Ecole Européenne d'Eté de Droit de la santé et Ethique biomédicale

30 juin - 8 juillet 2011

Salle de Conférences Faculté de médecine de Rangueil
133 Route de Narbonne - Toulouse

Français / Anglais avec traduction simultanée

Dirigée par : Anne-Marie DUGUET

Secrétariat scientifique : Bénédicte Bévière et Marion Faures

Organisée avec le soutien de la Région Midi-Pyrénées

En partenariat avec : l'European Association of Health Law, l'équipe 4 de l'unité 1027 de l'INSERM, la Fédération Française des Associations de Médecins Conseils Experts

Les projets Européens du FP7 : TECHGENE, GEN2PHEN et GEUVADIS

L'Ecole Européenne d'Eté de Droit de la Santé et Ethique Biomédicale est organisée avec le soutien du Ministère de l'Education Nationale de l'Enseignement Supérieur et de la Recherche

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Universités et organismes partenaires de l'Université Européenne d'été

Ecole Européenne d'été de droit de la santé et éthique biomédicale
European Summer School on health law and bioethics

Toulouse 30 juin/ 7 juillet 2011
Toulouse June 30/ July 7 2011

Salle de conférences Faculté de médecine 133 Route de Narbonne - Toulouse

LIVRE DES RESUMES
ABSTRACTS BOOK

Le comité d'organisation remercie tout particulièrement pour leur soutien :

Le Ministère de l'enseignement supérieur et de la recherche
La région Midi-Pyrénées
La faculté de médecine de Toulouse Purpan
La faculté de Médecine de Toulouse Rangueil
L'équipe 4 de l'unité 1027 de l'INSERM
Le service des relations internationales de l'Université Paul Sabatier
La Fédération Française des associations de Médecins Conseils Experts
Les universités et organismes partenaires en FRANCE et à l'étranger

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Présentation de l'Ecole Européenne d'été de droit de la santé et éthique biomédicale

Depuis 2006, un réseau multidisciplinaire, multiculturel et international d'enseignants, de chercheurs et de praticiens de la médecine et du droit organise une Ecole Européenne d'été de droit de la santé et éthique biomédicale. Cette thématique transversale intéressant à la fois les sciences médicales et les sciences humaines et sociales, est peu enseignée tant en FRANCE que dans les pays européens. Toulouse a acquis dans ce domaine une reconnaissance internationale.

L'objectif principal de l'Ecole Européenne d'été est de valoriser le savoir-faire de l'Université Paul Sabatier pour l'enseignement et la recherche en droit médical et en éthique biomédicale en initiant des travaux comparatifs entre les pays d'Europe et de l'étranger.
Notre public regroupe des étudiants français et étrangers du niveau master ou des internes en médecine, des doctorants et des jeunes chercheurs ainsi que des professionnels de la santé et du droit. Ce programme est validant pour la formation continue des avocats.

Le thème de 2011 porte sur les actions pour la santé et la recherche médicale en faveur des personnes vulnérables et des pays émergents ; auquel fait suite une session académique pour l'initiation au droit de la santé et à la bioéthique en Europe qui sera ciblée sur la génétique.
Le programme en FRANCE se compose de 2 périodes : 1) la première période de 4 jours regroupe : une journée d'échanges pour les jeunes chercheurs avec présentation des travaux, et concours pour un prix de 500 euros, un séminaire de 2 deux jours avec des ateliers, rédaction de synthèse et une journée pour la découverte des richesses culturelles de Toulouse et de sa région. 2) La deuxième période est une session académique de 5 jours sous forme de cours et de groupe de travail en vue de rédiger des publications. En parallèle, une session est organisée par André Gonçalo Dias Pereira et nos partenaires de l'Université de Coïmbra qui s'intitule : Convention on human rights and biomedicine –updated or outdated ?

Pour la sixième année ce projet se réalise sur la base du volontariat, les organismes partenaires finançant directement les frais de leurs participants, une subvention du Ministère de l'enseignement supérieur nous a été accordée chaque année, qui témoigne de la reconnaissance de la qualité de ce programme.

Le droit médical est un enseignement de troisième cycle organisé à Toulouse sous forme d'un Diplôme Interuniversitaire délivré sous le double sceau de l'Université Paul Sabatier (responsable Dr Anne-Marie Duguet) et de l'Université des Sciences Sociales (responsable Pr Claire Neirinck). Ce diplôme accueille un public de praticiens des professions médicales, de juristes avocats et magistrats, et de jeunes chercheurs. Un réseau de chercheurs français et étrangers s'est constitué, soutenu par l'Association de Recherche et de Formation en Droit Médical (ARFDM : www.arfdm.asso.fr), et l'unité 1027 de l'INSERM qui accueille régulièrement des doctorants étrangers. Depuis 8 ans la coopération s'est élargie au Canada avec des échanges dans le cadre de l'IIREB (Institut international de recherche en éthique biomédicale) www.iireb.org

L'idée d'associer plusieurs universités en Europe pour valoriser la recherche et l'enseignement du droit médical et bioéthique a émergé dans notre réseau. Un groupe s'est formé regroupant plusieurs universités françaises et des universités en Europe et à l'étranger. Chacune est impliquée dans notre projet à travers un enseignant ou un chercheur qui a des liens étroits personnels avec l'équipe de l'Université Paul Sabatier, et les chercheurs de l'Unité 1027 de l'INSERM

Le droit de la santé a une dimension européenne importante avec de nombreuses directives et recommandations pour les professionnels et les produits de santé. Ce biodroit intéresse beaucoup les étrangers qui souhaitent établir des liens de coopération avec les pays d'Europe.

Cinq sessions de l'Université Européenne d'été en droit de la santé et éthique médicale ont été organisées depuis 2006. Chaque fois, la mobilisation est internationale tant pour les participants que pour les conférenciers. L'ouverture aux étudiants anglophones a pu se faire grâce à la traduction simultanée. La session académique est organisée en anglais.
Le groupe d'enseignants et le réseau qui se sont réunis les années précédentes, s'est étendu aux pays de l'Europe de l'est et en Asie notamment vers la Chine. La dimension internationale, tant pour les enseignants que pour les participants, se confirme de plus en plus grâce à la traduction simultanée.
Une nouvelle forme de contribution s'est mise en place pour la valorisation et la diffusion des projets multicentriques Européens qui ont des axes juridiques et éthiques, tels que POSEIDON, RISET, ESHProject, ESQH Experience. En 2011 Geuvadis et TECHGENE.

Chaque année de nouveaux participants venus de pays étrangers s'ajoutent aux membres fondateurs (en 2011 une trentaine d' intervenants étrangers dont 12 venant des pays d'Europe) Ceci témoigne de l'investissement de nos universités partenaires et des efforts de promotion des associations et réseaux qui nous accompagnent. Il existe une reconnaissance trans - européenne de la formation, comme en témoigne l'implication de plusieurs universités Européennes et de l'European Association of Health Law qui est un partenaire fidèle.

Des liens spécifiques de coopération scientifique se sont progressivement mis en place et continueront de se développer. Plus particulièrement :

-avec les pays du Maghreb et du pourtour méditerranéen qui sont nos partenaires depuis la création en 2006. Nous avons crée avec eux le Réseau multidisciplinaire d'éthique, droit de la santé et déontologie EthiMED dont le premier atelier tenu en 2010 à Tozeur (Tunisie) reçu le patronage de la Commission nationale Française pour l'UNESCO afin d'initier des travaux avec les pays du Sud (Maghreb, Afrique). En 2011 l'Ecole Européenne d'été organisera, comme en 2010 des groupes de travail commun avec le Réseau EthiMED
- avec l'Amérique du Nord la coopération avec les Canada au travers de l'IIREB est une constante depuis la création en 2006. La participation de collègues venus des USA participants et conférenciers se renforce chaque année (Université de South Carolina en 2011)

- le Brésil est également représenté, les workshops de 2011 seront l'occasion de conforter nos liens avec ce pays dans la perspective du futur congrès Mondial de droit de la santé qui aura lieu dans ce pays en 2012.Le président Eduardo Dantas est un fidèle membre de notre réseau et participe chaque année à l'Ecole d'été.
- avec les pays d'Asie notamment la Chine grâce au partenariat qui s'est crée avec la China Health Law Society des étudiants venus de chine ont participé à l'Ecole d'été depuis 2008 et ont contribué aux ouvrages. Cette collaboration se renforce en 2011 avec la participation d'un enseignant de l'Université de Shandong et d'une délégation de Hainan Medical College et de Dalian Medical University. L'école d'été sera l'occasion de formaliser les conventions de coopération avec les universités de Hainan et de Dalian qui seront signées avec l'UPS.

Il n'existe aucun enseignement sous cette forme en Europe portant sur le droit de la santé et la bioéthique. On observe un réel besoin de faire connaître le droit européen de la santé (directives européennes, institutions) ainsi que les particularités de la réflexion éthique. Le droit comparé sur ces questions est l'occasion de nombreux sujets de thèses. Dans la perspective de cotutelles, les rencontres des futurs doctorants avec des universitaires étrangers sont très fructueuses. La publication annuelle d'un ouvrage à partir des principales présentations par les "Etudes Hospitalières" (www.etudes-hospitalieres.fr) est la concrétisation de la réflexion du groupe .Cette publication qui offre une chance aux jeunes chercheurs de s'initier à la mise en forme de leurs travaux.

La région Midi-Pyrénées attire chaque année de plus en plus de participants. Le riche patrimoine culturel, la convivialité et la gastronomie locale y contribuent certainement beaucoup. Je remercie très vivement tous mes collègues et les membres du comité pédagogique qui m'ont accompagnée dans cette entreprise, et en feront encore une fois cette année un succès.

Anne-Marie Duguet
Organisatrice de l'Ecole Européenne d'Eté
MD, PhD Maître de Conférences
Université Paul Sabatier

FORUM des Jeunes chercheurs
Young researchers' FORUM

30 juin 2011 de 9h à 17h
June 30th 2011 from 9am to 5pm

Salle de conférences de la Faculté de médecine de Rangueil
133 Route de Narbonne - Toulouse

Jury

Pr Berna Arda (Ankara, Turquie)
Pr Honjie Man (Jinan, PR China)
Marie-Angèle Grimaud (PhD, juriste consultante en droit et en éthique, Montréal)

Organisation

Les présentations se font soit sous forme de posters, soit sous forme de communications orales de 15 mn, avec power-point le 30 juin à 10 heures.
Presentations may be posters or oral presentations: 15 min talk with PowerPoint, on June 30th, 10 am.

Les posters seront mis en place à partir de 12h le 30 juin.
Posters will be hung on June 30th at noon.

Le jury fera une visite des posters et les auteurs devront être présents pour répondre aux questions à 17 heures.
The jury will visit the posters and the authors should answer to the questions at 5pm.

Le prix de l'ARFDM sera remis le 2 juillet lors de la cérémonie de clôture.
The jury will give the results for ARFDM award in the closing ceremony on July2 2010

Liste des présentations
Presentations list

Présentations orales du 30 juin (par ordre alphabétique)
Talk presented on June 30th (by alphabetic order)

1- Selda Coskun, Berna Arda
2- Louise Deffrennes
3- Marion Faurès
4- Mara Freitas
5- Marius Kedoté
6- Wang Lin
7- Yonghui Ma
8- Allane Madanamoothoo
9- Yue Shi
10- Wang Tianxiu
11- Hanène Turki
12- Tao Wu
13- Du Xuan

Posters du 30 juin (par ordre alphabétique)
Posters presentations on June 30th (by alphabetic order)

1- V. Anastosova, A. Mahalatchimy, E. Rial-Sebbag, A. Cambon-Thomsen
2- Gauthier Chassang, Christina Mischorr-Boch, Arja R. Aro, Anne Cambon-Thomsen
3- Romain Chassagneau Laurence Mabile Anne Cambon Thomsen
4- Katrin Griesche, Anne Cambon-Thomsen
5- Sophie Julia, Alexandra Soulier
6- Anna Pigeon, Gauthier Chassang, Anne Cambon-Thomsen
7- Emmanuelle Rial, Anne Cambon-Thomsen
8- Emmanuelle Rial-Sebbag, Sophie Julia, Gabrielle Bertier, Anne-Marie Duguet, Anne Cambon-Thomsen

Résumés pour le FORUM des jeunes chercheurs

Abstracts for the young researchers' FORUM

Présentations orales

Talks

Selda COSKUN*, Berna ARDA**
**(MSc, PhD Candidate) Ankara University Institute of Biotechnology, Socioeconomic Development and Biotechnology Department, Ankara, TURKEY*
** *(MD, Med. Spec., PhD)Professor, Ankara University School of Medicine, Medical Ethics Department, Ankara, TURKEY*

Labelling of genetically modified organisms in Turkey: an ethical perspective

Transforming biological systems with the aid and contribution of technology is a new notion developing with technical support to biological structures. It is an example of the surpassing of biological limitations, new applications of technology and fruitful combination of two seemingly distant fields or concepts by the human mind. The extremely rapid development of molecular biology and gene technology has become one of the popular topics for the public opinion after 1990's with the sensational biotechnology applications and large international projects. Gene technology has exerted its effect in all areas of life at present. Especially agriculture, medicine, husbandry, food, chemistry, energy and environment industries utilize gene technology intensively. Numerous studies are in progress in many laboratories of the world: meanwhile, we began to see the early results in our daily lives, kitchens' table, in the garden and on pharmacy shelves. However, countries also have to think about its consequences in the near or far future. Turkey is one of these countries to deal with the risks of the new gene technology.

By being part in Cartagena Biosafety Protocol, Turkey took her first step in making legislation in transboundary movements, production and other related issues on Genetically Modified Organisms (GMO). The Biosafety Law, the objective of which is to establish and implement a biosafety system in order to prevent the potential risks of the genetically modified organisms, protect human, animal and plant health; and ensure the sustainable use of the environment and biological diversity and to determine the procedures and principles governing the control, regulation and monitoring of these activities, was published on 26 March 2010. The law and the Secondary Legislation under the Law have been entered into force on 26 September 2010. The Biosafety Information Exchange Mechanism of Turkey, www.tbbdm.gov.tr has also been online since 4 October 2011.

While one of the major impacts of the Biosafety Law is on the prohibition of environmental release of GMOs, the other one is considered to be the labeling provisions of which application has started with the new regulatory system on biosafety. This study is going to discuss the labeling of GMOs in Turkey from an ethical perspective.

References:

- ***Arda B:*** Ethical respects of biotechnology and the case of Turkey. Journal of Biotechnology and Law 1: 210 –214, Sept.- October 2004.
- Law on Biosafety, Law number 5977 23.03.2010 (OJ No: 27533)
http://www.tbbdm.gov.tr, *Biosafety Information Exchange Mechanism of Turkey* 09.05.2011

Louise DEFFRENNES
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Recherche biomédicale chez les sujets vulnérables: législation et analyse de cas

Le principe d'équité implique un égal accès à tous à la recherche biomédicale. Cependant, les sujets vulénrables bénéficient d'une protection accrue qui peut parfois les exclure des protocoles de recherche. Ce fut le cas des patients atteints de la maladie d'Alzheimer.
Participer à la recherche est un acte volontaire nécessitant un consentement valide, libre, éclairé et express. La recueil du consentement des personnes vulnérables apparait complexe et le droit doit permettre la conciliation entre ce bénéfice et la certitude que le sujet, d'une façon ou d'une autre, adhère la recherche à laquelle il serait participant.
Différents textes internationaux prévoient la participation des sujets vulnérables à la recherche biomédicale et notamment la Déclaration d'Helsinki, les lignes directrices du CIOMS, la Convention d'Oviedo et enfin, la Déclaration universelle sur la bioéthique et les droits de l'Homme de l'Unesco. Tous définissent des conditions pour les recherches sur les personnes vulnérables et/ou inaptes à consentir.

En France, le Code de la Santé Publique (CSP) prévoit une protection particulière des sujets vulnérables (articles L1121-1 à L1126-11). Les recherches ne sont autorisées seulement si elles ne peuvent pas être réalisées sur d'autres catégories de population, si le bénéfice escompté est de nature à justifier le risque prévisible encouru ou si le bénéfice porte sur d'autres personnes placées dans la même situation (risque et contraintes minimales). Le consentement à la recherche doit respecter certaines conditions, aussi, le médecin investigateur a une démarche de médiation, visant à obtenir l'adhésion et l'acceptation des patients tout en respectant leur autonomie et leurs choix, ainsi, il établit une relation de confiance et il a un devoir de conseil et de protection, enfin, il doit expliquer les alternatives à la recherche.
Il convient de distinguer plusieurs catégories de sujets vulnérables, en effet, l'incapacité juridique concernant les mineurs (article L1121-7 CSP) et les majeurs protégés (article L1121-8 CSP) ne constitue qu'une partie de ces sujets, auxquels il convient d'ajouter les sujets non protégés juridiquement mais hors d'état d'exprimer leur volonté (cas des patients atteints de la maladie d'Alzheimer notamment) et enfin la vulnérabilité liée aux circonstances de la recherche (femmes enceintes (article L1121-5 CSP), personnes privées de liberté, personnes en hospitalisation sans consentement, personnes admises dans un établissement sanitaire et social (article L1121-6 CSP); d'autre part le cas des recherches en urgence (article L1121-1-2) et les cas de vulnérabilité sociale (pressions directes ou indirectes)).
L'originalité du droit français par rapport à la législation et aux recommandations internationles réside dans la possibilité qu'une autorisation soit donnée par une personne à la place d'un consentement. L'assentiment du sujet inapte à consentir est recherché, une opposition empêche la mise en oeuvre de la recherche.
Ainsi, le consentement apparait comme une protection imparfaite, dès lors que l'autonomie de décision est altérée. L'autorisation d'un tiers pose des questions éthiques, celles de la complexité des choix et des conflits de loyauté.
Les Comités de Protection des Personnes (CPP), ont donc un rôle majeur dans l'évalutaion des risques et des bénéfices et travaillent activement pour améliorer progressivement la protection de ces sujets. Une analyse de dix dossiers d'un CPP illustrera la manière dont est respectée la législation française par les investigateurs des protocoles de recherche.

Marion FAURES
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Patients et télésanté : entre responsabilisation et vulnérabilité

Les Technologies de l'Information et de la Communication (TIC) sont depuis les années 90 à l'origine d'une révolution dans le domaine de la santé au regard des pratiques médicales, de l'organisation des soins et même de la perception par le patient de sa santé.

La télésanté combine technologies domotiques, multimédia et Internet et ouvre ainsi des perspectives face au défi majeur que notre société doit relever : la prise en charge des personnes en perte d'autonomie (personnes handicapées, âgées, fragiles ou malades à leur domicile). Le domicile du patient devient le point de capitalisation de toutes ces informations grâce à la mise en œuvre de systèmes d'informations communicants et interopérables ou de plateformes partagées, et à la création d'un dossier médical personnel numérique.
L'enjeu est considérable : à titre individuel, il s'agit de pouvoir continuer à vivre en toute sécurité dans son cadre de vie habituel et familier ou de le rejoindre le plus rapidement possible après une hospitalisation.
Pour la société, il s'agit de pouvoir répondre aux besoins tant médicaux, qu'identitaires du patient : rompre l'isolement, conserver une autonomie de vie, retrouver du lien social.
A la dimension médicale du soin (médecins) s'ajoute une dimension d'accompagnement social et familial dans laquelle les professions médico-sociales (infirmières, kinésithérapeutes), les services d'aide à domicile, les aidants, et bien sûr le patient sont impliqués.
On passe ainsi d'une logique globale de santé à une logique de qualité de vie qui dépasse le cadre sanitaire (maladie, handicap). On parle de santé personnalisée.
La conception paternaliste du soin fondée sur l'asymétrie de la relation médecin/patient cède du terrain à une conception autonomiste dans laquelle l'individu est de plus en plus responsabilisé dans la prise en charge de son état de santé et associé à la prise de décisions le concernant.

Le droit français est très protecteur et tente de concilier responsabilisation du patient et prise en compte de sa vulnérabilité.
Le principe d'autonomie repose sur l'obtention du consentement libre et éclairé du patient et sur le droit à l'information : *«le patient a droit à une information loyale, claire et appropriée»*. Mais, un certain paternalisme (et donc pouvoir) du médecin à l'égard patient est maintenu : *«pour des raisons légitimes et dans son intérêt, un malade peut être tenu dans l'ignorance du diagnostic ou du pronostic »*.
L'exercice de la médecine à distance ne remet pas en cause cette conception.

Cependant cette législation atteint clairement ses limites dans le cadre d'un marché non régulé comme Internet où il est facile de contourner la loi d'un Etat. Ainsi le «e-patient» peut accéder librement à des produits de santé vendus en ligne, sans accompagnement médical.
ex : les autotests génétiques.
Le principe d'autonomie est alors poussé à l'extrême au détriment de la protection de la vulnérabilité. S'il est difficile de définir un cadre juridique international, ces pratiques pourraient toutefois faire l'objet d'une information claire sur les risques encourus par celui qui s'y adonne.

Références :

- **Rapport de Robert Picard** : Usage des TIC par les patients et les citoyens en situation de fragilité dans leurs lieux de vie - Août 2007.
- **Rapport de Pierre Lasbordes** : *La télésanté, un nouvel atout au service de notre bien-être, un plan quinquennal éco-responsable pour le déploiement de la télésanté en France* – 15 Oct. 2009.
- **Communication de la Commission au Parlement européen, au Conseil, au Comité économique et social européen et au Comité des régions** concernant *la télémédecine au service des patients, des systèmes de soins de santé et de la société* - 04 Nov. 2008.
- *Télémédecine : les préconisations de l'Ordre des médecins* – Janv. 2009.
- *Tests génétiques et impacts sur la société* - **Sandrine de Montgolfier** - Réseau Rodier, Etudes et synthèses - déc. 2008 - www.ethique.inserm.fr le 31 Mai 2011, rubrique Génétique, génomique et bioinformatique - Tests génétiques - Articles.
- **Avis n°86 du Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé** : *Problèmes posés par la commercialisation d'autotests permettant le dépistage de l'infection VIH et le diagnostic de maladies génétiques* - www.ethique.inserm.fr le 31 Mai 2011, rubrique Génétique, génomique et bioinformatique - Tests génétiques – Avis du CCNE.

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Vulnerability and the "right" to be hopeful in clinical health care

For when hope does awaken, an entire life awakens along with it.
One comes fully to life.
John S. Dunne

Vulnerability, a remarkable word, but what does it means? What is it and who are the vulnerable ones? What makes the individuals, groups, or even emerging countries, vulnerable? Which are the consequences of being vulnerable in order to a social, economical, but in this discussion, specially, in order to a clinical condition? Can these individuals, groups be hopeful to an effective protection based on Human Rights, law, good clinical practice and all the Bioethics principles who should lead the political and professional decisions in Healthcare?

Nowadays, hope and the *right to be hopeful* is a long and hard way, it's not specific, it's a nonfigurative and philosophic concept, but I'm particularly concerned about how to give hope to those who are in sickness and need help to decide about their own benefit (when they are evolved in clinical decisions). Hope is a way of thinking, feeling and acting. In fact, hope[1] is "a requirement for action and it remains opens to various possibilities and the necessity to change the desired outcome as the reality changes. Finally, we can't forget that hope is a phenomenologically positive state, and by definition, hope can never be false."

How to proceed for the empowerment and protection in favour of this individuals and groups, regarding the respect of bioethics principles in health care?

Universal Declaration on Bioethics and Human Rights (adopted by UNESCO's General Conference on 19 October 2005), article 8[2], respect for human vulnerability and personal integrity, WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects an national legislation will be taken into account in a bioethical approach.

Key words: vulnerability; hope; health care; bioethics

[1] **Elizabeth J. Clark**, PhD, MSW - You have the right to be hopeful - *The power of survivorship. The promise of quality care* - National Coalition for Cancer Survivorship (NCCS). Fourth Edition 2008.

[2] **NEVES, Maria do Céu** – The UNESCO Universal Declaration on Bioethics and Human Rights.

Marius KEDOTE
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Prévention de la Transmission Mère-Enfant du VIH/SIDA au Bénin :
Le consentement des femmes au dépistage est-il libre et éclairé?

Pour faciliter la prévention de la transmission mère-enfant (PTME), l'ONUSIDA et l'OMS (2004) ont suggéré dans une déclaration commune de principes, d'effectuer le dépistage systématique du VIH chez les femmes enceintes. Le dépistage rapide et à grande échelle du VIH a été le point focal du programme de PTME implanté en 2004 à l'échelle nationale au Bénin (CNLS, 2006).

L'analyse d'implantation du programme indique une faiblesse du programme au niveau de la prise en charge post dépistage où une proportion significative des femmes devient des « perdues de vue » (BAPS, 2006). Dans ces conditions, nous nous demandons si les femmes enceintes comprennent bien les implications du dépistage avant de se décider à faire le test. La question est de savoir si la décision de participer au dépistage est éclairée et motivée par des raisons valables.

L'objectif de ma présentation est d'analyser le caractère libre et éclairé du consentement des femmes enceintes quant au dépistage.

Pour atteindre cet objectif, nous avons utilisé des données provenant d'une enquête à celles d'une recherche qualitative collectées dans le cadre d'une analyse d'implantation du programme de PTME au Bénin. Cette analyse s'appuie sur un devis d'étude de cas multiples incluant six maternités choisies parmi les 56 sites fonctionnels.

En termes de résultats, hormis trois cas de dépistage à l'insu sur les 259 femmes qui ont été testées, le caractère volontaire du consentement au test est respecté sur les sites de PTME. Vingt-neuf cas de refus ont été identifiés. Les raisons les plus souvent évoquées par les femmes enceintes sont la peur du résultat positif et de ses conséquences sur la vie familiale dans 55,2% des cas et l'attente de l'accord ou du désaccord du mari dans 27,6% des cas. Si globalement le consentement a été volontaire sur tous les sites, son caractère éclairé est moins probant. Ainsi, les informations délivrées à celles-ci durant les conseils sont relativement différents d'un site à un autre.

