European Summer School on Health Law and Bioethics

5 - 8 September 2016 Toulouse (France)
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Faculté de Médecine 37 Allées Jules Guesde Toulouse France
Grand Salle Batiment B

Coordinator: Dr Anne-Marie DUGUET aduguet@club-internet.fr

GENERAL AGENDA

Grande Salle Batiment B

5 September 2016 9 am-7pm

5th FRENCH CHINESE SYMPOSIUM
Organized in the framework of the XU Guangqi programme

Health law and ethics: comparison France-China

Dinner on registration7.30 pm

6 September 2016

9 am WORKSHOP

Patients' rights and mediation

2 pm Young researchers' FORUM

7 September 2016

Ethics in Hospitals

8 September 2016

Working groups Xu Guangqi Programme

SUMMARY

2016 EUROPEAN SUMMER SCHOOL

5-8 September 2016

Faculté de médecine 37 Allées Jules Guesde Metro Carmes ou Palais de Justice Grande Salle Batiment B

5 September

5th FRENCH CHINESE SYMPOSIUM
Heath law and bioethics: Chinese-French comparison

Coordinated by Anne-Marie Duguet assisted by Gauthier Chassang

Organized in the framework of the XU Guangqi program 2016

CAMPUS FRANCE
Agence française pour la promotion de l'enseignement supérieur, l'accueil et la mobilité internationale http://www.campusfrance.org/fr

Programme

9.am Opening session AM Duguet-E.Rial- J. Larrieu

9.15-10.30 Session 1

Global ethics, the role of Chinese culture

Chairpersons: Pr He Fei (Professor 1st Affiliated Hospital of Kunming medial university) Anne-Marie Duguet Senior Lecturer Paul Sabatier University

- Humanitythinkings about the "Birth, Senility, Illness and Death" in medicaltreatment Pr He Fei
- The influence of Confucianethics in Traditional ChineseMedicine ethics. Pr Ma Zongren
- Ethic and legalproblems in multidisciplinarytreatment(MDT) Cheng Xin
- The ethics supervision in medical technology Cui Yue

10h30-10h45 Coffee break

10.45-12 Session 2

Law and ethics in public health

Chairpersons: Wu Tao (Assistant professor X'ian Medical University)-Maryse Lapeyre-Mestre Senior Lecturer University Paul Sabatier

- The progressive construction of health safety principles on drugs: the lessons of history. AurélieMahalatchimy-Florence Taboulet
- Legal framework and classification of vaccination in China Wu Tao
- Vaccine safety: The French Pharmacovigilance experience. MaryseLapeyre-Mestre
- Compensation of vaccine accidents: the French system. Anne-Marie Duguet

Lunch: Administrative Restaurant

2pm 3.30 pmSession 3

Ethics and law in medicinal and pharmaceutical research

Chairpersons : Jacques Larrieu Professor Toulouse1 Capitole University-Emmanuelle Rial INSERM Unit 1027

- Human embryonic Stem cells: what are the legal challenges at stake? Emmanuelle Rial-Sebbag.
- Law and ethics concerns raised by the patentability of a second therapeutic application JacquesLarrieu.
- Transferringpersonalhealth data with China for research uses under the new EU General Data Protection Regulation - Gauthier Chassang

3.30- 3.45 pm Coffee break

3.45pm- 5 pm Session 4

Health products and public health

Chairpersons Alexandra Mendoza-Caminade Senior Lecturer Toulouse1 Capitole University Florence Taboulet Professor, University Paul Sabatier

- The pharmaceutical trademarks, trademarks like others? Alexandra Mendoza-Caminade
- Legal protection of traditional medicines: the bath medicinal herbs of national minority of YAO in Congjiang.ChuanjuanZuang
- Misuse of psychoactive medicines and public health.Pr Anne RoussinPharmacologie, Faculté de Pharmacie,
- Ethics and access to medecines.Charlotte Lamure

7.30 pm Dinner on registration Restaurant La Brasserie de l'Opera Place du Capitole

2016 EUROPEAN SUMMER SCHOOL

Tuesday 6 September 2016 ***WORSHOP on patients' rights***

9am-10.30 am Patient rights in the EU*Chair personAnne-Marie Duguet*

Patient rights: a general framework
Joaquin Cayon de las Cuevas GRIDES University of Cantabria Spain

Is there a right to maximum waiting times at the EU level? Concerns and challenges
Joaquin Cayon de las Cuevas GRIDES University of Cantabria Spain

Complusory vaccination: a violation of patient rights ? *Gustavo Merino-Gomez* GRIDES University of Cantabria Spain

11.15am-12 Mediation *Chair Person Pr Florence Taboulet*

Medical disputes and mediation in hospital *Cheng Xin* 1st Affiliated hospital of Kunming medical University China

Mediation in Pharma-industry conflicts (generics and intelectual property).
Alexandre Pereira University of Coïmbra Portugal

3 pm- 5.30 pm

Young researchers'FORUM

Jury : Professeur Florence Taboulet Pr Wu Tao Dr Anne-Marie Duguet

Wednesday 7 September 2016 ***WORSHOP Ethics in Hospitals***

10am -12 Ethics in Organ transplantation

Present Situation of Ethics Committee in Organ Transplantation *Cheng Xin*
Ethics in artificial organs *AM Duguet*

2 pmHeart transplantation in Toulouse university hospital *Pr Camille Dambrin*

3.30pm Visit of the Canceropole : hospital and research center.

4.30 Meeting with Pr Bettina Couderc Canceropôle ethics committee .

Thursday 8 September 2016

Xu Guangqi project working group

Abstracts

Humanity Thinking About the "Birth, Senility, Illness and Death" in Medical Treatment

HEFei

Abstract: Human life from once to toddler, from the youth beautiful to Achieve International Success until to senility always intimate contact with medical, birth need to be in hospital, senility need to go to hospital for medical assistance, get ill need a doctor make diagnosis and give treatment, death also tend to get medical service although sometimes helpless, Hippocrates, the father of medicine once said:I will prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone. In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction. With saving lives and curing patients, at the same time, medical is also a subject about the humanities and morality. “Birth, Senility, Illness and Death " seem common rules in life, but in every medical links have the intimate contact with medical ethics. Test-tube baby, surrogate, malformation fetus, fission of conjoint babies these ethical medical behalves are ruled by medical ethics in clinical work; The existence of the lonely elder man, medical facilities and medical conditions supports to elder people, patient rights protection during they are in hospital, thinking of the implementation of euthanasia, all of these medical behaviors put forward higher requirements in the construction and implementation of medical ethics. To explore and thinking of the “Birth, Senility, Illness and Death” is advantageous to the medical institutions pay more attention to patients, care patients and solicitude patients, so as to the through the construction of medical ethics committee, constantly promote infiltration of medical humanities in medical institutions, finally achieve real "taking patients as the center" concept.

