(2008) 6:1 *GenEdit,* 1-9

INVOLVING THE PUBLIC IN PUBLIC HEALTH GENOMICS: A REVIEW OF GUIDELINES AND POLICY STATEMENTS

Denise Avard[1], Gabrielle Grégoire[2], Michèle S. Jean[3]

Public health genomics raises exciting possibilities for preventing or reducing the occurrence of both rare and common disease. However, this area of research raises challenging ethical, legal and social issues that should be addressed. One way of addressing these issues is through public involvement in the policy-making process. This GenEdit reviews how international guidelines and policy statements related to public health genomics address the issue of public involvement. Key areas of discussion are the values and goals justifying public involvement, the proposed activities to increase public involvement, who is and who represents 'the public', as well as the projected outcomes of such involvement.

An important goal of genomics in public health is to prevent or reduce the occurrence of both rare and common diseases. For example, newborn screening for phenylketonuria is a model for the prevention of treatable, rare genetic disorders. The demonstrable benefit of this programme is often mentioned in the hope that similar benefits may result from the use of population screening strategies. Similarly, in the era of genome-wide association studies, it is hoped that studying the interplay of genes with environmental and lifestyle factors for common diseases such as diabetes, heart disease, and cancer can help drive preventative strategies and reduce the risk of these common diseases.

Despite the optimism associated with newborn screening programs, genome wide association studies and the use of biobanks, the intermingling of genomics with public health raises social, ethical and legal challenges that have the potential to affect the lives of many citizens. An example is Tandem Mass Spectrometry (TMS), which allows simultaneous screening of a number of conditions during the newborn period.[1] In addition, for many conditions detected by TMS, no direct medical benefit is available, thus raising ethical, legal and social concerns about expanding the use of

1. Research Director, CRDP, Université de Montréal
2. Research Assistant, CRDP, Université de Montréal
3. Chair, Canadian Commission for UNESCO

 ISSN 1718-9314

newborn screening. Moreover, samples collected for newborn screening could identify carrier status and genetic susceptibility to adult onset diseases (e.g. BRCA1/2 for breast cancer or ApoE for Alzheimer's Disease) which, if disclosed to parents, may violate the child's privacy rights.[2] Likewise, public health research using whole-genome genotyping or in the foreseeable future, whole genome sequencing technology for genetic susceptibility testing, raises several concerns,[3] including: what to tell those who participate, whether to inform the extended family, and how samples or data will be used in the future.[4]

The identification of genetic determinants using genome-wide association studies requires large biobanks and their use raises additional ethical concerns regarding data privacy and security,[5] issues of discrimination, stigmatization and social harm, as well as concerns about reinforcing genetic exceptionalism or determinism.[6] In short, as we entertain the potential for genomics to promote public health, questions arise about the appropriateness of, for example, expanded newborn screening programs, the use of genetic susceptibility testing for common diseases, and the use of biobanks.

One safeguard to address these social, ethical and legal issues is public involvement. Involving the public in a debate on emerging scientific developments, such as genomics and public health, is recognized as a timely and fruitful approach to policy making.[7] Seeking public involvement in policy development and decision-making has been recognized as an activity that will help shape the health system,[8] build greater trust in science,[9] strengthen democratic ideals and enhance trust in governments,[10] improve the relevance and translation of research into practice,[11] empower citizens,[12] improve governance,[13] and provide access to unexploited knowledge.[14]

Greater public involvement in policy development has been propelled by a range of factors including public demand for accountability,[15] and as a means to counter public anxieties associated with advances in genomics, as was the case with (GM) food.[16] Moreover, linking genetics to public health rests on the principles of justice, public goods,[17] solidarity,[18] public trust,[19] and respect for cultural, religious, legal, and social diversity.