L'autonomie des patients à travers le consentement libre et éclairé a toujours été au cœur du débat sur le dépistage du VIH. La stigmatisation reste toutefois attachée à l'infection et le vécu de la maladie du VIH/SIDA demeure socialement éprouvante dans les pays à faible et moyen revenu (Anderson, 2009). La nécessité d'un consentement libre avant tout dépistage s'en trouve renforcée.

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Study on the Reform of the Medical Security System for the Migrant Workers

China is experiencing rapid urbanization and industrialization. More than 2 billion farmers, who are named as "migrant workers", have been poured into cities to work. The historical dual economic and social structure puts the migrant workers at a disadvantaged position in the labor market and urban life. It is one of Chinese society's urgent affairs to improve the medical security laws and regulations for migrant workers.

Recently, Chinese government concentrates on nationwide health insurance programs. The medical insurance system for urban workers and residents, and the new types of cooperative medical care system for rural population are established in every province and city. However, such medical insurance systems are difficult to meet the demand of the migrant workers because of their low incomes and frequently movements from urban to rural areas or among cities. Therefore, some local governments enacted special medical insurance policies for the migrant workers. But the inconsistency of these local policies worsen the transfer and implementation of medical insurance service for the migrant workers.

In March 2010, the National People's Congress of China launched the amendment of the Election Law. According to the new law, rural and urban residents enjoyed equal political right. This indicates the consistency of the traditional dual economic and social structure in rural and urban China. Therefore, the National People's Congress should gradually establish consistency medical insurance law system. The government should improve the related measures among different regions or types of medical insurance systems. In conclusion, the establishment of medical security system for the migrant workers should meet the special of demand of the migrant workers at present stage and based on the rules of legalization unity and isocracy. These measures will result in the promotion rather than the inhibition of free mobility of labor force and the urban-rural integration in China.

Key words: migrant workers, medical security, health system reform

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A duty based approach to Biobanking from a Confucian perspective

Nowadays, genetic databases and Biobanks have been particularly concerned with the sensitive nature of personal genetic information as well as its significant commercial value, especially those involving large populations. One tradition that is being challenged by these advances is the notion of informed consent, which was widely accepted as the reflection of individual autonomy and a rights-based conception in Western theories. I will examine challenges and limits to informed consent related to Biobanking, in the light of the duty-based theory of Confucian moral philosophy.

The development of Biobanks provide a new form of decision making mainly in two ways, first, as a tool that assists in carrying out existing and future research projects, its novelty is avoiding the direct contact of between research participants and researchers [1]. In more detail, with Biobank research, the purpose and direction of the new projects might not be fully known at the time when biological samples and consent were obtained, or the new studies may even be devised years after the individuals have died[2]. It poses difficulties to fulfill traditional informed consent criteria, which often covers face-to face, specific consent and information disclosure about the proposed study. New forms of consent have been introduced to cater for the innovation of decision making in Biobanks, such as open, blanket consent[3], which is given only once, but could be applicable for any future researches. However, they have been criticized as being either too vague or too inconsistent with individual rights. Second, the deposit of genetic information has an impact not only on the participant, but also on other people, e.g. family members. Thus this information is a kind of shared information among the family, and the genetic privacy is a kind of shared privacy among family members. However, traditional informed consent assumes that decision is made by a single individual based on his own value and life, and limits the following treatment or research only to this person. In Biobanks, it might be improper to seek for individual consent for genetic information, especially when there are conflicts between this person and his family members, because in fact this could also imply a family's genetic status. Furthermore, this individual right-based informed consent makes it more difficult for the protection of family privacy, prevention of possible harms and risks.

Adopting individual rights-based approach in the management of Biobank might be inappropriate while a duty-based Confucian familism approach could be a better alternative. Confucian moral philosophy focuses on the duties of an individual to the family, community, even for the whole country and it is grounded on "Five Standards": "ren", "yi", "li", "zhi", and "xin". These five standards represent "benevolence, social virtue", "justice, righteous, and rectify ourselves", "polite, ritual", "sense and ability to identify what is morally right or wrong", and "honesty, keep promises"[4].

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Among which "ren" (benevolence) is the core of Confucianism. A person's self-cultivate in Confucian is strongly associated with his virtuous action to others, and also tied to his role in a family and community. As Biobanks have distinguished public benefit and help to develop genetic medicine or therapy for genetic disease, it could be said that members of family or community may have the duty to disclosure his genetic information and contribute to the Biobank.

It is noted that the family members also have a duty to respect for other family member's not participating decision, because the unit in genetic information collection is a family[5], not an individual. Therefore, it is necessary to get family consensus before giving genetic information individually. This consent is a family consent which based on an idea of "family autonomy"[6]. The common property of genetic information reflects the intimacy of the family members and that is the reason why Confucianism lays great emphasis on family affinity. Each family member has the duty to protect genetic privacy of the whole family, which makes confidentiality of information in Biobank easier be fulfilled through a duty-based approach.

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To what extent shall we bet on private cord blood banking?

Becoming parents is one of the greatest wishes of a lot of couples. When their dreams come true, expecting parents have to face a lot of important issues before their baby is born: the name to give, the hospital for the delivery, breast or bottle feeding, etc. Recently, a new issue of whether or not to bank their baby's umbilical cord blood has mattered to them.

The collect and use of cord blood has many advantages for both medical and research field. Technically, it is immediately available and can be collected very easily from both vaginal deliveries and caesarean sections. Also, it represents a lower risk of infections and diseases than in bone marrow transplant and can be used as an alternative allogenic donor source to treat paediatric genetic, hematologic, immunologic and oncologic disorders.

In many countries a lot of advertising is being done in parenting magazines, direct mailings, and flyers in the obstetrician's office to encourage the expecting parents to give the umbilical cord blood after delivery. Moreover, the removal of umbilical cord blood doesn't hurt the mother nor the baby and it would be discarded anyway in case of refusal.

However, the main issue is not the cord blood banking itself but more about banking cord blood in a for-profit private cord blood bank where this practice is being presented as a "once-in-a-lifetime chance" to save the umbilical cord blood for possible use later to save the child's life.

This presentation aims at demonstrating to what extent shall we bet on the utility of private cord blood banks?

Key words: cord blood, cord blood banking, utility of cord blood.

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The History, Present Condition and the Trend of Chinese Medical and Healthy Rule of Law: Chinese Medical and Healthy Comments of the Rule of Law for 30 Years

中国医疗卫生法治的历史、现状与走向
——中国医疗卫生法治30年之评析

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摘要：1978年以来，我国的医疗卫生立法、医疗卫生执法、医疗卫生司法、医疗卫生守法、医疗卫生参与和医疗卫生法律监督工作取得了巨大的成就。1997年国家正式提出依法治国方略后，我国的医疗卫生工作正式走向法治化的轨道。目前，无论是从环节上，还是从整体的判断指标上分析，或者从实效上评估，都说明我国的医疗卫生法制架构已经基本形成。[1]符合科学发展观和和谐社会的医疗卫生法治工作正在完善之中。完善的措施既包括立法完善工作，还包括执法、司法、守法、参与和监督环节的体制、制度和机制的创新工作。
关键词：医疗卫生；立法；法律实施；法律监督

Since 1978, the work on the legislation, the law enforcement, judicial, law-abiding, the participation and the legislative supervision of Chinese medical and healthy has made a great progress. Chinese medical and health work went toward a normalize track of the legalization. Since 1997, the plan of managing state affairs according to law was advanced. At present, no matter judging from the indicators on the overall analysis, or results from the assessment on Chinese legal system, it indicated that medical and health system of our state has been basically formed. In line with the concept of scientific development and harmonious society of medical and health work is perfect in the rule of law. A perfect measure including the improving of legislation, the law enforcement, judicature, abiding by the law, participating and overlooking of the system and the innovating of system and mechanism.

Key words: health, legislation, law enforcement, legal supervision

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Ethical Thought of HIV/AIDS prevention and control in Hainan

With the construction of Hainan international tourism island, Hainan will certainly attract more and more tourists from around the world as a popular resort. It's very important for sustainable development of Hainan tourism to prevent and cure HIV/AIDS.

There are only 3 routes of HIV/AIDS transmission internationally recognized which are spreading through blood, sexual transmission and mother-baby transmission. In China, many people think vulnerable populations of HIV/AIDS are homosexual, illegal sex worker in our country and spirit drugs vein user. A few people even consider that may be infected by mosquito bites, casual contacts etc. So patients are widely discriminated against in society.
The government of Hainan province implements national policies conscientiously which are consulting and detecting for free for HIV/AIDS patients, offering free medicines for patients in financial difficulties and free education for their orphans. But lots of patients do not know about these policies. Even they know that they don't want to carry out consultation, examination and treatment, because of worries about themselves and their family discriminated and treated unfairly, the normal life and work limited. As the fundamental rights of patients having a direct bearing on their vital interests could not be protected Lead to the government can't help them timely.
The policies of HIV/AIDS prevention and treatment without ethics are blind, uncontrolled and dangerous and should not be applied. They should be based on ethics principles of respect and justice.
First of all, it's necessary for HIV/AIDS prevention and control to conduct various popularized activities, strengthen mass media propaganda and education .Improve the quality of health care to HIV/AIDS patients.
Secondly, the medical profession should respect the rights and dignities of the patients when they are homosexual, sex worker and spirit drugs vein user. He should not make difference between his patients and treat everyone fairly and just; he should treat everyone professionally and morally.
In the end, if the patients' legal rights are violated, the government should provide legal advice or legal aid to help them.

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Entre devoir de soigner et respect de la liberté: quelle attitude des médecins face à des grévistes de la faim?

Face à un/des gréviste(s) de la faim, le médecin vit un réel dilemme, appelant à une réelle réflexion éthique mais en tenant compte de certaines considérations juridiques.
La grève de la faim peut être définie comme le refus d'une personne saine de corps de s'alimenter. Elle constitue un moyen de pression par lequel le gréviste exprime son refus d'une situation estimée intolérable ou insupportable, une manière physique et extrême de contestation. Le gréviste de la faim agit volontairement et use de son corps pour s'exprimer en se basant sur le droit reconnu, incontesté mais juridiquement limité de disposer de son corps. Le gréviste de la faim, en mettant sa vie en danger, peut être considéré comme une personne vulnérable.
Les règles du Code de déontologie médicale tunisien s'imposent aux médecins mais ce Code, datant de 1991, ne mentionne spécifiquement le cas de la grève de la faim : déontologiquement, le médecin doit toujours avoir pour but de préserver ou de sauver la vie humaine. Tenu d'informer le gréviste des conséquences médicales de son attitude et de respecter, au nom du principe d'autonomie, la volonté du gréviste, soit son refus d'alimentation et peut-être même de soins, le médecin se retrouve face à un choix douloureux où sa conscience et son éthique personnelles devraient l'aider à décider. Le principe de bienfaisance serait aussi une aide à sa décision en considérant le gréviste non comme un malade mais comme une personne dotée de son libre arbitre : tenu de respecter les conventions internationales lui interdisant de recourir à l'alimentation forcée [1], le médecin doit être maître de sa décision au regard de nombre de considérations.

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Medical Assistance System in the City of China

With the rapid changes of social structures in China, it has already become a serious social problem for the poverty people living in cities that "illness leads to poverty, illness leads back to poverty and poverty leads to illness". The Chinese government should play the leading role for the improvement of the medical assistance system for the poverty city people and provide the basic health security for every person.

Shanghai is the first city that carried out medical assistance in 1992, followed by Dalian, Beijing and Wuhan who give exemption of the medical expenses. In March 2005, "The Advices on Pilot Work of Building up Medical Assistance System in the City", adopted by the Ministry of Civil Affairs, the Ministry of Health, Ministry of Labor and Social Security and the Ministry of finance of the P. R. China, have got trial implementation around the whole state.

However, the medical assistance is still in the trial and beginning stage, In addition to the lack of uniform medical assistance legislation, the medical assistance implementation is unbalanced for different cities and there is no mature mode to follow.

Currently, the medical assistance system in China has the following characteristics:

1) people to be assisted are defined;
2) the contents of the basic medical assistance are clarified;
3) the diversity of types of medical assistance;
4) the standards of low level of medical assistance are set;
5) the source of funds coming from the government is designated;
6) the subjects and departments involved are clarified.

However, there are still the following problems during the implementation:

1) the targets to be assisted are not flexible;
2) the patterns of medical assistance for major diseases have influences on the functions of the medical assistance system;
3) there are conflicts between the absolute insufficiency and relative overmuch;
4) the imperfection of medical assistance system still exist;
5) the administration is still not smooth.

Therefore, the followings should be emphasized for the purpose of making the system more perfect and complete:

1) dynamically targeting the people to be assisted and widening the coverage;
2) implementing the integrated assistance mode step by step;
3) setting up multiple financial funds mainly from the government to solve the conflicts between the absolute insufficiency and relative overmuch;
4) making the system more perfect step by step;
5) smoothing the administration of medical assistance.

Key words: medical assistance system, poverty, people in Chinese cities, the basic health security.

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Etude comparative sur le dépistage volontaire du VIH dans le CDAG français et la consultation du VIH/sida du CPCM chinois

Introduction

Actuellement, le SIDA est encore incurable, mais l'efficacité des traitements antirétroviraux est considérable et la qualité de vie des malades SIDA est beaucoup améliorée. En Chine, il y avait plus 68 000 décès dus au SIDA/VIH, et 370 000 personnes ont été infectées par ce virus jusqu'à la fin de l'octobre 2010 en Chine. En France, le nombre de découvertes de séropositivité est globalement stable depuis 2007. Afin de détecter davantage de séropositivité du VIH en précoce, des expériences françaises ont été considérées utiles pour les Chinois. Sauf des facteurs techniques, l'élimination de la discrimination et la protection de droits de l'homme à l'égard des personnes vivant avec le VIH qui favorisent également la lutte contre le VIH/SIDA parmi toute la population.

Méthode de la recherche

Les objectifs de la recherche sont de :

- Mettre en comparaison les organismes de la prévention du VIH/SIDA, le CDAG en France, et le CPCM en Chine ;
- Rechercher les points forts et utiles pour la prévention du VIH/SIDA en Chine ;

Des mesures concrètes sont mises en œuvre en vue de réaliser cette comparaison :

A. La recherche sur les textes réglementaires et législatifs concernant le système de santé et la prévention du VIH/SIDA :

✧ La recherche générale sur l'organisation du système de soins ;

✧ La recherche destinée spécialement à l'organisation du CDAG français et du CPCM chinois ;

B. La recherche, sur terrain ou par intermédiaire en France et en Chine, afin de reconnaître et comprendre les modes de fonctionnement des organismes de la prévention du VIH/SIDA :

✧ La visitation chez un CDAG français, celui de l'hôpital FERNANT-WIDAL(AP-HP), et l'analyse de la mode française sur le dépistage du VIH ;

✧ La pratique de la consultation au CDAG sous la responsabilité d'un médecin français en vue de comprendre mieux le fonctionnement du CDAG français ;

✧ La visitation dans une consultation du VIH/SIDA dans un hôpital à Pékin ;

✧ La mise en place des interviews sur des médecins chinois, les généralistes et les spécialistes, par Internet, courrier, téléphone... en fin de comprendre la situation la plus récente en Chine;

Résultats attendus

L'hypothèse de cette étude est que les expériences françaises dans le CDAG peuvent apporter des éléments utiles pour la prévention du VIH/SIDA en Chine, notamment pour la consultation du VIH/SIDA dans le CPCM. En parallèle, il faut répéter des différences entre les deux pays qui résultent des facteurs essentiels, comme :

- la population de ces deux pays étudiés ;
- la culture, notamment celle chinoise traditionnelle différente que celle française sur l'éthique, la sociologie, la socio-économie, la société et la justice ;

…

Mais, en revanche, toutes ces différences ne doivent pas empêcher la mise en pratique de l'élimination de la discrimination et la protection de droits de l'homme pour les personnes atteintes par le VIH, parce que l'efficacité de ces éléments dans la campagne de lutte contre le VIH/SIDA a été vérifiés au niveau mondial.

Enfin, une comparaison concrète sera réalisée en plusieurs aspects :
- Nombre de CDAG et de CPCM dans une ville de France/Chine
- Méthode de diagnostic dans le CDAG et le CPCM
- Financement de CDAG et de CPCM
- Dépistage anonyme et découverte d'une séropositivité dans le CDAG et le CPCM
- Lien avec les usagers dans le CDAG et le CPCM
- Confidentialité dans le CDAG et le CPCM
- Suivi et prévention de la détection d'une séropositivité

Résumés pour le FORUM des jeunes chercheurs
Abstracts for the young researchers' FORUM

Posters
Posters

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Ethical, Legal and Social Issues in Longitudinal Studies Involving Children: The MeDALL Project

The MeDALL Consortium - Mechanisms of the Development of ALLergy- is a collaborative project supported by the European Union under the Health Cooperation Work Programme of the 7th Framework programme (N° 261357) [http://medall-fp7.eu/]. It encompasses 23 public and private institutions. It is coordinated by Institut National de la Santé et de la Recherche Médicale (Inserm-France). MeDALL aims to generate novel knowledge on the mechanisms of initiation of allergy from early childhood to young adulthood, in order to propose early diagnosis, prevention and targets for therapy. A novel definition of phenotypes of allergic diseases and an integrative translational approach are needed to understand how a network of molecular and environmental factors can lead to complex allergic phenotypes. MeDALL collaborates with the major European birth cohorts of children (12,500 children from 6 young birth cohorts and the 21,127 from 7 older cohorts).
The MeDALL consortium addresses scrupulously the ethical, legal, social issues raised by its research and activities. Indeed, an entire work package led by Dr. Anne Cambon-Thomsen is devoted to ethical, legal and social issues. One of the first tasks of such WP is to identify the ethical issues raised within the project. This requires a dualistic approach. First an analysis of the concrete ethical questions faced by the project's partners, which implies a good understanding of the work being done by each partner. Second a legal and bibliographic survey permits to be aware of known challenges and to understand legal requirements as well as political tendencies on such issues.We already established a list of international, European and national websites to be regularly visited in order to track news on clinical research, biomarkers, children's rights and data protection. We also analysed the relevant international debates in the recent literature.
In MeDALL various ethical aspects have been highlighted. They are mainly related to the collection of human biological samples, the use of existing databases and stored biological samples, cross-border exchanges of human biological samples as well as animal experiments. Particular attention has been paid to ethical issues raised by paediatric biomarkers as this is one of the main research activities developed in MeDALL: What should be the scope and the extent of the informed consent given by parents to allow the participation of their children in the study? From which age assent of children must be taken into account? What are the best ways to better inform children on benefits and burdens attached to their participation in the studies? How and what kind of incidental findings must be returned to the participants? How potentially predictive biomarkers should be handled? All these aspects must be taken into account to develop a model of informed consent for MeDALL which is one of the first objectives of this WP.
We will present the work done regarding ethical, legal and social issues over the first half year of MeDALL. We will then discuss the place of ethics in MeDALL in order to propose a basic methodology on the development of the ethical debate in such kind of European research project.

Cassagnaud Romain, Mabile Laurence & Cambon-Thomsen Anne, on behalf of the BRIF International working group

BRIF: Bioresource Research Impact Factor. An International Working Group Towards An Operational Index To Promote And Recognise Sharing Of Biological Samples And Associated Data

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Coping with the enormous perspective that developing and emerging countries offer in terms of population databases, guidelines and tools need to be developed aiming at maximising access to resources by researchers in order to encourage research. However, there may be obstacle or difficulties to share bioresources. In developing and emerging countries, a long history of 'parachute research' whereby scientists obtain human samples from local participants without any either feedback, recognition nor contribution to local development has slown down research collaborations and data sharing. It is now an urge to find how to generate equitable international research collaborations with fair recognition.
A major dimension is the recognition of the effort for sharing such resources and of the work involved. The concept of a Bio-Resource Impact Factor (BRIF) has been introduced. The main objective of BRIF is to assess and promote the use of bio-resources internationally by creating a link between their initiators/actors and the impact of the scientific discoveries enabled by their use. The concept relies on a quantitative parameter for bio-resource use, similar to the Impact Factor for publications. Such a BRIF would make it possible to document: 1. quantitative use of a bio-resource, 2. research results involving it, 3. scientific and management efforts to set up and make available a valid bio-resource as well as their institution. A working group has been set up, with an online forum http://www.gen2phen.org/groups/brif-bio-resource-impact-factor. Its 115 participants would gain from additional input from developing and emerging countries. The work addresses 5 steps: 1. Creating a bio-resource unique identifier, as digital ID; 2. Standardising bio-resource acknowledgement in papers; 3. Cataloguing bio-resource data access and sharing policies; 4. Identifying other factors to take into account when calculating the Impact Factor; 5. Prototype testing, involving volunteer bio-resources and the help of journal editors. Such a system could be used to rationally evaluate bio-resource activities over time. Also, if taken into account in assessing researchers/contributors professional activity, the use of BRIF would probably promote both quality and sharing of Bio-resources worldwide and contribute to harmonising sharing policies.

Gauthier CHASSANG[1,2], Christina MISCHORR-BOCH[3], Arja R. ARO[3], Anne CAMBON-THOMSEN[1,2]

The production process of European guidelines for a public health genomics policy

Background: In 2009, the European Commission, DG SANCO, launched for 3 years the second stage of the European project Public Health Genomics[4], the PHGEN II project[5]. PHGEN II is coordinated by the European Center of Public Health Genomics (ECPHF) at Maastricht University in Netherlands and based on an interdisciplinary network of key experts such as Public Health experts, EU lawyers, Human Geneticists, Ethicists, System Biologists, Health Technology Assessment experts and patient groups.

The PHGEN II Goal: The project aims to develop the first set of "European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome-based Information and Technologies". Many genome-based technologies are on the brink of being introduced to Public Health Systems. The aim is to contribute to the preparation of policy makers and health systems. In this respect, current international and national policies dealing with the ethical, legal and social issues raised by genetic services in the clinical and research areas are taken into account. The diversity of health-related genetic technologies and associated genome-based information is considered to elaborate guidelines.

What is Public Health Genomics? Modern research in genetics and molecular biology offers new opportunities for the promotion of population health. Public Health Genomics (PHG) is the responsible and effective integration of genome-based knowledge and technologies into public policy and into health services for the benefit of population health in terms of prevention, diagnosis, treatment and healthcare.

Structure of the project: Three work packages (WP) develop specific guidelines concerning the quality assurance of genome-based technologies and genome-based information (WP QA), issues related to the provision of such technologies and information (WP Provision) and issues related to the use and different users of genome-based technologies and genome-based information, in a public health approach (WP Use). We concentrate on the WP Use.

Achievements

1. Bibliography: compilation of 100 existing guidelines (48 of interest for WP Use)
2. A tool to conduct a systematic analysis of the content of the existing guidelines
3. Listing of issues covered and gaps

We presently concentrate on filling the gaps. Proposals will be submitted to the consortium and external experts.

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[4] PHGEN I project (DG SANCO 2006-2008), archives documents are available online at the following address http://www.phgen.eu/typo3/index.php?id=126
[5] EU-Project No. 20081302, Official website of PHGEN II http://www.phgen.eu/typo3/index.php

We detail here the process used by the PHGEN II consortium in order to develop European Guidelines in the particular field of PHG, focusing on the work done within the work package Use/User of genome-based information and technologies.

Katrin GRIESCHE and Anne CAMBON-THOMSEN
on behalf of the POSEIDON Consortium
Inserm and Université de Toulouse III Paul Sabatier, UMR 1027, Toulouse, France

Main results and policy recommendations of the EU project POSEIDON "*Promoting Optimisation, Safety, Experience sharing & quality Implementation for Donation Organisation & Networking in Unrelated Hematopoietic stem cell (HSC) transplantation in Europe":*

POSEIDON was a project funded by the European Commission (EC) over 3.5 years, starting in June 2007. It aimed at improving the safety of Hematopoietic Stem Cell Transplantation (HSCT) and its access in Europe by concentrating on optimising steps prior to the actual donation: recruitment of donors, typing strategies and quality, organisation of donor registries/CBB (Cord Blood Banks). It involved 8 partners and was mainly a mapping exercise gathering information on the present situation in European states, using existing documentation, questionnaires and qualitative methods, content analysis of documents gathered by comparative qualitative or statistical analyses, use of economical analysis for generating models aiming at planning registry and CBB development, setting up training activities and actions for accreditation and quality assurance of immunogenetics laboratories. The different aspects of the donation chain were integrated in developing overall recommendations for professionals and policy makers.
The POSEIDON project helped implementing the EU public health programme by promoting quality implementation for histocompatibility typing and practical application of the Directive 2004/23 EC. It also dealt with volunteer donor recruitment and HSC donation. Main aspects were analyses of donor recruitment strategies in donor registries with proposals towards minorities, an effective boost of the quality process of HLA laboratories and an improved follow up of accreditation, improved models developed by economical analysis for measuring efficiency of registry / CBB and for prospective registry / CBB planning, a survey on existing education material for professionals and a line of action towards a European curriculum in histocompatibility and immunogenetics. The integrated report highlighted achievements in each part and listed specific sets of recommendations. The set of recommendations to professionals and policy makers includes 30 recommendations on the various aspects addressed and 15 transversal recommendations generated thanks to the interdisciplinary work of the POSEIDON consortium. The overall integrated results constitute an information package for professionals and policy makers at national and EU level.

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Are genetic testing technologies driving clinical activity?

Considering their diagnostic capacity, their potential for automation and their decreasing cost, the translation into clinic of next generation sequencing technologies - already available in research - looks like a unique opportunity, as the demand for genetic analysis is increasing in the health care system. Knowing that the majority of genetic diseases are molecularly and clinically highly heterogeneous, these innovative technologies would allow developing new diagnostic tools. But their clinical use raises major and previously unreleased issues. In a context of innovation which is meant to optimize clinical care by implementing new technologies without affecting traditional clinical values, how to maximize the translational relevance of genetic research for patients and for society? Our main concern is that the rapid penetration of systematic technologies into genetic medical departments blurs established frontiers between research and clinics.
Clinicians and laboratory personnel will require training to use the sequence data effectively and appropriate methods will need to be developed to deal with the incidental discovery of pathogenic mutations and variants of uncertain clinical significance. In addition the effective translation of genomic advances into better health care will inevitably require access to and integration of multiple databases, which is likely to raise logistical and ethical considerations. The pace of clinical integration will not be limited by the rate of technology development, but by the ability to accurately interpret the resulting data. High throughput technologies have the potential to transform the practice of medical genetics and related fields, but the vast amount of personal genomic data produced will increase the responsibility of geneticists to ensure that the information obtained is used in a medically and socially responsible manner. Clinicians, public health practitioners and relevant decision-makers should determine their strategies and approaches in an era of such rapid advances.

