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Guidelines for the screening of newborns were first introduced some 30 years ago. The fact that a majority of countries have now published their own guidelines for newborn screening testify to the importance of this particular subject. Thus the focus of this latest issue of GenInfo is on the screening of newborns. I invite you to first have a look at the latest issue of GenEdit entitled "*Newborn Screening, Banking and Consent*", and then browse through our FAQ section, also dedicated to this important topic.

Essential texts this month include the final report of the Australian Law Reform Commission on *Gene Patenting and Human Health* and UNESCO's International Bioethics Committee third outline of a *Declaration on Universal Norms in Bioethics*.

**NEWS**

The News section of GenInfo provides a brief listing of events for the coming year (organized by our team or linked organizations). We are also pleased to include a publications section with a summary of books, articles and editorials published by members of our team.

EVENTS

OCTOBER 2004

Symposium on Breast Cancer "S'informer pour Vaincre"

Date : October 2, 2004

Location : Hyatt Hotel (Complexe Desjardins), Montreal

Host : Réseau Québécois pour la Santé du Sein

Description : Invited speakers will present on the theme: What's new in diagnostic and surgical techniques, treatment and research?

The psychosocial aspects related to breast cancer will also be examined. This conference is open to the public. "Continuing education" credit is available for members of the medical community.

For additional information, contact Huguette Martin : Hmartin@rqss.qc.ca

La génomique et la vie socio-économique : assurance et emploi (IN the **Genomics and Public Health** conference series)

Date : October 4, 2004 at 12pm

Location : University of Montreal, Faculty of Law, salon des professeurs, A-3464

Host : Canada Research Chair in Law and Medicine

Description : Guest speaker: Yves Millette, Vice-President, Quebec Affairs, Canadian Life and Health Insurance Association. This conference is open to the public.

For additional information, visit : <http://www.crcdm.umontreal.ca>

Dix-Septièmes Entretiens du Centre Jacques Cartier "Oncogenetics : Achievements and Challenges"

Date : October 7 & 8, 2004

Location : Crowne Plaza, Montreal

Hosts :

- Centre Jacques Cartier, Dix-septièmes entretiens
- The National Centre for Scientific Research(France)
- CIHR, INHERIT BRCA's (Canadian Institutes of Health Research, Interdisciplinary Health Research International Team on Breast Cancer Susceptibility)
- Université de Montréal, Canada Research Chair in Law and Medecine
- Université de Montréal, Centre de recherche en droit public
- Université Laval, Canada Research Chair in Oncogenetics

Description : World experts will discuss the latest developments, as well as achievements and challenges in cancer genetics. The topics will include genetic susceptibility to breast, ovarian, paediatric, gastro-intestinal cancers, as well as multiple endocrine neoplasia, and hereditary cancer management.

Registration fee :

Regular Rate : \$300

Student Rate : \$150

For additional information visit: <http://www.humgen.umontreal.ca/CJC/> or contact Lucie Bucci

Dix-Septièmes Entretiens du Centre Jacques Cartier "Allocations des ressources en santé, enjeux, perspectives et choix éthiques et bioéthiques"

Date : October 7&8, 2004

Location : Université du Québec à Montréal (UQAM), room D-2000, Pavillon Athanase David, 1430 St. Denis

Hosts :

- Centre Jacques Cartier, Dix-septièmes entretiens
- Centre de Recherche en Éthique de l'Université de Montréal (CREUM)
- Canada Research Chair in Law and Medicine
- Institut de Formation et de Recherche sur les Organisations sanitaires et sociales et leurs réseaux (IFROSS)

Description : The main themes of the symposium are: 1) resources allocation: a new approach for the beginning and the end of life; 2) health policy and the aging population; 3) health services organizations: economic and ethical considerations; 4) access to healthcare: challenges and international perspectives.

Registration fee :

before September 20, 2004: \$135

after September 20, 2004: \$150

student rate: \$50

To register or for additional information, visit : <http://www.humgen.umontreal.ca/conf/allocationssante> or contact Michèle S. Jean (514) 343-6111 ext. 1449 or Marie Angèle Grimaud (514) 343-2138, or email : ejc.allocsante@umontreal.ca

La génomique et la santé publique : quel public ? (as part of the **Genomics and Public Health** conference series)

Date : October 20, 2004 at 12pm

Location : University of Montreal, Faculty of Law, salon des professeurs, A-3464

Host : Canada Research Chair in Law and Medicine

Description : Guest speaker: Christian Hervé, Professor and Director of the Medical Ethics, Health Law, and Public Health Laboratory, Paris.