This paper reviews how international guidelines and policy statements related to public health genomics address the issue of public involvement. We start with a brief overview of various organizations that have a mandate to work toward public involvement in general. Then, we review international policy statements that focus on public health genomics for insight into whether public involvement finds a voice in this sphere. We then focus our discussion on four questions that have been identified through an analysis of the literature on public participation: a) what are the values and guiding principles that justify public involvement? b) what are the proposed activities? c) who is, and who represents the public? and, d) what are the projected outcomes and how will these be evaluated?

Bringing the Public into Public Health Genomics

'Public involvement' in this article is used to denote interactions between the public and policy development agencies, and ranges from activities focusing on informing the public to activities that engage the public in research and policy-making.

A number of international organizations have a mandate to promote public involvement and have issued recommendations to guide the process. For example, the International Association for Impact Assessment (IAIA) created principles for public participation and plays an important role in advancing innovation and communication of 'best practices' for professional's, decision makers, and regulators.[20] Another major organization promoting public involvement is the International Association for Public Participation (IAP2), whose role is to help organizations and communities around the world improve their decision-making abilities by involving the people affected by those decisions. Their guidelines invite interested publics into the decision-making process

 ISSN 1718-9314

and show that public participation can range from informing to consulting, and ultimately, to empowering the public.[21]

Several other international organizations have developed recommendations promoting public involvement. The *Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters*, by the United Nations Economic Commission for Europe (UNECE) stresses the legal obligation of governments to involve all stakeholders (including the public), when addressing environmental issues, in order to build public accountability and transparency.[22]

Specific mandates concerning public involvement have been incorporated by the United Nations Educational, Scientific and Cultural Organization (UNESCO), which calls for public participation in their Constitution[23] and in their Directives.[24] The World Health Organization, which co-ordinates and leads on international health issues, also plays an important role in this field. The WHO Constitution, at Article 18(h), states that the functions of the World Health Assembly shall be:

> to invite any organization, international or national, governmental or non-governmental, which has responsibilities related to those of the Organization, to appoint representatives to participate, without right of vote, in its meetings or in those of the committees and conferences convened under its authority, on conditions prescribed by the Health Assembly[25]

At the regional level, the European Commission places emphasis on several approaches to public input, including parliamentary means, consultations with key organizations, and informal interactions with interested parties.[26] The Organization for Economic Co-operation and Development (OECD) has made substantial commitment to engaging the public in the policy-making process and developed guidance documents for their member countries.[27]

This brief overview broadly demonstrates the commitment of several international organizations to making the public an integral component of policy development and decision-making. This leads us to consider how "public involvement" is realized and defined in the policy statements addressing public health genomics. We searched for French and English documents published since 1995, by international and regional organizations, that included recommendations or statements about public involvement relevant to public health genetics using the following keywords: biobanks, newborn screening, genetic testing and pharmacogenomics. We categorize the results as follows.

What values and goals justify public involvement?

For purpose of this article, values are defined as beliefs, goals, or moral or ethical principles that contribute to recommendations. Most international and regional policy documents introduce the topic of public involvement by setting goals or guiding principles. We identified three recurring themes: i) building trust and public confidence, ii) demonstrating transparency and openness, and iii) a range of other goals such as: formulating culturally appropriate policies; promoting solidarity and collaboration; and stimulating democratic renewal and equity.

i) Trust and Public Confidence

Several policies state that public involvement is important for fostering trust and public confidence. In a report on confidentiality and genetic data, the International Bioethics Committee of UNESCO states the importance of discussing questions about genetic data with the public "…so as to ward off both morbid distrust and blind confidence".[28] The WHO guideline on genetic databases encourages public debate prior to establishing databases "…to heighten awareness and foster trust in the endeavour…".[29] In the context of pharmacogenomic research, the Human Genome Organization (HUGO), an international organization of scientists involved in genomic research, states that researchers have an obligation to engage the community so as "to earn the trust of the community".[30] HUGO's reference to trust is not limited to pharmacogenomics. In the context of gene therapy research, it "urges researchers, professional organisations,

 ISSN 1718-9314

sponsors and governments to listen and respond to public concerns".[31] The European Commission, in their recommendations on the use of genetic tests, maintains that:

