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National Immunization Programme

National Immunization Summit 2025

Technical Report

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Colombo Sri Lanka
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Epidemiology Unit,
Ministry of Health and Mass Media

National Immunization Summit 2025

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List of Contributors

*Consultant Epidemiologists**	Dr. Hasitha Tissera	Chief Epidemiologist
	Dr. Thushani Dabrera	Deputy Chief Epidemiologist, Epidemiology Unit
	Dr. Hathshya Munasingha	Consultant Epidemiologist, Epidemiology Unit
	Dr. Thilanga Ruwanpathirana	Consultant Epidemiologist, Epidemiology Unit
	Dr. Athula Liyanapathirana	Consultant Epidemiologist, Epidemiology Unit
	Dr. Sashimali Wickramasinghe	Consultant Epidemiologist, Epidemiology Unit
	Dr. Chinthana Perera	Consultant Epidemiologist, Epidemiology Unit
	Dr. Nimal Gamagedara	Consultant Epidemiologist, Epidemiology Unit
	Dr. Harendra Dassanayake	Consultant Epidemiologist, Epidemiology Unit

* The concept note compilation was carried out by the team of Consultant Epidemiologists.

Supporting Team	Dr. Prabha Abeykoon	Acting Consultant Community Physician, Epidemiology Unit
	Dr. Kumudu Weerakoon	Acting Consultant Community Physician, Epidemiology Unit
	Dr. Jinadari Amarasena	Acting Consultant Community Physician, Epidemiology Unit
	Dr. Hemal Chandrasena	Acting Consultant in Health Informatics, Epidemiology Unit
	Dr. Aruni Hathamuna	Senior Registrar, Community Medicine
	Dr. Anoma Marasinghe	Senior Registrar, Community Medicine
	Dr. Helanka Wijayatilake	Senior Registrar, Community Medicine
	Dr. Indumini Gunatilake	Senior Registrar, Community Medicine
	Dr. Dhivya Nathaniel	Registrar, Community Medicine
	Dr. Chamila Balasuriya	Medical Officer, Epidemiology Unit

Reviewers	Dr. Hasitha Tissera	Chief Epidemiologist
	Dr. Ananda Amarasinghe	Former Team Coordinator- VPD and Immunization- WHO Office for Papua New Guinea
	Dr. Jayantha Liyanage	Former Regional Advisor- Immunization System Strengthening, WHO- SEARO
	Dr. Sudath Peiris	WHO Consultant

Editor	Prof. Nuwan Wickramasinghe	Chair Professor of Community Medicine, Rajarata University of Sri Lanka

Co-editor	Dr. Sashimali Wickramasinghe	Consultant Epidemiologist, Epidemiology Unit

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Foreword

Sri Lanka's immunization program remains a cornerstone of national public health achievements, marked by significant milestones such as the elimination of polio, neonatal tetanus, measles, and rubella. These successes reflect decades of unwavering commitment, strategic investment, and the dedication of healthcare workers throughout the country. In the face of economic challenges, emerging infectious diseases, and shifting global health priorities, preserving these gains calls for strategic foresight, resilience, and continuous innovation.

Strengthening primary healthcare is central to sustaining high vaccine coverage, especially for vulnerable groups. Sri Lanka remains fully committed to expanding vaccine access, embracing innovative technologies, and refining immunization strategies to effectively address current needs and adapt to future public health challenges.

Despite Sri Lanka's graduation from Gavi support, strong collaboration with global partners such as WHO, UNICEF including Gavi remains essential to overcoming financial and logistical challenges, integrating new vaccines into the national schedule, and strengthening supply chain management.

Advancing digital health systems through immunization registries, electronic health records, and real-time surveillance will enhance data-driven decision-making and program efficiency. Equally important is ongoing investment in the healthcare workforce, with a focus on continuous training and professional development to ensure effective service delivery.

In alignment with the WHO Global Immunization Agenda 2030, the Ministry of Health will implement the recommendations of the Advisory Committee on Communicable Diseases (ACCD), as outlined in the conclusions of the National Immunization Summit 2025 Technical Report. Through continued innovation, strong collaboration, and unwavering commitment, Sri Lanka reaffirms its dedication to safeguarding the health of future generations.

Dr. Nalinda Jayatissa
Minister of Health and Mass Media

Foreword

Sri Lanka's National Immunization Program (NIP) has long been recognized as a model of success, both regionally and globally. This achievement is the result of sound health policies, strategic leadership, resilient systems, and the unwavering commitment of our healthcare professionals and partners. The collective efforts of the Ministry of Health, other government bodies, international agencies, and community stakeholders have ensured high immunization coverage and the protection of countless lives.

As we navigate a more complex public health environment, there is a pressing need to strengthen and future-proof our immunization efforts. The economic strain following the COVID-19 pandemic has highlighted the importance of securing sustainable financing and improving supply chain systems. While temporary support from partners like GAVI has been invaluable, our focus must now shift to long-term sustainability. Embracing digital transformation, particularly in immunization data management and real-time surveillance, will further enhance our ability to monitor, forecast, and respond effectively to vaccine-preventable diseases.

The recommendations outlined in the National Immunization Summit (NIS) 2025 Technical Report will not only shape the future of our immunization schedules, but also lay the foundation for forward thinking strategies and meaningful partnerships. I extend my heartfelt gratitude to all participants for their invaluable contributions and encourage continued collaboration as we work together to ensure a healthier future for all Sri Lankans.

Dr. Anil Jasinghe
Secretary, Ministry of Health and Mass Media

Foreword

It is with great pride and deep appreciation that I reflect on the extraordinary progress Sri Lanka has made in the field of immunization, culminating in the National Immunization Summit (NIS) 2025. This summit represents a defining milestone in our public health journey - an opportunity to unite national and international experts, health professionals, and key stakeholders in reaffirming our shared commitment to immunization as a vital pillar of preventive healthcare. Sri Lanka's National Immunization Program (NIP) has long been recognized as a beacon of excellence, underpinned by sound policies, scientific integrity, and, above all, the steadfast dedication of our exceptional healthcare workforce.

Our successes, from the elimination of polio, neonatal tetanus, measles, and rubella, to sustaining high vaccine coverage across all regions, demonstrate what is possible through coordinated effort and strategic vision. However, the evolving public health landscape demands that we remain vigilant and forward-thinking. Challenges such as vaccine hesitancy, misinformation, and the impact of digital media necessitate renewed focus on community engagement, evidence-based communication, and empowering frontline workers with the knowledge and tools to build trust and promote vaccine confidence. At the same time, we must embrace innovations in digital health and ensure the financial and operational sustainability of our immunization systems.

This publication reflects the shared insights, best practices, and strategic direction discussed during the Summit. It will serve as an essential guide for policymakers, healthcare professionals, and stakeholders engaged in shaping the future of immunization in Sri Lanka. I extend my sincere appreciation to the Epidemiology Unit for organizing this timely and significant forum and to all contributors whose efforts continue to strengthen our national immunization efforts. May this volume inspire continued collaboration and commitment to securing a healthier future for all Sri Lankans.

Dr. Asela Priyantha Gunawardena
Director General of Health Services

Foreword

Sri Lanka's National Immunization Program is widely recognized as a model of excellence, not just in the region but also on a global scale. The country's Expanded Program on Immunization (EPI) has consistently demonstrated outstanding achievements, marked by exceptionally low incidence of vaccine-preventable diseases and remarkably high vaccination coverage.

With a profound sense of pride and humility, I reflect on Sri Lanka's remarkable journey and enduring success in the field of immunization. Today, our nation rightfully earns global recognition for its unwavering commitment to safeguarding the health of its people. This achievement is a true reflection of the state's dedication to ensuring the well-being of all citizens, regardless of ethnicity or religion.

The success of our immunization efforts is largely attributed to the meticulously planned and effectively implemented program led by the Epidemiology Unit. This initiative has played a pivotal role in controlling communicable diseases and has significantly strengthen the national economy through improved public health outcomes, increased productivity, and enhanced efficiency.

The National Immunization Summit (NIS) 2025 served as a valuable platform to review the current immunization schedule, gather expert input on potential updates, and share the latest global strategies and trends in addressing vaccine-preventable diseases. This report synthesizes deliberations and opinions expressed by the participants during the summit. Report will be further discussed at the Advisory Committee on Communicable Diseases (ACCD) and decide on propose changes to the existing immunization schedule and new vaccine introductions.

This important event, organized under the guidance of the Deputy Director General of Public Health Services I, was a resounding success thanks to the tireless efforts of the Epidemiology Unit of the Ministry of Health. I extend my sincere appreciation to all stakeholders and contributors whose dedication and collaborative spirit made this timely and critical initiative a reality.

Dr. S.M. Arnold

Deputy Director General of Public Health Services I

Foreword

I extend my heartfelt congratulations and deep appreciation to the Epidemiology Unit of the Ministry of Health, for publishing the report following the National Immunization Summit (NIS) 2025.

UNICEF has a longstanding and valued partnership with the Ministry of Health and the Epidemiology Unit, to uplift the health of children in Sri Lanka. Childhood vaccines are a crucial public health tool, preventing serious diseases and saving lives. There are few countries that have prioritized immunization and experienced consequent success as Sri Lanka.

It is heartening to note that despite the recent challenges, Sri Lanka has maintained high immunization coverage rates for all routine vaccines. Sri Lanka has also been consistent in updating the National Immunization Program (NIP), including timely and appropriate introduction of new vaccines as per the national requirements. The NIS 2025 held in Sri Lanka has provided a critical platform to review the current program and consider necessary changes based on the best available evidence, ensuring that Sri Lanka remains at the forefront of immunization practices.

We note that the Immunization Summit was organized through a structured, evidence-informed approach, incorporating stakeholder engagement and alignment with both national and global health priorities. Experts from UNICEF were happy to provide inputs to the vaccine specific concept notes developed prior to the summit and rigorously evaluated by the in-country Technical Expert Groups.

UNICEF is pleased to be part of this national endeavor, providing both technical and financial support. We are confident that this summit yields valuable insights and contributes to the continued success of the NIP in Sri Lanka. UNICEF remains committed to our partnership and to supporting the health and well-being of all children in Sri Lanka.

Mr. Christian Skoog
Representative, UNICEF, Sri Lanka

Foreword

I extend my heartfelt congratulations to the Ministry of Health and the Epidemiology Unit for their exemplary leadership in organizing the National Immunization Summit 2025 and publishing the report. Your unwavering commitment to advancing public health in Sri Lanka is both commendable and inspiring.

Sri Lanka's immunization program stands as a model of excellence in the South-East Asia Region. The country's consistent efforts to maintain high immunization coverage - even amidst economic challenges and global health crises, reflect the strength and resilience of its health system. The strategic introduction of new vaccines tailored to national needs further underscores Sri Lanka's proactive and evidence-based approach.

The World Health Organization (WHO) is proud to support Sri Lanka in strengthening immunization systems, disease surveillance, adopting digital innovations, and enhancing risk communication and community engagement. Tackling vaccine hesitancy through behavioral insights and effective infodemic management remains a shared priority.

Looking ahead, enhancing breadth of protection across life course and ensuring the financial sustainability of the immunization program is critical. WHO encourages continued collaboration among the government, GAVI, and other partners to secure long-term funding and support the introduction of vaccines based on robust evidence. The summit's focus on reviewing immunization schedules, exploring new vaccine introduction opportunities across life course, strengthening immunization systems and guiding policy through research exemplifies Sri Lanka's forward-thinking vision.

Sri Lanka's contributions extend beyond its borders, offering valuable insights and best practices to the global health community. WHO remains a committed partner, providing technical expertise and policy guidance to ensure that no one is left behind in the pursuit of universal immunization.

Together, we can turn what is "Immunization for All is Humanly Possible" into reality - protecting everyone at all age group with safe and effective lifesaving vaccines to build a healthier future for all.

Dr. Alaka Singh
WHO Representative to Sri Lanka

Foreword

It is with great pride and a shared vision for the future that we present the Technical Report of the National Immunization Summit (NIS) 2025, held on March 28, 2025, at the Bandaranaike Memorial International Conference Hall, Colombo, Sri Lanka.

Building on the longstanding success of Sri Lanka's National Immunization Program (NIP), the summit convened over 175 delegates, including experts, policymakers, clinicians, researchers, and international health partners. This landmark event provided a high-level platform to review the existing immunization schedule, explore global innovations in vaccine development, and forge a consensus on the potential integration of new vaccines into the national program.

The summit featured a series of technical presentations and expert panel discussions focused on evaluating proposed changes to the existing immunization schedule and the potential introduction of new vaccines, including pneumococcal, influenza, respiratory syncytial virus (RSV), meningococcal, rotavirus, and dengue. Participants also engaged in discussions on ensuring the financial sustainability of the NIP, recognizing its critical role in long-term health system resilience.

This report encapsulates the collective insights, evidence-based conclusions, and strategic direction agreed upon during the summit. It is a testament to the multidisciplinary collaboration and reflects Sri Lanka's unwavering commitment to strengthening one of the most robust immunization programs in the Asia-Pacific region.

On behalf of the Epidemiology Unit, I express my sincere appreciation to all participants, resource persons, and partner organizations including WHO, UNICEF, Gavi, and national stakeholders for their invaluable contributions. We look forward to continued collaboration in our shared mission to protect the health of every Sri Lankan through enhanced immunization efforts.

Dr. Hasitha Tissera
Chief Epidemiologist

Participants at the National Immunization Summit 2025

Building on a strong immunization legacy since 1978, Sri Lanka has become a regional leader in vaccine adoption, equitable access, and evidence-based policymaking. The Epidemiology Unit of the Ministry of Health organized the National Immunization Summit (NIS) 2025, held on 28th March 2025 at the Bandaranaike Memorial International Conference Hall, Colombo. It served as a platform to reassess national priorities in light of disease burden in the country and global scientific developments, following earlier summits in 2001, 2007, and 2015.

The objectives of the NIS 2025 were to,

- review the current immunization schedule in relation to selected antigens;
- update stakeholders on global strategies and developments in vaccine-preventable diseases;
- explore the feasibility of introducing new vaccines and/or revising existing immunization protocols

The agenda included two technical sessions. Each topic began with a technical presentation by a Consultant Epidemiologist, summarizing key findings from expert-developed concept notes on disease burden, vaccine performance, safety, cost-effectiveness, and implementation in Sri Lanka. This was followed by guided discussions with a wide range of stakeholders including, members of the Advisory Committee on Communicable Diseases (ACCD), representatives from UNICEF, WHO, and Gavi, national and subnational health administrators, epidemiologists and public health specialists at both national and subnational levels, specialist clinicians across various medical disciplines, representatives from academic institutions and professional colleges, divisional-level public health officers and frontline implementers of the National Immunization Program (NIP), and officials from relevant government ministries and departments. The sessions enabled context-specific analysis and generated additional insights into the implications of vaccine introduction and schedule changes.

Executive Summary

Technical session I focused on proposed changes to vaccines currently included in the NIP, while technical session II explored new vaccines under consideration for introduction into the NIP. The summary of the key observations and conclusions is presented below.

