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8th World Congress on

Toxicology and Pharmacology

April 13-15, 2017 Dubai, UAE

Keynote Forum

(Day 1)

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Aristides M Tsatsakis, Toxicol Open Access 2017, 3:1 (Suppl)
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Aristides M Tsatsakis

University of Crete, Greece

Current status and challenges for toxicology and risk analysis in 21st Century: Integrating epidemiology experimental and computational data in real life exposures

Linking xenobiotic chemical exposure to health effects and diseases has been the subject of many experimental and epidemiological studies, though this issue remains a matter of permanent discussion and controversy. This issue is complicated by the multiple mechanisms of xenobiotic toxicity often involved, the uncertainties related to long term and low dose xenobiotic exposure, and the reliable identification of exposed and control groups. Exposure scenarios simulating real life is a complex issue as effects from multiply chemicals must be considered as a web of interactions that produce variety of mechanisms of effects and subsequently of health outcomes. In this respect linear –monomodal but also nonlinear effects can be seen in the range of low and/or high concentrations of exposures. Evaluating exposure effects is considered a multifactorial task that needs an integrated and systematic approach not only for long term actions but often for acute or sub chronic actions. Since such evaluations are highly work load and time consuming a sophisticated approach to identify the dominant actions and effects are in need. Real life is a variability and diversity of exposures the overall effect of which are pending on the certain case. Chemicals in general have a major impact on human and ecosystem health and highlighting the increasing need for effective and integrated means of risk assessment and exposure evaluation in human populations and biological ecosystems is crucial. This is not a trivial task and requires not only biomonitoring and exposure assessment but also combination of risk assessment with regulatory measures and actions. Harmonization in study methodologies by implementing OECD's adverse outcome pathway (AOP) approach and systematic dealing with confounders is required for a better characterization of exposure and understanding of the effects. Thus, the complex issue of links between chemical exposures and health problems and diseases is associated with multiple factors that are due to the expanding numbers of the chemical categories being present simultaneously or sequentially, the variety of mechanisms, mode of actions, adverse outcome pathways and effects involved but also on a large number of con-founders and also not less important to be encountered susceptibility due to genetics and epigenetics. Several epidemiological studies but also *in vivo* and *in vitro* experimental works showed that big majority of man produced consumer products even for dietary or life style purposes were found to act as endocrine disruptors, neuro developmental toxicants, immune toxicants and carcinogens in animals and humans. The general population experiences uncontrolled multi-chemicals exposure from many different sources at doses around or well below regulatory limits. Therefore, traditional chronic toxicity evaluations for a single chemical could possibly miss to identify adequately all the risks. For this an experimental methodology that has the ambition to provide at one strike multi-answers to multi-questions is hereby proposed: a long-term toxicity study of non-commercial chemical mixtures, consisting of common everyday life chemicals (pesticides, food additives, life-style products components) at low and realistic dose levels around the regulatory limits and with the simultaneous investigation of several key endpoints, like genotoxicity, endocrine disruption, target organ toxicity including the heart and systemic mechanistic pathways, like oxidative stress. In real life, the consumer is exposed to complex mixtures of chemicals via food and water consumption and via commercial products. Risk assessments, in general, however, focus on individual compounds. Therefore, the current regulatory approach does not assess overall risk in a highly relevant manner. This study will evaluate the cumulative toxicity of mixtures of different classes of pesticides alone and mixtures of different classes of pesticides together

with food additives and common consumer product chemicals in more realistic doses after long term exposure. If the hypothesis of an increased risk or even a new hazard not currently identified from cumulative exposure to multiple chemicals were shown to be true, this will provide further information to public authorities and research communities supporting the effort to replace today's single-compound risk assessment with a more robust cumulative risk assessment paradigm. Taking into consideration most recent aspects for risk assessment of individuals, where exposure assessment is personalized, we can realize the grounds and causation of the incomprehensible and hazy picture we face in our toxicology evaluations and the timely disagreement in facts among governmental and other international and authorial regulatory organizations throughout the world. It is a fact that as we expand the sphere of our knowledge in general we simultaneously expand the borders of our knowledge with ignorance. Being highly respectable to Socrates I suggest that the above sentence takes a step forward and clarifies for the public the deep meaning of the Socrates statement "I know nothing except the fact of my ignorance".