> The successful development and use of genetic tests is dependent on the interests and concerns of a wide range of stakeholders being recognized and responded to constructively. Failure to take this into account will result in a loss of confidence by certain stakeholders and could lead to an interruption in the developmental pathway that a diagnostic test follows from innovative scientific idea to clinical utility.[32]

ii) Openness/Transparency

Several policy statements call for openness and transparency.[33] In this regard, as early as 1990, the Council for the International Organization of Medical Services (CIOMS), a non-governmental organization that plays an important role in the protection of human rights in biomedicine, stated that "…plans for the medical use of genetic findings and techniques will be made openly and responsibly".[34] The rationale behind this proposal is that public fears about genetics are in part based on misconceptions that open discussions should help redress. In addition, WHO guidelines on the operation of large genetic databases state that this "…should be carried out in an atmosphere of openness, transparency and appropriate ethical scrutiny."[35] In the same vein, the European Union, in their *Resolution on future community action in the field of public health* encourages"…that all health-related activities in the Community have a high-degree of visibility and transparency, in order to promote better knowledge and thus enable a larger involvement of citizens".[36]

iii) Other goals

The goals of public involvement are not restricted to building trust and transparency. Some policy statements recognize the need to introduce diverse public perspectives in order to foster "dialogue and cooperation […] to establish and implement genetic services in a manner that is culturally acceptable and maximizes the health benefit to patients."[37] Others place the focus on health equity,[38] or speak of democratization and the need to "…enable a larger involvement of citizens",[39] as well as give people a right to be involved in decisions that affect their lives.[40] Based on the "right to equality", Disabled People International demands to be included in debates involving bioethical issues.[41] Furthermore, the International HapMap Consortium acknowledges that in socially and culturally sensitive environments, the contribution of the public is important and should be integrated into research by allowing the public the "…opportunity to share with investigators their views on the ethical, social and cultural issues…".[42] The International HUGO Statement *on Human Genomic Databases* states that "[p]ublic engagement is a prerequisite of public responsibility".[43]

What are the proposed activities to increase public involvement?

It is important to note that terminology for public involvement activities is varied and includes terms such as information, education, communication, consultation, engagement, participation, dialogue, partnership, collaboration and input, which are often used interchangeably. While a comprehensive review of each term is beyond the scope of this paper, public involvement may be loosely grouped into two activities: i) education, and ii) direct or indirect input.[44]

Public education is best characterized as providing information to the public, and is either seen as passive--if experts act on behalf of the public, or active--if there is an exchange of views (questions and answers). Public involvement--direct or indirect--is increasingly recognized as a more meaningful approach to public participation.[45] An indirect approach suggests the one-way flow of information from the public toward policy-making bodies (eg consultation, survey), whereas direct input is described as a two-way exchange between the public and policy making bodies (eg deliberative democracy).[46]

 ISSN 1718-9314

i) Education

Education as a public involvement strategy is supported by numerous organizations.[47] The WHO promotes education as an appropriate way to "improve awareness and understanding of genetics in general, and the medical potential of genomics in particular".[48]

The World Medical Association, an international organization of physicians, recognizes the important educator role of physicians.[49] Additionally CIOMS, and several international professional associations, recognize the influential voice of professionals in helping the public understand genetics and population health.[50] Other than recognizing the important role of general practitioners,[51] geneticists are reminded that "…they have much to learn from support and advocacy groups representing those with genetic disorders";[52] that nurses and genetic counselors should educate "the public regarding the expanding role of genetics and genomics as integral components in the promotion of the public's health and well-being";[53] that researchers are considered educators,[54] and that public and private research institutes should support public education programs that communicate "correct and full information".[55] Finally, according to the Council of Europe, the media plays an important role in the dissemination of information about genetics, and are considered key players in promoting "the widest possible participation by citizens in the discussion on the human genome".[56]

ii) Direct and indirect involvement

Direct or indirect involvement includes organizations, networks and stakeholder groups from patient groups, citizens, and communities. The nature of the involvement will be considered indirect or direct. Indirect involvement is one-way communication, such as using a consultation or a survey. Direct involvement is a two-way communication process and includes citizen workshops, dialogue, and deliberative and consensus conferences. A range of direct and indirect participation tools is outlined in the OECD handbook.[57]

Our review of policy statements indicates that both consulting the public (indirect/one-way) and involving the public in the decision-making process (direct/two-way) are noteworthy for the development of public health policies.

