CLINICAL R&T 2021

PEERS ALLEY MEDIA

October 25, 26 2021

VIRTUAL EVENT

International Congress on

## ADVANCES IN

# CLINICAL RESEARCH AND TRIALS

**Theme:**

Advancements and Approaches in Clinical Research and Clinical Trials


**Peers Alley Media**

**1126 59 Ave East, V5X 1Y9, Vancouver BC, Canada**

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# YOUR FIRST CHOICE FOR RESEARCH INGENUITY

# PROGRAM-AT-A-GLANCE

## CLINICAL R&T 2021

# DAY 1

MONDAY, OCTOBER 25, 2021

# Scientific Program

BST – British Summer Time

**Topics:** **Pre clinical research | Clinical research and clinical trials | Clinical study designs | Patient-centric clinical trials | Innovations in clinical trials | Patient recruiting retention | Clinical data management and statistics | Clinical and medical case reports | Pharmacovigilance and drug safety | Data management in pharmacovigilance | Drug discovery and development | CRO or sponsorship clinical trials | Bioethics and quality regulation | Post-marketing surveillance | Research and trials on oncology and AIDS**

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|---|---|
| 09:45-10:00 | **Opening Ceremony** |
| 10:00-10:25 | **Title: A better way to achieve informed consent without coercion**<br>**Roy G. Beran,** University of NSW, Australia |
| 10:25-10:50 | **Title: A new method for postural misalignmentof cerebral palsy**<br>**Ying Hou,** Nanjing Medical University, China |
| 10:50-11:15 | **Title: CRISPR/Cas9 engineered CAR-T Cells as a potential cancer therapeutic**<br>**Afreen Khan,** Era University, India |
| 11:15-11:40 | **Title: Sequel and therapeutic modalities of leptospirosis associated severe pulmonary haemorrhagic syndrome (SPHS); A Sri Lankan experience**<br>**Wimalasiri Uluwattage,** Teaching Hospital- Karapitiya, Srilanka |
| 11:40-12:05 | **Title: Successful liver transplant in a patient with acute cholestatic liver failure due to COVID-19 infection: A case report**<br>**Elham Pishgar,** Iran University of Medical Sciences, Iran |
| 12:05-12:30 | **Title: Comparison of the KIMS immunoassay with the commercial and in-house LC-MS/MS methods for substance abuse in urine**<br>**Gamze AVCIOGLU,** Karadeniz Ereğli State Hospital, Turkey |
| 12:30-12:55 | **Title: COVID-19 convalescent plasma in immunodeficient patients**<br>**Dina Rnjak,** University Hospital Zagreb, Croatia |
| **Lunch Break 12:55-13:25** | |
| 13:25-13:50 | **Title: First French experience of trans oral thyroid and parathyroid surgery about 140 cases**<br>**Greg DEROIDE,** Franco-Britannic Hospital, France |

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| 13:50-14:15 | **Title: Optimal designs for hypothesis testing inresponse-adaptive clinical trials**<br>**Marco Novelli,** University of Bologna, Italy |
| 14:15-14:40 | **Title: Modern technologies for forecasting, monitoring and optimal designing clinical trials operation**<br>**V. Anisimov,** Amgen Ltd, UK |
| 14:40-15:05 | **Title: Applying the adverse outcome pathway concept to questions in anaesthetic neurotoxicity**<br>**Jennifer Waspe,** Sheffield Teaching Hospitals, UK |
| 15:05-15:30 | **Title: Repair of traumatic defect of lower lip using Estlander technique and commisuroplasty in Cameroon**<br>**Brian Zilefac Ngokwe,** University of Yaoundé 1, Cameroon |
| 15:30-15:55 | **Title: A new inferential approach for response-adaptive clinical trials: The variance-stabilized bootstrap**<br>**Maroussa Zagoraiou,** University of Bologna, Italy |
| **Refreshment Break 15:55-16:10** | |
| 16:10-16:35 | **Title: Comparison of adverse effects among different GLP-1 receptor agonists added to basal insulin, and between GLP-1 receptor agonists and basal insulin versus basal-plus or basal-bolus insulin in Type 2 diabetes: A meta-analysis**<br>**A.Manov,** Mountain View Hospital, USA |
| 16:35-17:00 | **Title: Osmolality threshold for erythrocyte hemolysis**<br>**William A Anong,** Morgan State University, USA |
| 17:00-17:25 | **Title: The role of the super-relaxed state of myosin in human metabolism**<br>**Clyde Wilson,** University of California, USA |
| 17:25-17:50 | **Title: Rate and maintenance of improvement of myofascial pain: Dry needling alone vs. dry needling with intramuscular electrical stimulation**<br>**Kindyle Brennan,** The University of Mary Hardin-Baylor, USA |
| 17:50-18:15 | **Title: Trimodal treatment for high risk localizedprostate cancer**<br>**Roberto Paz-Manrique,** Oncosalud - AUNA, Peru |
| **End of Day 1** | |

# DAY 2

TUESDAY, OCTOBER 26, 2021

# Scientific Program

## BST – British Summer Time

**Topics:** **Globalization of clinical trials | Clinical trial site selection and management | Clinical trial forecasting, budgeting and contracting | Biomedical devices clinical research | Oncology clinical research | Clinical research informatics | Translational and experimental clinical research | Clinical research in psychiatry | Clinical research in occupational therapy | Pharmaceutical medicines | Clinical research in oral health | Clinical research for surgeon | Respiratory virus and COVID 19 | Diagnosis of COVID 19 | Prevention and disease control of COVID-19 | Treatment for corona virus**

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| 10:00-10:25 | **Title: O6 methylguanine DNA methyltransferase gene as an epigenetic marker in cervical carcinogenesis**<br>**Umesh Kumar,** IMS Ghaziabad University Courses Campus, India |
| 10:25-10:50 | **Title: Evolving perspective on adverse drug reactions in breast cancer drugs**<br>**Roma Ghai,** Kiet Group Of Institutions, India |
| 10:50-11:15 | **Title: Perceptions of medical students in Pakistan, KSA, and the US regarding the significance of case-based learning**<br>**Khalid AM,** CMH Kharian Medical College, Pakistan |
| 11:15-11:40 | **Title: An approach towards helping radiologist for segmentation and classification of MRI images using deep learning methods**<br>**Dhiraj pandey,** JSS Academy of Technical education, India |
| 11:40-12:05 | **Title: COVIDC: An expert system to diagnose covid-19 and predict its severity using Chest CT Scans: Application in radiology**<br>**Wajid Arshad Abbasi,** University of Azad Jammu & Kashmir, Pakistan |
| 12:05-12:30 | **Title: Clinical trials in Africa: Partnering for quality**<br>**Delva Shamley,** University of Cape Town, South Africa |
| 12:30-12:55 | **Title: Role of fluoxetine in pharmacological enhancement of motor functions in stroke patients: A randomized, placebo-controlled, single-blind trial**<br>**Karthickeyan Krishnan,** Vel's Institute of Science Technology and Advanced Studies, India |

**Lunch Break 12:55-13:25**

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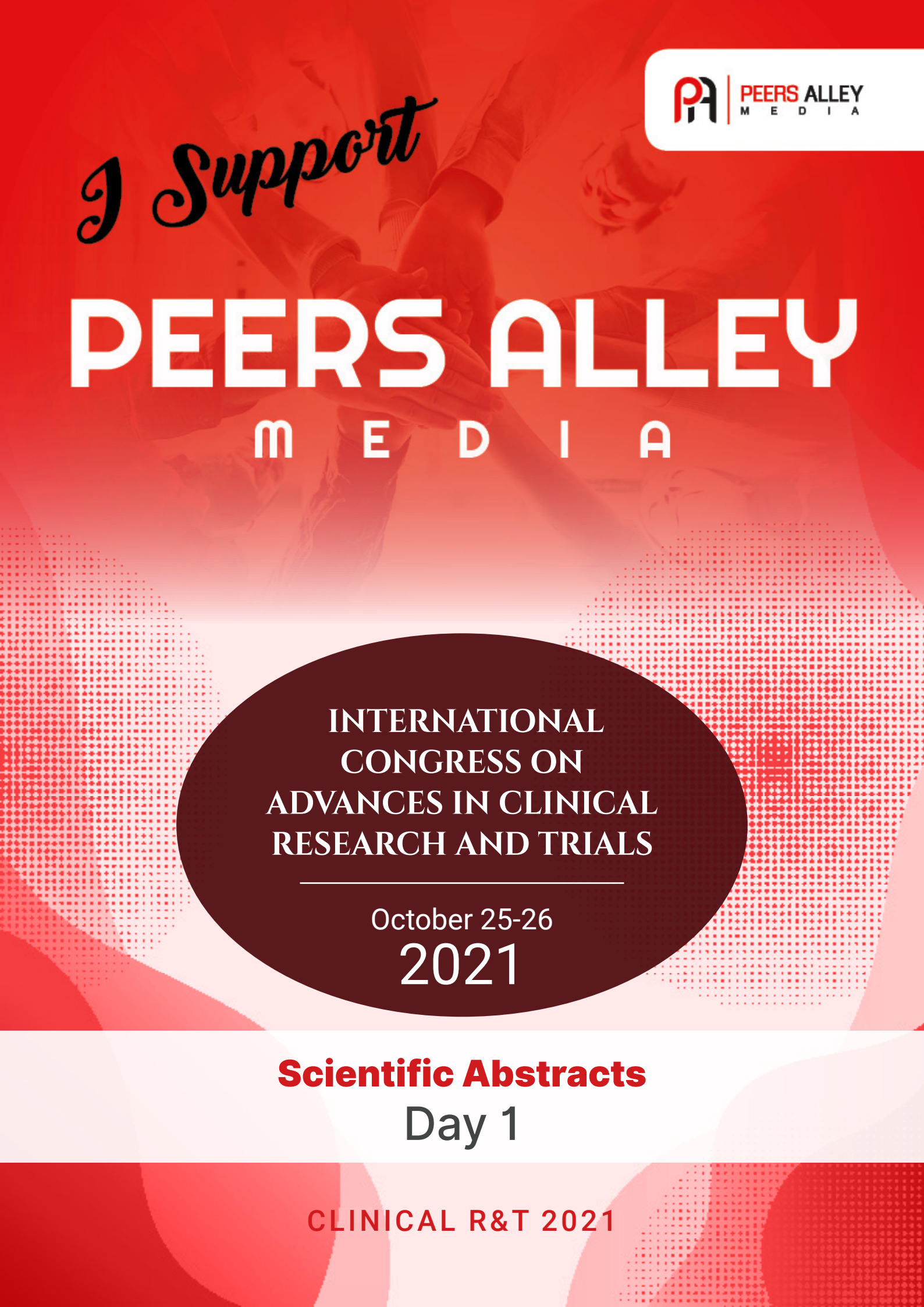
| 13:25-13:50 | **Title: Molecular analysis in periodontology**<br>**Salma Kaabshi,** University of the Western Cape, South Africa |
| 13:50-14:15 | **Title: A review of coronary artery thrombosis: A new challenging finding in COVID-19 patients and ST-elevation myocardial infarction**<br>**M Kermani-Alghoraishi,** Isfahan University of Medical Sciences, Iran |
| 14:15-15:40 | **Title: Effect of probiotics supplementation on disease progression, depression, general health, and anthropometric measurements in relapsing-remitting multiple sclerosis patients: A systematic review and meta-analysis of clinical trials**<br>**Seyedeh Zahra Hejazi Taghanaki,** Isfahan University of Medical Sciences, Iran |
| 15:40-16:05 | **Title: Refractory Schnitzler syndrome- changing our paradigm of thought**<br>**Yulia Tunitsky-Lifshitz,** Sheba Medical Center, Israel |
| **Refreshment Break 16:05-16:20** | |
| 16:20-16:45 | **Title: Evaluating peer-supported screening as a Hepatitis C case-finding model in prisoners**<br>**Betts-Symonds Graham,** Irish Red Cross, Ireland |
| 16:45-17:10 | **Title: The benefits of radiation to modern life**<br>**Alan E. Waltar,** Texas A&M University, USA |
| 17:10-17:35 | **Title: A clinical trial ofa novel electronic emergency surgery operations management tool**<br>**Simon Treissman,** Interiorhealth Authority, Canada |
| 17:35-18:00 | **Title: Sedation practices and clinical outcomes in mechanically ventilated patients in a prospective multicenter cohort**<br>**Eduardo Chirinos-Arroyo,** Hospital Casimiro Ulloa, Peru |
| 18:00-18:25 | **Title: ACE2 Down-regulation may act as a transient molecular disease causing RAAS dysregulation and tissue damage in the microcirculatory environment among COVID-19 Patients**<br>**Simone G. Ramos,** University of São Paulo, Brazil |
| **End of Day 2** | |
| **Closing Remarks** | |




# INTERNATIONAL CONGRESS ON ADVANCES IN CLINICAL RESEARCH AND TRIALS

October 25-26
2021

## Scientific Abstracts

Day 1

CLINICAL R&T 2021

# A better way to achieve informed consent without coercion

**Roy G. Beran**

*University of NSW, Australia*
*Griffith University, Australia*
*Moscow First State University, Russia*

**Objective:** To demonstrate a better way to achieve informed consent when recruiting individuals into clinical trials, without the perception of coercion.

**Scope:** This presentation follows years of adaptation to accommodate undertaking clinical trials, within private practice, in which the chief investigator is also the patients' clinician/therapist. The purpose of the method is to reinstate an higher degree of equipoise, between patient and research team, while ensuring patient autonomy and ethical considerations be respected.

**Results:** By transferring much of the informed consent process to a young scientist, rather than the patients' treating clinician, a senior professor, the patient has greater capacity to accept or reject that which is being proposed without the impression of undue influence, as may exist if the same procedure were conducted by the patients' clinician who holds a position of authority.

**Method Used:** The practice, conducting clinical trials, employed a trial co-ordinator/research assistant who discussed the Human Research Ethics Committee pre-approved patient information sheet(s) and consent documents with the patient, prior to the patient deciding whether, or not, to agreed or refuse entry to the trial. The patient would then sign the relevant documents, with the co-ordinator, in front of a witness, to confirm that it was an act of free will. Only then did the patient return to the clinician, to complete the consent process, with the capacity to seek further clarification, where required, and, when both parties were satisfied, the investigator would counter-sign the documents, thus reinstating greater equipoise between patient and research team while confirming the investigator's ultimate obligation to maintain responsibility for the process.

**Conclusion:** This method removed the perception of coercion while the chief investigator still retained ultimate responsibility for obtaining informed consent.

## Biography

Roy Beran, a neurologist, sleep physician and public health specialist, he is Conjoint Medical Professor -UNSW; Medical Professor -Griffith University; Medical Law Professor, Sechenov Moscow 1st State University.As founding Fellow of the Australasian College of Legal Medicine,its past president andcouncillor, he received Honorary Life Fellowshipandwas appointed 'Co-Head of Faculty' for training. He was Secretary General and remains Australian Governor and Vice President of World Association for Medical Law. He holds MBBS, MD, FRACP, FRACGP, Grad. Dip. Tertiary Ed., Grad. Dip. Further Ed., FAFPHM, FACLM, FRCP, FAAN, FACBS, B Leg. S, MHL and FFFLM (Hon), pioneered private practiceresearch,published ~350 papers, chapters and letters, presented > 400 papers, wrote/edited 17 books and serves numerous editorial boards, being editor in chief of "Medicine and Law" Journal.

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# A new method for postural misalignment of cerebral palsy

**Ying Hou**

*The Affiliated Suzhou Hospital of Nanjing Medical University, China*

**Objective:** To demonstrate the effects of a newly designed postural alignment relearning system on postural control dysfunction in a typical patient with cerebral palsy (CP).

**Design:** Evaluation before and after 8 weeks of Constraint Standing Training 3-dimensional postural alignment relearning system (see Fig. 1).

**Setting:** Department of Rehabilitation Medicine.

**Participant:** A 6-year-old girl with CP and postural misalignment on Gross Motor Function Classification System level I.

**Interventions:** Constraint Standing Training for 8 weeks to correct postural misalignment.

**Main Outcome Measures:** Parameters of lateral plain radiographs in static standing, posturography measurements in standing and walking, motor ability (Gross Motor Function Measure-88 [GMFM-88] scores, manual muscle testing [MMT] scores, muscle architecture), and gait kinematic parameters (40 3-dimensional parameters of arms, trunk, waist, and lower limbs).

**Results:** Knee hyperextension angle in static standing; peaks of knee flexion angle (KFA) when walking, hip flexion angle and

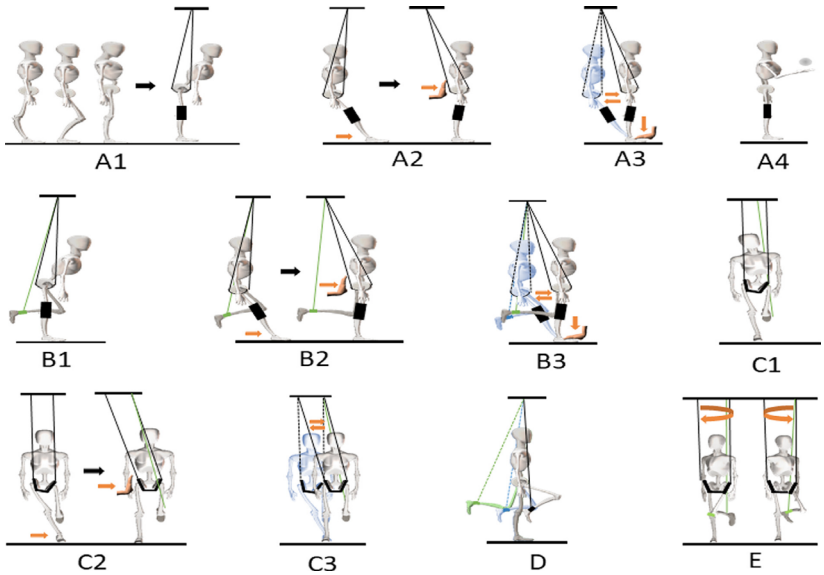


***Fig. 1*** *Protocol for the 5 steps of CST. Abbreviations: CST, Constraint Standing Training.*

ankle flexion angle in dynamic standing; and the KFA at initial contact in gait cycle all decreased significantly (P<.01). Scores of GMFM-88 sections D and E and MMT of 5 core stability muscles improved (P<.01). The velocities and range of motion of the arms, the 3-dimensinoal range of motion of the trunk and waist, and most of the parameters of the lower limbs showed statistically significant change (P<.01). Bilateral muscle thickness did not change significantly after the treatment (P=.738 left, P=.978 right), but the gluteus maximus morphology was changed: the muscle fibers became rounder, the interfiber space decreased, and the border lines of the muscle fibers got clearer.

