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# Poster Presentations

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## *Healthcare & Biosimilars 2018*



World Summit on

# Healthcare & Hospital Management

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International Conference & Exhibition on **Biologics and Biosimilars**

March 26-27, 2018 | Orlando, USA

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## Psychological work environment and suicidal ideation among nurses

Judith Shiao

National Taiwan University, Taiwan


Nurses are exposed to a poor psychological work environment; this may cause poor mental health, which is a risk factor for suicidal ideation. We investigated the association between the psychological work environment and suicidal ideation among hospital nurses in Taiwan. In 2015, we conducted a cross-sectional survey in Taiwan female nurses and applied stratified sampling by region (north, central, south, and east) to select representative centers for this study. Approximately 2%–8% of the hospitals from each region were selected. A self-report questionnaire including items on demographic data, the psychological work environment, and suicidal ideation was sent to our participants working in hospitals. Multiple logistic regression and population attributable risk analyses were performed to assess the effect of the psychological work environment on suicidal ideation. A total of 2,734 (76.8%) returned the questionnaires and were eligible for final analysis. The prevalence of suicidal ideation was 18.3%, and higher risk was found to be associated with the educational level of junior college or below, higher personal burnout, higher

client-related burnout, and always feeling stressed at work. Estimation of population attributable risk showed that higher personal and client-related burnout and always feeling stressed at work were the most crucial factors among nurses, accounting for 19.4%, 12.7%, and 9.9% of suicidal ideation, respectively. We conclude that considerable proportion of nurses developed suicidal ideation. A poor psychological work environment was relevant factors for suicidal ideation. This study provides relevant knowledge for nursing management levels in preventing the development of suicidal ideation among nurses. Not only for nurses' mental health, but for patient safety and care quality, further studies in improving nurses' psychological work environment are warranted.

### Speaker Biography

Judith Shiao is currently working at National Taiwan University College of Medicine and NTU Hospital, Taipei, Taiwan.

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## The effect of job burnout on the turnover intention of medical laboratory employees: A correlational study

Tasia Hilton

Saint Leo University, USA

**Problem & Background:** The field of medical laboratory science is experiencing a shortage of qualified professionals. In addition, many laboratories are seeing an increase in the voluntary turnover of current laboratory personnel. The laboratory plays a vital role in patient care, providing health care practitioners with the results of laboratory analyses that are used to help diagnosis and treat patients. Therefore, it is important to address the current and future shortage in the medical laboratory workforce. There is limited research on factors affecting the turnover intentions of clinical laboratory employees. This study aimed to examine the effect of burnout on the turnover intention of clinical laboratory employees in Florida.

**Methods:** This study used a cross-sectional survey to explore the relationship between burnout and turnover intention among clinical laboratory employees in Florida. The Maslach Burnout Inventory – General Survey and a demographic questionnaire were used to collect data from licensed clinical laboratory directors, supervisors, technologists, and technicians. The data were analyzed using linear regression and ANOVA in SPSS.

**Results:** This study included a subsample of 184 Florida state-licensed medical laboratory employees out of 1,000 invited participants. Among clinical laboratory employees in Florida,

the findings revealed significant predictive relationships between all three dimensions of burnout (emotional exhaustion, cynicism, and professional efficacy) and turnover intention. Also, the study revealed a statistically significant difference between different age groups and professional efficacy.

**Conclusion:** These findings suggest that emotional exhaustion and professional efficacy are the best predictors of turnover intention. In an effort to reduce turnover among medical laboratory employees, laboratory managers must create strategies that will reduce burnout, thus decreasing employee turnover intention.

### Speaker Biography

Hilton is Assistant Professor of Healthcare Administration at Saint Leo University in Savannah, Georgia. She is also certified by the American Society of Clinical Pathology as a Medical Laboratory Scientist. She received a Bachelor of Science degree in Chemistry from the University of South Carolina, a Bachelor of Science degree in Medical Laboratory Science from Armstrong Atlantic State University, a Master's degree in Healthcare Administration from Ashford University, and a PhD in Health Services - Healthcare Administration from Walden University. She has taught in higher education for over 7 years in the areas of chemistry, health science, and healthcare management. Hilton's 10+ years of medical laboratory experience includes working in the general core laboratory departments, toxicology, and health information technology. Her research interests include employee turnover, organizational commitment, and job burnout among medical laboratory personnel as well as student retention and satisfaction.

