Toronto, Canada, 9-10 April 2002

Report of a WHO Meeting on Collaboration in Medical Genetics

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EXECUTIVE SUMMARY

A WHO meeting on Collaboration in Medical Genetics was held on 9-10 April 2002 at the University of Toronto Joint Centre for Bioethics, a newly created WHO Collaborating Centre for Bioethics. The meeting was organized to respond to the recommendations of the soon-to-be released Report of the WHO Advisory Committee on Health Research on Genomics and World Health. The purpose of the two-day meeting was to formulate a WHO collaborating strategy relevant to the goals of the Noncommunicable Diseases and Mental Health Cluster which will promote genetic services and collaboration with national centres with special emphasis on developing countries.

Main expert recommendations made for WHO were the following:

- To strengthen the human **genetics programme in WHO** in conjunction with Regional Offices and the network of collaborating centres that would prioritize the implementation of prior WHO recommendations for the prevention and control of genetic disorders and congenital anomalies, perform critical evaluation of new technologies, and assess Member States' needs in genetic services, with particular attention to the interaction of environment and genes in the causation of common diseases.

- To develop and strengthen comprehensive **medical genetic services** linked to primary health care as the key strategy for the prevention and control of conditions with genetic causation that include genetic counselling, the appropriate use of safe and effective technologies, and the support to parent/patient organizations.

- To develop **ethics capacity** in genetics in developing countries that could be implemented through WHO Collaborating Centres which would offer in-depth training and short courses; to provide international normative leadership via the updating of guidelines and the development of partnerships with genetic providers and other stakeholders bearing in mind the ethical, legal and social issues of genetics services and the application of genetic/genomic technologies.

- To assist Member States in establishing undergraduate and postgraduate **education programmes** for the teaching of medical genetics for all health professions (physicians, nurses, psychologists, public health professionals, etc); in developing training modules on genetic counselling and application of genetics/genomics technologies in clinical practice; and in improving awareness of genetics among policy makers, community leaders, patient/parent organizations, journalists, and the general public.

- To assist Member States in assembling regional expert interdisciplinary advisory groups to recommend practical **regulatory systems** which will ensure the safety and effectiveness of medical applications of new genetic/genomic technologies before they are introduced on the market.

- To encourage Member States to develop their capacity to conduct genetic epidemiological studies to evaluate the claims of **potential benefits** of genomic technologies in comparison with the well-tried and current public health approaches in health promotion and disease prevention.

- To promote a **global public dialogue** with other agencies (e.g. World Trade Organization, World Intellectual Property Organization, UNESCO, and other UN agencies) on genetics as a global public good for health, to raise resources for research into genetics and global health, to create a mechanism to tap the voice of the developing world in a systematic way, and to develop networks of collaborating centers on genetics and bioethics including professional associations and academic organizations.
1. Introduction

At the end of April 2002, the WHO Advisory Committee on Health Research (ACHR) will release its report on genomics and world health, entitled The Report of the Advisory Committee on Health Research on Genomics and World Health ("ACHR Report"). The ACHR Report addresses, among other uses of genetics, the possible applications of new genomic knowledge for health care, as well as its technological risks and ethical, social and economic implications at a global level, with special emphasis on developing countries. The ACHR Report also includes a number of specific recommendations for the WHO in the areas of genetic services and applications of genomic knowledge to improve the world's health while reducing health inequities. To respond to the recommendations of the ACHR report, the WHO Noncommunicable Diseases and Mental Health Cluster (NMH), which has a well established Human Genomics Programme and a network of Collaborating Centres, convened a group of experts in medical genetics and bioethics on 9-10 April 2002 in order to advise on strategies to implement the recommendations of the ACHR Report pertaining to noncommunicable diseases.