Keywords: Medical Ethics, Humanity, Ethics Committee

The influence of Confucian ethics in Traditional Chinese Medicine ethics.

Pr Ma Zongren

First Affiliated Hospital of Kunming Medical University P.R.China

Traditional Chinese medicine is rooted in China's traditional culture, its generation and development process, infiltrated and influenced by the Chinese traditional culture. The ethics thoughts are rich and have a long history; they are the wealth of the Chinese history. Confucianism, especially in Chinese traditional medical ethics thought has extremely profound influence. Confucianism and Chinese medicine ethics thought are the essence of Chinese traditional culture. Confucian people-oriented thoughts and the help of patient's medical ethics of traditional Chinese medicine have consistency. Confucianism and Chinese medicine ethics reflects a positive attitude towards life.

"Ren" is the core thought of Confucian ethics, Mencius summarized Confucianism as: "people with Ren will love others". Under the influence of Confucian thought, the traditional Chinese ethics put forward "medical is Ren skills" which become the core thought of Chinese traditional medical ethics, and have profound effect to traditional Chinese medicine ethics. Confucian thought of filial piety let the people to be the doctor as the basic value of filial piety. Confucian thought of think more about other's matters as mine matters set up doctors' right work ethic value. Confucian humanity ideological requires doctors take the social responsibility consciously. Confucian ideas of control-self give the moral guidelines to doctors.

Confucianism not only put forward the ethical and moral standard system of "Ren", and summarizes and extracting a set of theories and methods about cultivate morality. The cultivate morality is overcome individual thoughts and behaviors not in conformity with the code of ethics, try to make self as the members of society with high standard moral. Confucius also emphasize this is the root of a personal, a family or the country. Influenced by the thoughts of Confucian of cultivate morality, the traditional medical ethics emphasizes doctors should strengthen the moral practice, it is acquire before study medicine, doctor should first to learn morality and the principle of how to be a morality person.it is also claims do not study medicine without morality, and without morality cannot be doctors.

Above all, Confucianism thought had a profound and aspects influence to the formation and development of traditional Chinese medical ethics, Confucianism thoughts laid a theoretical foundation for Chinese traditional medical ethics. For us to research this kind of influence, better inherit and carry forward the fine traditional medical ethics, to strengthen the construction of medical ethics in the new period, it is has important theoretical significance and practical value to build the system of modern medical ethics theory with Chinese characteristics.

Ethical and Legal Problems in Multidisciplinary Team (MDT)

Along with the advancement of medical technology, the kinds of diseases to people develops gradually from simple diseases to complex diseases, enormous changes have taken place in many disease treatment patterns, the traditional way to treating diseases of single subject in early times already unable to meet the demands of current complex diseases diagnosis, treatment and prevention. Therefore the multidisciplinary Team (MDT) model arises in many hospitals in China. MDT through clinical multidisciplinary team, based on the evidence medicine ideas as the guidance, regularly organize the clinical multidisciplinary discussion, and then put forward the treatment plan and regularly follow-up for patients. But according to current situation, the legal and ethical issues involved in the MDT is sustainable growth, as there is no clear legal guidelines and legal basis, when medical negligence or disputes happens during the diagnosis and treatment it is relatively weak to protect the physicians' or patients' rights and interests from MDT discussion;During MDT discussion always involving the right to life, the right to health, body right, the right of privacy, medication equality right and informed consent right, as there is no clear legal provisions or regulations, it is also very hard to effectively to protect the patients' rights; Specialists only through their professional knowledge focus on patients disease may carry out the interprofessional barriers and prejudice in the process of consultation and may make the subjective errors to damage the ethical process. How to though the hospital administration to standardize the MDT discussion process, gradual promotion the construction of hospital ethics committee as well as the ethics committee process in MDT discussion, all of these situation have important significance to awaking our awareness to focus on to protection the rights of the doctors and patients.

Key words: Multidisciplinary Team(MDT), Ethical, Legal, Rights protection

Ethical review on Medical Technology

CUIYue

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Abstract：As is well known, with the consummating of the diseasepatterns, the development of medical technology is changing with each passing day. But due to the uncertainty objective defects of medical technology, it is imperative to strengthen the construction of ethics of medical technology and so as to standardization the medical treatments.The State Ministry of Health issued medical technology application and management classification, which divided medical technology application into three categories. Hospital ethics committee plays a pivotal role, which should be strictly reviewed the process of the medical technology, especially mention the moral and the ethics. The medical technology should strictly accordanceby the ethics committee approval process audit, due to the time urgency, the audit process by the ethics committee gradually become a mere formality.So we have to establish information platform,strengthen the ethical education and establish the ethical supervision points.Though the above measures,information platformcan pay attention to the dynamic information of medical technology, Strengthen ethical education and improveethical consciousness.We will use the date and the example of our hospital to do the research accordance with the relevant laws and regulations standardize operation of the ethics committee in order to improve the medical treatments.

Keywords: MedicalTechnology, Ethics Committee, Information Platform, Ethical Education

The progressive construction of health safety principles on drugs: *the lessons of history*

Dr Aurélie MAHALATCHIMY (*Centre for Global Health Policy, University of Sussex, UK)*
Pr Florence Taboulet *(Droit pharmaceutique et Economie de la santé)*
Inserm UMR 1027 - Université Paul Sabatier Toulouse III

In order to commercialise safe, effective and innovative drugs, pharmaceutical labs invest in Research & Development.All this activity is framed by a set of rules that aims to protect patients' health and to promote firms' competitiveness. This legal corpus is always being built and evolving and becomes more and more concerned by the globalisation. One can identify a double movement between science and law :

- First, progresses of scientific knowledge and methodologies : in biostatistics, clinical research, analytical control, quality assurance procedures, vigilances, leading to Soft law,
- Secondly, health disasters: one can learn from these disasters and the political answer is usually to introduce legal reforms.

Consequently, there is a high legislative inflation, hardly understandable for the actors.
We will thus question the *meta-law*: the origin of all these rules. We will follow an historical perspective to show the fundamental principles' genesis of the pharmaceutical regulation, the 4 principles of health safety where these rules come from.
One can outline the impact of « cases », health scandals, on the French and European regulation, or even worldwide with ICH. We will see 3 different categories of cases :

- lacks of quality, with Stalinon® (1953),
- cases relates to safety, with Thalidomide® (1953) and Distilbene® (1946)
- cases relates to independency and transparency, when the quality of the information given by the lab is concerned, or more specifically, the quality of the links and exchanges between manufacturers and health authorities, with Vioxx® (1999) and Mediator® (1976-2009).