Technical session I

1. Polio Vaccines

- Adopt a 3-dose bivalent Oral Polio Vaccine (bOPV) schedule at 2, 4, and 6 months, along with two fractional Inactivated Polio Vaccine (fIPV) doses at 4 and 9 months, as the most appropriate approach, based on global evidence of cost-effectiveness and feasibility.
- Consider transitioning to a 3-dose hexavalent vaccine (replacing bOPV, fIPV, and pentavalent vaccines) at 2, 4, and 6 months. This depends on national funding and Gavi support. Health system readiness is crucial, and to address potential gaps in mucosal immunity, Acute Flaccid Paralysis (AFP) and environmental surveillance should be strengthened. A phased rollout is advised, maintaining the bOPV + fIPV schedule until logistics are stabilized.
- Explore shifting to an IPV-only 3-dose schedule without OPV. Though this enhances safety, it requires a major programmatic shift and high IPV coverage in line with WHO guidance. With fIPV coverage already over 98% in Sri Lanka, the country is well-positioned, but a cautious phased approach is recommended, especially if the hexavalent vaccine introduction is delayed.

2. Measles-Containing Vaccine (MCV)

- Given the absence of new measles cases since January 2025 and having passed three incubation periods, the recent outbreak is considered contained. As a result, introduction of a zero dose at 6 months could be delayed.
- Maintaining MCV1 at 9 months remains necessary to address waning maternal immunity in infants and ensure timely protection.
- Rescheduling MCV2 from 3 years to 18 months should carefully balance the potential for improved immunity with the risk of disrupting established child health services at the 3-year contact. A thorough assessment of health system impact is recommended before implementing any changes.
- Addressing vaccine hesitancy through improved communication strategies and sustained public engagement is necessary.
- Suboptimal surveillance for fever with maculopapular rash was noted, underlining the need to strengthen surveillance in both public and private sectors to detect the outbreaks early and ensure the confidence in outbreak detection.

3. Human Papillomavirus (HPV) Vaccine

- Deliberations centered on the transition to a single-dose HPV schedule, with two views.
    - One group of experts, representing the more favoured opinion, supported retaining the two-dose schedule. They cited concerns about the limited cervical cancer screening coverage in Sri Lanka, the relatively short duration

of only 11 years of global immunity data available for a single dose, and the variable certainty of evidence from the supporting studies.

- The other group of experts supported adopting a single-dose strategy, citing its global uptake in 67 countries, feasibility with close monitoring, cost-effectiveness, and programmatic feasibility. Although the two-dose schedule has longer term data onimmunity, the 11 years of data for the single dose show similar trends.

- WHO recommends ongoing monitoring of cervical cancer epidemiology and immunity research post-single dose. Prioritizing high-risk groups (e.g., immunocompromised individuals and survivors of abuse) for two doses of the HPV vaccine is necessary, although specific group definitions remain under review.
- Vaccination of male children was not recommended under the current context.
- Further discussion highlighted the need to strengthen cervical cancer screening programs. While booster doses in adulthood to address potential waning immunity were mentioned, they were not explored in depth due to limited data.

4. Adult Tetanus-Diphtheria (aTd) Vaccine

- Transitioning from Tetanus Toxoid (TT) to the aTd vaccine was discussed, aligning with WHO guidelines and enhancing protection against both tetanus and diphtheria, especially in the context of the global diphtheria resurgence. This shift was considered beneficial for maternal immunization and post-exposure prophylaxis.
- The need for routine booster programs for adolescents and adults was highlighted, given the waning immunity with age.
- Emphasis was placed on the importance of public awareness and acceptance, especially among vulnerable groups such as pregnant women. Advocacy efforts must clarify that diphtheria, like tetanus, is a toxoid, to ensure trust among healthcare providers and communities.
- Strengthening diphtheria surveillance and diagnostic systems was recommended to support early detection and effective response.

Technical Session II

1. Pneumococcal Conjugate Vaccine (PCV)

- Introduction of a PCV could be considered in prevention of invasive pneumococcal disease (IPD) in Sri Lanka, especially among children under five, despite limited measurable burden by local data.
- Both PCV-10 and PCV-13 have shown substantial global impact in reducing vaccine-type IPD, pneumonia, and nasopharyngeal carriage. Although efficacy
- Data for PCV-10 (SII) is limited, immunogenicity studies suggest comparable effectiveness to PCV-13 and PCV-10 (GSK).
- Vaccine selection should be guided by local serotype data due to the observed mismatch between circulating serotypes in Sri Lanka and those covered by current PCV formulations, which could impact vaccine effectiveness.

Executive Summary

- The phenomenon of serotype replacement, documented globally after PCV introduction, highlights the importance of robust, ongoing surveillance to monitor changing serotype patterns and vaccine impact.
- The available global evidence suggests that the return of investment for PCV is relatively low.
- Financial affordability and sustainability are major considerations, with PCV-10 estimated to cost approximately LKR 466 million per birth cohort. Authorities were advised to explore funding options through domestic sources or international support such as Gavi, while ensuring long-term program viability.
- Strengthening national surveillance systems is critical for accurate disease burden estimation, serotype monitoring, and post-introduction vaccine evaluation.
- The potential need for adult pneumococcal vaccination should be further assessed, in light of a perceived rise in adult IPD cases and the need to improve clinical management of invasive pneumococcal infections is a priority.

2. Meningococcal Vaccine

- Routine inclusion of the meningococcal vaccine in the NIP is not currently supported, due to limited epidemiological and laboratory data and the lack of robust surveillance for invasive meningococcal disease (IMD) in Sri Lanka.
- Strengthening laboratory capacity and improving the integration of clinical and laboratory surveillance systems were recommended to generate reliable data for future evidence-based policy decisions.
- The quadrivalent meningococcal conjugate vaccine is recommended for travelers to endemic countries, while Men5CV may be considered once it becomes available.
- Vaccination is recommended for high-risk individuals, such as those with asplenia, while routine use in closed settings is not advised based on current evidence.
- Additional recommendations included establishing a formal verification system for outbound pilgrim vaccinations, enhancing coordination between health and travel authorities, and maintaining a buffer stock of vaccines for outbreak response.

3. Influenza Vaccine

- Routine inclusion of influenza vaccines in the NIP was not recommended, due to challenges such as antigenic drift, short-lived immunity, and the need for annual vaccine administration.
- A targeted strategy focusing on high-risk groups was considered more practical and cost-effective. Priority groups identified included pregnant mothers, older adults (65+), pilgrims, healthcare workers, military personnel, and individuals with chronic respiratory conditions.
- Pregnant mothers were highlighted as a key target group, though improving public acceptance remains essential for successful implementation.
- Strengthening Sri Lanka's already robust influenza surveillance system was emphasized, with continued investment in laboratory capacity to support timely detection and response.

- It was noted that vaccination alone is insufficient; complementary strategies such as timely treatment, public education, and infection control measures must also be strengthened.
- Detection of both Northern and Southern Hemisphere virus strains in Sri Lanka highlights the risk of vaccine mismatch, highlighting the need for context-specific decision-making.
- Close monitoring and periodical reassessment based on national evidence was recommended, particularly in relation to prioritizing pregnant women and other high-risk populations for vaccination.

4. Rotavirus Vaccine

- Introduction of the rotavirus vaccine was not prioritized at this time, due to insufficient data on disease burden and cost-effectiveness in the Sri Lankan context.
- Continuous surveillance on rotavirus infection was recommended to enable future re-evaluation as more evidence becomes available.
- Strengthening surveillance for acute gastroenteritis in children under five was identified as a key priority, including the incorporation of laboratory confirmation for clinically suspected rotavirus cases.
- Establishing baseline intussusception surveillance among under five children at sentinel sites was also emphasized, to monitor potential adverse events following vaccination and support evidence-based policy decisions in the future.

5. Respiratory Syncytial Virus (RSV) Vaccine

- Introduction of an RSV vaccine into the NIP is not currently recommended, as existing data do not indicate a significant disease burden in Sri Lanka.
- However, it is a recognized need to strengthen the integrated respiratory virus surveillance system to better understand RSV seasonality, transmission patterns, and clinical outcomes.
- Use of monoclonal antibodies for prevention in high-risk groups (e.g., preterm infants or those with chronic lung or heart conditions) was discussed, but deemed not feasible at this stage due to high costs and limited supply availability.
- The potential integration of air quality monitoring with respiratory virus surveillance was highlighted as a valuable approach to assess environmental influences on respiratory disease trends.

6. Dengue Vaccine

- Accurate national and sub-national age-stratified seroprevalence data by serotypes are essential to guide any future dengue vaccine introduction, given the variability in disease transmission by serotypes and vaccine performance profiles.
- Thorough expert review by the National Medicines Regulatory Authority (NMRA) is required for vaccines such as QDENGA, including evaluation of Phase III trial data relevant to the Sri Lankan context.

Executive Summary

- Long-term pharmacovigilance and post-marketing surveillance were emphasized as critical for monitoring vaccine safety, detecting adverse events, and assessing vaccine impact performance.
- The potential need for a booster dose to ensure long-term immunity was noted as an area for future research and consideration.
- Detailed pricing and cost-effectiveness analysis should be integrated into the vaccine registration process to support informed decision-making.
- Identifying individuals with prior dengue infection was highlighted as an important strategy, as they are likely to derive greater benefit from vaccination. This consideration should be factored into future vaccine implementation plans.

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ACCD	Advisory Committee on Communicable Diseases
AEFI	Adverse Events Following Immunization
AFP	Acute Flaccid Paralysis
aP-HVV	Acellular Pertussis Hexavalent Vaccine
aTd	Adult Tetanus-Diphtheria Vaccine
bOPV	Bivalent Oral Polio Vaccine
EPI	Expanded Program on Immunization
fIPV	fractional Inactivated Polio Vaccine
HPV	Human Papillomavirus
IMD	Invasive Meningococcal Disease
IPD	Invasive Pneumococcal Disease
IPV	Inactivated Polio Vaccine
ITAG	Immunization Technical Advisory Group
JE	Japanese Encephalitis
MCV	Measles-Containing Vaccine
MMR	Measles, Mumps, and Rubella Vaccine
MR	Measles-Rubella Vaccine
NIP	National Immunization Program
NIS	National Immunization Summit
NMRA	National Medicines Regulatory Authority
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
RCCPE	Regional Commission for Certification of Poliomyelitis Eradication
ROI	Return on Investment
RSV	Respiratory Syncytial Virus
RVC	Regional Verification Commission

List of Abbreviations

SAGE	Strategic Advisory Group of Experts on Immunization
SDG	Sustainable Development Goals
SEAR	South-East Asia Region
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VAPP	Vaccine-Associated Paralytic Poliomyelitis
VDPV	Vaccine-Derived Poliovirus
VPD	Vaccine-Preventable Diseases
WHO	World Health Organization
wP-HVV	Whole-cell Pertussis Hexavalent Vaccine

Sri Lanka's Legacy and Leadership in Immunization

Initiated in 1978, Sri Lanka's immunization journey has transformed the country into a pioneer -setting benchmarks in coverage, equity, and innovation across the region.

Sri Lanka has long held a position of regional leadership in immunization, earning sustained international recognition for its robust, equitable, and evidence-informed approach to the delivery of vaccines through the National Immunization Program (NIP). Originally launched in 1978 as the Expanded Program on Immunization (EPI), in line with global World Health Organization (WHO) initiatives, the country's immunization program rapidly gained momentum, achieving Universal Childhood Immunization status; attaining at least 80% coverage of all EPI vaccines; within 12 years. Since then, the program has evolved into a model of excellence, consistently recording over 95% coverage for all routine infant and childhood vaccinations.

This remarkable achievement is underpinned by a strong public health system, rooted in the well-established network. The structural integrity of this community-based service delivery model has ensured sustained high immunization coverage at both national and sub-national levels, even amidst disruptions caused by the COVID-19 pandemic and the subsequent economic crisis. The impact of this sustained investment in immunization on Vaccine-Preventable Diseases (VPDs) has been profound. Sri Lanka reported its last case of poliomyelitis in 1993, achieved elimination of maternal and neonatal tetanus in 2016 and measles in 2019, and attained hepatitis B control status in 2024, marking significant public health milestones through effective vaccination. These achievements reflect the program's effectiveness in contributing to Sustainable Development Goal (SDG) targets, particularly those related to child survival and universal health coverage.

Recognizing immunization as a cornerstone of communicable disease prevention, the Government of Sri Lanka has consistently prioritized it as a strategic national investment. With sustained support from the WHO, the United Nations Children's Fund (UNICEF), Gavi, and other partners, the NIP has been strengthened through robust financing, institutionalized cold chain systems, sensitive VPD surveillance, rigorous Adverse Events Following Immunization (AEFI) surveillance, and seamless integration with maternal and child health services.

Background

Strategic Vaccine Introductions

Sri Lanka has established itself as a regional frontrunner in the prompt adoption of new vaccines, guided by robust scientific analysis, local epidemiological data, and alignment with global best practices.

Sri Lanka has also emerged as a regional pioneer in the timely introduction of new and underutilized vaccines (Figure 1). The country adopted the Japanese Encephalitis (JE) vaccine into the national schedule in 1988, ahead of many other countries in the region. The Rubella vaccine was incorporated in 1996 and subsequently replaced with the combined Measles-Rubella (MR) vaccine in 2001and Measles, Mumps, and Rubella (MMR) vaccine in 2011.

In 2003, Sri Lanka introduced the Hepatitis B vaccine into the infant schedule and in 2008, the Pentavalent vaccine (combining Diphtheria, Tetanus, and Pertussis, Hepatitis B, and Haemophilus influenzae type b) was introduced, following WHO prequalification and local safety assessments. More recently, the Human Papillomavirus (HPV) vaccine was incorporated into the routine immunization schedule for adolescent girls in 2017, aligning with WHO recommendations.