Biography

Professor Aristidis Michael Tsatsakis is the Director of the Department of Toxicology and Forensic Sciences of the Medical School at the University of Crete and the University Hospital of Heraklion. He is teaching the toxicology course for medical students for 30 years and specialization toxicology topics for postgraduate programs in few universities and supervised numerous PhDs. He received his PhD in Chemistry from Mendeleev University in Moscow 1986 and defended the title of Doctor of Science in Biology in University of Friendship of Nations in Moscow 2004. Prof Tsatsakis has written over 360 peer reviewed publications in prestigious journals, is holder of several patents and has given numerous lecturers as keynote and plenary speaker in international congresses. He has coordinated as PI over 40 scientific research and technology national, EU and international projects and established worldwide collaborations.

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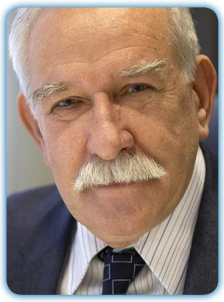

Wojciech Wasowicz

Institute of Occupational Medicine, Poland

Selenium and human health: Interactions with heavy metals

The function of Selenium (Se) as trace element for animals and humans has been known for several decades. Se is an essential microelement at low levels of intake and produces toxic symptoms when ingested at level only three to five times higher than those required for adequate intake. It is generally accepted that blood Se depends on dietary intake. According to some epidemiological data, low Se intake may be associated with higher cancer incidence and also implicated in cardiovascular diseases, diabetes and asthma. Beneficial role of Se is related to its role in the antioxidative system i.e. antioxidative enzymes (glutathione peroxidases; thioredoxine reductases) and several selenoproteins (i.e. selenoprotein P). In recent years, most attention was paid to Se in the context of cancer incidence reduction, which was demonstrated in animal studies and human clinical trials in relation to human cancer. Epidemiological studies, including retrospective, Prospective and also intervention ones, show that a low Se level, may increase the risk of certain cancers. However, it should be noted that there is also a relatively large number of studies, in which no effect of Se on cancer has been observed. From epidemiological point of view Se interaction with heavy metals raises a large interest. Although antagonistic influence of Selenium on bioaccumulation of mercury, Cadmium and arsenic in experimental animals is well known, interaction mechanism between those elements in humans has remained unexplained. However, in many cases the doses and character of exposure in experimental animals differed from dose observed in human exposure. To sum up, Selenium is important element for human health; however, relationship between Se and toxic elements should be taken into account. This kind of research may prove to have not only scientific as well as practical value.

Recent Publications

- Wasowicz W, Gromadzinska J, Rydzynski K, Tomczak J (2003) Selenium status of low-Selenium area residents: Polish experience. Toxicology Letters. 137: 95-101.
- Wasowicz W, Gromadzinska J, Rydzynski K (2001) Blood concentration of essential trace elements and heavy metals in workers exposed to lead and Cadmium. 14: 223-229.

Biography

Wojciech Wasowicz, PhD, is Full Professor at Nofer Institute of Occupational Medicine and Head of the Biological and Environmental Monitoring Department. He has a background in Biochemistry, Analytical Chemistry and Toxicology. He has wide experience with toxicology of metals and its interactions with microelements, oxidative stress markers, and antioxidant enzymes related to human health. The next field of interest is potential protective role of some antioxidants against chemicals. He shows great scientific activity confirmed by numerous publications and active participation in symposia, conferences and scientific meetings organized in Poland (Polish Society of Toxicology) and abroad (EUROTOX, IUTOX), and has given numerous lectures as keynote and plenary speaker in international congresses. His work has hitherto resulted in 170 scientific papers published mainly in journals of international recognition.

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Swamy K B

Universiti Sultan Zainal Abidin, Malaysia

"*Synsepalum dulcificum*" (Miracle fruit): A future potential anti-hyperglycemic and other herbal medicinal plants that protect the health of Kuala Terengganu people in Malaysia

Introduction: The study of previous researchers Ali *et al.* (1992) revealed the prevalence of non-insulin dependent diabetes mellitus (NIDDM) and deviated glucose tolerance among the Aborigines (0.3%, 4.7%) and Malays (4.4%, 11.3%) respectively. A variety of studies indicated that Malays have a relatively high prevalence of type 2 diabetes compared with other Asian ethnic groups.

Aim: The aim of the study is to evaluate the frequency of herbal medicine usage among the Terengganu population in Malaysia by conducting a research through systematic-survey analysis to know how frequently and for what common diseases the herbal medicine was used.

Materials & Methods: 1520 respondents (male and female), ages between 14 and above 70 years were selected by systematic random sampling from 5 directional areas of Kuala Terengganu state in Malaysia. The statistical analysis was done by using SPSS 21.0 package.