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Are published genomic data free for further uses? Legal and ethical issues1 in a context of data sharing.

The use of published information and data for generating electronic databases, such as LSDBs (locus specific databases), for meta-analyses and for new association studies is frequent. Current policies towards data sharing encourage access to and circulation of data. Nevertheless ethical issues are raised regarding informed consent of the person from whom the data were collected. Published, hence publicly available data are not necessarily data free to be used. Limitations given through the consent procedure may exist and the fact that data are published does not erase them. The problem is growing with the rapid technological advancement and more control by the citizens about the use of their data. Those issues are new challenges in the frame of the revision of the EU directive 95/47 on the protection of personal data. We analysed various possible solutions and studied the associated responsibilities of researchers, institutions, editors, ethics committees and data mining scientists. This reflexion led to propose to systematically indicate in the publication itself or as supplementary information possible other uses of data/samples included in the informed consent and other limitations and to ask the editors to consider introducing this in instructions to authors. It would provide useful information to potential users in order for them to decide whether to use the published data or not. It would be respectful of privacy rights and autonomy. Nevertheless it remains limited in cases where the consent is not indicating the possible further uses of data. Other solutions can be proposed in such cases.

[1] The work leading to these results has received funding from the European Community's seventh Framework program (FP7/2007-2013) under grant agreement n°200754, -the GEN2PHEN project and from the EU Public Health project Grant agreement no. 2008302 (PHGEN II)

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Genotoul societal platform *and Epidemiology and analyses in public health*,
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Analysis of International Legal Instruments for governing research biobanks

Biobank activities are regulated by various legal instruments which variable purposes. We focused on texts at international and European level which address the classic links between ethics and law. These rules, where the lines of demarcation are sometimes blurred, and which the professionals themselves often confuse, maintain the close links, well described in the field of biomedical research.

We analysed various texts applying to biobanks used in research, that vary in source (national and international), and in form (binding instruments and non binding instruments). At the international level, there are rules which have a gradually increasing binding force: *custom* can produce the effects of law but is not written down; *soft law* involves rules which are not binding, amongst which can be classed the declarations and conventions by international organizations whose object is to lead to legal obligations for signing countries. Despite this disparity, a similar movement towards governance has appeared to supervise the activity of biobanks both at international and national level.

The founding texts for the protection of persons involved in biomedical research were applied by analogy, to human biological samples used in research. So, when it became technically and scientifically possible to use materials from the human body previously stored for research purposes, it was to the protection of the research subjects that the public authorities referred to. The legal analogies between the human being, the materials from the body and the rights of human beings have founded the level of protection of subjects. The more the materials from the body are assimilated with the persons themselves, the more the duties of protection asserted by public authorities are far reaching. This protection is principally related to the fundamental rights. Whereas international regulation is oriented on the respect of ethical principles and traces the limits of the uses of genetics, European regulation has more concerns with the protection of fundamental rights and the elaboration of standards for biobanks' quality insurance. This analysis leads to question whether this protection is adequate and the legal instruments analysed relevant in practice.

Emmanuelle RIAL-SEBBAG, Sophie JULIA, Gabrielle BERTIER, Anne-Marie DUGUET, Anne CAMBON-THOMSEN

New Bioethics Law in France regarding human genetics: evolution, revolution or stagnation?

France just completed the process of revising its bioethics law nearly 7 years after its last revision (2004). This law addresses genetic testing among other aspects (e.g. embryo stem cell research, transplantation, medical aided procreation). In various French legal instruments genetic information is treated apart from other biologic information given its potential misuses and its familial dimension. The proposal for revising the law is focusing on two major points of genetics: communication of the genetic Information and optimisation of laboratory's quality. Based on professional secrecy medical doctors could not inform, on their own decision, family members about genetic characteristics, even if relevant for them. New procedures to allow medical doctors to disclose such information to family members are proposed; liability incurred in case of non transmission of the information and the role of patients associations to deliver relevant information are underlined. Although provisions on quality aspects in a bioethics law can be discussed, they aim to protect people through a high quality of laboratory tests and analyses performed, with regards to direct to consumer genetic tests on internet. A key role will be devoted to the "Agence de la Biomédecine" for assessing quality of laboratories and delivering information regarding such tests. Many other aspects have been discussed in the preparatory debates to the revision, such as consent issues (for deceased people) or biobanks and are absent from the proposal. However these issues are among the most problematic in research and practice. We will discuss the consequences of this lack of regulation.

Ateliers de droit médical
Health law workshops

1er et 2 juillet 2011 de 9h à 17h
June 30 201& from 9 am to 5 pm

Actions pour la santé et la recherche médicale
en faveur des personnes vulnérables et des pays émergeants
Health programs and medical research
in favor of vulnerable patients and emerging countries

Salle de conférences de la Faculté de médecine de Rangueil
133 Route de Narbonne - Toulouse

Programme

Actions pour la santé et la recherche médicale en faveur des personnes vulnérables et des pays émergents

1 Juillet 2011 : Vulnérabilité et populations vulnérables

9h 15- Accueil : Pr Daniel - Rougé Doyen de la faculté de Médecine de Rangueil
9h30- Présentation de l'Ecole Européenne d'été et perspectives - Anne-Marie Duguet

9h45- Conventions et recommandations internationales
Président de séance : Pr Berna Arda (Turquie)

- Morikawa Marcia Mieko, Université de Coïmbra (Portugal): *Degrees of vulnerability in human rights Access to health care and humanitarism.*
- Henriette Roscam Abbing, Université d'Utrecht (Pays-Bas): *Right to healthcare for undocumented migrants, European conceptual framework and situation in the Netherlands.*

10h 45- Pause

11h- Protection des populations vulnérables
Président de séance : Pr Henriette Roscam Abbing (Pays Bas) Session en coopération avec l'Association Européenne de Droit de la santé EAHL

- Sophie Paricard, Université Toulouse 1 Capitole (France): *L'encadrement de la volonté des personnes en fin de vie.*
- Washington Fonseca, UNIBAN (Brésil): *Euthanasia, orthotanasia: the inadmissibility of the right to kill terminally ill and vulnerable patients.*
- Paolo Girolami (Italie) *La médecine en milieu pénitentiaire à l'épreuve de l'éthique.*

13h- Déjeuner

14h- Conférence: Pr Christian Hervé -Laboratoire d'éthique médicale Université Paris-Descartes

De l'éthique de l'autonomie à celle de la vulnérabilité: la chaire francophone de bioéthique proposée par l'Université Paris Descartes

14h 45- Accès aux soins et à la recherche des populations vulnérables (1)
Président de séance :Pr Hongjie Man (PR China)

- Dean M. Harris, J.D.Clinical Professeur Associé, University of North Carolina (USA): *The Declaration of Helsinki: The Effect on Vulnerable Populations of the Provisions about Placebo-Controlled Trials and the Duties of Post-Trial Care.*
- François Hirsch, Aviesan (France): *Recherche technologique et vulnérabilité: ou comment résoudre un problème éthique ?*
- Anne-Laure Knellwolf , ISS Rome (Italy): *Medical research and vulnerable populations: Key ethical considerations for the clinical researcher*

16h15- Pause

16h30 - Accès aux soins et à la recherche des populations vulnérables (2)
Président de séance : Pr Christian Hervé (France)

- Eduardo Dantas, Vice President WAML (Brésil): *Economic vulnerability, consent and clinical research.*
- Bénédicte Boyer-Bévière, Maître de conférences, Université de Besançon (France) : *L'appréhension de la vulnérabilité des malades d'Alzheimer lors des recherches.*

- Jean-Paul Rwabihama (Rwanda) *Les migrants âgés et l'accès aux institutions de soin.*

Samedi 2 juillet 2011 : Pays du Sud et pays émergents

9h -Distribution des soins dans les pays du Sud et les pays émergents

Président de séance : Pr Isabelle Poirot-Mazères (France)

- Wafa Harrar-Masmoudi, Maitre-assistante Université de Carthage (Tunisie) : *La santé mentale en Tunisie*
- Pr Caroline Beatriz Fauri, Université de Porto Alegre (Brésil) : *Dix ans de nouvelle politique de santé mentale au Brésil*
- Bardaa Sami, W. Ben Anae, Z.Khemakem, A.Ayadi, K.Reguaieg, Z.Hammani, Samir Maatoug, (Tunisie) : *Actions sanitaires pour les réfugiés en Tunisie*

11h- Pause

11h15- Soins médicaux et recherches dans les pays émergents

Président de séance : Pr Abdelaziz Benharkat (Algérie) Session en coopération avec le réseau EthiMED

- Simona Gaudi, ISS Rome (Italie): *Post genomics of complex diseases in the Mediterranean Region.*
- Allane Madanamoothoo, Enseignante en droit ESC Troyes (France*) : Quel cadre juridique pour lutter contre les pratiques coutumières portant atteinte à l'intégrité corporelle des enfants en France ?*
- Rachid Mengeli, EHESS (France) : *Conteurs ou thérapeutes traditionnels?*

13h- Déjeuner

14h - Influence de la culture sur l'organisation des soins et de la recherche

Président de séance : Pr Dean Harris (USA)

- Hongjie Man, Professeur Associé Chandong University (Chine): *Informed Consent-The Universal Doctrine and Its Chinese Reality.*
- Rodica Gramma , State medical and Pharmaceutical N Testeminatu University (Moldavia): *The impact of some cultural aspects on the public health in Republic of Moldavia.*
- Pr Assia Benharkat, Université de Constantine (Algérie) *Médecine traditionnelle en Algérie: influence de la culture sur l'organisation des soins.*

15h30- Pause

15h 45-Médecine traditionnelle

Président de séance : Pr Samir Maatoug (Tunisie) Session en coopération avec la China Health Law Society

- Pr Liao Xiaoping, President of Hainan medical University (PR(China): *An Introduction of Traditional Chinese Medicine.*
- Tasnim Masmoudi ,Faculté de médecine de Sousse (Tunisie) *Médecine traditionnelle en Tunisie*
- Marius Kenote, PhD (Bénin) *Soins et recherche en médecine traditionnelle en Afrique Subsaharienne: défis de son intégration dans la médecine moderne.*

17 h- Séance de clôture et remise du Prix de l'ARFDM

Program

Health programs and medical research in favor of vulnerable patients and emerging countries

Friday July 1st 2011 Vulnerability and vulnerable populations

9h15- Welcome by Pr D Rougé Dean of the Medicine faculty of Rangueil
9h30- Presentation of the European Summer School and perspectives - Anne-Marie Duguet

9h45- International conventions and recommendations
Chair person: Pr Berna Arda (Turkey)

- Morikawa Marcia Mieko Coïmbra University (Portugal): *Degrees of vulnerability in human rights Access to health care and humanitarism.*
- Henriette Roscam Abbing ,Université d'Utrecht (The Netherland): *Right to healthcare for undocumented migrants, European conceptual framework and situation in the Netherlands.*

10h45- Coffee break

11h- Protection of vulnerable populations
Chair person: Pr Henriette Roscam Abbing (The Netherlands) Session in coopération with the European Association of Health Law (EAHL)

- Sophie Paricard Senior lecturer (University of Toulouse): *Framing the wills of patients ending life*
- Washington Fonseca Lawyer (Brazil): *Euthanasia, orthotanasia: the inadmissibility of the right to kill terminally ill and vulnerable patients.*
- Paolo Girolami (Italie) *Medicine in prison throuh the ethics perspective*

12h30 - Lunch

14h- Conference: Pr Christian Hervé -Laboratoire d'éthique médicale Université Paris-Descartes
From ethics of vulnerability to ethics of vulnerability : the French speaking chair of bioethics proposed by the Paris Descartes University.

14h45- Access to health care and to the research of vulnerable populations (1)
Chair person :Pr Hongjie Man (PR China)

- Dean M. Harris, J.D.Clinical Professeur Associé ,University of North Carolina. (USA) *The Declaration of Helsinki: The Effect on Vulnerable Populations of the Provisions about Placebo-Controlled Trials and the Duties of Post-Trial Care.*
- François Hirsch , Aviesan (France) *Technological research and vulnerability : or how to solve an ethical issue?*
- Anne-Laure Knellwolf , ISS Rome (Italy) *Medical research and vulnerable populations: Key ethical considerations for the clinical researcher*

16h15- Coffee break

16h30- Access to health care and to the research of vulnerable populations (2)
Chair person :Pr Christian Hervé (France)

- Eduardo Dantas, Vice president WAML (Brésil) *Economic vulnerability, consent and clinical research.*
- Bénédicte Boyer-Bévière, Maître de conférences Université de Besançon (France)*Taking into account the vulnarability of patients with Alzheimer involved in biomedical researches*
- Jean-Paul Rwabihama (Rwanda) *Elderly immigrants and the access to health care institutions*

Saturday July 2nd 2011: Emerging countries

9h- Health care distribution in Southern and emerging countries

Chair person: Pr Isabelle Poirot-Mazères (France)

- Wafa Harrar-Masmoudi, Assistant Professor University of Cathage (Tunisia) *Mental health in Tunisia.*
- Pr Caroline Beatriz Fauri University of Porto Alegre (Brazil) *Ten years of mental policy in Brazil*.
- Bardaa Sami,W.Ben Anae,Z.Khemakem ,A.Ayadi,K.Reguaieg,Z.Hammani Samir Maatoug , (Tunisie) *Health care programs for refugees in Tunisia*

10 h 45-Coffee Break

11h- Health care and researches in emerging countries

Chair person : Pr Abdelaziz Benharkat (Algérie) Session in cooperation with EthiMED network

- Simona Gaudi, ISS Rome (Italy) :*Post genomics of complex diseases in the Mediterranean Region*
- Allane Madanamoothoo, Enseignante en droit ESC Troyes (France *) : Which legal framework in France for fighting against the traditional practices that injures the child bodily integrity?*
- Rachid Mengeli, EHESS (France) *Story tellers or traditional health care provider ?*

12h30- Lunch

14h - Influence of culture on heath care organization and medical research

Chair person : Pr Dean Harris (USA)

- Hongjie Man Professeur Associé Chandong University (PRChina) *Informed Consent- The Universal Doctrine and Its Chinese Reality.*
- *R*odica Gramma , State medical and Pharmaceutical N Testeminatu University (Moldavia) *The impact of some cultural aspects on the public health in Republic of Moldavia.*
- Pr Assia Benharkat University of Constantine (Algéria) *Traditional medicine in Algeria : influence of culture on the heath care organization.*

15h30- Coffee Break

15h45- Traditional medicine

Chair person: Pr Samir Maatoug (Tunisie) Session in cooperation with the China Health Law Society

- Pr Liao Xiaoping President of Hainan medical University (PRChina): *An Introduction of Traditional Chinese Medicine.*
- Pr Tasnim Masmoudi Faculty of Medicine Sousse (Tunisia) *Traditional medicine in Tunisia*
- Marius Kenote PhD (Benin) *Health care and research on traditional medicine in Sub Saharian Africa: challenges of its integration in modern medicine*

17h15 - Award ceremony for the ARFDM Prize

Résumes

Abstracts

Marcia Mieko MORIKAWA
Université de Coïmbra (Portugal)

Degrees of vulnerability in human rights Access to health care and humanitarism.

Numerous instruments of International Human Rights address the protection of the right to health. States parties are responsible for adopting appropriate sanitary and social measures for the protection of the right to health. This protection system may in times of armed conflicts be completely disorganized or even annihilated. The effects of war are multifaceted and may result in humanitarian tragedies affecting the whole population of a country (civilians and combatants). Wounded persons (civilians or combatants) have the right to receive appropriate and effective health care.

Thinking about vulnerability as a concept of human rights, the situation of armed conflict is the worst one in terms of vulnerability – meaning the exposure of human beings to situations in which they need *extra care and protection*. Sometimes it means also the the lack of power itself to individual to ask for protection. Despite the idea of great vulnerability in wartimes, both International Human Rights Law and International Humanitarian Law (IHL) offer important protections for the right to health. As *lex specialis*, IHL offers the legal bases for a broad protection of the right to health in armed conflicts.

The right to health means *the right to access to health services* that must be organized in accordance with the rules of IHL. In wartime, it is the responsibility of the parties to an armed conflict to provide for the well-being and health of the population under their control (e.g. the occupied population,) and to facilitate assistance by neutral relief agencies according to IHL. Many rules of IHL provide the appropriate protection to the right to health such as the organization of health services, right to access, protection of medical facilities, the right to health against the effects of certain weapons, the prohibition to starve civilians and medical ethics in times of war.

Pr Dr Henriette ROSCAM-ABBING

Healthcare and irregular migrants: human rights framework and the Dutch situation

The right to have access to healthcare of irregular children is part of the International Convention on the rights of the Child (1989); for all irregular migrants it is specifically mentioned in the General comment no 14, 2000 by the UN Economic ands Social Council. States have positive obligations to ensure equal access to healthcare. It follows from European Union funded research that in practice equitable access to healthcare is not secured for irregular migrants.

The access is mostly very restrictive and if provided, the healthcare often is inadequate. Sometimes there is no access unless the irregular migrant pays the bill. Sometimes access is restricted to emergency care only. To meet with the shortcomings, civil society has organised outreach clinics beside the official healthcare system. Obstacles form the side of the irregular migrant include the obligation to identify oneself and fear from being denounced. The Medical follow-up is largely inadequate, health services are not adapted to specific ethnic related health needs, mental health services are not adequate, reproductive and sexual health services often not guaranteed.

In the Netherlands in theory the system gives access to healthcare services. In practice there are impediments: for primary and emergency care the irregular migrant has to pay the bill, unless proof of incapability, in which case the healthcare provider receives a certain percentage of the costs. Indirect accessible healthcare must be obtained from services who for this purpose have a contract with the Dutch College for Health Insurance.

The medical service must be necessary, taking into account the patients needs, and the expected length of stay (often unknown to the healthcare provider).

Investing in the health of the irregular migrant has public health advantages and is cost effective.

Sophie PARICARD,
Université Toulouse 1 Capitole (France)

L'encadrement de la volonté de mourir d'un patient particulièrement vulnérable, la personne en fin de vie.

Comment encadrer la volonté de mourir de ce patient particulièrement vulnérable qu'est la personne en fin de vie ? La question est délicate car elle soulève toutes les problématiques liées au refus de soins, à l'euthanasie et au suicide assisté.
Paradoxalement, alors même que la volonté exprimée est capitale car il s'agit de mettre fin à sa propre vie, l'encadrement de cette volonté n'est pas confié aux professionnels du droit dans le respect des traditionnels principes juridiques.

Soit le droit décide d'exercer un contrôle sur cette volonté, et c'est généralement le cas lorsque la législation en question accepte la prise de médicament mortifère, comme en Belgique, aux Pays-Bas, ou dans certains Etats d'Amérique. Mais alors il répugne à exercer un contrôle traditionnel sur cette volonté qui produit pourtant un effet de droit puisqu'elle justifie un acte médical mortifère. Et le contrôle est alors confié au seul corps médical. Il peut alors être qualifié de feutré dans le sens qu'il reste léger, ouaté pour le patient.

Soit le droit éradique tout contrôle et c'est généralement le cas lorsque la législation accepte le seul refus de soins. Il peut alors maximiser l'efficacité de cette volonté en rendant obligatoire le respect d'une telle volonté, ce qui est le cas le plus fréquent notamment dans les pays anglo-saxons. Il peut aussi neutraliser cette volonté, en confiant finalement la décision au seul corps médical, comme c'est le cas en France dans l'hypothèse où la personne est inconsciente.

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Euthanasia, orthotanasia: the inadmissibility of the right to kill terminally ill and vulnerable patients.

This study aims to address the legal aspects involved in the treatment of terminally ill and vulnerable patients through the use of techniques related to euthanasia and orthotanasia. The effectiveness of law depends directly on the dynamics established between law and social relations. Discussions related to ethical and legal limits are linked to the dignity of the patient regarding the extension and/or shortening of his life. These are some aspects of the human evolution, which are in vogue. Much is said regarding the right to live, which is considered the greatest value to be socially and legally protected. However, although life is considered a supreme right, is it worth nothing if apart from other precept which is currently much invoked: the human dignity.
Discussions about ethical & legal limits regarding patient's dignity in the extension and/or shortening their lives. Also, appreciation of assumptions inherent to human rights is discussed. Constitutional and civil rights applicable in Brazil and other countries are also object of study. Another point is worth mentioning: how to protect the exercise of rights of patients who find themselves in vulnerable condition, in situations where discernment is reduced or even there is no discernment at all? The subject of this study is to evaluate whether active or passive conducts accelerates the decision to keep a patient alive or if it´s better to shorten his path to death. Would shortening the life be the best treatment for the patient? Would it be worth to terminally ill patients (in a situation of vulnerability) such decision? Also, criminal aspects of orthotanasia and euthanasia before Brazilian and other countries legal systems´ are analyzed. It concluded that, with use of palliative care, the search for euthanasia is unnecessary. The dignity of the human person embodied in patient´s autonomy shall be above all treatments provided by science. This study addresses issues linked to Articles 4 and 9 of the Oviedo Convention.

Key words: suicide, euthanasia, orthotanasia, palliative care, right to die.

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La médecine en milieu pénitentiaire à l'épreuve de l'éthique

Il peut apparaître paradoxal de penser à la médecine en tant que composante fondamentale de l'appareil pénitentiaire en général et de la prison en particulier.
En effet, la médecine participe aux activités de la prison d'une double façon: d'un côté elle garantit, avec sa présence constante et le travail du soin des professionnels de santé du caractère humanitaire de l'institution pénitentiaire, de l'autre, elle constitue l'amortisseur le plus important de la dérive de violence à laquelle le monde de la pénalité est exposé.
Par rapport à la sanction de l'enfermement, on sait qu'on peut attribuer plusieurs fonctions à la prison: une fonction d'expiation, une fonction de dissuasion, une fonction de neutralisation et, en fin, une fonction de réadaptation.
Il n'est pas difficile de reconnaître dans toutes ces fonctions de la prison une tentative d'exorciser le mal et la violence que le délinquant porte imprimée dans son histoire et dont la victime est le témoin, la même tentative que la médecine exprime dans son combat contre le mal de la maladie et de la souffrance. La guérison n'est-elle un passage qui prévoit le temps du constat de la maladie et donc une expiation à travers un travail d'élaboration de la souffrance, le temps de la persuasion de l'utilité des remèdes offerts par la médecine (et donc de la dissuasion du recours à toute autre solution qui n'appartient pas au savoir médical), le temps de la mise en œuvre des ressources thérapeutiques au fin de neutraliser les effets néfastes de la maladie et, en fin, le temps de la restitution à l'état de santé précédent?
Néanmoins, il n'est pas difficile de constater que tous ces passages se déroulent tout au long de l'idée que la maladie constitue un événement troublant pour la vie de l'individu et de la collectivité.
Il en suit que il faut mettre en place des mesures de maîtrise du risque: risque de perte de contrôle de la maladie et donc risque de chronicité, risque de contagion, risque de mort…
Dans le langage pénitentiaire le terme risque se traduit par danger et, particulièrement, par la mise en danger d'un bien propre ou d'autrui et la personnification du danger donne lieu à la figure du sujet dangereux. Cette attitude à attribuer à la personne assujettie à une peine, (qui par définition se trouve dans un position de passivité et donc dans la position du patient), le rôle actif de l'agent, en tant que porteur d'un danger, cache la dimension passive de vulnérabilité à laquelle la contrainte de la punition l'expose, vulnérabilité qui, par ailleurs, constitue le domaine de compétence de la médecine. Derrière les barreaux, l'être vulnérable, le plus fragile du groupe, se trouve souvent encore plus vulnérable: la famille, les amis, les collègues...ne sont plus là pour le protéger. Et ce dernier serait à la merci des plus puissants. Il s'agit d'une vulnérabilité, qui, à cause du milieu dans lequel s'exprime, se prête à des remèdes qui sont contaminés par le germe de la mesure adoptée d'autorité et donc par l'autoritarisme.
Le défi éthique de la médecine en milieu pénitentiaire consiste alors dans un effort d'analyse, de mise en question, et de refus de toute forme d'autoritarisme dans le travail de soins à la faveur de sujets privés de la liberté.

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De l'éthique de l'autonomie à celle de la vulnérabilité : la Chaire francophone de Bioéthique proposée par l'Université Paris Descartes

Ce qui manque le plus à notre conception de la bioéthique est l'approche pluriculturelle qu'apportent l'UNESCO et les collègues des Pays du Sud quant à une bioéthique souvent présentée sous la forme de ses apparences et de ses préoccupations éthiques occidentales. En effet, si le classement de Shanghai intégrait, dans ses critères, la réalisation de telles co-tutelles en bioéthique et travaux de recherche en commun (sachant qu'autant les Pays du Nord profiteraient des expériences et travaux des Pays du Sud), la liste qui en est issue ne serait pas que scientifique mais également éthique, intégrant la nécessaire et urgente interdisciplinarité que même nos avancées techniques comme les nanotechnologies réclament. Une Chaire francophone de bioéthique se comprend en termes de création spéculative mais aussi d'évaluations du respect des droits et de l'humanité qu'elle prône. La bioéthique est l'expression intuitive d'un espace nouveau à construire qui répondrait par sa structure aux incohérences de notre actuel système mondialisé qui fait que la pauvreté progresse, que les morts par la famine sont devenus insupportables dès lors que nous prônons une dignité égale attribuée à tout être humain. Certains économistes, dont Amartya Sen, en concluent qu'au6delà des droits que l'on peut accorder aux individus citoyens, c'est l'accès à ces droits qui est majeur ("functionnings" ou "capabilities"), alors que la possibilité d'accéder à ces droits est discriminante. Ainsi, le premier des problèmes éthiques que sont les inégalités de santé apparaît déjà dans les Pays du Nord. Cette situation est encore plus préoccupante en ce qui concerne les Pays du Sud. Des recherches sémantiques sont alors nécessaires, réalisées dans une visée de création interdisciplinaire. Par exemple, d'une éthique de l'autonomie habituellement explicitée dans l'enseignement bioéthique se démasque la nécessité d'élaborer une éthique de la vulnérabilité comme Corinne Pelluchon[1] l'appelle si bien, éthique qui renverse la donne bioéthique depuis sa naissance aux USA et se préoccupe de ceux des plus faibles "qui ne peuvent plus" au sens de la faillite de la notion "d'estime de soi" comme processus d'accession à la liberté selon Paul Ricœur[2].

