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### Report of the Director-General 2002

#### I. Introduction

1. In this annual report I review the efforts of WHO to advance the health agenda, and point to the future directions of our work. The report highlights major events during the past year, noting both the achievements and the challenges that still need to be addressed. It also gives an account of how we are currently implementing our corporate strategy.

2. During 2000, the Executive Board endorsed four strategic directions for WHO's contribution to efforts to advance health at country level and globally\*. These form the basis of the General programme of work 2002-2005, and the Programme budget 2002-2003 adopted by the Fifty-fourth World Health Assembly\*\*.

3. The first direction **is to address the burden of ill-health among very poor populations**, taking account of the big contrasts in healthy life expectancy — between and within countries — giving particular emphasis to childhood illness; reproductive ill-health, including maternal mortality and morbidity; nutrition; communicable diseases; mental ill-health; injury and noncommunicable diseases.

4. The second is **to track and assess risks to health, and to help societies to take action to reduce them**. The emphasis is on enabling people to understand, then to limit, the risk factors for health. Risks may be associated with individual behaviour, dietary practices, use of tobacco and its products, exposure to violence, or influences within the environment.

5. The third is **to improve the performance of health systems**. This means being able to assess how well a health system is performing in relation to expectations, and to establish the reasons for differing performance of health systems. The methods need to be robust enough to enable the examination of health systems within a country, or the comparison of different national experiences. It also means a focus on options and means to improve the health system, concentrating on service delivery, resource management, financing mechanisms and stewardship.

6. The fourth, is **to encourage national policies which promote health**, with contributions from the economic, political and societal domains. The challenge is to find optimal means for investing in healthy futures through intergovernmental, national and local action.

7. The following report shows how we have contributed to improved health outcomes within each of these strategic areas, focusing on different aspects of our work.

#### II. Strategic direction 1: reducing excess mortality, morbidity, and disability, especially in poor and marginalized populations

##### Tackling communicable diseases

8. **HIV/AIDS**. At the end of 2001 we reported, once again, that the estimated number of people living with HIV has increased. The number of children living with HIV is now far larger than previously known. But we have, during the past year, seen the start of a real change in our collective ability to confront the epidemic. The agreements reached at the United Nations General Assembly special session on HIV/AIDS in June 2001 provide a strong platform from which different public, civil- society and private-sector groups will work together; learning from

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\* See document EBIO5/2000/REC/2. summary record of the first meeting

\*\* Resolution WHA54.20

those who have blazed a trail, scaling up best practice, and improving the well-being of millions people.

9. Prime ministers, finance ministers, planning ministers and health ministers are all focusing on the devastating effects of HIV and AIDS. Civil society, in particular people living with HIV, has greatly contributed to improving knowledge and to strengthening the moral imperative for action. Taboos are starting to erode. Governments are confronting the epidemic with a new openness. New information provides solid scientific evidence for the benefits of investing in poor people's health — including efforts to stem the spread of the HIV/AIDS epidemic. There is intense and widespread political commitment to act.

10. Within several countries we have seen examples of ways in which political commitment in support of focused and imaginative programmes is leading to reductions in the incidence of HIV. We have seen that communities and countries can turn the tide on HIV/AIDS. The reduction of prevalence in Cambodia, following earlier success in Thailand, has been noteworthy.

11. There are signs that a comprehensive response to the epidemic is at last becoming possible within poor countries. Lower-cost medicines for treating people infected with HIV are becoming available. Health systems that are providing essential services for people affected by, and at risk of, HIV infection in resource-poor settings are being studied and characterized. This creates exciting new opportunities for those seeking to invest in effective action to confront HIV/AIDS.

12. The priority now is to ensure wider access to reliable diagnosis and effective care. To this end, health staff is being trained to attend to people at risk of HIV infection and AIDS.

13. WHO is building up its contribution to national efforts to tackle HIV/AIDS. It is drawing upon its strengths and its expertise in the health sector to make optimal use of available resources. It works in close cooperation with the other cosponsors of UNAIDS, academic groups, nongovernmental organizations and private entities. WHO offers information about best practices and provides support to national efforts in the areas of voluntary counselling and testing, prevention of mother-to-child transmission of HIV, provision of care to mothers, and prevention of sexually transmitted infections.

14. WHO offers guidance on the care, treatment and support of people living with HIV/AIDS, including their nutrition, their access to antiretroviral and prophylactic drugs, diagnostic technologies, palliative care and psychosocial support. It also advises on blood safety and prevention and treatment of sexually transmitted infections. It collaborates with countries in strategically targeting interventions, including harm reduction and work with young people. The interventions are supported through a programme of surveillance, monitoring, and evaluation.

15. In all this work WHO helps to define norms and standards, and encourages and supports the development of new prevention technologies, especially research on microbicides and vaccines. WHO promotes the development of candidate vaccines based on HIV strains present in developing countries, facilitates their evaluation in clinical trials, and provides coordination of the international research effort on HIV vaccines. WHO is deeply involved in developing the agenda for HIV/AIDS research and in research and development related to new medicines in the context of conditions prevailing in developing countries.

16. **Stopping tuberculosis.** In November 1998, I launched WHO's Stop TB Initiative at the Global Conference on Lung Health in Bangkok and pledged WHO's strong support for an emerging collaboration known as the Stop TB Partnership. I am delighted to report that today over 120 organizations are working together against tuberculosis. They share common values and principles, a clear vision, a mission, and a comprehensive plan for control of tuberculosis: the Global Plan to Stop TB. The Partnership has broken the mould with its innovative approach to development. And we have learned more about what it takes to make partnerships work: transparency, imagination, trust and, above all, shared responsibility for jointly agreed goals. Our

role in the Partnership is to secure agreement to application of evidence-based strategies and to promote best practice.

17. The Global Plan to Stop TB has four clearly defined objectives: to expand our current strategy: directly observed treatment, short course (DOTS), so that all people with tuberculosis have access to effective diagnosis and treatment; to adapt this strategy to meet the emerging challenges of HIV and drug resistance; to improve existing tools by developing new diagnostics, new drugs and new vaccines; and to strengthen the efforts of Stop TB Partners so that proven tuberculosis control strategies can be effectively applied.

18. These objectives provide direction for individual Stop TB partners. Most importantly, the Plan ensures a monitoring mechanism, allowing different partners in, and donors to, tuberculosis control to assess progress and redirect efforts as needed. Strategic interventions like DOTS provide us with an opportunity to strengthen health systems and contribute to sustainable development. DOTS relies on secure routine delivery of health services through clinical facilities, health promotion activities, laboratory networks, community volunteers, drug and reagent supplies, and good management and administrative support.

19. The Global TB Drug Facility was launched in 2001 with the full involvement of WHO. It operates as a unique mechanism for ensuring the uninterrupted provision of quality-assured antituberculosis drugs for implementing DOTS. In a move to tackle the dual problems of insufficient treatment of active cases and the spread of drug resistance, the Facility grants free supplies of drugs only to those governments and nongovernmental organizations that adhere to proven and effective diagnostic, treatment and disease monitoring practices encompassed in the DOTS strategy.

20. In order to improve access to second-line antituberculosis drugs in countries where multidrug resistance is widespread, a partnership was established in 2001 with the pharmaceutical industry to provide these drugs at preferential prices. A mechanism known as the "Green Light Committee" reviews project applications and determines whether projects can benefit from this system. To date, the Committee has reviewed six potential projects for participation in the pooled procurement of concessionally priced second-line antituberculosis drugs.

21. The dual epidemic of tuberculosis and HIV, which is severest in the African Region, has been one of the challenges facing many governments in sub-Saharan Africa. With up to 80% of tuberculosis patients co-infected with HIV in some countries, health systems in several countries are struggling to cope with this problem. In collaboration with UNAIDS and other partners, WHO has developed a strategic framework to provide guidance to Member States to address this challenge.

22. The Stop TB Partnership estimates the five-year cost of tuberculosis control to be US\$ 9.3 thousand million, with a funding gap of about US\$ 4.5 thousand million. The 22 most-affected countries will contribute their share, but it is clear that a major injection of development assistance is needed to achieve global goals. The Plan is only as good as the action it produces. It is, therefore, flexible and adaptable. Nearly all the most-affected countries have prepared national plans to control tuberculosis, and in many cases the availability of resources is the principal factor that inhibits their implementation.

23. Combating other communicable diseases. Partnerships between national governments and voluntary and private entities are proving to be crucial to the success of programmes to control, prevent and eradicate different communicable diseases. Support has been provided to several time-limited programmes to eliminate diseases through the donation of medicines. The partnerships to eliminate leprosy and lymphatic filariasis were established some years ago and are achieving promising results. In 2001 collaboration was initiated with African countries to build sustainable programmes to combat African trypanosomiasis. Part of this collaboration involves donations both in cash and in kind from industry. In one case three medicines are being

donated and US\$ 25 million has been provided for logistics and service delivery over the next five years; in another, two specific drugs have been donated for five years; in a third, a drug has been donated for one year, together with funding over two years for disease management.

24. Within WHO we have recently integrated all aspects of research and development in vaccines against infectious diseases under a single umbrella, the Initiative for Vaccine Research.

### **III. Strategic direction 2: promoting healthy lifestyles and reducing factors of risk to human health that arise from environmental, economic, social and behavioural causes**

#### **Reducing tobacco use**

25. At the same time as the third round of negotiations opened on the framework convention on tobacco control, Adolf Ogi, Special Adviser to the United Nations Secretary-General on Sport for Development and Peace, and representatives from the International Olympic Committee, the Fédération internationale de Football Association, the Fédération internationale de l'Automobile, and Olympic Aid joined me to launch the campaign for Tobacco Free Sports. My message was straightforward: tobacco and sport do not mix. Sports must not be used to spread messages that are associated with disease and death. We need to break the dependence of sport on tobacco and tobacco sponsorship. At the same time, support must be provided for a worldwide increase in people's involvement in sport and physical activity.

26. WHO is linking up with many other groups to plan tobacco-free events in 2002 in order to highlight the importance of physical activity and sport as a means of improving people's health and promoting well being. These events, which began with the 2002 Salt Lake City Winter Olympics, will include the 2002 FIFA World Cup to be held in Japan and Korea.

27. The Fifty-fourth World Health Assembly adopted a resolution calling for greater transparency in tobacco control, and asking WHO to keep Member States informed of activities of tobacco companies' undermining public health\*.

28. A record number of 168 Member States took part in the third session of negotiations on the framework convention on tobacco control (22 to 28 November 2001). Regional preparatory consultations, hosted by Algeria, Bhutan, Brazil, Estonia, Islamic Republic of Iran, New Zealand, and Russian Federation, enabled countries to develop common negotiating positions. As a result, significant progress was made during the third session. Consultations before the fourth session, were hosted by Côte d'Ivoire, Egypt, India, Malaysia and Peru. Additionally, I attended the WHO European Ministerial Conference for a Tobacco- Free Europe (Warsaw, February 2002) where 48 of our European Member States had gathered to discuss the proposed text. Data released at the conference showed that young people in Europe — especially girls — are now smoking more than their parents, indicating that tobacco control is one of Europe major health challenges.

#### **Diet and physical activity for better health**

29. At the Fifty-fourth World Health Assembly we described the changes in diet, physical activity and tobacco use in many parts of the world, and presented evidence which links dietary patterns, nutrition and physical activity to the origins of noncommunicable diseases. We highlighted the great potential for disease prevention among populations and in individuals, and proposed a series of responses that would help countries to reverse these unhealthy trends. In January 2002, together with FAO, we convened a large and well-prepared experts' meeting in Geneva that agreed on the latest evidence on diet, nutrition and prevention of chronic diseases. At a consultation in April 2002, representatives of industry, consumers, and the health profession

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\* Resolution WHA54. 18.

commented on the experts' recommendations and shared views on possibilities for working together to promote better health. We propose to continue this work in alliance with appropriate organizations of the United Nations system, the World Bank, nongovernmental organizations, and private entities, in order to provide support to countries in stepping up their work on diet and nutrition in the prevention of noncommunicable diseases.

### **Effect of alcohol abuse on health**

30. Worldwide, 5% of all deaths of young people between the ages of 15 and 29 are attributable to alcohol misuse. In Europe, one in four deaths of men in the age group 15 to 29 is related to alcohol. In parts of Eastern Europe, the figure is as high as one in three. Globally, 140 million people are suffering from alcohol dependence. Around the world, alcohol misuse takes a heavy toll — damaging public and private life with countless traffic fatalities and injuries, fires in the home, drownings, suicides and violent crimes, it can also lead to indebtedness, ruined careers, divorces, birth defects, and children with permanent emotional damage.

58. We have established a WHO task force on alcohol policy and the Alcohol Policy Strategy Advisory Committee. Experts meeting in Valencia, Spain, in May 2002 will recommend policy options for addressing the aggressive marketing of alcohol products to children.