Results: According to our analytical study, 68.82% of population was using herbal medicine and 31.18% were using western and other systems of medicine. The purpose of using traditional medicine for the curative purpose was 43.98% (n=460), preventive 30.31% (n=317), sexual health (10.99%, n=115), cosmetic reason 6.50% (n=68) and for others (8.22%, n=86). For the curative purposes, 57.39% respondents used it for curing hypertension (n=264), diabetes (13.48%, n=62), arthritis and heart failure (9.35%, n=43), peptic ulcer and other diseases (3.48%, n=16), bronchial asthma (1.3%, n=6) and cancer and renal stones (1.09%, n=5). We also identified to our surprise, 99 medicinally used plants in Terengganu among which *Synsepalum dulcificum* (Miracle fruit) was extensively used by people as an anti-diabetic herbal medicine.

Discussion: Our present study revealed that 68.82% of the population in Terengganu preferred herbal medicine than other systems of medication to use.

Conclusion: Our results coincided with the WHO statement that 70% of the world population prefer herbal medicine as the treatment for their ailments.

Biography

Swamy K B has been awarded PhD by Andhra University, India. He has taken his Master's degree in Clinical Anatomy from Andhra Medical College, India, DMCh (Maternal & Child Health) and Medical degree (MBBS) from IGNOU, New Delhi. He has expertise in Human Genetics, Reproductive & Developmental Anatomy and also in Herbal Medicine. He has been the Genetic Counselor for many institutions, with prestigious grants from Malaysia. He has conducted many researches on Herbal Medicine and Diabetes, on "Brain size and Intelligence Quotient (IQ)". He has been the former Founder, Anatomist, Professor and Head of the Department for many Medical Schools in India as well as in Malaysia. He is an international Editorial Board Member for many reputed journals like *Anatomical Society of India* (ASI). Recently, he has been unanimously elected as an Executive Board Member for ASI and an Organizing Committee Member for the upcoming "9th Euro-Global Summit on Toxicology and Applied Pharmacology" to be held during June 22-24, 2017 at Paris, France.

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Jirova Dagmar

National Institute of Public Health, Czech Republic

Endocrine disruption and antimicrobials

Endocrine disruptors are hormonally active substances of natural or synthetic origin affecting the endocrine (hormonal) systems of humans. Such compounds can be found in chemical groups like steroids, cyclic hydrocarbons, phenols, flavonoids, phtalates, parabens or toxic metals. They are used as antimicrobials, biocides, plasticizers, surfactants, UV filters or fire retardants. They may be released from consumer products, e.g. cosmetics, toys, food packaging materials, household products, medical devices and other products of industry or agriculture. In the EU, they are banned for consumer products. Recently regulated CMR substances from the group of Antimicrobials/Preservatives (biocides) comprise: Chloracetamide (Reprotox. Cat. 2), Phenol (Mutagenic Cat. 2), Nonylphenol (Reprotox. Cat. 2), Parabens (pentyl-, phenyl-, benzyl- for absent data on reprotox.), Ketoconazole (Reprotox. Cat. 1B), Boron compounds (Reprotox. Cat. 1B), Formaldehyde (Carcinogenic Cat. 1B), Polyaminopropyl Biguanide-PHMB (Mutagenic Cat. 2). Significant reprotoxic effect has been proved in the past namely for distinct bisphenols (Reprotox. Cat. 2) or phthalates (Reprotox. Cat 1B or Cat. 2) which were subsequently banned. However, the production of analogous compounds is increasing underlining the necessity to test their safety including reprotoxicity. The European Commission's general policy is the use of alternative toxicological methods *in vitro* instead of conventional tests on vertebrates. Available methods *in vitro* to detect endocrine disruption are: OECD TG 455/457–Estrogen Receptor Transactivation Test Method, OECD TG 456–Effects on Steroidogenesis, OECD TG 236–ZFET, zebrafish embryo epigenetic assay, MCF-7 cell proliferation assay, Xenoscreen YES/YAS yeast assay. Results of a pilot study to prove applicability of methods *in vitro* to detect reprotoxicity are presented.

