SLACPT NEWS

THE OFFICIAL NEWSLETTER OF THE SRI LANKA ASSOCIATION OF CLINICAL PHARMACOLOGY AND THERAPEUTICS

December 2019, Volume 4, Issue 2

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Optimization of Medicines through Safe, Effective and Economic Prescribing

OFFICIAL NEWSLETTER OF THE SRI LANKA ASSOCIATION OF CLINICAL PHARMACOLOGY AND THERAPEUTICS

SLACPT

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Follow us on

Message from the President

Dear members,

The countdown to the 3rd Academic Sessions have now begun and the secretary and council members are busy organizing it. The last year did not go as planned by us due to the Easter Sunday bombing and the presidential elections. Now at the dawn of our academic sessions we are faced with yet another challenge the fear of a Coronavirus epidemic. However in spite of these challenges we have been able to contribute to several national activities relevant to Clinical Pharmacology and Therapeutics. Some of which include Formulating the National Medicine Policy Sri Lanka (2020-2025) and a Strategic Implementation Plan (2020-2021), National medication safety action plan, National Action Plan Implementation and Strengthening Team (NAP-IST) for combating antimicrobial Resistance and medicines pricing policy.

Sri Lanka had a partly written Drug Policy from the 1960s. It was "written" as elements of a policy, beginning from selection of drugs for the government drug supply and the Ceylon Hospitals Formulary in early 1960s, the Bibile Wickremasinghe report in 1971, the Cosmetics Devices and Drugs Act (1980). However, there was no comprehensive document.

There were attempts to develop a NMDP in 1991 & 1996; while the documents were accepted by the Ministry of Health, they did not reach the final step of cabinet approval. Hence no comprehensive document exists at present. The present effort building upon previous efforts brings together the elements of a National Medicinal Drug Policy (NMDP) in one document and has been developed based on WHO documents through discussion with all stakeholders. It is hoped that this effort will see a formal National Medicinal Drug Policy being adopted by the cabinet for the country.

The proposed NMP will be a foundation for quality health care of our citizens. It will be built on four pillars; timely and affordable access to medicines, having high- quality medicines that are safe and effective, rational use of medicines and a viable and responsible local pharmaceutical industry. Activities to achieve three of the four pillars are within the scope of our association.

Hence I invite all members of the SLACPT to play a role or provide comments in formulating the policy and implementing it. Looking forward in meeting all of you at our annual sessions.

Senior Professor Rohini Fernandopulle
President
SLACPT

Message from the Secretary

Keep CPT Alive and Productive in Sri Lanka

I am happy to give this message one year after I assumed the post as Secretary/SLACPT. It was a pleasant though busy year for SLACPT. We were mainly concentrating on making our association visible, conducting capacity building programmes and planning the academic sessions which is scheduled to take place on March 21st, 2020.

In 2006, Lancet published a commentary written by Simon R J Maxwell and David J Webb titled "Clinical Pharmacology – too young to die". Unfortunately, some of the factors suggested by the authors as contributors to this problem strongly exist in Sri Lanka even fifteen years later. I have reproduced few of them verbatim here:

> *".....CPT has never moved far from its academic roots: two-thirds of UK specialists are university-based. This academic bias has contributed to a lack of favour at times of personnel expansion in the health service. Fourth, its academic base has not been a safe haven. CPT has been a casualty of the changing emphasis in undergraduate medical education, away from scientific disciplines towards a more integrated and problem based programme. Distinct courses and assessments in CPT, formerly a staple in the curriculum, are disappearing, and with them, a reliable opportunity for the principles of CPT to be championed to students.....Fifth, while the valuable contribution made by CPT has been recognised by the export of its leading figures into senior academic positions or national organisations—e.g., regulatory agencies, pharmacovigilance, and health-technology assessment—this has also been a major drain, unmatched by new appointments. A final paradox is that because drugs are prescribed by nearly all doctors, most would see themselves (rightly) as practicing CPT every day....."*

I strongly believe that the SLACPT should be in the forefront in fighting these challenges to keep Clinical Pharmacology and Therapeutics alive and productive for the benefit of patients and public.

