

Third European Conference on Health Law

AN AGEING EUROPE. HEALTH LAW REVISITED

LEUVEN, 6-7 OCTOBER 2011

Table of Content

WELCOME	3
EAHL GENERAL INFORMATION	4-5
PRACTICAL INFORMATION	6
PROGRAMME	10-19
KEYNOTE SPEAKERS	20-24
WORKSHOPS	25-28
ABSTRACTS - ORAL PRESENTATIONS	29-90
ABSTRACTS - POSTER PRESENTATIONS	91-107

Special Thanks to



BRILL



6-7 OCT '11



LEUVEN

THIRD EUROPEAN CONFERENCE ON HEALTH LAW

THIRD EUROPEAN CONFERENCE
ON HEALTH LAW

6-7 OCTOBER 2011

LEUVEN, Belgium

Book of abstracts
& practical Information

Centre for Biomedical Ethics and Law



CENTRE FOR BIOMEDICAL ETHICS AND LAW
European association of Health Law

Dear Colleagues,

Welcome to the Third European Conference on Health Law organised by the Centre for Biomedical Ethics and Law of the university of Leuven, Belgium, in collaboration with the European association of Health Law!

The Belgian Team and the International Scientific Committee are very pleased to welcome you to our historical city of Leuven for the first European Conference on Health Law on European continental grounds.

Besides well-known for its beer culture and its historical architecture, Leuven is also the city with one of the oldest universities in Europe.

Since the foundation of the European association of Health Law in april 2008 and the second European Conference on Health Law in october 2009 in Edinburgh, the interests in the initiatives of the association have grown tremendously. This was reflected in the high number of registrants of 160 delegates that was already reached at the end of June and the high number of abstracts for oral presentations and poster presentations that was sent in. We are therefore delighted to present to you a very diverse programme of presentations all somehow linked to the general theme of this conference: *An Ageing Europe. Health Law Revisited.*

Nowadays Europe is facing a trend of demographic and social change that is likely to have a significant impact on our health systems in the coming decades. The primary concerns are related to the double challenge of population ageing and population decline. These changes will result in a shrinking workforce to handle the steady increasing healthcare needs of the very old, who will constitute the fastest growing segment of the population. adaptation of European health systems to the new system also makes it necessary to revisit familiar and less familiar health law problems.

As the previous conference, also this conference is both as an academic event and as an opportunity for networking and discussion. Therefore, besides academic presentations, also two workshops are organized. We invite you to actively participate in these workshops, as well in the discussions following each presentation.

We hope that you enjoy our academic and social programmes and that the Third European Conference on Health Law provides you with many opportunities to develop professional and personal connections.

Sincerely,

Herman nys & Tom Goffin

Centre for Biomedical Ethics and Law, university of Leuven

EAHL General Information

The European Association of Health Law was established in 2008 by a group of health lawyers in academic institutions from around Europe to provide a forum for health lawyers from countries in the Council of Europe and beyond to discuss and collaborate on issues of importance in the development of health law and related policies.

This initiative is unique in that it is the only association of health lawyers that focuses on the contributions of Europe. It, thus, adds considerable value to the national and international bodies in this area.

The Mission Statement of the European Association of Health Law is to strengthen the health and human rights interface throughout Europe, and to serve as an indispensable source of advice and guidance for the future of health law and policies in Europe.

Membership

There are four categories of membership:

1. Full membership
2. Associate membership
3. Institutional membership
4. Student Membership

Full membership is open to health lawyers in Europe, that is, those who are involved with health law and health law-related issues within Council of Europe countries.

Associate membership is open to those individuals who do not meet the above criteria but who can contribute substantially to the objectives of the Association.

Institutional membership is open to European University health law centres and law firms specialising in Health Law. Each institutional member will be represented by one employee, to be registered in the Members' Database. Institutional members will not have voting rights or any right to hold EAHL office, but otherwise will enjoy all of the privileges of full membership (save that institutional subscriptions fees to EJHL will apply).

Benefits of Full membership

- * - Full voting rights at EAHL General Assembly
- * - Eligibility to stand in elections for EAHL Directorate
- * - Reduced fees at EAHL-sponsored events
- * - Eligibility for reduced subscription rate to the European Journal of Health Law
- * - Inclusion in all EAHL calls for collaborators for new networks and projects

welcome | 5

- * - Inclusion in all EaHL distribution lists on activities and forthcoming events
- * - access to EaHL networks of expertise
- * - free newsletter
- * - full access to EaHL Website facilities

Benefits of Associate membership

- * - Inclusion in all EaHL distribution lists on activities and forthcoming events
- * - access to EaHL networks of expertise
- * - Inclusion in all EaHL calls for collaborators for new networks and projects
- * - free newsletter
- * - full access to EaHL Website facilities

Keynote Speaker

Dr. Tom Goffin

Biography

Tom Goffin is Master in Law (K.U.Leuven 2006) and Doctor in Law (K.U.Leuven 2011). Since September 2006 he works as a researcher at the Centre for Biomedical Ethics and Law. He was together with Prof. Herman Nys and Sarah Defloor responsible for Unit 6.4 Patient Rights of the “Eurogentest project”. With Professor Herman Nys as his promotor, Tom wrote his PhD on “the Professional Autonomy of the Physician”. Tom won the price for best poster on the “Founding Congress of the European Association of Health Law” (Edinburgh, 10-11 April 2008) with his poster “Autonomy in the Patient-Physicianrelationship: Clash of the Titans?”.

Tom created together with Sarah Defloor a website on Patient Rights in the 27 EU Member States (www.europatientrights.eu).

He is also one of the two co-authors of the regular feature “Selected Legislation and Jurisprudence - European Court of Justice” in the European Journal of Health Law and is one of the organizers of this Conference.

Abstract - Advance Directives. Diversity in a harmonizing Europe

Against a background of the growing value attached to patient autonomy in healthcare decisionmaking and extraordinary advancements in clinical treatment and in lifesustaining technologies, an increasing number of people decides to make up advance directives which will reflect their will once they are not capable anymore of giving their informed consent to a treatment or refusing a treatment.

Article 9 of the European Convention on Human Rights and Biomedicine stipulates in this perspective that ‘the previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes, shall be taken into account’.

Although one of the aims of the Biomedicine Convention was, and still, is to strive towards harmonized healthcare protection in Europe, several studies in recent years have shown that national regulations regarding advance directives differ very much from one country to another.

Besides this diversity, the words “shall be taken into account” of article 9 of the Biomedicine Convention are often questioned with regard to the legal binding status of advance directives.

The aim of this paper therefore is threefold:

1. To give a short overview of the different mechanisms used in EU member states to regulate advance directives;
2. To interpret the words “shall be taken into account” of article 9 in the light of today’s evolutions in health care regulations in general and of the case-law of the European Court of Human Rights specifically;
3. To answer the question which role advance directives play in health law today.

keynote Speaker | 21

Keynote Speaker

Dr. Radmyla Hretsova

Biography

Ms. Hretsova graduated from the department of international law of the Ukrainian Institute of International Relations at the Kyiv National University named after T. Shevchenko (all honors) in 1996.

She continued her studies as a post-graduate at the Institute of State and Law named after V. Korytsky at the National Academy of Sciences of Ukraine (specialty “criminal law, criminology, and criminal enforcement law”) where she defended her PhD thesis.

Ms. Hretsova has been a licensed attorney-at-law since 1996. She worked as legal counsel to large companies, as an associate, partner of law firms. In 2008-2010 she was the managing partner of Kyiv office of Moscow-based international law firm “Liniya Prava”. Currently she is the managing partner of Kyiv office of consulting company “Yurkraft Medical”.

Human rights also fall within the sphere of her interests. Ms. Hretsova passed 1,5 year training on interpretation and application of the European Convention on Human Rights organized by INTERIGHTS (London) and the Union of Advocates of Ukraine.

Ms. Hretsova is known as one of the Ukrainian leading specialists in medical law that she has practiced since 1999.

Abstract - Access of Elderly people to Affordable Health Care: problems and solutions

The accessibility of affordable health care to elderly people largely depends on the efficiency of the health care system, the level of social protection they can enjoy, as well as on the availability of legislative guarantees and opportunities to practically use them. In European countries, the number of elderly people is greatly increasing, while that of working-age individuals continues to decline. It will cause the increased need of health care services and, consequently, additional spending, although, according to several experts, the gravity of financial burden is being discussed. In any case, the strain may be decreased due to making health care systems more efficient.

The global and European organizations and institutions have elaborated a number of policies and guidelines aimed at improving health care systems under the new conditions. Enhancement of disease prevention, shift from secondary and tertiary health care to primary care, optimization of hospital network, increase of the choice among service providers, introduction/improvement of evidence-based clinical guidelines and drug formulary system, etc. are among the recommendations for national health care policymakers.

22 | keynote speakers

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

A few European countries currently undergo health care reforms. It is essential for them to account for the aforementioned recommendations. This is especially challenging for the transitional countries of Eastern Europe, chiefly for the CIS countries. In most of the latter, the right to access health care services the volume of which is not limited, free of charge is constitutionally guaranteed to everybody. In the meantime, unofficial payments for medical services and drugs are widely spread in the CIS countries, especially in those with government-financed health care experiencing underfunding. This creates financial barriers for many elderly people to access health care. The changes required to raise affordability of health care should not be limited to choosing the optimal model of health system financing (e.g., the compulsory medical insurance model) but should also improve funds pooling and services purchasing. Ensuring access to affordable health care to the most vulnerable groups of elderly people is also an important task for both the old democracies and the countries in transition. This requires adoption or revisiting of relevant plans and programs.

In some countries, special legislation to better protect patients' rights, including those of the elderly, is needed. In East European countries, the right to access health care is often limited by artificial barriers of bureaucratic nature that need to be eliminated by improving current legislation and law enforcement practice.

Health care services affordable to elderly people should be of appropriate quality. An important tool to raise the services quality is the development of law enforcement practice in the sphere of the elderly medical malpractice.

Access to health care of appropriate quality also presupposes access to innovative health care. A plan of measures aimed at preventing discrimination of the elderly with regard to innovative health care should be worked out at the state and international level.

It is also important to direct public opinion to eliminating ageism and to forming social solidarity, as well as to more actively involve NGOs, including professional ones, in contributing to improving organizational, financial and legal mechanisms of ensuring the right of the elderly to affordable health care.

workSHopS | 23

KeYnoTe sPeaKer

dr. andr  Pereira

Biography

andr  pereira graduated in Law at the university of Coimbra in 1998. He also attended courses abroad in Guttingen (1996/97), utrecht (1993 and 1999) and Helsinki (2000). In Coimbra, he completed a post-graduation in Medical law (1999) and a post-graduation in Civil Law (2002). He defended his thesis "Informed Consent within the patient-Doctor relationship" in 2003 and was awarded prize prof. Manuel de andrade for the best thesis in Civil Law in 2003. He has been invited for lectures and published more than 50 articles in legal journals or collective books in several European countries, in Brazil, China and Japan.

Abstract - The role of the family members and close persons in health care treatment

of incompetent patients. A European overview

Medical treatment of incompetent patients is becoming more frequent in an ageing society. In order to achieve a more humane response to the needs of these persons, several solutions have been tested in Europe.

The Common Law adopts the “best interests of the patient” formula. nevertheless, in England and Wales, with the enactment of the Mental Capacity act 2005, the best interests standard now operates within a detailed legislative framework, namely, the person lacking capacity should participate in the process of determining her best interests and the recognition which the act affords to the present and past wishes and feelings of the person lacking capacity and to the beliefs and values that would have been likely to influence her decision if she had had capacity.

In several countries of Continental Europe (Belgium, The Netherlands, Spain, for example), one finds a legal list of relatives and/or close persons who may receive information and decide for the patient.

finally, in other countries, like Portugal or Germany, the presumed consent is applicable, which is still based on autonomy, since the decision shall be in accordance with the presumed will of the patient.

In recent years, the role of health-care proxies and advance directives has increased. In my speech attention will be given to different legislative options in France, in Germany and Austria and the state of the art of the debate in Portugal, where there is still no binding legal text.

Moreover, the speaker will scrutinize who shall be considered a relative and a close person and their respective role in health care decisions, including, among other topics, the end of life, scientific research and organ donation.

24 | keynote speakers

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Keynote Speaker

Dr. Petra Wilson

Biography

Petra Wilson is senior director of the European Health and Care team in Cisco's Internet Business Solutions Group (IBSG). Her work focuses on helping health and care providers develop their strategies for making good use of communication and collaboration technology to demands of care provision for an ageing society, where patients' needs become wider and demands on health and care providers straddle many of the established silos of care organisation.

Originally trained in law, Petra spent several years as a lecturer and Senior Research Fellow at Nottingham University, UK, specializing in healthcare law. She has a Ph.D. in public health law from Oxford University, and has published widely on the legal aspects of using information technologies in healthcare.

Abstract - Legal and ethical issues for eHealth in the 21st Century: a European perspective

A scenario-based approach will be used to illustrate a range of ethical and legal issues affecting the delivery of eHealth services, devices and transactions. Particular attention will be paid to the ways in which European legislation and regulation is responding to the emerging challenges presented by eHealth. The presentation will cover issues arising from data sharing, use of medical devices, remote monitoring and cross border care.

workSHopS | 25

workSHoP

Phd/early career researchers

wednesday 5 october 13.00-18.00

Faculty of law

ProGraMMe

1. Introductions

All attending introduce themselves briefly

2. plenary 1

One of the experts speaks about their research and experience as a

doctoral student, and their subsequent career progression

3. Break out groups

In 3 groups with at least one expert in each, we will try and coordinate as far as possible expert research interests and PhD thesis fields. Each student has 10/15 minutes to present their work after which they receive feedback from the experts and answer questions from fellow PhDs. At the end of all the presentations and feedback, the PhDs get to ask the experts in their group questions

4. plenary 2

Reform in to one large group again, this time each attendant offers 2 or 3 points about what they have learnt regarding their work as a result of the day

5. Closing and networking

26 | worksh ops

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

WORKSHOP

E AHL distance learning teaching module

Wednesday 5 October, 16.00 – 18.00

Faculty of Law

Contributors to the module and colleagues from the University of Edinburgh will be present, to discuss the ongoing module development and teaching opportunities. A demonstration of Edinburgh Law School's online learning environment will be given. Any E AHL colleagues who wish to attend are very welcome.

This 10-week module aims to introduce students to areas of European law applicable to health care, and health systems and health policy.

The module will begin by looking at important milestones in the history of the EU, and those provisions in the Treaty of Lisbon applicable to health: The EU Competence Framework and EU structures and bodies.

Students will consider and debate the following areas:

- The relationship between law, politics and public health policies
- The EU health care law matrix of super-state, state and sub-state agencies
- EU preventive and incentive measures.

Despite the EU having economic liberalisation and deregulation as its basis, the Treaty does not preclude restrictions on freedoms where the 'protection of public health is concerned'. The freedoms in question apply to the imports of goods, the provision of services, freedom of establishment and movement of persons. These areas will be addressed specifically in respect of health care.

At relevant points in the module, specific issues will be addressed, including:

1. Organ donation
2. Tobacco regulation
3. Detection and control of communicable disease
4. The Cross Border Health Care Directive.

Towards the end, the module will consolidate earlier topics and discussion by looking at cross-border issues in specific Member States or regions. This will be facilitated by contributions by colleagues connected to the European Association of Health Law.

Colleagues have offered to provide material that will form the basis of a focussed discussion relating to cross border health care, be it reimbursement questions, provision or movement of services, health care delivery or access to care. Colleagues have in some instances agreed to draw up hypothetical scenarios based on existing jurisprudence or on the professional experiences of the colleague writing the scenario.

workSHopS | 27

Joint workshoP

euroPeAn Journal oF heAlTh law

Thurday 6 october, 14.30 – 16.00

ELDErLy AnD THE rigHT To CArE for HEALTH

ProGraMMe

1. Healthy ageing - a patient's rights perspective

Mette Hartlev, Professor of Health Law, University of Copenhagen

2. Surrogate decision making for incompetent elderly, the

role of informal representatives

Sjef Gevers, Emeritus Professor of Health Law, University of

Amsterdam

3. Elderly and the right to health care

Henriette Sinding Aasen, Professor of Social and Health Law,

University of Bergen, Norway

4. ICT and population ageing

Jean Herveg, Lecturer Medical Law and ICT, University of Namur,

Belgium

5. round table

28 | worksh ops

Third European Conference on **Health Law**

An Ageing Europe. Health Law Revisited

workshop

medical liability

Friday 7 October, 10.45-12.15

Towards a less aggressive, more effective and

prone to the reduction of medical error

Medical Liability legal framework - the

specific case of aging population

programme

1. Project presentation

2. Selection of legal rules concerning civil medical liability both in the public sector and in private practice, in Portugal - are aging and frail people more victims of mistakes than younger people

Andr  Dias Pereira

3. Court decisions on Portuguese civil liability on medical errors

Rafael Vale e Reis

4. Selection of portuguese criminal legal rules and court decisions concerning medical intervention

Daniela Costa

5. Round Table

**THIrD EuropEan ConfErEnCE
on HEaLTH LaW**

abstracts

oral presentations

Centre for Biomedical Ethics and Law

European association of Health Law

1. access to healthcare in poland - any alternative to public health insurance?