The purpose of the two-day meeting was to formulate a WHO collaborating strategy relevant to the goals of the Noncommunicable Diseases and Mental Health Cluster, which will promote genetic services and collaboration with national centres with special emphasis on developing countries. A number of reports of previous meetings of experts convened by WHO in the area of medical genetics and ethics were part of the background documents, as well as the Executive Summary and Recommendations of the ACHR Report and other selected documents (1-10).

Participants of the meeting were experts in medical genetics worldwide, with a predominance from developing countries, and who had long-lasting experience of working with WHO in the areas of genetics and ethics applied to health promotion and protection. Many participants were directors of existing WHO Collaborating Centres in Human Genetics. The Joint Centre of Bioethics of the University of Toronto, a newly created WHO Collaborating Centre for Bioethics, served as host of the meeting.

2. Use of genetic/genomic knowledge for the prevention and control of noncommunicable diseases

Noncommunicable diseases encompass a wide range of conditions with varying degrees of weight in the participation of genetic factors in causation. For the hundreds of known inherited single-gene diseases (hemoglobinopathies, cystic fibrosis, phenylketonuria, haemophilia, etc), DNA-based genetic testing is becoming a key tool in their diagnosis and prevention within the context of comprehensive genetic services. Most chromosome abnormalities, on the other hand, are caused by unknown factors and are not inherited; for the foreseeable future the tools for their prevention will continue to rely on screening of high risk pregnancies, with little input from the improved knowledge of the human genome. Even more challenging is the use of genetic technologies for the prevention of most common congenital anomalies for which genetic factors remain largely unknown. Fortunately, key causative environmental factors of congenital anomalies have been identified and this knowledge provides the right tools for their primary prevention (folic acid supplementation, rubella immunization, avoidance of teratogens, etc). When it comes to common diseases
resulting from environmental-gene interactions (cancer, cardiovascular diseases, mental illness, etc), DNA-based technologies will undoubtedly throw light on individual genes that confer an increased susceptibility to develop a particular disease of this kind. However, until each of these technologies proves to be effective and complements existing, well-tried health promotion approaches, it will not be clear whether this genomic knowledge will translate easily into measures for the prevention and management of diseases of environment-gene interaction.

Be that as it may, all technological developments whose application to health improvement is proven to be safe and effective will require an equitable and fair health system through which they can be delivered to the public. While this may seem obvious, the fact is that many developing countries have deficient and highly inequitable health systems. When it comes to services for the prevention and care of disorders with significant genetic causation (genetic services), their inadequacy, under-funding and inequity are of even greater magnitude. It is precisely because of this reality that previous WHO meetings of experts in medical genetics emphasized the need to implement measures to achieve a proper balance of priorities and resources allocation for the development of genetic services with a primary care approach within the context of public health (public health genetics or community genetics) (7, 8). A number of countries have followed and implemented these WHO recommendations with very good results. Examples include the prevention and control of thalassemias in Cyprus, Sardinia and Thailand, the comprehensive programme for the prevention of genetic diseases in Cuba, the maintaining of an excellent epidemiological registry of congenital anomalies in South America (ECLAMC) and many others. In addition, in line with WHO recommendations, many developing countries have developed significant human and technical resources in genetics with active professional societies and academic activities in universities. An example is the Latin American Network of Human Genetics where all professional societies of medical and human genetics are represented.

The reasons behind the lack of implementation of previous WHO recommendations on genetic services by some Member States do not reflect on their relevance or appropriateness, but rather on the combined effects of poverty, lack of resources including funding, load of infectious diseases and lack of political will on the part of some governments to prioritize health as a human right and as a public good. However, some developing countries have made a successful transition to providing an effective genetics service. Cuba is an example of a low-income country with a strong biotechnology industry and extraordinary health achievements. An objective assessment of Cuba’s achievements indicates that the primary responsible factor for both circumstances has been the political will to make health a right of all citizens. In fact, the applications of the biotechnology industry were implemented only after an equitable health system infrastructure was put in place, including a comprehensive network of genetic services.

