with HIV, the poor, sex workers, injection drug users, people in prisons.”

Strengthening prevention

Dr. Nordström also stressed the need for a strong gender perspective to ensure that both women and men have equal opportunities.

Finally, Dr. Nordström told delegates that, along with treatment, care and support, renewed attention must be paid to the prevention of HIV.

“Too many resources – time, energy and money – have been wasted on the debate over whether prevention or treatment should be the priority. At this conference we have come to a clearer understanding that it is not a case of doing one or the other. Millions have died through lack of both.”
G8 commitments to infectious disease can improve global health security

ST PETERSBURG – At their July meeting Group of Eight vowed to improve the ways in which the world cooperates on surveillance for infectious diseases, including improving transparency by all countries in sharing information. The G8 also committed to continued support to fight HIV/AIDS, tuberculosis, malaria, and to eradication of polio. Dr. Anders Nordström, acting Director-General of the WHO said, „Today the G8 spoke together on the essential need to tackle infectious diseases, because of their health, social, security and economic impacts”, „The commitments are detailed and specific, and represent another step forward in G8 leadership on public health.”

Dr. Nordström led a senior WHO team at the Summit to contribute to discussions on infectious disease and he addressed G8 leaders, in the presence of the Heads of State or Governments of Brazil, China, Congo, Finland, India, Kazakhstan, Mexico, South Africa and invited UN leaders. He underscored priorities for infectious disease, including the need to:

- Sustain the political and financial momentum for scaling up against the major infectious diseases and basic health services: HIV, tuberculosis, malaria, polio and immunization.
- Manage new disease outbreaks and threats – including a potential pandemic influenza outbreak.
- Improve access to existing and new drugs and vaccines though expanded markets and increased affordability.
- Ensure there are enough motivated health workers in health centres and hospitals and address the current four-million health worker shortage. The biggest shortages are in the poorest countries where the need is greatest.
- Invest in innovative financing. The United Kingdom’s support for the immunization Financing Facility, and the France/Chile/Brazil/Norway plan to fund HIV/TB and malaria drugs through airline ticket taxes are very promising.

The 12-page health outcome document includes G8 country’s commitments to: strengthen the global network for surveillance and monitoring; increase global preparedness for a human influenza pandemic; combat HIV/AIDS, tuberculosis and malaria; eradicate polio; make progress on measles and other vaccine-preventable diseases; ensure access to prevention, treatment and care including through research, the use of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and also strengthened health systems; and to address the health consequences of natural and man-made disasters.

The Russian Federation carried on the G8 tradition of supporting polio eradication and made a specific funding pledge for polio eradication, committing US$18 million to the programme, as did the United Kingdom in Gleneagles in 2005.

Global Health

Worldwide shortage of doctors, nurses and other health workers

Geneva – A new global partnership that will strive to address the worldwide shortage of nurses, doctors, midwives and other health workers has been launched. The Global Health Workforce Alliance will draw together and mobilize key stakeholders engaged in global health to help countries improve the way they plan for, educate and employ health workers. Its secretariat will be hosted by the World Health Organization.

Responding to the call by African Heads of State, the G-8 and the World Health Assembly for urgent solutions to the health workforce crisis, the Alliance will seek practical approaches to urgent problems such as improving working conditions for health professionals and reaching more effective agreements to manage their migration. It will also serve as an international information hub and monitoring body.

The Alliance will start an ambitious programme – the Fast Track Training Initiative – aimed at achieving a rapid increase in the number of qualified health workers in countries experiencing shortages. The initiative will work towards that goal through five strategies:

- Mobilizing direct financial support for health training institutions, through a model similar to that of the Education for All Fast Track Initiative – a global partnership between donor and developing countries to ensure accelerated progress towards the Millennium Development Goal of universal primary education;
- Training partnerships between schools in industrialized and developing countries involving exchanges of faculty and students, with the aim of improving the education of doctors, nurses, midwives and paraprofessional health workers, and training more of them now;
- Nurturing a new generation of academic leaders in developing countries with the support of experts in the clinical, public health and managerial sciences from around the world;
- Developing innovative approaches to teaching in developing countries with state-of-the art teaching materials and continuing education through information and communications technology;
- Assistance with the creation of planning teams in each country facing health work-
er shortages, drawing on the top leadership of the major schools, whose task will be to develop a comprehensive national health workforce strategy.

Fifty-seven countries, 36 of which are in sub-Saharan Africa, have severe shortages of health workers. More than four million additional doctors, nurses, midwives, managers and public health workers are urgently needed to fill this gap. An adequate health workforce is defined by WHO as at least 2.3 well-trained health care providers available per 1000 people and balanced in such a way as to reach 80% of the population or more with skilled birth attendance and childhood immunization.

“The inadequacy of the health workforce in many developing countries is a major obstacle to providing essential life-saving health services to millions of people who lack access now,” said Dr Timothy Evans, WHO Assistant Director-General. “Coordinated action to address this crisis at the global level, in regions and within countries must begin now.”

The Alliance will seek to spur country action implementing the ten-year health workforce plan set forth in The world health report 2006: Working together for health. The Report calls for national leadership to urgently formulate and implement country strategies for the health workforce, with backing by international assistance.

“The Global Health Workforce Alliance will bring together all the stakeholders needed to move forward on this plan with a view to sharing evidence-based practices countries can follow to expand their workforces and make them more effective,” said Dr Lincoln Chen, WHO Special Envoy for Human Resources for Health and Chair of the Alliance’s Board.

The initial partners of the Alliance include the Bill & Melinda Gates Foundation, the Canadian International Development Agency, the European Commission, the Global Alliance for Vaccines and Immunization, the Global Equity Initiative at Harvard University, the International Council of Nurses, the New Partnership for Africa’s Development, the Norwegian Agency for Development Cooperation, the Ministry of Public Health, Thailand, Physicians for Human Rights, the World Bank and WHO. Its executive director, Dr Francis Omaswa, is the former Director General of Health Services of Uganda.

The Government of Norway has donated US$ 3.5 million towards the Alliance’s operations during its first year. Seed money for its start-up was donated by the governments of Canada, Ireland and Sweden.