### **Genomics and human health**

31. During the past few years there have been intense debates on expectations, possibilities for, and concerns about, using new knowledge on the human genome to improve health. In 2001 I asked the WHO Advisory Committee on Health Research (ACHR) to prepare a report, which would help both decision-makers and concerned members of the general public to assess these issues for themselves. After a period of intense scholarship and several expert consultations, the report has now been published\*. It recognizes the potential for new research on the human genome to improve health. It also encourages the development of basic genetic services and research in developing countries in order to ensure that all countries have the capacity to respond to emerging issues related to genomics. It recommends international advocacy for policies that lead to the benefits of genomics being shared widely. so reducing health risks for all, an endeavour in which WHO would play a central role. In this regard, the recent five- year joint initiative of WHO and the United States National Institutes of Health will provide support to developing countries in strengthening research capacity in genetics and genomics.

### **Potential health effects of depleted uranium**

32. In 2001 we prepared a monograph on the health effects of depleted uranium summarizing all known health effects of exposure\*\*. In addition, we joined other organizations of the United Nations system to undertake field studies of the potential health effects of depleted uranium. Although the levels of depleted uranium in the environment and their public health impact in the Balkans suggested that they were not significant enough to affect health, further studies will be undertaken. In addition, we continue to work on the impact of ionizing and non-ionizing radiation on the health of all vulnerable populations.

### **Making our food safe**

33. WHO's Member States recognize the importance of reducing the potential of food to cause harm. Food safety is now seen as a worldwide challenge to public health. Resolution WHA53.15, adopted by the Health Assembly in May 2000, focuses on the need to develop sustainable, integrated food-safety systems for reduction of health risk along the entire food chain. WHO is carrying out this work in collaboration with FAO, notably within the FAO/WHO

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\* Genomics and world health: report of the Advisory Committee on Health Research, Geneva. World Health Organization. 2002.

\*\* Document WHO/SDE/PHE/01.1.

Codex Alimentarius Commission, and we have over the past year substantially increased our resources in this area.

34. Assessment of microbiological risk — the process to assess microbiological hazards in food — was initiated in 2000 in collaboration with FAO. While participating in the Food Chain 2001 Conference, (Uppsala, Sweden, March 2001) I emphasized the need to focus on direct risk to humans of contaminated food. We need to begin with the epidemiology of foodborne diseases and track them back through the food chain, all the way to the farm. This represents a tremendous challenge for all governments, and WHO is gearing up to respond to their needs.

### **Risks to health**

35. Risks to health is the theme of *The world health report 2002*. It will contain new information on the magnitude of major risks to people's health, including consumption of tobacco and alcohol, high blood pressure, physical inactivity, poor quality drinking-water, lack of access to sanitation, indoor-air pollution, inappropriate dietary patterns, certain sexual practices, and high cholesterol levels. It will set out options for reducing these risks, and stress the importance of surveillance as part of public health and health promotion. WHO is working with countries to establish systems for the surveillance of risk factors in order to yield information necessary for disease prevention and control. The goal is to achieve comparability of data over time and between countries, using common definitions of variables to be studied, and standardized instruments for data collection.

## **IV. Strategic direction 3: developing health systems that equitably improve health outcomes, respond to people's demands, and are financially fair**

### **Framing health policy and developing health systems**

36. Throughout the world, health systems are adapting to the challenges of responding to the conditions that have the greatest human and economic impact. At the same time, they are readjusting to the demands of chronic conditions, such as treatment of people with HIV/AIDS or noncommunicable diseases. This means developing health systems that encourage long-term, often lifelong, adherence to therapy, and linking hospital treatment to community care, emphasizing the critical role of families and community groups in the process. WHO is making available descriptions of best practice in building up health systems that maintain effective contact with people in need of care.

37. We are working with many countries to examine their health systems in order to make them more effective and efficient. Several have adapted the national approach to assessing the performance of health systems to local level.

38. I launched a consultative process in 2001 on the framework and methods for assessing the performance of health systems. Consultations were held in each WHO region, involving scientific experts and members of government. Eight technical consultations on specific topics were also held involving internationally renowned scientific experts.

39. I also set up a group to advise me on how WHO should apply the assessments of health systems' performance. In November 2001 it made recommendations to me on the consultative process, and the timing and conduct of future assessments. It supported the process through which both the international scientific community and the governments of Member States had been engaged in consultation.

40. Three new emphases guide our support to health systems. First, we are generating locally applicable information for national decision-makers on the costs and consequences of key interventions. This is being made available through WHO's CHOICE project. Secondly, we are preparing a world health survey that will enable Member States to obtain important information on the coverage of key interventions, levels of health and risk factors, and health expenditure. It will provide a sound basis for evaluating progress towards the United Nations Millennium

Development Goals (see paragraphs 53 and 54), as well as helping local health managers when they have to make difficult decisions. More than 70 Member States have asked to participate in the survey. Thirdly, we are starting to analyze ways to improve the resources available to health systems. We are drawing up technical guidance both for health-system financing and for use of human resources for health action.

### **Improving access to health information**

41. A key component of WHO's effectiveness is the quality and timeliness of the health information it makes available to countries. How WHO internally manages health information is as important as the way in which the information is disseminated. In 2001 I approved changes to production processes within WHO. These involved transferring responsibility for the quality of health information products to the various programmes, and the formation of an Organization-wide capacity for information dissemination. I intend in the future to improve planning of health information products so that each one responds directly to an identified health information need and to evaluate the effectiveness of products in communicating health information.

42. Moreover, WHO is the keeper of diverse and often unique sets of health data, which have to be preserved. WHO's internal information assets will be surveyed and catalogued in 2002 in order to make them more accessible and to increase use of health data within WHO and, particularly, within countries.

43. The *Bulletin of the World Health Organization* has been turned into an international journal of public health. All research articles are now subject to scientific review. Recent evaluations suggest that its articles have a significant impact. Agreement has been reached with a number of publishing houses to make available to developing countries, on the Internet, 1 000 medical and scientific journals at no, or low, cost. At the same time, WHO's own web site has been substantially remodeled, and we have participated in international initiatives on the communication of information.

### **Strengthening national disease-surveillance systems**

44. WHO plays a continuing role in strengthening national preparedness for disease outbreaks, and providing support for effective public health response. Support is provided by WHO teams from country and regional offices, headquarters, and the WHO Project Office for Global Surveillance and Response to Communicable Diseases in Lyon, France. Surveillance of harmful chemical incidents is undertaken within the framework of the International Programme on Chemical Safety. The outcome is a network of networks an efficient and proven global alert, verification and response system.

45. In 2001 WHO convened an expert group to prepare a second edition of its publication *Public health response to biological and chemical weapons*. The guide provides information on preparedness for, and response to, the deliberate use of biological and chemical weapons. Demand increased after events that took place in the United States of America in September 2001. A prepublication version was immediately made available to Member States on WHO's web site and the subject was debated by the Executive Board in January 2002. WHO's capacity to respond was strengthened, particularly in the epidemiological and laboratory techniques needed to detect, investigate and contain any outbreak.

46. WHO's response is designed to cooperate with national governments to contain any new — or long-standing — threat, particularly from emerging infectious diseases, epidemics, and drug-resistant infectious agents. This capacity is strengthened through links with the international public—health community. WHO helps to build up national resources for epidemic alert and response by improving capacities for laboratory services and epidemiology. In February 2001, with the assistance of the Government of France, the City of Lyon, France and the Mérieux Foundation, I opened the new office for global surveillance in Lyon, which will provide national officials in developing countries with training in detection of, and response to, epidemics.

### **Expanding access to essential medicines**

47. Since 1975, the Health Assembly has asked for definition of essential medicines and an improvement in people's access to them. During the past two years we have witnessed some promising developments. Many companies are now offering differential prices for their products with substantial discounts (and below-cost prices) for least developed countries. Moreover, the question of access to essential medicines was prominent at the Fourth WTO Ministerial Conference (Doha, November 2001). The Ministers declared that WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. The declaration provides welcome clarification on some of the flexibilities within the TRIPS agreement. Countries continue to require elucidation of the health implications of implementing WTO agreements, and WHO will continue to respond. It will pursue its work on access to essential medicines and health care technologies, focusing on ways to ensure equitability while respecting intellectual property rights.

48. The WHO Model List of Essential Medicines is a guide for drawing up national and institutional lists. Most countries have national lists and some also have provincial or state lists. Every two years since 1977 the Model List has been revised by the WHO Expert Committee on the Use of Essential Drugs. Over the past two years WHO has reviewed the procedures for updating its Model List in collaboration with Member States, WHO collaborating centres, members of expert advisory panels, organizations of the United Nations system, nongovernmental organizations, professional associations, national essential drugs programmes, academic groups, the pharmaceutical industry, and patients' associations. The main components of the revised procedures are strengthening the evidence base; broadening the global review process; linking selection to clinical guidelines; ensuring the independence of the Expert Committee in its scientific, normative and public health functions; and creating an essential medicines library which links the Model List with clinical guidelines, the WHO Model Formulary, and other normative information.

### **Improving health systems in emergencies**

49. WHO provides the most up-to-date information and the capacity to coordinate health-related responses to emergencies on the part of a range of groups involved in health action. In Afghanistan this task is taken on by the Regional Health Coordinator, who is helping to ensure that throughout WHO the best possible response is offered to meet the health needs of the people of Afghanistan (wherever they currently may be). WHO works closely with the national authorities in Afghanistan, other governments within the region, organizations of the United Nations system, nongovernmental organizations, and donors to help ensure availability of optimal information on the health and nutritional status of different population groups, synergy of strategies, coordinated action, and careful monitoring of results. The emphasis is on reconstruction of the country. Together with UNICEF, WHO is responsible for assessing needs and coordinating responses for improving health, and gives this task the highest priority.

50. We are currently reviewing ways to expand the impact on health of organizations working in emergency situations. This includes WHO's role in policy, operations, technical and administrative support. We are assessing how WHO mobilizes resources, expertise and finances to achieve its objective: to reduce avoidable deaths and illness that result from any type of natural or man-made disaster.

### **Impact of ageing populations on health systems**

51. In April 2002, I took part in the United Nations Second World Assembly on Ageing in Madrid, an important global event which reflected on the multiple implications of ageing for all aspects of society. Ageing is the silent revolution of our time. Never before in human history

have we experienced such a rapid ageing of our population, both in the developed and the developing world.

52. The ultimate goal is to ensure good quality of life for the highest number of individuals, whatever their age. WHO is firmly committed to implementing the policy it has set, and for this purpose has started to collaborate with different sectors and partners.

**V. Strategic direction 4: developing an enabling policy and institutional environment in the health sector, and promoting an effective health dimension to social, economic, environmental and development policy**

**Impetus for health**

53. **United Nations Millennium Development Goals.** The United Nations Millennium Summit Declaration and its related targets and indicators, cover several areas that are of direct relevance to the work of WHO, including goals to reduce child mortality; improve maternal health; combat HIV/AIDS, malaria and other diseases; and provide access to affordable, essential drugs in developing countries. These Millennium Development Goals provide a framework for charting our progress towards fulfilling commitments related to the Declaration.

54. To reach the Millennium Development Goals we need a fundamental change in the way we work together. This means shared agendas, new partnerships, funding mechanisms and monitoring, such as GAVI and the newly-formed Global Fund to Fight AIDS, Tuberculosis and Malaria. We are responding vigorously, with renewed will, to support effective action by all and to achieve results, with a stronger WHO presence in countries and increased capacity to provide support for effective local action. WHO will ensure a reporting process that does not overburden its technical programmes, yet ensures an appropriate and timely response from the entire Organization.

55. The International Conference on Financing for Development (Monterrey, Mexico, March 2002) provided a crucial opportunity to strengthen further the international commitment to achieving the Millennium Development Goals, to mobilize support for increased resources for development, and to agree on strategies for the effective, efficient and transparent use of those resources. WHO focused on evidence and experience from the health sector that can help to reach these goals, and on ways in which better health that should result from development can best be achieved and sustained.

56. **Health and human rights.** WHO strengthened its focus on health and human rights, building internal-capacity and advancing health on the international human-rights agenda. We have compiled an annotated bibliography and a global database of those involved in health and human rights. Training modules have been developed to raise the awareness of WHO staff. WHO contributed actively to the World Conference against Racism, Racial Discrimination, Xenophobia and Related Intolerance (Durban, South Africa, September 2001), the United Nations Commission on Human Rights, and the different bodies concerned with United Nations human rights treaties.

57. **Sustaining development and reducing poverty: the health contribution.** The World Summit on Sustainable Development to be held in Johannesburg, South Africa in September 2002 is the culmination of a 10-year review of progress in the field of sustainable development. A major objective is to find ways of tackling obstacles to implementation of Agenda 21<sup>\*</sup>; notably with regard to integrating trade, investment and finance issues into efforts to achieve sustainable development, and addressing the causes of growing poverty and inequalities. Health will play a more prominent role in the Summit than it did in the Conference on Environment and Development. Agenda 21 provided us with an important entry point into action for sustainable

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\* The Plan of Action adopted at the United Nations Conference on Environment and Development (Rio de Janeiro, Brazil, 1992).

development, and we will stress the linkages between health and poverty reduction, health in development policies and practices, health risks and determinants beyond communicable diseases, health hazards of the human environment, and the impacts of economic globalization on health. We will present the case that health is central to the overall process of achieving sustainable development in its three dimensions: social, economic and environmental.