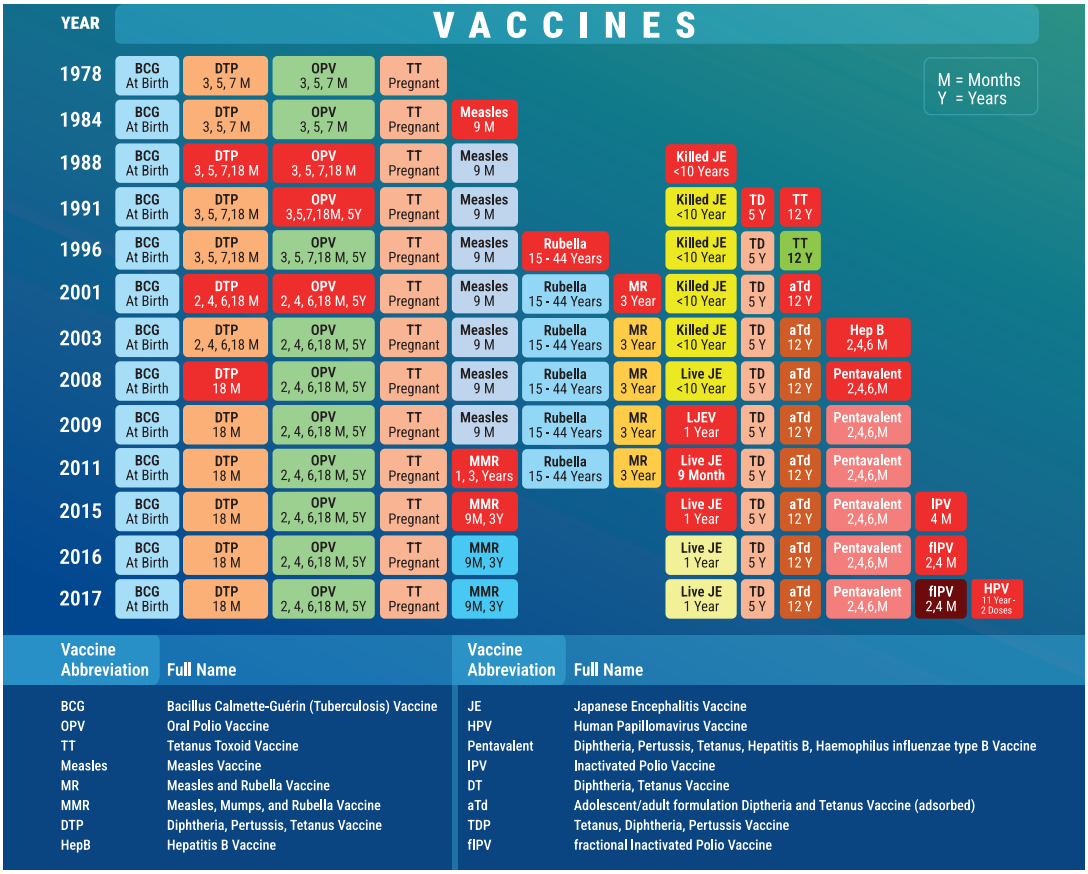

Figure 1: Evolution of the immunization schedule in Sri Lanka

All new vaccine introductions have been grounded in scientific rigor and guided by the deliberations of the Advisory Committee on Communicable Diseases (ACCD). This multidisciplinary technical advisory group, comprising leading experts from academic institutions, professional colleges, and key ministries, ensures that immunization policies are informed by local epidemiology, global evidence, global disease control targets, cost-effectiveness analyses, and health systems capacity.

Previous National Immunization Summits, Sri Lanka

Previous NISs paved the way for the introduction of, 2001: MR, Hep B, aTd 2007: Hib in Pentavalent, Live JE, Mumps in MMR (2 dose) 2015: IPV and HPV

Over the past two decades, the National Immunization Summit (NIS) has served as a key platform to bring together stakeholders from across the immunization landscape to deliberate on policy directions, review the current NIP schedule, and discuss the potential for introducing new vaccines. The NIS has evolved into a highly participatory forum where evidence, innovation, and consensus intersect.

The inaugural NIS was convened in 2001, during which pivotal decisions were forwarded to the ACCD to introduce the MR vaccine, Hepatitis B vaccine, and adult Tetanus-Diphtheria (aTd) vaccine. This was followed by the second NIS in 2007, which marked the introduction of the Pentavalent vaccine (which included Hib), the live JE vaccine, and Mumps as part of a two-dose MMR schedule. The third NIS, held in 2015, led to the inclusion of Inactivated Polio Vaccine (IPV) and HPV vaccine in the national schedule, further reinforcing Sri Lanka's commitment to protecting population health through immunization.

These summits allowed for strategic re-evaluation of the national immunization schedule and forward-looking planning for vaccine life-course approaches.

Strategic Process Leading to the NIS 2025

The successful convening of the NIS 2025 was the culmination of a structured, consultative, and evidence-informed process. It involved several strategic steps carried out over a period of several months, ensuring the participation of relevant stakeholders and alignment with both national and global immunization priorities. The preparatory phase integrated scientific rigor, epidemiological relevance, and multistakeholder involvement through the following systematic steps.

Background

This entire process was facilitated by the establishment of multiple Technical Expert Groups, alongside the formation of the NIS Working Group, which oversaw all programmatic and logistical aspects related to the organization of the NIS.

- *Identification of priority vaccines for immunization schedule modifications and new vaccine introductions*

Strategic preparations for the NIS 2025 were led by multiple Technical Expert Groups for evidence synthesis and a Working Group for program and logistics coordination.

The process of identifying priority vaccines for immunization schedule modifications and new vaccine introductions began with internal technical discussions led by Consultant Epidemiologists at the Epidemiology Unit of the Ministry of Health, under the leadership of the Chief Epidemiologist. These initial deliberations were based on local disease surveillance data, programmatic needs, and existing national immunization targets. The process was subsequently strengthened by input from subject matter experts, both nationally and internationally, representing vaccinology, infectious diseases, and public health. Their contributions provided critical insights into emerging disease threats, advancements in vaccine technologies, and global best practices. As a result, six vaccines, viz., Pneumococcal, Rotavirus, Influenza, Dengue, Respiratory Syncytial Virus (RSV), and Meningococcal, were shortlisted for detailed evaluation. Furthermore, the Polio vaccines. MMR vaccine, HPV vaccine, and Tetanus Toxoid (TT) vaccine were identified for proposed modifications within the existing immunization schedule.

- *Establishment of Technical Expert Groups*

For each of the selected vaccine candidates, a multidisciplinary Technical Expert Group was established (Annex I). These groups brought together a diverse range of expertise, including epidemiology, paediatrics, public health, immunology, microbiology, clinical medicine, obstetrics and gynecology, and immunization program implementation. Each group was tasked with conducting a comprehensive needs assessment, encompassing, but not limited to, the review of disease burden, vaccine effectiveness and safety profiles, global experiences, cost-effectiveness analyses, and the feasibility of integration into Sri Lanka's healthcare infrastructure. Each group worked in close liaison, drawing upon the available

scientific literature, clinical expertise, national data, and international guidelines to inform their recommendations.

- *Development of vaccine-specific concept notes*

The vaccine-specific concept notes prepared by multiple Technical Expert Groups served as preparatory, evidence-informed technical guidance to support decision-making at the NIS 2025.

Drawing from their analyses, the Technical Expert Groups, each led by a Consultant Epidemiologist at the Epidemiology Unit, compiled evidence-based concept notes for their respective vaccines. These documents were peer-reviewed and synthesized into clear, context-specific presentation materials. Special attention was paid to adapting global evidence to Sri Lanka's unique demographic, epidemiological, and economic settings, thereby facilitating more informed and locally relevant decision-making. Following the development of the concept notes, they were circulated among a broader group of experts, including representatives from academia and clinical practice. These experts brought additional perspectives from epidemiology, public health, microbiology, immunology, paediatrics, and clinical medicine. Their contributions strengthened the credibility of the findings, and added transparency to the evidence compilation process. They were shared with WHO and UNICEF regional offices and headquarters to be reviewed by vaccine focal points. The finalized concept notes (Annex II) served as preparatory, evidence-informed technical guidance to support decision-making at the NIS 2025, guiding discussions and consensus-building around each of the vaccines under consideration.

- *NIS Working Group*

The NIS Working Group was established to oversee all programmatic and logistical aspects related to the organization of the National NIS 2025. This group, led by the Chief Epidemiologist at the Epidemiology Unit, comprised Consultant Epidemiologists and their respective teams, including Senior Registrars and Registrars attached to the Unit. In addition, key development partners such as representatives from the UNICEF Country Office and the WHO Country Office were actively engaged as part of the committee, particularly in identifying and mobilizing funding support and technical inputs.

The Working Group met periodically in the months leading up to the summit to meticulously plan and monitor the preparatory process. Their concerted efforts ensured that critical timelines were adhered to, stakeholder coordination was consistently maintained, and all preparatory activities were strategically aligned with the broader objectives of the summit.

In the days leading up to the summit, the Working Group conducted a thorough dry run of the technical sessions to validate the content and identify potential logistical or operational issues. This proactive step ensured well-organized sessions, prepared moderators and presenters, and a smooth overall flow during the summit.

NIS 2025 - Overview

National Immunization Summit 2025

The NIS 2025 marked a key milestone in Sri Lanka's public health journey as the fourth national summit, building on previous gatherings that guided the NIP, promoted evidence-based decisions, and supported the systematic introduction of new vaccines.

The NIS 2025 provided a platform to review and reassess current immunization priorities, taking into account local disease burden and dvancements in global scientific evidence.

The NIS 2025 was held on 28th March 2025 at the Bandaranaike Memorial International Conference Hall, Colombo 07, Sri Lanka and the summit brought together a diverse group of subject experts, policymakers, and stakeholders at a critical juncture in the evolution of immunization, both in Sri Lanka and globally. It aimed to review and reassess current priorities in light of both local disease burden and global immunization developments.

Objectives of the NIS 2025

The key objectives of the summit were strategically formulated to align national immunization goals with the latest global guidance and country-level realities. These included,

1. Review the current immunization schedule with respect to selected antigens and solicit views for changes where necessary
2. Update stakeholders on current changes and advances in global vaccine preventable disease strategies
3. Explore feasibility for introduction of new antigens to the National Immunization Program and/or share updated development profiles

Stakeholder Engagement and Representation

The success of the NIS 2025 was underpinned by its diverse, inclusive, and multi-sectoral participation (Annex III). The summit witnessed the attendance of a wide array of national and international stakeholders, reflecting the multidisciplinary nature of immunization service planning and implementation.

The stakeholders included, members of the ACCD and other expert committees, representatives from UNICEF, WHO, and Gavi, national and regional health administrators, public health specialists and epidemiologists at both national and subnational levels, specialist clinicians across various medical disciplines, representatives from academic institutions and professional colleges, divisional-level public health officers and frontline implementers of the NIP, and officials from relevant government ministries and departments.

This broad representation ensured a credible, consultative, and transparent platform for technical deliberation and policy dialogue. The diversity of expertise and perspectives contributed significantly to the robustness of recommendations emerging from the summit.

Summit Program and Technical Deliberations

The event commenced with a formal inaugural session, graced by high-ranking dignitaries and development partners. Notable participants in the opening session included the Honorable Minister of Health and Mass Media, the Secretary to the Ministry of Health and Mass Media, the Director General of Health Services, and country representatives from UNICEF and WHO, and Program Manager for Middle-Income Countries of Gavi. Their addresses highlighted the importance of immunization to national health security and reaffirmed commitment to evidence-based policymaking and support for implementation.

The summit's main agenda was structured around two in-depth technical sessions, each focusing on distinct but complementary areas.

The technical sessions focused on,- reviewing and proposing changes and- exploring the feasibility of introducing new vaccines into the NIP.

Technical Session I: Vaccines in the current national immunization schedule - proposed changes
Technical Session II: New vaccines under consideration for introduction to the NIP

Each session was moderated by a global immunization expert and began with a brief technical presentation delivered by a Consultant Epidemiologist from the Epidemiology Unit. These presentations synthesized findings from comprehensive vaccine-specific concept notes developed by dedicated Technical Expert Groups, which were formed in advance of the summit as part of its strategic planning process. The presentations summarized key evidence on disease burden, vaccine performance, safety, cost-effectiveness, and operational considerations relevant to the Sri Lankan context.

Following each technical presentation, a guided and participatory discussion ensued. Key issues were debated with input from a range of stakeholders, leading to a context-specific exploration of the topic. Participants also contributed additional discussion points, many of which provided valuable insight into the broader implications of vaccine introduction or schedule modifications.

Concluding Session

As an important concluding element of the summit, a National Consultant to the WHO Country Office delivered a presentation on the financial sustainability of the NIP, emphasizing the need for long-term planning and the integration of immunization financing into broader national health and fiscal frameworks, especially in the context of transitioning support from global partners.

The summit ended with a summary of proceedings presented by the summit rapporteur, including the key recommendations, areas of consensus, and suggested next steps, to be formally submitted to the ACCD for further consideration and policy endorsement.

NIS 2025 - Inaugural Session

The inaugural session of the NIS 2025 commenced with welcome remarks delivered by Dr. Asela Gunawardena, Director General of Health Services, who extended a warm greeting to all distinguished guests, national and international stakeholders, and participants. He commended Sri Lanka's enduring commitment to immunization as a critical public health intervention and acknowledged the pivotal role played by technical experts, program implementers, partner agencies, and frontline health workers in achieving and sustaining high levels of vaccine coverage. He further highlighted the significance of the summit as a platform for evidence-informed dialogue and consensus-building to shape the future direction of the NIP.

Following the welcome, Dr. Hasitha Tissera, Chief Epidemiologist, delivered a comprehensive presentation outlining the objectives of the NIS 2025, along with an update on the current status of Sri Lanka's NIP. He emphasized the importance of this fourth national-level immunization summit, which follows the landmark summits held in 2001, 2007, and 2015, each of which had significantly contributed to reshaping national immunization policy. Dr. Tissera highlighted Sri Lanka's longstanding commitment to immunization, emphasizing the role of the Epidemiology Unit in sustaining high coverage and guiding evidence-based decision-making. He further outlined the evolution of the EPI since 1978, shaped by strategic responses to disease burden and global recommendations.

The opening remarks were delivered by three development partners collaborating with the NIP. Mr. Christian Skoog, the UNICEF Representative to Sri Lanka, reaffirmed UNICEF's steadfast support to the country's immunization program. He emphasized the longstanding and continued partnership of UNICEF in strengthening Sri Lanka's NIP, particularly during and after the COVID-19 pandemic. He also highlighted UNICEF's contributions to addressing vaccine hesitancy and supporting supplementary immunization activities. Acknowledging Sri Lanka's leadership in regional immunization performance, he expressed confidence in the summit's potential, financially supported by UNICEF, to catalyze progressive policy decisions grounded in collective expertise and shared goals.

Dr. Alaka Singh, WHO Representative to Sri Lanka, commended the country's 50- year commitment to the EPI and its consistent success in maintaining high vaccine coverage across all antigens, even during the COVID-19 pandemic. She acknowledged Sri Lanka's public health leadership in the South-East Asia region and emphasized the need to address emerging challenges, including the recent measles outbreak, immunity gaps, and vaccine hesitancy. Dr. Singh also highlighted the importance of enhanced surveillance, digital innovations, and community engagement, reaffirming WHO's continued support through technical expertise, data-driven policy guidance, and advocacy.

Dr. Masafumi Funato, Program Manager for Middle-Income Countries at Gavi's Country Delivery Department, expressed appreciation for Sri Lanka's strong commitment to immunization and noted that since Gavi's inception, it has supported the introduction of several new vaccines in Sri Lanka before the country transitioned out of Gavi support in 2016. Dr. Funato emphasized Sri Lanka's eligibility for transition support as a middle-income country and discussed Gavi's ongoing contributions to co-financing new vaccine introductions. He encouraged continued engagement with Gavi to support sustainable immunization financing and innovation.

Remarks were then delivered by Dr. Anil Jasinghe, Secretary of the Ministry of Health and Mass Media, who emphasized the Ministry's vision of strengthening preventive healthcare, with immunization recognized as a pivotal initiative. He expressed gratitude for the tireless efforts of the program implementers and highlighted key areas requiring greater focus, including the strengthening of the local evidence base and fostering of multi-stakeholder partnerships as essential steps to further enhance the country's commitment to immunization. Dr. Jasinghe also thanked development partners, UNICEF, WHO, and Gavi, for their steadfast support. He reaffirmed the Ministry's full commitment to translating the summit's outcomes into actionable policy recommendations.

