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# SLMA NEWS+

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**Management of acute stroke**

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**A death from Malaria in Sri Lanka after 17 years**

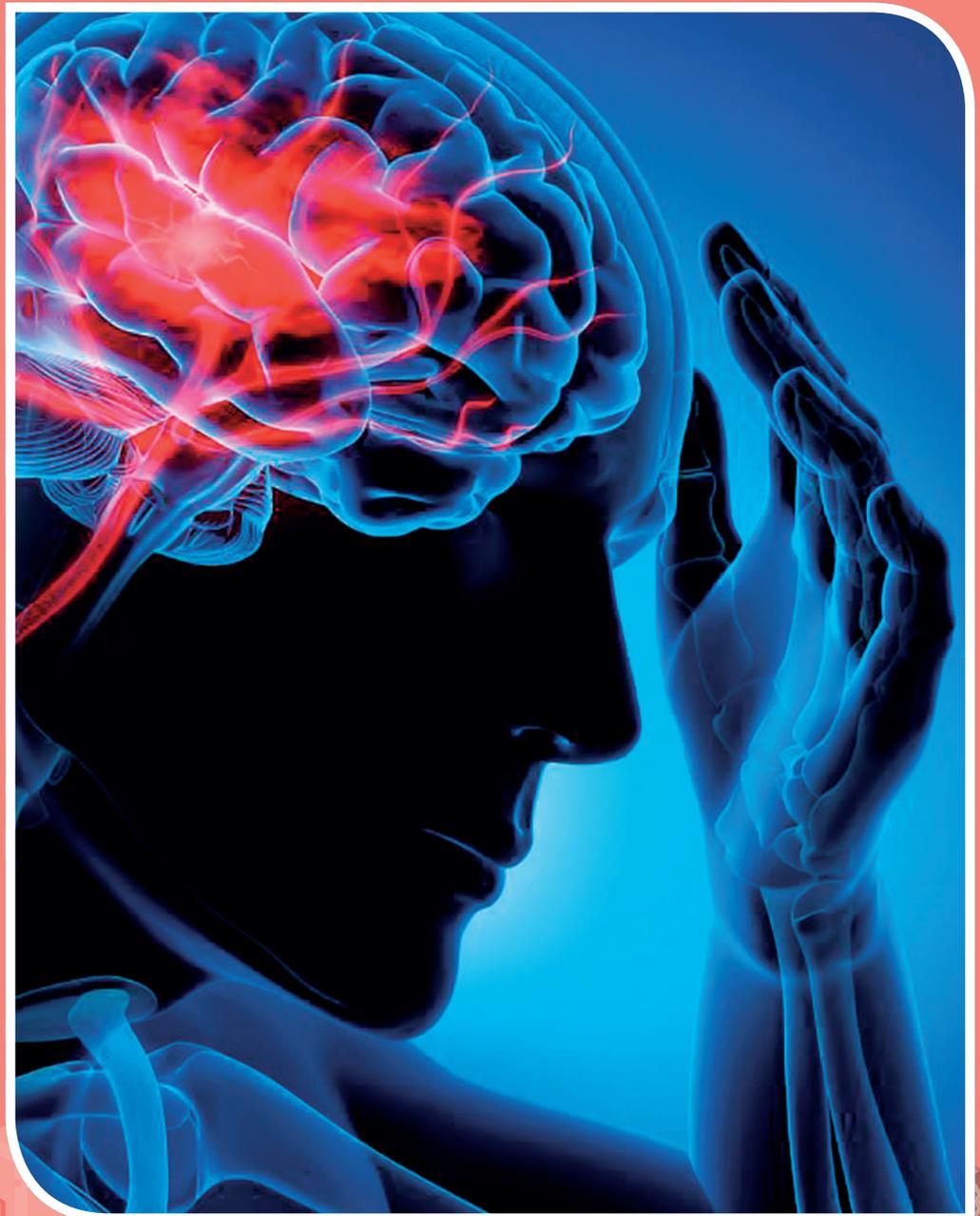
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**Towards Elimination of COPD**

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**Pharmaceutical supply in Sri Lanka**

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## Cover Story

**Management of acute stroke for primary care doctors in Sri Lanka**



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## SLMA President



### Dr Vinya Ariyaratne

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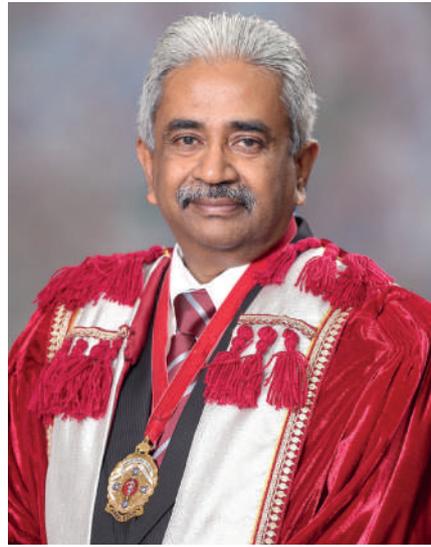


# President's Message

Dear SLMA Members,

It is a fact of life that the crisis faced by the Sri Lankan health sector is far from over. The shortages of medicines, reagents and consumables persist. The challenge of retaining human resources for health, including specialists, due to out-migration/emigration, is affecting the provision of quality health services.

During the previous month, Sri Lanka Medical Association (SLMA) has been engaged in various policy dialogues that have been convened by the Ministry of Health and other key stakeholders such as the World Health Organization (WHO). One of the key processes that SLMA has actively participated in is "sustainable health financing". Due to the prevailing economic crisis, the health sector has been affected in multiple ways. The government sees the continued provision of free healthcare delivery as a major challenge. As a result, possible solutions have been expressed by various individuals holding different positions in the political establishment without careful consideration of key factors on a rational basis. One such response has been the proposal to immediately establish paying wards in government hospitals. SLMA firmly believes that such major policy decisions should be taken after carefully studying the currently operating fee-levying models in health care institutions such as the Merchants' Ward of the National Hospital of Sri Lanka (NHSL), Vijaya Kumaranathunga Memorial Hospital and the Sri Jayawardenepura Hospital.



While such different options are being considered, I firmly believe that we should also carefully assess the recent policy changes and strategies that have been adopted by the health sector as possible solutions to meet the present crisis as cost-effective models. One such example is the Primary Health Care cluster system propagated by the World Bank (WB) funded Primary Care Strengthening Project (PSSP). This has now been recognized as a successful model in the Sri Lankan health sector by a majority of stakeholders, particularly the front-line health workers. The propagated model by the PSSP involves a "Cluster system" where Primary Medical Care Units (PMcus) drain to the closest apex health care centre, usually a Base Hospital. This enables all individuals receiving care at the PMCU to receive further health care requirements from the apex hospital to which the PMCU drains. The draining area centralized by the apex care hospital will then be self-sufficient in terms of laboratory services, in-ward services, operating theatre facilities and specialized care. It also enables a referral and back

referral system, where the patient will undergo minimum difficulties. There has been a notable buy-in from health administrators for this rather efficient system. The essential components of this model include improving prevention and control of NCDs, patient-friendly service delivery, technological innovations in the provision of services, reaching and empowering high-risk groups, public-private partnerships that would demonstrate efficiency, quality or other service delivery improvements, health information and communication, public relations, social mobilization and community engagement for primary health care.

The further development and enhancement of these elements would be of great service and use at this time of crisis and beyond. SLMA is currently contributing to this process by providing evidence and expert inputs through the Health Management Committee and plans to have a Plenary Session and a Symposium on the subject of 'Sustainable Health Financing' at the upcoming 136th SLMA Anniversary International Medical Congress in July 2023.

The SLMA, as the apex medical body in Sri Lanka, believes that the time is ripe for the PHC Model which has been proven to be successful, to be formally integrated into the Health Care System. For that to happen, there needs to be strong advocacy to promote further buy-in from all sections of the medical community, policymakers, key decision makers, as well as the general public.

**Dr Vinya Ariyaratne**  
**President SLMA.**

# Activities in Brief

(16<sup>th</sup> April 2023 - 15<sup>th</sup> May 2023)

## SLMA Saturday Talks

22<sup>nd</sup> April

'The Intoxicated Child: Spot the Diagnosis' by Dr Kavinda Dayasiri, Senior Lecturer in Psychiatry, University of Kelaniya

29<sup>th</sup> April

'Medically unexplained symptoms' by Dr Saumya Madhri Senanayake, Lecturer in Psychiatry, University of Colombo

6<sup>th</sup> May

'Bleeding per-rectum: Case based discussion' by Professor Dakshitha Wickramasingha, Professor in Surgery, University of Colombo

13<sup>th</sup> May

'Leaking female in Gynaecology' by Dr Champika Gihan, Senior Lecturer in Obstetrics & Gynaecology, University of Peradeniya

## Other Activities

19<sup>th</sup> April

The SLMA Doc 247 organized a webinar on 'Dengue: Update on Current Situation & Management'.