### **Investing in the health of poor people**

58. **The Commission on Macroeconomics and Health.** During the 1980s, economists tended to maintain that developing countries could only afford to invest in health once they had reached a higher level of income. I was convinced that this was wrong; there is an interaction: a healthy population is a prerequisite for growth as much as a result of it. When I joined WHO, I set up the Commission on Macroeconomics and Health, chaired by Professor Jeffrey Sachs, to examine this relationship; I received its report in December 2001.

59. The report is a turning point— for health, and beyond. The Commission argues for a comprehensive, global approach to sustainable development, with concrete goals and specific time frames. The proposed investments in health involve well-tried interventions that are known to work. They can be measured, in terms of the disease burden and performance of the health system. The emphasis throughout is on results: on investing money where it makes a difference. WHO will work with countries as they request, taking action and pursuing the ideas in this report. Indeed, I believe the report will have a profound influence on how we all go about our work.

60. We will collaborate with countries in assessing options for setting up time-limited national commissions on macroeconomics and health, or similar entities. These bodies would contribute to formulating a national long-term programme for scaling up essential health interventions within the context of preparation of poverty reduction strategy papers. Together with other partners, we will work with national commissions to establish epidemiological baselines, operational targets, and a framework for long-term donor financing.

61. In addition to the support provided for improving the performance of national health systems (see strategic direction 3) we will collaborate in preparing national health plans and funding proposals. We will fund operational studies to assess feasibility of community health-financing mechanisms. We will strengthen ties between debt relief and increased health spending, working with such initiatives as Heavily-Indebted Poor Countries, and with countries not in the initiative, to design national strategies and organize round tables for donors and other international partners. We will coordinate both existing and new mechanisms geared to increasing access to global public goods.

62. The momentum for new investments in health will be maintained only if the first disbursements make a real difference to the health of poor people. We must all be accountable for achieving better health outcomes. The world health survey will provide important information for this purpose (see paragraph 40). Variants of the survey's modules are being developed to help local managers of health programmes to monitor and manage delivery of services to particular communities.

63. We recently released a report entitled *Scaling up the response to infectious diseases: a way out of poverty\** that builds on the work of the Commission on Macroeconomics and Health. It provides a road-map for channeling fresh investment into existing interventions for combating infectious diseases, and methods for strengthening countries' health systems. The report also broadens the public-health paradigm, stressing that prevention as well as treatment is now fully accepted as a means of promoting health and attacking poverty.

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\* Document WHO/CDS/20027.

64. **Economic impact of ill-health.** A few conditions, such as malaria, HIV/AIDS, tuberculosis, traditional fatal childhood illnesses, reproductive health conditions and nutritional disorders, are directly biting into the economic growth of poor countries. At the same time, poor communities are affected by a rising incidence of cardiovascular diseases, mental illness, tobacco-related conditions, cancers and injuries. Surveillance of all these conditions and their impact within poor communities, and information on current levels of risk, provides vital support for framing optimal health policies and choosing the means to make programmes more effective.

65. Analysis of data from 31 African countries, from 1980 to 1995 showed that the annual loss of economic growth due to malaria has been as high as 1.3% per year. If this loss had been compounded for that 15-year period, it means that gross national product is 20% lower than it would otherwise have been. When HIV prevalence reaches 8% of the population — as is the case in at least 21 African countries — per capita growth is reduced by 0.4% each year. Given that annual per capita growth in Africa for the past three years has averaged 1.2%, this is a significant reduction.

66. Several of the Millennium Development Goals call for increased action to tackle global ill-health. However, it is becoming clear that health systems which spend annually less than US\$ 60 per capita find it very hard to deliver a reasonable minimum of services, even when they have been subject to extensive internal reform. If health professionals do not receive adequate salaries, and if essential diagnostics, medicines and vaccines are not available, the health system will not perform at a reasonable level.

67. Commitments to the Fund currently stand at over US\$ 2 thousand million. Of this, some US\$ 700 million to US\$ 800 million should be available for disbursement in the first year of its existence. Used wisely, these resources can make a significant difference to the impact of national policies and programmes, by expanding coverage, engaging new partners, and initiating new activities. When preparing applications for submission to the Fund, it will be crucial to show how the additional resources will add value to what is being done already, and to indicate how results will be assessed. WHO will collaborate with Member States as they respond to the invitation to submit applications to the Fund. We will pay particular attention to the needs of countries that receive grants from the Fund, or which require support when making their applications to the Fund. We are committed to ensuring the success and sustainability of this mechanism or bringing additional resources into international health.

68. As with all our work with Member States in building health partnerships, the first point of contact is WHO's country offices. As a support for the WHO Representatives, I have established a team at headquarters, with focal points in all the regional offices, to ensure that country offices have access to the information and advice they need for providing support to the Fund's country coordination mechanism. The team includes both staff with expertise in health systems and those with specialized knowledge on individual conditions. In addition, we offer web-based support through a bulletin board on which country groups can receive information and exchange experience and advice. Providing support to governments and their development partners as they gain access to resources from the Fund will become an important component of strengthening WHO's presence in countries.

69. Establishment of the Fund is a milestone in collective efforts to combat disease and to make a significant contribution to the reduction of poverty. As in any new venture, sharing and learning from experience will be crucial for the Fund's success.

#### **Working with others: improved links between WHO and the European Commission**

70. In this endeavour, as in others, WHO is working closely with international and intergovernmental bodies, seeking to ensure consistency of advice and support. In particular, cooperation between WHO and the institutions of the European Union, notably the Commission of the European Communities, has been strengthened at all levels. An exchange of letters

between WHO and the Commission, concluded on 14 December 2000, sets out a new framework for intensified cooperation that identifies objectives, priority areas, and activities, as well as procedures and arrangements for implementation, making WHO and the Commission partners in global health.

71. As a consequence, recent policy dialogues have covered health and poverty, accelerated action on major communicable diseases, health and environment, tobacco control, and sustainable development. Specific events have included a joint round table on major communicable diseases and the development of programmes for action; a joint statement on research on international public goods; participation of the European Commission in the negotiations on the framework convention on tobacco control; a joint statement on tobacco control; and a joint seminar on health and environment. Increasing collaboration with the European Commission at all levels is set in the context of the effective partnership that is currently being built up between the United Nations and the Commission.

## **VI. Conclusion**

72. This annual report indicates that we are moving ahead to improve and support health action as we build on the continued efforts of our staff in country and regional offices and at headquarters. The more detailed reports of the six WHO regions on their work and of the programmes on their activities supplement the information I have provided.

73. We know what needs to be done to achieve equity in health. Since the launching 25 years ago of the movement towards health for all through primary health care, we have seen the importance of using science to devise essential health interventions, of bringing them directly to the poorest and most vulnerable people — those who need them the most — and of working for health across different sectors.

74. We know how it can be achieved. WHO has secured agreement for global strategies to tackle the major health issues of our time. Many of these strategies have been endorsed at the highest political levels. They have concrete goals and specific time frames. Their costs are not unreasonable, and are dwarfed by the potential benefits. The strategies propose a range of cost-effective and well-tried interventions that are known to work. Their impact can be measured — in terms of reducing the burden of disease and improving the performance of health systems.

75. WHO is helping to ensure that precious investments in people's development lead to health equity and well-being. This is essential in order to maintain confidence and increase aid flows. Within WHO we know how to make investments in health yield extraordinary outcomes. They can make the difference between death and life, poverty and prosperity.

## **PUBLIC HEALTH**

### **ETHICAL ISSUE: DELIVERING BAD NEWS**

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**Abstract:** Ethical considerations in medicine have been subjects of debate from ancient times until today. Ethically, is it right that a patient know his negative diagnosis, or should he or she be protected from the truth? In Armenia, patients may be protected from knowing the truth; whereas, in the USA the belief is that the person has a right to know his diagnosis. Eventually, everyone dies; however, communicating bad news is a challenge for the most experienced health care provider. There is a 6 step protocol, which will assist a health care provider in breaking bad news to a patient: 1. getting started; 2. finding out what the patient already knows; 3. discovering what the patient wants to know; 4. sharing the information; 5. responding to the feelings of the patient; and 6. planning and follow up. There are cultural differences in the preferred handling of providing negative information, but there are also guidelines, which can assist the provider regardless of his or her background.

**Keywords:** **medical ethics, communication skills, health care provider - patient communication, fatal diagnosis, truth,**

**Introduction:** Have you ever been in a situation, where you had to tell someone very bad news about themselves? Hardly is there a need to explain how unpleasant it is to have to inform a person about news as shattering as they have a fatal disease. There are some health care professionals who are obliged to do this as part of their routine work! These people are oncologists. These specialists are set apart from other medical professionals in many ways, but there is one distinguishing feature: they know from the beginning that the majority of their patients are dying. In addition to a sound knowledge of clinical medicine, an oncologist has a need to develop specific communication skills to assist them with working with their patients to understand their diagnosis and prognosis. Regardless of how many times a physician has been through the experience, it is still a challenge to deliver news about a diagnosis of terminal cancer. It takes excellent preparation and training plus a great deal of compassion. Recently, a senior oncologist had to tell a colleague about him having pancreatic cancer. This was especially difficult because both physicians knew the devastating process of the disease. Conveying such news is a worldwide issue, but it is especially true in Armenia where patients are not routinely provided with information when they have a fatal diagnosis. The issue regarding delivering bad news is not only about whether to tell the patient, but how, when, and who has to tell it. Armenian Health Care Legislation accepted on March 4, 1996 says that "Every person has the legal right to have full information concerning his/her health status and to make his/her own decision in choosing a specific treatment." However, telling the patient the truth is not widely practiced by Armenian physicians. Neither health care providers nor the public are accustomed to hearing complete information about such medical matters.

In an oncology conference held on October 2002, at the National Academy of Sciences, Dr. Mihran Nazaretyan provided a presentation about "delivering bad news". The presentation raised considerable debate among the participants. Conclusions were reached that discussions on the topic should be kept in the hands of the clinicians rather those of politicians. It is an issue for Armenian medical professionals to resolve. Other points raised during the discussion period were that these problems are not just local; they are worldwide. Anyone who has to deliver bad news will experience some psychological distress. So, it is advisable to use established guidelines to assist with the problem.

So, what is bad news, or what makes news bad? According to Doctor Buckman, the author of a book on the topic, bad news is information that dramatically damages the perception of the patient about his future (4). The patient probably already has some knowledge or intuition about his present medical condition, and the extent of the bad news depends on how far the patient's awareness and expectations are from reality. If a doctor is going to estimate the potential negative impact of the diagnosis on a patient, it is imperative to find out how much the patient knows, and what the patient expects. Thus, the understanding by a person of his medical condition makes up a major factor, which contributes to complexity of the issue (4). Another factor is the social aspect of having a debilitating or terminal disease. Society, especially in high income countries, tends to admire health and wealth. So, if a person lacks these characteristics, they may be "marginalized" from the main stream of social life (4). A patient after learning of his fatal diagnosis, may believe he has been sentenced to no longer be a member of the society because society is a world belonging to the healthy and strong. The problem of alienation from society becomes even more severe when along with disability, the patient faces the perspective of dying.

There are those who may blame the physician when they do not want to hear the truth about their illness. This may be the main reason doctors may desire to deprive patients of their legal right to have the full information concerning their disease. This is understandable because health care providers are also humans who want to please their patients. Upon becoming physicians, they take an oath (Hippocratic), which says "do not harm" the patient. It is not natural to deliberately cause pain to their patients, either physically or psychologically. As Doctor Buckman says in his book, "For us to consciously inflict pain on a conscious patient seems to upset the normal rules of our relationship to our patient and is one reason we always try to avoid it." If the problem of delivering bad news in Armenia is going to be changed, the solution is to be found in the education of medical personnel.

Humans tend to blame the messenger for bad news (4). Not only could the patient resent the physician, but there could also be a subconscious identification of the messenger with the patient. The physician may also believe he is a failure for not being able to cure the patient. Buckman says that "when a person's health deteriorates, there must be somebody at fault" and that "deterioration and death must be attributable to a failure of the medical system or the staff" (4). In the minds of the public, modern medicine should be able to cure all illnesses. Other negative aspects associated with delivering bad news is that the health care provider is placed in a situation where he or she acknowledges that "I do not know".

A physician may also be concerned about the unpredictability of a patient's reaction. He may want to avoid a situation where he believe the patient will cry or become hysterical. Dealing with patients' emotions require skills, which are not easy to administer. It is natural to want to avoid such reactions. Not only does the provider have to admit to limited abilities, but he or she may not feel confident having to answer difficult questions and explain uncertainties. Yet, the literature indicates honesty and wisdom shown by the professional has a lot to do with the acceptance of the negative news. Professional management of the situation is associated with decreasing or smoothing the tension and acceptance of the situation.