WHO Reports from XVI International AIDS Conference

WHO HIV/AIDS Director Outlines Progress and Obstacles to Achieving Universal Access to AIDS Treatment

HIV treatment access reaches over 1 million in sub-Saharan Africa, WHO reports

16 AUGUST 2006 | TORONTO – Addressing a plenary session of the XVI International AIDS Conference, WHO HIV/AIDS Director Dr Kevin De Cock reported that the number of people receiving HIV antiretroviral therapy in sub-Saharan Africa has surpassed 1 million for the first time, a ten-fold increase in treatment access in the region since December 2003.

In low- and middle-income countries, just over 1.6 million persons were receiving antiretroviral therapy at the end of June 2006, a 24 percent increase over the 1.3 million who had access to the drugs in December 2005, and four times the 400,000 people receiving treatment in these countries in December 2003. Ninety-five percent of people living with HIV/AIDS today live in the developing world.

While WHO and UNAIDS reported significant increases in treatment access in several regions of the world, Dr De Cock emphasized that there is considerable work ahead to reach the G-8 and UN-endorsed goal of providing as close as possible to universal access to HIV prevention programmes, treatment, care and support by 2010. In his remarks today, he also laid out WHO’s vision for continuing to expand HIV treatment access, calling for new action to overcome barriers that, if unaddressed, will slow the rate of expansion in access to HIV treatment in the future.

“The combined efforts of donors, affected nations, UN agencies and public health authorities are providing substantial, ongoing increases in access to lifesaving HIV treatment,” commented Dr De Cock. “Yet, in many ways we are still at the beginning of this effort. We have reached just one-quarter of the people in need in low and middle-income countries, and the number of those who need treatment will continue to grow. Our efforts to overcome the obstacles to treatment access must grow even faster.”

Of the 38.6 million persons living with HIV globally, approximately 6.8 million people living in low- and middle-income countries require antiretroviral therapy now, meaning that about 24 percent of people in need worldwide were receiving antiretroviral therapy by end-June 2006. Coverage by region varied, from five percent in North Africa and the Middle East and 13 percent in Eastern Europe and Central Asia to 75 per cent in Latin America and the Caribbean. Sixty-three percent of persons on antiretroviral therapy in low- and mid-
Middle-income countries today are African, compared with 25 percent in late 2003. Although sub-Saharan Africa has the greatest number of people on treatment, and the second-highest rate of treatment coverage among those who need it, the region still accounts for 70 percent of the global unmet treatment need.

In addition to expenditures by countries themselves, treatment scale-up has been funded through the U.S. President's Emergency Plan for AIDS Relief; the Global Fund to Fight AIDS, Tuberculosis, and Malaria; the World Bank; other bilateral donors, and pharmaceutical companies through contributions such as the Accelerating Access Initiative. In general, progress has been greatest in countries receiving specific assistance from these initiatives.

Increasing Equitable Access

Speaking on efforts to ensure equitable access to treatment among all people who need it, Dr De Cock reported that current data do not indicate any systematic bias against women in treatment access, with the proportion of female ART recipients corresponding closely to, and in some cases exceeding, the proportion of people infected.

However, other inequities are clear. While an estimated 800,000 children below the age of 15 require antiretroviral therapy, only about 60,000 to 100,000 are estimated to be receiving it. One in 7 people dying of HIV-related illness worldwide is a child under 15 years of age, a fact that is largely due to the failure to scale up programmes for the prevention of mother-to-child transmission of HIV and to prevent HIV infection in young women, noted Dr De Cock.

Despite the successes of such countries as Brazil, Thailand, and Botswana, only about six percent of HIV-positive pregnant women globally are currently benefiting from antiretroviral prophylaxis to help prevent HIV transmission in childbirth. In contrast, pediatric HIV disease has been virtually eliminated in the industrialized world. People who contracted HIV through injecting drug use are also not receiving equitable access to treatment. In Eastern Europe and Central Asia, injecting drug users, a majority of them men, account for over 70 percent of HIV-infected persons, but only about a quarter of treatment recipients.

Dr De Cock encouraged delegates at the meeting to evaluate treatment efforts not only based on the number of patients receiving care, but on the quality of treatment outcomes as well. Noting that most patients in developing country treatment programmes present with late-stage disease, he emphasized that improving treatment outcomes will require both diagnosing HIV and starting treatment earlier.

“A three-and-a half times higher death rate after one year of therapy in HIV-infected citizens of resource-poor countries compared with Europeans and North Americans should not be viewed as acceptable, and we must commit to change it,” said Dr De Cock. “These priorities are not radical new insights but they do require altered commitment to saving human life.”

Moving Towards Universal Access

Looking forward, Dr De Cock outlined five strategic directions, each of which represents a critical area where the health sector must lead if countries are to make progress towards achieving universal access, and on which WHO will focus its technical assistance. These include:

- expanding HIV testing and counselling;
- maximizing prevention opportunities in health care settings;
- increasing access to treatment and care;
- strengthening health systems; and
- investing in strategic information.

While stressing that prevention, treatment and care are inextricably linked, Dr. De Cock called for an increased emphasis on prevention efforts where HIV transmission is most intense. He also emphasized the need to be guided by science when determining the effectiveness of prevention interventions.

Reviewing lessons learned from the “3 by 5” effort to rapidly scale up access to HIV treatment, Dr. De Cock cited the frailty of health systems – including human resources, physical infrastructure, laboratory capacity, procurement and supply systems, and fiscal management – as the key obstacle to widescale provision of HIV services, and called for the elevation of health systems strengthening among global political priorities. Dr. De Cock also cited the reliability and availability of strategic information, including epidemiology and surveillance, monitoring and evaluation, and operational research as essential in monitoring progress towards universal access.

Noting that only about 10 percent of people living with HIV in sub-Saharan Africa know their HIV status, Dr. De Cock added that WHO is working with UNAIDS to evaluate how countries are implementing HIV testing and counseling. A consultative process is under way to develop operational guidelines to help countries expand access to provider-initiated testing and counseling in health care settings, with a view to increasing uptake of treatment and prevention particularly in high prevalence countries. The guidelines will be issued later this year.