**Conclusions:** Postural alignment, motor ability, and gait may be homologous external manifestations of more fundamental core abilities, referring to correct standing posture cognition, muscle activation, and postural unconsciousness. Constraint Standing Training 3-dimensional postural alignment relearning system aimed to improve the static and dynamic standing control ability, may fix postural misalignment and improve motor ability and flexed-knee gait. Future work should use Constraint Standing Training with patients with different kinds of misalignment, choose sensitive indicators, observe the duration of each step, and reveal the mechanism causes postural misalignment.

## Biography

Ying Hou, MD. of rehabilitation medicine, MM. of neurology, Vice director of department of rehabilitation medicine of The Affiliated Suzhou Hospital of Nanjing Medical University. Research Area: Motor and Postural control of cerebral palsy and hemiplegia.

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# CRISPR/Cas9 engineered CAR-T Cells as a potential cancer therapeutic

**A. Khan** and **E. Sarkar**
*Era University, India*

CRISPR is the Noble prize winner customized gene editing tool that has taken the research world by storm being the efficient genome editor to fix cancer as well as several hereditary disorders as compared to other gene editing tools like Zinc-finger nucleases (ZFNs), Transcription activator-like effector nucleases (TALENs). CRISPR becomes the game changer in cancer therapeutics after the two recently published path-breaking clinical trials that reported the safety and efficiency of using CRISPR/Cas9 edited, patient-derived T cells (CAR-T cells) to treat refractory cancers.

This article discusses about the mechanism of CRISPR gene editing used in pre-clinical and clinical trials in oncology, focusing mostly on PD-1 knockout CAR-T cell therapy. It also discusses the shortcomings of CRISPR and the recent advances that overcome the hurdles.

## Biography

Afreen Khan obtained her M.Sc degree in Medical Biochemistry at Integral Institute of Medical Sciences and Research, Lucknow, India. She is currently in her third-year of her PhD in Medical Biochemistry at Era's Lucknow Medical College, India. Her main research interest centers early diagnosis and treatment of cancers. Her current research is a molecular analysis of various genes that participates in the progression of cancer to have a better understanding of the molecular pathways involved in cancer. Future prospects of her research focusses around development of efficient drug or gene therapy to as a potential cancer therapeutic.

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# Sequel and therapeutic modalities of leptospirosis associated severe pulmonary haemorrhagic syndrome (SPHS); A Sri Lankan experience

**Wimalasiri Uluwattage, Nalaka Herath** and **Theshanthi Weliwitiya**

*Teaching Hospital- Karapitiya, Sri Lanka*

**Background:** The emergence of leptospirosis-associated severe pulmonary hemorrhagic syndrome (SPHS) with high case fatality has been reported from many countries. Understanding of clinical disease and sequel of SPHS needs larger studies with adequate numbers. The purpose of this study was to describe the characteristics and sequel by different therapeutic approaches for SPHS in Leptospirosis in Sri Lanka.

**Methods:** This study was conducted at Teaching Hospital-Karapitiya (THK), Galle, Sri Lanka from June 2015 to December 2017. THK is the main tertiary care center for the Southern Province. All confirmed-cases of leptospirosis who presented during this period were admitted to five medical units of THK were included in this study. SPHS was defined as a patient presenting; haemoptysis, arterial hypoxemia (Acute Lung Injury Score < 2.5), haemoglobin drop (10% from the previous value), or diffused alveolar shadows in the chest radiograph, without alternative explanation other than leptospirosis.

**Results:** Of the 128 MAT confirmed cases of leptospirosis, 111 (86.7%) had acute kidney injury (AKI) whilst SPHS was seen in 80 (62.5%). Patients typically developed SPHS within the first week of illness, mostly on days 4 and 5. The case fatality rate of this study sample was 28.1% (n = 36), while for patients with SPHS, it was 41.5%. Most of the deaths (n = 19) were within the first 3 days of admission (on the same day 8, and within next 48 h 11). Among SPHS patients, 59 received therapeutic plasma exchange (TPE). The survival rate was higher (n = 35, 74.5%) when the TPE was performed within the first 48 h of detecting SPHS compared to patients in whom the procedure was done after 48 h (n = 5, 54.5%). Of the 19 leptosprosis patients with SPHS who did not receive TPE, 17 died (89.5%). However, the group of patients who received TPE was primarily the patients survived beyond day 3.

**Conclusions:** We observed that during the study period, SPHS was common and the mortality rate was higher in the study area. The treatment modalities tested need further evaluation and confirmation.

## Biography

Dr. Wimalasiri H. Uluwattage was a consultant physician attached to Teaching Hospital- Karapitiya, Galle, Sri Lanka with working experience in the field of internal medicine for 20 years. His main interests are on infectious diseases, especially Leptospirosis associated pulmonary hemorrhage which is an endemic disease entity in the region where he work. He has managed hundreds of similar cases during my carrier and involved in collaborative research on leptospirosis, participated in development of clinical guidelines and capacity building of medical professionals on the same topic.

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# Successful liver transplant in a patient with acute cholestatic liver failure due to COVID-19 infection: A case report

**Elham Pishgar, Farhad Zamani, Mohsenreza Mansoorian, Roghaye Sahraei, Neda Rahimian** and **Nazanin Alibeik**

*Iran University of Medical Sciences (IUMS), Iran*

This virus is from the coronavirus family, covid-19 causes involvement in various

Organs of the body, including the liver. But cases of liver failure are very rare and most of the liver involvement is transient hepatic tests impairment. A 42-year-old man with a free previous medical history presented to the Emergency Department of our hospital complaining of fever and cough, (PCR) assay of the nasopharyngeal swab for SARS-COV-2 was positive. The patient was treated with a diagnosis of covid-19 infection disease, during hospitalization, liver enzymes increased, due to the lack of reduction of liver enzymes after discontinuation of drugs a liver biopsy was performed, histology results were intrahepatic cholestasis, the patient developed liver failure, and eventually, the patient underwent liver transplantation surgery. The patient was discharged from the hospital with near-normal enzymes, on follow up visit patient, the subsequent visit, the patient was in good general condition and the liver enzymes were normal. This case highlights the ultimate importance of liver failure with the hepatic cholestatic pattern in covid-19 patient and liver transplant should be considered in severe hepatic failure.

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# Comparison of the KIMS immunoassay with the commercial and in-house LC-MS/MS methods for substance abuse in urine

**Gamze AVCIOGLU[1], Gulsen YILMAZ[2], Safak YALCIN SAHINER[3], L. Didem KOZACI[2], Ceylan BAL[2]** and **Fatma Meric YILMAZ[2]**

*[1]Karadeniz Ereğli State Hospital, Turkey*
*[2]Ankara Yıldırım Beyazıt University, Turkey*
*[3]Ankara Training and Research Hospital, Turkey*

**Introduction:** Substance use disorder is a public health problem that affects individuals and society negatively in terms of health, economics and social life1.There are many screening and confirmation methods for detection of substance abuse with different sensitivity and specificity2-4. Our aim for this study was to evaluate the diagnostic efficiency of the urine immunoassay based on KIMS (kinetic interaction of microparticles in solution) used in screening and follow-up in Alcohol and Substance Addiction Treatment and Education Centre (AMATEM) clinics in comparison with two LC-MS/MS methods(a commercial and an in-house method).

**Methods:** A total of 100 subjects who applied to the AMATEM for volunteered treatment were included in the study.Urine samples were analysed in the AMATEM Biochemistry laboratory using Roche Cobas® 6000 plus immunoassay system. An in-house LC-MS/MS method validated according to CLSI C62-A recommendations, was used for the confirmation of amphetamines, benzodiazepines, cannabis, cocaine and opiates, which has been included in the screening panel of the AMATEM.The confirmation analysis was performed with an ABSCIEX Triple Quad™ 3500 Instrument system. Eureka Lab Division Drugs of Abuse LC-MS/MS method (commercial method) was compared with the in-house LC-MS/MS method.

**Results:** The sensitivity results of the immunoassay for amphetamines, cocaine, opiates and cannabinoids were determined as 100, 100, 97 and 97, respectively. Due to the lack of TP and FN samples, sensitivity could not be calculated for the benzodiazepines. The specificity results of the immunoassay were found to vary between 83% and 100%. The immunoassay screening method has found to have an acceptable performance with sensitivity, specificity and accuracy values above 80% and met the DRUID recommendation for all parameters except the benzodiazepines.23 and 58 parameters were analysed by commercial and in-house LC-MS/MS methods, respectively. A method comparison study of the commercial and in-house LC-MS/MS method showed significant correlation between all parameters ($p<0.001$) except the benzodiazepines (oxazepam, $p=0.208$). The

commercial method showed bias from (-17.5) to 87.5 compared to the in-house method for all parameters using Bland-Altman analysis. Passing-Bablok analysis revealed a proportional bias for methamphetamine, MDMA, codeine and oxazepamand a constant bias for THC-COOH ($p<0.001$ for all parameters, except oxazepamp=0.165).

**Conclusion:** The diagnostic performance of the KIMS immunoassay was acceptable for opiates, cocaine and amphetamines, cannabinoids, but it was insufficient for benzodiazepines because of the sensitivity issue. The in-house LC-MS/MS method demonstrated a good agreement with commercial method, with the exception of the benzodiazepines.

# COVID-19 convalescent plasma in immunodeficient patients

**Dina Rnjak**[1] and **Sanda Ravlić**[2]

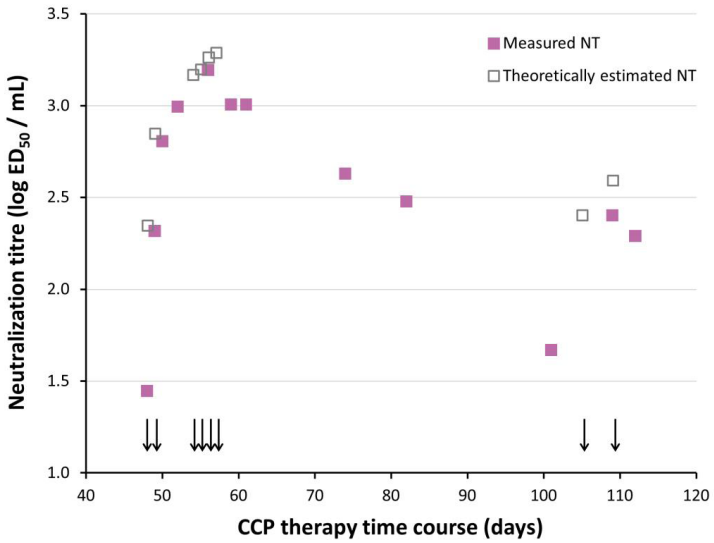
[1]*The Clinic for Lung Diseases Jordanovac, University Hospital Zagreb, Croatia*

[2]*The Centre for Research and Knowledge Transfer in Biotechnology of the University of Zagreb, Croatia*

**Objective:** Since the first described case in December 2019, the coronavirus disease 2019 (COVID-19) has been one of the most significant challenges of our time. The clinical spectrum ranges from asymptomatic to critical forms with acute respiratory distress syndrome and death. The patients with hematological malignancies are a vulnerable group to COVID-19, due to the immunodeficiency resulting from the underlying disease and oncological treatment.Here we report on a beneficial impact of a passive immunotherapy with convalescent plasma to treat a prolonged, active COVID-19 in a patient with a history of nasopharyngeal diffuse large B-cell lymphoma. The specific aim was to quantify SARS-CoV2 neutralizing antibodies in a patient plasma during the course of therapy.

**Methods:** Besides the standard of care treatment and monitoring, neutralizing antibody titers in patient's serum samples, calibrated according to the First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human), were quantified in a time-dependent manner. During the immunotherapy period peripheral blood flow cytometry immunophenotyping was conducted to characterize lymphocyte subpopulations.

**Results:** The waves of clinical improvements and worsening coincided with transfused neutralizing antibodies rises and drops in



the patient's systemic circulation, proving their contribution in controlling the disease progress. Besides the patient's lack of own humoral immune system, immunophenotyping analysis revealed also the reduced level of helper T-lymphocytes and immune exhaustion of monocytes.

**Conclusion:** Therapeutic approach based on convalescent plasma transfusion transformed a prolonged, active COVID-19 infection into a manageable chronic disease. This could be a long-term, ''chronic'' therapy for COVID-19 for this group of patients, especially for bridging the period when the immune system cannot produce by itself the antibodies needed for viral clearance.

Timeline of neutralization titers (NTs) measured in the serum samples of the immunodeficient case-patient during the therapy with SARS-CoV-2-specific convalescent plasma, together with their theoretical estimates. CCP infusions are denoted by arrows.

## Biography

Dr. Dina Rnjak was born in Osijek, Croatia in 1989. She obtained her medical degree at Faculty of medicine, Josip JurajStrossmayer University of Osijek. Her residency was at Special Hospital for Lung Diseases Zagreb and at The Clinic for Lung Diseases, University Hospital Zagreb. Dr. Rnjak is a member of the Croatian Thoracic Society, Croatian Respiratory Society, European Respiratory Society, Croatian Medical Association.

# First French experience of trans oral thyroid and parathyroid surgery about 140 cases

**Deroide G[1]** and **Honigman I[2]**

*[1]Franco-Britannic hospital-Foundation Cognacq-Jay, France*

*[2]Polyclinique de la Côte Basque Sud, France*

**Objective:** We evaluated the results of an initial series of patients who underwent Trans Oral Endoscopic Thyroidectomy Vestibular Anterior (TOETVA).

**Methods:** From February 2018 to April 2021, patients with an indication for thyroid surgery wishing to avoid cervical scars were included. Recurrent nerve neuromonitoring was routinely used. All the patients had follow-up visits. The pre- and intra-operative data, length of stay and complications were evaluated.

**Results:** 140 consecutive patients (134 women) aged 46 ± 12.4 years (15 to 70) with a mean BMI of 24.4 ± 4 were included. The indications for surgery included 15 papillary cancers, 7 oncocytic nodules, 16 toxic nodules, 20 cases of Graves' disease and 82 symptomatic goiters and/or nodules. The mean pre-operative diameter of the nodules was 3.81 ± 1.99 cm. The interventions performed were 83 loboisthmectomies, 51 total thyroidectomies and 6 isthmectomies. The mean operating time was 135 ± 45 min (40 to 262). Total calcemia was 2.07 ± 0.11 mmol/L (normal 2.2—2.5 mmol/L). Ten patients underwent conversion to open cervical surgery(7.1%). The complications were: 9 (6.4%) transient and 2 (1.4%) permanent recurrent nerve palsy, 10 cases (19,6%) of transient and 2 (3.9%) permanent hypoparathyroidism, Thirty cases (21,4%) of transient chin numbness. Thirty-five (25%) patients presented with transient post-operative skin ecchymosis. No hematoma, or surgical site infection were observed. All the patients declared themselves satisfied with the procedure.

**Conclusion:** The TOETVA technicis safe and reliable in well-selected patients wishing to avoid a cervical scar.

# Optimal designs for hypothesis testing in response-adaptive clinical trials

**Marco Novelli**
*University of Bologna, Italy*

Comparing the effects of several experimental groups is an old and well-known problem in the statistical literature which finds applications in many fields. In the past decades, a large body of literature about the design of experiments for treatment comparisons has flourished. However, the attention has been almost exclusively devoted to estimation precision, and not to optimal testing. We present a unified approach to derive optimal designs for testing the efficacy of several competing treatments. Adopting the general framework of heterogeneous treatment groups, which also encompasses the general ANOVA set-up with heteroscedastic errors, the design maximizing the power of the multivariate Wald test of homogeneity is derived. Specifically, this optimal design is a generalized Neyman allocation involving only two experimental groups. Moreover, to account for the ordering among the treatments, which is of particular interest in the clinical trial context for ethical reasons, we obtained the constrained optimal design where the allocation proportions reflect the effectiveness of the treatments. Although in general, the treatments ordering is a-priori unknown, the proposed allocations are locally optimal designs that can be implemented via response-adaptive randomization procedures after suitable smoothing techniques. The advantages of the proposed designs are illustrated both theoretically and through several numerical examples including normal, binary, Poisson and exponential data. The comparisons with other allocations suggested in the literature confirm that our proposals provide good performance in terms of both statistical power and ethical demands.

## Biography

Marco Novelli is assistant professor at University of Bologna. He received his Ph.D. in statistics from University of Bologna in 2016 with a thesis on Statistical inference in open quantum systems. During his PhD he visited University of Aarhus under the co-supervision of Prof. Ole E. Barndorff-Nielsen. His primary research interest is on developing statistical methodologies for randomized clinical trials. He is author of more than 20 referred papers, which cover both theoretical and applied topics, ranging from response adaptive designs to quantum statistics and from social to medical applications.

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# Modern technologies for forecasting, monitoring and optimal designing clinical trials operation

**V. Anisimov**

*Amgen Ltd, United Kingdom*

The multibillion clinical trials market is in an outstanding need of transformation with 80% of clinical trials failing to meet enrolment timelines. Using innovative statistical and AI technologies has a huge potential for improving the efficiency of clinical trials operation, risk-based monitoring and cost savings.

Patient enrolment is one of the main engines driving operation of clinical trials and is one of the major causes of drug development delays.

Analytic data-driven techniques and software tools are developed that allow to maximize the enrolment predictability and create predictions over time with mean and predictive bounds under various restrictionsat any stage of the trial.