This conference is open to the public.

For additional information, visit <http://www.crcdm.umontreal.ca>

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

Godard B., Marshall J., Laberge C., and Knoppers B.M. "Strategies for Consulting with the Community : The case of four large-scale genetic databases" *Science and Engineering Ethics* Vol. 10 No. 3, pp. 457-477.

Abstract : Large-scale genetic databases are being developed in several countries around the world. However, these databases depend on public participation and acquiescence. In the past, information campaigns have been waged and little attention has been paid to dialogue. Nowadays, it is important to include the public in the development of scientific research and to encourage a free, open and useful dialogue among those involved. This paper is a review of community consultation strategies as part of four proposed large-scale genetic databases in Iceland, Estonia, United Kingdom and Quebec. The Iceland Health Sector Database and Estonian Genome Project have followed a "communication approach" in order to address public concerns, whereas, UK Biobank and Quebec CARTaGENE have chosen a "partnership approach" to involve the public in decision-making processes. Following a comparison of community consultation strategies, the main concerns of the public are examined as well as the challenges of involving communities. Importantly, reported across all groups is the concern for confidentiality, respect of the individual, transparency, and the donor's right to access to their own result. However, even if researchers demonstrate a willingness to respect values such as fair representation, transparency and accountability, there is still a risk that the public will mistrust researchers and simply will not participate in sufficient numbers. Complications may arise when individual and community interests conflicts. The implementation of a partnership approach is definitely involving and costly; however, if used properly, this method can improve both participation and so database development.

Joly, Y., La pharmacogénomique : perspective et enjeux éthico-juridique, *Lex Electronica*, vol.9 n°3, Summer 2004, <<http://www.lex-electronica.org/articles/v9-3/joly.htm> > (date accessed : September 9, 2004).

Abstract : Pharmacogenomics is the study of whole genomes or substantial amount of genes involved in individuals' response to medicine. This new technique of drug development promises great benefits, but it also raises ethical, legal and social issues. This article analyses some of the ethical issues raised by pharmacogenomics using a method inspired from the principlism approach developed by Beauchamp et Childress.

Knoppers B. M., "Biobanks: simplifying consent" *Nat Rev Genet*. Vol. 5 No. 7, p. 485. (commentary)

Mbulu, H., « De la dignité de la vie à la dignité de la personne humaine : quelques distinctions dans le débat sur les techniques génétiques », *Lex Electronica*, vol. 9, no 3, Été 2004, < <http://www.lex-electronica.org/articles/v9-3/mbulu.pdf> > (date accessed : September 9, 2004).

Abstract : In this article, the author argues that from an ethical and legal standpoint, human dignity does not necessarily extend to the foetus or to the embryo.

Sheremeta L., Knoppers B. M., "Beyond the Rhetoric: Population Genetics and Benefit Sharing" *Health Law Journal* Vol. 11, pp. 89-118.

Abstract : In light of the trend towards population genetic research and the widening gap between the developed and the developing world, mechanisms are required to ensure that the benefits of this scientific revolution can be shared equitably.



GENEDIT

The primary focus of the editorial GenEdit, which is exclusively written for HumGen, is to enhance our current understanding of policy statements related to human genetics through comparative legal, social and ethical analysis.

CURRENT ISSUE

Volume II No.3
Newborn Screening, Banking and Consent
Claude Laberge, Linda Kharaboyan, Denise Avard

Newborn screening (NBS) programs are implemented as government sponsored public health initiatives. They aim to identify infants affected by inborn disorders that can result in mortality or lifelong disability if left untreated. This edition of GenEdit critically examines how existing guidelines and policy statements have addressed: (I) consent to screening for treatable diseases; (II) consent for untreatable diseases/ and a wider range of disorders; (III) consent to storage; and (IV) consent to future uses of stored samples. Finally, we conclude with a few recommendations to help address the issues of informed decision-making.