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## Unnatural self-poisoning suicidal deaths, implications in forensic toxicology

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Suicide is a complex, multifaceted problem and is categorized as one of the major causes of unnatural deaths in all age groups worldwide. Asian countries account for about 60% of global suicides. Iran had shown the highest increase rate of suicidal deaths among Eastern Mediterranean Region and Islamic countries. Intentional poisoning is the third method of suicide following hanging and self-burning in Iran. Therefore, we undertook a retrospective analytical study to investigate toxicology findings in completed suicides referred to Legal Medicine Organization, Tehran, Iran to define the most prevalent drugs and poisons in postmortem samples of self-poisoning completed suicides in a five-year study Period (2011–2015). All self-poisoning suicidal deaths during 2011–2015 were included in the present study. Death certificates of cases were reviewed and extracted data such as age, gender, marital status, employment status, forensic toxicology results for licit and illicit drugs, alcohols and poisons were entered into the designed questioners by a trained forensic toxicology specialist. As expected, more than one drug was used by subjects to commit suicide. The most prevalent toxic substance that was detected in

postmortem samples was phosphine gas liberated from aluminum phosphide or zinc phosphide tablets or powders. The total number of self-poisoning suicidal deaths was 674 with the predominance of men. Self-poisoning suicidal deaths were highest in the 21–30 years age category. As for occupation, the highest rate of completed suicide was among unemployed subjects. A higher frequency of poisoning was seen in single cases. Spring and autumn were the most troubling seasons regarding self-poisoning suicidal deaths. Meanwhile, the results of the present study will help to better tailor preventive efforts regarding restriction for the access to suicidal means.

### Biography

Akhgari Maryam has her expertise in Forensic and Analytical Toxicology as the Head of Forensic Toxicology Department, Tehran, Iran since 2004. Her responsibility is to decide about drugs and poisons related deaths, postmortem forensic toxicology, seized materials analysis and analytical method validation. She is one of the Members of Legal Medicine Research Center, Legal Medicine Organization, and Tehran, Iran as Associate Professor with about 40 published papers..

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# Accepted Abstracts

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## Use of audit to drive quality improvement in oral care on a neurological rehabilitation unit

Aisha O'Gilvie and Dianne Banagale

The Wellington Hospital, USA

**Introduction:** Oral hygiene is an essential aspect of patient care and helps prevent aspiration pneumonia and other systemic infections which subsequently lead to longer hospital stays and increased mortality rates.

**Material and Methods:** A preliminary audit of the compliance in providing oral care on 4 hourly basis revealed 54% compliance on a neurological rehabilitation unit. Further audits of staff knowledge and documentation, confirmed the need to train nursing staff and develop documentation to improve compliance with oral care. As recommended in

the literature, this hospital uses a 24 hour oral cleansing and suctioning system (SAGE Products Inc., Q4).

**Results and Conclusion:** On average, nurses achieved > 90% compliance in providing patients with oral care on a Q4 basis and improvement in oral hygiene status was noted with scores moving from minimal mouth care to good / moderate mouth care. Driving Compliance in Oral Care project is currently being implemented across all rehabilitation wards at The Wellington Hospital.

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## **Economic performance and governance: Evidence from community hospitals in New York city**

**Chul-Young Roh, Andrew Kim and Ileana Carillo**  
Lehman College, USA

Community hospitals in New York City hold a unique position in this turbulent era. While community hospitals are the hub of healthcare delivery in New York City, competition has intensified among hospitals as well as between hospitals and physician-owned facilities. Advances in healthcare technology have enabled a large number of complex procedures to take place in an outpatient service setting. The primary purpose of this project was to investigate the economic performance of community hospitals in New York City that provided general and acute healthcare services from 2001 to 2010. Given that years of chronic losses and

growing numbers of empty beds have caused the closure of some hospitals, while other hospitals are on the brink of collapse, the proposed project will measure the performance of community hospitals in the city by focusing on the roles and functions of hospital governance or governing boards. To do an in-depth analysis of the relationship between hospital governance and the productivity and performance of these hospitals, this study will employ two general approaches: hierarchical linear modeling (HLM) and Data Envelopment Analyses (DEAs).