Natalia Lojko

2. accessing Cancer Drugs; should age and social factors matter?

Amy Ford

3. acronyms of dying versus patient autonomy?

Amina Salkić & Anna Zwick

4. advance directives and the specification of the refused medical acts and the conditions of application

Tom Balthazar

5. aggravated health risks and private insurances

Sarah Deffoor

6. assumptions about information needs in informed consent procedures and the diversity of information needs in practice, with special reference to older persons and ethnic minorities

Manja C. Bomhoff, Yvonne M. Drewes, Jeroen Borghuis, Rachul E. van Hellemond, Aart C. Hendriks & Roland D. Friele

7. Can Clinical Ethics Committees help facing future Challenges in the Health Care professional's Daily routine?

Verena Stöhlinger & Magdalena Thüni

8. Capacity to consent to medical treatment: legal issues for guardian and proxy decision-making for incapacitated elderly patients in Ireland

Brenda Daly

9. Challenges in the evaluation of health law: the Dutch organ Donation act

R. Coppen & R.D. Friele

10. Conflict of Interest Issues in Biomedical research Involving Vulnerable Elderly Subjects

Sandra Liede

11. Continuous sedation at the end of life for older patients: an analysis of two guidelines

Kasper Raus & Sigrid Sterckx

12. eHealth platforms and how to resolve the dichotomy between sharing data and protecting privacy

Juergen Hohmann & Stefan Benzschawel

13. End of Life Decisions: addressing Will-related Issues of Terminally Ill patients in Georgia

Mariam Gvartadze

14. End of life decisions: the Italian case

Alexander Schuster

15. End-of-life decision-making: recent legal developments in Canada

Nola Ries

Titles of abstracts in alphabetical order

32 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

16. Euthanasia in a context of realization of human rights for a life

N.G. Goncharov & A.N. Pishchita

17. Extraterritorial laws in cross-border reproductive care

Wannes Van Hoof & Guido Pennings

18. French ehealth policy

Nathalie Ferraud-Ciandet

19. Health care across "The Pond": legal rights and obligations of US Citizens who seek medical care in Europe

Dean M. Harris

20. Health protection for the elderly: A human rights perspective

Henriette Sinding Aasen

21. Healthy Ageing - A Patients' Rights Perspective

Mette Hartlev

22. ICT and population ageing: what could be the added value from the directive on the application of patient's rights in cross-border healthcare?

Jean Herveg

23. Informed consent issue for elderly patients

Vugar Mammadov & Aytan Mustafayeva

24. Is ECJ's patient mobility jurisprudence endangering introduction of new medical procedures (treatments) into national social security health packages?

Tomislav Sokol

25. Legal and ethical considerations on international recruitment of health care work force

Miek Peeters & Yvonne Denier

26. Legal hinderances: establishing an electronic platform for integrated home care of chronic ulcers

Ellen K. Christiansen

27. Legal position of vulnerable clients in the future: improving or going backwards?

BJM Frederiks & VET Durenberg

28. Legislation on direct-to-consumer genetic testing in seven European countries

Pascal Borry, Rachel E. van Hellemond, Dominique Sprumont, Camilla Fittipaldi Duarte Jales, Emmanuelle Rial-Sebbag, Tade Matthias Spranger, Liam Curren, Jane Kaye, Herman Nys & Heidi Howard

29. Living organ donation by mentally incompetents: the clear benefit standard and the improvement of the European regulatory framework

Gilles Genicot

30. Medical Research Data-Sharing in the Era of Aging Populations

Shawn Harmon & Kuan-Hsun Chen

31. National electronic patient records: some legal issues

M.C. Ploem

32. Organ transplantation in an ageing Europe: what are the legal means to cope with the organ shortage?

abSTracTS | 33

Anne-Cécile Squiffi et

33. patient rights in Telemedicine: Experience of Ukraine

Iryna Senyuta

34. personal health monitoring and health law

Stefaan Callens

35. privacy in e-health put to practice: the concept of concierge as a physical and technical interface

Paul De Hert, Eugenio Mantovani, Paul Quinn & Matthias Enzmann

36. protection of incapacitated elderly in medical research

Clasine M. de Klerk

37. protection of the rights and legitimate interests of citizens of advanced age at participation in clinical researches in the Russian Federation

A.N. Pishchita & N.G. Goncharov

38. rationing: a marginal argument in the end-of-life debate?

Helena Peterkova

39. regulating the use of genetic tests: Is Dutch law an example for other countries with regard to DTC genetic testing?

R.E. van Hellemond, A.C. Hendriks & M.H. Breuning

40. Safe and effective medication for the elderly: the latest on the Avastin-Lucentis debacle

Rita-Mariï Jansen

41. Safeguarding rights in Decision-making for those with Diminishing Competence: Ethics Committees and procedural Justice

David Townend

42. Safeguarding the interests of incapable adults in health issues and rethinking family and state responsibilities

Kees Blankman

43. Self-determination of patients in Dutch public Health Legislation and new Challenges Coincided by the rise of Social Media platforms

Jeroen Borghuis, Rachul E. Van Hellemond, Manja C. Bomhoff, Yvonne M. Drewes, Roland D. Friele & Aart C. Hendriks

44. Services of general interest in health care

Diego Fornaciari

45. Surrogate decision making for incompetent elderly patients: the role of informal representatives

Sjef Gevers & Jos Dute

46. The construction and development of the modern concept of autonomy for an ageing population

Eduardo Dantas

47. The current status and new trends of Direct to Consumer advertising for medicinal products in the EU

Lynn Martens

34 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

48. The implications of autonomy in decision making on Europe's ageing population

Yohanna Dangata

49. The influence of Europe's Ageing Populations on the standard of disclosure expected of medical practitioners

N.J.B. Claassen

50. The legal value of advanced directives in the delimitation of the patient's consent

Virgilio Rodríguez-Vázquez

51. The palliative filter procedure for euthanasia requests: legitimacy and due care criteria

Sylvie Tack

52. The Role of Informed Consent in eConsent Implementations

Gene A. Gangan

53. The Sardinian model of the community based approach for aging

Federica Demuru, Salvatore Pisu, Michela Pintor, Maria Rita Pittau & Ernesto d'Aloja

54. Towards a methodology of health law evaluation

Roland D. Friele

55. Towards the shaping of a 'European' right to refuse life-saving treatment in end of life cases? An Italian perspective

Stefano Biondi

56. When the sexual side kicks in... a systematic review of the ethical debate on aged sexuality in residential care

Lieslot Mahieu & Chris Gastmans

abSTracTS | 35

health Protection For The elderly: a human rights Perspective

Henriette sinding Aasen

The number of people aged 60 and over is growing faster than any other age group. Those who survive to age 60 can also expect to live longer than before, and women longer than men. As people age, health problems increase, disability and illness rise significantly, and the need for health care services increases, especially at the very old ages (80 and above), which will be the fastest growing group in the years to come. Patients with dementia are increasing, in particular in high-income countries, due to the fact that more individuals reach the age of 80. It is estimated that the number of people living with Alzheimer and other forms of dementia will double every 20 years, in particular in low- and middle-income countries. In most countries worldwide today, although with great regional and national variations, older persons do not have sufficient access to appropriate health care services, and training in geriatric medicine is lagging behind the demand. In recent years, the issue of human rights for the elderly has been addressed more frequently all over the world. Accordingly, the notions of "active ageing" and "a society for all ages" are in frequent use in global as well as regional and national legal and policy framework. However, older men and women are at particular risk of human rights violations and thus requiring specific measures of protection. In this paper, the right to health protection for the elderly is conceptualized within international and European human rights regulation and strategies. Right to equitable access to health care of appropriate quality (Article 3 Biomedicine Convention), relevant provisions on health protection in the revised European Social Charter and the Charter of Fundamental Rights of the European Union, as well as important soft law instruments, will be discussed.

Contact: Henriette.aasen@jur.uib.no

Session: Thursday, "Willem Van Croy", 14:30-16:00

36 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Advance directives and the specification of the refused medical acts and the conditions of application

Tom Balthazar

Advance directives receive more and more legal recognition. Mostly as negative directives where a competent person can confirm that he does not want that certain medical acts will be performed when he will be no longer able to consent.

The application of advance directives can cause several problems as it is not always clear which directives were precisely given by the patient and in which conditions the advance directive has to be applied. Moreover the physician can estimate that respecting the advance directive can be irresponsible as the patient has good chances to recover if the refused medical acts (such as an cardiovascular reanimation or a hospitalization in an ICU) are performed.

An important question in the discussion about the legal value and the binding effect of advance directives is the wording of the directive. Is it allowed to refuse medical acts in general and vague terms or is it necessary to specify these acts in detail? What are the implications of directives that are not clear or not precise enough?

Besides the wording of the refused medical acts it is necessary to describe in which conditions the advance directive will have to be applied. For the formulation of these conditions the same question arises: how precise the directive has to be and what are the implications of a directive that does not describe in a specified way when it has to be applied?

Contact: tom.balthazar@ugent.be

Session: Thursday, "St. Barbara", 11:00-12:00

abSTracTS | 37

Towards The shaPinG oF a 'euroPean' riGhT To reFUse liFe-savinG TreatMent in end oF liFe cases? an iTalian PersPective

stefano Biondi

This paper aims at showing that, despite the different historical background, many European jurisdictions are experiencing a common trend towards the recognition of a right of terminally ill patients to refuse treatment and to have their advance directives enforced. particular emphasis will be placed on the Italian legal system.

The discussion will start with the analysis of a decision of the Italian Supreme Court of Cassation (n° 21748/2007) which stated that doctors should take the presumed will of patients in a persistent vegetative state into account when making decisions about suspending artificial nutrition and hydration. In doing so, the court remarkably relied not just on domestic and international legal sources but also on foreign authorities. The paper will then discuss how Italian courts made up for the lack of a consistent discipline in the field of advance directives and proxy decision-making (basing on general legal principles drawn from the Constitution or international sources or providing an extensive interpretation of existing legal institutions) and will analyse the Italian draft bill on "living wills" proposed by the majority (currently under parliamentary scrutiny), underlying the doubts concerning the constitutionality of many of its clauses.

The paper will then discuss how the English and french legal systems regulate life-saving refusal of treatment and advance directives. particular reference will be made to the English MCA 2005 and the french Code de la Santé, both of which affirm the necessity to take into account –to a different extent- the patient's known or presumed wishes.

In conclusion, the paper will underline how the jurisdictions concerned are "proceduralising" end-of-life decision-making and how the patients' views –although not always binding- are being given increasing consideration in such procedures.

Contact: stefano.biondi@email.it

Session: friday, "florquin", 14:00-15:30

38 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Saveguarding the interests of incapable adults in health issues and rethinking

family and state responsibilities

Kees Blankman

Safeguarding the rights and interests of incapable older people requires a tailored legislation and a suitable infrastructure. As for legislation regarding substitute decisionmaking in health matters, some European countries are still applying more or less outdated guardianship measures. A number of countries, specifically in Western Europe have modernized their guardianship legislation in the last two decades and some of them have amended it with specific legislation regarding continuing powers of attorney. The introduction of this legal instrument is strongly promoted by Recommendation (2009)11 on continuing powers of attorney and advance directives for incapacity, that was adopted by the Committee of Ministers of the Council of Europe on 9 December 2009.

As for infrastructure, protection and representation of incapable older people has always been primarily an obligation of the family, but for several reasons less and less family members can be found to take up this responsibility. In addition to family responsibilities, the state has an overall responsibility for providing an infrastructure in which measures of protection can be applied in accordance with human rights standards. This includes guidance and supervision being available for attorneys and guardians both family members and non family members and the development of professional standards.

Contact: c.blankman@vu.nl

Session: Friday, "St. Barbara", 10:45-12:15

abSTracTS | 39

assuMPTions aBouT inForMaTion needs in inForMed consent Procedures and The diversiTY oF inForMaTion needs in PracTice, wiTh sPecial reFereNce To older Persons and eThnic MinoriTies

manja C. Bomhoff, yvonne m. Drewes, Jeroen Borghuis, rachul E. van Hellemond, Aart C. Hendriks & roland D. friele

The Dutch 'Medical Treatment act' imposes a number of obligations on health care providers in order to enable patients to give informed consent for a medical intervention. according to these obligations, the physician gives information on the indication, the proposed treatment, alternatives, prognoses, risks, and possible side-effects prior to starting with a form of treatment. The physician must discuss what a patient reasonably would find relevant. all these requirements are prescribed and deemed essential to the decision-making process.

The informed consent procedure is based on several tacit assumptions on the abilities and needs of patients with respect to information needed to decide about treatment. However, questions can be raised not only about the effectiveness, understanding and recall of information, but also about patients' varying information needs and wishes in their decision-making process. Three examples might be illustrative. first, different cultural ideas on health and life may make some patients restrained of getting information about prognosis. Second, information about alternative treatments has been known to make some, especially older, patients doubt their physician's authority and expertise. Last, informed consent is constructed as an individual right and practice which may not be perceived by patients and their kin.

We assume that there are differences between what a patient reasonably would find relevant in a similar situation, as formulated by law, and what an individual patient finds relevant in his/her specific, individual context. Do current informed consent procedures leave enough room and flexibility for a true patient-oriented perspective?

In this study we examine this assumption from a legal and a social scientific stance, investigating informed consent in law as well as objectively, and in jurisprudence as well as practice and literature. Because of their differing attitudes and expectations, and their at times more vulnerable positions, older persons and ethnic minorities in all their diversity form two interesting groups to critically examine.

Contact: m.bomhoff@nivel.nl

Session: Thursday, "St. Gommarius", 11:00-12:30

40 | Abstracts

Third European Conference on Health Law

Self-determination of Patients in Dutch Public Health Legislation and New Challenges Coincided by the Rise of Social Media Platforms

Jeroen Borghuis, Rachul E. Van Hellemond, Manja C. Bomhoff, Yvonne M. Drewes, Roland D. Friele & Aart C. Hendriks

Since the 1980s, self-determination has been an important notion underlying Dutch health legislation, including laws in the field of public health. The recognition of patients' self-determination emerged in response to the dominant paternalistic attitude of health care providers. Yet, little is known about the actual consequences of this shift in the focus of public health law and health policy. This study concentrates on the ways in which self-determination in general and informed consent in particular are embodied in public health law in the Netherlands. In doing so, we will also analyse the central underlying assumptions and aimed goals of the public health legislation. In addition, we will examine to what extent the unexpected low uptake of recent public health initiatives, such as the vaccinations regarding the Human Papillomavirus (HPV) and the Influenza A N1H1, seem to reflect the sustainability and justification of the current Dutch public health policy. These recent developments might indicate a somewhat revolutionary change within the Dutch population regarding the 'blind' acceptance of scientifically grounded governmental health instructions—a change that might have been influenced by the rise of social media. Social media platforms and social networks provide individuals with the opportunity to express and share their opinions and doubts, and even to spread fearsome stories and fables. Nowadays, many individuals are likely to make decisions (partly) based on what they read in these social media platforms. It could be argued that this reflects a new form of patients' self-determination. The essential question to be answered is how policy makers and legislators should, if at all, incorporate these new challenges in their policies and legislation, also taking into account the importance of patients' self-determination.

abSTracTS | 41

Legislation on direct-To-consumer Genetic Testing in seven European countries

pascal Borry, rachel E. van Hellemond, Dominique sprumont, Camilla fittipaldi Duarte Jales, Emmanuelle rial-sebbag, Tade matthias spranger, Liam Curren, Jane kaye, Herman nys & Heidi Howard

An increasing number of private companies are now offering direct-to-consumer (DTC) genetic testing services. The tests offered range from tests for single gene, highly penetrant disorders to susceptibility tests for genetic variants associated with common complex diseases or with particular non-health-related traits. Although a lot of attention has been devoted to the regulatory framework of DTC genetic testing services in the U.S.A., only limited information about the regulatory framework in Europe is available. We will report on the situation with regard to the national legislation on direct-to-consumer (DTC) genetic testing in seven European countries (Belgium, the Netherlands, Switzerland, Portugal, France, Germany, United Kingdom). The paper will address whether these countries have legislation that specifically addresses the issue of DTC genetic testing or have relevant laws that are pertinent to the regulatory control of these services in their countries. The findings show that France, Germany, Portugal, Switzerland have specific legislation that defines that genetic tests can only be carried out by a medical doctor after the provision of sufficient information concerning the nature, meaning and consequences of the genetic test and after the consent of the person concerned. In the Netherlands, some DTC genetic tests could fall under legislation that provides the Minister the right to refuse to provide a license to operate if a test is scientifically unsound, not in accordance with the professional medical practice standards or if the expected benefit is not in balance with the (potential) health risks. Belgium and the United Kingdom allow the provision of DTC genetic tests. Although

relevant legislation that bind DTC companies exists at the European level (E.g. the in vitro medical diagnostic devices, consumer protection legislation, data protection legislation), the lack of a harmonized (European) approach at all levels is problematic in a context where services are offered through the internet.