The resource persons were Dr Ananda Wijewickrama, Consultant Physician, IDH and Professor Neelika Malavige, Professor in Immunology, Sri Jayawardenanapura University



24<sup>th</sup> April

The MoU between SLMA and 1990 Suwaseriya was renewed for another one year. Based on the MoU, SLMA will provide medical advisory services for COVID-19 and other medical emergencies through the SLMA DoC 247



24<sup>th</sup> April

The SLMA Expert Committee on Communicable Diseases organized a symposium on 'The World faces an upsurge of 7<sup>th</sup> Cholera pandemic: Be prepared to confront it'



The resource persons and the topics of discussion were;

'History, current global situation and steps to prevent cholera in Sri Lanka again' by Dr Thilanga Ruwanpathirana, Consultant Epidemiologist, Epidemiology Unit, MoH, 'Clinical presentation & management of cholera' by Dr Chamila Dalpatadu, Consultant Physician, University of Colombo and 'Laboratory diagnosis & preventive methods' by Dr Sujatha Pathirage, Consultant Clinical Microbiologist, MRI

24<sup>th</sup> April

A media seminar was conducted on 'Ethical reporting of sensitive issues including suicide'

The resource persons were Dr Chathurie Suraweera, Consultant Psychiatrist, NHSL, Colombo and Dr Sajeewana Amarasinghe, Consultant Psychiatrist, NHSL, Colombo



24<sup>th</sup> April

A media briefing was held at the SLMA council room to sensitize the public on 'Protection from extreme heat prevailing in the country' and 'Prevention of Leptospirosis'. The resource person was Dr Vinya Ariyaratne, President, SLMA



25<sup>th</sup> April

A clinical meeting was held with the collaboration of the Centre for Research in Tropical Medicine, University of Peradeniya

'Dengue - update on presentation & management' by Professor Udaya Ralapanawa, 'Central Nervous System, infections in the Tropics' by Professor Manoji Pathirage, and 'Meloidosis, a great masquerade

## Brief description of activities

in the topics' by Professor Chamara Dalugama. All resource persons were from Dept of Medicine, University of Peradeniya



### 25<sup>th</sup> April

A seminar on 'Understanding the dynamics of Cannabis use, cultivation legalization and popularization' was organized by the Expert Committee on Alcohol, Tobacco & Illicit Drugs in collaboration with CCT, ADIC and You PAH.

Dr Mahesh Rajasuriya, Director CCT introduced the objectives of the workshop

The topics covered at the workshop were; Evidence based use of cannabis in allopathic medicine, Role of cannabis in Ayurvedic/indigenous medicine, Cannabis industry, legalization, popularization and lessons learnt & what our response should be?

Dr. Padma Gunaratne, Past President of SLMA, Dr. Nimal Karunathilaka, retired Ayurvedic Commissioner, Dr. Vajira Senevirathne, Ayurvedic Pharmacologist, Dr. Manuja Perera, Editor of Tobacco Unmasked, Mr. Sampath De Saram, Executive Director of ADIC, Dr. Sajeewa Ranaweera, a member of SLMA expert committee, Dr. Jayamal De Silva, a member of SLMA expert committee, Prof. Narada Warnasuriya, President of SLMA expert committee and Prof. Diyanath Samarasinghe also spoke at the event.

Representatives from Colleges of Psychiatrists, Paediatricians, Neurologists and Community

physicians, representatives from Ayurvedic medicine and civil organisations participated at the event.



### 26<sup>th</sup> April

A joint Regional Meeting was held by SLMA in collaboration with the Clinical Society of Sri Jayawardenapura General Hospital

The theme for the regional meeting was 'Clinician's Role in Healthcare Quality & Patient Safety'



Dr Wimal Karannagoda, Healthcare Management Consultant spoke on 'Introduction with examples of issues related to quality & safety', Dr Ranjan

Dias, Consultant Surgeon, University of Sabaragamuwa on 'Surgical Safety', Dr Sridharan Sathasivam, DDG (Planning), MoH on 'What can be done to improve quality & safety in Healthcare : A Doctors' Role' and Dr Alan Ludowyke, Director, Healthcare Quality & Safety, MoH on 'What is done in Sri Lanka related to quality & safety in Hospitals'.

### 27<sup>th</sup> April

The SLMA Expert Committee on Medical Rehabilitation organized a lecture on 'Bladder management in spinal injury' by Dr Gayathri Baranasuriya, Senior Registrar in Rehabilitation Medicine.

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### 28<sup>th</sup> April

A therapeutic update on the topic 'Rational Use of Antibiotics during the Economic Crisis' by Dr Ananda Wijewickrama, Consultant Physician, IDH was organized by the Expert Committee on Medicinal Drugs



**2<sup>nd</sup> May**

A clinical meeting was held with the collaboration of the College of Anaesthesiologists & Intensivists of Sri Lanka on the topic *'Beyond the surface: Exploring the depths of back pain, diagnosis and treatment'*

The resource persons were; Dr Gayani Walpola, Consultant Anaesthetist, National Dental Hospital of Sri Lanka, Dr Lakshman Dissanayaka, Consultant Anaesthetist, National Institute of Nephrology, Dialysis and Transplantation, Dr Prasadini Karunaratne, Consultant Anaesthetist, Pain Management Unit, National Cancer Institute, Maharagama and Dr MD Champika Sujeewani, Consultant Anaesthetist, Pain Management Unit, NHSL



**3<sup>rd</sup> May**

A session of Expert Talks was organized on *'Preparedness for seasonal hazards in Sri Lanka'*



Dr Ananda Mallawatantri, President, ADRIMP introduced the objectives of the session, Dr Shiromani Jayawardena, Director (Weather forecasting decision support), Meteorology Department on *'Overview about the pre-monsoonal disturbances'*, Eng SPC Sugeeshwara, Director of Irrigation (Hydrology & Disaster Management) on *'Flood hazards and its Predictions during Pre-monsoon season'* Dr Gamini Jayatissa, Acting Director, Landslide research & risk management division, NBRO on *'Landslide hazards and its predictions during pre-monsoon season'* Mr Chathura Liyanarachchi, Acting Director (Preparedness), Disaster Management Centre (DMC) on *'Role of DMC for monsoon preparedness'* & Dr Jagath Amarasekara, Consultant Community Physician, National Dengue Control Unit on *'Preparedness of Health sector for possible disease outbreaks during monsoon season'*

**3<sup>rd</sup> May**

A media briefing was held at the SLMA council room to sensitize the public on *'Leptospirosis & Dengue'*. The resource persons were Dr Vinya Ariyaratne, President, SLMA and Dr Lahiru Koditiwakku, Council member, SLMA



**9<sup>th</sup> May**

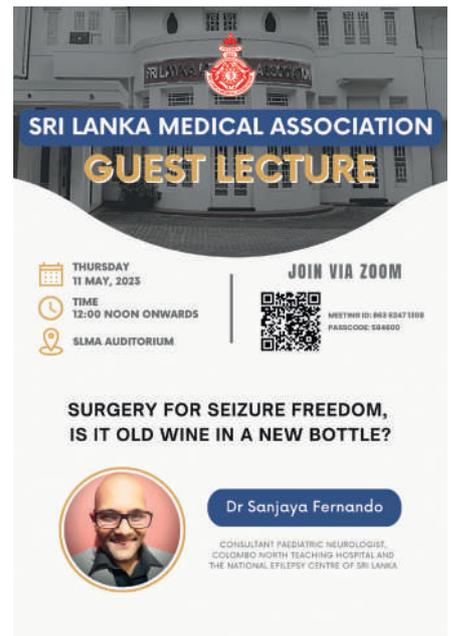
A media seminar on the topic *'Are we prepared for a Leptospirosis outbreak?'*

The resource persons were Dr Thushani Dabarera, Consultant Epidemiologist, Epidemiology Unit, MoH, Professor Panduka Karunanayaka, Professor in Medicine, University of Colombo and Dr Lilani Karunanayaka, Consultant Microbiologist, MRI



**11<sup>th</sup> May**

A guest lecture was organized on *'Surgery for seizure freedom, Is it old wine in a new bottle?'* by Dr Sanjaya Fernando, Consultant Paediatric Neurologist, Colombo North Teaching Hospital.



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# Management of acute stroke for primary care doctors in Sri Lanka

**Dr Padma S Gunaratne**

MBBS(SL), MD(SL), FRCP(Edin, Glasg, Lond), FCCP,  
Hon. FRACP, FAAN, FWSO  
Consultant Neurologist

## Introduction

Stroke is a leading non-communicable disease which is the second leading cause of death, worldwide. It is also the leading cause of adult disability. The life time risk of developing a stroke in an individual has increased by 50% over the last 17 years and 1 in every 4 people is estimated to have a stroke in their life time.(1) There has been a 70% increase in the incidence of stroke, a 43% increase in deaths caused by stroke, a 102% increase in the prevalence of stroke and a 143% increase in Disability Adjusted Life Years(DALYs) following stroke, from 1990 to 2019.(2) There is robust data to support that there are 10 stroke survivors for every 1000 people in Sri Lankan community.(3,4) Stroke is a catastrophe that attacks people leading to 20% mortality within the first year after the index attack with 50% of survivors suffering significant morbidity. Thirty per cent of stroke sufferers are between 20 – 60 years; the most productive age of their lives.

These data provide ample evidence to support the need for healthcare professionals to be well-equipped with knowledge and skills in the management of stroke.

## What is a stroke ?

**Stroke** was defined in 1970 by the WHO as a clinical syndrome of presumed vascular origin, typified by rapidly developing signs of focal or global disturbance of cerebral functions lasting more than 24 hours or leading to death.(5)

## What causes a stroke?

A stroke is caused either by a cerebral haemorrhage or a cerebral infarction. Eighty per cent of strokes are caused by cerebral infarctions and 15% by cerebral haemorrhages. Subarachnoid haemorrhages (SAH) account for about 5%. However, as SAH is with a different pathophysiology and a management approach, SAH is not included in the discussion of this article on the management of acute stroke.

## How would you diagnose stroke?

Diagnosis of a stroke is best made based on clinical features. An acute onset of neurological symptoms

is the characteristic feature of a stroke. Being able to mention what the patient had been doing at the time of the onset of symptoms is a characteristic feature which is useful in eliciting the acute nature of symptoms. Symptoms will be determined based on the area of the injury to the brain. Nevertheless, there are certain frequently occurring syndromes.

These are:

- Weakness or numbness of the face, arm and/or leg affecting one half of the body.
- Difficulty in speaking.
- Impaired vision in one or both eyes or double vision.
- Impairment in maintaining balance, vertigo or difficulty in swallowing.
- Sudden severe headache with altered consciousness.

