THE CROATIAN ACADEMY OF SCIENCES AND ARTS
The Department of Biomedical Sciences in Rijeka
JEAN MONNET INTER - UNIVERSITY CENTRE OF EXCELLENCE OPATIJA
UNIVERSITY OF RIJEKA
Faculty of Law
Faculty of Medicine
Department of Biotechnology
THE CROATIAN MEDICAL ASSOCIATION – Branch office Rijeka

28th Symposium

PERSONALIZED MEDICINE - RESEARCH DIAGNOSTIC: INDICATOR OR INFORMATION

Rijeka, November 12-13, 2018

1st day: November 12th, 2018

09:00 am

University Campus Rijeka, University Departments, Lecture Hall 0-030, Radmile Matejčić 2, Rijeka

Information

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Registration: 8,00 – 9:00 am

Participants who want a certificate from the Croatian Medical Chamber need to register on the day of the symposium.
Lunch and refreshments during break will be provided free of charge.
Parking is free and provided in the building of the Student Center Rijeka (Radmile Matejčić 5)

P R O G R A M
OPENING (09,00 – 09,30 h)

Introduction

Daniel Rukavina, Professor emeritus, Head, Department of Biomedical Sciences in Rijeka, Croatian Academy of Sciences and Arts, Rijeka, Croatia

Nada Bodiroga - Vukobrat, PhD., Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia, President of the Organizing Committee

Welcome speeches

Tomislav Rukavina, M.D., PhD., Professor, Dean of the Medical Faculty, University of Rijeka, Rijeka, Croatia

Vesna Crnić - Grotić , PhD., Professor, Dean of the Faculty of Law, University of Rijeka, Rijeka, Croatia

Snježana Prijić - Samaržija, PhD., Professor, Rector of the University of Rijeka, Rijeka, Croatia

I. PERSONALIZED MEDICINE – MEDICAL ASPECTS

09,30 – 10,40 h

Chairmen: Daniel Rukavina and Nada Bodiroga Vukobrat

Keynote lecture:

Hans - Peter Zenner, M.D., PhD., Professor, Chairman Ethics Commission, Medical Faculty, University of Tübingen, Tübingen, Germany
Cutting-edge aspects of modern personalized medicine

Giorgio Palù, PhD., Professor, University of Padova, Padova, Italy
New technologies in biomedicine

Coffee break: 10,40 – 10,55

10,55 – 14,50 h

Chairmen: Krešimir Pavelić and Nela Sršen

Giuseppe Damante, M.D., PhD., Department of Medical and Biological Sciences, University of Udine, Udine, Italy
Genetics and genomics for a personalised approach to the patient

Sabrina Pricl, PhD., Department of Chemical and Pharmaceutical Sciences**,** University of Trieste, Trieste, Italy
Self-assembling nanosystems for precision delivery of siRNA and small drugs to different cancer cells

Egbert Müller, PhD., Professor, TOSOH Bioscience GmbH and Technical University of Darmstadt, Darmstadt, Germany
Efficient separations of antibodies using Fc-gamma receptor based affinity column

Lunch with a panel of speakers: 12,10 – 13,10 h

Dalibor Krpan, M.D., PhD., Polyclinic K-Centar, Zagreb, Croatia,
Personalized approach to osteoporosis treatment

Đuro Josić, PhD., Department of Biotechnology, University of Rijeka, Rijeka, Croatia
Changes of food pathogen proteome after treatment with different inhibitors

Krešimir Pavelić, M.D., PhD., Juraj Dobrila University of Pula, Pula, Croatia
Personalized approach to cancer metastases treatment

Josipa Kern, PhD., School of Medicine, University of Zagreb, Zageb, Croatia;
Jadranka Mustajbegović, M.D., PhD., WHO CC Occupational Health, Zagreb, Croatia
Big data analysis – a new approach in medical and health diagnostics

CLOSING REMARKS: Krešimir Pavelić

2nd day - November 13th, 2018
Location: Faculty of Law, Hahlić 6, Rijeka

II. PERSONALIZED MEDICINE – ECONOMIC AND LEGAL ASPECTS

10,00 – 11,20 h

Chairmen: Nada Bodiroga Vukobrat and Hana Horak

Grega Strban, PhD., Professor, Faculty of Law, University of Ljubljana, Ljubljana, Slovenia
Personalised Diagnostics and Public Health Systems: interplay between principles of solidarity and self-responsibility

