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

CONFERENCE INTERNATIONALE

"Les inégalités d'accès aux soins et aux services de santé "

30 juin – 1er juillet 2014

Amphithéâtre Maury-Université Toulouse1 Capitole-
2, Rue du Doyen Gabriel Marty
Toulouse

FORUM des Jeunes chercheurs
2 Juillet 2014

SESSION ACADEMIQUE
4 et 5 Juillet 2014

Dirigée par : Anne-Marie DUGUET
Secrétariat scientifique : Jean Herveg (Namur Belgique)

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Pr Hugues Kenfack Doyen de la faculté Toulouse1 Capitole
Pr Daniel Rougé Pr de médecine légale Faculté de médecine de Rangueil Université Paul Sabatier

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Inequalities in health care Pr Pierre Mallia (Malte)
Patient's movement and medical liability in Europe? Dr. Geraldo Ribeiro (Portugal)
The new EU regulation on clinical trials on medicinal products. Faster or safer acces to research? Jilles Heringa (Pays-Bas)

12h30 Déjeuner

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Présidents de séance : Florence Crouzatier-Durand Maître de Conférences Université Toulouse 1 capitole Pr Annagrazia Altavilla.Aix Marseille /Bari (Italie)

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- Réseau Méditerranéen (Pr Mallia Malte)
- Projets avec la Chine (Pr Larrieu Alexandra-Mendoza-Caminade, Pr Yinhai Yan Southern medical University, Pr Hongjie Man Shandong University)
- Projets avec les USA (AM Duguet , Dean Harris). .

17h30 Séance de clôture

Propositions de thèmes pour 2015 AM Duguet et le comité scientifique

INTERNATIONAL CONFERENCE PROGRAMME

Monday June 30rd 2014

9 h *Openning session :* *Chairperson :*Anne-Marie Duguet Université Paul Sabatier

Pr Bruno Sire : President of Toulouse1 Capitole University
Pr Hugues Kenfack : Dean of the faculty Toulouse1 Capitole
Pr Daniel Rougé : Professor of forensic medicine- Faculty of medicine Rangueil -Paul Sabatier University

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*Chairpersons :*Pr Isabelle Poirot-Mazères Toulouse 1 Capitole (France) and Pr Henriette Roscam Abbing (Amsterdam Pays -bas)
*The right to health: a fundamental right..?*Pr Xavier Bioy Toulouse 1 Capitole (France)
Access to care: a complicated story :Renaud Bueb Senior lecturer Besançon University
The right of access to care:between equality and freedom Julia Schmitz Toulouse 1 Capitole (France)

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11h *Session 1 : Social inequalities in health : from the cell to the intervention*
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Social embodiment :Cyrille Delpierre INSERM Unit 1027 Toulouse (France)
Population Health Intervention research :Thierry Lang UPS, (France)

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14h - Session 2: Health policy: fight against health inequalities
Chairpersons: Pr Hélène Gaumont-Prat Paris VIII University -France and Pr Abdelaziz Benharkat (University of Constantine Algérie)
Territorial health inequalities: what problems for which solutions: Guillaume Rousset Senior lecturer Lyon III University (France)
Telemedicine: which challenges to struggle against health care inequalities? Allane Madanamoothoo , Groupe ESC Troyes (France)
*The provision ofsocial protection forGPs,lever of territorialequal accessto care?*Charlotte Hammel Toulouse 1 Capitole University (France)

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16h Session 3 : Vulnerable populations and access to care
Chairpersons : Sophie Paricard- MCU Toulouse 1 Capitole University -(France) and Pr Dean Harris (University of North Carolina- USA)

Health care and persons in detention: Pr Henriette Roscam Abbing, d'Utrecht (NL)
*Access to care for the poorest: the case of the homeless:*Pr Isabelle Poirot-Mazères (UT1Capitole)
Aging and social inequalities in health Jean Mantovani ORS MIP UMR/INSERM 1027

18h30- Reception at the Toulouse city hall

Tuesday 1st 2014

9h Session 4 : Access to health and discrimination
Chairpersons: Pr Xavier Bioy Toulouse 1 Capitole (France) and Pr Pierre Mallia (Malta)

Discrimination in access to care and personalized medicine: Bénédicte Bevière Senior lecturer Paris 8 (France)
Discrimination in health care and access to medicines: Pr Hélène Gaumont-Prat
Informal Fees as a Barrier for Access to Care. Pr Dean University of North Carolina USA

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Session 6 : Access to product and services and health inequalities in Europe

Chairpersons: Nathalie Valdeyron: Senior lecturer -Toulouse1 Capitole University France Pr Hongjie Man (Shandong University China)

Inequalities in health care: Pr Pierre Mallia (Malta)
Patient's movement and medical liability in Europe? Dr. Geraldo Ribeiro University of Coïmbra (Portugal)
The new EU regulation on clinical trials on medicinal products. Faster or safer acces to research? Jilles Heringa (Pays-Bas)

13h Lunch

14 h Social protection and access to care in foreign countries

Chairpersons : Florence Crouzatier-Durand Senior lecturer-Toulouse 1 Capitole and Pr Pr Annagrazia Altavilla.Aix Marseille /Bari (Italie)

Access to care abroad for Tunisian Citizens Pr Tasnim Masmoudi (Tunisia)
Right to Health and the Reform of Health Care Security System in China Pr Hongjie Man Law school Shandong University (China)
Vulnerables populations facing inequalities in acces to care A Feroui, K Sahki,A Zairi, B. Khoualdia,A Benharkat, Medicine Faculty of Constantine (Algéria)
*Access to care in Tunisia Legal and ethical aspects*S. Maatoug, W. Ben Amar; S. Bardaa, M. Zribi, Z. Hamami -University of Sfax (Tunisia)

Round table and discussion with the contribution of Pr Albert Arseguel Université Toulouse1 Capitole, and Pr Dean Harris University of North Carolina (USA) and the other foreign speakers

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16h -Overview of actions/projects for international cooperation in health law and bioethics

- Mediterranean network (Pr Mallia Malta)
- Projects with China (Pr Larrieu Alexandra-Mendoza-Caminade, Pr Yinhai Yan Southern medical University, Pr Hongjie Man Shandong University)
- Projects with USA (AM Duguet, Dean Harris).

17h30 Closing session

Proposals of topics for 2015 International conference: AM Duguet and the scientific committee.

Résumés

Abstracts

Le droit à la santé, un droit fondamental ..*?*

Pr Xavier Bioy Toulouse 1 Capitole (France)

L'accès aux soins présente l'aspect le plus tangible, le plus exigible même, du droit « générique » à la santé. Comme l'écrit M. Bélanger : « c'est l'accès à la santé qui est véritablement un droit. Le droit à la santé est alors « un programme, un objectif » »[1]. L'accès aux soins se présente parfois plus comme liberté que comme créance alors même qu'il est un droit « social ». Il se présente avant tout comme un droit pluriel, comportant plusieurs titulaires et plusieurs débiteurs. Le choix d'un droit fondamental le plus large possible se concrétise ainsi par des privilèges consacrés par l'Etat. Le droit d'accès aux soins présente deux faces : la première, de droit commun, est celle d'un droit objectif, consacré pour tous et dépendant des politiques publiques d'offre de soins, mais non « subjectivisé » car aucune procédure juridictionnelle efficace, encore moins spécifique, n'existe. En tant que service public constitutionnel, la santé publique implique l'action positive du gouvernement[2]. Au chapitre I^{er} du CSP : « Politique de santé publique », l'accès aux soins reste un objectif dont la poursuite incombe aux pouvoirs publics. En attestent l'absence de contentieux ou le refus d'ouvrir la procédure de référé-sauvegarde. La seconde face serait celle d'un droit subjectif, reconnu comme tel grâce à ses formes de juridicisation, notamment la judiciarisation. Mais le droit à l'accès aux soins se révèle alors plutôt catégoriel, garanti à certaines catégories ou situations seulement : les victimes de conflits armés, les enfants, les étrangers, les personnes handicapées, les malades en fin de vie, les gens du voyage … Toutes situations de vulnérabilité dans lesquelles des procédures plus ou moins spécifiques existent, faisant du droit d'accès aux soins un droit de l'homme partiellement opposable. La consécration du droit à l'accès aux soins apparaît sous deux formes différentes, soit directement, explicitement soit par d'autres droits, par « ricochet » (droit à la vie, dignité de la personne, non-discrimination). La jurisprudence constitutionnelle laisse au législateur le soin de graduer l'accès aux soins par la politique de prise en charge par l'assurance maladie. Seuls les soins considérés comme vitaux forment le noyau dur impliquant éventuellement la gratuité pour les catégories les plus économiquement faibles.

[1] Michel BELANGER, « Origine et histoire du concept de santé en tant que droit de la personne », *Journal international de bioéthique*, 1998, vol. 9, numéro 3, page 59.

[2] Le Conseil constitutionnel énonce que « la protection de la santé emporte (...) une obligation d'agir pour les ministres concernés », Cons. const., déc. n° 91-296 DC du 29 juill. 1991, Rec., p. 102.

L’accès aux soins, une histoire compliquée

Renaud Bueb Maître de conférences Université de Besançon (France)

Par le passé, l'offre de soin est en principe ouverte à tous. L'aide que l'on doit à son prochain interdit de discriminer. D'ailleurs, le problème ne réside pas dans les principes mais dans la réalité d'une offre de soins. L'Eglise puis l'Etat organisent un réseau d'hôpitaux. La monarchie absolue esquisse une politique de santé publique. Les idéaux de la Révolution française expriment la volonté d'assurer un système médical ouvert à tous. Au XIX° siècle, l'Etat organise la médecine, la pharmacie et continue à couvrir le territoire d'hôpitaux et d'hospices. Mais l'accès aux soins à un coût. Aussi les politiques de santé publique prennent en compte cette donnée afin que les plus démunis puissent avoir accès au soin. Le système public cohabite avec l'initiative privée, sociétés de secours mutuels, charité patronale, religieuse ou privée, etc... Après la première guerre mondiale, l'Etat instaure un système d'assurance sociale, devant favoriser l'accès aux soins pour tous les salariés. Cette ébauche d'Etat providence annonce la Sécurité sociale de 1945-46. Mais l'unification ne signifie pas accès égal à tous

Le droit d'accès aux soins : entre égalité et liberté

Julia Schmitz Toulouse 1 Capitole (France)

Le droit d'accès aux soins est un droit à l'effectivité à la fois faible et contradictoire.

Le droit d'accès aux soins est tout d'abord un droit à l'effectivité faible. En effet, le droit d'accès aux soins découle du droit à la protection de la santéconsacré par le 11° alinéa du préambule de la Constitution de 1946 selon lequel: « La Nation garantit à tous, notamment à l'enfant, à la mère et aux vieux travailleurs, la protection de la santé, la sécurité matérielle, le repos et les loisirs ». Ce fondement textuel imprécis a donné lieu à une interprétation jurisprudentielle elle-même fort imprécise.

En tant que droit créance, le droit d'accès aux soins est faiblement opposable à son débiteur, d'ailleurs largement indéterminé et dépend des possibilités de financement et des choix budgétaires.

Le droit d'accès aux soins est ensuite un droit à l'effectivité contradictoire. En se concrétisant, le droit d'accès aux soins décline les principes d'égal accès et de libre accès qui sont garantis aux usagers du système de santé. Mais ces deux déclinaisons peuvent entrer en contradiction car pour se réaliser, le droit d'accès *de tous* aux soins se confronte aux libertés individuelles de *chacun*. Liberté et égalité sont ici dans un rapport complexe et conflictuel puisque la mise en œuvre de l'égalité dans l'accès aux soins est à la fois la condition pour exercer la liberté d'accès aux soins, et sa limite.

Les inégalités sociales de santé et leur impact sur le système biologique

Cyrille Delpierre INSERM Unité 1027 Toulouse (France)

L'existence d'un gradient social de morbidité et de mortalité est un phénomène bien documenté en France et en Grande-Bretagne depuis le début du 20ème siècle, et maintenant bien documenté. Les études sur les inégalités sociales de santé (ISS) constituent un champ de recherche croissant et dynamique en Europe depuis les années 1980, la réduction des ISS représentant désormais une priorité en santé publique en France.*

Bien que le rôle de nombreux déterminants sociaux sur l'état de santé ait été largement mis en évidence, les processus par lesquels les déterminants sociaux influencent l'état de santé restent à investiguer. Ces déterminants peuvent avoir une influence toute particulière sur l'état de santé future en cas d'expositions précoces, durant la période fœtale ou l'enfance. Une difficulté majeure est ainsi de comprendre la façon dont ces déterminants sont liés et s'enchainent de l'enfance à l'âge adulte pour influencer l'état de santé. La mise en évidence de ces chaines de causalité implique de comprendre comment l'environnement, pris dans une définition large, devient biologique, comment il s'incorpore et peut altérer le fonctionnement normal pour favoriser le développement de pathologies sur le long terme. Il ne s'agit plus seulement d'expliquer les ISS par des expositions physiques, chimiques et des comportements de santé socialement différenciés mais aussi par des expositions susceptibles de modifier « directement » des processus biologiques favorisant à distance le développement de pathologies. Analyser le rôle des déterminants sociaux de la santé à travers leurs effets biologiques potentiels, en particulier à long terme, est une approche novatrice dans l'analyse des ISS.

L'impact de l'environnement sur nos systèmes biologiques est résumé par le concept d'embodiment que l'on pourrait traduire par incorporation biologique). Krieger décrit l'embodiment comme «la façon dont nous intégrons, comme tout organisme vivant, littéralement, biologiquement, le monde dans lequel nous vivons, y compris les circonstances sociales et écologiques». La notion d'embodiment se réfère au fait que chaque être humain est à la fois un être social et biologique qui intègre le monde dans lequel (s) il vit. Hertzman a écrit «le processus par lequel les différentes expériences humaines affectent systématiquement la santé et le bien être tout au long de la vie est appelé « incorporation biologique ». En conséquence, un environnement socio-économique défavorable pourrait modifier certains processus biologiques impliqués dans le développement de maladies sur le long terme, en particulier quand les expositions se produisent tôt dans la vie. En tant que processus au long cours, l'incorporation biologique à un niveau populationnel pourrait expliquer une partie du gradient social observé pour la grande majorité des maladies chroniques.

Social inequalities in health and embodiment

Delpierre C, Kelly-Irving M

The existence of a socioeconomic gradient of morbidity and mortality is a well known phenomenon in Europe as in the important variability existing across countries, particularly for mortality. Studies on social inequalities in health (SIH) constitute an increasing and dynamic

field of research in Europe since the 1980s, and in France the reduction of SIH represents a public health priority.

Although the role of numerous social determinants has been shown, we are still lacking knowledge on mechanisms, processes by which social determinants influence health. These determinants may have a quite specific influence on the future health status in case of early exposures, during preconception, foetal period or childhood. Then a major difficulty is to understand the way these determinants are linked from childhood to adulthood to influence health.

Identifying these causal chains implies understanding how the environment, in the broadest sense, becomes biological, how it is incorporated or embodied and can modify the normal functioning of the body to favour the development of pathologies over time. Explaining the production of SIH is not only a question of physical, chemical exposures and/or health behaviours socially distributed in the population, but also a question of how some exposures are likely to "directly" modify physiological processes involved in the development of diseases many years later in some groups of people, which is a very innovative way to analyse SIH. The impact of the environment on our biological systems is summarized by the concept of embodiment. Krieger described embodiment as « how we, like any living organism, literally incorporate, biologically, the world in which we live, including our societal and ecological circumstances ». The notion of embodiment refers to the fact that every human being is both a social and a biological organism that incorporates the world in which (s)he lives. Hertzman wrote « the process whereby differential human experiences systematically affect the healthfulness of life across the life cycle has been termed « biological embedding ». In consequence, a poor socioeconomic environment may modify certain biological processes involved in the development of future diseases, especially when exposures occur early in life. As a phenomenon occurring over the life course, at a populational level embodiment may partly explain the social gradient observed for the vast majority of chronic diseases.