The WHO has a longstanding interest in public involvement and recommends active participation by those interested and affected; building partnerships in decision making,[58] bringing together various cultural and religious perspectives about genetics and inheritance,[59] closer cooperation with patient and parent organizations,[60] public debates on the establishment of new genetic databases,[61] seeking the "voice" of the developing world, and developing networks of collaborating centres.[62] Furthermore, the WHO expects the World Health Assembly to "convene a public, high level meeting with the Director General",[63] to ensure the organization is appropriately informed.

As early as 1996, HUGO supported a participatory model and called for full collaboration between researchers and the community.[64] The policy statement *Principled Conduct of Genetics Research* encourages collaboration, co-operation, and co-ordination between individuals, populations, industrialized, and developing countries to promote scientific progress and as a source of "present or future benefit of all participants".[65] To further public participation in research, the suggestion is that "…where possible, representatives of participants in this research" should be involved in the review process.[66]

At the regional level, the Council of Europe creates an obligation for indirect involvement by requiring parties to "see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion […] and that their possible application is made the subject of appropriate consultation".[67]

As example of direct involvement from an interest group, Disabled Peoples' International (DPI), recommends "…the involvement of persons with disabilities at all levels in advice, information, education, and decision making concerning bioethics must be ensured".[68]

 ISSN 1718-9314

Who is and who represents the public?

The question of who is the public is an important one. There are many different "publics"; for example ordinary citizens, research participants, patients, individuals living in specific neighborhoods, and stakeholder groups representing individuals who *may* be interested in or affected by public policy. We distinguish two main categories: i) the general public (eg lay public, citizens), and ii) stakeholders representing voices from patient organizations involved in the policy-making process.

i) Several policy statements focus on the general public. For example, the WHO states that "genetic education should target the general public".[69] UNESCO's *Universal Declaration on the Human Genome and Human Rights*, and *International Declaration on Human Genetic Data* adopt a broad and diffused approach and point to the need to reach society at large.[70] The International Society of Bioethics notes that the public should comprise a broad representation of "…citizens from different backgrounds".[71]

ii) More frequently, the role of stakeholders is mentioned in policy statements addressing public health genomics.[72] The heterogeneity of stakeholder groups is vast and includes vulnerable groups,[73] support and advocacy groups,[74] persons and, more specifically, women with disabilities,[75] umbrella organizations,[76] parents,[77] patients and families, consumer groups, public watchdogs,[78] civil societies, and communities characterized by family, geography, ethnicity, or religion.[79] Such diversity of stakeholders makes it difficult to assess who represents the public in the context of public health genomics.

What are the outcomes of public involvement?

A key feature of public involvement must be the consideration of outcomes--in other words, is public involvement doing any good? While this question is increasingly raised, outcome studies are relatively rare.[80] The problem is that to get meaningful evaluations there must be clear and consistent terminology to describe public involvement, to define effectiveness, to develop evaluation designs, and to promote reliable measurement tools.[81]

The importance of outcome evaluation has been addressed in several policy statements. The WHO considers "the need to summarize tested and proven methods of public engagement and explore other innovative ways of promoting public dialogue".[82] The European Group on Ethics in Science and Technologies mentions that "studies at the community level on the interaction between research and development on the one hand, and of society on the other (dialogue between the scientific community, public perception of research and new technologies, role of the media...) should be strengthened".[83] HUGO mentions rightly that "without continuing evaluation, the potential for exploitation, duplicity, or abandonment, and abuse by all cannot be ignored. Like competence, continual review is imperative to respecting human dignity in international collaborative genetic research".[84]