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## **The green synthesis and antibacterial efficacy of CuO and ZnO nanoparticles against Gram-positive and Gram-negative bacteria**

**Mohammad F**

Aligarh Muslim University, India

Infectious diseases possess a big challenge for the scientists worldwide. Antibiotics were once a boon for mankind to combat the infectious diseases. However, the emergence of antibiotic resistance among superbugs is matter of great concern throughout the world. Recent advances in the field of nanotechnology particularly synthesis of metal nanoparticles of specific size and shape are suggestive of bright future of these materials. Nano-sized particles of the metal oxides viz. CuO and ZnO were successfully synthesized using aqueous and alcoholic extracts of *Swertia chirayita* as a reductant and stabilizer. The as-prepared nanoparticles were further characterized by using

Fourier transform infrared spectroscopy, X-ray diffraction, UV-visible spectroscopy, high-resolution transmission electron microscopy, scanning electron microscopy and energy-dispersive X-ray spectroscopy. These nanoparticles were evaluated for their antibacterial efficacy against Gram-positive (*Staphylococcus aureus*) as well as Gram-negative (*Escherichia coli* and *Salmonella enterica*) bacterial strains. Among the two metal oxides, CuO nanoparticles showed better antibacterial efficacy as compared to ZnO nanoparticles against both the Gram-positive and Gram-negative bacterial strains.

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## Physicians and nurses grieve too; loss, grief and mourning

Kimberly Richardson

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There is lack of direction when it comes to physicians and nurses coping with their own grief connected with the loss of a patient. It is unprofessional to cry or show too much emotion. The textbook of medicine teaches their students to distance themselves and create protective boundaries. Being emotional is a sign of weakness. This approach is impractical and damaging. Physicians and nurses are human and experience feelings of helplessness, guilt, uncertainty, isolation, disappointment, and depression after the death

of a patient. These feelings can lead to medical errors and burnout if not addressed. Working in the health profession can be very challenging. There is a need to have a better understanding of empathy development in the health profession and more education on how to improve the situation. Caring for dying patients can put a lot of stress on nurses and physicians and this can cause them to burn out or quit.

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## Hepatoprotective activity of aqueous seed extract of *Nigella sativa* against highly active antiretroviral therapy induced hepatotoxicity in rats

Kissi Mudie<sup>1</sup>, Daniel Seifu<sup>2</sup>, Feyissa Challa<sup>1</sup>, Abiy Abebe<sup>1</sup>, Asfaw Debella<sup>1</sup> and Atsbeha Gebregzabher<sup>1</sup>

<sup>1</sup>Public Health Institute, Ethiopia

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**Background:** Liver is a metabolically active organ responsible for many vital life functions. Due to its important activities, the liver is exposed to a number of insults and is one of the body's organs most subject to injury. In spite of tremendous advances in modern medicine, there are hardly any reliable drugs that protect the liver from damage and/or help in regeneration of hepatic cell. It is, therefore, necessary to search for effective and safe herbal drugs for the treatment of liver disease to replace currently used drugs of doubtful efficacy and safety.

**Aim:** The aim of this study was to investigate the hepatoprotective activity of aqueous extract of *Nigella sativa* seed in highly active antiretroviral therapy (Lamivudine, Zidovudine and Efavirenz) administered rats.

**Materials & Methods:** Sixty rats weighed between 150-200g were randomly divided into six groups and each group comprised of ten rats. Rats in group I were administered with distilled water. Rats in group II were administered with highly active antiretroviral therapy only. Rats in groups III - VI were administered 100, 200, 400 and 800mg/kg *Nigella sativa* plus highly active antiretroviral therapy respectively.

The treatments were given orally for 28 consecutive days. On the 29<sup>th</sup> day, all rats were sacrificed under light diethyl ether anesthesia; blood samples were collected for the assessment of biochemical parameters, while liver tissue was used for histopathological assessment.

**Results:** Serum levels of liver enzymes ALT, AST, ALP, and GGT were significantly ( $p < 0.05$ ) increased and albumin concentration was significantly decreased in animals treated with highly active antiretroviral therapy as compared to the normal control. Histopathological observations also revealed severe damage in the structure of liver tissue in animals administered with highly active antiretroviral therapy. Treatment of highly active antiretroviral therapy exposed animals with *Nigella sativa* showed marked improvement in both biochemical and histopathological findings. Rise in liver enzymes was almost restored to normal in animals treated with *Nigella sativa*.