[1]Corinne Pelluchon. Bioéthique et philosophie. Coll Léviathan. PUF, 209, 167-203.
[2]Paul Ricœur. Soi-même comme un autre. Le Seuil, 1990.

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"Declaration of Helsinki: The Effect on Vulnerable Populations of the Provisions about Placebo - Controlled Trials and the Duties of Post-Trial Care."

In recent years, researchers have been performing more trials in developing countries. This trend is likely to increase, and raises serious ethical issues about the effect on vulnerable populations. Some of these ethical issues relate to the principles of informed consent or beneficence, while other ethical issues relate to the principle of justice.

Justice requires that the benefits and burdens of research be distributed fairly. In addition to fairness in selecting human subjects, two other aspects of research raise important issues of justice. These two aspects are the use of placebo-controlled trials and the arrangements for post-trial care. In its Declaration of Helsinki, the World Medical Association (WMA) has issued a series of ethical pronouncements on those issues, but the WMA has failed to protect the interests of vulnerable populations.

The issue of placebo-controlled trials is whether a new treatment should be evaluated against the best existing treatment, if any, or against a placebo. If a proven method of treatment already exists, that method is referred to as the "standard of care." Rather than testing a new treatment against the standard of care, however, many researchers prefer to test new treatments against a placebo, because that might produce more useful data and might facilitate regulatory approval of new drug products. The WMA's Declaration of Helsinki initially provided that placebo-controlled trials are unethical when there is a proven method of treatment. Subsequently, the WMA changed its position to provide that it is ethical to conduct placebo-controlled trials under some circumstances, even when there is a proven method of treatment. By making that change, the WMA may be allowing researchers to increase the burden on human subjects of research.

The issue of post-trial care refers to the obligation which researchers owe to their human subjects after the trial is completed, under the ethical principle of justice. Initially, WMA's Declaration of Helsinki required researchers to provide the best proven treatments to all of the subjects in the trial. The WMA again retreated from its initial position, and substituted a provision which is vague and which fails to protect the interests of vulnerable populations.

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Recherche Technologique et Vulnérabilité, ou comment résoudre une tension éthique

De nombreuses technologies sont en cours de développement dans le domaine de la santé, offrant ainsi à la médecine du 21ème siècle des outils qui révolutionneront sans aucun doute la pratique médicale. Ces technologies touchent tous les champs de la médecine depuis le diagnostic jusqu'aux soins post-traitement, en passant bien entendu par la thérapeutique. Outil majeur du diagnostic, l'imagerie, qui permettra d'obtenir une vision 3D de plus en plus fidèle de l'organisme entier ou d'un organe, voire au niveau cellulaire grâce à de nouveaux endoscopes capables d'analyses histo-cytologiques en temps réel. La thérapeutique sera également bouleversée grâce notamment aux nouvelles méthodes chirurgicales qui font appel à l'informatique et à la robotique (simulation d'une intervention pré-opératoire, puis robotisation du geste chirurgical). La chimie biologique permettra également un bien meilleur ciblage des médicaments vers leurs cibles par l'encapsulation de principes actifs dans des nano-particules. Enfin de nouveaux dispositifs médicaux implantables permettront soit une délivrance intelligente de principes actifs par des nano-pompes les relarguant en fonction des besoins de l'organisme, soit la stimulation contrôlée intra-cranienne dans le cas de maladies neurodégénératives ou intra-cardiaques pour pallier aux déficiences du cœur. Enfin, la technologie va également envahir le champ de l'aide à l'autonomie pour les personnes à mobilité réduite, handicapées ou âgées notamment au travers des avancées de la domotique.
La question qui résulte de ce catalogue de prouesses technologiques est bien entendu en rapport avec le modèle économique qui les sous-tend. En effet, sans parler de l'aggravation de la disparité Nord-Sud en matière d'accès aux soins que constituera la mise sur le marché de ces technologies, pensons-nous avoir les moyens de financer leur utilisation dans nos sociétés dites industrialisées où l'accès aux soins primaires est déjà interdit à un grand nombre de nos concitoyens ? Différentes études économiques assurent que, par exemple, le maintien à domicile de personnes à mobilité réduite dans un contexte de pénurie en personnel de santé et en structures médicalisées, constitue une source d'économies substantielles. Cependant, n'assisterons-nous pas à une aggravation de la perte de lien social déjà observée ? La télé-surveillance ou la mise à disposition de systèmes robotisés à domicile permettent en effet de maintenir les patients dans leur cadre familier mais dans une solitude de plus en plus preignante. Toutes ces craintes rendent indispensables la mise en place d'études d'impact sociétal de ces technologies ainsi que le financement de chercheurs en sciences humaines et sociales animant des programmes ciblés sur ces thématiques. Ces recherches devraient permettre d'établir ou non de l'intérêt de ces nouvelles technologies et de là de leur acceptabilité sociale.

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Medical research and vulnerable populations:
Key ethical considerations for the clinical researcher

Clinical researchers performing clinical trials in southern countries including vulnerable subjects should be aware of key ethical principles for biomedical research as stated in regulations, guidelines and international recommendations such as:
- Appropriate level of ethical review in the host state and the state in which the funder is located
-Relevance of the research to be carried out in the host country
-Choice of control group accordingly
-Non commercialization of biological components derived from human body
-Protection of people privacy
-Clinical trial registration before study start
-Implementation of good clinical practices for the conduct of the trial

The purpose of the presentation will be a pragmatic approach on how to implement such ethical principles and will be illustrated by two studies in which ISS was/is involved:

-A randomised clinical trial published in Lancet in 2002 entitled "Efficacy of three short-course regimens ofzidovudine and lamivudine in preventing early and late transmission of HIV-1 from mother to child in Tanzania, South Africa and uganda: a randomised, doubleblind, placebo controlled trial).

-A pilot prospective cohort project (MedGENE) to study the genomic components related to the susceptibility of schizophrenia in adult in Italy (ISS-San Raffaele La Pisana).

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Economic vulnerability, consent and clinical research

Autonomy and consent are two of the most important issues in healthcare and clinical research today, especially because of their legal consequences (or side effects), raising new questions and dilemmas. And if all of this happens even in a "controlled environment", with non-urgent treatments and programmed interventions, the situation gets worse when there´s another component added to the equation: vulnerability. What happens, then, when this vulnerability is caused not only by (lack of) health conditions, but also for economic reasons? How can an economic vulnerable person truly exercise his/her autonomy when their consent is not desirable? Is there a way to protect these people?

Socioeconomic condition is an important component in the study of vulnerability as a limitation to the right of individuals to exercise autonomy in medical treatments and clinical trials.

These are the questions this study aims to answer, analyzing moral conflicts, legal options and ethical dilemmas, with a particular view of the Brazilian background.

Key words: vulnerability, autonomy, clinical research, bioethics.

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L'appréhension de la vulnérabilité des malades d'Alzheimer lors des recherches

En 2010, ont été dénombrées plus de 35millions de personnes malades atteintes de la maladie d'Alzheimer sur la population mondiale de 6,7 milliards d'individus. Ce chiffre devrait doubler tous les vingt ans, notamment en raison du vieillissement des populations et de l'augmentation de la durée de vie. Ce fléau constitue un enjeu majeur de santé publique en France et mobilise autant les pouvoirs publics que les acteurs institutionnels et sociaux, que les malades par leur participation à des programmes de recherches, que leurs accompagnants. Il constitue d'autant plus une priorité nationale que la vulnérabilité des patients est marquée par leur particulière fragilité en raison de la forte souffrance morale et psychologique de se voir peu à peu perdre leurs capacités de mémoire, leurs fonctions cognitives, leurs facultés de compréhension, de jugement, de raisonnement, au point de perdre peu à peu leurs repères, leur indépendance, leur autonomie, leur liberté et, plus largement, leur dignité. Cet état de précarité progressif et continu, en développement immuable et irrémédiable, suppose un accompagnement visant à protéger les patients pour ménager au mieux leurs conditions d'existence et leurs intérêts qu'ils peuvent de moins en moins défendre.

L'appréhension de la vulnérabilité des malades d'Alzheimer, sujets de recherche, suppose par conséquent une approche appropriée qui renvoie à des problématiques diverses. Comment intégrer le patient dans le processus décisionnel de la recherche alors qu'il perd peu à peu son autonomie, son identité et sa faculté d'intervenir ? Quels sont les moyens d'accompagnements possibles ? Comment appréhender la personne de confiance? Comment gérer les directives anticipées ? Comment les chercheurs doivent-ils réagir à l'égard de l'intégration progressive des proches à la prise de décision ? Faut-il privilégier la collégialité ? Faut-il prévoir des moyens complémentaires d'accompagnement quand on sait que les aidants deviennent eux-mêmes particulièrement vulnérables en raison des multiples missions auxquelles ils doivent faire face dans la durée ? Les institutions, les associations, les réseaux ont-ils un rôle à jouer pour mieux gérer la dépendance et l'assistance?

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Les migrants âgés et l'accès aux institutions de soin

Introduction

La prise en charge des personnes âgées implique une institutionnalisation des patients en perte d'autonomie. Avant une admission en Etablissement d'Hébergement pour Personnes Agées Dépendantes (EHPAD), ceux-ci passent d'abord par le circuit hospitalier du secteur aigu, puis en rééducation et réadaptation et si besoin, en unité de Soins de Longue Durée (SLD) avant d'intégrer un EHPAD. Ce parcours est moins accessible aux personnes âgées issues de l'immigration. Le but de ce travail est de décrire certains obstacles que rencontrent les migrants âgés en perte d'autonomie.

Méthode

A partir du Pôle de Soins de Longue Durée de l'hôpital Joffre-Dupuytren (AP-HP) qui collabore avec certains EHPAD du bassin de l'Essonne (91), nous nous sommes intéressés, de manière rétrospective, à la procédure d'admission des sujets âgés en institution, et un accent particulier a été porté sur l'institutionnalisation des migrants âgés du 1er janvier au 31 décembre 2009. Nous décrivons des facteurs socioculturels qui constituent un handicap à l'accès aux institutions de soin pour cette population.

Résultats

Les 15 EHPAD ayant une convention avec le pôle SLD ont admis 80 des 240 patients (33,3%) hospitalisés (âge moyen 83,2 ans). Dix-sept d'entre eux (21,3%) étaient issus de l'immigration dont 12 originaires du Maghreb. Sept autres immigrés du Maghreb n'ont pas été admis en EHPAD: 2 à cause de l'attente d'aide sociale, 3 hébergés à titre gracieux ne pouvaient intégrer une structure spécialisée non agréé par le département et 2 autres reconnus propriétaires d'appartement en France mais isolés de leur communauté d'origine. Ces 2 derniers entretiennent une réticence à une en EHPAD en souhaitant un retour au pays devenu irréalisable à cause de l'enracinement, du regard de leurs proches sur l'altération de leur intégrité physique ou psychique ou encore par défaut de structures adaptées autres que les centres d'accueil des vieillards (APPA). Enfin, la barrière de la langue a conduit à un diagnostic erroné, privant ainsi un patient d'un transfert en EHPAD. Le rôle des aidants et la présence des bénévoles représentent un soutien réconfortant pour ces patients.

Conclusion

L'accès des migrants âgés aux institutions de soin devrait prendre en compte leurs spécificités socioculturelles dans le respect des droits et de la dignité de la personne. D'autres études en sciences humaines pourraient améliorer la prise en charge de ces patients.

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La santé mentale en Tunisie

La santé mentale constitue un problème de santé publique. Le défi posé par cette question en Tunisie est à l'origine de la promulgation de la loi n°92-83 du 03 août 1992 relative à la santé mentale et aux conditions d'hospitalisation en raison de troubles mentaux, telle que modifiée par la loi n°2004-40 du 03 mai 2004. L'objectif de ladite loi est d'assurer le traitement des maladies mentales dans des dispositifs appropriés ; de clarifier et d'améliorer l'état des soins prodigués aux malades mentaux, notamment les possibilités d'hospitalisation. Elle consacre à cet égard le principe du libre placement, où le principe de l'hospitalisation consentie. Il demeure entendu que le régime de l'hospitalisation libre concerne les personnes dont l'état mental ne met pas en péril leur propre sécurité ou celle des tiers et ne rend pas impossible leur consentement, d'où l'exception admise par la même loi du régime de l'hospitalisation sans consentement, un régime rigoureusement conditionné à certains cas énumérés de manière limitative et décliné sous deux modalités : à la demande d'un tiers (HDT) ou d'office (HO).

Mental Health in Tunisia

Mental health represents a problem of public health. The challenge aroused by this issue in Tunisia found its answer in the law n°92-83 of August 03rd, 1992 relating to the mental health and the conditions of hospitalization due to mental disorders, modified by the law n°2004-40 of May 03rd, 2004. The aim of the aforementioned law is to assure the treatment of the mental illnesses in appropriate structures, to clarify and improve the state of the mental patients, in particular the possibilities of hospitalization. This law recognizes in this respect the principle of free placement, also known as the principle of the agreed hospitalization. It is worth mentioning that the regime of free hospitalization is related to persons whose mental state doesn't put in danger their own security or that of third parties and doesn't prevent them from expressing their consent, hence the law authorizes an exception, namely the hospitalization without consent, a regime strictly limited to certain cases and under two modalities: hospitalization at the request of a third (HDT) or automatic hospitalization (HO).

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Dix ans de nouvelle politique de santé mentale au brésil

Instaurée par la Loi Fédérale 10216 du 6/4/2011, la nouvelle politique brésilienne de santé mentale a rompu avec le modèle asilaire de traitement au profit du modèle communautaire, formé d'un vaste réseau d'assistance qui comprend les soins, la réhabilitation et la réinsertion sociale de personnes souffrant de troubles mentaux et d'addiction à l'alcool et aux drogues.

Ces objectifs ont été mis en place à travers les arrêtés du Ministère de la Santé, qui ont institué divers services à la place des anciens « hôpitaux psychiatriques ». Les nombreuses modalités de « Centres d'Accueil Psychosocial » (CAPS), créés par l'arrêté ministériel 336/2002, se chargent du premier accueil, de la médication, de l'observation et, pour les cas graves, de l'acheminement vers des hôpitaux généraux. Grâce à cela, le nombre de lits en hôpitaux psychiatriques a considérablement baissé. Les « Résidences Thérapeutiques », instaurées par l'arrêté ministériel 106/2000, ont également collaboré à cette réduction en accueillant les patients qui ne sont pas en mesure de rentrer chez eux. Chaque accueil correspond à la fermeture d'un lit en hôpital psychiatrique. Parallèlement, il existe des mesures d'incitation à la réinsertion sociale, qui privilégient une nouvelle idéologie en termes de santé mentale ; c'est le cas du « Programme de Retour Chez Soi » (Loi 10708/2003), qui verse pendant un an au patient une valeur mensuelle pour subvenir à ses besoins ; ou encore les « Coopératives Sociales » (Loi 9867/1999), qui offrent une formation professionnelle aux malades.

Néanmoins, le souci apparent du Gouvernement pour le malade mental ne résiste pas au conflit avec la réalité des services mis à disposition. Le conseil Fédéral de Médecine dénonce le manque national de lits et de médecins ; le temps d'internement est fixé par la loi, et non par le besoin du patient (arrêtés ministériels 2197/04 et 1612/05) ; les horaires de fonctionnement des CAPS sont restreints (arrêté ministériel 336/02) – ce qui a conduit l'OMS à demander l'édition de l'arrêté ministériel 2841/2010 qui a donné lieu à la création des CAPS AD III, fonctionnant 24/24 h et 7 jours/7. D'autre part, la Cour des Comptes de l'État a constaté, via l'arrêt 654/2005, revu en 2006 et 2010, que certaines politiques n'ont toujours pas été appliquées, à l'exemple de la prise en charge du transport du patient jusqu'au service de soin.
Ainsi, le manque de considération du gouvernement à l'égard des malades mentaux et des dépendants de drogues et d'alcool a changé d'adresse – des hôpitaux psychiatriques il s'est porté sur les maisons familiales ou les rues –, mais il existe toujours. Les cas chroniques et graves ne sont pas pris en charge et inquiètent les secteurs de l'assistance sociale et de la sécurité publique. Les actions sont encore timides et réthoriques, elles vont à l'encontre des principes de la dignité humaine, de l'universalité et de l'égalité de l'accès à la santé, défendus par la Constitution Fédérale du Brésil de 1988.

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Actions sanitaires pour les réfugiés en Tunisie

Suite à la crise libyenne, la Tunisie a mis en place depuis le début du mois de mars 2011 une stratégie d'intervention et d'actions sanitaires pour la prise en charge des réfugiés et des blessés libyens. Toutes les potentialités nationales civiles et militaires, publiques et privées ont été impliquées, en premier lieu, les structures les plus proches des frontières libyennes.
Ces actions ont comporté :

- la création de consultations de médecine générale au camp des réfugiés de Choucha à raison de 100 à 650 consultations par jour,
- l'approvisionnement permanent en médicaments à partir de la région de Sfax en collaboration avec les pharmaciens et la direction régionale de la santé,
- le renforcement des équipements et du personnel des hôpitaux de BEN GUERDENE, TATAOUINE, ZARZIS et des autres hôpitaux des villes du sud-est tunisien
- la prise en charge des blessés avec la collaboration des hôpitaux et des cliniques privées,
- l'accueil des libyens en privilégiant les femmes enceintes au dernier trimestre, les hémodialysés et certains handicapés tout en assurant gratuitement l'accouchement et l'hébergement durant un mois après,
- la sollicitation des donateurs et des organismes internationaux afin de participer à ces actions,
- l'envoi de dons, humanitaires et sanitaires, aux réfugiés.

Nos actions ont été renforcées et soutenues par l'adhésion et la coopération des citoyens des différents gouvernorats du sud tunisien et par la participation d'organismes internationaux : le Comité International de la Croix Rouge(CICR), le Programme Alimentaire Mondial (PAM) et le Haut-Commissariat des Réfugiés...

Nous pensons que les actions prioritaires à entreprendre dans les semaines à venir concerneront :

- l'approvisionnement en aliments
- la mise à disposition des médicaments surtout pour les maladies chroniques
- le règlement des honoraires de soins des malades hospitalisés.

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Post genomics of complex diseases in the Mediterranean Region

The research in the interaction between gene/genome activity and the impact of the environment on the individual psyche is certainly one of the most promising areas for the future of psychiatry.
The field of Social Psychiatry is particularly fertile in promises, especially the one concerning migration and mental health. Studies in functional genomics and individual deep sequencing opened new perspectives in understanding the interanction between genome and environment in complex diseases. The Mediterranean region offers a unique opportunity to study the effects of migration in mental health.
The United Nations stated that at least one third of all human beings live in a different place than the one where they were born.
Hundreds of millions of individuals migrate and change their way of life, adapting well or not to their new environment. This how diagnosis and treatment of patients may need adjustment for the psychiatrists from the cultural and from the pharmacological point s of view.
A number of assertions (such as schizophrenia is the same all over and represents 0.5 to 1% of the general population) can be challenged by the findings on migrants. For example, it has been found repeatedly that schizophrenia is more prevalent in a number of categories of migrants in some countries.
Is it of genetic origin, or due to environmental factors, both in the country of origin and in the country of migration?
We assesed a pilot project (MedGENE) in order to study the genomic components related to the susceptibility of schizophrenia in Italy (ISS- San Raffaele La Pisana).
These questions and others can be addressed by investigators in Mediterranean Genome Environment interaction NEtwork (MedGENE) for psychiatric diseases, along in collaboration with the World Association of Social Psychiatry with investigators from other parts of the world.

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Quel cadre juridique pour lutter contre les pratiques coutumières portant atteinte à l'intégrité corporelle des enfants en France ?

Chaque année, des millions d'enfants dans le monde sont encore victimes de pratiques coutumières portant atteinte à leur intégrité corporelle. Les pratiques coutumières se définissent comme des pratiques, héritées du passé, qui sont acceptées et respectées par l'ensemble des membres de la communauté. L'une, parmi les plus répandues et qui fera objet de cette présentation, est l'excision, communément appelée les « mutilations génitales féminines » sur le plan international, lesquelles se définissent comme toute lésion ou ablation partielle ou totale effectuée sur les organes génitaux féminins externes sans raisons médicales. Cette pratique est souvent considérée comme obligatoire dans le processus d'acceptation sociale de l'enfant ou celle des parents ou pour lui être bénéfique. Malheureusement, l'excision s'avère être très néfaste pour la santé de l'enfant, mettant parfois sa vie en danger, et est contraire à ses droits fondamentaux. On estime aujourd'hui à plus de 130 millions de filles et de femmes dans le monde qui sont touchées par cette pratique et environ cinquante pays dont 28 en Afrique sont concernés. En France, tout comme dans d'autres pays européen, la pratique et les problèmes de l'excision sont survenus avec l'immigration.
L'argument du respect de la coutume est souvent invoqué par les exciseuses et les familles pour justifier cet acte. Pour les anti-ethnocentristes, récusant l'intervention du droit pénal, des études anthropologiques et sociologiques seraient bien plus bénéfiques en la matière. Mais a-t-on le droit de sacrifier des millions de filles et de femmes au nom de la coutume et dans l'attente des résultats hypothétiques de ces recherches ? Ne devrons-nous pas plutôt agir, quitte à bafouer le principe de non-ingérence culturelle, afin de lutter contre cette pratique ? Parallèlement au droit international, en majorité, sinon unanimement, les Etats condamne cette pratique. Elle est prohibée au nom du respect des droits de l'homme, de la personne humaine et de la protection de l'enfance. En France, il n'existe pas, à ce jour, de loi spécifique à l'excision. Toutefois, cette pratique est pénalement sanctionnée dans le cadre des « violences volontaires ayant entraîné une mutilation permanente ».
Il s'agira dans cette présentation de démontrer en quoi l'excision porte atteinte aux droits fondamentaux des enfants et comment le cadre juridique en France permet d'y lutter.

Mots-clés : excision, mutilation, atteinte à l'intégrité corporelle.

Each year, millions of children around the world are still victims of customary practices affecting their physical integrity. Customary practices are defined as practices, inherited from the past, which are accepted and respected by all community members. One among the most widely performed and which will be aimed at in this presentation is female circumcision, commonly known as female genital mutilation in international law and which can be defined as complete or part removal of the extern and/or intern genital organs without any medical reason. This practice is often considered mandatory in the process of social acceptance of the child and/or her parents or to be beneficial to her. Unfortunately, female circumcision is very harmful to the health of the child, sometimes threatening her life, and is contrary to her fundamental rights. It is estimated that more than 130 million girls and women worldwide are

affected by this practice and about fifty countries, including 28 in Africa, are concerned. In France, similarly to other European countries, the practice and the issues of female circumcision occurred with immigration.

The respect of the tradition is often an argument invoked by those who perform this act and the family to justify this act. For anti-ethnocentric, rejecting the intervention of criminal law, anthropological and sociological studies would be more beneficial to this matter. However, do we have the right to sacrifice millions of girls and women in the name of custom and pending the hypothetical results of such research? Shall we not rather act, even if it is contrary to the principle of non-interference in cultures, to fight against this practice? In parallel with international law, most, if not unanimous, states forbid female circumcision. Indeed, this act is prohibited in the name of the respect of human rights, human and children protection.
In France, so far, there is no specific law regarding female circumcision. However, this practice is punishable by criminal law in the context of "voluntary violence causing permanent disfigurement".
This presentation aims at demonstrating in which way female circumcision affects the rights of children and how it is fought by the legal framework in France.

Keywords: female circumcision, mutilation, affecting the physical integrity.

Rachid MENDJELI
EHESS

Conteurs ou thérapeutes traditionnels ?
Le cas des « conteurs thérapeutes » de la Médina de Fès

Pour Marcel Mauss et Henri Hubert, les magiciens fondent la reconnaissance et la légitimité du métier de magicien sur la perception du fait que : "qui se sert d'une formule magique se croît à son égard, fût-elle des plus banales, un droit de propriété. Le paysan qui dit "la recette de ma grand'mère" est par là, qualifié pour s'en servir; l'usage de la recette confine ici au métier". Cette communication propose de définir et d'interroger les pratiques, les correspondances, les analogies et les différences entre le métier de thérapeute, le métier de magicien et le métier de conteur à partir d'une analyse de la mise en scène des techniques de soins et des remèdes traditionnels aux Maroc. Un cas observé et filmé lors d'une enquête en 2009 sur la place sur Boujloud à Fès servira de guide d'introduction et d'objet de réflexion à l'analyse des pratiques du métier de ces «conteurs» qui offrent un discours et des remèdes « thérapeutiques » dans l'espace de la Halqa. Quels sont les registres de légitimités mobilisés par ces « conteurs-thérapeutes » dans leur discours sur la relation de soin et sur l'efficacité des remèdes qu'ils proposent sur *le champ du marché thérapeutique de la médecine traditionnelle*? Il s'agit d'envisager ces phénomènes de croyances thérapeutiques comme le produit de discours qui fondent leur légitimité sur un processus dont on peut transposer les propriétés et les limites sur différentes formes d'activités de médiations qui s'offrent au «client», au «patient», au «touriste», ou au «malade» sur le *marché des échanges thérapeutiques des biens physiques et symboliques* de la Médina de Fès.

