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# Health Research



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To efficiently and promptly publish rigorous, accessible, and relevant material that will help health professionals in Sri Lanka in their practice, lifelong learning, and career development



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# Health Research



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Sri Lanka Journal of Health Research (SLJHR) is the official journal of the Ministry of Health, Sri Lanka.

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The scope of SLJHR extends to medical, nursing, professions supplementary to medicine, allied professions, complementary and alternative medicine and other health and health-related fields. The mission of SLJHR is to efficiently and promptly publish rigorous, accessible, and relevant material that will help health professionals in Sri Lanka in their practice, lifelong learning, and career development. Its main focus is research; however, it will support sharing of health innovations and best practices as well. It follows the guidelines and standards of the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE).

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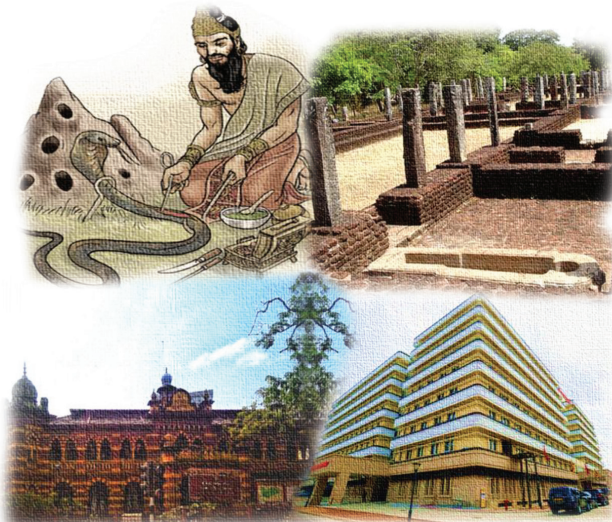
## The legendary health system of Sri Lanka

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Sri Lanka has a truly proud history of medicine which dates back over 2000 years according to the 'Mahavamsa' and ancient inscriptions. It was evident that several ancient rulers, including Kings Buddhadasa, Pandukabhaya and Maha Parakramabahu I, had practised medicine widely. Moreover, King Aggabodhi VII is known for his research in the field of medicine.

Amongst many important ancient milestones in this historical journey, the Hospital Complex in the Mihintale monastery is believed to be built by King Sena II, around 853 AD and is considered the oldest archeological evidence so far of a hospital of this nature in the whole world. Passing many important landmarks in this journey, the General Hospital, Colombo (now the National Hospital of Sri Lanka) was established during the administration of Sir Henry Ward (1855-1860). At present, the National Hospital of Sri Lanka has become the premier Teaching Hospital and the apex referral centre in the country. A major advance in the field of public health was the establishment of the system of Health Units with a Medical Officer of Health (MOH) as the Head of each Health Unit. The original Health Unit, the first of such a nature in Asia, was established in

Kalutara in 1926. This Health Unit system has undoubtedly pioneered the preventive health sector which has accomplished commendable health outcomes during the past few decades.

With incremental changes over the years, Sri Lanka comprised a network of curative and preventive health facilities when it gained independence in 1948. At present, the health system is predominantly Allopathic (Western), but still pluralistic with other alternative health care delivery methods, such as Ayurveda, Siddha, Unani and Homeopathy. Moreover, the 'traditional medical system' usually passed down from generation to generation has been playing an important role in health care. Today, this exemplary health system, with its dedicated workforce, has become resilient to diverse challenges, including pandemics and chronic non-communicable diseases with an ageing population. Even with the current economic crisis, this strongly founded health system stands steadily to serve the people of Sri Lanka. In this backdrop, the system is being further strengthened with evidence-based practice through research to further uplift the well-being of the nation.



## Deconstructing the “Free Health Service” in Sri Lanka

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Sri Lanka is renowned for its free health services, which cover all citizens (and sometimes even non-citizens), irrespective of their ability to afford healthcare. Sri Lanka has reported impressive health indicators in the past few decades: the lowest maternal mortality ratio in the South East Asian region, the eradication of poliomyelitis along with the elimination of malaria, measles [1], lymphatic filariasis [2], and Congenital Rubella Syndrome [3] from the country. The “free health” model was first adopted in the early 1950s to cover all citizens with state funded healthcare facilities and provide health services free of charge at the point of use. Even though it is called “free”, in reality, health services cost money and someone has to pay [4]. Moreover, there is no limitation on the amount of money spent on one person in this model [1,5]. However, the free health model has reduced health inequalities and the burden of many diseases in the country [6] by increasing service utilization and improving financial protection.

Free healthcare demand is based on the assumption that healthcare is a human right that should not be denied to anyone [7]. In that way, as it is like right to life, liberty, and the pursuit of happiness, it should be taken care of by the government. However, this right to free healthcare can be considered a self-defeating argument [7], and some argue that for many reasons, healthcare should not be considered a human right [8].

Despite its many benefits and achievements, the free health model faces many challenges. While free healthcare (FHC) policies may trigger an increase in the use of services, the evidence

of improved financial protection is mixed. People may still have to make direct payments for other services (high transport costs of seeking healthcare during after-hours, paid bystanders, or opportunity costs such as lost wages in seeking healthcare during normal work hours), leading to high out-of-pocket expenditure [9]. Moreover, if not properly anticipated and backed by increased supplies and medicines, FHC may have negative unintended consequences, such as patients having to pay for this scarce supply informally or in the private sector. Since there are no direct incentives for health workers in this system, the long-term staff motivation needed to maintain this service can deteriorate [9].

Welfare state models face common challenges such as increased social spending, growing inequality, and the need for severe budget savings [10]. Moreover, without proper targeting and monitoring, better-off population groups will benefit more from FHC policies than vulnerable population groups [9]. Even in post-growth welfare systems, five core dilemmas have been identified: how to maintain funding for the welfare system in a non-growing economy, how to manage the increasing relative costs of welfare, how to overcome structural and behavioural growth dependencies within the welfare system, how to manage the increasing need on a finite planet, and how to overcome political barriers to the transformation of the welfare state [11].

At the time of political independence, Sri Lanka has enjoyed the third-highest per capita income in Asia after Japan and Malaysia [12]. Furthermore, Sri Lanka has enjoyed economic

prosperity during the early years of independence with a trade surplus [13]. At that time, Sri Lanka had the finest chances for a rapid economic take-off; by and large, the economy performed poorly during the five decades of the post-independence period [13]. Now Sri Lanka is classified as a lower-middle-income country by the World Bank [14] when many countries in Asia have surpassed us in the economic front after independence [15]. Independent Sri Lanka's failure to live up to its initial promise in the area of economic development could be attributed inter alia to: (a) a foreign-exchange crisis which persisted till 1977 because the exigencies of electoral politics bound the country to welfare-oriented, inward-looking policies; and (b) the eruption of conflict between the two main communities as of 1983 [16]. Indisputably, Sri Lankan free healthcare model including the free medical education model need urgent reforms [17] and the avenues need to be explored where the health sector can generate revenue to the government.

The lack of resources in the health system in Sri Lanka has reached its zenith in the present economic crisis. The country is struggling to provide adequate resources to the health sector, with a lack of investment in medical technology and equipment. This has led to a shortage of drugs and outdated facilities, which have impacted patient care [18]. Health services rationing or restricting the access of some people to useful or potentially useful health services due to budgetary limitation [19] needs careful consideration in this context. Financial and resource constraints worsened by the current economic crisis put enormous pressure on policymakers and health authorities to consider explicit rationing [20] of healthcare services as well as other sustainable financing options besides traditional funding through general taxation.

Explicit rationing occurs when society enacts precise and transparent rules that determine the circumstances under which certain persons

can claim certain medical services [21]. When implemented based on well-defined, transparent and data driven criteria, explicit rationing has the potential to maximize nations' health, improve cost effectiveness and efficiency in health services and reduce health inequities [20,21]. Supplementary financing methods on the other hand, can increase state-owned health resources, incentivize the health workforce and minimize financial risk (especially among the poor). Ultimately, both will help to sustain the FHC model. However, a public outcry may be unavoidable if the existing information asymmetry is not addressed by increasing public awareness of such initiatives [22]. In contrast, implicit rationing of health services at the bedside or physicians' level may come in the form of prioritization of the neediest (due to scarcity) when ideally a larger group would have been benefited from the same health expenditure by explicit rationing. Implicit rationing can have more negative effects on health outcomes and financial protection of the poor, even in an FHC model.

Considering other available options, private financing initiatives (PFIs), which are a form of public-private partnership, include the private sector providing funding for public projects such as construction and operation of health infrastructure, sometimes, in exchange for long-term contracts with governments or public health providers. However, it is important to note that PFIs are criticized for their high public budgetary costs compared to other forms of financing. Furthermore, escalating costs associated with PFIs have been documented in the long term. Despite these criticisms, some governments and development agencies have promoted the use of private financial capital in healthcare as a means of promoting development [22]. Apart from these, donations and various charity provisions such as drug donations, constructions and renovations of the government health facilities by the private sector are some examples where private sector

provides financing while the public sector provides health services.

The other common mode of public-private partnership occurs when public sector undertakes financing and the private sector provides services [23]. Some examples include public financial assistance to patients undergoing predefined procedures in the private sector, outsourcing various facility services to private companies and not-for-profit contractual agreements for ambulance services [24].

Additionally, health insurance has been explored in the country over the past two decades. The majority of the health insurance sector is dominated by the growing private insurance industry owing to the lapse of the national health insurance scheme. Evidence suggests that private health insurance schemes have limited usefulness in providing financial protection and achieving universal health coverage [25]. Social health insurance (SHI) is another beneficial pathway explored by many countries. When different health risk groups and health resources are pooled in one (risk and resource pooling) without fragmentation in a SHI model, the desired population and service coverage can be achieved adequately. To successfully implement SHI, a country must have good socio-economic development, a large proportion of well-developed formal sector organizations, and a well-developed financial sector, including banks [26]. As informal sector accounts for two-thirds of the total employees in Sri Lanka [27], it requires a comprehensive feasibility assessment if SHI is selected as a health financing option, without forgetting the costs involved in such efforts. Although a publicly financed school health insurance scheme and a contributory insurance scheme (covering a specified set of benefits) for some public sector employees have been introduced [1], they are still largely yet to be explored.

In conclusion, we need to carefully re-envision the universal health coverage through “free health”

model, exploring many health financing options that can meet people's aspirations for health and social justice. First, complementary measures are needed for FHC policies to be successful, and sufficient financial resources generated through various means need to be provided at the facility level to compensate for both the loss of revenue at the provider level and the desired increase in the use of services. Second, policymakers should look for synergies between different sectors and ensure that FHC policies lead to a coherent health-financing architecture. Finally, all health services must be available to the most distant, needy, and vulnerable populations.

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## Update on critical issues faced by the health sector in Sri Lanka

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Sri Lanka, a country with a world acclaimed health system is 65,610 km<sup>2</sup> in size and has 22 million people. Its population is rapidly aging compared to countries with equal levels of socio-economic development. Sri Lanka is in the late stages of demographic and epidemiological transitions [1]. Sri Lanka had achieved strong health outcomes over and above what is spent on health over last 50 years. A well-established, reasonably well-functioning and robust health system in the country is credited to this achievement [1]. Further, over the years, expenditure on healthcare has grown steadily. It is reported to have grown at a compound annual rate of around 11% in the recent past, as reported by the Institute for Policy Studies (IPS). Per capita total health expenditure had risen to USD 163 in 2018 from USD 49 in 2005, according to the World Bank and National Health Accounts (NHA) of Sri Lanka [2].

On the economic front, for many years Sri Lanka's economic trajectory was not in the correct direction. Sri Lanka had a limited fiscal space to enhance its health expenditure even under normal circumstances, even before the current crisis. Over the years total health care expenditure was about 3.5% of Gross Domestic Product (GDP) while the government's contribution was around 2%. Moreover, out of the government budget only 8% was spent on health.

According to the IPS, Sri Lanka faced 4 main health challenges even before the current crisis [3]. In addition to that, authors wish to add a 5th challenge and abbreviate as 5Ds faced by Sri Lanka.

- 1) **D**isease burden shifts
- 2) **D**emographic Changes
- 3) **D**omestic Finance shifts
- 4) **D**onor transitions
- 5) **D**ebt overhang

The nation is currently facing a challenge in terms of a transition in disease burden, whereby non-communicable diseases are increasingly contributing to the total disease burden. The country's development endeavours are confronted with supplementary obstacles due to demographic shifts, such as a progressively aging population and diminishing fertility rates. The nation of Sri Lanka is currently encountering a situation of debt overhang, wherein the government is facing challenges in effectively managing its debt obligations. The country's development prospects are complicated by shifts in domestic finance and transitions in donor funding, as the government attempts to navigate a dynamic landscape of funding sources and priorities. The resolution of these difficulties necessitates a collaborative effort by all parties involved, along with a dedication to the pursuit of sustainable development strategies.

The Sri Lankan economy which was already weak, suffered additional setbacks due to the 2019 Easter Sunday bomb attacks and the COVID-19 pandemic. The impact of both regional and worldwide events had a negative effect on the inflow of foreign remittance and dollar earnings derived from unskilled labourers primarily employed in the Middle East, as well as from the tourism industry. The ban of importation of chemical fertilizer overnight led to a reduction of the harvest of rice and vegetable crop by more than 50% [4] and

due to the reduced yield of tea and rubber Sri Lanka's competitiveness in the world trade was affected, further reducing foreign exchange earnings. Moreover in 2019, the then government introduced the largest ever tax reductions in the Sri Lankan history. This resulted in losing around one million taxpayers between 2020 and 2022, which was a severe blow to an economy which was embedded with poor tax administration and widespread tax evasion for decades [5].

In April 2022, Sri Lanka's foreign reserves abated to less than USD 1.5 billion leading to a scarcity of foreign exchange to import even key essentials like food, petrol, and medicine. Furthermore, during the very same time frame, the overall foreign debt of the nation surpassed the amount of 51 billion US dollars. More than a half of the above debt is due to be paid by 2027.

Further, due to the domino effect, government's revenue has declined to 8.3% of the GDP by the end of 2021 [6]. Finally, in April 2022, Sri Lanka suspended repayment of foreign debt and declared bankruptcy and started negotiating with the International Monetary Fund on a rescue package.

In order to overcome the worst economic crisis since getting independence in 1948, Sri Lanka needed to more than double the country's tax revenue by 2026.

The Sri Lankan government has put forth a proposal for tax reforms that have the potential to substantially enhance tax revenue [5]. The proposed reforms aim to increase the current tax revenue of Rs 1.3 trillion in 2021 to Rs 3.1 trillion. The suggested reforms entail a tripling of the income tax collection from Rs 302 billion to Rs 912 billion, which may serve as a counterbalance to the expensive monetary financing that has adversely affected the overall economy [5]. The timing of these reforms is critical, given that Sri Lanka's overall economy has experienced a decline from USD 88 billion in 2018 to USD 73 billion in 2022, and is projected to experience further negative growth in 2023 [7]. In light of

the aforementioned economic context and the five challenges (5Ds), Sri Lanka's healthcare system is confronted with a variety of concerns that necessitate prompt consideration.

### Forex crisis

The shortage of the foreign currency will affect supply of drugs as nearly 80 - 85% of drugs used in Sri Lanka are imported. With the marked depreciation of the rupee there will be not only a shortage but also price increases as witnessed recently. The same scenario is applicable to medical instruments and equipment as almost all of them are imported to the country. Under these circumstances, developing and equipping new hospitals and existing hospitals respectively will be an enormous task.

### Training of health staff

The Ministry of Health's Education, Training, and Research (ETR) unit plays a pivotal role in supervising the education and training of healthcare personnel other than doctors and dental surgeons in the country. This division operates through a vast network of training schools located across the nation, with the aim of ensuring that healthcare professionals have access to high-quality training programs that are designed to improve their knowledge and skills.

The economic crisis and lack of funding have resulted in delays or suspensions of recruitment for health professional training. As a result, the consequences of the shortage of health professionals will likely manifest in the next 3 to 4 years due to the long training periods required to produce qualified health workers.

Sri Lanka is one of the very few countries in the whole world which has a mandatory overseas training component for post graduate medical trainees. UK and Australia are the most popular destinations for the overseas training for Sri Lankan doctors. The ministry of health offers a monthly stipend of 2000 Sterling Pounds or approximately 2000 Australian Dollars to trainees who are not pursuing employment and are traveling to the United Kingdom or Australia for a duration of one

year. Given the current foreign exchange crisis, the ministry has temporarily suspended payment of this allowance. This has affected the supply of medical specialists to the system.

### **Increase of indirect tax -VAT**

A key component of indirect taxes, Value Added Tax (VAT); was exempted on healthcare services until 2016 in Sri Lanka. A near zero or a reduced VAT rate is imposed on essential commodities such as basic food and healthcare services in most of the countries. Recently, VAT on health services in Sri Lanka was increased up to 15%. In a country where the health insurance penetration is less than 7%, imposition of 15% VAT on Health services is unjustifiable. This is more so as 55% of the outdoor treatment in Sri Lanka is catered by the private health sector [2]. As a result, the lower middle-income group which sought health care services in the private sector, now will move into already overburdened government health care services.

The imposition of a 15% VAT on healthcare services affects the senior citizens, especially those who live with a fixed interest income. This impact is more in Sri Lanka as it has one of the fastest aging populations in Asia. There are limited medical insurance covers available for those above 65 years in Sri Lanka. Certain illnesses such as mental illnesses are not covered and chronic diseases need high premiums.

### **Increase of income tax**

Like any other category of employees, the health sector employees too are badly affected by the recent income tax rise. The Sri Lankan government's introduction of higher income taxes comes at a time when the real income of people has significantly decreased, as evidenced by the rupee's depreciation against the USD from 200 to 370 and the high rate of inflation.

With the recent tax reforms, a person whose annual income is Rs 6 million (Rs 500,000 per month) will have to pay an income tax of Rs 1,308,000 per annum or Rs 109,000 per month. A person whose annual income is Rs 10 million (Rs 833,333 per month) will

have to pay an annual income tax of Rs 2,748,000 or a monthly income tax of Rs 229,000. Expressed from another angle, the progressive tax rates rise from 2.3% to 28.7% from earners of a monthly income of Rs 150,000 and Rs 1 million respectively [5].

As doctors in the state sector receive a relatively low basic salary compared to many non-health professionals, they have been able to secure concessions and several other allowances, such as DAT allowance, research allowance, telephone allowance, extra duty payment etc. The present tax reforms have not only increased the tax rates as described above but also considers all allowances as taxable income. Many doctors believe that formal sector employees like them are taxed while many in the informal sector who earn more than them are not paying taxes.

### **Increase in electricity tariff**

Health service is categorized as a 24/7 essential service. Therefore, the recent 66% increase in electricity tariffs will hurt the health sector disproportionately. The fuel prices also had been increased substantially over the last 8 months. With the meagre health budget of Sri Lanka, Rs 330 billion for 2023, whether the health sector can afford these increases in electricity and fuel prices needs to be considered very seriously.

### **Rising out of pocket health expenditure and elastic demand for certain health care disciplines**

The very high rate of inflation seen in the economy may eventually translate to higher prices for medical care, potentially leading to higher health spending and steeper rise in already high out of pocket health expenditure, which may even lead to catastrophic health expenditure.

In health economics, generally medical care is considered as having an inelastic demand. However, as described by Sherman Folland, Allen C. Goodman, and Miron Stano in their book titled 'The Economics of Health and Health Care' 8th edition (2017), few medical services, for

example certain aspects of plastic surgery, dental surgery and dermatology have elastic demand. Therefore, in an economic downturn, above medical disciplines will be “hit” harder than the other medical disciplines, especially in the private sector.

### **Mental health and nutrition of the children**

As reported in Lancet-Regional Health South Asia, the current economic crisis in Sri Lanka has majorly affected the mental health of the people, especially the children. Long closure of schools had led to behavioural changes in children. Regular power cuts had hindered online teaching and learning [8]. The economic crisis has already affected the nutritional status of our children. The poor nutrition status and reduced education attainment would have long term consequences on the country's economy and development.

### **Feminization of health workforce**

More women are attending medical school and becoming doctors. Currently, Sri Lanka has around 7500 medical students in the training pathway out of which nearly two thirds are females [9]. This trend is predicted to further increase. The Ministry of Health is the key employer for the doctors in Sri Lanka. Therefore, there would be a highly increased number of female doctors in the Ministry of Health in the near future.

Nevertheless, 4 main specialties of medicine, surgery, paediatrics and gynaecology are still dominated by males. However, this trend is fast reversing, though surgical subspecialties (Neurosurgery, Orthopaedics) are markedly male dominant. Further, laboratory based diagnostic subspecialties (histopathology, haematology, microbiology) are already feminized.

The authors foresee a future shortfall of male-dominated surgical trainees, as medical school graduates are becoming more feminized. This scarcity would stymie the establishment of the intended apex hospitals at the district and provincial levels in the pursuit of better universal healthcare coverage. As the medical profession

is getting feminized, there could be increased competition among female doctors to enter the specialties dominated by females in the future.

Female doctors in the Sri Lankan health sector are balancing a professional life with family and other interests, as is the trend in the global labour market. Part-time, flexi hours and shift work are expected to become increasingly popular as more women seek time off for childcare and breast-feeding. Sri Lanka health policy makers should take serious note of feminization of the medical doctor workforce and act proactively.

### **Outmigration of health staff**

Several health-related SDGs including universal health coverage will depend on the quality, skill mix, fair distribution, and adequacy of health workers.

As per WHO, by 2030, eighty million health workers will be needed globally. However, the supply of health workers is expected to be only around 65 million: creating a global shortage of 15 million health workers [10].

From a conceptual perspective, macrostructural and individual variables encourage health worker migration from resource-limited countries. Low salaries, poor working conditions, safety concerns, unstable and weak governments, poor educational and professional prospects specially for children are the major causes for out migration of skilled health workers. Within the context of global health workforce shortage, out migration of health workers from low- and middle-income countries to high income countries such as UK, USA, Australia is inevitable. This would further undermine the health services of the countries, with economic crisis like in Sri Lanka.

Given the above situation health care professionals including medical specialists, doctors and nurses tend to seek greener pastures now, more than ever.

Though there are different reports indicating different numbers of doctors who have already



“migrated”, the authors are of the view that our main “loss” comes from post graduate trainees who were already abroad in 2021/2022, undergoing their post MD training. Normally per year around 270-280 specialist trainees go abroad and around 250-260 return. However, in the year 2022 only a little more than 100 had returned.

A very reliable report from the Ministry of Health indicated that 304 medical officers had taken long term leave in 2022 and 136 medical specialists have taken long term leave or served vacation of post between 2017 and 2022. However, these figures may be grossly underreported as many doctors and specialists go abroad after taking short term leave or some without obtaining official leave at all. In the current system, serving of “vacation of post- VOP” takes a considerable time. Loss of highly trained medical workforce will be detrimental to the already resource limited health care system of Sri Lanka.

### **Retirement age for public servants**

The retirement age was 60 for all government servants until 2019. Then it was increased to 63 for the specialist doctors due to the perceived shortage of medical specialists. Further, in response to the demands by the doctors’ trade union, the age of retirement of doctors was raised to 61. Subsequently, an extraordinary gazette extended the mandatory retirement age for all public service medical officers up to 63 years of age.

Thereafter, the public sector retirement age for all categories including health workers was increased to 65 years on 20th January 2022 by the government headed by President Gotabaya Rajapaksa. However, the current President, Ranil Wickremesinghe’s 2022 interim budget proposed lowering the retirement age of public sector and semi-governmental employees to 60 years.

In Sri Lanka, deployment of health staff is based on service seniority and the staff are

transferred after a maximum of 4 years service at a particular station/ hospital. An officer with more service seniority could request and obtain a placement in a hospital in a big city. Due to this system, most of the senior and experienced staff are working in hospitals in big cities. Therefore, the hospitals in big cities will be the most affected, from the sudden reduction of mandatory retirement age.

Around 700 medical officers, 160 medical specialists and 3200 other categories would have retired by the end of December 2022 if not for an injunction order of a court regarding the retirement age. The court case is still pending.

Furthermore, many authors have commented on the Sri Lankan economic crisis from different perspectives. According to S Bandara, due to the present crisis scenario, worsening socio-economic landscape and human rights violations remain substantial threats to health in Sri Lanka [11]. Das speaks of effects of shortages of cancer drugs [12]. Matthias and Jayasinghe highlight the effects of stress and lack of health care on the increase of cardiovascular morbidities, importance of cost-effective interventions and establishing a stronger social protection system to help cope with escalating out-of-pocket expenses [13].

In summary, the health system of Sri Lanka is facing multiple crises that have mainly originated from sectors outside of health. The robustness of Sri Lanka’s healthcare sector can be ascribed to several factors, such as substantial investments in healthcare infrastructure and a skilled workforce, a prolonged tradition of dispensing universal health coverage, a potent public health system that prioritizes the disease prevention and timely detection, efficacious healthcare policies and initiatives, and a resolute political commitment to the healthcare sector. Another factor is probably the strong formal and informal social networks accessible to the patients. These networks are able to cushion external shocks by providing financial support to purchase services or goods from other

sectors. The aforementioned factors have played a significant role in enhancing health outcomes and the general welfare of the populace, thereby giving Sri Lanka's healthcare system with the

capacity to endure multiple challenges. Authors expect its resilience will help it to overcome the current economic crisis and return to its past glory soon.

### Author Declaration

**Author contributions:** DDeS designed and developed the concept, developed the manuscript and did the final editing. SDeA provided guidance and overall support to the project and revised the manuscript. PA attended to manuscript reading and other editorial support.

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## The impact of the economic crisis on the Sri Lankan health financing

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### Introduction

Sri Lanka is an island nation located in South Asia with a land area of 65,610 km<sup>2</sup> in close proximity to the southernmost tip of India and separated from it by a strip of sea. The country has a population of approximately 22.15 million with an annual average population growth rate of 0.53% [1,2]. Sri Lanka was recognized as a low-middle-income country with a Gross Domestic Product (GDP) per capita of USD 4013.7 in 2021 [2]. Following the 30-year war that ended in 2009, the country's GDP grew at an average of 5.3% from 2010-2019 driven by factors such as FDIs (Foreign Direct Investments), tourism, the exportation of goods and services, and improved international trade relationships. The GDP growth rate was recorded as -3.6% in 2020 attributed to the COVID-19 pandemic. In 2022, at the peak of the country's worst-ever economic crisis, the GDP growth rate plunged -7.8%, marking the country's greatest contraction in history, following a 3.5% GDP growth in 2021 [3].

Sri Lankan pluralistic health system has been universal and freely accessible to the public since 1930, consisting of the western-allopathic approach and other systems, namely Ayurveda, Siddha, Unani, Acupuncture, and Deshiya chikitsa. Allopathic medical care is the major contributor, of which 95% of inpatient care and 50% of outpatient care are provided by the public sector and the rest by the private sector [4]. According to the ministry of health in Sri Lanka, the government expenditure on health in 2020 was 1.68% of the Gross National Product (GNP). After 40 years since the establishment of the Act of

Parliament No.12 of 1952 "The Health Services Act", the first-ever National Health Policy for Sri Lanka was formulated in 1992 which identified many policy issues pertaining to the Sri Lankan health sector concentrating on decentralization of the health administration to the divisional level [4]. Currently, healthcare delivery is decentralized to a major degree and the ministry of health at the central level is responsible for the management of the health services of the country, as the lead agency in providing stewardship to health service development, implementation, delivery of strategies for health sector reform including the promotion of public-private partnership in health, development of health manpower including the enhancement of human resources, administrative and financial management and ensuring the provision of resources for health. The Provincial ministry of health is governed by the minister of health of the respective provincial council which further ensures a healthy population in the concerned province.

Despite the country's civil war that lasted for over two decades, Sri Lanka has achieved a significant progress in human and social development amidst an exacerbated budget deficit, and during the post-war the budget deficit was reduced from USD -3.89 billion in 2008 to USD -1.08 billion in 2020 [1], but with a volatile and a sluggish economic growth. The country's total expenditure on healthcare, both public and private, was 3.9% of the GDP in 2020 [2]. However, equitable distribution of healthcare resources and professionals has been quite challenging considering the economic status of

the country. Since the outbreak of the COVID-19 pandemic, Sri Lanka faced an alarming rise in the costs related to healthcare services as the government incurred LKR 117.5 billion of COVID-19 related expenditure in 2020 and LKR 53 billion from January to June in 2021 [5]. With the receding of the COVID-19 pandemic in Sri Lanka, a new challenge has arisen: a health catastrophe stemming from the economic and political crises. Sri Lanka slipped into default in May 2022 for the first time in history [6]. The severe shortage of foreign exchange reserves i.e. USD 7.6 billion in 2019 was reduced to less than USD 500 million in 2022 [7], import restrictions imposed by the government, and fuel shortage have stalled the provision of healthcare services, leading the ministry of health powerless to regularize the health services of the country, disturbing routine surgeries and clinical services [8]. To support the current crisis, the Sri Lankan government and the lending organizations such as World Bank and International Monetary Fund (IMF) have negotiated and approved a 48-month extended arrangement under the Extended Fund Facility of USD 3 billion [9].

### Glimpse of health expenditure

The proportion of CHE (Current Health Expenditure) to GDP has changed from 3.87% in 2010 to 4.08% in 2019 at an average and remained at about 3.8% for the nine-year period [10]. The CHE comprises both government and private contributions [11]. External health expenditure has been historically low and is around 1% [11]. The expenditure on public health as a percentage of GDP has fluctuated between 1.6% in 2016 to 1.9% in 2018 [11]. Healthcare spending in regional peers in South-Asian countries has averaged from 2.3% to 5.5% of GDP in recent years and hence, Sri Lanka is only comparable to lower-middle-income Asian countries [5].

### The flow of finance

Government is the main financier of healthcare which is provided at no price at the point of delivery. Interestingly, in the Sri Lankan healthcare financing system, the purchasing, pooling, and provider-split are not observed as a government act, though the government is the sole agent for all three. The treasury collects tax revenue and disburses the budget to the central government and provincial councils to ensure equitable and efficient healthcare delivery [12].

Institutions managed by the provincial and local governments are directly funded through the ministry of health and the finance commission via ways of government tax revenue and private spending [11]. Additionally, Army, Navy, Air force, Police, and Prison hospitals are managed by the respective ministries.

A major portion of the total investment in health is allocated to the recurrent expenditure consisting of salaries and wages. This applies both to the central and provincial levels. In 2019, the government was responsible for providing 47.2% of CHE and out of pocket expenditure contributed to 45.6% of CHE. In 2021, the budget allocation to health was LKR 24,500 million. Voluntary Health Insurance (VHI) contributed to about 5% of total private financing, while the private insurance market has shown considerable growth in recent years [11].

The finance commission of Sri Lanka ensures regional development within the country and is responsible for the provincial finances. All nine provinces are expected to engage in relevant developments to minimize inter-regional variations. Provincially funded health programmes and projects to uplift the quality of health services focuses on preventive aspects as health is considered a key socio-economic indicator.

The total financial availability for the provinces consists of the following;

- Block Grant



- Revenue share for recurrent expenditure
- Criteria Based Grant
- Province Specific Development Grant (PSDG)
- Development Projects

Together it makes the provincial financial pool of which allocations are made for each sector where health is prioritized, though there is no earmarked allocation for the health sector. Provincial capital health expenditure is mainly for durable and essential items like medical equipment and the recurrent expenditure is mainly for staff salaries.

The Provincial Planning Framework (PPF) is a framework that provides for a uniform set of Sustainable Development Goals (components) and outcomes (sub-components) for each province which allows inter-provincial comparability. After a needs assessment, the finance commission gives its recommendation on necessary budgetary allocations made for components and sub-components to the Treasury. However, the lack of an adequate accepted framework for provincial needs assessment has created issues in efficient fund allocation and mismatches between required allocation and received funds.

### Current situation of the Sri Lankan health system

Sri Lanka is currently facing its worst economic crisis since its political independence from British rule, following the COVID-19 pandemic. The COVID-19 pandemic triggered the most extensive economic crisis throughout the globe, but according to the article by Nazeeruddin, the economic crisis in Sri Lanka is not entirely due to the negative effect of the COVID-19 [13]. The researcher highlighted several reasons which led Sri Lanka into the current economic crisis in the study. Huge loans worth of USD 56.34 billion in 2020 taken by governments with higher interest rates compared to previous borrowings from international financial organizations is emphasized as one of the key reasons. The reduction of tax rates caused a huge revenue loss to the government from 11.6% in 2019 to 8%

of the total revenue in 2020 [13]. The reduced number of foreign arrivals from 2,521,000 in 2018 to 540,000 in 2020 crippled the tourism industry in Sri Lanka which generally generated 20% of its national income [13].

In the current context, Sri Lanka is facing many issues such as the lack of drugs and essential medications, migration of healthcare workers, and increased out-of-pocket expenditure due to inadequate financial allocations [14]. The scarcity of drugs is a global problem that spans low-income, middle-income, and high-income countries. Sri Lanka, as a developing country, undoubtedly faced this global issue even before the current economic downfall, yet studies are scarce. Drugs that are at high risk of shortage include essential life-saving medications, cardiovascular medications, oncology medicine, antimicrobials, etc. Parenteral drugs, more specifically sterile injectable drugs have been identified as more liable to shortage than other drugs [15]. The causes of drug shortages are multifactorial and all these will be ultimately affected by an ongoing economic crisis in the island. In literature, the causes of drug shortages have been categorized as difficulty in demand and supply. Supply is affected by a multitude of factors. These include the availability of raw materials, availability of facilities in the manufacturing process, and availability of transport [16]. Therefore, it is apparent that Sri Lanka, with the reduction in foreign exchange available for imports of drugs and raw materials along with the fuel crisis affecting the manufacturing process and transport, is at risk of a noticeable shortage of drugs. The most significant impact has been observed in the shortage of drugs treating cancer [17]. These drugs include bevacizumab, imatinib, paclitaxel, rituximab, anastrozole, and artemether acetate [17]. The primary cause for the shortage of these drugs has been identified as the lack of foreign exchange for drugs that are exclusively imported [17]. Such shortages in drugs affect patients

by worsening their disease progression and reducing the likelihood of survival. This is due to the substitution of alternative drugs, delay, and compromise in medical procedures, and difficulty in avoiding medical errors [16].

The issue of the health worker migration in Sri Lanka has been capturing increasing attention over the past years and in 2022, it has further aggravated due to the economic crisis in the country. According to the Government Medical Officers Association (GMOA), nearly 500 doctors have migrated during January to August 2022 [18]. There is a lack of data to assess the exact scope of migration of health workers from Sri Lanka even in the present context. Migration of health workers has mostly been an individual decision; however, the ministry of foreign employment is promoting the migration of skilled workers, notably health workers. The government is promoting circular migration of health professionals in the public sector by encouraging 5 years unpaid leave to work abroad [18], but with the limited pool of skilled healthcare workers there is a need of proper coordination between the different ministries as it is important for better human resource planning. However, the impact on each profession and specialty should be assessed individually.

### Conclusion and Recommendations

As discussed in the study, the Sri Lankan health system is currently facing challenges in providing quality healthcare for the general public due to the prevailing economic crisis. The country's health system achieved impressive milestones in the past, disregarding the minimum financial support and issues of equal distribution of healthcare resources and healthcare professionals throughout the country. As the current financial situation seems to exacerbate remaining issues and create new issues such as a shortage of essential life-supporting drugs, authorities need to reassess on how to provide effective health services to the general public. Public health financing is essential for Universal Health Coverage (UHC)

and health sector reform is a necessity with the aim of improving the efficiency and equity, while ensuring the sustainable healthcare financing and provision of public healthcare. In the current context, efficiency improvements in Sri Lanka are essential especially since the government total health expenditure cannot be increased due to the economic issues.

Efficiency gains are achieved through reforms that can be delivered 'within the system' so that the quality of care for the individuals is improved. Sources of inefficiencies have service-related (oversupply and overuse of equipment, inappropriate hospital admissions and length of stay, low use of infrastructure, investigations, and procedures), medicine-related (inappropriate and ineffective consumption, use of generics with comparatively higher prices), healthcare worker related (inappropriate or costly staff mix, unmotivated workers), and leakages related (waste, corruption, fraud) components.

Health systems all around the world are under strain, as a result of endless user expectations and goals to meet in the context of limited budgets and limited resources. Countries have been exploring ways to transform their healthcare systems in recent years, while many developing countries are attempting to enhance their health systems [19]. Health Technology Assessment (HTA) is essential for evidence-based decision-making and allocating health budgets towards achieving UHC. HTA systematically evaluates the effectiveness, costs, and health impact of a health technology while considering ethical and equity issues [20].

Implementing an HTA will influence evidence-based decision-making and health financing to gain maximum output from minimal input, while maintaining equity and efficiency. Importantly, Sri Lanka needs an in-depth analysis of the supply and demand side factors related to the healthcare market. Better healthcare financing allocation mechanisms with regard to the provinces, involving needs assessment would improve provincial healthcare.

## Author Declaration

**Author contributions:** All authors contributed to the conceptualization and design of the study. TLD, MA and IMK contributed to the acquisition of data. AUG, TLD, MA, and IMK contributed to the data interpretation and writing the manuscript. All authors read and approved the final manuscript.

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## Cost of a routine (planned) cardiac by-pass surgery at the National Hospital of Sri Lanka

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### Abstract

**Background:** Non-communicable disease (NCD) has become a major challenge in Sri Lanka. Over the last 40 years, ischemic heart disease (IHD) has been identified as one of the leading causes of NCD deaths in Sri Lanka. Coronary artery bypass graft (CABG) is a revascularization procedure that has been identified as an effective method for managing a patient with IHD. Therefore, estimating the approximate cost of CABG surgery in a public hospital would help in economic evaluations and managerial decision-making in public sector investments.

**Objective:** To estimate the approximate cost of an uncomplicated routine (planned) cardiac bypass surgery at the National Hospital of Sri Lanka (NHSL), Colombo.

**Methods:** This study was primarily based on secondary data. The data required for costing the procedure was extracted from 52 BHTs of patients who underwent CABG surgery at the NHSL during the last three months of the year 2019. Extracted data was used to determine the costing elements of each cost center. Direct and indirect cost centers were identified, and the cost of each center was determined by apportioning the available cost data by the step-down method using a weighted factor where applicable.

**Results:** The approximate cost of an uncomplicated CABG was Rs. 1.3 million per patient. Out of the total cost, 89% (Rs. 1.16 million) was expended on direct labor as salaries of different categories of staff. A major portion of it (56%) was spent on ICU care (Rs. 0.654 million) followed by post-surgical care at the ward settings (33.9%, Rs. 0.393 million). The highest cost of the material was recorded at the theatre which was 6% of the total cost (Rs. 78,960.00). The cost of total overheads was Rs. 29,517.00 which was about 2.2% of the total.

**Conclusion:** Although the approximate cost of a routine uncomplicated CABG surgery was Rs.1.3 million (\$ 7,027) as of December 2019 at the National Hospital of Sri Lanka, compared to more developed countries this is a fairly low cost. However, when the differences between health system organization and per capita health expenditure are concerned, this is quite evident to claim that the Sri Lankan health system has low-cost but effective models of delivering its care to people.

**Key Words:** Costing, CABG, National Hospital of Sri Lanka

## Introduction

Managerial cost accounting is about obtaining information in support of internal management processes often in terms of monetary values. Therefore, managerial decision-making of such functions as resource allocation, mobilization, and pricing of a product or service can be done based on systematic evidence [1]. This is particularly important in such services as coronary artery bypass grafting (CABG) because of its vitality and demand.

CABG is a revascularization procedure used in patients with cardiovascular disease (CVD). In this surgery, a healthy artery or vein is connected to a blocked artery to bypass the blocked segment. The aims of the surgery are to improve the quality of life by reducing the symptoms and improving survival by reducing the risk of further infarction in those patients who suffer from CVDs. CABG was identified as a cost-effective option for treating multivessel coronary disease in a study that was done for cost-effectiveness analysis of cardiovascular disease treatment in Japan [2].