Top level push to tackle priorities in sexual and reproductive health

GENEVA – Leaders of the World Health Organization (WHO) and UNFPA, the United Nations Population Fund, are coordinating action to reverse the global trend of deteriorating levels of sexual and reproductive health and reduce the adverse impact on mothers, babies and young people.
Globally, inadequate sexual and reproductive health services have resulted in maternal deaths and rising numbers of sexually transmitted infections (STIs), particularly in developing countries. WHO estimates that 340 million new cases of sexually transmitted bacterial infections, such as chlamydia and gonorrhoea occur annually in people aged 15 – 49, many untreated because of lack of access to services. In addition, millions of cases of viral infection, including HIV, occur every year. The sexually transmitted human papilloma virus (HPV) infection is closely associated with cervical cancer, which is diagnosed in more than 490,000 women and causes 240,000 deaths every year. Around eight million women who become pregnant each year suffer life-threatening complications as a result of STIs and poor sexual health. Annually, an estimated 529,000 women, almost all in developing countries, die during pregnancy and childbirth from largely preventable causes.

“There is a really worrying rise in the number and severity of sexually transmitted infections,” says Dr Anders Nordström, Acting Director-General, WHO. “But the consequences of poor sexual and reproductive health go well beyond Sexually Transmissible Infections. They lead directly to completely preventable illness and death. It is unacceptable today for a woman to die in childbirth, or for a person to become HIV positive for lack of information and resources.”

Young people are particularly vulnerable. More than 100 million curable sexually transmitted infections occur each year and a significant proportion of the 4.1 million new HIV infections occur among 15- to- 24- year-olds. In sexually active adolescents (aged 10-19 years), sexual and reproductive health problems include early pregnancy, unsafe abortion, STIs including HIV, and sexual coercion and violence. “It is clear that the Millennium Development Goals 5 and 4 to reduce mother and child deaths by 2015 cannot be achieved without investing in sexual and reproductive health,” says Ms Thouraya Ahmed Obaid, Executive Director, UNFPA. “For example, avert unintended pregnancy and reducing unmet need for family planning are key interventions in improving maternal health and reducing perinatal death. Yet, in developing countries and those in transition, an estimated 200 million women lack access to family planning.”

In addition, in some cultures, three million girls and young women are subjected each year to genital mutilation/cutting which, in recent studies by WHO, has been shown to significantly increase the risk of death and serious injury for newborn babies and their mothers around childbirth.

Following a high-level meeting on Friday, the leaders agreed the agencies will coordinate action in countries to ensure programmes are more effective and accountable for results. The aim is to scale-up work to put a number of global proposals and initiatives into action in countries: The Global Reproductive Health Strategy, endorsed by the World Health Assembly, a 2005 Resolution on achieving internationally agreed health-related development goals, including those contained in the Millennium Declaration, another on working towards universal coverage of maternal, newborn and child health interventions, and this year’s World Health Assembly Resolution agreeing to the Global Strategy to tackle sexually transmitted infections.

A communiqué issued at the end of the meeting identified a number of priority areas including:
- A coordinated action plan to implement the Global STI Prevention and Control Strategy;
- Support to countries to increase skilled health attendants in target countries;
- Coordinated workplans on improving reproductive, maternal, newborn and adolescent health;
- “One framework” plans for the 16 African countries covered by the strategic framework just completed by the UN agencies;
- Advocacy for inclusion of sexual and reproductive health in national economic planning such as Poverty Reduction Strategies (PRSs);
- Strengthening the linkages between HIV and sexual and reproductive health through coordinated action in HIV prevention, care and treatment;
- Joint training of country teams on the process for planning and working together at country level and joint competency reviews;
- Coordinated work in countries addressing:
  - Female genital mutilation/cutting
  - Obstetric fistula
  - Violence against women, including in emergencies
  - A pilot programme in two countries to introduce the Human Papilloma Virus (HPV) vaccine
- Human resources for health.
- The key is to make practical plans in order to implement these strategies,” says Ms Obaid. “We are faced with an urgent need to increase investment in sexual and reproductive health to ensure access to quality reproductive health services, including youth-friendly services, and to link HIV/AIDS and STI prevention with reproductive health services and vice versa.”
- Country support and advocacy are going to be vital elements for any successful attempt to reduce the impact of poor sexual and reproductive health,” says Dr Nordström. “Evidence shows that investments in and access to sexual and reproductive health, including family planning, are essential to breaking the cycle of poverty. This then frees national and household resources for investments in health, nutrition, and education, promoting economic growth with tangible returns.”

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WHO launches new plan to confront HIV-related health worker shortages

Crisis in human resources for health poses significant obstacle to global HIV/AIDS prevention and treatment

TORONTO – The World Health Organization (WHO), in collaboration with the International Labour Organization and the International Organization for Migration, announced the launch of a coordinated global plan to address a major and often overlooked barrier to preventing and treating HIV/AIDS namely the severe shortage of health workers, particularly in developing nations.

Called ‘Treat, Train, Retain’, the plan is an important component of WHO’s overall efforts to strengthen human resources for health and to promote comprehensive national strategies for human resource development across different disease programmes. The plan is also part of WHO’s work to promote universal access to HIV/AIDS services. Through its HIV/AIDS Programme, WHO is playing a central role in making the goal of universal access a reality.

Fifty-seven countries, mostly in sub-Saharan Africa and Asia (particularly Bangladesh, India, and Indonesia) face crippling shortages of health workers. WHO estimates that more than four million health workers are needed to fill the gap. Sub-Saharan Africa faces the greatest challenges. With 11 percent of the world’s population and almost 64 percent of all people living with HIV, the region has only 3 percent of the world’s health workers. Globally, health workers are also concentrated in urban areas, leaving shortages in rural areas.

In sub-Saharan Africa and elsewhere, the HIV/AIDS epidemic is contributing to health worker shortages. HIV/AIDS is an emerging source of mortality, loss of productivity and demoralisation among health workers. HIV/AIDS has also changed the way young people view health work, making it a less desirable career choice and leading to a lack of health workers trained to prevent and treat AIDS. In addition, many health workers trained in developing world health systems leave their jobs (or countries) for better-paying jobs in wealthy countries, in bigger cities, or in non-governmental organizations (NGOs).