With regards to the tension between “genetics” and “genomics”, an excessive emphasis in “genomics” has the potential to convey the wrong message that these technologies have a distinct autonomy out of the context of the delivery genetic health services or, worse, that they should take precedence before the development of an appropriate and equitable health care delivery system for disorders of genetic causation. Moreover, focus on any particular technology, however miraculous, rather than on a comprehensive health services strategy conveys a reductionistic approach to the prevention and control of genetic disorders, which could be achieved by many different approaches in addition to the application of genomics-based discoveries.
In conclusion, DNA-based genetic analysis is currently of extraordinary value for the diagnosis of single-gene diseases and has great potentiality for the determination of genetic predisposition to complex diseases. Genomic technologies are a tool that may enable the unravelling of molecular mechanisms of disease and extend the application of genetic services to many disease types, and thus contribute significantly towards global health improvement. There is, thus, no dichotomy between genetics and genomics. In accordance with the purpose of the meeting stated above and the experience of the participants in all aspects of genetic services (clinical, epidemiological, and laboratory), the recommendations to WHO that follow express the conviction that a prerequisite to harness the potentialities of genomics for health improvement in any country is the development and existence of an equitable infrastructure of genetic services linked to primary care within a community-based health system. The health system should have mechanisms to require objective assessment of the safety and effectiveness of new technologies. It should apply them to the population in the context of comprehensive services with due consideration of their ethical, social and economic implications.

All considerations about genetics and genomics, as stated in the ACHR Report (2), should be placed "in the context of the primacy of fundamental overarching strategies to improve health, for example through alleviation of poverty, development of health systems, improved education and classical public health approaches to disease control, prevention and health promotion" and "states must ensure that genome technology is used to reduce rather than exacerbate global inequalities in health status".

3. Main recommendations

After thorough discussion of the many initial strategic options proposed for the general goals outlined in the ACHR recommendations, the following seven major themes were identified. Each calls for specific actions by WHO, its network of Collaborating Centres and Member States. All of the following recommendations should be placed in the context of the overarching principles regarding genetic services, genomics-based discoveries and health equity discussed above.

3.1 Organization and staffing in Human Genetics at the WHO Headquarters, the WHO Regional Offices and the WHO Collaborating Centres in Genetics

Rationale

Through its Human Genetics Programme (HGN), the WHO has played a leading role in the development of community approaches for the prevention and control of noncommunicable diseases of single-gene causation in developing countries. Recommendations of experts' groups convened by WHO have been implemented successfully for the prevention and control of hemoglobinopathies, cystic fibrosis, haemophilia, and birth defects in countries such as Cyprus, Italy, Thailand, Brazil, China, India, Mexico, Bahrain, and Cuba. Several national comprehensive genetic services programmes have also been successfully put in place following WHO/HGN advisory groups' recommendations, a striking example being the Cuban National Programme for the Prevention of Genetic Diseases. In addition, recommendations of WHO/HGN expert groups regarding population surveillance of congenital anomalies have been successfully implemented in Europe and South America. Furthermore, the WHO/HGN has pioneered attention to ethical, legal and social issues in
medical genetics and the recommendations of its expert groups are highly regarded internationally.

With the current potential of genomic knowledge to improve health, new challenges face the world health community represented by WHO. Indeed, WHO Headquarters as well as its Regional Offices have the responsibility to lead, guide and advise Member States on the wise use of genomics-based discoveries for health improvement. To fulfil that role, the Human Genetics Programme at Headquarters should be strengthened. Given that issues in medical genetics are highly influenced by local realities (due to differences in degrees of socio-economic development, in prevalence of particular genetic diseases, in health priorities, in economic players, in lobbyists for private industry, as well as in traditions, culture and language), the WHO Regional Offices should develop the resources and capacity to implement their own genetic/genomic activities in their regions. The WHO should also make better use of existing Collaborating Centres in Genetics and Bioethics on a regional basis, for all the tasks recommended below. Furthermore, new collaborating centres should be named and a network developed. Such networks of collaborative centres will be crucial for technical cooperation, development of educational activities, training in genetics/genomics as well as fund raising. Thus, expensive duplication of same technology assessment efforts may be avoided.