Contact: pascal.Borry@med.kuleuven.be

Session: Friday, "St. Gommarius", 14:00-15:30

42 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Contact: stefaan.callens@med.kuleuven.be

Session: Friday, "Willem Van Croy", 14:00-15:30

Personal health monitoring and health law

Stefaan Callens

Personal health monitoring (PHM) can be defined as comprising all technical systems, processing, collecting, and storing of data linked to a person. Personal health monitoring allows monitoring parameters of that person, and leads to health-related information of that person. PHM covers a very wide area of products, services, procedures and techniques. It takes not only place for telemedicine purposes (for example monitoring a patient who suffers from diabetes or from cardiac arrhythmia from a distance), but also in case of the use of an alcohol slot in a car, to check someone's temperature in the airport, PHM involves several legal issues that are described in the paper. The paper analyses firstly the short term actions that are needed at the European level to allow personal health monitoring in respect of the interests and rights of patients. The short term actions are related to more harmonized medical liability rules at the EU level, to the conditions for health care professionals to deliver cross-border activities and to the notion of informed consent (not only in relation to the treatment plan but also to the use of the device and/or the processing of monitoring data). Introducing PHM in respect of patient rights implies also legal action at the EU level on the long run. These long term actions will also be presented in the paper and are related to a review of article 15 of the data protection directive, to the reorganisation of the health care system (and in particular the way in which hospitals are organized in their relation with health care professionals and with other hospitals or health care actors), to the risk of overconsumption and reimbursement of monitoring projects. The paper will finally analyse how health monitoring projects may change the traditional (non-) relationship between patients and pharmaceutical/medical device industry. Today, the producers and distributors of medicinal products have no specific contact with patients. This situation may change when applying telemonitoring projects. The paper analyses whether specific rules at the European level are needed with regard to the delivery of monitoring systems by distributors of medical monitoring devices.

abSTracTS | 43

Legal hinderances: establishing an electronic Platform For integrated home care of chronic ulcers

Ellen k. Christiansen

There is a saying that use of telemedicine and eHealth is hindered by legal obstacles. Legal "tangles" are accused of hindering the potential of telemedicine to be utilized. as it seems, lawyers and security experts often are considered to be "party killers" when it comes to development of technological solutions.

During the last two years, an interdisciplinary group at norwegian Centre for Integrated Care and Telemedicine (nST) at university Hospital of north norway has been in the process of accommodating a Danish technological platform for integrated home care of long lasting or chronic ulcers. There were legal challenges that needed to be handled, but there were other aspects to be handled as well.

The out patients' clinic for treatment of ulcers at the hospital had an apparently simple order for nST in 2009: They wanted an electronic platform for integrated home care of long lasting ulcers. GPs, health personnel from the local home care unit, specialist health care personnel and patients themselves should be able to cooperate electronically and discuss subjects related to the ulcer treatment. a technological platform for such cooperation is developed and put into use in Denmark. as the legislation in this field is quite similar in Denmark and norway, we thought implementation would be simple.

It turned out that both the implementation of the Eu-directive 95/46 EC on the protection of individuals with regard to the processing of personal data and the free movement of such data, the national legislation and practising of the directive in the two countries, were different. Hence, comprehensive adaptations had to be performed to make the Danish solution comply with Norwegian legislation.

Some other hindrances that had to be handled by the interdisciplinary team will be briefly reviewed as well.

Contact: ellen.christiansen@telemed.no

Session: Friday, "St. Gommarius", 14:00-15:30

44 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Contact: claasnj@ufs.ac.za

Session: Thursday, "St. Gommarius", 11:00-12:30

The influence of Europe's Ageing Populations on the standard of disclosure expected of medical practitioners

N.J.B. Claassen

It is a fundamental legal principle that in the absence of the required consent, medical treatment of a patient will be unlawful. This is the position however well executed the treatment might have been and irrespective of the objective benefit thereof to the patient. Information pertaining to a variety of aspects with regard to the proposed treatment as well as the consequences that could possibly result therefrom should be communicated to the patient. Knowledge of the relevant information in itself will not be sufficient to constitute effective consent, it is imperative that the patient must also understand the information given to such an extent that it would enable him/her to take an informed decision to continue with the proposed treatment or not.

As a result of the tremendous development that has taken place in the field of medicine in recent years, medical practitioners find it progressively difficult to adhere to the required standards for disclosure of information, even more so in situations where the patient is not able to fully grasp the information conveyed because of declining cognitive functions. This challenge faced by medical practitioners will undoubtedly be complicated in years to come as result of the ever-increasing lack of time at their disposal to explain the intricacies of proposed treatment, caused by the above-mentioned declining cognitive functions of an ageing patient population. This situation will unquestionably place countries' health systems under tremendous pressure and need to be addressed timeously.

The question is posed if it is fair to expect of medical practitioners to comply with the current standards for disclosure of information in view of the expected challenges that they have to face. A possible relaxation of the standards applied to procure a patient's informed consent is investigated by referring to an empirical study conducted in South Africa on patients whose state of mind could be described as 'intellectually absent'. A few proposals relevant to the discussion are made.

abSTracTS | 45

challenges in The evaluation of health law:

The Dutch organ donation act

r.Coppen & r.D. friele

Expectations regarding the impact of legislation are generally high. Improved insight into how legislation impacts on society may contribute to more realistic expectations of legislation and may lead to better quality of legislation. An interesting example of legislation with high expectations is the Dutch organ Donation act, which was enacted in 1998. Besides safeguarding the rights of donors and other persons involved (e.g. doctors, next of kin), the act was expected to increase the supply of donor organs by implementing an explicit consent system. Because the numbers of post mortem organ donors did not increase the Dutch government decided to evaluate the act in order to (be able to) adjust its organ donor policy.

This evaluation brought some methodological challenges. For example, the organ Donation act has both a safeguarding function as well as an instrumental function. In our evaluation we determined the legal framework set out by the safeguarding function and assessed whether there is room within this framework to increase the supply of

donor organs. This requires a multidisciplinary approach, involving lawyers and social scientists to work together and bridge their disciplinary differences, leading to unambiguous conclusions.

Another challenge is to assess the empirical effects of legislation. This requires an outcome indicator, a baseline-measurement and a control group. Organising these methodological requirements are not always easy when evaluating laws. Besides, there seems to be a rather complex relation between an act, its additional policy measures, and their impact.

In this paper we would like to elaborate on the methodological challenges for accurate evaluation of health law, based on our experiences with evaluating the Dutch organ Donation act.

Contact: r.coppen@nivel.nl

Session: Friday, "anna De paepe", 10:45-12:15

46 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Capacity to consent to medical treatment: legal issues for guardian and proxy decision-making for incapacitated elderly patients in Ireland

Brenda Daly

The Irish Law Reform Commission Report in 2003, *Law and the Elderly*, identifies a significant rise in the number of elderly people, and recommends greater legal protection for this section of society as there are many elderly people who may be vulnerable for reasons of ill health, disability, mental incapacity, as well as being dependent on social and economic assistance.

The aim of this paper is to consider the particular legal issues arising in relation to consent for medical treatment of incapacitated elderly patients in Ireland by guardian and proxy decision-makers. The paper commences with discussion of the extant law regarding capacity to consent to medical treatment. In particular, it will be necessary to analyse capacity in respect of the Mental Health Act 2001, as well as the relevant provisions under disability legislation. This paper will examine the specific role of guardians and proxy decision-makers in respect of consenting to medical treatment of incapacitated elderly patients.

Contact: brenda.daly@dcu.ie

Session: Thursday, "Willem Van Croy", 11:00-12:30

abSTracTS | 47

Contact: Yohanest@dangata.freemove.co.uk

Session: Friday, "St. Barbara", 10:45-12:15

The implications of autonomy in decision making on Europe's ageing population

yohanna Dangata

Historically, patient autonomy began to gather importance in medical practice over half a century ago following the outcry against inhumane practices in Nazi camps at the end of World War II, when human subjects were cruelly used for medical research without their consent. This led to legislation for regulation of the use of humans in biomedical research. Central to the subject of autonomy is the issue of consent, for it is now mandatory to obtain informed consent from any subject before their participation in any research. Although this was initially primarily for biomedical research, it soon involved all aspects of medical practice. Since then, medical law has evolved at national, regional and global level to facilitate the effective engagement of the stakeholders into partnership in the appropriation of autonomy for effective healthcare delivery. At present, a lot of the civilised world, including Europe, has made autonomy central to healthcare services. However, it is increasingly becoming apparent that, at the back of autonomy are rapid changes in demographic parameters such as increasing life expectancy and quality of life, shrinking working population; together with increasing costs of medical care in the midst of competing priorities.

The present paper aims to highlight the historical background of the evolution of autonomy, the impact of autonomy on the demographic trend of Europe's population,

the implications of Europe's demographic trends, and recommendations for the strategic position of European Health Law for shaping autonomy to match in pace with Europe's ageing population.

48 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

The construction and development of the modern concept of Autonomy for an ageing population

Eduardo Dantas

The development of the medical sciences brought along a raise in life expectancy. As a consequence, issues related to the treatment of the elderly became much more important, since they live longer, and are now a more representative percentage of society.

This paper aims to demonstrate that there is a gap in the way patients' autonomy is being discussed. All attention is focused on informed consent, and this approach is essentially wrong. Consenting is just a part of the process of choosing, and is not enough to allow older patients to exercise their right to autonomy. This can only be accomplished through the complete and understandable disclosure of all information regarding treatment, their options and possible consequences. This is especially significant when we look at the elderly patient, given the variety of unanswered ethical questions that have risen in the last decades, regarding capacity to consent, proxies/guardians, end of life situations and advanced directives.

A study in comparative law is presented in this paper, using European and Brazilian legislation, in order to discuss how disclosure of information, obtaining consent, and respecting choice is necessary to allow the exercise of true autonomy for the elderly patient.

Contact: eduardodantas@eduardodantas.adv.br

Session: Thursday, "St. Barbara", 11:00-12:30

abSTracTS | 49

aGGraVated health risks and Private insurances

sarah Defloor

private insurances have become more and more important in modern society. personal insurances especially, such as (additional) health insurance and life insurance, are increasingly supplementing social security coverage and social insurance. Moreover, personal insurances, e.g. a life insurance in view of negotiating a loan to buy a house, have become a social good.

In view of assessing risk and making the right calculation of premium, the private insurer needs information about risk and, more specifically in personal insurance, information about the insured person. As health risks play a significant role in personal insurance, the information needed often has a medical character. However, the collection of such health-related data for insurance purposes has the potential to encroach disproportionately on fundamental rights, such as the right to privacy and the right not to be discriminated against, as protected by for instance the European Convention on Human Rights and Biomedicine. This is most certainly the case as to what concerns elderly or ill persons. They have a so-called aggravated health risk, which is, according to the existing insurance techniques, difficult to insure, at least under standard conditions.

A legislative concern to improve the situation of persons with an aggravated health risk is noticeable in several European countries. This paper aims to address the legal difficulties which they may face in private insurances. The European law context will be examined, as well as the legal situation that exists in some EU Member States, such as the Netherlands, France and Belgium.

Contact: sarah.defloor@med.kuleuven.be

Session: Thursday, "florquin", 11:00-12:30

50 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Privacy in e-health put to practice: the concept of concierge as a physical and

technical interface

Paul De Hert, Eugenio Mantovani, Paul Quinn & Matthias Enzmann

Without the ability to control the use and disclosure of health information, the individual's right to health information privacy is endangered (Agre & Rotenberg 1997, Westin 1969; Peel 2010). Monitoring technologies and systems of medical surveillance makes sensitive data about health increasingly accessible, trumping individual control (Rynning 2008). A sizeable number of e-health applications at development stage deal with chronic diseases, whose incidence is likely to steadily increase in ageing societies. Starting from a concrete application in the development stage, the REACTION platform for Remote Monitoring of Patients with Diabetes, and drawing on two court cases, this paper presents a conceptualisation of the legal notion of informed consent, that we term "conciierge". Part 1 targets the management of electronic consents within remote monitoring applications like the ones being developed in REACTION. The concept for consent management is based on two technical requirements, patient participation in disease management, and user control of personal health data. It takes into account usability issues for patients as well as security and privacy principles, such as confidentiality and purpose binding. It also recognises that 'true' control over personal data can only be exercised as long as the data is in the patient's own hands. Part 2 focuses on two cases, the *Union des medecins belges* (Belgian Constitutional Court 2008) and *I v. Finland* (ECtHR 2008), harnessing the elicited technical requirements to the legal frameworks on patient consent and responsibility of the data handler. The legal analysis indicates that both informed consent and responsibility are not notions fixed in stone by the law, but that, through contextual application of the law, they can be re-appropriated creatively by those who are part of the chain of control over personal information. The article concludes that use can be made of elements such as mediation systems in public hospitals to give shape to a third legal persona, a "conciierge", that would reinforce control over personal health. The paper will finally look to the new Dutch national patient electronic record system to demonstrate the possibility of using such principles in practice.

Contact: emantova@vub.ac.be

Session: Friday, "St. Gommarius", 10:45-12:15

abSTracTS | 51

ProTeCtion oF incaPaciTaTed elderly in

Medical research

Clasine m. de klerk

Medical research with human subjects is no longer purely a national activity. To uniformly protect the participants and at the same time not interfere with the course of research, the European union (Eu) and the Council of Europe established rules and norms to regulate medical research in the Member States. firm regulation of medical research is particularly important when vulnerable people are involved, like incapacitated elderly. Does European law guarantee incapacitated elderly adequate protection when participating in medical research?

Sometimes it is inevitable that incapacitated persons will be included in medical research. The Clinical Trial Directive and the additional protocol of the Oviedo Convention concerning biomedical research both include conditions and criteria concerning research with these participants. In my paper I will discuss the similarities and differences between these European standards and, as an example, the conditions in the Dutch act on Medical research Involving Human Subjects. Generally accepted is the inclusion of incapacitated elderly in absence of alternatives and when the research has the potential to produce real and direct benefit to the participants. Conflicts occur where differences between the Council of Europe and the Eu are present, especially in the case of less comprehensive rules provided by the Eu in comparison with those by the Council of Europe. This includes for example the conditions for maximum risk level and the acceptance of present advance directives in non-therapeutic research. More differences could arise from the possibility for Member States to provide rules for more stringent protection. I will discuss the consequences of these different regulations for the protection of incapacitated elderly. finally I will conclude whether these multiinterpretable regulations guarantee an adequate protection for incapacitated elderly participating in medical research.

Contact: clasine_dk@hotmail.com

Session: Thursday, "anna De paepe", 14:30-16:00

52 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

The Sardinian model of the community based approach for aging

Federica Demuru, Salvatore Pisu, Michela Pintor, Maria Rita Pittau & Ernesto d'Aloja

In the attempt to figure out how Europe can face the problem of an ageing population and what efforts should be done by regional and national governments, compelled in particular to answer to the growing health needs of the aged society, we would like to point out the situation of Sardinia, since, even if a small portion of European countries, it's quite representative of the general condition that Europe is experiencing nowadays. Sardinia has the lowest birth rate of Italy, the percentage of elderly people is double compared to that of peninsular population, this is due also to a depopulation affecting particularly the internal areas of the island that is poor of job opportunities. Moreover, the local health system in general is not at a high level of efficiency, there are only few exceptions nearly concentrated in the biggest towns. This framework should make everyone think that Sardinia is not a good place to get older, but despite these data, in Sardinia there is the highest number of centenarians, the ratio male/female in centenarians is small; old people enjoy many years in good health, although chronic diseases are increasing, Sardinians show one of the lowest values of cardiovascular problems. Given the particular combination of Sardinian genes, the good environmental conditions or the healthy life style and put all these data in a side, our opinion is that the community based approach that still characterizes Sardinian society, the relations in which elderly are well integrated, respected, and the fact they still play an important role in their own families and communities, is the concern a public health system, a local and national government should promote and support.