The acronym "FAST" indicating Face, Arm, Speech and Time is being used globally to educate the public on the recognition of a stroke and the need for time dependent treatment.

## What should you do if you diagnose a stroke in the community?

A stroke is a medical emergency that needs time-dependent treatment to salvage ischaemic cerebral tissue leading to a better recovery. All acute stroke patients should be transferred to the closest hospital with CT scanning facilities at the earliest time possible. (6) Emergency Medical Technicians (EMT) of the Suwa Seriya Ambulance Service are trained in the diagnosis of stroke and are authorized to transfer patients to hospitals with CT scanning facilities, bypassing smaller hospitals. He/She is expected to make a booking for an emergency bed at the Accident & Emergency (A&E) unit prior to transferring the patient.

## What would happen at the Accident & Emergency?

All hospitals with CT facilities have to have a stroke care pathway established collaborating A&E, radiology, laboratory and medical/neurology units to provide time dependant emergency service to acute stroke patients. Many hospitals in Sri Lanka already have established pathways to suit the hospital. A graphical description of the pathway has to be placed visibly in the A&E for the benefit of all stakeholders.

There should be protocols in place for screening at triage, for emergency evaluation at A&E, for CT scanning of the brain at the radiology unit, intra venous thrombolysis and mechanical thrombectomy for ischemic stroke, post thrombolysis management and for ICU care providing due priority for the management.

The medical officer at the A&E should perform a rapid evaluation following a brief history taking and should stabilise the patient. Upon making a tentative diagnosis of stroke, he should evaluate the patient using the " Acute stroke protocol" available at the A&E.

The key features to establish are:

1. Time of onset of symptoms
2. Disability of the patient using "FAST"
3. Neurological assessment using the National Institute of Health Stroke Scale (NIHSS)(7)
4. Inclusion and exclusion criteria for thrombolysis (Fig 1)
5. Blood pressure
6. Blood should be sent for full blood count, INR and APTT
7. Random blood sugar

Patient should be sent for an unenhanced CT brain immediately, after informing the Radiology Department.

### **What should happen at the Radiology Department**

The Radiology department should prioritize acute stroke cases and arrange an unenhanced CT immediately. The CT should be seen by a specialist (radiologist / neurologist / internal medicine physician / emergency physician) immediately, not taking more than 20 minutes. CT angiography (CTA) could be performed without delaying the rest of the management in indicated patients. Further management would be determined based on the pathological diagnosis, whether the patient suffered an ischaemic stroke or a haemorrhagic stroke.

### **How does imaging help in the management of hyperacute stroke**

Computerized tomography (CT) and Magnetic resonance imaging (MRI) are the neuroimaging procedures available to image the brain. Recent technological advancements have made these investigations to be complimentary in the clinical setting in the presence of specialists in radiology. Nevertheless, the non-contrast CT brain which is freely available and familiar to all clinicians provides information adequate for the management of acute stroke in most patients.

### **CT scanning in acute stroke**

During the first hour after the ischemic stroke, unenhanced CT does not show much changes. Despite, the non-contrast CT at the earliest possible time is important as haemorrhagic stroke is precisely visible as a hyperdense area allowing reliable differentiation of ischaemic stroke from haemorrhagic stroke. Upon the diagnosis of stroke being made on the history, the normal CT excludes haemorrhage reliably and facilitates further management with thrombolysis and thrombectomy in eligible patients.

Early CT may show evidence of a hyperdense middle cerebral artery (MCA) sign indicating a thrombus in the M1 segment of the MCA. Loss of grey-white differentiation, attenuation of the lentiform nucleus, loss of the insular ribbon and hemispheric sulcus effacement are other features that may appear within the first 24 hours. Parenchymal hypodensity indicates established infarction.

CT perfusion studies are useful in differentiating the volume of ischaemic tissues that is salvageable by intravenous thrombolysis or mechanical thrombectomy, from the infarcted cerebral tissue (Non-salvageable). CTA of intracerebral vessels would provide more information pertinent for further management with thrombectomy in a patient with ischaemic stroke.

### **MRI scanning in acute stroke**

MRI scanning is more time-consuming, less frequently available and more complex in interpretation to the non-radiology specialists. But it has significantly higher sensitivity and specificity in the diagnosis of acute cerebral infarction. Diffusion-weighted imaging (DWI) would show infarcted tissue as a hyperintense area within minutes of infarction when the affected tissue appears normal on all other sequences. Changes in FLAIR images would start appearing about 8 hours after the onset of infarction. When DWI is combined with perfusion- weighted studies, they become useful in differentiating the volume of ischemic penumbra that is salvageable by intravenous thrombolysis or mechanical thrombectomy. Cerebral haemorrhage is most easily visible on susceptibility-weighted imaging (SWI).

MRA delineate the vascular tree during MRI. However, it is less sensitive in providing information in relation to luminal stenosis when compared to CTA.

### **Thrombolysis for ischemic stroke**

All patients with acute ischaemic stroke are potential candidates for IV thrombolysis and mechanical thrombectomy. All of them should be evaluated using the form available in the A&E for the management of

acute stroke.(Fig 1) They should fulfil all inclusion and absolute exclusion criteria. Relative exclusion criteria also should be considered. All who become eligible, should receive IV alteplase (rtPA) 0.9 mg/kg (Max 90 mg, 10 % of the calculated dose over 1 minute and the remainder over next 60 minutes) or IV tenecteplase 0.25 mg/kg (Max 25 mg over 5 seconds) within 4.5 hours from symptom onset.(8)Thrombolysed patients should be monitored closely at HDU / ICU over the next 24 hours for adverse reactions such as bleeding and rtPA-induced perioral and lingual oedema.

### **Mechanical thrombectomy for ischemic stroke**

Availability of facilities for interventional radiology in hospitals provides an opportunity for patients to receive advanced care for ischaemic stroke. Selected patients suspected to have large vessel occlusion should undergo CTA without causing a delay on thrombolysis. Patients who were detected to have proximal intracranial large vessel occlusion and fulfil criteria for intervention, should not wait to see the response to thrombolysis but should receive mechanical thrombectomy within 6 hours of symptom onset.(9) The wake-up stroke who are unaware of time of onset of symptoms and patients with large vessel occlusions beyond 6 hours up to 24 hours need further evaluation using perfusion studies of CT / MRI identification for salvageable cerebral tissue and should be offered mechanical thrombectomy for eligible patients.

Further management of all clinically stable stroke patients is best carried out in stroke units which are not all that sufficiently established yet in Sri Lanka.

### **General measures**

Blood pressure -

- Correct hypotension and hypovolaemia to maintain cerebral perfusion
- Blood pressure > 185/110 should be reduced to <180/105, using IV blood pressure-lowering agents prior to thrombolysis
- For acute ischaemic stroke patients with BP >220/120 who did not undergo thrombolysis or thrombectomy, consider lowering the BP by 15% in the first 24 hours after the onset of symptoms. Do not lower the BP in patients with BP <220/120 who would not receive IV thrombolysis.

Temperature - Treat hyperthermia and the cause

Blood glucose - Maintain between 140 - 180 mg/dl

Antiplatelets -

- Patients who received thrombolytics should be commenced on antiplatelet agents in 24 hours
- TIA or minor non-disabling ischaemic stroke who

did not undergo thrombolysis, should receive a loading dose of aspirin 300 mg and clopidogrel 300 mg immediately following ischaemic stroke conformation followed by dual antiplatelets with 75 mg of aspirin and 75 mg of clopidogrel for another 3 weeks.

Lipid-lowering treatment -

- High intensity statin, atorvastatin 40 - 80mg daily should be commenced immediately.

Swallowing assessment -

- All stroke patients should undergo a swallowing assessment carried out by an experienced nurse or a speech and language therapist within the first 24 hours prior to allowing oral fluids. Patients with dysphagia should have a nasogastric tube inserted to maintain hydration and nutrition.

Deep vein thrombosis -

- In addition to good hydration and early mobilization, intermittent pneumatic compression is recommended to prevent DVT for immobile patients.

Decompressive hemicraniectomy -

- There is a place for decompressive hemicraniectomy within first 48 hours of symptom onset for deteriorating MCA infarction patients.

Rehabilitation -

- Rehabilitation by a multidisciplinary team working in a stroke unit, should be commenced as tolerated by the patient at the earliest possible.

### **Management of Intra Cerebral Haemorrhage (ICH)**

The clinical differentiation of ICH from cerebral infarction is not all that reliable, but raised blood pressure, headache and seizures are commoner in ICH. Neuroimaging with an un-enhanced CT brain or MRI brain with SWI is essential for the diagnosis of a cerebral haemorrhage.

Unenhanced CT would depict ICH as a hyperdense area in the cerebral parenchyma. The most important risk factor for cerebral haemorrhage is chronic hypertension. Imaging with Digital subtraction angiography or CTA to delineate the vascular tree is indicated in patients suspected to have vascular anomalies such as aneurysms or AVMs. It is important to exclude vascular anomaly in young stroke, in strokes caused by cortical haemorrhages and when CT brain shows evidence of a vascular malformation.

### **Clinical assessment**

The ICH score is used as a standard scoring system for assessment of the severity of ICH.

## Intra Cerebral Haemorrhage Score

Variable	Score
Haematoma volume $\geq$ 30ml*	1
Age $\geq$ 80 years	1
Glasgow Coma Scale 3 – 4	2
Glasgow Coma Scale 5 – 12	1
Glasgow Coma Scale 13-15	0
Infratentorial haematoma location	1
Intraventricular haemorrhage	1

Scores range from 0 - 6 (least severe to worst possible)

\*ICH volume calculation is the product of 3 variables: Largest diameter of the haematoma on CT (A), largest diameter 90 degrees to A on the same CT slice and number of 10 mm CT slices on which the ICH is seen

### Management of acute ICH

Patients with acute ICH should preferably be managed in an ICU/HDU or a stroke unit setting, depending on the condition and the blood pressure of the patient.