**Specific actionable recommendations**

3.1.1 Strengthen WHO’s Human Genetics Programme with appropriate staff and resources to carry out all the recommendations on genetics and genomics of this report in its technical, normative and advocacy functions. The tasks of this core facility in medical genetics should include:

- Assistance to developing countries in implementing prior WHO recommendations for the development of medical genetic linked to primary health care.
- Facilitation, through the WHO Regional Offices, of intra- and inter-regional cooperation and collaboration.
- Use of the resources of the network of WHO Collaborating Centres.
- Constitution and maintenance of a task force of technical advisors in medical genetics and genomics to assist HGN in the recommended tasks.
- Facilitation of the transfer of appropriate medical genetic technologies after they are proven to be safe and effective.
- Development and dissemination of appropriate educational and training tools for health care workers and the general public in genetic services and genomics and facilitation of South-South and North-South collaboration in education and training in medical genetics.

3.1.2 Create Human Genetic Programmes in the WHO Regional Offices, to attend to the local needs of countries in the Regions in coordination with the HGN at Headquarters.

3.1.3 WHO/HGN should assess the current activities of its existing Collaborating Centres, create new ones according to needs and resources, and implement regional and global Networks of Collaborating Centres, in partnership with professional societies and universities.
3.1.4 Convene meetings in developing countries to assist defining priorities in health promotion and protection regarding noncommunicable diseases based on sound epidemiological knowledge and assessment of their impact in health.

3.2. Development and implementation of comprehensive medical genetic services within the health system

Rationale

The WHO has recognized the need for the delivery of medical genetic services to communities and populations and proposed the development of integrated medical genetic services that included primary health care approaches. It defined the purpose of medical genetic services as being to help people with a genetic disadvantage to live and reproduce as normally as possible. For these goals to be achieved, a control programme is required. The word control, derived from previous WHO initiatives for infectious diseases, was re-defined for inherited disorders to be an integrated strategy combining best possible patient care, with prevention by community education, population screening, genetic counselling and the availability of prenatal diagnosis. Succeeding WHO initiatives further developed and refined concepts for medical genetic services and control programmes, including an emphasis in primary health care involvement.

Globally a minimum 7.6 million children are born annually with a severe genetic disorder or birth defect, with 93% of these infants born in the developing world, contributing significantly to global infant mortality. As infectious diseases become better controlled, governments and health care planners should initiate and develop appropriate strategies and services for the care and prevention of genetic disorders and birth defects. The misconception still exists that medical genetic services, because of their ostensible association with expensive high-technology laboratory medicine and rare conditions, are not an appropriate endeavor for developing nations. However, although there are wide differences among developing countries, significant health improvement occurred at the turn of the century in a majority of them, leading to an epidemiological transition similar to that experienced in industrialized countries earlier in the 20th century. Close to one-half of the world’s population live in developing countries and are subjected to similar or higher rates of genetic disorders, birth defects and common complex diseases than in developed nations. Moreover, these countries, with more developing nations to follow, stand at the same medical genetic threshold as the industrialized world in 1960, yet few have well-established medical genetic services.

Consequently, a continually expanding disparity exists between medical genetic knowledge and technology and the requisite medical genetic services needed to apply this knowledge and technology in the service of people in developing countries. Justice and equity in health care necessitate the prioritization to narrow this considerable inequality in order to ensure the current and future care of those affected and the prevention of genetic disorders and birth defects in these nations, to augment both their capacity to benefit from future advances and their own contribution to this achievement.

Specific actionable recommendations

3.2.1 Encourage Member States to develop their health services for the prevention and control of diseases with genetic causation as a prerequisite for the application of genomic technologies. This could be done by convening meetings of public health experts, clinical
3.2.2 Ensure, through technical cooperation, that developing countries implement prior WHO recommendations to develop and implement comprehensive medical genetic services linked to primary health care, which include genetic counselling and the judicious use of appropriate genomics-derived advances.