Sri Lanka adopted a free health policy after its independence (1951). Therefore, the state sector healthcare is publicly funded (tax-based) and delivered free at the point of care [3]. The evolution of advanced medical technology amidst increasing demand for such care has amplified the cost of healthcare warranting raising cost awareness among policymakers, healthcare professionals as well as the general public [4]. The coronary artery bypass graft is one of the most expensive operative procedures in healthcare having considerable variations among countries, hospitals, and even among surgeons due to differences in its supply chain and practices [5].

Non-communicable diseases (NCD) have shown a sharp increase in prevalence contributing to the disease burden in the country over the last few decades. During the last 40 years, CVD has been identified as one of the leading causes of death in Sri Lanka. Compared to the other

countries in the region and the developed world, the contribution of CVD to NCD mortality is much higher in Sri Lanka [6]. A study that was done to estimate the risk of cardiovascular diseases in Sri Lanka has found that 25.4% of the population is at a higher risk of developing CVD [7].

The National Hospital of Sri Lanka performs about 550 CABG surgeries per annum [8]. Five cardiothoracic surgeons, three senior registrars, eleven designated medical officers, two dedicated operating theatres, five cardiothoracic wards, and an assigned staff of nurses and other support staff are currently involved in the above performance. However, there is a yearlong waiting for cardiac surgeries due to the escalated demand for the service.

Cost accounting is defined as the collection, assignment, and interpretation of cost-related data for managerial decision-making [1]. It is used for pricing, evaluating, and implementing cost-minimizing interventions as well as to compare different investment strategies. While there are several methods of costing that have been developed by various scholars, the ideal approach to capturing cost is dependent on what exactly is being produced.

When costing a service, some of the methods that can be utilized are activity-based costing, job costing and process costing [1]. Among them, activity-based costing, and job costing require a great deal of precision in data for a better estimate. However, it might often be difficult to assign specific costs to each unit because of the complexity of the operational activities and the nature of available data. To deal with these limitations, the accountants might prefer the method of process costing over the others [1].

Although a greater proportion (nearly 90%) of inpatient care is covered by the state sector, the approximate cost of individual procedures has not been estimated much. The aim of this study was to estimate the approximate cost of an



uncomplicated routine (planned) cardiac bypass surgery at the National Hospital of Sri Lanka.

### Methodology

The data for costing the procedure was primarily extracted from 52 BHTs of patients who underwent CABG surgeries at the NHSL Colombo during the last three months of the year 2019. Extracted data was used to determine the costing elements of each cost center.

Average salary details of the consultants, medical officers, nursing officers, health assistants, and staff of the other supportive services were obtained from the salary branch of the NHSL. The average number of staff involved in each procedure was determined based on their duty rosters while their labor was determined and weighted based on an estimated average time spent on a patient.

After reviewing the BHTs, a set of commonly performed investigations for an uncomplicated CABG was recorded. Costs of laboratory and other investigations were estimated and apportioned accordingly. However, the cost of the land and buildings were not included in the estimation.

Details of water, electricity, and communication bills and dietary expenses were collected from the supply branch of the hospital and apportioned according to an estimated weighted factor based on the number of beds available in the respective units.

It was assumed that the cost per patient on consultation and other services was directly proportional to the number of patient days that each patient had. Hence, it was weighted as per the time exposed for the consultation of the medical officers including the consultants. Finally, only the quantifiable cost elements were considered. Neither the opportunity cost nor the costs of qualitative elements (morbidity and quality-related costs) were taken into account.

According to the nature of the financial data available at the accounts department of the NHSL, it was not possible to assign costs to the identified

centers with confidence because of the bulk nature of paying utility bills. Therefore, this costing exercise used an estimated cost in those steps based on an average at each step. For instance, water consumption per patient was estimated per patient bed by dividing the total monthly expenditure on water by the number of total patient beds in the hospital. It was assumed that water consumption in each ward or unit was directly proportional to the number of patient beds that it had. It was also assumed that the capacity to hold any activity that utilizes water (including the activities of the staff, bystanders, and visitors) was dependent on the number of beds. In this context, cost per patient bed at any given step seemed to be the most appropriate method of apportioning a bulk cost in the given conditions of retrieving data.

Process costing is a methodology that allocates total costs of production to homogenous units produced via a continuous process involving multiple steps or departments [1]. For simplification, the average cost at each center was estimated utilizing the costs of direct labor, direct material, and overheads. In fact, this type of costing is characteristic of activity-based costing as well. Therefore, the approach of this costing exercise adopted a mixed method that utilized both process and activity-based costing concepts combined with the step-down method of cost allocation.

### Administrative clearance

The administrative clearance was obtained from the Deputy Director General of the NHSL. Privacy and confidentiality were ensured. None of the authors were involved in patient management at the wards.

### Identifying the Cost Centers

Considering the inward patient care, four cost centers were identified to which the cost could be assigned with reasonable assumptions. Nevertheless, they were all consistent with the care path of a patient who undergoes a routine surgery of CABG. Figure 1 illustrates the identification of those cost centers along the care path of a patient

who ends up with an uncomplicated outcome.

Once a patient was admitted to the hospital as planned, pre-surgical care was considered as “Cost center 1”, followed by the surgical care at the theatre, as “Cost center 2”. Mandatory post-surgical ICU care was considered as “Cost center 3” and mandatory post-surgical ward management as “Cost center 4”. Pre-assumptions were made that all the required pre-admission investigations were completed, and a management plan was available by the time of admission.

## Results

The total estimated labor cost through the entire care path was Rs.9,152,400 whereas the total labor cost per patient was Rs.1,166,162. The direct material cost per patient was Rs.101,160 while, the sum of estimated overheads was Rs.29,517. Therefore, the estimated cost of a routine CABG surgery was Rs.1,296,839 which was approximated to Rs.1.3 million. The results of the costing exercise with all the assumptions are summarized in Table 1. The percentage distribution of the total cost by the cost centers is illustrated in Figure 2.

## Discussion

The cost of any clinical intervention can be estimated in terms of direct costs (labor and material costs that are directly attributable), indirect costs (labor and material costs that are not directly attributable), and overhead costs (indirect costs that are not directly attributable to patient care such as administrative costs). Although the above have definitive accounting terms inherent to them, it is quite challenging to break the available data into them due to such complexities as overlapping and the inability to disintegrate the bulk form of costs. Therefore, cost accounting is not without limitations which warrant making reasonable assumptions to make outputs more rational and appropriate.

Out of the total cost of a CABG (Rs.1.3 million), 89% (Rs.1.16 million) was expended on direct labor. It primarily comprised salaries of different categories of

the staff. A major portion of it (56%) was spent on ICU care (Rs.0.654 million) followed by post-surgical care at the wards (33.9%, Rs.0.393 million). The highest cost of the material was recorded at the theatre which was 6% of the total cost (Rs.78,960.00). The total overhead cost was about 2.2% (Rs.29,517.00) of the total cost.

Economic analysis of surgical and interventional treatments for patients with complex coronary artery disease in China revealed that the average cost of a CABG surgery is \$ 13,842 [9]. It has also revealed that CABG bears a higher cost than primary coronary interventions (PCIs). However, since CABG has better clinical outcomes compared to PCI, they warranted the economic and health benefits of the CABG over the PCI [9].

United States of America bears a higher cost per CABG surgery which is around \$ 1,23,000. In South Korea the cost is around \$ 26,000 while in Singapore it is around \$ 17,200 [10]. Whilst the results of this study (\$ 7,027) cannot be compared with them side by side, it indicates that the total cost of a CABG in Sri Lanka is comparatively low. Although there are considerable differences between health system organization and per capita health expenditure in developed countries, it is quite evident to claim that Sri Lankan healthcare delivery is cost-effective. In fact, Sri Lanka has many health indices above the averages of regional countries and has acquired a much comparable status to developed countries.

This costing exercise was severely constrained by the inability to retrieve financial data appropriately. It was also limited to a selected cardiothoracic ward, a selected theatre, and a selected ICU at the NHSL. Since the analysis of this study was based on the apportioned costs devised from aggregates of financial data that were available, the best approach to interpret the estimate would be to compare it with the other estimates available in the literature. However, the availability of such literature in the Sri Lankan context is limited.

## Conclusion

CABG is a complex but vital surgical intervention needed to save lives in critical clinical events like ischemic heart disease. It attempts to deliver tailor-made care for each patient. Therefore, the overall management of the condition tends to differ from one patient to another causing a significant variation in the utilization of resources including time. This diversity is reflected in the path of patient care and therefore in the cost as well. The availability of expenditure data in bulk forms (as aggregates) makes it extremely difficult

to apportion the cost elements appropriately unless one would have rational assumptions and the best possible guesses. However, having at least an approximation of the costs of vital clinical interventions at hand is imperative to make fair decisions in terms of allocating resources and future investments. This costing study concludes that decision-makers can assume that a routine uncomplicated cardiac bypass surgery approximately costs Rs. 1.3 million (\$ 7,027) per patient in Sri Lanka at a public sector hospital like the National Hospital of Sri Lanka.

## Author declaration

**Author contributions:** All authors contributed to conceptualizing, designing, and carrying out the study.

**Conflicts of interest:** The authors declare no conflicts of interest concerning the research, authorship, and/or publication of this article.

**Ethics approval:** Ethics approval was not sought as the entire study was based on secondary data and no violation of ethics was observed by the design of the study.

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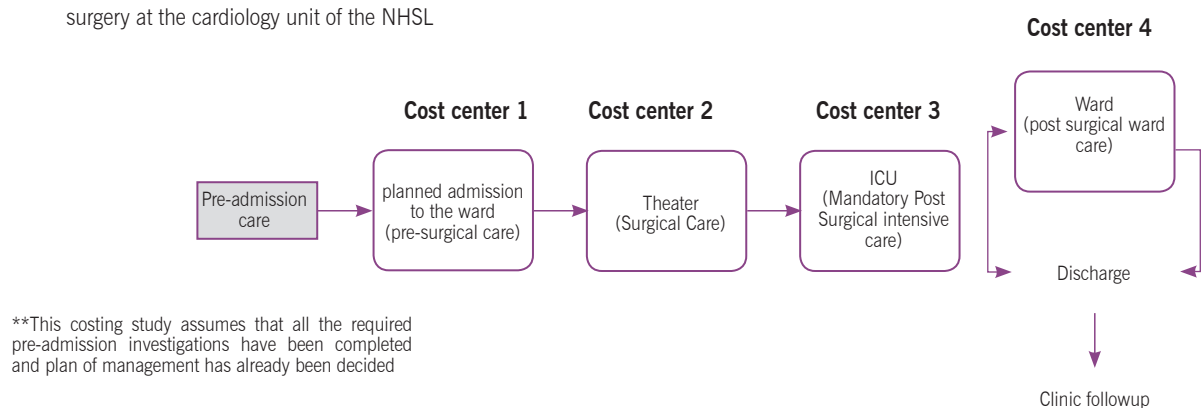
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**Table 1: Cost estimation of an uncomplicated coronary artery bypass surgery at the NHSL**

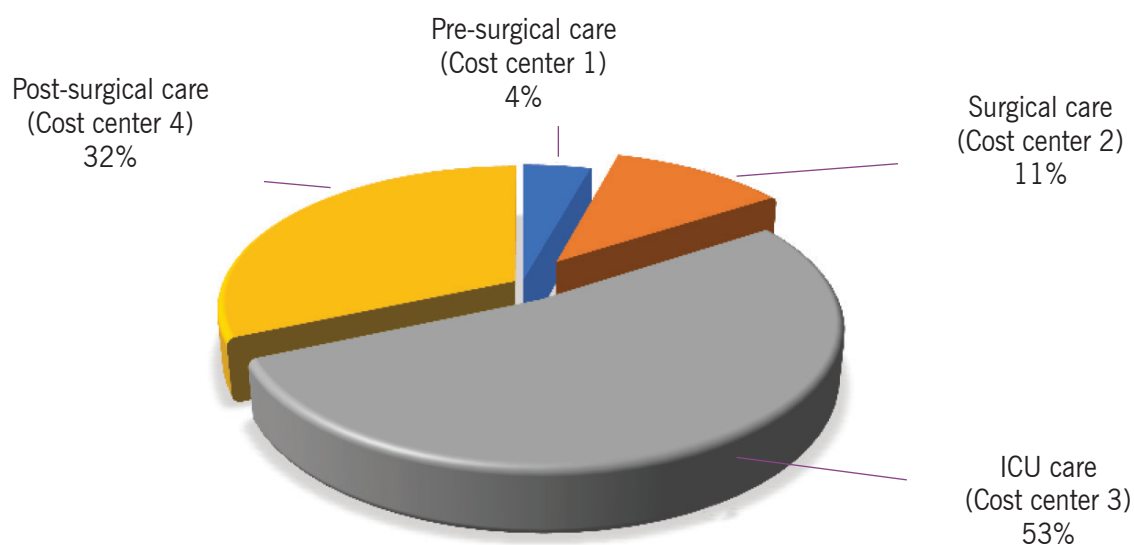
Cost center	Pre-surgical wards care	Surgical care at the theater	ICU care	Post-surgical wards care
	Rs. '000	Rs. '000	Rs. '000	Rs. '000
<b>Direct labor (wages)</b>				
<u>Consultants</u>				
Anesthetists	03* 732	03* 732	02* 488	-- --
Weighted factor**	0.2	0.3	0.5	
Estimated cost	<b>146.4</b>	<b>219.6</b>	<b>244</b>	
Cardiothoracic surgeons	05* 1220	05* 1220	03* 732	01* 244
Weighted factor**	0.2	0.5	0.2	0.1
Estimated cost	<b>244</b>	<b>610</b>	<b>146.4</b>	<b>24.4</b>
Cardiologists	02* 484	03* 1176	03* 784	01* 244
Weighted factor**	0.1	0.6	0.1	0.2
Estimated cost	<b>48.4</b>	<b>705.6</b>	<b>78.4</b>	<b>48.8</b>
<u>Medical officers</u>	16* 3136	06* 864	04* 864	04* 784
Weighted factor**	0.2	0.4	1.0	0.4
Estimated cost	<b>627.2</b>	<b>345.6</b>	<b>864</b>	<b>313.6</b>
<u>Nursing officers</u>	24* 1728	12* 864	12* 864	09* 648
Weighted factor**	0.5	1.0	1.0	0.5
Estimated cost	<b>864</b>	<b>864</b>	<b>864</b>	<b>324</b>
<u>Other health staff</u>				
Attendants	05* 305	--	--	01* 61
Health assistants	12* 516	06* 258	06* 258	04* 172
<b>A. Direct labor cost per day</b>	Rs. 2,751,000	Rs. 3,002,800	Rs. 2,454,800	Rs. 943,800
<b>B. Number of patients cared per month</b>	160	45	45	12
<b>C. Cost per patient per day</b>	Rs. 17,194	Rs. 66,730	Rs. 54,550	Rs. 78,650
<b>D. ALOS as per the sample</b>	3 days	1 day	12 days	5 days
<b>E. Total labor cost per patient</b>	<b>Rs. 51,582</b>	<b>Rs. 66,730</b>	<b>Rs. 6,54,600</b>	<b>Rs. 3,93,250</b>
Direct material costs				
Drugs & IV fluids				
- Indoor pharmacy				
- Local purchasing				
Medical gases				
Surgical & dressing materials				
- Surgical				
- Dressing				
	Rs. 3,250	Rs. 78,960	Rs. 12,680	Rs. 6,270
<b>F. Direct material cost per patient</b>	<b>Rs. 3,250</b>	<b>Rs. 78,960</b>	<b>Rs. 12,680</b>	<b>Rs. 6,270</b>
Indirect costs & Overheads				
Indirect labor				
- Radiography				
- Radiographers				
- MLTs				
- ECG technicians				
- Physiotherapists				
- Other staff				
Indirect materials				
- Materials for radiological investigations				
- Materials for laboratory investigations				
Diet				
Water				
Electricity				
Communication				
Administrative costs**				
<b>G. The sum of overheads per patient</b>				<b>Rs. 29,517</b>
<b>Estimation of the cost of CABG (Routine &amp; uncomplicated)</b>				
Total direct labor cost	(51,582+66,730+6,54,600+3,93,250)		Rs.	1,166,162
Total direct material cost	(3,250+78,960+12,680+6,270)		Rs.	101,160
Estimated overhead costs	(1,920+5,090+5,250+4,170+13,050+37)		Rs.	29,517
<b>The estimated cost of a CABG surgery</b>			Rs.	1,296,839
				<b>Approx. Rs. 1.3 million</b>

\* Weighting was based on the estimated share of time per patient at each cost center. The average number of staff in each unit was estimated based on the duty-roster information received from each unit. A caution was made to include only those who exclusively engaged with the care of CABG patients. \*\* The weighted factor indicates the proportion of the contribution of care by individual professionals. # The cost of direct materials was estimated based on randomly selected ten BHTs out of those referred ones (n=52).

Process map of routine by-pass surgery at the cardiology unit of the NHSL



**Figure 1: Care path and the identification of cost centers for an uncomplicated coronary artery bypass surgery**



**Figure 2: Percentage distribution of the cost among the cost centers**



## Cost saving and safety associated with centralised cytotoxic medicine reconstitution at National Hospital Kandy in 2019

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### Abstract

**Background:** Cytotoxic medicines are associated with occupational risks to the operators. Therefore, centralised cytotoxic medicine reconstitution by trained pharmacists was initiated in Sri Lanka in 2009. Centralised parenteral medicine reconstitution has many advantages such as quality assurance, error reduction, wastage reduction and cost saving. However, none of these have been analyzed and reported in Sri Lankan settings before this study. If the cost saving is of a considerable value, Centralised Medicine Reconstitution (CMR) can be applied to other expensive medicines which will help to reduce the cost of medical supplies.

**Objectives:** To analyse the cost saving and increased safety by reducing the medicine wastage due to the centralised parenteral cytotoxic medicine reconstitution in the National Hospital Kandy (NHK) in 2019.

**Methods:** The study was conducted using the data recorded in 2019 on the daily medicine balance book maintained at the Cytotoxic Reconstitution Unit (CRU) in NHK. The number of vials used, the quantity of each dose, and the price of the parenteral cytotoxic medicine were used to calculate the total cost and the medicine wastage in the CRU and ward, and compared.

**Results:** Theoretical medicine cost in wards to dispense 24 medicines was LKR 267.7 million, while the cost in the CRU was LKR 193.9 million. When it was reconstituted by the CRU, there was a wastage of 213,744.60 mg, and in wards, it was 4,353,153.60 mg. It showed a cost savings of LKR 73.8 million and a savings of 4,139,409 mg due to the CMR. The majority of cancer medications are cytotoxic, so reduction of medicine wastage also lowers the occupational risk and the risk to the environment.

**Conclusion:** CMR of cytotoxic medicine in NHK has shown a 27% cost reduction and increased occupational and environmental safety as determined by 95% reduction in medicine wastage in 2019. CMR of other costly parenteral medicines in addition to the cytotoxics would help to reduce the cost on medicines.

**Keywords:** cytotoxic, Centralised Medicine Reconstitution, cost saving, increased safety, wastage reduction

## Background

The Trade and Development Report 2022 mentions that the current economic recession has overwhelmed the whole world [1]. As a result, many countries have already taken decisions to reduce their expenses including that on healthcare. In addition, the prices of pharmaceutical raw materials and medicines have inflated to an unexpected level all over the world. Indulging in an economic crisis, Sri Lanka is also reaching a difficult situation in providing free healthcare through government health institutions. Decisions for reducing the health budget will not be a surprise. All healthcare institutions, especially public facilities need to search for survival strategies. Identifying the ways for cost reduction is important in this regard. Sri Lanka provides free healthcare in the public sector health institutions which includes free supply of medicines. As anticancer medicines are expensive, high expenditure on anticancer medicines is a major problem associated with chemotherapy [2,3]. The Ministry of Health Sri Lanka allocates nearly 2.8% of its total recurrent expenditure budget to the National Cancer Institute of Sri Lanka (NCISL), the largest cancer hospital in the country.

Anticancer medicines/cytotoxic medicines are highly toxic chemicals. Their toxicity is not limited to cancer cells. Consequences of exposing the normal cells to cytotoxics could range from mild rashes to gene mutations and even to cancers. In addition, exposure to cytotoxics could be teratogenic. Therefore, special precautions are recommended to handle cytotoxic medicines [4]. Parenteral cytotoxic medicines are recommended to be reconstituted in cytotoxic reconstitution units (CRUs) following aseptic techniques by trained healthcare professionals [4]. CRU is a specially made environment with restricted access. Air supply to the environment is controlled and medicines are reconstituted inside a biosafety cabinet or a class IIA laminar air flow cabinet.

Use of closed system medicine transfer devices in reconstitution is advised [5]. Adherence to aseptic techniques by the operators who are in personal protective equipment (PPE) like gowns, caps, shoe covers, face shields, etc. is also included in the guidelines for cytotoxic reconstitution. This specially made environment and the practices ensure the sterility of the preparation and the reduced occupational risks to the operators. However, some of the countries with developing economic statuses do not follow these guidelines and recommendations [6-10].

There was a remarkable shift in the method of reconstitution of injectable cytotoxics in 2009 in Sri Lanka. Till 2009, all parenteral cytotoxics were reconstituted in the respective cancer wards with the available facilities by nurses who were not specifically trained for the purpose. However, since 2009, NCISL has started to reconstitute parenteral cytotoxics in a centralised unit with specialized facilities by qualified pharmacists who are specially trained for the purpose. Since 2010, National Hospital Kandy (NHK) and Teaching Hospital (TH)s Kurunegala, Karapitiya and Rathnapura also have started CMR of cytotoxic medicine. CMR is expected to reduce the cost of medicines and the occupational risk associated with the exposure to cytotoxics considerably. Cytotoxic waste generation is another problem associated with chemotherapy. Higher the wastage, higher the risk to the environment and the workers. If the wastage could be reduced, the environmental and occupational safety would be increased and it is important to measure the reduced cost and the increased safety [11].

According to the literature, there were no published reports on studies conducted in Sri Lanka on cost saving, wastage reduction or increased safety due to centralised cytotoxic parenteral medicine reconstitution. Therefore, it was important to systematically analyze the cost savings and the increased safety by measuring the wastage reduction associated with centralised

reconstitution of cytotoxic medicines in Sri Lanka.

## Objectives

The objective of the study was to analyze the cost saving and increased safety through medicine wastage reduction associated with the centralised parenteral cytotoxic medicine reconstitution in the NHK in 2019.

## Methods

This retrospective study was done using the data of regularly used parenteral cytotoxic medicines reconstituted at the CRU, NHK during 2019. Administrative approval to conduct the study was obtained from the hospital administration prior to the study.

All parenteral cytotoxic medicines reconstituted at the CRU, NHK during 2019 were included while the medicines with no records on the number of vials, strength or the dose were excluded. Details in the daily balance book maintained at the CRU were used to collect the data. The name, dose, strength, the total number of prepared doses and the total number of vials used for reconstitution of the respective medicines in each day were collected. The unit price of each medicine was collected using the 2019 annual estimate of the NHK.

The cost reduction was analyzed obtaining the difference between the cost of reconstitution of medicines at the ward and that at the CRU. As the cytotoxics were entirely reconstituted at the CRU, the cost associated with ward-based reconstitution was calculated theoretically. However, the cost associated with CRU reconstitution was calculated using the actual data.

The cost of each medicine reconstituted at CRU was calculated using the equations 1-5. Then the cost of each cytotoxic medicine reconstituted at the CRU was added up to obtain the cost of all cytotoxic medicines and trastuzumab

reconstituted at the CRU (Equation 6).

Before CRU was established at NHK, medicines were reconstituted at wards by nursing officers. There, the practice was to use one medicine vial for one patient ignoring the remaining in the vial. Therefore, the number of vials theoretically used in 2019 were calculated based on one medicine vial for one patient.

Total number of vials were decided based on the equation 8 where any decimal value (part of a vial) was considered a vial as the remaining in the vial was needed to be discarded if not used immediately or within 8 hours.

The cost saving associated with CMR of each cytotoxic medicine was calculated by the difference between the cost of reconstitution of medicines at CRU and that of wards (Equation 10). The total cost saving associated with centralised preparation of all parenteral medicines was calculated by adding the cost savings observed from each medicine (Equation 11).

The total quantity of medicine A that was actually needed was calculated using the data in the daily balance book (Equations 12-14). Total quantity of medicine A used in 2019 at CRU was calculated using the equations 15-17. Total quantity of medicine A used in 2019 at wards was considered as NAZ and Z was the medicine quantity of the vial A. NAZ was considered similar to QA and it was used in calculating the medicine quantity used in wards (Equations 18-20). The wastage of each medicine was calculated by the difference between the total quantity used and the total quantity required. The wastage at the CRU and at wards were calculated using the equations 21 and 22, respectively. Wastage reduction was calculated as the difference between the wastage at wards and that at the CRU (Equation 23) and the total wastage was calculated using the equation 24.

E.g.: Medicine A is reconstituted at the CRU;

$$\text{Total number of vials of medicine A used in Day 1} = n_{A1} \dots (1)$$

$$\text{Total number of vials of medicine A used in Day 2} = n_{A2} \dots (2)$$

$$\text{Total number of vials of medicine A used in 2019 } n_A = \sum_{i=1}^{365} n_{Ai} \dots (3)$$

$$\text{Unit price of A} = Y_A \dots (4)$$

$$\text{Cost of reconstitution of medicine A in 2019 at CRU} = n_A Y_A \dots (5)$$

Cost of cytotoxics if reconstituted at cancer wards, NHK

$$\text{Total number of vials of medicine A used on Day 1 in all wards} = N_{A1} \dots (6)$$

$$\text{Total number of vials of medicine A used on Day 2 in all wards} = N_{A2} \dots (7)$$

$$\text{Total number of vials of medicine A used in 2019 in all wards } N_A = \sum_{i=1}^{365} N_{Ai} \dots (8)$$

$$\text{Cost of reconstitution of medicine A in 2019 in all wards} = N_A Y_A \dots (9)$$

$$\text{Cost saving associated with centralised preparation of medicine A} = (N_A - n_A) Y_A \dots (10)$$

$$\text{Total cost saving due to centralised medicines preparation} = \sum_{j=1}^k (N_j - n_j) Y_j \dots (11)$$

Where k = number of parenteral medicines used in 2019

$$\text{Quantity of medicine A that was needed for the Day 1} = x_{A1} \dots (12)$$

$$\text{Quantity of medicine A that was needed for the Day 2} = x_{A2} \dots (13)$$

$$\text{Total quantity of medicine A that was needed in 2019 } X_A = \sum_{i=1}^{365} X_{Ai} \dots (14)$$

$$\text{Total quantity of medicine A used in Day 1 at CRU} = R_{A1} \dots (15)$$

$$\text{Total quantity of medicine A used in Day 2 at CRU} = R_{A2} \dots (16)$$

$$\text{Total quantity of medicine A used in 2019 at CRU } (R_A) = \sum_{i=1}^{365} R_{Ai} \dots (17)$$

$$\text{Total quantity of medicine A used in Day 1 at wards (theoretical)} = N_{A1} Z = Q_{A1} \dots (18)$$

Where Z is the medicine quantity of the vial A

$$\text{Total quantity of medicine A used in Day 2 at wards (theoretical)} = Q_{A2} \dots (19)$$

$$\text{Total quantity of medicine A used in wards (theoretical)} (Q_A) = \sum_{i=1}^{365} Q_{Ai} \dots (20)$$

Where k= number of parenteral medicines used in 2019

$$\text{Wastage of medicine A at CRU} = R_A - X_A \dots (21)$$

$$\text{Wastage of medicine A at wards (theoretical)} = Q_A - X_A \dots (22)$$

Wastage reduction of medicine A = medicine wastage at ward (theoretical) - Medicine wastage at CRU

$$= (Q_A - X_A) - (R_A - X_A) = Q_A - R_A \dots (23)$$

$$\text{Total wastage reduction, Q-R} = \sum_{j=1}^k (Q_j - R_j) \dots (24)$$

Where k = number of parenteral medicines used in 2019

Environmental and occupational safety was determined based on the equations 25 - 27.

$$\text{Environment and occupational risk} = \text{Cytotoxic waste generation} \cdot x \dots (25)$$

Where x = other factors

If x is constant,

$$\text{Environmental and occupational risk} \propto \text{Cytotoxic waste generation} \dots (26)$$

$$\text{Environmental and occupational safety} \propto \frac{1}{\text{Environmental and occupational risk}} \dots (27)$$

## Results

Actual number of vials of each medicine used for reconstitution at CRU were calculated using the equation 3 and given in the table 1. The theoretical number of vials of each medicine used for reconstitution at all wards were calculated using the equation 8 and given in the table 1.

According to the table 1, Paclitaxel injection 30 mg/5ml vial has been highly used (10,099). Next highly used vial was Cyclophosphamide inj. 200 mg (6,391). But, 1,037 number of vials of Cyclophosphamide inj. higher strength (1 g) have also been used. Paclitaxel injection 260 mg vial was less used (742).

Cost of medicines reconstituted at CRU was calculated using the equation 5 and given in the table 2. The theoretical cost of medicines reconstituted at wards were calculated using the equation 9 and given in the table 2. Cost saving by the CRU reconstitution for one medicine was calculated using the equation 10. The total cost saving by the CRU reconstitution was calculated using the equation 11 and given in the table 2.

Table 2 shows that a higher cost saving, 66,551,576.91 Sri Lankan Rupees (LKR), was observed with centralised reconstitution of Trastuzumab Injection 440 mg. However, there was no cost saving observed by centralised reconstitution of some of the medicines such as Actinomycin D inj. 500 mcg, Melphalan injection 50 mg powder and Vinorelbine Injection 10 mg.

The total required quantity, the total quantity used at CRU and the quantity required for reconstitution at wards were calculated using the equations 14, 17 and 20 and values are given in the table 3.

According to the table 3, the total required quantity of all medicines was 13,237,534.56 mg and the total quantity used from all medicines at the CRU was 13,679,888.50 mg. The theoretical quantity requirement for reconstitution at wards was 17,891,749.5 mg. Medicine wastage

occurred at CRU, at wards and the wastage reduction due to centralised reconstitution were calculated using the equations 21, 22 and 23, respectively and given in the table 4. According to table 4., negative values could be observed in the wastage of some of the medicines (Vincristine sulphate and Ipsofomide) reconstituted at the CRU. Therefore, for analysis of total cost saving and total medicine wastage reduction, calculations had to be done without (adjusted) these two medicines. Final results without these two medicines (adjusted) are shown in the table 5.

Table 5 shows the adjusted total cost saving by CMR done at CRU, NHK in 2019 and was LKR 73,831,207.61. Adjusted total medicine wastage reduction by CMR was 4,139,409.00 mg.

## Discussion

Covid pandemic has highly affected the Sri Lankan health sector during 2020 and 2021. It would have made variations to the number of cancer patients visiting and admitting to the hospitals, thus the year 2019 was selected assuming that the latest year with least changes to the number of patient admissions to the hospitals. In 2019, the expenditure on dispensing 24 cancer medicines was LKR 193.9 million, while the cost of dispensing the same medicines in wards would have costed LKR 267.7 million. Therefore, a cost saving of LKR 73.8 million could be observed by CMR at the CRU. It was a 27% cost saving due to centralised reconstitution compared to the ward reconstitution. A total quantity of all medicines 13,237,534.56mg was required for the patients and due to a definite wastage occurrence, a wastage of 213,744.60mg quantity was observed when dispensing through CRU while a wastage of 4,353,153.60mg quantity was seen when dispensing through wards. As cancer medicines are highly toxic, the reduction in medicine wastage reduces the risk to the environment and to the personnel who are handling the waste.



When comparing the results with that of previous research studies, some differences could be observed. Edward et al. (2013) reported that the reduction of medicine wastage was nearly 50% [12]. But in this study it was found that the reduction of medicine wastage was nearly 95%. This research was conducted in 2019 but Edward et al. (2013) have conducted their study in 2013 [12]. The technical improvements resulted from 2013 to 2019 could be a reason for this difference in high amount of wastage reduction. In one of the researches conducted in 2020 in USA, the medicine wastage reduction was 79.5% [13]. In that study, 17 cytotoxic medicines have been considered while in the current study 24 medicines were considered. The differences in the medicines and the number of medicines might lead to differences in the results as the wastages and the costs of different medicines are different [8].

The amount of cost saving in NHK was nearly US\$ 414,650 in 2019. But some research cases reported US\$ 70,000 [12], US\$ 580,000 [13], US\$ 530,000 [5] in one year and US\$ 700,000 in 2018 [14]. Some researchers found US\$ 21,000 cost saving in 6 months [15]. Edward et al. (2013) considered 21 medicines [13] in their study, but its cost saving was higher than that of NHK. Generally, the prices of medicines in the USA are higher compared to the prices of medicines used in Sri Lanka. This might be the reason for higher cost savings resulted in the studies conducted in USA [6,12,13]. In addition, in this research conducted at NHK, the regular medicines and Trastuzumab were considered. Prices of regular medicines are less than the named-patient medicines and if those were considered, a higher cost saving in comparison to the current results could have been observed. In addition, a US\$ 21,000 of cost saving has been observed by a study conducted in France [15]. There, the cost saving by centralised medicine preparation was lower than the results of our study, as the number of medicines considered

were low compared to the current study. Under this discussion, we can say that numerous factors such as economic status of a country, number of medicines and vials considered, study period and the duration, and the prices of the medicines affect the cost saving.

The volume present in the vial or strength of the vial may be different from one brand to another. Then the wastage will differ which affects the cost saving as well. Training and the experience of the person involved in the process also affect the cost and the wastage of medicines. Less trained or less experienced staff can also be a factor for a high wastage and for high costs. Number of the patients considered in a study and the duration of the research can also be identified as factors that can affect the results.

At the beginning of the research, all parenteral medicines were expected to be analysed, hence the data on 28 medicines reconstituted at the CRU were collected. But, due to poor documentation practices, some of the data could not be retrieved leading to inadequate data availability. Finally, only 24 medicines were included in the study. If all these medicines which were omitted had been included in the study, a higher cost saving could have been obtained.

According to the equation 27, environmental and occupational risks have been greatly reduced as cytotoxic wastage has been reduced by more than 4 kg in weight due to CMR, compared to the ward reconstitution.

Poor documentation observed at the CRU limited the number of medicines considered in the study. Unavailability of number of vials, doses, and prices led to exclusion of some of the medicines from the study. The second limitation in the study was that all the ward related calculations were done theoretically, assuming a similar practice for all the medicine usage for all wards. However, in a hospital, medicine usage is not uniform. Therefore, medicine usage should be handled



case by case. This was not possible as there is no ward-based reconstitution practice currently in NHK for cancer medicines thus, uniform practice was assumed and proceeded.

This study reports a high cost-effectiveness in the CMR of cytotoxics at CRU, NHK. Also, a similar medicine wastage can be seen in other expensive parenteral medicines such as antibiotics. Therefore, we suggest establishing centralised units for all parenteral medicine reconstitutions without limiting to cytotoxics which can reduce the expenditure for parenteral medicines. In addition, it will reduce the risk to the environment as the medicinal wastage is reduced. Further, the quality of the medicine administered to the patients can be ensured with a higher possibility for medication error reductions. The same suggestion can be further extended even to establish medicine pre-preparation units for all medicines. Individualized dose determinations will improve the therapeutic outcome in addition to ensuring the quality and safety. Individualizing the doses will improve the cost effectiveness of the therapy thus, the cost for medicines could be reduced. It is an important measure to reduce the cost of medicine procurement as well. If the prescribers take the lead on individualized prescribing, the pharmacists can support individualized dose dispensing at a centralised unit which is the current practice in many of the

developed countries. Another suggestion is to optimize the documentation system maintained at the CRU as poor documentation affects the data retrieval and inventory control procedures in the hospital.

## Conclusion

In 2019, centralised cytotoxic medicine reconstitution in NHK has saved LKR 73.8 million by 24 medicines with respect to a theoretical ward reconstitution. Also, 4,139,409 mg of medicine wastage reduction could be observed by centralised cytotoxic medicine reconstitution in NHK in 2019 with respect to 24 cytotoxic medicines, thereby increasing the safety to the environment and the workers. Results revealed that CMR can be applied for other high-cost medicine preparations such as reconstitution of antibiotics.

According to the study, CMR reduces the cost of medicines in large amounts. It also reduces the wastage of medicines. Therefore, patients, workers and environment safety will be improved. By establishing centralized facilitated units, the quality of the end user products can be assured, thereby patient safety can be ensured. By implementing dosage individualization at CMR units, the expected therapeutic outcomes can be successfully achieved. All these will lead to cost minimization at therapeutic interventions.

## Author declaration

**Author contributions** : All authors contributed to the study and manuscript preparation. WTDW involved in planning, data collection, analysis and writing; BDK contributed by planning, editing and supervision; AGSUB involved in planning, editing and supervision; LCPTL contributed in planning, writing, editing and supervision.

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**Ethics approval and consent to participate** : Study involved no animal or human participants thus neither ethics approval nor the consent to participate were required.