“WHO has a unique role to play in helping countries mount an effective, comprehensive and sustainable response to the AIDS epidemic,” said Dr. Anarfi Asamoa-Baah, Assistant Director-General of WHO. “The shortage of health workers is devastating public health systems, particularly in the developing world, and it is one of the most significant challenges we face in preventing and treating HIV. WHO is launching ‘Treat, Train, Retain’ to confront this crisis.”

Dr Sigrun Mogedal, the Norwegian government’s Ambassador for HIV/AIDS said “WHO’s ‘Treat, Train, Retain’ plan provides a much-needed boost to national health systems that will have an impact far beyond HIV/AIDS. By increasing the number of well-trained, healthy and motivated health workers, the plan will provide significant benefit to health systems generally.”

The ‘Treat, Train, Retain’ plan will be implemented under the umbrella of the Global Health Workforce Alliance, hosted by WHO, which was established in May 2006 and is a partnership of governments, aid agencies, civil society groups and multilateral organizations.

“‘Treat, Train, Retain’ draws on the growing body of evidence and experience of what works in improving the performance of the health workforce,” said Dr Francis Omaswa, Executive Director of the Global Health Workforce Alliance. “It will accelerate the adoption of best practices on critical issues like the increased roles and responsibilities of community health workers in combating HIV/AIDS and promoting better health at household and community level.”

‘Treat, Train, Retain’ will focus on those countries most severely affected by HIV/AIDS, and incorporates a menu of options that countries can adapt to their specific needs. WHO estimates that it will cost a minimum of US$7.2 billion over the next five years to implement the plan in the 60 countries with the highest HIV burden, and it could cost substantially more – up to US$14 billion. This corresponds to an annual per capita cost of approximately US$0.60 in the countries concerned, or between two and five percent of the levels of health expenditure typically found in low-income countries.

‘Treat’

Although health workers are at the frontline of national HIV/AIDS programmes, they often do not have adequate access to HIV/AIDS services themselves. The ‘Treat’ component of the plan represents a full package of HIV/AIDS prevention, treatment and care services that should be made available to health workers on a priority basis and tailored specifically to their needs. These include:

• Specially designed awareness and anti-stigma and discrimination campaigns

• Testing and counselling services

• Priority access to antiretroviral treatment for health workers and their families

• Protection from HIV transmission in the health care environment, including access to post-exposure prophylaxis

‘Train’

The ‘Train’ aspect involves strategies for countries to expand the numbers of new health workers and maximize the efficiency of the existing workforce. These include:

• Recruiting and training additional health workers

• Shifting tasks from more- to less-specialised health workers (e.g., from specialists to physicians, physicians to nurses, and nurses to community health workers and lay providers including people living with HIV)
WHO's Priority Action Steps

- Increasing the number of graduates by improving and expanding pre-service training in medical and nursing schools, and incorporating AIDS-specific training
- Providing in-service training to health workers already in the health system to empower and better equip them with the skills needed to more effectively care for patients living with HIV/AIDS
- Providing in-service training to health workers already in the health system to empower and better equip them with the skills needed to more effectively care for patients living with HIV/AIDS

‘Retain’

‘Retain’ relates to a set of interventions to help ensure that countries are able to keep existing workers employed in the health system. These include:
- Instituting policy changes, codes of practice and ethical guidelines to minimize migration of health workers from low-income countries to developed countries.
- Diminishing the draw of private-sector and NGO HIV/AIDS programmes on workers in public health systems.
- Improving the quality of the workplace environment, including establishing occupational health and safety procedures, reducing the risk of contracting HIV and other blood-borne diseases and addressing workplace issues such as stress and burnout.
- Supporting staff and families with HIV by guaranteeing job security, prohibiting discrimination, providing social benefits and adjusting work demands.
- Providing financial incentives, as well as non-financial incentives such as career and training opportunities, transport and HIV treatment access for family members.

WHO and UNICEF tackle problem of lack of essential medicines for children

The first international Expert Consultation on Paediatric Essential Medicines, jointly held by the World Health Organization (WHO) and the United Nation's Children's Fund (UNICEF), has delivered a plan to boost access to essential medicines for children.

Dr Howard Zucker, Assistant-Director General at WHO said “Children are often hailed as the hope and future of humanity, but they don’t benefit enough from pharmaceutical research and technology. Too often, the right medicines for children, in the right dosages and formulations are missing from the spectrum of available treatment options. WHO and UNICEF will work quickly with partners to change this.”

Ten million children die every year, many of them from diarrhoea, HIV/AIDS, malaria, respiratory tract infection or pneumonia. Effective interventions - classified on WHO's list of essential medicines - exist for these illnesses but there's a lack of knowledge of how best to use these medicines in children, and a lack of paediatric formulations of them.

A top priority resulting from the meeting is to dramatically expand access to much needed child-focused formulations such as fixed dose combinations (several pills in one), crucial for children's correct use of medicines and treatment adherence. The plan also calls for the improvement of medicines and prescribing guidelines addressing the entire range of infant and child care needs. Priorities include respiratory infections, neonatal care, palliative care for end stage AIDS, for HIV/TB co-infection and for other opportunistic infections, and improved electronic access to the latest WHO drug information.

The WHO Expert Consultation warned that without a model of best practice guidelines and paediatric formulations, and a buy-in at national levels right down to local care centres, then children - who in many countries make up half of the population - will continue to be considered as therapeutic orphans.

“For example, it is worrying to see very few medicines suitable for children in resource-poor settings where there is enormous need. For these children, we must address cost issues and ensure the right medicine formulations exist”, said Dr Hans Hogerzeil, WHO's Director for Medicines Policy and Standards. “The expert consultation was unanimous in its support for urgent, specific actions, which will significantly improve the chances for children to access the right medicines.”
WHO

According to Hanne Bak Pedersen, Senior Adviser Pharmaceutical Policy, UNICEF Supply Division, “UNICEF is concerned that children's access to medicines is very low in many resource limited settings. Furthermore, there is a lack of availability of several paediatric formulations. Based on the work of this new project and WHO clinical recommendations, UNICEF Supply Division will strengthen and expand the dialogue with industry on paediatric formulations for HIV/AIDS to promote the development of the missing medicines for children.”