Contact: federicademuru@gmail.com

Session: Thursday, "St. Gommarius", 14:30-16:00

abSTracTS | 53

French eHealth Policy

nathalie ferraud - Ciandet

France and health system relies on multiple actors such as health insurance (compulsory & complementary), more than 300 000 professionals including general practitioners, pharmacists and laboratories; 4 000 hospitals representing more than a million of employees. In 2000, the World Health Organization considered the French health system as the best worldwide. Still, major gaps remain in terms of access due to social and geographical disparities. With a deficit exceeding Euros 11bn, health expenditures grow faster than national wealth. In 2004, the French Government announced a national healthcare information technology (IT) program, composed of: the Saisam Vitale Smartcard and France's Electronic Health record (EHR) - the 'Dossier Médical personnel' (DMP). France is one of the forerunners in the European Union designing a legal framework adapted to the use of eHealth with Denmark, England, Estonia, Finland, Norway, Scotland, Slovak Republic and Sweden. This paper gives an overview of the French e-Health policy till March 2011 concerning the governance of eHealth (1), the deployment of eHealth applications (2) and of the infrastructures (3).

Contact: nathalie.ferraud-ciandet@grenoble-em.com

Session: Thursday, "florquin", 11:00-12:30

54 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Accessing Cancer Drugs; should age and social factors matter?

Amy Ford

The European population is aging. Cancer predominantly affects older generations and brings the issue of access to expensive cancer drugs into sharp focus. This paper examines how the National Health Service (NHS) in England decides which treatments to provide, when it cannot afford them all.

Without a positive appraisal by the National Institute for Health and Clinical Excellence,

mandating provision of a treatment by the NHS, local health authorities (Primary Care Trusts (PCTs)), are free to decide whether to provide a particular drug. However, as with all public bodies, it is a well established principle of English administrative law that PCTs are not at liberty to fetter the exercise of their own discretion. They must recognise the possibility that some patients will have exceptional circumstances, so any policy prohibiting the funding of a drug cannot be absolute.

In the absence of statutory guidance on what constitutes exceptional, clinicians are left guessing which patients might be eligible for funding on the grounds of their exceptional circumstances. Using the context of cancer drugs, this paper examines the concept of exceptionality from clinical, moral and legal perspectives, focussing on the role of social factors, including age, in determining exceptionality. I will review cases where the PCTs' decision not to fund drugs has been subject to legal action, reflecting on the extent to which the courts have provided guidance on interpreting the term exceptional. I will argue that this concept has a limited role in the allocation of scarce resources at a local level.

Contact: amy.ford@manchester.ac.uk

Session: Thursday, "Anna De Paepe", 11:00-12:30

abSTracTS | 55

services of General interest in health care

Diego fornaciari

The concept of services of general interest plays a crucial role in the application of competition law to the health care sector. Services of general interest are divided into non economic services of general interest and services of general economic interest. non economic services of general interest, e.g. the provision of compulsory health insurance, do not fall under the scope of competition rules. according to article 106, §2 Treaty on the functioning of the European union (TfEu) undertakings entrusted with the operation of services of general economic interest are subject to competition rules in so far as the application of these rules does not obstruct the performance, in law or in fact, of the particular tasks (public service obligations) assigned to them. This means that health care players, entrusted with services of general economic interest, can restrict competition if this is necessary for the performance of their public service obligations (e.g. providing quality of care, continuity, access, etc.). also, the concept of services of general interest is of importance when governments wish to provide financial aid to health care players. under certain conditions, financial aid to health care players entrusted with services of general economic interest, can be allowed under competition legislation.

There is, however, uncertainty regarding how health care players can or should be entrusted with services of general interest. In e.g. Belgium, hospitals and health care professionals are entrusted with services of general economic interest, but this conclusion can only be made by analyzing the different legislation. also, the content of these services is not clear. To apply the exemption of article 106, §2 TfEu an explicit and clear entrustment of services of general economic interest (and the different public service obligations) is desirable. Such an entrustment will contribute to an Europa proof national health policy.

Contact: diego.fornaciari@med.kuleuven.be

Session: Thursday, "florquin", 14:30-16:00

56 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Contact: v.dorenberg@vumc.nl

Session: Thursday, "St. Gommarius", 14:30-16:00

Legal position of vulnerable clients in the future: improving or going backwards?

BJM Frederiks & VET Durenberg

Two vulnerable groups in our society are minors with a psychiatric disorder and people with an intellectual disability. The demand for care is growing every year in both sectors. In the near future both groups will face a lot of similar dilemmas. More people are diagnosed with a mild intellectual disability and persons with severe intellectual disabilities get older. Due to psychological, behavioral, addiction or adhesion problems (especially for a growing number of young people with mild intellectual disabilities) the

need for support and good care is becoming a big issue. The same can be said for minors with a psychiatric disorder. These minors have a predisposition for severe psychiatric problems at an older age.

The legal position of people with intellectual disabilities and minors with psychiatric problems has one main feature: too much attention to the right to self-determination. This right, which is seen as one of the basic principles of health law, presupposes freedom: each individual has the right to decide how to shape his life. Self-determination is, however, not the only guiding principle in supporting persons with an intellectual disability and minors with a psychiatric disorder. Due to changes in client population, but also beliefs about care and support, other principles in health law need to get more attention.

In the current legal framework, the Dutch Psychiatric Hospitals Act, self-determination is the leading principle. An important question is whether this central feature is enough to support clients in such a way that their abilities are developed and good care is taken into account. The Dutch government is preparing new legislation to replace the Dutch Psychiatric Hospitals Act. We recommend this legislation take into account the right to development and the right to good care, to face the dilemmas in the near future.

abSTracTS | 57

Contact: r.friele@nivel.nl

Session: friday, "florquin", 10:45-12:15

Towards a Methodology of health law evaluation

roland D. friele

Health law is primarily meant to provide safeguards. Safeguards for both patients and care providers. However, health law is increasingly being employed in an instrumental way, to change the functioning of health care. Examples can be found in different types of legislation for instance, on blood-supply. In this case legislation is also meant to restructure the organization of the blood-supply in order to increase the safety of blood-products. also legislation on complaint is not only intended to offer patients the fundamental right to file a complaint, but also to make care providers learn from complaints and therewith improve the quality of care. and, finally, legislation on the financing of health care in the netherlands, is used to introduce more competition among care providers in the hope that this will lead to an increased quality for a reasonable price. Thus, health law has become an instrument of policy makers. policy rhetoric wants us to believe that changing legislation in health care will lead to better health care quality, will help to contain costs, will assure accessibility and the fulfillment of patients' choices. It is the role of the research-community to critically analyze these claims, by conduction solid research.

Solid research requires solid methodologies. In our field, such methodologies are not readily available, since they should be based on a combination of legal and empirical research. research traditions in law and the empirical research are different. However, cooperation between researchers from both fields should be more than a simple division of tasks. Instead it should be based on a shared definition of the research problem and on complementary research strategies.

In this paper, I will present an overview of the methodological problems we encountered while evaluating several health laws, and I will present possible solutions for these problems. This overview is based on our experiences with nine formal evaluations of health care legislation in the netherlands. all of these evaluation were performed by a research team consisting of both lawyers and health services researchers in the netherlands. With this overview I intend to contribute to the development of a shared methodological framework for the evaluation of health law.

58 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

The Role of Informed Consent in eConsent Implementations

Gene A. Gangan

Data privacy is a valid concern in these times when information can spread beyond borders and through countless recipients in a matter of seconds. Some patients consider their health records private and should only be seen and used by their trusted healthcare

professional. However, health records may also be deemed important by other entities beyond the circle of care providers. This paper discusses the importance of informing the patient of the consequences that could arise from consenting or dissenting on the use of a health record. The paper further discusses requisites for an eConsent system as an important part of an Electronic Health Record system that will make it flexible enough to allow the patients to control the exchange of their records, without putting too much strain in the provision of care by the healthcare professionals. This may prove to be complex as it is difficult to find the balance between patient privacy and security concerns and the type of treatment the healthcare professionals can give if the patient puts too much restriction in the use of his record. Sample scenarios and implementations of eConsent vis-a-vis the legal environment are likewise presented in the paper.

Contact: genegangan@yahoo.com

Session: Friday, "St. Gommarius", 10:45-12:15

abSTracTS | 59

end of liFe decisions: addressinG willrelaTed issues of TerMinally ill PaTienTs in GeorGia

mariam gavtadze

palliative care is part of contemporary medicine aimed at relieving individuals from pain during the terminal stage of illnesses and providing psychological and spiritual support. The definition of palliative care has been incorporated in the laws of Georgia on Healthcare and patient's rights and has been an integral part of Georgian medicine since 1999.

Thousands of people in Georgia are in need of palliative care, but only a limited number can benefit from it in three hospices in the country, addressing the medical, social and emotional needs of patients and their families. However legal assistance is also of great importance for this vulnerable population since terminally-ill patients often do not have energy and resources to manage their legal affairs.

unresolved legal problems may further deteriorate a patient's quality of life. Terminally ill patients might require legal assistance related to the issues of inheritance, custody, social security benefits, pensions, etc. Existing data prove that in order to solve the questions pertinent to wills and inheritance, patients in Georgia often necessitate aid from the attorneys with significant experience in the field.

In 2009 the open Society Georgia foundation – Law and Health Initiative established free legal aid service for palliative care patients. As a result several prominent law offices cooperate with the project, providing free of charge legal consultations and relevant representation to the patients. Lawyers frequently assist palliative care patients and their families in preparing wills and all necessary documents for distribution of legacy according to the Georgian legislation. The lawyers also play a crucial role in negotiating with the notaries for the notaries to visit the patients at home/hospices in order to complete, sign and notarize the patients' wills. The presentation will further explore different legal and practical aspects of addressing the will-related issues for palliative care patients in Georgia.

Contact: mariamgavtadze@hotmail.com

Session: Thursday, "St. Barbara", 14:30-16:00

60 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Contact: gilles.genicot@ulg.ac.be

Session: Friday, "Anna De Paepe", 10:45-12:15

Living organ donation by mentally incompetents: the clear benefit standard and the improvement of the European regulatory framework

Gilles Genicot

In a desperate effort to reduce organ scarcity, given the growing demand for transplantation and the insufficient supply of post mortem organs, we increasingly turn to living donors and may even perceive mentally incompetent people as an additional and easy source of organs, particularly if they are a perfectly compatible match. Since

such vulnerable people are deemed to be incapable of giving free and informed consent that would justify taking part in a procedure that is not in their own medical interest, and since the removal of solid organs (kidneys or liver lobes) generates high risks for the donor, this is bound to raise serious ethical issues.

A survey of the legislative framework currently governing organ donation by mentally incompetents in Belgium and neighbouring countries reveals that widely diverging viewpoints exist on the proper legal solution to this problem, ranging from a total prohibition to various degrees of permissiveness. This regulatory framework is unsatisfactory, because it fails to strike an adequate balance between the conflicting interests at stake: respect for vulnerable persons, among which the elderly, and duty to help people in desperate need. In addressing the underlying moral dilemma that results from the necessity to balance these principles, it appears that both a radical utilitarian approach and a categorical prohibition seem inadequate and should be rejected, and that the clear benefit standard more fairly balances these competing obligations and is thus the most coherent approach. It can exceptionally allow procurement of organs from mentally incompetents, as a last resort, in case the intended recipient is a close relative or primary caregiver of the prospective donor, and in compliance with extensive procedural safeguards aimed at protecting his health and welfare. Our current legal provisions are not compliant with that standard, and should be revised.

abSTracTS | 61

Contact: j.k.gevers@amc.uva.nl

Session: Thursday, “Willem Van Croy”, 14:30-16:00

surroGaTe decision MaKinG For incoMPeTenT elderLY PaTienTs: The role oF inForMal rePresentaTives

sjef gevers & Jos Dute

Informal or unofficial representation refers to the practice (more common in some European jurisdictions than in others) that persons not designed by a court or by the patient himself act as his proxy in case of incompetence. If the law provides for this, it is usually next of kin (spouse, children etc.) who are allowed to act in such a capacity. In addition to legal arguments (e.g. the ‘right to family life’ in art. 8 European Convention on Human rights), there are several other reasons why informal representation should be possible: in many cases there may be no proxy designated by the patient; if the need for representation is urgent and only needed for a specific situation, addressing a court would seem inadequate or impractical; finally, family members may be expected to best know the values and wishes of the patient and to act in accordance with them.

at the same time, informal representation raises several questions such as: are family members always familiar with what their relative would have wished, free from personal interests, ready to take responsibility and not too easily overpowered by emotions? and did the patient really know and accept that they would represent him? The basic legal concern, however, is whether in case of informal representation there are sufficient procedural and other safeguards to protect the incompetent patient from representatives who do not serve his best interests. This question has become the more relevant since not only the Biomedicine Convention, but also the recommendations (99) 4 and (2009) 11 require appropriate protection of incapable adults against the adverse effects or even misuse of surrogate decision making.

In addressing these issues, after briefly surveying the law on informal representation in a number of European countries, we will focus on Dutch law that gives a prominent role to surrogate decision making by next of kin. Taking account of the relevant conventions and recommendations, we will argue that informal representation as such is not at variance with international/European standards. It does even have a number of advantages when compared with other forms of representation (e.g. in that it is flexible, does not disproportionately encroach on legal competence, and avoids stigmatization and administrative burdens). However, an ‘informal’ approach to surrogate decision making should always go together with sufficient protection of the incompetent patient. This means that, for instance, national law should provide safeguards concerning the decision that the patient is incompetent, the limits of the decision making power of informal representatives, and effective forms of conflict resolution.

62 | Abstracts

Third European Conference on Health Law
An Ageing Europe. Health Law Revisited

Euthanasia in a context of realization of human rights for a life

N.G. Goncharov & A.N. Pishchita

The human rights for a life, on health protection, reception of medical aid are declared in acts of the majority of the democratic states of the world. At the same time, legalizations euthanasia it is actively discussed at the state and international levels. The majority of the states opposes euthanasia, however the part of the countries and separate territories of the states has already legalized it or actively work in this direction.

In the modern world there is no common opinion on a problem of a parity euthanasia both the right to human life and the citizen. The most actual problems of legalization euthanasia in aspect of maintenance of human rights for a life are the following.

1. Means human rights for a life an opportunity to dispose of the life exclusively in the personal interests?
2. The person the right to stop the life at any moment has?
3. Other persons have the right to render such person assistance in realization euthanasia?

The problem of legalization euthanasia demands the weighed decision which considers the basic problems of this legal and public phenomenon, contradiction of national legislations, a position of legal and public institutes, including the international organizations, religious establishments.

Contact: alexpischita@mail.ru

Session: Friday, "St. Barbara", 14:00-15:30

abSTracTS | 63

Medical research daTa-sharinG in The era oF aGinG PoPulaTions

shawn Harmon & kuan-Hsun Chen

Biomedical research is not only a means of extending human life so that we might grow older, but also a means of enabling elderly people to actively improve their quality of life. for example, participation in medical research promotes social integration and connectedness and feelings of usefulness and self-esteem, and this is true of elderly participants, who are all too frequently a marginalised group in society. additionally, participation in medical research serves as a means to honour socio-moral duties, and the research undertaking itself must be better understood as having that function for all participants, including researchers. In this paper, we argue that, for reasons relating to (1) the practical realities of, and pressures created by, aging populations, (2) the character of elderly person participation in medical research and the corresponding duties this imposes (or should impose on researchers), and (3) the demands of human rights, including rights to health and rights relating specifi cally to the elderly, data-sharing in the medical research setting must be increased. additionally, we argue that the law is an important means of achieving this increased level of data-sharing.

Contact: shawn.harmon@ed.ac.uk

Session: Thursday, "anna De paepe", 11:00-12:30

64 | Abst racts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Health care across "The Pond": legal rights and obligations of US Citizens who seek medical care in Europe

Dean M. Harris

US citizens are not covered by routine legal requirements for cross-border care within Europe, such as the EHIC, E112, Kohll/Decker cases, or bilateral agreements. Also, US citizens may enter most European countries without a visa or proof of health insurance. Despite reform efforts, millions of Americans still have no health insurance. Most ageing Americans have insurance from Medicare, but Medicare generally does not pay for services outside the US, even in emergencies. Some ageing Americans retire in Europe, while others may seek less expensive services through medical tourism.

Legal rights and obligations of Americans are determined primarily by laws of the particular European country. For example, the UK adopted regulations for the National Health Service on "Charges to Overseas Visitors." These regulations provide that the NHS is obligated to recover charges for services to overseas visitors, and overseas visitors

are obligated to pay, unless an exemption is applicable. In an emergency, an overseas visitor is not obligated to pay for outpatient services at a hospital or other facility, but the overseas visitor is usually obligated to pay for inpatient hospital services if the emergency condition required admission as an inpatient.