The address by the Honorable Dr. Nalinda Jayatissa, Minister of Health and Mass Media, marked a significant moment in the session. While acknowledging the collective efforts of all stakeholders in sustaining Sri Lanka's exemplary immunization achievements, he reiterated the importance of aligning national efforts with regional and global immunization trends and recommendations. Dr. Jayatissa also appreciated the sustained support with international partners WHO, UNICEF, and Gavi in overcoming financial and logistical challenges. He reaffirmed the Ministry's unwavering commitment to strengthening immunization in the country and highlighted the importance of the summit as a pivotal step towards sustaining and expanding the Government's commitment to universal health coverage through strengthened primary healthcare. He concluded by pledging high-level political commitment and intersectoral coordination to ensure the effective implementation of the summit's recommendations.

Following these inaugural speeches, the session concluded with a ceremonial group photograph, capturing the presence of key dignitaries, development partners, health sector leaders, and all distinguished participants.

NIS 2025 - Technical Session I

Technical Session I – Outline

During this session, vaccines were discussed based on a consolidated body of evidence, including local disease burden, global and regional data on safety and efficacy, updated guidance, and country-specific factors, with a focused review on four vaccines: polio vaccines, Measles-Containing Vaccines (MCV), HPV vaccine, and TT vaccines.

The session was moderated by Dr. Jayantha Liyanage, a Public Health Specialist and former Regional Adviser for Immunization System Strengthening at WHO SEARO, who brings extensive global experience in immunization. The discussion on each vaccine commenced with a 15-minute technical overview presented by a Consultant Epidemiologist from the Epidemiology Unit. These presentations were based on in-depth vaccine-specific concept papers, developed by Technical Expert Groups established as part of the summit's preparatory process.

Each presentation was followed by expert-led, interactive discussions that incorporated stakeholder input and real-time feedback collected through a QR code system, enabling critical analysis and a deeper understanding of the policy and programmatic implications of proposed schedule changes.

Polio Vaccines

Dr. Sashimali Wickramasinghe, Consultant Epidemiologist, delivered a concise presentation on polio vaccines, outlining key milestones in Sri Lanka's polio immunization history, the current vaccine schedule and national coverage levels. Her presentation also highlighted updated global and regional recommendations, proposed schedule modifications, and the supporting scientific and programmatic evidence leading to these proposed changes.

Current Schedule

At present, the current polio vaccine schedule is as follows.

- Oral Polio Vaccine (OPV) at 2, 4, 6, 18 months, and 5 years
- Fractional Inactivated Polio Vaccine (fIPV) at 2 and 4 months

Points for Discussion

The following key points were discussed during the summit session.

- the most appropriate bivalent OPV (bOPV) schedule
- the most appropriate IPV schedule
- introduction of the Hexavalent vaccine in place of Pentavalent vaccine

Summary of the Presentation

In considering potential schedule modifications, two primary options were proposed as follows.

1. Option1 (along with Pentavalent vaccine)

   Continued use of bOPV 3 doses at 2, 4, and 6 months and fIPV 2 doses at 4 and 9 months

2. Option 2

   Transition from Pentavalent vaccine to Hexavalent vaccine (with the whole cell pertussis component) 3 doses at 2, 4, and 6 months

Both options were critically evaluated in light of global evidence on vaccine safety and effectiveness, cost implications, and their alignment with WHO recommendations. In addition, programmatic factors such as operational feasibility, health system capacity, and vaccine availability were discussed to assess the suitability of each option within the local context. A summary comparison of both options is presented in Table 1.

Table 1: Comparison of proposed two options of polio vaccines

Characteristic	Option 1 - bOPV + IPV schedule (with Pentavalent vaccine)	Option 2 - Hexavalent schedule
Schedule	bOPV: 3 doses at 2,4, and 6 months fIPV: two doses at 4 and 9 months	3 doses at 2,4, 6 months
Vaccine availability	No change.	Limited availability of wP-HVV.
Cost	No change. (Final cost per child USD 3.78)	Final cost per child for ap-HVV USD 64.62 and wP-HVV USD 9.09.
Effectiveness	High immunogenicity. No issues related to effectiveness when IPV and MCV are simultaneously administered.	High immunogenicity. But, does not induce strong mucosal immunity.

Safety	Risk of VAPP: **Sri Lanka has reported only one confirmed VAPP case and one probable case for the last 5 years.** Risk of VDPV: **Sri Lanka has not reported any VDPV cases.**	No risk of VAPP, VDPV.
Programmatic feasibility	Feasible. No major changes in the existing schedule are required.	Feasible. No major changes in the existing schedule are required. More convenient for the client and the healthcare workers.
WHO position	Latest SAGE recommendation for bOPV is 3 doses. There is no demonstrated benefit from booster doses of OPV after completion of the recommended primary series of 3 OPV doses and at least 1 IPV dose. Optimum immunogenicity is obtained when fIPV 1 is given at 14 weeks and fIPV 2 is given 4 months after fIPV1. **This fIPV schedule was recommended by the RCCPE and the ITAG for Sri Lanka.**	May be considered for countries with very low risk of poliovirus importation and sustained high routine immunization coverage (DTP3 >90%). **WHO has considered Sri Lanka as having high readiness to transition to an IPV only schedule.**

* aP-HVV: acellular Pertussis-containing Hexavalent Vaccines; ITAG: Immunization Technical Advisory Group; RCCPE: Regional Certification Commission for Polio Eradication; SAGE: Strategic Advisory Group of Experts on Immunization; VAPP: Vaccine-Associated Paralytic Poliomyelitis; VDPV: Vaccine-Derived Polio Virus; wP-HVV: whole-cell Pertussis-containing Hexavalent Vaccines

Key Deliberations on Discussion Points

Considering global evidence on vaccine efficacy, safety profiles, and SAGE recommendations, as well as programmatic feasibility and cost-effectiveness, the following deliberations were made regarding the discussion points.

Based on the above, the most appropriate bOPV schedule was considered as 3 doses administered at 2, 4, and 6 months, while the optimal IPV schedule was considered to be 2 doses of fIPV given at 4 and 9 months.

The introduction of the Hexavalent vaccine to replace the Pentavalent vaccine prompted two main viewpoints during the discussion. One group expressed concerns about the Hexavalent vaccine's potential lack of mucosal immunity. In response, it was highlighted that the associated risks could be mitigated through existing Acute Flaccid Paralysis (AFP) surveillance and strengthening of environmental surveillance, which would enable early detection of poliovirus circulation and allow for swift intervention.

The other key point of discussion focused on the readiness of the health system to adopt the Hexavalent vaccine. It was noted that while the long-term benefits of integrating Hexavalent, such as reduced injection burden and improved compliance, are recognized, the transition should be approached cautiously. Until there is assurance of a stable supply chain and sufficient financial and logistical resources, a phased approach was recommended. Specifically, it was proposed that the current strategy of using bOPV along with two doses of fIPV could be maintained as a feasible and effective interim solution.

Additional Discussion Points

Additionally, the possibility of transitioning to a three-dose IPV schedule without the use of OPV was raised for further consideration. This approach, while offering certain advantages, represents a significant shift from the current bOPV-IPV combination schedule. WHO guidance recommends a cautious and phased transition, starting with high coverage of at least two IPV doses while continuing the use of bOPV, and with Sri Lanka having already achieved over 98% coverage for both fIPV doses, the country is positioned for this transition. The potential benefits of an IPV-only schedule were acknowledged, particularly in terms of improved safety.

Measles Containing Vaccine

Dr. Athula Liyanapathirana, Consultant Epidemiologist, delivered a comprehensive presentation on measles epidemiology and vaccine coverage in the country, with special emphasis on the recent outbreak in 2023-2025. He further elaborated on the importance of closing existing immunity gaps, emphasizing the role of targeted immunization campaigns and strategies. His presentation also incorporated recommendations from the Regional Verification Commission (RVC), supported by global evidence and WHO guidelines, all of which were used to inform the focus questions guiding the session's discussions.

Current Schedule

At present, the MCV schedule includes two doses of MMR vaccine given at 9 months and 3 years.

Points for Discussion

The following key points were discussed during the summit session.

- temporary introduction of an additional 'zero dose' of MCV at 6 months
- the optimal timing for MCV1 administration
- the optimal timing for MCV2 administration

Summary of the Presentation

The introduction of a zero dose of MCV at 6 months was discussed based on several key factors. The early decline of maternal antibodies leaves most infants susceptible to measles by this age, supporting early vaccination in high-risk settings. WHO recommends a supplementary zero dose between 6–9 months during outbreaks or where infant risk is elevated, as MCV is safe and immunogenic in this age group. This dose is intended to supplement the routine two-dose schedule. The estimated cost is approximately USD 1.90 per child, with minimal additional delivery effort and potential savings from reduced vaccine wastage. Given the high return on investment associated with measles vaccination, the zero dose is considered both immunologically and programmatically sound. However, as the outbreak has since subsided, with zero new cases reported since January 2025, ongoing epidemiological monitoring was advised before implementation.

It was presented that the optimal timing for MCV1 must balance reducing primary vaccine failure, which decreases with age, and minimizing the risk of measles infection before vaccination, which increases with age. In 2011, Sri Lanka shifted MCV1 from 9 to 12 months for better seroconversion, but this led to an accumulation of susceptible infants nearing 12 months, contributing to a measles outbreak in 2013, particularly among those aged below 12 months. Delaying MCV1 to 12 months could leave this high-risk group unprotected for a longer period, despite higher seroconversion rates at 12 months. However, high coverage of both MCV1 and MCV2 ensures long-term immunity. Given these concerns, the NIP position was highlighted as to maintain MCV1 at 9 months to protect infants from measles at the highest risk.

The WHO 2017 position recommends administering MCV2 at 15–18 months in countries with ongoing measles transmission, where MCV1 is given at 9 months, which applies to Sri Lanka. However, in countries nearing elimination with MCV1 at 12 months, MCV2 timing should be

based on programmatic factors. Sri Lanka's MCV2 coverage exceeds 99% at 3 years, with minimal dropout risk, and recent outbreak data suggests that missed vaccination contributes to susceptibility as much as primary vaccine failure. While advancing MCV2 to 18 months could provide immunological benefits, it may disrupt critical healthcare touchpoints like growth monitoring and nutritional assessments carried out at 3 years. Given Sri Lanka's high vaccination coverage and integrated healthcare system, it was discussed that shifting MCV2 to 18 months should be carefully evaluated.

Key Deliberations on Discussion Points

As per the evidence presented, it was noted that the measles outbreak has apparently ceased, with zero new cases reported since January 2025 and three incubation periods have been passed since the last case. However, it was emphasized that sensitive and timely surveillance must be maintained, particularly to meet the expected non-measles, non-rubella discard rate, ensuring early detection and response in case of any new emergence.

Given this stable situation, it was suggested that the introduction of a zero dose of the measles vaccine at 6 months could be delayed. It was further highlighted that, although early vaccination is crucial in high-risk settings, the current context with robust surveillance, allows for a more careful evaluation of the benefits and risks of introducing this additional early dose.

It was considered appropriate that MCV1 should continue to be administered at 9 months, as this schedule has been effective in protecting infants during a period of increased susceptibility. In light of the present epidemiological trends, there was consensus that there is no immediate justification for changing this timing.

Finally, it was suggested that the timing of MCV2 warrants further review, particularly the implications of shifting it to 18 months from the current schedule at 3 years. While earlier administration may enhance immunity, concerns were raised about potential disruption to critical child health services delivered at the 3-year contact. Hence, it was advised that any changes be preceded by a careful assessment of healthcare system impacts and long-term coverage outcomes.

Additional Discussion Points

The importance of exploring the root causes of vaccine hesitancy and addressing public concerns was discussed in detail. Ongoing efforts to address hesitancy were shared, emphasizing the need for continued engagement and tailored communication strategies to effectively reach hesitant communities.

Regarding surveillance, it was noted that the current monitoring for fever with maculopapular rash is falling behind the expected level. This raises concerns about confidently declaring the cessation of the outbreak. It highlights the critical need for strong and sensitive surveillance systems to avoid underreporting and to ensure timely detection of any new cases. The Epidemiology Unit's initiatives to strengthen both outpatient and inpatient surveillance in public and private sectors, along with improvements to field level case-based response activities, were presented.

Human Papilloma Virus Vaccine

Dr. Sashimali Wickramasinghe delivered a comprehensive presentation on the HPV vaccination program in Sri Lanka. She covered the global, regional, and national burden of cervical cancer, the cervical cancer elimination initiative, and the WHO's position and recommendations, highlighting their applicability to the local context.

Current Schedule

At present, the HPV vaccine is offered to girls who have completed 10 years of age (Grade 6), following a 2-dose schedule administered 6 months apart.

Points for Discussion

The following key points were discussed during the summit session.

- the single-dose HPV schedule for girls at completion of 10 years
- HPV vaccine for high-risk populations
- gender-neutral vaccination to protect males

Summary of the Presentation

Deliberations on the single-dose HPV schedule noted that during the SEAR-ITAG meeting in August 2024, Sri Lanka was recommended to consider transitioning to a single-dose schedule. It was highlighted that global evidence shows sustained immunogenicity and potentially comparable protection to multi-dose regimens, though effectiveness data remain of low certainty. It was also noted that this shift could reduce vaccine costs (around 20% of the national vaccine budget), simplify logistics, and improve coverage by removing the need for a second school visit. Notably, it was highlighted that 67 countries globally, including several countries in the WHO South-East Asia Region, have already adopted or are in the process of adopting a single-dose HPV vaccination schedule. However, concerns were raised about the need to revert to a two-dose schedule if long-term immunity wanes. Additionally, it was noted that the cervical cancer screening program, primarily based on Pap smears, has not yet met coverage targets, which may hinder elimination efforts.

Regarding high-risk groups, it was noted that immunocompromised individuals, including women living with HIV, are more susceptible to HPV infection and related cancers. WHO recommends at least a two-dose HPV vaccination schedule for these groups, with a three-dose schedule (at 0, 1–2, and 6 months) preferred where feasible. Additionally, it was noted that the main high-risk groups include immunocompromised individuals, people living with HIV/AIDS, and those with a history of sexual abuse.

Regarding gender-neutral vaccination to protect males, it was highlighted that according to WHO's 2022 position paper, if female HPV vaccination coverage exceeds 50%, adding male vaccination is unlikely to be cost-effective compared to a girls-only strategy. Furthermore, it was noted that achieving over 80% coverage in girls significantly reduces the risk of HPV infection among boys. It was further highlighted that cost-effectiveness analyses suggest nationwide gender-neutral vaccination is generally feasible only in high-GDP countries.

Key Deliberations on Discussion Points

As mentioned above, deliberations on key points were informed by multiple sources, including WHO position papers, SEAR-ITAG country-specific recommendations, local vaccination coverage data, and national evidence on complementary cervical cancer prevention strategies, such as screening and curative care services.

During the discussion on the single-dose HPV vaccination schedule, two key viewpoints emerged. One group expressed caution, noting that while current evidence shows sustained immunogenicity for up to 11 years after a single dose, this duration is shorter than that observed for the two-dose schedule. They also pointed out that the available evidence is of variable certainty and raised concerns about Sri Lanka's relatively weak cervical cancer screening programme and limited curative care capacity. As a result, they recommended continuing with the two-dose schedule until stronger evidence becomes available or other pillars of cervical cancer control are strengthened.