Population Health Intervention research

Thierry Lang IFERISSUPS, (France)

Social Inequalities in Health (SIH) are at a particularly high level in France and reducing them has been recently recognised as a priority public health issue. Since the determinants are numerous, within and outside the health system, the whole spectrum of health interventions has to be analysed and modified in order to take into an account SIH. Population Health Intervention research has to be developed. In the Midi-Pyrénées region a shared process and tools have been designed in cooperation between researchers and projects leaders with this objective in mind and these tools have been experimented and assessed on five projects

Les inégalités territoriales de santé : quels problèmes pour quelles solutions ?

Guillaume Rousset Maitre de Conférences Lyon III (France) IFROSS

La lutte contre les inégalités territoriales de santé, aussi appelées « déserts médicaux », fait l'objet d'une attention soutenue des pouvoirs publics depuis plusieurs années. Les enjeux sont nombreux et concernent tous les acteurs du système de santé : les patients en termes d'accès aux soins, les professionnels de santé à propos de leur installation, et bien entendu les pouvoirs publics à travers le type de régulation mis en place. Face à ces enjeux, il s'agit ici de se poser deux questions clefs : l'une, préalable, consiste à déterminer quelle est la nature, l'étendue et les spécificités de ces inégalités ; l'autre, cruciale, pousse à s'interroger sur la manière de lutter contre ces déserts médicaux. Sur ce point, il faut relever la distinction entre les mesures incitatives et coercitives, la pertinence de chacune d'entre elles devant être étudiée, jusqu'aux dispositifs les plus récents issus du Pacte Territoire Santé.

La télémédecine: quels enjeux pour lutter contre les inégalités de soin

Allane Madanamoothoo , Groupe ESC Troyes (France) Enseignante-Chercheuse en Droit
217, Avenue Pierre Brossolette, 10000 Troyes

La télémédecine regroupe « *les actes médicaux, réalisés à distance, au moyen d'un dispositif utilisant les technologies de l'information et de la communication (TIC)* ».

Elle permet de consulter et poser un diagnostic à distance grâce à la téléconsultation, suivre des maladies chroniques notamment grâce à la télé-expertise, la télésurveillance médicale et la régulation médicale, limiter les déplacements des patients et des médecins qui représente un avantage considérable pour les personnes âgées ou parfois agitées et améliorer l'accès aux soins principalement pour certaines régions en manque de médecins qui se traduise par la difficulté d'obtenir un rendez-vous.

En ce sens la télémédecine représente un enjeu majeur dans la lutte contre les inégalités des soins en France. Pour autant, la France semble être en retard sur les thématiques e-santé par rapport à d'autres pays. D'où des solutions à trouver aux principaux freins notamment réglementaires, financiers et culturels afin que la télémédecine sans se substituer à la pratique médicale traditionnelle la complète.

Mots-clés : télémédecine, actes médicaux, inégalités des soins, freins à la télémédecine

Abstract

Telemedicine includes "medical acts performed remotely by means of a device using the information technology and communication (ICT)."

It allows to view and diagnose remotely through teleconsultation, follow chronic diseases thanks to tele-expertise, telemonitoring and medical control, restrict the movement of patients and physicians which is a significant advantage for elderly or sometimes agitated people and it also improves access to primary care for some areas where there is a lack of doctors which leads to the difficulty of getting a medical appointment rapidly.

In this sense telemedicine represents a major challenge in fighting against inequalities of care in France. However, France seems to be behind on e-health issues compared to other countries. This is why it is important to find solutions to major barriers mainly regulatory, financial and cultural ones so that telemedicine without replacing entire traditional medical practice completes it.

Keywords: Telemedicine, medical acts, inequalities of care, barriers to telemedicine

L’octroi d’une protection sociale aux médecins généralistes, levier d’égalité territoriale d’accès aux soins ?

Charlotte Hammel Université Toulouse 1 Capitole (France)

Près de quatre-vingts ans après la mise en place d’un système de protection sociale par le législateur, le système de santé français continue de pâtir de la contrepartie offerte à l’époque au corps médical : la reconnaissance de la Charte médicale. Cette Charte, intégrée au Code de déontologie médicale, consacrait cinq grands principes d’exercice de la profession médicale, parmi lesquels la liberté d’installation des médecins. Ce principe, comme celui de la liberté tarifaire, interviennent à la suite d’un échec évident des pouvoirs publics à mettre en place un service public de santé assurant une permanence des soins, à travers l’institution depuis disparue des officiers de santé. Il continue aujourd’hui d’être un obstacle à la réalisation d’une égalité territoriale de l’accès aux soins. Régulièrement critiqué, ce principe n’est pas pour autant remis en question, du fait de forces politiques en présence rendant difficile son évolution, voire sa disparition. Le législateur se retrouve donc devant une tâche ardue : conjuguer la réalisation de l’objectif à valeur constitutionnelle d’égalité d’accès aux soins, qui passe par une répartition homogène des praticiens sur le territoire, avec le caractère libéral de la profession médicale exercée en secteur ambulatoire. Le contexte normatif international de reconnaissance d’une accessibilité aux soins de premier recours, la dévolution au médecin traitant de cette mission et le creusement des inégalités de santé accentuent le défi posé au législateur et l’invitent à proposer des solutions nouvelles pour réaliser une permanence territoriale des soins. La protection sociale, dont la branche de l’assurance-maladie fut largement combattue par le corps médical dans le passé, constitue peut-être un levier inédit. Le peu d’impact des mesures financières d’incitation, la mutation de la démographie médicale du fait de sa féminisation, le désintérêt croissant des jeunes médecins pour le secteur libéral peuvent être autant d’atouts mis à la disposition de l’Etat pour enfin résorber les déserts médicaux.

Health care and persons in detention

Pr Henriette Roscam Abbing,Université d'Utrecht (Pays-Bas)

Equity in access: prisoners and health States obligation to ensure equity in access to necessary healthcare of appropriate quality falls to everyone, including persons in prison (covering all institutions in which a state holds people deprived of their liberty). In 1995, WHO Europe initiated the Health In Prison Programme in order to promote health and tackle health inequalities in prison setting, and limit the spread of communicable diseases when prisoners return to the community. Despite these efforts, jurisprudence of the European Court on Human Rights shows that prison healthcare in European countries does not receive sufficient priority of health systems. Good quality prison healthcare, including efficient measures of prevention, reduces the financial burden on country's health system. For the sake of health and wellbeing of detained people and of the population at large, health systems must effectively commit themselves to good prison health practices.

L'accès aux soins des plus démunis. L'exemple des « sans domicile fixe ».

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L'image du « sans abri », du va-nu-pieds, traverse l'histoire et dépasse les frontières, il n'a pas de toit mais toutes sortes de désignations -mendiant, indigent, clochard, gueux et vagabond, galvaudeux …-, et une place dans la société, celle des marges. Il est ainsi le paradigme de l'exclu et du pauvre, la figure paroxystique de la précarité et du dénuement. Comme tel, il a toujours intéressé les pouvoirs publics, le plus souvent pour des raisons de sécurité, d'ordre public et de contrôle social, mais aussi des préoccupations sociales et sanitaires.

Quel que soit le terme utilisé, les personnes sans domicile forment aujourd'hui, et de plus en plus alors que la crise économique fragilise les plus démunis, une population hétérogène aux contours extrêmement variés, faiblement définie juridiquement et difficilement quantifiable, mais au vécu similaire. De fait, la vie dans la rue alimente des pathologies particulières comme elle pose des difficultés accrues d'accès aux droits et aux prestations de santé.

Au-delà des droits reconnus à tous et des prestations délivrées par principe sans exclusive ni discrimination, se pose la question de l'effectivité de ces droits. A et égard, le constat s'impose d'un décalage persistant entre d'une part les droits affirmés, les dispositifs de soins dédiés et les objectifs de qualité affichés par de l'assurance maladie, et d'autre part la réalité vécue par les populations de « sans abri ». Obstacles structurels, saturation des services, attitudes de non recours ou de renoncement, dysfonctionnements administratifs, méfiances et réticences des professionnels, blocages culturels, … les obstacles à un égal accès aux droits et aux soins sont multiples qui sont autant de freins à l'efficacité des politiques de solidarité. Or l'existence d'un nombre croissant de personnes en marge du système social et sanitaire est un enjeu politique et démocratique et conduit aussi à s'interroger sur la pertinence des dispositifs juridiques en vigueur. Si l'investissement consacré à la lutte contre le sans-abrisme par l'Etat est parmi les plus importants en Europe, les résultats obtenus sont décevants.

Une fois le constat dressé, tel qu'il apparaît dans divers rapports et études, il convient alors de reprendre les propositions et recommandations faites: il faut ici agir non seulement sur les déterminants profonds du non recours aux droits et aux prestations mais aussi sur les orientations du système de protection sociale, sur l'organisation du système de soins et sur les articulations entre politiques publiques.

Vieillissement et inégalités sociales de santé

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Quels que soient ses lieux d'exercice, la recherche en santé publique considère souvent que les inégalités sociales de santé doivent être situées au cœur de ses problématiques, pour ce qu'elles intéressent à la fois la « question sociale » et les questions relatives aux états de santé et aux rapports à l'offre de soins, au sens le plus large du terme. De nombreuses recherches ont montré que loin de se réduire dans nos contextes contemporains de société, les inégalités sociales de santé tendent à s'accroître sensiblement[3], et qu'elles s'accroissent également avec l'avancée en âge, en fonction de parcours de vie différentiels et des aléas qui s'y attachent[4].

Les inégalités devant le vieillissement se mesurent d'abord évidemment en termes d'inégalités devant la mort. Songeons simplement que les statistiques françaises d'espérance de vie s'établissent au-delà de 90 ans dans certaines catégories sociales parmi les plus favorisées,… alors que les plus récentes données des « Morts de la rue »[5] mesurent à un peu plus de 46 ans l'espérance de vie moyenne des personnes SDF. Mais, s'il apparait souvent difficile de se doter de données statistiques assurées, il est bien d'autres dimensions à considérer, à commencer par les données d'espérance de vie en bonne santé, ou sans incapacité. Malgré les hétérogénéités qui caractérisent de plus en plus les « catégories socio-professionnelles », les différences et les gradients sont très marqués entre d'une part les « inactifs » et les « ouvriers » et les « cadres supérieurs »[6].

Ill faut considérer plus avant la grande complexité des processus qui participent au fil du temps à creuser les inégalités de santé, et faire appel en ce sens à des informations de natures différentes, notamment aux démarches qualitatives. Parmi les facteurs accumulés dans le temps figurent ces liens avérés par de multiples recherches entre sentiment de bien-être ou de mal-être dans le vieillissement et espérance de vie en bonne santé. Le propos se décline en termes de « sentiment de l'existence » parmi les personnes âgés, sentiment relatif de rester plus ou moins en bonne santé, sentiment de rester plus ou moins en phase avec son propre monde de référence, ou sentiment d'inutilité, sentiment de sécurité ou d'insécurité…[7] Dans les sociétés « jeunistes » que nous connaissons, l'avancée en âge se traduit par « *un complexe* » pour les individus, une discrimination au plan sociétal, dans lequel les plus favorisés parviennent à continuer à se représenter en âge comme citoyens « en santé », alors que les « autres », les plus fragiles et les plus isolés entrent plus ou moins rapidement dans l'engrenage de la perte de prise et de la perte de santé[8].

En tant qu'équipe de recherche, nous nous attachons tout particulièrement à l'étude d'une autre dimension qui participe è la complexité évoquée, qui concerne les déficit d'accès aux soins et

[3] Cf. notamment : Collectif. (2000) « Les inégalités sociales de santé ». Recherches. La Découverte. Inserm.

[4] Cf. Lang T. « Inégalités sociales de santé : une construction tout au long du cours de la vie ». In « Dossier : Les inégalités sociales de santé ». ADSP n° 73. 2010.

[5] Associations qui s'impliquent dans l'accompagnement de la fin de vie des 'grands précaires »

[6] Montaut A. « Inégalités sociales de santé et avancée en âge ».In « Dossier : Les inégalités sociales de santé ». ADSP n° 73. 2010.

[7] Se référer aux travaux de Clément S. & alii durant les années 90 à 2010.

[8] Montaut A. Op. cit.

aux services, le non recours ou le recours tardif à l'offre d'aide et de soins, le repli sur soi et sur l'espace famille, la non demande… observables parmi les plus démunis. Nous en apporterons quelques exemples tirés de nos travaux récents, se rapportant notamment aux situations et parcours de de migrants, confrontés à la fois aux problématiques du vieillissement, de l'altérité et de la pauvreté.

Nous interrogerons par-là sur les besoins d'adaptation des dispositifs français dédiés aux personnes vieillissantes, leurs limites face aux situations les plus complexes, et notamment celles qui impliquent les personnes atteintes de troubles cognitifs et du comportement de type Alzheimer, et leur entourage familial.

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Discrimination dans l'accès aux soins et médecine personnalisée

Par madame Bénédicte BEVIERE-BOYER[9], Maître de conférences-HDR à l'Université de Paris VIII – Paris Lumières, Laboratoire de droit médical et droit de la santé EA1581[10].

Mots clefs: Médecine personnalisée, Médecine stratifiée, Médecine individualisée, accessibilité, égalité d'accès, discrimination(s).

La médecine[11] personnalisée[12], basée sur une connaissance de plus en plus précise de l'individu d'un point de vue génétique, biologique, épigénétique et environnemental, pose la question fondamentale de l'égal accès de tous aux soins qu'engendre cette nouvelle pratique médicale en devenir. Les avancées tant préventives que thérapeutiques développent une revendication croissante des personnes pour en bénéficier. Cette demande s'accroit d'autant plus que la relation médicale, initialement basée sur un modèle paternaliste, puis sur l'autonomie de la volonté, est susceptible d'évoluer. Davantage informée, la personne tend à devenir active, participative et revendicative concernant les actes de soins réalisés sur sa personne. Elle l'est d'autant plus que les moyens prédictifs qui se mettent en place sont susceptibles de lui permettre de mieux connaître ses potentialités à développer certaines maladies, d'y parer par des mesures préventives, de s'y préparer, d'opérer des choix de comportements, d'être plus attentive aux développements précurseurs de la maladie, à son apparition et à son traitement. Cette plus grande implication génère une demande croissante d'accès aux médecines de pointe générées par la médecine personnalisée.