- Indicators for monitoring
  - Level of consciousness
  - Vital parameters
  - Pupillary size and reaction to light
  - Worsening neurological signs
  - Appearing new neurological signs
  - Body temperature
  - Blood glucose level
  - Oximetry
- **Blood pressure management**
  - BP management for acute ICH with IV antihypertensives has to be carried out with intensive BP monitoring preferably in an ICU / HDU setting.
  - If initial systolic blood pressure (SBP) is  $>220$  mm Hg, blood pressure should be lowered to 220 mm Hg immediately.(10)
  - For patients who present with SBP of 220 – 150 mm Hg, an attempt should be made to reduce the SBP to 140 mm Hg within the first one hour and to maintain long-term to reduce haematoma expansion, if the patient remains stable.
  - Lowering SBP  $<130$  mm Hg is not recommended and could be potentially harmful.
  - Intravenous Labetalol should be used as a bolus dose or as an infusion. Intravenous Hydralazine is an alternative. Oral antihypertensives agents should be started at the same time to maintain an acceptable blood pressure long-term.
- If the ICH patient is on long-term anticoagulants, withhold anticoagulants and implement procedures to reverse the effects of anticoagulants.
- Severe ICH patients should be managed with monitoring of Intra Cranial Pressure (ICP) in an ICU setting.
- Indications for ICP monitoring
  - GCS  $< 8$

- Impending trans tentorial herniation
- Significant intraventricular haemorrhage
- Acute hydrocephalus
- Elevate head end of the bed to 30 degrees.
- Paracetamol could be used regularly for body temperatures  $>38^{\circ}\text{C}$ .
- Intravenous 0.9% saline should be used to maintain hydration. **Do not use 5% dextrose.**
- Intravenous hypertonic saline can be used to reduce cerebral oedema in patients up to serum Na 145 m. mol per litre.
- Repeat cranial CT and external ventricular drainage is recommended for progressive hydrocephalus.
- Early seizures ( $<14$  days) are treated with intravenous antiepileptic medication and continued for several days and weaned off when the patient is better or free of further seizures.
- Neurosurgical intervention should be considered early in cerebellar haematomas, hemispheric ICH with life-threatening mass effects or obstructive hydrocephalus.
- When the condition is stable the patient should be transferred to the stroke unit for further rehabilitation.

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**FORMS & RECOMMENDATIONS FOR THROMBOLYSIS FOR ACUTE STROKE  
ETU / WARD / ICU / STROKE UNIT**

Name:..... Age:.....Yrs Date:.....

BHT No:.....

Gender : Female / Male

**Time:**

At onset of stroke:	:.....	am/pm	At arrival to OPD	:.....	am/pm
At arrival to CT room:	:.....	am/pm	At completing CT brain	:.....	am/pm
At commencing thrombolytic	:.....	am/pm	Thrombolytic Agent used	:.....	
At beginning of CT Angiogram	:.....	am/pm	At arterial puncture	:.....	am/pm
Flow achieved at	:.....	am/pm			

**THROMBOLYSIS CHECK LIST**

INCLUSION CRITERIA		YES	NO
1	Diagnosis of ischemic stroke with a measurable neurological deficit (Defined as impairment of language, motor function, cognition, gaze, vision or neglect)		
2	Symptom onset within 0-4.5 hours		
3	Age ≥ 18 years		

ABSOLUTE CONTRAINDICATIONS		YES	NO
	Past history of Intra Cranial Haemorrhage		
	Arteriovenous malformations		
	Intracranial neoplasms (Intra-axial)		
	Intracranial or intraspinal surgery over last 3 months		
	Major surgery within 14 days		
	Sub Arachnoid Haemorrhage suspected		
	Active internal bleeding		
	Platelet count <100,000/cmm		
	INR >1.7		
	Heparin given within last 48 hours with elevated APTT		
	LMWH within 24 hours unless the coagulation tests* are normal		
	*APTT, INR, Ecarin clotting time, TT, Factor Xa assays, Platelet count		
	Direct thrombin inhibitor or factor Xa inhibitor within 48 hours unless the coagulation tests* are normal		
	*APTT, INR, Ecarin clotting time, TT, Factor Xa assays, Platelet count		
	NCCT showing hypodensity > 1/3 of the cerebral hemisphere		

RELATIVE CONTRAINDICATIONS		YES	NO
	Intracranial neoplasm (probably recommended if extra axial)		
	Aneurysms - Recommended if unruptured and unsecured aneurysm <10mm Risk is unclear if size is greater		
	Ischemic stroke within 3 months. (Risk is raised; degree of rise is unclear)		
	Acute anterior Myocardial Infarction within last 3 months		
	GI or GU surgery within 21 days. (Consider treating with rtPA if there are no structural bleeding lesions)		
	Major extracranial trauma within 14 days		
	Arterial puncture at a non-compressible site within 7days		
	Rapidly improving symptoms. (rtPA should be administered if remaining symptoms are disabling)		
	Minor stroke (Typically NIHSS score <5) (Risks Vs benefits should be weighed)		
	Seizure at onset with post ictal residual deficits		
	SBP >185 or DBP>110 (Treatment could be recommended if BP can be lowered safely)		
	Pregnancy		
	Blood Glucose < 50mg/dl (Treating with rtPA could be considered if disability remains even after correction of blood glucose )		

IF THROMBOLYTICS WERE NOT GIVEN, THE REASON		YES	NO
	Haemorrhagic Stroke		
	Outside the time window		
	Severity (<4 or >25 NIHSS)		
	Co-morbidity/ Medication/lack of consent		
	Others (Please state)		

CRITERIA FOR ACUTE ENDOVASCULAR TREATMENT		YES	NO
1.	Age > 18 yrs		
2.	NIHSS SCORE ≥ 6		
3.	Time from symptom onset to groin puncture < 6hrs		
4.	Premorbid functional status (MRS 0 - 2)		
5.	ASPECTS score ≥ 6 on baseline CT scan		
6.	Presence of intracranial large vessel occlusion		

# SRI LANKA MEDICAL ASSOCIATION

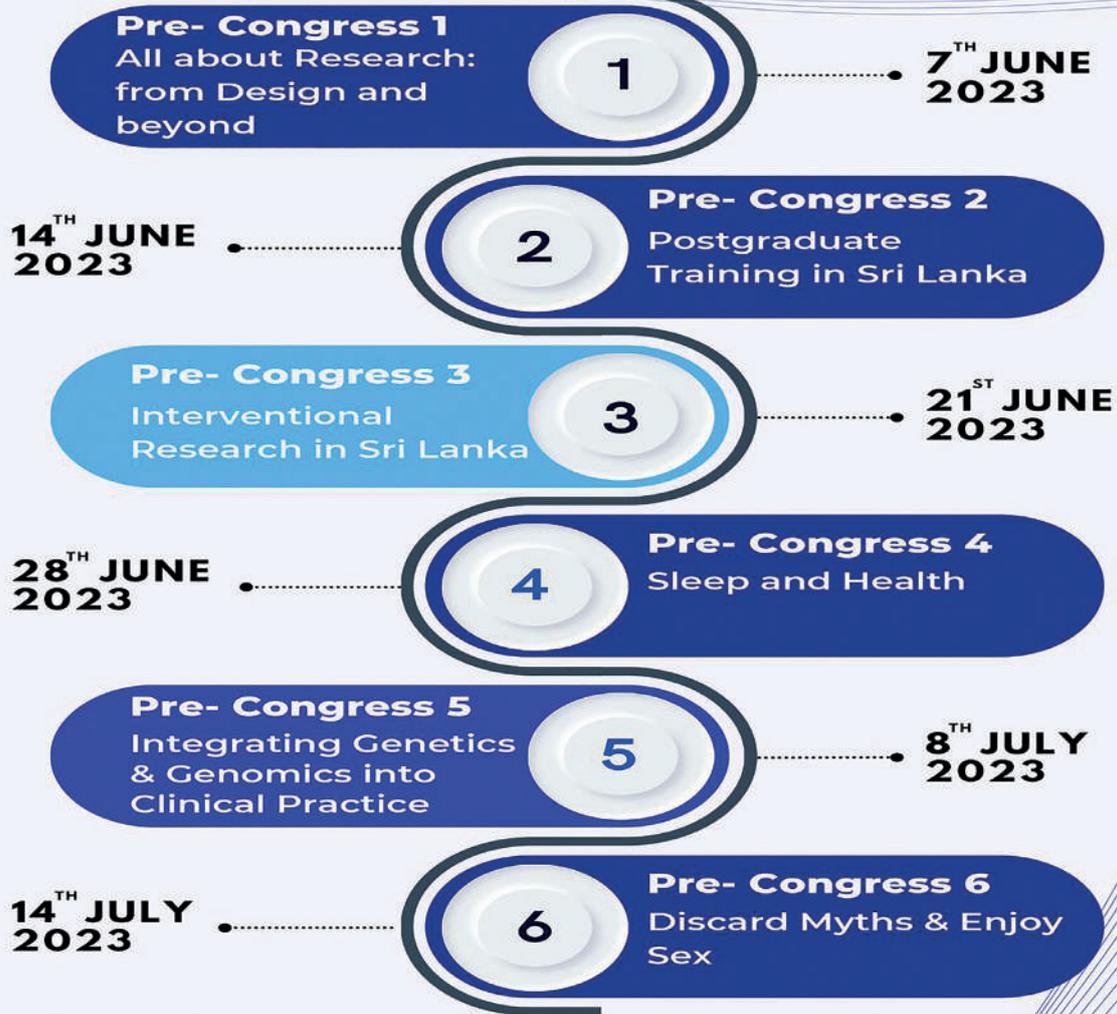
## 136<sup>TH</sup> ANNIVERSARY

### INTERNATIONAL MEDICAL CONGRESS 2023



“Towards Humane Healthcare, Excellence, Equity, Community”

## Pre Congress Workshops



**Registration Fee**  
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Office: No.6, Wijerama House,  
Wijerama Mawatha, Colombo 07.