Lucia Ruggeri, PhD., Professor, School of Law, University of Camerino, Camerino, Italy **Algorithm and predictive medicine: the need for a specific regulatory framework**

Jasminka Godnic - Cvar, PhD., Professor, Medical University of Vienna, Vienna, Austria
Impacts of new social and economic developments on employees' health

Nada Bodiroga - Vukobrat, PhD., Professor, Faculty of Law, University of Rijeka, Rijeka Croatia; **Hana Horak**, PhD., Professor, Faculty of Economics and Business, University of Zagreb, Croatia
Research Diagnostics: Indicator, Information - What about legal boundaries?

Coffee break: 11,20 – 11,35 h

11,35 – 14,35 h

Chairmen: Marija Kaštelan Mrak and Danijela Sokolić

Marija Kaštelan Mrak, PhD., Professor, Faculty of Economics; **Danijela Sokolić**, PhD., Assistant Professor, Faculty of Economics, University of Rijeka, Rijeka, Croatia
Issues in identifying the economic parameters of individualized service

Ivana Kunda, PhD, Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia; **Ana-Lena Hoffmann**, attorney-at-law, Stuttgart, PhD student, Faculty of Law, University of Rijeka, Rijeka, Croatia
Data protection in telemedicine

Martina Bajčić, PhD., Assistant Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia
Framing biomedical advances in legislative drafting

Ana Pošćić, PhD, Assistant Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia; **Adrijana Martinović**, PhD., Assistant Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia
Legal framework for personalized medicine in Croatia

Sanja Barić, PhD., Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia; **Matija Miloš,** mag.iur, Faculty of Law, University of Rijeka, Rijeka, Croatia
Bodily privacy as a benchmark for legislating on personalized medicine: an indicator of expanding fundamental rights or a policy objective?

Dario Đerđa, PhD.; Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia
Administrative legal protection in health insurance

Jasmina Mutabžija, PhD.; POSLuH hosting d.o.o., Zagreb, Croatia
Legal implications of the use of nanotechnology in medicine

Vanja Smokvina, PhD; Assistant Professor, Faculty of Law, University of Rijeka, Rijeka, Croatia
Diagnostics and sport: indicator or information - what are the consequences?

Gerald G. Sander, PhD., Professor, M.A., Mag. rer. publ., University of Applied Sciences - Public Administration and Finance, Ludwigsburg, Germany
Right not to know

CLOSING REMARKS : Nada Bodiroga - Vukobrat

Lunch with a panel of speakers: 14,35 – 15,30 h

The scientific symposium is supported funded by the Croatian Science Foundation project No. 5709 "Perspectives of maintaining the social state: towards the transformation of social security systems for individuals in personalized medicine", and the University of Rijeka project No. 13.08.1.2.03 "Social security and market competition", with friendly support of the Hanns-Seidel-Stiftung.

New technologies in biomedicine

Giorgio Palù
University of Padova, Padova, Italy

The presentation will deal with some of the advanced technologies that are currently used in biomedical research. For the sake of exemplification, the exploitation of those technologies which are carried out at the Department of Molecular Medicine of the University of Padova, Medical School will be described. Gene therapy approaches for cancer and AIDS will be discussed as well as the construction of new oncolytic viruses and new vaccines. Genetic modifications that provide new functions to infectious pathogens, that falls into the domain of dual use research, will be reported also in the context of their biosafety, biosecurity social and ethical impact. The utility of gene drives to alter reproduction of insect vectors responsible of transmitting malaria and other emerging infections will be debated as well as stem cell manipulation and genome editing for regenerative medicine.

Genetics and genomics for a personalized approach to the patient

Giuseppe Damante
University of Udine, Udine, Italy

The personalized (precision) medicine draws information from the individual genome, proteome, environment in order to diagnose, treat or even prevent a pathology. About 30 years ago, the medical community started to identify disease-specific molecular features in order to use pathological profiles for classification, i.e. in oncology. However, only recently, such an approach is used to provide efficient tools for disease management. Thus, nowadays, thanks to personalized medicine- based approaches, both diseases diagnosis, prognostic prediction and treatments are steadily increasing. The need for personalized medicine is also currently related to the increasing costs of both patients' treatments and drug development. In fact, the personalized approach allows to define the proper patients' treatment using specific compounds chosen based on their own genetic alteration, but even to use "old" drugs readapted for new therapeutic purposes (repurposing).