In contrast, the other group considered the existing evidence sufficient for implementation and suggested that potential waning immunity could be addressed with a catch-up dose if needed. They highlighted that 67 countries globally (including several countries in the WHO South-East Asia Region) have adopted or are transitioning to a single-dose schedule, indicating growing global confidence. Based on this, it was suggested that Sri Lanka could begin the transition with close monitoring and readiness to adapt if necessary. It was also highlighted that, despite cervical cancer screening not having reached the desired level in Sri Lanka, if evidence generated through research conducted in developed countries finds any long-term immunity gaps with a one-dose schedule, that information could be used to decide whether to provide an additional dose to those who have received a single dose of the HPV vaccine.

Considering the deliberations and discussions, the prevailing opinion among experts was to maintain the two-dose schedule.

With regard to the other main discussion points, it was emphasized that high-risk groups (such as immunocompromised individuals, including women living with HIV and survivors of sexual abuse) should be prioritized within the national public health program, though any consensus were not reached on exact high-risk groups.

Additionally, it was discussed that, under the current epidemiological and programmatic context in Sri Lanka, vaccinating male children would not be a priority and it was concluded that the focus should remain on maintaining and improving high coverage among girls.

Additional Discussion Points

During further discussions, it was pointed out that the majority of high-income countries that have adopted a single-dose HPV schedule also have stronger cervical cancer screening programs in place, with or without gender-neutral vaccination. Hence, the importance of strengthening screening programs to similar levels in the Sri Lankan context was further justified, as it would help mitigate any risks associated with a reduced-dose regimen.

Additionally, it was highlighted that clinical experience suggests the peak incidence of cervical cancer occurs later in life. This raises the question of whether a booster or additional dose might be needed in adulthood to ensure long-term protection, particularly if single-dose immunity wanes over time. However, this point was not discussed in detail, as further research and data are needed to assess its feasibility.

Adult Tetanus-Diphtheria Vaccine

Dr. Harendra Dasanayake, Consultant Epidemiologist, presented on the transition from TT to the aTd vaccine. He summarized the global uptake of the transition from TT to aTd vaccines, highlighting the shift in the global vaccine market and the additional benefit of enhancing immunity to diphtheria that come with the transition. Dr. Dasanayake also shared the current epidemiology of tetanus and diphtheria in Sri Lanka and presented global evidence on the efficacy and safety of the aTd vaccine, emphasizing its broader protective benefits compared to the traditional TT vaccine.

Current Schedule

The current vaccination schedule for tetanus and diphtheria according to the NIP is given in Table 2.

Table 2: Current vaccination schedule for tetanus and diphtheria according to the national immunization schedule of Sri Lanka

Stage of Life	Vaccine
2 months	DPT-HepB-Hib 1st dose
4 months	DPT-HepB-Hib 2nd dose
6 months	DPT-HepB-Hib 3rd dose
18 months	DPT 4th dose
5 years	DT
11 years	aTd
Post exposure following trauma	
With no documented evidence of schedule completed	Two doses of tetanus toxoid at least four weeks apart with third dose at least six months after the second dose and booster doses at least one year apart. Five doses in total for long-term protection
With documented evidence of receiving 06 or more doses of tetanus toxoid	Not needed after trauma
Having a contaminated wound without proof of a tetanus shot in the last 5 years	Need to get one dose
If 10 years after 6 doses	Need to get a booster dose
Within 5 years of last TT dose, if having documentation of receiving three doses of tetanus toxoid	Need no another dose of tetanus after trauma
If have not had a tetanus shot in the last five years following three doses of tetanus toxoid	Need one booster dose of TT (If given 2 doses of TT - long term or lifelong immunity is developed)
Adolescent under 12 years of age having documented evidence of 5 doses of tetanus containing vaccine	Not necessary to administer tetanus vaccine,
if the adolescent is around12 years	Should be vaccinated with booster dose of aTd
Pregnancy	
With no documented evidence of receiving six doses of TT containing vaccine	
1st dose	1st pregnancy after 12 weeks POA
2nd dose	1st pregnancy after 6-8 weeks after first dose
3rd dose	2nd pregnancy after 12 weeks POA
4th dose	3rd pregnancy after 12 weeks POA
5th dose	4th pregnancy after 12 weeks POA

With documented evidence of receiving six doses TT containing vaccine	
If 10 years passed since the final dose of TT	1 booster dose of TT containing vaccine in 1st pregnancy
Tetanus containing vaccine not indicated	
Already received 5 doses of TT containing vaccine during pregnancy	Not indicated for present pregnancy
Received 6 doses according to national immunization schedule and within 10 years since the last dose	Not indicated for present pregnancy
Received 6 doses according to national immunization schedule and within 10 years received a booster dose	Not indicated for present pregnancy

Points for Discussion

The following key discussion points were raised during the summit session.

- transition from TT to aTd vaccine
- target populations

Summary of the Presentation

It was presented that the WHO has recommended transitioning from TT to Td vaccine, as reiterated in the 2017 Tetanus Vaccine Position Paper. This transition was highlighted as crucial to prevent diphtheria resurgence, especially as immunity wanes in adulthood due to inadequate booster doses. It was also noted that WHO and UNICEF now recommend replacing TT with Td from age four onwards, including during pregnancy.

It was noted that transitioning to the Td vaccine provides dual protection against tetanus and diphtheria, especially important for older populations. It was highlighted that while Sri Lanka has eliminated neonatal tetanus, continued maternal vaccination is necessary to sustain this success. It was also emphasized that Sri Lanka, being in a high-risk region, still reports sporadic diphtheria cases despite high DPT3 coverage. It was highlighted that the minimal additional cost of Td is justified by improved efficiency and potential outbreak prevention. It was further noted that the transition does not require programmatic changes as Td fits the current schedule. It was also noted that the discontinuation of TT supply by UNICEF may lead to shortages, while Td supply is assured through multiple WHO-prequalified manufacturers.

Key Deliberations on Discussion Points

It was noted that, considering the benefits outweigh the risks, the global resurgence of diphtheria, and the alignment with international recommendations, discussions were in favor of transitioning from TT to aTd vaccine in the NIP. This shift was viewed as an important step to enhance protection by providing immunity against both tetanus and diphtheria, while also aligning with WHO guidelines and practices already adopted by many countries.

It was discussed that for maternal immunization and post-exposure prophylaxis, TT could be phased out and replaced with aTd to ensure broader protection during pregnancy and in response to injuries. Additionally, it was noted that for adolescents and adults, there is a need to strengthen routine booster vaccination programs to maintain adequate immunity, especially as protection wanes with age.

Additional Discussion Points

One of the additional points discussed was the need to carefully assess public acceptance and potential concerns when introducing new antigens into the existing immunization schedule, particularly when they involve vulnerable populations such as pregnant mothers. It was noted that ensuring community trust and clear communication are essential to avoid misconceptions and resistance, which could hinder vaccine uptake. It was noted that the diphtheria component, like the tetanus component, is a toxoid; an important point for advocacy with healthcare providers and the community.

In addition, in light of the global resurgence of infectious diseases, the importance of strengthening the sensitivity, timeliness, and overall capacity of national surveillance and diagnostic systems for diphtheria was emphasized, to enable early detection and effective response.

NIS 2025 - Technical Session II

Technical Session II – Outline

Technical Session II entailed an in-depth evaluation of new vaccines for potential integration into the NIP. Similar to technical session I, the deliberations included a synthesized body of epidemiological and clinical evidence for each antigen, with a predominant emphasis on quantifying the national disease burden to enable context-specific prioritization. Additionally, global and regional data pertaining to vaccine safety profiles, immunogenicity, and efficacy, alongside the latest global recommendations were systematically reviewed. These scientific inputs were triangulated with country-specific programmatic considerations, including health system capacity and cost-effectiveness analyses, to inform evidence-based decision-making. Six vaccines were selected for detailed review during this session, viz. pneumococcal vaccine, meningococcal vaccine, seasonal influenza vaccines, rotavirus vaccine, Respiratory Syncytial Virus (RSV) vaccine, and dengue vaccines.

The session was moderated by Dr. Ananda Amarasinghe, former Team Coordinator for VPD and Immunization at WHO Representative Office for Papua New Guinea, who brings extensive global expertise in immunization program implementation and policy development. Each vaccine-specific discussion was initiated with a technical briefing delivered by a Consultant Epidemiologist from the Epidemiology Unit. These presentations were grounded in comprehensive, vaccine-specific concept papers developed by Technical Expert Groups convened as part of the summit's preparatory work.

As in the previous session, each presentation was followed by a structured and interactive discussion facilitated by global and regional technical experts, leading to the exchange of diverse perspectives among stakeholders. Given the complexity and critical nature of the information presented, a few presentations were supplemented by focused panel discussions to elicit in-depth expert insights on priority vaccines. Additionally, real-time engagement was enabled through the use of a QR code-based system, which allowed participants to submit questions and comments throughout the session.

Pneumococcal Vaccine

Dr. Chinthana Perera, Consultant Epidemiologist, delivered a detailed presentation based on the concept note prepared for the potential introduction of the pneumococcal vaccine into the NIP. The presentation covered key areas such as disease transmission, global and local disease burden with a focus on morbidity and mortality, circulating pneumococcal serotypes in Sri Lanka, WHO-prequalified vaccines and their characteristics, programmatic feasibility of vaccine introduction, and cost analysis data.

The presentation was followed by a panel discussion featuring three eminent panelists; Dr. Asvini Fernando (Consultant Pediatrician), Prof. Sanath Lamabadusuriya (Emeritus Professor of Pediatrics), and Dr. B.J.C. Perera (Consultant Pediatrician). On behalf of the panelists, Dr. Asvini Fernando delivered a brief presentation as an addendum to Dr. Perera's. She elaborated on the WHO-prequalified vaccines, addressed issues related to serotype coverage, need for close monitoring of possible serotype replacement in the country, and discussed cost factors and other relevant concerns regarding the potential vaccine introduction.

Points for Discussion

The following key discussion points were raised during the summit session.

- introduction of pneumococcal vaccine to the NIP
- sustainability of funding

Key Deliberations on Discussion Points

It was noted that the available and evolving evidence on invasive pneumococcal disease (IPD) in Sri Lanka suggests the need to consider the potential added value of introducing Pneumococcal Conjugate Vaccines (PCVs). Although local data remain limited, they indicate a measurable burden of pneumococcal disease, particularly among children under five years of age.

It was highlighted that both PCV-10 and PCV-13 have demonstrated substantial impact in various settings worldwide. These vaccines have shown effectiveness in reducing the incidence of vaccine-type IPD, as well as pneumonia and nasopharyngeal carriage of the included serotypes. It was pointed out that while efficacy data for PCV-10 (SII) are not well established, its effectiveness Is expected to be comparable to PCV-13 and PCV-10^{GSK}, based on immunogenicity studies.

However, an important consideration affecting the potential impact of PCVs in Sri Lanka is related to serotype coverage. Surveillance data indicate that a proportion of the serotypes responsible for IPD in the country are not included in either PCV-10 or PCV-13. This raises questions about the adequacy of serotype coverage provided by the available vaccines and whether either formulation would offer sufficient protection against the serotypes most prevalent in the Sri Lankan setting. Against this background, it was recommended that the epidemiological landscape of circulating serotypes be carefully considered in the decision-making process.

Another important issue is serotype replacement, which has been observed in several countries following the introduction of PCVs. While the overall burden of IPD decreases

significantly with vaccination, there have been instances where non-vaccine serotypes have emerged and caused disease. Although the magnitude and clinical relevance of serotype replacement vary across settings, this phenomenon highlights the importance of continuous post-introduction surveillance to vigorously and meticulously monitor serotype distribution and vaccine effectiveness over time.

Affordability and sustainability of funding were identified as key considerations in the potential introduction of PCV. The estimated cost of implementing PCV-10 for a single birth cohort in Sri Lanka is approximately 466 million LKR (1.5 million USD), representing a significant financial investment for the national health system. Ensuring sustainable financing mechanisms, including potential co-financing arrangements, domestic budget allocations, and partnerships with global health funding agencies, will be crucial to support long-term program viability and uninterrupted vaccine supply.

In summary, though the introduction of a PCV in Sri Lanka holds strong promise in terms of disease prevention and potential direct and indirect health benefits, several scientific and programmatic factors must be considered by relevant authorities. These include the local serotype distribution, vaccine selection based on serotype coverage, the risk of serotype replacement, financial affordability and sustainability, and the broader public health implications of vaccine introduction. Continued and enhanced surveillance, together with cost-effectiveness analyses focusing the choice of PCVs and target populations, will be essential to guide an evidence-based decision on the integration of PCVs into the NIP. Further, the option of available limited Gavi funding support for PCVs introduction need to be considered carefully.

Additional Discussion Points

The role of adult vaccination was raised as an important consideration, particularly given the observed increase in pneumococcal disease cases in clinical settings, which, although not yet captured in national surveillance data, may reflect a growing burden in the context of Sri Lanka's rapidly ageing population.

Furthermore, the importance of strengthening the surveillance system was repeatedly emphasized, as it is critical for accurately assessing disease burden, tracking serotype trends, monitoring vaccine impact, and informing policy decisions. Additionally, improving disease management practices was highlighted to ensure timely and effective treatment of invasive infections.

Meningococcal Vaccine

Dr. Nimal Gamagedara, Consultant Epidemiologist, delivered a presentation on the meningococcal vaccine, focusing on the global and local disease burden, criteria for vaccination strategies against meningococcal disease, vaccination for high-risk groups, and WHO-prequalified meningococcal vaccines.

Points for Discussion

The following key discussion points were raised during the summit session.

- introduction of meningococcal vaccine to the NIP
- using meningococcal vaccines as a preventive measure of sporadic outbreak management in closed settings
- vaccination of travelers, individuals with special clinical conditions with Men5CV

Key Deliberations on Discussion Points

With regard to the introduction of the meningococcal vaccine to the NIP, based on the currently available limited local evidence on invasive meningococcal disease (IMD) in Sri Lanka, routine inclusion in the NIP is not justified at present. Compounding this issue is the fact that epidemiological data from clinical cases are not routinely linked with laboratory investigation results, making it difficult to develop a comprehensive understanding of the true disease burden. This lack of integration between clinical surveillance and laboratory confirmation limits the reliability and completeness of existing data. Hence, based on this context, the current evidence does not support the need for national-level vaccine introduction. Strengthening the surveillance system was emphasized as a critical next step, particularly through enhanced laboratory capacity, improved case reporting mechanisms, and better linkage of epidemiological and laboratory data, in order to generate accurate and actionable evidence to guide future vaccination policy.

Further, it was noted that travelers departing for countries where IMD is endemic should be vaccinated with Men5CV for broader protection. Until Men5CV becomes available in Sri Lanka, the currently recommended option remains the quadrivalent meningococcal conjugate vaccine, which provides coverage against serogroups A, C, W, and Y.

In addition to that, it was pointed out that the use of meningococcal vaccines routinely as a preventive measure in closed settings is not justified at present, based on the available evidence. However, individuals with specific high-risk clinical conditions, such as asplenia, should be vaccinated with Men5CV. It was suggested that, in the interim, until Men5CV becomes available in the country, these individuals should be vaccinated with the currently available quadrivalent meningococcal conjugate vaccine.