The analysis of this case highlights the necessity of compliance with the 4 principles of health safety:
1. The **Evaluation principle** for the evaluation's rigor of pharmacovigilance situations and more globally, for the system good governance,
2. The **Precautionary principl**e to "dare" to take decision of marketing authorisation withdrawal,
3. The **principle of assessors' independency** and health authorities, with a good management of conflicts of interests,
4. The **Transparency principle** of the openly debated evaluation and health protection measures.

Those 4 main principles should enrich all activities and decisions of both labs and health authorities. They are "matrix principles" with global significance, for national, European and international legislations. They are interrelated principles all along the drug development.
Thus, we can talk about the "hardcore" of a culture that should be shared by every actor for collaboration: firms, health authorities, health professionals (doctors, pharmacists), patients.
This base could also be used as an analysis grid for any dysfunction and for any reform, and should be applied and transferred in the initial and continuous training of any actor.

Legal framework and classification of vaccination in China

Classification des vaccins en Chine

Wu Tao Maître de conférence18629616661@163.com

Résumé

Les vaccins sont classés en deux catégories en Chine, pour tous les citoyens, le type 1 est pratiquement impératif mais théoriquement facultatifet pris en charge 100% par l'Etat, le type 2 véritablement volontaire et payé par l'usager. Lors des réactions inattendues sans faute, ceux de type 1 sont indemnisés par l'Etat et ceux de type 2 par les fabricants. Dans la pratique, il existe des problèmes relatifs à l'équité causés par cette classification. Par exemple, les vaccins contre la poliomyélite concernent tous les deux types, les vaccins vivants atténués par voie orale sont gratuits et ceux inactivés injectables sont payants. En cas de la réaction inattendue sans faute, la compensation serait significativement différente. La protection de la santé publique est le but de la mise en place de vaccination impérative, donc la majorité de personnes suivent cette politique et éventuellement certaines subiraient des préjudices (graves) afin de protéger les intérêts collectifs. Si les même préjudices seraient indemnisés différemment selon les types des vaccins, l'injustice serait véritable, parce que l'indemnisation assurée par l'Etat ayant beaucoup plus de confiance que celle par les fabricants en Chine, notamment quand le litige avec les fabricants serait souvent pénible pour les usagers et l'indemnisation ne serait pas bien assurée. En conséquence, la recherche se consacrera à la légitimité du fondement de la classification de vaccins. En parallèle, le nouveau mode de compensation serait discuté selon les résultats antérieurs.

Mots clefs

vaccination/vaccin, classification, réactions inattendues, compensation/indemnisation

Vaccine safety: The French Pharmacovigilance experience.

Maryse Lapeyre-Mestre
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Vaccines correspond to the definition of drugs, and like all other categories of drugs (for humans or for animals), they are submitted to a pre-clinical and clinical evaluation, including clinical trials on healthy volunteers and sometimes on patients with various diseases. As for other drugs, clinical trials for vaccines are essential but unfortunately are insufficient to anticipate the benefit-risk profile of drugs when they are used at the whole population level: the main reasons for this insufficient knowledge of the real benefit-risk profile is that the number of subjects included in clinical trials is very low, and this population is generally selected and not really representative of the targeted population. Indeed, these points underline the need for both patients and their doctors of the vaccine safety monitoring following market authorization. In France, this monitoring is performed by the pharmacovigilance system, based on spontaneous reporting, with a mandatory reporting for serious or unexpected adverse effects of drugs, including vaccines. Following the Public Health crisis after mass vaccination against Hepatitis B virus in the mid 90's, this spontaneous reporting system has been completed by pharmacoepidemiological investigations, often based on electronic health care databases, as well as in France than in other occidental countries. These pharmacoepidemiological methods (case-control or cohort studies, self-controlled cases series, observed-expected comparisons) have been used to investigate vaccine-related adverse outcomes (Guillain-Barre syndrome or narcolepsy and H1N1 vaccine; auto-immune diseases and antipapilloma virus vaccine, intussusceptions and rotavirus vaccine…). To this date, evidence from pharmacovigilance data suggests the excellent benefit-harm ratio of vaccines, much higher than that of many other classes of drugs.

Compensation of vaccine accidents: the French system

AM Duguet UMR/INSERM 1027 Université Paul Sabatier

Wu Tao Maître de Conférence Xi'an Medical Universty

In the French Civil Law, the indemnistation of damage related to a medical act is based on the principle of fault . For a long time in the event of compulsory vaccination the jurisprudence and the law have provided specific solutions.Indeed compulsory vaccinationsare enforced by the state for public health reasons and no one can escape from it. These vaccinations are free of charge and organized by the public health services. The goal is to protect the population from epidemics and to eradicate some diseases such as smallpox and polio.

Thus the Conseil d"Etat has recognized in 1962 in Lastrajoli Case the principle of presumption of fault to compensate accidents of compulsory vaccinations performed by doctors of the public health service. The law of January 1, 1964 introduced no fault system for the indemnification of compulsory vaccinations

Since the Law of 4 March 2002, in respect of the principle of national solidarity, compensation for damages related to compulsory vaccination is conferred on the National Compensation Board of Medical Accidents (ONIAM) on the basis of Article L.3111- 9 of the Code of Public Health.

Apart from mandatory vaccinations several types of vaccines are at the disposal of health professionals in order to protect specific groups. Decrees impose mandatory vaccinations to prevent occupational hazards . As soon as a regulatory text requires a vaccination for the exercise of a profession, the ONIAM may receive directly compensation claims.

On the other hand to other vaccines are recommended only in the individual interest of protection of certain groups. Compensation claims related to recommended vaccinations or to vaccination for individual purposes cannot benefit of the very favorable regime for mandatory vaccinations offered by the ONIAM for mandatory vaccinations.

Consequently, the victms may claim against the health professional who prescribed or performed the act, but they will have to make the evidence of a fault which is very rare. An action against the pharmaceutical company is possible on the basis of liability for defective products (Act of 19 May 1998).The major issue is to establish the causal link between the defect and the damage alleged which is very difficult.Nevertheless, the ONIAM may be seized only on the basis of drug injury compensation, whose conditions are not suited to vaccine damage (severity threshold).

The principle of vaccination is increasingly controversial, some associations are opposed to mandatory vaccinations and endanger public health because of a potential resurgence of disappeared diseases such as disphteria.. An information policy is necessary both to the public and the health professionals.

Bibliography :

Daisy Ngirabatware L'indemnisation des accidents vaccinaux Les Etudes Hospitalières Mémoires numériques de la BNDS www.bnds.fr

Law and ethics concerns raised by the patentability of a second therapeutic application JacquesLarrieu.

Transferring personal health data to China for research uses under the new EU General Data Protection Regulation

Gauthier Chassang, Lawyer, INSERM UMR1027/US13.