"When things do not go your way, remember that every challenge — every adversity — contains within it the seeds of opportunity and growth." - Roy T. Bennett

Professor Shalini Sri Ranganathan
Secretary
SLACPT

COUNCIL OF SLACPT FOR 2018/2020

Seated from left to right: Professor Shalini Sri Ranganathan (Secretary), Professor Gita Fernando (Immediate Past President), Senior Professor Rohini Fernandopulle (President), Professor R. L. Jayakody, Professor Priyadarshani Galappatthy (Vice – President), Professor Chandanie Wanigatunga.

Standing from left to right: Dr. Chamila Mettananda, Dr. Sujeevani Kurukulasuriya, Dr. G.V. Nilangika Sandakumari (Assistant Treasurer), Dr. Priyanga Ranasinghe (Assistant Secretary), Dr. Chamari Weeraratne, Dr. Thilanka Seneviratne (Social secretary), Dr. Roshini Murugupillai (Editor), Professor Nirmala Wijekoon.

Council members absent in the photograph: Professor Asita de Silva (President Elect), Dr. Thiyahini Sunil Navaratinarajah (Treasurer), Dr. Sarath Gamini de Silva, Professor Pradeepa Jayawardena, Professor Sudheera Jayasinghe, Dr. Kumuthini Sanchayan, Dr. Malintha Balasuriya.

Wall of Fame

The Sri Lanka Association of Clinical Pharmacology and Therapeutics is very pleased to announce that three of its members have been promoted to the ranks of Senior Professors and Professor in Pharmacology in the year 2019.

Professor L.M Hettihewa of Faculty of Medicine, University of Ruhuna, has been promoted to Senior Professor in Pharmacology with effect from 19.01.2019

Professor Priyadarshani Galappatthy of Faculty of Medicine, University of Colombo, has been promoted to Senior Professor in Pharmacology

Dr. Chamari Weeraratne of Faculty of Medicine, University of Colombo, has been promoted to Professor in Pharmacology

The council and the members of Sri Lanka Association of Clinical Pharmacology and Therapeutics Congratulate and rejoice in the achievements of Professor L.M Hettihewa, Professor Priyadarshani Galappatthy & Professor Chamari Weeraratne and wish them all success.

Update on Corona Virus Disease (COVID-19)

Following the first reports of cases of acute respiratory syndrome in the Chinese Wuhan municipality at the end of December 2019, Chinese authorities identified a novel coronavirus (2019-nCoV) as the main causative agent. The outbreak has rapidly evolved affecting other parts of China and outside the country with 75,765 confirmed cases globally, and 2,129 deaths. As of now 27 countries have reported at least one confirmed case.

On 12 February 2020, the novel coronavirus was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). WHO recently announced that the official name for the disease causing the 2019 novel coronavirus outbreak is COVID-19. Best practices for severe acute respiratory infection (SARI) including infection prevention and control and optimized supportive care for severely ill patients are essential.

Outbreaks of novel virus infections among people are always of public health concern, especially when there's little knowledge about the characteristics of the virus, how it spreads between people, how severe are the resulting infections and how to treat them.

For further reading on care of hospitalised adult and paediatric patients with COVID-19, click the following links:

http://www.epid.gov.lk/web/images/pdf/Circulars/Corona_virus/revisionsummary.pdf

https://www.who.int/docs/default-source/coronaviruse/clinical-management-of-novel-cov.pdf

Pharmacology teachers' community grows. . .

Our heartiest congratulations and best wishes for the young academics, newly recruited for the post of probationary lecturer at the Department of Pharmacology, Faculty of Medicine, University of Ruhuna.

Dr. R.A. Wasana Sevwandi
(from 10.04.2019)

Dr. M.T. Madhushika
(from 15.10.2019)

Dr. S.A Mendis
(from 23.01.2020)

Prescribing Without Evidence - Fish Oil Dietary Supplements

Compiled by Dr. G.V. Nilangika Sandakumari, Dr Priyanga Ranasinghe & Professor Chandanie Wanigatunga

Fish oil dietary supplements (FODS) contain the omega-3 fatty acids (OM3FAs), mainly eicosapentaenoic acid (EPA) and docosahexaenoicacid (DHA). Despite the widespread use of FODS, there is considerable dilemma regarding their benefits and appropriate use among both prescribers and consumers (1). For patients with elevated triglyceride (TG) levels, the American Heart Association has recommended 2–4 g/day of EPA+DHA (2). Prescription products are indicated as dietary supplements to reduce TG levels in adults with severe (≥500 mg/dL) hypertriglyceridemia (2, 3).