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**Table 1: Number of vials used at CRU and all wards (theoretical) in NHK in 2019**

Description	Actual number of vials used at CRU	Actual number of vials used at wards
Actinomycin D inj. 500 mcg vial	1	1
Asparaginase 10,000 IU vial	29	33
Bleomycin sulphate Inj.15 000 units vial	373	406
Carboplatin inj. 450 mg/45 ml vial	2,276	3,111
Carboplatin inj.150 mg/15 ml vial +diluent	45	48
Cisplatin injection 50 mg vial	3,338	4,154
Cyclophosphamide Inj. 1 g vial	1,037	1,415
Cyclophosphamide inj. 200 mg vial	6,391	6,785
Cytarabine Inj. 100 mg/5 ml vial	497	587
Cytarabine injection1g in 10 ml vial	22	37
Dacarbazine Inj. 200 mg vial	941	1079
Daunorubicin HCl inj.20 mg vial	286	312
Docetaxel injection 20 mg vial	124	130
Docetaxel injection 80 mg vial	1,308	1,734
Doxorubicin HCl inj.10 mg vial	5,072	5,237
Doxorubicin HCl inj.50 mg vial	1,142	1,392
Epirubicin hydrochloride Inj.10 mg vial	22	26
Epirubicin hydrochloride Inj.50 mg vial	1,320	1,416
Etoposide injection 100 mg vial	1,017	1,207
Fluorouracil inj. 1g, 20 ml vial	4,679	6,429
Gemcitabine hydrochloride inj.1g	2,354	2,930
Gemcitabine hydrochloride inj.200 mg	330	342
Iposphomide 1g	622	694
Melphalan injection 50 mg powder with solvent	2	2
Mesna injection 200 mg in 2 ml	1,242	1,324
Methotrexate injection 1 g vial	48	499
Mitomycin injection 2 mg vial	331	417
Oxaliplatin injection 100 mg vial	1,475	2,043
Oxaliplatin injection 50 mg vial	116	130
Paclitaxel injection 260 mg	742	1,047
Paclitaxel injection 30 mg/5 ml vial	10,099	10,784
Paclitaxel Nanoparticle Inj 300 mg	6	8
Trastuzumab Injection 440 mg vial	1,134.4	1,584
Vinblastine Sulphate Inj 10 mg vial	176	212
Vincristine sulphate injection 1mg vial	1,188	1,675
Vinorelbine Injection10 mg Vial	1	1

**Table 2: Cost saving of CRU at NHK in 2019**

Description	Unit Price (LKR)	Cost of medicines at CRU (LKR)	Cost of medicines at ward (LKR)	Cost deference (Ward-CRU) (LKR)
Actinomycin D inj. 500 mcg vial	643.36	643.36	643.36	0
Asparaginase 10,000 IU vial	4,682.98	135,806.42	154,538.34	18731.92
Bleomycin sulphate Inj.15 000 units vial	945.99	352,854.27	384,071.94	31217.67
Carboplatin inj. 450 mg/45 ml vial	2,610.01	5,940,382.76	8,119,741.11	2,179,358.35
Carboplatin inj.150 mg/15 ml vial + diluent	2,296.52	103,343.4	110,232.96	6,889.56
Cisplatin injection 50 mg vial	461.14	1,539,285.32	1,915,575.56	376,290.24
Cyclophosphamide Inj. 1 g vial	250.00	259,250.00	353,750.00	94,500.00
Cyclophosphamide inj. 200 mg vial	97.92	625,806.72	664,387.2	38,580.48
Cytarabine Inj. 100 mg/5 ml vial	93.69	46,563.93	54,996.03	8,432.1
Cytarabine injection1g in 10 ml vial	92.28	2,030.16	3,414.36	1,384.20
Dacarbazine Inj. 200 mg vial	333.01	313,362.41	359,317.79	45,955.38
Daunorubicin HCl inj.20mg vial	255.48	73,067.28	79,709.76	6,642.48
Docetaxel injection 20 mg vial	570.80	70,779.20	74,204.00	3,424.80
Docetaxel injection 80 mg vial	750.35	981,457.80	1,301,106.90	319,649.10
Doxorubicin HCl inj. 10 mg vial	75.66	383,747.52	396,231.42	12,483.90
Epirubicin hydrochloride Inj.10 mg vial	305.88	6,729.36	7,952.88	1,223.52
Epirubicin hydrochloride Inj.50 mg vial	1,006.12	1,328,078.40	1,424,665.92	96,587.52
Etoposide injection 100 mg vial	172.47	175,401.99	208,171.29	32,769.30
Fluorouracil inj. 1g, 20 ml vial	241.14	1,128,294.06	1,550,289.06	421,995

Description	Unit Price (LKR)	Cost of medicines at CRU (LKR)	Cost of medicines at ward (LKR)	Cost deference (Ward-CRU) (LKR)
Gemcitabine hydrochloride inj.1 g	618.46	1,455,854.84	1,812,087.80	356,232.96
Gemcitabine hydrochloride inj.200 mg	176.98	58,403.40	60,527.16	2,123.76
Iposphomide 1 g	1,733.51	1,078,243.22	1,203,055.94	124,812.72
Melphalan injection 50 mg powder	5,000.00	10,000.00	10,000.00	0.00
Mesna injection 200 mg in 2ml	68.00	78,812.00	84,116.00	5,304.00
Mesna injection 200 mg in 2ml	68	5,644.00	5,916.00	272.00
Methotrexate injection 1 g vial	1,707.85	81,976.80	852,217.15	770,240.35
Mitomycin injection 2 mg vial	1,528.91	506,069.21	637,555.47	131,486.26
Oxaliplatin injection 100 mg vial	913.49	1,347,397.75	1,866,260.07	518,862.32
Oxaliplatin injection 50 mg vial	534.85	62,042.60	69,530.50	7,487.90
Paclitaxel injection 30 mg/5 ml vial	426.78	4,310,051.22	4,602,395.52	292,344.30
Paclitaxel injection 260 mg	5,000.00	3,710,000.00	5,235,000.00	1,525,000.00
Paclitaxel Nanoparticle Inj300 mg	87,921.91	527,531.46	703,375.28	175,843.82
Trastuzumab Injection 440 mg	148,023.97	167,918,391.60	234,469,968.50	66,551,576.91
Vinblastine Sulphate Inj. 10 mg vial	532.61	93,739.36	112,913.32	19,173.96
Vincristine sulphate injection 1 mg vial	84.86	100,813.68	142,140.5	41,326.82
Vinorelbine Injection10 mg Vial	12,000.00	12,000.00	12,000.00	0.00
Total		194,823,855.50	269,042,059.10	74,218,203.60



**Table 3: Total required quantity, total quantity used at CRU and quantity required for reconstitution at ward at NHK in 2019**

Drug name	Total required quantity (mg)	Total quantity used at CRU (mg)	Quantity required for reconstitution at ward (mg)
Actinomycin D	0.5	0.5	0.5
Asparaginase	264,460	290,000	330,000
Bleomycin sulphate	5,439	5,595	6,090
Carboplatin	1,034,842	1,042,200	1,407,150
Cisplatin injection	162,116	166,900	207,700
Cyclophosphamide	2,271,973	2,315,200	2,772,000
Cytarabine	66,832	71,700	95,700
Dacarbazine	184,825	188,200	215,800
Daunorubicin HCl	5,545.5	5,720	6,240
Docetaxel injection	99,741	107,120	141,320
Doxorubicin HCl	108,868	108,880	122,150
Epirubicin hydrochloride	59,361.5	66,220	71,060
Etoposide	94,784.5	101,700	120,700
Fluorouracil	4,607,214	4679,000	6,429,000
Gemcitabine hydrochloride	2,443,751	2,459,000	2,998,400
Iposphomide	633,395	622,000	694,000
Melphalan	2	100	100
Mesna	24,004,8.45	248,400	264,800
Methotrexate	47,423.8	48,000	499,000
Mitomycin	833	834	834
Oxaliplatin	151,292.3	153,300	210,800
Paclitaxel	492,955.5	497,690	598,140
Trastuzumab	499,136	499,136	696,960
Vinblastine Sulphate	1,474.85	1,760	2,120
Vincristine sulphate	1,567.108	1,223	1,675
Vinorelbine	2	10	10
Total	13,237,534.56	13,679,888.5	17,891,749.5

**Table 4: Medicine wastage reduction by centralised reconstitution at NHK in 2019**

Name of the medicine	Medicine wastage by centralised reconstitution (mg)	Medicine wastage by ward reconstitution (mg)	Medicine wastage reduction (mg)
Actinomycin D	0	0	0
Asparaginase	25540	65540	40000
Bleomycin sulphate	156	651	495
Carboplatin	7358	372308	364950
Cisplatin	4784	45584	40800
Cyclophosphamide	43227	500027	456800
Cytarabine	4868	28868	24000
Dacarbazine	3375	30975	27600
Daunorubicin HCl	174.5	694.5	520
Docetaxel injection	7379	41579	34200
Doxorubicin HCl	12	13282	13270
Epirubicin hydrochloride	6858.5	11698.5	4840
Etoposide	6915.5	25915.5	19000
Fluorouracil	71786	1821786	1750000
Gemcitabine hydrochloride	15249	554649	539400
Iposphomide	-11395	60605	72000
Melphalan	98	98	0
Mesna	8351.55	24751.55	16400
Methotrexate	576.2	451576.2	451000
Mitomycin	1	1	0
Oxaliplatin	2007.7	59507.7	57500
Paclitaxel	4734.5	105184.5	100450
Trastuzumab	0	197824	197824
Vinblastine Sulphate	285.15	645.15	360
Vincristine sulphate	-344.108	107.892	452
Vinorelbine	8	8	0
Total	202005.492	4413866.49	4211861

**Table 5: Adjusted total cost saving and total medicine wastage reduction comparing CRU and wards at NHK in 2019**

Total cost of medicines reconstituted at CRU (LKR)	193,865,655.00
Total cost of medicines reconstituted at ward (LKR)	267,696,862.60
Total cost saving by CMR (LKR)	73,831,207.61
Adjusted total medicine wastage at CRU (mg)	213,744.60
Adjusted total medicine wastage at ward (mg)	4,353,153.60
Adjusted total medicine wastage reduction by centralised reconstitution (mg)	4,139,409.00

## Dermatological manifestations among patients with COVID-19: The Sri Lankan experience

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### Abstract

**Background:** Patients diagnosed with COVID-19 demonstrate a wide spectrum of cutaneous manifestations, some of which are at a high prevalence. These manifestations, of which some are unique, have been considered to occur due to COVID-19 infection and the associated inflammatory response. Furthermore, there are reports on exacerbation of previously diagnosed dermatoses and cutaneous side effects of medications and vaccines administered.

**Methodology:** The first phase of the study included a descriptive cross-sectional study conducted at the National Hospital of Sri Lanka (NHSL) among PCR-positive COVID patients to identify their skin conditions. Secondly, to ascertain an overall understanding of the country's situation, a comprehensive questionnaire was circulated among the members of the Sri Lanka College of Dermatologists, to obtain information on the patients they have encountered.

**Results:** Out of the patients at NHSL only 1.7% (n=8) had developed associated skin manifestations. Two (0.4%) developed novel conditions: thrombophlebitis and a maculopapular exanthem. Six (1.3%) patients had exacerbation of pre-existing conditions including eczema, psoriasis and discoid lupus erythematosus. The dermatologists revealed a wide variety of manifestations with the majority experiencing an exacerbation of pre-existing conditions and a few developing novel lesions including COVID-toes and Kawasaki-like diseases in children which are considered specific for COVID-19.

**Conclusions:** The study demonstrates a range of COVID-19-associated dermatoses. These can present before or with other COVID-19 symptoms. Further, studies are necessary to precisely determine the timing and pathophysiology of different manifestations. Dermatological findings are important and should prompt the early involvement of dermatologists as appropriate.

**Keywords:** COVID-19, Cutaneous Manifestations, Sri Lanka

### Background

COVID-19 is considered a multisystem disorder. An increasing number of cases related to dermatological manifestations have been reported [1]. The published data describe a complex range of skin manifestations

associated with the infection [2]. The first patient was described in Thailand in early 2020 as having a petechial rash similar to dengue fever [3]. There is a wide variation in the prevalence of skin lesions associated with COVID-19 infection. A large-scale study

in China including 1099 COVID-19-positive cases had only 0.2% developing dermatological manifestations, while a series of 88 patients in Italy reported a high prevalence of skin manifestations of 20.4% [4].

As new information gathers, distinct cutaneous patterns are being linked to COVID-19. They develop at different stages in the disease course and are associated with unique durations, different degrees of severity, and prognosis [5]. Especially with ongoing vaccination programs and the emergence of new variants, the number of patients without typical symptoms of COVID-19 is increasing and certain dermatological manifestations may point towards an early diagnosis of COVID [2]. It is unclear whether the cutaneous manifestations of COVID-19 are a direct consequence of an aberrant immune response or due to the inherent pathogenesis of the disease itself [6]. These lesions are recognized less, due to the lack of routine dermatology consultations during the pandemic [2]. It remains to be determined whether COVID-19 infection can directly cause a worsening of pre-existing chronic inflammatory diseases such as psoriasis or atopic dermatitis. However, there exists a large body of evidence that shows exacerbations are due to the disruption of routine treatment of such skin conditions [7].

The drug regimens used for the treatment of COVID-19 patients could result in cutaneous adverse effects or aggravation of previous dermatological disorders [3]. Generalized pustular reaction and worsening of psoriasis due to hydroxychloroquine are widely reported [8]. The immune response against the virus may enhance drug allergy. The concomitant excessive production of proinflammatory cytokines may be a contributing factor [9]. The frequently linked medication-related dermatoses in COVID-19 are erythema-multiforme-like patterns, generalized pustular erythema and Stevens-Johnson Syndrome [10].

In some cases, skin manifestations may help identify asymptomatic COVID-19 carriers or in others, predict a more severe disease [10]. Chilblains are reported more frequently in younger

patients and seem to predict a milder disease. Fixed livedo reticularis and retiform purpura appear in older patients and tend to predict a worse prognosis [10].

The patterns of cutaneous manifestations can be classified into the following: exanthema (varicella-like eruption, papulovesicular, and morbilliform eruption), vascular (similar to chilblain, livedoid and purpuric lesions), urticarial and acral-papular eruptions [7,8,10-14]. Overall, vesicular lesions and pseudo-chilblain which is commonly recognized as “COVID toe” may represent the most characteristic skin manifestations of COVID-19 [2]. Maculopapular eruptions, urticaria and “COVID toe” (pernio-like lesions/ pseudo chilblains) are known as the most common mucocutaneous manifestations [15]. Out of the exanthema patterns, the “varicella-like” lesion is a specific and early skin manifestation and could signify useful evidence in asymptomatic or mildly symptomatic patients [16].

Dermatology’s outlook on the COVID-19 pandemic is multi-dimensional. It is important that clinicians are aware of the spectrum of COVID-19 skin manifestations, improving testing for the virus and clinical management [2]. While many countries have made scientific publications on dermatological manifestations, Sri Lanka has no documented evidence. This study was conducted to identify the prevalence, disease spectrum, and clinical behaviour, and to establish a link between dermatological manifestations and the severity of COVID-19.

## Methodology

The study was conducted in two phases. The first consisted of a descriptive cross-sectional study conducted at the National Hospital of Sri Lanka (NHSL) with the approval of the Ethics Review Committee of NHSL, where patients with RT-PCR positivity were examined for the development of novel dermatological manifestations, exacerbation of existing conditions and medication-related skin conditions. To achieve these targets, 476 patients

were screened within a period of two weeks at the NHSL COVID treatment units. These patients were followed up at two and four weeks after the initial screening via phone calls by questioning whether they have noticed any change on their skin during the period. Out of 476, 468 follow-up calls were answered by the patient or a family member. If they responded positively, a physical visit was arranged to identify the development of the dermatological condition. In the second phase, to obtain a broader view of the country's situation, a questionnaire was circulated among all dermatologists who are members of the Sri Lankan College of Dermatologists. This includes dermatologists stationed all over the country, working at both government and private sector hospitals. Fifty-two (65%) responded out of eighty dermatologists.

## Results

The study population at NHSL consisted of 476 RT-PCR-positive COVID-19 patients who were being treated in the hospital. The cohort consisted of 261 males with a male: female ratio of 1.2:1. During initial evaluation and follow-up for four weeks, eight patients (1.7%) reported skin manifestations and two patients (0.4%) developed novel dermatological manifestations. Out of the patients with new skin lesions, the first had thrombophlebitis in the left calf area which had developed during inward treatment for COVID-19. This had spontaneously subsided over a couple of days. The second patient developed a maculopapular exanthem towards the completion of fourteen days of COVID positivity. This patient complained of an itchy papular rash with ill-defined erythematous maculopapular eruption over both upper and lower extremities. The condition resolved over a couple of days with emollients and antihistamines.

Six patients (1.3%) had exacerbations of previously diagnosed dermatological conditions. Four of them (0.9%) experienced an exacerbation of eczema, mainly in the lower limbs and all of

them had discontinued their routine treatment due to a multitude of reasons after being diagnosed with COVID. All these patients were commenced on appropriate treatments. One case (0.2%) each with widespread discoid lupus erythematosus and psoriasis had mild exacerbations due to the stoppage of the immunosuppressive medication. Since the conditions were not disabling, treatment was re-commenced at the discharge from COVID treatment.

The expert opinion sought through dermatologists all over the country yielded many cases with a wide clinical variety. Acute urticaria was the commonest reported condition (n=9) with the majority (n=6) presenting after two weeks of the diagnosis of COVID and the other three developed while being treated at hospitals and intermediate COVID care centres. The condition had responded well to anti-histamines. The maculopapular eruption was another common lesion among patients (n=5). The majority have developed lesions during the early part of the illness. These were itchy lesions that were mostly in the extremities and associated with fever and cervical adenopathy in one case. Pityriasis rosea was seen among four patients. These patients have developed mildly itchy lesions with a scaly margin mainly involving the knees and forearms. Some did not have evidence of the classical herald patch. While the condition subsided with treatment, the lesions remained to a lesser degree during follow-up visits. A lesion similar to "COVID toes" that had developed 2-3 months after the diagnosis of COVID-19 was reported by one dermatologist. Diffused hair loss several months following the diagnosis of COVID was reported by one patient. The patient shown in Figure 01 presented with vesicular eruption mimicking varicella zoster infection within one week after being diagnosed to have COVID-19 infection. But in contrast to varicella zoster, there was no fever and the vesicles first appeared on the trunk and then spread to the limbs with only a few lesions on



the face. Tzanck smear was negative and lesions improved with supportive care. Other reported lesions included, exanthems (n=2), erythema multiforme (n=1), dermatomyositis (n=1), oropharyngeal candidiasis in a diabetic patient, miliaria rubra (n=1) and contact dermatitis due to face mask (n=1).

Dermatological manifestations have been reported among children who have tested positive as well. The “Kawasaki-like” disease, which is a well-known entity among children with COVID-19 had been reported by two dermatologists. Both of these children have developed periorbital swelling, conjunctival redness, blotchy erythema, tiny pustules over upper limbs and trunk, cervical lymphadenopathy, proximal muscle pain, nail fold telangiectasia and small joint swelling. Prior to the onset of fever one child had experienced acute urticaria as well. The same child went on to develop post-COVID multisystem inflammatory syndrome in children (MIS-C). Other lesions among the paediatric population included pityriasis rosea (n=2), erythematous nodules (n=2), petechial lesions (n=1) and vasculitic rashes (n=1).

The major proportion of patients diagnosed with COVID-19 that dermatologists have encountered was due to exacerbation of existing dermatological conditions. Exacerbation of psoriasis (n=10) was the commonest complaint among patients. Most of these exacerbations were due to withholding of routine medication, especially immunosuppressive treatment and not having access to regular treatment at intermediate centres and COVID home care. A few patients (n=3) with stable plaque psoriasis had gone on to develop severe erythrodermic psoriasis which has necessitated hospital admission and intensive treatment. There were no reports of overlapping cutaneous manifestations. The summary of the conditions developed with patient numbers is given in Table 1.

Medication usage and vaccination have also

contributed to dermatological manifestations. One patient had developed truncal acne after being treated by dexamethasone for severe COVID pneumonia and the other patient developed a large urticarial lesion on the back, 12 hours following the first dose of the AstraZeneca vaccine.

## Discussion

This study highlighted the wide spectrum of cutaneous manifestations described concurrently or after the diagnosis of COVID-19 in other studies [7]. Cutaneous manifestations of COVID-19 were reported late in the course of the pandemic and there was a paucity of literature illustrating dermatological presentations [17].

The prevalence of dermatological manifestations among patients with COVID-19 had a wide variation from 0.2 - 20.4% [4]. Among the patients at NHSL, 1.7% had developed either a novel skin manifestation or has experienced an exacerbation of a previously diagnosed condition.

A systematic review on the topic revealed that around 12% of the cutaneous manifestations occur before other COVID-19 signs, highlighting their importance in assisting in the detection of the infection [18]. Despite this, most studies have been unable to identify a correlation between dermatological manifestations and disease severity or establish a temporal relationship with the disease [11,18,19]. The current study population did not reveal any convincing evidence to suggest a correlation, mainly due to the non-specificity of the symptoms and the low proportion of affected patients (1.7%).

In dermatological practice, immunosuppressants are used for the management of autoimmune and inflammatory diseases such as psoriasis, atopic dermatitis, systemic lupus erythematosus, and dermatomyositis among many other conditions [14]. With the onset of COVID, these immunosuppressants are best withheld while maintaining the delicate balance between treating COVID and keeping the dermatological condition

under control. This decision should be based on a multitude of factors and the involvement of a dermatologist is important to avoid unnecessary morbidity to the patient.

The commonest morphologies among PCR-confirmed patients in other studies included morbilliform, pernio-like, urticarial, macular erythematous, vesicular, papulosquamous, and retiform purpura-like lesions. Perno-like lesions were considered to be more COVID-19-specific than other dermatologic manifestations. Such propensity towards certain lesions was not seen in this study and a mixture of various and rather non-specific conditions were noted in the cohort of patients. This highlighted the importance of vigilantly identifying skin lesions and treating them appropriately. A limitation of the survey conducted among the dermatologists was that some of the cutaneous manifestations may have

been undetected or not referred to a dermatologist due to practical issues.

## Conclusions

In conclusion, this study demonstrated a wide range of COVID-19-related dermatoses. These cutaneous manifestations can present before, concurrently or following other COVID-19 symptoms. Among the patients at NHSL, 1.7% had developed either a novel skin manifestation or experienced an exacerbation of a previously diagnosed condition. However, further studies are necessary to precisely determine the timing of cutaneous findings and to ascertain the pathophysiology behind different morphologies. It is important that dermatological findings should not be overlooked as signs of COVID-19 and should prompt the early involvement of dermatologists as appropriate.

## Author Declaration

**Author contributions:** JA and VJM contributed to the conceptualization and design of the study. All authors contributed to the acquisition and analysis of data. JA and VJM contributed to the data interpretation and writing of the manuscript. All authors read and approved the final manuscript.

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**Table 1: Summary of dermatological manifestations from both phases of the study**

Novel dermatological manifestations (Number of patients)	Novel dermatological manifestations among the paediatric population (Number of patients)	Exacerbation of previously diagnosed dermatological conditions (Number of patients)	Medication and vaccine-related dermatological manifestations (Number of patients)
<ul style="list-style-type: none"> <li>• Acute urticaria (9)</li> <li>• Maculopapular eruptions (5)</li> <li>• Pityriasis rosea (4)</li> <li>• Vasculitic rash (2)</li> <li>• Exanthems (2)</li> <li>• Erythema multiforme (1)</li> <li>• Blistering lesions (1)</li> <li>• Contact dermatitis (1)</li> <li>• Dermatomyositis (1)</li> <li>• COVID toes (1)</li> <li>• Miliaria rubra (1)</li> <li>• Thrombophlebitis (1)</li> <li>• Maculopapular eruptions (1)</li> </ul>	<ul style="list-style-type: none"> <li>• Kawasaki disease(2)</li> <li>• Pityriasis rosea (2)</li> <li>• Erythematous nodules (2)</li> <li>• Petechial lesions (1)</li> <li>• Vasculitic rash (1)</li> </ul>	<ul style="list-style-type: none"> <li>• Psoriasis (11)</li> <li>• Eczema (7)</li> <li>• Chronic urticaria (2)</li> <li>• Contact dermatitis (1)</li> <li>• Tinea incognito (1)</li> <li>• Fungal infections – Dermatophytosis (1), Candidiasis (1)</li> <li>• Venous ulcers (1)</li> <li>• Chronic paronychia (1)</li> <li>• Acne rosacea (1)</li> <li>• Pemphigus vulgaris (1)</li> <li>• Lepra reaction (1)</li> <li>• Alopecia areata (1)</li> <li>• Bullous disorders (1)</li> <li>• Discoid lupus erythematosus (1)</li> </ul>	<ul style="list-style-type: none"> <li>• Steroid-induced acne (1)</li> <li>• Urticarial lesions following vaccination (1)</li> </ul>



**Figure 01: Vesicular eruption mimicking varicella zoster infection**



# An assessment of the effectiveness of supervision in preventive healthcare institutions under the purview of the Regional Directorate of Health Services, Kalutara

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## Abstract

**Background:** Supervision is an essential element in primary healthcare. It is not only the number that matters but the quality and effectiveness of supervision as well. Ineffective supervision is a cause of poor performance that can lead to sub-optimal health outcomes.

**Objective:** To assess the effectiveness of supervision in preventive healthcare institutions under the administrative purview of the Regional Directorate of Health Services (RDHS), Kalutara

**Method:** A descriptive cross-sectional study was designed and carried out in all preventive sector healthcare institutions under the administrative purview of the RDHS, Kalutara. The entire population of the supervisors (Regional Director and Deputy Regional Director of Health Services, Consultant Community Physician, Medical Officer-Maternal & Child Health, Regional Epidemiologist, District Dental Surgeon, Supervisory Public Health Nursing Officers, Supervisory Public Health Inspector, Medical Officers of Health, Additional Medical Officers of Health, Supervisory Public Health Inspectors, Public Health Nursing Sisters, and Supervisory Public Health Midwives) and supervisees (Public Health Inspectors and School Dental Therapists) in the RDHS division except the Public Health Midwives (PHMs) was included in the study as their actual numbers are low. The selection of PHMs, the major category of supervisees, was subjected to random sampling. Self-administered questionnaires, focus group discussions, and observatory visits were used to collect the data. Data were analyzed both quantitatively and qualitatively. The effectiveness of supervision was assessed utilizing Manchester Clinical Supervision Scale (MCSS-26). Knowledge, attitudes, and practices of supervisors were assessed through a self-administered questionnaire and to some extent through observations.

**Results:** The overall response rate was 67.8%. The knowledge related to supportive supervision among the supervisors was moderate. The level of knowledge was not significantly different among the different categories of supervisors. The level of attitudes towards supervision was also moderate. However, it was significantly different among the supervisory categories. As per the scale devised through the questionnaire, the supervisory practice was moderate as well, but it was not significantly different among the different categories of supervisors. The mean score of MCSS-26 was 65.67 indicating that overall supervision was ineffective by its threshold limit of 73. Apart from the administrative function of supervision, the supportive and educational functions were largely ineffective.

**Conclusion and recommendations:** The effectiveness of supervision was suboptimal in preventive care health institutions of the RDHS division Kalutara. Appropriate measures that focused on enhancing supportive and educational functions of supervision are therefore required to improve the effectiveness of supervision among different categories of supervisors in the division. Designing and implementing more focused training and development activities to improve knowledge, attitude, and practices in supportive supervision; facilitating, encouraging, and empowering the supervisors to implement their post-supervisory recommendations; and utilizing the MCSS-26 as a tool of measuring supervisory effectiveness for the purpose of monitoring and evaluating the supervisory activities, are therefore recommended to improve the effectiveness of supervision in the division.

**Keywords:** Supervision, Effectiveness, Preventive Healthcare, MCSS-26

## Background

Supervision is a continuous process that guides, trains, and encourages workers to improve their skills and performance, so they can reach the expected quality and standards in healthcare delivery [1]. There are three basic functions of supervision; the administrative function that organizes the supervisees and their work to achieve the organizational objectives, the educational function that improves the knowledge and skills of the supervisees, and the supportive function that reduces job-related stresses and fosters the self-awareness of the workers to cope with their work [2].

In its simplest terms, supervision is overseeing the subordinates by competent and authorized personnel. In contrast to traditional practices that are characterized by authoritarian type of attitudes and behavior, the contemporary practices of supervision are characterized by shared performance, goal setting, mentoring, and open communication [3]. While traditional practices are often criticized for their failures in sustaining employee motivation and satisfaction, contemporary practices are praised for their ability to improve them. Nevertheless, contemporary practices are preferred by workers as they are more responsive to realities [4].

The term 'effectiveness' refers to the extent to which a specified intervention, procedure, or service

does what it intends to do for a specified population [5]. Effective supervision is expected to provide not only a conducive environment for workers to reflect on their practices but also to develop the required skills and knowledge [6] for better performance. Thus, the effectiveness of supervision refers to the extent to which supervision can achieve those attributes under given circumstances. Factors that affect the effectiveness of supervision are diverse and multitude. A good understanding of the local contexts, supervisor-supervisee relationship, constructive feedback, scheduled supervisions, knowledge and skills of the supervisors, nature of assessment, approach to counseling, and career guidance to supervisees are among them [7]. According to Mor-Barak et al., task assistance, social and emotional support, and interpersonal interactions are significantly associated with beneficial outcomes for the supervisees. However, the same factors can be detrimental if they are not effectively met [8].

Supervision improves the quality of healthcare by enhancing skills and performance. It is an intervention that helps to sustain optimum healthcare delivery by enabling and empowering the workers. However, Avortri et al., argued that supervisions in low-income countries are suboptimal, unsupportive, and demotivating [9]. Bosch-Capblanch et al., observed that compared to no supervision, supervision has relatively a minor or no impact on health workers' knowledge



or practice implying that supervision in primary healthcare (PHC) is presumably not as effective as one would expect [10]. Therefore, intervening to improve the effectiveness of supervision in PHC is needed. However, understanding what constitutes effectiveness is important before intervening [11].

The establishment of 'Health units' to provide preventive healthcare for the Sri Lankan community started way back in 1926. The first unit was established in Kalutara [12]. Since then, the preventive healthcare system in a district evolved to the present organization as illustrated in Figure 1.

The health unit in contemporary settings is known as the Medical Officer of Health (MOH) division. It covers a well-defined geographic area that coincides with the politico-administrative division of the country at the level of the Divisional Secretariat. The office, which is headed by a Medical Officer (MO), serves an approximate population of 60,000-100,000 with a core team comprising Public Health Midwives (PHM) and Public Health Inspectors (PHI) accompanied by Public Health Nursing Sisters (PHNS) and Supervisory Public Health Inspectors (SPHI) as supervisors. There are 353 MOH offices across 25 districts on the Island [13]. There are thirteen MOH offices under the purview of the Regional Directorate of Health Services in the Kalutara district. The approximate population assigned to each office varies from 37,000 to 137,000 people depending on the population density of the area [14]. The cadre distribution of the preventive sector in the district is illustrated in Table 1.

Supervision in the preventive health sector is hierarchical. The district supervisors are supposed to supervise the divisional supervisors, who in turn are supposed to supervise the field officers under them. All the preventive sector health institutions of a district generally come under the administrative and technical purview of an RDHS office at the district level.

Supervision is an essential element in primary healthcare. It is not only the number that matters but the quality and effectiveness of supervision as well. Ineffective supervision is a cause of poor performance [11] that can lead to sub-optimal health outcomes. The supervisors are more focused on technical matters of supervision than non-technical elements that help to improve its effectiveness [15]. Thus, the ineffectiveness of supervision has always been a concern in primary healthcare (PHC). Ineffectiveness and poor quality of supervision significantly affect the optimal outcomes of family health services [15]. However, the effectiveness of supervision in the Kalutara RDHS has not been assessed in previous studies.

## Objective

The objective of this study was to assess the effectiveness of supervision in preventive healthcare institutions under the administrative purview of the RDHS office, Kalutara.

## Methodology

A descriptive cross-sectional study was designed and carried out in the Kalutara district covering all preventive sector healthcare institutions that come under the administrative purview of the RDHS Office. The ethical clearance of the study was obtained from the Ethics Review Committee of the Postgraduate Institute of Medicine, Colombo and the administrative approval was obtained from the respective provincial and regional health authorities.

The entire population of the selected categories in the division that get involved in the process of supervision (i.e., both supervisors and supervisees other than the PHMs), was included in the study. The selection of PHMs was subjected to random sampling because their population is large compared to all other categories. The sample size was calculated for the finite population of PHMs at a 95% confidence level with a 5% margin of error. The entire population of PHMs was framed and then subjected to random selection. Therefore,

the estimated sample comprised 9 regional level supervisors (i.e., RDHS, DRDHS, CCP, MO-MCH, RE, DDS, SPHNO, SPHID), 64 divisional level supervisors (i.e., MOHs, AMOHs, SPHNSs, SPHMs, and SPHIs), and 265 supervisees (i.e., PHMs, PHIs, SDTs). Two sets of self-administered questionnaires (one for the supervisors and one for the supervisees), three structured focus group discussions (FGDs) aiming to gain insight into the factors that can affect the effectiveness of supervision from the viewpoint of administrators (i.e., RDHS and DRDHS), supervisors (i.e., CCP, MO-MCH, RE, DDS, SPHNO, SPHID, MOHs, AMOHs, PHNSs, SPHMs, and SPHIs), and supervisees (i.e., PHMs, PHIs, and SDTs), and several observatory visits were used to gather the required data. Administrators and regional supervisors were selected entirely while divisional supervisors and supervisees were selected randomly. Data were analyzed both quantitatively and qualitatively. The effectiveness of supervision was assessed by utilizing the modified Manchester Clinical Supervision Scale (MCSS-26) [16]. The MCSS-26 is a scale with 26 items in which 9, 10, and 7 items can be devoted to measuring the attributes related to administrative, supportive, and educational functions of supervision respectively. The total score of the scale is 104 and a score of more than 73 (approximately 70%) is considered as the threshold for effectiveness. The effectiveness assessment of each function was done against the best expected. The expected best in each in category was 36, 40, and 28 respectively. Being on par with the cutoff point of the overall scale, the same percentage (70%) was considered as the cutoff point of effectiveness in each supervisory function as well.

Manchester Clinical Supervision Scale (MCSS) is designed to measure the supervisees' perceptions of supervisory effectiveness [17]. Originally developed by Winstanley, J. [18], it is now believed to be the longest-established, internationally validated research questionnaire

to measure the effectiveness of supervision in healthcare [16].

The knowledge, attitude, and practice of the supervisors were assessed using a scale developed to measure each attribute. The knowledge assessment was done by using 15 true/false statements while a 5-response Likert scale of 12 and 20 items respectively was used to assess the attitude and practice. The threshold values are indicated in the respective tables of data presentation. Since the scale was developed by the author, it was validated by expert opinion and pilot testing.

## Results

The response rate for the supervisors' questionnaire was 70.3% (n=45, N=64) whilst it was 67.1% (n=178, N=265) for the supervisees' questionnaire. The overall response rate of the questionnaires was therefore 67.8% (n=223, N=329). The response rate of the FGDs was 100%.

## Quantitative findings

The SPHIs had the lowest average score of knowledge 10.8 (SD:1.64) in supportive supervision while the AMOHs had the highest average score of 12.57 (SD:1.01). The level of knowledge among the supervisors, in general, was moderate with an average score of 12.18 with an SD of 1.43 (Table 2). There was no statistically significant association between the level of knowledge and the category of the supervisor ( $p=0.39$ ) (Table 3). The level of attitudes was moderate among the supervisors having an average score of 30.33 with an SD of 3.45 (Table 4). The MOHs had the highest average score ( $\bar{x}=31.33$ ,  $SD=3.28$ ) while SPHIs had the lowest ( $\bar{x}=27.80$ ,  $SD=7.69$ ). There was a statistically significant association between the level of attitudes and the category of the supervisor ( $p=0.001$ ), the senior-level supervisors tend to have better attitudes than the junior-level supervisors (Table 5).

The practice of supervision among the supervisors was moderate with an average of 57.91 having an SD of 5.69 (Table 6). The MOHs had the lowest average ( $\bar{x}$ =54.78, SD=6.38) while SPHMs had the highest ( $\bar{x}$ =61.80, SD=4.92). There was no statistically significant association between the level of practice and the category of supervisor ( $p$ =0.536) (Table 7).

The effectiveness of supervision and its functions (administrative, supportive, and educational) were assessed using MCSS-26 (Table 8). The threshold value of effectiveness of supervision was considered 73 based on the postulations made by its authors [16]. The Cronbach's alpha of the MCSS-26 scale was 0.821 in this assessment indicating a higher scale reliability.

The mean score of MCSS-26 in the study sample was 65.67 (SD=8.49) and it indicated that supervision was by and large ineffective by the threshold limit of 73. Although the mean score of the administrative function was almost 79% ( $\bar{x}$ =28.41) of the best expected ( $\bar{x}$ =36), the mean score of the other two functions, supportive and educational, were 55.5% ( $\bar{x}$ =22.2) and 55.1% ( $\bar{x}$ =15.43) respectively. It implied that apart from the administrative function, the supportive and educational functions of supervision were ineffective.

The correlations between the MCSS score and the level of perceived competency ( $r$ =0.866), motivation ( $r$ =0.778), and satisfaction ( $r$ =0.807) among the supervisees were strongly positive and significant (Table 9). It was also found that the correlations between the outcomes of supervision were strongly positive and significant ( $r$ >0.722) implying that the effective supervision was positively associated with the levels of competency, motivation, and satisfaction of the supervisees.

Although the correlations between the administrative functions of supervision and

its outcomes were positive, the associations were weak and mostly statistically insignificant ( $r_1$ =0.214,  $p_1$ =0.004;  $r_2$ =0.123,  $p_2$ =0.102;  $r_3$ =0.115,  $p_3$ =0.126). Contrarily, the associations between the other two functions, namely, supportive and education, and the outcomes of supervision were strongly positive and statistically significant ( $r_4$ =0.750,  $p_4$ <0.001;  $r_5$ =0.732,  $p_5$ <0.001;  $r_6$ =0.750,  $p_6$ <0.001;  $r_7$ =0.683,  $p_7$ <0.001;  $r_8$ =0.613,  $p_8$ <0.001;  $r_9$ =0.664,  $p_9$ <0.001). These findings implied that in contrast to the administrative function of supervision, the supportive and educational functions of supervision were significantly associated with positive outcomes of supervision (Table 10).

### Qualitative Findings

In the focus group discussions, all the participants in all three groups, namely, administrators, supervisors, and supervisees, agreed that supervision should be an integral part of primary healthcare. Additional responsibilities vested upon the supervisors often tend to compromise the supervisory activities. Therefore, supervisors frequently adjust their supervisory schedules to those additional responsibilities. Although the supervisors prefer to have uninformed visits, such practices often put supervisees in agony as they have no time to get prepared for supervision. The selective supervision which was frequently adopted by some of the supervisors also worried the supervisees as much as they do in uninformed supervisory visits. Because uninformed visits are often perceived by the supervisees as a strategy of the supervisors who try to find some fault with them.

It was stressed that stereotype supervision provides no room for innovation. Conventional supervisory checklists are time-consuming and less productive. Worsening the facts, the vacant posts of supervisors, particularly the SPHMs, compromised the hierarchical supervision. It has led the PHMs to perceive that they were

insufficiently and/or negatively assessed during the supervisory sessions.

Insufficient peer support and lack of coordination among the supervisors often instigate repetitions and overlapping of supervisions. It was emphasized that regional supervisors were not keen on post-supervisory recommendations and suggestions made by the divisional supervisors.

Further emphasis was placed on the fact that some divisional supervisors had not gone through refresher training despite the regional office's best efforts to make sure that everyone does. This has occurred because it is not practical to call each divisional supervisor for training at once.

Amidst all the challenges, the 'Team supervision' which was adopted by the regional officers as a measure to overcome the resource constraint, was praised by the supervisees.

During the field visits, it was observed that the general approach to supervision was not satisfactory on many occasions. The supervisor-supervisee relationship was more formal and technical in most of the supervisory sessions. The supervisors rarely exhibited satisfactory leadership qualities during their supervision. This evaluation was based on an observation checklist that highlighted the supervisor's overall approach to supervision, their relationship with the supervisees while supervising them, the leadership skills of the supervisors, their emotional intelligence, and the managerial duties carried out by them. They were not emotionally intelligent enough to understand the true needs of the supervisees. Supervisors tend to pay more attention to technical aspects of supervision than the managerial functions that are required to energize and motivate the subordinates to run the extra mile go above and beyond.

## Discussion

It is worthwhile to note that the higher scale reliability of the MCSS-26 provided some statistical evidence to justify its applicability to local settings. Although it has not been widely utilized in local settings before, it has been recommended for a variety of health settings including fieldwork.

The MCSS-26 score failed to reach the threshold limit of 73 as postulated by Winstanley and White [19]. It indicated that the supervisions were largely ineffective at the divisional level. Except for the administrative function of supervision, the other two functions (supportive and educational) were mostly ineffective. Convincing evidence emerged from the FGDs to assume that supervisors were more focused on technical matters of supervision than non-technical elements that improve effectiveness. This finding was consistent with the observations made by Kaushalya and Mapitigama [15]. As they suggested, by and large, the supervisions in the preventive sector are authoritative, mechanical, and non-responsive. Moreover, Samaraweera et al., [20] who studied the quality of interactions between the PHNSs and the PHMs during supervision reported similar and consistent findings.

Just like it was hypothesized, this study found that the effectiveness of supervision was positively associated with the outcomes of supervision. Nevertheless, the supervisory functions were also positively associated with the competency, motivation, and satisfaction of the supervisees.

Although the average level of knowledge among the supervisors was categorized as moderate based on the set limits, the other supervisory categories scored relatively higher average scores in the knowledge compared to SPHIs. However, there was no statistically significant association between the level of knowledge and the category of service ( $p=0.484$ ) to conclude that one category of supervisors was more adequately knowledgeable than another to

do the supervision.

The attitude score of the supervisors was 30.33 (out of 48) with an SD of 3.45. The practice score was 57.91 (out of 80) with an SD of 5.69. Therefore, those attributes need improvements. The attitudes of the supervisors were significantly different ( $p=0.001$ ) from one category to another. However, such a difference was not observable in their practices ( $p=0.589$ ). Therefore, a more focused approach is required to improve the attitudes and practices of the institutional supervisors.

### Conclusion and recommendations

Supervision is a process that should deal with the needs, competencies, expectations, and philosophies of both supervisors and supervisees. The goal of supervision, therefore, should be the

professional growth as well as the development of individual workers which will result in optimized care in the end. Therefore, the effectiveness of supervision is an essential requisite for improving primary healthcare. This assessment found that the effectiveness of supervision was suboptimal in RDHS division Kalutara and, therefore, needs improvements. Designing and implementing more focused training and development activities on improving knowledge, attitude, and practices in supportive supervision among the supervisors; facilitating, encouraging, and empowering the supervisors to implement their post-supervisory recommendations; and utilizing the MCSS-26 as a tool for measuring supervisory effectiveness of the supervisors, are therefore recommended to improve the effectiveness of supervision in the division.

### Author declaration

**Author contributions:** All authors contributed to conceptualizing, designing, and carrying out the study.

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**Ethics approval:** Ethics approval was obtained from the Ethics Review Committee of the Postgraduate Institute of Medicine, Colombo.