The use of personal health data from patients or healthy people is essential to ensure quality research and innovations in life sciences (e.g. in clinical trials, e-health and m-health innovations, biobanking). In the era of big data, international scientific collaborations rely on the availability of personal health data and on the cross-border exchanges of research datasets which most of the time involve personal health data related to identifiable natural persons with specific conditions.

In Europe[1], personal health data are considered as a special category of data deserving a high level of protection due to the particular risks their processing entails for the respect of the fundamental rights of individuals[2] and regarding the potential misuses of such kinds of data. Therefore they are particularly protected by law.

In the European Union (EU), after several years of intensive reform, the recent adoption of the new Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data[3] (General Data Protection Regulation - GDPR) has been an historic moment in the European history of fundamental rights protection. With the GDPR, the EU updates the rules previously fixed by the Directive 95/46/EC and intends to ensure a high level of personal data protection in all the sectors of activity, including in scientific research, and to preserve the free flow of data through a responsible approach (accountability) involving both data processing actors established within the EU and, under certain conditions where the GDPR finds application, foreign partners established in non-EU countries. While the field of research has not been at the heart of the EU law reform[4], the GDPR also applies to scientific research and actors processing personal data will have to comply.

Taking the example of a fictive data exchange between research institutions established in France and China, this talk aims to present the rules fixed by the EU GDPR and the related guarantees that need to be observed by the research project partners in order to perform international transfer of personal health data from the EU territory to non-EU countries.

The pharmaceutical trademarks, trademarks like others?

Alexandra Mendoza-Caminade

[1]Council of Europe Convention n°108 for the Protection of Individuals with regard to Automatic Processing of Personal Data, 1981.

[2] Charter of Fundamental Rights of the European Union, 2000, modified in 2010.

[3] Official Journal of the European Union L 119/1, 4 May 2016.

[4] The EU data protection law has been mainly motivated by the new risks for individual privacy and data protection sparked by the rapid evolution and spreading of information and communication technologies in the society, with social networks, connected objects or programs for example, but also by the recent scandals revealing organized intrusion and massive surveillance of European citizens from foreign countries [e.g. NSA PRISM program] and by recent judgments of the Court of Justice of the European Union reinforcing the protection of EU data abroad [e.g. CJEU, Schrems *vs* Data Protection Commissioner, Case C-362/14, 13/11/2015].

Summary :

Pharmaceutical trademarks: limited specificities

The drug is first protected by the patent, usually supplemented by a supplementary protection certificate. But these industrial property rights are subject to the terms of protection at the expiration of which the drug is free of law. Once the patent has entered the public domain, the drug can be protected by other rights of intellectual property. Indeed, intellectual property can protect a name or an original form of the drug by copyright. Its shape may also be protected by a law on industrial designs and models. But the most common way is the trademark: it will allow the differentiation of medicines for patients but also for doctors.

Like other industrial property rights, the brand remains an optional use and there is no legal obligation to use it. Yet it is essential for the laboratory to retain exclusivity as a trademark, because industrial property is of course also subject to a period of ten years but can be renewed indefinitely by the holder. The brand helps to perpetuate the reputation acquired by the product and the loyalty of the patient. This protection will prohibit specialty generics manufacturers to choose the same or similar name to sell their own medicine.

If protection of the drug by the patent is the main protection, the brand also plays an important role, and it gives the holder interesting prerogatives. The analysis of the pharmaceutical brand shows that it essentially appears as a mark like the other (I), and that there are limited specificities (II).

Protection juridique en médecine traditionnelle : les bains médicinaux du peuple YAO de Congjiang.

(Legal protection of traditional medicines: the bath medicinal herbs of national minority of YAO in Congjiang.)

Chuanjuan ZHUANG – Université Toulouse I Capitole

Congjiang est une ville de montagne située dans le sud de la Chine. Son climat subtropical est propice à la croissance de nombreuses plantes qu'utilise abondamment la minorité ethnique YAO pour lutter contre les maladies.

Avec une pratique plurimillénaire, l'ethnie possède un savoir-faire performant et efficace qu'elle conserve jalousement et qu'elle met en œuvre au travers de bains médicinaux utilisant parfois jusqu'à plusieurs centaines de plantes différentes, adaptées au baigneur et au contexte.

Les secrets de ce savoir-faire actuellement transmis oralement sont dès lors convoités et donc menacés. Comment les protéger, notamment contre des appropriations étrangères ?

Le droit relatif aux savoirs traditionnels en Chine permet d'envisager deux types de protections différentes : défensive ou positive.

La protection défensive : Le droit des brevets en Chine peut apporter une protection défensive lorsque les savoir-faire traditionnels sont réputés comme faisant partie de l'état de la technique. Lorsque c'est le cas, ils sont protégés contre le dépôt abusif de brevets. Cette possibilité est donc offerte aux bains de Congjiang s'il est possible de décrire et documenter par écrit, ou d'incorporer dans des bases de données spécifiques ce savoir-faire pour lui faire intégrer l'état de la technique, ce qui n'est actuellement pas le cas.

Inconvénients : la perte du caractère secret de ces connaissances et l'impossibilité par la suite du peuple autochtone YAO de breveter leur savoir-faire. Cette solution pourrait donc nécessiter leur consentement préalable.

La protection positive : En Chine, le droit des marques prévoit la protection d'une marque certifiée, notamment en fonction de son indication géographique. Les bains de YAO peuvent utiliser cette possibilité existante. Une démarche dans ce sens a déjà été déployée par la ville de Congjiang, mais à son avantage.

Il existerait par ailleurs une possibilité offerte par la Convention sur la Diversité Biologique (CDB) de 1992, mais qui n'a pas encore été intégrée par la Chine : un dispositif dénommé « consentement préalable en connaissance de cause » qui pourrait imposer, s'il était appliqué, l'obligation d'un partage des bénéfices et avantages apportés par les savoir-faire traditionnels lors du dépôt et de l'exploitation des brevets correspondants.

Mais il convient de préciser que l'ensemble de ces protections défensives et positives sont actuellement en Chine d'une efficacité très incertaine.

传统医药知识法律保护个案分析-从江瑶族药浴

(Legal protection of traditional medicines: the bath medicinal herbs of national minority of YAO in Congjiang.)