**Conclusion:** *Nigella sativa* through its antioxidant activity effectively protects highly active antiretroviral therapy induced liver toxicity.

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### **How patients perceive healthcare services: A case of Ayub Teaching Hospital, Abbottabad – Pakistan. SERV service QUAL quality**

**Muhammad Ali**

Baskent University, Turkey

A field study was conducted in Ayub Teaching Hospital in the outpatient department, to evaluate the level of service quality offered by the healthcare services with a view to identifying the relationship between service quality dimensions and overall service quality. The researchers used the SERVQUAL instrument for the purpose of assessing the quality of the service offered by the healthcare workers at the outpatient department in Ayub Teaching Hospital. A sample of 246 patients in the outpatient department participated in the questionnaire survey. The results revealed that patients are dissatisfied with three dimensions (tangibles, reliability, and assurance), but they are satisfied with the other two dimensions (responsiveness and empathy). This research adopts the marketing concept to measure the health care services. The SERVQUAL tool was modified as per need to

meet the requirements in accordance with the nature and scope of the research. Patients' attitudes toward service quality dimensions were the concern of the research. Consequently, based on the results, the new structure can be designed by adopting strategies that improve the quality of services in order to provide effective services and gain patients' satisfaction and propensity to further recommend the services of health care to other patients. This study investigates the health care quality in a small area in Pakistan. Future research can adopt the SERVPREF technique, which is a more developed technique than SERVQUAL in order to measure service quality as it provides a two-factor solution for the dimensionality of health service quality.

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## **Depletion of social capital and decline of competency among DOTS healthcare professionals: Evidence from field experiences in India**

**N Ravichandran**

Hamdard University, India

**Background:** Single-window care and treatment for tuberculosis and HIV co-morbidities is still a distant dream, which further fueled by health poverty and incapacity of healthcare system in India. Nevertheless, the study aimed at measuring the intensity of social capital and their degree of competency of DOTS healthcare-personnel in providing care and treatment to tuberculosis and HIV/AIDS co-morbidities.

**Methods:** The cross-sectional study conducted during September – February 2017 in Delhi-National Capital Region with 300 DOTS healthcare-personnel who provide HIV/AIDS care and treatment.

**Results and Conclusion:** Over three-fifths (61%) studied healthcare professionals consented that diluting the prescribed tuberculosis management practices. The study found that one-third of healthcare-personnel are familiar with RNTCP guidelines. Two-thirds (64%) reported that sputum diagnosis is appropriate method for tuberculosis presence, Painstakingly, about one-fourth (24%) stated MDR drug is ineffective in HIV co-infection, one-fifth (21%) quoted wrong tuberculosis resistance procedures while a half (50%) admitted that not following the revised guidelines for treatment regimen.

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## **Assessing the impact of lean practices on sustainable performance of health care systems**

**Omar Awad AlJaberi and Matloub Hussain**

Abu Dhabi University, UAE

In recent years, both researchers and practitioners have paid attention to sustainability issues in the health care sector, but, despite the sensitivity of the topic, a comprehensive framework is yet missing. The purpose of this study is to investigate the impact of lean practices on sustainable performance and to develop a framework to measure sustainability in the health care sector in UAE. Moreover, this study will investigate the relationship between lean practices and organization sustainability performance through the Confirmatory Factor Analysis (CFA) and Structural Equation Model (SEM). Also, it will examine the impact of the organizational innovation climate on the process of accelerating the relationships between lean practices and organization sustainability performance. In addition, the triple bottom line will be used to measure the sustainability

which is not commonly used before in the literature for this purpose. The study results are a useful tool for practitioners who are seeking effective utilization of sustainability factors and creating a competitive advantage within their organizations. Furthermore, the implementation of the sustainability framework will help practitioners be more alert on what will influence their organizations' performance to lead them to higher sustainable consequences. Finally, there are some limitations on this study; first, this study focuses only on the geographic area of UAE.

Second, the study is limited to the health care sector. Third, the study did not measure the impact of sustainability on the organization's employees or customers.

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## Change! Is medical tourism a wakeup-call for transforming your medical practice?