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Informed Consent: The Universal Doctrine and Its Chinese Reality

Cf Textes

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The impact of some cultural aspects on the public health in Republic of Moldova

Cf Textes

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Médecine traditionnelle en Algérie:
Influence de la culture sur l'organisation des soins.

L'exposé mettra l'accent sur le fait qu'il n'existe pas dans la culture Maghrébine de sens univoque de la maladie, mais tout un faisceau de significations complexes.

Leur connaissance peut contribuer à lever le malentendu fondamental représenté par la collision de deux systèmes de pensée, celui du malade et de son groupe adhérant totalement à un modèle culturel de la maladie, et celui du médecin prenant fermement et exclusivement appui sur une attitude scientifique et technique.

Cependant nous sommes obligés de faire constater que le vécu, les convictions et l'attente du patient et de ses proches, ne sont pas sans importance, et leur compréhension, "intégrée" à la démarche médicale, est susceptible d'affiner et de rendre plus fructueuse la relation thérapeutique, d'éviter les embûches diagnostiques, et en définitive, d'aider le patient à "gérer sa souffrance et son traitement, en accord avec son Médecin" (Y. Pelicier) et dans son environnement socioculturel.

Cette approche n'est possible que par la fonction spirituelle du praticien, et à cet égard, il est édifiant de remarquer que dans la culture arabo-islamique, le terme de "Hakim" qui désigne le médecin, veut dire en même temps le savant et le sage, individualisé par son humanité, sa bonté et son charisme.

Ce travail va, sur la base d'études réalisées, tenter d'étudier comment l'on pourrait envisager scientifiquement l'intégration de la médecine traditionnelle à la médecine conventionnelle en matière d'organisation des soins en Algérie. Pour cela, nous serons amenés à rappeler l'évolution de notre société et de son histoire caractérisée par des colonisations successives qui ont certes marqué la population Algérienne, mais qui n'ont pas réussi le processus de déculturation ou d'aliénation culturelle.
Nous verrons que même durant la période postcoloniale, la mémoire collective a prévalu sur les idées véhiculées par la technologie et le modernisme.

Nous verrons comment la médecine traditionnelle, qui fait partie de ce riche patrimoine culturel, est apparue en fait comme une pratique fortement ancrée et utilisée par toutes les couches sociales algériennes, à un moment où nous sommes tentés de croire que la médecine conventionnelle a supplanté radicalement la médecine dite "anti-scientifique".

Mots clés : culture, intégration, soins, aliénation, mémoire, modernisme.

Liao XAOPING
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An Introduction of Traditional Chinese Medicine

1. The contribution and achievement of traditional Chinese medicine

There are many outstanding traditional Chinese physicians and schools in ancient China. Hua Tuo is the pioneer in anesthesia. Li Shizhen, compiling the Compendium of Materia Medica, which is a masterpiece for its wide collection of herb and herbal medicine, is a world-famous botanist,. In Qing dynasty, Epidemic Febrile Disease School made great contribution to the development of traditional Chinese medicine. The Confluence of Chinese and Western Medicine School, whose representatives are Tang Rongchuan and Zhang Xichun, pushed ahead the combined treatment of Chinese and Western medicine. Over the past half century, traditional Chinese medicine has scored outstanding accomplishment at home and abroad.

2. The situation of Chinese traditional medicine in China

The capacity of medical service of traditional Chinese medicine has been enhancing steadily and rapidly in terms of quality, number and scale. The curative effect of traditional Chinese medicine has been recognized widely, such as in the fight against SARS. The productivity of traditional Chinese medicine goes rapidly. The numbers of Chinese traditional planting bases and clinical research bases have been increasing. The deeper researches have been conducted, taking on a multi-subject cooperation. The comprehensive professional quality has enhanced.

3. The situation of Chinese traditional medicine abroad.

Traditional Chinese medicine is getting more and more influential around the world. Acupuncture and moxibustion have been approved to be legal medical treatments in the United States, and the number of people receiving acupuncture and moxibustion in the United States has increased dramatically. Traditional Chinese medicine also enjoys great popularity in European Union, Japan, Australia and so forth.

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La médecine traditionnelle en Tunisie.

Malgré l'absence de reconnaissance par le système de soins moderne et l'existence d'une législation répressive, la médecine traditionnelle connaît en Tunisie un essor mis en évidence par différentes enquêtes d'opinion auprès des patients. Cet engouement pour une médecine traditionnelle considérée autrefois comme une marque de « sous-développement » pourrait s'expliquer par le fait qu'elle remplit une fonction sociale visant à combler les limites et les insuffisances de la médecine moderne fondée sur les preuves.
Nous analysons dans notre travail les différents aspects juridiques (exercice illégal de la médecine) et sociologiques des pratiques traditionnelles de soins.

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Soins et recherches en médecine traditionnelle en Afrique subsaharienne : Etat des lieux et défis de son intégration dans la médecine moderne

La déclaration d'Alma-Ata (1978) soulignait l'importance de la Médecine Traditionnelle (MT) en matière de soins de Santé Publique. Deux décennies plus tard, les Chefs d'États africains ont déclaré que la période 2001-2010 comme «Décennie de la MT africaine» lors des Sommets de l'UA tenus à Abuja (Nigeria, 2001) et à Lusaka (Zambie, 2001). A l'heure du bilan, cette présentation vise à faire l'état des lieux de la MT et à présenter les défis de son intégration au système de santé en Afrique.

Situation de la médecine traditionnelle

En Afrique subsaharienne, 80-85% de la population aurait recours aux guérisseurs traditionnels (OMS, 2010) soit par tradition culturelle (concordance philosophique avec les cultures autochtones), soit par faute d'autres alternatives en raison des difficultés d'accès aux soins conventionnels, du coût plus élevé des médicaments conventionnels, etc. Ainsi, au Ghana, au Mali, au Nigeria et en Zambie, pour 60% des enfants atteints de forte fièvre due au paludisme le traitement de première intention fait appel aux plantes médicinales administrées à domicile (UNESCO, 2010).

La volonté de promouvoir la MT dans les systèmes sanitaires nationaux a abouti à la mise en place à la redynamisation des Programmes Nationaux de Pharmacopée et de Médecine Traditionnelle (PNPMT) dans les ministères de santé. Ce qui a permis dans certains pays l'établissement du cadre juridique des praticiens de la MT, le renforcement de leurs capacités techniques, l'installation de jardins de plantes médicinales et l'homologation des médicaments traditionnels.

En ce qui concerne la recherche en MT, plusieurs initiatives ont été lancées pendant la décennie pour évaluer l'innocuité, l'efficacité et la qualité des préparations traditionnelles à base de plantes utilisées dans le traitement des maladies prioritaires. On peut citer les études ethno-médicales d'identification des produits traditionnels efficaces contre le paludisme. Par exemple, une étude au Bénin a permis la valorisation en 2005 d'une combinaison de plantes (Agbaya); produit très efficace validé par l'OMS.

Par ailleurs, de rares pays disposent de loi encadrant la recherche en MT. Ainsi la loi n° 2010-40 portant sur le code d'éthique et de déontologie pour la recherche en santé au Bénin englobe des dispositions spécifiques aux conditions et normes de déroulement des recherches en MT.

Quelques défis de l'intégration de la MT au système de santé

L'intégration de la MT et la MM butte sur de nombreux défis :

- L'amélioration des mécanismes de collaboration entre PMT et praticiens de la médecine conventionnelle (Shetty, 2010).
- Pour la mise sur le marché, une série de tests rigoureux en laboratoire et d'essais pour tester l'efficacité et l'innocuité VS des tests de qualité et les normes de production de médicaments traditionnels moins rigoureux ou contrôlés (Shetty, 2010).

Doit-il y avoir adéquation de l'application à la MT des exigences internationales relatives aux mises sur le marché des médicaments ?

- Le manque cruel de ressources financières dans les laboratoires et centres de recherche dédiés à la MT et la faiblesse d'accès aux plates-formes technologiques.
- L'émergence de risques de tensions entre la protection des connaissances dans leur contexte traditionnel et la promotion d'une plus large utilisation et diffusion des savoirs traditionnels (Taubman, 2010).
- Plusieurs difficultés inhérentes à un manque de réglementation, d'évaluation, de contrôle, de formation, de normes éthiques qui encadrent la MT, etc.

Textes
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Informed Consent: The Universal Doctrine and Its Chinese Reality

1. Brief Introduction of Informed Consent Doctrine

Informed consent is the dominant doctrine in modern physician-patient relationship. It is based on the ethical principle of autonomy which rooted in the West culture. In the 20th century, it was set up by the American courts by precedents, and was spread world widely after 1970s. It change the traditional paternalism model of physician-patient relationship greatly and established a new model that every competent person controlling his own fate in a medicine. The informed consent principle consists of the patient's right to make medical choice, and the corresponding obligation of the physician to deliver sufficient and proper information to make a rational, wise and free choice. The physician has duty to give information such as the nature of the illness, the benefits and risks of proposed treatment, alternatives and other information necessary to the patient. The informing shall be made in a manner that the patient can understand. A consent form may be needed in case of operation or other invasive treatment. To tell whether the physician's informing meets the requirement, the American courts developed three deferent standards, namely physician standard, objective physician standard and the subjective physician standard.

2. The Chinese Legal Transplantation of Informed Consent

The Chinese history of inform consent can only be traced back to the Regulation Governing the Administration of Medical Institutes by the State Council in 1994. It is the first time that a Chinese decree recognizes the duty of obtaining consent from the patient or his family before treatment of diagnosis. However, no duty of inform is required. In 1998, the Law on Licensed Medical practitioners passed by the Standing Committee of National People's Congress reaffirmed the principles above. Article 55 of Tort Liability Law states, "During the diagnosis and the treatment, the medical staff shall explain the illness condition and the relevant medical measure to the patient. If any operation, special examination or special treatment is needed, the medical staff shall explain the medical risks, alternate medical plan and other information to the patient in a timely manner, and obtain a written consent from the patient. In case it is not suitable to inform the patient, the patient's family member shall be informed and give the written consent instead. When a medical staff breaches the duty above, the medical institute shall be found liable for any patient's damage caused by it." Article 56 says, "In case of emergency, when the written consent from the patient or his family member is not available, necessary treatment shall be taken only if the proposed medical plan is approved by the head of the medical institute or an authorized person."

3. Individualism and Collectivism - Cultural Conflict

Although the informed consent doctrine is introduced to China and adopted by the Chinese statutes rapidly in the past two decades, the effect is still doubtful somehow.

There is a cultural conflict between China and the West in the way of making medical decisions. The informed consent doctrine is a rooted firmly in the west culture and tradition. The belief and spirit of autonomy, which is the fundamental ethical basis of informed consent, is derived from the Jewish-Christian culture and philosophy concentrating on individualism. Comparatively, the Chinese culture is much more of collectivism. In ancient Chinese (probable even of East Asia) tradition, families, rather than the individual person, were the most important units in the society. Although things changed a lot in the past century, families still play a key role in many ways, especially in the area of medical issue. In China, it is more common to leave the right to know and decide in medical issues to the family numbers rather than the patient. Usually, it is not the patient but his family who is informed of the patient's medical condition and the benefits, risks, alternatives and other information concerning the proposed treatment. And it is also the patient's family who makes the decision and authorizes doctors to proceed the treatment thereafter. This tradition justifies the earlier statutes' valuing the family's consent and signature more than that of the patient. In the Chinese medical practice, it is probably fine for the physician to give the patient the information in case it is only a cold or high blood pressure. Nevertheless, if it is a cancer, and other severe even mortal illness, the physician will never tell the patient himself. The physician may be even complained by the patient's family if he informs the patient. And commonly it is the patient's family who make the final decision. Sometimes it drives the physician into a dilemma to choose to obey the law or respect the tradition.

4. Irrational Medical Decision and Conflict of Interests

What makes things even worse, is the situation when the family member is not able to make a rational choice for the patient, even has a conflict of interests with the patient. For most of the case, the family will do the best for the patients and make the favorable decision. However, sometimes the family can decide rationally, which may do harm to the patient. In the end of 2007, there was a well-known case in China called "Xiao Zhijun event". Xiao Zhijun is low-income peasant from South China living in Beijing. His seven- month-pregnant wife caught pneumonia and fall into a coma. After Xiao deliver her to a hospital, the physicians urged that a caesarean must be performed with no delay to save the life of both the mother and the child. Nevertheless, Xiao didn't believe what he was told and refuse the operation, in spite of the physicians' repeated persuasion. Neither the mother nor the child survived. It caused tremendous argument about the justification and rationality of family's role in making medical decision. It can be more problematic when there is conflict of interests between the family member and the patient.

5. What is informed consent regarded?

On the other hand, dose the Chinese patient really understand what they are informed? Because of the strained relationship between the patients and doctors, and the heavy burden of legal liability for the medical industry, the doctors tend to treat the informed-consent as a defense of their professional risks or the excuse in the malpractice law cases. Therefore, the informed-consent is simplified as a pile of forms and clauses which are far beyond the patients' understandings and knowledge. In this case, informed-consent doesn't contribute to the construction of the trusting relationship between the doctors and patients; on the contrary, it makes them feel estranged.

6. Informed Consent in a Limited Medical Access Society

There is another thing may have a negative effect on the practice of informed consent is the limited medical access in China. With the largest population on the globe, China is still a source-limited society concerning health service. According to World Health Statistics 2010

by the WHO, the numbers of physicians, nursing personnel, dentistry personnel and pharmaceutical personnel per 10,000 population are 14, 10, 1 and 3, while the American comparing numbers are 27, 98, 16 and 9. There are too many patients for the physician to treat which makes the physician out of patience. When a physician hardly has a minute to examine the patient and give the prescription soon after, how can you expect the physician to spare his precious to tell everything he found to the patient and wait for the patient's decision before further diagnosis or treatment is performed? Furthermore, unlike in the U.S., the Chinese do not have private physician of their own, which means it is much more difficult to establish a trusting relationship between the patient and the physician (not "his physician"), when they are utterly strange to each other.

7. Conclusion

As a conclusion, the informed-consent needs to make some adjustment according to the difference of culture and tradition. And it should not only stay on the cold paper. What really matters is the respect of human beings showed during the procedure of informing and consenting, and the mutual-trusting, cooperative, and friendly relationship between the medical professionals and the patients.

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The impact of some cultural aspects on the public health in Republic of Moldova

The phenomenon of culture is a very complex one and has tens of definitions. Analysing these definitions we can see that the culture is determined by the ways we think, feel and act, which are typical for a certain population or society with a subsequent manifestation of these ways in concrete things. The vague term of culture includes those systems of values which, under the influence of various factors (and often of some ideologies), have been accepted during the evolution process and have entrenched as norms of behaviour of a human community.
Several aspects will be analysed specific for the perception of the culture of health and of the role of healthcare system in the Republic of Moldova, a country with a culture specific for Eastern Europe.
The poor economic situation which the country is facing for 20 years now has essentially decreased the requirements for people's quality of life, especially for those living in the rural areas. People are happy to have the minimum for surviving and respectively change their attitude towards their own welfare and state of health. Often a disease is perceived only there is a severe pain, when the condition becomes unbearable and diseases become terminal.
The population's priorities are strongly influenced by poverty and lack of money. Most of the people, saving money, tend to invest it in material things (like immobile, cars, etc.), ignoring the importance of expensive investigations, preventive or recuperation treatments.
To go to a doctor means to spend time and money, but in our rural cultural context, this is worth merely when there is a real health problem, without having in habit a regular preventive examination.
Thus, statistical official data (www.statistica.md) shows an increase in cases of cancer detected in its advanced phase, an increase in chronic cardiovascular diseases and diabetes, a high mortality rate in persons at their working age, etc.
Most of our population expects, in a passive manner, the healthcare service to provide them with treatment, but do not undertake any measures of disease prevention for themselves, activity in which they should involve themselves in an active manner. The patient is waiting for a "miraculous cure", since they perceive the doctor as a "*curing*". The responsibility itself to prevent a disease or to undertake some measures of prevention is totally entrusted merely to the healthcare system.
Unfortunately, the healthcare system, being under-resourced (financial and human recourses), however, is able to cover only a part of therapeutic necessities and very few screening, prevention and health promotion activities.
Which are the roots of such a passive attitude on behalf of our patient? Why do they expect everything to come from the system, without manifesting any interest of participation even when it is about their own health?
One of the reasons of this particular attitude of population in relation to healthcare system and to their own health can be explained by the paternalistic attitude of doctors, which has been promoted during the totalitarian communist regime.
Even after 20 years since Moldova was proclaimed an independent country, our culture still remains strongly influenced by the communist's values and ideology, which persisted for more than half of a century. The principles of a socialist or "collectivistic" ethics with a

pronounced paternalistic character have been promoted in the society. The community took full responsibility for making decisions to the benefit of individual. In such relation it is refused to the individualised *"I"* to determine its faith and to be responsible for it, and priority is given to the principle "*the most benefits to the highest number of persons*".

The impact of this approach has also strongly impregnated in the doctor-patient relationship. The problem of patient information was (and unfortunately still remains to be) considered a technical one rather than ethical. If the consent was needed from the patient or their relatives, the conception of "sacral lie" was preferred, which till the 90's it was promoted in some deontological books.

The paternalistic attitude of the state and system in the period of communist regime has radically changed the perception of the patient's own individuality. I convinced myself in this fact during my professional experience in recent years.

In the period 2004-2006, working within a municipal hospital as a bioethics specialist I was mainly responsible for the development of a sample of patient informed consent, since it became compulsory when the healthcare system implemented the mandatory health insurance (in 2004). I would like to note that till that moment the term of informed consent was strange to both the doctors and patients. I was personally asking patients in the hospital's admission department some simple questions of an informed consent in order to find an optimal sample of a standard form. Questions were related to: patient's wish to keep in strict confidentiality the information about their health or should a trustworthy person be assigned to whom the information will be communicated; their attitude of whether to be involved, during their hospitalization period, in the teaching process of medical students and residents; their attitude towards blood products, etc.

I was amazed at the reaction of many patients, who did not want to answer the questions, reproaching the following: "*We came here to be treated not interrogated! You are doctors you should know better what to do!*"

Thus, the patient voluntarily places full responsibility and decision making of the doctor's shoulders, therefore, giving him a sacral status. The doctor is expected to take final decisions, and being trained in an old manner, the doctor considers as a norm the fact that he is attributed full decision power.

Unfortunately, the reality is that many of the practitioner doctors do not give any importance to this form of consent, ignoring it even in cases of invasive interventions with high risk to the patient life. Or, often, the consent is formally signed without the patient being aware of the responsibility he/she assumes or without being interested to enter into detail.

The curriculum of higher medical education did not foresee programs for training future doctors in the area of fundamental principles of human rights and such important terms as *the informed consent, informing the patient, confidentiality, the right to choose*, etc. were interpreted from the perspective of community interests and the public health benefit, fact which today generates more conflicts both ethic and legal.

Given the imperfect legislation, reduced ability of patients to impose and protect their rights, dominant paternalistic culture accepted by most of the practitioner doctors, today we are witnessing serious cases where the disappointed patients undertake radical and violent actions. This is the case of a surgeon being physically attacked by the husband of an oncologic patient who had died during the intervention. The accusations given by the man grieved by the loss of his wife were: "*You have promised to me that everything will be all right… but you have killed her*". Maybe the doctor has promised something impossible, thus avoiding details about the risks thinking that his obligation is to protect the family, motivating merely with the good intentions and thus assuming the full responsibility for the tragic event. The patient and her family, in their turn, blindly believed in the magic power of the doctor, without insisting on him giving all details or without wanting to know the limits of today's

medicine possibilities and, especially, of that medicine (healthcare services) provided in hospitals from Moldova.

In conclusion we can note that it is necessary to change the type of relation between patient and healthcare system and between doctor and their patients. The one of the most important tasks we have in training of medical staff, both at the undergraduate and professional development levels is the change of paternalistic attitude by promoting the dialog with the patient and respecting their fundamental rights and freedoms. On the other hand, it is very important to inform the population about the responsibilities they should take in relation to their behaviour and decisions, and their consequences on one's own health.

It is a problem of culture, perception, and attitudes which is very difficult to change in a society, since it has ingrained during the years. It is obvious that radical changes are necessary and should be implemented, otherwise we cannot claim the status of a democratic state, which tends to integrate into the European Community.

Liste des participants

List of attendees

	ATTENDEES	Countries	Statut
1	ANASTASOVA VELIZARA	Bulgarie	participant
2	ANTZ JEAN EDOUARD	France	participant
3	ARDA BERNA	Turkey	président de séance
4	BARDAA SAMI	Tunisia	participant
5	BEATRIZ FAURI CAROLINE	Brazil	conférencier
6	BENHARKAT ABDELAZIZ	Algerie	conférencier
7	BENHARKAT ASSIA	Algerie	conférencier
8	BEVIERE BENEDICTE	France	conférencier
9	BHARDWAJ MINA	United Kingdom	participant
10	BORRY PASCAL	Belgium	conférencier
11	BREUNING MARTIJN	The Netherlands	conférencier
12	CALVAS PATRICK	France	conférencier
13	CAMBON-THOMSEN ANNE	France	conférencier
14	CARRASCO TRISTANA	France	participant
15	CHASSANG GAUTHIER	France	participant
16	CHAVES MARIANNA	Portugal	participant
17	CHEN LING	PR China	participant
18	COSKUN SELDA	Turkey	participant
19	DANTAS EDUARDO	Brazil	conférencier
20	DEFFRENNES LOUISE	France	participant

	ATTENDEES	Countries	Statut
21	DUCHIER JENNY	France	participant professionnel
22	DUCOURNEAU PASCAL	France	conférencier
23	DUGUET ANNE-MARIE	France	conférencier
24	DUGUET JULIEN	France	participant
25	DUGUET LIONEL	France	participant professionnel
26	EVERS-KIERBOOMS GERRY	Belgium	conférencier
27	FAURES MARION	France	participant
28	FEREIRA ANNA	Portugal	participant
29	FERNANDEZ XOSE M	United Kingdom	conférencier
30	FONSECA WASHINGTON	Brazil	conférencier
31	GADANI VARSHA	USA	participant
32	GALLINI ADELINE	France	participant
33	GAUDI SIMONA	Italy	conférencier
34	GIROLAMI PAOLO	Italy	conférencier
35	GRAMMA RODICA	Moldova	conférencier
36	GRIESCHE KATRIN	Allemagne	participant
37	GRIMAUD MARIE ANGELE	Canada	conférencier
38	GUEDJ MYRIAM	France	participant
39	HAOULIA NAIMA	France	conférencier
40	HARRIS DEAN.M	USA	conférencier

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41	HERVE CHRISTIAN	France	conférencier
42	HERVEG JEAN	Belgium	conférencier
43	HIRSCH FRANCOIS	France	conférencier
44	JAUTROU HENRI	france	participant
45	JULIA SOPHIE	France	participant
46	KEDOTE MARIUS	Bénin	conférencier
47	KNELLWOLF ANNE-LAURE	Italy	conférencier
48	KORICIC ANDREJA	Croatia	participant
49	LEONARD SAMANTA	United Kingdom	conférencier
50	LIAO XIAOPING	PR China	conférencier
51	LU JIANYANG	PR China	participant
52	MA YONGHUI	United Kingdom	participant
53	MAATOUG SAMIR	Tunisia	conférencier
54	MADANAMOOTHOO ALLANE	France	participant professionnel
55	MA'N H. ZAWATI	Canada	conférencier
56	MAN HONGJIE	PR China	conférencier
57	MANCHEC ALAIN	France	participant professionnel
58	MANCHEC ARMELLE	France	participant professionnel
59	MASMOUDI HARRAR WAFA	Tunisia	conférencier
60	MASMOUDI TASMIN	Tunisia	participant

	ATTENDEES	Countries	Statut
61	MATOS MAFALDA	Portugal	participant
62	MENJELI RACHID	France	conférencier
63	MORIKAWA MARCIA	Portugal	conférencier
64	NEVA LUKIN	Croatia	participant
65	NGO PHONG	France	participant
66	NIGRO VICENZO	Italy	conférencier
67	OLSENA SOLVITA	Lettonie	conférencier
68	PARICARD SOPHIE	France	conférencier
69	PEREIRA ANDRE	Portugal	conférencier
70	PETERKOVA HELENA	Croatia	participant
71	PIGEON ANNA	France	participant
72	POIROT-MAZERES ISABELLE	France	président de séance
73	POVEY SUE	United Kingdom	conférencier
74	PRUDIL LUKAS	Czech Republic	conférencier
75	REYNAUD DELPHINE	France	participant professionnel
76	RIAL EMMANUELLE	France	conférencier
77	ROSCAN ABBING HENRIETTE	The Netherlands	conférencier
78	ROUGE DANIEL	France	président de séance
79	RWABIHAMA JEAN-PAUL	Rwanda	participant
80	SANCHEZ ALBOR ROSARIO	Espagne	participant professionnel

	ATTENDEES	Countries	Statut
81	SERRES ISABELLE	France	participant professionnel
82	SHI XIAOGIN	PR China	participant
83	SHI YUE	PR China	participant
84	SOULIER ALEXANDRA	France	participant
85	SOUSA FREITAS MARA CRISTINA	Portugal	participant
86	SU YUJU	PR China	participant professionnel
87	TURKI HANENE	Tunisia	participant
88	VAN DER BAUMEN TOBIAS	The Netherlands	conférencier
89	VAN GYSEGHEM JEAN-MARC	Belgium	conférencier
90	WANG LIN	PR China	participant
91	WANG LING TIANXIU	PR China	participant
92	WR DE WERT GUIDO M	The Netherlands	conférencier
93	WU JINGJING	PR China	participant professionnel
94	WU TAO	PR China	participant
95	XIE XIEJU	PR China	participant
96	XUAN DU	PR China	participant
97	XUE XIAOYAN	PR China	participant
98	YNTEMA HELGER	The Netherlands	conférencier

Visite culturelle
Cultural tour

Visite culturelle
Cultural tour

3 Juillet 2011 de *9h à 18h*
July 3 2011 from 9 am to 6 pm

History and way of life in the Mountain of Pyrénées

Luchon

An unparalleled abundance of architechture.
A result of the huge interest in its thermal springs from the 1760s onwards, the little Pyrenean village of Luchon has undergone an amazing transformation over the centuries on its way to earning the title of Queen of the Pyrennes. Next to the small slate-roofed Pyrenean houses clustered around the church sit opulent residences that line up along the allées d'Etigny, each trying to outdo the other in splendour and outward appearance of opulence.