High priority will be placed on ensuring a holistic approach to child care and treatment, including addressing quality of life issues such as producing painless remedies over injections, better tasting medications and investigating new mini tablet presentations.

H5N1 Virus

Indonesia holds avian influenza expert consultation

June 2006 – The continuing avian influenza outbreak in Indonesia, involving both humans and animals, was the focus of a three-day international consultation starting in Jakarta.

On 13 June, Indonesia’s National Committee for Avian Influenza Control and Pandemic Influenza Preparedness, known as Komnas FBPI, asked the World Health Organization and other UN agencies to “urgently convene” an international consultation of experts to:

• Review the status of the H5N1 virus in humans and animals
• Provide recommendations to control the virus in both animals and humans
• Review lessons learned for rapid response and containment, and
• Provide an authoritative risk assessment of avian influenza in Indonesia in both human and animals.

Emphasis will also be placed on considering the climate zone requirements linked to distribution and use whenever new product formulations are made. For example, chewable or soluble powders are preferred over syrups as they do not require refrigeration and are less bulky to transport.

The plan will immediately be sent to countries for feedback on how best to implement the recommendations at the local level. In addition, WHO will consider several children's medicines for inclusion in the WHO Essential Medicines List in March 2007.

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“Indonesia’s Ministry of Health has already demonstrated a great degree of transparency and collaboration since the first case appeared last year," said Dr. Paul Gully, a senior advisor for communicable diseases at the World Health Organization. “Indonesia has quickly acknowledged all cases publicly, teamed up with WHO for rapid field investigations, and provided virus isolates to the WHO H5 Reference Laboratory Network to enable monitoring of the evolution of the H5N1 virus. This consultation, Indonesia is taking another step to assess how best to protect the health of its people. The results will certainly be of great importance to all worldwide, who are eyeing the risk of the next pandemic.”

This consultation brought together experts from Indonesia’s Ministries of Health and of Agriculture, with those from the World Health Organization, the Food and Agriculture Organization, UNICEF and experts from Airlangga University Surabaya, Udayana University Bali, Persahabatan Hospital, U.S. Centers for Diseases Control and Prevention, France’s Epicentre, Hong Kong University, NAMRU-2 laboratory and Japan’s National Institute for Infectious Diseases.

Indonesia became the focus of international attention last month when the largest cluster of human H5N1 cases was identified. The outbreak involved eight members of a single family in Kubu Sembelang village, Karo District, of North Sumatra. Samples confirmed the presence of the virus in seven members of the family, and is presumed that the initial case was also infected with H5N1. Seven of the eight family members died. The outbreak was considered controlled on June 12, three weeks after the death of the last case with no new cases reported.

The H5N1 virus is considered firmly entrenched in poultry throughout much of Indonesia, and this widespread presence of the virus has resulted in a significant number of human cases. This year alone, Indonesia has reported more than 33 cases with 27 deaths. Unless this situation is urgently addressed, sporadic human cases are likely and human-to-human transmission is possible.

Results from the expert consultation were provided to Komnas FBPI on Friday, 23 June.

Viet Nam eliminates maternal and neonatal tetanus

In a joint news release the Ministry of Health of the Socialist Republic of Viet Nam, the World Health Organization and the United Nations Children’s Fund (UNICEF) announced that.

Hanoi/Manila/Bankok/Geneva – Viet Nam has eliminated maternal and neonatal tetanus as a public health problem. The disease, that kills tens of thousands of newborn each year, most of them in developing countries, is often called the “silent killer” because many newborn affected by it die at
Medical Science, Professional Practice and Education

Improved formula for oral rehydration salts to save children’s lives

Improved formula means better treatment for life-threatening diarrhoeal dehydration

The World Health Organization (WHO) and UNICEF today announced a new formula for the manufacture of Oral Rehydration Salts (ORS). The new formula will better combat acute diarrhoeal disease and advance the Millennium Development Goal of reducing child mortality by two-thirds before 2015.

Diarrhoea is currently the second leading cause of child deaths and kills 1.9 million young children every year, mostly from dehydration.

The latest improved ORS formula contains less glucose and sodium (245 mOsm/l compared with the previous 311 mOsm/l). The lower concentration of the new formula allows for quicker absorption of fluids, reducing the need for intravenous fluids and making it easier to treat children with acute non-cholera diarrhoea without hospitalization.

ORS use is the simplest, most effective and cheapest way to keep children alive during severe episodes of diarrhoea. The ORS solution is absorbed in the small intestine, thus replacing the water and electrolytes lost. WHO provides the only updated international quality specifications for this formula and UNICEF is a leading supplier of ORS to poor countries. WHO and UNICEF have jointly issued guidance for the production of the new ORS.

WHO and UNICEF recommend that countries manufacture and use the new ORS in place of the previous formula. WHO and UNICEF will help national authorities develop manufacturing guidelines and procedures for the new formula. Establishing the local production of ORS will be a key step to ensure countries can meet their own needs in controlling diarrhoeal disease.

According to UNICEF and WHO, oral rehydration therapy should be combined with guidance on appropriate feeding practices. Provision of zinc supplements (20 mg of zinc per day for 10 to 14 days) and continued breastfeeding during acute episodes of diarrhoea protect against dehydration and reduces protein and calorie consumption to have the greatest impact on reducing diarrhoea and malnutrition in children.

Before the age of one month. Since 1991, TT vaccine has been routinely given to pregnant women throughout Viet Nam through its Expanded Programme on Immunization resulting in a high vaccination coverage rate; accelerated activities began in 1993.

In 2000, 58 countries in the world had yet to eliminate maternal and neonatal tetanus. Vietnam is the ninth country and first East Asian country within the priority country group that has been assessed and validated as having eliminated these diseases. The other eight are Eritrea, Malawi, Namibia, Nepal, Rwanda, South Africa, Togo and Zimbabwe. Major contributors of financial and technical support to maternal and neonatal elimination efforts in Viet Nam include: the Bill & Melinda Gates Foundation, Beckton & Dickinson (a medical technology company), the government of Japan, AusAid, US Fund for UNICEF, UNICEF and WHO.

The next Communication from the WMA Secretary General will appear in the December issue, which will contain a report on the WMA General Assembly in South Africa.
Medical Science, Professional Practice and Education

The revised monograph for the new ORS formula will be published in the fourth edition of The International Pharmacopoeia. It is also available on the WHO website.