Chuanjuan ZHUANG – Université Toulouse I Capitole

从江县位于中国南部的大山深处，该地区的亚热带气候很适合各种植物的生长。当地瑶族人民在与疾病斗争的过程中，只能依赖这些大山中随处可见的植物。

经过上千年的采用与实践，当地瑶族逐渐掌握了各种药用植物的性能与药效，并配成多种中草药组成如今的瑶族药浴配方。一次药浴所用的草药，少则几十种，多则上百种。所用药物因地制宜，功能多种多样。

几千年来瑶浴都以口授形式相传，且传内不传外。因此瑶浴随时面临着湮灭的危险。如何保护这些传统医药知识，尤其是面临国外不法侵占时如何保护？

中国对传统医药知识的法律保护主要有以下两种保护模式：防御性保护与积极保护。现行专利制度为传统知识的消极保护提供了空间。
即把从江瑶族浴药知识转化为专利法上的在先技术，从而排除他人就从江瑶族浴药获得专利权。具体操作为把从江瑶族药浴知识文献化或将其录入数据库，使之符合专利法上的在先技术的形式要求。但目前情形并非如此。

缺点：瑶浴秘密性的丧失会使瑶族人民永远失去了对于浴药获得专利权的可能性。因此，在将浴药知识在先技术化之前，应当征得瑶族人民的同意。

积极保护：中国现行商标法已对集体商标和证明商标作出规定，因此可利用该规定对瑶浴进行地理标志保护。目前'从江瑶浴'已被从江县人民政府注册为证明商标，并已拟定《从江瑶浴证明商标使用管理规则》来对从江瑶浴进行保护。

根据1992年《生物多样性公约》的规定，事先知情同意制度可以确保从江瑶族人民公平合理的分享利用瑶浴药传统知识而产生的惠益。但中国现行法律对这些制度尚未做出规定。

因此，目前在中国对传统医药知识无论是消极保护还是积极保护均无太大效率。

Misuse of psychoactive medicines and public health

Pr Anne Roussin

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Diverted use and abuse of psychoactive medicines is a worldwide concern for public health. Opioid painkillers abuse has been considered as an epidemy in the US and diverted use of these prescription medicines, including weak opioid analgesics, are observed all around the world. In France, a national system of evaluation and prevention of such problematic use of psychoactive substances including prescription medicines has been implemented in response to WHO concerns. This system of addictovigilance will be presented.

Ethics and access to medecines.

Charlotte Lamure

The pharmaceutical industry is one of the sector making the most important profits before the oil sector. Access to medicines is an essential element in the realization of the fundamental right to health understood as the state of complete physical mental and social well-being according to the preamble of the Constitution of WHO in 1946. However, many inequalities persist in the world. More than 10 million deaths could be prevented if access to medicines for all was guaranteed.

Therefore, it should be studied whether the inclusion of ethical considerations, particularly by pharmaceutical companies related to the sufficiency access to medicines.

Sadly, the lack of ethical considerations by pharmaceutical companies in access to medicines is notable and is illustrated through numerous examples. They are from the same behavior of pharmaceutical companies. Pharmaceutical companies have unethical behaviors. Some practices are anti-competitive. Indeed, in terms of generic drugs pharmaceutical companies have developed different strategies to delay or even prevent this phenomenon. Futhermore, the research is interested and some diseases are neglected like tropical diseases. The prices of some medicines are unjustified. This drugs' price inflation was very widely denounced all around the world. At the same time, the IP system is not suitable for developing countries. The TRIPS Agreement, which provides a minimum of IP related protection for the World Trade Organization (WTO) member states, has been the subject of many criticisms on the international stage and it would impose on poor countries a system of inadequate IP and patterned after the model of Northern countries.

Even so, pharmaceutical companies have undertaken to favour access to medicines through various initiatives as the development of new R & D model to foster innovation, donations of pharmaceuticals products… Moreover The TRIPS agreement itself provides exceptions for the patent law converning the protection of public health: the regulatory exception and especially the system of compulsory licenses.

The different business initiatives demonstrate a willingnes to become more involved in access to medicines. However, despite the successes, they are not sustainable over time and are not intended that a certain population with a single disease. Beyond these actions, a more in-depth reflection should be conducted through the concept of health as a global public good.

Patients´ rights: a general framework

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Historically the physician-patient relationship was asymmetric and ruled by the principle of beneficence. “All for patients but without patients” could summarize the rationale of this vertical link. Nowadays, at least at the legal level, the paternalistic model has been transformed into a horizontal and symmetric system,governed by the principle of autonomy,in order to allow patients to be co-participant in the clinical decision making. In spite of patients' rights vary in different countries and in different jurisdictions, often depending upon prevailing cultural and social norms, it is currently possible to talk about a general framework composed of two types of rules with different nature and scope. First, international human rights declarations (the 1948 Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, the1966 or the International Covenant on Economic, Social and Cultural Rights). At the European level, it is important to emphasize the 1950 Convention for the Protection of Human Rights and Fundamental Freedoms (Rome Convention), developed in the context of the Council of Europe. Despite of the absence of a specific mention in the Rome Convention, the case-law of ECtHR has allowed the protection of patients´ rights connecting them to other positive and negative rights recognized by the Convention, especially the right to respect for private and family lifeaccording to Article 8 of the text.

In the other side, we must refer to other instruments as specific treaties onpatients´rights. In this regard, the 1997 Convention on Human Rights and Biomedicine 1997 -Oviedo Convention- can be presented as the first comprehensive multilateral treaty regarding biomedical human rights issues. Although theOviedo Convention is not really original, since some of its principles had already been included in more general terms in previous international human rights agreements, it is important to note that patients´ rights were developed for the first time in a binding instrument. Any way, let us take into account the Convention was conceived from the very beginning as a “framework instrument“with a gradual approach in order to create a solid basis for further developments.

More recently, the 2000 Charter of Fundamental Rights of the EU recognices the right of access to preventive health care and the right to benefit from medical treatment but “under the conditions established by national laws and practices”.This clause invites us to consider whether there should be a common minimum standard for healthcare in the EU.Although the Directive of 2011 on patients' rights in cross-border healthcare has been a first (but insufficient) step in the right direction, this is probably one of the greatest challenges of European health law of the future.

Is there a right to maximum waiting times at EU level? Concerns and challenges

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When we deal with patients´rights one uses to think in traditional rights connected with information, consent, confidentiality, facilities or access. In fact, it has traditionally placed special emphasis on strengthening quantitative and qualitative aspects of health care, but it is undeniable that an efficient health system is also necessarily linked to the respect to a maximum waiting times for procedures. As is well known the phenomenon of waiting times when they are not assumable, is likely one of the mail failures of a public health system.

Nevertheless, “waiting lists" are not necessarily a negative notion. Indeed, waiting lists can be a tool for planning and rationing access to the public health care system if they are really reasonable. But it should be emphasized that the delay becomes a dramatic problem when it is too long, producing, besides the eventual deterioration of the patient's clinical condition, a serious loss of public confidence in the public health system.