# A death from malaria in Sri Lanka after 17 years

## Failure to elicit travel history in a febrile patient - a fatal error!

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Consultant Physician,

Member, Technical Support Group,

Anti Malaria Campaign.

Fever is undoubtedly one of the commonest causes for patients to consult doctors. We have been taught as third year medical students, on commencing clinical work, the importance of obtaining a travel history in any patient who presents with fever. If a febrile patient has travelled to a malaria endemic country within the past one year, it is mandatory to examine a blood film for malaria parasites and perform the Rapid Diagnostic Test for malaria. These facilities are freely available in all provincial, district and base hospitals in Sri Lanka.

In April 2023, a Sri Lankan trader returned home after a business tour in an African country. The next day he developed high fever and abdominal pain. **Over the next 5 days he consulted 3 MBBS doctors who treated him with paracetamol, antibiotics and analgaesics. None of the doctors elicited a travel history from the patient.** Unfortunately, the patient had not taken malarial prophylaxis and did not divulge his recent travel to an African country to any of the doctors. The blood was therefore not tested for the malarial parasite. Thus valuable time was lost in diagnosing and treating this patient, resulting in disastrous consequences.

**The patient died on day 6 of fever due to multi organ failure complicating Plasmodium falciparum malaria in a private hospital in Colombo. The diagnosis of malaria was established about 10 minutes before his death. This precious life could have been saved if the travel history was elicited and the blood tested for malaria at the onset of fever and treated promptly.** The death was thus avoidable and regrettable. Currently, the low level of clinical suspicion in a background of low disease burden leads to significant delay in diagnosis of malaria.

Sri Lanka was declared " malaria free " by the World Health Organization in August 2016, after the last endogenous patient with malaria was detected in Sri Lanka in October 2012. However, despite elimination of malaria, Sri Lanka remains receptive and vulnerable to the reintroduction of malaria at any time . Receptivity to malaria results from the continued presence of the vector, Anopheles culicifacies and the eco system in the country, temperature and breeding sites.

Sri Lanka is vulnerable to reintroduction of malaria due to international travel and the large migrant working population, risking the introduction of the malarial parasite to our nation. Since the elimination of malaria in Sri Lanka, around 50 patients with exogenous malaria have been detected annually. Currently, the Anti-Malaria Campaign conducts a very comprehensive program to prevent the reintroduction and spread of malaria in Sri Lanka from these patients. The program has been successful so far and Sri Lanka has been free from any endogenous malaria since 2013. All prospective travelers to endemic countries are advised to take prophylaxis provided free of charge.

Malaria is a disease that is highly preventable, treatable and curable. It is important to emphasize that every single day a malaria patient is left untreated, the chances of survival of the patient decreases and the transmission of the disease to others and the real danger of reintroduction of malaria to Sri Lanka increase considerably. If malaria is re-established in Sri Lanka, its impact on an overburdened health system, would lead to devastation of a scale not seen before, especially in a population that now lacks immunity to malaria.

In conclusion, I wish to emphasize the importance of obtaining a travel history in a patient with fever and testing the blood repeatedly for the malarial parasite. All patients diagnosed as malaria must be immediately informed to the 24 / 7 National malaria hot line 011 7 626 626. The national guidelines in the treatment of malaria must be followed to the letter.

## Benefits of formulated Nutrition in Managing COPD <sup>1,2,3,4</sup>

Inclusion of nutritional support in COPD, mainly in the form of Oral Nutritional Supplements (ONS), can **help to overcome energy and protein imbalances, improve anthropometric measures, increase the grip strength** and most importantly **improve the nutritional status and functional capacity** of the patients



## Enriched Nutrition for Easier Breathing & Improved Pulmonary Outcomes

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# Year in Review: Towards Elimination of COPD

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## Updated definition of COPD

Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2023 report has proposed an updated definition of COPD as “a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnoea, cough, expectoration and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction”<sup>(1)</sup>. Compared to the previous version, this definition has highlighted the ‘often-progressive nature’ of the illness and considered risk factors beyond ‘exposure to noxious particles or gases.

## The rising burden of COPD

Global impact due to chronic respiratory disease is rising. According to the World Health Organization (WHO), COPD is the third leading cause of death; causing 3.23 million deaths in 2019. Systematic analysis of the global disease burden had shown that low-income countries contribute to over 85% of the world COPD burden. In 2017 the estimated prevalence of COPD in South Asia was 6-7%<sup>(2)</sup>.

Burden of Lung Diseases (BOLD) survey in Sri Lanka revealed an overall COPD prevalence of 10.5% (males 16.4%, females 6.0%). This was higher in the urban areas when compared to rural settings (6.4% Vs 4.1%)<sup>(3)</sup>. Analysis of respiratory disease mortality in Sri Lanka during the period of 1997-2014 revealed very high mortality among those aged over 45 years due to chronic lower respiratory diseases, where COPD was a major constituent, with a peak of over 32,500 deaths per year in the eighth decade<sup>(4)</sup>.

## Pathophysiology of COPD

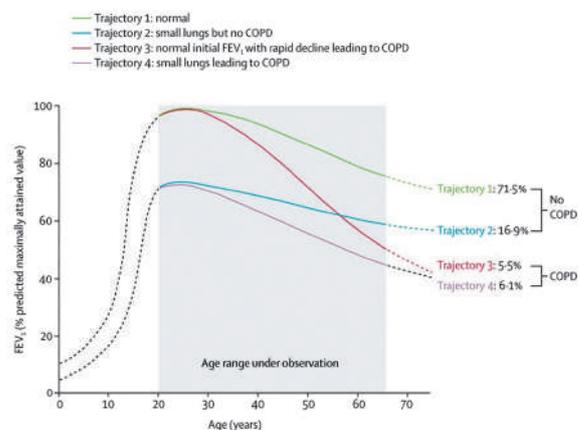
Chronic airway inflammation is responsible for pathological changes observed in COPD. Repeated injuries to and subsequent repair of central and peripheral airways, lung parenchyma, alveoli and the vasculature lead to progressive structural changes. This process occurs over decades. At later stages destruction

of the terminal bronchioles is well-established when the emphysematous lesions become large enough to be visualized on thoracic multidetector CT scans. Early COPD is characterized by destruction and loss of the terminal and transitional bronchioles before a decline in lung function is observed, even in the absence of emphysematous destruction, where the surviving airways have narrowed lumina and thickened walls. The subsequent “irreversible disease” would be characterized by parenchymal destruction and remodelling of significant numbers of terminal and transitional bronchioles.

## Lung function trajectories and development of COPD

In human lung development, there is a ‘growth phase’, a ‘plateau phase’ followed by a ‘decline phase’ which occurs with natural ageing processes. Genetic abnormalities and environmental exposure can alter the natural lung growth and ageing processes causing alteration of normal lung function trajectories. For example, maternal tobacco smoking, maternal undernutrition, intrauterine growth restriction, preterm birth, recurrent respiratory tract infections, air pollution, active smoking in adolescents affect lung growth and this population is more prone to gain low peak lung function<sup>(5)</sup>.

In 50% of patients, COPD can be a result of accelerated lung function decline, while in the rest of the patients it is due to a reduction in the peak lung function gained at 30 years of age despite a normal rate of lung function decline. However, 75% of individuals with reduced peak lung function gain at 30 years do not progress to develop COPD<sup>(5)</sup>. (Figure1)



**Figure1** – Development of COPD would depend on peak lung function gain at 30 years and rate of decline. (Source: Lung function trajectories in health and disease, Lancet 2019)

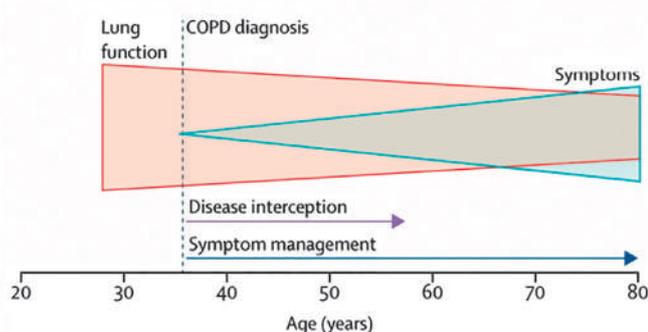
### Early diagnosis: Spirometry and its limitations

According to GOLD 2023, COPD should be considered in appropriate clinical contexts (progressive dyspnoea, chronic cough or sputum production, recurrent lower respiratory tract infections and a history of exposure to risk factors), but demonstration of post-bronchodilator FEV<sub>1</sub>/FVC < 0.7 is needed to confirm the diagnosis<sup>(1)</sup>.

Irreversible airflow obstruction is not specific for COPD, as it can be seen in chronic asthma and other chronic respiratory diseases. When a fixed value (0.7) is used as a diagnostic cut-off, COPD may be over-diagnosed in elderly populations and underdiagnosed in younger populations. This can be minimized if a 'lower limit of normal value' of FEV<sub>1</sub>/FVC is used, based on age and sex specific norms. It would be important to understand that with the current spirometry criteria, early airway changes and emphysematous destruction of the lung parenchyma are not identified and COPD may be diagnosed at a stage, usually in the sixth to seventh decades of life, where the pathological changes of airways have already progressed to an irreversible state<sup>(1)</sup>.