Discussion

Historically, public health policies addressing, for example, newborn screening, predictive genetic testing, pharmacogenetics and genomic research using biobanks have been created by researchers and health professionals, with patients and research participants either left out of the policy development process, or if they were consulted, it appeared as lip service to the principle of public involvement.[85] Increasingly, governments and health professionals recognize the need to strengthen public involvement, and to inform, consult and actively engage the public in policy-making. It is reassuring that there is emphasis at the international level on public contribution to the development of policies in public health genomics. To help untangle the complex issues that underlie public involvement we have addressed four specific questions and noted the following:

First, two predominant values emerge in the document review: public engagement is considered important to build trust and to show openness or transparency. It is important to note some reference to the fact

 ISSN 1718-9314

that public involvement is a prerequisite to public responsibility insofar as it furthers both equity and democracy, especially in the context of culturally sensitive issues.

Second, we distinguish and categorize public participation as two distinct processes: education and participation. We note that most policy statements focus primarily on the need for education. Professional organizations tend to place the emphasis on education whereas non-governmental organizations like the World Health Organization, UNESCO, the European Commission and HUGO tend to promote two-way interactions between professionals and the public.

Third, definitions of "the public" focus on stakeholders and patient groups, however the general public is also mentioned as an important actor. Although both stakeholder groups and the general population are mentioned, they differ in their motivation. Patient groups generally focus on illness experiences, whereas the general population brings more general concerns to the discussion. It will be important to ask who represents patient groups and who represents the general population. In a multicultural society this is not an easy task. Recruiting for public participation should take into account social diversity including varying levels of education, socio-economic status, political affiliation, demographic characteristics such as age, race and ethnicity, disability, gender and sex, and religion. These characteristics and others may influence values, knowledge of the issues, and the applicability of the findings. A broad representation of the population or of stakeholder groups has the potential to produce results that will be widely accepted, as well as enhance respect between diverse groups with varying opinions, and respond to varying needs and concerns.

Fourth, evaluating the impact of public involvement is complex and underdeveloped. A major reason is that in general there is no well defined evaluation process, and thus the effectiveness of public involvement is not well known. Research in this area will be highly relevant.

Conclusion

To conclude, these are the early days of public health genomics. There is growing awareness that the door must be open for patients, patient organizations and the public to participate and explore the ethical, legal and social implications of these new developments. However, the challenges facing the implementation of public involvement are many. This review suggests that the complexity of public involvement, such as: what are the assumptions? who is the public? how, and, to what end? must be addressed. Moreover, an important question remains as to whether the outcome of public involvement is in fact made use of by policy makers.

The authors would like to thank Genome Canada and Genome Quebec for their financial support.

 ISSN 1718-9314

[1] Avard D, Vallance H, Greenberg C, Potter B, "Newborn screening by tandem mass spectrometry: ethical and social issues" (2007) *Can J Public Health* 98:284-286.

[2] Wilcken B, "Recent advances in newborn screening" (2007) *J Inherit Metab Dis* 30:129-133; Avard D, "Research and Public Health Surveillance Using Newborn Bloodspots in Canada" in Knoppers BM ed, *Genomics and Public Health: Legal and Socio-Ethical Perspectives* (Boston: Brill, 2006); Bailey DB Jr, Beskow LM, Davis AM, Skinner D, "Changing perspectives on the benefits of newborn screening" (2006) *Ment Retard Dev Disabil Res Rev* 12:270-279.

[3] McBride CM, Brody LC, "Point: genetic risk feedback for common disease -Time to test the waters" (2007) *Cancer Epidemiol Biomakers Prev* 16:1724-1726.

[4] McGuire AL, Caufield T, Cho MK, "Research ethics and the challenge of whole-genome sequencing," (2008) *Nat Rev Genet* 9:152-156.