3.2.3 Partnership should be strengthened with parent/patient organizations, which can play an important role in public awareness, information and education, political influence, peer support, stimulation of research, communication with the clinical and scientific/academic communities and fundraising.

3.3 Bioethics and the ethical, legal and social (ELSI) issues of genetics

Rationale

Ethical, legal and social issues permeate inextricably biomedical research in human subjects and the practice of medicine and public health. Technological advances in any discipline have renewed awareness about their ethical implications, particularly when they enable human beings to do things that were impossible in the past. Genomics technologies are no exception and, indeed, their advent and development at an exhilarating pace are challenging societies in a number of long held moral assumptions. At the beginning of the Human Genome Project it was clear in the industrialized nations leading the project, that society wanted a close ethical scrutiny of scientific research and applications. While it is debatable whether genetics and its supporting genomic technologies and genomics-based discoveries pose unique ethical issues with respect to other scientific and medical applications to health, there is consensus that their magnitude and qualitative nature are distinctive enough to warrant a leading role for WHO. This is particularly true on issues related to justice and the appalling disparities and inequities in health care throughout the world. Over the past several years, a number of international organizations and professional and scientific associations (most notably UNESCO, the Human Genome Organization and WHO itself) have tackled important ethical issues and issued declarations and guidelines on issues such as justice in access for health care for genetic disorders; potential for genetic discrimination in health access and in the workplace; threats of racism and eugenics; privacy and confidentiality of genetic information and databases; and the injustice of North-South disparity; and the unfair practices of patenting and restrictive licensing of genomics-based discoveries by many corporations and governments of the North.

In industrialized countries where most genomics research takes place, ELSI implications are the subject of scholarly work and practical applications (for example the United States ELSI programme at the National Institutes of Health). Furthermore, the extensive use for research in individuals, families and populations for the identification of genetic influences in disease has brought to the foreground the need to update ethical guidelines in genetic research and to strengthen their ethical review at national and international levels for the protection of research subjects and their communities. A major concern in this area has been the hurdles to research imposed by gene patenting and restrictive licensing by multinational corporations and governments of developed countries. Another major ethical concern is the risk of exploitation of populations of developing countries and vulnerable groups in developed countries, whose genomes may be of interest to scientists and corporations from
industrialized countries. Most bioethical initiatives in developing countries have thus far been "imported" from developed countries with built-in social, economical and cultural biases. While there are universal values and international agreed norms, developing countries do not necessarily share the same particular ethical traditions or values prevalent in the West. There is thus a need for a more global focus on bioethical issues.

The new WHO Ethics in Health Initiative is the appropriate locus from which to build on earlier initiatives (Proposed International Guidelines in Medical Genetics (9), ELSI action plan for WHO (5)) and take a strong normative leadership in ethics and genetics. Through this Initiative, WHO should work together with existing programmes in its Regional Offices, such as the Regional Programme in Bioethics in AMRO and its collaborating centres for bioethics. In addition, there should be coordination with other international agencies as UNESCO, scientific organizations as the Human Genome Organization, and governmental institutions such as the Fogarty Center of National Institutes of Health in the USA, and regional bioethics networks. It is of fundamental importance that the ethics discourse avoid an excessively theoretical approach and be tightly linked to the complex reality of populations in developing countries and their quest for social justice and the right to health.

Specific actionable recommendations

3.3.1 Ensure that the overarching principles of justice and equity in health are the basis to ethically assess the practices of private corporations, governments and academic institutions with regards to genetic services and genomic technologies, particularly with respect to intellectual property issues.

3.3.2 Assist developing countries in capacity building in ethics of genetic services and genomic technologies, which should adhere to universal values while respecting local cultural norms and traditions. Specific recommended actions include in-depth training such as Master's level postgraduate courses as well as short courses in genetics and ethics for a variety of stakeholders such as health professionals, researchers, patient organizations and policy makers. Partnerships with regional and national genetics and bioethics organizations, universities and collaborating centres on bioethics should be established to implement these actions.