Prescription products may contain up to 90% OM3FA, whereas over-the-counter FODS contain roughly between 30-50% OM3FAs, depending on the product. Hence, more FODS capsules per day are needed to achieve prescription-strength and AHA-recommended amounts of OM3FAs. As a result, the cost advantages over prescription products are lost (4).

FODS are not approved by the US FDA to treat disease and they are not categorized as over-the-counter drugs. Because FODS are considered as dietary supplements, there is less rigorous regulation regarding efficacy, safety, content, and chemical integrity (3). Studies have raised concerns about the OM3FA content and chemical integrity of FODS.

- In an analysis done in USA, comparing actual versus stated label amounts of EPA and DHA in commercial FODS, over 70% of the products were shown to contain lesser amounts than stated. (5)
- Oxidized lipids, an indication of lipid decomposition, were unacceptably high in more than 80% of over 35 FODS from New Zealand, while only 8% met international standards for acceptable peroxide and total oxidation levels (6).
- Similar observations have been noted in Canada, with 50% of the products exceeding the recommended levels for markers of oxidation (8).

Furthermore, studies have also shown that leading commercially available FODS also contain more than 30 other fatty acids, including significant levels of saturated fat. In addition higher levels of lipid oxidation products have also been noted, which may interfere with biological activity, leading to adverse clinical consequences (1). These data indicates that there is a need for further research prior to advocating FODS and the necessity to raise awareness about the quality and appropriate use of FODS among prescribers and consumers.

To conclude, as a product without rigorous FDA regulation and with varying levels of fatty acids and oxidation products, FODS are not an appropriate substitute for prescription OM3FA products in patients diagnosed with certain medical conditions, such as very high triglyceride levels.

Further reading

1. Hilleman D, et AL. “Prescription omega 3 fatty acid products and dietary supplements are not interchangeable”, Managed Care Jan. (2016) 46 52 B

2. Kris – Etherton PM, et al: “Fish consumption, fish oil, omega 3 fatty acids and cardiovascular disease.” Circulation. 106 2002 ;2747 – 2757

3. R.P. Mason, S.C.R. Sherratt, “Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits” Biochemical and Biophysical Research Communications 483 (2017) 425- 429

4. Zargar A et al. “Long chain omega – 3 dietary supplements: a review of the National Library of Medicine Herbal Supplement Database”, Metabolic Syndrome Related Disorders 9(2011)255-271

5. Kleiner A.C. et al “A comparison of actual versus stated label amounts of EPA and DHA in commercial omega -3 dietary supplements in the United states”, J. Sci. Food Agric. 95(2015)1260 – 1267

6. Albert B.B. et al “Fish oil supplements in New Zealand are highly oxidized and do not meet label content of N-3 PUFA”, Sci. Rep.5(2015) 7928

7. Ritter J.C. et al “Quality analysis of commercial fish oil preparations”, j. Sci. Food Agric. 93(2013) 1935 – 1939

8. Stefan A. Jackowski et al “Oxidation levels of North American over-the-counter n-3 (omega-3) supplements and the influence of supplement formulation and delivery form on evaluating oxidative safety”, J Nutritional Science. 2015; 4: e30. Published online 2015 Nov 4. doi: 10.1017/jns.2015.2

Safe Use of Medicines

Safety of valproic acid and its derivatives in pregnancy

Valproic acid and its derivatives valproate semisodium and valpromide are teratogenic. In utero exposure can cause congenital malformations and severe psychomotor developmental disorders in childhood.

Measures were put in place in the European Union since 2014 to prevent in utero exposure to these teratogenic drugs, including a recommendation to not prescribe valproic acid to girls, pregnant women or women of childbearing age unless there is no alternative treatment, and to better inform the patients about the need for effective contraception. Stringent measures in the European Union followed after a review of data by the European Medicines Agency (EMA) in mid-2018, including changes to the summaries of product characteristics (SPCs) and patient leaflets for the medicines concerned. Valproic acid is now contraindicated in pregnant women and in women of child bearing age unless all the conditions of the "pregnancy prevention programme" are fulfilled. Valproate semisodium and valpromide are now contraindicated in pregnant women for the treatment of bipolar disorder.