[5] Sheremeta L, *Population Biobanking in Canada: Ethical, Legal and Social Issues* (Ottawa: Canadian Biotechnology Advisory Committee, 2003); Swede H, Stone CL, Norwood AR, "National population-based biobanks for genetic research" (2007) *Genet Med* 9:141-149.

[6] Secretary's Advisory Committee on Genetics, Health and Society, *Policy Issues Associated with Undertaking a New Large U.S. Population Cohort Study of Genes, Environment, and Disease* (Washington: Department of Health & Human Services, 2007) 1-56.

[7] Potter B**,** Avard D, Wilson BJ, "Newborn blood spot screening in four countries: stakeholder involvement," (2008) *J Public Health Policy* 29:121-142; Joly PB, Rip A, "A timely harvest" (2007) *Nature* 450:174.

[8] World Health Organization (WHO), *Ninth Futures Forum on health systems governance and public participation* (Copenhagen: WHO Regional Office for Europe, 2006) 1-34.

[9] Wynne B, "Public engagement as a means of restoring public trust in science--hitting the notes, but missing the music?" (2006) *Community Genet* 9:211-220.

[10] WHO, *supra* note 8.

[11] Tallon D, Chard J, Dieppe P, "Consumer involvement in research is essential" (2000) *BMJ* 320:380-381.

[12] Cooke M, "Arguments for Deliberative Democracy" (2000) *Political Studies* 48:947-969; Institute on Governance, *The Democratic Deficit, Citizen Engagement and Consultation: A Roundtable Report* (Ottawa: Institute on Governance, 2005) 1-16.

[13] André P, Enserink B, Connor D, and Croal P, *Public Participation: International Best Practice Principles* (Fargo: International Association for Impact Assessment Special Publication Series No. 4, 2006).

[14] Tallon, *supra* note 11.

[15] Abelson J, Giacomini M, Lehoux P, Gauvin FP, "Bringing 'the public' into health technology assessment and coverage policy decisions: from principles to practice" (2007) *Health Policy* 82:37-50.

[16] Nuffield Council on Bioethics, *The Use of Genetically Modified Crops in Developing Countries* (London: Nuffield Council on Bioethics, 2003).

[17] Knoppers BM, "Of genomics and public health: Building public 'goods'?" (2005) *CMAJ* 173:1185-1186.

[18] Knoppers BM, Chadwick R, "Human genetic research: emerging trends in ethics" (2005) *Nat Rev Genet* 6:75-79.

[19] Cambon-Thomsen A, Sallée C, Rial-Sebbag E, Knoppers BM, "Populational Genetic Databases: Is a Specific Ethical and Legal Framework Necessary?" (2005) *GenEdit* 3:1-13.

[20] Andre, *supra* note 13.

[21] International Association for Public Participation, *IAP2 Public Participation Spectrum* (Denver: International Association for Public Participation, 2005).

[22] United Nations Economic Commission for Europe, *Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters* (Aarhus: United Nations Economic Commission for Europe, 1998).

[23] United Nations Educational Scientific and Cultural Organization (UNESCO), *UNESCO Constitution* (London: UNESCO, 1945).

[24] United Nations Educational Scientific and Cultural Organization (UNESCO), *Directives Concerning UNESCO's relations with non-governmental organizations* (UNESCO, 1995).

[25] World Health Organization (WHO), *Constitution of the World Health Organization* (New York: World Health Organization, 1946).

[26] European Commission (EC), *European Governance: Towards a more coherent framework for consultation – General principles and minimal standards for consultation of interested parties* (Brussels: European Commission, 2002).

[27] Organization for Economic Co-operation and Development (OECD), *Engaging Citizens in Policy-making: Information, Consultation and Public Participation* (Paris: OECD, 2001); Organization for Economic Co-operation and Development (OECD) , *Citizens as Partners: OECD Handbook on Information, Consultation and Public Participation in Policy-Making*, drafted by Gramberger M, (Paris: OECD, 2001) 1-112.