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**Table 1: Public health workforce of the Regional Directorate of Health Services division, Kalutara**

District Officers/Supervisors	Number	Institutional Officers	Number
Regional Director	01	<b>Supervisors</b>	
Deputy Regional Director	01	Medical Officer of Health	13
Consultant Community Physician	01	Additional Medical Officer of Health	19
Regional Epidemiologist	01	Public Health Nursing Sister	16
Medical Officer of Maternal & Child Health	01	Supervising Public Health Midwife	07
District Dental Surgeon	02	Supervising Public Health Inspector	09
Supervising Public Health Nursing Officer	01	<b>Supervisees</b>	
District Supervising Public Health Inspector	01	Public Health Midwife	290
		Public Health Inspector	72
		School Dental Therapist	16
<b>Total</b>	<b>09</b>		<b>442</b>

**Table 2: The knowledge related to supportive supervision of the supervisors**

Category of Supervisor	Knowledge score						
	Mean	SD	95% CI	Score range		Possible range	
				Min	Max	Min	Max
MOH	12.56	1.74	11.42 – 13.69	10	15	0	15
AMOH	12.57	1.01	12.04 – 13.09	11	15		
PHNS	12.00	1.53	11.13 – 12.86	10	14		
SPHM	12.20	0.84	11.46 – 12.93	11	13		
SPHI	10.80	1.64	9.36 – 12.23	08	12		
All	12.18	1.43	11.76 – 12.59	08	15		

**Table 3: The association between the level of knowledge and the category of service**

Category of Supervisor	Level of knowledge			Total	Test Statistics
	Low <sup>1</sup>	Moderate <sup>2</sup>	High <sup>3</sup>		
MOH	1	4	4	9	Fishers's exact test 7.924 p = 0.39
AMOH	0	6	8	14	
PHNS	2	5	5	12	
SPHM	0	3	2	5	
SPHI	1	4	0	5	
Total	4	22	19	45	
<sup>1</sup> Low (0-10), <sup>2</sup> Moderate (11-13), <sup>3</sup> High (14-15)					

**Table 4: Attitudes related to supportive supervision of the supervisors**

Category of Supervisor	Attitude score						
	Mean	SD	95% CI	Score range		Possible score	
				Min	Max	Min	Max
MOH	31.33	3.28	29.18 – 33.47	27	36	12	60
AMOH	30.50	1.78	29.56 – 31.43	27	33		
PHNS	30.42	3.20	28.61 – 32.23	25	35		
SPHM	30.40	1.14	29.40 – 31.39	29	32		
SPHI	27.80	7.69	21.06 – 34.54	20	40		
All	30.33	3.45	29.32 – 31.33	20	40		

**Table 5: The association between the level of attitudes and the category of service**

Category of Supervisor	Level of attitudes			Total	Test Statistics
	Low <sup>1</sup>	Moderate <sup>2</sup>	High <sup>3</sup>		
MOH	0	9	0	9	Fishers's exact test 14.302 p = 0.001
AMOH	0	14	0	14	
PHNS	0	12	0	12	
SPHM	0	5	0	5	
SPHI	2	2	1	5	
Total	2	42	1	45	

<sup>1</sup>Low (0-24), <sup>2</sup>Moderate (25-36), <sup>3</sup>High (37-48)

**Table 6: The practice of supportive supervision among the supervisors**

Category of Supervisor	Practice score						
	Mean	SD	95% CI	Score range		Possible range	
				Min	Max	Min	Max
MOH	54.78	6.38	50.61 – 58.94	46	64	20	100
AMOH	57.43	5.64	54.47 – 60.38	48	67		
PHNS	59.08	4.94	56.28 – 61.87	52	66		
SPHM	61.80	4.92	57.48 – 66.11	54	66		
SPHI	58.20	5.80	53.11 – 63.28	50	64		
All	57.91	5.69	56.24 – 59.57	46	67		

**Table 7: The association between the level of supervisory practice and the category of service**

Category of Supervisor	Level of supervisory practice			Total	Test Statistics
	Low <sup>1</sup>	Moderate <sup>2</sup>	High <sup>3</sup>		
MOH	2	7	0	9	Fishers's exact test 6.409 p = 0.536
AMOH	1	12	1	14	
PHNS	0	11	1	12	
SPHM	0	4	1	5	
SPHI	1	4	0	5	
Total	4	38	3	45	
<sup>1</sup> Low (0-50), <sup>2</sup> Moderate (51-65), <sup>3</sup> High (66-80)					

**Table 8: Scores of MCSS-26 by the function of supervision and the category of supervisee**

Function of supervision/Category of supervisee	Range of the scale	Mean	SD	Range	95% CI	
					Lower bound	Upper bound
<b>MCSS-26 (Total)</b>		65.67	8.49	34-89	64.42	66.93
- PHM	0-104	64.97	8.97	34-89	63.40	66.54
- PHI		67.82	6.27	55-83	65.94	69.71
- SDT		64.40	11.5	52-76	50.12	78.68
<b>Administrative</b>		28.41	4.30	16-34	27.40	28.68
- PHM	0-36	28.41	4.30	16-34	27.66	29.17
- PHI		26.73	4.32	19-34	25.43	28.03
- SDT		30.20	1.79	28-33	27.98	32.42
<b>Supportive</b>		22.20	5.29	10-38	21.42	22.99
- PHM	0-40	21.67	5.32	10-38	20.74	22.60
- PHI		23.93	4.77	14-35	22.50	25.37
- SDT		20.20	6.68	13-27	11.90	28.50
<b>Educational</b>		15.43	3.59	07-27	14.90	15.96
- PHM	0-28	14.88	3.58	07-27	14.26	15.51
- PHI		17.16	2.93	11-23	16.28	18.04
- SDT		14.00	5.00	09-19	07.79	20.21

**Table 9: Statistical association between the MCSS-26 score and the three outcomes of supervision**

		Outcomes of supervision		
		Competency	Motivation	Satisfaction
<b>MCSS-26 score</b>	Pearson r	0.866*	0.778*	0.807*
	Significance	0.000	0.000	0.000
n=178				
*Correlation was significant at 0.01 level (2-tailed)				

**Table 10: Correlation between the function and the outcomes of supervision**

Function of supervision		Outcome of supervision		
		Competency	Motivation	Satisfaction
Administrative	Pearson r	0.214* (r <sub>1</sub> )	0.123* (r <sub>2</sub> )	0.115* (r <sub>3</sub> )
	Significance	0.004 (p <sub>1</sub> )	0.102 (p <sub>2</sub> )	0.126 (p <sub>3</sub> )
Supportive	Pearson r	0.750* (r <sub>4</sub> )	0.732* (r <sub>5</sub> )	0.750* (r <sub>6</sub> )
	Significance	0.000 (p <sub>4</sub> )	0.000 (p <sub>5</sub> )	0.000 (p <sub>6</sub> )
Educational	Pearson r	0.683* (r <sub>7</sub> )	0.613* (r <sub>8</sub> )	0.664* (r <sub>9</sub> )
	Significance	0.000 (p <sub>7</sub> )	0.000 (p <sub>8</sub> )	0.000 (p <sub>9</sub> )
n=178				
*Correlation was significant at 0.01 level (2-tailed)				

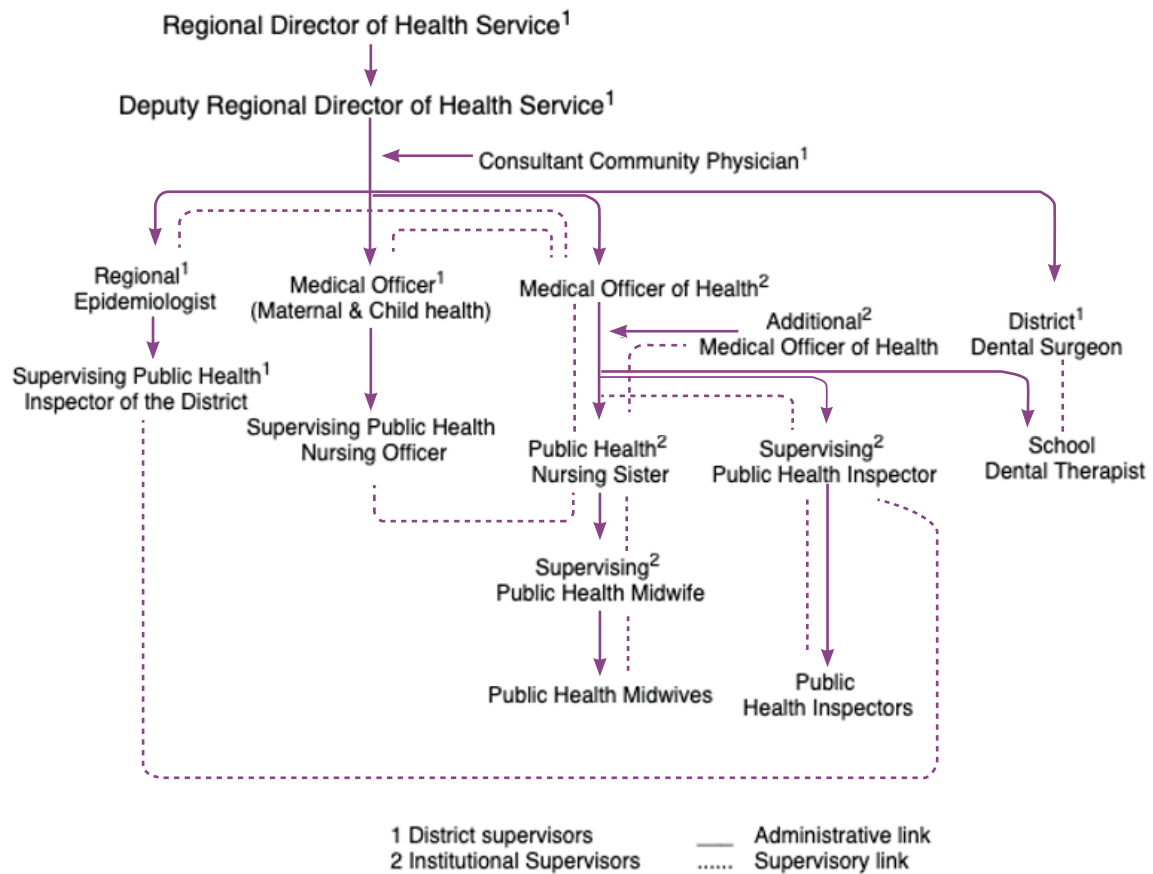


Figure 1: Organization of the district preventive healthcare system

## Development of a complex intervention package for dengue prevention

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### Abstract

**Introduction :** Complex interventions are widely used in public health practices with noteworthy health impacts. Communication for Behavioural Impact (COMBI) plan is an effective method directed at enacting behaviour change to benefit health and social development which encourage precise behavioural outcomes and is effective in planning a behavioural change for dengue control. The aim of this study was to develop an intervention package to change the behaviour to prevent dengue in one of the highest dengue-endemic areas of Sri Lanka.

**Methods:** The development of the intervention package was formulated according to the two phases, the 'Theoretical phase' and 'Modelling phase' of the framework for 'Developing and Evaluating Complex Interventions'. World Health Organization's 10 key steps in planning COMBI strategies were followed in order to develop the present intervention package. A situational market analysis was conducted in the highest dengue-endemic area in Kurunegala district to identify the Specific Behavioural Objectives (SBOO) for the COMBI plan. The development of the COMBI plan was conducted using the mixed methodological approach including quantitative and qualitative designs.

**Results:** The overall goal of the COMBI plan was to decrease the morbidity and mortality due to dengue illness by improving the dengue prevention behaviours among householders. The SBOO for the plan were to improve the proper waste management practices according to the '3R concept' (Reduce, Reuse and Re-cycling) and to improve the dengue prevention practices by 30 minutes of weekly cleaning. The strategies of intervention package were to conduct a community empowerment program to improve household waste management and weekly practices on dengue prevention by conducting administrative mobilization and public relationship, public advocacy, community mobilization, personal selling, advertising, and point of service promotion during follow-up.

**Conclusion:** Developing a COMBI plan for an area after the identification of SBOO would be feasible to implement in order to empower the community to prevent dengue and improve community health services.

**Keywords:** Complex interventions; dengue; behaviour; waste management; COMBI



## Introduction

Dengue is a vector borne viral infection which is transmitted by a bite of an infected *Aedes* mosquito. It has become a major health problem globally as well as locally. Both tropical and sub-tropical areas of the world are affected by dengue illness. Dengue fever outbreaks have been documented in every continent except Antarctica [1]. Importantly, South-East Asian (SEA) region is one of the most seriously affected regions among the endemic areas globally [2]. Dengue is a leading public health problem in Sri Lanka which affects all 26 districts and all age groups [3,4]. The effect of dengue on Sri Lanka has been increasing in the last two decades. There was a 4.3-fold rise of cases in 2016 compared to 2010 during the same period. There were peaks of cases which coincided with monsoons. In 2016, Western province reported the highest number of Dengue Fever (DF) cases (43%; n=18186) and Gampaha (12121), Kurunegala (4889), Kalutara (4589), Batticaloa (3946), Ratnapura (3898), and Kandy (3853) were the other mostly affected areas. By the end of 2017, 180,000 people were affected due to the outbreak situation in Sri Lanka [5]. Of the 26 districts in Sri Lanka, Kurunegala district has reported a drastic hike in the dengue cases during 2017, which was the most severe epidemic during last two decades. There were 167,198 reported dengue cases in the country by November 2017. Out of the total, 10,087 cases were reported from Kurunegala district which was ranked fourth at the national level [4]. In 2017, the managing capacity of the district exceeded due to an unbearable number of dengue patients which became a disaster for the curative sector healthcare institutions in the Kurunegala district. Moreover, there was an interruption of reporting of cases to the epidemiology unit which led to the delay in preventive activities by the preventive sector healthcare institutions [6]. Even with the increasing knowledge and awareness about dengue prevention, many community members did not take necessary actions to address it.

Many strategies have been employed to tackle the outbreaks, but the key components of outbreak response are household and community level behavioural and social interventions. Moreover, leadership and planning for sustainable community participation, transfer of technical knowledge and skills in planning, and measures to ensure sustainability at each level are identified as key issues in dengue prevention. Many community-based dengue control programmes focus only to improve knowledge and to increase awareness assuming that there will be a change in behaviours. However, behavioural change is important in effective implementation of control activities to prevent and control dengue [2].

Complex interventions are widely used in public health practices. The three main stages can be identified in the development of a complex intervention packages including 'development of the intervention, piloting and evaluation of the effectiveness' [7-9]. The methodical development of the intervention using theory and a thorough description of the developed intervention will aid in its proper evaluation following implementation of the intervention. Importantly, other people would replicate the developed intervention. The behavioural interventions would focus on identifying key risk reduction actions at the household and community level to minimize negative health consequences. Moreover, the application of multiple approaches is essential to be included to achieve the success to ensure community-located outbreak prevention through achieving specific behavioural results [10]. A systematic review revealed that community mobilization programmes are effective interventions in reducing *Aedes aegypti* entomological indices [11]. Notably, multi-stakeholder partnership leads to achieve successful outcomes of the interventions. Furthermore, the importance of incorporating health education and capacity building for the development of the programmes

to prevent communicable disease is highlighted [12]. Therefore, there is a need to empower the community through multi-stakeholder participation to achieve a sustainable solution for dengue prevention and all steps to be taken to minimize the dengue burden by changing behaviour of the community members. Importantly, systematic development of a complex intervention with minimum risk of bias is currently needed and it needs to be culturally and geographically suited.

Communication for Behavioural Impact (COMBI) is defined as a methodological approach that cautiously combines a range of communication interventions implied to encourage people and families to implement and maintain healthy behaviours. It uses a managerial view to plan social mobilization and communication for behavioural impact in public health. The importance of social mobilization for prevention and control of dengue has gathered pace internationally in recent years. Furthermore, COMBI planning provides a comprehensive and innovative managerial perspective on planning social mobilisation and communication for behavioural impact, which is intended for programme managers to use in integrating interventions to effectively manage dengue. Moreover, to ensure sustainable dengue prevention, the COMBI plans should address the various at-risk populations and it needs to be adopted culturally [13]. Importantly, the COMBI theory encourages precise behavioural outcomes. Also, it is effective in planning a behavioural change for dengue control. Further, it is an important strategy for imposing behaviour change to benefit health and social development [2,10,14,15]. Notably, COMBI is a different approach which ensures the community mobilization, communication, and community participation into a single cohesive approach focused on behaviour to improve individual well-being which is an ideal tool for dengue prevention [2,16]. Furthermore, studies with scientifically

developed intervention packages for dengue prevention are insufficient. In this backdrop, to prevent the occurrence of dengue outbreaks the behaviour of the community needs to be changed. Thus, the development of an intervention for the prevention of dengue based on evidence was a timely need. Importantly, the results of this study would enable responsible authorities to strengthen control strategies to improve dengue prevention activities.

The aim of the study was to develop a complex intervention package to change the behaviour of the householders for dengue prevention in the Kurunegala district, Sri Lanka.

## Methods

A complex intervention process was formulated according to the 2008 guide and was modified with the revised framework of 'Developing and Evaluating Complex Interventions: New Guidance' [7-9]. This framework provides a guideline for using a stepped approach which separates different elements and for using the probable active component in developing the intervention. The development of the intervention package was formulated according to the two phases including 'Theoretical phase' and 'Modelling phase'.

Theoretical phase is to identify the evidence base and appropriate theory to gather relevant information to find out the effective intervention packages for dengue prevention. Thus, the facts for the theoretical phase were identified from various sources, including existing evidence. The modelling phase consists of the modelling process and outcomes assessment. The model of the present study was the COMBI theory to empower the community to change the behaviour and ensure sustainable dengue control. The World Health Organization's (WHO) 10 key steps in planning COMBI strategies were followed in order to develop the present intervention package [2,17,18]. Accordingly, a Situational Market Analysis for Communication Keys (SMACK) was conducted in the highest dengue endemic area

in the Kurunegala district (Kurunegala MOH area) to identify the Specific Behavioural Objectives (SBOO) for the plan after preparing preliminary behavioural objectives. The SBOO were finalized using the results of the SMACK which was conducted using mixed methodological approach including quantitative and qualitative methods.

### Quantitative study

A descriptive cross-sectional study was conducted in the highly endemic area in the Kurunegala district during January 2019. The required number of 496 individuals in the separate households was taken randomly as the study sample. It was conducted using a pre-tested, validated, interviewer-administered questionnaire.

### Qualitative study

A qualitative study was conducted among adults between 18 to 70 years in the Kurunegala district from December 2018 to February 2019. For Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs), 8 to 10 participants from the stakeholder group and the community group were taken as the study sample. Total 12 KIIs were conducted among health and non-health stakeholders. Eighteen FGDs were conducted in the particular setting until a theoretical saturation point was achieved. There were 138 participants for the FGDs including 68 from the community non-leader group, 29 from the community leader group and 41 from the stakeholder group. 'Strengths, Weaknesses, Opportunities, Threats (SWOT)' were assessed using qualitative method.

After analysing the results of mixed methodological studies, the intervention package was finalized by modified Delphi method with expert opinion from specialists in public health from the National Dengue Control Unit (NDCU), Health Promotion Bureau (HPB), provincial level, general medicine, the grass-root level experts and an advisor of the international COMBI institute. The developed plan with the SBOO, strategies,

activities for implementation of the intervention and monitoring of the intervention were presented to the panel of experts and finalized. The management team prepared the schedule, budget plan, mobilization for resources and activity plan for the implementation of the developed intervention with the guidance of an economist.

## Results

### Theoretical phase

There are different types of behavioural theories for health education, health promotion and behaviour change. Of them, Health Belief Model (HBM) [19,20], Seven Doors Model for Behaviour Change [21,22], the Community Capacity Building Model for Sustainable Dengue Problem Solution (CCB-SDPS) [23-26], and Communication for Behavioural Impact (COMBI) planning [2,17,27] were the behaviour change models widely used for dengue prevention. Taking the effectiveness of the already conducted studies, planning abilities, implementation, and feasibility issues and the consensus of the expert panel in to consideration, this intervention was formulated using the COMBI theory. According to the literature review, the components of effective intervention packages were, building partnership with multi-stakeholders, waste management at households, improving garbage collection, entomological risk surveillance, capacity building at grass root level, stakeholder meetings, formulation of local steering committee, community working group formation and ensuring intra-sectoral coordination. The major factors associated with sustainable prevention of dengue are adequate knowledge of dengue and dengue prevention, positive attitudes towards the dengue prevention, adequate dengue prevention practices among the community members, adequate health seeking behaviour and high-risk perception on dengue, adequate dengue prevention behaviours, adequate community capacity for sustainable dengue prevention and adequate management of wet containers to prevent vector proliferation. The

identified theories and components were used to develop the appropriate model. According to studies, knowledge, attitudes, practices, health-seeking behaviours, and community capacity are the major factors influencing the behaviour change. Therefore, those were considered as the main components for behaviour change to achieve sustainable dengue prevention in the highly endemic area in the district.

## **The Modelling Phase**

### **Step one**

Overall goal was to decrease the morbidity and mortality due to dengue illness by improving the dengue prevention behaviours among the householders in a highly endemic division in the district.

### **Step two**

Expected preliminary behavioural objectives were formulated prior to development of Specific Behavioural Objectives (SBOO).

### **Step three**

#### **Quantitative study**

According to the quantitative analysis, mean knowledge on dengue prevention was 43.7% (SD 13.36; range 10 - 82). Of the participants, 57.7% (n=286) had good attitudes, 24.2% (n=120) had adequate dengue prevention practices, 44.6% (n=221) had good health seeking behaviours and 38.7% (n=74) had perceived that the community capacity is adequate for dengue prevention. Only 19% was knowledgeable on the importance of early notification of suspected cases and 19.2% (n=95) had adequate overall behaviours on dengue prevention.

#### **Qualitative study**

The analysis of SWOT in relation to achieving the behavioural objectives are depicted in Table 1. Consumer need, cost, convenience analysis revealed that the majority (80%) is more benefit than the cost. Moreover, people can earn extra money from manufacturing compost and

home gardening using compost. Time taken for dengue activities is more beneficial than disease management. When considering the risk perception on dengue, it was very low and one-fourth of them perceived that it is not a deadly disease, and they believed so if their family is not affected by dengue. Moreover, when considering competitors, there were no alternative behaviours or services being offered for this community. But, the priority is shifted to control other outbreak situations such as leishmaniasis control activities in the area. The preferred methods of communication among the community were group discussions (43.4%), awareness through telephones (17.3%), displaying of notices or handbills (15.7%), other modes like street drama (12%) and one to one communication (11.5%).

### **Step four**

The Specific Behavioural Objectives (SBOO) were to adopt proper waste management practices according to 3R method (Reduce, Reuse and Recycling) among the householders to reduce vector density and to improve the regular weekly dengue prevention practices by allocating at least one day a week to practice 30 minutes of cleaning to improve dengue prevention behaviours. Branding the theme was planned to distribute among the participants of the workshops [Figure 1].

### **Step five**

The main strategy was to conduct a community empowerment programme to improve household waste management and weekly practices on dengue prevention by conducting the administrative mobilization and public relationship, public relations, public advocacy, community mobilization, personal selling, advertising and promotion, and point of service promotion during follow up. Table 2 shows the activities which were identified by the developed COMBI based intervention.

Two-day workshops were planned to conduct with 25-30 participants per workshop. Day one [Session I] was for motivation and the awareness

on dengue prevention, which was planned to be conducted by the district Health Promotion Officer (HPO). Educational presentation on awareness on dengue and consequences of dengue disease, identification of dengue vectors and vector control strategies and the importance of at least 30 minutes premises inspection per week, waste management according to 3R concept, and interactive lecture on composting and organic farming were conducted during the session. Session II was a skill improvement session of two sub-components. Demonstration of composting, organic farming and interactive discussion session using an information guide with the participants and a session including constructive discussion with feedback of peers and trainer through analyzing the problems of the workshop for the participants were planned to be conducted as the component of session two. Day-two also had two sessions. A household inspection and entomology survey were planned to be conducted by trained entomological assistants. Session II comprised practical demonstration of composting lead by the community leader group and community base small group discussion at the households to identify the practical problems. Thereafter, theoretical problems were planned to be addressed.

### **Step six**

The finalized plan (intervention package) was presented to the stakeholders to get their feedback prior to finalizing the intervention plan.

### **Step seven**

The management team consisted of the first author and public health specialists. The technical advisory group consisted of public health specialists with the collaboration of Regional Director of Health services (RDHS), district HPO, and Provincial vector control officer, Medical Officer of Health (MOH) and public health inspectors. The collaborating agencies were Ministry of Health, RDHS office, MOH office, Agriculture department and District secretariat,

Kurunegala, Sri Lanka.

### **Step eight: Monitoring and Evaluation**

Monitoring and evaluation were planned to be conducted after the community empowerment program according to their needs. It was planned to follow up weekly for one month by the research team following the implementation sessions. The follow up was mainly focused on personal selling and supplemented by the counselling after assessing their compliance. The desired behavioural objectives are planned to repeat weekly for four weeks, and post-intervention evaluation is planned to carry out after three months of completion of the intervention program. Weekly observational record was designed to document [Supplementary file 1].

### **Step nine: Impact Assessment**

A pilot study was planned to be conducted to assess the feasibility issues and outcomes of interest including changes in knowledge, attitudes, vector control practices, dengue prevention behaviour and community capacity. Entomological surveys were planned to carry out to assess the impact on vector densities. The behavioural impact was planned to be assessed by observations of management of waste according to 3R concept, outdoor, indoor water containers, water storages and roof gutter at the household level during the implementation of the finalized plan. After piloting the developed intervention package, a cluster randomized trial was planned to conduct to assess the effectiveness of the complex intervention package.

### **Step ten: Scheduling and Budget**

The action plan was developed after taking expert opinion from the panel of expert.

### **Discussion**

The rationale for a complex intervention is to develop a theoretical understanding of the likely process of change, by drawing on existing evidence and theory, supplemented, if necessary, by new primary research, qualitative approach



with the stakeholders or the targeted population [9]. In addition, there may be lots of competing or partly overlapping theories [27]. However, the research team needs expert opinion on relevant disciplines to find the most appropriate theory and as the complex interventions have several dimensions of complexity, it may be to do with the range of possible outcomes, or their variability in the target population, rather than with the number of elements in the intervention package itself. It follows that there is no sharp boundary between simple and complex interventions [9]. The interventions have been developed according to different models and planning processes. The COMBI approach is successfully demonstrated that correct problem identification synergized with community engagement can potentially reduce *Aedes* proliferation and dengue morbidity in Malaysia and Sri Lanka [28,29]. Out of the COMBI based interventions, Malaysia used integrated marketing communication techniques to inoculate this behavioural change to the target group. Therefore, the COMBI approach has successful with correct problem identification and community engagement [28]. The use of the Delphi technique instead of face-to-face consultative meetings had the advantage of not requiring the experts to take time off their schedules to contribute to the study. It allows the experts to respond at any time convenient to them and to contact any source of information if needed. Further, this process facilitated the independence of forming opinion and perspectives as it prevented the manipulation of opinion by influential individuals, which could happen in a face-to-face consultative meeting [30]. In the process of development of the intervention plan, there was a quantitative study to finalize the SBOO. For that, validated tools were used to conduct the current situation marketing analysis as a major step in the COMBI planning process. The generalizability of an intervention package depends on the effectiveness and validity of models, theories, methods used for the development process. In the

present study, after considering the effectiveness of the already conducted studies, planning abilities, implementation, and feasibility issues with the consensus of the expert panel, COMBI planning was identified for the development of the interventional package. Importantly, the COMBI theory was used to plan the process of community empowerment program, because it is a proven and effective method for behaviour change for dengue control and widely utilized in planning process in different countries [14]. Moreover, the process of conducting current situation market analysis is also performed by mixed methodology with representative samples. Therefore, the generalizability of the intervention to high endemic areas could be done with adaptation to setting. Notably, incorporation of similar programs for prevention of dengue through behavioural change to the public health system of Sri Lanka seems feasible and cost effective [29]. Moreover, a community-based dengue prevention and control process enables key stakeholders in the community to actively prevent and control their dengue problem [26]. Importantly, the studies in the Dominican Republic [31], Colombia [32], Hulu Langat [28] and Thailand [26] revealed that the interpersonal communication was an effective way to achieve greater success of a community-based programme. Therefore, the present intervention package was aimed to empower the community by developing a sustainable dengue control process at the grass root level with the involvement of multi-stakeholders. Importantly, the dengue problem can be solved by conducting the community-based dengue prevention process with the active participation of key stakeholders in the community. Moreover, sustainability of community-based dengue prevention and control comprise activities depending on the larval breeding sources, control adult mosquitoes, apply personal protection, introduce dengue symptom detection, and outbreak prevention [33]. In Sri Lanka also there is a clear need to address above areas especially waste management and vector



control [29]. Importantly, the specificity of the intervention messages of the present study was waste management according to 3R concept aiming source reduction from both outdoor and indoor vector breeding places. Formalization of waste management would empower the community members to identify breeding sites and removing them. It would not be that difficult or labour intensive or costly than managing dengue cases or conducting mass cleaning campaigns. Such specific messages have been used to achieve successful behavioural outcomes in the interventions in other countries [28,29,32,34,35]. Solid waste management is a growing challenge to many countries. Improper waste management increases the breeding places for many vectors resulting in proliferation of vector-borne diseases [36]. Moreover, the presence of solid waste around households, such as cans, car parts, bottles, old and used tyres, plastic materials, broken clay, glass vessels and coconut shells create outdoor breeding sites for *Aedes* mosquitoes and represented in our ecosystem the most productive container types. Maintaining solid waste for a long time often more than seven days supports the breeding of *Aedes aegypti* [37] and increases the transmission of dengue. Moreover, interventional studies were developed according to COMBI with two SBOO including 30 minutes' inspection on Sunday and improve the proper waste management practices. The identified SBOO were management of water containers twice weekly and scrubbing of any containers found to contain larvae. Furthermore, a study carried out in Malaysia revealed that the knowledge, attitudes and practices were influenced by the interventional programme during its implementation weeks. However, the outcome evaluations at the end of the study revealed that COMBI programme failed to achieve the desired behavioral impact of the programme. The multi-stakeholder collaboration is one of the suggested solutions to overcome the problems of the programme, because there was lack of human

resources and funding. Furthermore, they suggested to improve the health sector participation for the awareness of the community to prevent dengue [38]. Therefore, for the development of the present intervention package, the multi-stakeholder participation was ensured. Similar to the present study, community empowerment programs were conducted in Cuba [39,40] and Myanmar [35]. Moreover, behaviour change intervention package was developed to manage household water containers in the Philippines, 2012. Further, this study revealed that other factors such as social and political environment are needed to explain community responses to new dengue vector control interventions [34]. Therefore, the present study was developed using a new communication strategy with multi-stakeholder participation. Another study conducted in Cuba revealed the importance of the community-based strategies such as organizational management, entomological risk surveillance, capacity building and community work for vector control. The community empowerment strategy increased community involvement and added effectiveness to routine *A. aegypti* control [40]. The efficacy of community-controlled partnership-driven interventions was found to be superior to the vertical approach in terms of sustainability and community empowerment. Moreover, a study in Sri Lanka, revealed that the vector control interventions had a significant impact on vector densities (BI) and on dengue incidence. It revealed that rigorous vector control programs lead to reduction of the disease and economic burden of dengue in endemic settings [41]. When considering the intervention packages in the studies, use of scientific evidence in the development process was insufficient. Therefore, to develop the present intervention package, the evidence from most of the effective intervention packages were utilized. Not only that, but also the identified gaps of the failed interventions were considered to gain better outcomes of interest.

Therefore, the present intervention package can be considered as a scientifically developed intervention for sustainable dengue prevention.

## Conclusion and Recommendations

Developing a COMBI plan for an area after the identification of specific behavioural objectives would make it feasible for implementation in order to empower the community to prevent dengue in the area and to improve community health services. Scientifically developed COMBI based planning process can be used to bring about satisfactory control of dengue with the

participation of the community in high endemic areas to achieve sustainable dengue prevention. This type of intervention can be applied to any locality after conducting the situation marketing analysis of the relevant area and developing area specific COMBI plan with the support of the preventive sector healthcare institutions in any country. Moreover, future research can be conducted using the COMBI planning process in the other endemic areas in preventing dengue outbreaks in the region or globally. There is a need of long term follow up to understand sustainability of the interventions.

### Author declaration

**Author Contributions:** All authors contributed to the conceptualization and design of the study. Original draft was written by the PI (RMNUR) and it was reviewed by the other co-authors including CA, AB, NP, AA, SM. All authors read and approved the final manuscript.

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**Table 1: SWOT analysis for dengue prevention behaviours**

<b>1.</b>	<b>Strengths</b>	<p>Guidelines, monitoring and technical support from the National level (National Dengue Control Unit-NDCU)</p> <p>Well established preventive sector with dedicated team for management</p> <p>House to house inspection by Dengue Field Assistants at field level</p> <p>School/Workplace dengue promotion activities</p> <p>Support from other stakeholders</p> <p>Availability of fogging facilities and case by case fogging activities</p>
<b>2.</b>	<b>Weaknesses</b>	<p>Delays in notification</p> <p>Poor health seeking behaviours</p> <p>Gaps in law enforcement</p> <p>Lack of community participation</p> <p>Not considered as a priority area prior to monsoonal period (lack in preparedness)</p> <p>Poor attitudes of the community members</p> <p>Improper urbanization</p> <p>No proper monitoring and evaluation mechanism for dengue management activities</p> <p>Poor waste management and no established waste management system</p> <p>Lands without proper ownership</p> <p>Gaps in national policies and legislations related to vector control</p> <p>Inadequate financial allocation for dengue prevention activities</p>
<b>3.</b>	<b>Opportunities</b>	<p>Availability of Dengue Field Assistants at field level</p> <p>Availability of fogging facilities</p> <p>Waste collection by local government authorities</p> <p>Dengue committee meetings at all levels (divisional level, district level and National level) with multi-stakeholder participation</p> <p>National and regional level policies to prevent dengue</p> <p>Availability of grants for research activities</p>
<b>4.</b>	<b>Threats</b>	<p>Political pressure against law enforcement</p> <p>Increase in natural disasters which deviate the attention from dengue prevention to the disaster response activities</p>



**Table 2: Activities to achieve targeted objectives to prevent dengue**

<b>1.</b>	<b>Administrative mobilization and public relations</b>
	<ul style="list-style-type: none"> <li>• To formulate a training manual of 'COMBI based community empowering for sustainable dengue control' for field officers with the support of public health specialists.</li> <li>• To conduct consultative meetings and Key Informant Interviews (KII) with health and non-health stakeholders to assess the need for dengue prevention in the area.</li> <li>• To discuss with the heads of healthcare institutions on how to prepare an action plan for dengue management for the healthcare institutions.</li> </ul>
<b>2.</b>	<b>Public Advocacy</b>
	<ul style="list-style-type: none"> <li>• To conduct advocacy programmes to motivate the officials of local government authority ("Pradeshiya Sabha") of the area, religious leaders, and the community leaders to get the support for waste management.</li> </ul>
<b>3.</b>	<b>Community Mobilization</b>
	<ul style="list-style-type: none"> <li>• To identify volunteer leaders for the sustainability of the dengue prevention.</li> <li>• To train the leader group to conduct Training of Trainers (TOT) programme.</li> </ul>
<b>4.</b>	<b>Personal Selling, Advertising and Promotion</b>
	<ul style="list-style-type: none"> <li>• To select non-leader group and leader groups among the community.</li> <li>• To conduct training workshops for non-leader community participants with interactive discussion.</li> <li>• To brand the theme with the material.</li> </ul>
<b>5.</b>	<b>Point of service Promotion during follow up</b>
	<ul style="list-style-type: none"> <li>• To conduct weekly follow ups using a 'Weekly follow up observation record' in all three languages for four weeks.</li> </ul>

**Theme of the Behavioral Change:**

**Waste Management**

**According to**

**3R - Concept**

**(R-REDUCE, R-REUSE, R-RECYCLE)**



**Clean Your Premises**

**At least 30 minutes Per a Week**



**Let's Have a Dengue Free Environment**

Figure 1: Theme of the behavioural change intervention

# An extended Susceptible-Exposed-Infected-Recovered (SEIR) model with vaccination for forecasting the COVID-19 pandemic in Sri Lanka

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## Abstract

**Background:** After declaration of a Public Health Emergency of International Concern (PHEIC) by the World Health Organization, Novel Corona Virus had been spreading throughout the world despite various degrees of movement restrictions and availability of multiple safe and effective vaccines. Vaccination rate against COVID-19 is one of the infection rate's main determinants. The role of modelling in predicting the spread of an epidemic is important for health planning and policy making.

**Objective:** This study aimed to construct a compartmental epidemiological model incorporating vaccination coverage, vaccination rate, vaccine efficacies and applied a computational tool for predicting the evolution of different epidemiological variables for COVID-19 in Sri Lanka.

**Methods:** We used a dynamic Susceptible-Exposed-Infected-Recovered-Vaccinated (SEIRV) model and simulated potential vaccine strategies under a range of epidemic conditions. The predictions were based on different vaccination coverages (5% to 90%), vaccination-rates (1%, 2%, 5%) and vaccine-efficacies (40%, 60%, 80%) under different  $R_0$  (2,4,6). We estimated the duration, exposed, and infected populations.

**Results:** When the  $R_0$  was increased, the days of reduction of susceptibility and the days to reach the peak of the infection were reduced gradually. At least 45% vaccine coverage is required for reducing the infected COVID-19 population to mitigate a disastrous situation in Sri Lanka.

**Conclusion and recommendations:** The results revealed that when  $R_0$  is increased in the SEIRV model along with the increase of vaccination efficacy and vaccination rate, the population to be vaccinated is reducing. Thus, the vaccination offers greater benefits to the local population by reducing the time to reach the peak, exposed and infected population through flattening the curves. The prediction models will lead to policy relevance despite the significant uncertainty associated with real-time forecasting in complex systems with timely predictions and steadfast reports.

**Keywords:** COVID-19; SEIRV model; Vaccine efficacy; Vaccination rate

## Introduction

### Background

After declaration of a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO), Novel Corona Virus had been spreading throughout the world despite various degrees of movement restrictions and availability of multiple safe and effective vaccines [1]. According to the Weekly epidemiological update on COVID-19 on 11th May 2021, there was a 4% reduction of the number of new COVID-19 cases and deaths globally, with over 5.5 million cases and over 90,000 deaths for the past week. Although there was a 13% reduction of the newly reported weekly caseload in the Eastern Mediterranean and a 23% reduction in Europe regions, South-East-Asia (SEA) shows upward trends for the 9th consecutive week, which reported a further 6% increase as of 9th May 2021. Further, new deaths were increasing in SEA (15%) and Africa (3%), while India remained the primary concern as the contributing country for half of the global cases and nearly one-third of global deaths [2]. Similar to the regional situation, the number of cases was rising in Sri Lanka, with 2375 per day (14th to 19th May 2021). A total of 147,720 individuals were confirmed as infected by May 19, 2021 [3,4]. Strain B.1.1.7 was a more transmissible variant that was initially detected in the United Kingdom (UK), was circulating in Sri Lanka at that time [5]. Therefore, early understanding of the epidemic and demand dynamics was fundamental in health planning and policymaking, especially when the resources are limited.

### Compartmental models for prediction

Compartmental models can be used to project scenarios with various disease control measures individually or as a useful combination for evidence-based policy formulation and alteration. With the purpose of forecasting, different forecasting models were proposed by various academics and research groups. However,

these forecasting models had their strengths and limitations. Therefore, they need to be interpreted cautiously. Furthermore, the underlying data were changing rapidly [6,7]. There were broad categories of mathematical models for COVID-19 forecasting, such as mass action compartmental models, structured metapopulation models and Agent-Based Network Models. Epidemiologists have been using mass action compartmental models over a period of hundred years which are famous for simplicity in both analysis and outcome assessment [8]. Importantly, from early December 2020, mass vaccination programs were started against the COVID-19 pandemic. Pfizer/BioNTech, Oxford/AstraZeneca, Janssen, Moderna and Sinopharm vaccines were included in the WHO Emergency Use Listing (EUL) and were widely used globally [9]. By 19th May 2021, 9.35% of the world population had received at least one dose of the COVID-19 vaccine and 1.56 billion vaccine doses were already administered globally [10,11]. In Sri Lanka, 1,397,999 individuals (2.6% of the population) were vaccinated by at least one dose of vaccine out of Covishield, Sinopharm or Sputnik-V vaccines through mass vaccination programmes [3,12]. More importantly, public health interventions successfully limited the initial rapid transmission of COVID-19 in many countries. However, the epidemic recrudescence could occur due to the relaxation of these measures without achieving elimination or high levels of herd immunity risks [13].