NIS 2025 - Technical Session II

Additional Discussion Points

It was recommended to establish a proper mechanism to ensure the authentication of meningococcal vaccines administered to pilgrims traveling to countries where vaccination is mandatory. It was highlighted that strengthened coordination between health authorities and travel services is essential to ensure compliance and protect public health. Further, it was noted that maintaining a buffer stock of the vaccine is important for use in outbreak response measures, when necessary.

Influenza Vaccine

Dr. Chinthana Perera, Consultant Epidemiologist, delivered a concise presentation covering key areas such as disease transmission, global and national disease burden, high risk groups, global recommendations on vaccination, and the recommendations from the Working Group on Evidence Review for Influenza Vaccination for Sri Lanka - 2018. The presentation also included information on available influenza vaccines, the programmatic feasibility of vaccine introduction, and cost analysis data.

The presentation was followed by a panel discussion featuring three eminent panelists; Prof. Hemantha Senanayake (Emeritus Professor of Obstetrics and Gynecology), Dr. Ananda Wijewickrama (Consultant Physician), and Dr. Jude Jayamaha (Consultant Virologist). Given the critical points to be discussed, Dr. Perera's presentation was supplemented by focused panel discussions to elicit in-depth expert insights on these aspects from the expert panelists.

Points for Discussion

The following key points were considered for the discussion.

- introduction of influenza vaccine to the NIP
- high risk target groups for consideration

Key Deliberations on Discussion Points

Regarding the introduction of the influenza vaccine to the NIP, it was highlighted that several vaccine-related factors must be carefully evaluated in the Sri Lankan context. Given that influenza viruses undergo frequent antigenic drift, vaccine formulations must be updated annually to match the circulating strains. Additionally, it was noted that the immunity conferred by the vaccine typically lasts for about six months to one year, which necessitates yearly vaccination. This requires significant logistical and operational planning to ensure timely procurement, distribution, and administration of the correct vaccine formulation prior to the onset of the influenza season. Such an approach also demands consistent and substantial financial investment in both vaccine acquisition and delivery infrastructure.

Given these challenges, a high-risk group vaccination strategy has been identified as a more beneficial, feasible, and cost-effective approach. Pregnant mothers were noted as a priority group. Though vaccination has been proven safe and effective during pregnancy, it was reiterated that the importance of considering public acceptance when introducing the vaccine to this group should not be overlooked, especially given the lower maternal mortality attributable to influenza in recent years.

Other target groups discussed included older adults, particularly those aged 65 years and above, pilgrims, especially those traveling to crowded settings, and healthcare workers. The evidence presented suggests that these groups have been prioritized for vaccination in other regional settings as well.

Additional Discussion Points

It was highlighted that Sri Lanka has a robust influenza surveillance system in place, including sentinel site surveillance, and that laboratory capacity is continuing to expand.

In addition, it was suggested that military personnel and individuals with chronic lung diseases should be considered high-risk groups. This needs to be further explored with supporting evidence and an assessment of programmatic feasibility.

It was also emphasized that vaccination alone is not sufficient to reduce influenza-related morbidity and mortality and other measures, such as timely clinical management, public awareness, and infection prevention practices, must be reinforced.

Furthermore, it was noted that since both Northern and Southern Hemisphere influenza virus strains have been detected, mismatches between circulating strains and vaccine composition can lead to reduced vaccine efficacy and effectiveness.

In summary, it is recognized that continued monitoring based on country-specific evidence, and periodic reassessment of the need to vaccinate high-risk population groups, particularly pregnant women, is essential and necessary.

Rotavirus Vaccine

Dr. Thushani Dabrera, Consultant Epidemiologist, made a succinct presentation on the rotavirus vaccine. Her presentation covered details of global disease morbidity and mortality, the local disease burden, particularly focusing on infectious diarrheal diseases among children, available rotavirus vaccines, global recommendations on vaccination, and cost analysis evidence.

Points for Discussion

The following key points were considered for the discussion.

- introduction of rotavirus vaccine to the NIP
- surveillance and further evaluation

Key Deliberations on Discussion Points

Based on the available burden studies, the forum concluded that introducing the rotavirus vaccine is not a high priority. However, it was noted that ongoing surveillance and monitoring of the disease burden remain essential to reassess the situation as new data becomes available. This is particularly important given that there are no comprehensive costing data available.

Additionally, it was highlighted that establishing a robust surveillance system to monitor acute gastroenteritis in children under five is important. This system should include laboratory confirmation of rotavirus cases to improve the accuracy of data and guide public health interventions. Furthermore, it was noted that, even in a future scenario where the introduction of the vaccine becomes necessary, baseline intussusception surveillance should be established at sentinel sites to enable close monitoring of any adverse events following vaccination. These measures will help build a more comprehensive understanding of the disease burden and vaccine feasibility, informing future decisions regarding the introduction of the rotavirus vaccine.

Respiratory Syncytial Virus Vaccine

Dr. Nimal Gamagedara, Consultant Epidemiologist, delivered a presentation on the RSV vaccine, focusing on the disease burden both globally and locally. He highlighted the potential role of the vaccine in the prevention and control of RSV-related illness as well as global recommendations on RSV vaccination.

Points for Discussion

The following key points were considered for the discussion.

- introduction of RSV vaccine to the NIP
- surveillance and further evaluation

Key Deliberations on Discussion Points

As per the currently available evidence, the discussions deliberated that there is no indication of a significant RSV-related disease burden in Sri Lanka that would justify the immediate introduction of RSV vaccines into the NIP. However, it was emphasized that this deliberation is based on limited data, and there remains a critical need to strengthen the existing integrated respiratory virus surveillance system. A robust surveillance framework would enable better characterization of RSV seasonality, transmission patterns, and clinical outcomes.

The use of monoclonal antibodies for RSV prevention in high-risk groups, such as preterm infants or those with chronic lung or heart conditions, was also discussed. However, based on the current RSV disease burden in Sri Lanka, the high cost of monoclonal antibody products, and their limited global availability, the use of these interventions in the national context is not justified at this time.

Additional Discussion Points

It was suggested that respiratory virus surveillance efforts be coupled with air quality monitoring data to provide a more comprehensive understanding of contributing environmental factors.

Dengue Vaccines

Dr. Hasitha Tissera, Chief Epidemiologist, deliberated a detailed account on dengue disease burden, highlighting how the disease epidemiology has changed in the local context. He discussed dengue vaccines, especially the three live-attenuated tetravalent dengue vaccines that have been licensed in other countries or are in Phase III clinical trials: CYD-TDV, TAK-003, and TV003, along with their efficacy and safety evidence, together with their potential applications.

Points for Discussion

The following key points were considered for the discussion.

- safety and efficacy of dengue vaccines
- factors to be considered in dengue vaccine introduction in Sri Lanka

Key Deliberations on Discussion Points

It was noted that key challenges for the introduction of the dengue vaccine include the need for accurate seroprevalence data at both national and sub-national levels to effectively guide vaccine deployment, particularly given regional variations in transmission intensity. Additionally, it was noted that robust post-vaccination safety monitoring, including comprehensive surveillance that goes beyond hospitalization data to capture the full spectrum of disease severity and ensure long-term vaccine safety across diverse population groups, is essential.

It was highlighted that key factors for the registration of the dengue vaccine (QDENGA) in Sri Lanka include an expert review by the National Medicines Regulatory Authority (NMRA), which involves a thorough risk-benefit assessment with input on safety and efficacy. It was emphasized that the decision should also be based on an analysis of Sri Lankan data from Phase III clinical trials to evaluate the vaccine's effectiveness and safety in the local population.

Another critical consideration highlighted was whether booster doses are needed for long-term immunity. It was also noted that long-term pharmacovigilance and safety monitoring are essential, including post-marketing surveillance and additional studies to address any identified safety concerns from pre-licensure trials. Furthermore, it was highlighted that the registration dossier should transparently include price details and consider the vaccine's cost-effectiveness in relation to reducing the dengue burden in Sri Lanka.

Additional Discussion Points

It was highlighted that, given the change in severity of subsequent infections, individuals with a proven record of previous dengue infection would benefit from the vaccine. It was noted that this factor should be carefully considered when planning future vaccination programs.

Financial Sustainability of the National Immunization Program

Dr. Sudath Peiris, serving as a National Consultant to the WHO Country Office, delivered a key concluding presentation at the summit. He focused on the financial sustainability of the NIP, highlighting the importance of long-term strategic planning. He highlighted the critical need to embed immunization financing within the broader national health and fiscal policies, particularly in light of the gradual transition away from support provided by global partners.

Dr. Peiris pointed out that, in general, the return on investment (ROI) from immunization is very high. While all new vaccine introductions yield a strong ROI, the magnitude of this return can vary depending on the specific vaccine. He further elaborated that published global evidence

on the ROI of vaccines shows that vaccines such as measles, HPV, and hepatitis B offer a high return on investment due to their substantial public health impact and cost-effectiveness, whereas PCV tends to show a comparatively lower ROI, primarily due to its higher cost relative to the burden of disease averted.

He presented that, in Sri Lanka, despite an increase in GDP and government spending on health, the proportion spent for vaccines has decreased over time. Since the inception of the NIP, a substantial portion of vaccine costs has been covered by immunization partners such as UNICEF, Gavi, and WHO.

He highlighted that the prioritization and timing of new vaccine introductions are often heavily dependent on the availability of public funding. Thus, he recommended that implementing more efficient methods of vaccine procurement could help reduce overall vaccine costs. Additionally, he stressed that close monitoring of vaccine forecasting and efforts to minimize avoidable vaccine wastage could contribute to marginal reductions in the annual cost of vaccines.

Summary

The summit concluded with a summary of the proceedings delivered by Prof. Nuwan Wickramasinghe, Chair Professor of Community Medicine at Rajarata University of Sri Lanka, who served as the rapporteur of the NIS 2025. He presented the key recommendations, areas of consensus, and suggested next steps emerging from two technical sessions.

He began by reiterating the overarching objectives of the summit. He outlined that the compiled evidence on global and local disease burden, vaccine safety and efficacy, updated global recommendations, and country-specific programmatic factors, including, but not limited to, programmatic feasibility and cost-effectiveness, were considered during the deliberations. More importantly, he provided an overview of the key deliberations held for each vaccine, focusing on the key discussion points set out in technical session I, which focused on vaccines in the current national immunization schedule and proposed changes, and technical session II, which focused on new vaccines under consideration for introduction to the NIP.

In closing, Prof. Wickramasinghe briefly outlined the proposed next steps, which include the formal submission of the summit recommendations to the ACCD. This marks a critical step in ensuring that the discussions held at NIS 2025 are translated into actionable policy decisions aimed at strengthening immunization services and improving public health outcomes in Sri Lanka.

NIS 2025 - Technical Session II

Vote of Thanks

Dr. Thilanga Ruwanpathirana, Consultant Epidemiologist, on behalf of the Epidemiology Unit, proposed the vote of thanks. He extended his gratitude to all the delegates.

Dr. Ruwanpathirana extended his gratitude to key figures from the Ministry of Health and Mass Media, including the Honorable Minister, Secretary, Additional Secretary, Director General of Health Services, DDG – PHS I, and other DDGs, for their leadership and support. He also expressed appreciation to Provincial and Regional Directors of Health Services, consultants, deans, academic staff of medical faculties, and representatives from professional colleges for their continued collaboration. Acknowledgement was given to members of the ACCD, technical expert groups, and representatives from SLMA, NMRA, SPC, and PGIM for their valuable technical contributions.

He thanked former Chief Epidemiologists and former Directors of Maternal and Child Health for their past service. Gratitude was conveyed to directors and consultants from the Family Health Bureau, Health Promotion Bureau, and the Medical Research Institute for their efforts in advancing public health. He recognized the work of provincial and regional epidemiologists, MO epidemiology, and Medical Officers of Health, along with medical directors from the tri-forces and police for their continued service. Appreciation was also extended to donor agencies, including country representatives and staff from UNICEF for their financial support, and to the WHO Country Representative, SEARO staff, WHO Sri Lanka team, and representatives from Gavi and UNFPA for their multifaceted contributions.

He further thanked the session moderators, rapporteur, event comperes, event managers, and venue staff for their role in the successful execution of the summit. Lastly, he expressed heartfelt gratitude to all staff of the Epidemiology Unit for their dedication and hard work.

National Immunization Summit Working Group

Name	Designation
Dr. Hasitha Tissera	Chief Epidemiologist
Dr. Thushani Dabrera	Deputy Chief Epidemiologist
Dr. Sashimali Wickramasinghe	Consultant Epidemiologist, Epidemiology Unit
Dr. Athula Liyanapathirana	Consultant Epidemiologist, Epidemiology Unit
Dr. Nimal Gamagedara	Consultant Epidemiologist, Epidemiology Unit
Dr. Thilanga Ruwanpathirana	Consultant Epidemiologist, Epidemiology Unit
Dr. Chinthana Perera	Consultant Epidemiologist, Epidemiology Unit
Dr. Sudath Peiris	External Consultant, WHO
Dr. Ananda Amarasinghe	Former Team Coordinator, VPD and Immunization, WHO Representative Office for Papua New Guinea
Dr. Jayantha Liyanage	Former Regional Advisor, Immunization System Strengthening, WHO- SEARO
Dr. Dhammika Rowel	Health and Nutrition Officer, UNICEF
Dr. Manjula Kariyawasam	Immunization Consultant, UNICEF
Dr. Sameera Hewage	National Professional Officer, Health Advocacy & RCCE, WHO Sri Lanka
Dr. Buddhika Mahesh	Consultant Community Physician, RDHS Colombo
Prof. Nuwan Wickramasinghe	Chair Professor of Community Medicine, RUSL
Dr. Praba Abeykoon	Acting Consultant Community Physician, Epidemiology Unit
Dr. Kumudu Weerakoon	Acting Consultant Community Physician, Epidemiology Unit
Dr. Hemal Chandrasena	Acting Consultant Health Informatics, Epidemiology Unit
Dr. Aruni Hathamuna	Senior Registrar Community Medicine
Dr. Helanka Wijayatilake	Senior Registrar Community Medicine
Dr. Chamila Balasuriya	Medical Officer

Technical Expert Group – Pneumococcal Conjugate Vaccine

Name	Designation
Dr. Chinthana Perera	Consultant Epidemiologist
Prof. S.P. Lamabadusuriya	Emeritus Professor in Paediatrics, University of Colombo
Dr. B.J.C. Perera	Consultant Paediatrician
Dr. LakKumar Fernando	Consultant Paediatrician
Dr. Asvini Fernando	Consultant Paediatrician
Dr. Sanjeewa Kularatna	Associate Professor, Health Services and Systems Research, Duke-NUS Medical School, Singapore

Annex I

Technical Expert Group – Influenza Vaccine

Name	Designation
Dr. Chinthana Perera	Consultant Epidemiologist
Dr. B.J.C. Perera	Consultant Paediatrician
Prof. Hemantha Senanayake	Consultant Obstetrician and Gynaecologist
Prof. Neelika Malavige	Professor in Immunology, University of Sri Jayewardenepura
Dr. Ananda Wijewickrama	Consultant Physician
Dr. Jude Jayamaha	Consultant Virologist, MRI
Prof. Nuwan Wickramasinghe	Chair Professor of Community Medicine, Rajarata University of Sri Lanka

National Certification Committee for Polio Eradication & Measles, Rubella, CRS Elimination

Name	Designation
Prof. Lalitha Mendis	Professor in Microbiology, University of Colombo
Dr. Hasitha Tissera	Chief Epidemiologist
Dr. S.M. Arnold	DDG/PHS I
Dr. Sashimali Wickramasinghe	Consultant Epidemiologist
Dr. Athula Liyanapathirana	Consultant Epidemiologist
Dr. Palitha Abeykoon	Consultant Community Physician
Dr. B.J.C. Perera	Consultant Paediatrician
Dr. Nihal Abeysinghe	Former Chief Epidemiologist
Dr. Tissa Vitharana	Former Consultant Virologist
Dr. Geethani Galagoda	Consultant Virologist
Dr. Janaki Abeynayake	Consultant Virologist
Prof. Pujitha Wickramasinghe	Professor in Paediatrics
Dr. Rasika Gunapala	Consultant Paediatrician
Dr. Pradeep de Silva	Consultant Physician
Prof. Channa Senanayake	Chair, National Containment Task force for Polio Viruses

The abstracts of the 10 vaccine-specific concept notes (prepared by multiple Technical Expert Groups), which served as preparatory, evidence-informed technical guidance for decision-making at the NIS 2025, are provided in this Annex.