In light of this consideration, the doctrine of EUCJ offers some answers to the problem of waiting times. According to case-law if the delay arising from waiting lists of a Member State appears to exceed an *acceptable time* having regard to an objective medical assessment, the competent institution may not refuse the authorization to treat the patient in another Member State sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

However, trying to stop the increasing concept of cross-border healthcare, we should note an immediate reaction. After a first failed attempt, a restricted conception seems to win the battle in Directive of 2011 on patients' rights in cross-border healthcare. Of course, the Directive recognizes, as a manifestation of the free movement of persons, the right of European patients who are treated in other Member States to be reimbursed of expenses by the Member State of affiliation, without any prior authorisation. However, this right to reimbursement is not absolute since it has material and procedural limitations. As relevant here, the Member State of affiliation may refuse prior authorization when healthcare can be provided on its territory within a time limit which is medically justifiable. Compared to the EUCJ case-law the Directive adopts the term of “medically justifiable time limit”, as a vague legal concept. Casuistic analysis will be required according to circumstances of each case. Is this a victory of national sovereignity of the Member States? Could it be corrected by EUCJ? If so, in which way? These are, at the same time, concerns and challenges to be addressed.

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He has been a visiting professor to different universities in Europe (Spain, Netherlands, Portugal, Czech Republic, Latvia) and Latin America (Brazil, Argentina, Mexico, Colombia, Costa Rica, Cuba, Dominican Republic). At present he coordinates the annual Patients’ Legal Protection Meetings at International University Menéndez Pelayo, Spain (since 2008) and is taking part of the Executive Board of the Ibero-American Network of Health Law and the Advisory Board of the European Association of Health Law.

He has an important international expertise in lecturing, networking and researching on health law, taking into account a multidisciplinary and comprehensive approach. 17 years of educational and research experience with a wide list of articles, publications and oral presentations concerninghealth law topics such aspatients´ rights, health systems, patient-consumer approach, medical liability and reproductive rights. He also has an extensive practical experience in preparing drafts on legal rules regarding healthcare issues for different countries.

Compulsory vaccination: a violation of patients´rights?

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Despite the benefits of general vaccination of the population in recent years we have witnessed the emergence of a social feeling against vaccination. The recent deaths caused by measless infection in Germany and United States and by diphtheria in Spain put the spotlight of media in this social problem

Usually, low infection risks, alternative medical therapies, or even the beneficial effects of experiencing childhood diseases (e.g. benefits for children's personality development and stronger immune systems) are taken by the population as facts. It's obvious that Art. 8 par. 1 of European Convention on Human Rights (ECHR) guarantees inter alia respect for private life, including the protection of the physical and mental integrity of the individual and the freedom to decide if one wants to undergo medical treatment or not. However, Art. 8 par. 2 ECHR also refers to protection of health and protection of the rights of others.

Both the Austrian Bioethics Comission (Bioethikkommission) in the recommendations contained in the " Vaccination report - Ethical Aspects (Opinion of the Austrian Bioethics Commission)" in June 2015 and the Committee on Bioethics of Spain in the report "Ethical and legal issues rejection of vaccines and proposals for a necessary debate" in january 2016 analyse different measures to be taken to fight against the unjustified rejection of vaccines, including even compulsory vaccination not only for non-vaccinated health workers in order to avoid patients to be exposed to additional health risks in a medical institution but also in another specific situations.

CV

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Medical disputes and mediationin hospital

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First Affiliated Hospital of Kunming Medical University continuous improves the Medical SecurityManagement.Builds up the hospital actual "integration" processing system in dealing with medical disputes, Medical Administration Department and the Hospital Complaint Management Office analyzenearly two years' medical disputes treatment process and mechanism, research and establish the procedure of dealing with medical disputes. Whenmedical disputes occurred, patients can firstly go to consult or communication with doctors, if such negotiation fails, then patients can complain to Hospital Complaint Management Office to put out their objections. After complaints, the Hospital Complaint Management Office will organize the clinical department of medical quality control and evaluation team to discuss the disputes, after this if it still cannot form uniform conclusion, Medical Administration Department will organize the hospital quality control and evaluationcommittee to discuss the case and form the last conclusion to give to the patients.If the patients still not satisfy the result then they can though the three ways to solve the disputes, Identification, Mediation and Law suit. For example with the year of 2013, there are 21 cases medical disputes patients complain to Hospital Complaint Management Office, and thoughwith the "integration" processing system and after the work of quality control and evaluation, mediate solve disputes didn't happen to compensate for a total of 15, the rate of solve the medicaldisputes reached 71%.The construction of medical disputes "integration" processing system let the hospital medical dispute mediation rate is greatly increased, ending of the patients directly come to medical administration department to chaos, standardize the way of deal with medical dispute from a disorderly state into an orderly state.

Mediation in Pharma-industry conflicts (generics and intelectual property),

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In order to promote the use of generics and to reduce the fiscal effort with medicines in Portugal, Law 61/2011 strengthened the autonomy of the administrative authorization procedures of medicines concerning the existence and infringement of industrial property rights, and established a mechanism for dispute settlement between patents and generics, subjecting them to mandatory arbitration. However, the scope of jurisdiction of this arbitration tribunal has raised a number of issues, particularly with regard to the validity of patents. This communication provides an overview of legislation and recent case law on this issue and gives some suggestions for improving the current regulation

« Pooling » Intellectual Property Rights (IPR) at European Level: a way to encourage and facilitate innovation

F. Le Corre, G. Chassang, M. Roques, E. Rial-sebbag

Patents are one of the main keys to innovation, conferring to the patentee the right to exclude others from making, using, or selling a claimed invention, for a specified period from its filing date. Ensuring thereby a monopoly to the patent holder on his invention, making the protected technology unusable by a third-party without a license.

Thus, to use several patented technologies for their projects, researchers have to negotiate IPR with different patent holders which is time consuming and expensive. Ultimately, a simplified access to protected inventions could be put in place while preserving the patent-owners' rights, thanks to a collaborative mechanism.

Several domains of expertise can be targeted by stakeholders who can decide to propose a global governance of patents for a better access and visibility of technologies, which is essential to avoid the advantage of the 'hubs' of knowledge remaining in the hands of a privileged few.

Inspired by some existing examples, a collaborative model based on the mutualisation of IPR regarding patents could be proposed to facilitate the transfer of technology for medical research at large, within a European infrastructure level (BBMRI-LPC).

Benefits-sharing is how researchers can be encouraged to make discoveries. IPR and benefits sharing are not necessarily opposed. A fair return on investment for researchers and companies has to be guaranteed for the perenity of these IPR, motivating innovation. The pooling of IPR and global licensing model are just a mean to reach this goal more easily.