[28] International Bioethics Committee, *Report on Confidentiality and Genetic Data* (Paris: International Bioethics Committee, 2000) at para. 81.

[29] World Health Organization (WHO), *Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights - a WHO Report* (Geneva: World Health Organization, 2003).

[30] Human Genome Organization (HUGO), *Statement on Pharmacogenomics (PGx): Solidarity, Equity and Governance* (Montreal, Human Genome Organization, 2007).

[31] Human Genome Organization (HUGO) Ethics Committee, "Statement on Gene Therapy Research" (2001) *Eubios Journal of Asian and International Bioethics* 11:98-9.

[32] European Commission (EC), *Ethical, Legal and Social Aspects of Genetic Testing: Research, Development and Clinical Application* (Brussels: European Commission, 2004) at p. 23.

[33] WHO, *supra* note 29; Council for International Organization of Medical Sciences (CIOMS), *The Declaration of INUYAMA, Human Genome Mapping, Genetic Screening and Gene Therapy* (Geneva: Council for International Organization of Medical Sciences, 1990); European Union (EU), *Decision No. 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of community action in the field of public health (2003-2008)* (European Union, 2002).

[34] CIOMS, *ibid*.

[35] WHO, *supra* note 29, reccommendation 20.

[36] European Union (EU), *Resolution on future community action in the field of public health* (European Union, 1999) at p. 574.

[37] World Health Organization (WHO), *Medical Genetic Services in Developing Countries: The Ethical, Legal and Social Implications of Genetic Testing and Screening* (Geneva: World Health Organization, 2006) at pp. 79-80.

[38] EuropaBio, *Human Medical Genetic Testing* (EuropaBio, 2004); World Health Organization (WHO), *Collaboration in Medical Genetics* (Toronto: World Health Organization 2002).

[39] EU *supra* note 36.