Or, force est de reconnaître que la médecine personnalisée n'est pas accessible à tous de manière égale. Paradoxalement, le progrès qu'elle engendre n'induit pas une égalité d'accès. Plusieurs discriminations existent. La première est naturelle. La médecine stratifiée, premier stade de la médecine personnalisée, basées sur une appréhension plus fine des caractéristiques biologiques et plus particulièrement génétiques des personnes, notamment l'identification des anomalies moléculaires, créé des sous-groupes stratifiés de personnes. Certains patients peuvent bénéficier des traitements efficaces compte-tenu de leurs données génétiques. D'autres pas. Cette exclusion peut alors être ressentie comme une

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[10] http://www.univ-paris8.fr/EA-1581-Droit-medical-et-de-la

[11] « science ayant pour objet la santé; l'art de prévenir et de traiter les maladies» : Dictionnaire de l'Académie Française: nom féminin XIIème siècle, *medecine*, emprunté du latin *medicina*, « art du médecin ; remède » : http://atilf.atilf.fr/academie9.htm

[12] Il ne sera pas fait état des incertitudes concernant la définition même de la médecine personnalisée qui a plusieurs appréhensions possibles. Sur cet aspect: Rapport Office parlementaire d'évaluation des choix scientifiques et technologiques (OPECST) n°1724, Assemblée nationale, n°306 Sénat, 22 janvier 2014, « Les progrès de la génétique, vers une médecine de précision ? Les enjeux scientifiques, technologiques, sociaux et éthiques de la médecine personnalisée » par A. Claeys et J-S. Vialatte, p.14. http://www.senat.fr/fileadmin/Fichiers/Images/opecst/auditions_publiques/rapport_1724_medecine_perso_provisoire.pdf; European Science Foundation, rapport octobre 2012, p.14: http://www.esf.org/uploads/media/Personalised_Medicine.pdf:

discrimination. Pourtant, cette nouvelle appréhension de l'accès aux médicaments, loin d'être discriminatoire, se justifie par des données physiques, biologiques et médicales. A ceci s'ajoute la discrimination économique puisque les coûts générés par l'accès à la médecine personnalisée demeurent encore élevés et, par conséquent, difficilement d'accessibles, ce qui restreint l'égalité. Enfin, cette médecine de pointe n'est pour l'instant réalisée que dans des plateformes localisées dans des grandes villes, ce qui en limite l'accès pour les personnes isolées d'un point de vue géographique.

Pourtant, progressivement, ces différentes formes de discriminations sont susceptibles de se réduire et, pour certaines d'entre, elles disparaître. Par exemple, les coûts de séquençage de l'ADN sont en diminution constante. Décrypter un génome humain complet est évalué actuellement à environ 1000 dollars alors qu'il nécessitait une centaine de millions au début des années 2000. En matière de coût, la médecine personnalisée est susceptible de devenir, peu à peu, accessible à tous. De même, au niveau génétique, la seconde phase de développement de la médecine personnalisée tendrait à une médecine individualisée à chaque personne. Cette perspective, pourrait, si elle se développe, engendrer un nouveau paradigme de la pratique médicale, de la recherche et de son accessibilité. Même les coûts seraient susceptibles de se réduire et de se résorber, la pratique de la médecine individualisée permettant d'éviter les coûts injustifiés actuels des médicaments inactifs et inopérants sur certains patients. L'Etat doit se préparer et rester vigilant à l'égard de ces différentes évolutions au regard notamment de l'Assurance maladie et des complémentaires-santé. Il lui faut aussi trouver de nouveaux moyens permettant de limiter l'isolement médical géographique pour garantir le principe de l'égal accès de tous aux soins issus de la médecine personnalisée.

Discrimination aux soins et accès aux médicaments

Hélène Gaumont-Prat Professeur des Universités Directeur du Laboratoire Droit de la santé (EA 1581) Université Paris VIII-Paris Lumières, Ancien membre du Comité Consultatif National d'Ethique

Le droit à la santé est reconnu par la Communauté internationale comme « un droit fondamental ». L'article 25 de la Déclaration universelle des droits de l'homme le consacre et l'Organisation mondiale de la santé (OMS) y fait référence à plusieurs reprises.

La santé n'est pas un concept juridique mais elle est appréhendée en droit de plusieurs façons : d'une part par le droit de la santé, et d'autre part par les droits fondamentaux au travers du respect de la personne et de la vie humaine, ce qui se traduit par un droit fondamental à être soigné, à bénéficier des traitements impliquant l'accès aux médicaments. Le défaut d'accès aux médicaments, apparaît alors comme un cas de discrimination et trouve sa place dans ce colloque des 30 juin-1er Juillet 2014 intitulé « Les inégalités d'accès aux soins et aux services de santé ».

On constate l'émergence d'un droit d'accès au médicament en termes de qualité et de quantité dont le fondement serait à la fois la protection de la dignité de l'être humain et la protection du malade. Le législateur a pris conscience de cette problématique et a adopté des mesures pour améliorer la situation des malades en attente, situation qui touche autant les pays du Nord que les pays du Sud.

L'exigence de qualité vise la qualité des méthodes de commercialisation, de distribution des médicaments, de préservation du monopole pharmaceutique au plan national et la lutte contre la falsification de médicaments. L'exigence de quantité vise la production et l'accès notamment aux médicaments essentiels, aux médicaments orphelins et aux médicamentspédiatriques.

Informal Fees as a Barrier for Access to Care.

Pr Dean Harris University of North USA

Informal payments for health care services are common in many countries, including several countries in Europe. In fact, the European Commission's 2014 EU Anti-Corruption Report recognized the continuing concern about informal payments for health care in the EU. Recent studies have shown that this still is a serious problem in Central and Eastern European (CEE) countries.

Informal payments are defined in many different ways. Sometimes, they are referred to as "unofficial fees" or "payments under-the-table." They include payments in cash or in kind, and might be given before or after treatment is rendered. Some informal payments are given to doctors or other health workers. In addition, informal payments can include the cost of supplies such as drugs that patients or their families need to buy, even though the supplies should have been provided by the health care facility.

Informal payments have several adverse consequences. Most importantly, they impose a barrier for access to care. In many countries, governments try to promote access to care by setting low official fees for public health care services. Informal payments can interfere with that type of government policy by increasing the amount that patients are required to pay as a practical matter. If people cannot afford the informal payment, they might be denied access or they might refrain from seeking necessary care for themselves or their families. Informal payments could also have the effect of forcing people into poverty—or forcing poor people even further into poverty. For all of these reasons, informal payments increase the social problems of inequity and inequality.

No easy remedy exists for the problem of informal payments. Possible alternatives include enacting legal prohibitions against requesting or accepting informal payments, raising the official salaries of health workers to reduce their need to receive informal payments, and "formalization of fees" by raising the official fees while prohibiting informal payments.

This presentation describes the problem of informal payments with particular attention to countries in Europe. The presentation reviews recent data on the characteristics and prevalence of informal payments, and then analyzes the effect of informal payments on access to care. Finally, the presentation analyzes potential policy responses to reduce the collection of informal fees for health care services.

Inequalities in health care

Pr Pierre Mallia (Malte)

In General the Maltese populations enjoy a free health care. Private practice exists and one can say there is indeed a dual service. Obviously private care renders better attention. Moreover 'Family Doctors', being those who see the same patient in primary care, exist only in private practice. General practitioners in the government free health service practice in health centres but patients are not guaranteed the same doctor for follow-up.

Access to private care can be obtained by private insurance but not all can afford it. Moreover primary care cover is limited. Insurances also have been known to look at personal hospital files simply by having a note on the policy. Private access is important for secondary care as it may help bypass the first level of queue when one sees a specialist privately. This is not cheating. One merely sees the specialist earlier privately.

Other areas of concern about equality which will be discussed are, access to reproductive technologies, access for young adults aged 15 to 18, especially because this group is prone to disease which can go unnoticed, and End of Life care which is not optimal mostly for fear of moral reasons. Finally one should mention the Cross-border directive which seems to be aimed for the more rich countries in the EU with countries like Malta certainly being not only at a disadvantage but being discriminated against.

Free medications have also been of concern recently with some medications and indeed hospital procedures being available only to certain categories of patients. This of couse is due to costs but when one does not get an immediate angiogram immediately after a heart attack because one has a tumour (even though not terminally ill), then one has cause for concern.

Patient's movement and medical liability in Europe?

Dr. Geraldo Ribeiro (Portugal)

Despite the fact that the transposition period of Directive 2011/24/EU has passed in 25 October 2013, it remains to be determined whether actually we are walking into an internal European healthcare's market. Especially when the primary objectives of the Directive are the coordination of systems and the responsibility of Member States in providing health care.

Even tough the European Union's treaties recognizethe freedom of circulation of services and the directive aims at promoting the patient's movement by regulating cross-border healthcare, there are no certainties that this efforts will be enough and effective for the implementation of such a market.

In addition to the issues of financial responsibility for medical procedures performed abroad that will be swiftly treated in this presentation, it is yet to be determined which medical liability legal regime protects the patient, both in terms of right to life, physical integrity or health, or in terms of protection of personal data.

Freedom of movement and consequent access to health care cannot be limited only to immediate access to such services, without taking into account the necessary guarantees of quality in delivery of heath treatments and of getting an effective judicial protection.

The emerging liability of a potentially harmful medical procedure cannot be artificially disconnected from the creation of a free access to the market and the protection of the rights and interests of the patient.

It should therefore be determined how to articulate the Directive 2011/24/EU with the EU instruments in force, including the Brussels I Regulation and the Rome I and Rome II Regulations, relevant in the Area of Freedom, Security and Justice, true integrator of access to health care for all citizens of the European Union. This is particularly important when, with regards to the applicable law, no uniform rules are found regarding non-contractual obligations arising out violations of privacy and rights relating to personality.

We intended to deepen the debate to this problems stemming from the freedom of movement of patients and to what extent this could bring advantages or constraints in access to health care. Especially when concerned are the guarantees of personal rights such as life, physical integrity, health and data protection, in particular civil liability.

The new EU regulation on clinical trials on medicinal products. Faster or safer acces to research?

Jilles Heringa (Pays-Bas)

The EU very recently adopted a regulation 'on clinical trials on medicinal products for human use' to introduce one regulatory framework for clinical trials in the European Union.[13] This regulation will replace the current clinical trials directive (2001/20/EC). This new piece of legislation will define the process of the assessment of clinical trials on medicinal products in the European Union for the years to come.

In my presentation I will first critically review the proposed regulation and its legal basis in EU law. I will describe the scope of the regulation and the main features of the assessment process and its consequences. What are the goals and what is the focus of the regulation: internal market, product safety or the protection of human volunteers participating in clinical trials? I will discuss whether the regulation is in line with the Biomedicine Convention of the Council of Europe and the Declaration of Helsinki of the World Medical Association.

Second, from a more substantive point of view, I will discuss what may be the role of ethical considerations and ethics committees during the assessment of a clinical trial. What is the importance of good methodology and a sound assessment of risk and burden during the assessment process?

Finally, I will assess the consequences of the EU regulation in relation to fast and safe access to clinical research in the European Union.

I am looking forward to discussing:

- if the regulation will prevent clinical trials from flowing to non-EU countries?
- will the new regulation contribute to the level of protection for human subjects participating in clinical trials in the European Union?
- the situation of patients who do not meet the sometimes stringent criteria to participate in a clinical trial. Do they have a right to try? And if so, how may a right to try have an effect on the organisation of good clinical research?

Jilles Heringa, MA, LL M

I will present my personal views only

- Independent Researcher;

- Legal Advisor at the Central Committee on Research involving Human Subjects (CCMO), The Netherlands;

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[13] OJ L 158, 27.05.2014, p. 1.

L’accès aux soins en Tunisie: aspects légaux et éthiques

S. MAATOUG, W. BEN AMAR; S. BARDAA, M. ZRIBI, Z. HAMMAMI

En Tunisie, toute personne a le droit à la protection de sa santé dans les meilleures conditions possibles. Elle a droit d’accéder aux prestations préventives, curatives, palliatives, de diagnostic et de réadaptation fonctionnelle avec ou sans hospitalisation à titre onéreux ou gratuit.

Ainsi, les établissements publics hospitaliers et sanitaires sont ouverts à toutes les personnes dont l’état requiert leurs services. Ils doivent être en mesure d’accueillir les malades de jour et de nuit ou, en cas d’impossibilité, d’assurer leur admission dans un autre établissement.

Tout patient est libre de choisir l’établissement sanitaire où il sera pris en charge, dans les limites des possibilités dont il dispose et tout en observant les dispositions spécifiques prévues par les différents régimes de prévoyance, de sécurité sociale et d’assurance maladie.

Cette liberté peut être limitée dans le secteur public ou le patient ne peut pas choisir son médecin, pour des raisons financières, dans certains régimes de sécurité sociale et d’assurance maladie ou en cas d’hospitalisation sans consentement.

En cas de limitation des possibilités du choix pour des raisons financières, c’est à l’état que revient la responsabilité de garantir à tous les citoyens les prestations sanitaires et sociales adéquates.

Tous les patients ont droit aux soins, à l’écoute et aux conseils du médecin et ce avec le même dévouement et sans discrimination aucune.

La prestation de soins de qualité nécessite, une infrastructure et des équipements satisfaisants, une coopération entre tous les soignants ou établissements pour assurer la continuité des soins, la compétence médicale, l’obligation de donner des soins attentifs et fondés sur le dernier état des connaissances médicales ainsi que l’obligation des médecins d’entretenir et de perfectionner leurs connaissances.

Enfin, Le médecin soit soigner avec la même conscience, tous les malades sans discrimination aucune. Le médecin a l’obligation de soigner tous les patients avec la même conscience professionnelle quelque soient leur état de santé, handicaps, conditions sociales (âge, sexe, situation familiale, conditions économiques…). Les établissements publics ne doivent établir aucune discrimination entre les malades en ce qui concerne les soins.

Lorsque les soignants sont tenus de choisir entre les patients justiciables d’un traitement particulier qui ne peut pas être offert à tous: la greffe d’organe…, les patients ont droit à ce qu’une méthode équitable de sélection leur soit appliquée. Ce choix doit être fondé sur des critères médicaux et sans discrimination.

POPULATION VULNERABLE FACE AUX INÉGALITÉS D'ACCÈS AUX SOINS EN ALGERIE

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La question de l'accès aux droits est au cœur des enjeux d'égalité et de citoyenneté.

La protection de la santé est une condition essentielle à la cohésion sociale et à la stabilité économique et constitue l'un des piliers indispensables au développement. L'accès aux soins de santé est un élément essentiel du droit à la santé

Dans notre exposé, nous parlerons du droit à la santé qui est garanti par différents instruments internationaux et régionaux des droits humains ainsi que par de nombreuses constitutions nationales.

L'égalité d'accès aux soins de santé suppose en effet que les soins soient accessibles à tous et à toutes, en droit comme en fait. Il s'agit donc de supprimer les obstacles ou les barrières que certains individus ou groupes pourraient rencontrer pour accéder aux prestations prévues par le système de santé.

En Algérie,l'accès aux soins est inégal pour les citoyens car ils sont tributaires de leur positionnement géographique et des moyens mis à leur disposition par l'état.

De plus, suivant les régions, les catégories de personnes présentées comme vulnérables peuvent varier.

Après une revue des différents points soulevés plus haut, nous ferons un état des lieux de la situation en Algérie et nous donnerons des exemples inégalités d'accès aux soins de santé (santé maternelle, sujets âgées).

Il est important de préciser que pour une population de plus de 36 millions d'habitants en 2009, un territoire qui fait 2 381 741 km^2, la dépense de santé en **Algérie** est passée de 3,48 % du P.I.B en 2000 à 5,79 % du P.I.B en 2009 et que 80 % des dépenses de santé sont prises en charge par l'Etat.

Mots clés : accès aux soins, inégalités,état des lieux.

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L’accès des Tunisiens aux soins à l’étranger

Pr Tasnim Masmoudi Medicine Faculty of Sousse (Tunisia)

Right to Health and the Reform of Health Care Security System in China

Man Hongjie

(Law School of Shandong University, Jinan, China)

The right to health service is a basic human right, requiring the government to promote health service, and satisfy the health need of people. After 1949, an effective health service system, which dramatically enhanced the level of health service, was set up. However, there were problems such as the heavy burden of the government and enterprises, vase gap of coverage between urban and rural area and the low quality of medical service, etc. Therefore, in the Reform and Opening-up period, the Chinese health service system has been reformed. Nonetheless, during this reform, there was a tendency of over-marketization, which prejudice the right to health care. From 2009, China put forward a new proposal of health care reform. As the core of the reform, several schemes of health care security, such as Health Care Scheme for Urban Employees, Health Care Scheme for Urban Resident and New Rural Cooperative Medical Care (NRCMC), were promoted. These schemes cover the most of the population. However, a universal health care scheme should be set up in order to ensure the right to health care for all.