In 2010, UK began a consultation regarding overseas visitors and requested comments on consolidation of the regulations. The government issued its response in 2011, and stated it would undertake further review of fundamental issues. Legal alternatives under consideration include a revised definition of “residence,” requiring health insurance for overseas visitors, and using immigration authorities to help collect debts owed to the NHS by non-residents.

Like other countries, the UK is trying to balance healthcare goals with the need to preserve limited resources. Efforts to achieve that balance in European countries may lead to significant changes in legal rights and obligations of US citizens seeking medical care in Europe.

Contact: Dean_Harris@unc.edu

Session: Friday, “Anna De Paepe”, 14:00-15:30

abSTracTS | 65

healThY aGeinG - a PaTienTs’ riGHts

PersPecTive

mette Hartlev

Experts agree that a broad variety of initiatives and interventions is needed to deal with the challenges caused by the demographic development. It is necessary to look at both preventive strategies as well as measures to tackle an increasing number of elderly patients in the health care and social services. This paper will focus on preventive strategies and aims at exploring patients’ and human rights perspectives of public health initiatives to promote “Healthy Life Years” (HLY).

research has shown that increases in health care spending due to aging can be halved, if HLY increases proportionate with life expectancy. Hence, from a public health perspective it is of utmost importance that the population is and stays fit and healthy as long as possible. However, along with the demographic development we are facing a boom in life style diseases which constitutes an impediment for a positive HLY development. Smoking and obesity is considered to be the major causes in this regard.

Both internationally and nationally there has been a strong commitment to reduce smoking, and it seems that a combination of information, economic incentives and legal regulation has been successful. To find a “patients’ rights-compliant” strategy to combat obesity is more challenging. In contrast to smoking, obesity is not directly dangerous for other persons’ health, and interventions are, thus, harder to justify. However, the demographic development calls urgently for preventive interventions, and it is worth considering whether elements of the smoking strategy could be suitable in this area as well.

The paper will consider selected preventive measures to fight obesity, and discuss whether patients’ right to privacy, self-determination and family life is sufficiently balanced towards public health interests and interests of other persons. The question of discrimination of elderly patients based on non-compliance with public health initiatives will also be addressed.

Contact: mette.hartlev@jur.ku.dk

Session: Thursday, “Willem Van Croy”, 14:30-16:00

66 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

ICT and population ageing: what could be the added value from the directive on the application of patient’s rights in crossborder healthcare?

Jean Herveg

The European Commission and Member States are well aware of the necessity to face the consequences of population ageing. The Commission seems to be convinced that ICT might be part of the solution. It cites that telemedicine could improve access to specialised care in areas suffering from a shortage of expertise, or in areas where access

to healthcare is difficult. Furthermore, in its view, telemonitoring could improve the quality of life of chronically ill patients and reduce hospital stays. And services such as teleradiology and teleconsultation could help to shorten waiting lists, optimise the use of resources and enable productivity gains.

The current contribution proposes to investigate to which extent Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare could open opportunities for ICT in helping solving the problems raised by population ageing. In this respect, the paper will focus more specifically on provisions regarding European reference networks, cooperation on national ICT systems interoperability and the eHealth network.

European reference networks are networks connecting healthcare providers and centres of expertise. They should help improving access to diagnosis and provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise. They also could be focal points for training and research, information dissemination and evaluation. In this respect, the Directive provides that one of their objectives could be facilitating mobility of expertise, virtually or physically, which implicitly refers to the use of ICT.

The Directive also encourages the creation of an eHealth network. The latter should interconnect national authorities in charge of eHealth with in view facilitating cooperation and the exchange of information.

Contact: jean.herveg@fundp.ac.be

Session: Thursday, "Willem Van Croy", 14:30-16:00

abSTracTS | 67

ehealth PlaTForMs and how To resolve The dichoToMY BeTween sharinG daTa and ProTecTinG PrivacY

Juergen Hohmann & stefan Benzschawel

an electronic health records (EHr) platform is one of such new forms of collection storage and exchange of information, which have gained importance in the field of health care. It aims to share for each patient his/her most relevant medical information by interdisciplinary and intersectoral health staff. furthermore, the exchange and transfer of sensitive data as well as the combining of samples with other metadata (data-mining) are seen as key success to discover unknown factors influencing disease susceptibility and development. But equally sharing implies the danger of misuse. Will eHealth platforms, under the guise of medical progress, enable everyone to access health data when deemed necessary?

The paper provides an analysis of the impact of eHealth on the Eu data protection legislation, where personal health data enjoy the highest level of protection, which by various international conventions is furthermore enshrined as fundamental human right. Indeed, IT systems can protect against misuses and even enable secure statistics. The cornerstones are (a) certificate-based user authentication, (b) role-based user management with pre-registered users, (c) separated storage of identification data and medical data, (d) encryption of medical data, (e) individual access restrictions through IT-consent declarations, (f) logging and automatic notifications as psychological barrier against unjustified "emergency" accesses, (g) technical non-disclosure guarantee with respect to administrators and intruders. for statistical usage, IT data protection is based on four pillars: (1) encrypted medical reports are never used, (2) stripped fragments of the medical reports are stored in parallel, (3) fragments are definitively without any person identifying data, (4) Governmental IT-consent are mandatory for using the data fragments.

Currently, the European Commission envisages to simplify the system of notification and to promote the concept of "privacy by design" (CoM (2010) 609). It will also require new technical solutions for the ex-post detection of data protection infringement as well as effective security break operations in case of non-compliance.

Contact: juergen.hohmann@igss.etat.lu

Session: friday, "Willem Van Croy", 14:00-15:30

68 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

SAFE AND EFFECTIVE MEDICATION FOR THE

ELDERLY: THE LA TEST ON THE AVASTIN–LUCENTIS DEBACLE

Rita-Mariï Jansen

A problematic area of medication therapy for the aged is the off-label use of medication. The Avastin–Lucentis debacle illustrates the ethical, policy and even legal dilemmas encountered with such use. Avastin is authorised for the systemic treatment of metastatic colorectal and breast cancer by intravenous infusion. Ophthalmologists are using intraocular injections of Avastin (off-label) to treat age-related macular degeneration (AMD), a chronic disease among the elderly. AMD is the leading cause of blindness in people over 50 years of age. Anti-VEGF (vascular endothelial growth factor) therapy such as the use of Avastin has led to impressive results. Off-label use has become an important part of mainstream, legitimate medical practice worldwide and accounts for an estimated 21 per cent of drug use overall, especially in certain therapeutic fields such as geriatrics. The off-label use of Avastin is controversial because there are anti-VEGF drugs on the market authorised for AMD, such as Lucentis. Lucentis is, however, extremely expensive and costs approximately 50 times more than Avastin. Many patients therefore cannot afford Lucentis. Ophthalmologists do not have the backing of randomised, controlled trials or the blessing of the manufacturer of Avastin. In May 2011, the results from the first year of Comparison of AMD Treatment Trials (CATT), a large, randomised clinical trial comparing Lucentis and Avastin, were released. On efficacy, the results for the drugs were the same. The study was, however, not statistically powerful enough to identify meaningful differences in systemic, drug-related, adverse events and long-term safety. Ongoing trials will bring clarity in the future. Currently, there is conflict between cost-conscious health authorities in European Union (EU) member states and the EU drug regulators that ensure that medicines are safe and effective. There are examples of cost-cutting solutions by health authorities which risk undermining the fundamental principles of the regulatory framework. It is however of no use having noble, but unrealistic and unattainable goals. In the meantime, risk is being shouldered by patients and doctors.

Contact: jansenr@ufs.ac.za

Session: Thursday, “Anna De Paepe”, 14:30-16:00

abSTracTS | 69

conflict of interest issues in Biomedical research involving vulnerable elderly

Subjects

sandra Liede

Experimental biomedical research in the clinical setting exposes human participants to an uncertain amount of harm and risk, leading into categorizing research subjects as somewhat vulnerable. Vulnerability may appear e.g. as risk of being disposed to exploitation by the people conducting research, as in cases of financial conflict of interest. Some individuals, such as the elderly, are considered to be in a state of greater vulnerability due to health matters and limited decision-making capacity - and thus limited autonomy. The dignity and safety of vulnerable elderly research subjects is protected both nationally and internationally commonly by e.g. added or surrogate consent requirements. However, these requirements may not prevent the possible exploitation of elderly subjects in a conflict of interest situation. This paper aims to analyse the many binding and non binding regulative instruments and expressions governing conflict of interest in clinical research. Special attention will be paid to the judicial efficacy of conflict of interest clauses and consent requirements. The interests characteristic of elderly research subjects, the prohibition to do no harm as an underlying universal principle of research as well as the magnitude of surrogate consent will be analysed. The focal point of the paper will be the Finnish legal system in the European context.

Contact: sandra.liede@helsinki.fi

Session: Thursday, “anna De paepe”, 11:00-12:30

70 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Access to healthcare in Poland - any

alternative to public health insurance?

Natalia Lojko

Similarly to many countries in Europe, Poland is facing a great challenge resulting on the one hand from aging population, and on the other - shortage of public funds. Meanwhile, Polish healthcare system is predominantly public. Traditionally, no private funding has been allowed within public hospitals and private healthcare insurance is virtually non-existent. There has been no healthcare market. Nor, in the past, was there any specific list of services guaranteed under public insurance. In my presentation I will look at whether there are any alternatives to publicly financed healthcare in Poland - especially in private instruments and behind the borders, in other EU countries.

Contact: natalia.lojko@yahoo.com

Session: Thursday, "Florquin", 11:00-12:30

abSTracTS | 71

Contact: lieslot.mahieu@med.kuleuven.be

Session: Thursday, "St. Gommarius", 14:30-16:00

when The sexual side KickS in... a sYsTeMaTic review OF The eThical deBaTe on aGed sexualiTY in residenTial care

Lieslot mahieu & Chris gastmans

admission into a nursing home might challenge the way in which individuals experience their sexuality, but it does not automatically diminish their need and desire for sexual fulfillment. Despite the fact that sexuality is an intrinsic part of human existence, the sexual expression of geriatric residents remains a touchy subject for a lot of caregivers and family members. It evokes a variety of ethical issues and concerns, especially when dementia patients are involved. This paper is based on a systematic review of argument-based ethics literature focusing on sexuality in institutionalized elderly. The overall objective of this review was to examine the ethical arguments and concepts grounding the debate on sexuality within a nursing home environment. A systematic search was conducted in a number of electronic databases leading to the final inclusion of twenty-five appropriate studies. A thematic analysis of the included literature led us to distinguish two major groups of ethical arguments, related to principles and to care. Ethical arguments related to principles are particularly guided by the principle of respect for autonomy and the concomitant notion of informed consent. Arguments related to care were also apparent within the research literature although they received considerably less attention than the arguments related to principles. Human characteristics such as dignity, singularity, intersubjectivity and historicity are considered of paramount importance within the care approach. We conclude that there is a pressing need for better defined, more fundamental normative philosophical-ethical conceptualization of the values at stake, one that is capable of restoring the voice of incompetent elderly patients.

72 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Informed consent issue for elderly patients

Vugar Mammadov & Aytan Mustafayeva

Today we can accept the priority and the exceptional importance of patient rights that are central among rights and freedoms of citizen, and which are an integral component of successful development of the civil society. Each of us is well aware of importance of these rights when he/she has to act as a patient. When it comes to health - the main human welfare, we want to be sure that our rights and legitimate interests are properly protected by law.

One of the main patient rights in the modern world is the right to informed consent to medical intervention based on the recognition of personal and physical immunity of man, the autonomy of the individual. Informed consent to medical intervention is the cornerstone of the whole system of legal support for medical activities in the developed constitutional states. The informed consent, which is a prerequisite for any medical intervention, means the patient voluntary adoption of treatment after the doctor gives full information about the intervention.

There are groups of patients that cannot be considered competent to give consent for medical intervention, but elderly people are not belonging to such groups. This means

that decision-making on the health of elderly patients must not be taken by their children that is normal behaviour in our part of the world, not by management of the hospitals, but by elderly patients themselves.

As for Azerbaijan, the Constitution (Article 148) stipulates that the accepted norms of international law are an integral part of its legal system. During the last decade there is a process of active integration of Azerbaijan into the global legal space. Our country recognizes the willingness to respect international standards on human rights, which implies the need to harmonize national law and social order in conformity with the principles of modern law, ethical standards of civilization.

In the Basic Law of the country there is a special Article (41) "The right to health protection". It states, in particular:

«I. Everyone has the right to health protection and medical care;
II. The State takes the necessary measures to develop all types of health care, based on various types of property, guarantees sanitary-epidemiological welfare, creates conditions to develop various forms of medical insurance;
III. Officials concealing facts and incidents that pose a risk to health of man and the nation shall be prosecuted according to law».

Contact: vumammadov@yahoo.com

Session: Thursday, "St. Gommarius", 11:00-12:30

abSTracTS | 73

Contact: lynn.martens@callens-law.be

Session: Thursday, "florquin", 14:30-16:00

The current status and new Trends of direct To consumer advertising For Medicinal Products in The eu

Lynn martens

There exist detailed care professionals regulation at the Eu-level regarding advertising and promotion of medicinal products. These rules are laid down in the Community Code 2001/83/EC and in national legislation of the Member States.

The presentation explains firstly important concepts such as e.g.: 'information' vs. 'advertising', 'DTC-advertising' vs. 'oTC-advertising', advertising vis-a-vis patients vs. advertising vis-a-vis health care professionals, as well as the legal rules applicable to these concepts.

In the second part of the presentation recent Eu case law (e.g. Doc Morris case, aBpI/MHra case,...) and its consequences is analyzed

In the third part of the presentation the recent initiatives at the Eu level regarding DTCadvertising will be described and in particular the proposal for the Directive regarding information to the general public on medicinal products subject to medical prescription.

74 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Medico-legal issues of rare diseases treatments

Hajrija Mujovic - Zornic

This paper addresses complex issues of diagnosis and treatment of so-called rare diseases concerning the elderly population, primarily from an ethical and legal standpoint, given the context of patient rights, medical decision-making and resources of the health system. It starts with the basic human rights of every individual regardless of his age. The basis of the legal status of any follow from appropriate legal framework and estates. Then runs the specifics when it becomes related to aging population. Amounts to the claim that the problems of rare diseases for this population are multiplied and more difficult because it is a rare diseases, which is often paired with the main diseases that have these persons. For example, it can be seen through the cases of difficulty of diagnosing conditions such as rare form of dementia. In addition, there is a difference in the treatment of patients, such as Serbia, where health care of the same state of illness to the case of newborns or young patients is so much better than in the case of older patients. It seems important that people suffering with rare diseases are entitled to the same quality of medical treatment as those suffering with more common conditions. The health system in Serbia is characterized by underdevelopment health care services related to rare diseases, it also creates major problems in health protection of elderly.

Contact: hmujuvic@idn.org.rs

Session: Thursday, "Florquin", 11:00-12:30

abSTracTS | 75

Contact: mp@zorgnetvlaanderen.be

Session: Thursday, "florquin", 14:30-16:00

leGal and eThical consideraTions on inTernaTional recruiTMenT of health care work Force

miek peeters & yvonne Denier

Due to population ageing, current shortages in health care personnel (in particular specialist doctors and nurses) are expected to increase enormously in the coming years. In our presentation, we will outline the various legal and ethical dimensions of international recruitment of healthcare work force.

Within the law of the European union's internal market, health care workers have the right to work or establish themselves in another Member State. Driven by the Single Market act, the Eu tends to facilitate labour mobility even more in the future. In this perspective, the Commission recently launched the Green paper on the modernisation of the professional Qualifications Directive. In the meanwhile, there is also the specific debate on Eu-level about where to go with European health care work force, initiated by the Commission's Green paper on the European workforce for health in 2008.

Since health care work force is fundamental to an integrated and effective health system and shortages constitute a major threat to the performance of health systems, labour mobility and especially international recruitment require important ethical considerations. More specifically, we have to provide answers to various questions regarding the particular clinical-ethical context (the relationship between health care workers and their patients), the institutional context (institutional employment policy and support), the more general national context (issues of social justice, national education and employment policies), as well as the international context (issues of global justice and international recruitment).

76 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Rationing: a marginal argument in the end-of-life debate?