Additional information on diarrhoea can be found on UNICEF’s Facts for Life website and on the WHO Child and Adolescent Health web site: http://www.who.int/medicines/publications/pharmacopoeia/ors

Detailed recommendations concerning the provision and production of ORS are provided in a revised joint WHO/UNICEF publication, ‘Oral Rehydration Salts: Production of the New ORS’: http://www.who.int/child-adolescent-health/publications/CHILD_HEALTH/WHO_FCH_CAH_06.1.htm

The antimalarial, artemotil, manufactured by ARTECEF BV, is a parenteral (non-oral) artesunate preparation intended for the treatment of severe malaria, such as cerebral malaria, which may cause a lowered degree of consciousness and thus preclude oral intake of medicines. Malaria leads to more than one million deaths yearly, of which over 75% occur in African children under 5 years of age infected with the cerebral form of the illness.

Products newly listed:
- Efavirenz, 50mg Hard Capsule, Merck Sharp & Dohme BV, The Netherlands
- Efavirenz, 200mg Hard Capsule, Merck Sharp & Dohme BV, The Netherlands
- Tenofovir, 300mg Tablets, Gilead Sciences, Inc., United States
- Artemotil, 50mg/ml solution for injection, ARTECEF BV, Germany
- Artemotil, 150mg/ml solution for injection, ARTECEF BV, Germany

Three new antiretrovirals and two antimalarials have been added to the World Health Organization’s list of prequalified medicines. Tenofovir and efavirenz (in two different strengths) and artemotil (also in two different strengths) are crucial products for the treatment of HIV/AIDS and malaria respectively and will considerably boost the choice of therapy in resource-poor countries.

Tenofovir, produced by Gilead Sciences, Inc. was recommended in WHO’s 2003 AIDS treatment guidelines mainly as an option for the second-line treatment of AIDS. In 2006, its use will be expanded to first-line treatment.

The second antiretroviral is efavirenz, manufactured by Merck Sharp and Dohme BV. This product is one of the medicines recommended by WHO for first-line treatment and is a preferential drug in treatment programmes for patients with HIV/tuberculosis co-infection.

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- Artemotil, 150mg/ml solution for injection, ARTECEF BV, Germany

New AIDS and malaria medicines added to prequalification list

Needleless immunisations possible in the future?
A new approach to an old problem.

Reuter. A press release from a British Pharmaceutical Conference in Manchester reports research carried out at the School of Pharmacy at University of London has found a means of applying low-frequency ultrasound to the skin coupled with a product which makes the skin more permeable. Vaccines then applied to the skin in liquid form are then easily absorbed. Researchers tested the tetanus vaccines on mice and rats and will now proceed to trials on human skin.

The leader of the research, Afendi Dahian, commenting on the potential for removing the problems associated with needle delivery is reported as saying “Needle usage can spread blood-borne diseases if someone is accidently pricked with a needle or if a needle is reused. Also you need a doctor or trained nurse to administer a vaccine using a needle.” He hoped that a hand-held, low frequency ultrasound could be developed for use in hospitals and clinics.

Male circumcision update: Ongoing clinical trials are key to validating the link between male circumcision and protection against HIV infection

As trials continue, UN agencies work to ensure that current male circumcision practices are safe

17 AUGUST 2006 | TORONTO – In June 2006, the US National Institutes of Health announced that, following an interim review, two ongoing trials in Uganda and Kenya examining the link between male circumcision and the risk of acquisition of HIV infection in men should be continued. The trials are scheduled to end in July 2007 and September 2007 respectively. Data from these studies will be important in val-
validate findings reported in July 2005 from the Orange Farm Intervention Trial in South Africa, funded by the French Agence Nationale de Recherches sur le SIDA (ANRS), which showed a reduction of 60% or more in the risk of acquiring HIV infection among circumcised men.

The interim data from the ongoing Uganda and Kenya trials were reviewed in June 2006 by the Data and Safety Monitoring Board (DSMB), which recommended that the studies continue on the grounds that there were not yet enough data to draw firm conclusions. The DSMB further proposed that an additional interim analysis of data from the two studies take place within the next year. “The results of the two ongoing trials will help clarify the relationship between male circumcision and risk of HIV in differing contexts, which is key to determining the reproducibility and application of the Orange Farm findings,” noted Dr Kevin De Cock, Director, WHO HIV/AIDS Department. “While we await these important results, UN partners and others are working to provide coordinated guidance and support to countries to help improve the safety of current male circumcision practices.”

An additional trial assessing the impact of male circumcision on the risk of HIV transmission to female partners, led by researchers at Johns Hopkins University, is currently under way in Uganda with results expected in late 2007. The effect of male circumcision on reducing the risk of HIV transmission among men who have sex with men has been studied but has not been the subject of a trial.

**GUIDANCE AND SUPPORT EFFORTS NOW UNDERWAY**

WHO, UNFPA, UNICEF and the UNAIDS Secretariat emphasize that their current policy position has not changed and that they do not currently recommend the promotion of male circumcision for HIV prevention purposes. However, the UN recognizes the importance of anticipating and preparing for possible increased demand for circumcision if the current trials confirm the protective effect of the practice. Recent mathematical modelling based on an assumed reduction of HIV transmission of 60% in circumcised men suggests that, if this level of protection is indeed confirmed and if male circumcision were widely practised, the number of HIV-related infections and deaths could be considerably reduced over a twenty-year period in sub-Saharan Africa.

Countries currently considering how to improve the safety of current services will need to ensure that male circumcision is implemented by appropriately trained practitioners with adequate equipment in hygienic settings, and with close follow-up and post-operative care. Countries should ensure that the procedure is being performed under conditions of informed consent, confidentiality, and counselling tailored to the individual, emphasizing the continuing need for multiple HIV prevention measures.

