



GENINFO

Newsletter on the Ethical, Legal and Social
Issues in Human Genetics

EDITORIAL | LAWS AND POLICIES | EVENTS | TEAM PUBLICATIONS

November-December 2008



For this edition of GenInfo, we would like to first mention that our colleague, Gillian Nycum, has temporarily left her position as HumGen Coordinator for her maternity leave. We wish her all the best with the new baby!

In the meantime, it is with pleasure that I introduce Ms. Thu Minh Nguyen, as Co-Editor in Chief of GenInfo. Ms. Nguyen will be working closely with me.

Another important item is the publication of the revised version of the *Declaration of Helsinki* (Seoul, October 2008). This latest version contains substantial changes, and we invite you to consult it.

Finally, it is also a pleasure to announce the publication of a new editorial in our GenEdit. The issue is entitled: "Biobanks and Longitudinal Studies: Where Are the Children?"

Happy Reading!

Karine Sénécal and Thu Minh Nguyen

Co-Editors in Chief, HumGen International

EDITORIAL



Biobanks and Longitudinal Studies: Where Are the Children?

Julie Samuël, Nola M. Ries, David Malkin and Bartha Maria Knoppers

Abstract: The inclusion of children in longitudinal research using biobanks raises specific ethical and legal issues. This article analyzes ethical frameworks concerning participation in biobanks and suggests that such frameworks, developed in the context of competent adults as research subjects, are not adapted for research involving children. It concludes that there is a need to elaborate guidelines specific to biobanks and longitudinal studies involving children and provides recommendations regarding parental authorization, the child's assent and consent, and on the return of results in this context.

(2008) 6:3 *GenEdit*, 1-8

INTERNATIONAL / REGIONAL

International Chamber of Commerce: Access and Benefit Sharing: General Observations and Positions

Paris - May 16, 2008

Link: [URL](#)

Key Words: Benefit Sharing - Intellectual Property - Patents

NATIONAL

Canadian College of Medical Geneticists (CCMG), Canadian Paediatric Society (CPS): Guidelines for Genetic Testing of Healthy Children - Addendum

Ottawa - April 4, 2008

Link: [URL](#)

Key Words: Access Info/Material - Counseling (general) - Genetic Testing - Man/Paternity - Minor/Child - Research - Woman/Maternity

EuroGentest Network of Excellence: Recommendations for Genetic Counselling Related to Genetic Testing

Leuven - August 29, 2008

Link: [URL](#)

Key Words: Community/Population - Confidentiality - Consent - Counseling (general) - Counseling (Post-test) - Counseling (Pre-test) - Family - Follow-up - Genetic Testing - Incompetent Adult - Insurer/Insurance - Minor/Child - Patient/Participant/Individual - Privacy - Professional - Psychosocial Aspects - Right not to Know - Third Party

International Society for Biological and Environmental Repositories (ISBER): 2008 Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research

Bethesda - March 1, 2008

Link: [URL](#)

Key Words: Access Info/Material - Biobank - Communication of Results - Confidentiality - Data - DNA - Storage - Tissue

National Society of Genetic Counselors (NSGC): Direct to Consumer Genetic Testing

Chicago - January 1, 2007

Link: [URL](#)

Key Words: Carrier Status - Commercialization - Communication of Results - Competence - Counseling (general) - Counseling (Post-test) - Criteria - Family - Genetic Information - Genetic Services - Genetic Testing - Patient/Participant/Individual - Predictive Testing - Privacy - Professional - Psychosocial Aspects - Standard of Care

StemGen

For a comprehensive database of international, regional and national legislation and policies on stem cell research and related therapies, visit [StemGen](#). A unique feature of StemGen is the [STEM CELL WORLD MAP](#), which describes the policy approaches adopted in over 50 countries.