3.3.3 Update guidelines for medical genetic services and develop guidelines for research ethics in genetics and genomics. Ethical guidelines should be tailored to the medical needs of Member States and be developed in partnership with genetic service providers, patient organizations and other stakeholders.

3.3.4 Assist developing countries to ensure that the development and strengthening of ethical capacities are integrated with the development of regulatory structures (discussed in section 3.5), for the protection of individuals and communities which are the subjects of genetic research, and for the protection of the public against the application of genomic technologies and discoveries of unproven safety and effectiveness.

3.3.5 Through technical cooperation, and in partnership with Regional Offices' programmes, collaborating centres and academic and professional organizations, WHO should assist Member States in the development of expertise in the particular ethical issues of genetics/genomics research within the ethics committees that review biomedical research.
Specific steps are short courses in ELSI of genetics research for members of ethics research committees at regional and national level.

3.4 Knowledge and education in genetics

Rationale

New discoveries in genomics and bioinformatics provide technological support for ongoing evolution of clinical and laboratory genetic services implemented for the improvement of global health. Societies need to be appropriately prepared to harness the potential benefits of these technologies, while avoiding its perils. In particular, it is important that health professionals, policy makers and the general public develop the necessary knowledge to be able to critically assess promises and claims that sometimes are exaggerated by misconceptions or economic interests. This can only be achieved by a major effort to increase the quality of education in this field at all levels, including health professionals, policy makers, opinion leaders, the media and the general public.

Education and training in medical genetics for health professionals is currently limited worldwide and, particularly, in developing countries, although a number of valuable initiatives exist in several countries. For example, Cuba has launched a number of relevant initiatives such as the introduction of 50 hours of genetic education in the medical schools curriculum. In addition, Cuba has instituted a six-month master level postgraduate course in genetic counselling for family physicians to implement community based genetic services as part of their nationwide programme for the diagnosis and prevention of genetic disorders.

In all Member States, there is a crucial need to improve awareness and understanding of genetics in general and its applications in health, not only among health professionals and the general public, but also among governments, health services administrators, policy makers, legislators and the media.

Specific actionable recommendations

3.4.1 Assist Member States in establishing appropriate programmes for the teaching of medical genetics to all health professions (physicians, nurses, psychologists, public health professionals, etc), both at undergraduate and postgraduate levels. Specific recommended actions are workshops for medical school leaders and faculty in developing countries to develop a core-curriculum in genetics, tailored to the national and regional needs. The WHO Collaborating Centres should be a resource for these educational and training activities, in partnership with universities and national and regional human genetic societies.

3.4.2 WHO should specifically target public health professionals and health policy makers for special courses and workshops in genetics and its relevance for public health. In addition to health professionals, important targets of workshops in genetics education are: policy makers and opinion leaders, patient/parent organizations, journalists, and the general public.

3.4.3 Contribute, through technical cooperation, to promote the development of educational materials for different targets according to local needs. Specific recommended actions are the development of training modules on topics such as genetic counselling and the application of genetics and its supporting genomic knowledge in clinical practice. Such
educational materials should harness the advances in information technology (CD roms, Internet, etc) and ensure that they are culturally appropriate. WHO Collaborating Centres in Genetics should help develop the educational materials for different targets for their own regions and countries in conjunction with local genetic professionals and other stakeholders.

3.4.4 The ethical, legal and social implications of medical genetics services and their supporting genomic technologies should be an integral part of the education in genetics at all levels and for all targets.