Protection sociale et accès aux soins

Table ronde du 1er juillet 2014

Présentation sommaire Florence Crouzatier-Durand Maître de conférences HDR en droit public

Définie comme étant l'ensemble des dispositifs de prévoyance collective et de protection qu'une société accorde à ses membres pour les assurer et les aider à faire face aux principaux risques sociaux, la protection socialeest un mécanisme de prévoyance collective. Retraite, santé, prévoyance, action sociale … en France, les mécanismes de protection sociale apparaissent dans des dispositifs tels que la Couverture maladie universelle, le chèque santé, ou l'Aide médicale d'Etat.

Au-delà de nos frontières, il est intéressant d'avoir un regard européen sur ces mécanismes alors même que la crise financière s'avère avoir un impact conséquent sur la protection sociale. En Grèce, environ 40 % de la population n'a plus d'assurance maladie. Au Portugal, des patients doivent choisir entre se nourrir et acheter des médicaments. Si la France reste épargnée, le bilan de l'Observatoire 2013 de l'accès aux soins présente des indicateurs inquiétants. Quel est le rôle de l'Union européenne en matière de protection sociale ?Alors que la crise économique accroît les besoins de politique sociale, on note des reculs dans de nombreux pays : restriction de l'accès à l'assurance maladie et aux soins en Grèce, exclusion du système de soins de personnes étrangères en situation irrégulière en Espagne et au Royaume-Uni, remise en cause régulière de l'Aide Médicale d'Etat accordée aux étrangers en situation irrégulière en France.

Enfin, le projet de loi signé par le Président Obama le 23 mars 2010 (Loi Public 111-148 : la loi de la protection du patient et des soins accessibles) est la loi la plus vaste et la plus importante en santé aux Etats-Unis depuis la création de *medicare* et *medicaid* en 1965 (l'assurance maladie pour les personnes âgées et pour les pauvres). Parmi les avancées espérées de cette loi, notons l'extension de la couverture d'assurance santé ainsi que la régulation de l'assurance santé qui devrait mettre fin à certaines pratiques des assureurs pour ne pas payer les frais de santé. La règle de « l'émission garantie » (« the guaranteed issue ») prévoit que chaque assureur a l'obligation d'émettre une assurance santé à toute personne, quelle que soit sa situation antérieure. Elle devrait permettre à 20 millions d'Américains, qui ne disposent pas aujourd'hui d'une couverture santé, d'en avoir une.

Des spécialistes français, européens et internationaux participent à cette table ronde chacun précisera les caractéristiques du système auquel il appartient avant que les points de vue ne soient confrontés, les failles analysées, les améliorations proposées afin que les liens entre protection sociale et accès aux soins soient précisés dans une perspective comparatiste.

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Les organisateurs remercient le projet

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L'ARFDM offre un prix de 500 euros pour le FORUM à la meilleure présentation d'un jeune chercheurs de moins de 35 ans. ***The ARFDM offers a 500 Euros prize to the best presentation of a young researcher under 35***.

Les thèmes des présentations peuvent être ceux de l'Ecole d'été, mais plus largement un sujet portant sur le droit de la santé ou la bioéthique. ***Topics will be those of the European Summer school, or more widely, on health law and bioethics.***

Les présentations se font soit sous forme de posters, soit sous forme de communications orales de 15 mn, avec power-point le 2 Juillet à 9 heures. ***Presentations may be posters or oral presentations:15 mn talk with power-point , on July 3 rd , 9 am***.

Les posters seront mis en place à partir de 8h30 le 2 Juillet . ***Posters will be hung up on July 3rd , 8.30 am*** Le jury fera une visite des posters et les auteurs devront être présents pour répondre aux questions. ***The jury will visit the posters and the authors should answer to the questions.***

Membres du Jury ***Members of the Jury:***

Professeur Henriette Roscam Abbing Pays Bas

Professeur Allanne Madanamoothoo ESC Troyes

Professeur Tasnim Masmoudi Tunisie

Le prix de l'ARFDM sera remis le 2 juillet à 17h . ***The jury will give the results for ARFDM award on July 2nd at 5 pm.***

Le texte des meilleures présentations, sélectionné par le Jury, seront publiés dans un ouvrage édité par Les Etudes Hospitalières. ***The text of the best presentations, selected by the Jury, will be published in a book edited by Les Etudes Hospitalières.***

FORUM DES JEUNES CHERCHEURS

Liste des présentations *Presentation list*

Présentations du 2 juillet (par ordre alphabétique)
Presentations on July 2nd (by alphabetic order)

1. Atienza Macies Elena
2. Chaves Ana Lopes
3. Cheng Xin
4. Coussens Thibaut
5. Dambo Mathide
6. Di Zhang
7. Garido Sara
8. Laidaoui Dalila
9. Marchand Marie
10. Monziols G
11. Sbaihi Attika
12. Veito Villar Miguel

Poster presentations

Anna Pigeon

Gauthier Chassang

Alexandra Soulier

Laurence Mabille

C.Farnos

Résumés pour le FORUM des jeunes chercheurs

Abstracts for the young researchers' FORUM

Présentations orales

Talks

DOPING AND HEALTH PROTECTION IN SPAIN: A LEGAL PERSPECTIVE

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Abstract

When studying doping issues in depth from a multidisciplinary approach, one is faced with material considerations which involve serious and complex problems and that consequently give rise to outstanding reflections of different nature (i.e. economic, social and related to the mass media), but the issues underlying the health sphere are particularly addressed.

That is to say, this presentation aims to answer the following questions: *Why is doping a burning issue nowadays? Is sporting credibility at stake after corrosive doping scandals? What can be said about doping and physical enhancement?* It is not new or unknown that the phenomenon of sport has acquired during the last decades a spectacular dimension, which has been effectively projected in many areas: (a) the social and cultural one; (b) the economic one and (c) the legal dimension, as doping regulation is a subject showing a deep normative shift related to Health Law. Thus, the ultimate purpose of this paper is to address the abovementioned questions in order to be able to offer a general background of the health risks and the side effects which doping gives rise.

This paper especially considers the legal implications of doping from the Spanish legislation perspective. This country undertook the task of developing and enacting a long-awaited regulation: the Organic Law 3/2013, enacted on the 20th of June, protecting athlete's health and fighting against doping in sports, which has been published on the 21st of June, 2013. Likewise, the 30th of April 2013 the Operation Puerto trial's resolution was made public.

Moreover, apart from dealing with the protection of the athlete´s health -a backbone of the antidoping policy-, ensuring equal opportunities for competitors and preserving sport values (e.g. fair play) are the three central pillars on which this paper is based. Thus, as far as equal opportunities are concerned, this paper considers the view of sport as a business, where economic reasons are paramount. In this context, fraud and unfair competition are two aspects well worth considering. On the other hand, and as far as the preservation of sport values is concerned, the relationship between ethics and sport comes into play, and doping becomes actually one of the main problems associated to both professional and amateur sport, which are encompassed under the fuzzy definition of "fair play".

Lastly, the liability of those involved in doping cases (i.e. healthcare agents, coaches or athlete's managers) is also considered. For this purpose, addressing all these issues from the point of view of Criminal Law is essential to fully understand the legally protected interest in doping. In this sense, the views held by the majority doctrine is related to "public health" as the legally protected interest.

Consent of minors to organ transplantation

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This essay carries out a critical analysis of the consent of minors to organ transplantation.
Many juridical and ethical issues are brought to light when dealing with organ transplantation, namely: autonomy, consent and the right to life and physical integrity.
In this case, minor's consent is related to all of them. In fact, when we think about minor's consent and organ transplantation, the following issues come to mind: the degree of autonomy of minors, their capacity to consent and, obviously, the defense of their life and physical integrity, where the parental responsibilities assumes all relevance.
For a better comprehension of this essay, the subject is framed within the scope of personality rights. Next, we will briefly outline the main concepts and types of organ transplant.
Then, we analyze the relevant legislation in Portugal. In fact, in Portugal, the consent must be provided by the parents of minors, since the exercise of parental authority is uninhibited, or, in case of inhibition or, if there are no parents, by the court. Only minors with the capacity of understanding and expressing their will are consulted. In other words, minor donors (and not all minor donors!) are attributed a secondary role in this process.
To analyze the solution, we compare the requirements for donor consent of adults and minors, namely: a non-coerced, informed, free of charge, up-to-date, personal, written consent and issued by a person with capacity. We will then determine if they are applied in the consent of the minor donor. Furthermore, we also examine the ultimate objective of parental responsibilities: Children's best interests
Finally, we assume a critical position regarding the established legal regime and give our contribution to the discussion, based on the object of parental responsibilities and on the personal nature of consent. For many patients, transplantation is a synonym for better quality of life and survival; for others, it is the only chance of survival. The nobility of the end of transplating organs does not justify unethical means. Even if the life of a brother or sister is at stake.

KEYWORDS: Organ Transplantation, Minors, Consent, Parental Responsibilities

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Present Situation of Ethics Committee in Organ Transplantation

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Ethics committee is composed of medicine, ethics and other related professional multi-disciplinary experts. Based on certain ethical principle, in order to solve and demonstrate, guiding the ethical problems of medical institutions in medical practice. In the clinical application it also responsible for regulating, consultation and discussion the ethical decisions and policies.

With the continuous development of the contemporary clinical application technology, more and more medical clinical application technology is incorporated into the scope of medical ethical review. Through the ethical review, ensure the biological medical behavior and medical research comply with the strict scientific and reliability , fully protect the personal rights and interests of the subjects or patients.

Committee of Organ transplantation reviews and approves or disapproves all living donor transplants. This committee confirms the voluntariness of the donor, determines that there is no financial or other exchange involved in the donation and documents the relationship between the donor and recipient.[14] its mission is to protect the patient's life, health, interests and dignity.

Since March 2007, The Centre Government of People's Republic of China had take huge efforts in the work of organ transplantation and organ distribution [15] [16] . <the Regulations on Human Organs Transplantation >was approved by the State Council and came into effect on May 1, 2007[17]. which provides the clinical application of human organ transplant technology must be in the scope of ethical review, and the human organ transplant technology clinical application and ethics committee set up as one of the essential organization of the application, thus, organ transplant ethics committee carry out the important role in organ transplantation in People's Republic of China.

BACKGROUD IN CHINA

With the development of General surgery, the continuous improvement of the immunosuppressive drugs, enhancement of organ preservation conditions, makes organ transplantation as an easier way in medical treatment, but at the same time, organ transplantation faces enormous ethical dilemma.

Modern organ transplantation now spans more than 55 years. Its success has been one of the most remarkable scientific an clinical accomplishments of the 20th century.[18] In China human organ transplant technology began in the late 1960s', compared with foreign countries it late about more than ten years, but

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our country's organ transplant technology is developing very rapidly, in some organ transplant center, organ transplants have reached the international level. Since March 2010, Ministry Health Department of China started the Donation after Cardiac Death (DCD) work, as of November 2013, totally of 1231 cases of implementation for donation. But, facing huge number of receptors for demand, insufficient source of organs is still restricts the work all over the country.

CONFLICTS

1.Traditional moral concepts leads to the shortage of organs. In China, there has never been a generally known professional code comparable to the “Hippocratic Oath” in western medicine. However, the value system of medical ethics in China has a long tradition, which is applicable in guiding our transplant practice. The creation of these ethical guidelines has been greatly influenced by major religious an philosophical system of ancient China.[19] the Confucian thought of "body hair skin, by the parents, dare not damage, the beginning of the filial piety", "Xiao" and "birth to complete skin, dead to lights". Many families think take out the organ after the death, would it be death without the "body", so they hold quite a rejection. And people know such little about organ donation, don't understand the specific process, so the work is hard to widely in practice.

2.Available organs for transplantation in short supply.Due to the limited number of donation organs, compared to the number of patients treated needing for organ transplants, there is a huge gap between the two. Each year about 1.5 million people in China for the time of End-stage Organ failure need organ transplantation, but each year only about 10,000 people can be able to get the organ. Organs in proportion to the number of demanding and supplying is 150:1[20]. A lower rate of organ transplantation below most countries in the world[21], makes China face more serious shortage of donor.

3. The high cost of organ transplant.Kidney transplants in the United States is about $40,000, Heart transplant is about $150,000 Liver transplant is about $200~300,000. Immunosuppressant drugs use cost nearly $10,000~20,000 per year. In China, a kidney transplant is about ￥150,000, a lung transplant is about ￥300,000, heart transplant is about ￥500,000,Liver transplant is about ￥600,000~700,000. Receptors after transplantation, there are a series charge of nursing, monitoring, taking immunosuppressant; it will inevitably cause an enormous economic burden to one family.

4. Lacking of good communication skills.Ethics committee review for the organ transplantation often require closely communication with family members. As families and relatives facing the absence of pain, Combined with the influence of Chinese traditional culture and religious. It is easily cause family members don't understand and misunderstanding the work. Although organ transplant ethics committee must corroborate the authenticity of donation willingness, but if the questions are inappropriate, families could easily give up donation.

SOLUTION AND SUGESTION

1. Implement the principle of Medical Ethics.Referred to <The Declaration of Helsinki of World Medical Conference >[22], clinical trial must conform to the ethics principle, in order to justice, respect personality, makes effort to benefit the participants, and as far as possible to avoid damage. So in work of the organ transplant ethics committee reviewing, it should pay attention to grasp and use of the principle of Medical Ethics.

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(1)The principle of Informed Consent.Informed consent is one of the basic rights of patients, only patients signed the informed consent, it can be able to carry out the organ transplants. Informed consent allows donors to know the detailed steps of organ transplantation, based on a reasonable assessment of risk, so as to choose whether or not willing to donate organs.

(2)The principle of respecting. It also known as the principle of Independent. Everyone should respect the donor's full autonomy. Organ donation is a great progress of human civilization, it's function is not only the development of medicine, but more for Ethics, Law and Social Science, it promoted the knowledge of the death and also promoted peoples' respecting for life. So the organ donation Ethics Committee should be given the respect at any time, let the donor completely make the voluntary donation decision.

(3)The principle of Harmless. Everyone has the right to life; life is a natural person basic personality right. The Civil law of the People's Republic of China Article 98 stipulates that "The Citizens Shall Enjoy the Rights of Life and Health"[23]. As a result, people should be respected for life. Organ transplant ethics committee should hold the purpose of ensure that medical technology realize the human's life and dignity, both donor and receptor life should not threatened by any factors.

(4)The principle of Confidential. In order to protect the patients' message and information, medical institutions in conducting organ transplantation should be strictly confidential obligations at work, ensure any donator or receptor do not know each other and do not affected by any public opinion.

2.Build the relationship of transplant ethics committee with human organ donation coordinator.Organ donation coordinator is different from medical physicians, the main work for them is to find out the hospital potential organ donors, cooperate with clinical departments to finish the selection and evaluation of the potential organ donors, communicating with the donors' family members, witnessed organ procurement process and participate the allocation of organs. In the organ donation transplantation career, organ donation coordinator is one of important link, it can be said "no coordinator, no organ donation". Since 2013 China held human organ donation coordinator training classes, organized of neurosurgery, neurology, emergency and intensive medicine to participate into the class, in order to promote the development of organ transplantation in China.

The emergence of human organ donation coordinator instant the role to communicate with the family; shorten the time of evaluation; Simplifies the process of the discussion. Ethics committee should collocation relations with coordinator team, with the help of the coordinator team, more convenient, more justice to the reviewing of organ transplantation.