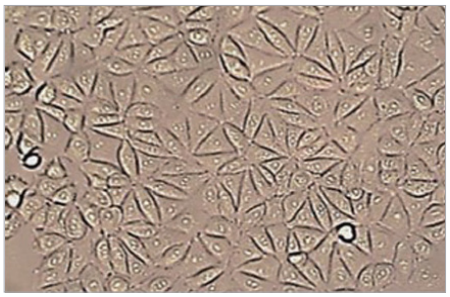

Figure 1: *OECD TG 455/457-VM7Luc4E2 cell line, kindly provided by Prof. M. Denison, UC DAVIS, for research purposes.*

Biography

Jirova Dagmar, MD, PhD, graduated and received her PhD at the Charles University in Prague. Her professional specialization is in Dermatotoxicology and Immunotoxicology, focused on safety assessment of cosmetics and other consumer products. She is holding a position of the Head of Centre of Toxicology and Health Safety at the National Institute of Public Health, Prague, Czech Republic. She is the author of more than 200 publications in scientific journals, proceedings and monographs, posters or articles and publications for the public. She was the Principal Investigator in number of research projects in the field of alternative toxicological methods for evaluation of health risks of chemicals and consumer products.

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Mukul P Pore

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Preclinical development of biopharmaceuticals (r-DNA Products)

Biopharmaceuticals are an important component of pharma industry & have grown exponentially in the last decade. The growth is driven by factors such as growing pressure for affordable product development, advances in biochemical and molecular biology instrumentation, growing demand for biosimilar drugs to address ever growing chronic diseases, increasing number of off-patented therapeutics and monoclonals. Great successes were achieved and multiple life-altering therapies were developed for indications like cancer, rare genetic diseases, and immune disorders. Significant guidance has been released by regulatory agencies to help the rational and scientifically based development of these complex products. The goal of preclinical development of biosimilar is to demonstrate that, the drug is 'highly similar' to the reference biologic product in terms of 'Safety, Efficacy and Quality'. Monitoring biopharmaceutical drug safety deserves special attention. In this presentation, challenges in the preclinical development of biologicals (particularly 'Biosimilars') will discussed in short. Key features of biotechnology-derived molecules (Biosimilars including Vaccines), how they compare to traditional chemical drugs, and the impact these features on preclinical safety testing during their development will also be discussed.

Biography

Mukul P Pore is one of the founders and is the Lifetime Director of INTOX Pvt. Ltd. which is a well-known GLP certified contract research organization. He is a Diplomate of the American Board of Toxicology (DABT), European Registered Toxicologist (ERT) and Fellow of Indian Society of Toxicology (FST). He has designed and conducted number of toxicology studies for diverse kind of products - pharmaceuticals, agrochemicals, biotechnology products, specialty chemicals, vaccines, medical devices, industrial chemicals etc., during his experience of over 28 years in regulatory/descriptive toxicology. Since 1996, he has played an important role in establishing and bringing INTOX to international standard and repute. He is an *Ad Hoc* specialist for AAALAC International, USA (2010-2013; 2013-2016; 2016-2019). He is member of many professional bodies/societies including Indian Society of Toxicology (STOX), Chinese Society of Toxicology, Japanese Society of Toxicology (JST), UK Registry of Toxicology and Laboratory Animal Scientists Association of India. He was nominated on 'REACH Expert Committee" as "Expert in the field of Environment, Health and Safety" by Ministry of Chemicals & Fertilizers, Govt. of India (2015). He was nominated as Advisor of Editorial Board of "*Toxicology International*" journal in 2009.

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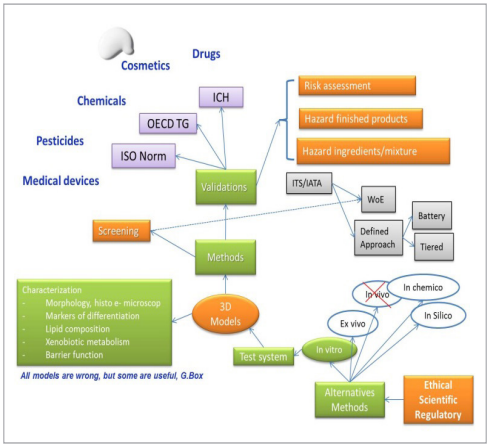
Christian Pellevoisin

Episkin Academy, France

Reconstructed skin models and methods for hazard and risk assessment of chemicals and cosmetics