Helena Peterkova

With no doubt the end-of-life decision making is considered to be one of the most complex and most difficult legal and ethical issues, especially when a dispute arises between different expectations of the patient or their next of kin on one hand and a clinical judgement of the health worker on the other hand. Leaving the area of requesting assisted suicide or mercy killing aside, the question of defining the proper care in the terminal phase of an illness is supposed to be crucial. Indeed, to be confronted by patients and their families demanding a futile care actually seems to have become the part of every day clinical practise of the doctors.

The health care provided to the patients at the last stages of their lives is considerably expensive – in accordance with the statistics available the expenditures paid for the treatment of dying patients represent the major category of the budget of the national health care systems in the developed countries. In a resource constrained system where the scarce resource situation occurs, the group of terminally ill might be at risk as far as rationing will be done only with respect to the criterion of life expectancy and cost effectiveness.

It is most unfortunate that according to some legal opinions the doctors use a futile care argument often as an explanation for the de facto rationing which is inevitably to be made by doctors but often because of the eventual criminal consequences not to be admitted at the same time.

Contact: helenpeterkova@seznam.cz

Session: Friday, "Florquin", 14:00-15:30

abSTracTS | 77

ProTecTion of The riGhTs and leGiTiMaTe inTeresTs of ciTiZens of advanced aGe aT

Participation in clinical researches in The Russian Federation

A.n. pishchita & n.g. goncharov

The urgency of a problem of protection of the rights and legitimate interests of citizens of advanced age is defined not only demographic and medical aspects. The problem of additional legal protection of the rights of citizens of advanced age at rendering of medical aid by it and carrying out of clinical researches every year gets the increasing value. Patients of advanced age are the capable citizens possessing all rights of the citizen and the person. However, in connection with numerous diseases and age features of mental activity they, more often, not in a condition it is high-grade and actively to protect the inalienable laws to a life and health. Especially this problem is actual at carrying out of clinical researches with participation of patients of advanced age, not capable to protect the legitimate interests. In given clause legal aspects of protection of the rights and legitimate interests of such patients within the limits of the current legislation of the Russian Federation are considered. Observance of the legal rules of carrying out of clinical researches with participation of patients of advanced age allows providing to patients realization of their civil rights, and to medical workers to carry out the professional work on the lawful bases.

Contact: alexpishchita@mail.ru

Session: Thursday, "anna De paepe", 14:30-16:00

78 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

National electronic patient records: some legal issues

M.C. Ploem

New information and communication technologies are rapidly being introduced in health care. A major innovation in this respect is the so called electronic patient record (EPR): hospitals and health care institutions make use of electronic records and electronic systems to register, store and exchange information on patients. More and more, these new ways of data processing are being used for sharing medical data within regions and countries. In the Netherlands, the government developed a strategy and a law to realize a nationwide electronic patient record (n-EPR). Because the project raised important legal and practical questions and caused considerable concerns within society, especially among medical professionals, the proposed legislation never reached its final status (the law was rejected in March 2011 by the First Chamber of Parliament). Similar developments took place in other countries implementing an n-EPR. Although these problems do not imply that innovations such a national (or European) EPR should not be encouraged, they do raise the question under which conditions technological progress in this field can go on. In this respect, lessons can be learned from the experiences with the introduction of an n-EPR in the Netherlands. This paper discusses some of the main legal issues raised by the (former) plans of the Dutch government to introduce a nationwide patient record as well as their possible solutions in terms of legislative and self regulatory activities.

Contact: m.c.ploem@amc.uva.nl

Session: Friday, "Willem Van Croy", 14:00-15:30

abSTracTS | 79

Continuous sedation at The end of life For older Patients: an analysis of Two Guidelines

kasper raus & sigrid sterckx

Introduction

It is widely acknowledged that every person has a right to palliative care and adequate pain relief. If we are to achieve this, special attention must be paid to the issue of the ageing population, since, for example, in Belgium in 2007, half of all people dying were aged 80 or older. nevertheless, statistics also show that, in Belgium and The Netherlands, pain relief with a possible life shortening effect and continuous deep sedation occur significantly less frequently in older patients. It is important to investigate why this is so, since under-treatment of pain in older patients is a well-known problem.

Goal

We will investigate whether the current Belgian and Dutch guidelines on continuous sedation at the end of life are suited to address the specific needs and characteristics of older patients. We will focus on a recent Belgian and Dutch guideline on continuous sedation and investigate whether certain elements in these guidelines could make it less likely that the practice will be used for older patients. Attention will, inter alia, be paid to issues of patient consent and proportionality. These are central issues in the sedation guidelines, but they often pose problems in relation to elderly patients. Research in Belgium indicates that only 32% of older (80+) patients for whom an end of life decision is made are competent when the decision is taken. This implies that consent is often difficult to obtain, as well as that assessing proportionality of the sedation to the severity of symptoms may be problematic, since this often includes self-reporting.

Contact: Kasper.raus@uGent.be

Session: Friday, "St. Barbara", 14:00-15:30

80 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

End-of-life decision-making: recent legal developments in Canada

Nola Ries

This presentation will discuss the current state of Canadian law in two areas relevant to end-of-life decision-making: (1) withdrawal of life-sustaining treatment; and (2) physician-assisted suicide. A goal is to share experiences from the Canadian context and invite discussion about similarities and differences with European law.

Withdrawing treatment: Canadian law protects the right of a patient with decisionmaking capacity to consent to or refuse life-sustaining interventions. Difficult legal issues arise, however, when the patient lacks capacity and conflicts arise between health care providers and a substitute decision-maker (SDM) about the appropriate plan of care. Analysing a series of court rulings from 2008 to 2011, the presentation will discuss whether care providers require consent from a SDM to withdraw treatment from a patient who has no prospect of recovery. The case law involves situations where health professionals argue that continuing intervention is "tantamount to torture", but the SDM refuses to consent to withdrawal of treatment. The presentation will also consider whether a patient's advance directive can compel continuation of treatment that is considered medically futile.

Physician-assisted suicide: Assisting suicide is currently a criminal offence in Canada. In a landmark 1993 constitutional challenge, the Supreme Court of Canada (SCC) upheld the law by a narrow majority. A court challenge filed in April 2011 now seeks to strike down the criminal prohibition and argues that "the principles of liberty, autonomy and equality, as well as the humanitarian commitment to preventing unnecessary suffering and to preserving the dignity of the individual, justify decriminalization." The litigants include two Canadians who accompanied a terminally ill family member to a Dignitas clinic in Switzerland to obtain an assisted death. The presentation will discuss the possible outcomes of this case, suggesting it is likely that courts will no longer find persuasive the arguments that prevailed in the 1993 SCC decision.

Contact: nries@law.ualberta.ca

Session: Thursday, "St. Barbara", 14:30-16:00

abSTracTS | 81

The legal value of advanced directives in the delimitation of the patient's consent

Virgilio Rodríguez-Vázquez

Advanced Directives (AD) are concerned with borderline situations of life termination. Their legal recognition is the outcome of a social debate encapsulated by the legend "for a dignified death." However, the so-called 'Ley Básica de autonomía del paciente' (Basic Law for the patient's autonomy) does not limit the application of AD to the abovementioned borderline situations, as such name identifies the document with which patients choose the kind of care and health treatment that they are willing to be subjected to at any given moment, not only in a terminal situation. The same denomination covers two very different situations which determine, in my opinion, an important difference in the value attached to the AD document. On the one hand, it covers the expression of a given patient's will in relation to an extreme situation of life termination, i.e. a situation

where the patient is in a state of irreversible unconsciousness, completely dependent on others and being fed and hydrated artificially. On the other hand, the above expression covers those cases where a patient is in a state of reversible unconsciousness, which is temporary and can be reversed by means of the required medical action.

The present paper aims at examining the legal value of aD in the latter situation, namely in relation to medical treatment in those cases where patients cannot express their consent due to their being in a state of unconsciousness or temporary disability.

The paper is divided into four parts:

1. The introduction makes a terminological clarification of the phrase advanced Directives.
2. The second part deals with the issue of “informed consent” as the necessary precondition to carry out any medical intervention, as well as with the potential scenarios where such consent cannot be obtained, in which case it is necessary to resort to what is known as “presumed consent”
3. The third part analyses the legal value that aD can have in determining the extent of a patient’s consent, drawing a distinction between two widely accepted views: on the one hand, the view which attributes a relative value to the aD document, considering it as a guide in the inquiry over alleged consent; on the other hand, the view that argues that the advanced directives should have an absolute value regarding the patient’s will when s/he cannot express such will.
4. In the fourth part, I present my conclusions.

Contact: virxilio@uvigo.es

Session: Thursday, “St. Barbara”, 11:00-12:30

82 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Acronyms of dying versus patient autonomy?

Amina Salkić & Anna Zwick

After decades of discussion the German legislator recently passed an act regulating living wills (Patientenverfügung) and the decision making process at the end of life. Its declared objectives are the respect of the right to self-determination of incompetent patients and the increase of legal certainty at the end of life.

An important difference to the regulations in other countries is that the involvement of a surrogate decision maker is compulsory, even when the living will seems to be unequivocal. However, the patient can influence the appointment of this surrogate decision maker by using one of the following advance directives: power of attorney (Vorsorgevollmacht) or custodianship directive (Betreuungsverfügung). There are no other advance directives regarding end-of-life decisions apart from these three forms. During the last couple of years the use of abbreviated orders such as DNR (do not resuscitate) has increased significantly not only abroad, but also in Germany. There are also many other forms like DNAR, DNI, AND, NFR or CPR. It happens that physicians write these initials in the patient’s medical chart without having consulted the patient or his health care surrogate. Such acronyms don’t meet the conditions for advance directives laid down in the German law.

Published data describe less intensive care for DNR patients and the danger of misinterpretation and confusion with living wills in the sense of “do not treat”. This practical experience raises many issues. Which different forms of code status designations exist? What is their legal value? Is existing law evaded? Under which conditions are these acronyms obligatory and for whom? Especially in a legal system where living wills are binding, the value of code status designations for the patient must be analysed: Do such acronyms actually strengthen the patient autonomy or could they rather be seen as a paternalistic relic which compromises autonomy?

Contact: anna.zwick@imgb.de

Session: Friday, “Florquin”, 14:00-15:30

abSTracTS | 83

end of life decisions: The Italian case

Alexander schuster

as many other countries also Italy has been heavily debating the issue of end of life decisions in the last decade. no legislative measure deals specifically with this field.

Therefore, critical cases had to be decided by medical centres and ultimately by courts based on general principles drawn from a variety of legal sources, both national and

international.

Especially after the case of Eluana Englaro, a woman who entered into a persistent vegetative state in 1992 and eventually died in 2009, Italian society became aware of the legal and ethical implications of advanced directives. Since 2008 parliament is discussing a bill introduced by the government that has been recently approved by the Lower Chamber and is expected to pass by the end of the year.

The paper will sketch out the legal situation in Italy and the bill and carry out a comparative analysis. It will demonstrate that the Italian legal system has filled the vacuum through general principles of law and that the bill is not in line with constitutional and international standards. Dignity and consent are values that are not subject to political majorities and that are common ground in the European context.

Contact: alexanderschuster@gmx.net

Session: Thursday, "St. Barbara", 14:30-16:00

84 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Patient Rights in Telemedicine: Experience of Ukraine

Iryna Senyuta

An innovative telemedicine project has been launched in our state with due account of Euro integration vectors of the development of Ukraine, implementation of international legal standards in health care and in human rights, implementation of national medical reforms. The state has started applying a complex approach to implementation of telemedicine into medical activity: starting with regulatory regime up to practical mechanisms of its functioning.

The key document in the context of telemedicine is order of the Ministry of Health of Ukraine "On implementation of telemedicine in health care institutions" of March 26, 2010, No. 261.

Taking into account international standards (for instance, the Regulation on medical examination, "telemedicine" and medical ethics, World Medical Association, 1992), domestic legal base, we can crystallize the possibilities of patients in the sphere of telemedicine, in particular, right to: 1) accessibility of medical services necessary for the patient because of his health status, including geographical accessibility; 2) timely and qualified medical care, including free choice of doctor; 3) safety of telemedical services; 4) confidentiality and integrity of information on the state of health; 5) timely, complete, reliable and accessible medical information; 6) admission of other medical employees (to alternative doctor's opinion); 7) respect to patient's time; 8) innovation, including technological ones.

The role of telemedical care, its social effect is gradually increasing in Ukraine, the principles of its implementation are being formed, the forms of its implementation are being expanded, and together with it there increases the catalogue and the scope of possibilities for patients, implementation of their rights in health care is being improved.

Contact: prlawlab@ukr.net

Session: Friday, "St. Gommarius", 10:45-12:15

abSTracTS | 85

is ecJ's PaTienT MoBiliTY JurisPrudence endaGerinG inTroductiOn oF new Medical Procedures (TreaTMenTs) inTo naTional social securiTY heaTh PacKaGes?

Tomislav sokol

The European Court of Justice has, in the years following *raymond Kohll v. union des caisses de maladie*, developed a considerable jurisprudence regarding patient mobility within the Eu. These cases have dealt with the social security coverage of a health treatment obtained in a Member State in which a patient is not socially protected. The Court of Justice has emphasised the entitlement of persons to obtain health care outside the state of social protection (competent state) to be covered by the competent state social security system. one aspect of the case-law, concerning the extent of social coverage of health care by national social security systems has, however, arisen to become especially important. according to the Court of Justice, using broad legislative definitions of

social security health care coverage (without enumerating in detail concrete medical procedures which are covered) can lead to the competent state having to cover the most effective treatment that could fit into those definitions, obtained anywhere in the EU. The aim of the paper is to investigate the relevant case-law by the European Court of Justice and see whether this jurisprudence may have a negative impact upon the introduction of new medical procedures into the social packages of covered health care in EU Member States.

The paper first describes early Court of Justice case-law and secondary EU legislation that set some important principles which have influenced the subsequent patient mobility jurisprudence. The mentioned analysis is followed by an investigation of relevant aspects of patient mobility case-law, and, particularly, of the recent *Elchinov* judgement. Finally, using examples of UK and Slovenia, the paper submits that the latest judicial development could make introduction of new medical procedures into national social security packages harder and more cumbersome (which could be detrimental to the important role of new medical technologies, including new treatments, in increasing the lifespan of people with chronic conditions and multiple diseases), emphasising the need for the Court of Justice to modify its approach. This issue is especially significant in the context of providing more efficient health care to the elderly, whose numbers are increasing in Europe due to the process of population ageing and of the overall importance of medical innovation within the evolving European context.

Contact: tomislav.sokol@student.kuleuven.be

Session: Friday, "Anna De Paepe", 14:00-15:30

86 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Organ transplantation in an ageing Europe: what are the legal means to cope with the organ shortage?

Anne-Cécile Squifflet

Within the context of an ageing population, the organ shortage tends to become more acute. Roughly speaking, on the one hand, the demand for organs grows, as older and older people are qualified as potential recipients and are put on waiting lists. On the other hand, the offer does not increase at the same pace and its quality deteriorates over the time, as the donors are ageing too.

Faced with this situation, the States and the international organizations are willing to find ways in which they could increase the availability of organs, so as to serve a growing number of patients in need of a transplant. One of these ways consists in enacting new legal instruments or bringing changes to the existing legal framework, in order to encourage the activity of transplantation and to remove the remaining obstacles which impede it.

The aim of the present contribution is to examine what Belgium and the European Union have done in this respect.

As for Belgium, the act on organ removal and transplantation of 13 June 1986 has been modified several times with an acknowledged objective of fighting the organ shortage. Some of the changes made have been welcomed, some others raise several issues.

As far as the European Union is concerned, its action in the field of organ donation has taken the form of an Action Plan and a Directive on safety and quality to be transposed by the Member States for August 2012. These European initiatives give rise to some comments, which currently remain preliminary as the concrete effects of the EU action are not likely to be felt immediately.

Contact: anne-cecile.squifflet@uclouvain.be

Session: Friday, "Anna De Paepe", 10:45-12:15

abSTracTS | 87

can clinical eThics coMMiTTees help FacinG FuTuRe challenGes in The health care ProFessional's daiLY rouTine?

verena stbhlinger & magdalena Th uni

new technologies, intercultural issues and an aging population increasingly lead health care professionals to the boundaries of the legal system and to severe ethical challenges.