The personalized approach has already obtained substantial success in two major classes such as the oncological field and the monogenic abnormalities-related one. Indeed, diverse tumour sub-types are already treated based on the presence of a specific genetic mutation: as for ovarian cancer the presence of BRCA1/2 genes mutation predicts the efficacy of PARP inhibitors treatments. A similar approach has been used for the therapeutic approach of monogenic diseases caused by a specific mutation present in the patient. Furthermore, in the near future, the use of gene editing (by the CRISPR/CAS9 system) is expected to provide a solid approach to efficiently correct mutations within causative genes in patients burdened by diverse monogenic disorders.

Of course, the implementation of personalized medicine requires great effort and cooperation in the medical field. A recent open resource in which phenotypic and genotypic data of about 500.000 subject are present is an excellent example of it (The UK Biobank resource – Nature 2018). The network medicine approach, by which molecular and clinical features of diseases generate a connection map, is a novel approach expected to provide even novel tools for disease management.

Self-assembling nanotechnology for cancer personalized medicine

Erik Laurini, Domenico Marson, Suzana Aulic, Maurizio Fermeglia, Sabrina Pricl
University of Trieste, Trieste, Italy

Theranostics is a new field of medicine which combines specific targeted therapies based on specific targeted diagnostic tests. With a key focus on patient cantered care, theranostics provides a transition to conventional medicine to a contemporary personalized and precision medicine approach. The theranostic paradigm in cancer involves nanoscience to unite diagnostic and therapeutic applications to form agents for diagnosis, drug/gene delivery and treatment response monitoring. In this respect, our team as a part of a pan-European task force in the field has developed a series of innovative theranostic systems which proven to be excellent agents in cancer imaging and therapeutics in vivo.

Specifically, exploiting the quintessence of nanotechnology, i.e., the self-assembling process of small, amphiphilic molecules, we created a series of high-performance, non-toxic nanosized micelles that, depending on the specific chemistry, are able to (e.g.): Encapsulate anticancer drugs with high loading capacity, enhance drug potency and combat drug resistance by promoting cellular uptake whilst decreasing drug efflux; perform specific and effective gene silencing via targeted small interfering RNA (siRNA) delivery; Provide PET images with significantly superior imaging quality relating to sensitivity, specificity and accuracy when compared to the clinical standard [18F] FDG.

In this contribution we will report in details the full pathways leading to these three types of nanosystems, from their computer assisted molecular design to their in vivo performance.

References

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Liu X et al. Adaptive amphiphilic dendrimer-based nanoassemblies as robust and versatile siRNA delivery systems. Angew Chem Int Ed Engl. 2014;53(44):11822-7.

Efficient separations of antibodies using Fc-gamma receptor based affinity column

Egbert Müller[1,2] and Laila Saleh Gale[1,2]
[1]TOSOH Bioscience GmbH, Griesheim, Germany
[2]Technical University of Darmstadt, Darmstadt, Germany

We have developed a new analytical column using human FcγRIII receptor protein. Fc-gamma receptors are membrane proteins and play an important role in the mediation of immune responses. The binding sites of Fcg receptors are located at the hinge region of human IgGs. They have high affinities for IgG. Because the natural FcγRIII protein are unstable under acidic and alkaline conditions, it was modified by site directed evolution to achieve a ligand with greater stability. The tuned receptor was immobilized on a TSKgel resin.
Glycosylation of IgG has an impact on binding to the FcRγRIII and thereby influences antibody dependent cellular cytotoxicity (ADDC) activity. Consequently, the FcγRIII analytical column allows separation of therapeutic antibodies based on their ADCC activity. It is an efficient tool for affinity separation and analytical evaluation of efficacy and quality of therapeutic antibodies. Application examples and the possible binding mechanism are discussed.