Another important direction – creating optimal enrolment design by solving the problem: which countries and how many sites to select that enrol the fastest with minimal cost to get a desired probability to complete in time (PoS). The analytic tools are developed using different criteria of optimality (non-linear constraint optimization, genetic evolution and metaheuristic algorithms) for various scenarios including restrictive enrolment.

At the interim stage, the data-driven Bayesian technique for enrolment re-projection is developed. If a study is likely to go late, the design can be adjusted, and the optimal number of additional sites needed to reach a desired PoS can be evaluated.

Modelling enrolment is an underlying methodology for data-driven centralized statistical monitoring of the enrolment performance. The newly developed methodology allows to detect unusual data patterns (low and high enrolling sites, countries, regions), predict future enrolment performance at site/country level, detect low-active and dormant sites.

The results are illustrated by some case studies.

## Biography

V.Anisimov is working in pharma industry since 2002. He is currently Principal Data Scientist, Center for Design & Analysis, Amgen, based in London, UK. Prior to this, he worked for GlaxoSmithKline and Quintiles (IQVIA) and led the development and implementation of the innovative statistical methodologies for modeling clinical trials operation. Internationally recognized expert in this area. Had also been granted the status of Honorary Professor in the School of Mathematics and Statistics, University of Glasgow, UK.

Vladimir started his career in academia and prior to switching to pharma industry he worked as university professor and served for 20 years as Professor & Head of Applied Statistics Department established by himself at Kiev National University, Ukraine.

Received PhD, ScDr degree and diploma of Professor in Applied Statistics, published 200 papers and several books, supervised 24 PhD theses. Led a numerous number of various projects and some EU and UK grants.

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# Applying the adverse outcome pathway concept to questions in anaesthetic neurotoxicity

**J. Waspe**[1] and **T. Hansen**[2]

[1]*Sheffield Teaching Hospitals, UK*

[2]*University Hospital Odense, Denmark*

The Adverse Outcome Pathway framework was developed by toxicologists as a means to address limitations in chemical toxicity evaluation and risk assessment. This was part of a transformation strategy to reduce reliance on *in vivo* studies and increase methods for predicting toxic outcomes based on computational and *in-vitro* analyses of interactions between a toxicant and a biological system.

The Adverse Outcome Pathway framework synthesizes and appraises data from *in-vitro*, in-silico, *in-vivo* and human studies into a single, dynamic platform. The structure is founded on identifying a series of objectively evaluated, essential,biological Key Events, and conducting multilevel analyses of available data supporting or refuting causal relationships between adjacent Key Events, termed Key Event Relationships, see figure. Each pathway encompasses data at molecular, cellular, organ, organism and often population level. In essence, multiple biologically plausible, bitesize systematic reviews are undertaken to evidence each pathway. This novel structure

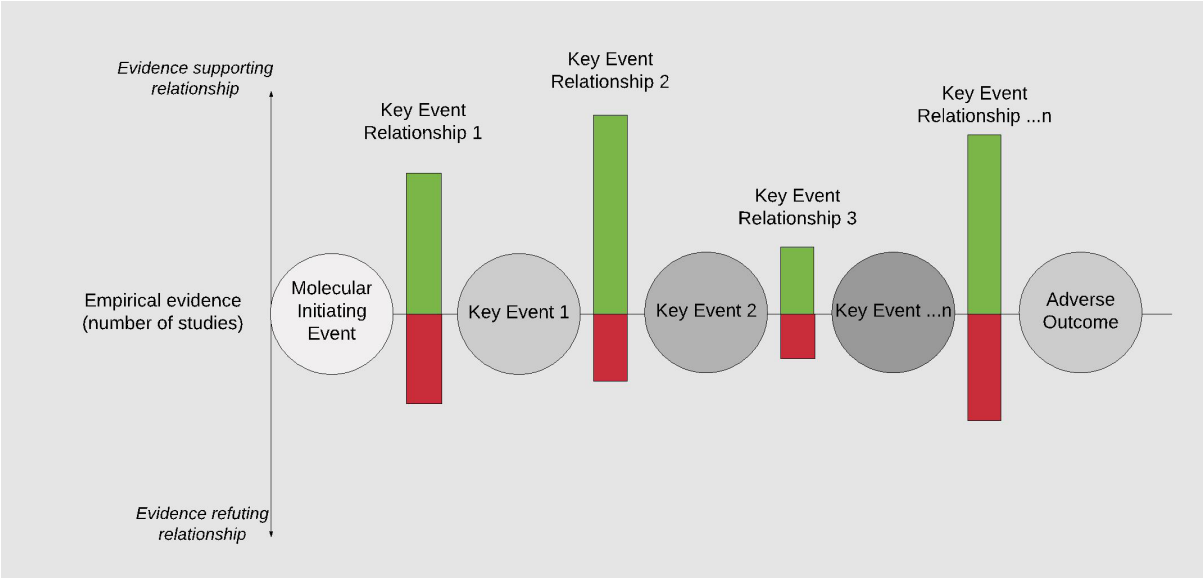


***Figure 1.*** *Basic Adverse Outcome Pathway structure*

lends itself to use in areas of clinical research where there are translational science questions or uncertainties,however potential benefits of applying this framework to clinical questions are yet to be seen.

This work details the development and structure of adverse outcome pathways and discusses the potential adoption of adverse outcome pathways in clinical research, with a specific focus on anaesthesia. As an example, development of an adverse outcome pathway to aid understanding of the potential for anaesthesia to cause adverse neurodevelopmental outcomes is discussed.

## Biography

Jennifer Waspe is an Academic Clinical Fellow and trainee in anaesthesia in South Yorkshire. She graduated from the Karolinska Institute in 2017 with a Master's degree in Toxicology and has subsequently focused her academic interestson exploring the integration of methods used in toxicology into clinical research;the wider application and development of Adverse Outcome Pathways for this purposeis one such method.

Her interests involve evaluating the impact of perinatal exposure to neuroactive chemicals, as well as investigation of environmental exposures impacting the perinatal period.

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# Repair of traumatic defect of lower lip using Estlander technique and commisuroplasty in Cameroon

**Brian Zilefac Ngokwe[1], Karl Kwedi[1], Guiliane Djoumekoum[1], Alex Franklin Diffo[1]** and **Max Lessle[2]**

*[1]Yaoundé I University, Cameroon*
*[2]Hôpital Protestant Ngaoundéré, Cameroon*

Human bite is a challenging public health concern. It may be seen in both victims and aggressors following assault.

Lips are structures that play an essential role in aesthetics and in different functions such as nutrition and speech.

Effects of human bite are both social and medical.

Although rarely life threatening, the treatment of these defects can be complex and may have significant impact on the patient's facial function and aesthetics.

One way of managing lip bites is by lip reconstruction.

The goals of lip reconstruction include maintenance of oral competence, sufficient oral access, adequate tissue match in terms of colour and texture, proper symmetry as well as preservation of the apparent commissure and preservation of sensation. The use of flaps for the reconstruction of large defects with low risk of necrosis is possible given the abundant blood supply of the lips.

We report a case of surgical reconstruction of the lower lip using the Estlander technique in a 53-year-old man following a traumatic human bite. We proceeded with a reconstruction using the Estlander technique on AG followed by a commisuroplasty to respect facial symmetry with great aesthetic results.

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# A new inferential approach for response-adaptive clinical trials: The variance-stabilized bootstrap

**M. Zagoraiou, A. Baldi Antognini** and **M. Novelli**
*University of Bologna, Italy*

Adaptive experiments are sequential procedures in which the decision about how to proceed is made according to a pre-established rule that makes use of the information accrued along the way. Widely used in several experimental fields, they are nowadays considered as a gold standard in the clinical context for treatment comparisons, where the goal of maximizing the patients care often conflicts with the aim of drawing correct inferential conclusions.

To overcome in some sense the above-mentioned drawback, many authors suggested suitable Response-Adaptive (RA) randomization procedures, i.e. sequential allocation rules in which the treatment allocation probabilities change on the basis of earlier responses and past assignments. Even if RA procedures induce a complex dependence structure between the outcomes since the observations are no longer independent, several authors provided the conditions under which the classical likelihood-based asymptotic inference is still valid. These rely essentially on the functional form of the limiting allocation proportion of the treatments – i.e. the target – induced by a given RA procedure. Even if these conditions are apparently satisfied for several RA procedures of the literature, in many circumstances these are not sufficient to guarantee the applicability of classical likelihood-based inferential procedures.

The aim of this talk is to discuss disadvantages and limitations of the classical likelihood-based approach in sequential clinical trials for treatment comparisons managed via RA randomization. In particular, we will stress the crucial role played by the target, that could i) compromise the quality of the CLT approximation of the standard MLEs and ii) lead to a vanishing Fisher information, thus severely undermining any likelihood-based inferential method.

Then, we propose an inferential methodology for RA designs which, by exploiting a variance stabilizing transformation into a bootstrap framework, is able to overcome the above-mentioned drawbacks, regardless of the chosen allocation procedure as well as the desired target.

## Biography

Maroussa Zagoraiou is Associate Professor of Statistics at the Department of Statistical Sciences, University of Bologna.

She received a PhD in Statistics, University of Bologna. Her main research interests lie in optimal design theory for both linear and non-linear models, and sequential methods, with applications to computer/industrial experiments and clinical trials.

She has published several papers on international peer-reviewed journals (including The Annals of Statistics, Biometrika, Statistical Methods in Medical Research, Electronic Journal of Statistics, Statistics in Medicine, Bernoulli).

She has taken part in a large number of meetings and has acted as a referee for international statistical journals (including Annals of Statistics, Biometrics, Biometrika, Electronic Journal of Statistics, Statistical Science, Statistics in Medicine).

She has been actively involved in some bio-medical and agricultural applications of statistics. She is Associate Editor of Biometrics and Co-editor of Statistica.

# Comparison of adverse effects among different GLP-1 receptor agonists added to basal insulin, and between GLP-1 receptor agonists and basal insulin versus basal-plus or basal-bolus insulin in Type 2 diabetes: A meta-analysis

**Andrey Emanuilov Manov, Ashan Thomas Hatharasinghe** and **Katrina Equinox Lopez**

*Mountain View Hospital, USA*

Diabetes mellitus type 2/ DM2/ - is increasing in incidence in United States and throughout the world mostly due to increasing Obesity epidemy- around 40 % of adult people in USA. Two are the major defects of the disease- insulin resistance which sets up the stage 4-7 years before DM type 2 is diagnosed and relative to the increased resistance insulin deficiency. After the diagnosis of DM type 2 the Insulin resistance stays usually constant while the Insulin deficiency progresses necessitating the intensification of the therapy and eventually the need of Insulin. Initially the insulin is started usually as a basal and eventually as the DM type 2- progresses we add bolus rapid acting insulin to major meal- basal plus regimen/BP/ and eventually to every meal- basal- bolus /BB/ insulin. This intensification of the therapy is frequently able to control DM type 2, but leads to significant 3-4 kg weight gain with risk of hypoglycemia.

Other option of intensification of the therapy of DM type 2 is to add to the oral anti - diabetic medications only basal Insulin and GLP1- RAs. GLP1-RAs decrease post prandial blood sugar as the rapid acting insulin does and the long acting GLP1-RAs also decrease fasting blood sugar. GLP1- RAs suppress the appetite and theoretically might lead to weight loss and less incidence of hypoglycemia compare to BP/BB Insulin regimens, because they act on glucose dependent manner- increase the endogenous insulin production only if the blood sugar is elevated.

In our meta- analysis we concentrated our efforts into looking at the side effect of GLP 1-RAs and basal- Insulin combination compare to BP/BB insulin combination like weight loss/ gain, incidence of hypoglycemia, adverse events- mainly the gastrointestinal ones.

Our secondary end point was the change in HbA1c between GLP1-RAs and basal insulin group compare to BP/BB insulin group in patients with HbA1c 7-11%.

This is the first meta- analysis as far as we now comparing those 2- combinations – BB/ BP insulin to GLP1-RAs and basal insulin in the terms of looking as a primary end point at the side effects of those combinations.

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# Osmolality threshold for erythrocyte hemolysis

**William A. Anong[1,2], Victoria M. Richardson[1]** and **Kay Woollen[1]**

*[1]Winston Salem State University, USA*

*[2]Morgan State University, USA*

In this study, we defined the minimum osmolality threshold for normal and sickle red cell hemolysis. Postmortem findings from water intoxication deaths was limited to edema of the brain and lungs with osmolality of 108-mEq/L (216-mOsm/Kg), far lower than the physiological osmolality of 135 -145-mEq/L (270 – 295-mOsm/Kg). We investigated whether such low osmolality had any effect on the integrity of the erythrocyte membrane and to what extent. We hypothesized that red cell membrane's ability to deform/reform under shear confers the cell highresistant to changes in serum osmolality. Appropriately, collected whole blood was centrifuged to separate plasma from red cells. The packed cells were washed three times and re-suspended (~25% hematocrit) in isotonic solution. 50-µl of the 25% suspension was incubated in solution ranging from 290 to 65-mOsm/kg sodium chloride (NaCl). Following incubation, the supernatant and pellets were analyzed for hemoglobin (spectrometry) and glycophorin A (GPA) content by western blotting techniques. Red cells hemolyzed when osmolality decreased to less than 190-mOsm/Kg and 170-mOsm/Kg for normal and sickle erythrocytes respectively. Below 190-mOsm/Kg (normal) and 170-mOsm/Kg (sickle), membrane rupture was rapid -displaying an S-shaped "cooperativity" pattern similar to that of oxygen-hemoglobin binding curve. Complete (100%) hemolysis occurred at ≤150-mOsm/Kg. Hemoglobin content was ~50% lower in cells exposed to hypotonic compared to isotonic or hypertonic solutions.Erythrocytes show more resilience to changes in osmolality, remaining intact at 216-mOsm/kg because of its flexible membrane and cytoskeletal network of proteins. These findings provide insights into how normal,sickle cell and perhaps elderly patients would withstand changes in serum osmolality during dehydration/rehydration states. To alleviate pain in sickle cell patients, IV fluid is routinely administered,irrespective of the hydration status to slow or manage the sickling process. Hence, electrolyte balance and fluid volume replacements during acute episodes of pain may significantly benefit African American who are disproportionately afflicted bythe sickle cell disease.

## Biography

Dr. William Anong is an Associate Professor and Program Director, Medical Laboratory Science at Morgan State University. Prior to the recent appointment, he was an Assistant Professor; Clinical Chemistry course & Lab director in the Department of Clinical Laboratory Science at Winston Salem State University. He holds a PhD from Purdue University and an MBA in Healthcare Management. He is a Board Certified Clinical Chemist (NRCC), Specialist in Chemistry (ASCP) & Medical Laboratory Scientist (ASCP). He has broad expertise in clinical laboratory testing and management: having served also as a consulting Lab Director, clinical and technical expert for startup immunoassay and toxicology labs. Dr. Anong's research, scholarly presentations and publications in refereed journals focuses on electrolyte disorders, red cells protein studies and optimizing clinical laboratory Standard Operating Procedures. Dr. Anong is a reviewer for several journals including the Journal of clinical Laboratory Medicine and Clinical Laboratory Science Journal. He holds membership in several professional organizations, Dr. Anong served as State President (2019/2020) for the North Carolina State Society for Clinical Laboratory Science, represented the state as a delegate to the American Society for Clinical Laboratory Science national meetings.

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# The role of the super-relaxed state of myosin in human metabolism

**Clyde Wilson, Nariman Naber** and **Roger Cooke**
*University of California, USA*

**Background:** There are two states of myosin in resting skeletal muscle, one having a metabolic rate (ATPase) ten times higher than the other, providing a path for manipulating resting metabolic rate (RMR) by ~1000 Cal/day. In the disordered-relaxed state (DRX) myosin undergoes futile cycling and is available for force production. In the super-relaxed state (SRX) myosin heads bind to each other and their thick-filament backbone, providing muscle economy by inhibiting futile cycling. The SRX is destabilized by muscle activation and by piperine, the active compound in black pepper.

**Methods:** Human vastus lateralis biopsies were obtained from lean and obese subjects. The slow release of nucleotides by myosin in the SRX was measured by incubating permeable fibers in a fluorescent analog of ATP and chasing with ATP.

**Results:** SRX populations (and lifetimes) were 0.48 ± 0.04 (148 ± 5 sec) in lean and 0.41 ± 0.05 (176 ± 7 sec) in obese subjects. The addition of 100 μMpiperine decreased the SRX population 25 ± 4% in lean and 21 ± 4% in obese subjects, with little change in lifetimes. Piperine had no effect in human cardiac cells, a requirement for a drug to safely treat obesity or type-2 diabetes.

**Discussion:** The SRX is destabilized by phosphorylation in response to muscle activation, which we propose underlies much of the elevated caloric expenditure in the 5-10 min after physical activity. The increased metabolism after brief activity can account for as many calories as the proceeding activity itself, helping to explain the metabolic benefits of regular movement throughout the day.

**Conclusions:** Analogs of piperine with greater specificity (piperineKd = 3 μM) could provide an effective treatment for metabolic diseases in humans. The partitioning between the SRX and DRX from movement and other factors likely contributes significantly to the dynamic range of RMR.

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# Rate and maintenance of improvement of myofascial pain: Dry needling alone vs. dry needling with intramuscular electrical stimulation

**K. Brennan[1], K. Elifritz[2], M. Comire[3]** and **D. Jupiter[4]**

[1]*The University of Mary Hardin-Baylor, USA*
[2]*Virginia Sports Medicine Institute, USA*
[3]*Inspire Physical Therapy, USA*
[4]*The University of Texas Medical Branch, USA*

**Study Design:** Prospective, randomized

**Background:** Dry needling (DN) and electrical stimulation (NMES) have independently been shown to be efficacious in treating myofascial pain syndrome (MPS). Combining intramuscular electrical stimulation (IMES) with DN for MPS treatment has not been studied extensively, but initial results are promising.

**Objectives:** To determine the difference in the rate and maintenance of improvement in pain and disability for DN alone compared to DN/IMES in MPS.