Polio Vaccines

Introduction: Poliomyelitis is caused by the poliovirus, an enterovirus with three serotypes. Types 2 and 3 have been eradicated, while type 1 remains endemic in Pakistan and Afghanistan. The Global Polio Eradication Initiative aims to eradicate polio by 2029.

Two vaccines are currently used:

- Oral Polio Vaccine (OPV): The bivalent OPV (bOPV), containing types 1 and 3, is used in routine immunization. It is highly effective but carries the risk of rare but serious adverse events: Vaccine-Associated Paralytic Poliomyelitis (VAPP) and Vaccine-Derived Polioviruses (VDPVs).

- Inactivated Polio Vaccine (IPV): Contains all three types. Its effectiveness depends on age at first dose, number of doses, and dosing intervals. Fractional IPV (fIPV, 0.1 ml intradermally) is safe and immunogenic. When the first dose is given at ≥14 weeks and the second ≥16 weeks later, fIPV is found to be non-inferior to two full IPV doses. Therefore, the recommended schedule is one dose at 14 weeks and another at least 4 months later, aligning with other vaccines at 9 months. This schedule provides the highest immunogenicity and may be carried out using full dose IPV or fIPV.

Strategies to be discussed at the summit:

1. The most appropriate bivalent OPV (bOPV schedule) for Sri Lanka
2. The most appropriate IPV schedule for Sri Lanka
3. Can Sri Lanka introduce the hexavalent vaccine in place of pentavalent vaccine

Current Sri Lanka schedule:

8 weeks of age	OPV 1 + fIPV 1
16 weeks of age	OPV 2 + fIPV 2
24 weeks of age	OPV 3
18 months of age	OPV 4
5 years	OPV 5

WHO recommendations (WHO Position paper, 2022):

Annex II

Vaccine schedule	Recommendation
bOPV plus IPV	**3 doses of bOPV: s**tarting at 6 weeks of age with at least 4 weeks between doses. **2 doses of IPV (full-dose IPV or fIPV):** First dose at 14 weeks of age, with a second dose 4 months later
Sequential IPV–bOPV schedule	Two doses of IPV, with first dose starting at 8 weeks of age, and the second dose after an interval of 4–8 weeks. Following this, at least 2 doses of bOPV should be given, spaced 4–8 weeks apart
IPV only schedule	A primary 3-dose series of IPV beginning at 8 weeks of age, with a minimum 4-week interval between doses. OR A primary 3-dose series of IPV beginning at 6 weeks of age, with a minimum 4-week interval between doses, with a booster dose given 6 months or more after the third dose.

Proposed schedules for Sri Lanka:

Option 1 - bOPV and fIPV schedule

OPV	2months, 4 months, 6 months
fIPV	4 months, 9 months

Option 2 - IPV only combined preparation schedule - Hexavalent vaccine

wP containing Hexavalent vaccine	2 months, 4 months, 6 months

These two options were compared based on characteristics such as schedule, cost of vaccine procurement, programmatic feasibility, vaccine effectiveness, safety, vaccine availability and WHO position.

Deliberations: Both options generate a strong immune response against poliomyelitis. Option 2 is the safer choice, as it eliminates the risk of VAPP, a rare but serious adverse event following immunization (AEFI) associated with OPV and programmatically much easier to administer when compared to option 1. However, the introduction of Option 2 is 2.4 times more costly than the option 1.

Main reference: WHO position paper 2022

https://iris.who.int/bitstream/handle/10665/357167/WER9725-eng-fre.pdf?sequence=1

Measles Containing Vaccine

Measles is a highly contagious viral disease that can lead to severe complications and death. It was a major public health issue in Sri Lanka, affecting most children until the measles vaccine was introduced in 1984 as a single dose of monovalent measles vaccine at the age of 9 months. Vaccination reduced the incidence significantly, with intermittent outbreaks occurring in the years 1999-2000, 2013-2015, and 2023-2025, revealing ongoing challenges in controlling the disease. The 1999–2000 outbreak, affecting mainly unvaccinated adolescents, led to the introduction of a second dose in 2001. The 2013–2015 outbreak was linked to a schedule change in 2011 that delayed the first dose, leaving infants vulnerable due to waning maternal antibodies. In 2019 Sri Lanka was certified as measles eliminated by the WHO.

In the 2023 outbreak, the highest incidence rate was observed among infants under nine months of age, who were awaiting their first dose of Measles Containing Vaccine (MCV) 1. This was likely due to the weaning levels of maternal antibodies, which were almost exclusively vaccine-derived by this time and insufficient to protect them against the disease. This was supported by the observation that the measles incidence in the below 9-month age cohort increased with age, peaking closer to nine months. The high incidence observed among individuals aged 20 to 30 years on the other hand, could be linked to a historical immunity gap in this group, stemming from variations in immunization schedules, catchup campaign strategies and low immunization coverage during their childhood. This immunity gap was confirmed through a community seroprevalence study conducted in 2015, which demonstrated a clear immunity gap among individuals aged 15 to 16 years at the time and are now in the 25 to 26-year age group.

In response to the 2023 measles outbreak, Sri Lanka implemented extensive control measures. Surveillance and case-based response activities were strengthened. In addition, based on the recommendations of the World Health Organization (WHO) and the Advisory Committee on communicable Disease (ACCD), a series of special immunization campaigns were conducted. Although the Supplementary Immunization Activity (SIA) conducted in January 2024 in 9 selected High risk (HR) districts, targeting infants aged 6-9 months achieved high coverage in (95%) the catchup campaign targeting young adults aged 20-30 age group in selected settings with high transmission rate conducted in 12 HR districts, November 2024 achieved a low coverage among the target population. Based on the country report of the national verification committee for 2023, the South-East Asia Regional Verification Commission (SEA-RVC), at its ninth meeting in September 2024, reclassified Sri Lanka as having “re-established measles transmission. The SEA-RVC recommended considering a revision of the immunization schedule shifting MCV2 from 3 years to 18 months of age. Deliberations were also made on the timing of MCV1 and administering a zero dose (MCV 0) at the age of 6 months.

Annex II

Human Papilloma Virus Vaccine

Introduction: HPV vaccination is the first pillar of the Global Strategy for the Elimination of Cervical Cancer, which targets vaccinating 90% of girls by the age of 15 by 2030. Currently six vaccines are available to prevent cervical cancer, five of which are pre-qualified by the World Health Organization (WHO).

Sri Lanka introduced the HPV vaccine in 2017 as part of its school-based immunization program. Under this program adolescent girls receive two doses of the vaccine, at completion of 10 years (Grade 6), with the second dose administered six months after the first. The coverage of the first dose of the HPV vaccine exceeds 80% in all districts.
Strategies to be discussed at the summit:

1. Introduction of a single dose schedule for HPV vaccination
2. Offering the HPV vaccine for high-risk groups (e.g.: immunocompromised individuals, sex workers)
3. Introducing gender-neutral vaccination to protect males.

Current WHO position (WHO position paper 2022):

- The priority purpose of HPV vaccination is prevention of cervical cancer.
- Target groups:
    - For prevention of cervical cancer: primary target group for HPV vaccination is girls aged 9-14 years before they become sexually active. Achieving over 80% coverage in girls also reduces the risk of HPV vaccination for boys.
    - Vaccination of secondary target populations e.g.: females >15 years, boys, older males or MSM is recommended only if feasible and affordable and dose not divert resources from vaccination of primary target population or effective cervical cancer screening programs.
- Vaccination schedule
    - 2-dose schedule: current evidence supports 2-dose schedule in primary target group from 9 years and for older age groups for which HPV vaccines are licensed.
    - Alternative single-dose schedule: as an off-label option, a single-dose schedule can be used in girls and boys 9-20 years. As of 04 February 2025, globally, a total of 67 countries have reported to have adopted a single dose schedule of HPV vaccine.

  - Current evidence shows a single dose has comparable efficacy and duration of protection as multi-dose schedules and can offer programmatic advantages. Can offer substantial benefits that could outweigh potential risk of lower level of protection if efficacy wanes over time, but there is current evidence for this.
- While HPV vaccination is the primary prevention intervention, it does not eliminate the need or screening later in life (since the existing vaccines do not protect against all high-risk HPV types and limited impact on disease in women olde than vaccine-eligible groups).

Recommendations given for Sri Lanka at the 15th SEAR-ITAG meeting in2024: To consider the introduction of a single-dose schedule for HPV vaccination and conducting catch-up vaccination for girls who missed HPV vaccination, in line with the latest SAGE recommendations.

Deliberations:

1. There is accruing evidence for the immunogenicity, efficacy and effectiveness of a single-dose schedule compared to multi-dose schedules. However, there is a need for more high-quality studies and continued follow-up of single-dose cohorts for understanding the relative duration of protection for reduced dose schedules.
2. HPV vaccination should be complemented with high-performance screening methods, such as HPV DNA testing, to achieve cervical cancer elimination goals. Currently Sri Lanka relies primarily on pap smear testing for cervical cancer screening, which has a number of limitations, including the coverage of the target groups.
3. There are substantial programmatic benefits in introducing a single dose, such as cost reductions, simplification of the logistics for HPV vaccine delivery, improving coverage, enabling access for other important target groups, increasing the availability of HPV vaccine doses for countries that have not yet been able to introduce HPV vaccination.

High risk group vaccination: WHO recommends at least a two-dose HPV vaccination schedule, with a three-dose schedule where possible for high-risk groups. The main high-risk groups identified are: immunocompromised women and men, including people living with HIV/ AIDS, and children and adolescents who have faced sexual abuse.

Therefore, provision of the HPV vaccine for these high-risk groups may improve the mortality and morbidity due to HPV related cancers among these groups.

Male child vaccination: According to the latest WHO position paper, if female coverage exceeds 50%, adding male vaccination is unlikely to be cost-effective for cervical cancer prevention. Therefore, the most effective and cost-efficient strategy remains increasing female coverage.

Main reference: (WHO position paper 2022)
https://iris.who.int/bitstream/handle/10665/365350/WER9750-eng-fre.pdf?sequence=1

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Adult Tetanus Diphtheria Vaccine

Introduction and current situation: Vaccination is one of the most cost-effective public health strategies for controlling vaccine-preventable diseases. The World Health Organization (WHO) has recommended replacing the Tetanus Toxoid (TT) vaccine with the Adult Tetanus-Diphtheria (Td) vaccine to ensure continued protection against both tetanus and diphtheria, given recent resurgences of these infections in several regions.

Sri Lanka has successfully controlled these diseases through its Expanded Program of Immunization (EPI), which includes vaccines targeting tetanus, diphtheria, pertussis, hepatitis B, and *Haemophilus influenzae* type B. However, transitioning from TT to Td is necessary to sustain these achievements, particularly to strengthen adult immunity against diphtheria and maintain tetanus protection.

Evidence of disease burden: Tetanus, caused by Clostridium tetani, leads to severe complications, and while neonatal tetanus cases in Sri Lanka remain below the elimination threshold, non-neonatal cases persist. Diphtheria, caused by Corynebacterium diphtheriae, has re-emerged in various regions, with declining adult immunity due to the absence of booster doses. In Sri Lanka, diphtheria remains a controlled but potentially resurgent disease, given the increasing immunity gaps observed in the adult population.

Safety and efficacy of the vaccine: Extensive research confirms the safety and efficacy of Td-containing vaccines. A systematic review by McMillan et al. (2017) analyzing 21 studies found no significant increase in adverse maternal or infant outcomes following antenatal Td vaccination. Similarly, Hall et al. (2020) studied 145,883 pregnancies among U.S. military personnel and found no increased risk of adverse outcomes, even with first-trimester exposure. Tseng et al. (2022) further confirmed that Td vaccination during pregnancy did not increase risks for preterm birth, fetal growth restriction, or neonatal complications, except for minor associations with preeclampsia and intrauterine infection, which aligned with broader epidemiological trends.

Cost effectiveness and cost implications: Cost analyses indicate that replacing TT with Td would result in only a minimal additional cost of $0.01–$0.03 per dose. This is offset by reduced cold chain requirements and the cost savings associated with preventing diphtheria outbreaks. Additionally, with UNICEF discontinuing TT procurement in 2020, TT production is declining, increasing the risk of future shortages. In contrast, the Td vaccine market remains strong, with fifteen global manufacturers ensuring stable supply.

The transition to Td is a strategic, cost-effective measure to enhance protection against tetanus and diphtheria. Given rising diphtheria risks and the declining TT supply, adopting Td ensures sustained immunity, minimal programmatic changes, and long-term public health benefits.

Pneumococcal Conjugate Vaccine

Streptococcus pneumoniae is an encapsulated bacterium. About 100 distinct pneumococcal serotypes have been identified throughout the world, with a small number of these serotypes accounting for most diseases in infants. Serious pneumococcal infections include pneumonia, meningitis, and febrile bacteremia. Pneumococcal resistance to antimicrobials is a serious and rapidly increasing problem worldwide. It is estimated that about one million children die of pneumococcal disease every year.
The Indoor Morbidity and Mortality (IMMR) data, Sri Lanka, indicate that all-cause pneumonia cases increased from 2020 to 2023, while the case fatality rate (CFR) of children aged 0-5 years has declined from 4.9% in 2020 to 1.8% in 2023. According to the IMMR data, the number of reported meningitis cases increased from 3,239 in 2020 to 4,634 in 2023. However, the case fatality rate (CFR) of children aged 0-5 years has declined from 0.33% in 2020 to 0.26% in 2023.

Two polysaccharide-protein conjugate vaccines have been on the market since 2009, the 10-valent (PCV10) and the 13-valent (PCV13) vaccines. Most SEAR countries have already introduced PCV into their national immunization schedules for children. Both PCV10 and PCV13 are safe and effective and have both direct (in vaccinated individuals) and indirect (in unvaccinated individuals living in communities with vaccinated children) effects against pneumococcal disease caused by vaccine serotypes. Several studies done in Sri Lanka have identified pneumococcal serotypes circulating in Sri Lanka, and a considerable number of serotypes are not covered by the PCV10 or PCV-13.