Lunch in Luchon

Saint Bertrand-de-Comminges

Saint-just de Valcabrère basilica
The completion of this basilica in the 12th century was the final stage in a series of modifications to a suburban quarter of roman settlement of Lugdunum. The church contains numerous fragments of architecture and sculptures emanating from the ancient town within its walls. It is this reuse of materials that provides the basilica with its undeniable originality.

Sainte-Marie cathedral and cloister
The construction of the first Romanesque cathedral was built during the episcopate of Bertrand de l'Isle, an edifice characterised by the widespread recycling of roman materials and by its nave. From around 1150 onwards, the Romanesque cathedral underwent several transformations, of which an imposing keep-belltower and the enlargement of the cloisters are the most impressive.

ADVISE:
We recommend putting sport shoes.

Session académique
Academic session

4-8 juillet 2011 de 9h à 17h
July 4-8 2011 from 9am to 5pm

Introduction to health law and bioethics in Europe: genetics

English session

Coordinated by Anne-Marie Duguet and Anne Cambon-Thomsen

Salle Jacques Pous Faculté de médecine
37 Allées Jules Guesde 31000 Toulouse

INTRODUCTION TO HEATH LAW AND BIOETHICS IN EUROPE: GENETICS

Salle Jacques Pous Faculté de médecine 37 Allées Jules Guesde 31000 Toulouse (France)

PROGRAMME

Coordinated by Anne-Marie Duguet and Anne Cambon-Thomsen

4th July 2011

9 am *Health and Human rights in Europe in the era of medical and technological Innovation:* ***Henriette Roscam Abbing*** *(The Netherlands)*
Why health law and bioethics: patients' perspective ***Solvita Olsena*** *(Latvia)*

2 pm Respect of privacy, professional secrecy and confidentiality in Europe and in the world ***Andre Pereira*** *(Portugal)* ***Lukas Prudil*** *(Czech Republic),* Privacy and Confidentiality: Global Perspectives on the Need to Balance Multiple Public Policies ***Harris M. Dean*** *(USA)*

5th July 2011*

9 am *Genetic information and its legal dimension:* ***Tobias Van der Baumen*** *(The Netherlands)*

Paternity test via internet and its legality with regard to data protection ***Jean-Marc Van Gyseghem*** *(Belgium)*

2 pm *Ethical aspects of genetic databases:* ***Sue Povey*** *(UK)*
Genetic testing in multifactorial diseases: ***Anne Cambon-Thomsen*** *(France)*

6th July 2011*

9 am *Legal framework and ethical dimension of genetic tests for diagnosis:* ***Samantha Leonard*** *(UK),* ***Sophie Julia*** *(France)*
Predictive genetic tests in practice: a psychological and ethical perspective ***Gerry Evers-Kiebooms*** *(Belgium)*

2 pm *Genetic testing in multifactorial diseases:* ***Anne Cambon-Thomsen*** *(France)*
Direct to consumers genetic tests. Past, present and future: ***Pascal Borry*** *(Belgium)*

Direct to consumers' paradoxes: ***Pascal Ducournau*** *(France)*

7th July 2011*

9 am *Ethical aspects of human biological materials collections and biobanks in genetics:* ***Emmanuelle Rial-Sebbag*** *(France)*
The donor's consent of human material for its storage and use in biological collections ***Naima Haoulia*** *(France)Return of Research Results in Population Biobanks:* ***Ma'n H. Zawati*** *(Canada)*

2 pm *Ethical aspects of sequencing in research and in clinical contexts*: ***Alexandra Soulier*** *(France)*
Return of survey on "Am I fine with having my genome sequenced and put in a database" performed in the framework of the GEUVADIS project and discussion about challenges of large scale sequencing: ***Anne Cambon-Thomsen***, ***Alexandra Soulier*** *(France)* ***Gabrielle Bertier*** *(Spain).*

8th July2011*

(for a mixed audience of scientists and non-scientists)*
Bioinformatics and Sequencing platforms of use in Europe for genetic research and diagnostics

9 am **Bioinformatics resources at the European Bioinformatics Institute (EMBL-EBI):**
Genomics: A View from Hinxton: ***Xose M Fernandez*** *(UK)*

11 am **Next generation sequencing issues (I)**
Clinical issues related to next generation sequencing (NGS) ***Martijn Breuning*** *(The Netherlands)*

2 pm **Next generation sequencing issues (II)**
Next-Generation Sequencing (NGS) approach to limb-girdle muscular dystrophies: ***Vincenzo Nigro*** *(Italy)*
NGS (Next Generation Sequencing) -related informed consent issues ***Helger Yntema*** *(The Netherlands)*

Sessions in collaboration with the teams of the European FP7 projects :
TECHGENE (www.techgene.org*), N°* 223143, ***GEN2PHEN (***www.gen2phen.org*); N°* 200754
and GEUVADIS (www.geuvadis.org***)*** N°261123

Résumés pour la SESSION ACADEMIQUE
Abstracts for the ACADEMIC SESSION

Prof.dr.Henriette ROSCAM-ABBING

Health and Human rights in Europe in the era of medical and technological Innovation

In relation to health, human rights (individual and social) have become increasingly important for the protection of the rights of the patient. In this field, the individual and social human rights are closely interrelated.

Basic values to be observed are human dignity, freedom, equality and solidarity. These values lay at the basis of human rights instruments in Europe relevant for health (Council of Europe: European Convention on human rights, European Social Charter, Convention on Human rights and Biomedicine, European Union: Charter of Fundamental rights). Human dignity is the core of European human rights law, health care is a prerequisite for the preservation of human dignity. Free choice and self-determination are fundamental constituents of life.

The informed consent must be observed in health related maters. In exceptional circumstances, restrictions to individual human rights for health related reasons may be necessary. In that case, they must be prescribed by law, be justified by their lawfulness, be necessary in the circumstances and in accordance with the principle of proportionality.

Financial solidarity is a requisite for ensuring equal access to health care for all of appropriate quality. Equality and solidarity are under pressure of limited resources, with a high price tag attached to innovation. The prohibition of discrimination is relevant in relation to health related individual and social human rights.

Individual rights aim at the protection of the individual sphere (non interference) but next to negative duties they also impose positive duties on the state.

Of the health related individual rights, the right to respect for private life is particularly important: it brings to expression self-determination in relation to health issues, it relates to physical and mental health and to informational privacy.

The European consensus on common values concerning the application of biology and medicine does not prevent that there are different views on their exact scope and content. These differences are brought to expression in the margin of appreciation the European Court of Human Rights leaves the member states, both in their decision to intervene and once having intervened to the rules for achieving a balance between competing public and private interests. The pertinent legal framework must be coherent, proportional and in conformity with the obligations under the ECHR. The margin of appreciation is relevant in particular in areas such as artificial procreation, abortion and euthanasia/assisted suicide.

The developments in genetics give rise to questions about the proper interpretation of human rights, about responsibilities and legal duties. Especially the Full Genome Sequencing (FGS) and Full Genome Analysis (FGA) raise questions about informed consent, whether one has a right to have an FGA performed when there is no or little proven clinical utility, and the future health benefit is only theoretical, and whether this justifies a substantial attack on private life. Human rights impose on States the positive duty to allow to the market only safe and good quality tests and screening technology.

Solvita OLSENA

Why health law and bioethics: patients' perspective

Health law and bioethics play an important role in medical practice and medical science today. The main aim of health law is to protect the welfare and safety of the patient in any health care situation, to regulate interactions of professionals and patients, and to resolve the conflicts which can arise. Another influential regulatory role in health care relations plays medical ethics and bioethics as a set of moral standards, codes of behavior and critical evaluation of moral issues arising as a result of modern health care and medical research.

The patients' rights and interests are the main general legitimate aims of the health care system. In order to achieve substantial results in application of health law and theories of bioethics, it is always important to explore and secure the rights and interests of the patients'. It is important to keep in mind the focus on the individual patient in the health care system and to promote his/her importance. Focus on the patients' rights means that other legal interests and rights in the health care field should be applied in conjunction with the patients' rights. In order to secure patients' rights, it is important to safeguard, that health care professionals are able to perform their duties in accordance with the highest standards of patients' rights.

As health care field today contains many different stake holders and is serving very different interest besides the rights of patients, it is necessary to discuss those interests and interactions between the different stake holders.

An overall aim of health care law is stated in the Article 1, Convention on Biomedicine (Council of Europe, 1997): "Parties [..] shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine". Therefore protection of integrity and other human rights, prohibition of discrimination will be addressed in the presentation as well.

Solvita Olsena Dr. iur., MD Riga Stradins University, Latvia Solvita.Olsena@rsu.lv

André DIAS PEREIRA (Portugal)
Assist-Professor of Law, University of Coimbra
Centre for Biomedical Law
Governor of the World Association for Medical law
andrediaspereira@hotmail.com

Monday 4th July **2 p.m.**
Respect of privacy, professional secrecy and confidentiality in Europe and in the world

Summary:
International and European sources of law of confidentiality in the physician-patient relationship will be explained and a debate about the fundamentals of the health-care's duty of confidentiality will be promoted.
The second part of the class concerns the justification grounds for a legal breach of confidentiality, especially consent, presumed consent, necessity and some statutory authorizations.
The participation and practical examples coming from the audience is encouraged.
Moreover, there will a special mention to the confidentiality and non-discrimination rules in the field of HIV-AIDS as well as about confidentiality in the area of reproductive technologies.

Key-words: Patient's privacy; doctor's confidentiality; justification clauses; consent; legal authorizations for breach of confidentiality. HIV-AIDS; Reproductive Technologies.

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Harris M. DEAN
J.D.Clinical, Associate Professor, University of North Carolina. (USA)

"Privacy and Confidentiality:
Global Perspectives on the Need to Balance Multiple Public Policies"

The goal of medical privacy is not merely to prevent individuals from suffering embarrassment or discrimination as a result of disclosing their personal information. Rather, medical privacy protects the public health, by encouraging individuals to obtain necessary care and to disclose personal information to their health care professionals.

However, there are competing public policies which require disclosure of confidential information, even if the patient does not consent to the disclosure. For example, public policies and laws require medical professionals to inform governmental agencies about infectious diseases, gunshot wounds, and suspected abuse of children. The goal is to achieve the best balance among these multiple public policies, in order to provide enough protection for medical privacy without preventing us from meeting other needs of society, such as control of communicable disease, research, and medical treatment.

Different countries and cultures will balance these competing policies in different ways. For example, in the United States, laws of various state governments prohibit unauthorized disclosure of patient information, but may also impose legal liability on health care professionals for failure to disclose a patient's threat to harm another person. As a general rule, federal regulations in the United States also prohibit unauthorized disclosure of medical information, but those regulations contain a complex set of exceptions for situations in which disclosure is permitted.

Some countries provide even more protection for the privacy of medical information. Meanwhile, some other cultures are more flexible about disclosing information to members of a patient's family, who participate as a group in making decisions about treatment of the patient. Finally, the economic issue of opportunity cost may lead people to different conclusions about the amount of resources that should be devoted to protecting medical privacy, especially in countries with limited health care resources.

Tobias VAN DER BAUMEN

Genetic information and its legal dimension
Title changed to Samples and Data – A legal dichotomy

The different fields of ~omics technologies are technology and data driven. Access to high quality samples and data has become crucial for the competitiveness of the European life sciences economy. In the literature this development led to the term "tissue economy"[21]; the commodification of the human body is therefore a reality which contradicts international human rights law. Biomedical sciences and biobanking in Europe have made major steps towards harmonisation and shared ethical / legal standards for the collection and processing of data and samples in research. Still, biobanks and researchers face substantial legal difficulties in the field of data protection and sample management although both legal domains are often seen as synonymous[22]. Data protection law has been harmonized in the EU 15 years ago while sample rights fall under the competence of the Member States of the EU. Despite the Data Protection Directive the field of data protection shows a substantial degree of deviation as Public Health has been excluded from the harmonisation in Art. 8 (4) / Recital 34 of the Directive. In legal practice biobanks seem to have substantially less difficulties to cope with national legal requirements in the field of sample management. The lecture discusses the legal frameworks, the analogous use of data protection principles in sample management, experiences of different biobanks in Europe and potential ways forward. The S. and Marper vs United Kingdom case[23] will be analysed to highlight the "confusion" in law about the nature and the roots of data protection and sample rights. At the moment, policymakers seem to build their decisions on an insufficient evidence base which underestimates the potential value of biobanks for European Public Health. Within the last years little progress has been achieved with regards to the development of a unified legal framework in Europe. The diversity in the legal system is also reflected in the different approaches of Ethics Committees towards biobanking and biomedical sciences. The upcoming recast of the Data Protection Directive does not seem to resolve the "confusion". To secure the responsible and effective use of data and samples, more efforts are needed to come up with legal pathways for a solution of the sample / data dichotomy.

Tobias Schulte in den Baeumen *Assistant Professor /Attorney-at-Law Department Genetics & Cell Biology Faculty of Health, Medicine and Life Sciences Maastricht University*
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My work focuses on the legal implications of new genome-based technologies and knowledge. My range of interests covers the various fields of law involved, such as data protection, pharmaceutical law, medical products and European law. I am also working in interdisciplinary research teams on Health Technology Assessment (HTA) and the development of guidelines in genomics. Before joining the University of Maastricht in September 2008 I have been serving as a Senior Researcher within the team of the "Public Health Genomics European Network" in Bielefeld / Germany (2006 – 2008). Prior to this I served a Lecturer and Researcher at the Institute of Health and Medical Law at the Law School of the University of Bremen / Germany (2003 – 2006). I am a member of several expert groups on the legal aspects of biobanking with focus on data protection and the different regulatory regimes for samples and data.

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[22] Schulte in den Bäumen, Paci, Ibarreta, Data Protection and Sample Management in Biobanking – A legal dichotomy, Genomics, Society and Policy, Vol 6, No 1, pp 33 - 46
[23] S. and Marper v. The United Kingdom - 30562/04 [2008] ECHR 1581 (4 December 2008)

Jean-Marc Van Gyseghem

Paternity test via internet and its legality with regard to data protection

Genetic tests are more and more used for various purposes (police, healthcare, etc). These tests are often used to identify individuals in procedures relative to family entry and settlement or filiations.
There is no doubt about the general craze for this kind of tests with respectable reason but, sometimes, with more ambiguous aim. Anyway, the commerce of genetic testers is really thriving and above all with the boom of the services accessible through the Internet.
Such tests are seen, by some people, as the Genie of the lamp which make them capable to reach their dreams of truth.
As we see the evolution of the science, the society - seen in a general way – dreams to know all the secrets of the human body. This includes its origin and the biological links with its environment. This quest gives, sometimes, the illusion to some people that they will have answers to all their question of identity.
The subject of genetic is very broad and is even too much to be seen in its whole during this European summer University. This is the reason we will analyze the genetic tests in the matter of filiations to try and see if there are lawful with regards to data protection.
This discussion will be preceded by a reminder of the notions of gene and genetic tests.
It is accepted that each human being differs from the other ones by his genome. He is the heritage, by half, of its biological parents who may not be the legal/social ones. This heritage can be found in the nucleus of each cell by taking the form of 23 chromosomes; these chromosomes are made up of DNA.
The analysis of such molecule on several individuals will allow the researcher to find the biological elements which link these individuals together.
By explaining this, we easily understand that the DNA can be very important in tracing each individual from its biological parents (upstream and downstream). It has also a high level of privacy. Indeed, DNA contains much information on the individual whom it's coming from.
By talking about privacy, we should have a look to the national and international regulation which protects individuals against illegal exploitation or access by a third party.
In addition, the DNA can be found on several supports as blood, hair, nails, etc and survives to the death of the individual himself. This increases the risk of disclosure of data which is contained in the DNA.
In the speech during the European Summer School, we will analyze the paternity tests with regard to Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. It is one approach amongst other ones but it will give us the opportunity to analyze the phenomenon of paternity tests accessible through the Internet.

* Member of the Bar of Brussels and Head of the "Liberties and information society" Unit of the Research Center on Information, Law and Society of the University of Namur – Belgium (www.crids.eu).

Sue POVEY
MD FMed Sci Emeritus Professor of Human Genetics at UCL, London UK

Ethical issues arising in the curation of Locus-Specific Variation Databases . (LSDBs)

There has been much debate about the ethical questions raised by the increasing amount of whole human DNA sequences being generated every day faster and at reducing cost and appearing in the public domain. This talk will however consider primarily the ethical problems encountered by the curators of genetic information in databases devoted to one gene or one disease. More than 1,000 Web-based locus-specific variation databases (LSDBs) are listed on the Website of the Human Genetic Variation Society (HGVS). These individual efforts, which often relate phenotype to genotype, are a valuable source of information for clinicians, patients, and their families, as well as for basic research. Most were originally compiled from published research which was already in the public domain, although it is not clear how many of the donors realised how widely accessible their data would be when they agreed to the research.. The initiators of the Human Variome Project recently recognized that having access to some of the immense resources of unpublished information already present in diagnostic laboratories would provide critical data to help manage genetic disorders. However, there are significant ethical issues involved in sharing these data worldwide. In 2010 an international working group presented guidelines addressing ethical issues pertaining to the curation of human LSDBs providing information via a Web-based interface. See Povey et al Human Mutation. 2010 Nov.31(11):1179-84.
The talk will discuss the major issues encountered both in drafting the guidelines and subsequently the experience of trying to apply them in the LSDBs curated by Dr Rosemary Ekong and the author.
http://www.LOVD.nl/TSC1 and http://www.LOVD.nl/TSC2
These databases are supported by the Tuberous Sclerosis Alliance

SUE POVEY *MD FMed Sci Emeritus Professor of Human Genetics at UCL, London UK: After obtaining a degree in Natural Sciences (genetics) in Cambridge in 1964? Sue Povey qualified in medicine in 1967 .She spent two years in clinical practice, one of them in Algeria with the Save the Children Fund, before becoming a scientist at the MRC Human Biochemical Genetics Unit at UCL from 1970 until 2000.She then became Haldane Professor of Human Genetics at UCL retiring in December 2007. Most of her research has been on genetic variation , finding genes and building genetic maps for the human genome, although in the ten years between 1997 and 2007 she was also responsible for the official names for all human genes. Until 2009 her only published contribution to ethical issues was to be one of the authors of the MRC operational and ethical guidelines for the handling of Human Tissues and Biological samples for Research (2001).A major long term interest has been in the genetic disorder Tuberous Sclerosis for which she now maintains two variation databases, one for each gene involved This led eventually to her leading a working group associated with the Human Variome Project in the effort to produce practical ethical guidelines for the curators of such databases.*

Samantha LEONARD, Sophie JULIA

Legal framework and ethical dimension of genetic tests for diagnosis

Background

Clinical genetics is a relatively new field, in which rapidly advancing technology produces many challenging ethical dilemmas. Genetic testing offers the potential for early recognition and treatment of disease, can allow for lifestyle decisions based on an understanding of what the future holds, and can aid planning of education and healthcare provision. However this potential to do good is tempered by the conflicts that genetic testing brings – the conflict between autonomy and the shared nature of genetic information, the potential to alter self-image, family relationships and to stratify society. As a consequence of these issues, the scientific, ethical, legal and social implications of genetic testing have continued to be subject to debate both nationally and internationally.

Genetic testing in a clinical context

Genetic tests may provide information of a highly private nature and require consent. There are two broad categories of genetic test:

Diagnostic tests are carried out to detect variations in one or several genes, in order to confirm or rule out a diagnosis. They are used in clinical health care settings when symptoms of genetic disease are already present.
Predictive tests aim to identify a genetic mutation in an individual who does not yet show any symptoms associated with a genetic mutation.

They allow us to determine whether a person is a carrier of a mutation which may be inherited and associated with disease in offspring, or they may show that a person is affected by a specific disease or at risk of being affected in the future. They may also reveal an increased risk for other family member or for the child of an ongoing pregnancy. As the results of a genetic test are not just of importance for the person to be examined, but also for an entire family, for example, particular care from a medical, ethical and legal perspective is necessary. In all cases, it should be ensured that every measure is preceded by a qualified consultation and counselling.

As patients' understanding of the results and consequences of the test is an integral part of genetic testing we have to consider the quality of genetic counselling services associated with genetic testing. Article 12 of the European Convention on Human Rights and Biomedicine requires appropriate genetic counselling prior to predictive or carrier testing. Analysis of the international guidelines and policies related to genetic counselling found that there is no legislation directly related to genetic counselling in the great majority of these countries.

Overview of session

The first part of this session will cover some of the major ethical issues surrounding the use of genetic testing in a medical context, including the nature and content of the information given and counselees understanding of it, psychological support, need for consent, autonomy, confidentiality, and fear of discrimination. The second part will focus on issues surrounding non-disclosure of genetic information within families, from both French and UK perspectives.

Gerry-Evers KIEBOOMS
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Predictive genetic tests in practice: a psychological and ethical perspective

Most disorders with onset in adolescence or later in life are caused by environmental factors, genetic factors and their interaction. Genetic testing of asymptomatic persons for one or more genes involved in these multifactorial diseases, called genetic susceptibility testing, usually has limited clinical utility. The situation is completely different in the context of predictive testing for monogenic late onset diseases with autosomal dominant transmission.

After the **description of the difference between genetic susceptibility testing and predictive testing for monogenic disease** the presentation will deal with predictive testing for neurodegenerative diseases that are currently untreatable and for which no preventive measures are available to prevent symptoms or to delay the disease onset. The example of Huntington's disease will be used to illustrate the clinical practice and the impact of predictive testing as well as the importance of a multidisciplinary approach. Hereby special attention will be paid to the **psychological and ethical dimension of predictive testing for HD in adults as well as to prenatal diagnosis during pregnancy and preimplantation genetic diagnosis in embryos (PGD)**. This will also be illustrated by case presentations. Particular attention will also be given to (1) the revision of the "Guidelines for predictive testing for HD" that were initially published by an international ad hoc committee consisting of professionals as well as members of the International Huntington Association (2) the formulation of guidelines for PGD. The initiative for this revision of guidelines and for the extension to PGD was taken by the Working Group Genetic Counselling/Genetic Testing of the European HD Research Network.

The multidisciplinary approach to predictive testing for HD has in the meantime been used as a model for predictive testing for **other late-onset neurodegenerative diseases**, e.g. autosomal dominant spinocerebellar ataxias (SCA), autosomal dominant amyotrophic lateral sclerosis, early-onset hereditary Alzheimer disease,… It has also been a helpful starting point and valuable foundation for **predictive testing for hereditary cancers** or hereditary heart diseases (or hereditary subforms of multifactorial diseases e.g. hereditary breast- and ovarian cancer caused by a mutation in the BRCA1- or BRCA2 gene). The availability of preventive measures (regular surveillance aimed at early diagnosis or preventive surgery) is a major difference with predictive testing for neurodegenerative diseases.

Predictive testing of asymptomatic minors is a problematic issue, in particular if no preventive measures are available. This will be the topic of the last part of the presentation.

*In the Center for Human Genetics of the University of Leuven, Belgium, **Gerry Evers-Kiebooms**, PhD Psychology, elaborated the unit "Psychosocial Genetics" and was its head till end 2010. The main objectives of her group: (1) Research about the psychological aspects of genetic counseling and genetic testing, with particular attention paid to predictive testing for late onset disease; (2) Psychological counseling and support in the context of a multidisciplinary approach for predictive testing; (3) Integrated genetic education for the population at large and for specific target groups.*
Her academic career started in the Department of Psychology in 1989 and was continued in the Faculty of Medicine. Since 1.1.2011 she is Special Emeritus Professor in the Department of Human Genetics. She coordinated many national, European and international research projects and was a partner in many others. Her interest for the ethical implications of genetic counseling and testing increased over the years and since 1996 she is a member of the Belgian Advisory Committee on Bio-ethics. She was a member of the Professional and Public Policy Committee of the European Society of Human Genetics for more than 10 years and is a member of the Board of the ESHG. She started the Working Group Genetic testing/Genetic Counseling in the European Huntington's Disease Research Network and was its leader till mid 2010.

Anne CAMBON-THOMSEN

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Genetic testing in multifactorial diseases: clinical utility or clinical futility?

The situation regarding genetic testing in multifactorial diseases (like asthma, autoimmune diseases, coronary diseases, diabetes etc.) where risk factors are assessed, is very different from that in mendelian diseases, where molecular diagnostics are routinely done. However it is not always easy to find one's way in the vocabulary used in the literature: multifactorial, common, complex, plurifactorial, oligogenic etc. So the first aim of this course will be to clarify definitions.
Although genetic factors and family susceptibility in numerous multifactorial diseases have been known for long in some cases, interest in genetic research on such diseases has grown in the last 10-15 years and the rate of discoveries has increased markedly. This is due to different factors: the use of numerous genomic markers and powerful molecular methodologies, statistical and bioinformatics tools, large collections of biological samples and associated data and international exchanges; especially genome wide explorations, popularising hypothesis free studies as compared to candidate gene studies have led to the description of numerous markers associated to various diseases allowing risk calculations, with often low relative risks, in a context of ignorance about gene-gene and gene-environment interactions that hamper the practical use of such results at an individual level. So the second aim of this course will be to underline the characteristics of results generated in genetic studies of multifactorial diseases. Their present clinical significance leads to a general call for caution: although such studies are extremely important to understand better the mechanism of multifactorial diseases: very few genetic markers associated to such diseases are of clinical utility; they rather represent a clinical futility in most cases. But at the same time the progresses of knowledge are a reality in a context where one pushes to accelerate the translation to clinical application as a sort of gold rule. Thus, discourses, promises and hopes, associated to the difficulty of the matter are blurring the landscape of todays genetics.
In such a context different professional groups have joined efforts to work on this topic (see ref 1), among them the PPPC (Public and professional policy committee) of the European society of human genetics. The recommendations from this society on this topic are copied below (see ref 2). The third aim of this course will be to explain the background of such recommendations.
In conclusion we will discuss about the meaning of genetic risks in different situations and their ethical dimensions.