International Conference - 2020 Vision: The Impact of Science on Society

Organized by: Genome Canada

Date: October 22-24, 2008

Location: Vancouver, British Columbia, Canada

Information:

2nd Congress of the European Academy of Paediatrics

Organized by: European Academy of Paediatrics
Date: October 24-28, 2008
Location: Nice, France
Information:

ESF-UB Conference in Biomedicine - Biobanks

Organized by: European Science Foundation
Date: November 1-6, 2008
Location: Sant Feliu de Guixols, Spain
Information:

CIHR Café scientifique - "Genetic Testing: What's In It For Me?"

Organized by: Montreal Children's Hospital in collaboration with Canadian Institutes of Health Research, McGill University and l'Université de Montréal
Date: November 5, 2008
Location: Montreal, Quebec, Canada
Information: Café-Bar Le Saint-Sulpice, Montréal
suimei.chiu@muhc.mcgill.ca

Génome Québec multidisciplinary mini-symposium "Genetic Testing: the Power of Knowledge"

Organized by: Génome Québec
Date: November 7, 2008
Location: Montreal, Quebec, Canada
Information:

58th Annual Meeting of the American Society of Human Genetics

Organized by: American Society of Human Genetics
Date: November 11-15, 2008
Location: Philadelphia, Pennsylvania, United States
Information:

Workshop on Collecting, Storing, Protecting and Accessing Biological Data Collected in Social Surveys

Organized by: National Academy of Health Sciences
Date: November 17, 2008
Location: Washington, (D.C.), United States
Information:

12e Journées annuelles de santé publique : influencer l'histoire (2008)

Organized by: Institut national de santé publique du Québec
Date: November 17-20, 2008
Location: Quebec, Quebec, Canada
Information:

3rd Symposium on ethics and scientific integrity in medical research

Organized by: Respiratory Health Network of the FRSQ
Date: November 20-21, 2008
Location: Montreal, Quebec, Canada
Information:

Genes for Health

Organized by: GRaPH-Int & Human Genetics Society of Australasia
Date: May 3-6, 2009
Location: Fremantle, Australia
Information: <http://www.graphint.org/australia2009/>, Call for abstracts now open.
Deadline for submission is December 31, 2008 / Appel de résumés. Date de soumission : 31 décembre 2008.

 TEAM PUBLICATIONS

Avard D., Grégoire G., Coly B., Bucci L.M., Farmer Y., "La participation du public dans la santé publique : l'implication des communautés culturelles dans le dépistage des maladies héréditaires", (2008) 39:3 *Pratiques et Organisation des Soins*, 231-242

Abstract: In the genetic era, public participation to health services' planning is deemed particularly important, albeit infrequent. This paper argues that if research-derived health services are to be relevant to the public, the public must be actively involved. To develop successful public participation, we need to understand its aims, the different participation levels, to define the public, to identify participation mechanisms, practical challenges, and to cope with the lack of evidence to support it. We draw upon a selective review of international guidelines and the experience of a multicultural community consultation regarding sickle cell screening to address these issues. We conclude by pointing to specific challenges such as the important disparity in terminology, the necessity to evaluate the range of participation tools and their impact on health services, and the need for both educational and support measures.

Avard D., Joly Y., "**Improved Understanding of Genetic and Genomic Influences on Drug Disposition and Action: Implications for Children**", (2008) 10:5 *Pediatr Drugs*, 275-278

Abstract: [Not available]

Joly Y., Sillon G., Silverstein T., Krajcinovic M., Avard D., "**Pharmacogenomics: Don't Forget the Children**", (2008) 6 *Current Pharmacogenomics and Personalized Medicine*, 77-84

Abstract: Does the inclusion of children in pharmacogenomic research raise new ethical issues? Through an exploration of the relevant laws, policies, guidelines and literature, we have identified five areas of concern and assessed their potential impact. These include (1) the difficulty of assessing risk and the ethics of invasive sampling, (2) the consent and assent process, (3) the circumstances under which and to whom the results of trials should be returned, (4) the effect of pharmacogenomics on identifying and treating orphan groups, and (5) the effect of pharmacogenomics on the pediatric drug approval process and patient recruitment. We conclude that while including pharmacogenomics in research projects involving children does indeed raise ethical concerns, none of these are insurmountable, and in fact, pharmacogenomics provides a promising outlook for the development of research that will benefit children.