### Early COPD, Pre-COPD and PRISm

COPD represents a spectrum of a disease. Hence, GOLD 2023 proposes a new terminology to identify each disease stage, making diagnosis, treatment and preventive strategies more effective. This classification highlights the importance of early diagnosis of COPD at an earlier stage, way before they become overtly symptomatic, where therapeutic interventions may in fact reverse or halt the disease progress, as opposed to mere symptom control. (Figure 2)



**Figure 2** – Importance of early diagnosis of COPD for effective disease control (Source: Lancet Commission 2022 on Elimination of COPD)

**Early COPD** - Biological, first stages of the disease in an experimental setting.

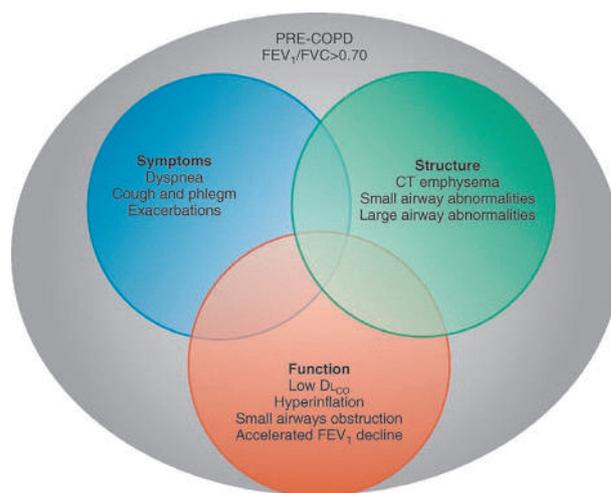
**Mild COPD** - Less severe airflow obstruction measured spirometrically.

**Young COPD** - COPD in patients aged 20–50 years.

As a result of having never achieved normal peak lung function in early adulthood and/or from shorter plateau and/or early lung function decline.

**Pre-COPD** - Individuals of any age, with respiratory symptoms and/or other detectable structural (e.g., emphysematous) and/or functional abnormalities (e.g., hyperinflation, reduced lung diffusing capacity, or rapid FEV<sub>1</sub> decline), in the absence of airflow obstruction on post-bronchodilator spirometry (i.e., FEV<sub>1</sub>/FVC>0.7) (1). (Figure 3)

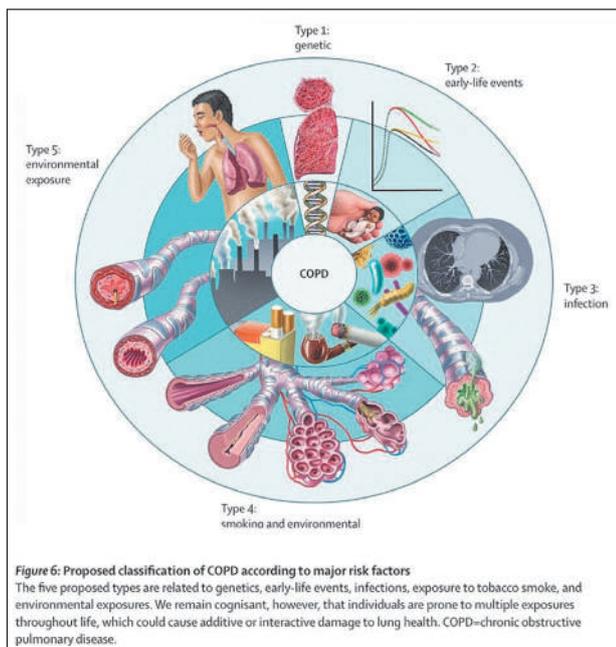
**PRISm** – The term PRISm (Preserved Ratio, Impaired Spirometry) has been proposed to describe individuals with proportionate reduction of FEV<sub>1</sub> and FVC resulting in preserved FEV<sub>1</sub>/FVC (≥ 0.7) and FEV<sub>1</sub> < 80% of reference after bronchodilation.<sup>(1)</sup>The prevalence of this condition varies from 7.1% to 20.3% and a high prevalence is observed in current and former smokers. PRISm is associated with increased all-cause morbidity and mortality. PRISm can transition to normal, obstructive or restrictive spirometry, with time (6).



**Figure 3** – Pre-COPD is considered in the absence of post-bronchodilator airflow obstruction (Source: Clinical spectrum of PRISm. Am J Respir Crit Care Med. 2022)

### COPD beyond smoking

Tobacco smoking is the well-known COPD risk factor over the past several decades. However, not all smokers develop COPD. Non-smoking risk factors have been identified in low-middle income countries to account for 60 -70% of COPD<sup>(1)</sup>. Lancet commission 2022 on 'Elimination of COPD' has suggested a new classification based on aetiology, highlighting the importance of identifying the aetiology in order to execute effective diagnostic, preventive and treatment strategies towards elimination of COPD<sup>(7)</sup>. Genetic factors, early-life events, infections, tobacco smoke and environmental exposures are recognized as the five main risk factors for COPD. (Figure 4)

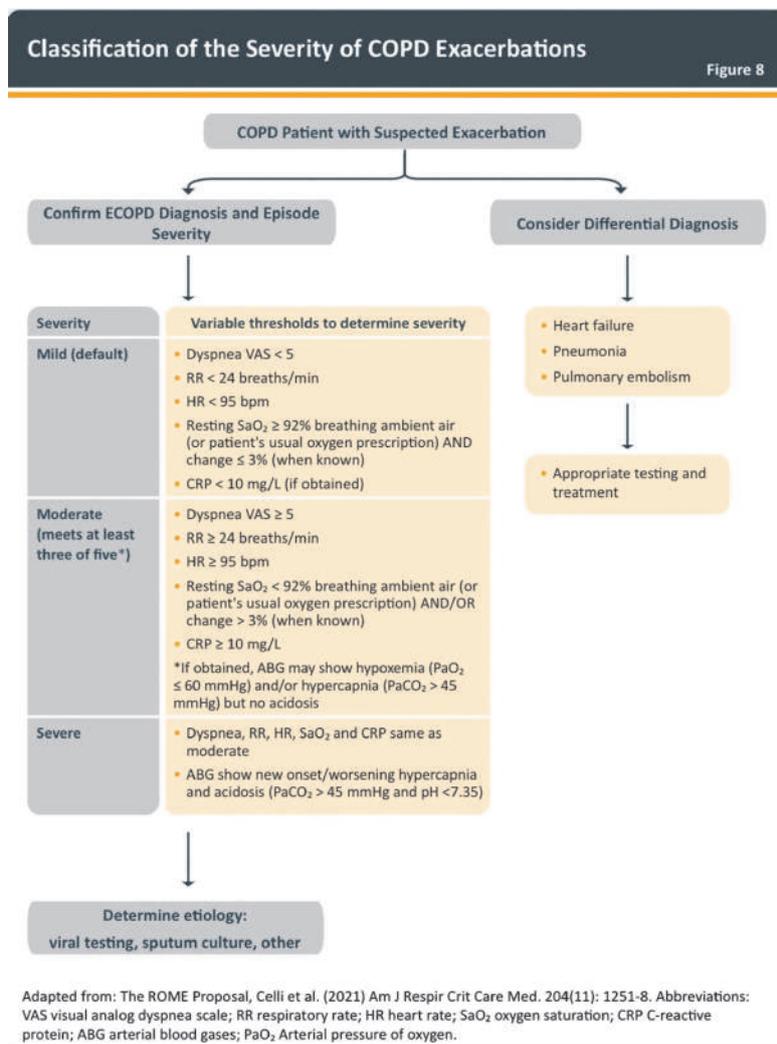


**Figure 4 – Proposed classification of COPD based on major risk factors** (Source: Lancet commission report 2022 on elimination of COPD)

**Role of COPD exacerbations**

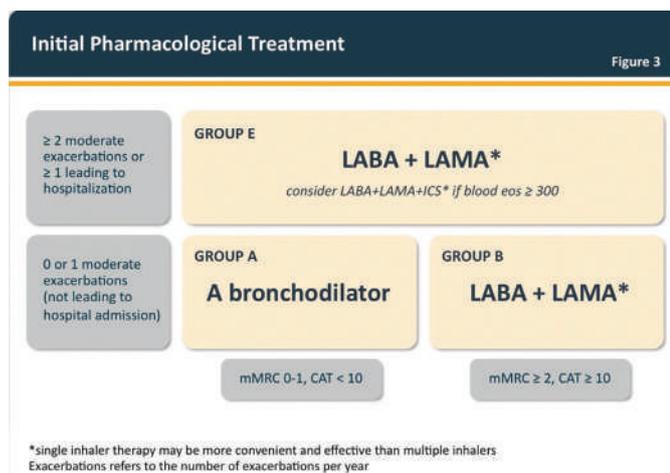
New GOLD 2023 definition for acute COPD exacerbation is “an event characterized by dyspnoea and/or cough and sputum that worsen over  $\leq 14$  days, which may be accompanied by tachypnoea and/or tachycardia and is often associated with increased local and systemic inflammation caused by airway infection, pollution, or other insult to the airway”.

In the acute setting, heart failure, pneumonia, and pulmonary embolism can mimic COPD exacerbation<sup>(1)</sup>. Respiratory exacerbations can occur in patients with Pre-COPD as well<sup>(7)</sup>. GOLD 2023 proposes a new criterion to classify COPD exacerbation based on its severity, in contrast to the previous categorization based on the type of treatment or the treatment setting. Here dyspnoea assessed by visual analogue scales (VASs) play an important role in the classification criteria. (Figure 5)



**Figure 5 – Classification of COPD exacerbation based on severity** (Source: Global initiative for Chronic Obstructive Lung disease 2023 report)

Exacerbations lead to accelerated decline in spirometric lung function in COPD and hence such patients with exacerbations need to be on more intensive pharmacological and non-pharmacological treatment modalities. Therefore, Instead of group C and D in previous ABCD assessment tool and treatment algorithm, GOLD 2023 has proposed a new Group E, where all patients with one or more exacerbations warranting hospital admission are included and treated with combined bronchodilators<sup>(1)</sup>. (Figure 6)



**Figure 6** – GOLD 2023 proposed treatment category of Group E based on exacerbation frequency and severity (Source: Global initiative for Chronic Obstructive Lung disease 2023 report)

**A glimpse beyond inhalers**

As with other chronic respiratory diseases like cystic fibrosis and non-cystic fibrosis bronchiectasis, neutrophil driven inflammation leads to progression of the structural abnormalities and exacerbations. Unfortunately, treatment targeting neutrophil function, have not proved beneficial in COPD treatment mainly due to increased risk of infections<sup>(8)</sup>.