**Methods:** Forty-five subjects were randomly assigned to the DN (n=25) or DN/IMES (n=20) group. Both groups received six weekly treatments and completed NDI and NPRS questionnaires at weeks 0, 3, 6, and 12.

**Results:** Both groups showed improvement between weeks 0 and 6 on NDI (p=0.008 and 0.00002, respectively) and NPRS scores (0=0.017 and p=0.018, respectively). No changes were noted in the DN or DN/IMES groups between week 6 to 12 on NDI (p= 0.497 and p=0.714, respectively) or NPRS (p= 0.801 and p=0.164, respectively).

**Conclusion:** DN and DN/IMES demonstrated improvement in disability and pain at 6 weeks of treatment that was maintained for 6 weeks following cessation of treatment.

## Biography

Dr. Brennan is a professor in the Doctor of Physical Therapy Program at the University of Mary Hardin-Baylor (UMHB) where she teaches medical differential diagnosis, the musculoskeletal courses, and a dry needling elective. Additionally, she oversees the research curriculum, conducts research studies, serves on the Investigational Review Board, and practices clinically at the UMHB Cru Community Clinic. Dr. Brennan earned her PhD in Physical Therapy at Texas Woman's University, is a board-certified Orthopaedic Clinical Specialist (OCS) and completed all four levels of manual therapy certification through the North American Institute of Orthopaedic Manual Therapy. Her dry needling certification was earned through Kinetacore. She has practiced clinically in multiple outpatient settings over the past 24 years, and served as the Director of Clinical Research in the Orthopaedic Surgery Department at Baylor Scott and White (BSW) for 10 years, before accepting a full- time faculty position at UMHB.

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# Trimodal treatment for high risk localized prostate cancer

**R. Paz-Manrique**

*Oncosalud - AUNA, Peru*

**Background:** Prostate cancer is the second most prevalent neoplasm in men worldwide and the first leading cause of death around the globe. High-risk prostate cancer represents 15% of all prostate cancer patients and, by definition, multimodal treatments are encouraged in order to achieve control of the disease, and even potential cure. Available treatments for such patients have been compared and there is no definitive evidence related to the superiority between surgery (radical prostatectomy – RP) and radiation therapy with or without hormone therapy.

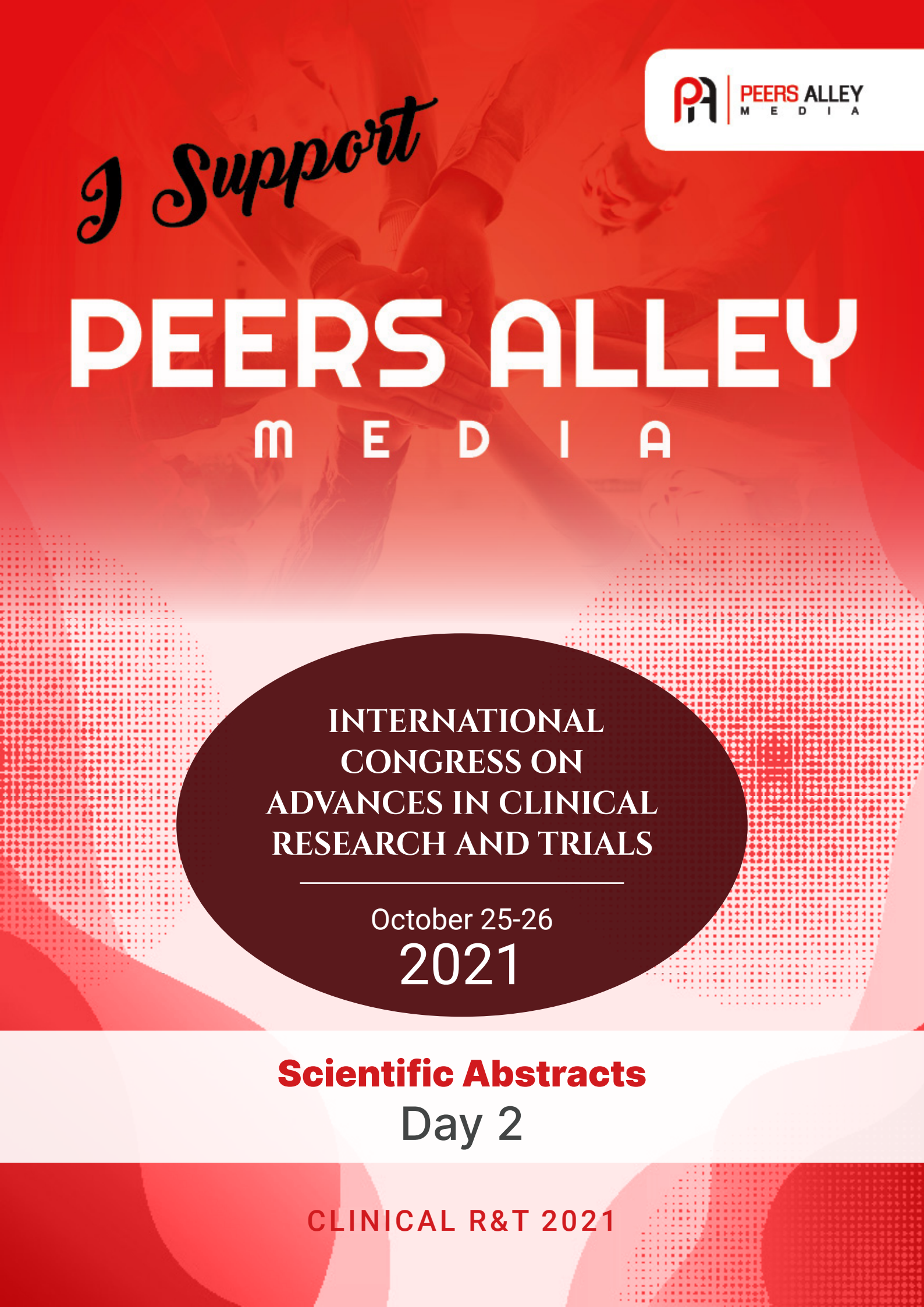
**Aims:** To compare two multimodal treatment of high-risk prostate cancer: radical prostatectomy associate to adjuvant external radiation therapy and androgen deprivation therapy versus external radiation therapy plus androgen deprivation therapy .This study will analyze the following outcomes: time to PSA recurrence, metastasis free survival, defined as time to first clinical or radiological progression or death from any cause; overall survival, adverse events according to graduation of Common Terminology Criteria for Adverse Events (CTCAE) v5.0 (17) and, quality of life assessed by Expanded Prostate Cancer Index Composite (EPIC) questionnaire life.

**Methods:** This is a proposed design and protocol for a phase II, prospective, randomized, open-label, and multicenter trial, including a total of 322 patients with localized high-risk prostate cancer.

**Potential impact of the study:** At the best of our knowledge, there aren't any randomized controlled trials to analyze the trimodal treatment. The possible outcomes of this study will offer a better evidence to high-risk prostate cancer and its results will change the standard treatment in this set of patients by reducing significantly local recurrence and offering a potential cure for this malady.

## Biography

R. Paz-Manrique, Surgical oncologist from Lima, Peru, actually devoted to urology oncology. Member of the American Society of Clinical Oncology (ASCO), the American Urological Association (AUA), the European Association of Urology (EAU) and the only Peruvian member from the Society of Urologic Oncology (SUO), the most important society related to urology oncology worldwide. Research graduate and teaching assistant of PPCR (Principles and Practice of Clinical research), an important educational program from Harvard T. H. Chan School of Public Health.

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2021

## Scientific Abstracts
Day 2

CLINICAL R&T 2021

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# O6 methylguanine DNA methyltransferase gene as an epigenetic marker in cervical carcinogenesis

**Umesh Kumar**[1] and **Garima Rathi**[2]

[1]*IMS Ghaziabad University Courses Campus, India*

[2]*Delhi Public School Ghaziabad, India*

**Background:** MGMT, a DNA repair gene, encodes the protein O6methylguanine DNA methyltransferase, which repairs the O6 alkyl guanine, adducts formed by alkylating agents. In tumor cells where intentional alkylating chemotherapeutics is given to arrest the uncontrolled proliferation of the tumor cells the activity of this gene comes directly in the way of effectiveness of the therapy. When this gene is silent by epigenetic mechanisms like promoter hypermethylation, cancer cells respond in much efficient way to the alkylating chemotherapy. We have checked the extent of epigenetic silencing of the MGMT gene by promoter hypermethylation in cervical cancer patients.

**Materials and Methods:** Genomic DNA isolated from 60 cervical tumors employed for sodium bisulfite conversion of DNA was performed by MSP and the results obtained correlated with the level of the MGMT expression, stage/grade of the disease and clinicopathological parameters.

**Results:** Total percentage of promoter methylation in MGMT gene in cervical cancer samples was found ~20. Tumors in clinical stage Ib&IIa, MGMT methylation was found 12.5% and 50% respectively. Promoter hypermethylation in SCC and adenocarcinoma was found to be 33.33% and 14.29% respectively.

**Conclusion:** MGMT gene shows the potential to be a good therapeutic marker in cervical carcinomas as this is silent up to a good extent in it.

## Biography

Umesh Kumar is currently working as Associate Professor in School of Biosciences, IMS Ghaziabad University. He has done his doctoral thesis entitled "Epigenetic Regulation in Breast Carcinogenesis" in University of Delhi. From his thesis he was able to publish his interesting findings in peer reviewed international journals of repute. Dr Kumar joined Division of Molecular Oncology in Institute of Cytology & Preventive Oncology (ICMR), which was also WHO collaborated South East Asia Referral Laboratory for the Diagnosis of HPV induced Cervical cancer. Later he shifted to Dr. B. R. Ambedkar Center for Biomedical Research, University of Delhi in 2010. After his doctoral thesis He joined Stem Cells Biology Laboratory for his Post Doc in National Institute of Immunology, New Delhi in 2014 where he has published a research in the field of Epithelial ovarian cancer stem cell in Nature Oncogene. In 2016, he worked in Department of Biochemistry as Scientific Officer in Department of Biochemistry, University of Delhi up to July 2017.

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# Evolving perspective on adverse drug reactions in breast cancer drugs

**Roma Ghai** and **M.A. Sheela**

*Kiet Group of Institutions, India*

According to the American Institute of Cancer Research, if breast cancer is not detected early enough, it is the second largest cause of death among women. Breast cancer death rates have decreased by 40% in recent decades as a result of increased awareness and advancements in screening and treatment. However, medications used to treat breast cancer can have adverse effects. Efforts are being made all around the world to detect and counter these negative consequences. As a result, it is necessary to bring it to the attention of physicians through anticancer medication adverse drug response monitoring. This study explores the possible ADRs in individual case reports compiled from reputable journal databases such as Google Scholar, Science Direct, Cochrane Library and PubMed. Breast cancer drugs such as 5-fluorouracil, cisplatin, sunitinib, doxorubicin, cyclophosphamide, and topotecan are commonly used to treat the disease. A specific approach to monitor the ADR is necessary to deal with them. This study looks at the complexities of ADRs caused by anti-cancer medicines and how that data can subsequently be used by the clinicians who are serving in the tertiary health care system.

## Biography

Roma Ghai, working in KIET School Of Pharmacy, KIET Group of Institutions, Ghaziabad, India since 2009. She is having total 15 years of teaching experience and also have been guiding M.Pharm students in their research projects. She have 3 patent publications to her credit and she has written two books; one on "Pharmacological & Toxicological screening for B.Pharm and M.Pharm students' as per PCI curriculum and second book on "Text book of Pharmacovigilance" as per PCI curriculum for 8th B.Pharm semester students.

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# Perceptions of medical students in Pakistan, KSA, and the US regarding the significance of case-based learning

**Khalid AM[1], Sohail M[2], NaiyarI[3], Khalid H[4], Riaz M[4]** and **Baig M[5]**

*[1]CMH Kharian Medical College, Pakistan*
*[2]Avalon University School of Medicine, USA*
*[3]CMH Kharian Medical College, Pakistan*
*[4]Azra Naheed Medical College, Pakistan*
*[5]King Abdulaziz University, KSA*

**Objective:** This study aims to determine the perceptions of medical students in Pakistan, KSA and the US regarding the significance of case-based learning (CBL).

**Methods:** For this cross-sectional study, data were collected by administering an online questionnaire to students in medical schools across Pakistan, KSA and the US.

**Results:** A total of 344 medical students participated in this study, the great majority of whom agree that CBL paves the way for developing a sound understanding of the core subject, provides insight into real-life experiences, helps them transform from fact memorisers into problem solvers, and keeps them engaged during sessions, which motivates them to attend more of these. A comparison of respondents from Pakistan and KSA shows that CBL promotes deep learning and fostered their critical thinking; however, there was a difference in perception in some categories, including CBL as a tool used for grasping key concepts ($p$ = 0.004), providing insight into real-life experiences ($p$ = 0.001), offering a platform for self-directed learning ($p$ = 0.000), nurturing collaborative abilities ($p$ = 0.004), and maintaining students' engagement ($p$ = 0.002).

**Conclusion:** Our study shows that the selected cohort of medical students perceive CBL as an effective learning tool, as the majority feel overwhelmingly positive towards it. This study thus proposes the introduction of clinical exposure for medical students early in MBBS programmes, which willhelp promote collaborative skills and self-directed learning among them.

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# An approach towards helping radiologist for segmentation and classification of MRI images using deep learning methods

**Dhiraj Pandey**

*JSS Academy of Technical Education, India*

The use of digital images for medical diagnostics is fast rising nowadays. Regardless of how convenient MRI scans are, identifying and classifying brain tumours is still a difficult task. The traditional approach necessitates the examination and analysis of the MRI scan by a radiologist, as well as the accurate interpretation of the test results.

The presence of a human analyst is one of the system's fundamental flaws. The whole process of tumour detection and classification depends solely in the skills and expertise of the radiologist. Moreover, this is also a very impractical solution where large numbers of covid effected cases are coming to radiologist and in turn making them stressful also. Therefore, computer assisted diagnosis are highly desirable for addressing this problem in this pandemic time for covid effected cases and it will certainly help the burden of radiologist in accurate detection and further treatments.

In this talk, major discussion will be based on how Deep learning-based approaches can be used to improve the diagnosis task. The task primarily consists of two sub problems. First part of the discussion will be focused on identification of abnormal tissue, i.e., whether the brain contains any tumour cells or not. In the second part classification of the tumour type will be discussed in details. Automatically categorizing the tumour type is a relatively more challenging task comparing to the binary classification of normal and abnormal tissue and convolutional neural networks are found to be very successful in biological tasks.

## Biography

Dhiraj Pandey received his Ph.D. in Computer Science and Engineering from Manipal University in August 2018. He received his B.Tech degree in Information Technology in the year 2003 and an M.Tech degree from the University School of Information Technology, GGSIPU, New Delhi in the year 2007. He has more than 17 years of rich academic experience. He joined the Department of Computer Science and Engineering at JSS Academy of Technical Education Noida in January 2011 and currently working as Associate Professor there. His recent research interests include assistive technologies, image processing, and information security allied areas. He is a Senior Member of IEEE. He has published more than 20 papers in SCI/Scopus indexed Journals and Conferences.

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# COVIDC: An expert system to diagnose covid-19 and predict its severity using Chest CT Scans: Application in radiology

**Wajid Arshad Abbasi, Syed Ali Abbas, Saiqa Andleeb, Ghafoorul Islam, Syeda Adin Ajaz, Kinza Arshad, Sadia Khalil, Asma, Anjam, Kashif Ilyas, Mohsib Saleem, Jawad Chughtai** and **Ayesha Abbas**

*University of Azad Jammu & Kashmir, Pakistan*

Early diagnosis of Coronavirus disease 2019 (COVID-19) is significantly important, especially in the absence or inadequate provision of a specific vaccine, to stop the surge of this lethal infection by advising quarantine. This diagnosis is challenging as most of the patients having COVID-19 infection stay asymptomatic while others showing symptoms are hard to distinguish from patients having different respiratory infections such as severe flu and Pneumonia. Due to cost and time-consuming wet-lab diagnostic tests for COVID-19, there is an utmost requirement for some alternate, non-invasive, rapid, and discounted automatic screening system. A chest CT scan can effectively be used as an alternative modality to detect and diagnose the COVID-19 infection. In this study, we present an automatic COVID-19 diagnostic and severity prediction system called COVIDC (COVID-19 detection using CT scans) that uses deep feature maps from the chest CT scans for this purpose. Our newly proposed system not only detects COVID-19 but also predicts its severity by using a two-phase classification approach (COVID vs non-COVID, and COVID-19 severity) with deep feature maps and different shallow supervised classification algorithms such as SVMs and random forest to handle data scarcity. We performed a stringent COVIDC performance evaluation not only through 10-fold cross-validation and an external validation dataset but also in a real setting under the supervision of an experienced radiologist. In all the evaluation settings, COVIDC outperformed all the existing state-of-the-art methods designed to detect COVID-19 with an F1 score of 0.94 on the validation dataset and justified its use to diagnose COVID-19 effectively in the real setting by classifying correctly 9 out of 10 COVID-19 CT scans. We made COVIDC openly accessible through a cloud-based webserver and python code available at https://sites.google.com/view/wajidarshad/software and https://github.com/wajidarshad/covidc.

## Biography

Wajid Arshad Abbasi received the Ph.D. degree in bioinformatics from the Pakistan Institute of Engineering and Applied Sciences (PIEAS), Islamabad, Pakistan on an HEC fellowship. He is currently a Faculty Member with the Department of Computer Sciences and Information Technology, University of Azad Jammu and Kashmir, Muzaffarabad, Pakistan. He has also been awarded the IRSIP by the Government of Pakistan for his research work with the Colorado State University, USA. His research interests include applications of machine learning in bioinformatics and the analysis of biomedical data.