Knoppers B.M., "**Of biobanks: medical data and population genetics: whither identifiability?**", *La protection des données médicales. Les défis du XXI^e siècle/The protection of medical data. Challenges of the 21st century*, L.G.D.J., France, 2008, 79-88

Abstract: [Not available]

Knoppers B.M., Brand A.M., "**From Community Genetics to Public Health Genomics - What's in a Name?**", (2008) 12 *Public Health Genomics*, 1-3

Abstract: [Not available]

Nycum G., Avard D., Knoppers B.M., "**Familial communication of genetic information: experiences and complexities**", (2008) 12:2 *Network News*, 18-20

Abstract: A variety of factors influence the communication of genetic information within families. In the case of breast cancer for example, the issues can overlap and combine in ways that give rise to conflicting obligations. Moreover, in most cases, a failure to communicate does not appear to be active or intentional, but rather it is either passive or the outcome of carefully measured balancing of different approaches to protecting family members and the family environment. Whether there is a moral or a legal obligation to disclose genetic information within families cannot be considered in isolation from the multiple and potentially compounded complexities that weigh into deliberations about this communication.

Potter B.K., Avard D., Entwistle V., Kennedy C., Chakraborty P., McGuire M., Wilson B.J., "**Ethical, Legal, and Social Issues in Health Technology Assessment for Prenatal/Preconceptional and Newborn Screening: A Workshop Report**", (2009) 12:1 *Public Health Genomics*, 4-10

Abstract: Prenatal/preconceptional and newborn screening programs have been a focus of recent policy debates that have included attention to ethical, legal, and social issues (ELSI). In parallel, there has been an ongoing discussion about whether and how ELSIs may be addressed in health technology assessment (HTA). We conducted a knowledge synthesis study to explore both guidance and current practice regarding the consideration of ELSIs in HTA for prenatal/preconceptional and newborn screening. As the concluding activity for this project, we held a Canadian workshop to discuss the issues with a diverse group of stakeholders. Based on key workshop themes integrated with our study results, we suggest that population-based genetic screening programs

may present particular types of ELSIs and that a public health ethics perspective is potentially highly relevant when considering them. We also suggest that approaches to addressing ELSIs in HTA for prenatal/preconceptional and newborn screening may need to be flexible enough to respond to diversity in HTA organizations, cultural values, stakeholder communities, and contextual factors. Finally, we highlight a need for transparency in the way that HTA producers move from evidence to conclusions and the ways in which screening policy decisions are made.

Potter B.K., Avard D., Graham I.D., Entwistle V.A., Caulfield T.A., Chakraborty P., Kennedy C., McGuire M., Griener G.G., Montgomery M., Wells G.A., Wilson B.J., **"Guidance for considering ethical, legal, and social issues in health technology assessment: Application to genetic screening"**, (2008) 24:4 *International Journal of Technology Assessment in Health Care*, 412-422

Abstract: [Not available]

Stanton-Jean M., Callu M.F., **"Participation des usagers et pratiques cliniques"**, (2008) 3 *Pratiques et Organisation des Soins*

Abstract: [Not available]

Tassé A.M., Godard B., **"L'encadrement législatif de la vente directe des tests génétiques et le système de santé québécois"**, (2007) 15 *H.L.J.*, 441

Abstract: The increasing availability of direct to consumer genetic tests, particularly over the Internet, raises a number of difficult to answer legal questions for health care professionals. While lawmakers have enacted an exhaustive legislative scheme aimed at ensuring the efficiency and universality of publicly funded health care, genetic services sold outside the public system. An analysis of both Quebec and Federal legislation highlights the gaps in the current legal framework with regards to freely available genetic services. The varied impact of failing to address direct to consumer sales of genetic testing services is identified, including implications for consumer protection, control and regulation of testing, and their integration into the public health care system. According to this analysis, resolving these problems, in light of the need for consumer protection, and controlling the use of genetic tests is an essential first step towards the integration of genetic services into the public health care system.

 EDITORIAL TEAM

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