It is crucial that stronger measures be taken to prevent in utero exposure of children to the teratogenic effect of any medicines. Healthcare professionals must take the time to inform patients about the risks associated with taking such medicines during pregnancy and about the measures put in place to prevent pregnancy, and they must ensure that these measures are followed throughout the treatment.

Uppsala Monitoring Centre (UMC) organized the medicine safety week from 25 -29 November 2019. This together with #MedSafetyWeek, an international social media campaign are the UMC's efforts to raise awareness of adverse drug reactions and national reporting systems. Theme for 2019 was polypharmacy. Studies have repeatedly shown that polypharmacy is a risk factor for preventable adverse drug reactions (ADR) and adverse drug-drug interaction.

This campaign aimed to:

- Encourage people who take multiple medicines, especially the elderly or those with long-term conditions, to report ADRs,
- Urge healthcare professionals to review their patients' medication intake, especially when prescribing or administrating multiple medicines, and to be vigilant to monitor, detect and report ADRs to the national drug regulatory authority.

We call that Sri Lanka too should organize such medicine safety week to raise awareness of medicine safety issues among public, pharmacists and doctors. Main stream media and social media can be partners in this process.

For further reading: https://www.who.int/medicines/news/2019/medicines-safety-week/en/

Antibacterial Corner

SLACPT takeoff AMU & AMR capacity building

Keeping in line with its theme *"optimization of medicines through safe, effective and economic prescribing"*, SLACPT takes initiative to organize capacity building programme on antimicrobial utilization (AMU) and antimicrobial resistance (AMR). The first workshop addressing "Role of pharmacists in AMU and AMR", which also carries CPD points, will be held as the pre-congress workshop on 19th March 2020 from 8.30am – 5.00pm at PGIM Academic Centre at 85, Rodney Street, Colombo 8.

Time	Topic	Resource person
8.45-9.00am	Introduction – Purpose of Workshop	Professor Shalini Sri Ranganathan
9.00-9.15am	AMR and AMU- Brief overview	Professor Rohini Fernandopulle
9.15-9.45am	Role of pharmacists in rational use of antimicrobial agents (AMA)	Professor Chandanie Wanigatunga
9.45-10.15am	Role of the pharmacist in the drug and therapeutic committee of the hospital on AMR containment	Professor Rohini Fernandopulle
10.15- 10.30	Tea	
10.30-11.00 am	Surveillance of AMR and AMU in Sri Lanka	Dr Savini Senadheera
11.00-11.30am	Role of Pharmacists in AMU studies	Professor Shalini Sri Ranganathan
11.30 am-12 noon	ATC classification and DDD for Pharmacists	Professor Shalini Sri Ranganathan
12 noon-12.30 pm	WHO's AWaRe classification of AMA	Dr Priyanga Ranasinghe
12.30 - 1.15 pm	Lunch	
1.15- 1.30 pm	How pharmacists can contribute to antibiotic stewardship programmes?	Professor Shalini Sri Ranganathan
1.30-3.30pm	Group work and open discussion	Moderators – all resource persons
3.30-3.45pm	Summary of local Studies	All resource persons
3.45-4.00pm	Forming A Pharmacists Network for AMR and AMU	All resource persons
4 pm	Awarding certificates and Tea	

Those who are interested to participate in the March 2020 workshop, please register soon as there are only limited vacancies. SLACPT is happy to conduct similar capacity building workshops, on request. Contact the SLACPT office for further details.