Use of foodomics methods as a tool in research and assurance of food quality and safety

Đuro Josić
Department of Biotechnology, University of Rijeka, Rijeka, Croatia

According to definition of Cifuentes, foodomics is "a discipline that studies the food and nutrition domains through the application and integration of advanced –omics technologies to improve consumer's well-being, health and knowledge" [1]. Consequently, foodomics requires reliable qualitative and quantitative information about food components by use of genomics, transcriptomics, proteomics and metabolomics methods, as well as already well-established methods for food analysis. This integrative approach enables much higher level of understanding of changes during food processing and storage, as well as detection of markers of food quality and safety. Together with newly developed high-throughput sample preparation procedures, mass spectrometry based foodomics approaches became increasingly important. They are utilized in different foodomic studies, mainly for abovementioned investigations of food quality and safety, but also for detection and documentation of counterfeit foods and beverages. Mass spectrometry based foodomcs analyses enable studies of different food components as well as reliable quantification of individual high- and low-molecular food components in highly complex samples such as different food matrices. Our investigations of changes of food pathogens, namely Gram positive and Gram negative bacteria after treatment with different disinfectants illustrates the use of proteomics methods for the virulence and pathogenicity of food borne bacteria, their adaptation and survival under stress conditions and detection of possible biomarker candidates for food poisoning.

[1] A. Cifuentes, J. Chromatogr. 1216 (2009) 7109.

Personalized approach to cancer metastases treatment

Krešimir Pavelić
Juraj Dobrila University of Pula, Pula, Croatia

In this lecture I shall present and discuss current issues in tumor metastases treatment in the context of the widely acceped cancer stem cell theory. We propose to intensify development of new treatment strategies for malignancies that target tumor „stemness" biomarkers as to advance cancer treatment in general. Analysis and understanding of „steamness" pattern is a prerequisite for such approach. I shall present an example of analysis of different tumors' "stemness" by use of STRING database-generated interactomes.

Big data analysis – a new approach in medical and health diagnostics

Josipa Kern and Jadranka Mustajbegović
Croatian Academy of Medical Sciences, Zagreb, Croatia

Coming from Greek *diagnostikos* the word diagnostic means "able to distinguish" – distinguish a specific characteristic (i.e. disease) among a mass of others. The process of identification of specific diagnosis is diagnose or diagnosing. A process of diagnosing in medicine starts with symptoms, data coming from patient like anamnesis or exam given by health professionals.

Big data is buzzword relating to data characterized width 3V: Volume, Velocity and Variety. Number of data, i.e. (big) *volume*, has been implied by collecting the data through variety of organizations, social media, business transactions etc. Their rapid inflow, sometimes from sensors and smart metering in real time is the characteristics we describe as (big) *velocity*. Data comes in all types of formats – from structured, numeric data in traditional databases to unstructured text documents, email, video, audio, stock ticker data and financial transactions (https://www.sas.com/en_us/insights/big-data/what-is-big-data.html). This characteristic we describe as (big) *variety* (variety of data formats).

Healthcare is rich of data – there are specific health data of a particular individual (or a population) enabling to make particular diagnose and treatment, or, potentially help to prevent epidemics, cure disease, cut down costs, etc. A lot of information has been generated in healthcare every day (anamnesis, demographic data, status, laboratory test, medical images and signals both as videos or still images, sound, voice).

Problem of big data and their incorporation in the diagnosing is related mostly to their structure – most of them are non-structured (e.g. images, signals, texts, voice, videos etc.). Dealing with textual data (like diagnoses) usually coding is used (e.g. International Code of Diseases, or, for gender, 1 for males, 2 for females can be used). The bigger problem is with signals and images or text (like e.g. recommendations). Traditionally, such measurements are taken at specific points in time and noted on a patient's chart. Physicians actually see less than one percent of these values as they make their rounds—and treatment decisions are made based upon these isolated readings. Similar situation is with textual data (like "stories", written or recorded as voice). Such data are traditionally taken as number of classes (categories), but textual data ask for natural language analysis what is not easy to do because of complexity of natural languages themselves (in number of languages, their grammar, synonym and homonym, etc.).

Key words: big data, medical and health diagnosis

Personalised diagnostics and public health systems: interplay between principles of solidarity and self-responsibility

Grega Strban
Faculty of Law, University of Ljubljana, Ljubljana, Slovenia

It should be noted that personalised means made for or directed or adjusted to a particular individual. Hence, personalised medicine would mean medical treatment, which encompasses not only acute treatment, but also medical diagnostics (without which treatment could go the wrong way and potentially be even harmful), which is adjusted to an individual patient. Already Hippocrates argued that it is far more important to know what person the disease has than what disease the person has.