Pramod Goel  
Placidway, USA

Globalization and the constant technology innovation are resulting in a continuous evolution of business environment. Easily accessible information is resulting in unprecedented options for consumers while putting pressure on medical service providers to revolutionize their practice and adapt to ever changing environment. Today, a medical practice must think how to compete in a very crowded and competitive marketplace. They are faced with business challenges such as: Financial stability: ensuring long term financial viability, transforming practice, consistent growth; Customer loyalty: re-thinking patient engagement, winning new customers and retaining them; Competition: differentiating practice with uniqueness, setting apart from others and Knowledge: continuous learning new techniques, accessing new equipment/technologies. Medical tourism has been touted as the next big thing. There is a lot of noise, expectations, and myths. You have to consider issues such as: Does medical tourism provide a solution to your financial vows? Will it be worth the effort to change your business practices to include medical tourism in your portfolio of services? Can medical tourism help you expand/

diversify your customer base? Will medical tourism help you in improving your competitive advantage? The session will provide five critical points a medical practice must consider today in order to create a sustainable business practice domestically as well as globally. It will provide tools and techniques to compete in the new economy, such as: Revenue modeling that can help generate more income and profitability Customer acquisition and retention, creating better patient experience; Customer focused employees who are trained and productive while adapting to change; Business and clinical process management that are efficient and less expensive Innovation to introduce new services, new revenue channels. With medical practices, experiencing so much change they must learn to become comfortable with the change. The ability to manage and adapt to rapid change is difficult because of organizational structure, culture, and socio-economic challenges. The organizations that adapt quickest will create a competitive advantage, while the practices that refuse to change get left behind.

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## **From brand vs. generic to biologic vs. biosimilar: The regulatory challenge and the search for a holistic solution**

**R R Kishore**

Indian Society for Health Laws and Ethics, India

**T**here is a fundamental difference between Generics and Biosimilars. "A generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." About a Biosimilar, small differences in structure or chemistry due to the processes and chemicals used in the culture, purification, storage, etc., may result in differences in efficacy, safety and immunological outcomes as compared to a Biologic. As such, Biosimilars, are in many ways analogous to generics, but are not generic drugs. The question is, "Can the need for preclinical and clinical studies

be eliminated in case of Biosimilars before they are put to therapeutic use"? The issue is intricate attracting different viewpoints and it is currently not clear if separate evidence for each indication will be required. The approach so far adopted in the USA and Europe has been heterogeneous and the matter needs to be studied in-depth. In this paper, I examine the issue from multiple perspectives i.e., the academic, industry, regulatory agencies, patients and clinicians in an attempt to search a holistic solution.

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## **Microtubule associated Tau squired by molecular chaperones in Alzheimer's disease**

Subashchandra Chinnathambi<sup>1,2</sup> and Nalini V Gorantla<sup>1,2</sup>

<sup>1</sup>CSIR-National Chemical Laboratory, Pune, India

<sup>2</sup>Academy of Scientific and Innovative Research, India

**A**lzheimer's disease (AD) is a neurodegenerative disease characterized by progressive cognitive decline. It accounts for 60%-70% of total dementia cases. The extracellular plaques of amyloid beta and the intracellular neurofibrillary tangles of Tau protein are the hallmarks of AD. Tau is a microtubule-associated protein, which stabilizes the microtubules and maintains neuronal structure as well as trafficking. It is amenable to various post-translational modifications (PTMs), which influence its microtubule binding affinity. The most exclusively studied PTM is hyperphosphorylation, which affects the microtubule binding and leads to Tau aggregation. Other PTMs include glycation, acetylation, methylation, nitration etc. Chaperones such as Hsp70 and Hsp90 tries to resolve the toxic conformations of

Tau which is then either folded to its native form or in the downstream is degraded and eliminated from the cell. But in diseased conditions, the chaperones fail to remove the mutated or toxic Tau species. Chaperones are also involved in lysosomal degradation of Tau by a process called chaperone mediated autophagy (CMA) and helps in removal of modified Tau. The cellular machinery directs Tau degradation via UPS. In the other hand, inhibiting the chaperone activity would lead to degradation and elimination of toxic Tau species. Small molecules inhibitors against chaperone activity are known to be effective in clearance of the aberrant Tau from cell.