3.Gradually change the traditional ideas.Traditional moral ideas in the process of organ transplantation restrict the work continuously, especially the ethics of death, influenced by the history of China. Therefore, Countries should disseminate the life value to the public and motivate the enthusiasm of the organ transplant ethics committee.

4.Improving the mechanism of public opinion so as to the relevant laws and regulations.Media should play a positive promotional role in organ transplantation, respecting the wishes of donors and their families, and cooperate with medical institutions to carry out propaganda work. At the same time, our country should improve relevant laws and regulations, specificationthe local legislative power of organ transplantation, give the guarantee to the right of reviewing for ethics committee in the organ transplantation.

Nowadays in China, the Regulation has been promulgating, but the situation of people's awareness and traditional skills still remain. Institutions of medicine, should establish the mechanism of ethics, in order to enhancement the function of supervision, so as to keep people's dignity and interests.

Key Words*Organ transplantation; Ethics committee; Ethics situation; Regulation;*

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The legality of sex change surgery based on the fundamental right to health and the free disposition of the human body

Author: Sara Garrido (Portugal)

The main objective of this work is to state the legality of sex change surgery based on the fundamental right to health and the free disposition of the human body.
Nevertheless, the concept of health is not univocal and unchanging. It is rather the result of a historical and dialectical process, which causes constant changes and understandings, whether they come from a different place and time, both the culture and the values that underpin every society.
Health is currently understood, particularly by the WHO, as a state of true well-being, whether it is physical or mental, and not merely the absence of disease.
This is the broad concept that fosters the health care of the transgender issue because, although the body of a transsexual is physiologically healthy (there is absence of disease), it is not healthy in all its dimensions.
Moreover, it should be mentioned that this issue has not only changed the concept of health, as well as the concept of the patient.
The term patient has suffered a transformation as it is a security subject whose rights should be protected more intensely.
However, it became difficult to limit the border between legality and illegality of medical interventions with regard to safeguarding the physical integrity of the subject.
The option of a surgical intervention in relation to the transgender issue is part of this problem, since it is not a peaceful classification and as lawful in most jurisdictions.
Such a medical intervention is understood to be correct in situations of hermaphroditism and intersex states.
However, the transsexual subject does not have this right since it is considered to have a mere individual aspiration which is contrary to the ideals and social knowledge.
This procedure is considered contradictory to the principle of the unavailability of the human body. Moreover, there is an inexistence of scientific arguments for this effect.
In the past, the law considered that the dichotomy between physical and psychological sex should be overcome by mental treatment which has repeatedly failed. However, we do not agree with this perspective.
If it is true that the physical integrity is worthy of protection, this cannot be an obstacle when it is an essential part of the treatment of a liberated and healthy human development. However, we reject the extremist positions that put in the forefront the primacy of the will, otherwise these shall pave the way to full liberality in matters of this delicate nature.
However, we believe that the dignity of the human person should prevail in this subject.
Consequently, the self-placement of the transsexual subject in circumstances of transsexual surgery, although contrary to the principle of biological truth and the limits imposed by social collectivity, must be a reputable decision, provided that the subject has the capacity, knowledge, autonomy, and an accurate diagnosis to do so.
Therefore, a sex change surgery, as a therapeutic purpose, is no more than the assertion of the right to self-determination and protection of their physical integrity, in its mental dimension.

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Protection des collections d'échantillons biologiques : et si la vérité se trouvait au musée ?

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Collections d'œuvres d'art, collections de tumeurs... le fossé peut paraître important entre ces deux objets, pourtant l'analyse de leurs régimes juridiques respectifs fait ressortir un ensemble de points communs et constitue une intéressante source d'inspiration afin de perfectionner les modalités de protection des collections biologiques. Selon une jurisprudence constante, une collection représente un ensemble d'objets formant un tout indivisible dont la valeur réside dans la réunion des éléments qui la composent[24]. Les finalités des collections sont diverses: culturelles, scientifiques, techniques etc... Certaines d'entre elles acquièrent même un " intérêt public" emportant avec lui de nombreuses conséquences juridiques.

Les collections d'échantillons biologiques se sont affirmées en quelques années comme un outil indispensable à la recherche scientifique. En offrant d'importantes potentialités d'innovations, économiquement valorisables à terme, elles ont par là même attiré les convoitises de nombreux acteurs aux statuts mais surtout aux intérêts divergents.
Rares et précieuses, ces collections se doivent d'être protégées contre les risques de confiscation, d'utilisation inadéquates, de dissémination ou encore de destruction. Face à cette problématique, le code de la santé publique apporte une réponse peu satisfaisante. Le régime juridique applicable à ces collections s'intéressant davantage aux modalités de constitution de celles-ci plutôt qu'à leur protection et à leur valorisation.

Dans ce contexte, l'analyse du régime protecteur posé par le code du patrimoine et applicable aux collections muséales, peut s'avérer instructif dans une recherche d'éléments permettant la sécurisation de l'utilisation et des échanges de collections biologiques. De manière prospective, pourquoi ne pas envisager d'adapter le régime des biens classés au titre des monuments historiques ou celui des collections sous label "musée de France[25]" aux collections d'échantillons biologiques.

Nul doute que cette adaptation devra prendre en compte plusieurs impératifs liés à la spécificité des collections biologiques. A l'instar des collections scientifiques et techniques classiques, le nouveau régime devra concilier les nécessités liés à la protection des collections sans pour autant compromettre leur utilisation pour des activités de recherche.

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[25] Art. L410-1 C. Patrimoine: " Est considérée comme musée, au sens du présent livre, toute collection permanente composée de biens dont la conservation et la présentation revêtent un intérêt public et organisée en vue de la connaissance, de l'éducation et du plaisir du public."

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"A la recherche d'ovocytes"

Mathide Dambo

La médecine, ces dernières années, a connu des avancées considérables permettant à des couples ayant des problèmes de fertilité ou risquant de transmettre une maladie de devenir parents par le biais de la procréation médicalement assistée.

L'homme et la femme (de moins de 43 ans en France) confrontés notamment à des problèmes de stérilité peuvent recourir à l'assistance médicale à la procréation (AMP) avec tiers donneur qui consiste en un don de gamètes (ovocytes ou spermatozoides) par un donneur à un couple en vue d'une AMP[26].

Sera abordée dans cette étude plus spécifiquement l'activité relative au don de cellules germinales femelles car bien que très marginale (seulement 145 naissances sont survenues grâce au don d'ovocytes en 2008[27]), c'est la plus problématique car il y a une pénurie d'ovocytes qui créé un fossé énorme entre l'offre et la demande.

[26] Art. 1244-1 CSP

[27] Rapport de l'Igas paru en Février 2011

Ethique de l'apprentissage en formation théorique en droit algérien

D. Laidaoui- A.Sbaihi- A. Mostefaoui- F.Merah.

La question sur l'apprentissage de l'éthique reste très marginale dans le domaine de l'éthique médicale, si le droit du malade devrait être un objectif de formation et d'évaluation obligatoire pour tout futur médecin quelque soit sa spécialité cet enseignement théorique doit être spécifique au cursus. La formation de l'éthique vise à transmettre des connaissances théoriques aux étudiants en médecine, mais aussi leur permettre d'acquérir des compétences une fois médecin:
-- D'acquérir de l'expérience et de l'assurance en matière de diagnostic et de thérapeutique.
-De développer le sens du respect et de l'éthique à l'égard de la vie humaine et du patient.
-D'apprendre à faire face de manière autonome à des situations d'urgence.
Assurer une formation tout au long du cursus dans différentes disciplines pour fournir aux médecins un savoir être et un savoir faire leur permettant de garantir une qualité de relation avec le patient ce qui nous conduit à dire que: l'éducation éthique devrait avoir pour but l'amélioration des soins et de la conduite professionnelle.

Mots clés: L'éthique -Formation du médecin- Respect de l'autonomie du patient-

Enjeux de la nouvelle réglementation française relative à la substitution des médicaments biologiques similaires et éclairage économique

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En 2006, la première autorisation de mise sur le marché a été délivrée par l'European Medecines Agency pour un médicament biologique similaire ou « biosimilaire », suite à la tombée dans le domaine public du brevet protégeant le médicament biologique de référence. Depuis cette date, quatorze biosimilaires ont été commercialisés en Europe, générant de nouvelles perspectives économiques, notamment en termes de maîtrise des dépenses, et requérant une adaptation du cadre réglementaire.

L'Europe, pionnière, a défini la notion de médicaments biologiques similaires dans le code communautaire des médicaments dès 2004 [1] : « un médicament biologique qui est similaire à un médicament biologique de référence ne remplit pas les conditions figurant dans la définition des médicaments génériques, en raison notamment de différences liées à la matière première ou de différences entre les procédés de fabrication du médicament biologique et du médicament biologique de référence, les résultats des essais précliniques ou cliniques appropriés relatifs à ces conditions doivent être fournis ». L'article de la directive est accompagné de « guidelines » de production afin de limiter la variabilité du produit et les risques d'immunogénicité. Par ailleurs, la Commission européenne considère que la mise en œuvre de mécanismes juridiques et réglementaires, ainsi que la politique de substitution relèvent de la responsabilité exclusive de chaque Etat membre [2].

En France, les pouvoirs publics cherchent à promouvoir ces médicaments afin de mieux maîtriser le poids des médicaments biologiques, très contributeurs en matière de dépenses. L'Inspection générale des affaires sociales chiffre les économies pour la Sécurité Sociale française à 300 millions d'euros par an à l'horizon 2017. Dans cette optique, l'article 47 de la loi de financement de la Sécurité Sociale pour 2014 [3] autorise le pharmacien à délivrer, par substitution au médicament biologique prescrit, un médicament biologique similaire appartenant au même groupe biologique similaire, en initiation de traitement ou afin de permettre la continuité d'un traitement, si le prescripteur n'a pas exclu la possibilité de cette substitution. Ce texte prévoit également l'information du prescripteur de la substitution [4]. Le

décret d'application de cette loi est à paraître, mais d'ores et déjà, les enjeux et les limites de la substitution apparaissent.

La substitution peut avoir un impact négatif sur la dynamique de la baisse des prix, déjà débutée par la mise en concurrence entre les traitements. Elle peut aussi, dans l'éventualité d'un prix relativement faible fixé par le Comité économique des produits de santé, poser la question de la rentabilité du développement des biosimilaires, déjà incertaine. Elle modifie aussi les responsabilités des acteurs de la santé pour l'acte de prescription et de délivrance pour des molécules non strictement identiques [5]. Ainsi, des ajustements de l'organisation du système de santé devront être envisagés, notamment une amélioration de la communication interprofessionnelle et entre le milieu ambulatoire et hospitalier, afin de garantir la traçabilité de la prescription dans le parcours de soin du malade. La substitution peut apparaître alors comme un moyen d'améliorer l'efficience et la sécurité de la prise en charge médicamenteuse du patient tout en satisfaisant la contrainte de limitation du budget socialisé.

[1] Directive européenne2004/27/CE du 31 mars 2004 modifiant la directive 2001/83/CE

[2] Rapport de consensus de la commission européenne « what you need to know about biosimilar medical products », 2013

[3] Loi n°2013-1203 du 23 décembre 2013 de Financement de la Sécurité Sociale pour 2014

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Promouvoir la sécurité sanitaire des tests génétiques dans le cadre du e-commerce : les leçons à tirer du médicament

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Internet apparaît comme un centre commercial ouvert sur le monde où en un clic il est aisé de remplir son panier de produits licites mais aussi illicites comme des tests génétiques. Les entreprises qui les commercialisent sont essentiellement basées aux Etats-Unis.[28]

Au sein de l'Union Européenne, ils sont régis par la Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro. Les importantes divergences dans son interprétation et application, du fait des récents progrès scientifiques et technologiques, ont nui à la sécurité de ces tests, à leurs performances et à leur libre circulation sur le marché intérieur. Parmi eux, certains permettent de confirmer un diagnostic médical alors que d'autres tentent d'évaluer le risque d'apparition d'une maladie multifactorielle. Afin de pallier les carences du système réglementaire actuel, un règlement du Parlement Européen et du Conseil visant à encadrer ces produits est en cours d'adoption.[29] Il tient compte des documents d'orientation élaborés par le Groupe de travail pour l'harmonisation mondiale mis en place par le Canada, les Etats-Unis d'Amérique, l'Australie et le Japon, relatifs à la traçabilité, la sécurité, les performances, la classification des risques ou encore l'évaluation clinique des tels dispositifs. Cette convergence internationale de la réglementation est un prérequis essentiel au e-commerce des produits de santé. A défaut et en raison des problématiques éthiques et juridiques émanant de l'information génétique que produisent les tests d'ADN, la France a fait le choix d'en interdire la vente en

ligne en réservant l'accès à ces dispositifs au moyen d'un circuit traditionnel très

[28]Gauthier CHASSANG, Florence TABOULET, « Tests génétiques et médicaments en ligne : Quels points communs ? » Les Etudes hospitalières - Edition 2012

[29]Rapport sur la proposition de règlement du Parlement Européen et du Conseil relatif aux dispositifs médicaux de diagnostic in vitro (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)) Commission de l'environnement, de la sante publique et de la sécurité alimentaire – avril 2014

encadré,[30] à la

différence d'autres pays qui autorisent ce e-commerce.

Parallèlement, l'e-commerce des médicaments se développe. En effet, la vente en ligne des médicaments de prescription médicale facultative est autorisée en France depuis 2013 suite au long processus d'harmonisation de la réglementation au niveau européen et international. Cette harmonisation permet la mise sur le marché de médicaments de qualité, sûrs et efficaces. Alors que 62 % de médicaments vendus sur internet sont des contrefaçons selon l'OMS[31] et qu'ils arrivent en tête des saisies des produits contrefaits selon le dernier rapport des Douanes françaises,[32] aucune de ces contrefaçons n'a été retrouvée dans les officines françaises. Dès lors, la France a fait le choix de n'autoriser la vente en ligne qu'au bénéfice de celles-ci, afin de tirer profit de la sécurité sanitaire exemplaire de la chaîne d'approvisionnement légale et traditionnelle du médicament.[33,34]

Fort de ces avancées, l'étude menée ici autour du e-commerce des médicaments permet de tirer des enseignements visant à promouvoir la sécurité sanitaire des tests génétiques dans le cadre du e-commerce.

Ainsi, nous analyserons le cadre juridique du commerce en ligne des médicaments (I) avant de porter notre attention au développement du cadre applicable aux tests génétiques (II).

[30]Arrêté du 27 mai 2013 définissant les règles de bonnes pratiques applicables à l'examen des caractéristiques génétiques d'une personne à des fins médicales

[31]Bulletin of the WHO, Growing threat from counterfeit medicines, 2010.
[32]Rapport « Douanes Résultats 2013 »- Février 2014
[33]Les cahiers de l'Ordre national des pharmaciens « La qualité de la chaîne du médicament à l'heure de la mondialisation » - Octobre 2013
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Le soin en milieu carcéral

Problématique de la prise en charge

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Les dispositions de la Constitution algérienne précisent que les infractions commises à l'encontre des droits et libertés, ainsi que les atteintes physiques ou morales à l'intégrité de l'être humain sont réprimées par la loi. Les textes de loi algérienne garantissent la protection des personnes vulnérables notamment les détenus. En matière d'accès aux soins ce qui spécifie la médecine pénitentiaire c'est le lieu où vivent les personnes qui est suffisamment influant pour obliger la médecine à laquelle elles s'adressent à particulariser son exercice car le milieu carcéral est un lieu de concentration de problèmes sanitaires. Le détenu se trouve confronté à plus de problèmes de santé qu'à l'extérieur.