3.5 Establishment of simple regulatory systems for genomic technologies

Rationale

Genomic technologies have a very broad scope of potential health applications, including improving the diagnosis of infectious diseases and single-gene disorders, prenatal diagnosis, newborn screening, determination of genetic predisposition to develop complex diseases in interaction with environmental factors, gene therapy, development of new vaccines and therapeutics, and determination of individual responses to drugs (resistance, adverse reactions, etc). However, before this potential is realized, a number of issues must be recognized and acted upon. The process of development of these technologies is very complex, laborious and expensive. Even more complex is the determination of the clinical validity and utility of each technology, and the safety and effectiveness of its use in the population. Technologies are initially developed in research projects and sometimes begin to be applied in the experimental stages, when their clinical validity and utility are still not fully known. Since most of these technologies are developed by the for-profit commercial sector of industrialized countries, there is a risk that their primary goal of producing returns to investors may come into conflict with the goal of improving health with equity. Introduction of genomic technologies and genomics-based knowledge that are not in accordance with the health needs of a nation, or before their safety and effectiveness are proven, can be detrimental for health, may increase inequalities and even be exploitative of populations of developing countries (2).

However, most developing countries lack adequate systems to assess the potential harms and benefits of genomic technologies for health before they are introduced and to regulate their application within the health system.

Specific actionable recommendations

3.5.1 Assist Member States through technical cooperation to develop appropriate simple regulatory systems for the protection of subjects of genetics research and for the assessment of safety and effectiveness of genomic technologies and discoveries before their introduction and application in the health system.

3.5.2 Constitute standing interdisciplinary advisory committees to make recommendations to WHO Regional Offices and Member States on practical ways that governments can fulfil their responsibility of ensuring the safety and effectiveness of medical applications of new genomic technologies without unreasonable hurdles. While lessons learned from existing advisory committees in industrialized countries should be considered (i.e. the Secretary’s Advisory Committee on Genetic Testing in the USA, the Ontario
Commission for Genetic Testing in Canada), process and mechanisms should be adapted to the characteristics of each country.

3.5.3 Contribute to capacity building for the regulation of medical applications of genomics in the ministries of health and technology of Member States. For this purpose, national and international resources should be utilized in implementing local and regional workshops for relevant personnel for the proper assessment of genomic technologies.

3.6. Maintain a balance between conventional and well-tried approaches to health promotion and medical applications of genomics

Rationale

While there is no doubt that DNA-based genetic testing has become an essential tool for the prevention and control of single-gene disorders, the exact impact of new genomics discoveries on improving health care will only be known in years to come. The ACHR report (2) states that "there remain many uncertainties about the validity of the current predictions for the benefits to health..." that "it is vital that genomics research is not pursued to the detriment of the well-established methods for clinical practice, and clinical and epidemiological research...." and that "some of the claims for the medical benefits of genomics have undoubtedly been exaggerated".

Indeed, it is unclear whether the identification of specific gene susceptibilities will translate into safe, cost-effective and equitable strategies for the prevention of complex diseases of environmental-gene interaction. Many of these diseases (cancer, cardiovascular diseases, diabetes, obesity) have dramatically increased their prevalence in developed and developing countries. This is not due to changes in genes but rather to the action of environmental factors such as unhealthy diets, deficient physical activity, tobacco consumption, industrial contaminants and psychosocial stress. There is concern that the pressure from commercial interests of the biotechnology and pharmacological industries to introduce genomic products for determining individual genetic susceptibilities, may divert public health actions from well tried cost-effective public health approaches based on control and modification of environmental determinants that affect all the population. This is particularly worrisome in developing countries whose deficient resources and regulatory capacity make autonomous policy decisions more difficult.

WHO should thus encourage Member States to develop the capacity of their public health policy and research institutions for the critical evaluation of the safety and cost-effectiveness of potential genomic approaches for the prevention and control of noncommunicable diseases in comparison with well-tried population-based public health approaches. The evaluation should include medical, ethical and social aspects of the use of such technologies, such as best use of scarce resources, potential for stigmatization and discrimination, and potential of increasing health inequities.