### SEIR model and extensions

Several compartmental models belong to the basic Susceptible-Infectious-Recovered (SIR) class. In the SIR model, the total population (N) is divided into compartments of Susceptible (S), Infectious (I) and Recovered (R). The SIR models are extended to SEIR models by adding an Exposed (E) compartment based on the same principle. It is assumed that every individual in the population is going through those four roles from susceptibility

to recovery [Susceptible (S)-> Exposed (E)-> Infected (I)-> Recovered (R)]. Although real-life situations have some limitations, this has been used as a basic model for different epidemics [8,14]. Due to the proven effect of prevention of infection by vaccination, Vaccination (V) was also included in the SEIR model, and the Susceptible-Exposed-Infected-Recovered-Vaccinated (SEIRV) forecasting model is formulated.

### **Vaccination rate, vaccination coverage, vaccine efficacy, and effectiveness of the vaccination**

Vaccination rate against COVID-19 is one of the infection rate's main determinants (along with the vaccine efficacy and effectiveness). It should be considered with the other factors related to the spread of the disease, such as adherence to preventive measures. Reduced infection rates begin with varying vaccination rates across countries. It has been observed that the infection rate after vaccination shows two trends including an 'inverted U-shaped trend' and a 'L-shaped trend' [15]. Sri Lanka started Covishield (AstraZeneca) as the COVID-19 vaccine for the country's vaccination programme from 29th January 2021 [16]. Even though the efficacy data of the different COVID-19 vaccines vary in different global studies, there should be a minimum of 50% efficacy for the WHO emergency use licensing of a COVID-19 vaccine [17]. Further, the efficacy of the same COVID-19 vaccine can vary with the variant of the virus that depends on the vaccine schedule. For instance, it could be whether only the first dose was taken or whether the person completed the schedule [18]. It was found that the effectiveness of the Covishield (AstraZeneca) vaccine after the first dose was 76% (95% CI: 61-85%) and 86% (95% CI: 53-96%) following the completion of both doses against the alpha variant (B.1.1.7) which was the predominant variant in Sri Lanka during the study period [19].

### **Aim of the study**

The present study aimed to construct a compartmental epidemiological model incorporating vaccination coverage, vaccination rate, vaccine efficacies and applied a computational tool for predicting the evolution of different epidemiological variables for COVID-19 in Sri Lanka to contribute to policymaking. We applied a dynamic SEIRV model for this purpose. The predictions were based on the SEIRV model without vaccination, evolution of infectious proportion under different vaccination coverages (5% to 90%), vaccination rates (1%, 2%, 5%) and vaccine efficacies (40%, 60%, 80%) at different  $R_0$  (2,4,6). The model was used to estimate the duration and infected population following different vaccination coverages.

### **Method**

#### **Compartmental epidemiological model**

We constructed a compartmental epidemiological model (Figure 1) with vital dynamics describing the number of individuals in a fixed population who are susceptible to infection (S), exposed (E), infected (I), recovered (R), and vaccinated (V) [8,14]. This simple deterministic model has several structural assumptions, including homogenous mixing of a closed population, no stratification of transmissibility by subpopulations, and complete and permanent immunity after natural infection.

A set of ordinary differential equations governs the flow of individuals between compartments. We extracted publicly available data with permission from the official website of the Health Promotion Bureau of the Ministry of Health, Sri Lanka. The data was cross-checked with the daily update on the website of the Epidemiology Unit, Ministry of Health, Sri Lanka [3,4]. We used anonymized data for this analysis and extracted data relevant to cases reported from 11th March 2020 to 15th May 2021. Based on reported cases and the documented parameters, the model was validated for its ability to predict the number of cases for a period of 14 days in February 2021



and model fitting is illustrated in Supplementary file I (S1 File).

Any personally identifiable data was not included in the analysis of this study. Python programming language was used for the development of the model. We have considered three hypothetical values for  $R_0$  [Basic reproduction number, 'New infections generated by each infectious individual in a susceptible population without transmission reduction measures']. Predictions for the SEIRV model were made when the  $R_0$  value is 2, 4 and 6. Parameter beta ( $\beta$ ) represents the transmission rate of the COVID-19. As one of the main assumptions, we assumed that the transmission rate  $\beta$  for both the susceptible and vaccinated populations is equal during the model development stage.

### Model equations

The flow of individuals through the compartments of the model is determined by a set of Ordinary Differential Equations (ODE). The time-variant parameters such as rate of change of susceptible population, exposed population, infected population, recovered population and vaccinated population is obtained by derivatives with the following equations. Given the SEIRV model with transition forces, the ODEs are derived as below.

$$\frac{dS}{dt} = -\beta I \left(\frac{S}{N}\right)^\alpha - \delta \varepsilon S \quad (1)$$

$$\frac{dE}{dt} = \beta I \left(\frac{S}{N}\right)^\alpha + \beta I \left(\frac{V}{N}\right)^\alpha - \sigma E \quad (2)$$

$$\frac{dI}{dt} = \sigma E - \gamma I \quad (3)$$

$$\frac{dR}{dt} = \gamma I + \zeta V \quad (4)$$

$$\frac{dV}{dt} = \delta \varepsilon S - \beta I \left(\frac{V}{N}\right)^\alpha - \zeta V \quad (5)$$

### Disease characteristics

The available COVID-19 data was used as the disease characteristics in this exploration (Table

1). However, there is still substantial uncertainty around these estimates and how they apply to a given setting, and there are insufficient data on which to base credible parameter distributions.

### Mass vaccination programme

We modelled an indiscriminate mass vaccination programme where 13,151 individuals received their first dose of vaccine against COVID-19 during the first 100 days of the vaccination campaign in Sri Lanka (as would be expected in the absence of a reliable and scalable method of determining either pre-existing immunity or active or incubating infection) [3]. The model parameters are presented in Table 2.

### Vaccination coefficient in the model

A combination of 'vaccination efficacy' and 'vaccination rate' is known as 'vaccination coefficient' in the model. Notably, the vaccination efficacy and vaccination rate are determined by the health authorities. When the  $R_0$  and rate of vaccination are constant and vaccination efficacy is increased (40%, 60% and 80%), the vaccination coefficient will be increased in line with the increased efficacy. Therefore, it implies that the increase of vaccination coefficient would increase the vaccinated population while reducing the exposed and infectious population to reach its maximum within a lesser number of days. Moreover, when the  $R_0$  is constant, vaccination efficacy and rate of vaccination are increased, the vaccination coefficient is also increased. Therefore, the number of vaccinated populations from the susceptible population is also increased. As a result, the number of exposed, infectious populations decline and reach the equilibrium level in the early days in the graphs, which indicates that the COVID-19 crisis can be controlled if we increase the efficacy and rate of vaccination. Under a lower level of vaccination coefficient, the equilibrium comes in later days of the graphs while it increases the exposed and infectious populations.



## Results

As in a pandemic like COVID-19, a compartmental model is a good approach for comprehension and analyzing epidemiological data. However, the model needs to be adjusted to consider specific aspects of the epidemic under analysis [25]. First, we predicted the SEIRV model dynamics without vaccination. Thereafter, the predictions were based on, evolution of infectious proportion under different levels of vaccination coverages (5%, 15%, 30%, 45%, 60%, 75%, 90%), SEIRV under different levels of vaccine efficacies (40%, 60%, 80%) with the current rate at different  $R_0$  and SEIRV under combined co-efficient (vaccine rate x vaccine efficacy) different levels of vaccination rates (1%, 2%, 5%), different vaccine efficacies (40%, 60%, 80%) and different  $R_0$ .

### Prediction based on the SEIRV model without vaccination.

We observed how SEIR dynamics are affected without vaccination for COVID-19 at a specific time in the system's evolution with different  $R_0$  values. When the  $R_0$  equals 4, the susceptibility will be reduced around 75 days. Thus, the number of days to reach the peak of the infection curve will be 105 days. In addition, approximately 6.2 million individuals will be infected at the peak of the infection curves, respectively. Thus, around 3 million individuals in 90 days will be exposed at the peak of the exposed curves. Furthermore, the susceptible curve crosses with the recovered curve in 95 days with 6 million individuals. Moreover, the susceptible curves stabilize around 115 days with susceptible 0.1 million individuals. Furthermore, the recovered curves stabilize with 21.8 million around 125 days (Refer Figure 2 and S1 Table).

### Evolution of infectious proportion under different levels of vaccination coverage

Using the SEIRV model, we predicted the proportion of the infected population for the different vaccination coverages taking into account the vaccination rate of the first 100 days in Sri Lanka

(Per day vaccination rate=0.06%). According to the findings, if there are 5%, 15%, 30%, 45%, 60%, 75% and 90% vaccination coverages, the time of reaching the peak proportion of the infected individuals will be reduced by 40, 30, 25, 22, 21, 20 and 19 days respectively (Table 3). Moreover, after 45% vaccine coverage of the susceptible individuals, there will be a relatively slow reduction of peak reach for the proportion of the infected population. Therefore, at least 45% fully vaccine coverage will be adequate for reducing the infected population to control the outbreak since there is no prior immunity in the local community.

### Evolution of SEIRV under different vaccine efficacies and $R_0$ of 4 with per day vaccination rate of 0.06% (First 100 days)

We observed how the dynamics of SEIR are affected by vaccination for COVID-19 at a specific time in the system's evolution in the first 100 days after initiation of the vaccination campaign in Sri Lanka. As a result, vaccines with different efficacies as a response strategy applied to the COVID-19 epidemic was assumed at  $R_0$  value of 4.

### $R_0=4$ ; Efficacy= 40%, 60%, 80% with per day vaccination rate 0.06%

When  $R_0$  is equal to 4, with 40%, 60% and 80% vaccine efficacies at the current rate of vaccination (0.06% per day), 79,943, 119,144 and 157,852 individuals can be vaccinated in 50 days, and the susceptibility will be reduced around 65, 70 and 75 days respectively. Thus, the number of days to reach the peak of the infection curve will be 105, 110 and 115 days, and 5 million, 4.5 million and 4 million individuals will be infected at the peak of the infection curves, respectively. Furthermore, 2.5 million individuals in 90 days, 2 million individuals in 95 days and 1.5 million in 100 days will be exposed at the peak of the exposed curve, respectively. Correspondingly, the susceptible curve crosses with the recovered curve in 90 days with 5 million, in 95 days with 6

million and 6.5 million populations in 100 days. Moreover, the susceptible curves stabilize around 125 days with 0.5 million, 120 days with 0.4 million individuals and 115 days with susceptible 0.25 million individuals (Figure 3; S2 Table).

Evolution of SEIRV under different vaccine efficacies (40%, 60%, 80%) and different per day vaccination rates (1%, 2%, 5%)

The SEIRV predictions were performed for the different COVID-19 vaccine efficacies and the vaccination rates (per day) of 1%, 2% and 5% (Fig 4).

#### **$R_0=4$ ; Efficacy= 40%; Vaccination rates of 1%, 2% and 5%.**

When  $R_0$  is 4 with vaccine efficacy of 40% and vaccination rates of 1%, 2% and 5%, 1.03 million, 1.86 million and 3.74 million individuals can be vaccinated in 35 days, 35 days, and 25 days respectively. Moreover, 3.11 million, 0.81 million individuals and 1,478 individuals will be infected at the peak of the infection curves, and 1.36 million, 0.33 million, and 589 individuals will be exposed at the peak of the exposed curves, respectively. Furthermore, the susceptible curves cross the recovered curve in 105 days, 90 days, and 35 days, respectively (Figure 4a; S3 Table).

#### **$R_0=4$ ; Efficacy= 60%; Vaccination rates of 1%, 2% and 5%.**

When  $R_0$  is equal to 4 with the efficacy of 60%, 1.47 million, 2.57 million and 4.9 million individuals can be vaccinated in 30 days, 28 days, and 20 days respectively. If there is a 1% vaccination rate, the number of days to reach the peak of the infection curve will be 125, and 1.8 million individuals will be infected at the peak of the infection curve, and 53,773 and 91 will be infected with 2% and 5% vaccination rates respectively. In addition, at the peak of the exposed curves, 0.76 million individuals, 21,041 individuals, 225 individuals will be exposed with 1%, 2% and 5% rates, respectively. Furthermore, the susceptible curves cross with the recovered

curve in 100 days, 65 days, and 30 days with 10 million individuals (Figure 4b; S3 Table).

#### **$R_0=4$ ; Efficacy= 80%; Vaccination rates of 1%, 2% and 5%.**

When the vaccine efficacy is 80% with the vaccination rates of 1%, 2%, and 5%, 1.86 million individuals, 3.19 million individuals and 5.87 million individuals can be vaccinated in 35 days, 25 days, and 20 days. Moreover, 0.81 million individuals in 135 days, 5,883, and 84 individuals will be infected at the peak of the infection curves, respectively. Furthermore, 0.33 million individuals in 130 days, 2,321 and 35 individuals will be exposed at the peak of the exposed curves. The susceptible curves cross with the recovered curve in 90 days, 40 days, and 25 days respectively, around 8 million individuals (Figure 4c; S3 Table).

### **Discussion**

Predictive models have taken on a newfound importance in response to the spread of the COVID-19 pandemic and causative agent [26]. There are widespread public discussions on COVID-19 based on the features of epidemiological curves. For understanding the dynamics of the pandemic and assessing the effects of various intervention strategies, the epidemiological models and their graphical representations are valuable tools. However, the parameters may be affected by the inadequate explanations of these models' representations, usefulness, and inherent limitations. Notably, accurate public interactions and communications are vital during any disastrous situation like the COVID-19 global pandemic. Moreover, explaining the current circumstances, actions, and intended outcomes is a timely need to gain the support and cooperation of the public and stakeholders to manage the critical situation, prevent the spreading of fake news, and minimize voluntary compliance [27].

The compartmental models were invented during the late 1920s, which are the most commonly used models in epidemiology.

Moreover, different approaches using agent-based simulations are still founded on those basic models [25]. The SEIR model is frequently used to explain the COVID-19 pandemic, which is fundamental and a reasonably good fit for this disease [14]. However, during the COVID-19 pandemic, the number of deaths has often been highly inaccurate for many reasons, and the number of infected has also been incorrect. There can be undiagnosed cases during that period because of limited testing, which lead to inaccurate reporting [25,28]. The type of model is an extension of SEIR with the intervention of vaccination. The proposed model uses the predictors as in the parameter table (Table 2). The model was built based on the conceptual framework developed with the predictor selection. Moreover, due to the static nature of the parameters, which does not reflect any internal or external change during the epidemic is a limitation of these models [8,28]. Furthermore, the predictive capability of the tool is highly dependent on several preliminary data for parameter estimation. Notably, an essential parameter in epidemic modelling is the 'basic reproduction ratio/ratio ( $R_0$ )', which is the 'expected or average number of individuals an infected person subsequently infects'. The size of the  $R_0$  can be varied since it is determined by averaging many cases [25]. With the constant  $R_0$ , increase vaccination efficacies, and increased rate of vaccinations lead to increased vaccination coefficient. Therefore, it leads to an increased number of vaccinated populations from the susceptible population. As a result, the number of exposed, infectious populations are reduced and reach the equilibrium level at early days in the prediction graphs, which indicates that the COVID-19 crisis can be reduced if we increase the vaccine efficacy and the rate of vaccination. Under a lower level of vaccination coefficient, the equilibrium comes in later days of the prediction graphs while it increases the exposed and infectious populations. Therefore, we must give more attention to bring more efficient vaccines

for COVID-19, and the rate of the vaccination campaigns need to be improved as a disaster mitigation strategy. Theoretically,  $R_0$  is varied, which estimates the speed at which a disease can spread in a population. Therefore, the  $R_0$  is increased in the SEIRV model along with the increase of the vaccination efficacy. Moreover, the population to be vaccinated is also decreased for respective  $R_0$ . Furthermore, when  $R_0$  is increased in the SEIRV model along with the increase of both vaccination efficacy and vaccination rate, the population to be vaccinated is also declined. Hence, the vaccination offers the greatest benefits to the local population by reducing the time of peak arrival and infected population.

In addition, the infection fatality ratio (IFR) of COVID-19 acts as a simple factor in the mortality effects of vaccination and does not alter the relative conclusions. The IFR estimates this proportion of deaths among all infected individuals. There are limited serological studies to calculate IFR accurately during outbreaks. In such situations, estimates need to be made with routinely available surveillance data, which generally consist of time series of cases and deaths reported in aggregate [29]. When considering the available data, it is almost similar to the study in China [21]. During the first 10 to 12 months, the mitigation policies reduced overall cumulative mortality without necessarily relying on the emergence of an effective vaccine. The model presented in this study revealed that the overall benefit of vaccination of a population is helping to suppress the epidemic curve by minimizing infected populations. However, the local benefits deteriorate with any additional prolongation of the vaccine development process and delaying availability. When transmission slows due to accumulated population immunity derived from infection, the benefit of vaccination needs to be assessed by conducting proper post-vaccination trials [30,31]. Moreover, the public health measures strongly influence the feasibility

of vaccine trials during a COVID-19 epidemic. Although high background risk of infection results in reduced marginal risks to participants, a substantially greater public health benefit results in low background risk during the period before vaccine availability [31,32].

### Conclusion and Recommendation

The results revealed that when  $R_0$  is increased in the SEIRV model along with the increase of vaccination efficacy and vaccination rate, the population to be vaccinated is reducing. Thus, the vaccination offers greater benefits to the local population by reducing the time to reach the peak, exposed and infected population through flattening the curves. The prediction models will lead to policy relevance despite the significant uncertainty associated with real-time forecasting in complex systems with timely predictions and steadfast reports. Thus, the proposed model can serve as a tool for health authorities for planning and policymaking to control the pandemic by cost-effectively implementing appropriate vaccination campaigns.

### Limitations

The predictors of the SEIRV compartmental model have been analyzed using ODEs. The model predicts the plausible parameters with the

robust estimation within the limitations. One of the significant limitations of the model is that it does not include the natural death and birth rates assuming those are constant [28,31]. Internal and external validation of the model is vital for the robust prediction of the ODEs in the model. Thus, the models were applied in the series of equations to get the equilibrium in the SEIRV model. Then, the simulation of the validated model was performed to obtain the policy scenarios of the proposed model. Usually, the SEIR model consists of initial parameters, which predicts as those are applied to the model precautionary [30,32]. Initially, the model comprises one exposed individual, and the rest of the population is considered a susceptible population [33,34]. Therefore, the predictors were handled with care in the model to avoid overestimation or underestimation. Second limitation was, we did not estimate the reproductive ratios from data in a particular population which is useful for that population. However, the parameters such as vaccination efficacy and vaccination rate can be adjusted according to the implementation of preventive strategies. Thirdly, with the availability of limited similar studies, prediction results difficult to compare and discuss. It is also a limitation factor for the study.

### Author declaration

**Author contributions:** All authors contributed to the conceptualization and design of the study. The formal analysis was done by SPJ (Software), RMNUR and TKT (Re-analyzed with same data set to improve the quality). The original draft preparation was done by RMNUR. IG, PCW and SB contributed to manuscript preparation and finalization. The manuscript was reviewed by MSDW, SPJ, TKT, and YA. All authors read and approved the final manuscript.

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**Table 1: Disease characteristics**

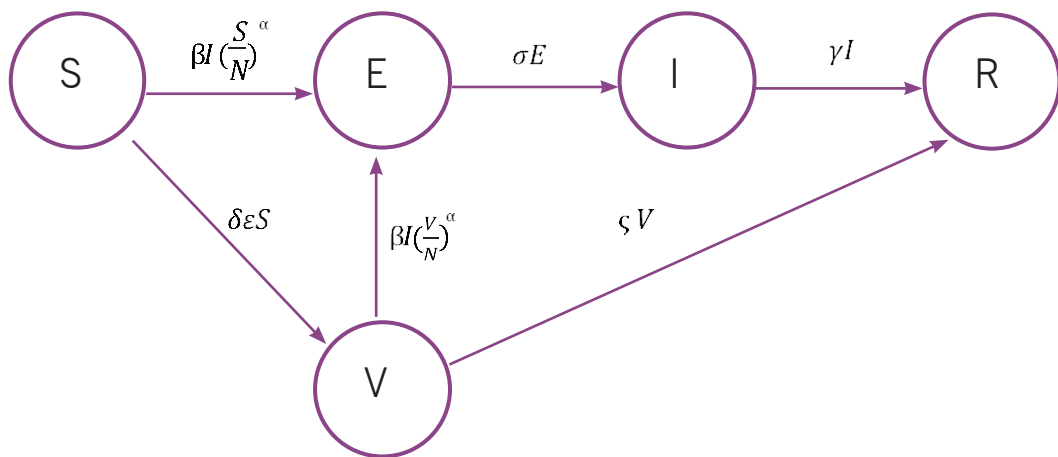
Parameter	Modelled value	Reference
$R_0$	2, 4, 6	Assumed
The latent period prior to infectivity	3.2 days	[20]
Duration of infectivity	8.5 days	[1, 9]
Time from infection to death	22 days	[21]
Infection Fatality Ratio (IFR)	0.66%	[2, 21]

**Table 2: Values for the model parameters corresponding to the Sri Lankan COVID-19 situation**

Parameter	Definition	Value	Units	Reference
N	Population 'Number of individuals in the population'	21,919,000	number	[22]
S	Susceptible 'Individuals in the population not infected, vaccinated, or immune'	$21,919,000 - 1$ $=21,918,999$	number	
E	Exposed 'Individuals infected but not yet infectious'	1 (on day 1)	number	Assumed
I	Infected 'Individuals able to transmit infection'	0 (on day 1)	number	
R	Recovered 'Individuals neither infectious nor able to be infected'	0 (on day 1)	number	
V	Vaccinated 'Vaccinated individuals who have not yet achieved protective immunity'	0 (on day 1)	number	
$R_0$	Basic reproduction number 'New infections generated by each infectious individual in a susceptible population without transmission reduction measures'	2.53	dimensionless	[20]
$\alpha$	Abrogation of infectivity as the susceptible fraction falls	1.2a	dimensionless	[23,24]
$\beta$	Transmission coefficient from infected individuals ( $R_t, \gamma$ )	Derived	$\text{day}^{-1}$	
$\gamma^{-1}$	Infectious period - 'Time from the onset of infectiousness to reversion to non-infectiousness'	8.5 days	$\text{day}^{-1}$	[1,2]
$\delta$	Vaccination rate 'Proportion of the <i>Susceptible</i> population undergoing vaccination each day'	0.06%	dimensionless	[3]
$\epsilon$	Vaccine efficacy 'Relative risk reduction of infection achieved through vaccination'	40%, 60%, 80%	dimensionless	Assumed
$\eta^{-1}$	Latent period 'Time from exposure to the development of infectiousness'	3.2 days	$\text{day}^{-1}$	[20]
$\zeta^{-1}$	Time to protective immunity after vaccination	21 days	$\text{day}^{-1}$	Assumed
IFR	Infection fatality ratio 'Proportion of all infections that result in death'	0.66%	dimensionless	[21]

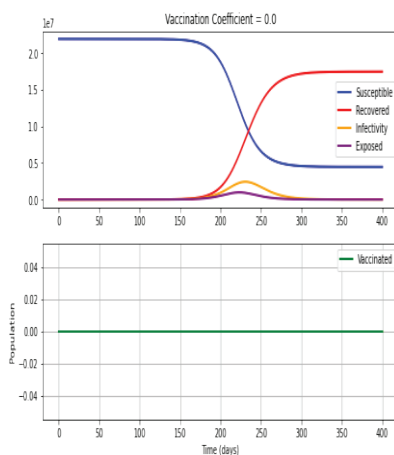
**Table 3: Relationship between different vaccination coverages with the infected proportion and time of peak arrival**

Percentage of vaccine coverage	Proportion infected out of Susceptible (21.9 million)	Time of peak arrival
5%	6.80%	Day 40
15%	2.70%	Day 30
30%	1.80%	Day 25
<b>45%</b>	<b>1.60%</b>	<b>Day 22</b>
60%	1.50%	Day 21
75%	1.45%	Day 20
90%	1.44%	Day 19

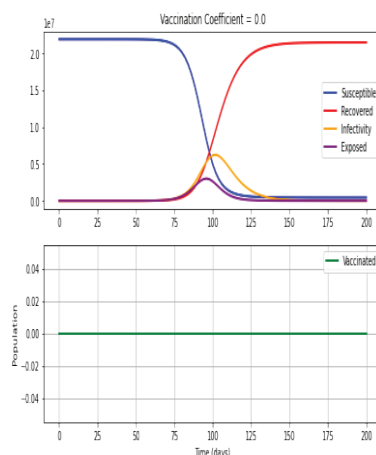


**Figure 1: SEIRV Model with Transition Forces**

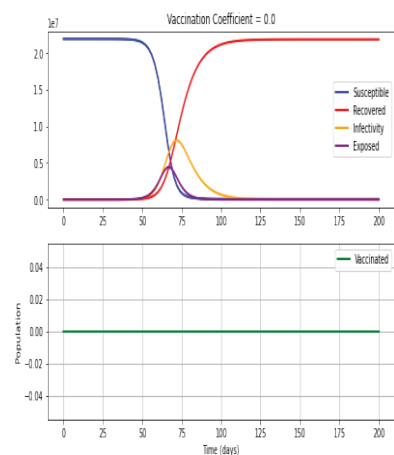
**$R_0=2$**



**$R_0=4$**



**$R_0=6$**



**Figure 2: Evolution of infectious proportion without vaccination with different  $R_0$  values**

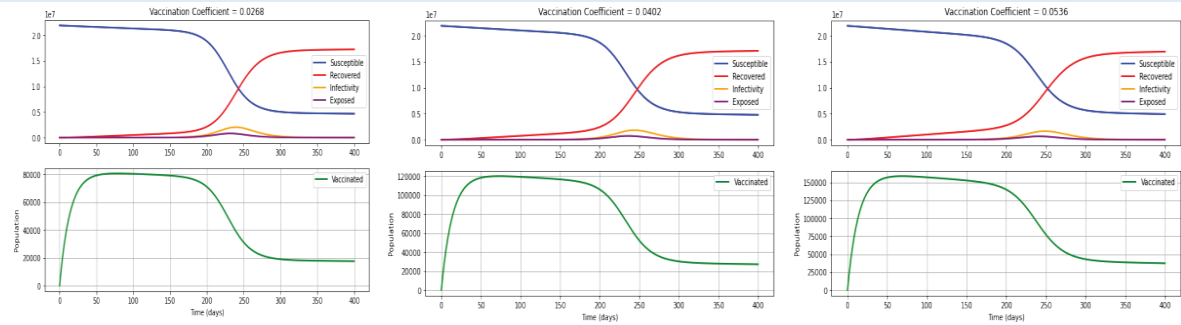
## $R_0$ Vaccine Efficacy

40%

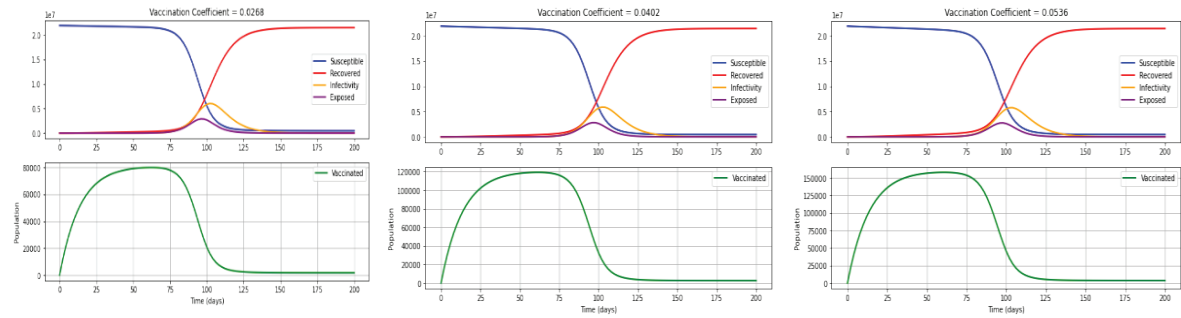
60%

80%

2



4



6

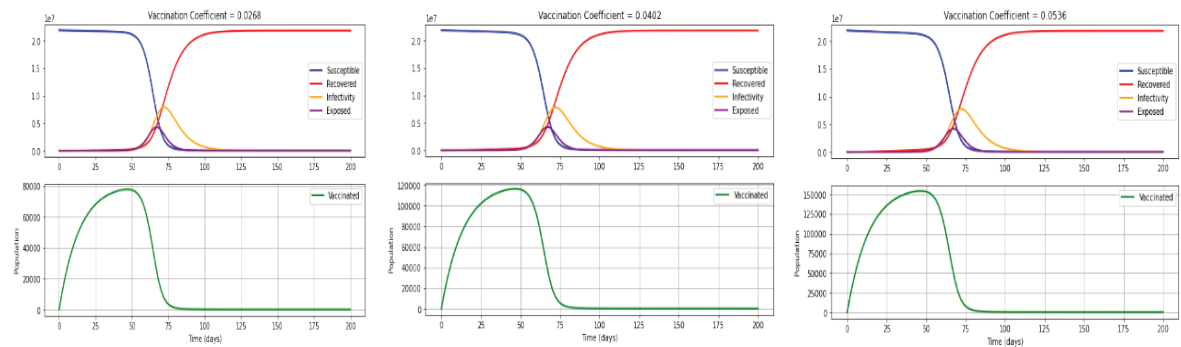


Figure 3: Prediction based on the SEIRV model considering the parameter  $R_0$  ( $R_0=2,4,6$ ) and Vaccine efficacy variation (Vaccine efficacy=40%,60%,80%)

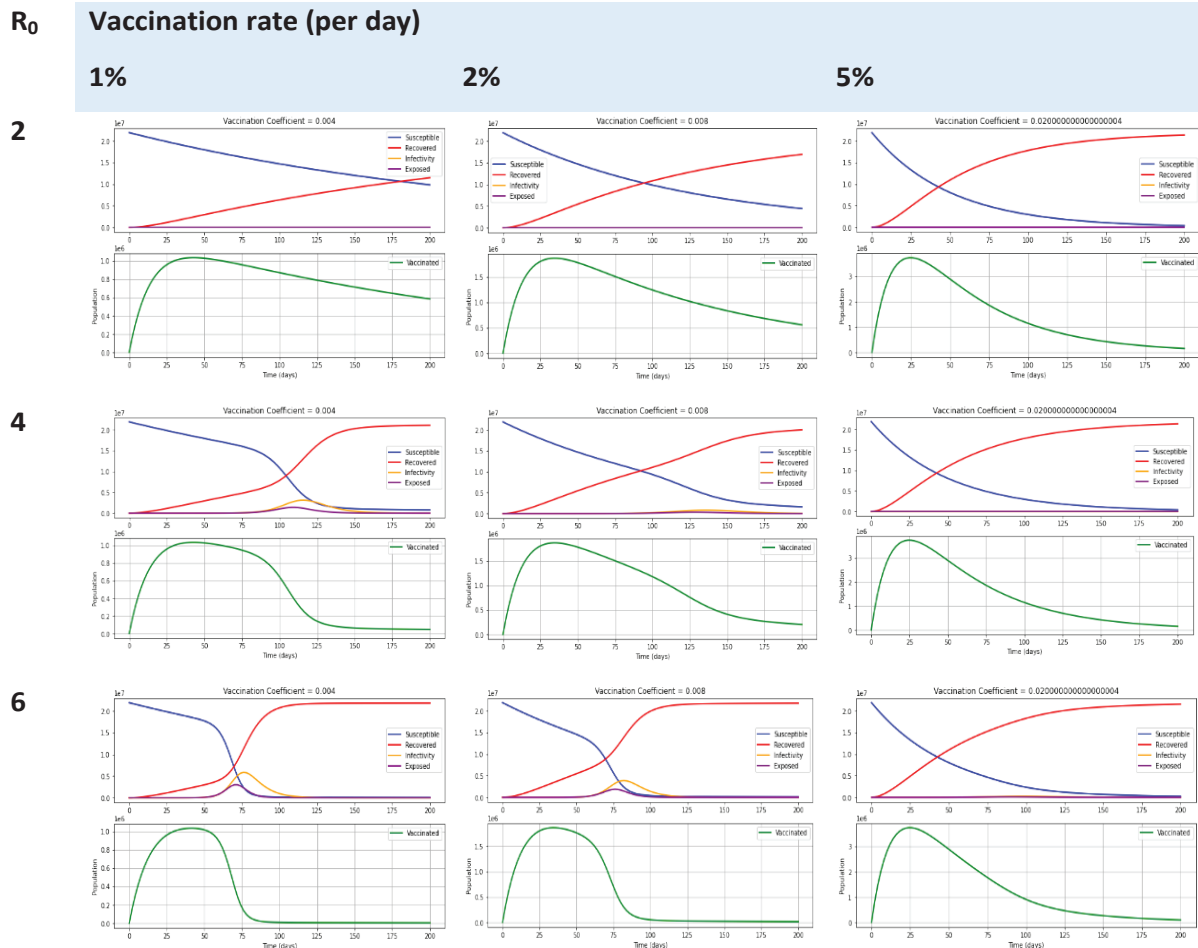


Figure 4a: Evolution of SEIRV under different levels of Vaccination rates (1%, 2%, 5%),  $R_0$  of 2, 4, 6 with 40% Vaccine efficacy

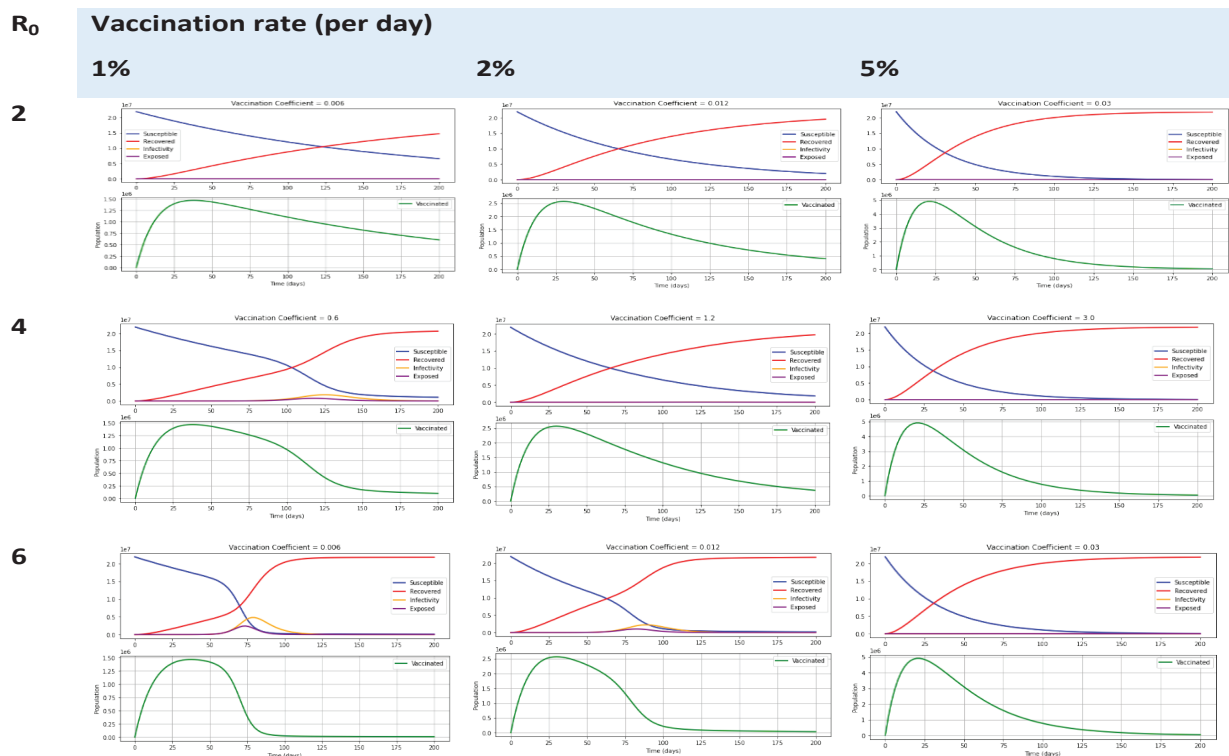
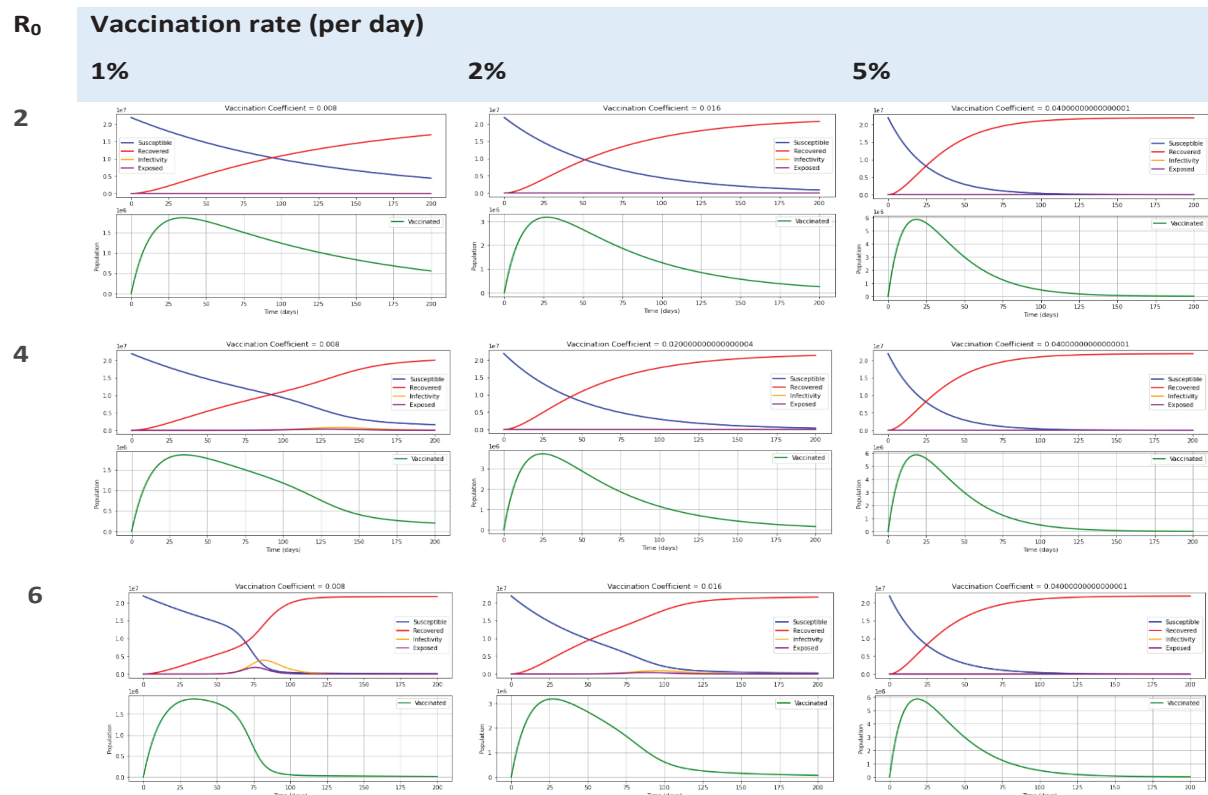


Figure 4b: Evolution of SEIRV under different levels of Vaccination rates (1%, 2%, 5%),  $R_0$  of 2, 4, 6 with 60% Vaccine efficacy



**Figure 4c: Evolution of SEIRV under different levels of Vaccination rates (1%, 2%, 5%),  $R_0$  of 2, 4, 6 with 80% Vaccine efficacy**  
**Supporting Information (Supplementary files)**

## S1 File. Model validation

Supporting file, one is 'Model validation'

## Model Validation

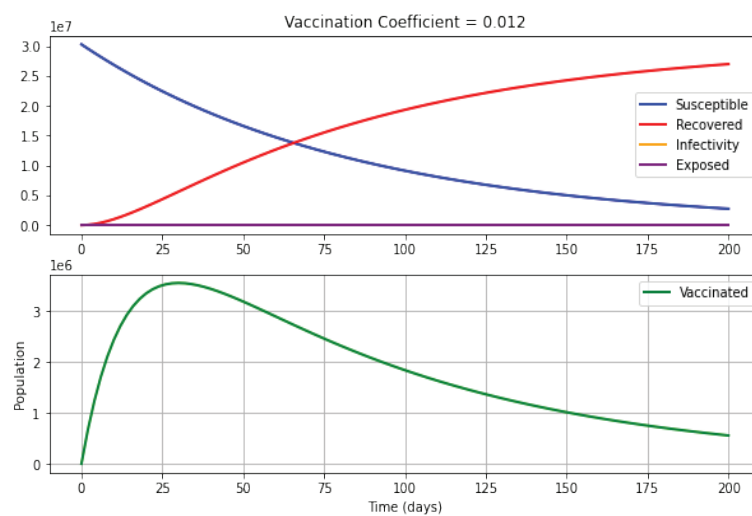
Since the situation of New Delhi, India was similar to the Sri Lankan situation of the COVID-19 during the first quarter of 2021, we used the same data for validating the present SEIRV model. In addition, the time frame of the New Delhi situation is also similar to the Sri Lankan conditions (a parallel time frame). Accordingly, the validation component has supplemented the model that we have used in the analysis. Furthermore, we have considered  $R_0$  of 2, 4, 6 in this analysis.