**Patients' rights:** Patients have the right to know about their health, but this does not imply that they are to be inflicted with that information in an unsympathetic or unconcerned manner. The Armenian law says that a person has rights to his medical information. Ethically, it should be stressed that a patient should be alert and mentally competent to understand the situation (4). It should be stressed that choosing not to talk about the diagnosis with the patient does not make the illness go away. Although the negative information may upset the patient, the subsequent impact of learning about the illness will cause much more consternation. Eventually, the patient will know, and he will recognize important information was denied to him. This is predictably more damaging than if the patient had the news when it was first discovered. The physician needs to remember that the illness is the cause of the distress, not the communication.

**Guidelines:** An essential skill for a physician is being able to communicate bad news. The first

step is called “getting started”. To begin, the physician has to be sure of his facts. He needs to have as much information as is available to prepare to talk with the patient. Then, the right environment has to be created by ensuring privacy and an appropriate setting (5). An adequate amount of time should be set aside, and every attempt should be made to avoid interruptions. It is helpful if significant other people such as a spouse could be present.

The next step is to try and establish what the patient and his family already know about the medical problem (5). For example, the physician could ask the patient to describe his condition and then ask the patient what he thinks is happening. This is the time when attempts should be made to clarify what the patient understands about his or her medical history and recent investigations. If it appears the patient is going to require more support, another appointment could be scheduled.

Critical to any communication activity is the exercise of listening skills. These skills are most important in verbal communication; yet, frequently ignored. Patients often complain their doctors do not let them talk. This is true in Armenia where the physician does not typically consider the patient as a team member or a partner in the medical regime. Buckman points out that on the average, the time a patient is allowed to talk before being interrupted by the physician is approximately 18 seconds, and only 23 percent get to finish their opening statements (4). Professionals tend to view patients as laypeople and may treat them accordingly. They may talk “down” to their patients; and in many cases, dominate the conversation.

The patient should have the opportunity to talk and have their questions answered. Moreover, they should be encouraged to talk. When the patient is attempting to speak, the health care provider should try not to interrupt. Also, it is advised to maintain eye contact, and not be uncomfortable with short silences. If the patient stops speaking, do not rush to fill the space. The patient may be thinking or too emotional to express his or her thoughts. If the physician tries to break the silence, the best way may be to ask the patient what he or she was thinking that made them pause (4).

The third step suggested in communicating bad news is to establish how much the patient or parents of a young child, may want to know (5). People handle information differently depending upon many factors including cultural and socio-economical reasons. The person preparing to convey the bad news, may ask the patient whether he or she wants to know the full details of their condition? If the patient declines, he or she may be asked if there is someone else who should receive the information. Another way is to say that some people do not want to hear what is wrong with them. And if that is the case, who would the patient want to be told about the information (5)?

The fourth step is the most difficult because it is when the negative information is shared. Again, there is done only after there is advanced preparation. When it is time to deliver the bad news, it should be done in a sensitive but straightforward manner (5). The information should be provided in simple language that is easily understood. Communication techniques such as avoiding technical jargon, using pauses, checking for understanding, and using silence are helpful.

Then, it is time to move to the fifth step and that is to respond to the feelings. Patients and their families may react in a variety of ways such as tears, strong emotions, or even a sense of relief at finally knowing the diagnosis (5). It is normal at this stage to exhibit denial or disbelief. However, the patient and his family must be given time to react, and the emotions should be acknowledge. They need support. Attempts to determine their feelings should be made if it is not obvious. However, they should not be rushed. Time should be allowed for the patient and the significant others to express their feelings.

The final step is used to establish the plan (5). The plan may include other tests or additional treatments. The patient needs to know he or she is not going to be abandoned. Both the health care provider and the patient should work together for the best outcomes. It is best to establish the next appointment and also to give contact information should there be additional questions. This is a sensitive time in which listening and responding are reciprocal activities. In this regard,

Beauchamp and Childress write that “some patients...are calm, attentive, and eager for dialogue, whereas others are nervous or distracted in ways that impair or block understanding. Many conditions limit their understanding, including illness, irrationality, and immaturity” (3) So, the person who has to provide negative information has an uneasy task of adjusting many types of moods and emotions from their patients. Speak clearly, listen well, repeat information if necessary, and be supportive and empathetic.

**Diversity of viewpoints:** During a class about “delivering bad news” taught to 31 Master of Public Health students enrolled in a Health Services Management course at the American University of Armenia, they became very involved in the discussion of the topic. Most of the class were physicians, and many expressed it was too soon to introduce these concepts to Armenia. They said that people are not used to these straight forward behaviors. Typically, the patient’s family first is provided with the negative information. It is their decision whether the patient should be told about his or her fatal diagnosis. Many of the class felt the patient would be additionally burdened with the knowledge. The victim should be allowed to live out his or her days in a more happy state. However, there were a few MPH students who demanded that the patient had a right to know. Some believed a dying person needed time to plan the rest of his life or get things in order before dying. Others thought that if the patient heard the bad news he would leave the doctor and not come back. There was concern the patient might even be so stressed that he or she would commit suicide. The discussion was dynamic with students lining up behind whichever philosophy best suited his or her beliefs. Some questioned what if a wrong diagnosis was received, and the patient was incorrectly told the wrong information? This would cause unnecessary suffering. One student provided a story from someone in her family about such a situation.

When the American course instructor was asked about Western beliefs on the topic, many were surprised to hear that if an American were denied the truth, a law suit could occur and the medical license of the provider would be at stake. Some students, on the other hand, reported that many patients in Armenia do not trust their doctors. If they heard a bad diagnosis, they would leave for Russia or another country to obtain another opinion.

**Leaving the door open:** During the conference, mentioned earlier in the article, two cases from personal experiences were mentioned regarding patients who were told the truth. In one case, a woman told the audience about her 81 year old grandmother, who was informed she had terminal cancer. The woman said the old woman received the bad news stoically, without giving in to panic or depression, and managed to keep her high spirits until her death.

In a second situation, a father talked about his daughter who was diagnosed with leukemia. He said he and his wife were extremely unwilling to let their child know she had a short time to live. However, later, they were convinced by their doctors to do so. In time, the child was informed about the situation. Her reaction produced some emotional response from the child. The father said she learned to cope with the frustration and led the rest of her life just as any other healthy child would live. She did not show signs of hopelessness or distress.

These two examples represent cases, where bad news was delivered to two people at two different stages of life. Undoubtedly, learning about such news is difficult regardless on a person’s age. However, the authors believe every one has the legal and moral right to know his or her diagnosis. But, what if the patient expresses a desire not to be informed about the truth? There is a proverb that knowing the bitterest truth is better than living with the sweetest lie. However, it would be cruel to try and convince or force a patient to hear bad news before they are ready to receive it. In such case, the medical worker should make the patient feel comfortable to come back and obtain the truth whenever they are ready to hear it. In summary, one of the greatest challenges of a health care provider is having to convey bad news to a patient. After an active discussion among MPH students attending a class on the topic, there was one thing they all agreed upon. It was clear regardless of the situation that the provider must never deliberately lie to the patient. Everyone acknowledged that patients have the right to

hear honesty from their health care providers. Some people argue that withholding information is also a form of deceit.

During this time of social transition and health care reforms spearheaded by many western and European ideals, issues concerning medical ethics such as this one will continue to be raised and debated. There are cultural differences in the preferred handling of providing negative information, but there are also guidelines such as those suggested by Dr. Buckman, which can assist the provider regardless of cultural backgrounds. These steps are 1) getting started; 2) finding out what the patient already knows; 3) determining how much the patient wants to know; 4) sharing the information; 5) responding to the patient his or her significant others; and 6) establishing plans for follow up with the patient (5). These guidelines are suggestions, and they are worthless unless the provider also uses compassion and understanding during these challenging and difficult occasions.

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## Prevention of Birth Defects by Folic Acid Supplements and Food Fortification:

### A New Challenge for Public Health

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#### Abstract

*Neural tube defects (NTDs) are among the most common birth defects and contribute to both infant mortality and serious disability. NTDs include anencephaly, spina bifida, and encephalocele. NTDs occur in approximately 1 per 1,000 births, with an estimated 4,000 pregnancies affected with NTDs each year in the United States. More than one third of these pregnancies are spontaneously lost or electively terminated; thus, about 2,500 infants per year are born annually in the US with an NTD<sup>1</sup>. During 1996--2001, a 23% decline was reported in NTDs in the United States since folic acid fortification of all enriched cereal grain products was made mandatory in 1996. Folic acid fortification of flour and monitoring of the occurrence of NTDs are important achievements in modern public health. Recent evidence indicates an important role of folic acid in reducing coronary heart disease and possibly in Alzheimer's disease, reinforcing the importance of food fortification with folic acid as a major public health policy issue internationally.*

#### Introduction

Observational studies and randomized controlled in the 1980s and 1990s showed that 50% or more of NTDs can be prevented if women consume a folic acid-containing supplement prior to and during the early weeks of pregnancy<sup>1-3</sup> in addition to the folate in their regular diet. The

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British Medical Research Council reported on reduction of over 70% in NTDs in women given folic acid prior to onset of pregnancy<sup>1</sup>. Based on analysis of these and other US studies, the US Public Health Service (USPHS) and Centers for Disease Control and Prevention (CDC) developed recommendations<sup>4,5</sup> for folic acid supplements for women in the age of fertility, including women with previous NTD-affected pregnancy and those with no history of a previous NTD-affected pregnancy.

Most children born with an NTD (95%) are born to couples with no family history of these defects. Since neural tube closure occurs during the first 4 weeks of gestation, folic acid intake must be taken before and very early in pregnancy<sup>5</sup>. Pre- and periconceptional supplementation with a multivitamin containing 400 (0.4 mg) µg of folic acid prevents the occurrence of >50% of NTDs. The US Public Health Service recommends that all women of childbearing age who are capable of becoming pregnant take 400 µg of folic acid daily. Implementing this method of primary prevention prevents 50% or more of these serious disabling birth defects.

### **Methods of Prevention**

Consistent daily ingestion of folic acid supplements by women of childbearing age is necessary because approximately half of pregnancies are unplanned<sup>6,7</sup>. However, experience with this recommendation, even in the United States where health consciousness is high, less than 1/3 of women in the age of fertility followed this recommendation<sup>8,9</sup>. Despite support from strong advocacy groups such as the American Academy of Pediatrics<sup>10</sup> and the March of Dimes<sup>2</sup> actively promote this CDC supplementation, achieving higher coverage of the target group seemed to be beyond reach. This led to a re-evaluation of strategy to find a more effective method of preventing this important birth defect.

In March 1996, the United States Food and Drug Administration mandated that enriched cereal-grain products be fortified with 140 µg of folic acid per 100 g of flour<sup>15</sup>. In 2001, Honein et al reported that “a 19% reduction in NTD birth prevalence occurred following fortification of the US food supply”<sup>11</sup>. At the same time, the Canadian federal government also instituted regulations mandating fortification of all flour with folic acid in addition to previous requirements of vitamins B, niacin and iron fortification of flour<sup>12</sup>. The Canadian approach to public health nutrition issues, has since 1979 mandated fortification of salt with iodine, milk products with vitamins A and D, and flour with iron, and vitamins B, and now have added folic acid<sup>14</sup>. This approach has recently been reinforced in policy documents of the Canadian federal ministry, Health Canada (Nutrition for Health: An Agenda for Action, 2001).

In Israel some foods are fortified by law (margarine and 1% milk with vitamins A and D). The Ministry of Health has been debating extending food fortification<sup>15</sup>, and has been working since 1999 to promote enrichment of flour with folic acid, vitamins B and iron, in keeping with the Canadian and US approaches. In 2001, the first flour fortification by a major flour manufacturer in Israel, with folic acid, iron and vitamins B,

came into effect. Regulations are in process of development in the Ministry of Health, based on the Canadian model of mandatory fortification of basic foods with essential vitamins and minerals.

### **Folic Acid and Coronary Heart Diseases.**

The effect of folic acid in reducing serum homocysteine levels has also major implications for coronary heart disease, the leading cause of death in most countries. Cumulative evidence, most recently including from the Framingham study of risk factors for heart and other cardiovascular diseases is indicating that high levels of homocysteine is a marker for high risk of mortality from cardiovascular disease and that folic acid supplementation lowers homocysteine levels<sup>16</sup>. Recently reported evidence also suggests that folic acid may play an important role in prevention of Alzheimer's disease<sup>17</sup>.

### **Conclusion**

Prevention of birth defects by this simple method has been shown to be cost-effective and

successful. With low birth rates, every effort feasible should be taken to ensure healthy pregnancies and newborns. The compounding evidence on a role of folic acid in reducing elevated homocystein levels, a risk factor for coronary heart disease, is another major reason for Central Asian Republics to adopt the Canadian, US, and Israeli approaches of fortification of flour with folic acid, along with other essential micronutrients to reduce iron deficiency anemia and vitamin B deficiency, particularly among populations in economic and social distress.