Objets connectés : l'utilisation des données à caractère personnel des usagers dans le contexte d'une réflexion éthico-numérique

Morgane Roques, Frédéric Le Corre

La santé connectée est apparue lors de la fusion entre le numérique et la santé. De cette rencontre sont nés différents produits, mais bien que source d'innovation, ce phénomène n'en demeure pas pour autant exempts de problématiques variées. En effet, objets connectés, applications mobiles, utilisation des données de santé… autant d'innovations qui ne cessent de stimuler le marché, mais qui ne manquent pas d'impacter les acteurs du domaine.

Le mouvement d'innovation qui anime le développement des objets connectés en santé amène les utilisateurs de ces dispositifs d'une part, mais aussi tous les autres acteurs qui gravitent autour de la sphère de la e-santé comme le législateur d'autre part, à s'interroger notamment sur la nature même des données collectées par les objets connectés (santé/ bien-être) et sur les droits rattachés à ces données à caractère personnel.

Le flou entourant la distinction entre les données de santé et de bien-être s'est manifesté lors de l'émergence du mouvement du *quantified-self*. Or, cette distinction est primordiale pour déterminer les règles juridiques qui s'appliquent à ces différents types de données à caractère personnel. On peut donc s'interroger sur le fait de savoir si les données de bien-être répondent à la loi Informatique et Libertés de 1978[5] comme le font les données de santé[6] ?

En l'absence d'un éclairage sur la définition juridique des données de bien-être, et dans le cadre où l'utilisation de ces données n'est pas placée sous l'égide de la loi informatique et libertés, les conditions d'utilisation des données de bien-être devraient être moins strictes que pour les données de santé. Ces dernières jugées plus sensibles, mais dont la définition demeure *a priori* imprécise. Les données de bien-être étant collectées hors de tout contexte médical, elles devraient donc échapper au niveau de protection et à la surveillance associés au traitement de données de santé, sous réserve de certaines précautions. Situation ambiguë dans la mesure où les fabricants de dispositifs n'hésitent pas à mettre en avant les bienfaits de ceux-ci pour la santé.

En outre, l'utilisateur d'un dispositif peut s'interroger sur les droits dont il dispose sur « ses » données, bien qu'il soit reconnu classiquement que les données personnelles ne sont pas appropriables. Il n'existe effectivement pas de droit de propriété sur une donnée en tant que telle mais la personne source dispose néanmoins de prérogatives sur celles-ci qui relèvent du droit à la vie privée. Qu'en est-il des pouvoirs des autres acteurs du monde des objets connectés qui interviennent dans l'utilisation de ces données ? Ceux qui réalisent un certain nombre de traitements sur des données peuvent-ils se considérer à un certain moment comme propriétaire de ces données ? *A fortiori* lorsque celles-ci sont anonymisées ?

Il est nécessaire pour les utilisateurs comme pour les fabricants, distributeurs et exploitants de ces dispositifs de prendre conscience des problématiques liées au numérique, au bien-être et à la santé, afin d'assurer une protection appropriée des données à caractère personnel collectées dans le souci du respect des droits des personnes conciliés avec les réalités du numérique.

[5] Loi n°78-17 du 6 janvier 1978 relative à l'information, aux fichiers et aux libertés.

[6] Récemment le règlement (UE) 2016/679 du 27 avril 2016 relatif à la protection des personnes physiques à l'égard du traitement des données à caractère personnel et à la libre circulation de ces données, définit les « données concernant la santé » comme « les données à caractère personnel relatives à la santé physique ou mentale d'une personne physique, y compris la prestation de services de soins de santé, qui relèvent des informations sur l'état de santé de cette personne » ; considérant 35 du Règlement (UE) 2016/679 « Les données à caractère personnel concernant la santé devraient comprendre […] toute information concernant […] l'état physiologique ou biomédical de la personne concernée, indépendamment de sa source, qu'elle provienne par exemple d'un médecin ou d'un autre professionnel de la santé, d'un hôpital, d'un dispositif médical… ».

Information du patient : un droit du patient consacré par le tribunal administratif.

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Résumé :
Le tribunal administratif (TA) tunisien admet la responsabilité du médecin sur le fondement de la faute prouvée mais également sur celui de la faute présumée.
Des jugements récents du tribunal administratif reconnaissent le défaut d'information comme source de responsabilité médicale, citons :

1. L'arrêt n°38643 du 31 Décembre 2007 :

Considérant (…) que parmi les motifs de soumission du patient au traitement dans les meilleures conditions, figure le choix du praticien qui procède à son traitement. La garantie de son droit à ce choix ne peut se réaliser que si le patient est informé de tous les moyens et méthodes du traitement, et des actes médicaux que le médecin a l'intention de procéder à son égard, et averti des complications et conséquences éventuels qui en résultent, et lui accorde la chance de choisir ce qui est disponible d'autre méthodes de traitement ou le recours à un autre praticien (…).

2. L'arrêt n°27458 du 29 Juin 2011 :

Considérant que le défaut par le cadre médical d'informer le patient des chances de succès de l'opération chirurgicale, et des risques qu'elle peut générer, a anéanti son droit de s'en désister, et lui a fait perdre la chance d'éviter les danger qu'il a effectivement subis, et de ce fait l'évaluation de l'indemnisation due au titre de préjudice qui en résulte, sur la base des chances d'éviter les complications qui en sont effectivement générées, ou de réduire au moins ces dernières en cas de non recours aux actes médicaux qui en sont la cause .

Nous discutons cette jurisprudence tunisienne avec le droit comparé français.

Les spécificités des médicaments orphelins : un gage d'accès au traitement des maladies rares ?

Marion Bourdoncle, Blandine Juillard-Condat, Florence Taboulet

L'universalité du droit à la protection de la santé a été inscrite en 1946 dans le Préambule de la Constitution de l'Organisation mondiale de la Santé. Ce principe a été réaffirmé dans l'article 35 de la charte des droits fondamentaux de l'Union européenne et est formulé en droit national dans le code de la santé publique[7]. Les patients atteints de maladies rares ont ainsi le droit de bénéficier des services de prévention, de diagnostic et de traitement au même titre que les malades souffrant de pathologies de plus forte prévalence. Pourtant, aucun traitement n'existe pour de nombreuses maladies rares ; on parle alors de maladies orphelines. Pour inciter les laboratoires pharmaceutiques à développer et à commercialiser des médicaments destinés à ces maladies, une politique européenne du médicament orphelin a été mise en place au début des années 2000[8]. Dès lors, plusieurs dizaines de médicaments ont été enregistrés dans ce cadre européen. La prise en charge de ces traitements relève toutefois des organismes de protection sociale nationaux, ce qui entraîne des disparités dans leur mise à disposition effective pour les patients. A travers ce travail, nous dresserons dans un premier temps un état des lieux sur l'accessibilité des médicaments orphelins en Europe et en France. Nous étudierons ensuite leurs spécificités et nous nous pencherons sur les limites des dispositions européennes pour les principaux acteurs : collectivités, laboratoires pharmaceutiques et patients.