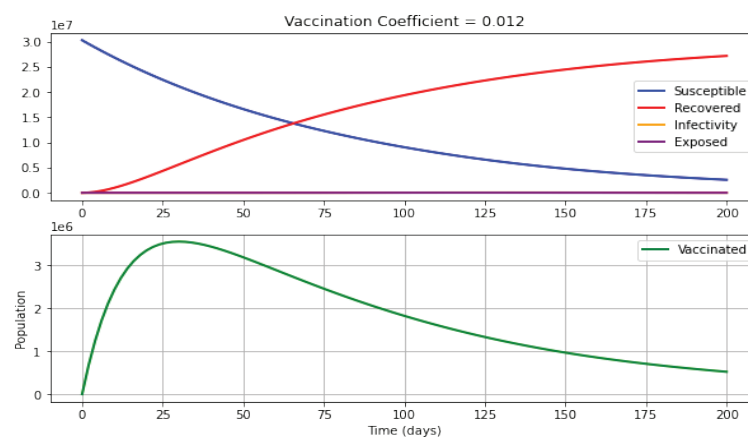
**S1. Table 1: Model parameters for validation**

Parameter	Value (New Delhi)	Value (Sri Lanka)
Incubation period	5.74	5.5
Hospitalization period	21	22
Population	30,291,000	21,919,000
$R_0$	2,4,6, (Assumed)	2,4,6, (Assumed)
Vaccination rate 2%	2 %	1%,2%,5%
Vaccine efficacy	60% (Assumed: AstraZeneca)	40%,60%,80%
Social distancing and other policies	0	0
Source: CDC (www.cdc.gov)		

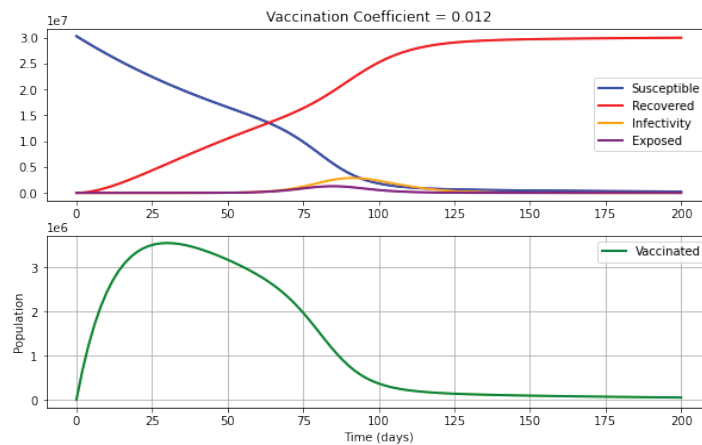
**$R_0=2$**



**$R_0=4$**



$R_0=6$



**S1. Table 2: SEIR model validation and simulation for New Delhi in India (Population)**

$R_0$	Infection	Exposure	Vaccinated
2	11	5	3,549,725
4	54,993	21,503	3,549,705
6	2,872,463	1,286,209	3,549,523

**S1 Table: Evolution of infectious and exposed population without vaccination**

$R_0$	Vaccination coverage	Exposed population	Infected population
2	0	979,423	2,427,735
4	0	3,019,928	6,248,497
6	0	4,423,387	8,118,512

**S2 Table: Evolution of SEIRV under different levels of vaccine efficacies and different  $R_0$**

$R_0$	Vaccine efficacy	Vaccinated population	Exposed population	Infected population
2	40%	80,256	811,368	2,028,917
	60%	119,792	730,670	1,836,608
	80%	158,502	651,930	1,646,643
4	40%	79,943	2,887,652	6,023,035
	60%	119,144	2,814,030	5,898,324
	80%	157,852	2,759,222	5,780,785
6	40%	77,869	4,290,311	7,966,180
	60%	116,289	4,253,997	7,886,468
	80%	154,369	4,218,349	7,804,450

**S3 Table: Evolution of SEIRV under different Vaccination rates at  $R_0=2,4,6$  with the Vaccine Efficacy of 40%, 60% and 80%**

Vaccine efficacy	$R_0$	Vaccination rate	Vaccinated population	Exposed population	Infected population
<b>40%</b>	2	1%	1,034,457	238	627
		2%	1,862,458	12	31
		5%	3,739,425	4	1
	4	1%	1,034,383	1,369,746	3,114,015
		2%	1,862,427	325,594	807,301
		5%	3,739,416	589	1,478
	6	1%	1,032,464	3,003,732	5,876,928
		2%	1,862,034	1,878,969	3,888,296
		5%	3,739,362	113,954	279,796
<b>60%</b>	2	1%	1,467,069	33	86
		2%	2,568,631	4	11
		5%	4,907,112	1	3
	4	1%	1,467,020	764,680	1,814,842
		2%	2,568,611	21,041	53,773
		5%	4,907,106	225	91
	6	1%	1,466,123	2,417,586	4,823,162
		2%	2,568,430	2,201,900	994,094
		5%	4,907,083	14,420	5,897
<b>80%</b>	2	1%	1,862,458	31	12
		2%	3,186,149	2	6
		5%	5,866,696	1	2
	4	1%	1,862,427	325,594	807,301
		2%	3,186,132	2,321	5,883
		5%	5,866,691	35	84
	6	1%	1,862,034	1,878,969	3,888,296
		2%	3,186,013	402,552	953,785
		5%	5,866,675	2,644	1,101

## Application of Motivation, Opportunity and Ability (MOA) model to COVID-19 preventive behaviours: A web-based survey

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### Abstract

**Background:** New variants of COVID-19 are emerging as part of the evolutionary cycle of the viruses. Therefore, a combination of positive behaviours is still endorsed to gain maximum protection from COVID-19. In this context, many behaviour-related models have been adopted to understand the behaviour dynamics of the disease. The MOA model is a well-known model used to understand consumer behaviour.

**Objectives:** The aim of this study is to determine the motivation, opportunity and ability to perform key positive COVID-19 preventive behaviours among a sample of internet users to help to get an insight into future behavioural interventions in Sri Lanka.

**Methods:** An online descriptive cross-sectional survey was conducted through the HPB-SL official Viber channel to assess nine selected behaviours' (Handwashing, Cough Etiquette, Avoid touching the face, Wearing face masks, Surface cleaning, Keeping a 1m distance, Avoiding crowds, Avoiding ill, Self-isolation) motivation, opportunity and ability during December 2020 to January 2021. A ten-point unipolar Likert behaviour scale was developed for the three selected attributes (motivation, opportunity and ability). An unrestricted self-selected survey sampling method was followed.

**Results:** Out of the invitations sent, 475 respondents answered the survey giving response rate of 88.4%. The motivation, opportunity and ability were high for mask-wearing out of the selected nine behaviours. Overall, females had higher motivation for the selected nine behaviours. Even though motivation and ability are higher for washing hands, the opportunities are low for washing hands. Similar motivation, opportunity and ability were seen for cough etiquette. Furthermore, higher education qualifications and increasing age had higher motivation, opportunity, and ability than lower education qualifications and younger age groups.

**Conclusions and recommendations:** The MOA model provides a good insight into the practicality of COVID-19 preventive behaviours in the field. The findings of this study can be used to implement successful behaviour change programmes at the field level in the future.

### Keywords

COVID-19, Primary prevention, Motivation, Web-based surveys

## Introduction

The COVID-19 pandemic caused devastating global health, economic and social consequences. Effective COVID-19 prevention warrants sustained behaviour change and vaccination. Millions of the population are currently vaccinated globally, and the demand for the vaccine is hardly met, aggravating inequity. Moreover, understanding the long-term effectiveness and effect of the vaccine on the transmission of the disease is yet to be explored. Furthermore, the emergence of new disease strains is still occurring at a regular pace. Therefore, the importance of COVID-appropriate behaviours during the post-vaccination period to control COVID-19 has still not diminished [1].

A combination of positive behaviours is endorsed to gain maximum protection from COVID-19. Many behaviour-related models have been adapted to understand the behaviour dynamics of the disease. For example, the Swiss Cheese model originally applied to prevent workplace accidents is advocated for COVID prevention by many [2]. It describes providing multiple layers of preventive mechanisms to avoid the harm done by small breaching of preventive measures.

The Swiss Cheese model and other relevant models can be used to predict how people decide on adopting specific behaviours.

The motivation (M), opportunity (O) and ability (A) - (MOA) model proposes that individual behaviour is determined by motivation, opportunity and ability to implement the behaviour [3]. According to this model, motivation is the habitual /emotional response or analytical decision to execute a particular behaviour. It is moderated by two factors: ability, knowledge or the skills needed for the behaviour and opportunity representing all external controls like time and resources [4,5]. Therefore, it is proposed that a particular behaviour is a product of the multiplication of motivation, opportunity and ability. A reduction in any element results in

a drastic behaviour reduction [4,6].

Based on the evidence, nine key positive behaviours were identified to promote among the general public in Sri Lanka. Namely, washing hands frequently and properly, covering the mouth with the arm when coughing and sneezing, avoiding touching the face, nose or mouth, keeping a one-meter distance, avoiding crowds and social gatherings, using a face mask when going out, cleaning the surfaces regularly, avoiding close contact with those who are ill and, self-quarantining when sick [7].

The endorsed few key positive behaviours challenged many social norms and natural behaviour of humans. Humans have become social living beings during evolution over the years [8] However, social distancing is considered one of the most effective strategies for COVID prevention. Similarly, the face is regarded as a component of the self-image [9] Nevertheless, people are being asked to ask to cover it with a face mask. Evidence suggests a person typically touches their face 15-20 times habitually in an hour [10,11]. However, during the COVID-19 epidemic, people were asked not to touch their faces.

Furthermore, many cultures were promoting helping and looking after ill persons. However, people were asked to avoid close contact with the sick during the epidemic. Many recommendations regarding behaviour changes required to prevent COVID-19 were sudden, and the WHO requested the general public to upgrade their behaviour rapidly during the last year. However, people became increasingly unresponsive; finally, pandemic fatigue and message fatigue were evident in many parts of the world [12]. Hence, efficient management of message fatigue is critical through addressing peoples' motivation, opportunity and capability to implement positive behaviours in the community [12].

Moreover, the type of behaviour intervention-

law (fiscal measure, regulations), education, communication /social marketing depends on the element deficient for a particular behaviour [5,13]. Hence determining the deficient element for a specific behaviour is essential and timely to implement evidence-based interventions to modify positive behaviours to prevent COVID-19. Therefore, the present study aims to determine the motivation, opportunity and ability to perform key positive behaviours among a sample of internet users to get an insight into future behavioural interventions in Sri Lanka. Determining the motivation for preventive behaviours will help health policymakers plan effective behaviour change campaigns. It will provide much-needed evidence for effective campaigns. Evidence about the level of opportunities will provide insight for grassroot health workers and other village-level community influencers to adjust their strategies at the ground level.

## Objective

The objective of this study was to determine the motivation, opportunity and ability to perform key positive COVID-19 preventive behaviours among a sample of internet users to help to get an insight into future behavioural interventions in Sri Lanka.

## Materials and method

An online descriptive cross-sectional web survey was launched in December 2020 to January 2021 for a period of 2 months through the HPB-SL official Viber channel, which consisted of 454,534 followers at the time of deployment. Sri Lankans who are 18 years or older were invited to participate. The proportion of individuals with an estimated level of perceived motivation or availability of the opportunity and the ability to adopt any key behaviour in Sri Lanka was taken as 50% since no data was available. A minimum of 537 subjects was required with a precision level of 5% using a standard formula with a non-response rate adjustment of 40% [14]. An unrestricted self-selected survey sampling method

was followed. The non-response rate of this study was 11.55%.

## Development of the questionnaire

Perceived motivation, availability of an opportunity and ability to perform nine key behaviours were asked on a numerical analogue scale. The three-page final questionnaire included the basic characteristics of the participants on the first page. Participants were able to review the answers and change them by using the back button before submission. Previous research studies on motivation, opportunity and ability were considered in developing the scale. We held several stakeholder meetings with national-level programme managers, field health workers, UN agencies, and community-based organizations to obtain input to the scale. The scale's content validity was established with community medicine experts. The scale was designed as a unipolar scale. Answers were developed on a ten-point Likert scale; ability from very easy (0) to very hard (10), motivation from no motivation at all (0) to extremely motivated (10) and availability of opportunity not at all (0) to most of the time (10). The questionnaire was translated into two languages (Sinhala and Tamil). The questionnaire was pretested using standard cognitive probes among colleagues. The technical functioning was tested among five potential participants, and necessary corrections were made to make the form easy to fill in less than three minutes.

## Data collection and analysis

Participants were recruited through invitations via Viber messages. Data was collected through a Google form embedded in a Viber message; responses were automatically collected to an excel sheet stored in the Google Drive of the official HPB account, to which only the Principal Investigator had access. Responses were collected, coded, validated, and analysed using SPSS software. Results were expressed as means (standard deviations), and ANOVA was used to determine



any statistically significant difference.

## Results

Basic socio-demographic characteristics of the survey participants

The response rate of the sample was 88.4%, and 475 responded. The mean age of the sample was 40.42 years ( $SD \pm 12.16$ ). Most participants were males (58%) and were educated to G.C.E A/L or above (96%). The main socio-demographic characteristics of the sample are given in Table 1.

### Motivation, opportunity and ability for each positive key behaviour to prevent COVID-19 infection

The highest motivation, opportunity and ability were demonstrated for wearing a mask. Even though motivation and ability are higher for washing hands, the opportunities are low for washing hands. Similar motivation, opportunity and ability were seen for cough etiquette. The ability to avoid touching the face is low, even though the motivation and opportunity are high. The motivation is high for avoiding crowds and self-isolation. However, opportunities and abilities are lacking. Similarly, motivation is high to keep at least a one-meter distance and clean surfaces, but ability and opportunity are low. Avoiding illness had a wide variation in opportunity despite high motivation (Figure 1).

### Socio-demographic factors and motivation, opportunity and ability for each positive key behaviour to prevent COVID-19 infection

There was a statistically significant difference in motivation in handwashing and wearing facemasks with gender. Similarly, in the opportunity to avoid touching the face, wearing a facemask and surface cleaning, females scored more than males (Table 2). The ability to handwash, cough etiquette, and wear a mask significantly differed according to age. The ability to handwash, cough etiquette, wearing masks increased as the age increased except for the > 60-year age group. Those with higher educational qualifications had statistically significantly better motivation for

handwashing, avoiding touching the face and wearing masks. Occupation, civil status and race did not have much variation in motivation, opportunity and ability except for mask-wearing (Table 2).

Our study found that physical and social distancing overall had lower mean values for motivation, opportunities, and abilities than personal hygiene-related behaviours. Furthermore, regarding physical and social distancing measures, females had higher motivation for keeping a one-meter distance. The ability to avoid ill and self-isolation significantly differed with age (Table 3). Those with higher educational qualifications have better motivation to keep one-meter distance, avoid crowds, and avoid ill persons and self-isolation. Civil status and occupation did not vary much in motivation, opportunity and ability. However, the Sinhala ethnicity had better opportunities and the ability for self-isolation (Table 3).

## Discussion

Our study found that motivation, opportunity, and ability are high for mask-wearing, which can be easily implemented. All other behaviours had a reasonable level of motivation; however, the opportunities and abilities were comparatively low. Overall, females had higher motivation. In addition, higher educational qualifications and increasing age had higher motivation, opportunity, and ability compared to lower educational qualifications and younger age groups.

Findings similar to our study have been reported by a survey conducted to assess the barriers and facilitators of adherence to social distancing, which reports that men are less adherent than women. One of the key explanations for this difference was the lower risk-taking by females<sup>8</sup>. The explanation given by the authors tally with our study findings as well. A similar finding is also reflected in another study by Clark et al.<sup>15</sup> in a much larger international sample that reports that the female gender is more likely to engage in COVID-19-related

voluntary compliance behaviours than males. Although our study found that increase in age had an association with some of the behaviours (handwashing, cough etiquette, wearing masks), the study by Clark et al. 15 reports age is generally unrelated to behaviours (wearing masks, social distancing, hand washing and staying at home). These differences in the two studies may be due to the better distribution of age categories in their sample than our research, which consisted of a younger population.

In the present study, physical and social distancing had lower mean values for motivation, opportunities and abilities compared to personal hygiene-related behaviours. This distinction is reflected in other research as well. A study by Wisman et al. 16 reveals that compliance related to hand washing and cough behaviours is uniformly distinct from compliance related to social distancing behaviours. Barret and Cheung 17 suggest that knowledge and socio-cognitive perceptions may result in this difference. The authors further suggest that the overall emphasis paid at the time of the epidemic for the particular behaviour is important, and they have found a lower rate of hand hygiene behaviour compared to social distancing in their study. At the time of the present study in Sri Lanka, the emphasis was mainly on personal hygiene behaviours, and there was comparatively a low interest in social distancing measures.

The findings of this study have many potential implications for COVID-19 prevention behaviours in Sri Lanka. Firstly, it will provide

the much-needed evidence for behaviour change interventions for specific behaviours required for COVID-19 prevention. The evidence can be used to target customised behaviour change programmes based on socio-demographic characteristics. Secondly, it provides the particular behaviour change interventions to focus on (improve motivation, increase the opportunity or increase ability). These can be provided by ways of means of law (fiscal measure, regulations), education (giving knowledge and skills) or improving communication (social marketing) depending on the deficient element of a particular behaviour 5,13. Finally, the MOA model provides the much-needed monitoring framework for behaviour change interventions.

The main limitation of this study is the representativeness of the study population. Since this was an online survey done through Viber, selection bias is unavoidable. Therefore, it might affect the generalizability of the study findings.

## Conclusion

The motivation, opportunity and ability are high for mask-wearing out of the selected nine behaviours. Overall, females had higher motivation; higher educational qualifications and increasing age had higher motivation, opportunity, and ability than lower educational qualifications and younger age groups. The MOA model provides a good insight into the practicality of COVID-19 preventive behaviours. The findings of this study can be used to implement successful

behaviour change programmes at the field level.

### Author Declaration

**Author contribution:** MSDW, MGSNSP, VCNV, and SASCK were responsible for conceptualization, conducting the study, and writing the manuscript. BMIG, WMPCW, VCNV, and SASCK reviewed the draft manuscript. All authors reviewed and approved the final manuscript.

**Conflict of interest:** The author(s) declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

**Ethics approval:** This study was approved by the Ethics Review Committee of the Post Graduate Institute of Medicine - University of Colombo, Sri Lanka.

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**Table 1: Socio-demographic characteristics of the survey participants (n=475)**

	Characteristic	n	%
Sex*	Male	275	58.0
	Female	199	42.0
Education*	Up to G .C. E (O/L)	19	4.0
	Above G .C. E (A/L)	455	96.0
Employment**	Employed	376	79.5
	Not employed	97	20.5
Civil status****	Married	349	74.1
	Single	116	24.6
	Divorced/widowed	6	1.3
Race*****	Sinhala	395	84.0
	Tamil	61	13.0
	Muslim	10	2.2
	Other	4	0.8
Residence	Colombo	136	28.6
	Gampaha	83	17.5
	Kaluthara	26	5.5
	Other	230	48.4

\*missing values (n=1), \*\* missing values (n=2),

\*\*\* missing values (n=3), \*\*\*\* missing values (n=4), \*\*\*\*\* missing values (n=5)

Table 2 : Distribution of mean scores of MOA of personal hygiene-related behaviours according to the socio-demographic characteristics

Variable	Handwashing			Cough Etiquette			Avoid touching the face			Wearing face masks			Surface cleaning		
	M	O	A	M	O	A	M	O	A	M	O	A	M	O	A
<b>Gender</b>															
Male	<b>8.81*</b>	8.50	8.93	9.03	9.09	9.12	8.36	<b>8.56*</b>	8.48	<b>9.39**</b>	<b>9.55**</b>	<b>9.49**</b>	8.04	<b>7.54**</b>	7.64*
Female	<b>9.09*</b>	8.71	9.04	9.26	9.28	9.36	8.53	<b>8.85*</b>	8.60	<b>9.68**</b>	<b>9.87**</b>	<b>9.82**</b>	8.34	<b>7.96**</b>	7.99*
<b>Age (years)</b>															
<30	8.86	8.71	<b>8.94**</b>	9.20	9.06	<b>8.90**</b>	8.43	8.60	8.34	9.29	9.54	<b>9.27**</b>	8.35	8.13	7.89
31-45	8.79	8.40	<b>8.74**</b>	9.10	9.22	<b>9.14**</b>	8.35	8.69	8.44	9.62	9.76	<b>9.71**</b>	8.15	7.54	7.66
46-60	9.16	8.79	<b>9.39**</b>	9.03	9.27	<b>9.60**</b>	8.69	8.73	8.85	9.45	9.7	<b>9.76**</b>	8.03	7.87	7.93
>60	9.37	8.93	<b>9.39**</b>	9.43	8.73	<b>9.43**</b>	8.07	8.77	8.64	9.57	9.5	<b>9.54**</b>	8.3	7.33	8.04
<b>Education</b>															
Up to O/L	<b>8.26**</b>	<b>8.42*</b>	8.89	8.89	<b>8.53**</b>	<b>8.68*</b>	<b>8.00**</b>	9.00	<b>8.06*</b>	<b>8.68**</b>	<b>9.26**</b>	<b>8.84**</b>	8.95	8.79	8.68
Above A/L	<b>8.96**</b>	<b>8.6*</b>	8.98	9.13	<b>9.20**</b>	<b>9.24*</b>	<b>8.45**</b>	8.67	<b>8.56*</b>	<b>9.55**</b>	<b>9.70**</b>	<b>9.66**</b>	8.14	7.68	7.75
<b>Occupation</b>															
Employed	8.92	<b>8.50*</b>	8.92	9.12	9.21	<b>9.29**</b>	8.42	9.21	8.56	<b>9.55*</b>	9.71	<b>9.71**</b>	8.06	7.6	7.67
Not Employed	8.97	<b>8.94*</b>	9.20	9.15	9.00	<b>8.96**</b>	8.45	9.00	8.42	<b>9.35*</b>	9.59	<b>9.33**</b>	8.58	8.19	8.24
<b>Civil status</b>															
Married	8.92	8.54	8.96	<b>9.05**</b>	9.16	9.25	8.38	<b>8.62*</b>	8.54	9.53	9.69	<b>9.69**</b>	<b>8.06*</b>	<b>7.55*</b>	7.68
Other	8.97	8.73	8.97	<b>9.39**</b>	9.19	9.10	8.64	<b>8.91*</b>	8.47	9.47	9.68	<b>9.43**</b>	<b>8.47*</b>	<b>8.18*</b>	8.03
<b>Race</b>															
Sinhala	8.93	<b>8.52*</b>	8.95	9.10	9.16	9.19	8.43	8.68	8.51	<b>9.48*</b>	9.67	<b>9.59**</b>	8.19	7.75	7.79
Other	8.91	<b>8.94*</b>	9.09	9.27	9.23	9.39	8.43	8.74	8.63	<b>9.70*</b>	9.78	<b>9.80**</b>	8.06	7.59	7.76
M - Motivation O - Opportunity A - Ability															

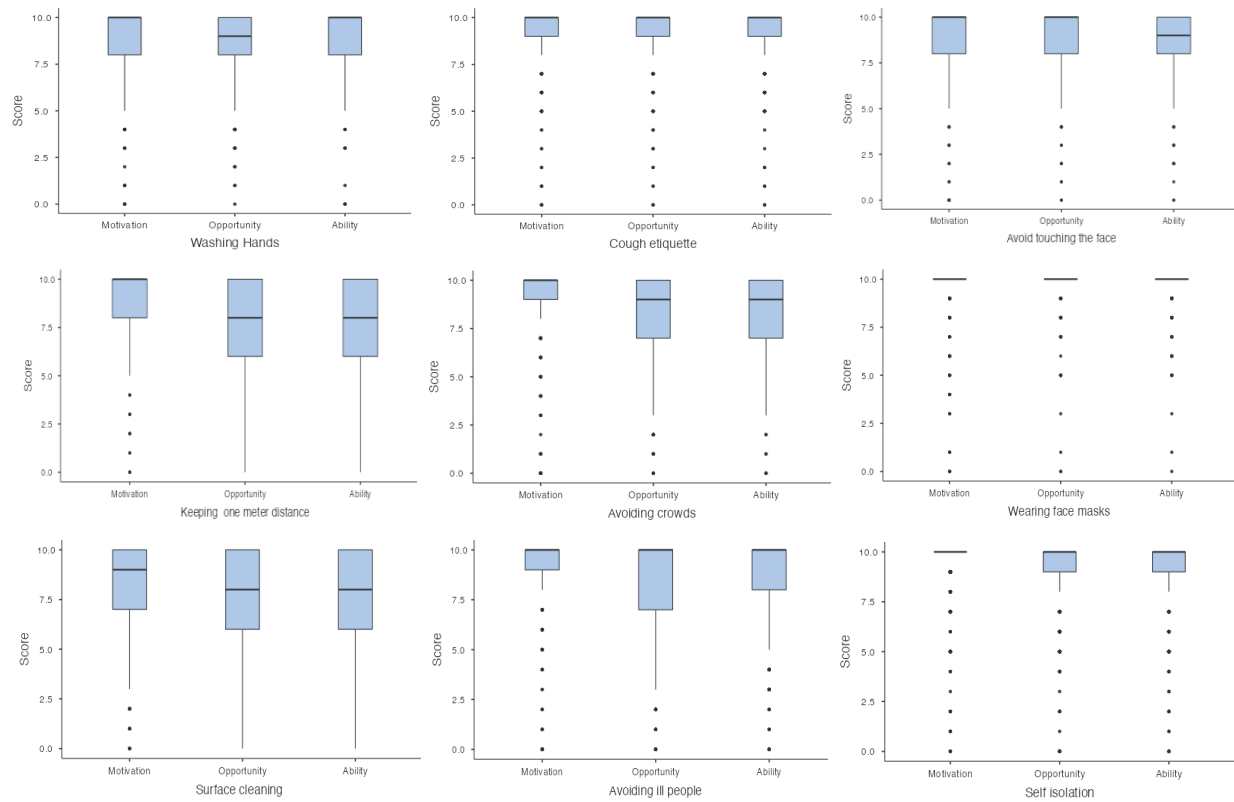
\* / \*\* Statistically significant ( $p < 0.05^*$ ,  $< 0.01^{**}$ )



**Table 3 : Distribution of mean scores of MOA of physical and social distancing behaviours according to the socio-demographic characteristics**

Variable	Keeping a 1m distance			Avoiding crowds			Avoiding ill			Self-isolation		
	M	O	A	M	O	A	M	O	A	M	O	A
<b>Gender</b>												
Male	<b>8.83*</b>	7.82	7.90	9.04	8.10	8.22	8.94	8.48	8.73	9.31	<b>8.83*</b>	8.98
Female	<b>9.07*</b>	7.68	7.76	8.76	7.84	8.04	8.68	8.07	8.25	9.49	<b>9.12*</b>	8.97
<b>Age (years)</b>												
<30	8.85	7.97	7.99	8.84	8.11	8.1	8.73	8.17	<b>8.07*</b>	9.18	8.79	<b>8.83*</b>
31-45	8.97	7.65	7.74	8.86	7.77	8.04	8.71	8.27	<b>8.52*</b>	9.46	8.92	<b>8.80*</b>
46-60	8.79	7.71	7.88	8.96	8.22	8.25	8.93	8.38	<b>8.71*</b>	9.43	9.34	<b>9.43*</b>
>60	9.43	8.23	8.04	9.57	8.5	8.71	9.7	8.73	<b>9.32*</b>	9.27	8.2	<b>9.14*</b>
<b>Education</b>												
Up to O/L	<b>8.42**</b>	8.84	8.68	<b>7.95**</b>	8.74	<b>8.21*</b>	<b>8.21*</b>	8.89	8.89	<b>8.21*</b>	8.89	8.89
Above A/L	<b>8.95**</b>	7.71	7.80	<b>8.97**</b>	7.96	<b>8.14*</b>	<b>8.85*</b>	8.28	8.51	<b>8.86*</b>	8.28	8.51
<b>Occupation</b>												
Employed	8.9	7.68	7.78	8.91	7.88	8.09	<b>8.75*</b>	8.24	8.47	9.42	<b>9.01*</b>	8.93
Not employed	9.04	8.08	8.07	8.99	8.42	8.33	<b>9.15*</b>	8.57	8.75	9.25	<b>8.71*</b>	9.16
<b>Civil status</b>												
Married	8.97	7.74	7.82	8.92	7.92	7.82	8.78	8.23	<b>8.55*</b>	9.39	8.98	8.99
Other	8.85	7.74	7.85	8.97	8.14	7.85	8.96	8.43	<b>8.34*</b>	9.4	8.8	8.89
<b>Race</b>												
Sinhala	8.97	7.68	7.73	8.87	7.91	8.05	8.79	8.27	8.53	9.42	<b>9.01**</b>	<b>9.00*</b>
Other	8.73	8.18	8.38	9.19	8.41	8.62	9.03	8.47	8.51	9.22	<b>8.66**</b>	<b>8.86*</b>
M - Motivation O - Opportunity A - Ability												

\* / \*\* Statistically significant (p<0.05\*, <0.01\*\*)



**Figure 1: Motivation, opportunity and ability for each positive key behaviours to prevent COVID-19 infection**

## The knowledge and attitude on pain management and their associated factors among nursing students at the school of nursing, Vavuniya

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### Abstract

**Background:** Pain control in patients is important as untreated pain impede their response to treatments and negatively affect their quality of life. Optimal pain management requires adequate knowledge, positive attitudes, and competent pain assessment measures. Nurses are key players and have an essential role in pain management. Applying nursing roles requires that nursing students attain adequate knowledge about pain, its management, and positive attitudes towards it.

**Aim/s:** To assess the knowledge and attitudes on pain management and their associated factors among nursing students in the School of Nursing, Vavuniya.

**Methods:** A descriptive cross-sectional study was conducted with the total study population of second-year (n=97) and third-year nursing students (n=43) at the School of Nursing, Vavuniya. The study was conducted using a pre-tested self-administered questionnaire that included the modified Ferrell and McCaffery (2012) Knowledge and Attitude Survey Regarding pain (KASRP). Data were described using descriptive statistics, and associations were assessed using the Mann-Whitney U and Kruskal Wallis tests. Significance was set as  $p < 0.05$ . The ethical clearance was obtained from the Rajarata University of Sri Lanka.

**Results:** The response rate was 97%. The majority belonged to the age group between 23-25 years (n=112, 80.0%). The mean age was 23.7 years (SD +1.102). Majority were female (n=135, 96%), Sinhalese (n=107, 76%) and Buddhist (n=98, 70%). Most of the students had “poor” knowledge on pain management (n=98, 70%) and had “fair” attitudes (n=98, 70%). “Good” attitudes were reported by 7% (n=10) of the students. The median of the total correct answers for knowledge was 13 (IQR=5) out of 30 questions, and the median attitude score was 8 (IQR=4) out of 15 questions. The year of study and additional study of reference materials were significantly related to knowledge and attitudes towards pain management ( $p < 0.01$ ).

**Conclusion:** The overall knowledge among nursing students on pain management was “poor”, and most had fair attitudes towards pain management. Pain management education needs to be strengthened, and positive attitudes should be cultivated through curricular reforms in nursing education.

**Keywords:** Pain Management, Knowledge, Attitudes, Nursing Students

## Introduction

Pain is an unpleasant sensation experienced by both sick and healthy people. Pain is a major source of distress for patients and their families as well as health care providers. Patients may experience pain as a result of injuries, acute & chronic illnesses, and medical or surgical procedures. It can lead to physical consequences such as increased oxygen consumption and alterations in blood glucose metabolism. In addition, the experience of untreated pain may lead to long-term psychological, physiological, and behavioral consequences for a person [1].

All people have experienced pain at some point of the life continuum from birth to death, especially while being in hospitals. Similarly, every nurse may experience managing a patient with pain at some point in his or her nursing career [2]. One of the important responsibilities of health care personnel is to relieve as much pain as possible. This comes in the same line with the “American pain society” (1995) cited in Goodrich [3] which labeled pain as the “Fifth vital sign” to emphasize the importance of assessing the pain frequently and providing appropriate treatment. The undertreatment of pain can delay healing and may develop into chronic pain that can limit daily activities, increase disability, and increase anger and fear that may negatively affect the quality of life. If ineffectively managed, acute pain can lead to negative physiological and psychological ramifications including the development of chronic pain syndromes [4].

Nurses play an important role in assessing and managing patients’ pain during hospitalization. They spend most of their time at the patient’s bedside as compared to other health care professionals. Patients and their families have the right to receive pain management timely and effectively [5]. Pain management is a crucial part of patient management that helps to deliver high-quality nursing care. The research findings on the knowledge and attitudes of registered nurses

towards the pain management of adult medical patients in Bindura hospital, Zimbabwe identified that they had inadequate knowledge (64.5%) and attitudes (56%) regarding pain management [6]. Similarly, the investigation of knowledge and attitudes regarding pain management among nurses in Hong Kong medical units showed a deficit in knowledge and attitudes related to pain management (47.72%) [7].

Student nurses must have sound knowledge and attitudes regarding the management of pain. Consequently, if student nurses are insufficiently educated and ill-prepared to relieve pain, ultimately the patient will suffer [8]. For this reason, nursing students must be well knowledgeable about pain and its management to improve patient outcomes and collaborate efficiently with other health care professionals to manage the pain successfully [9].

Nursing students have to learn and serve patients in their entire training period of 3 years in the clinical setting. Most of the time, they meet patients who are needed to be relieved of pain. Implementing the role of the caregiver in providing comfort, nursing students should achieve a comprehensive knowledge of pain and its management during the nursing program [8]. Adequate knowledge of pain and appropriate pain attitudes are prerequisites for nursing students to engage in pain management of patients [9]. Research on nursing students’ knowledge and attitudes regarding pain is limited. These limited studies also identified that nursing students had poor knowledge and attitude regarding pain management [3,10]. Student nurses’ knowledge about pain management was poor, especially in the areas of pharmacology [11]. The same finding was confirmed in another study as nursing students had inadequate pain knowledge and inappropriate pain management attitudes [12]. Using the Nurses’ Knowledge and Attitude Survey Regarding Pain (NKASRP), a study identified that student nurses had inadequate knowledge of pain management [13]. Because of the knowledge

deficit related to pain and pain management, there should be a real need for improving the content of pain and management in the undergraduate nursing education curriculum [14].

Pre-registration nursing education in Sri Lanka, is based on a three-year diploma level nursing program delivered by 15 schools of nursing that are attached to the Ministry of Health. It is aimed at preparing nurses who will be able to utilize a comprehensive range of knowledge, skills, and attitudes in caring for patients. There is no separate module or section to teach pain management in the present curriculum of the basic nursing diploma program. The pharmacology part II module is devoted to teaching medicines acting on different systems of the body rather than pain-managing medicines. The majority of the clinical subjects familiarizes the students with pain as a symptom of disease through the lecture-based method. Therefore, the amount of time that is allocated for teaching pain management in the nursing curriculum is unknown. Exposure to the clinical subjects and the second part of pharmacology commence with the second year of training. Moreover, second-year and third-year students involve more in pain management in the clinical setting. There was no research conducted among nursing students in this area in Sri Lanka. Based on this rationale, the study was conducted to investigate the level of knowledge and attitude and associated factors regarding pain management among the second-year and third-year nursing students at the school of nursing Vavuniya in Sri Lanka.

## Methods

The quantitative descriptive cross-sectional study method was applied to investigate the level and factors associated with knowledge and attitude on pain management among nursing students at the School of Nursing, Vavuniya from June to September 2019. School of nursing, Vavuniya is the youngest nursing school in Sri Lanka which follows the uniform curriculum as

the rest of the other nursing schools. The study population included second-year and third-year nursing students because they handle pain management of patients compared to the first-year students and have theoretical exposure to pain management. The total study population of 144 was used for the study.

Data were collected using a structured pretested self-administered questionnaire. The instrument of this study consisted of three sections; (1) participants' background and biographic information, (2) student nurses' knowledge of pain management, and (3) attitudes towards pain management. Section two consisted of 30 items; 28 knowledge-related questions were derived from 'knowledge and Attitude Survey Regarding Pain (KASRP) which was developed by Ferrell and McCaffery (2012) and the researcher added two questions based on content exposure of pharmacology. Section 3 was developed using two questionnaires because of the need to assess attitudes separately. It consisted of 15 questions; nine questions from KASRP and six questions from the tool developed by Manwere, Chipfuwa, Mukwamba, and Chironda (2015). Section 3 consisted of questions in true/false and multiple-choice types. Sections two and three were not adopted to or validated in the Sri Lankan setting. Before the actual data collection, appropriate modifications were done based on the pre-test results which were done with nursing students in another nursing school and experts' opinions. In this study, internal consistency, and reliability of the questionnaire were measured by Cronbach's alpha for a total scale was 0.72. The tool was prepared and administered in English because the nursing curriculum is conducted in English medium. The ethical clearance was obtained from the Rajarata University of Sri Lanka.

All the data in the study were statistically analyzed using SPSS 20. The data was organized, tabulated, analyzed, and interpreted by using descriptive and inferential statistics based on

the objectives of the study. In order to assess their level of knowledge, students were asked to select the most suitable answer for the questions. Correct responses or the questions were given a score of one, incorrectly answered items or those not answered were assigned a score of zero. The scores were then converted to “percentages” for the ease of understanding. The levels were interpreted according to the percentages as (1) poor  $\leq 50\%$ , (2) fair  $51\% \leq 74\%$ , or (3) good  $\geq 75\%$ ).

Inferential statistical analyses were used to test the hypotheses and address the research questions of the study. The nonparametric tests were used for inferential statistics because the data did not follow a nominal distribution. Mann Whitney U and Kruskal Wallis tests were used to assess the significance while, Spearman's correlation test was used to assess correlation. Finally, the results were interpreted as a statistically significant association if p value was less than 0.05 and with a 95% confidence interval.

All the participants were informed well through information leaflets and informed written consent was obtained voluntarily. None of the participants were harmed physically, psychologically, emotionally, socially, or economically.

## Results

From all 144 selected sampled students, responded rate was 97.2% (n= 140). Of the sample 96.4% (n= 135) were female while 3.6 % were (n=05) male. The mean age of the study group was 22.5 (SD +1.07). More than half of the respondents were aged 23-25 years (80%) and 20-22 years of age accounted for 15%. The greater proportion of participants was Sinhalese (76.4%) and Buddhist (70 %).The majority reported the advanced level as the highest education level (68.6 %). Most of the students 97(69.3%) were in the second year whereas 43 (30.7%) students were in the third year.