An editorial in *The British Medical Journal* in June 2002 states that “The failure of European governments to mandate universal fortification of flour with folic acid has allowed a continuing epidemic of preventable human illness. It is ironic that the United Kingdom has not required fortification, as it was a randomised controlled trial from the United Kingdom that conclusively proved that supplementation with synthetic folic acid prevents about 75% of spina bifida and anencephaly common and serious birth defects. This study provided the primary scientific basis for the United States, Canada, Chile, and other countries to require fortification”, and “Rare is the opportunity to implement a sustainable, inexpensive, and effective intervention to prevent major human diseases. Folic acid fortification of flour is one of those rare opportunities. The available evidence argues that governments that do not ensure that flour is fortified with sufficient folic acid are committing public health malpractice”<sup>18</sup>.

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## **RESPECT FOR PERSONS WHEN WEALTHY COUNTRIES CONDUCT HEALTH AND MEDICAL RESEARCH IN LESS WEALTHY COUNTRIES**

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Citizens of countries of the former Soviet Union, Africa, South America, Asia, and others are often the subjects of research by entities outside their own national boundaries. International non-governmental organizations, foreign governments, or private enterprises such as pharmaceutical companies may sponsor or conduct such research. The very nature of the circumstances requires that special precautions be taken to protect the subjects of the research. Ethical review committees and related bodies must assertively engage with researchers and subjects alike to provide such protection. Toward this end there have been a number of international efforts resulting in several significant documents. This article is concerned with the extent to which four such documents, all developed by highly credible international health and medical research organizations, address the question of respect for persons.

Collectively, the four documents offer ethical guidelines that address a broad range of concerns. These include but are not limited to informed consent, cultural variables, privacy, inducements to participate as a subject, interventions to subjects in control groups, standards of care, sharing outcomes of research with subjects, and respect for persons. Space in this article does not allow detailed exploration of every aspect of these documents. Therefore, discussion is limited only to respect for persons. It is believed that when respect for persons is present in research ethics guidelines it enhances the probability that the well-being and rights of subjects will have been addressed. Acknowledging that this assumption is fundamental to the boundaries placed on this work, the four documents were analyzed for references to respect for persons.

### **Analysis of Selected Health and Medical Research Ethics Documents**

In 2002 the Nuffield Council on Bioethics published a wide ranging report on the ethics of health care research in developing countries. The Council held as their central aim in producing the report, "...to consider how individuals and organizations from developed countries should

conduct themselves when sponsoring or undertaking research related to healthcare in developing countries (Nuffield: 2002: 131)."

The report listed four duties, principles to guide researchers. They were:

- the duty to alleviate suffering
- the duty to show respect for persons
- the duty to be sensitive to cultural differences
- the duty not to exploit the vulnerable (Nuffield: 2002: 50)

The way the authors of the Nuffield Report, the Working Party, described the process of showing respect for persons is manifest in their discussion. They indicated that humans were worthy of respect because they have the capacity to develop complex relationships and cultures. Further, they noted that by recognizing that each person was worthy of respect, this provided fundamental guidance when making decisions. Thus, one would consider what they value as important, help them to express their potential, help to create conditions that enhance their lives, and avoid violating their intimate relationships. They considered the constraints that respect for persons places on one attempting to alleviate suffering, noting that in alleviating suffering one must not violate other interests (Nuffield, 2002: 51), and noted that individual autonomy was an important manifestation of respect for persons (Nuffield, 2002: 57).

The Working Party stated, "Respect for persons is a fundamental moral duty (Nuffield, 2002: 71)," and, "The principle of respect for persons requires that we do not conduct research without their consent (Nuffield, 2002: 77)." When conflicts arise, such as a conflict between respect for persons and respect for culture, the Working Party was not explicit regarding which should prevail. Rather, they implied that reflection and caution should be employed in making decisions, and that individual respect could not be ignored (Nuffield, 2002: 77). They noted that in some societies it was necessary for the whole community to consider whether to participate in research, and that in those societies participation was not an exclusively individual choice (Nuffield, 2002: 133). When research subjects are illiterate the Working Party considered it not respectful to ask a consenting subject to "sign" a written agreement, but to devise some other means to assure understanding and informed consent (Nuffield, 2002: 136).

In their discussion of the avoidance of exploitation, the Working Party considered what they referred to as "parity of respect," or equal respect. They distinguished between treatment based on parity of respect and treating everyone identically, stating that one must consider cultural contexts and other circumstances when making decisions. They held that parity of respect allowed people in one circumstance to be treated from those in another, if the situation warranted and if researchers could justify the action morally (Nuffield, 2002: 90). Regarding standards of care and the avoidance of exploitation, the Working Party described a complex relationship to the principle of respect for persons. It was characterized by stating that a universal standard of care and identical treatment from one context to another were not necessarily the only ways to assure respect for persons. In the same discussion they asserted, "...justice demands equal respect (Nuffield, 2002: 137)." This is noted, not to suggest that the Working Party was inconsistent, but to emphasize the complexity of the issues.

Another important document was produced by the World Health Organization (2000), *Operational Guidelines for Ethics Committees That Review Biomedical Research*. In describing the role of an ethics committee, the WHO held that the dignity of individuals should be respected. They noted that regardless of the importance of the research, it must be held subordinate to the welfare of research subjects (World Health Organization, 2000: 1).

In 1998 the Council for International Organizations of Medical Sciences (CIOMS) and WHO published, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.

They listed three "General Ethical Principles." These were, "...respect for persons, beneficence and justice." Respect for persons was described as having two fundamental aspects: "respect for autonomy" and "protection of persons with impaired or diminished autonomy...(CIOMS and WHO, 1998: 1)."

In October, 2000 the World Medical Association Declaration of Helsinki (WMADH) updated, *Ethical Principles for Medical Research Involving Human Subjects*. Annexed to the document was, *Ethical Principles for Practice and Research*, which listed five principles: Respect for persons, beneficence, non-maleficence, proportionality, and justice. Respect for persons was described as recognition of the autonomy and self-determination of individuals and special vigilance in safe guarding people with diminished autonomy. The description stated further, "...fundamental respect for the other...should be the basis of any interaction between professional and client (WMADH, October, 2000: 45)."

### **Respect for Persons Who Are Subjects in Health and Medical Research:**

#### **Ten Principles**

The writers of the four selected ethics documents represented all parts of the world, and came together in separate groups, and at different times. Also, although the documents were not of equal depth regarding their treatment of the topic of respect for persons, and although every document did not treat every aspect of respect, still certain inferences and conclusions can be drawn. Ten principles of respect for persons involved in health care research emerged. In highlighting these principles it is not suggested that they are the only ones cited in the documents reviewed, nor that other principles are less important. Rather, these ten appeared to be held as exceptionally important.

1. Respect for persons is a paramount principle.
2. Respect is a moral duty that people owe to one another.
3. Respect requires action, demonstration of respect.
4. Research subjects are to be treated as an end in themselves, never as a means to an end.
5. When conflicts arise between the well being of research subjects and the larger study, respect requires that the well being of the research subjects prevail.
6. Not only are individuals to be respected, but also those things that they value, such as family and societal relationships.
7. Truth, full disclosure, and informed consent are essential to respect.
8. Parity of respect may, but does not always, require identical treatment from one research context to another.
9. The autonomy of people, whether they elect to express it as part of a collective or as individuals, must be respected.
10. Respect requires that people with diminished or impaired autonomy should be afforded exceptional deference and protection.

#### **Conclusion**

When creating or updating ethical guidelines for the conduct of health care research, it may be useful to consider the ten principles above. When establishing guidelines for research in countries that are among the least wealthy or which have not yet developed tried and effective guidelines, researchers have an exceptional duty to respect persons. Of course, in addition to respect for persons, there are many other factors to consider. The ten principles, thus, are offered

only as one aspect of a comprehensive set of ethical guidelines when wealthy countries conduct health and medical research in less wealthy countries.

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## **Problems and Perspectives of Nursing Development in Kazakhstan**

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The current political process coupled with economical and social transformation is at significant crisis level in all dimensions and levels of a society in Kazakhstan. Health care is not exception, where negative tendencies in the last few years had gained systematic character and special acuteness. The situation is aggravated by accumulation of various problems arisen in the past and continuing presently which renders negative influence on health care services.

The necessity to overcome this crisis condition in health services requires stabilization of parameters influencing health services in urgent manner for the republic. Medical education plays an extremely important role in this complicated situation. The doctrine of national medical education is always regarded as a key factor for internal state policy in reflecting the strategic tasks for the future health care. In the light of these conditions, currently, medical educational institutions undergo economic and other transitions that dictate immediate decision on questions connected to professional training of future specialists. These decisions must be timely and optimal in all dimensions, while developing delivery methods of training, one must meet requirements of health services needs.

In comparison to other foreign countries, the Republic of Kazakhstan lags many years in nursing development. This has resulted in deterioration of quality of the nursing care, due to mass migration from a trade of the professional nursing specialists to other professions (e.g., physicians). Our calculations show that in 1998-1999, the average ratio of the nursing specialists to the doctors in our country is 2.3.

Now, we have a situation where disproportionate personnel distribution exists in health services. The reasons for this imbalance can be explained with the following; first, increased share level of medical activity for certain medical services which could be carried out only by well trained nurses; secondly, demeaning role of the nurses, whose functions are reduced to helper of the physician, and often their job did not required technical work or required professional nurse qualification.

Given this background of transformations in our society, we carried out profound analysis of nursing profession in Kazakhstan; we are revealing the necessity of reforming nursing education. In the accessible literature, there are few works of research from Kazakhstan reflecting only narrow aspects of nursing /1,2,3/. At the same time in Russia and other foreign countries are given more attention to nursing studies in multiple directions/4,5,6,7/.

Despite of an obvious urgency and scientific requirement, as well as its practical importance, research showing the impact of nursing in modern health care was not carried out in multidimensional level. The research in this area must address the complex and social nature of this problem with a study influence of various medical and social factors. This defines importance of the work undertaken. In this paper, we propose a concept that develops and defines strategy for advancement of nursing education in Kazakhstan. This conceptual framework purports nursing education as a reform, and proposes as an independent branch of medicine with standards similar orientation to international levels.

We identify the tasks for this reform process as follows:

- To analyze and disseminate the development trends for contemporary nursing in the country and abroad,
- To estimate the condition of nursing staff in the republic health care and to reveal most typical tendencies determining the requirements in nursing reforms,
- To demonstrate the necessity and basic directions of nursing education reform in Kazakhstan;
- To develop and implement the organizational model of higher nursing education on scientific basis,
- To develop and implement methodology of nurse training in the republic,
- To develop and implement the basic tenets of the nursing concept, organizational technologies and recommendations for their realization in the area of nursing specialist training.

With this research, it is the first time, the social hygiene and organizational research for development dynamics and contemporary nursing research in Kazakhstan is carried out. The perspectives of higher nursing education in Kazakhstan with the purposes of expansion of functions and strengthening the role of the nurses are shown. In these work, declarations are scientifically proven, the alternative ways of nursing education reform are determined, the organizational model of higher nursing education in Kazakhstan is developed, and the major elements of the conceptual development in nursing are realized. We used scientifically proved methodological approaches to establish organizational technologies on realization of the concept in the area of nursing training under conditions of stabilization and steady development while protecting and strengthening the health of the population of the republic.

More specifically, we analyze a situation in public health area in Republic of Kazakhstan concerning nursing specialists, where we examine social hygiene, professional factors, and conditions affecting on rational use and increase of quality of work for medical workers. This is an analytical study of the nurses in reforming of public health services, which includes fundamentals of nursing concept. We underline the required technologies and mechanism to realize scientifically developed an optimal organizational model for medical personnel, specifically for nursing education training.

The analysis of nursing development in the country and abroad has yielded some general decrees, laws and rules for this process. In this aspect, our literature research on contemporary nursing and related issues in Kazakhstan and abroad, as well as other analytical, sociological literature research of various aspects of nursing personnel activity in system of public health services of Kazakhstan, revealed that there are systematic factors causing increase of demand for nursing services and the highly skilled nursing staff. Following are the few of the patterns emerged:

- Unprecedented increase of demand of the population for medical services as at large,
- Demographic changes occurring in a society,
- Change in level and structure of morbidity (chronic pathologies, occurrence of unknown diseases such as HIV/AIDS).
- Creation of more economic and effective kinds of the qualified medical aid (hospital based nursing care, long-term nursing care/nursing homes, hospice, etc.).
- Imbalance of personnel structure of public health services in the country.