[7] CSP L.1110-1, CSP L.1110-3
[8] Règlement (CE) n°141/2000

LES NOUVELLES DISPOSITIONS LEGALES EN MATIERE DE CONSENTEMENT A LA RECHERCHE BIOMEDICALE EN TUNISIE

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RESUME :

La recherche biomédicale est définie comme étant « *toute expérimentation organisée et pratiquée sur l'être humain en vue du développement des connaissances biologiques ou médicales* » (1). La recherche est certes indispensable à l'essor des sciences médicales. Toutefois, elle a toujours soulevé un débat éthique qui préoccupe les sociétés et les civilisations (2). De plus, elle requiert un corpus réglementaire et législatif évolutif pour répondre aux nouvelles questions soulevées par ses progrès incessants.

Dans notre travail, nous nous sommes intéressés à la question de la place et aux conditions de validité du « *consentement dit libre et éclairé* » de la personne soumise à une recherche scientifique ou médicale dans notre contexte tunisien. Il nous a semblé utile d'aborder ce sujet étant donné la promulgation récente dans notre pays de textes réglementaires régissant l'expérimentation médicale, notamment les obligations en termes d'information et de recueil de consentement.(3-4)

Ainsi, nous nous proposons dans ce travail d'exposer les nouvelles dispositions légales en matière de consentement et l'information dans le domaine de la recherche biomédicale en Tunisie, de discuter ces dispositions par rapport au droit comparé, et les situer par rapport aux exigences éthiques à respecter dans ce domaine.

Mot-clé : recherche biomédicale, consentement, éthique médicale

Références :

(1) : Code français de la santé publique : article L1121-1, complété par le décret article R1121-1

(2) Les essais cliniques de nouveaux médicaments chez l'homme, IXème Conférence Annuelle Tunis , Abdelaziz Ghachem

(3) JORT : Journal Officiel de La République Tunisienne**,**Décret n°2014-3657 du 3octobre 2014, page 2749- 2750

(4) JORT: Journal Officiel de La République Tunisienne,Arrêté du ministre de la santé du 13 Janvier 2015, page 308 -23.

INFORMED CONSENT IN OBSTETRICS: THE EPISIOTOMY

Maria Negrao

Informed consent is a matter of respect for the patient as a human being ensuring active participation regarding health care. This consent is based on two fundamental pillars: understanding, which is the doctor's duty to clarify, and consent.

In order to be a valid consent, it must be given based on an effective communication between patient and doctor and also between the patient and other health professionals, although there are some exceptions legally typified, situations in which is not possible to obtain consent (informed or not informed).

This article is limited to only one specific medical practice: the episiotomy. Episiotomy is a surgical cut in the perineum(the muscular area between the vagina and the anus) made just before delivery to enlarge the vaginal opening and the birth canal. This practice is one of the most common procedures in obstetrics, despite of all known risks, like dyspareunia, urinary and fecal incontinence and infection.

Routine episiotomy is not an evidence-based practice (and it's even unrecommended by World Heatlth Organization, dedicated to reduce the episiotomy rate) , but the majority of obstetricians persist in using it routinely for convenience, to finish the delivery more quickly. Some obstetricians defend that the episiotomy is sometimes necessary, although there are other obstetricians who claim that natural laceration is preferable and that the episiotomy is never necessary, so they never perform an episiotomy on a parturient.

The problem is that the current childbirth paradigm is a highly interventionist one, often leading to disrespect, abuse and neglect by health professionals towards women. This paradigm is the so called clinical paternalism, which, inobstetrics, is totally disproportionate, given that childbirth is a natural and physiological eventfor which the woman's body is prepared (with few exceptions), and it does not require intervention, but instead, requires support and observation by the obstetrician when it occurs in the hospital.

Regardless, episiotomy is still a medical practice, which means it's necessary to obtain an informed consent before proceeding and cutting a woman's perineum. In the majority of the cases, not only in Portugal, the informed consent formalities are not fulfilled, disrespecting fundamental human rights.

Episiotomy can configure a situation of obstetric violence, which is the institutional violence against women in the context of assistance to pregnancy, childbirth and postpartum and it can be effected in various ways, such as denial of care, negligence of the woman's needs, verbal humiliations, physical violence, invasive practices, unnecessary use of medication, forced medical intervention, dehumanization and unkindness.

This is, in fact, a serious issue because we can fit episiotomy within the category of female genital mutilation - one of the most serious traditional practices of discrimination against women and violation of fundamental rights - because in some cases, we are facing a harmful practice of female genital organs for non-medical reasons, and in many cases, without the prior informed consent of the women. These are situations in which we cannot consider there was an informed consent. Obstetrician doctors must be aware of it, or else they must be punished for the violation of the law, guidelines and last but not least, human rights.

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Present Situation of Ethics Committee in Organ Transplantation

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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. 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. 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. Its mission is to protect the patient's life, health, interests and dignity. At present, there are some conflicts about the Ethics Committee in Organ Transplantation**,** such as the traditional concepts of organ transplantation, available organs for transplantation, the cost of organ transplantation and some community skills to doctors, facing these problems, the Regulation has been promulgating by Chinese government and some concept and thinking is conversion, but for institutions of medicine, should establish the mechanism of ethics committee, in order to enhancement the function of supervision, so as to keep donor’s dignity and interests.

Ethics in artificial organs

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Abstract

Artificial organsare usedin medical practicetoreplace an organorafailing functionand manyprostheses have beendeveloped for this purpose. Based ontechnical developments,the prostheses areincreasinglyefficient andnot onlycan recoveralost functionbut sometimesdo better thanthe organ orjointreplacedwhich raises thequestion of enhancement. One ofethicalquestionsis theboundary between the two. How far shouldthefailing function be replaced? Increasingthe individual'sabilities,is it acceptable?
Biotechnologyand miniaturization ofdeviceshas enabledthe developmentofgenuineartificial organssuch asthe artificial heartwhich aims toreplacethe natural organthat isdefinitively andirreversibly altered.In such circumstances, the replacement of vital organsraises the issue of the duration and quality of survival. Since these situations are still experimental, ethical questioning concerns the conditions of the experiment, the choice of subjects and the information given to them. The subject will have the choice between the artificial heart and ventricular assist devices that are used for several years. Ethical reflection on artificial prolongation of life and the decisions to switch off the assistance device will be presented.
Finallyartificial organspave the wayto new technologiesand to choicesof research that mightgenerateexcessivebelief bythe public inmachine reliabilityand provideexcessivehopes.

Key words: artificial organs, ethics, prosthesis, artificial heart, enhancement, left ventricular assistance.

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