Dans le cadre de la réforme de la justice et de l'humanisation des établissements pénitentiaires **et d**ans une perspective de prise en charge socio – sanitaire des détenus, le ministère de la santé, de la population et de la réforme hospitalière a répondu à la sollicitation de la Commission Nationale Consultative de Promotion et de Protection des Droits de l'Homme et des mesures sanitaires ont été prises par les pouvoirs publics ces mesures interviennent à différents niveaux pour affirmer l'appartenance du détenu au groupe social et l'amélioration de la couverture par l'affectation de moyens matériels conséquents ,Un rattachement des soins aux instances hospitalières de l'ensemble de la population a été ordonné 16 Mars 2004 parun arrêté interministériel qui réserve dans le service de médecine légale de l'hôpital concerné, à défaut de service de médecine légale, dans le service de médecine interne, une aile aménagée pour l'hospitalisation des détenus

Malgré ces efforts le médecin n'ayant pas reçu de formation pour l'exercice de la médecine carcéral se trouve face à de nombreuses problématiques éthiques. Le code de la santé et le code de procédure pénale et le code de la reforme pénitentiaire ne prévoient pas malheureusement des spécificités pour chaque circonstances. Son positionnement entre règles sécuritaires et règles professionnelles fait qu'il soit le maillon central d'une chaîne de tensions

Notre problématique aborde le sujet délicat « éthiques des soins et problématique

de la prise en charge en milieu carcéral».

Mots clés : soins ,milieu carcéral, problèmes éthiques

PEOPLE WITH DISABILITIES AND GENETIC EXCEPTIONALISM

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Abstract

The progress of medical science in last years has been undoubtedly exceptional. Surgical procedures are been refined, the healthcare becomes safer because of techniques of prevention of adverse events, new medicaments are being created and new medical devices are being tested. In this scenario, one of the medical branches that has increase its presence and perhaps our expectations too is clinical genetics. In this sense, the number of medical procedures that use today screening or genetic testing is much higher than in previous years.

In some way , genetic has created a strange atmosphere. Its speed, its promises (often not created by geneticists themselves at all) has raised an horizon sometimes not entirely justified.

And the world of Law has participated in this phenomena. Almost from its beginning Law has seen genetics as something strange, different, something that should always get the best guarantees and protections. And this, in my opinion, is not quite correct. As the European Union has said, we must abandon the genetic exceptionalism, because genetics is, indeed, just another medical science.

In this paper we want to analyze the Spanish and Portuguese legislation concerned of genetic information and, to be more specific, the information and procedures with peolpe with disabilities. We will prove that both of them have fallen (the Spanish rather than Portuguese) in the error of exceptionalism without limit and both of them give people with disabilities an unjustified and discriminatory treatment.

Mandatory informed prenatal genetic testing: a perspective from China

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ABSTRACT

The applications of genetic technologies are increasing fast in China, especially the potential use of prenatal genetic testing, which raise the concern of eugenics and how China should use these technologies reasonably, especially in the unique situation of China. This paper argues that mandatory informed prenatal genetic testing with opt-out in poor areas is justifiable. The prenatal genetic test should be provided to pregnant women routinely, and they have to be given information about the availability of testing, at the same time as they can opt-out from the test according to their own judgment. This policy should be applied in underdeveloped areas of China. People in poor areas will benefit from this proposal, and it is not eugenics, both because of the opt-out procedure and the voluntary nature of any follow up，especially it is not intent to pursue a reproductive goal of a nation or group. There are two reasons for this proposal: the information from prenatal genetic testing is crucially important for parents to make reasonable reproductive decisions, and it will create incentives for the government to provide resources and services in underdeveloped areas. Because of resource constraints in China, at the present day, prenatal genetic testing cannot be available everywhere.

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The ethical dimensions and the tools for data sharing in genetics within evolving frameworks

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Data as well as biological sample international sharing is paramount in health research. While policy declarations from numerous research institutions and funders encourage such sharing a number of difficulties and needs are identified in practice to "make it happen". This movement in the context of the availability of large scale sequencing technologies for studying human genomic variation is confronted with legal and ethical aspects regarding privacy, confidentiality, clinically useful information and the duties attached. Issues related to identifiability, consent process and regulation of access challenge the existing framework. The evolving legal framework regarding exchanges of biological samples (no unified legal EU framework for research) and personal data protection (Directive in revision) is challenged. Examples from various consortia and projects are analysed to enlighten the different facets at stake, from the P3G consortium (Public population projects in genomics and society), the international consortium on cancer genomics, European infrastructures such as BBMRI (Biobanking and Biomolecular Resources Research Infrastructure) or ESGI (European sequencing and genotyping) and other EU projects. The focus will be on Charts, Codes and tools to foster sharing, especially hSERN (human sample exchange regulation navigator) that gives information on theoretical and practical legal aspects for exchanging biological samples across borders and the BRIF initiative (Bioresource research impact factor) that aims at providing ways to recognise the efforts to make available valid bioresources and at measuring their use. Thus from policy willingness to incentives a whole culture of samples and data sharing is on its move, but not without difficulties.

Revision of the Data Protection Directive in Europe: consequences for immunogenetics and medical genetics professionals and researchers.

G. Chassang, V Anastasova, A. Pigeon, E. Rial-Sebbag, A. Cambon-Thomsen

In January 2012, the Commission published a draft proposal of the General Data Protection Regulation (DPR), which would replace the existing Data Protection Directive (Directive 95/46/EC) and become law in the 28 Member States. This revision was initiated in order to reinforce rights of individuals and to remedy the legal uncertainty stemming from fragmentation in the way personal data protection was implemented across member states. Another key goal was to increase the Regulation's ambit to better cover emerging fields resulting from rapid technological developments. As a Regulation the data protection measures will directly apply in Member States law without necessitating any transposition. The Medical Science Committee of Science Europe issued an opinion paper on the proposal, welcoming the update of the Directive, but also urged to maintain the interests of fundamental research in Europe, which were not fully taken into account in the proposed text of the European Parliament. Science Europe agreed on a joint Position statement co-signed by the Chairs of various Committees. In October 2013, the Civil Liberties and Home Affairs (LIBE) Committee of the European Parliament has adopted amendments to the Data Protection Regulation that would have a potential negative impact on research if allowed to pass into law, regarding the use of identifiable data and of pseudonymised health data in research, the consent requirements and their exceptions, and a profound re-organisation of the administrative measures of data protection. The Regulation also reinforces individual control over data management; right to information and access to data as well as new obligations for data controllers. Also genetic data are explicitly defined as sensitive information. Some steps of negotiations are still underway at EU level. A plenary vote in the European Parliament is expected in spring 2014. Considering that immunogenetics has both a clinical and a research side the present work examines the various changes at stake and their consequences on the practice of immunogenetics. This is important in order to be prepared, to set up relevant procedures and necessary education and endure no blockage in the activities as the new Regulation will be implemented.

The experiences and views of health care professionals, researchers and patient associations regarding information and feedback of results in the context of next generation sequencing in oncology

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The ethical and practical issues raised by next generation sequencing (NGS) have been studied mainly from a normative point of view. We have been interested in gathering opinions from various stakeholders in the framework of two European FP7 projects projects in renal oncology: Genomics of Kidney Cancer research project (Cagekid), an ICGC project, and TArgeted therapy in Renal cell cancer: GEnetic and Tumour related biomarkers for response and toxicity (EuroTARGET). We gathered both qualitative interview data as well as quantitative questionnaire data in the context of the use of high throughput omics technologies, (especially Next generation sequencing as applied to generate whole genome, or whole exome sequencing). A questionnaire was distributed to clinicians/researchers attending various genetics meetings in Europe in 2013. In addition to this questionnaire, researchers, clinicians and patient representatives in oncology using high throughput technologies were identified via contacts with participants involved in the two projects. We also conducted a pubmed search to identify authors involved in projects using whole genome or exome sequencing in renal oncology. A semi-structured interview guide was elaborated with a focus on four different themes (as in the questionnaire): 1) information provision before testing; 2) the communication of research results; 3) the disclosure of incidental findings; and 4) the sharing of data with the research community. Interviews were conducted by phone or skype between July 2013 and January 2014. Interviews were recoded and transcribed. Content analysis of transcripts was conducted using the 4 aforementioned themes. Subthemes and issues related to these four initial main themes were then further identified inductively. We report here some of the qualitative and quantitative results from clinicians/researchers first and from the interviews with representatives of patient associations.

Of the 95 respondents to the questionnaire, 88% work as researchers and/or clinicians in a field related to oncology and half (52%) use NGS in some aspect of their work; 56% of respondents state that they provide specific information about NGS to participants or patients before enrolling them in a study or using their samples for sequencing. The majority, 83% had never received requests from physicians or patients for access to NGS data to inform treatment decisions. Regarding feedback of results in a research setting, 54% or respondents think that results stemming from NGS studies should be provided to individual participants and 72% think that actionable incidental findings should be disclosed to participants. Finally, 53% of respondents think that specific measures and/or limitations should be implemented for the sharing of NGS data/results with colleagues in the scientific community.

Six interviews were conducted with clinicians/researchers and three with representatives from patient associations. Professional interviewees mentioned that indeed, when using high throughput technologies the information in the informed consent was a bit more detailed:

"It's a bit more detailed actually, so we have a whole brochure about the … Consortium. With more details."

"(the information is) *different of course. We need to ask the patients, ask our patients, our patients' families, to analyze their samples, samples using new technologies. So it is very time-consuming*."

"Of course in the analysis we did not concentrate on the germ-line mutations, germ-line variants, but anyway once we sequenced the entire genome, inevitably we have a chance to look at the germ line variants of these patients. So I think the patients should be informed of the possibilities when we analyze their samples. I think this is very important."

Reporting results as well as incidental findings was highly correlated with their immediate clinical usefulness. Issues raised by the question of sharing data in the survey include, with whom to share data, the responsibility to keep participants unidentifiable, the timing of sharing with respect to the time of publication of results, as well as a suggestion of a model of sharing results.

All three patient associations representatives highlighted that there is lack of understanding by patients of genetics and genomics, and more specifically about sequencing in cancer research.

"I suppose they talk about looking for biomarkers, and there's an understanding, I think, about what biomarkers are, but I don't think there is a lot of understanding or a lot of familiarity with talk of sequencing and the cancer genome,…"

What patients do want to know (which is not necessarily specific to genomics research), includes the aim, the constraints for the researchers, the risks and benefits to the patients. Two representatives thought that, compared to other biomedical research, there should be some specific kind of information for genomic sequencing. Interestingly, in some ways countering the above view, the third interviewee raised the issue that when technologies are so complex, and patients don't understand, they, in fact, may not need all the details and what they want is more basic. Regarding individual research results, interviewees felt it was a personal matter that every patient should decide on for themselves but patient involvement from the beginning is critical.

Such empirical data from stakeholders is a valuable contribution to the ongoing discussion of how to responsibly handle information and feedback results to patients and research subjects.

Tracing and Measuring the impact of bioresources: an incentive to share biological samples and associated data

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An increasing portion of biomedical research relies on the use of bioresources such as databases and collections of samples. Sharing of such resources is essential for optimising knowledge production. This is an ethical imperative that has to be balanced by the protection of individuals. In later years, the generation of large datasets by new techniques and establishing of biobanks for studying disease cohorts or populations have become an essential tool in biomedical research in general and this has created a need for giving credit to researchers and institutions who spend time and effort to create and maintain bioresources. A bioresource can be a biobank, a database, or a set of bioinformatics software tools. In order to incentivise sharing and use of bioresources, the BRIF (Bioresource Research Impact Factor) initiative has been developed. BRIF aims to create metrics for bioresource use, modelled on the Journal Impact Factor. An international working group communicating online has been set up and several steps have been taken. Among them we focus here on two aspects: 1) defining a process to uniquely and persistently identify bioresources based on existing schemes; 2) organising their easy tracing in publications through a standardised citation rule. For this latter purpose we collaborate with science editors, and a metajournal (Open Journal of Bioresources) has been created in order to provide citable marker papers for bioresources. An analysis of existing identification schemes has been conducted and a critical overview led to propose a decision process to choose an identifier system according to the different kinds of bioresources. For the traceability in publications a questionnaire was sent to a sample of science journals editors and a workshop with some of them was organised. A proposal was agreed upon that is now submitted as guideline in preparation to the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network. As a general perspective, the BRIF initiative will hopefully facilitate data and resource sharing.

Disclosure of genetic information to family members: does the French legal framework solve the dilemma?

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Genetic information is often considered as specific, among other biological information, because of its personal and family dimension. When a person is diagnosed with a serious genetic anomaly, the disclosure of this information can be relevant for other family members when prevention measures or treatment exist. The transmission of this information raises legal issues for professionals: how to preserve confidentiality and privacy of personal medical information? How to ensure the right to know of the relatives when the information to be disclosed can be of interest for their health? The French legislator tried, in 2004, to draw a balance between these principles by implementing the “genetic information procedure to family members. The lack of adoption of enforcement decrees made the law not applicable since a revision occurred in the new bioethics law (2011). This procedure tends to favor information of relatives by creating a primary legal obligation for the index subject to inform his family members. It also creates professional obligations notably in the ways this information has to be formalised and disclosed when the subject do not want to communicate it. The French legal system is almost complete) as many texts (legal and good practices) have enriched the procedure throughout 2013 In the light of these legal novelties we will make a comparative analysis to address
-The equilibrium of the principles referred to in the law,
-Their adequacy to the practices,
-The remaining unclear points (responsibilities not to disclose, genetic information relating to minors)

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Data protection e-health and mobile health 3 - 4 July 2014

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3rd July 2014

9 am -10.15 am Maria Celia Fernandez-Aller (Spain): **The Big Data Phenomenom**

Coffee break

10.30 am - 12 Nicolas Terry (USA): **Big data and US Health privacy**

Lunch

2 pm- 3 pm Henriette Roscam Abbing : **Electronic health records**

3 pm – 4 pm Dean Harris (USA) : **Medical Errors Caused by Using Electronic Health Records: Patient Safety and Legal Liability.**

Coffee break

4.15pm - 5.30 pm Jean Herveg (Belgium): **General Overview of Protection of Medical Data in European Law**

4th July 2014

9 am 10.15 am Nicolas Terry (USA): **Mobile Health and Medical Apps**

Coffee break

10.30 am-12 am Jean Herveg (Belgium): **Data protection and cloud computing services**

Lunch

2pm-3pm Allane Madanamoothoo (France): **An overview of privacy regarding data protection in the UK**

Coffee break

3 pm- 4 pm Gauthier Chassang (France): **Health Data data and biobanks in the EU legal context.**

4.pm 5pm Open discussion on comparison EU/ US

ABSTRACTS

The Big Data Phenomenom

Maria Celia Fernandez-Aller Technical University of Madrid)

Big data refers to the exponential growth both in the availability and in the automated use of information: it refers to very big digital datasets held by corporations, governments and other large organizations, which are then extensively analyzed using computer algorithms. Big data can be used to identify more general trends and correlations but it can also be processed in order to directly affect individuals. The expectation from big data is that it may ultimately lead to better and more informed decisions.

There are numerous applications of big data in various sectors, including healthcare, mobile communications, smart grid, traffic management, fraud detection, marketing and retail.

We will focus on healthcare, which is rapidly transitioning from a volume to value based system. Data analytics will be a critical success factor not only to measure operational performance but to be able to analyze patterns and predict clinical and financial outcomes.