However, personalised medicine is how medicine has always been practised. Data (clinical, laboratory, imaging etc.) are gathered and information that can be used for decision making is provided in the context of a particular patient. It might be that some healers practice a more massive approach, but is not the case with the so called traditional or official or professional medicine, financed also by the public health systems. The latter might take the form of national health service or mandatory health insurance. Nevertheless, the concept of personalised medicine implies a new approach. Molecular medicine adds an additional dimension to what can be learnt about an individual through DNA-based testing. This can be predictive long before conventional clinical markers are measurable, and useful in the context of identifying the health risk for family members. Hence, while personalised medicine is not new, it is significantly enhanced by the addition of DNA-based information.

Therefore, individualisation by prediction is essential also for personalised diagnostics. The question might be how public health systems can support (to a larger or to a more minor extent) new forms of medical diagnostics. It might be essential how personalised diagnostics is classified. If it is experimental, the question whether it is the duty of public health systems to finance experimental medical services might arise. It might be perceived as a domain of the state and research projects, rather than solidarity community of public health system. They might incorporate services of personalised diagnostics in their benefits catalogue, if such treatment is recognised as a standard in the international medical circles (as also emphasised by the CJEU). It might also be the domain of an individual, his or her private financing and private health insurances.

The question is who might be responsible for medical advancement, also through personalised diagnostics. Should it be in the domain of solidarity, which might have distinctive emanations, e.g. like vertical, horizontal or intergenerational solidarity. Or, should it be the (self-) responsibility of individual patients and possibly their private health insurances. To this end defining the social risk of sickness or disease and distinguishing it from a private risk is crucial. Moreover, such distinction might have important consequences for an insured person on financing side (i.e. contributing rate) and benefits side (e.g. the level of co-payments or sickness cash benefit). It goes without saying that advanced medicine should be encouraged, but at the same time regulated, in order to minimise its possible shortcomings.

Algorithm and predictive medicine: the need for a specific regulatory framework

Lucia Ruggeri
School of Law University of Camerino, Camerino, Italy

The use of algorithm is fundamental for the development of the Predictive Medicine which needs to profile individuals by analysing a massive amount of information. The stratification process permits prior individualisation of a homogeneous group of people who are predisposed to certain illness.
This predictability allows intervention with appropriate treatments that prevent the development of the disease or that allow treatment of the disease at its earliest stages.
Profiling requires the collection of sensitive data, the sharing of data and their use for purposes other than that for which the data were collected. The GDPR (General Data Protection regulation) governs the collection of data in the medical field, mentioning both genetic data and personalized medicine, but lacks an appropriate regulatory framework for the use of algorithms which increasingly constitute the basis for therapeutic choices, as well as public and private investments in the health market.
It is necessary to provide a control on the use of algorithms in the biomedical field. This issue is crucial to maintain a high and effective protection of fundamental rights such as privacy and health, in the medicine of the present and the future.
The risk of a progressive weakness of the principles of solidarity and non-discrimination is high: for this reason, the role of legislation is crucial to stimulate a conscious and appropriate use of the algorithm in public and private decision-making processes.
Key words: Predictive medicine, Algorithm, Data protection, Health

Impacts of new social and economic developments on employees

Jasminka Godnic-Cvar
Medical University of Vienna, Vienna, Austria

According to the WHO definition of health, and the decision of the World Health Assembly in 1977, health is understood as a condition that permits all subjets to lead a socially and economically productive life i.e. to work. Here, therefore I analyzed the benefits of work for the employee. Work is not only securing existence, but has other beneficial aspects too: social integration, self-fulfillment, and time structure. Thomas Mann has brought it to the point: "Working is often difficult and sometimes a joyless and laborious poking; but not having work - that's hell!". Still nowadays, having a health supportive job is a privilege even in highly developed countries.
Furthermore, the issue of keeping subjects employed until the retirement age has been discussed in the latest decade intensively. Changes in the world of work and the demographic shift (fewer young people entering the world of work, and aged people kept at work) has brought about our concerns considering the healthy ageing at work (which leads in turn a wholesome life capacity after retirement too). Moreover, the changing world of work has brought about a series of new health problems, which we have to take care of in order to keep the employees healthy.
The concept of workability (= sum of factors that put a woman or a man in a position to successfully accomplish a given task) and the "house or work capability" by Juhani Ilmarinen has been born. Workability can be achieved by supporting the stable bal-