Possible solutions to these questions has given us an opportunity to develop a new system of nursing education in view of social and economic conditions of Kazakhstan representing multilevel continuous system of nursing education. This contains four levels, which differs from the former one in many dimensions. First, it is economically feasible, this is especially important at times where there is a deficiency in health care budgets. Second, it has been designed in levels, so that each level represents the logically completed cycle of education for attainment of certain qualification while establishing basis for training at the subsequent level. Third, the system allows continuous ascend to the professional level. That is, as one fulfills the certain term, always can continue on training at higher level. Fourth, the transition from one level to another stimulates the students in obtaining the knowledge and professional skills. Fifth, the system promotes expansion of a circle of duties of the medical sister, gives an opportunity for employment by organizing, teaching and research activity. Sixth, it serves to increase the prestige and service growth of the medical sister.

So, the continuity in educational process, especially in nursing education will be realized. Multilevel preparation feature of the experts of nursing provides transition of the students from one level to another in a voluntary way, thus, they have an opportunity to continue in training after their day job at various public health services through practical applications.

The reform package which developed by our team is now legally enacted, and recorded in documents such as:

- The Concept of development of average medical (pharmaceutical) education in Republic of Kazakhstan », authorized by the decision of board MOH of Republic of Kazakhstan from 16.08.1995?. for ? 28/2;

- The decision of the Ministry of Work and Social Protection « About the statement of the qualifying characteristics on an again entered specialty on nursing » from 24.07.1995?. for ? 5-1, where a level of payment of work of the assistant of the nurses, specialized nurses and nurse-manager also is determined;

- The order Ministry of Health of Republic of Kazakhstan «About the statement of the requirements to show the experts carrying out professional activity in medical organizations, carrying out professional activity, for ? 227, where the new posts of the nurses are determined in connection with reforming nursing.

- The order of Almaty City Health Administration, November 28, 1997 ? 398 « About introduction of new posts of the experts in city hospitals», which has ratified the typical duty regulations of the assistant of the main doctor on nursing and manager (organizer of nursing) in schools.

The expedient preparation of nurses with the highest level of education is dictated by the following factors.

- By necessity of the profound preparation of the teachers for medical colleges given medical personnel a special preparation,
- By creation of a new control system for average medical personnel, allocation of the key experts to various level for work in ? ? ? ,
- By opportunity of using the experts with optimum nursing education for treatment, rehabilitation of the patients, and work with medical equipment,
- By necessity not with the purpose of replacement of the doctors, but to increase the quality of rendering medical aid and medical services to the population.

Based above stated factors, and also based on existing and working documents, such as «Concept of Nursing Development (pharmaceutical) Education in Republic of Kazakhstan», it is necessary to direct all efforts on achievement of an overall objective of the reform of in nursing education - preparation of new generation of the nurses at various levels (new form of education). The results of our research suggest that priority decisions in nursing education concept will provide the basis for additional refinements for new situations in the future.

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### **Clinical protocols (quality standards) of health services for the population of rural areas as main component of health services quality management in Kyrgyz Republic**

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Health services quality improvement in our country require establishment of quality management system at all levels of health services provision. These issues have greater importance in rural areas that now suffer from social and economical difficulties, and have certain climatic and geographical characteristics /1/. These are major determinants of internal diseases growth within rural population.

Health services quality is currently perceived as aggregated dimensions of the process based on scientific and practical healthcare achievements that lead to health care and promotion of the population. Level of Quality for health services at rural communities must be staged and planned based on quality criteria and achievement of outcomes of health facility activities.

Effectiveness and quality of health services require optimal utilization of human, logistical, technical and financial resources.

Currently, health services quality assessment is still a complicated issue due to complexity and irregularity of the observation target and multi-dimensional measurement requirements. Due to this complexity, quality achievements in rural healthcare must be clearly staged. International practice indicates that health services quality can be achieved and assess only with standards. There are no other approaches to this issue. /2/.

A standard means a normative document that regulates rules, norms and requirements for standardized object. It must be approved by appropriate authority, and should be valid during

certain period of time. This might contain both minimum, and acceptable set of norms. Guaranteed minimum set of requirements assures same volume and quality of provided health services to all citizens despite their place of residence.

Standard should be based on sound balance between two principles:

1. It shouldn't become an impediment to the implementation process of scientific and technological achievements;
2. It should have stable requirements during certain period of time.

Health services quality standardization in a form of clinical protocols seems to be reasonable considering new conditions of healthcare development. Ministry of Health has already started to develop new clinical Protocols. It conforms healthcare and medical science development concept. According to this concept documentation of health services provision should be transformed to a protocol form stage by stage.

It was considered that clinical protocol, as a standard of health services quality, is “a systematically developed provisions aimed on assistance to healthcare professional and patient to take correct decision regarding provided health service under certain clinical conditions” /4/. It is a unified benchmark for the guaranteed set of a number of preventive, diagnostic, clinical, and rehabilitative activities for certain nosological disease form. Execution of the activities included to clinical protocol anticipates achievement of certain quality level and clinical effectiveness for certain nosological form. Standards should be based on systematic approach and target health professionals on certain actions in certain situations, consider not only medical aspect of health service provision, but also social, ethical, common norms.

Thus, clinical protocols are required conditions for health facility functioning under the conditions of mandatory health insurance. It also is an important component of health services quality assessment system. Clinical protocols might become a background for the development of price making and pecuniary motivation for healthcare professionals.

It also should be noted that developed clinical protocols are essentially processual ones. They are based on common ideology, i.e. common principles of prevention, diagnostic, and treatment. Clinical protocols also reflect major priority objectives and criteria of health services quality at different levels of rural healthcare. Common approaches to standardization of patient transfer through the stages of health services provision create conditions for clear continuity.

Development of clinical protocols is based on utilization of:

- International disease classification ICD-10;
- Common classifiers of functional and laboratory tests adapted with consideration of international requirements to clinical procedures.

Clinical protocols are essentially quality standards. It is related to the fact that satisfaction to protocol requirements is an optimal way to perform for health professional in certain clinical case; subsequently it improves its quality.

Changes in clinical protocols occur in space (at the stages of health service provision) and in times (during the process of clinical actions). Dynamic changes of the content of stages, development and deepening of our understanding of the healthcare services lead to necessary correction of separate standard indicators in clinical protocols. They are not set forever, and they should be reviewed and improved periodically.

# **HEALTH SERVICES QUALITY PROVISION AND CONTINUOUS IMPROVEMENT AS A KEY FACTOR FOR HEALTHCARE REFORMS IN KYRGYZ REPUBLIC**

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Main goal of healthcare reforms in Kyrgyz Republic is improvement of health status of the population through health promotion, ensuring fairness of health services, cost-effective resource utilization, and cost containment practice. (2).

Ljubljana charter on healthcare reforms (1996), approved by the Ministers of Health or their representatives of all European countries, states in one of its chapters that any reform should be aimed on continuous health services quality improvement, as well as increase of its efficiency. It also should include a developed strategy of this goal attainment.

Issues of health services accessibility and quality improvement are of major importance at the current stage of healthcare reforms (5). Reforms that are carried out and implementation of the basic principles of Mandatory Health Insurance (MHI) pursue main goal that includes establishment of healthcare system as a system of patients' protection that can be achieved through provision of full volume of health services quality and efficiency.

Currently the status of healthcare facilities is being changed. They become more independent in terms of their clinical, diagnostic and administrative activities. Implementation of MHI legislatively establishes competition between healthcare facilities for patients, a right of patients to choose healthcare facility that provides health services of the appropriate quality at the level of modern requirements. Fee charged for healthcare services depends to level and volume of provided care, accordance to required quality standards, professional skills and technical equipment of the facility.

The issues of quality provision and improvement are part of the National Healthcare Reform Strategy "Manas". It requires explicit scientific analysis and justification of new approaches to health services quality in Kyrgyzstan.

Since a concept of quality was first raised in the area of health services delivery, there is an ambiguous understanding of the term "health services quality". The easiest definition of quality can be found in the works of E. Deming, who is a pioneer of quality improvement in the industry: "to do right things in a right way".

Currently quality means a set of characteristics of the object related to its ability to satisfy fixed and assumed needs. International standard describes a quality system as a system consisting of organizational framework, responsibility and resources aimed on implementation of quality administration.

Definition of health services quality was given by F. Donabedian as "accordance between actually provided health services and previously established criteria" (9). Further development of medical science and healthcare in general predetermined different understanding and interpretation of health services quality concept. In a number of cases this concept was applied to characterize execution of pure clinical activities (diagnostic methods, clinical protocols, and rehabilitation, etc.) or medical technologies. Other cases health services quality was linked with population health status indicators only, and assessed the same way. Sometimes health services quality was related to standards or indicators of quality that included volume of health services provided to the patients with different diseases.

Many researches define health services quality as application of achievements of the modern medical science and technology according to the principle of its maximized usefulness to health without increase of the risks. A quality extent was defined as provision of health services that provide the best balance of health risk and benefit, and health services cost, i.e. efficient health

services within resources that were allocated by the government and individuals to spend on health services (8).

A WHO definition of the quality aggregated different approaches to quality: “Healthcare quality means appropriate implementation (in accordance with the norms) of interventions that are known as safe, accessible to the public, and impact on mortality, morbidity, disability and malnutrition rates”. Main quality characteristics are accessibility, safety, affordability, stability of the process and outcomes, development (improvement of the process and outcomes), validity, and cost-effectiveness.

Thus, health services quality is provided by a wide range of components: professionalism and competence of the staff, efficiency and safety of used medical technologies, cost-effectiveness of the chosen methods, accessibility and comfort of health service provision, satisfaction of medical and psychological and social expectations of the patient.

Importance of implementation of a valid quality assurance system is increasing more and more due to implementation of legislative basis for health facilities’ activities expertise as a part of MHI. A fact that health system reform is addressed firstly on economic issues of the sector makes it more valuable. Healthcare system in general and healthcare facilities particularly seeks not only for the additional funding, but the ways to reduce costs of services provision. It might have negative impact on health services quality. In this regard a need in established quality control system and quality improvement reflects transition from extensive healthcare development to intensive one. It is definitely one of the key issues of healthcare reforming process.

Factors (criteria) that influence on quality assessment and control are to be clearly understood. We can divide these into two groups:

1. Selection of medical technology in each case. Medical technology is a number and certain order of various activities, prevention, diagnostic, treatment and rehabilitation methods needed for attainment of certain outcomes (4).

2. Initial condition of a facility, available human and material resources, and appropriate organizational forms.

Second group is closely related to adequacy of selected technologies and their observance. It also depend on the qualification level of healthcare professionals, including observance of ethical and deontology principles.

Currently various methods and technologies are used together with appropriate tools of quality control and assessment (7).

Quality and effectiveness dependence and interrelation with selection of medical technology determine the need to identify its benchmarks. It is also linked with development of clinical standards in terms of realistically achievable and legislatively approved types and volumes of health services at different stages and under certain conditions. Consequently, health services quality assessment means accordance of the conditions and framework of preventive, diagnostic, clinical, and rehabilitative technologies to the established standards of patient satisfaction.

Current health services quality and efficiency assessment systems are based on utilization of all three existing approaches: structural, processual, and the last priority one that is based on final outcomes. Accordingly a framework (structural standards), process (technologies) of health services provision (technology or processual standards), and health facility’s outcomes are to be standardized.

It should be mentioned that until today only two levels of health services control system were identified: intra-sectoral, and extra-sectoral. Intra-sectoral level includes healthcare facilities and healthcare authority, extra-sectoral level includes all the rest, e.g. Licensing-Accreditation System (LAS) and Mandatory Health Insurance Fund (MHIF).

We agree with some researchers (N.I. Vishnyakov et al.) (1) that suggest to identify three levels of quality control:

- control by health services provider (internal quality control);

- control by organizations that don't depend on health services consumers and providers (external quality control);
- control by health services consumers (consumer quality control).

Quality assurance is a multidimensional issue and can't include only tightened quality control. Issues of health services quality improvement moved to different level of validity and priority for all healthcare system subjects. Both health services consumer and provider are objectively interested in quality, even though they differently distribute its priorities. On the level of the society it is expressed in reduction of direct and indirect losses due to reduction of morbidity and mortality; on the level of individual enterprise due to improved labor efficiency; on the level of individual patient due to reduction of costs on health rehabilitation and in additional expenditures due to improved labor potential (3).

Existing quality control system leads only to formation of health facility or health professional penalty provision mechanism due to low quality health services provision. It is known that health care system have been developing extensively. The main attention has been paid to increase of healthcare facilities network, its logistical support and human resources provision to satisfy the need of a facility. For today all opportunities of this method are exhausted. There is need in a systematic approach to mobilization of all listed below determinants of health status improvement, time costs, risk level to patient, and cost-effective resource utilization while providing health services:

- material and technical basis, information base;
- health services management;
- qualification of healthcare human resources;
- state and behavior of patient.

As we can see this approach anticipates establishment of the quality management concept, i.e. implementation of management methods based on progressive scientific achievements into health services quality system. Health services quality control system mainly consists of multilevel monitoring of health services implementation process on the basis of integration and co-ordination of activities involved in health services quality provision. In turn it establishes a basis for continuous quality improvement.

