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

The Return of Primary Care

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

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

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

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



health care approaches and the core of comprehensive systems, all too often primary care appears to have been assigned the status of a general ideology and one in which primary care was, in fact, an end in itself.

The WHO has recognized that the narrow interpretation of the Alma Ata Declaration has resulted in its failure. Not only has it led to primary care becoming the substitute for systematic development of health systems in some countries, in other cases, it has been used as a defense by funders to curtail improvements already underway.

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

In countries where this is the case, patients and health professionals with the financial means have simply left. The emigration of

thousands of professionals here0.0951or a2W cort h0B06ust be a-o(rginallit isutur)10(e)8(.uecess

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

Health impact of counterfeit medication

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

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

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

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

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

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



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

Free and accessible to anyone, the up-to-date, authoritative information is aimed primarily at physicians, other health care practitioners, and public health providers, enabling their training, continuing education,

enabling their training, continuing education, and professional development.

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

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

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

The report can be downloaded from WHO website: http://www.who.int/social_determinants/en/
Clarisse Delorme, WMA Advocacy Advisor

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

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

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

Introduction

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

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

tion of information, and for transfer to the

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Introduction

In recent times sex differences in cardiovascular disease have gained increased attention. We are learning that the mortality of acute myocardial infarction in young



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

Acknowledgement:

We greatly appreciate the secretarial help of Stefanie Roehner.

Grant support:

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

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

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

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

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

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

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

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

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

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

Development Projects

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

Projects at grassroots level

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

Support in developing appropriate policies

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

Global partnerships to improve oral health

Working in close partnership with the WHO, other UN agencies, health professions and organisations the Federation collaborates to improve oral health worldwide. Active involvement with FDI's corporate partners is another way of engaging broadly in promoting better oral health. See Live. Learn.

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

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

The AMB is a member of the Council of the World Medical Association and is the founder of the Portuguese Language Medi-

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

*e Macedonian Medical Association -
MMA, in Macedonian language *Makedon-
sko leka the MMA**



the highest state honour, the 11th October Award.

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

Continuing medical education, continuing medical development and professional guidelines are key factors in high quality and rational health protection, therefore the Educational Centre has been established for the regulation, promotion, organizing, monitoring and evaluation of CME and CPR.

The MMA with financial support of Ministry of Health produced and distributed free of charge to all doctors GUIDLINES FOR

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

The MMA has a clear stand that more profound education in ethics is an integral part of CME. Besides the textbook on ethics for our colleagues, the MMA translated in

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

The Fiji Medical Association (FMA) is a professional association, established under the Fiji medical and dental practitioner

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