Eosinophilic inflammation is defined when eosinophils are present in more than 3% of total white cell counts in the sputum, bronchoalveolar lavage and biopsy specimens. Blood eosinophil levels correlate with sputum eosinophil count moderately. Immunological treatment to reduce type 2 inflammation like anti-interleukin-5, anti-interleukin-5-receptor antagonists, interleukin-4–interleukin-13-targeting monoclonal antibodies, which are extensively used in asthma management, have not shown proven efficacy in COPD management. Thymic stromal lymphopietin (TSLP) antibodies and anti-interleukin 33 monoclonal antibodies are still being investigated for COPD patients (7).

Airway remodelling refers to a collective process of structural changes in the airways resulting in enhanced collagen deposition in the subepithelial basement

membrane, disruption of the epithelial barrier, epithelial cell-state change (mucous metaplasia and/or mesenchymal transition), and smooth muscle hypertrophy, leading to narrowing of the airway lumen. Other immunotherapies including G protein-coupled receptor modulators, mitogen-activated protein kinase inhibitors etc. may reverse airway remodelling but they are still being tested at research level<sup>(7)</sup>.

**Conclusion: Towards elimination of COPD**

Elimination of COPD needs effective approaches to avert new cases and reverse the disease process in patients with already established COPD. Identification of risk factors is important in COPD elimination. Exploring the history of exposure to risk factors is important in diagnosing pre-COPD and PRISm patients who have chronic respiratory symptoms but do not fulfil the spirometry criteria of COPD. Early diagnosis is crucial for exposure prevention and haltering further progression of the inflammatory process. Second, by prohibiting smoking and minimizing exposure to air pollution since childhood, a significant proportion of COPD can be reduced. Since COPD exacerbations lead to accelerated disease progression, reducing the frequency of COPD exacerbations could be a strategy for COPD elimination. Development of curative and lung regenerative treatment methods may help in reversing the disease.

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# Sri Lanka Medical Association

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**July**



# Pharmaceutical supply in Sri Lanka: Can we do it better?

## Professor Priyadarshani Galappatthy

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Senior Professor and Chair Professor of Pharmacology  
Faculty of Medicine, University of Colombo

This is part 2 of the article. Part 1 was published in the April 2023 Newsletter.

## National Medicines Quality Assurance Laboratory

The quality of medicines is checked by the National Medicines Quality Assurance Laboratory

(NMQAL), which comes under the authority of the NMRA, but it is not an accredited laboratory. The capacity of the NMQAL is inadequate to do quality testing of marketed drug samples. The quality testing capacity in the country can be enhanced by increasing the capacity of the NMQAL and by identifying additional independent laboratories, such as University laboratories and other government laboratories, that can perform quality testing of medicines (6).

## Medical Supplies Division

The Medical Supplies Division (MSD) is the agency responsible for identifying medicines for purchasing for the state sector hospitals, based on the suggestions and requests given by specialist colleges and consultants. MSD is also the agency responsible for distribution of supplies to public sector facilities which includes 622 Hospitals and 475 central dispensaries/primary care units (10). The medicines are selected from the essential medicine list, which has about 383 products and includes 675 items by different dosage forms. The last formulary revision in 2019 included a total of 1346 pharmaceutical items listed for purchasing for the requirements of the government sector categorised according to vital (14), essential (675) or non-essential (657) items, which includes all different strengths and dosage forms. The most recent revision to the list of medicines required for the hospitals, finalised in April 2023, was made by a committee chaired by the DGHS with representatives of all speciality colleges and associations. It has identified a list of 850 priority items which includes 753 stock items and 97 items to be supplied on a named patient basis.

Tenders for purchasing are scheduled according to ascending prices and evaluated technically at 3 levels based on the total value of the tender. Government of Sri Lanka (GOSL) funded tenders up to Rs 200 million, Department procurement committee (DPC) of the SPC; up to Rs 500 million, Ministry Procurement Committee (MPC) of the Ministry of Health; and for tenders more than Rs 500 million, Cabinet Appointed Procurement Committee (CAPC) are responsible for selecting and awarding the tenders. Public facilities are given less than 10% of their allocated budget for direct procurement needs and all other procurements are dealt centrally by the Medical Supplies Division and the SPC.

Delays in the procurement process can occur due to difficulties in scheduling technical evaluation committee (TEC) meetings at different levels (e.g MOH and Cabinet) based on the availability of its members. Poor coordination between the main stakeholders including the SPC, MSD and NMRA and members not being prepared for the tasks at hand when attending meetings are identified as factors contributing to delays. Avoidable and unavoidable delays in procurement have contributed to the current shortage of medicines and devices in the country. Giving deadlines for vetting and approvals at each level could streamline processes to avoid delays.

Holding regular meetings of the national Drug and Therapeutics committee (DTC) quarterly, chaired by the DGHS will help to discuss technical issues pertaining to medicines reported by hospital DTCs to take actions. Adding any costly new medicines to the formulary should be made only after discussion on efficacy and cost effectiveness at the national DTC meetings. This type of Health Technology Assessments (HTA) is done even in developed countries to ensure essential medicines and affordable medicines are supplied at all times.

MSD does not have a central technical committee to discuss and decide on technical issues related to purchase orders and tender applications. Establishing a technical committee comprising of representatives of medical specialties and having regular meetings at the MSD would help to address the technical issues during tender processes such as consideration of prices quoted and required specifications. This would help in overcoming some of the delays during tender procedures and to take decisions based on needs of the country.

Analysis of the cost of medicines purchased for the country on an annual basis, providing such information to all stakeholders and considering the annual budget available for purchasing medicines would be helpful in deciding the priority list of items within the budgetary constraints.

### State Pharmaceutical Corporation

The State Pharmaceutical Corporation (SPC) is the agency responsible for the procurement. The SPC procures through both national and international tendering procedures. The tenders are awarded considering the price quoted, past performance, quality of samples submitted for the offered product and registration status. Lack of transparency on the amount spent, the type of medicines purchased, and awarded prices are some of the deficiencies in the processes of procurement (11).

The lead time to bring down the annual supplies of medicines from the time of submitting the requests to the SPC is about 10-12 months. An analysis of this lead time by the different steps in the procurement process should be carried out. Implementing an effective electronic system where all parties can monitor the state of the procurements of all tenders could overcome these problems.

Though the Sri Lankan health system is decentralized, medical supplies are purchased centrally by the SPC (both imports and local drugs), and the quarterly drug requirement, based on estimated demand, is distributed by the MSD to Regional MSDs located in the 25 districts.

### Purchasing process of pharmaceuticals

The purchasing process begins with forecasting the annual requirements for the country. The quantity needed is decided by the pharmacists in the hospitals based on the consumption of each medicine in the previous year and usually by adding about 10% to the last year's supply. Whether the stocks were adequate and there was a surplus is also considered. However, it is also noted that the estimates from the hospitals are not an accurate representation of their actual requirement. Although the data is available for the hospitals/institutions in the current Medical Supplies Management Information System (MSMIS) system, it is not optimally utilized in forecasting the requirements. The number of pharmaceuticals purchased is reviewed every 2-3 years as decided by the formulary committee.

The publicly available current essential Medicines List (EML) is the 4<sup>th</sup> revision of 2009. It has been revised since, and a list prepared in 2021 is used during procurement. The medicines in EML and those not in EML but are required for patient management as decided by the

formulary committee are submitted to be purchased by the SPC. The medicines are categorized as Vital, Essential and Non-essential (VEN).

Box 1 : Vital, Essential and Non-essential (VEN) classification of medicines

V - Vital medicines are potentially lifesaving and crucial for providing basic health services. They should be available at all times. There are 14 vital items identified. (Eg. adrenaline, 0.9% sodium chloride)

E - These are medicines that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford. Essential drugs are effective against less severe but are nevertheless significant forms of illness but are not absolutely vital to providing basic health care. (Eg. losartan 50mg, amoxicillin 500mg)

N - Nonessential medicines are used for minor illnesses are of questionable efficacy or have a comparatively high cost for a marginal therapeutic advantage. (Eg. amlodipine 5mg, erythromycin 250mg)

The items are categorised as regular, complementary or to be supplied on a named patient basis. Regular items are approved to be included in the formulary for regular use by the 4 levels of healthcare facilities. These items are to be regularly supplied by MSD. Complimentary Items are essential medicines for priority diseases for which specialized diagnostic or monitoring facilities and/or specialist medical care and /or specialist training are needed. Named patient items are issued for a particular patient for a specific indication.

The MSD does not consider the total budget available for the medical supplies provided by the treasury in preparing the list of items to be purchased for the public sector. This results in overbudgeting of the purchases and going into debt for supplies that are beyond the budgetary allocation or severe shortage of even essential medicines for the country due to lack of funds to purchase the tenders awarded.

An analysis of expenditure on medicines by the MSD showed that 10-12% of medicines supplied accounted for more than 70% of the total expenditure on medicines, indicating the focus of state procurement on high-cost, low-volume medicines. Regular analysis of items purchased and expenditure for each of the items would help to identify those costing most and to consider affordability of those items and pay special attention to them during tender procedures and distribution to hospitals. The government audit reports which have analysed the procurement processes of selected medicines have also given many recommendations for

improvement of the system by all stakeholders, which should be addressed and rectified.