“Even if further trials show a lower risk of HIV infection in circumcised men, male circumcision will not provide complete protection against HIV infection,” said Catherine Hankins, Chief Scientific Adviser, UNAIDS. “Circumcised men can still contract HIV and pass it to their partners. If male circumcision is proven to be effective, it must be considered as just one element of a comprehensive HIV prevention package that includes correct and consistent use of condoms, reductions in the number of sexual partners, delaying onset of sexual relations, and voluntary and confidential counselling and HIV testing to know one’s HIV serostatus. Just as combination treatment is more effective than single drug therapy for people with HIV, combination prevention is more effective than reliance on a single HIV prevention method.”

Since the reporting of the Orange Farm study findings, the UNAIDS Secretariat, WHO, UNFPA, UNICEF, the World Bank and other partners have been working together to develop a range of guidance documents and practical materials for countries or institutions that choose to improve the safety of and/or scale up male circumcision services, now or in the future. The UN Work Plan on Male Circumcision, which was developed with financial support from the US National Institutes of Health, the UNAIDS Secretariat, the ANRS and the Bill & Melinda Gates Foundation, includes the development of technical guidance as well as survey methodologies that can help countries to determine their needs and capacity to enhance services, and help track implementation and changes in sexual behaviour. As part of the UN plan, a number of country stakeholder meetings are also being organized to help countries assess the current status of male circumcision including human rights, ethical and cultural aspects, evaluate clinical capacity, and define knowledge gaps.

While this programme and policy work is ongoing, some high HIV prevalence countries are already working to improve the safety of current male circumcision practices and some are considering whether and how to offer male circumcision in an HIV prevention context. UN agencies emphasize that the final results of the ongoing trials will be essential to determining the efficacy of circumcision in preventing HIV infection in men in differing social and cultural settings. Once the findings of these trials have been announced and reviewed in 2007, WHO, the UNAIDS Secretariat and their partners will define specific policy and programming recommendations.

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Regional and NMA News

The medical profession: the scene across the world

The following report gives some indication of activities or problems exercising the medical professional organisations or issues addressed in NMA publications since the last Regional and NMA news.

General

Differing problems of migrant physicians continue to exercise both groups of migrants and members of the profession in the host country. Apart from the global concern about shortage of physicians as part of the growing shortage of healthcare workers generally and the moral problem of recruiting from countries already undersupplied with physicians, there are dilemmas arising from political decisions by governments to solve this problem. In certain countries of both North and South America there have been actions- in one case to the advantage of the migrant if not to his country of origin. In the particular host country express concern is about shortage of physicians as part of the host country. Apart from the global concern about inequity in working conditions between medically qualified EU nationals and Non-EU migrant physicians, has not only led to demonstrations but also to the threat of strikes.

Demonstrations have also taken place in one war- torn country in the Middle East where physicians have not been paid for six months

Canada

Much of Canadian Medical Association’s Annual meeting was dominated by the relationship between public and private medicine. Delegates voted on more than 20 motions concerning the relationship between the public and private sectors, approving a motion to request the government to remove bans preventing physicians practising in both sectors but in addition requested the CMA to develop a code of conduct for doctors who do this, which would balance professional autonomy with social responsibility. The meeting voted against the establishment of health insurance services which would lead to a parallel private system. The Retiring President Ruth Collins- Nakai left no doubt that Canadian MDs “continue to support the principle that access to care must be based on need, not ability to pay”. The new President, Dr. Colin McMillan made clear that human resource issues in the health field remain a key CMA priority.

(see CMA Sept, 2006-175(6))

Germany

There have been a series of demonstrations and strikes in the hospital sector over the past few months. These have recently been settled and a report on these actions will appear in the next issue of WMJ

The Exopharm newsletter (www.exopharm.de/newsletter) also reports concern about an initial draft proposal in the context of health reform in Germany. It proposes radical changes in the provision of medication under the health insurance system.

France

INPADHUE (trade union of practitioners qualified outside the European Union), following two strikes of emergency care physicians earlier this year which sought to further their demand for the same working conditions and remuneration as their French colleagues, further demonstrations in Paris have now taken place in Paris. They are seeking a re-opening of negotiations on the legislation governing doctors with foreign qualifications working in France and have threatened further actions if their request is not met. According to the report these actions have been going on for two years.

America

Subsequent to the Annual Meeting of the American Medical Association, AMA News reports that delegates voted to press Congress to make it quicker and easier for foreign doctors to obtain visas to work and stay in the USA. Also reported is the adoption of new ethical policy placing an obligation on physicians to disclose all relevant information to their patients, making “therapeutic privilege” no longer acceptable, as it creates a conflict between the physician’s obligation to promote patients’ well-being and respect for their autonomy by communicating truthfully”. The opinion states that if patients ask to be not
informed or a proxy told this should be respected. Other adopted policy includes that stating that the public soliciting of organs from living donors is ethically acceptable under certain conditions including the provision that it does not unreasonably disadvantage others on the organ waiting list. The policy adopted is intended to help guide doctors through the issues study of which will continue. (see http://www.ama-assn.org/ama/pub/category/16450.html).

AMA news also reports the formation of a Council on Physician and Nurse supply. This is part of the Consortium for Workforce Research Policy, a joint programme of Pennsylvania’s School of Medicine, School of Nursing and the Leonard Davis Institute of Health Economics and will monitor and address the problems of what many say is a growing shortage of physicians and nurses across the USA. Interestingly there is also a report that following a five year study by a work-force of the Massachusetts Medical Society there is a shortage of primary care physicians in Massachusetts. The report “2006 Physician Workforce Study” also refers to severe to critical shortages of specialists in some other disciplines.

United Kingdom

Following a debate and resolution at the Annual Meeting of the BMA (ARM), the Association is engaged in formulating views on the future of health service provision in the UK. In addition it is consulting its members in preparing its response to the proposals of the Report “Good Doctors: Safer Patients – proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients”. This report by the Chief Medical Officer contains radical proposals of which have caused grave concern to the profession concerning the regulation of the profession and changes in the functions of the General Medical Council, the regulating body, some of which have caused grave concern to the medical profession. In particular, the proposals to remove responsibility for the overview of medical education and are thought to be a retrograde step. Following the ARM a well attended meeting entitled “Improving health in the developing world: what can national medical associations do?”, was attended by a number of representatives of National Medical Associations and many others from bodies with an interest with these problems. The conference was held under the BMA’s Strategic Grant Agreement with the Department for International Development. Speakers in the opening session included Professor Paul Hunt, UN Special Rapporteur on the Right to Health and in the afternoon Mr Gareth Thomas, UK Parliamentary Under-Secretary of State for International Development The final session was opened by Dr Kgosi Letlape, President of the WMA, followed by formal presentations from two NMA speakers. There were very lively discussions after each session, and Dr. Edwin Borman, Chairman of the BMA International Committee, summarising up and suggesting an agenda for co-operation, emphasised the key challenge for NMAs to develop Advocacy; that the Right to Health and other principles of human rights provided a good basis for dialogue with governments; and the importance above all of Partnerships with others to achieve policies to improve the health of the poor and the associated social problems.