PAST ISSUES

Volume II No.2
Genetics and Life Insurance : A Comparative Analysis
Trudo Lemmens, Yann Joly, Bartha M. Knoppers

Volume II No.1
Protecting Genetic Information: A Comparison of Normative Approaches
Patricia Kosseim, Martin Letendre and Bartha Maria Knoppers

Volume I No.1
Stem Cells in a Pluralistic Society: Consequences of Proposed Canadian Legislation



NEW LAWS & POLICIES

The following section contains new policy (legal, ethical) statements on human genetics from international, regional and national sources.

We are constantly searching for documents to enrich our data bank. If your organisation has published policy statements relating to genetics, or if you are aware of such new publications, please be kind enough to **send us** the relevant information and we will consider including them in the data bank.

German National Ethics Council, *Biobanks for Research*, Berlin, March 17, 2004, http://www.ethikrat.org/english/publications/Opinion_Biobanks-for-research.pdf (date accessed: August 26, 2004).

This Opinion relates exclusively to biobanks used for medical research. These are deemed to include biobanks containing samples and data originally collected or recorded for medical purposes – e.g. diagnosis – but subsequently to be employed for medical research (for instance, specimens for cellular examination in pathology departments, DNA samples in human genetics departments, or blood samples collected in the course of neonatal screening).

Biobanks are an important resource for identifying the causes and mechanisms of a large number of diseases, including in particular ones that are widespread among the population. Our ever greater understanding of the human genome is increasingly making it possible to determine the role not only of external factors such as environmental agencies or lifestyle, but also of hereditary factors (genes) in the causation of or disposition to disease (genetic epidemiology). Genetic epidemiology studies not the individual but population groups.

Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council, *A Patent System for the 21st Century*, Washington, D.C., 2004, <http://www.nap.edu/books/0309089107/html/> (date accessed: August 26, 2004).

Patents on novel, useful inventions - and copyrights on works of art, literature, and other forms of expression - are issued on the assumption that although firms and individuals have many incentives to create, some innovations are more likely to be forthcoming and attract investment if inventors are granted exclusive ownership rights. These rights give inventors opportunities to recoup initial investments by temporarily impeding imitators. In exchange for periods of exclusivity, inventors must disclose the knowledge underlying their creations - knowledge that may in turn lead to further innovation. The committee - made up of experts in areas such as biotechnology, intellectual-property law, engineering, business management, pharmaceuticals, and telecommunications - recommended several measures to maintain the patent system's strength in some areas, or to enhance it in others.

Coriell Institute for Medical Research, *Policy for the Responsible Collection, Storage, and Use of Samples from Named Population for the NIGMS Human Genetic Cell Repository*, August 25, 2004, <http://locus.umdnl.edu/nigms/comm/submit/collpolicy.html> (date accessed: September 2, 2004).

This document describes the policy under which the NIGMS Human Genetic Cell Repository will obtain and distribute samples from groups of individuals from named populations with the objective of including the samples in the Human Variation Collection (in which samples are identified as coming from the members of a particular population). Such samples are typically used for research in which groups, rather than individuals, will be the fundamental unit of analysis and in which inter-group comparisons will be a primary goal (for example, population genetics or genetic epidemiological studies).

The UK Biobank, *Sample Handling and Storage, Subgroup Protocol and Recommendations*, Manchester, July 07, 2004, <http://www.ukbiobank.ac.uk/Sample%20Storage%20report/Sample%20Handling%20and%20Storage%20Subgroup%20report%20for%20comment.pdf> (date accessed: August 26, 2004).

This document summarises the work and recommendations of the UK Biobank Sample Handling and Storage subgroup. The group went through several iterations of process development to produce the draft set of recommendations described here on:

- blood collection protocols and volumes;
- blood transport (process, temperature and recommended transit times);
- blood processing protocols (fractionation protocol, pre-storage biochemistry);
- storage of blood fractions (temperatures, storage formats);
- structure and organisation of UK Biobank involved in the processing of blood samples.

Gene Therapy Advisory Committee, *Operational Procedures for the Gene Therapy Advisory Committee in its Role as the National Ethics Committee for Gene Therapy Clinical Trials*, London, June 12, 2004, <http://www.advisorybodies.doh.gov.uk/genetics/gtac/sop12june2004.PDF> (date accessed: September 2, 2004).

This document gives guidance on the procedures that should be followed in the United Kingdom when proposals are made to conduct gene therapy research on human subjects. It details the information that should be submitted in order to enable the Gene Therapy Advisory Committee (GTAC) to assess the acceptability of gene therapy research proposals. It also sets out GTAC's practices and procedures to meet its obligations as the national research ethics committee for gene therapy clinical research, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Sydney, August 31, 2004, <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/> (date accessed: September 2, 2004).