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# Clinical trials in Africa: Partnering for quality

**D. Shamley[1], E. Ezeani[2]** and **I.Okoye[3]**

*[1]University of Cape Town, South Africa*

*[2]University of Florida, USA*

*[3]University of Nigeria, Nigeria*

Clinical trials are requisite for testing the safety and effectiveness of promising treatments and deciphering new knowledge into concrete benefits for patients. They present opportunities to innovate promising, novel remedies. A dearth of local evidence to guide treatment in Africans is creating an increased interest in clinical trials to improve patient care. This is primarily due to limited health care services leading to poor health outcomes on the continent. Investment in oversight of Human Research Ethics committees and Medicines Regulatory Authorities in Africa has improved the potential for many countries to host clinical trials. However, the distribution of trials remains poor across the continent, resulting in limited treatment options for patients. Countries such as South Africa and Egypt host significantly higher volumes of clinical trials than other African countries. This landscape is set to change and will need innovative, culturally sensitive, guidelines and structures to ensure efficiency of operations and sustainability of the ongoing effort to structure the growing clinical trial enterprise in Africa. To achieve this, we need to establish strategic partnerships whose aim should be to achieve harmonized, accredited Clinical Trials Units capable of running trials to meet international Good Clinical Practice standards. We will present a platform which aims to address these requirements.

## Biography

Dr. Shamley is Director of the Clinical Research Centre at UCT and Head of the Division of Clinical Anatomy and Biological Anthropology. She has a track record of postgraduate student supervision to PhD level, publications and grant success. External consultancies include peer reviewing for journals, grant reviewing for the HTA (UK), NRF (SA), AREF (Chaired), Flanders Foundation (Belgium) and EDCTP (Chaired)(EU). Her research programme includes proteomics and genomics of latent effects of adjuvant therapy in breast cancer survivors. Dr Shamley is also committed to the development of care pathways for post cancer treatment morbidity, which will provide evidence for the Cancer Survivorship Plan for SA. She has developed an innovative Early Warning System (EWS) to identify patients at risk of developing complications in response to treatment. In addition to her research work she is Co-Director of the African Clinical Trials Consortium.

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# Role of fluoxetine in pharmacological enhancement of motor functions in stroke patients: A randomized, placebo-controlled, single-blind trial

**Karthickeyan Krishnan[1,2], Muthuraj K[3], Nandhini K[2], Yalamanchili Dharma Teja[2],Vikrama Simha Reddy[2], Neethu Sara Raju[2]** and **Kiran Kumar Rathinam[2]**

*[1]Vel's Institute of Science Technology and Advanced Studies (VISTAS), India*
*[2]SRM College of Pharmacy, India*
*[3]SRM Institute of Science and Technology, India*

**Objectives:** The current study was designed to evaluate the effectiveness of fluoxetine in motor recovery and its safety in stroke population with more severe motor deficit for a period of 90 days.

**Scope:** Stroke is the primary cause of disability worldwide, the second most common cause of dementia and the third leading cause of death. Only few studies were conducted to study the role of fluoxetine in motor recovery in either ischemic or hemorrhagic stroke patients with probably less severe paresis

**Methods:** Patients who had acute or subacute stroke with hemiparesis and aged between 18 and 80 years with medical research council (MRC) scale score <4 were included in this randomized, Single-blind, placebo-controlled trial in 1:1 ratio to placebo or fluoxetine 20 mg/day orally for 90 days. The primary outcome measures were changes in barthel index, time taken to complete nine hole peg test and number of hand tapping movements in 30 seconds by the affected limb between baseline, 45$^{th}$ day and 90$^{th}$day.

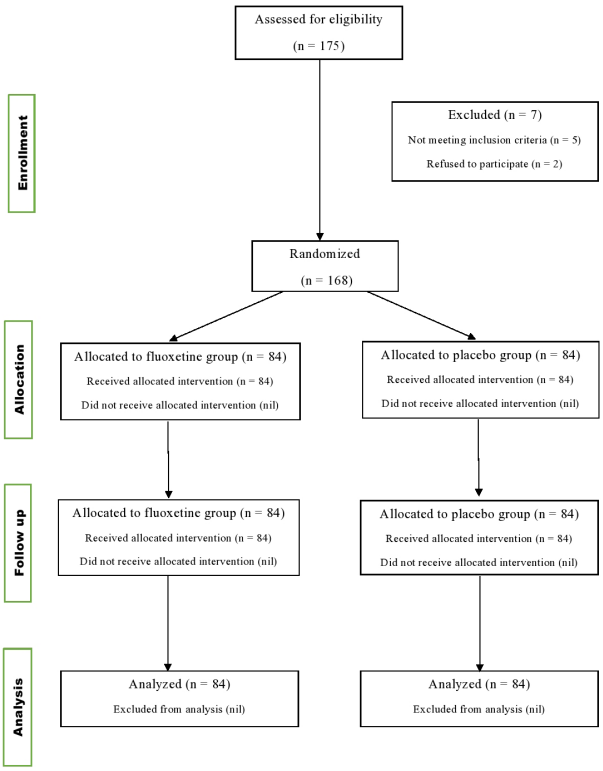


**Figure 1:** CONSORT Flow chart

**Results:** A total of 168 patients were assigned to fluoxetine (n = 84) or placebo (n = 84) group. Mean BI score significantly improved at 90th day in fluoxetine group (70.42 ± 10.56) than in placebo group (44.23 ± 8.52). Mean dexterity value decreased significantly at 90$^{th}$

**Table 1.** Patient's Hemiparesis Sidewise Distribution & Medical Research Council (MRC) Scale Wise Distribution:

| HEMIPARESIS SIDEWISE DISTRIBUTION | | | |
|---|---|---|---|
| **Study Group** | **Hemiparesis** | **No of patients** | **Percentage** |
| Fluoxetine (N=84) | Left side | 37 | 44.05% |
| | Right side | 47 | 55.95% |
| Placebo (N=84) | Left side | 43 | 51.19% |
| | Right side | 41 | 48.81% |
| **MEDICAL RESEARCH COUNCIL (MRC) SCALE WISE DISTRIBUTION** | | | |
| **Study Group** | **MRC score** | **No of patients** | **Percentage** |
| Fluoxetine (N=84) | Score 1 | 12 | 14.29% |
| | Score 2 | 44 | 52.38% |
| | Score 3 | 28 | 33.33% |
| Placebo (N=84) | Score 1 | 2 | 2.38% |
| | Score 2 | 47 | 55.95% |
| | Score 3 | 35 | 41.67% |

day (2.61 ± 0.81) compared to baseline (3.98 ± 0.53) in fluoxetine group. However higher rate of decrease of mean dexterity value was seen in fluoxetine group when compared to placebo group. Mean number of hands tapping movements in 30 second increased significantly at 90$^{th}$ day (16.33 ± 3.58) compared to baseline (9.83 ± 2.92) in fluoxetine group. Few ADR reported during this study were dizziness, drowsiness and insomnia.

**Conclusion:** Early prescription of fluoxetine is safe and may enhance motor function in patients presenting with severe motor impairments after stroke.

## Biography

Karthickeyan Krishnan, completed his UG degree in 2006 and PG degree in Pharmacy Practice Specialization in the year 2008 under the affiliation of the Tamil Nadu Dr. M.G.R. Medical University, Chennai, India and passed in First class with Distinction and he received Gold Medal for securing First place in PG degree. He won many Prizes and Certificates in both curricular and extra-curricular activities.He completed his MBA degree in Hospital Management in the year 2007 and completed his Post Graduate Diploma in Clinical Research course with First class in the year 2010. He completed his Ph.D., degree in Faculty of Pharmacyin the year 2018.

Karthickeyan Krishnan participated as Speaker in Asian Association of Schools of Pharmacy Conference organized by Haiphong University of Medicine and Pharmacy, Haiphong City, Vietnam in the year 2016 and Speaker at Joint Event on Global Pharmacovigilance and Advanced Pharmacy organized by Colchester Hospital University NHS Foundation Trust, UK held at Sydney, Australia in the year 2018.

Karthickeyan Krishnan is having more than 25 research papers to his credit and reviewer and editorial board member in various National and International Journals. He is having more than 14 years of experience in Pharmacy Practice teaching and research. He received 4 Outstanding Teacher Awards in his career. Life Member in Various Professional bodies both at National and International level..

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# Molecular analysis in periodontology

**S. Kaabshi**

*University of Westren Cape, South Africa*

**Introduction:** Rapid advances in genomic technologies in recent decades led to highlight the essential role of genetic analyses in clinical practice and research.Molecular techniques such as next generation sequencing, have sped up the pace of biological research, along withraising expectations. This technology facilitated the construction of an enormous human gene reference libraries that helped to explain many diseases pathogenesis including periodontitis.

**Objective:** The aim of this study was to review current available technologies involved in detecting genetic variants involved in periodontitis development.

**Methodology:** A comprehensive review of literature was conducted on Medline using the combination of these terms: "periodontitis", "genetic variants", "molecular analysis", "SNPs".

**Results:** Several genotyping methods have been developed for genetic variant detections ranging from the most efficient way to link a variant with phenotype, Genome Wide Association Studies, to the tools of the trade, Single Nucleotide Polymorphisms microarrays. Other common techniques includes MassARRAY SNP Genotyping and TaqMan snps genotyping. Approaches such as candidate gene analysis have gained wide popularity due to their numerous advantages ranging from efficiency to cost effectiveness.

**Conclusion:** Explaining the pathogenesis of periodontitis relies on research interpretation of host susceptibility components.Dentists should be able to take the advantage of available molecular knowledge to improved patient care. Clinical findings give the warning sign of current condition; however, genetics componentof periodontal disease will provide the likelihood of disease initiation before it occur.

## Biography

Salma Kaabshi is a PhD student in dental school at the university of the western cape,SA, involved in molecular biology field with interest in bioinformatics and genetic scopes. She is involved in a number of multicentered projects focusing on human oral and general health.

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# A review of coronary artery thrombosis: A new challenging finding in COVID-19 patients and ST-elevation myocardial infarction

**M Kermani-Alghoraishi** and **R Ghahramani**

*Isfahan University of Medical Sciences, Iran*

As the COVID-19 pandemic continues, more information on the non respiratory effects of the coronavirus is obtained. Cardiovascular complications, especially acute coronary syndromes, are rare. However, they prove to be effective factors in the mortality rate of COVID-19 subjects. In a narrative review repot we discuss about thrombose formation in coronary arteries in COVID-19 patients.

As a matter of fact, the SARS-CoV-2 invades by binding to angiotensin-converting enzyme 2 (ACE2) receptors presented on the surface of human cells. Interestingly, these receptors are present not only in the respiratory system, but also in cardiovascular system, causing direct damage to the virus. The main pathology of acute coronary artery thrombosis and ST-elevation myocardial infarction (STEMI), is due to severe systemic inflammation in patients with COVID-19, contributing to plaque rupture and thrombosis with the release of inflammatory cytokines. However, this severe inflammation can lead to a rise in the volume of thrombosis in the target vessel and formation of spontaneous thrombosis in non-culprit vessels as well as stent thrombosis, activating the coagulation cascade.

This phenomenon reveal the special angiographic pattern in the form of extensive and multivessel thrombosis, regardless of atherosclerotic plaques, has posed a new therapeutic challenge. This has been associated with an increase in the incidence of stent thrombosis.

Technically, percutaneous coronary intervention with aspiration thrombectomy and injectable antiplatelet are the mainstay of treatment for these patients. In addition, it is vital that appropriate antiplatelet and ischemia treatment after the intervention be taken into account.

## Biography

Mohammad Kermani-Aghoraishi is assistance professor of interventional cardiology at Isfahan University of Medical Sciences, Isfahan, Iran. He is also deputy of Interventional Cardiology Research Center of Isfahan Cardiovascular Research Institute.

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# Effect of probiotics supplementation on disease progression, depression, general health, and anthropometric measurements in relapsing-remitting multiple sclerosis patients: A systematic review and meta-analysis of clinical trials

**Seyedeh Zahra Hejazi Taghanaki[1], Shahrzad Mirashrafi[1], Faezeh Sarlak[1], Amir Reza Moravejolahkami[1], Mohammad Ali Hojjati Kermani[2]** and **Mohsen Haratian[3]**

*[1]Isfahan University of Medical Sciences, Iran*
*[2]ShahidBeheshti University of Medical Sciences, Iran*
*[3]Hamadan University of medical Sciences, Iran*

**Background:** Probiotics may have a promising role in chronic autoinflammatory diseases. The current systematic review and meta-analysis investigated the effects of probiotics on disease progression, depression, general health, and anthropometric measurements in Relapsing-Remitting Multiple Sclerosis (RRMS) patients.

**Methods:** The English literature search was performed using PubMed, Scopus, Web of Science, and the Central Cochrane Library through January 2021. Random effect models were used to synthesise quantitative data by STATA14.

**Results:** From a total of 152 identified entries, four trials were included in quantitative synthesis (n = 213; 106 as intervention, 107 as control). An additional six studies with the same structure and different markers were also systematically reviewed. The pooled effect size showed that Expanded Disability Status Scale (EDSS) (WMD = −0.43; 95% CI = −0.65, −0.20; P < .001), Beck Depression Inventory-II (BDI-II) (WMD = −3.22; 95% CI = −4.38, −2.06; P < .001) and General Health Questionnaire (GHQ) (WMD = −4.37; 95% CI = −6.43, −2.31; P < .001) were improved following probiotics supplementation. However, body weight and body mass index did not statistically change.

**Conclusion:** Our findings revealed that probiotics supplementation can improve disease progression, suppress depression, and general health in MS patients; although, further investigations may be needed.

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# Refractory Schnitzler syndrome-changing our paradigm of thought

**Yulia Tunitsky-Lifshitz[1,2], Ramit Maoz-Segal[1], Tima Davidson[1,2], Yulia Volchek[1,2]** and **Nancy Agmon-Levin[1,2]**

*[1]Sheba Medical Center, Israel*

*[2]Tel Aviv University, Israel*

**Background:** Schnitzler syndrome (SchS) is a rare auto-inflammatory disease characterized by urticarial exanthema, fever, bone and muscle pain and monoclonal gammopathy. Currently there is a lack of data regarding diagnostic imaging (e.g., PET-CT) and treatments of this disease, particularly in refractory cases. Herein, we describe a case of variant SchS with unique findings on PET-CT and successful therapeutic interventions with immunoglobulins and B cell depletion, therapies that were used only in classical SchS till now.

**Case presentation:** A 57 years old female was referred to our centre for evaluation of monthly episodes of atypical urticarial rash accompanied by fever, malaise and joint pain. Laboratory findings revealed elevated inflammatory markers, liver function tests and leukocytes during the episodes as well as a monoclonal peak of IgG kappa. Skin biopsywas consistent with neutrophilic dermatosis and no evidence of malignancy. On PET-CT subtle ill-defined infiltration of subcutaneous fat were observed in several sites, compatible with skin lesions presented on physical examination. The disease was steroid responsive in the beginning but upon progression it became high dose steroid dependent. Biological targeted therapies IL-1 and IL-6 inhibitors failed to relieve the symptoms. Hence plasmapheresis and anti-CD20 monoclonal antibody were used, leading to clinical resolution.

**Conclusions:** Our patient is the third worldwide to be successfully treated with Rituximab. In this line of thought it seems that B-cell depletion therapy can serve as a practical and efficient solution in refractory cases of SchS when the disease persists despite standard anti-inflammatory therapy. Rituximab is a drug that targets pathological clones, such is the case with lymphoproliferative diseases, IgG4 related disease and so on. In refractory SchS, it seems that changing our paradigm of thought and targeting this pathological clone, can be beneficial.

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# Evaluating peer-supported screening as a Hepatitis C case-finding model in prisoners

**Graham Betts-Symonds**

*Irish Red Cross/Irish Prison Service, Ireland*

**Background:** Hepatitis C Virus (HCV) infection is endemic in prison populations, and HCV management in prisons is suboptimal. Incarceration is a public health opportunity to target this cohort. Community peer support increases HCV screening and treatment uptake. Prison peer workers have the potential to support the engagement of prisoners with health services and reduce stigma. This study's primary aim is to evaluate peer-supported screening as a model of active HCV case finding with a secondary aim to describe the HCV cascade among those infected including linkage to care and treatment outcomes.

**Methods:** An observational study was conducted in a medium-security Irish male prison housing 538 inmates, using a risk-based questionnaire, medical records, peer-supported screening, laboratory-based HCV serology tests and mobile elastography.

**Results:** A prison peer-supported screening initiative engaged large numbers of prisoners in HCV screening (n = 419). The mean age of participants was 32.8 years, 92% were Irish and 33% had a history of injecting drug use. Multiple risk factors for HCV acquisition were identified including needle sharing (16%). On serological testing, 87 (21%) were HCV Ab +ve and 50 (12%) were HCV RNA +ve of whom 80% were fibroscaned (25% showing evidence of liver disease). Eighty-six percent of those with active infection were linked with HCV care, with 33% undergoing or completing treatment. There was a high concordance with HCV disclosure at committal and serological testing (96% for HCV Ab +ve and 89% for HCV Ab −ve).

**Conclusion:** Peer-supported screening is an effective active HCV case-finding model to find and link prisoners with untreated active HCV infection to HCV care.

## Biography

Graham Betts-Symonds is Programme Director for the Community Based Health in Justice Programme serving all Irish Prisons and Director of the Global Reference Centre for Community Based Health in Detention working with the ICRC and IFRC Geneva.

Graham has worked with the Hepatology Teams of the Mater Hospital Dublin, UCD and HepCare Europe project in this mass screening project and previously with St. James Hospital GUIDE Clinic for mass HIV testing in Irish Prisons in 2015 leading to high uptake of testing.

He has worked with the International Red Cross in the fields of health, disaster preparedness and risk reduction in over forty countries over the last thirty years to build local community resilience for health and disaster risks through community capacity building.

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# The benefits of radiation to modern life

**Alan E. Waltar**
*Texas A&M University, USA*

The numerous ways that harnessed radiation is benefiting modern life is largely unknown to the general public. Whereas there is a growing recognition for the role that nuclear energy must play in the ever-expanding need for sustainable and clean electricity, the role that radiation plays in the fields of medicine, agriculture, modern industry, space exploration, and environmental stewardship is often hidden. Yet radiation technology is crucial to these non-power applications and grossly exceeds the power applications-- both in jobs and the overall economy.