ance between requirements and resources in everyday working life – is the basis for "health, well-being and effectiveness" (= functional capacity) = the individual basis for the ability to work (Juhani Ilmarinen).
A favorable workability is a prerequisite for productivity: flexibility, innovation and competitiveness for the employees. The crucial turn in managers' attitude concerning health promotion of their employees is to convince them, that investing in health of their employees is going to pay back in a rate of even 1:5.
In my presentation, I am going to discuss a few important aspects of the impact of work on the employees: work and age, work and chronic diseases, work and gender, measures for keeping or increasing workability of employees.

Research diagnostics: Indicator, Information - what about legal boundaries?

Nada Bodiroga Vukobrat[1] and Hana Horak[2]
[1]Faculty of Law, University of Rijeka, Rijeka, Croatia
[2]Faculty of Economics, University of Zagreb, Zagreb, Croatia

Health and healthcare issues in patient-doctor relation become today one of the most challenging issues in the economy of knowledge where highly sophisticated services like health care services play important role in the society based on digital economy.
Data protection in the digital world, and processing on a daily basis a number of information is one of the most important achievements that must be considered when analysing regulatory framework in micro and macro surrounding. Data and data protection are crucial and the most important issue in process of connecting and consolidating information. In-depth analysis and studies have shown that the main discrepancies are between different regulatory frameworks of the Member States and within the different stages of implementation of EU legal actions on national level. It is important to recognise that today without interdisciplinary approach in personalized medicine we cannot reach all benefits that new technologies can provide.

Issues in identifying the economic parameters of individualized service

Marija Kaštelan Mrak, Danijela Sokolić
Faculty of Economics, University of Rijeka, Rijeka, Croatia

Following our past interest in the evolution of business models in personalized medicine we propose to address the issue of technology scaling as a quest for reaching economies of scale in new markets. Introducing new technologies from the economic angle has traditionally been visualized as a staged process, or rather a loop of iterations involving three stages: research accompanied by market targeting; market entry or market creation, when needed; and third, redesign for mass-dissemination. The latter stage often went under the term market scaling. The economic logic of such a process was straightforward: designing products and services for mass production would lead to lower production costs, thus increasing attractiveness/availably of a technology to a larger population. The consequence was that investments in R&D were recuperated in the shortest possible period. Furthermore, under favorable market conditions, a well-designed technology was capable of earning sufficient returns to finance a new round

of investments. However, when it comes to disruptive technologies and the new trends of personalizing services, the traditional idea of technology scaling may need some refinement.
We argue that technology development loop for personalized medicine should be analyzed in order to define up to what point of the technology enhancement process we keep needing mass production effects. We believe scale (along with issues of market concentration) will be present all the way until the level of clinical practices. Under such perspective, even though we call the technology personalized, it does not in effect fall out of the traditional development path.

Data protection in telemedicine

Ivana Kunda and Anna-Lena Hoffmann
Faculty of Law , University of Rijeka, Rijeka, Croatia

Telemedicine, or provision of health care services on distance, is becoming increasingly important, not as much for the comfort of the patients, but rather for the reason of accessibility of quality health services in the areas where such option in the traditional form would not be economically efficient. This is facilitated by the information and communication technologies as means of connecting a patient to a health professional. An inevitable component of telemedicine is transmission of patient's health data, which as of recently is subject to the General Data Protection Regulation. Because the GDPR does not explicitly address telemedicine, this paper is intended to identify the issues related to protection of such data. The analysis focuses on specific features of telemedicine to study the operation and effects of the general principles of data protection and legal grounds for data proceeding, especially of the consent. Also provided is an insight into other questions portraying particularities of data protection in telemedicine, such as data subject's rights, data privacy by design and by default and data breaches.

Framing biomedical advances in legislative drafting

Martina Bajčić
Faculty of Law, University of Rijeka, Rijeka, Croatia

This paper investigates how biomedical advances are addressed in legislation. In keeping with the latest biomedical advances, legislatures need to redefine and reframe established legal categories, (e.g. of kinship categories). Although the legislature and drafters not only rely on scientific, biomedical inputs, but also borrow scientific terminology, they nevertheless frame it according to their objectives and needs. However, to what extent do drafters, by defining and regulating new and sensitive areas of human life, impose a certain conceptualization, which in turn may impact the broader perception and set the course for jurisprudence? Since, departing from critical discourse analysis, language is never neutral, the linguistic choices in biomedically relevant legal discourse also carry with them ideological implications (Garzone 2018).