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1: Becker F, van El CG, Ibarreta D, Zika E, Hogarth S, Borry P, Cambon-Thomsen A, Cassiman JJ, Evers-Kiebooms G, Hodgson S, Janssens AC, Kaariainen H, Krawczak M, Kristoffersson U, Lubinski J, Patch C, Penchaszadeh VB, Read A, Rogowski W, Sequeiros J, Tranebjaerg L, van Langen IM, Wallace H, Zimmern R, Schmidtke J, Cornel MC. Genetic testing and common disorders in a public health framework: how to assess relevance and possibilities. Background Document to the ESHG recommendations on genetic testing and common disorders. Eur J Hum Genet. 2011, Apr;19 Suppl 1:S6-44.
2: van El CG, Cornel MC; ESHG Public and Professional Policy Committee. Genetic testing and common disorders in a public health framework. Eur J Hum Genet. 2011 Apr;19(4):377-81.

"RECOMMENDATIONS from the European Society of Human Genetics (extract from ref 2)
(1) Human genetics and genomics researchers should avoid generating too high expectations of the applications of their results for diagnosis, treatment and prevention.
(2) Evaluation of the clinical utility of genetic testing possibilities for common complex disorders should take place before large-scale applications.
(3) Studies in which the potential for translation of research findings to the clinic is investigated are urgently needed. Prioritization should follow generally accepted quality criteria for good health care. Tests of proven clinical utility and cost effectiveness should be implemented first.
(4) Where clinical utility is likely, but evidence is partly lacking, studies need to accompany the implementation in pilot programmes. (5) Monogenic conditions can serve as examples for common complex diseases, both in strategies to identify etiological pathways and in strategies to develop health care in a responsible way.
(6) Sufficiently qualified health-care professionals should be available when genetic tests for common disorders are offered directly to the consumer. These professionals should be able to interpret genetic and other risk information and provide genetic counseling where applicable.

(7) Adequate regulation is necessary to guarantee truth-in-labelling and truthful promotion of genetic tests as in vitro diagnostic devices. The IVD Directive could be adapted to accommodate this. Both pre-market review and post-marketing evaluation are needed.
(8) Genetics in common disorders may lead to tailoring of health care to the needs of individuals or subpopulations. Stratified medicine will only be successful if health-care insurance is based on solidarity.
(9) Especially in developing countries, governments have an extra duty to avoid an access gap to genetic testing with proven clinical validity and cost-efficiency.
(10) European member states should sign and ratify the European Convention on Human Rights and Biomedicine (http://conventions. coe.int/Treaty/EN/Treaties/html/164.htm) and secure privacy and non-discrimination regarding genetic information."

Anne Cambon-Thomsen, graduated as MD at the University of Toulouse, France in 1978 and is presently Director of Research in CNRS (French national centre for scientific research). She is a specialist in human immunogenetics and holds a masters in human biology and degrees in medical statistics and in health ethics. She directed two research units on immunogenetics and population genetics in Toulouse and presently leads an interdisciplinary team on "Genomics, biotherapies and public health", involving human and social sciences as well as health sciences, in the context of research in epidemiology and public health at Inserm (National Institute for Health and Medical Research, Unit 1027) at the Faculty of Medicine of Toulouse. She also leads a "Genetics and Society" platform at the Toulouse-Midi-Pyrénées Genopole. She is involved in several EU projects in genomic sciences, public health genomics and biobanks, where she is responsible of ethical, legal and social aspects. She sits in several scientific advisory boards of international projects and is member of the scientific council of Inserm and of the board of the European and French Societies of Human Genetics. She is a former member of the French national advisory bioethics committee and of the European Group on ethics of science and new technologies and Chaired the Life sciences operational ethics committee in CNRS. She worked in the recent years on societal aspects of biobanks, biotherapies and genetic testing.

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Direct-to-consumer genetic tests. Past, present and future.

An increasing number of private companies are now offering direct-to-consumer (DTC) genetic testing services. The tests offered range from tests for single gene, highly penetrant disorders to susceptibility tests for genetic variants associated with common complex diseases or with specific traits. This presentation wants to discuss some of the concerns related to these services, including the right to (medical and genetic) information, the advertising of genetic tests, the quality of genetic testing services (the quality of the genetic tests -in terms of validity and utility-, the quality of laboratories and the quality of the persons providing the genetic services), the individualized medical supervision, information and genetic counseling, informed consent, genetic testing of minors, respect for private life, research, oversight of genetic testing, and the impact on the healthcare system. The presentation will as well provide an overview of the regulatory mechanisms that could be used to deal with these DTC genetic tests.

***PASCAL BORRY**, PhD, is professor of bioethics at the Centre for Biomedical Ethics and Law, Faculty of Medicine, K.U.Leuven (Belgium). His research interests are in the areas of the ethical, legal and social aspects of genetics and genomics. His main publications focus on genetic testing and screening relevant to newborn, children, and adolescents; biobanking; direct-to-consumer genetic testing; and the relation between empirical and normative approaches in bioethics. He acts as the programme coordinator of the Erasmus Mundus Master of Bioethics (www.masterbioethics.org). Since 2009 he is member of the Professional and Public Policy Committee of the European Society of Human Genetics. (https://www.eshg.org/120.0.html) In 2006, Pascal Borry received the triennal prize for biomedical ethics Professor Roger Borghgraef. He has been a visiting scholar at the Case Western Reserve University (Cleveland, Ohio, US), Université de Montreal and McGill University and is affiliated researcher at the VU University Medical Centre Amsterdam.*

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Direct To Consumers' Paradoxes

Genetic tests sold directly on the Internet have been available to consumers as far back as 2000. These tests provide information about susceptibility to several diseases and/or about "ancestry". The emergence of this new market raises a number of questions : for instance, many medical and genetic professionals are expressing their concerns, individually or through their professional associations, and are demanding that new regulations be drawn up or appropriate measures be applied to curb the new offer. Some of the stumbling blocks in the professional debate are the scientific validity of the genetic testing kits on offer, and the fact that the offer is aimed directly at consumers since prescriptions are not mandatory and the interpretation of results no longer requires the assistance of a medical professional. These concerns seem to have generated a social movement of a novel nature, with citizens demanding total freedom of access to these tests without being required to undergo a medical examination – all this in the name of such contemporary values as autonomy and personal freedom (see for instance the way the petition "My DNA, my Choice" was circulated). It may seem interesting to contrast the terms of the debate with the life experiences and actual perceptions of the users themselves. An original socio-anthropological survey based on interviews (N = 20) with online test users, most of whom were approached through online social networks, has evidenced the fact that, while remaining prudent about the scientific validity of such tests, the said users believe them to be an extremely valuable tool in the field of health and in the field of ancestry. The self-descriptions gathered from users suggest that they are *in fine* deceived by the actual validity of the tests, and yet retain a degree of awareness. Understanding this paradoxical position appears to be very helpful as it leads us to consider the controversy between the advocates of a somewhat paternalistic concept of medicine and the promoters of individual freedom of access to genetic information from a new perspective : it draws the attention, in the first place, to the skills and the ability of users to carry out a critical analysis and suggests thoughts about the concrete conditions of their development.

Pascal Ducournau *is Senior Lecturer in Sociology, at Albi University, (France); currently member of the Unit Inserm 1027, Toulouse (France) and associate member of the LISST, Toulouse Le Mirail University (France). His research field is sociology of health and sciences. He focuses on contemporary evolutions of health care relationship and health practices (see for instance the project he coordinates on DTC Genetic Testing: http://tegalsi.hypotheses.org/), as well as the role of bioethics within these transformations.*

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Ethical aspects of human biological materials collections and biobanks in genetics

BIOBANKS IN PERSPECTIVE

The ten last years have seen the development of structured biobanks for research according two steps. The first step was constituted by structuration of single biobank in order to ensure security and safety of samples gathered as well as respect of fundamental rights of source-persons. These units have issued some home-made solutions in order to guaranty quality procedures and respect of ethical and legal principles. The second step consisted in the elaboration of networks of biobanks in order to make them able to exchange biological samples and associated data. Biobanks faced then some difficulties regarding their non-coordinated procedures which encouraged them to create more standardized tools.

We are now in a third phase with the emergence of infrastructure of biobanks.. Passing from the preparatory phase of Biobanking and Biomolecular Resources Research Infrastructure, to its operational phase, BBMRI-ERIC is about to be implemented in the next few months. During the preparatory phase we studied various governance policies to propose a sustainable ELSI approach for BBMRI-ERIC. This transition has been pushed by the adoption of a new legal status for infrastructures in Europe through the Council Regulation on the Community legal framework for a European Research Infrastructure Consortium [24] (ERIC). From the work done during the preparatory phase results that the societal context where biobanks develop their activities must be taken into account.

Firstly, biobanks must be identified among research tools. This implies to get a global and accepted legal definition of "what a biobank is". Several definitions have been already adopted in national binding instruments as well as in standardisation documents. We propose a basic definition to identify the future participants in the BBMRI-ERIC: "Biobanks are infrastructures designed to store, organize, use and provide human biological samples and associated data for research project"[25].

Secondly, the ethical principles at stake have to be defined and analysed in a prospective way in order to ensure the pillars to be respected. In this perspective a particular attention has to be put on informed consent, secondary uses, withdrawal and public engagement. We propose some core ethical principles to be respected: autonomy, dignity and respect to ensure people some level of control on their materials. From an ethical point of view, the goal of the future BBMRI-ERIC infrastructure will be to propose to the BBMRI community some strong agreed principles. Those principles should be "in action", discussed or modified by the community, which supposes some consultation mechanisms from the central coordination of BBMRI towards biobanks[26].

From biomedical research to research biobanking

During the preparatory phase, we identified some legal analogies between biomedical research (protection of the whole body, its elements and the person herself) and the uses of human biological elements. We demonstrated that this situation can be a roadblock for research using human biological materials, as the existing legal rules for biomedical cannot

[24] EC No 723/2009 of 25 June 2009, OJ L 206, 8.8.2009, p. 1

[25] Research is one of the fields covered by the definition, it can also apply to therapeutic as well as judicial biobanks

[26] CHADWICK RUTH AND STRANGE HEATHER, 2009 'Harmonisation and standardisation in ethics and governance: conceptual and practical challenges' in H.Widdows and C.Mullen (eds) the Governance of Genetic Information: Who Decides? Cambridge 201-13

apply ipso facto to research biobanking. As a consequence to conduct research with body elements particular attention should be addressed to the type of regulation to be applied, the informed consent content and form, and the Ethics committees 'policies.

On the specific point of informed consent and in order to improve the research biobanking, we propose to move from a traditional approach based on a legal protection of participants, to a pro-active participation where the consent is seen as a part of a larger process of individual involvement[27].

If biobanks challenge the "post-genomic age"[28] (Gottweis and Lauss, 2010), the future European infrastructure will raise more than scientific issues probably relating to public acceptance, sustainability and communication.

Emmanuelle Rial-Sebbag- Lawyer-, Graduate in health law (Faculty Bordeaux), Ph.D in Health Law (mention very honourable, University Paul Sabatier Toulouse). She is working since 2000 at the INSERM Unit 558 in Toulouse (Epidemiology and public health analysis: risks, chronic diseases and handicaps) in the team Genomics and public health: interdisciplinary approach (Dir: Anne Cambon-Thomsen) as a researcher in law and bioethics. She is currently attached to the Social and Sciences University (LISST) for a post-doc on Direct to consumer Genetic tests. She is an Associate lecturer in bio-law and bioethics at the University of Medicine in Toulouse (Purpan). She will integrate the INSERM as a permanent researcher in October. She is involved in several research projects at National, European and International level, on the topics of biobanking, innovative therapies and biomedical research involving human beings. She is responsible for several teaching and educational sessions especially on the ethical and legal aspects of biomedical research involving human, patients' rights regarding biobanking. She is actually developing a new research field on the Governance of Research in biotechnology and the role played by regulations at national and European level.

[27] RIAL-SEBBAG E.,. DUGUET A.M and CAMBON-THOMSEN A., 2009b, From Medical Biobanks To Research Tools: Re-Use Of Samples, Governance And Human Rights in : New Challenges for Biobanks: Ethics, Law and Governance, Eds Kris Dierickx and Pascal Borry p. 87-94, Intersentia

[28] HERBERT GOTTWEIS AND GEORG LAUSS, 2010, Personalized Medicine, Vol. 7, No. 2, Pages 187-195.

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The donor's consent of human material for its storage and use in biological collections

Blood, organs, cells and tissues donation provide unique opportunities to assist others and improve the biomedical research. However, the legal status of the human body appears to be hybrid that's why it requires a *sui generis* approach, due to its emergent nature as both a subject and an object of law. In France, the inviolability of the human person has led the respect of many juridical and ethical principles including donors' information and consent. So as to preserve the human dignity, contributors must give "fully informed" consent and beyond this guarantee, many wish to grant them the right to control the fate of their biological material. Some argue in the other hand, that doing so would thwart the progress of biomedical research. Regardless of the cause, it is clear that research participants' bodily integrity and autonomy may not be protected if they consent to contribute without first being informed of all the information that would potentially influence their decision to contribute. Accordingly, to help ensure the complete protection of contributors' rights and interests, it is crucial to assure a fundamental informed consent process particularly regarding the storage of human biological material in collection or biobank. The article L. 1243 al. 2 of the public health code provides that:" *The terms "collections of human biological samples" refers to the reunion, used for scientific purpose, of biological samples taken from a group of people identified and selected based on clinical or biological characteristics of one or more group members, as well as derived from those samples*". The expression"biobank" can be considered as a synonymous of "collection" despite its strong economic connotation (and its link to property law more than to biomedical research). Thereby, collections lead an ethical question: can contributors retain ownership or control over their biological material? Does the requirement of fully informed consent means that the donor knows that researchers or other entities may profit from products developed from research? Obviously, this is not to say (and absolutely understandable) that researchers can request use of a sample for other study than the initial one. Nonetheless, many potential contributors are uneasy about the thought of others profiting from their biological material, especially if this would violate the contributor's religious or moral beliefs. Likewise, some individuals may feel that it is unfair for them to be expected to contribute gratuitously when researchers and institutions stand to make enormous commercial gains from these donations. The example of famous American cases (Greenberg v. Miami Children's Hospital) shows that contributors should be told that, while research using their biological material may lead to diagnoses, treatments, or even cures, their access to these treatments may be restricted for example, if the treatment is patented). Thus, the question of the fate of the donations raises many interrogations and ethical issues that we will try to study by the light of law. In order to discuss those questions, we will focus on two main points:

I/ The requirement of contributor's fully informed consent for the storage of human material in biological collections or biobanks.

II/ The use of the material donated for different purposes than the initial destination.

Ma'n H. Zawati

Return of Research Results in population Biobanks

Abstract

In 2009, *Time Magazine* named "biobanks" as one of the 10 ideas changing the world. Since their inception, however, biobanks have faced various ethical and legal challenges. Whether these pertain to informed consent, access by researchers, commercialization, confidentiality or governance, biobanks continue to address jurisdictional matters, operational difficulties and normative frameworks that strive to stay abreast of current scientific advances. Yet, with some biobanks now having completed their recruitment objectives and with research currently being performed on data and samples, one topic has become the focus of ongoing debates: the return of research results to participants. **This presentation examines this complex and contemporary subject matter. After suggesting the exclusion of some tangential issues usually flanking this debate, this presentation reviews** the current practices of biobanks on the disclosure of research results to participants. It then focuses more specifically on the debate in the literature before turning to a review of the typology of recent reforms being suggested.

Biography

Ma'n H. Zawati (LL.B., LL.M.) is a Lawyer and an Academic Associate at the Centre of Genomics and Policy at McGill University. He coordinates the ELSI and Privacy Task Force of the Canadian Partnership for Tomorrow Project, a pan-Canadian research study of 300,000 Canadians that explores how genetics, environment, lifestyle and behaviour contribute to the development of cancer and other chronic diseases. Mr. Zawati's work focuses on the legal and ethical aspects of population genomics and on the duties of health professionals in medical research. He is currently a seasonal lecturer at the University of Montreal, teaching Biological Sciences Law and Civil Liability.

Alexandra SOULIER1, Sophie Julia 1,2, Anne Cambon-Thomsen1

Ethical issues related to high throughput technologies in genetic testing

As the demand for genetic analysis is increasing in the health care system, the extension of diagnostic tests for genetic disorders is urgently needed. The majority of genetic diseases are molecularly and clinically highly heterogeneous and until recently, the available techniques lacked the required capacity to test several genes in parallel. Next generation sequencing technologies provide a unique opportunity to develop new diagnostic tools for heterogeneous genetic diseases. But their clinical use raises major and previously unreleased issues which need to be brought into sharp focus. The general problem could be summarized as follows: the rapid penetration of systematic technologies into genetic medical departments blurs established frontiers between research and clinics. A huge amount of personal medical data will therefore be produced, including a large part of results irrelevant to any particular clinical problem but which may be of importance to the patient in other ways or in the future. Our present inability to interpret most of the data requires careful ethical consideration but questions of personal data storage, eventual updating and possibilities to re-contact patients and families are also involved and require the development of appropriate rules or guidelines prior to clinical implementation. Clinicians, public health practitioners and relevant decision-makers should also determine their strategies and approaches in an era of such rapid advances. Main general challenges raised by HTT will be discussed and some positions proposed.

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Having a joint degree in philosophy and in political science, Alexandra Soulier is currently a phd student in bioethics, while working at E.U.-funded projects managed by the Inserm, France. She draws on a wide set of methodologies from the social sciences and the humanities. Her areas of interest are: philosophy of science, medical ethics, ethics of research biobanking.

ANNE CAMBON-THOMSEN(1), A SOULIER(1), G BERTIER(2) AND THE GEUVADIS CONSORTIUM

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Return of survey on «Am I fine with having my genome sequenced and put in a database» performed in the framework of the GEUVADIS project and discussion about challenges of large scale sequencing

Professional and family attitudes regarding large scale genetic information generated through next generation sequencing in research.

While genomic science is advancing tremendously, medical, ethical, legal, and social questions are arising regarding genetic information. Ethical aspects of genetic testing related to the use of high throughput techniques pose the problems of status of large scale genetic information regarding privacy and confidentiality, clinically useful information and the duties attached, health related information where no immediate clinical measure exists. Although most of the traditional ethical/legal frames that have developed over years for genetic research and applications continue to apply, some aspects need specific attention for research: The source of samples for sequencing; the type of consent; the scope and duration of studies; the right to withdraw; the concerns for the family; privacy issues (sensitivity of data; data access); return of results. A main feature of this accelerating technology development is a certain blurring between clinical and research contexts. Questions raised by large scale genetic technologies applications are:

- Can the same type of regulation apply to targeted tests and to genome-wide sequencing?
- Does sequencing require a different level or kind of consent than other genetic tests or medical assessments?
- Should whole-genome sequencing method be performed for children or incompetent adults?
- How to communicate results when their interpretation remains uncertain and what kind of results should be communicated?
- Should participants be informed of incidental findings that unequivocally predict serious disease that can be prevented or ameliorated by early detection? What if the disease cannot be prevented or ameliorated?
- How to regulate sequencing services offered directly to consumers?

  In order to get insights on such issues group discussions and questionnaires were conducted in the context of an EU funded projects (GEUVADIS) in the professional contexts (research groups in genetics) and in family situations in 5 countries. Results show a variety of attitudes, that seem influenced by the national context; generally the importance of clear information, understanding of the aims and transparency was underlined. Results also highlight the necessity of addressing such issues at an early stage by collaborative efforts of geneticists, ethicists, social scientists, patient representatives and decision makers.

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Genomics: A View from Hinxton

The European Bioinformatics Institute (EMBL-EBI) is a non-profit academic organisation with a mandate to provide biomolecular data resources to biological and medical research. The EBI develops services to access these biological databases and tools to explore the wealth of information stored in them (Ensembl, European Nucleotide Archive, ArrayExpress, UniProt, etc.).
Resources for -omics data are growing at an unprecedented pace following the wide-uptake of next-generation sequencing and other ultra-high throughput technologies by life scientists. It has also put the need for public repositories providing public and unrestricted access to biological data at the centre of biology.
We are witnessing a paradigm shift in contemporary medicine, as clinicians begin to embrace genomic tools (including "whole genome" interrogation with several key papers published in the last months) in what has been called personalised medicine (practitioners would argue that medicine is always personal based on family history and other individual facts) where disease is redefined in terms of biological or biochemical events. Thus, doctors will diagnose and ultimately treat patients with new drugs that target a patient's specific genetic profile.
Integration of heterogeneous data (gene-expression profiles, individual genomes) is the first step towards the delivery of new targeted drugs in this path from *bench to bedside*. Some examples where genome information has already enabled personalised health care will be discussed. Determination of molecular signatures for cancer diagnosis and prognosis examples is a reality in women with breast cancer, where 30% of cases are characterized by over-expression of *HER2* (a cell surface protein) making standard therapies ineffective. Similarly 40% of patients with metastatic colon cancer are unlikely to respond to commonly used treatments having a mutated form of the *KRAS* gene.
This high-throughput revolution threatens to drown us in data. There is an ongoing, and growing, need to collect, store and curate all this information in ways that allow its efficient retrieval and exploitation. The IT challenge in harnessing this data is matched by the need to educate the key stakeholders. We achieve this through our involvement in European consortia (*e.g.* GEUVAIDS) and our participation in large international endeavours such as the 1000 Genomes Project confirms the EBI as one of the few places in the world with the resources and expertise to fulfil this important task.
In this seminar I will attempt to provide an update based on some of these contributions, as well as an outlook on what's coming in this area.

Xosé M. Fernández *has background in molecular biology and leads the Outreach and Training group from the Protein and Nucleotide Database group at the European Bioinformatics Institute.*
He has recently been involved in several activities: leading to publications, establishment of workshops, training research clinicians and scientific coordination of international meetings, focused on the application of new technologies (so-called Next-Generation Sequencing or NGS) to the clinic.
His work at the EBI got him involved in the coordination/ writing of several work-packages for EU research projects (FP6 & FP7).

Prof.Dr. Martijn H. Breuning, Leiden, The Netherlands

Clinical issues related to Next Generation Sequencing (NGS)

High throughput sequencing of human exomes and genomes opens up unprecedented potential for improving diagnosis and the elucidation of causes of inherited disease, congenital aberrations, intellectual disability, and psychiatric disease. The plasticity and variability of the genome poses a formidable challenge to distinguish between 'normal' variants, and (potentially) pathogenic mutations.
The generation of vast amounts of sequences from patients or diseased tissues will not be the problem. However, the correct interpretation of the results will require painstaking scrutiny of detected variants, and careful analysis by comparing large numbers of well characterized cases on a global scale, as well as additional testing on a functional level.
During this presentation examples of various pitfalls and intricacies will be discussed: incorrect interpretation of variants, both ways: variants missed as pathogenic mutation as well as variants incorrectly classified as pathogenic, and incidental additional findings with important implications for patients.
I will argue that this situation is not at all new in medicine, with the introduction of every technical innovation similar problems have occurred, and have in time been properly addressed.
Next generation sequencing is unique since its results will have implications not only for the patient him- or herself, but also for family members. Therefore correct interpretation of sequencing data, and careful genetic counseling are of utmost importance.

Biography Prof.Dr. M.H. BREUNING
Date of birth, June 26, 1952. Secondary School: Gymnasium at Eindhoven, The Netherlands. Study Medicine: University of Amsterdam: 1971-1979. M.D.: May 16, 1979. Ph. D. research: Central Laboratory of the Blood Transfusion Service at Amsterdam: 1979-1983. Ph.D.: March 8, 1984, title thesis: Genetics of human CML targets. Specialisation clinical genetics: 1983-1984 at Groningen, 1989-1991 at Rotterdam. Certified as clinical geneticist: October 1, 1991.
Appointed full professor of Clinical Genetics February 1, 1998, holds this position until the present day.

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Vincenzo NIGRO,
MD, Telethon Institute of Genetics and Medicine, Napoli, Italy;
Laboratorio di Genetica Medica, Dipartimento di Patologia Generale and CIRM,
Seconda Università degli Studi di Napoli, Italy

Next-generation sequencing approach to limb-girdle muscular dystrophies

The term limb-girdle muscular dystrophy (LGMD) broadly defines a progressive weakness that begins from the proximal limb muscles, due to a genetic defect that is distinct from the X-linked dystrophinopathy. LGMDs are an example of both clinical and genetic heterogeneity: clinically, by reason of the description of non-LGMD phenotypes associated with LGMD genes and of LGMD phenotypes associated with originally non-LGMD disease genes; and genetically, by reason of the description of new LGMD genes that further increase the diagnostic complexity. In about 40% of LGMD patients the genetic cause of their dystrophy is not discovered by traditional tests. New powerful approaches for DNA analysis, like exome sequencing or RNASeq are going to revolutionize the field, also providing information about the true penetrance of LGMD mutations.
We have performed CGH array of all neuromuscular genes (Motor Chip). This contains 425 nuclear genes, 245 of which are associated with neuromuscular phenotypes while the remaining 180 were selected as putative disease genes for their involvement in neuromuscular functions. Validation experiments have clearly demonstrated that Motor Chip efficiently detects deleterious losses or gains in many different disease genes even when only one exon is involved.
We next performed whole exome sequencing in 16 LGMD samples belonging to distinct families. All samples were analyzed by the SOLiD platforms we have in the facility and CGH array by the Agilent platform. A number of mutations in non-LGMD genes were identified. This further enhance our knowledge of these disorders.