 ISSN 1718-9314

[40] *Ibid.*; International Bioethics Committee (IBC), *Report of the IBC on Ethics, Intellectual Property and Genomics* (Paris: International Bioethics Committee, 2002).
[41] Disabled People International (DPI), *The Right to Live and Be Different* (Solihull: Disabled People International, 2000).
[42] International HapMap Consortium, "Integrating Ethics and Science in the International HapMap Project" (2004) *Nat Rev Genet* (2004) 5: 467-475.
[43] Human Genome Organization (HUGO), *Statement on Human Genomic Databases* (London: Human Genome Organization, 2002).
[44] Abelson, *supra* note 15.
[45] Abelson J, Forest PG, Eyles J, Smith P, Martin E, Gauvin FP, "Deliberations about deliberative methods: issues in the design and evaluation of public participation processes" (2003) *Soc Sci Med* 57:239-251; Hiller EH, Landenburger G, Natowicz MR, "Public participation in medical policy-making and the status of consumer autonomy: the example of newborn-screening programs in the United States" (1997) *Am J Public Health* 87:1280-1288.
[46] Gauvin FP, Abelson J, "Primer on Public Involvement" (Toronto: Health Council of Canada, 2006).
[47] EU, *supra* note 33; World Health Organization (WHO), *Declaration of Ministers of South America Over Intellectual Property, Access to Medicines and Public Health* (Geneva: World Health Organization, 2006); Human Genetics of Australasia, *Newborn Blood-Spot Screening* (Human Genetics of Australasia, 2004).
[48] World Health Organization (WHO), *Genomics and World Health* (Geneva:World Health Organization, 2002).
[49] World Medical Association (WMA), *Declaration on the Rights of the Patient* (Lisbon: World Medical Association, 1981).
[50] CIOMS, *supra* note 33.
[51] World Health Organization (WHO), *Sickle-Cell Aneamia (Report by the Secretariat)* (Geneva: World Health Organization, 2006).
[52] World Health Organization (WHO), *Statement of WHO Expert Advisory Group on Ethical Issues in Medical Genetics* (Geneva: World Health Organization, 1997).
[53] International Federation of Human Genetics Societies, *Conclusions of the Workshop on the Science and Ethics of Eugenics* (Beijing: International Federation of Human Genetics Societies, 1998).
[54] World Health Organization (WHO), *Medical Genetic Services in Latin America* (World Health Organization, 1998).
[55] Council of Europe, *Protection of the Human Genome by the Council of Europe Doc. 9002* (Strasbourg: Council of Europe, 2001).
[56] Council of Europe, *Recommendation 1512 (2001) on the Protection of the Human Genome* (Strasbourg: Council of Europe, 2001).
[57] OECD, *Citizens as Partners: OECD Handbook on Information, Consultation and Public Participation in Policy-Making*, *supra* note 27.
[58] WHO, *supra* note 8.
[59] WHO, *supra* note 37.
[60] World Health Organization (WHO), *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services* (Geneva: World Health Organization, 1997).
[61] WHO, *supra* note 29.
[62] WHO, *supra* note 38.
[63] World Health Organization (WHO), *Statement of the WHO Expert Consultation on New Development in Human Genetics* (Geneva: World Health Organization, 2000).
[64] Human Genome Organization (HUGO), *Statement on Benefit Sharing* (Vancouver: Human Genome Organization, 2000).
[65] Human Genome Organization (HUGO), *Statement on the Principled Conduct of Genetics Research* (Human Genome Organization, 1996).
[66] *Ibid.*
[67] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Council of Europe International Digest of Health Legislation, 1997) at art. 28.
[68] Disabled People International (DPI), *Position Paper on Bioethics* (Disabled People International, 2005).
[69] WHO, *supra* note 37 at p. 69.
[70] UNESCO, *Universal Declaration on the Human Genome and Human Rights* (Paris: UNESCO, 1997); UNESCO, *International Declaration on Human Genetic Data* (Paris: UNESCO, 2003).
[71] International Society of Bioethics, *Bioethics Declaration of Gijòn* (Gijòn: International Society of Bioethics, 2000).
[72] EC, *supra* note 32; EU, *supra* note 33; McGuire, *supra* note 4; WHO, *supra* note 52; International Atomic Energy Agency, *Screening of Newborns for Congenital Hypothyroidism* (Vienna: International Atomic Energy Agency, 2005); DPI, *supra* note 68; UNESCO, 1997, *supra* note 70; UNESCO, *Universal Declaration on Bioethics and Human Rights* (Geneva: UNESCO, 2005); EuropaBio, *supra* note 38.
[73] UNESCO, 1997, *supra* note 70.
[74] WHO, *supra* note 52.
[75] DPI, *supra* note 68.
[76] European Society of Human Genetics, *Provision of Genetic Services in Europe: Current Practices and Issues* (European Society of Human Genetics, 2001).
[77] International Atomic Energy Agency, *supra* note 72.
[78] EC, *supra* note 32.
[79] HUGO, *supra* note 64.
[80] Abelson J, Gauvin FP, "Assessing the Impacts of Public Participation: Concepts, Evidence, and Policy Implications" (2006) *Ottawa, Canadian Policy Research Network Inc.* 1-39.
[81] Abelson, *supra* note 15; Rowe G, Marsh R, Frewer LJ, "Evaluation of a deliberative conference" (2004) *Science, Technology,& Human Values* 29:88-121; Abelson J, Forest PG, Eyles J, Casebeer A, Martin E, Mackean G, "Examining the role of context in the implementation of a deliberative public participation experiment: results from a Canadian comparative study" (2007) *Soc Sci Med* 64:2115-2128.
[82] WHO, *supra* note 38.
[83] European Group on Ethics in Science and New Technologies to the European Commission, *Opinion No.10 Ethical Aspects of the 5th Research Framework* (European Group on Ethics in Science and New Technologies to the European Commission, 1997) at p. 7.
[84] HUGO, *supra* note 65.
[85] Kelson M, "The NICE Patient Involvement Unit" (2005) *Evidence-Based Healthcare & Public Health* 9:304-307.

 ISSN 1718-9314