With all its potential for innovation, big data may also pose significant risks for the protection of personal data and the right to privacy, as it increases the risk that people can lose control of their own data. In particular, big data raises concerns about: a) the sheer scale of data collection, tracking and profiling; b) the security of data; c) the transparency, which implies sufficient information given to individuals; d) inaccuracy, discrimination, exclusion and economic imbalance; d) increased possibilities of government surveillance.

We will analyze how to apply the "specified, explicit and legitimate" purposes to big data; as well as the general compatibility assessment and the specific provisions on "further processing for historical, statistical or scientific purposes", including appropriate safeguards that may help data controllers meet the compatibility test. The legal requirements are well established in the Directive 95/46/EC and will be modified by the Proposed Data Protection Regulation.

Big Data & U.S. Health Privacy

Nicolas Terry, Hall Render Professor of Law
& Director of the Hall Center for Law, Indiana University Robert H. McKinney School of Law

This presentation discusses the challenge to U.S. health data protection posed by “big data” collection and analytic processing. The challenge is serious because of some limiting characteristics in the U.S. data protection legal model. That model is characterized by (1) sector/domain-specific data protection, (2) a preference for downstream protection models (confidentiality, security, breach notification) rather than upstream models (anonymity and privacy), and (3) a theoretical basis rooted in liability rather than property or quasi-property approaches.

As I have argued in two recent papers (“Protecting Patient Privacy in the Age of Big Data” 81 UMKC L.Rev. 385-415 (2013); Big Data Proxies and Health Privacy Exceptionalism,” 24 Health Matrix 65-108 (2014)), these characteristics leave the traditional model of U.S. health data protection vulnerable to big data practices. In part, this is because big data brokers are able to create "proxies" for protected health data in relatively unregulated space.

This presentation argues that, while “small data” rules protect conventional health care data (doing so exceptionally, if not exceptionally well), big data facilitates the creation of data proxies that are relatively unprotected. As a result, the current, carefully constructed, appropriate and necessary model of health data privacy will be eroded. The presentation explains the relevant characteristics of U.S. privacy law and how it protects "small" data, identifies the health data pools that "feed" big data, and analyses the application of current U.S. data protection. The presentation concludes with a description of recent reports (including recommended legislation) from the White House, the Federal Trade Commission and the President's Council of Advisors on Science and Technology.

Electronic health records
Electronic Health Record, cross border care and the rights of the patient

Henriette Roscam-Abbing

Ensuring continuity of cross-border healthcare often depends on the transfer of personal data concerning patients' health. Obviously patients' rights in relation to their medical file – eg. to have access to their personal health data, to have data deleted, to give informed consent about medical necessary transfer of personal data outside the immediate doctor -patient relationship, apply in the case of medical treatment in the home-country as well as in the context of cross border healthcare. In case personal data are transferred through the electronic health record, interoperability of resp. health ICT systems is essential. Apart from technical issues and the legal basis of the technical system, a sound legal framework of safeguards for protecting personal data from the perspective of the patient is required. Such a framework should pay attention in particular to variations among countries in the implementation of commonly shared informational privacy standards. Patients' rights in the context of electronic health records are the same as when the file is off line, including the right to be informed about who is authorised to have access. For the patient to have trust in healthcare, transparency in relation to personal medical data, whether off line or on line, whether in national or in cross border health care, is a key condition.

Medical Errors Caused by Using Electronic Health Records: Patient Safety and Legal Liability.

Dean M Harris J.D. (USA)

Electronic health records (EHRs) can improve patient safety and quality of care. For example, computerized physician order entry (CPOE) systems enable clinicians to enter orders for drugs by computer rather than in manual form. CPOE can be safer than manual entry of drug orders by avoiding problems with handwriting or similar drug names and by providing alerts about patient allergies and interactions between drugs.

However, experts have also recognized that the use of EHRs could have some negative effects on patient safety. One group of researchers found that CPOE systems can cause 22 types of medication errors. Therefore, experts recommend training, monitoring, careful planning with involvement of clinical staff, and analysis of data about problems in using EHRs.

EHRs could have significant effects on the liability of health care providers and on the process for resolution of claims. No one knows for sure how the use of EHRs will affect malpractice liability, but we can identify some possible effects of EHRs on liability for malpractice and the process of litigation.

As physicians gain access to more information about their patients in EHRs or broader collections of data, courts will need to evaluate whether physicians have satisfied their duty to review the appropriate information for purposes of diagnosis or treatment. Other questions are likely to arise about a physician's decision to override drug alerts or clinical recommendations in a clinical decision support (CDS) system.

The application of malpractice law to the use of EHRs will depend in large part on the evolution of medical practice and the reaction of legislatures to any adverse effects of increased liability. Legislatures may have the power to change malpractice law if they perceive that imposition of liability is having adverse effects on availability and cost of malpractice insurance, the cost of medical care, or access to needed healthcare services. If the imposition of malpractice liability interferes with the adoption and use of EHRs, legislatures might take action to limit legal liability as a way to encourage the use of information technology in the healthcare system.

This presentation compares the progress on EHRs in Europe and the United States. Then, the presentation analyzes the positive and negative effects of EHRs on patient safety. Finally, it analyzes the potential effects of EHRs on liability for medical malpractice.

General Overview of Protection of Medical Data in European Law

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Introduction

On 27 July 1990, the European Commission submitted to the Council a proposal of a directive on the processing of personal data ([35]).The objective assigned to the directive was to facilitate the free movement of personal data within the European Community while maintaining a high level of protection for the citizens with regard to the processing of personal data. The proposal has been adopted on 24 October 1995 and is widely known since as the *privacy directive* or the *data protection directive*. It provides the general rules applicable to the processing of personal data in all the Members States.

1. Identification of data processing

The application of data protection rules begins with the identification of processing of personal data which falls under the scope of the directive ([36]).

2. The purpose principle

Then, we have to determine the purposes for which the personal data are collected. These purposes must be specified, explicit and legitimate. In other words, the data protection directive requires that the data controller has to pursue a specified, explicit and legitimate purpose when collecting, using, communicating or storing personal data concerning the patient in order to provide him with appropriate state of the art healthcare. And as we all know, the purpose principle is of the utmost importance in the application of data protection rules. Personal data cannot be processed in a way incompatible with the purposes for which they had been collected.

3. Fair and lawful processing principles

Personal data should be fairly processed in compliance with the purposes communicated to the data subject by the data controller. Personal data should also be lawfully processed. This refers to the compliance with special rules applicable to the processed data. In healthcare, lawfulness refers notably to the rules regarding professional secrecy.

4. Quality principle

Furthermore, personal data must be adequate, relevant and not excessive in relation with the purposes for which they are processed.

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35 Com(90)314final – SYN 287.

36 See provision 3 of the Directive.

They also should be accurate and, where necessary, kept up to date. When the personal data processing purposes are achieved, data cannot be kept in a form which permits the identification of the data subject ([37]).

5. Legitimacy principle and the ban to medical data processing

The directive lists the situations in which a processing of personal data can occur ([38]). With respect to this, it stipulates that processing of medical data is prohibited excepted in the enumerated situations ([39]). Regarding medical data, the ban to process them will be lifted thanks to the exception provided for the processing of personal data for medical purposes. The directive only requires specifically that the processing must be realized under the supervision of someone bound to professional secrecy or to any equivalent duty of secrecy. Of course, the use of ICT in healthcare will also be subject to the general conditions regarding the lawfulness of the data processing. With respect to this, the level of security will obviously impact the legitimacy assessment and the analysis of the compatibility of any operation performed upon personal data.

6. Data subject's rights

6.1 Information right

The data controller must provide the data subject from whom data relating to him or herself are collected with information on the processing of personal data ([40]).

6.2 Access right

The data subject has the right to access personal data relating to him ([41]).

6.3 Opposition right

At any time, the data subject may oppose the processing of personal data relating to him. In order to be successful, the claim must be grounded on compelling legitimate grounds relating to the data subject's particular situation to the processing of data relating to him, save where otherwise provided by national legislation. Where there is a justified objection, the processing instigated by the data controller may no longer involve those data ([42]). In healthcare, this mechanism could be used to prevent any reference to HIV-related information in the medical record in special circumstances.

6.4 Individual automated decision

The directive provides that everyone has the right not to be subjected to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate certain personal aspects relating to him, such as his

37 See provision 6 of the Directive. See below for further developments on this topic.
38 See provision 7 of the Directive.
39 See provision 8 of the Directive.
40 See provisions 10, 11 & 13 of the Directive.
41 See provisions 12 & 13 of the Directive. See below on this topic.
42 See Provision 14 of the Directive.

performance at work, creditworthiness, reliability, conduct, etc. ([43]). In healthcare, this refers, by instance, to the control of the patient's insurability by means of an electronic insurance card.

7. Confidentiality and security

The data controller must ensure the confidentiality and the security of the processing of personal data ([44]).

8. Notification to the national supervisory authority

The processing of personal data should be notified by the data controller to the national supervisory authority ([45]).

9. Specific risks

Processing that are likely to present specific risks to the rights and freedoms of data subjects should be subject to prior examination ([46]).

10. Public registry

The national supervisory authority has the duty to keep a public registry with all the processing that have been notified ([47]). This is one of the measures enabling the data subject to exercise his rights on the processing of personal data.

11. Transfer of personal data

The transfer of personal data to a third country is subject to special rules ([48]. In short, this kind of operation is prohibited except when the country of destination ensures an adequate level of protection for personal data.

12. Access to judicial remedies

The data subject must have access to appropriate judicial remedies. The Directive provides that any person who has suffered damage as a result of an unlawful processing operation or of any act incompatible with the national provisions adopted pursuant to the Directive is entitled to receive compensation from the data controller for the damage suffered. The data controller may be exempted from this liability, in whole or in part, if he proves that he is not responsible for the event giving rise to the damage ([49]).

13. Some issues with the data protection directive

13.1 Lack of harmonization

43 See Provision 15 of the Directive. This right is not limitless.
44 See Provisions 16 & 17 of the Directive.
45 See Provisions 18 & 19 of the Directive.
46 See Provision of the Directive.
47 See Provision 21 of the Directive.
48 See Provisions 25 & 26 of the Directive.
49 See Provisions 22 & 24 of the Directive.

The harmonization of data protection rules concerns only restrictions on personal data processing on the ground of protecting the rights and liberties of the data subject. Therefore, disharmonies can find a cause in legal aspects that are not been subjected to the harmonization.

By instance, rules on professional secrecy may impose restrictions on the use of ICT in healthcare and may prevent some communication of personal data.

Public health or social security requirements may impose the communication of various personal data to public bodies for quality control or for funding purposes.

In both cases, this kind of national requirements may vary from country to country and even within a same country regarding the national distribution of powers.

Of course, the data protection directive is not the cause of this kind of discrepancies between national legislations. Their cause must be found in national laws and in the rules regarding the distribution of powers between the European Union and the Member States and within the Member States.

On the other hand, the data protection directive allows for questioning the legitimacy of using ICT in healthcare notably in terms of costs for the healthcare system. By instance, is it legitimate to implement costly and non-efficient ICT in healthcare when there is a huge funding deficit in healthcare? This approach allows us to demonstrate that the legitimacy requirement may help to oppose to the implementation of inefficient information systems in healthcare, which is, in our view, a good point in favor of the data protection directive.

13.2 The phrasing of the prohibition to process medical data

From a data protection point of view, the ban to process medical data is considered as the best protection possible for the data subject. Where there is no processing, there is no risk for the data subject.

But, from a medical point of view, it can be quite disconcerting. Indeed, it might be uneasy to explain to a health practitioner that the use of medical data is forbidden except when being in one of the situations listed in the data protection directive. Of course, one of these situations concerns the processing of medical data for medical purpose. But, nevertheless, the first principle is to oppose any processing. This might lead to some serious misunderstanding, especially when implementing new ICT in a non-friendly environment.

Therefore, our suggestion would be to discuss the possibility to change the phrasing of the ban and to state that: "*The processing of medical data may only occur under the direct order and constant supervision and monitoring of a professional healthcare practitioner for the following purposes* (…)" and then to finish the provision with stipulating that "*The processing of medical data is otherwise forbidden*".

13.4 Data quality in healthcare

One of the major risks, besides the use of personal data for illegitimate purposes, lies in the wide dissemination of incorrect personal data. Therefore, one condition to allow for the free circulation

of personal data is that the data controller must ensure the quality of the processed data. Somehow, strong requirements regarding data quality should be the normal counterpart to the possibility given to data controllers to process personal data.

As mentioned before, in the current state of the legislation, the quality principle implies that personal data must be fairly processed in compliance with the purposes indicated to the data subject by the data controller. Personal data must be lawfully processed and the purposes for which the personal data have been collected must be specified, explicit and legitimate. Personal data cannot be processed in a way incompatible with the purposes for which they had been collected. Furthermore, personal data must be adequate, relevant and not excessive in relation with the purposes for which they are processed. Personal data also should be accurate and, where necessary, kept up to date. When the personal data processing purposes are achieved, data cannot be kept in a form which permits the identification of the data subject.

As we can see, the data quality principle is formally quite well established. But the question is whether or not it has been fully implemented, whether or not all its implications have been totally and completely exploited. Is it sure that we have used all the possibilities, all the opportunities offered by ICT in healthcare to improve the data quality and therefore the quality of the healthcare provided to the patient?

It is quite difficult to have an informed opinion on this matter due to the lack of enough exhaustive and serious studies on the topic. But, too often, it seems that ICT have just replaced the paper in the management of the patient's data. This raises the legitimacy of the use of ICT in healthcare. If it was only about that, was it worth to put the patient's rights and liberties in jeopardy?

In response to this issue, wouldn't be possible to strengthen the data quality principle by adding that the use of ICT in healthcare must improve the informational quality of the data used to provide the patient with adequate state of the art healthcare? Of course, it would imply to monitor the data quality.

A minima, shouldn't we consider that the processing of medical data is equivalent to a medical act subject to state-of-the-art rules? *A maxima*, shouldn't we consider to impose procedures when processing medical data?

In our view, the data protection directive should not be drafted only in a way to facilitate the selling of more ICT to hospitals or health practitioners. It should mainly aim at improving the quality of the healthcare provided to the patient based upon real and efficient and measurable requirements. The proposal of a general data protection regulation does not seem to bring anything new on this issue.

13.5 Data protection and patient's rights on data processing

The data subject is entitled to get some information from the data controller about the processing of personal data. Therefore, at least, except when the data subject already has it, the data controller must provide the data subject with the following information:

(a) the identity of the controller and of his representative, if any;

(b) the purposes of the processing for which the data are intended;

(c) any further information such as

- the recipients or categories of recipients of the data,
- whether replies to the questions are obligatory or voluntary, as well as the possible consequences of failure to reply,
- the existence of the right of access to and the right to rectify the data concerning him,

in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.

The data subject has the right to consent to the processing of personal data, the right to access personal data concerning him and, in some circumstances, the right to oppose to the processing of personal data. He also has a right to judicial remedies in case of damages caused by a violation of data protection rules.

In our view, those rights contribute to the empowering of the patient in healthcare. When exercising them, the patient should have a better understanding of his health condition and he also would be in a better position to exercise his right of self-determination when being taken care of by a health practitioner or when participating in medical research.

We think that it is really important to strengthen the patient's rights about the processing of personal data. His rights are firmly stated in the data protection directive but it is not sure whether or not they are fully exploited in healthcare. The proposal for a general data protection does not bring anything new with respect to this. However, we could wonder whether or not the intervention of the national supervisory authority in an authorization scheme might lead to a weakening of the patient's control over his personal data. Indeed, in this case, it could be assumed that the control will be performed by the national supervisory authority instead of the patient. We could argue that this public body has more power and resources to perform the duty but in the same time it takes the things off the patient's hands. It is somehow contradictory with the empowering theory. Obviously, a better combination of both forms of control should be conceived.