Among the participants, the majority have not

referred to any extra reading materials on pain management (78.57%, n=110) while (21.43%, n=30) have referred to extra reading materials. Of the sample, the majority had not participated in the pain education program (90.71%, n=127) while only 13 (9.29%) had participated in the pain management education program which was arranged for nurses parallel to the in-service training program.

Considering the knowledge and attitude on pain management of the participants the median correct answers for knowledge was 13 (IQR= 5) out of 30 answers while the median total correct answers for attitude was 8 (IQR= 4) out of 15 correct answers.

Among the participants, the majority had poor knowledge (70 %, n=98) while 30 % (n= 42) were reported for fair knowledge. There was no one who had good knowledge (n=0). Among the participants majority had fair attitude (70 %, n=98) while 7.1 % (n=10) for good attitude and 22.9% (n= 32) reported for poor attitude.

Table 1 shows the distribution of level of knowledge and attitudes on pain management by their academic year. Among the second-year students majority reported for poor knowledge (81.44%, n= 79) while majority of third-year students reported for fair knowledge (55.81%, n=24). Of the students who participated from their second year and third year, majority had fair attitudes reported by 66 (68.04%) and 32 (74.42%) students respectively.

Table 2 shows the students who had extra reference to pain management reported more fair attitudes (66.67%, n= 20) and fair knowledge (60%, n=18).

The students who had been exposed to the pain education program majority reported fair attitudes (53.85 %, n= 7) and 69.23% (n= 9) had poor knowledge. Majority who had fair attitudes reported by the students not been referred to any extra reading material (71.65%,



n= 91) (Table 3). A significant difference in median scores both knowledge ( $p=0.000$ ) and attitudes ( $p=0.000$ ) were identified regarding the academic year. And also, there is a significant difference in the median score of both knowledge ( $p= 0.037$ ) and attitudes ( $p=0.012$ ) that were identified regarding reference to extra reading materials. There is no statistical significance between the median score of knowledge ( $p=0.410$ ) and attitudes ( $p= 0.278$ ) identified for the exposure to the pain education program (Table 4). Spearman's correlation test indicates the positive correlation between knowledge and academic year (0.398), attitude and academic year (0.323),

## Discussion

In this study, the majority had poor knowledge and fair attitudes. Other researchers in other countries have reported similar results which show a deficit of knowledge and attitudes toward pain management [8, 12]. The results of the current study line with the study done in Louisiana showed severe knowledge deficits relating to pain and pain management [13]. Proving the results, the study among Iranian nursing students identified that nursing students had inadequate knowledge of pain management [14]. And also, a study conducted among baccalaureate nursing students determined that the students had inadequate knowledge and attitudes regarding pain management [3]. Proving the results, the undergraduate nursing students' knowledge and attitude regarding the pain management of children in Upper Egypt reported a higher percentage of participating students who had less than 50% of the total score of knowledge and attitude regarding pain [10].

In the current study, there is no statistically significant relationship between exposure to randomly conducted pain education programs with both knowledge and attitudes toward pain management. The results line with the findings of the study in Palestine showed there were no

statistically significant differences between the nurses' total average score on knowledge of pain management and demographic characteristics, except for their initial level of education [15]. Contrast findings of the study showed that there was a significant difference found in the nursing students' scores related to pain management training [8].

The current findings of this study also revealed that the majority (70 %) of the nurses had a moderate attitude towards pain management. The study findings were inconsistent with the study in Saudi Arabia, nursing students had lack of attitude towards pain management [16]. Moreover, the contrast findings of the study in Jordan showed that the attitude among nursing students towards pain management was negative [17].

The present study reported the year of study and additional study of reference materials were significantly related to both knowledge and attitudes toward pain management. Third-year students had more knowledge and attitudes than second-year students. In contrast to the results of the current study the University of Connecticut (UConn), School of Nursing, found that juniors performed better than 4th and 5th-year seniors when caring for hematology/oncology patients [18]. This may be related to repeating education on pain in both classroom and clinical settings of the third-year students.

This study is limited to the knowledge and attitude of nursing students in a single nursing school. Therefore, this study is implicated for further research to conduct the study in several nursing schools or compare the knowledge and attitude of nursing students with staff nurses.

## Conclusion and recommendations

In light of all of these findings, it is thought that the present study will help in the nursing curriculum to provide opportunities to plan and include pain education programs for nursing students. The findings highlight the nursing

school's role is to motivate the students to improve their knowledge and attitude through extra reading on available reference materials and participation in educational programs. Pain management

education needs to be strengthened and positive attitudes should be cultivated through curricular reforms in nursing education in Sri Lanka.

### Author declaration

**Author contributions:** All authors contributed to the conceptualization and design of the study. KMMGPK, HADCC and WMSKW contributed to the acquisition of data and conducted the data analysis. WMSKW contributed to data interpretation and writing the manuscript. All authors read and approved the final manuscript.

**Conflicts of interest:** The authors declare that they have no conflicts of interest concerning the research, authorship, and/or publication of this article.

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**Table 1: Knowledge and attitudes by academic year of the students**

	Level	Second year		Third Year	
		F	%	F	%
Knowledge	Good	-	-	-	-
	Fair	18	18.56	24	55.81
	Poor	79	81.44	19	44.19
Total		97	100	43	100
Attitudes	Good	5	5.15	5	11.63
	Fair	66	68.04	32	74.42
	Poor	26	26.81	6	13.95
Total		97	100	43	100

**Table 2: Knowledge and attitudes by extra reference of reading materials on pain management**

Attitude level	Extra reference of reading materials on pain management				Knowledge level	Extra reference of reading materials on pain management			
	N	%	N	%		N	%	N	%
<b>Good</b>	5	16.67	5	4.54	<b>Good</b>	0	-	0	-
<b>Fair</b>	20	66.66	78	70.91	<b>Fair</b>	18	60	24	21.82
<b>Poor</b>	5	16.67	27	24.55	<b>Poor</b>	12	40	86	78.18
Total	30	100	110	100		30	100	110	100

**Table 3: Level of knowledge and attitudes with exposure to pain educational program**

Attitude level	Exposure to pain educational program				Knowledge level	exposure to pain educational program			
	N	%	N	%		N	%	N	%
<b>Good</b>	2	15.38	8	6.3	<b>Good</b>	0	-	0	-
<b>Fair</b>	7	53.85	91	71.65	<b>Fair</b>	4	30.77	38	29.92
<b>Poor</b>	4	30.77	28	22.05	<b>Poor</b>	9	69.23	89	70.08
Total	13	100	127	100		13	100	127	100

**Table 4: Relationship of selected associated factors with the level of knowledge and attitude of the participants**

	Knowledge			Attitude		
	Median	IQR	significance	Median	IQR	significance
<b>Academic year</b>						
Second year	13	5	<b>P=0.000</b>	7	3	<b>P= 0.000</b>
Third year	17	3		9	3	
<b>Extra reference</b>						
Reference	18	3	<b>P= 0.037</b>	9.5	4	<b>P=0.012</b>
No reference	11	3.5		7	3	
<b>Pain education program</b>						
Participated	14	5	P=0410	6.5	4	P= 0.278
Not participated	13	4		6	5	

## Case report of de Winter Syndrome and ST-elevation myocardial infarction

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### Abstract

Chest pain is the presenting complaint of a myriad of illnesses, ranging from life-threatening causes such as acute myocardial infarction (AMI) to comparatively benign causes like gastroesophageal reflux. Less than half of patients presented with chest pain suggestive of cardiac origin have classic diagnostic features in the electrocardiogram (ECG). However, identifying the elusive ECG findings of an AMI is a diagnostic challenge.

Subtle ECG changes can easily be missed unless specifically looked for. De Winter syndrome is one such diagnosis, which may evolve into ST-elevation myocardial infarction (STEMI) or vice versa. This is a case of a successfully managed 46-year-old male, who presented with suggestive chest pain and ECG evidence of de Winter syndrome.

**Keywords:** De Winter syndrome, STEMI equivalents, ST-elevation myocardial infarction, Case report

### Introduction

Chest pain is a common symptom with which patients present to the emergency department. But, only less than half of these patients have a diagnostic ECG. Despite the advent of sophisticated medical investigations, ECG remains the cornerstone of the diagnosis of the acute coronary syndrome. It is now evident that a proportion of these patients do not have guideline-stated diagnostic features of ST-elevation myocardial infarction (STEMI), yet have an occlusion that would benefit from early coronary interventions. Such ECG patterns are now known as 'STEMI-equivalents'.

De Winter syndrome is an ECG pattern seen in proximal left descending artery occlusion, which may benefit from management similar to that of STEMI.

### Case presentation

A 46-year-old previously healthy man presented to the emergency department of the District General Hospital, Kalutara with sudden onset chest pain which started one hour ago. The pain started while he was walking to his workplace. It was a classical tightening type of chest pain associated with sweating and radiation to the left arm. The pain persisted until he arrived at the hospital.

On admission, he was in pain but hemodynamically stable. He was not breathless and maintained adequate saturation on room air. He had no signs of acute heart failure. His initial ECG showed 2 mm ST segment elevation in leads V2 to V4 with reciprocal ST segment depression in lead III and aVF. The second ECG showed up-sloping ST depressions of more than 2 mm, tall prominent symmetrical T waves in leads V3 to



V5 with ST elevation of 1 mm in aVR and 2 mm in V2. The inferior leads, lead II, lead III and aVF showed more than 2 mm ST depressions (Figure 01).

Bedside echocardiogram showed anteroseptal hypokinesia with an approximate visual ejection fraction of 45-50%.

According to the ECG findings, the first diagnosis was anterior STEMI which later on evolved into de Winter syndrome. As primary percutaneous coronary intervention (PCI) was not feasible within 120 minutes, fibrinolysis was selected as the treatment after excluding contraindications.

After giving loading doses of oral Aspirin 300 mg and Clopidogrel 300 mg, intravenous (IV) Enoxaparin 30 mg bolus was administered. It was followed by intravenous Tenecteplase. Fifteen minutes later, subcutaneous Enoxaparin 60 mg was given. The patient was continuously monitored for electrical or haemodynamic instability and bleeding complications. He continued to have mild chest pain, which was managed with IV morphine. Post-thrombolysis ECG (after 60 minutes) showed resolution of ST segment elevations with frequent ventricular ectopics (Figure 02).

Repeat ECG taken two hours after the thrombolysis showed sinus rhythm with evolving ST elevations in leads V5 to V6. Therefore, the patient was transferred to the National Hospital of Sri Lanka for a rescue PCI. Angiogram revealed a mid-left anterior descending (LAD) artery occlusion with a heavy thrombus burden in the proximal segment. Ballooning and stenting of the mid-LAD artery were done. An ECG resolution was noted along with Q waves in the anterior leads (Figure 03).

Post-procedure ejection fraction was 45-50% with anterolateral hypokinesia. The patient was discharged after two days of hospital stay and arranged for a follow-up at the cardiology unit.

## Discussion

De Winter syndrome is an ECG pattern associated with acute LAD artery occlusion. It was first described by De Winter and colleagues in 2008 [1]. It is a non-progressive pattern of ECG changes appearing on precordial leads. This can be seen in about 2% of patients with anterior myocardial infarction [2]. Characteristic ECG features are tall symmetrical prominent T waves in precordial leads and upsloping 1-3 mm ST depressions at J point [1]. QRS complexes are usually narrow. In some cases, there may be a poor progression of the R wave [1]. The patients with this ECG pattern are younger and mostly males compared to those who had anterior STEMI [2]. Though a tall symmetrical T wave was considered an early feature of STEMI, in patients with de Winter pattern of ECG, these tall symmetrical T waves do not evolve until reperfusion [2]. Troponin I can be normal or slightly elevated at the time of the ECG recording. De Winter syndrome and ST-elevation myocardial infarction can evolve into one another.

ECG abnormalities other than ST elevations can be indicators of myocardial injury. Identification of non-diagnostic and subtle ECG changes is crucial in preventing malignant dysrhythmias and cardiac death.

Though primary percutaneous coronary intervention (PCI) is the standard of care in STEMI, in circumstances where primary PCI is not available or delayed for more than 120 minutes, fibrinolysis is recommended within 12 hours of the onset of symptoms, provided there are no contraindications [3,4]. Patients with higher risk, the elderly and who are offered treatment within two hours from symptom onset get the most benefit from thrombolysis. Fibrin-specific agents such as Tenecteplase are preferred. In cases of failed thrombolysis or those with evidence of re-occlusion, rescue PCI is indicated [4].

In this case, a young male patient presented with a history of ischemic-type chest pain and

ECG was diagnostic of de Winter syndrome. He was treated with primary fibrinolysis. Post thrombolysis ECG initially showed resolution, but subsequent ECG was evident of re-infarction. The patient underwent rescue PCI. Due to the heavy thrombus load, post-procedure anticoagulation with enoxaparin was continued.

## Conclusion

It is necessary to carefully evaluate the

ECGs for elusive and perilous features to identify possible impending cardiac death. Subtle changes in ECG can be easily missed unless the clinicians especially look for them. De Winter syndrome and STEMI may evolve into one another. Assessment of symptoms and resolution of symptoms after thrombolysis is crucial in diagnosing failed thrombolysis and reinfarction.

## Author declaration

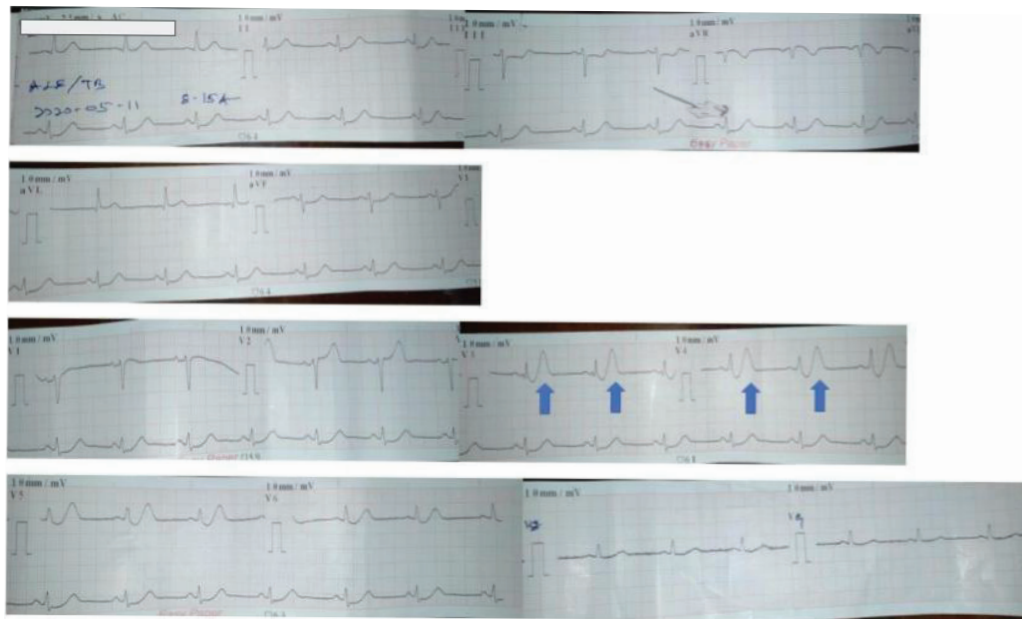
**Author contributions:** GMS led the clinical management of the patient and reviewed the manuscript. WHM performed a literature survey and wrote and edited the manuscript. Both authors read and approved the final version of the manuscript.

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**Ethics approval and consent to participate:** Written informed consent was obtained from the patient for publication of this case report.

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(Arrows show de Winter T waves.)

Figure 01: The ECG findings on admission

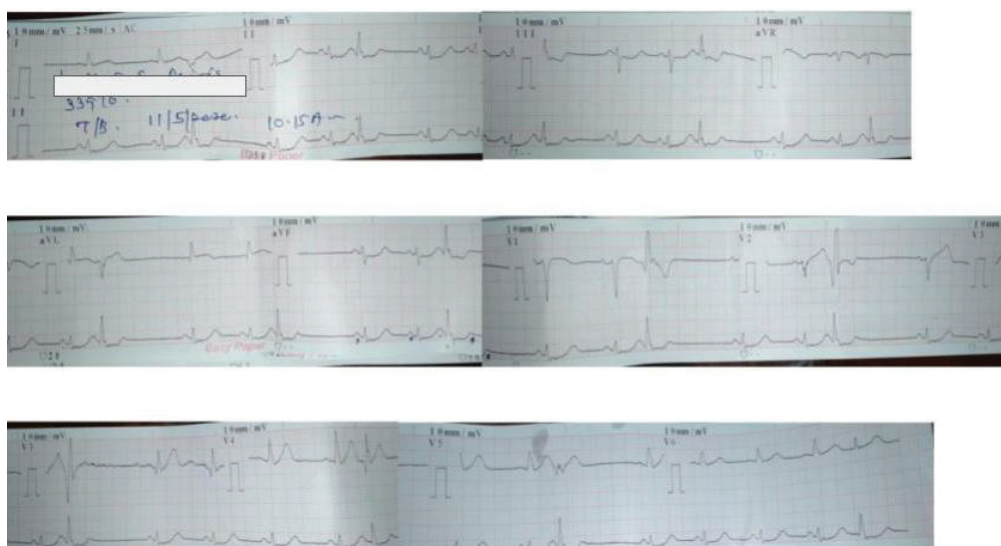


Figure 02: Post-thrombolysis ECG

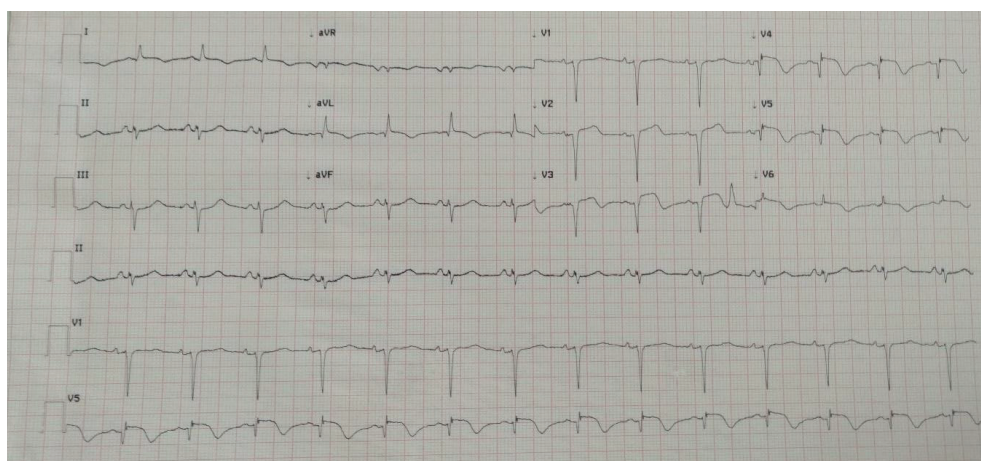


Figure 03: The ECG following rescue PCI

## The migration process from commercial to open-source learning management system for sustainable capacity building in primary healthcare service

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### Abstract

Data migration could be a complex yet necessary activity during the lifecycle of an information system. All the e-Learning resources and activity material for all the available courses were migrated from a commercial platform to the free and open-source Moodle platform to ensure the availability of necessary features such as ability to monitor progress of learners, assessing the learning and to ensure sustainability. The migration process was methodically planned and executed, preserving the integrity of the data and rectifying omissions, errors, and inconsistencies. Utilising the existing Moodle e-Learning platform of the Ministry of Health as a shared resource is a practical and more long-lasting method of delivering e-Learning materials with the goal of enhancing the competence of healthcare professionals.

### Introduction

The Ministry of Health and Ministry of Provincial Councils and Local Government in Sri Lanka have embarked on a five-year project to strengthen primary healthcare in the island, named the Primary Healthcare System Strengthening Project (PSSP). The project's long-term goal is to fill a gap in the provision of people-centred primary healthcare services across the nation to increase both primary healthcare utilisation and quality [1].

With 71% of global and 81% of Sri Lankan deaths attributed to non-communicable diseases (NCD) [2], the Primary Healthcare Systems Strengthening Project has a significant focus on preparing the local healthcare system to meet this NCD challenge. Diabetes, cardiovascular diseases, respiratory conditions, and cancer were considered priority NCDs for this project.

E-learning is the practice of delivering educational materials and facilitating learning

experiences via the use of digital technologies. It includes a variety of strategies, including simulations, online classes, and virtual classrooms [3].

Due to the COVID-19 epidemic, which has compelled many academic institutions to move their teaching and learning online, e-learning has gained importance in the contemporary environment [4]. E-learning has a number of benefits in this situation, including the capacity to provide content asynchronously and remotely, letting learners learn at their own pace and according to their own timetable [5].

Additionally, because it enables students with impairments, geographic restrictions, or other limitations to access educational information from anywhere with an internet connection, e-learning can be more inclusive and accessible compared to traditional classroom-based education [5].

### Challenges

One of the key gaps noted in the local primary



care setup is the need for an ongoing capacity-building programme for the medical officers attached to over 500 Primary Medical Care Institutions in the country. Dispersed geographical distribution with resulting transport challenges and difficulty in arranging cover-up doctors for the PMCIs favoured the adoption of an e-Learning approach.

A commercial e-Learning platform developed by a local software vendor company that hosts government and private e-Learning content for its subscribers was entrusted with content development under the direction of relevant directorates and units responsible for the content area. The medical officers received five courses from the learning management system. The topics covered in the courses included the function of the medical officer in the primary medical care institution and NCD related courses such as cardiovascular diseases, screening and managing NCDs and diagnosis and management of diabetes mellitus. Tuberculosis diagnosis and management was also recognised as an important course for those working at primary healthcare settings [6].

Monthly costs for the platform, lack of features, presence of errors, and not knowing how to use the commercial platform along with problems with creating material and making changes resulted in sub-optimal utilisation therefore, challenging the sustainability.

### **Migration to a sustainable e-Learning solution**

The learning management system (LMS) Moodle, which is free and open-source, enables educators to design, deliver, and manage online courses [7]. It promotes e-Learning by offering a thorough framework for organising online courses and enabling communication, collaboration, assessment, and customised learning experiences for students. Due to its many features and affordability, previous literature considers Moodle as a sustainable way of delivering e-Learning content [8]. The Moodle platform ([http://elearn.](http://elearn.health.gov.lk/)

[health.gov.lk/](http://health.gov.lk/)) was jointly launched by the Health Information Unit (HIU) and the Education, Training and Research (ET and R) unit of the Ministry of Health for the continuation of education in the institutions under the direct purview of the ET and R unit during the pandemic. These institutions included PSM and paramedic training schools, nurses training schools and regional training centres. Since this platform was free, permission was obtained from the relevant authorities to migrate the content from the commercial platform to the Moodle platform.

A team of health informaticians worked together to coordinate the migration process. There are many strategies that can be used for the migration of information. Since the process needed to be completed within a limited time window, the Big Bang data migration approach was used [9]. Big Bang data migration is a data migration approach where there is transfer of all the data in one big operation from one system to another [9]. This method stands in contrast to other data migration strategies, where data is moved over a longer period of time in smaller batches. The migration process was carried out in four phases (Figure 1) [10]. The team conducted an initial examination of the content that was found within the courses that were hosted on the commercial platform or the legacy information source during the first step of source destination mapping in order to create an accurate picture. In addition to this, the storyboards that accompany each of the courses were utilised, so that the overall structure of the courses could be understood. Following the completion of an assessment of types of information contained within the source, an assessment of the features available within the destination was carried out, after which source and destination mapping was carried out for each of the materials. The material was first extracted from its source during the second phase of the process. This was performed while the live commercial platform was still in operation, and

the team took extra precautions to ensure that the users were not disrupted in any way during the process. The third phase was the intermediate stage of organising the material. During this phase, it was identified that there were certain materials in the legacy information source that were either missing or inconsistent. These inconsistencies were then compared to the storyboard that was provided. This was an issue that needed to be resolved before moving on to the next step. Therefore, discussions were carried out to rectify the shortcomings. The final phase was uploading the material to the destination, or the Moodle platform. To overcome the challenge of data quality concerns, following the migration process, the courses within the new system were assessed by an independent team of health informaticians. The medical background of the migration team was also useful during this assessment, where several omissions, inaccuracies, and inconsistencies in the content were identified and rectified accordingly. Almost immediately after the Moodle platform was made available in the year 2021, more than forty individuals enrolled in the

available courses (Figure 3). By the end of 2022, over 300 users were enrolled in the platform, following at least one of the five courses, and annually, more Medical Officers working in the Primary Healthcare setup are added as decided by the PSSP.

## Conclusion

In conclusion, the features on the Moodle platform were compatible with the commercial source system, and the data migration process, when done methodically, was attainable in the given time frame. With the current economic crisis, a government organisation can afford to maintain the Moodle platform because it is free and an open source. Also, it is currently managed by the ET and R unit of the Ministry with the supervision of a team of health informaticians which further enhances its sustainability. Utilising the existing Moodle e-Learning platform of the Ministry of Health as a shared resource is a feasible and more sustainable approach to delivering e-Learning content for the purpose of capacity building among healthcare workers

## Author Declaration

**Author contributions:** CW and SKPAF attended to information need identification, Data migration process planning and coordination, Gap analysis, Manuscript writing, Literature review and Revision of the Manuscript. Institutional decision making, resource allocation, supervision and final approval of the manuscript was done by AKSBDA.

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**Administrative approval:** Administrative approval has been obtained from the Additional Secretary Medical Services, Ministry of Health.

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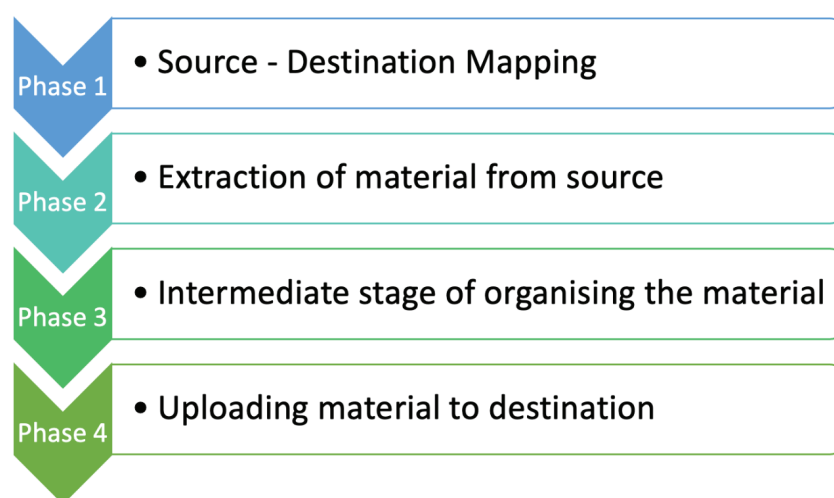
**Funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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**Figure 1: Phased out Source - Destination information migration process**

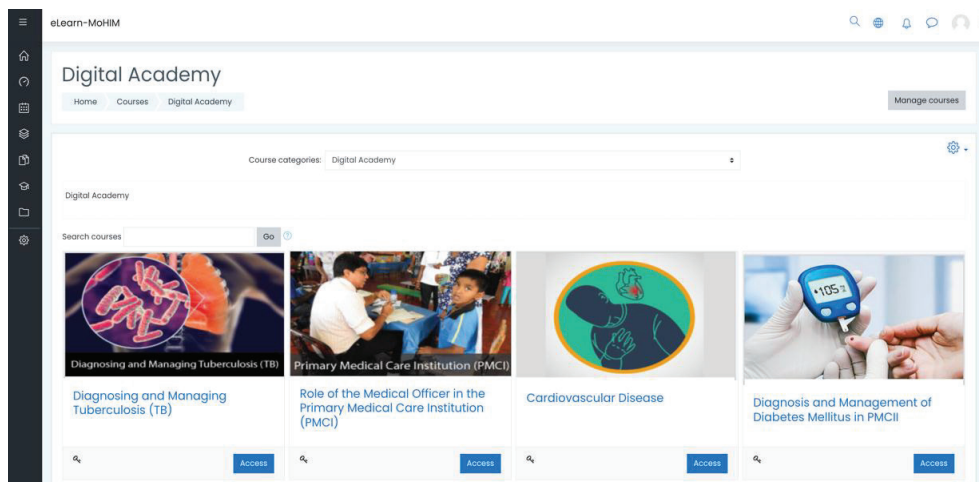


Figure 2: Courses within the Moodle platform following the Migration of the Material

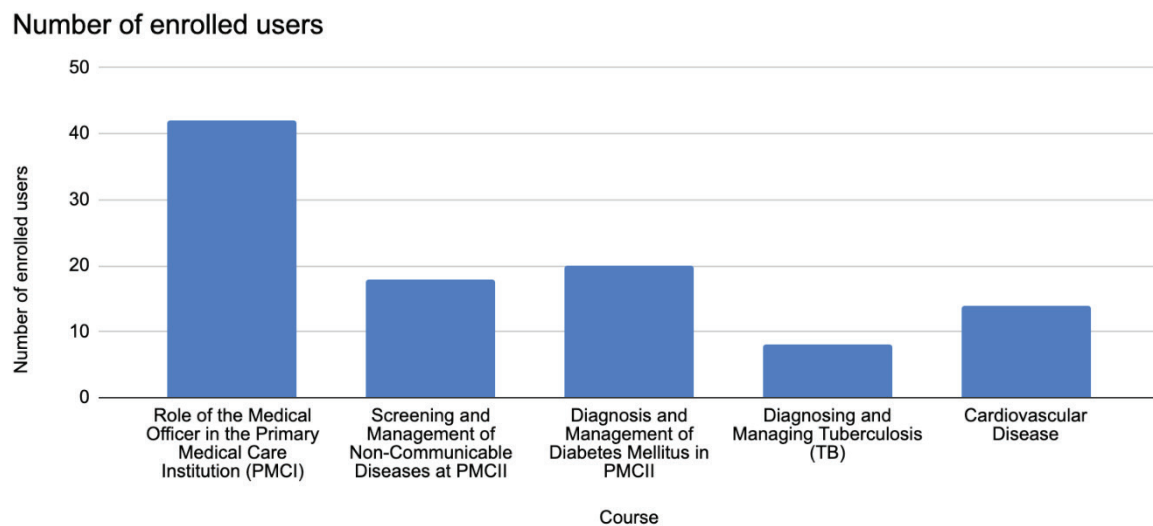


Figure 3: Number of enrolled users immediately following introduction

# A digital health solution for parasitological surveillance at Anti-Malaria Campaign, Sri Lanka

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## Abstract

The Anti Malaria Campaign in Sri Lanka is a public health initiative aimed at preventing and controlling the spread of malaria in the country. The outcome of the malaria control program is improved by effective surveillance. The National Malaria Strategic Plan highlights the lack of a web-based surveillance system for malaria as a weakness in the central-level availability of malaria parasitological surveillance data. DHIS2 (District Health Information Software 2) is a global-good, health management information system recommended by WHO. Creating a malaria information system based on DHIS2 and incorporating an interactive dashboard are employed to enhance the prompt accessibility of data at the national level.

## Introduction

The Anti Malaria Campaign (AMC) is the focal point of the Ministry of Health, Sri Lanka for the prevention and control of malaria. The Program oversees the prevention of malaria reintroduction (PoR) and ensures a malaria-free, Sri Lanka. The AMC has a central and regional network that includes regional malaria offices and treatment facilities that are linked to the curative health sector. In 2016, the World Health Organization (WHO) recognized Sri Lanka as a country free of malaria [1]. It was a significant public health achievement in Sri Lanka's history. However, Sri Lanka reports approximately 50 imported malaria cases yearly. At this stage, the AMC's two main strategies are to carry out imported case monitoring and vigilant parasitological and entomological surveillance. The national malaria strategic plan has identified the lack of a web-based surveillance system for malaria as a weakness in the central-level parasitological surveillance data availability [2]. Therefore, proposing a digital health surveillance system as a cost-effective solution for malaria parasitological data flow management benefits AMC's timely decision-making.

## Malaria Surveillance

The third pillar of core intervention, according to the WHO Global Technical Strategy for Malaria 2016–2030, is malaria surveillance. Surveillance plays a major role in settings of any level of transmission. Preventing the reintroduction of malaria is crucial for countries attempting to eliminate it as well as for countries that have already achieved this goal [3]. The effectiveness of the malaria control program is improved by effective surveillance of the disease.

In Sri Lanka, parasitological surveillance activities are being carried out by teams comprised of a Parasitologist, Public Health Laboratory Technicians (PHLT) and Public Health Field Officers (PHFO). Parasitological surveillance is conducted in two ways: passive case detection and active case detection. Active Case Detection is the detection of malaria infections in the community by health workers. The process of screening of people who are visiting medical facilities consists of passive case detection (PCD) and activated passive case detection (APCD). The medical facility that has a PHLT and/ or PHFO performs the testing. In PCD, patients with fever

and an overseas travel history to a malaria-endemic country and patients with symptoms and signs suggestive of malaria are screened for malaria while in APCD, all fever patients attending health institutions are screened for malaria. The most significant approach suggested by AMC is PCD [4]. Rapid Diagnostic Tests (RDTs) are also performed as a supplemental tool, although microscopic screening is the gold standard diagnostic technique. This process encourages early case diagnosis and reduces malaria spread. Before transfusion, all donor blood is being screened for malaria by PHLTs in Sri Lanka.

All suspected malaria cases are reported to the AMC. Malaria control activities in all districts are monitored monthly at the review meeting with Regional Medical Officers in charge of malaria in respective districts. The diagnosis of malaria is confirmed by laboratory tests for malaria (Rapid Diagnostic Test, microscopy, and PCR where necessary). The AMC is also in charge of dispensing all the drugs required for treating malaria. Each confirmed case of malaria is assessed by the case review committee which is a subgroup of the Technical Support Group independently concerning classification and case management. The Anti-Malaria Campaign's operations are guided by the National Malaria Strategic Plan for Elimination and Prevention of Reintroduction.

### **The Problems and Solutions**

Despite the frequent execution of malaria monitoring, there are gaps in the surveillance data that is available in the anti-malaria campaign for timely decision-making. Therefore, it was important to establish a long-term solution for the flow of surveillance data. The solution needed to cater to both national level and regional level requirements with minimum cost. Several malaria-endemic countries have tried different digital health solutions for malaria data flow management. Cambodia introduced Microsoft Access based national malaria information

system in 2009. It was gradually evaluated into SQL based information system with real-time case reporting [5,6]. Thailand's electronic malaria information system (eMIS) is based on both mobile and web-based technology which caters to laboratory results, case registration, case investigation and case follow-up [7].

To help countries to strengthen and monitor their national routine surveillance systems and to facilitate the use of data for decision-making, data standards and tools have been established by WHO. The WHO recommends using the DHIS2 platform as a digital health solution for malaria [8]. Currently, at AMC both malaria case investigation and entomology surveillance are operational using an electronic health information system. Further, all malaria cases and potential vector breeding grounds are also mapped using GIS maps. DHIS2 platform is used in the development of these systems. A single platform helps improved resource utilization and collaborative data analysis. Further, the support for DHIS2 design, development, implementation and capacity building is provided by regional Health Information Systems Programme (HISP) groups. Sri Lanka also has an established HISP node to provide necessary support within the country. Therefore, customization of DHIS2 could be done with minimum cost to incorporate parasitological surveillance data. Further, Sri Lanka has several public health information systems based on the DHIS2 platform [9]. Therefore, DHIS2 was selected as the preferable solution for catering to AMC's new information system needs.

### **DHIS2**

DHIS2 is a global public good, web-based platform that is widely used as a health management information system (HMIS). DHIS2 is now considered, one of the world's largest HMIS platforms. There are 73 low- and middle-income countries using it. The University of Oslo is the global partner leading the development of the DHIS2 software [10]. DHIS2 provides two

types of data collection modules. Those are the aggregated and the tracker modules. For the data collected as a data set which represent aggregated or summarized data, the aggregated module is used. When collecting individual-level data such as case-based which needs individual-level follow-up, it is recommended to use the tracker module.

### Design and Implementation

In any system design, the initial step is requirement gathering. A team involving the Director AMC, consultant community physician, medical officers, parasitologist, a few regional malaria officers and registrar-health informatics led the burden of initial requirement gathering. When creating a digitalized solution for health data management, it is not simply to replicate the paper-based data-collecting formats in the electronic system. Therefore, as the initial step, the data collection form was revised in view of the digital data collection. Recently a shared spreadsheet was created as the first step in digitization. The data fields available in that spreadsheet were also incorporated. Following numerous online and in-person sessions, the data collection form was finalized. In the malaria parasitological surveillance case scenario, regional blood samples from individuals are collected and followed up. Therefore, the tracker module was selected to cater the individual data entry and follow-up.

In the DHIS2 the three main data dimensions are the data element, the organization unit and the time period. The data elements were created by mapping the fields in the finalized data-collecting form. To facilitate the data analysis, most of the data elements were created as drop-down items using option sets. MOH level was selected as the lowest data entering organizational unit as the AMC needed to analyse data at the MOH level. Further, the system was designed in a way that maintains the flexibility for system extension up to institutional levels whenever the facilities become

accessible in the future. When considering the time period, data entry was planned daily. To provide decision-making support at the national level a national-level dashboard was created with DHIS2 (Figure 1).

### Limitations and Challenges

Out of the three data dimensions in DHIS2, the most challenging dimension was deciding on the organizational structure. Anti-malaria Campaign is needed to collect data at the MOH level. However, the lowest level of the paper-based data flow was established from the regional malaria office (RMO) level which represented the district level most of the time. Further, the data collection occurred at RMO offices, field and curative health institutions distributed throughout the RMO region. Due to the complex nature of the organizational structure, it was decided to use a hybrid method of data collection and entry. The data collected at the institutional level using the paper-based format was planned to enter according to the MOH area at the RMO level. Further, in some case scenarios, blood samples were tested in one district while the patient's living area belongs to another district. This created the need for accessing the MOH areas of a different district. However, the architecture of DHIS2 does not allow that. Therefore, it was decided to enter those limited scenarios by AMC headquarters as they have access to all the organizational units in Sri Lanka.

### Conclusion

The use of a free and open source, web-based platform supported an easy design and implementation process. Identification of key stakeholders early and getting them involved in the development has smoothened the development process. The integrated dashboards with timely information are important in providing decision-making support at the national level.

### Author Declaration

**Author Contributions:** All authors contributed to the requirement gathering,

system designing, system testing, manuscript writing, literature review and revision of the manuscript. Institutional decision-making, resource allocation and supervision by KDNPR. Overall Coordination and Final Approval of the Manuscript by NVJT and PUC. System development and concept of the Manuscript by AIKR.

**Conflicts of interest:** The authors declare that they have no conflicts of interest concerning the research, authorship, and/or publication of this article.

**Administrative approval:** Administrative approval has been obtained from the Anti-Malaria Campaign

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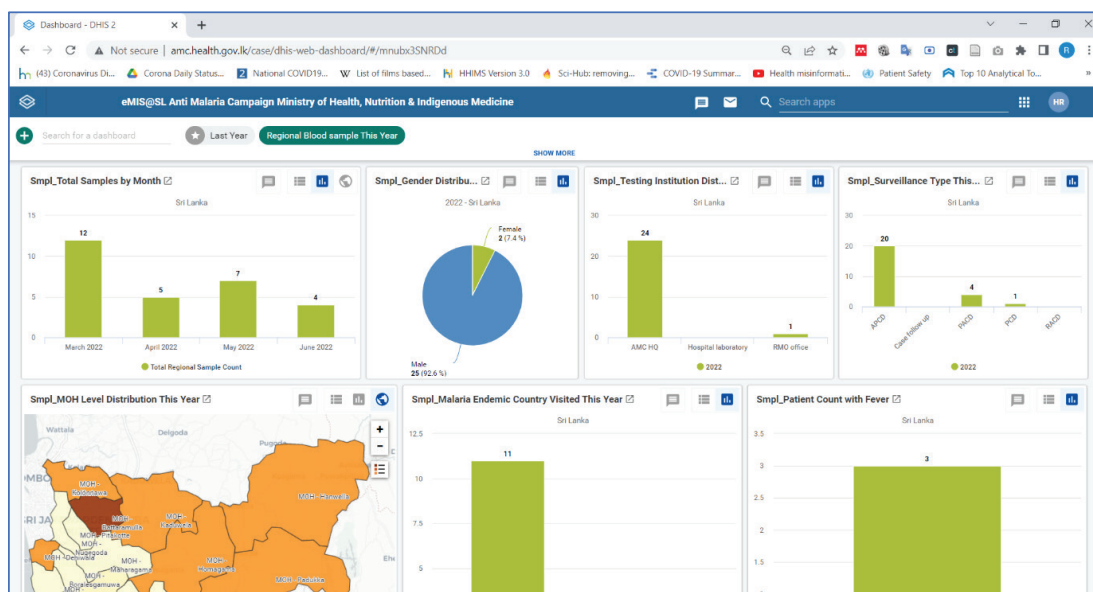


Figure 1: Administrative Dashboard

## Human resource management in curative care institutions of Sri Lanka during turbulent times

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The healthcare sector in Sri Lanka faces significant challenges in managing human resources, especially during turbulent times. According to the World Health Organization, there were 36.31 medical doctors, 11.92 nurses, and 24.39 midwives per 10,000 population in 2021. Approximately 53% of the health budget is allocated to health staff and the current human resource profile reflects the government's efforts to ensure adequate staffing in curative care institutions. However, despite recruiting around 4500 physicians, nurses, and midwives annually, various obstacles persist, affecting the effective management of human resources.