Legal framework for personalized medicine in Croatia

Ana Pošćić and Adrijana Martinović
Faculty of Law, University of Rijeka, Rijeka, Croatia

Personalized medicine requires individual approach to prevention, diagnosis and treatment based on individual patient's profile and personal situation. It relies on the processing of a large amount of data about a person's genes, proteins, and environment and on their correct and timely implementation in order to find a customized solution for treating each individual patient. The personalized medicine paradigm has shifted the focus from treating a disease to treating a patient. The innovative individualised approach has changed the field of medicine in general, including, for example, the way clinical trials are conducted.
Law, on the other hand, is concentrated on regulating social behaviour in a general manner. By definition, it should not be individualised. The overarching ideal and principle of legal certainty makes it difficult to quickly adapt regulatory framework to recognise innovations. The authors will use the personalized approach to diagnose the state of legislation and pinpoint specific issues which require further attention. The question is, are customized legal solutions needed to respond to the paradigm shift in medicine? Can promises of personalized medicine be realized in the existing regulatory framework? Special attention will be devoted to the legal position of patients and their experience and involvement in decisions concerning their health.

Uses and abuses of bodily privacy in regulating personalized medicine

Sanja Barić and Matija Miloš
Faculty of Law, University of Rijeka, Rijeka, Croatia

The notion of "personalized medicine" implies that the "personalized" medical treatment is tailored to individual patients. The personalization of the medical intervention bears with it the potential to expand one's capacity to make choices that alleviate medical conditions and, blurring the line between healing and self-improvement, improve one's livelihood. In law, the natural reflection of personalized medicine thus appears to be privacy, traditionally associated precisely with the ability to choose. In this paper, we want to probe and critique the role of privacy as an enabler of choice in the debate on regulating personalized medicine. Our discussion proceeds in several parts. We first examine how arguments from privacy are deployed in the existing debates on personalized medicine. Then we reflect on the connection between privacy and the body, developing a notion of "bodily privacy". We then proceed to examine two of its functions: first, to define relationships to one's body and between different bodies and, secondly, to serve as a boundary between different discourses that revolve around individual bodies in the context of personalized medicine. We conclude by commenting on how law may adapt to enhance the agency of individuals in a matter of rapid scientific progress.

Diagnostics and sport: indicator or information - what are the consequences?

Vanja Smokvina
Faculty of Law, University of Rijeka, Rijeka, Croatia

Diagnostics is of extreme importance in the prevention of doping in sports. The World Anti-Doping Agency (WADA) in its World Anti-Doping Code defines doping as the occurrence of one or more of the anti-doping rule violations set forth in the Code. It seems that the modern medicine and/or bio-medicine is always one or more steps ahead in the possibility to ensure athletes the use of prohibited substances or methods which could give them a chance to have a better sporting achievement or result. That is the reason why more attention should be given in the diagnostics process because the insurance of a fair sporting competition and the prevention of fraud is of a paramount importance.

Key-words: doping, sport, diagnostics, prevention

Legal implications of the use of nanotechnology in medicine

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Nanotechnology is a very complex scientific discipline which entails the manipulation of matter on an atomic, molecular, and supramolecular scale. It could also be called a science of new possibilities, because it can have an extremely wide range of applications in many fields. One of those fields is medicine, in which nanotechnology can be used to prevent, detect and treat diseases in an innovative manner, as well as to decrease the costs of health care. This amalgam of medicine and nanotechnology, called nanomedicine, constitutes a great challenge for lawmakers for at least two reasons. One, its use may have a negative or at least an unpredictable impact on the environment and health of patients and two, it is one of those rapidly emerging and changing fields in which the law traditionally lags behind the developments. This paper explores the legal treatment of nanomedicine in the European Union, with the aim of establishing whether the right balance has been struck between the technological benefits and the associated risks. In addition, particular attention is also given to the challenges that nanotechnology as a whole and nanomedicine in particular pose to the conventional intellectual property protection regime in the European Union.