Modern medicine benefits from radiation technology all the way from the development and testing of new drugs to nuclear medicine for unique diagnostic and therapeutic remedies. The field of agriculture benefits enormously from new strains of grains developed via radiation mutation techniques, along with improved animal production and safe food (via irradiation). Modern industry could not exist without the myriad processing techniques possible only via radiation instrumentation. Space exploration is greatly augmented by harnessing power from radioactive decay. Environmental protection and cleanupis enhanced via a variety of radiation tracer techniques.

But even our day-to-day activities are enormously enhanced by the clean air and water now widely available--due in large part to radiation technology. Personal products such as super-absorbent materials (e.g. diapers), parasite-free cosmetics, precious gems, sandpaper for the shop, fertilizer for the garden, safety for travel, and security at our borders are all the beneficiary of harnessed radiation.

Yet the growth of such industries is constantly being thwarted by an unfounded public fear of the word "radiation." Recent advances in radiation biology have clearly demonstrated the need to reject the current Linear No-Threshold (LNT), which advocates radiation to be a danger at ANY level.

## Biography

Alan E. Waltar, PhD (UC Berkeley), is Past President and Fellow of the American Nuclear Society, Retired Professor and Head of the Department of Nuclear Engineering at Texas A&M University, retired Director of Nuclear Energy at the Pacific Northwest National Laboratory, and General Chair of the 2018 ANS/HPS Technical Conference on Low-Level Radiation. He has written two textbooks on fast reactors and two non-technical books on radiation for the general public. He recently served as editor of the 26 chapter section on Medical, Industrial and Agricultural Applications of Nuclear Technology for the new Elsevier Encyclopedia on Nuclear Energy (and authored two of the chapters). He helped found the Summer Institute for the World Nuclear University (participating in 14 annual events) and has led People-to-People nuclear delegations to China and India.

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# A clinical trial of a novel electronic emergency surgery operations management tool

**Simon Treissman[1], Douglas Kingsford[1], James Baughan[1], Andrea Burrows[1], Ross Cuthbert[1], Suzanne Gardner-Clark[1]** and **Amin Yazdani[2]**

*[1]Interiorhealth Authority, Canada*
*[2]A.Y. Technologies, Canada*

**Background:** Approximately 20% of all surgery performed in Canada is scheduled by allocation into emergency operating room time. There is currently no national standard for managing how this mixture of emergent, urgent, and semi urgent surgical cases should progress to the operating room.

**Methods:** We introduced a novel dynamic multi priority emergency surgery waitlist management system to a medium-sized Canadian acute care hospital from December 1, 2018, to February 28, 2019. Our hospitals critical incident reporting system was monitored before and during the study for any evidence of related adverse patient safety events.

Internet-based user acceptance surveys were collected from users at 28 days and 89 days into the study.

**Results:** 703 operations were scheduled for 684 patients. The electronic systemwas reliable and had no outages or shutdowns over 89 days. There was no detectable change in the incidence of adverse patient safety events during the study. Overall, there were 54 system users enrolled in the study. The user acceptance survey results were not statistically significant but did show a preference for the new scheduling system in the surgeon usergroup, all other users preferred the originalsystem.

**Discussion:** While there are evident efficiencies from the use of information systems in other industries the safe introduction of a such a system in the emergency surgery setting has never been fully realized. The authors relate the development of the novel multi-priority emergency surgery waitlist management system that was introduced in this study. The challenges of implementing this system and the limitations of the study are discussed.

**Conclusion:** The introduction of a novel emergency surgery waitlist management system into this active operating room setting for 89 days was not associated with a change in reported patient safety events. The tested system was reliable and was preferred by some surgeonusers.

## Biography

Simon Treissman is a Canadian urologist fromKamloops, British Columbia. Dr. Treissmangraduated from the University of Toronto's faculty of medicine in 1990 andqualified in urology at Dalhousie University in Nova Scotia in 1995. Dr. Treissmanwas accepted as a fellow by the Royal College of Physicians and Surgeonsof Canadain1995. In addition to Canadian qualifications in urology Dr. Treissmanis a Board eligible urologist in the UnitedStates.

Treissman has an interest in surgical operations management and in emergency surgery waitlist management. Simon is working to complete an MBA at Thompson Rivers University and he is the founder of On Time OR Scheduling which is technology startup registered in British Columbia (April 4, 2018. BC 1160867).

Treissman is available as a consultant in surgical services management through his business consultancy Precision Surgical Scheduling. Other interests include downhill and cross-country skiing, sailing and scrimshaw.

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# Sedation practices and clinical outcomes in mechanically ventilated patients in a prospective multicenter cohort

**Eduardo Chirinos-Arroyo[7], Romina E. Aragón[1,2], Alvaro Proaño[1,2], Nicole Mongilardi[1,3], Aldo de Ferrari[1], Phabiola Herrera[1], Rollin Roldan[4], Enrique Paz[5], Amador A. Jaymez[6], José Portugal[4], Roció Quispe[4], Roy G. Brower[1]** and **William Checkley[1,8]**

[1]*Johns Hopkins University, USA*
[2,3]*Universidad Peruana Cayetano Heredia, Peru*
[4]*Hospital Nacional Edgardo Rebagliati Martins, Peru*
[5]*Hospital Nacional Guillermo Almenara Irigoyen, Peru*
[6]*Archbishop Loayza National Hospital, Peru*
[7]*Hospital Casimiro Ulloa, Peru*
[8]*Johns Hopkins University, USA*

**Objectives:** We sought to study the association between sedation status, medications (benzodiazepines, opioids, and antipsychotics), and clinical outcomes in a resource-limited setting.

**Design:** A longitudinal study of critically ill participants on mechanical ventilation.

**Setting:** Five intensive care units (ICUs) in four public hospitals in Lima, Peru.

**Patients:** One thousand six hundred fifty-seven critically ill participants were assessed daily for sedation status during 28 days and vital status by day 90.

**Results:** We followed 1338 (81%) participants longitudinally for 18,645 ICU days. Deep sedation was present in 98% of participants at some point of the study and in 12,942 ICU days. Deep sedation was associated with higher mortality (interquartile odds ratio (OR) = 5.42, 4.23–6.95; $p < 0.001$) and a significant decrease in ventilator (− 7.27; $p < 0.001$), ICU (− 4.38; $p < 0.001$), and hospital (− 7.00; $p < 0.001$) free days. Agitation was also associated with higher mortality (OR=39.9, 6.53–243, $p < 0.001$). The most commonly used sedatives were opioids and benzodiazepines (9259 and 8453 patient days respectively), and the latter were associated with a 41% higher mortality in participants with a higher cumulative dose (75th vs 25th percentile, interquartile OR= 1.41, 1.12–1.77; $p < 0.01$). The overall cumulative dose of benzodiazepines and opioids was high, 774.5 mg and 16.8 g, respectively, by day 7 and by day 28; these doses approximately doubled. Haloperidol was only used in 3% of ICU days; however, the use of it was associated with a 70% lower mortality (interquartile OR = 0.3, 0.22–0.44, $p < 0.001$).

**Conclusions:** Deep sedation, agitation, and cumulative dose of benzodiazepines were all independently associated with higher 90-day mortality. Additionally, deep sedation was associated with less ventilator-, ICU-, and hospital-free days. In contrast, haloperidol was associated with lower mortality in our study.

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# ACE2 Down-regulation may act as a transient molecular disease causing RAAS dysregulation and tissue damage in the microcirculatory environment among COVID-19 Patients

**Simone G. Ramos[1], Bruna A.C. Rattis[1], Giulia Ottaviani[2], Mara R. N. Celes[1,3]** and **Eliane P. Dias[4]**

*[1]University of São Paulo, Brazil*
*[2]University of Milan, Italy*
*[3]Federal University of Goias, Brazil*
*[4]Fluminense Federal University, Brazil*

Severe acute respiratory syndrome coronavirus 2, the etiologic agent of coronavirus disease 2019 (COVID-19) and the cause of the current pandemic, produces multiform manifestations throughout the body, causing indiscriminate damage to multiple organ systems, particularly the lungs, heart, brain, kidney, and vasculature. The aim of this review was to provide a new assessment of the data already available for COVID-19, exploring it as a transient molecular disease that causes negative regulation of angiotensin-converting enzyme 2 and, consequently, deregulates the renin-angiotensin-aldosterone system, promoting important changes in the microcirculatory environment. Another goal of the article was to show how these microcirculatory changes may be responsible for the wide variety of injury mechanisms observed in different organs in this disease. This new proposed concept of COVID-19 provides a unifying pathophysiological picture of this infection and offers fresh insights for a rational treatment strategy to combat this ongoing pandemic.

After entering the body, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infects the alveolar epithelial by engaging ACE2 and promoting its negative regulation. The down-regulation of ACE2 leads to renin-angiotensin-aldosterone system (RAAS) dysregulation, which associated with the exacerbated innate immunity response, favors the appearance of immunothromboses in the microcirculation. These immunothrombi result from the activation of inflammatory and coagulation pathways through a cytokine storm, resulting in endothelial dysregulation, leukocyte activation, neutrophil extracellular trap (NET) generation, complement deposition, and platelet consumption. Pre-existing dysregulation of the RAAS in elderly patients and patients with heart disease, hypertension, diabetes mellitus, chronic diseases, and obesity may contribute to an unfavorable outcome in coronavirus disease 2019. Tissue damage can occur through a wide range of mechanisms, including tissue hypoxia, damage by reactive oxygen species (ROS), ischemia/necrosis, ischemia-reperfusion injury, hemorrhage, and/or thromboembolism. These changes, if left untreated, can lead to multiorgan dysfunction and death. Ang II, angiotensin II.

## Biography

Simone G Ramos, graduated in Medicine from the Federal University of Pernambuco (1987), master's degree (1993) and doctorate (1995) in Human Pathology from FMRP, University of São Paulo, post-doctorate in Cardioneuropathology of SIDS (sudden infant death syndrome) (1997/1998) and doctorate in ScienzeAnatomo-Patologiche/UniversitàdegliStudi di Milano (2000) in sudden death cardioneuropathology with emphasis on chronic Chagas' heart disease and SIDS. In 1998, she joined the Department of Pathology at FMRPUSP as a teacher/researcher through a public exam. In October 2012, she obtained the Degree of Free Teaching and is currently an Associate Professor. Currently, she works with Pulmonary Pathology, Cardiovascular Pathology and Autopsy Pathology, acting mainly on the following themes: experimental pulmonary pathology, vascular pathology with emphasis on the pathogenesis of abdominal aneurysms, experimental cardiovascular pathology and general pathology.

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# INTERNATIONAL CONGRESS ON ADVANCES IN CLINICAL RESEARCH AND TRIALS

October 25-26
2021

## Accepted Abstracts

CLINICAL R&T 2021

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# Threats and intimidations received by clinicians and scientists after communicating scientific findings contrary to corporate interests

**C. Bennett[1], N. Olivieri[2]** and **S. Hoque[1]**

*[1]University of South Carolina, United States*

*[2]University of Toronto, Canada*

**Background:** We previously described harms experienced by clinicians and scientists after they published accounts of adverse drug reactions. We now report on threats and intimidation leveled against these individuals.

**Methods:** Data were from governmental hearings or agencies, universities, university-affiliated associations, media, and journals. Content and timing of threats and intimidation were evaluated.

**Findings:** Twenty-six individuals reported 27 findings contrary to corporate interests, and were targets of threats and intimidation from corporate employees (23 individuals), university employers (11 individuals), and regulatory personnel (4 individuals). Actions occurred after individuals communicated with pharmaceutical employees (14 threats/intimidations), presented at government/regulatory agency hearings (4 actions), published their findings (4 actions), presented at conferences (3 actions), had news media interviews (2 actions), or communicated with regulatory agency personnel (2 actions), a research ethics board (1 action), or journal editors (1 action). Threats began within weeks of the initial communication of findings. Scientists' and clinicians' stated reasons for communicating findings included concerns over: drug safety (21 individuals), drug efficacy (3 individuals), and data integrity (2 individuals). Communications resulted in drug or device withdrawals (14) andblack box warnings (7). At two institutions (12.5%), department chairs supported clinicians over corporate executives. Fourteen individuals experienced harms, including loss of academic positions.

**Conclusion:** Scientists and clinicians who communicate findings should be cognizant that threats, intimidation, and harms may follow, particularly after presentngfindings contrary to.

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# Blood serum microRNA profiles of pregnant women as biomarkers of pre-eclampsia evaluation

**A. Kondracka[1], I. Jaszczuk[2], D. Koczkodaj[2], A. Filip[2]** and **A. Kwaśniewska[1]**

[1]*Independent Public Teaching Hospital No. 1, Poland*

[2]*Department of Cancer Genetics with Cytogenetic Laboratory, Poland*

**Introduction:** Pre-eclampsia is a pregnancy-related syndrome characterized by hypertension and proteinuria that makes its appearance after 20 weeks of gestation. It develops approximately in 2–10% of all pregnancies. Pre-eclampsia, as a severe complication during pregnancy, is a major cause of maternal and perinatal morbidity and mortality.

**Objectives:** The aim of the study was to assess the possibility of utilizing selected microRNAs at the earliest possible stage as safe biomarkers of severe complications of pregnancy, such as pre-eclampsia.

**State of konowledge:** Nowadays, there are many trials aimed at finding effective methods for pre-eclampsia prediction at the early stage of pregnancy, before the onset of clinical signs. Although the precise pathophysiology of pre-eclampsia remains unknown, early prediction of the syndrome would allow the initiation of proper preventive therapy to savethe mother and future child. Current strategies for pre-eclampsia prediction are assessments of combinations of maternal risk factors, ultrasound parameters and different biomarkers (proteins, circulating cell free DNA and microRNAs). Studies of microRNAs in particular offer great potential for diagnosis and therapy in pregnancy-related disorders. The fraction of specific placenta-related circulating microRNAs in the serum of pregnant women who present symptoms of pre-eclampsia after 20 weeks of gestation, and show the strongest changes in the level, can play an important role in the development of placenta-related complications.

**Conclusions:** Further research into the level of microRNAs in the blood serum of pregnant women with pre-eclampsia will allow a practical way of utilizing selected microRNAs at the earliest possible stage as safe biomarkers of severe complications of pregnancy.

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# Practical course in pediatric surgery ministered by students of an Academic League in Salvador- BA, Brazil

**L. Pereira[1], C. Schlang[1], D. Ramos[1]** and **B. Xavier[2]**

*[1]Academic League of Pediatric Surgery, Brazil*

*[2]Hospital Martagão Gesteira, Brazil*

On the past few decades, medical student's interest in a surgical career has been decreasing. AcademicLeagues are institutions linked to medical school,that are managedby medical students. Simulationis an educational technic based on tasks and reproductionof procedures throughan artificial model. This article reports a practical course on Pediatric Surgery from students to students using simulation based learning.

A practicalCourse for 30 students (divided in fivegroups). Groups take turns on each proposed subject matter on pediatricsurgery (acuteabdomen, acutescrotum, bowel obstruction, obstructive jaundice and abdominal masses). Students received flowcharts on managing each syndrome. Before the course begins, a pretest was given to all students to evaluate performance on the subjects. At the end of the course the same tests were applied as an evaluation of learning for comparison. At the end a course evaluation chart was submitted.

25 students answered the evaluation chart and 21 of the man swered both tests. Pretest grades rangedfrom 0 to 9,2, (4,1 average), post test grades rangedfrom 3,5 to 10 (7,5 average) students's grades variatedfrom 8% to 77% (34% average). The course was well evaluated by the participants regarding classes, organization, instructors and subject matter.

All participants showed positive variationontest grades. Results suggests that simulation based learning helps acquataince with the subject matter. Academic leagues make students to learn with themselves and stimulate teaching, research and extension. We believe that courses like the secan enhance students interest for surgery.

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# Effects of lifestyle change intervention on semen quality in healthy young men living in highly polluted areas in Italy: The FASt randomized controlled trial

**Luigi Montano[1], Elisabetta Ceretti[2], Francesco Donato[2], Paolo Bergamo[3], Claudia Zani[2], Gaia Claudia Viviana Viola[2], Tiziana Notari[1], Sebastiana Pappalardo[1], Danilo Zani[2], Stefania Ubaldi[1], Valentina Bollati[4], Claudia Consales[5], Giorgio Leter[5], Marco Trifuoggi[6], Angela Amoresano** and **Stefano Lorenzetti[7]**

[1]*Local Health Authority (ASL), Italy*

[2]*University of Brescia, Italy*

[3]*National Research Council (CNR-ISA), Italy*

[4]*University of Milan, Italy*

[5]*ENEA Casaccia Research Center, Italy*

[6]*University of Naples Federico II, Italy*

[7]*Italian National Institute of Health (ISS), Italy*

Human semen quality is affected by metabolic, lifestyle and environmental factors. The latter may be responsible for low semen quality and for substantial differences in different areas of the same country or region in relation to the environmental pressure conditions of the territories. The aim of this study (Fertilità, Ambiente, Stili di Vita, FASt Study, grant of Italian Ministry of Health) was to evaluate the short-term effects of mediterranean diet and physical activity intervention on semen quality of healthy young men living in three highly polluted areas of Italy (Brescia-Caffaro, Sacco River Valley, Land of Fires).344 healthy young men (18-22 years) were enrolled and after randomization 1:1, 188 were allocated to lifestyle change intervention group (4-month Mediterranean diet pathway and a program of moderate physical activity) and 156 were allocated to control group. The two groups were homogeneous at baseline foranthropometric characteristics and semen parameters. Of the 344 subjects enrolled, 263 subjects (76%) completed the follow-up attending all visits, undergoing examinations and laboratory analyses: 137 in the intervention group and 126 in the control one. The adherence to Mediterranean diet and physical activity level

increased more in the intervention than control group from start (t0) to the end (t4) of the study period (t-tests for unpaired data at t4: $p<0.0001$ and $p=0.03$, respectively). Sperm concentration, total and progressive motility and proportion of normal morphology cells increased in the intervention but decreased in the control group, with statistically significant differences between the two groups at t4 ($p=0.03$; $p=0.0001$; $p=0.0003$; $p=0.002$, respectively).