Difficult decisions such as withholding or withdrawal of life-sustaining treatments as well as the determination of the patient will in critical situations influence the clinical and nursing daily routine and challenge the process of reaching informed consent. Within the last decade, this phenomenon has led to an institutionalisation of the clinical decision making process and to the establishment of clinical ethics committees (CEC) in hospitals in Germany and Austria. Additionally, health care professionals are confronted with financial responsibility and implicit rationing on a micro level. Against this background and a population decline pressure on health care professionals will raise in the future. In this context CECs could play a significant role, by bringing more transparency in the clinical decision-making process and by supporting the professionals in critical situations thereby helping to assure a high quality patient care and respect for patients' rights. The UNESCO's division of Ethics of Science and Technology stated in 2005 that "Bioethics Committees are most effective when their incorporation into government is statutory [...] because this grants them stability and legitimacy [...]". So far, there is no legal requirement for implementation of CECs in Germany or Austria. Even though there exists some research basically assessing the implementation and functioning of CECs, no systemic and legal evaluation of CECs in Germany or Austria has been carried out. Hence, research assessing a statutory implementation and legal impacts of CECs still needs to be done. The paper at hand is aiming at closing this research gap by conducting a comparative legal analysis of existing European and US frameworks. Based on these insights the legal establishment of CECs in Germany and Austria will be discussed.

Contact: verena.stuehlinger@umit.at

Session: Friday, "florquin", 10:45-12:15

88 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Contact: sylvie.tack@ugent.be

Session: "Friday, "St. Barbara", 14:00-15:30

The palliative filter procedure for euthanasia requests: legitimacy and due care criteria

Sylvie Tack

In the past decade the Netherlands, Belgium and the Grand Duchy of Luxembourg legally accepted the carrying out of euthanasia by physicians in their territory. Under strict conditions, this act can be performed on adult terminally ill, non-terminally ill, psychiatric and incapable patients. In practice, however, many Catholic health care institutions require patients to successfully pass through the palliative filter before euthanasia requests can be granted. This policy is generally motivated by the concern to timely detect false euthanasia requests and to guarantee the effective exercise of the right to palliative care. The palliative filter usually concerns the obligatory advice of institutional experts regarding possible palliative care alternatives. In some institutions this even implies that all such services are to be administered first before euthanasia can take place.

Although a well-developed palliative filter undoubtedly increases the quality of the euthanasia process, it majorly affects the patients' legal position. However, this procedure is not explicitly prescribed by law and its legitimacy and due care criteria are questionable.

Due to their right to freedom of association and religion, health care institutions are generally allowed to formulate a mission statement, specify institutional goals and establish the necessary organisational structure. Consequently, health care institutions are generally allowed to develop policies elaborating their ethical stances on euthanasia and implement institutional procedures, such as the palliative filter.

Nevertheless, this institutional freedom is bound by the obligatory respect for the rights and freedoms of others, such as enforceable patients' rights. This implies that patients should at least give their informed consent before the palliative filter procedure can be started. Respect for patients' rights also involves that the palliative experts are independent and professional, and that their advice is timely formulated, clearly motivated and carefully saved in the patients' medical files.

saFeGuardinG riGhTs in decision-MaKinG For Those wiTh diMinishinG coMPEtence: eThics coMMiTTees and Procedural JusTice

David Townend

one of the challenging aspects of an ageing population is the way that mental competence slips away from the competent adult in late onset diseases and conditions such as dementia. Mirroring the emerging competence of adolescence, the problem of managing the increased dependence on the decision-making of other people in the case of the individual who has in adult life had the expectation of autonomy, is particularly difficult for the law. It is made more difficult as the individual may not understand the loss.

The safeguards that ensure continuing respect for the dignity and interests of the patient whose self-determination is increasingly challenged are, in daily decision-making, the fiduciary duties of the immediate family and health carers. This paper first asks whether such decisions need to be supported and overseen much more by ethics committees. For such a safeguard to function effectively, the quality of not only the decisions but also the process of decision-making must be visibly high. Traditionally, ethics committees are seen as advise-giving committees within the medical establishment, and there is a very great reluctance to see them as judicial or quasi-judicial bodies. This paper compares the functions of ethics committees with other tribunals. It separates the substantive and procedural aspects of the work. It examines commonly expected aspects of procedural justice in legal tribunals, and asks whether these are legitimate expectations for the procedures of ethics tribunals. It concludes that whereas the substance of the decisions made in ethics committees is very different from those made in law tribunals, expectations concerning procedural justice (for example, the duty to give reasons, transparency about conflicts of interests, the constitution of the committees, the appeal procedures, and the process of reaching decisions about ethics) should be the same in ethics and law fora.

Contact: d.townend@maastrichtuniversity.nl

Session: Thursday, "Willem Van Croy", 11:00-12:30

90 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Regulating the use of genetic tests: Is Dutch law an example for other countries with regard to DTC genetic testing?

R.E.van Hellemond, A.C. Hendriks & M.H. Breuning

Individuals have high expectations about the benefits of genetics. For several reasons, including the aging population, more and more individuals are increasingly eager to learn more about their genetic profile and future health. Companies seek to appease this 'hunger' of individuals by offering Direct-to-consumer (DTC) genetic tests via internet. Individuals often overestimate the benefits of these tests that are generally offered without adequate information. Several European States are considering the introduction of legislation to regulate the supply of and access to DTC genetic tests to protect their citizens against health risk. The Netherlands already has such legislation in place. The Act on population screening (the Act) seeks to offer protection against harmful screening by way of a permit system. We have examined whether the Act can serve as an example for other European countries. Furthermore, we have analyzed its effectiveness and compliance with the standards adopted within the framework of the European Union and the Council of Europe.

We concluded that in its present form, the Act cannot serve as an example for other European countries with respect to the regulation of DTC genetic tests. The Act suffers from a number of practical shortcomings, is inconsistent with some European Union legal standards and too liberal compared to the normative criteria of the European Court of Human Rights, the Biomedicine Convention and the Protocol concerning Genetic Testing for Health Purposes.

Contact: r.e.van_hellemond@lumc.nl

Session: Friday, "St. Gommarius", 14:00-15:30

abSTracTS | 91

exTraTerriTorial laws in cross-Border

reProductive care

wannes van Hoof & guido pennings

The growing prevalence of cross-border care means that countries can no longer determine what citizens do the way they did in the past. This has recently become painfully clear in the highly regulated field of assisted reproduction. Countries still impose restrictions on which people should have access to reproductive technologies and still consider certain treatments and techniques to be immoral, but now citizens can simply evade these restrictions by going abroad. Several countries, including Belgium, France, Germany, the UK, ... have had issues of comity when their citizens went to countries like Ukraine, the US or India for commercial surrogacy. Because some countries do and others do not recognize commercial surrogacy contracts, the children that result from this treatment sometimes remain 'stateless', in between two legal systems.

Some countries react to their citizens going abroad to evade restrictions by implementing even more restrictive laws. Turkey has recently become the first state to ban reproductive travel in pursuit of donor gametes. Several states in Australia have enacted or are considering laws that prohibit international commercial surrogacy. We will investigate the consistency and morality of extraterritorial legislation on cross-border reproductive care (CBRC).

The only widespread existing extraterritorial regulation of private life concerns female genital cutting (FGC), sex with children and (largely in the past) abortion. We develop an analogy with these cross-border crimes to evaluate the morality of similar legislation in cases of CBRC. The dissimilarity in these analogies shows that extraterritoriality is a radical position that is generally inappropriate in the case of CBRC. Subsequently, we consider alternative state reactions to CBRC for law evasion: preventing travelling, and discouragement and forbidding aiding and abetting. After consideration of all these different options, it is concluded that legislation of CBRC should be modest, tolerant and nuanced.

Contact: wannes.vanhoof@ugent.be

Session: Friday, "anna De paepe", 14:00-15:30

THIRD European Conference

on HEALTH LAW

abstracts

poster presentations

Centre for Biomedical Ethics and Law

European association of Health Law

abSTrAcTS | 93

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

1. Access rules stimulating the exchange of biological specimen within biomedical research

Michiel Verlinden, Nadine Ectors & Isabelle Huys

2. A Research Paper as a Standpoint for Further Law Amendments

Violetta Zopunyan

3. Bodies revealed: the interaction among human rights and commercial interests

Ronalds Rozkalns

4. Patient-Friendly Guides: A New Step in Promotion of Human Rights in Patient Care in Armenia

Arthur Potosyan

5. Patient Rights in Palliative Care under the Legislation of Ukraine

Iryna Senyuta & Olena Chernilevska

6. Policy response to aging population: access to health care for the elderly people in the Republic of Macedonia

Filip Gerovski

7. Population ageing as a change factor of health care systems - the case of Poland

Pawel Bialynicki-Birula

8. Private organizations in residential care for the elderly: general patterns and the

English case

Maarten Janssens & Johan Put

9. Quest for the right to end-of-life decisions in children with terminal illness

Ștefana Maria Moisă, Beatrice Ioan, Silvia Dumitraș, Rodica Gramma, Mariana Enache, Andrada Pervu, Gabriel Roman, Radu Chiriță, Ingrith Miron

10. Romanian palliative care system

Mariana Enache, Gabriel Roman, Beatrice Ioan, Silvia Dumitras, , Ștefana Maria Moisa, Rodica Gramma, Andrada Parvu, , Radu Chirita

11. Sailing in Rough Seas: The United States of America's Long Voyage to National Health Care

John P Conomy

12. Statutory Old Age in Ageing Europe

Marek Benio

13. The “proportionality principle” and superseding the “principle of consent” for donor genetic material and data held by bio banks

Polichronis Voultzos, Fotios Chatzinikolaou, Eleni Zagelidou, Nikolaos Raikos, Charoula Florou, Eleni kalyva, Nikolaos Vasileiadis

14. Usefulness of advance directives in Romania - Preliminary study in intensive care units

Silvia Dumitras, Mihaela Buzduga-Ciubotariu, Beatrice Ioan, Mariana Enache, Andrada Parvu, Rodica Gramma, Ștefana Maria Moisa, Gabriel Roman, Radu Chirita

Titles of Abstracts in alphabetical order

abSTracTS | 95

sTaTuToRY old aGe in aGeinG euroPe

marek Benio

falling fertility rate and rising life expectancy in the past decades is a steady tendency leading to ageing of societies in Europe, although at a different pace. family policies and immigration policies accepted in many countries fail to change this tendency. It is clear now that in order to save the pension systems based on intergeneration income transfer from collapsing, the extension of economic activity of older members of society and postponement of real retirement age becomes necessity. at the same time ageing of individuals no longer prevents them from work at the age of 60 or 65. Thus in many European countries legal measures to extend the duration of economic activity have been taken. Most of them postpone statutory minimum pension age or level it up for women. Such approach, it is claimed in this paper, does not necessarily lead to postponement of real retirement age. Many individuals faced with longer work in the same working conditions will abuse sickness leaves, claim disability pensions or become unemployed. This paper goes beyond the extension of statutory pension age. It examines economic effects and legal possibilities of abandoning statutory pension age as necessary condition to claim a pension. Instead, it sets proposals to force development of “Silver Economy” understood not only as economy of older consumers, but as economy of older workers, too. adjustment of labour conditions to the possibilities and needs of older workers, reduction of workload, late career training, part time retirement and part time employment of pensioners are only few measures to postpone real age of retirement without negative effects of postponing only statutory pension age. Empirical evidence in the paper shows that extension of real retirement age leads to higher employment and sustainable pension systems.

Contact: beniom@uek.krakow.pl

n° of poster: 1

96 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Population ageing as a change factor of health care systems - the case of Poland

Pawel Bialynicki-Birula

The paper addresses the issues of circumstances of health care change as a consequence of population ageing in Poland. Author will take up multiaspect deliberations on diverse factors that determine organizational and financial aspects of access to health care services by the elderly. Paper will be divided into three parts. In first, diagnostic one, the paper will contain thorough description and analysis of demographic structure and

related processes concerning population in Poland. The main goal of the preliminary research will be to grasp logic and direction of changes as far as ageing is concerned. In next step the main focus will be put on questions concerning organizational and financial aspects of restructuring health care sector in order to provide health care for elderly. The last part of the paper will concern legal aspects of providing health care for the elderly in Poland. Binding law regulations as well as institutional and organizational arrangements will be presented. Then the circumstances of access barriers will be discussed. Much attention is to be paid to the questions concerning access to affordable health care and the possibility of covering services for the elderly. The discussion will take into consideration the possibilities of broadening base of health care financing and promotion of voluntary health insurance being in the centre of public debate in Poland. As a result of carried analyses the essence of necessary health care changes regarding ageing population in Poland will be seized. The aim of the discussion is to formulate conclusions of applicable character concerning circumstances of carrying out public policies in health care regarding just and equal access to health care for the elderly.

Contact: bialynip@uek.krakow.pl

N° of Poster: 2

abSTracTS | 97

sailinG in rouGh seas: The uniTed sTaTes of aMerica's lonG voYaGe To naTional health care

John p Conomy

The voyage of the American nation to the harbor of national health care did not begin with Barack Obama but came to crucially important fruition during his presidency. Current reforms in United States (US) Health Care have dealt with inclusion and control of alarming health costs. Nationally enacted measures have led to divisiveness, animosity and frightening incivility involving the American public and their political representatives. Reform policies already set into law under "Obama Care" now stand court challenges under the "Commerce," "Enumerated powers" and "necessary and proper" clauses of the Constitution of the United States. Public opposition to Health Care reform and frank antagonism to it have been spearheaded by the newly-elected "Tea party" members of the US Congress. The outcome of heated legal and Congressional contests will determine if the US will join those nations of the world providing a fundamental role for government in the health care of all its people, or whether health care for the nation will continue to operate as a private sector jumble on the parts of the academic, scientific, clinical, business and political communities.

Contact: 2br02b@msn.com

n° of poster: 3

98 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Usefulness of advance directives in Romania - Preliminary study in intensive care units

Silvia Dumitras, Mihaela Buzduga-Ciubotariu, Beatrice Ioan, Mariana Enache, Andrada Parvu, Rodica Gramma, Stefana Maria Moisa, Gabriel Roman, Radu Chirita

Objectives: The evaluation of the ICU-physicians' attitude towards the Advance Directives (AD), as well as the opportunity and feasibility of the AD implementation in the context of the Romanian legislation.

Material and method: The study was developed on a lot of 196 ICU-physicians from hospitals all over the country and is based on the application of a questionnaire with 26 closed questions (internal consistency coefficient of 0,75). There were used descriptive statistical methods for analyzing the results, using SPSS 14.

Results: For the decisions making in severe patients without chances of recovery after resuscitation (end-state, irreversible coma, permanent vegetative state) and in patients in terminal phases: >45% of ICU-physicians consult the family before deciding upon not initiating the basic life support (believing that this intervention would not bring any benefit to the patient); >35% of ICU-physicians ask for the family's consent for the

interruption of the intensive care therapy previously initiated; 59,9% of ICU-physicians consider that AD would reduce the proportion of abusive treatments that would not benefit the patient; >50% of ICU-physicians consider that AD would set limits to reanimate these categories of patients; >60% of ICU-physicians consider that AD respect patient autonomy and its dignity; >40% of ICU-physicians consider that AD would clarify the conflict of ideas on the therapeutic decision, the medical team and between the medical team and the family; 100% of ICU-physicians consider necessary public education on AD.

Conclusions: ICU-physicians consider that AD are useful, especially in problematic situations in which besides the professional responsibility of the doctor, the moral responsibility is added (the physician's and the family's).

Key words: Advance Directives, ICU-physicians, end-stage patients, terminal patients
Acknowledgement: Work performed under the project „Postdoctoral studies in ethics of health policy”, project co-financed by European Social Fund Operational Programme Human Resources Development 2007-2013

Contact: dumsilvia@yahoo.com

N° of Poster: 4

abSTracTS | 99

romanian Palliative care sYsTeM

mariana Enache, gabriel roman, Beatrice ioan, silvia Dumitras, , stefana maria moisa, rodica gramma, Andrada parvu, , radu Chirita

objectives: Evaluation of the palliative care system in romania related to the population needs in socio-economic post-communist context.

Methodology: Desk research was used. Sources: Ministry of Health statistics, documents of the national association of palliative Care, Hospice foundation studies.

results: palliative care was introduced in romania in 1990 by promoters, charitable foundations, mainly supported by external partners. In January 1992 was founded the romanian association for Development of palliative Care, in March was opened a hospice for children with aIDS, in april -romanian-English Hospice foundation “House of Hope” . Today there are registered 31 suppliers (10 public and 21 private). Comparing the number of people assisted by these services and the estimated needs, only 5% of the potential beneficiaries have access to specialized services. In 26 counties (of the 41 existing), there are no palliative care services. a national survey conducted on a representative sample, 1,250 adults, (error - 2.3%) rank the needs of patients as follows: 70.1% need pain medications, 54.7% - qualified for home visits, 35.1% - qualified to discuss with the patient about fears related to the disease, 11.4% - religious assistance, 15.6% - unqualified caregiver for patient monitoring, 10.1% - special equipment.

Conclusions: In the context of chronic underfunding, a non-stimulating and deficient health legislation, palliative care in romania has developed slowly, progressive and the service levels are below requirements.