Main goal of health services quality management is to provide maximum efficiency of healthcare resources of the country to provide population with adequate health services. Resource management, its structural relation and functioning for execution of set structure, process and outcome standards, can implement it. It is possible only under condition of labor remuneration based on volume and quality of provided health services.

Quality management system is a process aimed on provision of effective healthcare services. It is based on a set of purposeful activities in a form of closed cycle, it also includes:

- planning (data collection, analysis, development and assessment of decision alternatives, determination of objectives and goals for quality improvement, allocation of resources, development of standards and methods of quality surveillance);
- evaluation and monitoring;
- comprehensive evaluation of health service outcome and continuous quality improvement by continuous problem solving and process improvement (10).

Main principle of quality control system is integration of the efforts in health services quality management, particularly unity of the principles and close relation of abovementioned levels of quality control. Great attention is paid to internal control, which is an integral part of expertise within mandatory health insurance system. Internal control is the closest one to health services providers and consumers. It is implemented by heads of divisions that have clear picture on what are realistic possibilities of the staff. Based on abovementioned it is clear that internal control has strongly pronounced preventive features.

Following are the quality objects that directly influence on health services quality:

- resources (qualified health professionals, buildings, equipment, etc.);

- process (utilization of latest clinical and diagnostic technologies on the basis of quality standards improvement);
- outcome (achievement of planned clinical outcomes from medical, economical and social perspectives).

Definition of resource supply requirements demands development of economic mechanisms for health services quality management. Resource distribution mechanisms within and between health facilities should motivate interest in health outcomes, most rational resource utilization in healthcare system in general.

Further improvement of MHS plays an important role in establishment of competitive environment oriented on motivation of social responsibility on health services quality improvement.

At the same time quality and efficiency of health services can be significantly increased by involvement of the patient as an active partner that is interested in own health.

Health services provision management anticipates development of clinical and diagnostic standards (clinical protocols). Evidence based medicine is a basic principle that should base clinical protocol development activities.

Clinical outcomes management pays special attention to formation of adequate health facilities indicators system that should reflect outcomes and patient satisfaction degree.

Thus, main regulations of health services quality management system include:

- systematic approach that anticipates comprehensiveness and continuity;
- integration of all levels and frameworks of quality control and provision;
- standards and criteria of health services quality should be oriented on indicators of public health;
- exclusion of groundless duplication of controlling functions by the subjects of health services quality management system;
- clear differentiation of the responsibilities;
- common information space within quality management system.

Development of health services quality research is constantly changing. There is a need to seek for conditional models of social systems and characteristics marked as health services quality system models.

## **Interaction between outpatient healthcare facilities and sanitary epidemiology stations as a way to improve efficiency of PHC performance and state sanitary inspectorate**

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Review of collaboration between outpatient healthcare facilities (OHF) and sanitary epidemiology stations (SES) shows that specialists of these facilities do not perceive themselves and their organizations as a part of one common system – Primary Health Care (PHC).

Goal of this research is to review the range perspectives of collaboration between OHF and SES as PHC facilities and identify some areas of their inter-sectoral collaboration. The importance of this issue is evident for the PCH organizations. Their interaction among parts of PHC system has not been properly discussed in the literature.

PHC is a multicomponent basis for healthcare system of any country. It includes a facility network that serves as a first contact points for the population that is main consumer of health services. The need in healthcare services is related to changes in health status that often occur as

a consequence of environmental factors. Hence, PHC scope of interests and activities includes health status of the population as well as inhabiting and activity environment.

From the main PHC elements identified by WHO (1) we consider following ones related to the issue discussed in this article:

- Provision of good quality water;
- Basic sanitary conditions;
- Infectious diseases control and immunization;
- Assistance to food product supply and rational nutrition;
- Occupational healthcare;
- Patient and community education on contemporary healthcare issues.

It is important to note that environmental hygiene includes all aspects of human health, including quality of life (2). This requires control, assessment, correction and prevention of the impact of environmental factors that can negatively influence on health of present or future generations (3, 4). Advocacy for healthy life style is one of the elements that provide reason for such activities.

Due to above mentioned interaction between SES and OHF, one would define activity effectiveness on disease prevention, health maintenance and implementation of environmental hygiene at local level.

OHF specialists should be the first to react to the changes in health status of the population. This includes possible impact of harmful factors. It is obvious that OHF specialists should participate in development and implementation of appropriate programs. It would be logical to conclude that OHF execute significant volumes of the activities related to environmental hygiene services. They also should implement activities in close collaboration with organization from this sector.

In our opinion these elements not only reflect opportunities, but also oblige development of inter sectoral links aimed on the best clinical, sanitary hygiene, and social effectiveness of OHF and SES activities.

Both PHC components, OHF and SES, work in our country for many years. Currently OHF specialists evaluate relations between OHF and SES mostly negatively. They regard SES only as a regulating organization, and SES specialists also consider themselves as regulating authority. There is a need to organize and implement joint activities in the way that will enable transformation of controlling authority to collaborating organization working to achieve common goal in health maintenance and promotion. This particular approach will provide most effective sanitary inspectorate at local, and finally at the national levels.

**Long period of existence and generally positive outcomes shows the need in this system even under existing controversial standings. However our point is to improve effectiveness of systems' performance and its elements.**

Following are advantages of the system that are not implemented or unnoticed by the special lists. These advantages are based on functions and responsibilities, as well as organizational management of PHC physician and OHF in general. OHF generally posses objective information on demographic situation of the served territory, regularly conduct census, consider age, gender and social features, know morbidity structure and characteristics of patient visits.

PHC physician differs from other healthcare specialists because he/she knows the patients, their living conditions, families, community (5). These provide PHC physician with information on specific factors and conditions including: knowledge on service coverage areas, and link changes in health status of the population with realistic environmental factors. OHF physician can actually develop community educational activities in the area of environmental hygiene.

**OHF and SES have established connections on the issues of infections within population of served territory, vaccinations, food or acute occupational poisonings.**

**It is necessary to emphasize the role of family practitioner as a community leader as it was stated in 1994 at the conference of WHO and WONCA. This leadership is realized by district physicians, and with OHF activities in general. However, it will be possible to solve**

**the significant community problems only with participation of local authorities and public organizations. This area requires interaction between OHF and territorial SES as a governmental organization that have certain functions and rights (6).**

**A multi-dimensional aspect of OHF physician's activities requires certain volume of special knowledge on hygiene issues. These knowledge will enable them to work on preventive activities according to characteristics of the served population, and expand their views to investigate difficult health problems. Furthermore, they need to evaluate the problems by linking them to environmental hygiene, and finding ways and methods to solve arising problems (7).**

**OHF specialists should obtain this knowledge with assistance of new educational programs using new forms and methods of teaching. Existing programs need analysis and improvement, inclusion of the issues related to hygiene, environmental and sanitary legislation, new technologies of epidemiological research and statistical analysis, evidence based practice, etc. It will provide expansion of services interaction, activity effectiveness improvement, and will result in good health status and environment improvement.**

**Thus, there is a real need in development and improvement of intrasectoral collaboration between OHF and SES.**

## **TO THE EVALUATION OF THE ECONOMIC EFFICIENCY OF PLASMAPHERESE IN RHEUMATOID ARTHRITIS**

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Medico-social significance of rheumatoid arthritis (RA) is mainly determined by falling ill the persons are capable to work. So during last 10 years the temporal lack of capacity in Russian Federation increased in 42-43% in consequence of rheumatic disease (RD) among the reasons of all temporal disability. For that RD, including RA happened to be on II rate in cases and on III rate for the number of temporal lack of capacity days, let pass only acute inflammation of respiratory tract, injury and poisoning [1, 2, 3]. According to the national research the rheumatic diseases take in USA II rate among all the chronic illness of adults after hypertonia and every year's lack of capacity in consequence of RD is over 20 billion dollars, which is equivalent to 1% of total national products [4, 5].

Many civilized countries (USA, Great Britain, France, Japan, Sweden) concern RA as the most important state problem and special finances devoted to the solving this problem, the main idea of it increasing the effect of therapy, of initial and secondary prophylaxis medicine [6, 7, 8].

Thus, the social significance of RA is determined not only by its spreading over, but the tremendous economic damage caused to the society, patient, his family as the result of his temporal lack of capacity and disablement. So, the first 3 years 37,5 % patients lose their ability for work through the progressive tarts growing worse of destructive changes in joint for first 5 years of illness and that's why there was a revision of therapy tactics in RA in the early period of disease, including intensive methods of therapy [9, 10].

The part of economic profit getting through the using this method of treatment plays the considerable role in our society.

The economic impact of the ways of treatment RA depends on the length of the course, cost and duration of remission have been got after using this or that method of treatment. We have carried out the economic effective calculation from lowering the cost of treatment using the extracorporal and medicine method of curing RA.

The patient RA were divided into 3 groups:

I (n=34) – D-penicillaminum (DP) in combination with plasmapherese (PA),

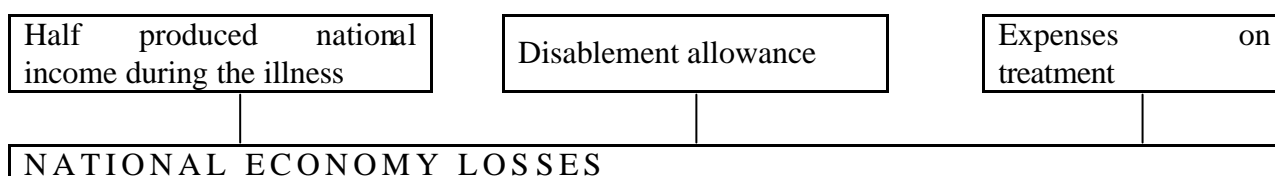
II (n=65) – cyclophosphamidum and plasmapherese,

III (n=30) – synchronous system enzymotherapy with plasmapherese.

The control groups consist of patient having the antirheumatic therapy complex without plasmapherese.

In this case the economic effects of extracorporal methods of treatment was determined on difference of economic outlay and loss, connected with the temporal lack of capacity and taking the medicine and extracorporal treatment [11].

Quantity of national economy loss was calculated as a sum of three parts:



According to the Republic statistic facts the average quantity of disablement was 391.9 tenge, the production of national income for 1 day's work of 1 person – 696.6 tenge.

The quantity of national economy expense connected with illness and treatment of 100 patients represented in fig. 1, there is the least outlay in using II therapeutic complex, some more – in the I complex and the largest is registered in using the synchronous and plasmapherese system of enzymotherapy.

Comparison of average quantity of economic effects showed that the combination with extracorporal methods in difference with medicine ways has less national economy losses for 100 patients RA in 89 402.1 tenge at the II degree and 42 200.2 tenge at the III degree .

The treatment by different complexes counting the hard rheumatoid process differently influenced in length remission. Thus, its growing up the economic effects depended on the cost of a day's illness. The biggest economic effect from increasing the length of remission is watched in treating by I therapy complex, however the patients of this group constantly took the main drug DP during 10-11 months.

Using extracorporal methods of treatment – plasmapherese, in particular advantageously differs from DP by economic effects which are 89 402 tenge, 41 200.1 tenge for 100 patients of II and III degree accordingly.

Besides, medicine treatment differs from extracorporal by side influence, preventing to continue the treatment.

Combination of cytostatic medicine and PA used for the hard form RA seemed to be more preferable than system enzymotherapy synchronous with plasmapherese according to the group of patients, first of all, on the length of keeping the clinical effects.

The total expense, connected with the treatment of 100 patients by the I therapy complex, exceeded the losses in control group in 175 918.6 tenge in the II degree of activity and 61 763.1 tenge in III degree of activity. However, these losses are leveled by increasing the length of remission of the I main group with II degree of activity, and the cost of a day's treatment when it didn't depend on using plasmapherese, was confronted in price, but in the III degree the difference achieved 797.5 tenge. Economic expense connected with the treatment of patients of

the II therapy complex in whole exceeded the losses in control group over 41 606 tenge, though for the increasing of remission a day's cost lowered in 1,4 times. In the III degree the cost of treatment equal in the both groups, but the using of extracorporeal method let prolong the remission twice and that's why to lower a day's cost in 1,7 times.

National economy losses in III main group exceeded on 6,5% in control group, but the expense were lowered in 1,7-1,9 times, it was the condition of short hospital treatment and 3-times' increasing of remission, while the expense didn't depend on difficulty of process.

So, the using of extracorporeal methods of treatment RA has definite advantage, comparing with medicine methods. It was shown in using the intensive therapy, including cytostatic medicine and plasmapheresis. In contradistinction to a long traditional therapy with D-penicillaminum, cytostatic therapy influence on immunity of RA and promote the steady remission.

Consequently, to use the plasmapheresis for treatment RA is the best of treating and must take the definite place in antirheumatic methods.