Study results showed that an intervention based on Mediterranean diet and regular physical activity determine an improvement of semen quality.To our knowledge, our study is the first Randomized Controlled Trial to evaluate the effects of a dietary and physical activity intervention on semen quality of healthy young men.

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# Pharmacological management of early postnatal hypotension in extremely premature infants: Complications, controversies and effects of maternal factors

**Rita P. Verma**

*Nassau University Medical Center, USA*

**Introduction:** Early postnatal hypotension (EPH) has been associated with mortality and long-term neurodisabilities in extremely low-birth-weight (ELBW) infants (birth weight <1000 g). Despite extensive research and multiple therapeutic options, there is no consensus among clinicians on the optimum pharmacological management of this morbidity. Recent evidence has suggested that the adverse outcomes associated with EPH may be attributable to the therapeutic interventions and not to the morbidity per se. The current standard of care of hypotension in ELBW involves a regimen of volume expansion, inotropes, and hydrocortisone, instituted in a sequential and escalating order until the desired improvement in blood pressure is achieved. There is no recent systematic report on the adverse effects of this standard clinical practice.

**Objective:** We investigated the complications associated with the current practice of managing EPH with escalating doses of inotropes (VI) followed by hydrocortisone (HC) given sequentially for refractory hypotension in ELBW neonates. We also evaluated effects of maternal conditions on EPH and its treatment.

**Methodology:** In a retrospective case-control study the complications and adverse outcomes associated with VI (VI) and HC (HCVI) treatments in ELBW neonates were compared with contemporaneous normotensive medication naïve controls (C) via standard univariate and multivariate analyses. Neonatal demographics and clinical characteristics, as well as maternal factors were also compared between the groups.

**Results:** VI (n=74) Vs. C (n=124): Birth weight (BW), gestational age (GA) and receipt of antenatal steroid (ANS) did not differ. The occurrence of gestation associated diabetes mellitus (GDM) and risks for patent ductus arteriosus (PDA), intraventricular-periventricular hemorrhage (IVH), spontaneous intestinal perforation (SIP), ventriculomegaly (VM) and oxygen dependence at 36 postmenstrual week of life (BPD) were higher in VI group. HCVI (n=69) Vs. C: HCVI recipients had lower BW, GA and receipt of ANS. The risks for IVH, BPD, air leaks and PDA were higher in the treated infants. The occurrences of SIP, VM and GDM did not differ while that of maternal hypertension trended to be less in HCIV recipients ($p = 0.06$).

**Conclusions:** Hypotensive ELBW infants treated with either vasopressor-inotropes or with hydrocortisone-vasopressor-inotropes are susceptible to IVH, BPD and PDA. Those who receive inotropes may be at additional risks for SIP and VM. GDM increases the occurrence of hypotension which responds to VI and does not need HC. Maternal hypertension does not contribute to VI responsive and trends to decreases VI refractory hypotension.

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# Acceptance of COVID-19 vaccination during COVID-19 pandemic in Nepal

**Gaire A[1], Basyal D[1]** and **Panthee S[2]**

[1]*Tribhuvan University, Nepal*

[2]*Sustainable Study and Research Institute, Nepal*

**Introduction:** On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak a "public health emergency of international concern." Several COVID-19 vaccines are now being developed, but little is known regarding public acceptance of the vaccine in low and middle-income nations like Nepal.

**Objective:** This study aimed to determine the prevalence of COVID-19 vaccination acceptance and its factors among Nepalese people.

**Method:** On December 2020, a web-based cross-sectional survey was conducted using a convenience sample technique. A bilingual, self-administered questionnaire was sent to research participants via social media sites and email. Logistic regression analysis (SPSS Version 26.0) was used to model important variables that predict vaccination uptake among respondents.

**Result:** Out of 576 individuals polled, 540 (93.8 percent) said they would accept COVID-19 immunization whenever it became available, with 232 (42.96 percent) wanting to get vaccinated as soon as possible and others (57.04 percent) delaying vaccination until the vaccine's safety was established. Being male, believing the pandemic's effect on income is high or very high, and believing in the efficacy of COVID-19 vaccination or valuing doctor's recommendations all increased the likelihood of accepting COVID-19 vaccination.

**Conclusion:** Nepalese people have a high level of acceptance and belief in COVID-19 immunization (93.8 percent).If the vaccination is given away for free or is covered by health insurance, acceptance jumps to 98.1% according to survey. It was a reflection of the strong demand for the vaccination. To increase vaccination coverage, immunization programs should be structured to eliminate barriers such as vaccine cost and accessibility. The public's concerns regarding vaccination safety can be resolved via health education and communication from authoritative sources.

# Replacing permuted block design with big stick design in stratified randomization

**CAI Hong-wei**[1] and **ZHOU Xun**[2]

[1]*The First Affiliated Hospital of Xi'an Jiaotong University, China*

[2]*Xi'an Combaray Life Science Technology Co., Ltd., China*

The PBD (Permuted Block Design) is the most widely usedrandomization method in clinical trials due to its comparatively simplicity. However, greater selection bias may appear, especiallyin open-labeled trials, because thePBD requires absolute balanceat the end of each block . The BSD(Big Stick Design) method is one of the MTI(Maximum Tolerated Imbalance)procedures, which can make the allocation process more unpredictable while maintaining the advantages the PBD. So it is theoretically superior to the PBD method. However,some practical problems in stratified randomization hinder the application of the BSD method: such as the risk of serious imbalance for entire trials with the increasing of strata, the uncertainty of the reproducibility of randomization schedule, and the danger of greater selection bias in extreme cases. We propose solutions to the above three implementation problems, and explores the feasibility and effects of the solutions through simulations.

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# Assessment of carbon monoxide inhalational poisoning in flame burned patients at a Kenyan National Hospital

**Edward Nandi Mackutwa[1], Stanley Ominde Khainga[1], James Muturi Ndung'u[1]** and **Charles Anangwe[2]**

[1]*University of Nairobi, Kenya*

[2]*Kenyatta National Hospital, Kenya*

**Background:** Victims of flame burns invariably inhale smoke which contains potentially toxic gases that may contribute to their morbidity and mortality. The most significant inhalational toxin in many fires is carbon monoxide (CO). This study aimed to assess clinical evidence for possible CO poisoning and measureCarboxyhemoglobin(COHb) levelsonfirecasualtiespresentingtoatertiaryteachingandreferral hospital in Kenya. The gold standard, serum COHb spectrophotometry was unavailable hence pulse CO- oximetry was utilised to measure carboxyhemoglobin saturation(SpCO).

**Methodology:** This was a prospective descriptive study. It was approved by institutional ethics committee. Eighty non-pediatric patients presenting with acute (<24 hours) flame burns were recruited and assessed forpotentialCOpoisoning.COHblevelswereassessedbyMasimoSET RRadical57TMpulseCO-oximeter; a device approved by the US Food and Drug Administration (2008) and validated for non invasiveSpCO measurement. Statistical Package for Social Sciences version 21 was used foranalysis.

**Results:** 44% of the patients were females and 56% males. Excluding wound pain, common complaints were confusion (28.7%) and headache (26%). Mean total burn surface area (%TBSA) was 30.9% and SpCO was 5.48%. Only 7 patients had SpCO above 10%. Average time lapse between incident to SpCO measurement was 8 hours 50 minutes. Twenty-eight-day mortality was 38.7%. Analysis d of a relatively longtimelapse.Neitherclinical symptomsnormortalitycouldbeascribedtocarbonmonoxideexposure.

Neither clinical symptoms nor mortality could be ascribed to carbonmonoxide exposure. %TBSA, GCS and oropharyngeal injury correlated significantly with mortality

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# *In silico* exploration of bioavailability, druggability, of fatty acids

**Hayat Elharafi[1], Naoual Elhamdani[1], Hajar Tebbaai[2]** and **Aziz Aboulmouhajir[1,2]**

[1]*Chouaib Doukkali University, Morocco*

[2]*University of Hassan II, Morocco*

The bioavailability and the respect of the "Lipinski Rules", the drugability of lipid molecules "fatty acids" has been approached via appropriate chemoinformatics methods. To this we are explored some physicochemical (partition coefficient, solubility, TPSA), general (DL) and specific druglikeness scores (GPCR, ICM, KI, NLR, PI and EI drug scores), for a large seriesof 47 fatty acids containing saturated fatty acids (24 SFA), monounsaturated fatty acids (11 MUFA) and polyunsaturated fatty acids (12 PUFA). The results obtained have in silico clarified for each fatty acid its degree of bioavailability, druggability of its use therapeutically, cosmetically as well as nutritional product.

# Delivering disability competencies of MCI's revised competency based curriculum at a medical university in North Karnataka

**Hemamalini Gururaj** and **Archana Dambal**

*SDM Medical College, India*

**Background:** India has ratified with the United Nations Convention on the Rights of Persons with Disabilities and has passed the Rights of People with Disabilities Act in 2016. There is need for training healthcare professionals in disability competencies as people with disabilities are many and marginalized. Disability competencies were introduced in the foundation course of revised competency based medical curriculum for Indian medical graduates by the Medical Council of India [MCI] just prior to the rollout of the programme. We intend describing our center's experience in implementing the same.

**Methods:** FC 4.5.1 TO 4.5.8 of MCI foundation course guidelines were resource material. Eight faculty members participated. Setting was the lecture theatre. The suggested and actual teaching learning methods are compared for each competency. Notes made from delivering disability competencies, photographs, videos and reflections from students were source of data.

**Results:** We used sensitizing lectures of 15 minutes each for FC 4.5.1, 4.5.2 and 4.5.4[cognitive] with interesting set induction, student narratives of family members with disability, buzz groups for interaction and self-directed learning activity using mobile phones. We facilitated FC 4.5.3 and 4.5.5 [skill/affective domain] demonstrating unacceptable and acceptable disability etiquettesusing standardized patients and role play. We conducted a forum theatre of the oppressed for FC 4.5.6. We introduced our learners to universal design in our campus for teaching 4.5.7. As a part of the principle of inclusivity we involved two staff members with motor disabilities for delivering FC 4.5.8 in an interview. We assessed the learners using written reflections and obtained feedback on a rating scale.

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# Transplantation of photo biomodulation preconditioneddiabetic stem cellsaccelerates ischemic wound healing indiabetic rat

**Houssein Ahmadi** and **Abdollah Amini**

*Shahid Beheshti Medical University, Iran*

**Background:** Diabetic foot ulcer is the most costly and complex challenge for patients with diabetes. We hereby assessed the effectiveness of different preconditioned adipose-derived mesenchymal stem cells (AD-MSCs) and photo biomodulation protocols on treating an infected ischemic wound in type 1 diabetic rats.

**Methods:** There were five groups of rats: (1) control, (2) control AD-MSCs [diabetic AD-MSCs were transplanted(grafted) into the wound bed], (3) AD-MSC + photobiomodulation *in vivo* (diabetic AD-MSCs were grafted into the wound, followed by *in vivo* PBM treatment), (4) AD-MSCs + photobiomodulation *in vitro*, and (5) AD-MSCs +photo biomodulation *in vitro* + *in vivo*.

**Results:** Diabetic AD-MSCs preconditioned with photo biomodulation had significantly risen cell function comparedto diabetic AD-MSC. Groups 3 and 5 had significantly decreased microbial flora correlated to groups 1 and 2 (all,p = 0.000). Groups 2, 3, 4, and 5 had significantly improved wound closure rate (0.4, 0.4, 0.4, and 0.8, respectively) compared to group 1 (0.2). Groups 2–5 had significantly increased wound strength compared to group 1 (all p =0.000). In most cases, group 5 had significantly better results than groups 2, 3, and 4.

**Conclusions:** Preconditioning diabetic AD-MSCs with photo biomodulation *in vitro* plus photo biomodulation *in vivo* significantly hastened healing in the diabetic rat model of an ischemic infected delayed healing wound.

# Oral microbiome signatures in head and neck cancer

**Indranil Chattopadhyay**

*Central University of Tamil Nadu, India*

Head and neck squamous cell carcinomas (HNSCC) are a major cause of cancer morbidity and mortality. Tobacco smoking and chewing, areca (betel) nut chewing, alcohol consumption and poor oral hygiene are major risk factors for HNSCC. Human papilloma virus (HPV) infection is another known risk factor for oropharyngeal cancer (OPC). Despite advancement in cancer treatment, HNSCC has a poor prognosis with 5-year survival rates of <50%. Bacterial infection is one of the major causes of chronic inflammation which facilitates development of oral cancer through cell proliferation, the inhibition of apoptosis, oncogene activation, and angiogenesis. Recent advancement in metagenomic technologies may be useful in identifying oral cancer–related microbiome, their genomes, virulence properties, and their interaction with host immunity. It is very important to address which bacterial species is responsible for driving oral carcinogenesis. Alteration in the oral commensal microbial communities have potential application as a diagnostic tool to predict oral squamous cell carcinoma. The study aims to develop saliva-based oral microbiome and cytokine biomarker panel that screen oral cancer patients based on the level of the microbiome and cytokine differences. Streptococcus anginosus may be considered as a non-invasive diagnostic biomarker for oral cancer patients only. Oncobacteria such as S. anginosus, V. parvula, P. endodontalis, and P. anaerobius may contribute to the development of OSCC by increasing inflammation via increased expression of inflammatory cytokines such as IL-6, IL-8, TNF-α, IFN-γ, and GM-CSF. These oncobacteria and cytokines panels could potentially be used as a non-invasive biomarker in clinical practice for more efficient screening and early detection of OSCC patients.

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# Clinical progression of patients with COVID-19 in Lagos State, Nigeria

**JP.C. Mbagwu[1], J.O. Olajugba[2], Paula-Peace James-Okoro[3]** and **Obidike Blessing[4]**

[1]*Imo State University, Nigeria*

[2]*University of Lagos, Nigeria*

[3]*Covenant University, Nigeria*

[4]*Imo State University, Nigeria*

**Background:** The majority of COVID-19 research has been devoted to characterizing the epidemiology and early clinical aspects of the virus. In Lagos, Nigeria, we looked at the temporal progression of COVID-19 patients. We included 1337 confirmed COVID-19 cases in our study from February 27th to March 27th 2020. Of the 1337 patients enrolled, the median age was 50 years old, and 800 (59.83%) were male while 537(40.16%) were female.

**Method:** In symptomatic patients, the time from the beginning of signs to admission was 4(2–7) days. Fever occurred in 217(16.2%) while cough occurred in 211(15.78%) patients respectively. Patients were given 5–6 treatment, including nutrition support, supplementary oxygen, and antiviral medicines (e.g., Remdesivir, dexamethasone) in a limited percentage of cases. The assessed median period of infection in all patients was 10 days after the start of symptoms (95 confidential intervals [CIs]: 8–11 days). The duration of fever was slightly longer in patients admitted to intensive care units (ICU) than in those who were not (31 days versus 9 days, respectively, P<0.003).

**Results:** On day 7 after the onset of symptoms, radiological deterioration of the original picture was found in 500 (37.39%) patients. On day 13, 154 of these patients (94.5%) showed signs of radiological improvement. The average time it took for upper respiratory tract samples to test negative for reverse transcriptase PCR was 10 days (90 percent confidence interval: 10–12 days). Virus clearance was more significant in ICU patients than in non-ICU patients (P<0.003).

**Conclusions:** Community members should continue to adhere to the recommended methods of preventing the spread of COVID-19 infection and patients should seek care early to reduce the risk of mortality associated with the infection as rapidly as possible.

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# Preoperative bacteriuria positivityon urinalysis increases wound complications inprimary total hip arthroplasty regardless of the urine culture result

**Linbo Peng, Yi Zeng, Yuangang Wu, Jing Yang, Fuxing Pei** and **Bin Shen**

*Sichuan University, China*

**Background:** Current evidence does not recommend screening urine culture and curing asymptomatic bacteriuria (ASB) before joint arthroplasty. The bacteriuria count on pre-operative urinalysis is a more common clinical parameter. We aimed to investigate whetherthe bacteriuria count on preoperative urinalysis can increase postoperative wound complications in primary total hip arthroplasty (THA).

**Methods:** We conducted a retrospective study that included patients who underwent primary THA in our institution from 2012 to 2018.Receiver operating characteristic (ROC) curves were first generated to evaluate the predicted value of leukocyte esterase(LE), nitrite, bacteriuria, and pyuria in the urinalysis for superficial wound infection. Then, all included patients were divided into two groups according to the preoperative urinalysis: a bacteriuria-positive group and a bacteriuria-negative group.The primary outcome was the superficial wound infection rate within three months postoperatively, and the secondary outcomes included wound leakage, prosthetic joint infection (PJI), pulmonary infection, urinary tract infection (UTI), readmission rateand length of stay (LOS) during hospitalization. We utilized univariable analyses to compare the outcomes between the two groups. A multivariable logistic regression model was generated to explore the potential association between bacteriuria andoutcomes.

**Results:** A total of 963 patients wereincluded in the study. One hundred sixty patients had abnormal urinalysis. Bacteriuria was diagnostically superior to LE, nitrite, and pyuria according to AUCs. Among thepatients, 95 had a positive bacteriuria on preoperative urinalysis, and only 9 (9.5%) had a positive urine culture. The bacteriuria-positive group had a higher superficial wound infection rate (4.2% vs. 0.6%, P=0.008), higher wound leakage rate (11.6% vs. 4.5%, P=0.007),higher readmission rate (5.3% vs. 1.3%, P=0.015) within three months postoperatively and longer LOS (6.19± 2.89 days vs. 5.58± 2.14 days, P=0.011). After adjustment, the bacteriuria-positive group had a significantly increased risk of superficial wound infection (OR=7.587, 95%CI: 2.002 to 28.755, P=0.003), wound leakage (OR=3.044, 95%CI: 1.461 to 6.342, P=0.003), and readmission (OR=4.410, 95%CI: 1.485 to 13.097, P=0.008).

**Conclusion:** Preoperative bacteriuria positivity on urinalysis significantly increased the risk of postoperative wound complications, readmission, and LOS in primary THA regardless of the result of the urine culture. Urinalysis is a fast and cost-acceptable test whose advantages have been underestimated.