Speaking of Public Health he referred to the challenges and problems of population groups and Public Health, also to the need for healthcare systems to be fit for purpose if, for example, the health-related MDGs were to be achieved in relation to specific populations and the burdens imposed by “neglected diseases” addressed. He finally stressed the importance of Collaboration, a pure form of which was the Links movement, a system enabling health professionals in developed and developing countries to work together to regenerate health systems.

Book review

Innate Immunity to Pulmonary Infection

Chair; Siamon Gordon, Sir William Dunn
School of Pathology, University of Oxford, UK

In the glorious setting of Cape Town, South Africa, at the recently-opened Institute of Infectious Disease and Molecular Medicine of the University’s Faculty of Health Sciences, the Novartis Foundation held a symposium on the highly-relevant topic of Innate immunity to pulmonary infection. Lung infection is a major cause of morbidity and death in developing, as well as developed countries. In South Africa, there is an explosive combined epidemic of Tuberculosis and HIV, but also a great deal of infection in adults and children by other microorganisms, including pyogenic bacteria such as *S. pneumoniae* and *H. influenzae*, viruses such as influenza and respiratory syncytial virus (RSV) and fungal agents such as *Pneumocystis carinii* and *Cryptococcus* (nosocomial, 2 immunodeficiency and primary). In addition, there is an increasing incidence of asthma, associated with urbanization. All of this occurs against an historical background of occupational lung disease in miners (silico-anthracosis and asbestosis) and environmental factors associated with a rural lifestyle. While TB and AIDS are receiving increasing attention and attracting international research effort, scientific studies of other aspects of lung infection, many treatable or preventable, are relatively neglected.

The subject of innate immunity has moved towards the centre of immunology and is key to the pathogenesis of and vaccination strategies for infectious diseases. Whilst much has been learnt with regard to cellular and molecular mechanisms of innate resistance to infection, this has still received little application to human diseases. The lung
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is a key target for environmental pathogens, as well as for opportunistic infection, and could be a fertile source of cells and clinical/pathological materials to investigate disease in a genetically varied population. Genetic as well as environmental factors which determine the outcome of infection are still poorly understood.

NHS Healthcare system in UK shows divergence following Devolution in the Four Kingdoms

Devolution: a map of divergence in the NHS -Smith T. & Babington E in BMA Health Policy Review Summer 2006 BMA. ISSN 1750-0885

In this article, it is interesting to note that the Devolution of powers to Scotland, Wales and (eventually) to Northern Ireland shows signs of divergence in the way in which national policies are developing, which raise questions as to whether the National Health Service in the United Kingdom hitherto regarded by some as monolithic, can be so described in the future. As this article in the summer issue of Health Policy Review from the British Medical Association's Health Policy and Economic Research Unit comments, while superficially it could be argued that the aims in England are the same as those in Scotland and not dissimilar to those in Wales and Northern Ireland (all wishing to streamline the acute sector and provide more care in the community and broad commonalities in broad policy objectives across the UK), these aims are being pursued within different political and contexts and political communities.

This is succinctly illustrated in the reference to a note by Scott Greer (1). Commenting on Scottish policy direction, and referring to its broad tone of professionalism, trust in the markets and managers – who have been called in, in increasing numbers, to reform the English NHS” he continues – “under the slogan partnership, Scotland has restored its planning capacity and sharply reduced the role of managers while eliminating the purchaser-provider divide and the market manipulating policies that English policymakers use to try and create competition”.

It is further illustrated by Smith and Babingtons’ comment on Wales (where the Health and Social Care (Wales) Act 2003 provided powers to take forward policies in NHS healthcare etc.) – “much more so than in England or Scotland, policy is concerned with health rather than healthcare and there is a greater emphasis on public health. Political rhetoric has been directed against the causes of ill-health in society with less attention played to the management of the system”.

In this article in BMA Health Policy and Economic Research Review published by the BMA (but not necessarily reflecting BMA policy), in a section entitled “Strategic direction”, Scott Greer (1) is quoted as having given labels to three distinct approaches: England characterised by markets and management: the Scotland by new professionalism – focused on clinical management: Wales as being primarily “localist”: Northern Ireland is labelled Uneventful management” but the authors comment that while this is beginning to change it is the least changed of the four countries.

After concentrating on the political, philosophical and policy divergences behind the divergences in the NHS, the authors analyse some of the implications for doctors working in the United Kingdom, dealing with the need for them to position themselves in relation to the four different strategic directions in which policies are moving. Finally in a section entitled “Different working environments for doctors” in the context of the strategic directions and organisational context, they address the question “to what extent does the NHS remain a national health service?” and consider the implications for doctors in the four countries.

This fascinating article will be of considerable interest to both policy makers and physicians in both developing and developed countries who are in the process of, or considering, health policy change. It will prove an eye-opener to those who have hitherto observed the huge organisation of the UK National Health Service and its relatively uniform policy direction with both admiration and scepticism. Reading about these trends following devolution in the UK is well worth the effort and to be widely commended.

Other articles in this issue of the review include the problems of management of long-term conditions in a system under reform, the reality of choice in the political context of health and the role of quality in NHS productivity, providing a most valuable thought provoking resource.


Autumn meetings

AMA-CMA International Conference on Physician Health, Ottawa, Ontario, Canada 30 November - 2 December, 2006

Further information: cma.ca/physician-health

The Institute of Medical Law, International Conference “Global Safety and Rights in Healthcare” Hospital Phuket, Bangkok, Thailand, 13 -15 December 2006.

Further information: ww.imrab.se/phuket