**Role of specialist Colleges and Associations**

The preparation of lists of medicines to be supplied to the hospitals via the MSD are prepared based on requests and decisions by the medical specialists and during formulary revisions. With the availability of many very expensive new medicines, particularly biologics with the unit cost exceeding LKR 100,000, if several of those are included into the formulary list to be provided by the state, without giving due consideration to the available medicines budget and cost effectiveness, funding will not be available to supply even the essential medicines. Therefore, when requests are made to include very costly medicines where the cost per patient exceeds over a particular ceiling (eg. LKR 1 million or 1.5 million annually, as decided by the MoH) especially on a long-term basis, Health Technology Assessment (HTA) considering the cost effectiveness of those matched to our GDP need to be performed. HTA is done by even the high-income countries such as UK, which provides medicines through the state sector, according to the guidelines issued by bodies such as National Institute of Clinical Excellence (NICE) based on HTA. The College of oncologists should be commended for doing cost effectiveness analysis of the oncology medicines recently and identifying the medicines which are cost effective to be supplied through the Ministry of Health to patients in Sri Lanka.

The representatives of the colleges who serve in many committees on NMRA, MSD and SPC also need to attend the meetings regularly and provide their expert advice without delay to expedite the registrations and selection of suppliers for tenders. It is also important to ensure that the medicines are used rationally to avoid any wastage of medicines due to irrational prescribing. Some monitoring of the usage of especially costly medicines such as immunoglobulins, albumin solutions, expensive antibiotics and biologics would be important.

**Pharmaceutical supply in the private sector**

Pharmaceuticals are provided to patients in the private sector through 3,297 island wide retail pharmacy outlets at 1.6 licensed retail pharmacies per 10,000 population (6), which includes the SPC owned nationwide chain of *Rajya Osu Sala* outlets and franchise *Osu Salas*. The *Osu sala* outlets ensure quality assured products at affordable prices in the private sector and has been functioning as an unofficial price regulator in the private sector over the years. The affordability of medicines in Sri Lanka reported by nation wide studies (8), prior to recent price controls can be attributed to the presence of government owned *Rajya Osu salas*, supplying medicines at affordable competitive prices, that other

retail outlets must compete with. Most of the medicines procured through the SPC are essential medicines to be delivered to public facilities via the MSD, but nonessential medicines are also procured for the *Rajya Osu Sala* outlets to meet the public demand.

As a share of total health expenditure in Sri Lanka, private health expenditure has increased from 45% in 2000 to 57% in 2018 (4). The chief drivers of demand are higher incomes, an aging population, and rising prevalence of NCDs (6). Both the volume and value of medicines sold at retail pharmacies have seen a steady increase in the period of 2015-2019. The demand for pharmaceuticals in Sri Lanka is largely fulfilled by generics (6). Approximately 82% of pharmaceutical expenditure in Sri Lanka is on generic medicines, with the balance being spent on patented medicines.

With the rise of GDP significantly with the end of the conflict in Sri Lanka in 2009, and the rising income, people were spending more out-of-pocket for healthcare expenditure. According to the Household Income and Expenditure Survey (2016), the monthly household out of pocket expenditure on private healthcare is approximately LKR 1,695. The largest proportion of this expenditure was spent on fees to private medical practices (33%) and 26.6% is spent to purchase medical or pharmacy products (6).

**Pharmaceutical importers**

Over 180 private local firms are registered importers with the NMRA. These include local conglomerates who distribute drugs from multi-national companies as well as smaller regional manufacturers(6). Government hospitals account for about 33% of overall imports and doctors with private clinics account for about 3% of imports. Approximately 50% of medicines issued by doctors at private dispensaries/clinics are imported. Most medicines (96%) sold by pharmacies in the local market are also imported. India is the largest source of pharmaceuticals for Sri Lanka accounting for nearly 50% of imports, followed by Pakistan and France with imports less than 10% each.

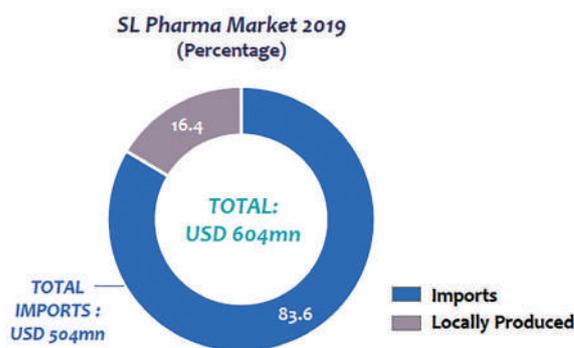


Figure 2 : Sri Lanka Pharmaceutical market 2019 (from reference 6)

### Local pharmaceutical manufacturers

In Sri Lanka 16.4% of pharmaceuticals are supplied by local manufacturers including SPMC(6). In 1987, the State Pharmaceuticals Manufacturing Corporation (SPMC) was founded. It is now the largest drug manufacturer in Sri Lanka, providing 43 medicines to the MOH at low profit margins. Currently, 20 manufacturers approved by the NMRA are in operation and about 5 new facilities are to be commissioned or are currently being added on by local manufacturers.

Locally manufactured products are generally supplied to the public sector via SPC through open tenders, and buy-back deals, as well as to the private sector through distribution networks. There were 17 locally produced pharmaceutical products before the buy-back agreement. Currently, there are about 150 locally manufactured brands listed in the NMRA. Most of these products have different dosage forms; capsules, tablets, syrups, including recently introduced parenteral products and intravenous infusions, which make up over 300 types and dosages of medicines manufactured in Sri Lanka.

Local manufacturers currently produce about 8.5 billion units of medicines per year (6). However, they are currently not operating at full capacity and can expand their supply to the market. Identifying the top essential molecules sold in Sri Lanka, by both volume and value and across both the public and private sectors and encouraging more than one local manufacturer to supply the market, can reduce the reliance on imports for most used essential medicines such as atorvastatin, metformin, and losartan. Limiting the number of new brands coming into the market by allowing the innovator and generics by local manufacturers and some imported generics of proven quality could improve efficiency of NMRA while ensuring supply of essential medicines to the country (7).

### Medicines donations

With the severe shortages experienced from early 2021, several donor agencies and other well-wishers both overseas and local including some professional medical colleges stepped in, to provide the essential medicines to the hospitals. These have helped in maintaining stocks of at least some of the essential medicines such as insulin, enoxaparin, warfarin, thyroxin, streptokinase, tenecteplase, immunosuppressants for transplanted patients and some anticancer medicines to name a few, that were supplied in varying quantities to meet at least the demands partially.

While the donations helped to meet the shortages to some extent, several problems were also encountered with donations similar to the problems noted with

donations received during the 2004 Tsunami period. Large stocks of expired or very short expiry medicines, those which are not needed, medicines labelled in foreign languages, and those in different strengths and dosage forms that were unfamiliar to the patients and healthcare workers are being received and supplied to hospitals. After the Tsunami, large stocks of such expired and unwanted medicines had to be destroyed at an enormous cost to the country at the Puttalam cement factory. There are medicines donation guidelines developed by WHO and Sri Lanka also developed guidelines for accepting donations, and requests were made to adhere to those guidelines, but they are not followed in some instances. The impact of the donations during the current economic crisis remains yet to be analyzed.

### Summary recommendations for improving the supply of medicines

1. Efficient coordination between MSD, NMRA and SPC during the procurement process.
2. Considering the government budgetary allocation for pharmaceuticals when prioritizing the list of items to be supplied and take steps to purchase the essential list of items before purchasing the other items.
3. Obtaining accurate forecasting of quantities required from hospitals based on previous consumption figures with coordination between MSD and hospitals and distribution to hospitals and regional stores based on actual consumption and stocks remaining to minimize wastage of valuable medicines purchased.
4. Adherence to strict criteria when granting Waiver of registration (WOR) to pharmaceuticals and requesting all companies submitting bids for government tenders for any unregistered products, to submit all documents required, given in WOR guidelines.
5. All products that were awarded government tenders on WOR to submit a full dossier for registration of the product subsequently and any product that was awarded a tender previously on WOR to be considered for subsequent tenders only if it is registered.
6. All submissions for registration of essential medicines for which there are limited suppliers to be evaluated on an expedited basis and decisions taken on registration promptly.
7. Increasing the staff at NMRA urgently, by obtaining special permission.

8. Increasing the quality testing capacity of NMQAL and obtain testing from other independent laboratories capable of performing quality testing.
9. SPC to identify modifiable reasons for long lead time of 10 -12 months for supply of pharmaceuticals and take steps to reduce this lead time by efficient coordination.
10. SPC to consider the government budgetary allocation and liaise with MSD to decide on priority pharmaceuticals before opening Letters of Credit, if funding is not adequate to purchase all requests sent by the MSD.
11. National Drug and Therapeutics committee meetings (DTC) chaired by the DGHS to be held quarterly and any costly new additions to the formulary to be done only after decision at the national DTC meeting considering the efficacy and cost effectiveness data of such medicines.
12. MSD to establish a technical advisory committee that meets regularly to provide recommendations on decisions required during processing of tenders and the procurement process, and to review the data on annual budgetary allocation, purchases and cost analysis of supplies to provide recommendations.
13. MSD, SPC and NMRA to address all issues raised in government audit reports and rectify the deficiencies noted.
14. Medicines donations to be accepted only when they are according to accepted guidelines and consider donations when forecasting of pharmaceuticals for next tenders.
15. The Specialty Colleges to consider HTA of all high-priced medicines used in their specialty and request items in to the formulary considering the national budgetary allocation for pharmaceuticals and all specialists requesting new high-priced medicines on named patient basis, to do so giving justification on efficacy, safety, disease burden in the country and based on cost effectiveness analysis. This process is to be coordinated by an intercollegiate committee.
16. Increasing the pharmaceutical manufacturing locally for identified, most commonly used essential medicines, giving buy back guarantee foructs to be purchased by the MSD, providing equal rights to both the SPMC and other manufacturers.

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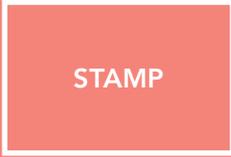
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