Specific actionable recommendations

3.6.1 Through technical cooperation, develop the capacity of the Ministries of Health and universities of Member States to conduct genetic epidemiological studies to evaluate claims of potential benefits of the applications of genomics for the prevention and control of noncommunicable disease and compare them in their safety and effectiveness with well-tried public health approaches.
3.6.2 Organize, in cooperation with appropriate stakeholders, interdisciplinary workshops at regional levels for capacity building in the critical evaluation of applications of genomic knowledge in health promotion and protection, leading to the development of cooperative research networks for the evaluation of health applications of genomics-based discoveries.

3.6.3 Convene an annual forum on public health and genomic approaches for health improvement in developing countries, with wide interdisciplinary representation, including public health professionals, clinical practitioners, scientists, policy makers and patient organizations, to discuss the best research and policy strategies for health improvement on noncommunicable diseases in developing countries.

3.7 Promote a global public dialogue to advocate for health equity in international debates and in increasing the availability of resources for genomics research targeted to the health needs of developing countries

Rationale

Genetics research and applications, coupled with the new genomic technologies, have the potential to alter the way we conceptualize health and disease, and to give us deeper understanding of the way that genes interact in complex ways with the environment to determine our future health status. Additionally, the new technologies are being used as tools of economic activity, mainly by the industrialized world. There is much discussion of intellectual property protections, the patenting of DNA and genes, the flow of DNA and pathological specimens from South to North, and the commercialization of genetic databases. Furthermore, with the development of related technologies that might allow the use of plants to manufacture health care products and of other plants that are genetically modified to contain important food supplements, there is a growing realization of the convergence of health, environment, and agricultural technologies.

As WHO's mandate is to advocate for health and health equity throughout the world, with particular emphasis on developing countries, it can no longer leave issues such as intellectual property and commercialisation of genomic technologies to be dealt with by other organizations without its input. It has pointed out the deep interconnectedness of poverty and poor health. This Group has identified the following requirements for the achievement of health equity: (a) a balance between research development and health care provision; (b) an economic analysis of the global nature of genetic disease and available interventions; (c) a global public dialogue to foster international collaboration in health promotion and disease prevention; (d) the identification of, and increase in, resources targeted to the health needs of developing countries; and (e) the development of international mechanisms to address intellectual property and benefit-sharing issues.

A proper way to address these issues is to initiate a global dialogue through a process that will systematically address all these issues holistically, expertly, and transparently, and which will include representatives of developing countries and the various concerned stakeholders. Thus, WHO, working with its Collaborating Centres, could lead discussions with other agencies (e.g. UN agencies, World Trade Organization, World Intellectual Property Organization, etc) on how best to achieve this global public dialogue specifically focusing on genetics/genomics and all the various factors that need to be taken into account to ensure
global health equity. While intellectual property protection is a good incentive for invention and innovation, it is not a useful tool to deal with equity and justice in distributing the results of innovation. WHO and its Collaborating Centres could explore alternative approaches. It could, for example, explore the notion of genetics/genomics as a global public good for health. Global public goods have the characteristics of being non-rivalrous (when used by one, they are not diminished for others) and non-exclusive (they are available to all).

Specific actionable recommendations

3.7.1 WHO and its network of Collaborating Centres should explore ways of raising resources for research into genetics and global health and mechanisms to tap the voices of the developing world in a systematic way, so to advocate for increased public knowledge of genetics and to dissect hype from reality.

3.7.2 WHO and its Collaborating Centres should contribute to a global public dialogue on health equity in the application of genomics and genetics. Specific steps would be:

- Prepare discussion documents on genomics/genetics and on population genomic databases as global public goods for health.
- Develop further the concept of benefit-sharing and suggest mechanisms for its implementation in genetics research and application.
- Identify and link networks of stakeholders (e.g. networks of genetic professional associations, regional bioethics centres, academic organizations for equity in health) to further develop the concept of global public goods for health.
- Summarize tested and proven methods of public engagement and explore other innovative ways of public dialogue.

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