One of the key challenges in Sri Lanka's healthcare sector is brain drain, where qualified professionals seek better opportunities abroad, leading to a shortage of skilled personnel within

the country. Additionally, staffing shortages pose a significant issue, particularly in rural areas, making it difficult to provide quality healthcare services uniformly. Furthermore, the heavy workload often demotivates healthcare staff, affecting their performance and the overall service quality.

To mitigate these challenges and improve human resource management in the healthcare sector, the ministry of health has implemented several measures. A notable measure among these is the establishment of the Human Resource Management Information System (HRMIS) to strengthen workforce planning, enabling better resource allocation and management. The creation of a dedicated unit for human resource management further emphasizes the government's commitment to addressing HR

challenges effectively. Additionally, capacity development programs have been initiated to enhance the skills and knowledge of the healthcare workforce, while the provision of incentives aims to boost staff morale and retention.

Beyond government initiatives, healthcare institutions themselves can play a crucial role in enhancing human resource management. By promoting employee engagement, institutions foster a positive work environment that encourages staff satisfaction and commitment. Implementing flexible work arrangements can

prove beneficial in maintaining a well-balanced workforce. Furthermore, investing in training and development programs is essential to enhance the capabilities of healthcare professionals and keep them abreast of the latest advancements in medical practices. Furthermore, optimizing workforce utilization, prioritizing critical functions, maximizing resource utilization, ensuring optimal resource allocation, communication and engagement, and developing contingency plans are crucial for curative care institutions to prepare for unforeseen challenges and crises.

## Instructions to authors: Sri Lanka Journal of Health Research

The Sri Lanka Journal of Health Research publishes the following types of articles: editorials; leading articles; original articles including original research articles, systematic reviews and meta-analyses; case reports/case series; clinical audits; cover stories; picture stories; brief reports; updates on evidence-based practices in health policy and systems; manuscripts on continuous medical education; perspectives; opinion articles; commentaries; review articles; correspondence/ letters to the editors; notices/ obituaries/ appreciations; and innovations.

**Please refer to the following documents for more details:**

- 1) Author guidelines;
- 2) Organization of the manuscript for original research;
- 3) Manuscript review flowchart;
- 4) Review process and decision framework;
- 5) Ethics framework; and
- 6) Author declaration

### I. Author guidelines of the Sri Lanka Journal of Health Research

This document is intended to guide the authors in submitting manuscripts to the Sri Lanka Journal of Health Research (SLJHR), the official journal of the Ministry of Health, Sri Lanka. SLJHR is an open-access, peer-reviewed journal. Its mission is to efficiently and promptly publish rigorous, accessible, and relevant material that will help health professionals in Sri Lanka in their practice, lifelong learning, and career development.

#### 01. Who is an author?

The SLJHR reserves the status of authorship for those who deserve credit for the intellectual contribution to the manuscript and can take the responsibility for the work. This is based on the International Committee of Medical Journal Editors (ICMJE) recommendations. The ICMJE also recommends that the authorship be based on the following four criteria:

- i) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- ii) drafting the work or revising it critically for important intellectual content; AND

iii) final approval of the version to be published; AND

iv) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he/she has done, an author should be able to identify which co-authors are responsible for other specific parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. All those designated as authors should meet all four criteria for the authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged.

The corresponding author is the individual who takes the primary responsibility for communicating with the journal during manuscript submission, peer- review, and publication processes. The corresponding author typically ensures that all administrative requirements of the journal such as providing details of the authorship, Ethics Review Committee approval, clinical trial registration

documentation and disclosures of relationships and activities are properly completed and reported although these duties may be delegated to one or more co-authors. The corresponding author should be available throughout the submission and peer-review process to respond to editorial queries timely, cooperate with any requests from the journal for data/additional information, and respond to critiques/ questions on the work after publication.

## **02. Types of manuscripts that SLJHR will consider:**

The SLJHR will accept the following types of manuscripts for publication: editorials; leading articles; original articles including original research articles, systematic reviews and meta-analyses; case reports/ case series; clinical audits; cover stories; picture stories; brief reports; updates on evidence-based practices in health policy and systems; manuscripts on continuous medical education; perspectives; opinion articles; commentaries; review articles; correspondence/ letters to the editor; notices/obituaries/ appreciations; and innovations.

Further details about the format of each of these types are described under 03 (A) below.

## **03. Preparation of manuscripts for SLJHR and submission to the Journal:**

### **03 (A) Preparation of manuscripts**

#### **1. Editorials and leading articles**

These give a balanced overview of the current state of development of an emerging area. They usually do not exceed 1,500 words and are devoid of any tables and illustrations. It might have references. These may be solicited by the editors from the experts in a given field and SLJHR does not accept unsolicited manuscripts under this category.

#### **2. Original articles**

The SLJHR entertains the following categories of original articles: original research articles; systematic reviews; meta-analyses. Original research articles are based on original research studies where there is primary data collection.

Original articles have to adhere to the reporting guidelines relevant to the respective study design. These reporting guidelines help authors describe the study in adequate detail for it to be evaluated by editors, reviewers, readers, and other researchers. The authors are encouraged to visit EQUATOR (Enhancing the Quality and Transparency Of health Research) Network (<https://www.equator-network.org/reporting-guidelines/>) which is an international initiative that aims to improve the quality of research publications and US National Library of Medicine ([https://www.nlm.nih.gov/services/research\\_report\\_guide.html](https://www.nlm.nih.gov/services/research_report_guide.html)) which provide a comprehensive list of reporting guidelines and other material to help improve reporting.

The reporting guidelines for specific study designs are as follows:

Manuscript sections of original articles: Please refer to the document below titled “Organization of the manuscript for original research for the Sri Lanka Journal of Health Research”.

#### **3. Case reports/Case series**

The SLJHR will only publish cases with valuable clinical lessons. Case reports and case series should be prepared conforming to the Consensus-based Clinical Case Reporting (CARE) guidelines (<https://www.care-statement.org/checklist>). The word count is 1,500 for a case report and that for a case series is 2,000. These should not contain more than two tables/ illustrations and five references. It could contain up to a maximum of two pictures. Case series need Ethics Review Committee approval but not case reports. However, obtaining the patient's consent is mandatory for case reports.

Type of study	Reporting guidelines
Randomised trials	CONSORT and Extensions
Observational studies	STROBE and Extensions
Systematic reviews	PRISMA and Extensions
Study protocols for clinical trials and systematic reviews	PRISMA-P, SPIRIT
Prediction model for individual prognosis or diagnosis	TRIPOD
Diagnostic accuracy studies	STARD
Case reports	CARE and Extensions
Clinical practice guidelines	AGREE, RIGHT
Qualitative research	SRQR, COREQ
Animal pre-clinical studies	ARRIVE
Quality improvement studies	SQUIRE
Economic evaluations of health interventions	CHEERS

#### 4. Clinical audits

‘Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through a systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.’ (www.nice.org.uk. Principles of Best Practice in Clinical Audit 2002). Clinical audits are not considered as original research by the SLJHR. The authors are encouraged to go through the related links and the following when they submit manuscripts based on clinical audits. [https://www.hqip.org.uk/wp-content/uploads/2018/02/documenting-local-clinical-audit-a-guide-to-reporting-and-](https://www.hqip.org.uk/wp-content/uploads/2018/02/documenting-local-clinical-audit-a-guide-to-reporting-and-recording.pdf)

[recording.pdf](https://www.hqip.org.uk/wp-content/uploads/2018/02/documenting-local-clinical-audit-a-guide-to-reporting-and-recording.pdf) (Documenting local clinical audit: A guide to reporting and recording, Healthcare Quality Improvement Partnership, UK). The word count is 1,500 – 2,500.

#### 5. Cover stories

Authors need to submit cover stories based on a contemporarily or historically important issue/event in the areas of health services management and delivery. It needs to be submitted preferably with a picture that will appear on the front cover of the journal. If there is no picture associated with the cover story, the editors will find a suitable picture for the article. The title has to be catchy and the lead paragraph has to summarize the main ideas of the article. The word count is 250.

#### 6. Picture stories

This is an unstructured narrative consisting of less than 300 words based on a picture that is powerful enough to create an understanding and/or empathy among the readership towards an issue that is important yet not sufficiently attended in healthcare delivery. The stories should also briefly discuss what is portrayed in the picture and should also highlight the challenges to the healthcare system. The picture could be an image or an illustration.

#### 7. Brief reports

Brief reports could be based on original research, novel public health and patient management interventions, hospital management practices, etc. Public health innovations and best practices that have yielded evidence-based results are also considered. Brief reports should be limited to 2,000 words, three tables/illustrations and ten references, and may have an unstructured abstract of fewer than 300 words.

Articles that are based on ongoing projects without evidence-based results will not be accepted. Please see



**B.11 below too.**

## **8. Updates on evidence-based practices in health policy and systems**

These manuscripts need to be based on updates on health policy and guidelines relevant to Sri Lanka. The implications to the health system strengthening, patient care and public health practices should be highlighted. Unstructured articles with a word count of less than 1,000 are considered. Those do not require an abstract. Necessary references should be stated. Those articles without tangible outcomes will not be accepted. Please see B.11 below too.

## **9. Manuscripts on continuing medical education**

These could be concerning medical, nursing, paramedical or professions supplementary to medicine. The article should clearly demonstrate the author's expertise in the area. Only the articles of sufficient quality which have clearly demonstrated the worth of the article in assisting relevant health professionals in carrying out their professional responsibilities effectively and efficiently will be published. The word count should be less than 750. Please see B.11 below too.

## **10. Perspectives**

Perspectives intended for publishing in SLJHR has to present a new and unique viewpoint on existing problems, fundamental concepts, or prevalent notions on a specific topic, propose and support a new hypothesis or discuss the implications of a newly implemented innovation. These could also focus on current advances and future directions on a topic. They need to be intended to stimulate a discussion. These articles may contain original data as well as personal opinions. Abstract, tables and figures are not warranted. There can be references. The word count is 2,000-3,000.

## **11. Opinion articles**

Opinion articles present the author's

viewpoint on the strengths and weaknesses of a hypothesis or scientific theory. Opinion articles are generally based on constructive criticism and should be backed by evidence. However, opinion articles do not contain unpublished or original data. These articles promote scientific discourse that challenges the current state of knowledge in a particular field. Opinion pieces are also relatively short articles, of around 2,000-2,500 words, typically with a short abstract of about 150 words, at least five references, and one or two figures or tables.

## **12. Commentaries**

Commentary articles are generally agenda-setting, authoritative, informed and often provocative expert pieces calling for action on topical issues about scientific research and its political, ethical and social ramifications. They do not simply snapshot a problem, but roadmap a proposed solution in detail. Alternatively, comment pieces can be writerly historical narratives or conceptual or philosophical arguments of pressing contemporary relevance, told with authority, colour, vivacity and personal voice. These attempts to bring an original perspective before the widest readership, through erudite reasoning and giving examples. Commentaries can draw attention to or present criticism on a previously published article, book, or report, often using the findings as a call to action or highlighting a few points of wider relevance to the field. Commentaries do not include original data and are heavily dependent on the author's perspective or anecdotal evidence from the author's personal experience to support the argument. However, if an author intends to publish such content, he/she can solicit permission from the editors to submit this to SLJHR. Commentaries are usually short articles of less than 1,000 words and are in most cases invited by editors from experts in the field. They include a few references, and one or two tables and figures. No abstracts are needed.

### 13. Book reviews

These have to be unbiased analyses, as decided by the Editorial Committee, of books from the fields of medicine, nursing, allied health Sciences, complementary and alternative Medicine and related fields published during the last two years in Sri Lanka. The review should consist of an introduction including the bibliographic details of the book, intended audience, scope and objectives and a critical analysis of its contents. The editors of the newly published books are encouraged to send them to the journal if they wish to have a review published in SLJHR. If the Editorial Committee agrees that the relevant book needs a review published in SLJHR, it will seek the contribution of the experts of that field to write the review. The word count is 1,000.

### 14. Correspondence/Letters to the editor

Correspondences are the readers' reactions to technical and other material published in SLJHR. These are made as a reply to a previously published article in SLJHR. These could range from methods to implications. These should be submitted within four weeks of the online publication of a manuscript. The original authors will have to frame appropriate responses to such correspondence. Correspondence submissions are not usually peer-reviewed and will be edited appropriately without altering the original meaning to suit the publication. These have to be less than 300 words and need to have a maximum of two authors.

### 15. Notices/Obituaries/Appreciations

We welcome suggestions of the readers to inform us of those deserving an obituary in SLJHR. These suggestions can be emailed to [sljournalhr@gmail.com](mailto:sljournalhr@gmail.com) with the word 'Obituary notice' in the email title. The editors' decision will be the final. Notices and appreciations will be decided by the editors based on the objectives of SLJHR and the Ministry of Health, Sri Lanka. The word count is 500.

### 03 (B) Submission of the manuscript

The first issue of the SLJHR will be made from the articles submitted through email to the Editorial Office. From the second issue onwards, to submit an article, the corresponding author needs to log in to the journal management system through <https://sljhr.sljol.info/author/login/?submit=True>. The authors who have an ORCID account can log in through that and those who do not have will have to create an account. Once you sign in, you will be directed to the manuscript submission.

The manuscript submission consists of five stages: start; author details; article details; upload files; and review and submit. On the start page, there is an 'Author agreement'. You will be notified of the following submission requirements and you will have to make a declaration that your manuscript adheres to all these submission requirements. Please note that the SLJHR does not charge any publication fee from authors.

B.1	The manuscript has not been published elsewhere nor submitted to another journal for consideration for publication. If the manuscript has been partly or fully published elsewhere, a full statement of all previous publications should be attached. This should include the presentations of abstracts made from the same original article/clinical audit or other publication types. Any such work should be referred to specifically and referenced in the new manuscript. Copies of such material should be included with the manuscript to help the editors assess the situation about the redundancy of the material to be published. Authors are also encouraged to submit any previous communications from other journal editors or reviewers if the manuscript has been previously submitted to another journal.
B.2	The manuscript will not be submitted to another journal for review until the final decision is reached by the editorial board of SLJHR. If the authors decide to withdraw a manuscript from review, it could be immediately notified through the online system.
B.3	If the manuscript is accepted for publication, the authors grant the Ministry of Health, Sri Lanka a license to publish the article and to identify itself as the original publisher. Please read the Copyright Notice below.
B.4	The submission file needs to be in Microsoft Word or RTF file format.
B.5	The text is double-spaced; uses 10-point NewsGoth Lt BT font; all page numbers and line numbers are inserted; and all illustrations, figures, and tables are placed after the reference list.
B.6	The text adheres to the stylistic and bibliographic requirements outlined in the Author Guidelines, which are found in the “About the journal” tab.
B.7	The co-authors have read the manuscript and approved its submission.
B.8	A duly filled Cover Letter and the Author Declaration form should be separately uploaded. All authors have to place their signatures in the Cover Letter.
B.9	The authors agree to the terms of the Copyright Notice, which will apply to this submission if and when it is published by this journal.
B.10	The authors declare that the article is free from any conflicts of interest and ethical issues. When the authors have obtained Ethics Review Approval from an Ethics Review Committee accepted by the Ministry of Health Sri Lanka, it should be uploaded together with the manuscript. The administrative approval letters need also to be uploaded especially when the article/research is related to the work carried out by the Ministry of Health, Sri Lanka.
B.11	When a manuscript is submitted under the categories of brief reports, updates on evidence-based practices in health policy and systems and manuscripts on continuing medical education, it is always good to include a description of the author’s expertise in the respective areas in the Cover Letter.

#### 04. Copyright notice

The public has the freedom to use, copy, distribute, remix, adapt, and build upon the authors’ work, as long as they credit the author/s for the original creation. The Ministry of Health, Sri Lanka will be identified as the original publisher. Authors of the articles published in SLJHR retain

the copyright of their articles. The authors, the Ministry of Health Sri Lanka and the readers are free to reproduce and disseminate the published work provided that the original work is properly cited.

#### 05. Privacy statement

The personal information which appears in

SLJHR will be used exclusively for the stated purposes of this journal and will not be made available for any other purpose or to any other party.

## 06. Editorial procedure

Each manuscript submitted to the SLJHR is evaluated by the editors in chief. The manuscripts that do not meet the criteria listed under the Author Guidelines of SLJHR will be returned to authors without considering its content for review. The manuscripts which have been submitted following the Author Guidelines will be further processed.

## 07. Peer-review process

The SLJHR follows a double-blind peer review process, which means that both reviewer and author remain unknown to each other. Each article is reviewed by two independent reviewers and a statistical expert within three weeks. The names of the authors will not be revealed to the Editorial Committee until the final decision on the acceptance/rejection of the manuscript is taken. The estimated time from submission to the first decision is within 10 weeks.

The review will focus on health implications, originality of the work, the scientific rigour of the manuscript and ethical conduct. The review will be done among the members of the editorial committee if it is within the expertise of the committee. If the editors in chief/editorial committee feel that the submitted article needs review by an external reviewer, it will be reviewed by two members of the external review panel. The external reviewers will be experts on specific content areas and will represent different categories of health professionals.

Each reviewer is supposed to go through the whole manuscript, make the necessary comments and changes in the manuscript in its MS Word document using Comments and Tracked Changes, and also give independent

recommendations at the time of submitting the decision. When submitting recommendations, they will have to declare that they do not have any conflicts of interest in reviewing the relevant manuscript. The final decision on the manuscript will be made based on 'The decision framework for the Sri Lanka Journal of Health Research'. Selected articles based on that framework will be discussed at the editorial committee meeting.

The editorial committee meeting will be held once in two months at the start. All the reviewers are supposed to send their comments two weeks before this meeting. All primary reviewers are supposed to join the meeting in person or through video conferencing. An attendance policy will be in place to ensure adequate participation of the editorial committee members to the meeting.

### The decisions for any manuscript will be as follows:

- 'Accepted'—Manuscript is accepted for publishing without further revisions to the manuscript;
- 'Revisions required'—The author needs to resubmit the manuscript with suggested minor or major changes to the article for review by SLJHR again; and
- 'Rejected'—The author is not entitled to resubmit the same manuscript to SLJHR again.

The comments and recommendations will be communicated to the authors within one week after the decision is made. Resubmission after revisions will have to be submitted within three weeks. All resubmissions will have to be submitted in compliance with the instructions stated in the due format addressing each concern/comment made by the editors and reviewers.

Two reminders will be sent to the authors about the deadlines for resubmissions. If there is no response from the authors even after two

reminders or the resubmission is delayed without any valid reason, these articles will be removed from the system.

When the members of the editorial committee also wish to submit manuscripts to SLJHR, these too will be processed in the same way as all other manuscripts received by the journal. However, due to conflicts of interest, these manuscripts will not be reviewed and edited by the same members and they do not participate in the final decision-making process. The number of manuscripts published where the Editorial Committee members and editors in chief are involved will be kept to a maximum of one.

### Authors' appeal

All authors have the liberty to appeal if they think the decision of the SLJHR on a submitted manuscript is unfair. Such appeals will be answered by the editors in chief based on the stated editorial policy. However, in an appeal, the decision of the editors in chief will be final.

### Comments of readers and authors

Readers and authors are also welcome to submit comments to the published articles. Authors of the criticized article have the opportunity for responding to such comments. All such written material should be submitted as any other manuscript through an online submission system.

## 08. Section policies for future publications in SLJHR

No	Type of the manuscript	Open submissions	Solicited submissions	Peer-reviewed
1	Editorials/Leading articles	-	x	x
2	Original articles	x	-	x
3	Case reports/Case series	x	-	x
4	Clinical audits	x	-	x
5	Cover stories	x	x	x
6	Picture stories	x	x	x
7	Brief reports	x	x	x
8	Updates on evidence-based practices in health policy and systems	x	x	x
9	Manuscripts on continuous medical education	x	-	x
10	Perspectives	x	x	x
11	Opinion articles	x	-	x
12	Commentaries	-	x	x/-
13	Book Reviews	-	x	x
14	Correspondence/Letters to the editor	x	-	-
15	Notices/Obituaries/Appreciations	-	x	-

## II. Organization of the manuscript for original research for the SLJHR

### General comments

- The SLJHR entertains the following categories of original articles: original research articles; systematic reviews; meta-analyses. Original research articles are based on original research studies where there is primary data collection.
- All original articles will have to adhere to the reporting guidelines relevant to the respective study design as specified in the Author Guidelines.
- All parts of the manuscript, including tables and figures, legends, references must be of double spacing. The computer language is English (UK).
- Keep abbreviations to a minimum, particularly when they are not standard. If it is necessary to use an abbreviation, make sure it is spelt out fully in the text or a legend the first time it appears.
- The word count for the manuscript, excluding the abstract, references, figures and tables and supplementary material is 2,500–4,000.
- The manuscript should accompany a 'Title Page', which contains general information about the article

and its authors. This usually includes the manuscript title, author information, any disclaimers, sources of support, word count, and sometimes the number of tables and figures.

### Title of the manuscript

- The title should be clear and concise, reflecting the essence of the study. It may be catchy/interesting to the reader.
- It may specify the study population and the study setting and may contain important keywords.

- A full stop is not needed at the end of the title and it cannot contain the phrases such as “a study on”/“an investigation into”.

### Authors

- The list of authors should be in the order of which the names should appear at the time of publication.
- The full name and the institutional affiliation of all authors, and the email address of the corresponding author need to be stated. The ORCID of the first/ corresponding author needs to be included.

### The main text: General comments

- The manuscript has to be arranged according to the following sections: abstract; background; objectives (need not be divided as general and specific); methods (without any subheadings); results (may contain subheadings); discussion (without any subheadings); conclusions and recommendations; information under author declaration with author contribution, conflicts of interest, ethics approval, acknowledgement and funding; references; and tables and figures.
- In each section, the sentences have to be clear and short. Each sentence should start with a word and not with a number or an acronym. Each paragraph usually conveys a single idea and may consist of several sentences. It is better to shift to the next paragraph when a new idea is generated.

### Abstract

- The abstract should be structured under the following headings: background, objectives (to include the general objective only), methods (a concise version of study design, study setting, study duration, study population, sampling technique, sample size, study instruments, data collection, statistical



analysis and any other relevant information), results (on the specific objectives in a concise form), conclusions (according to the specific objectives) and recommendations, and keywords (derived from the title, usually 3–5).

- The word count is 350.

### Background

- The Background starts by defining the research problem (central concept of the study or the dependent variable).
- Description of the nature of the problem (the discrepancy between what it is and what it should be), the size and severity (magnitude) of the problem and distribution of the problem (who is affected, where, since when, and what are the consequences for those affected and for the services).
- An analysis of the major factors that may influence the problem (probable causes) and the unknown factors, and a discussion of why certain factors need more investigation if the problem is to be fully understood.
- A description of any solutions to the problem that have been tried in the past, how well they have worked, and why further research is needed (justification for your study).
- A description of socio-economic and cultural characteristics and an overview of health status and the healthcare system in the country/district, as far as these are relevant to the problem.
- Justification for the study should be based on the identified gaps—theoretical gaps, methodological gaps, empirical gaps and contextual gaps. Potential benefits of the study findings (how the knowledge generated will be useful and generally applicable to solve the identified research problem) should be mentioned here. The justification has to be done convincingly.

### Objective/s

- Objective/s should be clearly phrased in operational terms using action verbs (not to use action verbs such as to understand, to study, etc.). The general objective, and when indicated, specific objectives have to be included. Inclusion of the study setting, study population and the study period within the statement of the objective is not essential unless the inclusion of these clearly explains the objective/s furthermore.

### Methods

- This section has to contain the following whenever appropriate in a single paragraph (however, there is no need to have subheadings for the following or name these subcategories in the text): study design; study setting; study period; study population/s with inclusion and exclusion criteria; sampling method and sample size; study instruments; study implementation with relevant details such as data collectors and training of them; data analysis; administrative requirements; ethical issues; and definitions of relevant variables/ operationalisation of the variables.

### Results

- Results have to be written in the past tense.
- The sample size and the response rate need to be stated.
- Description of the sample in terms of relevant socio- demographic characteristics is necessary where relevant.
- The author may organize the results into different paragraphs for the different objectives.
- Detailed results should be presented in tabulated form (tables) whenever appropriate. Figures/charts may be used sparingly according to the need. Tables and figures should be numbered according to the order in which it appears in the text.

- The maximum number of tables to be included is four and the maximum number of figures is two. Other material may be included as supplementary material separately as suitable.
- Always the percentages described in the text should be supported by the relevant raw data (frequencies) in parenthesis and vice versa. eg: 78.5% (n=252)
- Relevant descriptive and inferential statistics should be presented in detail with an interpretation of the findings in the text.
- Important values need to be in bold.
- The font size of the content in each cell should be adjusted to fit the size of the cell.
- No space should be kept between parenthesis and the value included in the parenthesis. eg: 78.5% (n=252)
- When there are two or more categories in respect of a single variable, make sure that every value in the range belongs to either category.

### Discussion

- This section must include the results in contrast to the findings of other studies along with the public health relevance of the findings, suggestions for future research and ethical issues. Limitations of the study, if any, need to be included here.

### Conclusions and Recommendations

- Conclusions should be the answers to the objective/s written in summary form with minimal statistical information.
- Recommendations should be relevant and arising out of the study. Those should be practical and clearly stated in terms of implementation.

### References

- The Vancouver style needs to be followed.
- Just enough references that are required for your paper are to be cited.

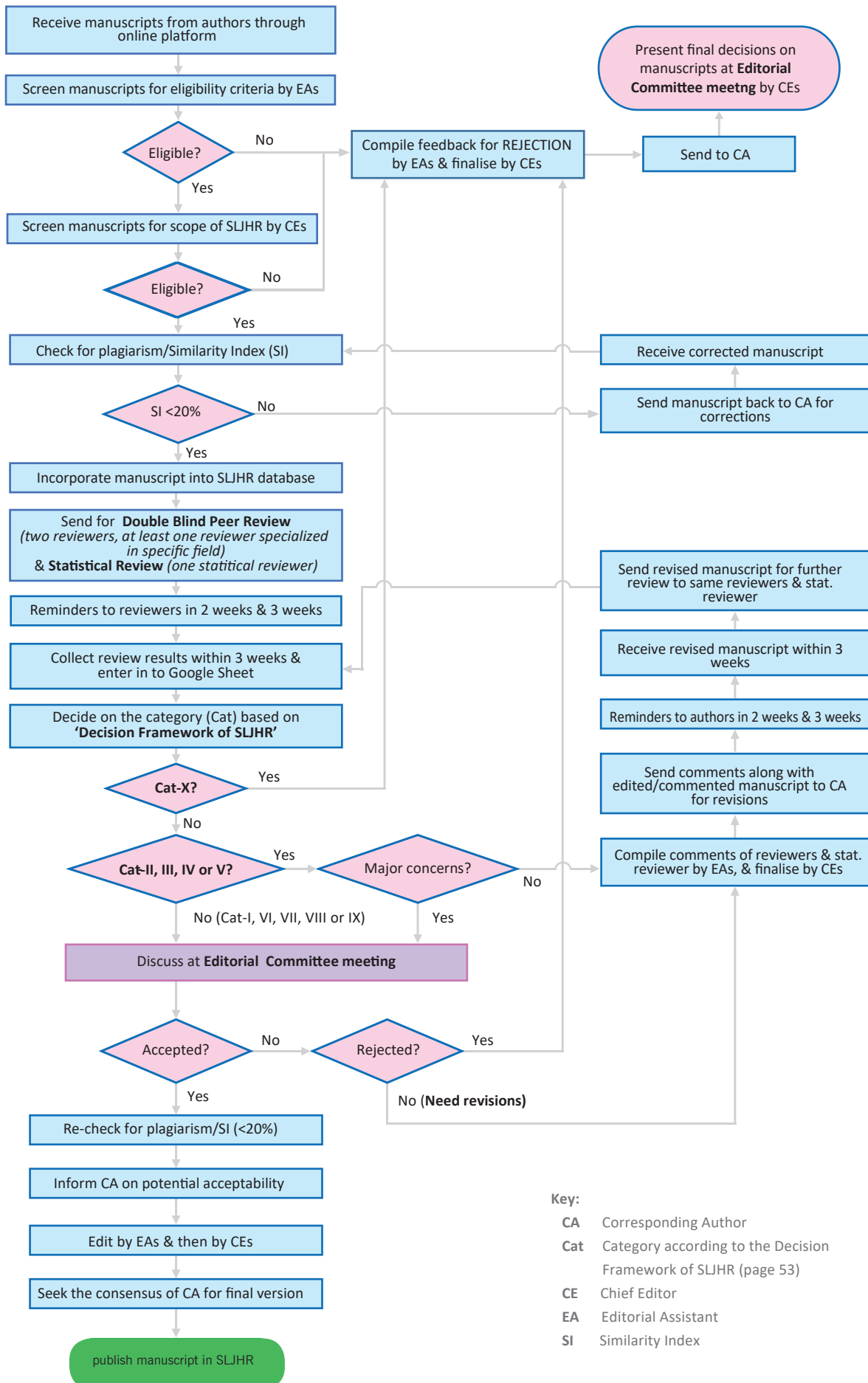
### Tables and Figures

- The row heading and text inside each cell should be left-aligned and the numerical values should be right-aligned.

### Author declaration

- **Author contributions** – The respective roles performed by individual authors from conception to the dissemination of the research should be mentioned.
- **Acknowledgements (optional)** – this has to be confined to those who do not qualify to be an author, but still who have extended support in carrying out the research.
- **Funding and conflicts of interest** – All financial and non-financial conflicts of interest need to be declared. Sources of funding are also to be mentioned.
- **Ethics approval and consent to participate** – If your study involves human subjects and/or animals, you need to provide the name of the Ethics Review Committee. If the study was exempted from the review process by an Ethics Review Committee, this too needs to be stated. If verbal informed consent was obtained, the reason/s for not obtaining the written consent must be provided.

### III. Manuscript review flowchart



Each manuscript will be screened by the editorial board (editors in chief/nominated editorial committee member/editorial assistants) to see whether the article has been prepared according to the instructions given in the Author Guidelines and to see whether the required material eg: Author Declaration, Ethical Clearance (when needed) and other supplementary material have been attached. (This will be applied from the second issue onwards).

1. Each manuscript will be reviewed by two reviewers, at least one from the discipline concerned or related to the discipline maintaining the anonymity of both the authors and the reviewers. Hence the journal policy would be to maintain a double-blind review. However, if the editorial committee/reviewers feel that the author(s) need help to develop the manuscripts, this will be accommodated through a separate panel of advisors of SLJHR.
2. The Manuscript Review Form contains a clear marking scheme to ensure uniform assessment of manuscripts, and the reviewers will be requested to give the reviewer decisions on the reviewed manuscript as 'Accepted without revisions', 'Minor revisions are required', 'Major revisions are required' and 'Rejected'.
3. The decisions on the further proceeding of the manuscript will be given based on the decision matrix of SLJHR shown. N.B. In case any editorial committee member wishes to discuss or inquire about any article, at any point, it is allowed. Articles for which the editorial committee or editors in chief thinks need special review will be sent to a third reviewer.
4. The comments and recommendations of the reviewers and editors will be communicated to the authors within one week of making the decision.
5. Authors are advised to fill up the table in due format addressing each comment of the reviewers and editors, and also advised highlighting the changes they have made to the manuscript following reviewer comments. Revised manuscripts will have to be submitted within 3 weeks of receiving manuscripts for revise.
6. Two reminders on the deadlines for resubmission will be sent to the corresponding authors after two weeks and three weeks of sending the manuscript revision notifications. If there is no response from them after three weeks of sending the manuscripts for revision and if the resubmission is delayed without any valid reason, these articles will be removed from the system of the SLJHR.
7. The revised articles submitted by the authors after addressing the reviewer comments will be re-sent to the same reviewers. If the reviewers are happy that the articles need no further revisions, those manuscripts will be discussed in the editorial committee meeting before being published. Once approved by the editorial committee for publication, the language and content will be improved by the editorial assistants and the language experts. The final manuscript for publication will be sent to the author by the editors in chief with the suggested final revisions, and once the author agrees to the final revisions, the manuscript will be published in the Sri Lanka Journal of Health Research.

Reviewer 1 Reviewer 2	Accepted without revisions	Minor revisions required	Major revisions required	Rejected
	Accepted without revisions	Minor revisions required	Major revisions required	Rejected
Accepted without revisions	<b>Category-I</b> Accepted and manuscript will be discussed at editorial committee meeting (EC) before informing authors.	<b>Category-II</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-IV</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-VII</b> Manuscript will be discussed in EC followed by a decision.
Minor revisions required	<b>Category-II</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-III</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-V</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-VIII</b> Manuscript will be discussed in EC followed by a decision.
Major revisions required	<b>Category-IV</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-V</b> Revisions required – Manuscript will be discussed at EC only if there are major concerns raised by reviewers/chief editors. Otherwise, chief editors send reviewer comments to authors without waiting for EC's decision.	<b>Category-VI</b> Manuscript will be discussed in EC followed by a decision.	<b>Category-IX</b> Manuscript will be discussed in EC followed by a decision.
Rejected	<b>Category-VII</b> Manuscript will be discussed in EC followed by a decision.	<b>Category-VIII</b> Manuscript will be discussed in EC followed by a decision.	<b>Category-IX</b> Manuscript will be discussed in EC followed by a decision.	<b>Category-X</b> Rejected. manuscript will not be discussed in EC and chief editors inform the decision to the author.

1. At the submission of any manuscript, the authors need to make a declaration that the manuscript is free from any conflicts of interest and ethical issues. When the authors have obtained ethics review approval from an Ethics Review Committee (ERC) accepted by the Ministry of Health Sri Lanka, it should be uploaded together with the manuscript. The administrative approval letters need also to be uploaded especially when the manuscript/research is related to the work carried out by the Ministry of Health Sri Lanka.

2. Based on the tools & guidelines developed by the National Health Services UK, available at the following links,

- <http://www.hra-decisiontools.org.uk/ethics/>
- <https://www.nsft.nhs.uk/Get-involved/Documents/Is%20my%20Project%20Research%20Evaluation%20or%20Audit.pdf>
- [http://www.salisbury.nhs.uk/Information For Patients / Departments/ Research/ Research Docs / Documents/defining-research.pdf](http://www.salisbury.nhs.uk/InformationForPatients/Departments/Research/ResearchDocs/Documents/defining-research.pdf)

The Editorial Committee may exempt the following types of articles from the need to have ERC approval:

- Research involving secondary use of data (use of data initially collected for another purpose) when no form of identifier is involved. E.g., personal health records, employee records, student records, computer listings, banked tissue. If any form of identifier is involved and/or if private information of individuals is involved, ERC approval is necessary.

- Quality assurance studies, program evaluation, audits, performance reviews, improvements of the health services which include activities normally administered in the ordinary course of operation in the Ministry of Health Sri Lanka which have been undertaken on the instructions of the Secretary of Health or with the approval of the Secretary of Health are exempted from ERC review. If data collected for such activities is later analysed for a research purpose, it could be considered secondary use of information not originally intended for research. However, if these endeavours include activities that are not normally administered in the ordinary course of operation in the Ministry of Health Sri Lanka and designed specifically to undertake the study in question, these need ERC approval.

- Research about individuals in the public arena using only publicly available or accessible records without contact with the individual/s does not need ERC approval. However, research about a living individual in the public arena if s/he is to be interviewed and/or private papers accessed needs ERC approval.

- Research that are involving naturalistic observation in public venues.

- Research that is based on the review of published/ publicly reported literature.

3. All the other original research needs ERC approval. The ERC approval date has to precede the data collection of the study.



### Important:

All authors are advised to read the following before they place their signatures on the last page of this document. Please check all applicable boxes and provide additional information as requested.

### Title of the manuscript:

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### 01. Correspondence with the editorial office

The corresponding author declared on the title page of the manuscript is: [Insert name here.]

- This author submitted this manuscript using his/her account in the editorial submission system.
- We understand that this corresponding author is the sole contact for the editorial process (including the editorial submission system and direct communications with the office). He/she is responsible for communicating with the other authors about progress, submissions of revisions and final approval of the manuscript.
- We confirm that the email address shown below is accessible by the corresponding author, is the address to which corresponding author's editorial submission system account is linked, and has been configured to accept email from the editorial office of Sri Lanka Journal of Health Research. [Insert the email address you wish to use for communication with the SLJHR here.]

### 02. Conflicts of interest

- Potential conflict of interest exists:

We wish to draw the attention of the editor to the following facts, which may be considered as potential conflicts of interest: [State the nature of the potential conflicts of interest below.]

- No conflict of interest exists.

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial or non-financial support for this work that could have influenced its outcome.

### 03. Funding

- Funding was received for this work.

All of the sources of funding for the work described in this publication are acknowledged below: [List funding sources and their role in study design, data analysis, and result interpretation.]

- No funding was received for this work.

### 04. Intellectual property

- We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, concerning intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

## 05. Research ethics

- We further confirm that any aspect of the work covered in this manuscript that has involved human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.
- Ethics review committee approval was obtained and administrative clearance has been obtained from the respective organizations.
- Written consent to publish potentially identifying information, such as details of the case and photographs, was obtained from the patient(s) or their legal guardian(s).

## 06. Authorship

The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following four criteria:

- i) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- ii) drafting the work or revising it critically for important intellectual content; AND
- iii) final approval of the version to be published; AND
- iv) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. For more information on authorship, please visit <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> too

- All listed authors meet the ICMJE criteria. We attest that all authors contributed significantly to the creation of this manuscript, each having fulfilled the criteria as established by the ICMJE.
- One or more listed authors do(es) not meet the ICMJE criteria.
- We believe these individuals should be listed as authors because: [Please elaborate below.]
- We confirm that the manuscript has been read and approved by all named authors.
- We confirm that the order of authors listed in the manuscript has been approved by all named authors.

## 07.

- We certify that the manuscript has not been published elsewhere nor submitted to another journal for consideration for publication. If the manuscript has been partly or fully published elsewhere, a full statement of all previous publications should be attached. This should include the presentations of abstracts made from the same original article/clinical audit or other publication types. Any such work should be referred to specifically and referenced in the new manuscript. Copies of such material should be included with the manuscript to help the editor assess the situation about the redundancy of the material to be published. Authors are also encouraged to submit any previous communications from other journal editors or reviewers if the manuscript has been previously submitted to another journal.

08.

- We certify that the manuscript will not be submitted to another journal for review until the final decision is reached by the editorial board of SLJHR. If the authors decide to withdraw the manuscript from review, it will be immediately notified through the online system.

09.

- If the manuscript is accepted for publication, we grant the Ministry of Health, Sri Lanka the authorization to publish the article and to identify itself as the original publisher. We have read the Copyright Notice in the Author Guidelines.

**We the undersigned agree with all of the above.**

Author's name (First, Last)	Signature	Date
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N.B. Please note that all authors need to put their signatures. E-signatures are acceptable. The corresponding author cannot sign on behalf of other authors.

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Deconstructing the “Free Health Service” in Sri Lanka

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### Instructions to authors: Sri Lanka Journal of Health Research

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- Review process and the decision framework
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- Author declaration



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