Economic expense on 100 patients RA (tenge)

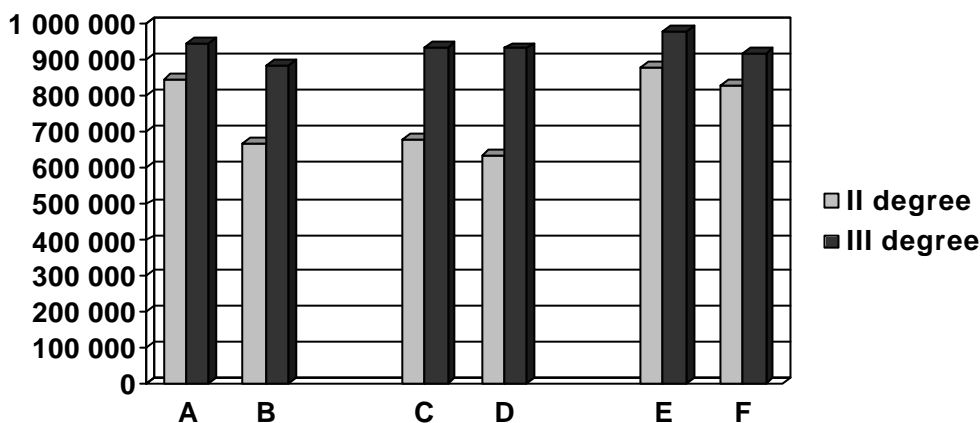


Figure 1.

A – I main group,      B – I control group,  
 C – II main group,    D – II control group,  
 E – III main group,    F – III control group.

A day's cost of treatment and remission of 100 patients (tenge)

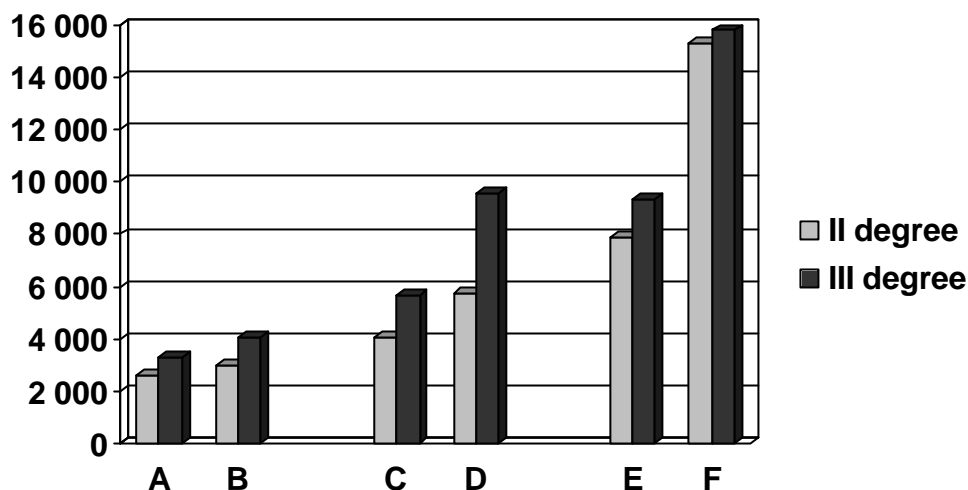


Figure 2.

A – I main group,      B – I control group,  
 C – II main group,     D – II control group,  
 E – III main group,    F – III control group.

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## REVIEWS

### Critical appraisal of published research

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#### Introduction

Reading medical journals can be time consuming, and most medical and public health specialists have become adept at skimming contents by reading titles and abstracts. Getting to grips with the details of papers and conducting a critical appraisal of the research may be a task many difficulties because they are not research experts and have not had trained in the appraisal of papers during previous education. This difficulty may be particularly acute for junior specialists embarking on their first research towards a higher degree.

The purpose of critical appraisal of a paper is to find out if the methods and results of the study are sufficiently valid to produce useful information. It is necessary to remember that the prime objective of appraising is assessing the hard facts of the study but not the authors. Sometimes a research project may be the best which could be carried out but because of unforeseen circumstances the results are of limited value.

This appraising work of the article of the researchers from Australia is just an example of critical reading of scientific paper. The paper was published in British Medical Journal, in 2001, and is a part of the Gatehouse project, which takes place in metropolitan Melbourne till present time.

**Critical Appraisal of “Does bullying cause emotional problems? A prospective study of young teenagers”** ( by Lyndal Bond, John B. Carlin, Lyndal Thomas, Kerry Rubin, George Patton BMJ 2001; 323:480-4)

#### I. Abstract

##### Objectives.

To investigate the relation between recurrent peer victimization and onset of self reported symptoms of anxiety or depression in the early teen year (average age 13). This publication is a part of large intervention study (Gatehouse project) aimed using prospective data to examine the relation between history of victimization (in year 8) and the incidence of self-reported symptoms of anxiety and depression.

##### Study design.

Prospective cohort study, which was continued over two years. In this study the cohort is categorized according to whether exposed or not exposed to a factor of intervention to promote the emotional well-being of young people (Patton et al., 2000). But in this paper intervention effects in this trial are not the main focus (Bond et al., 2001). In this part of study authors tried to explore link between repeated peer victimization and onset of anxiety and depression. For this purpose they used unmatched internal control group, which was identified after questionnaire completion (Table 1 in Bond et al. 2001). According to the results of the students' answers researchers classified subjects into two groups: exposed (victimized) and unexposed (non-victimized) (Bond et al. 2001).

##### Methods.

The authors used a cluster randomized controlled design for allocation of education districts to intervention or control status. For selection of the twelve schools from “intervention” districts and fourteen from the “control” districts they used simple random sampling.

To collect data authors used self-administrated questionnaire at school, completing of them took approximately 40 minutes, absent students were surveyed at schools at a later date or by telephone (Bond et al. 2001).

Results are based on participants for whom information about victimization and mental health status was available for all waves or who had missing data at either wave 1 or wave 2 only. Latter were defined as non-bullied and free of depression’s symptoms for the wave for which the data were missing.

As statistical tools for estimation authors used calculations of odds ratio and tested with chi-square test, robust “sandwich” estimates, multiple logistic regression using survey estimation methods (Stata Statistical Software version 6.0)

## **Results of the study.**

According to the study (Bond et al. 2001) the prevalence of victimization at the second survey point in year 8 was 51% (95% confidence interval 49% to 54%), and the prevalence of self reported symptoms of anxiety or depression was 18% (CI 16% to 20%).

The incidence of self reported symptoms of anxiety or depression in year 9 (7%) was significantly associated with victimization reported either once (odds ratio 1.94, CI 1.1 to 3.3) or twice (2.30, CI 1.2 to 4.3) in year 8.

Researchers conducted adjustment for availability of social relationships and for socio-demographic factors after simple bivariate analysis, and found that repeated victimization remained predictive of self reported symptoms of anxiety and depression for girls (2.6, CI 1.2 to 5.5) but not for boys (1.36, CI 0.6 to 3.0). And, finally, newly reported cases of bullying in year 9 was not significantly associated with prior self reported of symptoms of depression and anxiety.

## **Conclusions of the study.**

A history of victimization and poor social relationships predicts the onset of emotional problems in adolescents, especially in girls. Previous recurrent emotional problems are not significantly related to future victimization. Reduction in bullying in schools could have a sufficient impact on the emotional well-being of young people (Bond et al. 2001).

## **II. Discussion.**

### **Strengths.**

- According to Elwood (2002), who recommends to use different selection schemes to identify eligible population and participants, this study clearly follows in definition of target population (young teenagers), of source population (young teenagers, who study in districts of metropolitan Melbourne), eligible population (students of 26 schools), participants (who took part in study at least once).
- Sampling – using of cluster randomization for the allocation of education districts both to intervention and control status, and simple randomization for schools selection and as a consequence - representative sample - 3623.
- Prospective cohort study design.
- Good response rate – 2860 (79%) participated in at least one wave of data collection and 2559 (71%) provided data for this analysis.
- Low level of loss in follow-up – 8 %.

- Clear definition of victimization (four points)
- Reproducibility – self-administered questionnaire for non-clinical populations and ease of reading for young adolescents (Fleisch reading ease 78.5) (Bond et al. 2001).
- Authors used unmatched internal control group and to avoid possible confounders applied randomization for sampling and multiple logistic regression models with appropriately adjusted 95% confidence intervals (Greenland et al. 1993, cited in Bond et al. 2001 p482).
- Ethics approval was granted by the Royal Children’s Hospital ethics in human research committee. Participation was voluntary, with written parental consents required.

### **Weaknesses.**

- In description of study design and methods authors made an accent just on their randomized controlled study (Gatehouse project).
- Not clearly stated control group in this prospective cohort study.
- In final part authors have mentioned about intervention, and that the intervention “did not contain activities focusing on victimization” and data were collected during the intervention. Despite on type of activities, which didn’t concern about victimization issues, there is a potential source of bias in the study, because of possibility of indirect intervention’s influence.
- According to Cyranowsky et al. (2000) prepubescent boys are more likely than girls to be depressed, but during adolescence dramatic shift occur: between ages of 11 and 13 years, this trend in depression rates is reversed. And female predominance in depression is clearly not a new phenomenon (Wolk et al. 1995, cited by Cyranowsky et al. 2000). The authors confirmed this well-known fact. May be it would be rather important to explore problem of social relations which were excluded by multiple logistic regression from analysis as the potential confounders.
- Quality control – symptoms of anxiety or depression were diagnosed according to self reported answers but not confirmed by specialist.
- Validity – self reported cases of bullying and symptoms of anxiety and depression- what about accuracy of reports?
- There is no information about reasons of drop out from study - it could be source of possible bias.

### **III. Conclusion**

#### **Internal validity of the study.**

This study explores hypothesis about relation between recurrent peer victimization and self-reported cases of anxiety or depression among young teenagers. According to received results this hypothesis was verified.

As was mentioned above, in Discussion part, authors used random sampling for the selection of the subjects, response rate was 79%, a loss during follow-up – 8%. These points should minimize selection bias. Regarding observation bias – in this study outcomes were dependent on self-reported symptoms, without any confirmation of specialist, but in other hand may be it is more important to examine emotional well-being of young teenagers.

Bond et al. (2001) in their paper inform readers about intervention which took place in schools with intervention status. They refers to fact that this intervention “did not contain activities focusing on victimization”. But it is doubtful and could be source of bias.

Authors used unmatched internal control group, and to model potential confounders applied multiple logistic regression.

Researchers presented their data well, gave information about entire sample, number of participants, missing data and how they operated with these data. The statistical results reported in this paper are  $p < 0.05$  (Tables 2,3 in Bond et al. 2001) in regard to the difference in incidence of anxiety after repeated bullying between groups, including adolescent girls.

### **External validity of the study.**

The eligible population consists of all young adolescents, who study in 26 schools of Metropolitan Melbourne and could have been recruited in Gatehouse project but because of different reasons did not take part in the study. Participation in this study was based on voluntary will with written parental consent.

Using cluster randomization researchers have drawn the eligible population from source population – all young teenagers of Metropolitan Melbourne.

Target population of the study – young teenagers with their problems of the pubescent age. On an international basis, despite on traditions in different societies and various sociological characteristics, victimization issues are relevant (Bond, Glover 2001, Brown 2001, Simons et al. 2001).

### **Public health implication**

- Victimization is one of the many factors, which influence mental and emotional status of young adolescents. Further actions could be directed to prevention of bullying (Brown 2001) or statement how much bullying is measurable process to control. In other hand, it is important to identify other related to onset of anxiety or depression in teenagers factors.
- This paper presented just part of large study but in any case the experience of Gatehouse Project would be useful the field study in schools as settings for Health promotion activities. “The school, as a social structure, provides an educational setting in which the total health of the child during the impressionable years is a priority concern” (Allensworth and Wolford, 1998 cited in Tones and Tilford, 2001).
- This study confirmed that prevalence of anxiety or depression more higher in adolescent girls than boys.
- In frameworks of school setting probably it will be useful in future to conduct such prospective cohort study with baseline in primary school and to follow-up till finishing of high school (college).

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### **Kappa-analysis: new and old method**

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One of important aspects of understanding the measures of disease is the variability inherent in their use. In variety of readings, examinations, and findings, requiring judgement, such variability is present. The uncertainty of information obtained by interview has stimulated a desire to use more objective methods of examination, laboratory tests, skin tests, or other markers of disease in measuring morbidity whenever possible. The procedure selected depends on the component of the disease spectrum that the investigator is studying. Two aspects of these "objective" tests are important in epidemiology: accuracy or validity, and variability, reproducibility, or precision.

Two types of variability in findings interpretation were found: interobserver (which represents inconsistency of interpretation of the findings among different specialists) and intraobserver (which reflects the failure of a specialist to be consistent with himself in independent interpretations of the same set of findings).

It is possible that some proportion of the degree of agreement could have arisen by chance. In order to minimize the degree to which chance agreements affect the interpretation of such data, a measure of agreement has been developed that is known as *kappa*,  $\kappa$ . Kappa represents the difference between the observed degree of agreements plus the degree of agreement expected to occur by chance, relative to the degree of agreement that would occur by chance alone.