In 2003, the 7th Amendment to the Cosmetics Directive introduced in Europe the regulatory framework for the phasing out of animal testing for cosmetics purposes. Since 2013, this testing and marketing ban fully entered in force and is now part of the European Cosmetic Regulation. Following this European regulation, we observe outside Europe a strong trend for a progressive shift to non-animal methods for safety of ingredients and cosmetics products. Mechanistic approaches to replace the animal are based on *in silico*, in chemico and *in vitro* assays that can inform on one or more key events of adverse outcome pathways (AOP). To be as predictive as possible of human being, such individual *in vitro* test systems rely more and more on cells of human origin with a 3D organization which better mimic the vivo situation. To this point of view, Reconstructed Human Epidermis (RHE) presents several advantages that make it an alternative method of choice for evaluating some safety endpoints. To date, several alternative methods in toxicology have been developed based upon *in vitro* skin: Skin penetration, skin corrosion/irritation, phototoxicity and genotoxicity. However, an *in vitro* alternative method must be validated before being recognized by the concerned regulatory bodies. Today, two alternative methods based on *in vitro* skin models have been validated as full replacement methods to animal, the OECD-TG 431 for *in vitro* skin corrosion and the OECD-TG 439 for *in vitro* skin irritation of chemicals. Moreover, two other methods based on human reconstructed epidermis and full thickness models have been submitted for validation in the field of sensitization and genotoxicity.



Biography

Christian Pellevoisin, after a PhD in Neuroscience at the French National Institute of Health and Medical Research, had a temporary teaching position at the University of Tours, France. He joined L'Oréal in 2000 at the Life Science Research Center where he introduces computer tools for *in vitro* toxicology. He was In-charge (2004) of scientific communications in the Field of Alternative Methods and Tissue Engineering. In 2011, he joined EPISKIN, a subsidiary of L'Oréal, dedicated to development and production of reconstructed human epithelia. He is In-charge of EPISKIN Academy, a transversal program to support the use of 3D models for efficiency and safety assessment and to relay EPISKIN commitments to 3Rs by training scientists, students and future stakeholders to the scientific and regulatory challenges of alternative to animal testing. He wrote several scientific publications and is Member of ISO technical committee 194 for biological and clinical evaluation of medical devices.

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Sahar Y Issa

Alexandria University, Egypt

A novel solution for ongoing medicolegal problem: Online Traceable Authenticated Reliable Result (OTARR) - Unique electronic application from Dammam Poison Control Center

The development of online computerized medical record database has in general complied with the actual needs and conditions in the modern healthcare system to deal with tremendously increasing medical emergencies. As poisoning is a known grave medical emergency, from here came the need to initiate and update OTARR (Online Traceable Authenticated Reliable Result); a pioneer computerized toxicological database in the medically revolutionized Saudi Kingdom. Dammam Poison Control Center (DPCC) has medicolegal intimate services; and the result of analysis and consultation should be secure, concise, fast and at the same time comprehensive. OTARR is a novel online multi - purpose web application that is freely available on both intra (Ministry of Health network), and internet as a toxicology and medicolegal secure resource.

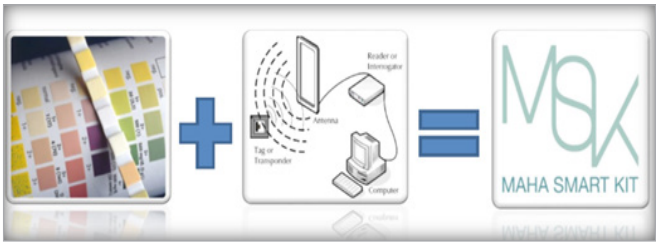

Figure (1): *Maha Smart Kit (MSK); adulteration detection container and radio-frequency identification technology.*

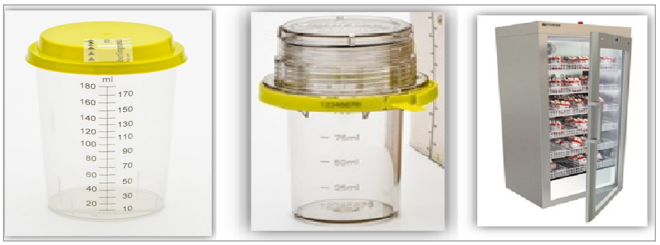

Figure (2): *Adulteration detection container, RFID container and RFID smart fridge*

Biography

Sahar Y Issa has completed her Doctorate degree in Clinical Toxicology & Forensic Medicine in 2008, from Faculty of Medicine, Alexandria University, Egypt and is a Lecturer of Clinical Toxicology & Forensic Medicine in the same University. She is currently a Consultant Toxicologist and Medical Director, supervising Emergency Toxicology, Molecular Toxicology and Therapeutic Drug Monitoring units in Dammam Poison Control Center, MOH - Saudi Arabia. She has published more than 25 papers in reputed journals and serving as an Editorial Board Member of repute.

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