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From the WHO

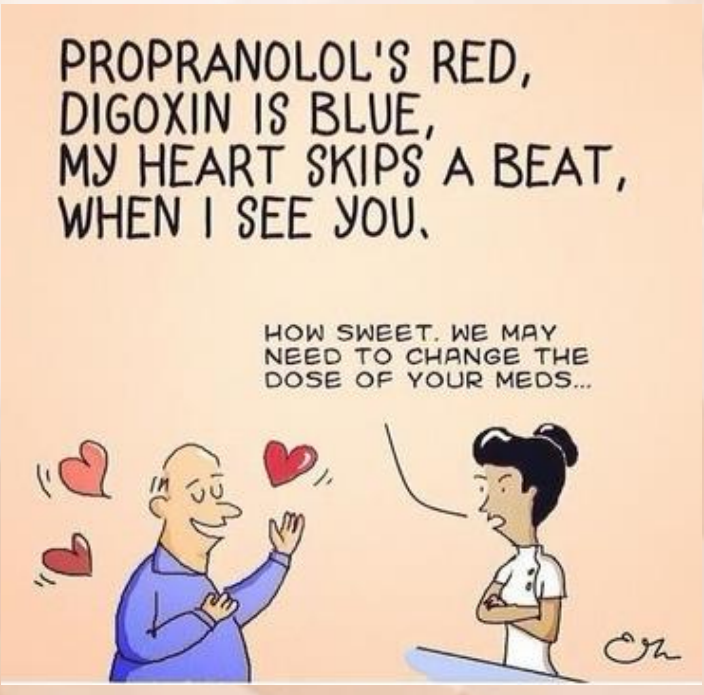
WHO launched a Pilot Procedure for Prequalification of Human Insulin

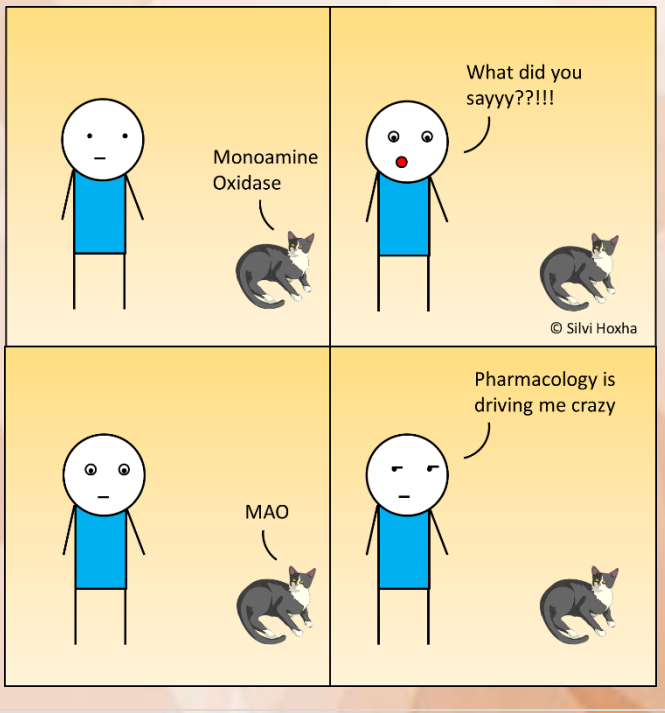
Compiled by Professor Shalini Sri Ranganathan

Marg Ewen of Health Action International expressed her concerns reporting that: "An estimated 100 million people with diabetes need it. This includes all with type 1 diabetes, plus 20 to 30 per cent of people with type 2 diabetes. Without access to insulin, people with type 1 diabetes will die and people with type 2 are at increased risk of blindness, amputation and kidney failure—even premature death. The sad reality, however, is that more than half of those who need insulin cannot access or afford it. And as the global diabetes disease burden continues to worsen year over year, the problem will only increase if not immediately addressed" (https://haiweb.org/hai-launches-innovative-global-study-to-improve-access-to-insulin/)

Taking this message seriously, the World Health Organization has launched Pilot Procedure for Prequalification of Human Insulin in order to improve access to safe, effective and quality assured human insulin. Human insulin falls under the category of bio-therapeutic products (BTP) (therapeutic materials produced using biological means, including recombinant DNA technology) and regulatory assessment of those products according to internationally acceptable guidelines and standards can be challenging in some countries. Like vaccines prequalification programme, the WHO has stepped in to help the National Medicine Regulatory Authorities by way of pre-qualifying human insulin. We need to wait to see the change.

For further information click onto:
https://www.who.int/medicines/regulation/prequalification/pq_human_insulin/en/





Upcoming Events . . .