From a practical point of view for the patient, we should consider to impose to the data controller a pro-active duty to send to the patient, on a regular base, an intelligible report of the medical data related to him and to organize a better communication between the healthcare practitioner and the patient: at the appropriate moment, the health practitioner should provide the patient with the information that will be used when treating him. That could permit to avoid some misunderstanding in the transmission of some vital information regarding the patient's condition.

14. Proposal for a general data protection regulation

On 25 January 2012, the European Commission has issued a proposal for a general data protection regulation (COM (2012) 11 final) aiming at replacing the privacy directive. The fundamental ideas underpinning the proposal are the necessity to adapt the current legal framework to the development of new technologies and to put an end to existing disharmonies between national laws, while maintaining a high level of protection for the citizen.

Mobile Health and Medical Apps

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There is a widespread belief that mobile health is poised to be a major force in U.S. healthcare. Investments in mobile health companies and announcements of major products by market-leading companies raise expectations of either healthcare disruption or at least significant forced changes in downstream (customer-facing) aspects of conventional healthcare.

In two papers I have challenged the likelihood of meaningful disruption of healthcare by the current generation of conventional health information technology (HIT),assigning blame to both the current state of the technology and deficiencies in health care financing and processes. See Information Technology's Failure to Disrupt Healthcare. 13 Nev. L.J. 722 (2013); Pit Crews With Computers: Can Health Information Technology Fix Fragmented Care? (Houston Journal of Health Law & Policy, 2014).

The approach of mobile health developers and entrepreneurs differs from either traditional healthcare bricks-and-mortar providers or those who make extensive use of current generation HIT. Being customer-facing it also appears consistent with contemporary calls to reform healthcare from a push model to one where patients only pull necessary resources.

Mobile health faces some meaningful barriers to implementation. First, its business model is opaque. Will it feature inexpensive services but at great scale or will customers be expected to pay a premium for convenience? If mobile health is offered as an adjunct to conventional healthcare or in some hybrid form what changes in the existing healthcare financing system will be required?

Second, mobile health faces serious regulatory hurdles. In the U.S. the most challenging regulatory issues are at the federal level. The FDA's 2013 Industry Guidance on Mobile Medical Applications answered few questions while both the FTC and HHS are examining mobile health products from the perspectives of health privacy and security.

Data protection and cloud computing services

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1. Definition of cloud computing

The NIST defines cloud computing as "*a model for enabling convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction*." ([50])

2. Cloud computing characteristics

Cloud computing presents the following characteristics:

On-demand self-service. A consumer can unilaterally provision computing capabilities, such as server time and network storage, as needed, automatically and without requiring human interaction with each service provider.

Broad network access. Capabilities are available over the network and accessed through standard mechanisms that promote use by heterogeneous thin or thick client platforms (e.g., mobile phones, laptops, and PDAs).

Resource pooling. The provider's computing resources are pooled to serve multiple consumers using a multi-tenant model, with different physical and virtual resources dynamically assigned and reassigned according to consumer demand. There is a sense of location independence in that the customer generally has no control or knowledge over the exact location of the provided resources but may be able to specify location at a higher level of abstraction (e.g., country, state, or datacenter). Examples of resources include storage, processing, memory, network bandwidth, and virtual machines.

Rapid elasticity. Capabilities can be rapidly and elastically provisioned, in some cases automatically, to quickly scale out, and rapidly released to quickly scale in. To the consumer, the capabilities available for provisioning often appear to be unlimited and can be purchased in any quantity at any time.

Measured Service. Cloud systems automatically control and optimize resource use by leveraging a metering capability at some level of abstraction appropriate to the type of service (e.g., storage, processing, bandwidth, and active user accounts). Resource usage can be monitored, controlled, and reported providing transparency for both the provider and consumer of the utilized service.

3 Classification of cloud computing services

A cloud infrastructure is the collection of hardware and software that enables the five essential

[50] See Art. 29 WP, opinion 05/2012 on Cloud Computing, 01.07.2012 and the NIST website www.nist.gov./itl/cloud.

characteristics of cloud computing. The cloud infrastructure can be viewed as containing both a physical layer and an abstraction layer. The physical layer consists of the hardware resources that are necessary to support the cloud services being provided, and typically includes server, storage and network components. The abstraction layer consists of the software deployed across the physical layer, which manifests the essential cloud characteristics. Conceptually the abstraction layer sits above the physical layer.

Cloud computing services are usually classified under three categories: Infrastructure as a service, Platform as a service and Software as a service.

> **Software as a Service** (SaaS). The capability provided to the consumer is to use the provider's applications running on a cloud infrastructure. The applications are accessible from various client devices through either a thin client interface, such as a web browser (e.g., web-based email), or a program interface. The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, storage, or even individual application capabilities, with the possible exception of limited user-specific application configuration settings.
>
> **Platform as a Service** (PaaS). The capability provided to the consumer is to deploy onto the cloud infrastructure consumer-created or acquired applications created using programming languages, libraries, services, and tools supported by the provider. The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, or storage, but has control over the deployed applications and possibly configuration settings for the application-hosting environment.
>
> **Infrastructure as a Service** (IaaS). The capability provided to the consumer is to provision processing, storage, networks, and other fundamental computing resources where the consumer is able to deploy and run arbitrary software, which can include operating systems and applications. The consumer does not manage or control the underlying cloud infrastructure but has control over operating systems, storage, and deployed applications; and possibly limited control of select networking components (e.g., host firewalls)."

4. Models of cloud computing services

There are 4 models for cloud computing services.

> **Private cloud**. The cloud infrastructure is operated solely for an organization. It may be managed by the organization or a third party and may exist on premises or off premises.
>
> **Community cloud**. The cloud infrastructure is shared by several organizations and supports a specific community that has shared concerns (e.g., mission, security requirements, policy, and compliance considerations). It may be managed by the organizations or a third party and may exist on premises or off premises.
>
> **Public cloud**. The cloud infrastructure is made available to the general public or a large industry group and is owned by an organization selling cloud services.
>
> **Hybrid cloud**. The cloud infrastructure is a composition of two or more clouds (private, community, or public) that remain unique entities but are bound together by standardized

or proprietary technology that enables data and application portability (e.g., cloud bursting for load-balancing between clouds)."

5. Issues to tackle with cloud computing services in healthcare

- physical location of the servers (and data processing fairness/transparency);
- identification of personal data processing (distinction between the 3 categories of cloud computing services);
- identification of the data controller and the data processor and the person bound to professional secrecy or to any equivalent duty of secrecy who has to supervise the processing of medical data;
- information of the data subject;
- exercise of patients and data subject's rights
- professional secrecy;
- security and confidentiality;
- transfer of personal data outside European Union, etc.

An overview of privacy regarding data protection in the UK

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The first legislation in the UK dealing with data protection was the Data Protection Act 1984. This Act was then further replaced by the Data Protection Act 1998 which came into force in March 2001. It implements the EU Data Protection Directive. On the one side, the aim of the Data Protection Act is that anyone who processes personal information must comply with different principles. For instance, information must be processed for specified purposes, be adequate, relevant and not excessive, be accurate and up-to-date. On the other side, according to the Act, individuals have a right of access in order to know what information is being hold about them whether on a computer or a certain filing systems. In case they believe they have been a victim of a breach of the Data Protection Act, they can complain to the Information Commission who is in charge of the enforcement of the Data Protection Act. Moreover, according to the Data Protection Act 1998 fines may be imposed on data controllers in breach of the law. The Act also states that any document or other material used to commit the offence can be forfeited, destroyed or erased. However, although the penalties settled by the Act, the latter still remain insufficient. Indeed, according to the European Commission, the UK government has defectively implemented 15 articles out of the 34 articles Directive. The main issue is therefore how far the Data Protection Act 1998 effective?

Key words: privacy, data protection, rights

Human research biobanks and health data protection in the European Union

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Human research biobanks have become increasingly important tools for supporting progresses and innovations in medical and scientific researches, to organise and preserve biological resources that will serve to develop health-related knowledge (e.g. better understanding of complex diseases, notably of genetic and environmental factors influencing disease risks and treatments). Human research biobanks maintain and provide access to human biological materials and associated data for research uses, as platforms for international research collaborations. While biobanks contain large sets of data that tend to enlarge across the years, while they already play an important role by contributing to research achievements, they remain relatively new actors, both in the international research world and in legal landscapes. Among the various specific rules biobanks have to respect there is the EU personal data protection legal framework. Indeed, it is commonly agreed that a wide access to such data and human biological samples must be balanced by concern for the interests of research participants (i.e. persons from whom biological resources are obtained), what notably includes the respect of individual privacy and personal data protection.

Since 2012 the European Commission initiated a profound reform of the existing European Union (EU) by proposing a General Data Protection Regulation to be adopted by the EU Parliament and the Council of the EU for replacing the current EU Directive 95/46/EC concerning the protection of individuals with regard to the processing of their personal data and their free flow. This proposed Regulation still be drafted and is not yet officially adopted as a EU law. However, the text has already been modified by amendments from the EU Parliaments and includes some new rules that will impact the activities of research operators, including biobanks, in several ways.

During this session we will first explain the concept, content, activities and organisation movement of human research biobanks in the EU in order to present and discuss the relevant personal data protection rules that currently apply to their activities, as well as those that are newly proposed within the proposal for a General Data Protection Regulation (not yet adopted).

Proposition de cooperation Proposal for cooperation

L -UNIVERSITA' TA' MALTA
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SKOLA MEDIKA
MEDICAL SCHOOL

BIOETHICS RESEARCH PROGRAMME

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Proposal for a Mediterranean Network of Bioethics

Over the past fifty years bioethics has grown into a large network of people with national and international associations. Recently there is also a push towards a globalized ethics. Nevertheless regional bioethics remains important. In Europe many regions have united their efforts and apply for EU projects together in order to harmonize efforts and have a better understanding of the need of patients of the respective regions.

Unfortunately this has not been the case for Southern Europe. Moreover, this region, being the northern border of the Mediterranean has historically been involved with northern Africa and eastern Europe in the widespread Mediterranean. Recent event of migration have created ethical issues of their own, but southern European countries, in general having a more deontological approach and being more harmonized perhaps in normative values, have not yet succeeded in bringing together their academic views on bioethics and ethics education.

A recent paper asked the question 'Is there a Mediterranean Bioethics', requested by the editor of the Journal *Medicine in Health Care and Philosophy* (ed. Prof. Henk ten Have). There is of course a Mediterranean culture; ethics is not that homogenous when it comes to southern Europe and northern Africa. Nevertheless the strategic nature of these countries provides an opportunity for dialogue and can provide a catalyst from which global ethics can benefit.

It is being proposed that a Mediterranean Network of people working or teaching in the field of bioethics be set up. Participating as a region in EU projects may be more beneficial and

moreover countries can try to get together for regional meeting and perhaps apply for projects to study regional problem. With the approach of the EU's Horizon 2020 now is the opportune moment to set up such an organization.

It would be opportune to start by contacting people we know in the following countries:

Southern Europe: France, Spain, Italy, Malta, Greece, Cyprus

Northern Africa:Egypt, Tunis, Libya, Algiers

Eastern Mediterranean: Turkey, Israel

Should the proposal be accepted we should get a number of signatories, and arrange for a meeting to approve a statute and select an executive committee. We will then agree on an action plan.

Pierre Mallia

LISTE DES PARTICIPANTS

LIST OF PARTICIPANTS

LIST DES PARTICIPANTS –ATTENDEES LIST

N°	Name	First name	Country
1	ALTAVILLA	ANNAGRAZIA	FRANCE
2	ANDRIEU	SANDRINE	FRANCE
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5	BENHARKAT	ABDELAZIZ	ALGERIA
6	BOUSQUET	NADEGE	FRANCE
7	BOYER-BEVIERE	BENEDICTE	France
8	BUEB	RENAUD	FRANCE
9	CAILLET	CELINE	FRANCE
10	CHAP	HUGUES	France
11	CHASSANG	GAUTHIER	France
12	CHEKROUN	MERRYL-ANNA	France
13	CHENG	XIN	PR CHINA
14	CI	PUWA	PR CHINA
15	CROUZIT	BEATRICE	France
16	CRUBEZY	ERIC	FRANCE
17	DAMBO	MATHILDE	FRANCE
18	DAVID	BRUNO	FRANCE
19	DELPIERRE	CYRILLE	FRANCE
20	DIEBOLT	VINCENT	FRANCE
21	DOLS	MATHILDE	France
22	DUGUET	ANNE-MARIE	FRANCE
23	DUGUET	LIONEL	FRANCE
24	FANG	XIONG	PR CHINA
25	FERNANDEZ-ALLER	MARIA CELIA	SPAIN
26	FILIPPI	ISABELLE	FRANCE
27	GABORIT	EMILIE	France
28	GARRIDO	SARA	Portugal
29	GAUMONT-PRAT	HELENE	France
30	GEBRE	EMNET	France

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36	HORSITTISOMBOON	THIRASAK	France
37	HOU	JIAWEI	PR CHINA
38	JINHAI	YAN	PR CHINA
39	KAUTZMAN	CHRISTIAN	USA
40	KENFACK	HUGUES	France
41	KLEIN	EDOUARD	France
42	LAIDAOUI	DALILA	ALGERIA
43	LAMURE	CHARLOTTE	FRANCE
44	LANG	THIERRY	France
45	LAPEYRE-MESTRE	MARYSE	FRANCE
46	LARRIEU	JACQUES	France
47	LEK	SOVAN	FRANCE
48	LI	BEI	PR CHINA
49	LI	MOU	PR CHINA
50	LI	SHU	PR CHINA
51	LI	SIRUI	PR CHINA
52	LI	WANG	PR CHINA
53	LIANG	CHUXIN	PR CHINA
54	LISONG	DING	PR CHINA
55	LOPES-CHAVES	ANA	Portugal
56	MAATOUG	SAMIR	TUNISIE
57	MADANAMOOTHOO	ALLANE	FRANCE
58	MALLIA	PIERRE	MALTA
59	MAN	HONGJIE	PR CHINA
60	MASMOUDI	TASMIN	TUNISIA
61	MENDOZA-CAMINADE	ALEXANDRA	France
62	MESCHIA	CLARA	France

N°	Name	First name	Country
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65	MORGADO	PEDRO	Portugal
66	MORVILLERS	NICOLAS	FRANCE
67	OUSSEDIK	RAFIK	ALGERIA
68	PARICARD	SOPHIE	France
69	POIROT-MAZERES	ISABELLE	France
70	RAMDJEE-KESSAVDJEE	BRUNO	france
71	RAMOS	VERA	Portugal
72	REMOND	JEAN-JACQUES	FRANCE
73	RIBEIRO	GERALDO	Portugal
74	ROSCAM-ABBING	HENRIETTE	THE NETHERLANDS
75	ROUSSEAU	PIERICK	FRANCE
76	ROUSSET	GUILLAUME	France
77	ROUSSIN	ANNE	FRANCE
78	SANCHEZ	ROSARIO	FRANCE
79	SBAIHI	ATIKA	ALGERIA
80	SCHMITZ	JULIA	
81	SHILIN	DU	PR CHINA
82	SONG	XINZHE	PR CHINA
83	TABOULET	FLORENCE	France
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86	VALDEYRON	NATHALIE	France
87	VEITO-VILLAR	MIGUEL	Portugal
88	WAN	BOWEI	PR CHINA
89	WEIGUANG	YAO	PR CHINA
90	WU	QIONG	PR CHINA
91	YANG	LUMING	PR CHINA
92	YANG	YUE	PR CHINA
93	YE	TING	PR CHINA
94	ZHAI	DUANGYANG	PR CHINA

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