In December 2002, the federal Attorney-General asked the ALRC to examine the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues.

The ALRC released an Issues Paper, [Gene Patenting and Human Health \(IP 27\)](http://www.austlii.edu.au/au/other/alrc/publications/issues/27/) <<http://www.austlii.edu.au/au/other/alrc/publications/issues/27/>> in July 2003, which defined the scope of the inquiry and outlined questions for discussion.

A further consultation paper, [Gene Patenting and Human Health \(DP 68\)](http://www.austlii.edu.au/au/other/alrc/publications/dp/68/) <<http://www.austlii.edu.au/au/other/alrc/publications/dp/68/>>, was released in March 2004.

The final report, [Genes and Ingenuity: Gene Patenting and Human Health \(ALRC 99\)](http://www.austlii.edu.au/au/other/alrc/publications/reports/99/) <<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>> was delivered to the federal Attorney-General before the reporting deadline of 30 June, 2004 and was tabled in federal Parliament on 31 August, 2004.

The International Federation of Gynecology and Obstetrics (FIGO), *Recommendations on Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health*, London, November 2003, http://www.figo.org/content/PDF/ethics-guidelines-text_2003.pdf (date accessed: September 2, 2004).

The Committee has issued guidelines on a number of ethical issues, which have been published in collected form in November 2003 in a booklet entitled "Recommendations on Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Study of Ethical Aspects of Human Reproduction".

Human Genetics Commission, *Choosing the Future: Genetics and Reproductive Decision-making*, London, July 2004, <http://www.hgc.gov.uk/choosingthefuture/ChooseFuturefull.pdf> (date accessed: September 2, 2004).

The Human Genetics Commission (HGC) advises the UK Government on the ethical, legal, social and economic aspects of developments in human genetics, as well as their effects on health and healthcare. In undertaking this project, HGC established a Working Group to examine the implications of developments in human genetics for the kinds of choices facing people having children, and the wider social impact of these choices. The terms of reference and membership of the Working Group are given in Annex 1.

Progress in molecular biology means we know an increasing amount about our genetic make-up. It also means that we can know more about the genetic make-up of our children. While many people welcome progress in genetic science and what it means for identifying and reducing the risk of having children with genetic disorders, some concerns have been expressed about the impact of this science not only on society generally, but also on our understanding of the meaning and value of human life.

The European Association for Bioindustries (EuropaBio), *Human Medical Genetic Testing. A EuropaBio Position Paper*, Brussels, May 2004, http://www.europabio.org/articles/article_317_EN.doc (page accessed: September 9, 2004).

This position paper has been prepared by EuropaBio, the European Association for Bioindustries, and includes input from independent experts. It is intended for policy-makers and the public at large.

Genetics & Public Policy Center, *Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, Preliminary Policy Options Related to the Genetic Testing of Human Embryos*, Washington, 2004, [http://www.dnapolicy.org/downloads/pdfs/policy_pgd.pdf;\\$sessionid\\$2WDPIC1AAASWACOBAT3RNWQ](http://www.dnapolicy.org/downloads/pdfs/policy_pgd.pdf;$sessionid$2WDPIC1AAASWACOBAT3RNWQ) (date accessed: September 9, 2004).

The report by the Genetics and Public Policy Center at Johns Hopkins University outlines policy options to address the scientific and ethical challenges raised by genetic testing of human embryos.

The Bioethics Council of New Zealand, *The Cultural, Ethical and Spiritual Dimensions of the Use of Human Genes in Other Organisms*, Wellington, August 2004, <http://www.bioethics.org.nz/publications/human-genes-final-report-aug04/cultural-ethical-and-spiritual-dimensions-of-human-genes-in-other-organisms.pdf> (date accessed: September 9, 2004).

This document is the first major report by Toi te Taia the Bioethics Council to the Minister for the Environment on a dialogue with members of the New Zealand public. It focuses on the cultural, ethical and spiritual aspects of biotechnology.



DRAFTS

The Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research*, Strasbourg, June 30, 2004, http://www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/Activities/Biomedical_research/Protocol_Biomedical_research.pdf (date accessed: August 27, 2004).

The Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on biomedical Research was approved by the Steering Committee on Bioethics (CDBI) on 20 June, 2003. The Draft Protocol has been submitted to the Committee of Ministers of the Council of Europe. They will consult the Council of Europe's Parliamentary Assembly for an opinion, prior to proceeding to examination of the draft Protocol with a view to its adoption. The Draft Protocol will be the first international legally binding instrument to address the whole field of biomedical research on human beings i.e. it is not confined to pharmaceuticals.

Singapore/Government, *The Human Cloning and Other Prohibited Practices Act 2004, Bill No. 34/2004*, July 20 2004, <http://www.parliament.gov.sg/Legislation/Htdocs/Bills/0400034.pdf> (date accessed: September 2, 2004).

An Act to prohibit the placing of a human embryo clone in the body of a human or an animal and certain other practices associated with reproductive technology. Be it enacted by the President, with the advice and consent of the Parliament of Singapore, as follows: [. . .]

International Bioethics Committee (IBC), United Nations Educational, Scientific and Cultural Organisation (UNESCO), Elaboration of the Declaration on Universal Norms on Bioethics: Third Outline of a Text, Paris, 27 August 2004, http://portal.unesco.org/shs/en/file_download.php/49171e727c7935ea103ffb385a3ae6c3PublicOutline3_en.pdf (date accessed: September 9, 2004)

This third version of an outline of a Declaration on Universal Norms on Bioethics was elaborated by the Drafting Group of the International Bioethics Committee at its Fourth Meeting, held in Paris from 25 to 27 August 2004, immediately after the Eleventh Session of IBC (Paris, 23-24 August 2004). This outline is not complete. It is not to be considered definite but as a step in the drafting process of the Drafting Group and of the IBC in its entirety.



Q What is newborn screening?

A Newborn screening (NBS) programs are implemented in all Canadian provinces and territories as well as in most industrialised countries around the world.

The aim of NBS is to identify newborns at risk of developing disorders that may not be readily identified by medical practitioners and which can result in mortality or lifelong disability in the absence of immediate treatment. Most newborn screening programs today offer screening for Phenylketonuria (PKU) and congenital hypothyroidism (CH), which are hereditary disorders that are universally screened for because they are rare and initial symptoms are either minimal or too vague to lead to timely diagnosis.

Since health is a matter of provincial jurisdiction in Canadian law, each province decides which disorders to include in their NBS panel. Quebec currently screens for PKU and CH and tyrosinémie.

Q Is consent required for newborn screening?

A According to Quebec's Civil Code (CCQ), in principle, explicit parental consent is required for all medical interventions performed on minors who are not able to provide consent. In the case of NBS, current practice in Quebec demonstrates that when screening for treatable disorders, informed refusal is preferred to explicit informed consent. Consent is presumed and justified on the basis that when a disease is treatable, a newborn has the right to be screened and treated. This approach has been adopted by these three tests being explicitly considered as routine tests by the Collège des Médecins du Québec.

Currently, there are no untreatable disorders included in Quebec's newborn screening panel. In the future, if such diseases were to be included, explicit parental consent would be required according to existing best practice guidelines.

In all cases, parents have the right to be informed of the diseases tested for, as well as the goals and objectives of the screening program.

Q What questions can be foreseen by the banking and subsequent use of newborn bloodspots?

A Each blood specimen taken from the heel of newborns is screened and is then kept for approximately one year for confirmatory testing. In addition to quality assurance, sometimes specimens are kept for longer periods for different purposes such as research, post mortem identification and diagnosis.

Outside of Quebec, when samples are stored in an anonymized fashion (where personal identifiers or links with individual identity are removed) consent is not required for subsequent use. However, research using identified samples (those labeled with personal identifiers such as name), or coded samples (those labeled with a code to protect the individual) requires explicit consent. The same is true with regards to third party access to stored samples.



Your Feedback

We believe that information exchange is a two-way process and we would appreciate some feedback concerning your thoughts on this new format for the GenInfo Newsletter. The following is a brief survey and your opinion will allow us to tailor future newsletters to serve you better.

1. How would you describe yourself? Specify, if possible.

Specify

2. How useful do you find the information that is provided by GenInfo?

Not useful

Very useful

1 2 3 4 5 6 7 8 9 10

3. With the information that has appeared in GenInfo, have you taken any of the following measures after reading it? (Check all that apply)

You have :

Other

4. How could we improve GenInfo so that it responds to your needs?



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