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# Tuberculosis in an urban hospital setting: Descriptive epidemiology among patients at Kenyatta National Hospital TB clinic, Nairobi, Kenya

**Linet Makori[1], Haggray Gichana[2], Elvis Oyugi[3], George Nyale[4]** and **James Ransom[3,5]**

[1]*Tuberculosis Management Center, Kenyatta National Hospital (KNH), Kenya*

[2]*Jomo Kenyatta University of Agriculture and Technology, Kenya*

[3]*Ministry of Health, Nairobi, Kenya*

[4]*Kenyatta National Hospital, Kenya*

[5]*Piret Partners Consulting, USA*

**Background:** The prevalence of tuberculosis (TB) in low-to-middle-income countries is larger than that observed in developed countries. This study aimed to characterize TB disease among patients diagnosed at Kenyatta National Hospital (KNH) in Nairobi, Kenya, for public health action.

**Methods:** We conducted a descriptive cross-sectional study at KNH TB clinic from January to December 2015. Data were extracted from TB clinic in- and out-patient registers, entered into MS-Excel.Descriptive and associative statistics were calculated with Open-Epi software.

**Results:** A total of 1,551 TB cases were identified, with mean age of 31.5±16.5 years while 771 (49.7%) were <32 years old. Bivariate analyses showed significant associations between younger age (<32 years) and being hospitalized for the infection (OR 8.18, 95% CI 6.47-10.38, p<0.0001) and being diagnosed by sputum microscopy (OR 2.12, 95% CI 1.39-3.25, p=0.0005).

**Conclusion:** Younger patients were more likely to be diagnosed at a sicker stage of disease than their older counterparts and to be hospitalized as a result. This calls for intensified TB case finding among younger people by use of more rapid TB tests to diagnose TB earlier.

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INTERNATIONAL CONGRESS ON ADVANCES IN CLINICAL RESEARCH AND TRIALS

October 25-26, 2021

# Update on bacterial and antibiotic susceptibility profiles among patients attending a tertiary referral hospital in Tanzania

**Manase Kilonzi, Omary Mashiku Minzi** and **Wigilya P. Mikomangwa**

*Muhimbili University of Health and Allied Sciences, Tanzania*

Antibiotic resistance (AR) is one of the global health threats of the 21st century. AR delays the recovery of patients as well as increasing treatment costs, morbidity and mortality. The World Health Organization (WHO) warns that the world is moving to a post-antibiotic era where common infections and minor injuries could lead to death. Inappropriate use of antibiotics includes the use of incomplete doses, self-medication, empirical treatment and use of human medicines in treating animals, which accelerate the emergence and spread of AR.

This was a hospital-based, cross-sectional study conducted from July–November 2019 at Bugando Medical Center (950-bed capacity) laboratory (ISO: 15189) in Mwanza, Tanzania. The study focused on the following commonly used antibiotics: cellwall-targeting antibiotics including penicillins, third-generation cephalosporins and vancomycin; and ciprofloxacin and protein synthesis inhibitors including gentamicin, erythromycin, chloramphenicoland nitrofurantoin.

Of the 172 bacterial isolates tested, the majority (66.9%) were Gram-negative bacteria. Most of the bacterial isolates were identified as Staphylococcus aureus (28.5%), followed by Klebsiella pneumonia (22.1%) and Escherichia coli (19.2%). Of the 75 bacterial isolatesisolatesfrom urine, 33.3% were E. coli and 24% were K. pneumoniae. More than one-half (58%) of the blood isolates were S. aureus, followed by K. pneumoniae (24.2%). The three above mentioned bacteria are named by the WHO as of great concern in the global fight against AR. The present findings emphasize the need for special attention when attending to patients infected with these three micro-organisms.

In summary, the tested clinical bacterial isolates exhibited high resistance to commonly used antibiotics. This study recommends enforcement of rational uses of antibiotics through the implementation of antibiotic stewardship.

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# Intra-articular dual drug delivery for synergistic rheumatoid arthritis treatment

**Mariam Zewail[1], Noha Nafee[2,3]** and **Nabila Boraie[2]**

*[1]Damanhour University, Egypt*

*[2]Alexandria University, Egypt*

*[3]Kuwait University, Kuwait*

Systemic rheumatoid arthritis (RA) regimens fail to attain effective drug level at the affected joints and areassociated with serious side effects. Herein, an attempt made to improve therapeutic outcomes of both leflunomide (LEF) which is a disease modifying antirheumatic and dexamethasone (Dex) through local delivery of combination therapy by intra-articular route. LEF and Dex were encapsulated in nanostructured lipid carriers (NLCs) and PLGA nanoparticles (NPs), respectively. Both nanocarriers were loaded into chitosan/b glycerophosphate (CS/bGP) thermo-sensitive hydrogels and injected intra-articularly in adjuvant induced RA rat model. Particle size of LEF NLCs and selected Dex NPs formulations were 200 and 119 nm, respectively. Dex NPs and LEF NLCs showed a sustained release profile for up to 58 and 17 days, respectively. After 14 days of treatment remarkable joint healing was observed for groups treated with Dex NPs in combination with either free LEF or LEF NLCs in CS/bGP hydrogel. Joint diameter measurements, TNF a levels and histopathological examination of dissected joints showed comparable values to the negative control group. This might be attributed to the synergistic effect of drug combination besides the ability of nanocarriers loaded hydrogel to prolong joint residence time and enhance joint healing potential.

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# COVID-19 dynamics across the US: A deep learning study of human mobility and social behavior

**Mohamed Aziz Bhouri[1], Francisco Sahli Costabal[2], Hanwen Wang[3], Kevin Linka[4], Mathias Peirlinck[4], Ellen Kuhl[4]** and **Paris Perdikaris[1]**

[1]*University of Pennsylvania, USA*

[2]*Pontificia Universidad Católica de Chile, Chile*

[3]*University of Pennsylvania, USA*

[4]*Stanford University, USA*

We present a deep learning framework for epidemiology system identification from noisy and sparse observations with quantified uncertainty. The proposed approach employs an ensemble of deep neural networks to infer the time-dependent reproduction number of an infectious disease by formulating a tensor-based multi-step loss function that allows us to efficiently calibrate the model on multiple observed trajectories. The method is applied to a mobility and social behavior-based SEIR model of COVID-19 spread. The model is trained on Google and Unacast mobility data spanning a period of 66 days, and is able to yield accurate future forecasts of COVID-19 spread in 203 US counties within a time-window of 15 days. Interestingly, a sensitivity analysis that assesses the importance of different mobility and social behavior parameters reveals that attendance of close places, including workplaces, residential, and retail and recreational locations, has the largest impact on the effective reproduction number. The model enables us to rapidly probe and quantify the effects of government interventions, such as lock-down and re-opening strategies. Taken together, the proposed framework provides a robust workflow for data-driven epidemiology model discovery under uncertainty and produces probabilistic forecasts for the evolution of a pandemic that can judiciously inform policy and decision making. All codes and data accompanying this manuscript are available at https://github.com/PredictiveIntelligenceLab/DeepCOVID19

# T cell ALL in a child with Ataxia telangiectasia; diagnosis and management challenges

**Ahmed Omaima, Felimban Yara S** and **Al-Mehdar Abeer**

*King Abdul-Aziz Medical City, Saudi Arabia*

Ataxia telangiectasia (A-T) is a rare childhood autosomal recessive neurodegenerative chromosomal instability disorder. It is characterized by high risk of haematological malignancies with T-cell phenotype being the most common, which can present first before the diagnosis of A-T made. The chromosomal instability in A-T increases the toxicity to radio- chemotherapeutic agents, creating the treatment modification challenges and the deviation from the optimal management protocols. In this case report we present a 14-month-old boy diagnosed as T cell –ALL. Based on his early presentation, family history of childhood lymphoma, and high AFP, inherited predisposition was suspected, and genetic testing confirm A-T. This report represents the crucial part of clinicalsuspicion of A-T in similar casesas well as highlighting the importance of an early A-T diagnosis that prevents toxic death due to the extensive regimen of radio- chemotherapeutic agents. The report summarizes the toxicity

# The safety of metronidazole in pregnancy

**Ozioma C Nwosu** and **Kathaleen Bloom**

*University of North Florida, USA*

Medication use during pregnancy carries risks of teratogenicity, preterm birth, and spontaneous abortion. CDC's guidelines advocate for the use of metronidazole for the treatment of bacterial vaginosis (BV) in pregnant women. A literature review assessing the safety of metronidazole during pregnancy was conducted. Metronidazole was found to be effective in preventing preterm births when used in conjunction with other antibiotics. Its use did not predict birth defects or congenital abnormalities. It was however associated with a 70% increased risk of spontaneous abortion. This risk should be interpreted cautiously in light of the confounder which is the severity of genitourinary infection.

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# Application of modern technology in herbal healthcare delivery: A case study of South Western Nigeria

**S. A. O. Ogirima**

*Ladoke Akintola University of Technology, Nigeria*

This explores the perception of Nigerian herbal practitioners on the application of modern technology in herbal healthcare delivery inSouth Western Nigeriawith respect toprovide medical healthcare service to the patient within the geographical Region. Questionnaire was set up for the herbal practitioners in selected domain categories (usefulness of the technology for patients and practitioner's practice; perceived knowledge about the use of telediagnosis) was developed and administered. The Evaluation performances based on three performance metrics thus, the System Reliability Index (SRI), System Degree of Relevance (SDR), and System Ease of Usage (SEU) for evaluation are 3.42, 3.15.and 2.88 respectively. The hypothesis derivative crouch coefficient ranges between 0.72 and 0.85 for the validity and reliability respectively of the system. The majority of herbal practitioners (80%) preferredmodern technology application in terms of improving patient management and satisfaction. Othersherbal practitioners (20%)preferred existing method of diagnosis (Face-to-Face)and also have reservations for the technical reliability, privacy, practice expenses, cost of setting up the equipment, time, trust, skill, and diagnostic accuracy of patient. Majority of the herbal practitioners agreed and supports the concept of modern technology and its application into the current practitioner's practice in terms of information sharing about diseases and its treatment and improvement of healthcare delivery in South Western Nigeria.

# Artificial intelligence and cancer biomarker discovery

**Shrikant Pawar**[1] and **Aditya Stanam**[2]

[1]*Yale University, USA*

[2]*University of Iowa, USA*

Machine learning techniques, such as feature selection, have been applied with increasing frequency in biomarker discovery. Feature selection usually has fewer required assumptions compared with statistical tests. Many of them can take the interaction between genes and their joint power into consideration. The genes that are weak biomarkers by themselves but have a strong joint power can therefore be identified. Biomarker discovery is a fast-growing field with many new ideas continuously being proposed. So far none are perfect, considering that the method is data dependent and no universal agreement on the evaluation of a method's performance has been established. In this presentation, we will discuss importance of using neural networks, support vector machines, random forests and unsupervised clustering techniques for classification and predictions.

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# Hyper bili rubinemia with mild COVID-10 Patient: A case report

**Sirwan K. Ahmed, Rawand A. Essa, Dunya H. Bapir** and **Chawan P. Abubakr**

*University of Raparin, Iraq*

**Introduction and importance:** Increased total serum bilirubin rarely reported in mild COVID-19 patients. It occurs mostly in severe cases, particularly in those who have liver diseases and admitted to an intensive care unit. The main cause of increased liver biochemistries in Covid-19 patients related to used drugs, the presence of the ACE2 receptor in the liver, and robust inflammatory response. However, limited studies available regarding to jaundice in COVID19 patients.

**Case presentation:** Here we present a case of hyperbilirubinemia in a mild asymptomatic COVID-19 patient, the patient was diagnosed by RT-PCR three days prior to presentation fever, dark urine, and of acute onset of jaundice. The patient was diagnosed by physical examination and laboratory findings, and treated successfully by high-quality natural honey.

**Clinical discussion:** A recent study of COVID-19 increased total serum bilirubin have been reported, mostly after the appearance of the COVID-19 symptoms. The case in the current study was a 48-year-old male patient who was diagnosed with mild COVID-19 three days prior to presentation. After 2 days increased total serum bilirubin.

**Conclusion:** Honey is a natural medicine to treat Jaundice in mild COVID-19 patients. However, significant data on larger studies are still lacking to decide. Our case guides for the clinical treatment of conjunctival icterus in mild COVID-19 patients.

# Beneficial effects of berberine and quercetin against pulmonary complications of experimental pulmonary arterial hypertension and some relevant mechanisms

**Soodeh Rajabi, Hamid Najafipour** and **Ahmad Beik**

*Kerman University of Medical Science, Iran*

**Objectives and scope:** Pulmonary arterial hypertension (PAH) is a severe disease characterized by pulmonary vascular remodeling leading to a rise in pulmonary vascular resistance and pressure. Here, we assessed the effects of two herbal derivatives quercetin and berberine, on experimental PAH.

**Methods:** Male Wistar rats were assigned to control, monocrotaline (MCT), vehicle, berberine, quercetin and berberine+quercetin groups. PAH was induced by a single injection of MCT. After disease implementation (3 weeks), treatment groups received intraperitoneal injection of vehicle, berberine, quercetin or berberine+ quercetine once a day for 3 weeks. On day 43, the right ventricular systolic pressure (RVSP) was measured as an index of pulmonary arterial pressure.The lungs were used for histological and biochemical assessments.

**Results:** RVSP and lung inflammatory cytokines,TNF-α and IL-6 significantly increased in the MCT group. MCT also increased the level of Malonedialdehyde (MDA) and diminished the content of total antioxidant capacity (TAC), the activity of superoxide dismutase (SOD), Glutathione peroxidase (GPx), catalase, and Bax/Bcl-2 ratio in the lungs. Treatment with berberine and quercetin separately and in combinationsignificantly recovered all of these alterations.

**Conclusion:** Quercetin and berberine ameliorated pulmonary vascular remodeling by decreasing inflammation and fibrosis and increasing apoptosis and antioxidant/oxidant balance. This herbal derivatives may be considered as a therapeutic goal against PAH in future experiments.

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# Evaluating the impact of pharmaceutical care services on antiepileptic drug tolerability among patients living with epilepsy

**Unyime Israel Eshiet[1], Jegbefume Matthew Okonta[2]** and **Chinwe Victoria Ukwe[2]**

*[1]University of Uyo, Nigeria*

*[2]University of Nigeria, Nigeria*

**Background:** Therapeutic management of epilepsy is usually long-term; thus, patient tolerability of prescribed antiepileptic drugs should be a major consideration as it affects compliance to therapy.

**Objectives:** The aim of this study was to determine the impact of pharmaceutical care services on antiepileptic drug tolerability among patients living with epilepsy.

**Method:**This study was an open, randomized, controlled, longitudinal, and two-arm parallel prospective study with a 6-month patient follow up period. Patients were recruited from the neurology and medical out-patient clinics of two selected epilepsy referral centres. Recruited patients were randomized into one of the two study groups: Pharmaceutical Care (PC) or Usual care (UC) groups. Patients in the UC group received the usual care provided in the hospitals, while patients in the PC group received PC services in addition to the usual care provided in the hospitals. The impact of PC on antiepileptic drug tolerability was evaluated using a patient reported antiepileptic drug tolerabiltity scale. The evaluation was done at baseline (pre-intervention), 3 months, and 6 months post intervention. Data were analyzed using the IBM SPSS version 25.0. Statistical significance set as $p < 0.05$. Ethical approval was obtained from the Health Research and Ethics Committees of both hospitals.

**Results:** Patients in the PC group had a significantly lower antiepileptic drug tolerability score than those the UC group at 3 months and 6 months - (Pre-intervention: 0.97 versus 1.13; $t = -1.081$; $p = 0.281$), (3 months: 1.13 versus 0.71; $t = 3.084$; $p = 0.001$), (6 months: 1.00 versus 0.60; $t = 3.083$; $p = 0.001$), indicating a significant improvement in antiepileptic drug tolerability among those in the PC group over time.

**Conclusion:** Pharmaceutical care interventions that included education and counselling services significantly improved antiepileptic drug tolerability among patients living with epilepsy.

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# Randomized clinical trial of the accuracy of patient-specific implants versus CAD/CAM wafer in orthognathic surgery

**Xudong Wang, Biao Li** and **Kai Liu**

*Shanghai Jiao Tong University College of Medicine, China*

**Background:** Previous studies have demonstrated the advantages of patient-specific implants (PSIs)for maxilla repositioning in orthognathic surgery.However, its accuracy compared to the use of thesurgical wafer fabricated with computer-aided design/computer-aided manufacturing (CAD/CAM) is unknown.This randomized controlled trial aimed to compare the accuracy of PSIs and CAD/CAM wafer for maxilla repositioning in orthognathic surgery.

**Methods:** After registration (ClinicalTrials.gov ID: NCT02914431, registration date: September 20, 2016), 64 patients requiring orthognathic surgery were randomly assigned to use either PSIs (group I) or CAD/CAM surgical wafer (groupII)to reposition the maxilla in the Department of Oral and Craniomaxillofacial Surgery at Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, from November 2016 to August2019. The outcome evaluation (including the centroid position, translation and orientation discrepancies of the maxilla) was completed by comparing virtual plans with actual results.

**Results:** The maxilla position discrepancy was 1.41 ± 0.58 mm in group I and 2.20 ± 0.94 mm in group II; the between-group difference was significant ($p < 0.001$). For group I, the largest translation discrepancy was 1.02 ± 0.66 mm in the anteroposterior direction, and the largest orientation discrepancy was 1.85 ± 1.42 ° in pitch. For the group II, the largest translation discrepancy was 1.23 ± 0.93 mm in the mediolateral direction, and the largest orientation discrepancy was 1.72 ± 1.56 ° in pitch.

**Conclusion:** Using PSIs in orthognathic surgery resulted in a more accurate maxilla position than CAD/CAM surgical wafer.However, it is not clear whether the same results would be obtained at other clinical centers. We will conduct a multicenter randomized controlled study to further confirm this conclusion (ClinicalTrials.gov ID: ChiCTR1900027035, registration date: October29, 2019).

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