Vincenzo NIGRO *http://www.vincenzonigro.it Born in Naples 28th July 1960*
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Studies

1987	***MD** University of Naples "Federico II"*
1987-1988	***Fellow** in General pathology, Second University of Naples, Italy*
1988-1994	***Host** at the International Institute of Genetics and Biophysics; CNR, Naples*

Research and Professional Experience

1992-1999	***Assistant Professor** in General Pathology, Second University of Naples*
2000-2006	***Associate Professor** in General Pathology Second University of Naples*
2000-present	***Associate Investigator** at TIGEM (Telethon Institute of Genetics and Medicine) Naples*
2007-present	***Director** of "Mutation Detection" core at the Second University of Naples*
2005-present	***Coordinator** of PhD in Medical Genetics at the Second University of Naples*
2006-2010t	***Full Professor** of General Pathology at the Second University of Naples*
2010-present	***Full Professor** of Medical Genetics at the Second University of Naples*

In 1982 he started an internship at the Institute of General Pathology and Oncology, under the guidance of Gianfredo Puca and continues after graduating in Medicine, with a fellowship of the Italian cancer research association (AIRC), devoting himself to the study of the mechanism of action of the estrogen receptor. From 1989 to 1994 he worked as host of the International Institute of Genetics and Biophysics (IIGB), CNR, Naples under the supervision of Edoardo Boncinelli at first and then Antonio Simeone (developmental biology, identification of transcription factors that regulate embryogenesis and the formation of brain). In 1992, he created his research team for the study of muscular dystrophies. He published 92 articles in

international journals, receiving a total of 2,623 citations, calculated from the Scopus database. Among the most significant research, the identification of delta-sarcoglycan and mutations that cause limb-girdle muscular dystrophy (LGMD2F, quoted from 60 reviews), the identification of the gene that causes the cardiomyopathy of the BIO14.6 hamster, a leading experimental model (quoted from 42 reviews). He coordinated the service "mutation detection" at the Second University of Naples. He is currently responsible for research projects on the gene therapy of delta-sarcoglycanopathy at TIGEM and on the diagnosis of unknown LGMDs at the Second University of Naples.

Helger YNTEMA

Department of Human Genetics, Radboud University Nijmegen Medical Centre, The Netherlands

Next Generation Sequencing (NGS) : related informed consent issues

For many years Sanger sequencing has been the golden standard in DNA diagnostic laboratories. However, implementing gene tests for all known monogenic diseases is impossible in single laboratories. Moreover, the cause of many genetic diseases is still unknown. Together with genetic heterogeneity adding another level of complexity to clinical diagnosis, diagnostic yield remains overall relatively low. Targeted Next Generation Sequencing approaches allows rapid and affordable analysis of genetic variation in multiple loci in parallel. This has been of enormous value in recent disease gene identification studies, especially when expanded to the exome. In a recent family-based exome sequencing study we showed that rare *de novo* mutations can be reliably identified and may explain the majority of cases with mental retardation (Vissers et al, 2010). These results demonstrate that exome sequencing is becoming a robust approach for identification of genetic variation and can be implemented in a diagnostic setting, even for genetically heterogeneous and largely unexplained common disorders like mental retardation.

In this presentation the development and validation of a diagnostic workflow for exome sequencing in genetically heterogeneous disorders will shortly be discussed. The main focus of the presentation will be on the informed consent issues related to these new developments in diagnostic testing. In genome wide genetic testing there is a small chance that gene alterations could be identified by chance that are not related to the disorder being investigated. These are called co-incidental findings. An example of this could be a gene alteration associated with an increased risk of cancer or a neurological disease in a child, that could have important consequences for other family members. Questions like "Should patients have the opportunity whether or not to be informed about these co-incidental findings ("right not to know")?" and "When should a co-incidental finding be reported to the patient?" will be addressed.

Biography- Helger Yntema, PhD

Helger Yntema is a clinical molecular geneticist in the Division of DNA diagnostics at the Department of Human Genetics, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands, since 2008. Her main focuss is diagnostic testing of mental retardation with or without multiple congenital anomalies.

After finishing her biology education in 1995 at the Radboud University Nijmegen, Helger Yntema started her scientific career as a junior scientist at Medical Spectrum Enschede, The Netherlands, for 1 year. From 1996-2001 she worked as a PhD student at the Department of Human Genetics in Nijmegen on a project concerning molecular genetics of nonspecific X-linked mental retardation. For this dissertation, a research period of 5 months was spent at the Institut de Génétique et de Biologie Moléculaire et Cellulaire (IGBMC) in Strasbourg (France). Until she started her training for clinical molecular geneticist in 2004, she worked as a postdoc, funded by a fellowship of the Dutch Brain Foundation (Hersenstichting Nederland) on the identification of genes for X-linked mental retardation, mainly focussing on the identification of deletions and duplications using BAC-microarrays.

ANNEXES
Annexes

L'Institut International de Recherche en éthique biomédicale IIREB

Le réseau EthiMED

L'Institut international de recherche en éthique biomédicale (IIREB)

L'Institut de recherche en ethique biomédicale est un institut sans murs mis sur pied en Mai 2001 par le Pr Chrisitian Hervé du laboratoire d'éthique Médicale et de droit de la santé et de santé publique et la Professeure Bartha Maria Knoppers du Centre de génomique et de Politique de Mc Gill qui l'ont codirigé pendant plusieurs années, par la suite, l'IIREB fut co-dirigé par le professeur **Christian Hervé** du Laboratoire d'Éthique Médicale et de Santé publique de Paris V et par Madame **Michèle S. Jean** du Centre de recherche en droit public de l'Université de Montréal.

LA MISSION DE L'IIREB

L'IIREB a pour mandat entre autres:

De **promouvoir l'interconnexion** sous un horizon pluridisciplinaire de divers réseaux nationaux et internationaux de chercheurs qui s'intéressent aux questions de la recherche en éthique biomédicale; de mettre en dialogue au Québec, en France et au niveau international des personnes provenant d'institutions diversifiées et de disciplines variées (professionnels de la santé, juristes, anthropologues, sociologues, philosophes, éthiciens, épidémiologistes) qui ont un intérêt pour la recherche en bioéthique;

De **stimuler la recherche**, la formation et la diffusion des connaissances dans le domaine de la recherche en éthique biomédicale;

De **créer une synergie** entre les universités et les établissements universitaires de santé en vue d'une intégration de l'éthique;

De **susciter le débat** entre professionnels et le grand public sur les enjeux éthiques de la recherche en éthique biomédicale.

LES FONCTIONS DE L'IIREB

Elles sont les suivantes :

- une fonction structurante et de coordination par l'interconnexion de réseaux et de partenaires et par des appuis à des échanges internationaux ;

- une fonction mobilisatrice en stimulant des interactions dynamiques entre les différents partenaires ;
- une fonction de formation et d'enseignement en appuyant la mobilité étudiante. Le facteur déterminant, c'est d'avoir des étudiants boursiers pour assurer la relève. Pour ce faire, il faut cibler la clientèle d'étudiants qui offre le plus de potentiel pour obtenir des retombées optimales ;

- une fonction de sensibilisation du public en mettant en place des mécanismes de diffusion et de vulgarisation des travaux de l'IIREB et en créant le plus rapidement un site propre à l'IREB et des adresses de courriers électroniques propres. Ces infrastructures permettront d'assurer la visibilité de l'IIREB.

LE PONIT D'ANCRAGE DE L'IIREB

Les points d'ancrage de l'IIREB, anciennement le Laboratoire d'éthique médicale et le Centre de recherche en droit public de l'Université de Montréal, est maintenant le Laboratoire d'éthique médicale et de droit de la santé et de santé publique de la faculté de médecine de Paris-Necker.

LA PROGRAMMATION SCIENTIFIQUE

Les quatre axes principaux de la programmation de l'IIREB sont les suivants :

Axe 1 : L'éthique de la recherche;
Axe 2 : La génétique humaine (recherche et soins);
Axe 3 : Les systèmes de santé et les réseaux de soins;
Axe 4 : La nanomédecine et la nanosanté

L'IIREB a élargi sa programmation à d'autres préoccupations de recherche en éthique biomédicale telles les méthodologies d'enseignement en éthique de la recherche, l'accès équitable aux ressources, la problématique des allocations de ressources, la santé publique, la prévention des maladies, la biodiversité, la diversité culturelle et les croyances religieuses; les essais cliniques dans les pays en voie de développement.

LE PLAN D'ACTION DE L'IIREB

Les stratégies d'intervention combinent des actions relevant de la formation, de la recherche, de transfert des connaissances, d'appui technique, de collaboration, de renforcement dans le domaine de la recherche en éthique biomédicale, à savoir :

- Programme de bourses de missions et de stages à des chercheurs et de jeunes chercheurs intéressés par la problématique de la recherche en éthique biomédicale; Ce programme a été étendu à l'Europe, l'Europe de l'est, l'Afrique, l'Asie et l'Amérique latine;

- Accueil de stagiaires et missionnaires provenant de partout dans le monde;

- Formation dans le domaine de la recherche en éthique biomédicale;

- Débats publics et transfert de connaissance par voie de séminaires d'experts, colloques internationaux, ateliers, conférences, table rondes etc;

- Soutien aux activités de diffusion dans le domaine de la recherche en éthique biomédicale

- Établissement des liens et signature d'ententes formelles de collaboration et d'affiliation avec des centres de bioéthique et des institutions en Europe, aux États-Unis et au Canada;

- Maillage entre les centres de bioéthique universitaires et les institutions cliniques et création de nouveaux réseaux;

- Diffusion de l'information à la communauté scientifique.

Elles s'inscrivent dans le sillage de la programmation de l'IIREB et lui permettent d'atteindre le plus haut niveau d'impact et de visibilité.

LES ACTIVITÉS DE L'IIREB

Les activités de l'IIREB s'inscrivent dans le sillage de sa programmation (axe 1 : L'éthique de la recherche; Axe 2 : La génétique humaine (recherche et soins); Axe 3 : Les systèmes de santé et les réseaux de soins) et lui permettent afin d'atteindre le plus haut niveau d'impact et de visibilité. Les stratégies d'intervention combinent des actions relevant de la formation, de la recherche, de transfert des connaissances dans le domaine de la recherche en éthique biomédicale.

L'IIREB a eu aussi une mission éducative puisque par des stages et missions elle a permis aux jeunes chercheurs d'acquérir une expérience. De nombreux concours de stages et de missions furent organisés.

QUELQUES RAPPORTS DE MISSIONS ET DE STAGES

- Marianne Dion Labrie, Confidentialité des banques de données génétiques/cliniques et participation citoyenne, Stage effectué à l'Unité 558 de l'INSERM et au Génopole Midi-Pyrénées, Toulouse, France, 2006.

- Sébastien Lanctôt, La confidentialité et l'informatisation de l'information génétique : le cas de l'assurance - une étude comparée France/Québec, stage effectué à l'Institut des Assurances de Paris, France, 2006.

- Lise Lévesque, Méthodes de recherche et outils de collaboration en nutrigénomique : implications pour l'éthique de la recherche, stage effectué au Wageningen University and Research Centre - Pays Bas, 2006.

- Marie–Chantal Fortin, Représentations autour de l'anonymat dans le don altruiste et transplantation rénale. Entretien avec des transplanteurs français et québécois, stage effectué à l'Université Paul Sabatier, Toulouse, France, 2006.

- Darquise Lafrenière, Débat public et prise de décision en matière de technologies génétiques, stage effectué à l'Université François-Rabelais de Tours et à l'Université de Toulouse – Le Mirail, Toulouse, 2005.

- Isabelle Ganache, Stage d'observation «Génétique, génomique et société» : Dialogue et interdisciplinarité, stage effectué au Cardiff Center for research in Genomics and society et au Center for Economics and Social Aspects of Genomics (CESAGEN) Cardiff University, 2005.

- Amélie Perron, Exploration des modalités de dispensation des soins à deux populations vulnérables - Contexte d'itinérance et de détention pénitentiaire, stage effectué au Centre

d'Hébergement et d'Accueil aux Personnes Sans-Abri et Samu Social de Paris, Prison de la santé, Hôpital de Fresnes, Paris, 2004.

- Marius Kédoté, Identification des mécanismes de mise en application effective du suivi de protocoles de recherche approuvés par un comité d'éthique, stage effectué au Centre Lémantique d'éthique et à l'OMS – Genève Suisse, 2004.

- Dominic Desroches, L'intégration de l'éthique à la recherche scientifique et technologique : les leçons du modèle danois, stage effectué au Center for Etk og Ret ' Copenhague Danemark, 2004.

- Eric-Alain Laville, Legal Aspects of Health Data Privacy in The Catalan Healthcare System, stage effectué à l'Université de Barcelone – Espagne, 2004.

- Chantal Bouffard, Prémisses à la réflexion éthique : l'étude des représentations du diagnostic préimplantatoire chez les chercheurs(e)s, médecins et patient(e)s français, stage effectué Strasbourg à Paris et Montpellier, France, 2004.

- Estelle Mongbé, Une expérience pratique du fonctionnement du Département éthique, commerce, droits de l'Homme et législation de l'organisation mondiale de la santé (SDE/ETH) stage effectué à l'OMS, Genève, Suisse, 2004.

- Erica Sutton, "Ethical and Social Issues related to Prenatal genetic Testing", Stage effectué au John Hopkins University/National Human Genome Research Institute, 2003.

- Manoushka Charles, Le partage des droits et des responsabilités lors du suivi communautaire de personnes ayant un problème de santé mentale, stage effectué à l'université de Genève, Suisse, 2003.

- Maylis Michot, Évolution de l'information donnée au patient. Quelles perspectives pour l'avenir de la relation médecin malade en France à la lumière de la jurisprudence canadienne et québécoise? De la notion d'information médicale à la notion de vivre au jour le jour la prise en charge proposée, Stage effectué au CRDP, Université de Montréal, 2003.

- Éric Racine, Éthique, communication et empathie en éthique clinique, stage effectué au Chantal Labelle, La bioéthique en Europe : Union Européenne et Conseil de l'Europe, stage effectué à l'Université libre de Bruxelles, 2002.

- Claudine Fecteau, La communication de l'information génétique aux membres de la famille – une étude comparée Québec / France, stage effectué à l'unité 558 de l'INSERM à Toulouse, France, 2002.

- Chantal Labelle, Les conceptions de la bioéthique dans les société américaine et européenne, stage effectué à l'Université Libre de Bruxelles, 2002.

- Henri Mbulu, De la dignité de la vie à la dignité humaine, Stage effectué au Luxembourg, 2002.

- Didier Caenepeel, stage en éthique clinique effectué au centre d'éthique Médicale de l'Université catholique de Lille, 2002.

- Geneviève Caillé, Réflexion générale sur les liens unissant l'éthique, la science et la démocratie - L'exemple du comité Consultatif National d'Éthique (CCNE), stage effectué au Centre de Recherche Sens, Éthique Société, CNRS-IRESCO – Paris, 2002.

- Isabelle Mondou, Stage effectué à la Maison Médicale Jeanne Garnier, Paris, France 2002.

- Paule Savignac, Formation des soignants à l'éthique clinique et de la recherche, Assistance publique des hôpitaux de Paris, 2003.

- Julie Boussuge, Intégration des tests génétiques à la pratique clinique : Évaluation et analyse de la demande de recours aux tests génétiques – Étude bilatérale France/Québec, stage effectué au CRDP, université de Montréal, 2002.

- Muriel Bouquier, Analyse des enjeux éthiques dans la chaîne de responsabilité patient-clinicien-chercheur à l'occasion d'une analyse génétique de la création d'une banque d'ADN, stage effectué au CRDP et au CHUM à Montréal, 2001.

Pour les rapports de stages, voir le site http://www.iireb.org/fr/rapportbourses.html
Pour les rapports de missions de l'IIREB, voir le site : http://www.iireb.org/fr/rapports.html.

SÉMINAIRES D'EXPERTS ET SYMPOSIUM INTERNATIONAL

Séminaires d'experts

Chaque année, des rencontres d'experts scientifiques sont organisées sur des thèmes d'actualité, ce afin de réfléchir sur les enjeux du transfert de connaissance entre le milieu de la recherche, le système de santé et la population. Ces rencontres donnent lieu aux Actes de séminaires d'experts, ouvrages collectifs publiés aux éditions Dalloz.

Symposium de l'IIREB

Le Congrès de l'AMDM a abrité le symposium de l'IIREB qui s'est tenu le 9 août 2006 à Toulouse. Le thème de ce Symposium est le suivant : *Enjeux liés à l'utilisation du matériel biologique et des données informatisées dans le cadre de la recherche : Beaucoup de bruit pour rien?* Les actes du symposium ont été publiés et sont disponibles.

OUVRAGES

Voici quelques ouvrages publiés par l'IIREB :

- HERVE C., M. STANTON-JEAN, PA MOLINARI, MA GRIMAUD , C. RIBAU (dir) Pour des recherches biomédicales communes avec les pays du Sud Paris, Éditions Dalloz, Collection thèmes et commentaires, 2010, 159 pages.

- HERVE C., M. STANTON-JEAN, PA MOLINARI, MA GRIMAUD , E. LAFORET (dir) L'Humain, l'Humanité et le Progrès Scientifique, Paris, Éditions Dalloz, Collection Thèmes et commentaires, 2009, 182 pages.

- HERVE C., M. STANTON-JEAN, PA MOLINARI, MA GRIMAUD (dir) Généticisation et responsabilités, Paris, Éditions Dalloz, Collection Thèmes et commentaires, 2008, 182 pages.

- HERVE C., M. STANTON-JEAN, PA MOLINARI, MA GRIMAUD (dir) La nanomédecine. Enjeux éthiques, juridiques et normatifs, Paris, Éditions Dalloz, Collection Thèmes et commentaires, 2007, 164 pages.

- KNOPPERS BM et C. HERVE (dir), Matériel biologique et informatisation : beaucoup de bruit pour rien?, Bordeaux Études Hospitalières, 2006, 84 pages.

- HERVE C., BM KNOPPERS, PA MOLINARI, MA GRIMAUD (dir), Système de santé et circulation de l'information - Encadrement éthique et juridique Paris, Éditions Dalloz, Collection Thèmes & commentaires, 2007, 195 pages.

- DOUCET H., É. GAUDREAU et MA GRIMAUD (dir.), Éthique et recherche qualitative dans le secteur de la santé : Échanges sur les défis, Montréal, Collection Cahiers scientifiques, 2006, 118 pages.

- HERVE C., BM KNOPPERS, PA MOLINARI, G. MOUTEL et MA GRIMAUD (dir), Éthique de la recherche et santé publique: où en est-on? Paris, Éditions Dalloz, Collection Thèmes & commentaires, 2006, 172 pages.

- HERVE C., BM KNOPPERS, PA MOLINARI, G. MOUTEL (dir), Place de la bioéthique en recherche et dans les services cliniques, Paris, Éditions Dalloz, Collection Thèmes & commentaires, 2005, 215 pages.

- HERVE C., BM KNOPPERS, PA MOLINARI, G. MOUTEL (dir), Éthique médicale, bioéthique et normativité, Paris, Dalloz, Collection Thèmes et commentaires, 2003, 221 pages.

- HERVE C., BM KNOPPERS, PA MOLINARI, G. MOUTEL (dir), Éthique médicale, bioéthique et normativités, Paris, Éditions Dalloz, Collections Thèmes et commentaires, 2003, 221 pages.

Pour plus d'informations sur les ouvrages voir http://www.iireb.org/fr/ouvrages.html

ARTICLES

De nombreux articles ont été également publiés par récipiendaires de stages et de missions de l'IIREB. Voici quelques uns :

- E. SMITH E. , J. BEHRMANN J., MARTIN C . , WILLIAMS-JONES B, , Reproductive Tourism in Argentina : Clinic Accreditation and its Implication for Consumers, Health Professionnals and Policy Makers, 2009, Developping World Bioethics.
- RACINE E. C. FORLINI, Cognitive enhancement, lifestyle choice or misuse of prescription drugs? Ethics blind spots in current debates, 2008, Neuroethics.
- WILLIAMS J.R. , International Collaboration on research Ethics: Lessons from Africa, 2007, NCEHR Communiqué , volume 15, numéro 1.
- CAILLE G., «Réflexion éthique et débat démocratique, Quelle parole pour les sages?» Revue éthique publique (à paraître).

- RACINE E., «Que peut-on apprendre d'un stage en éthique clinique? Analyse d'une expérience internationale» Revue Ethica (à paraître).

- MICHOT-CASBAS M, M. THOMAS, D. GREGOIRE, F. POCHARD, G. MOUTEL, J. GARBAY, PA MOLINARI, C. HERVE, «Évolution de l'information donnée au patient.» .

- SUTTON EJ et AL., "Turner Syndrome: Four Challenges Across the Lifespan" (2005) American Journal of Medical Genetics, 57-66.

- SAINT-ARNAUD J, G. CARROLL, «Enjeux éthiques et processus décisionnels en santé communautaire» (2005) La pratique infirmière en santé communautaire.

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Réseau multidisciplinaire méditerranéen de recherche en éthique, déontologie médicale et droit de la santé

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IREB

COMMISSION NATIONALE FRANÇAISE POUR L'UNESCO

Inserm
Institut national de la santé et de la recherche médicale

ARFDM

Présentation du réseau

Avec plusieurs collègues francophones et anglophones, nous avons créé un réseau multidisciplinaire de recherche en éthique médicale, déontologie et droit de la santé qui intégre les aspects multiculturels. Ce réseau associe des pays européens, des pays du pourtour méditerranéen et des pays d'Afrique. La création de ce réseau fait suite à une collaboration suivie depuis 10 ans entre des équipes en France et des équipes du Maghreb, et à des échanges organisés dans le cadre d'une coopération INSERM/DGRSRT, entre l'Unité 558 de l'INSERM et le CHU de Sousse.

Nous souhaitons élargir le cercle de nos contacts pour répondre aux besoins de nos chercheurs et de nos partenaires et poursuivre à une plus grande échelle les activités déjà initiées. Actuellement notre groupe comprend des médecins, juristes, sociologues anthropologues, spécialiste de bioéthique, de diverses cultures et de plusieurs pays.

Objectifs du réseau :

Veille scientifique

Recueil bibliographique échanges d'informations ciblées, publications d'études de rapports et d'ouvrages, organisation de rencontres, Symposiums, ateliers.

Formations des acteurs

Recherche appliquée à l'évaluation des besoins et des pratiques; échanges de professionnels ou de chercheurs par des bourses ou des missions auprès des équipes partenaires du réseau.

Création de supports et d'instruments de formation pour les professionnels et des responsables

Thèmes de collecte / recherches

Ethique de la recherche biomédicale, mise en place de comités d'éthique dans les pays émergents

Collections, échanges d'échantillons et de données

Protection du corps et des produits du corps humain (transplantation d'organes)

Ethique et santé publique (migrants âgés)

Ethique et culture Droits des patients Etc….

Constitution du réseau :

Les personnes ressources peuvent être : doctorants, chercheurs, enseignants, professionnels, organismes publics ou privés, associations etc…Nous souhaitons rassembler des personnes déjà impliquées dans ce type de recherches, ou disposant

d'une expertise dans ces thèmes parce qu'appartenant à d'autres structures universitaires, professionnelles, ou associatives…

Les membres du réseau sont soit des référents ayant une expertise sur les thèmes choisis pour initier et encadrer les travaux ou des formations , soit des acteurs qui effectuent les recherches ou participent aux ateliers de réflexion.***Le but est de faciliter les interfaces, de bénéficier des acquis et des expériences pour les actualiser et les valoriser, et non pas de constituer une nouvelle structure susceptible d'entrer en concurrence avec les multiples réseaux déjà existants.***

Mise en place du réseau

- Une liste de ***personnes ressources*** par thème a été établie à partir des contacts existants et des propositions des partenaires. Ces personnes ont été sollicitées pour effectuer un travail de compilation en vue de constituer un ***corpus documentaire***. Des groupes de travail se réuniront lors d'ateliers en vue de la publication d'ouvrages..

Deux ateliers seront organisés chaque année, un à Toulouse lors de l'Ecole Européenne d'été de droit de la santé et éthique biomédicale qui réunit chaque année depuis 2006 un panel international de chercheurs et de professionnels, et un autre comme événement satellite d'une manifestation scientifique internationale. Le premier atelier a eu lieu en 2010 à Tozeur à l'occasion des Journées internationales méditerranéennes de médecine légale. Cet atelier a reçu le parrainage de la Commission nationale Française pour l'UNESCO.

Le réseau favorise la ***mobilité des chercheurs ou des professionnels*** entre les pays du Nord et du Sud grâce à des missions pour des professionnels ou des séjours pour des doctorants auprès des équipes partenaires du réseau. Le réseau recherchera les moyens financiers en répondant à des appels d'offres ou en sollicitant des sponsors. Le but est de développer une expertise en assurant une réflexion multidisciplinaire et internationale et de développer un savoir faire par la formation des décideurs et des professionnels.

Le ***comité de pilotage*** oriente les choix et les missions du réseau plusieurs personnalités ont donné leur accord pour y participer:

Pr Christian. Hervé Paris, Michèle Jean Montréal, Pr Amel Aouij-Mrad Tunisie, Pr Nabil Ben Salah Tunisie, Anne-Laure Knellwolf Rome, Pr G de Olivera Coïmbra, Dr François Hirsch Paris, Assia Benharkat , Edouardo Dantas Brésil, Christian Byk Paris, Pierre Deschamps Canada, Pr Sadef Beloucif Paris, Annagrazia Altavilla Italie, Simona Gaudi Rome, André Gonçalvo Dias Pereira Portugal, Pr Claude Huriet Paris, Marie-Angèle Grimaud Canada, Pr F Merah Algérie, Patrick Thonneau IRD Tunisie, Pierre Delpla France, Kamel Ayari Tunis, Danielle Laudy Canada

POWER POINTS

- *Harris Dean* J.D.Clinical Professeur Associé, University of North Carolina (USA): *The Declaration of Helsinki: The Effect on Vulnerable Populations of the Provisions about Placebo-Controlled Trials and the Duties of Post-Trial Care*

- *Simona Gaudi* ISS Rome (Italy) *Post genomics of complex diseases in the Mediterranean Region*

- *Harris Dean* Privacy and Confidentiality: Global Perspectives on the Need to Balance multiple Public Policies