SLACPT Academic Sessions – the premier event in our academic calendar this year, yet again promises to be an academic fiesta covering a spectrum of interesting topics in Clinical Pharmacology and Therapeutics, bringing cutting-edge knowledge, research and practice in crucial areas right to our doorsteps. It will be held from 19th – 21st March 2020 in Colombo.

The SLACPT Academic Sessions consists of:

- A pre-congress workshop on 19th March 2020
- The ceremonial inauguration and induction of the president including the prestigious SLACPT Oration, on the evening of 20th March 2020
- The main congress on 21st March 2020

Glimpse of tentative schedule of the main congress:

Type	Topic	Speaker
Plenary 1	Professor Bibile, Essential Medicines Concept and its Global Influence	Dr. Krisantha Weerasuriya, Emeritus Professor, University of Colombo
Symposium 1: Integrating clinical pharmacology into patient care		
Speaker 1	Paediatric Clinical Pharmacology - The Australian experience of integration into a tertiary referral service.	Professor Noel E. Cranswick Director, Clinical Pharmacology Unit, Department of Medicine, Royal Children's Hospital Associate Director, Melbourne Children's Trials Centre, Murdoch Children's Research Institute Associate Professor, University of Melbourne
Speaker 2	The Need for clinical pharmacology in patient care in Sri Lanka	Dr. Upul Dissanayake Consultant Physician, National Hospital of Sri Lanka
Speaker 3	Challenges to postgraduate training in clinical pharmacology	Dr. Sachith Abhayaratna Senior Lecturer, Department of Pharmacology, Faculty of Medicine, University of Colombo
Speaker 4	Challenges to postgraduate training in clinical pharmacology: a Trainees Experience	Dr. Priyanga Ranasinghe Senior Lecturer, Department of Pharmacology, Faculty of Medicine, University of Colombo
Speaker 5	Clinical Pharmacology in Critical Care	Professor Vasanthi Pinto, Professor in Anaesthesiology & Critical Care Department of Anaesthesiology & Critical Care, Faculty of Medicine, University of Peradeniya
Tea Break		

Symposium 2: Pearls in Pharmacovigilance		
Speaker 1	Anaphylaxis – Immunologist's perspectives	Dr. Rajiva de Silva, Consultant Immunologist, Medical Research Institute, Colombo
Speaker 2	Recent signals in pharmacovigilance	Dr. Chamila Mettananda, Senior Lecturer in Pharmacology, Department of Pharmacology, Faculty of Medicine, University of Kelaniya
Speaker 3	Vaccine vigilance – Role of Cohort Event Monitoring	Dr. Kumuthini Sanchayan, Senior Lecturer in Pharmacology, Department of Pharmacology, Faculty of Medicine, University of Jaffna
Plenary 2	Translating the understand of the diversity of genetic variants involved in drug response and metabolism in the Sri Lankan population into clinical implementation of pharmacogenomics in Sri Lanka	Professor Vajira Dissanayake Chair and Senior Professor in Anatomy, Faculty of Medicine, University of Colombo Director, Human Genetics Unit, University of Colombo
Lunch (Poster Viewing)		
Plenary 3	National Medicines Policy: Emphasizing on recent changes	Professor Asita De Silva, Senior Professor in Pharmacology, Faculty of Medicine, University of Kelaniya
Free Paper Presentations		
Symposium 3: Teaching Pharmacology to medical students in the 21st century		
Speaker 1	A multi-faceted approach to enhancing medical education	Dr. Chen Zhi Xiong, Senior Lecturer and Integration Lead Educator (Medicine), Deputy Education Director – Medicine Department of Physiology, Yong Loo Lin School of Medicine, National University of Singapore
Speaker 2	Integrating pharmacology with clinical teaching Simulation - the way forward.	Dr. Thilanka Senevirathna, Senior Lecturer, Department of Pharmacology, Faculty of Medicine, University of Peradeniya
Speaker 4	Challenges to undergraduate training in Pharmacology in a university located in the periphery	Dr. Roshini Murugupillai, Senior Lecturer in Pharmacology, Department of Clinical Sciences, Faculty of Health-Care Sciences, Eastern University, Sri Lanka
Closing ceremony and awards		

Write to us!

SLACPT welcomes suggestions from readers towards improving the image of the Association and the newsletter. Please send your suggestions to:
Email: office@slacpt.lk