This paper was realised within the project “postdoctoral Studies in the field of Health policy Ethics” poSDru/89/1.5/S/61879, co-financed by European Social fund by Sectorial operational program for the Development of Human resources 2007-2013.

Key words: palliative care, legislation, hospice, needs, dignity

Contact: emafirst@yahoo.com

n° of poster: 5

100 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

POLICY RESPONSE TO AGING POPULATION : ACCESS TO HEALTH CARE FOR THE ELDERLY PEOPLE IN THE REPUBLIC OF MACEDONIA

Filip Gerovski

The Constitution of the Republic of Macedonia provides for the right to health care without discrimination, including discrimination based on age, financial status or residence. In 2002, 15% of the population in the Republic of Macedonia was above the age of 60 with a tendency to reach 33% by 2050. In 2008, 30,05% of the retired persons received minimal pension (approx. 100 Euro) while only 0,29% received maximal pension (approx. 500 Euro).

Whereas most of the population lives in the urban areas, the larger number of rural

areas are populated mostly (and some places only) by the elderly.

The aim of this research is to analyze the policy response of the Macedonian government to the aging population, within the context of the geographical and financial aspects of the access to healthcare of the elderly.

Due to unevenly populated areas of the country and lack of infrastructure and/or medical personnel and equipment mostly in rural areas, elderly people in some rural communities have unequal access to healthcare compared to the urban population. The lack of public transport and bad road infrastructure contribute to this problem. Further, despite the citizenship-based health insurance for all, patients still need to pay co-payments for the health services (with some exceptions). Considering the low living standard, it is very difficult to afford the co-payments, especially for long hospital stays. The lack of medicine and other materials in pharmacies and health care facilities contribute to the problem since the patients need to buy them and then ask for reimbursement. These issues are addressed in the recently adopted national strategies on health and on aging/elderly population. This poster presents the findings of the analysis of the policies and how they address the problems of the access to healthcare by the elderly.

Contact: filip.gerovski@studiorum.org.mk

N° of Poster: 6

abSTracTS | 101

Private care organizations in residential care for the elderly: General Patterns and The English case

Maarten Janssens & Johan put

Governments of welfare states are bound by a range of legal dispositions to provide their citizens with adequate social care. In taking up this responsibility, quite often they make use of private care providers, which they heavily regulate and in some cases also subsidise. Yet, in doing so these governments risk to infringe certain aspects of the freedom of association and the liberty to conduct a business.

The project framework which will be presented at the poster session, looks into the legal position of private care organizations in the residential care for the elderly in the light of three clusters of universal legal principles: the right to care, the freedom of association/liberty to conduct a business and the prohibition of discrimination. Two parts of this project will be highlighted.

The first part is concerned with a new framework to classify different types of welfare states. This framework is built around two axes:

- the preference of a system for non-profit or commercial providers
 - the level of discretion enjoyed by private providers in the provision of care
- four types of welfare states can be distinguished in it: the discretionary non-profit model, the discretionary commercial model, the vendor non-profit model and the vendor commercial model.

The second part is about the position of the English system of residential care for the elderly in this framework and about how it performs against the three clusters of universal legal principles. This system is very much based on the use of market forces to achieve a qualitative and efficient provision of care. regulation tends to focus on outcomes, rather than on procedures or on the nature of the care provider. In some respect however, questions can be asked about the effectiveness of mechanisms safeguarding the access to and the quality of care.

Contact: maarten.janssens@law.kuleuven.be

n° of poster: 7

102 | Abstracts

Third European Conference on Health Law
An Ageing Europe. Health Law Revisited

Quest for the right to end-of-life decisions in children with terminal illness

Stefana Maria Moisă, Beatrice Ioan, Silvia Dumitraș, Rodica Gramma, Mariana Enache, Andrada Pervu, Gabriel Roman, Radu Chiriță, Ingrith Miron

Cancer currently causes 10% of infantile deaths worldwide, and acute lymphoblastic leukemia represents 23.3% of all cancer cases in children.

In Romania, Intensive Care Units admit terminal cases, with no chance of recovery. Most deaths occur in Intensive Care Units.

We present the case of a 9 year old girl with terminal high risk acute lymphoblastic leukemia, hospitalized in the Oncology Department and afterwards in the Intensive Care Unit of “St. Mary” Emergency Children’s Hospital in Iassy, Romania, who developed immediately after being admitted a fourth degree coma and cardio-respiratory stop, followed by death. The clinical and paraclinical picture was impressive: liver and spleen 10 cm under the rib cage, 800.000 white blood cells in the peripheral blood with 93,8% lymphoblasts.

The presented case had a clear indication for non-resuscitation according to international protocols, but do-not-resuscitate orders are not legislated in Romania. Therefore, resuscitation was attempted, but unsuccessful.

The dignity of end-state pediatric patients is rarely an object of concern. Still, any death should be dignified. Therefore, the patient received pain relief medication, appropriate sedation while being mechanically ventilated and family access was permitted in the Intensive Care Unit. A death with dignity is more properly described as “a life with dignity until it’s very end”. All human beings have dignity in virtue of their humanity. The goal of this paper is to discuss ways of honouring the best interests of children with terminal illnesses, since children raise the most difficult ethical and legal concerns when terminal medical conditions occur.

Acknowledgement: Work performed under the project „Postdoctoral studies in ethics of health policy” POSDRU /89/1.5/S/61879, co-financed by European Social Fund Operational Programme Human Resources Development 2007-2013.

Contact: stephaniemed@yahoo.com

N° of Poster: 8

abSTracTS | 103

PaTienT-FriEndLY Guides: a new sTeP in ProMoTion oF huMan riGhTs in PaTienT care in arMenia

Arthur potosyan

armenia is one of the South-Caucasian countries which still suffer from imperfect legislation, defective regulations and lack of awareness in the field of human rights and its practical implementation in health care. as a result, it is difficult for medical and even legal professionals to implement and protect the patients’ rights.

Within the triangle relationship among medical and legal professionals and patient, the latter is more vulnerable to abuse of his/her human rights because of the lack of information on available protection mechanisms. That is why one of the key activities of a collaborative fellowship program (fp) supported by open Society Institute Law and Health Initiative and the open Society foundations – armenia was to develop userfriendly guides on human rights in patient care for three special and highly -vulnerable population groups - injecting drug users (IDu), people living with HIV/aIDS (pLWHa) and people kept in penitentiaries.

patient-friendly guides (pfGs) have a standard structure with simplified and easy-to-read content based on the targets’ needs and the armenia practitioner Guide on Human rights in patient Care - another product of the fp available on www.healthrights.am, both in armenian and English.

pfGs are user-oriented and explain country-specific provisions and regulatory instruments on protection and implementation of human rights in patient care. a special focus is put on disclosing logical chains of complaining procedures if one of those rights is violated.

pfGs were disseminated among IDu, pLWHa and detained people in prisons and police departments with the support of national stakeholders in the field and civil society organizations. follow-up meetings with the target groups are conducted to further discuss and explore law and health issues, to receive the readers’ feedback and to collect cases.

It is planned to develop and distribute another set of 3 pfGs on different topics.

Contact: info@healthrights.am

n° of poster: 9

104 | Abstracts

Third European Conference on Health Law

BODIES REVEALED: THE INTERACTION AMONG HUMAN RIGHTS AND COMMERCIAL INTERESTS

Ronalds Rozkalns

1.1. From February 18 to May 22, 2011 the exhibition of real human body specimens took place in one of the largest shopping center of Riga, Latvia. More than 200 specially preserved organs and full body specimens were displayed in 9 galleries within the exhibition under brand name "BODIES REVEALED".

Following the information found on exhibition's web site more than 28 million people in New York, London, Washington, Mexico City, Amsterdam Prague and other cities had already visited the exhibition.

It was assured the bodies of people showcased at "BODIES REVEALED" had donated their bodies for scientific research and all of them had died a natural death.

1.2. Hot discussions started just after the opening of exhibition in Riga. Two opinions were observed:

1.2.1. After the words of organizers of the exhibition their target is "giving visitors the opportunity to view the beauty and complexity of their own organs and systems". Though visitors were asked to buy entrance-tickets for 4-8 Latvian lats (~6-11 EUR). The organizers of the exhibition publicly didn't hide their commercial interest. They even showed preparedness to sue local municipality for giving recommendations for pupils and their parents not to attend the exhibition as this warning had dramatically decreased the planned income.

1.2.2. Several legal and bioethical professionals considered as inadmissible to obtain any financial gain from exposing human bodies. The organizers of the exhibition deserved severe criticism from religious organizations as well as from local municipality. Although no legal consequences followed.

1.3. The purpose of this presentation is to determine the interaction among human rights of dead persons and commercial interests of a private institution.

From one point of view it's necessary to assign if a private institution while performing its commercial activities can ensure observation of human rights of dead persons. On the other hand it must be considered if such activities are conformable with the requirements of Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine (hereafter - Convention on Human Rights and Biomedicine). Both the preamble and article 1 of Convention on Human Rights and Biomedicine requires the protection of the dignity and identity of the human being. Article 21 of Convention on Human Rights and Biomedicine in its turn stipulates that the human body and its parts shall not, as such, give rise to financial gain.

Contact: ronalds@latnet.lv

N° of Poster: 10

abSTracTS | 105

PaTieNt riGhts in PalliaTive care under The leGislaTion oF uKraine

iryna senyuta & olena Chernilevska

one of the most vulnerable segments in the "patient" category is palliative patients transformed into such ones by the criterion of their health condition at the end of their lives.

ukrainian legislator pays more and more "regulatory" attention to the legal status of such patients since in many cases we speak about the terminal stage of life, about complicated decisions at the end of your earthly life. There are plenty of issues connected with palliative problems: starting with legislative to institutional ones. We will focus on the rights of palliative patients which we classify into general ones that are the ones available for all patients, and special ones which have their own peculiarities.

The general ones include, in particular, the right of patient to: 1) respect for dignity; 2) prohibition of tortures, cruel, inhuman or degrading treatment; 3) consent and refusal from medical, including palliative interference; 4) medical information; 5) qualified medical care; 6) medical secrecy; 7) freedom of choice in the sphere of medical, including palliative, care provision; 8) prohibition to be subjected to medical, research or other experiments without free consent; 9) admission of other medical staff, family members, guardian, notary and lawyer to him/her; 10) freedom of belief and admission of priests

to him/her.

The catalogue of special ones includes the right to: 1) efficient treatment of pain; 2) qualified, available, uninterrupted palliative care of different forms; 3) prevention and reduction of sufferings which appear in the background of the progressing disease; 4) assistance in overcoming physical, psychosocial and spiritual problems; 5) prohibition of purposeful speeding-up of death of an incurable patient for the sake of termination of his sufferings; 6) assistance aimed at family support.

Contact: prlawlab@ukr.net

n° of poster: 11

106 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

Access rules stimulating the exchange of biological specimen within biomedical research

Michiel Verlinden, Nadine Ectors & Isabelle Huys

Biomedical research makes increasingly use of human biological specimen, collected during clinical interventions and/or within a scientific setting. Great promises are expected from sharing biological specimen and associated data within and between networks or partnerships of biobanks.

Several projects studied and developed guidelines and best practices in relation to the governance of biobanks and/or biobank networks; however, with limited focus on access rules (1-2).

In a first phase, the project investigates the following aspects of arrangements on access and use of biological specimen and associated data in research projects: (a) custodianships of samples shared within the network; (b) existence and mandate of access committee; (c) criteria for review of research proposals and priority setting between different proposals; (d) scope of access and use; (e) return of samples; (f) sharing of research results within the network; (g) cost recovery plan and differentiation between researchers inside and outside the network and industrial partners; (h) acknowledgement and intellectual property arrangements; (i) commercialization of research results and benefit sharing; (j) incentive mechanism to share human biological specimen and data; (k) protection of interests of the donors; (l) sanction and dispute resolution mechanism (3-7). The investigation is based on a review and analysis of access policies and guidelines developed by amongst others ISBER, TubaFrost, EOR TC, P3G, BBMRI.EU, OECD, Privileged, Integrated Biobank of Luxembourg, String of Pearls Initiative.

In a second phase, the project will study to which extent these access rules stimulate and/or hamper the exchange of biological specimen and associated data in research activities. The results of the project can assist biobanks and biobank networks to develop their access rules.

References: (1) Hallmans G. et al., *Methods in Biobanking, Methods in Molecular Biology*, 241-260 (2011); (2) Riegman P.H.J. et al., *Molecular Oncology*, 213-222 (2008); (3) Fortin S et al., *Public Health Genomics*, 104-114 (2011); (4) Joly Y. et al., *Human Genetics* (2011); (5) Yuille M. et al., *Briefings in Bioinformatics*, 14-24 (2008); (6) Lemrow S.M. et al., *Cancer Epidemiol. Biomarkers Prev.*, 1533-1535 (2007); (7) Lopez-Guerrero J.A. et al., *European Journal of Cancer*, 2924-2929 (2006)

Contact: michiel.verlinden@pharm.kuleuven.be

N° of Poster: 12

abSTracTS | 107

The “ProPortionalITy PrinciPle” and suPersedinG The “PrinciPle oF consenT” For donor GeneTic MaTerial and daTa held BY Bio BanKs

polichronis voultzos, fotios Chatzinikolaou, Eleni Zagelidou, nikolaos raikos, Charoula florou, Eleni kalyva, nikolaos vasileiadis

The fundamental but vague and contested legislative and administrative “proportionality principle” must be frequently applied in Bio-law and Bioethics where these are often counter weighted with the (almost) equally significant interests and legal rights, which

are often determined by uncertainty. The fundamental principles and values of the Bioethics (as well as their absolute or otherwise nature), which are the basis for resolving these weightings are determined by the type of Bioethics that we choose to select. These principles furthermore determine the “legality” of a legislative and administrative provision, its interpretation and implementation, in accordance with the circumstances, where the subject’s role often appears to be significant (e.g. the perspective on the patient’s part). More specifically, in order that medical research may be served by the said Bio Banks, where the said medical research also relates to the interests of persons who will be born in the future, the “principle of respect for consent” by the donor of the genetic material and the data to the Bio Bank that arises from the fundamental “principle of self-determination” in Bioethics and Bio-law must be superseded. This supersession rocks the foundation (in at least the Western model) of Bioethics. It is difficult to have the donor’s adequately informed consent, since at the time of its provision in addition to the impracticality of comprehensive information in terms of all the scientific aspects of forthcoming research, every future use of the donor’s genetic data cannot be known. The renewal of the consent for every new use is an absolute impediment to medical research. It is particularly difficult to obtain the “adequately informed consent” of not only the specific donor but also of the social group to which the said donor belongs. Various wide ranging types of consent have been proposed in order to “legitimize” research for material that is held by the Bio Banks. This paper recommends a specific type of consent, whose adoption respects the “proportionality principle” as it is usually implemented in other sectors of the broader, unclear and interdisciplinary sector of Bioethics, as well as (Bio) law, which operates within the interplay of the legislative and administrative sources at both a national and a supra-national level.

Contact: fch2311@yahoo.gr

n° of poster: 13

108 | Abstracts

Third European Conference on Health Law

An Ageing Europe. Health Law Revisited

A Research Paper as a Standpoint for

Further Law Amendments

Violetta Zopunyan

Driven by the need to improve implementation of human rights in patient care, a comprehensive gap-analysis of health legislation is required to determine the main focuses of further advocacy and actions by state bodies and society.

Within a collaborative Fellowship Program (FP) supported by Open Society Institute Law and Health Initiative and the Open Society Foundations – Armenia, a Health Legislative Research (HLR) project was conducted by means of analyzing Armenian health legislation in comparison with international and regional human rights standards. HLR was designed to use the 14 patient rights enshrined in the European Charter of Patient Rights (ECPR) as guiding principles, and the binding provisions concerning domestic law were presented and analyzed for each of those rights. We used an approach of drawing parallels between international/regional and national Armenian health legislation to reveal the legal and implementation issues as well as other procedural gaps in the protection of rights and responsibilities of both patients and health care providers. Research findings provided proof of the growing importance of health law reforms. The recommendations resulting from the Research can be used by the National Assembly and the Ministry of Health to initiate legislative amendments and additions or draft new legal acts aimed at enhancing better protection for human rights in the health care sphere, as well as improving the effectiveness of the mechanisms of their implementation. The Research also could be a useful advocacy tool for civil society organizations in the field. The far-reaching objective of the HLR is to bring the domestic legislation into line, to the extent possible, with the international standards, and to outline measures to safeguard the effective exercise and performance of human rights in patient care which will give the legal professionals an opportunity to successfully represent a patient or a health provider in court.

Contact: zopunyan@healthrights.am

N° of Poster: 14