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## **Biosimilars and the management of double binds**

**Toine Pieters**

Utrecht University, Netherlands

**P**harmaceutical regulators have a dual responsibility. On the one hand, they need to protect and promote public health; while on the other hand, they have a role in stimulating pharmaceutical innovation through scientific advice, regulatory guidelines and other forms of regulatory dialogue. Although regulators are acclaimed for their scientific expertise and independence, they are also criticized for being a source of bureaucracy and thus stifling innovation. I will analyze the emergence of the EU biosimilar regulatory framework and the need for biosimilar ambassadors within

hospitals. I demonstrate that in an uncertain environment, European regulators have created a regulatory framework for biosimilars that stimulates innovation while attempting to maintain high safety standards. But, alignment with doctors is essential in order to stimulate the cost-effective application of biosimilars in clinical practice. This case study provides valuable lessons on how to handle the biosimilar challenges in a highly volatile pharmaceutical sector and within a specific regulatory and healthcare framework.

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## Nutritional management cirrhosis of the liver disease: A case report category : Nutritional sciences

Verona Mulgrave, Oyonomo Ntekim and Chimene Castor  
Howard University, USA

**Background:** According to the Nation Center for health Statistics cirrhosis of the liver is the 12<sup>th</sup> leading cause of death in the U.S and it is primarily caused by alcoholic liver disease. National Center for Health Statistics indicated cirrhosis is higher in blacks than in whites and the highest mortality rate is among Hispanics. Results from NHANES Study the frequency of steatohepatitis and cirrhosis varies significantly by ethnicity: 45% Hispanics, 33% whites and 24% among blacks, Mexican Americans and Blacks have a greater risk of developing liver disease than their white counterparts.

**Research Question/Hypothesis:** The objective of this study is to investigate the importance of specific nutrients in the nutrition management of cirrhosis of the liver.

**Methods used in the Investigation:** This study was a single-subject case report of a 49-year-old African American male that was diagnosed with several comorbidities including idiopathic cirrhosis of the liver. This subject was chosen at random from the Howard University Hospital.

**Results and Conclusion:** Patient had several nutrition diagnoses including malnutrition, inadequate oral intake, and impaired nutrient utilization and increase energy and nutrient requirements. Nutrition plays a key role in the management of cirrhosis of the liver specifically restricting fluid and sodium, providing adequate carbohydrate, protein and medium chain fatty acid as well as micronutrients such as B vitamins and the fat-soluble vitamins.

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## The end of clinical trials in biosimilars development

Francois-Xavier Frapaise  
Merck, France

In his book, *"The End of History?"*, published in the National Interest in 1992, Fukuyama argues that the advent of Western liberal democracy may signal the endpoint of humanity's sociocultural evolution and the final form of human government. In the same vein, based on recent development of sophisticated analytical methods and evolution of regulatory guidance, one should discuss the relevance of the current clinical development model for biosimilars and raise the (long term) question: "Is it the end of clinical trials in biosimilar development?" or more realistically "could we in a not too distant future drastically reduce the financial and operational burden of biosimilar clinical trials?" It is well known that proteins have unique structural organisation patterns and even those that are chemically identical may have different biological effects due to structural folding differences, without mentioning the effect of post-translational modifications. However, with the current exponential development of multiple sophisticated analytical methods enabling comparability assessment between originators and candidate biosimilars both structurally (orthogonal methods) and functionally (compound-dependent), considering the lack of sensitivity of many clinical models to detect meaningful differences between follow-on biologics and reference compounds, and

the recent evolution of regulators perspective on this matter, the relevance of the current clinical development model can legitimately be questioned. Even if this is not ready for prime time, we observe through interaction with regulators trends that are compatible with this possible long-term perspective, namely: reliance on healthy volunteer PK/PD studies only to support some biosimilar compounds registration (without testing the candidate biosimilar in oncology patients), wider acceptance by FDA/EMA of extrapolation from one indication to all other approved indications of the reference compound (e.g. infliximab), and agencies willingness if not encouragement to test clinical biosimilarity in non-approved indications of the originator compound! When one considers the financial and operational burden of running pivotal trials based on clinical endpoints (skeletal-related events) in some indications (e.g. osteoporosis, metastatic prostate cancer), the likely acceptability of surrogate markers (BMD in osteoporosis), one can predict biosimilars clinical trials designs and endpoints are likely to significantly evolve in the coming years. However, one important question remains open, at least for immunogenic compounds (e.g. adalimumab), namely the opportunity to predict immunogenicity based on non-clinical models.

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