Invasive pneumococcal disease (IPD) cases have been reported in countries that have introduced pneumococcal conjugate vaccines (PCVs), caused by serotypes not included in the vaccine (serotype replacement). This could potentially affect the long-term effectiveness of pneumococcal vaccination programs. The estimated cost of the PCV10 vaccine for a single birth cohort in Sri Lanka, excluding catch-up vaccination, is 466 million LKR. Therefore, a careful assessment of the cost-benefit ratio of introducing the pneumococcal vaccine would be a major deciding factor for its implementation in Sri Lanka.

Meningococcal Vaccine

Neisseria meningitidis, a Gram-negative, oxidase-positive, encapsulated diplococcus, causes Invasive Meningococcal Disease (IMD) of which a severe illness manifesting as meningitis and septicemia. Six serogroups (A, B, C, W-135, Y, and X) are responsible for most of the cases. In 2019, it was estimated that meningitis led to 2.51 million cases and 236,000 deaths globally with N. meningitidis accounting for 17.3% of cases ranging from 8·5% in Australasia to 21·4% in central sub-Saharan Africa while 13.6% of all-age meningitis deaths; the second most common cause for meningitis related deaths worldwide. In children younger

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than 5 years of age, proportions of deaths due to N meningitidis were similar to that in adults. The epidemiology of IMD is dynamic with variations in serogroup distribution, carriage prevalence, across different age groups and geographic regions. Carriage prevalence rises from 4.5% in infants to a peak of 23.7% in 19-year-olds due to their socio behavioral risk factors while it declines to 7.8% in adults of 50 years of age. The WHO's "Defeating Meningitis by 2030; A Global Road Map" initiative emphasizes the importance of having high vaccine coverage, equitable access and tailored immunization strategies in alignment with epidemiological evidence. The Global Road Map targets implementing locally appropriate vaccination strategies in all countries by 2024.

Objective of this review is to explore circumstances in Sri Lanka that will guide authorities to consider meningococcal vaccines in prevention and control of meningococcal disease in the country. We evaluated data available on meningococcal disease burden globally as well as locally while exploring the evolution of global recommendations on meningococcal vaccine through literature searching together with WHO position papers (2011, 2015 update and 2024), systematic reviews, RCTs, UNICEF pricing data and international vaccination guidelines.

Though there are sporadic IMD cases occur in closed settings such as prisons and military camps, no significant IMD burden exists in the general population while mortality and complications associated with IMD were low in the country. In contrast, laboratory confirmation of sporadic bacterial meningitis cases with serogroups was minimal due to limited diagnostic facilities in Sri Lanka.

Based on the available evidence, the introduction of meningococcal vaccines into Sri Lanka's Expanded Program on Immunization (EPI) is not justified. However, vaccination of high-risk groups, that include those traveling to endemic countries, students leaving to overseas universities, and individuals having high-risk clinical conditions, with Men5CV vaccine is justified instead of quadrivalent meningococcal conjugate vaccines being used at present in the county when Men5CV can be made available in the country. Further, routine vaccination in closed settings is also not warranted due to low complication of IMD and such sporadic outbreaks are well controlled with effective preventive and control measure including antibiotic prophylaxis. Strengthening meningitis surveillance including laboratory surveillance through a comprehensive case line-listing system is crucial for early outbreak detection and response. Future directions include understanding local carriage patterns to optimize vaccination strategies and assessing existing and emerging serogroups such as X, which pose potential threats. Tailored vaccination program based on local epidemiology is critical for effective meningococcal disease prevention and control in future.

Influenza Vaccine

Influenza viruses are single-stranded RNA viruses classified into four types A, B, C, and D based on their nucleoprotein antigen. Among them, influenza A and B are the primary public health concerns, causing seasonal influenza, while only influenza A has caused pandemics. In tropical and subtropical areas, transmission occurs year-round, influenced by rainfall and humidity. Seasonal influenza infects up to 1 billion people and 650,000 deaths annually. The global influenza-associated respiratory mortality rate averaged 5.9 per 100,000, ranging from 4.5 in the Eastern Mediterranean to 6.2 in the Americas. In Thailand, influenza infections cost 23-63 million USD each year, with 56% of the cost due to lost productivity from missed workdays.

Influenza circulates year-round in Sri Lanka, with seasonal peaks from May to July and November to January. Sentinel surveillance of human influenza leveraging GISRS is carried out under two main components; outpatient-based Influenza-like illness (ILI) surveillance and hospitalized Severe Acute Respiratory Infections (SARI) surveillance.
From 2020 to 2024, influenza positivity rates of influenza samples (both surveillance and clinical samples) varied, with 8.8% in 2020 and 2.1 % in 2021, followed by an increase to approximately 18% over the last three years. Influenza deaths reported in Sri Lanka range from 91 in the year 2017 to zero reporting in the year 2021 mainly due to the COVID pandemic. In the year 2024, 17 influenza deaths were reported. Most influenza-related deaths in Sri Lanka have been associated with multiple comorbid conditions.

Influenza vaccines include inactivated (IIV), live attenuated, recombinant, and adjuvant formulations for different age groups. Inactivated vaccines, the most common, are egg or cell-based and available as trivalent (TIV) or quadrivalent (QIV) formulations. WHO recommends that all countries incorporate seasonal influenza vaccination into their public health strategy. Due to the yearly changes in viral antigenic configuration and the limited duration of protection provided by the vaccine, influenza vaccination must be administered annually. This requires significant logistical efforts to ensure timely vaccine delivery of the effective vaccine, along with substantial investment in vaccine procurement. National policymakers and health program planners should consider country-specific factors such as high-risk groups, disease burden, program feasibility, financial sustainability, and cost-effectiveness when making evidence-based decisions on introducing influenza vaccines.

Rotavirus Vaccine

Background: Rotavirus is a highly contagious virus causing severe diarrhea, primarily affecting children under five. It leads to significant morbidity and mortality worldwide, particularly in low-income countries. Annually, it causes 125 million diarrhea cases, 25 million outpatient visits, and 2 million hospitalizations. Before vaccines, rotavirus was responsible for 500,000 child deaths yearly.

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Sri Lankan context: Sri Lanka's surveillance focuses on hospitalized diarrheal cases, with no routine data on outpatient rotavirus infections. Hospitalization data from 2022-2024 indicate an estimated 6,548 annual cases of rotavirus diarrhea among children under five. Effective diarrhea management has significantly reduced mortality, but economic burdens remain due to medical costs, lost productivity, and caregiver responsibilities.

Rotavirus vaccine overview: WHO recommends including rotavirus vaccines in national immunization programs, particularly in high-mortality settings. Four WHO-prequalified vaccines, Rotarix, RotaTeq, Rotavac, and ROTASIILare available, with varying doses and costs. Vaccine effectiveness is highest in low-mortality countries (90-95%) and lower in high-mortality regions (44-70%).

Cost-effectiveness and economic impact: A Rotarix-based immunization program in Sri Lanka is estimated to cost $787,600 annually, potentially preventing 5,930 hospitalizations per year. The cost per averted case is $132, with a 74% reduction in hospitalization costs. However, additional costs for surveillance and program management must be considered. Beyond direct medical expenses, families face financial strain from lost wages, transport costs, and psychological stress.

Challenges and recommendations: Supply-chain instability and financial constraints pose challenges for vaccine introduction. A comprehensive burden of disease study is essential to assess feasibility. Surveillance should be expanded to track vaccine impact and safety. Strengthening overall diarrheal disease control including sanitation, ORS, and nutrition would provide broader public health benefits.
Conclusions: While rotavirus contributes significantly to pediatric diarrhea, vaccination alone addresses only 30% of cases. A holistic strategy focusing on prevention, treatment, and healthcare access may yield greater long-term benefits. Further economic and epidemiological assessments will inform evidence-based decision-making on vaccine introduction in Sri Lanka.

Respiratory Syncytial Virus Vaccine

Respiratory Syncytial Virus (RSV) is a major cause of viral respiratory tract infections, particularly affecting young children and the elderly. RSV, an RNA virus of the Orthopneumovirus genus in the Pneumoviridae family, has no significant animal reservoir. It is responsible for 1 in 50 deaths among children aged 0 – 60 months and 1 in 28 deaths among infants aged 28 days to 6 months, with more than 95% of RSV-related deaths occurring in Low-and Middle-Income Countries (LMICs). In addition to children, RSV poses a significant health risk to elderly individuals, especially those with chronic lung disease, heart disease, or immunosuppression, contributing to increased hospitalizations and mortality.

The objective of this review is to assess the RSV disease burden in Sri Lanka and provide evidence-based directions for policymakers to consider RSV immunization products (RSV Monoclonal Antibodies & Vaccines) in prevention and control of RSV disease in the country. We evaluated available research data on RSV disease burden in Sri Lanka and conducted a comprehensive literature search for recommendations, including the 2024 SAGE recommendations, systematic reviews, randomized controlled trials (RCTs), UNICEF and CDC pricing data, and international vaccination guidelines to generate evidence.

The FDA has approved three RSV vaccines though none of them have yet received WHO prequalification. Recently few developed countries have introduced RSV immunization products for both pregnant mothers and elderly individuals into their National Immunization Programs. Immunization strategies include maternal vaccination, monoclonal antibodies (MCA) for neonates, and vaccines for the elderly. Maternal RSV vaccination, recommended from 28 weeks of gestation, provides passive immunity to newborns, reducing the risk of severe RSV infections in infants. A single dose of long-acting MCA (Nirsevimab) is recommended for neonates before their first RSV season, particularly for those whose mothers were not vaccinated, at least, two weeks before delivery or those with underlying some clinical conditions. In Sri Lanka, a significant variation in estimated prevalence of incidence of RSV disease was observed due to methodological differences among these studies. For example, in a study conducted during 2022 – 2024 using 131 respiratory samples of suspected ARTI which were tested for respiratory viruses, no RSV virus was detected while a hospital-based study on RSV disease found RSV prevalence as 4.25% to 4.7% among children under five compared to incidence rates ranged from 28.3 to 31.3 per 100,000 person-years, with case fatality rates of 1.08% to 3.63% in another hospital-based study on RSV disease.

Based on the available evidence on RSV disease burden and risk factor prevalence of RSV disease, high cost of RSV immunization products (RSV MCA and RSV Vaccines) concluded that introduction of RSV MCA or RSV vaccines into National Immunization Program is not justified while the integrated respiratory virus laboratory surveillance to be strengthened so as to monitor RSV disease trend of RSV disease in Sri Lanka to decide appropriate measures of RSV disease prevention and control in years to come.

Dengue Vaccine

Introduction and current situation: Dengue is a mosquito-borne viral disease primarily transmitted by Aedes aegypti and Aedes albopictus mosquitoes, with four distinct serotypes (DENV-1 to 4). It poses a significant global public health challenge, affecting an estimated 3.8 billion people in Asia, Africa, and the Americas. Despite improvements in clinical management, dengue remains a major public health concern due to the lack of specific antiviral treatment and the limited sustainability of vector control strategies.

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Evidence of disease burden: Incidence of dengue has increased dramatically, with over 13 million cases and 8,000 deaths reported globally in 2024, highlighting the urgent need for effective control measures. In Sri Lanka, dengue is endemic, with seasonal peaks during monsoon rains. In 2024, the country reported 49,873 cases and 24 deaths, with a case fatality rate (CFR) of 0.05%.

Severe disease (DHF/DSS), often linked to secondary infections via antibody-dependent enhancement (ADE), can lead to plasma leakage, severe bleeding, and organ impairment. Early diagnosis and supportive management, particularly timely fluid resuscitation, are critical. However, conventional vector control faces challenges, including insecticide resistance and difficulty in eliminating breeding sites.

Safety and efficacy of the vaccine: Vaccination offers a critical addition to dengue prevention strategies. An ideal vaccine should provide protection against all serotypes, be effective across age groups and serostatus, and reduce the risk of hospitalization and severe disease. Recent advancements in vaccine development, including next-generation vaccines such as TAK-003, demonstrate improved safety and efficacy profiles, particularly among seropositive individuals. Overall, TAK-003 vaccine efficacy against virologically confirmed dengue due to any serotype was 64% (95% CI: 58–69) in seropositive subjects, and 54% (95% CI: 42–63) in seronegative subjects.

WHO position (2024)

The World Health Organization advocates integrated approaches combining surveillance, vector control, and immunization to reduce dengue mortality and morbidity by 50% by 2030. According to the 2024 WHO position paper on dengue vaccines, TAK-003 is recommended for immunization programs in areas of high dengue transmission, particularly targeting children aged 6–16 years, ideally starting vaccination 1–2 years before the peak incidence. A subnational introduction may be considered where transmission intensity varies. Use in low to moderate transmission areas is not broadly recommended pending further evaluation, especially concerning efficacy and safety in seronegative individuals, particularly for DENV-3 and DENV-4 in seronegative individuals.

National introduction of a Dengue vaccine in Sri Lanka (Risk-benefit and cost-effectiveness perspective): A comprehensive risk-benefit assessment by the National Medicines Regulatory Authority (NMRA) is crucial for registration. An independent review of safety and efficacy data from the local Phase III clinical trial conducted in Sri Lanka will be important. The potential need for a booster dose to maintain long-term immunity and economic considerations, including cost-effectiveness concerning dengue burden reduction, should be factored into the decision-making process. Furthermore, robust post-marketing pharmacovigilance should be mandated as a prerequisite for registration, with post-licensure

studies addressing any safety concerns identified during the pre-licensure phase. These measures are essential to ensure that vaccine implementation is evidence-based, safe, and well-suited to the Sri Lankan context. Therefore, national-level introduction of a dengue vaccine requires careful consideration of multiple factors in the future, including cost-effectiveness, budgetary impact, cold chain logistics, and public acceptance.

Financial Sustainability of Sri Lanka's National Immunization Program: An Analysis in relation to GDP and Government Health Expenditure Trends

The National Immunization Program (NIP) of Sri Lanka has achieved substantial public health success, maintaining high immunization coverage rates since its inception. Financial sustainability is critical to preserving these gains, particularly as external funding sources diminish. This examines the trends in Gross Domestic Product (GDP) and government health expenditures from 1997 to 2023, with specific reference to vaccine procurement financing.

Following the launch of the Expanded Program on Immunization (EPI) in 1978, Sri Lanka relied heavily on external support from UNICEF and later GAVI. Full domestic financing was achieved by 1995, with supplementary Gavi support. Gavi fully supported vaccine procurement during the 2023–2025 economic crisis. The National Immunization Policy, endorsed in 2014, emphasizes the provision of safe, efficacious, and cost-effective vaccines, with the aim of achieving sustainability and equity.

Analysis reveals that while both GDP and total government health expenditures have steadily increased over the review period, the relative proportion of these funds allocated to vaccine procurement has declined. The percentage of GDP spent on vaccine procurement peaked during the early 2000s but demonstrated a consistent downward trend thereafter. Similarly, vaccine expenditure as a proportion of total health spending has decreased since 2004 demonstrating adequate fiscal space for allocating more movement funds for vaccines and immunization.

Economic evaluations utilizing the Cost-of-Illness (COI) and Value-of-a-Statistical-Life (VSL) approaches highlight the significant return on investment (ROI) in immunization, estimated at approximately 20 to 50 times the initial costs. These findings underscore the high economic and social value of sustained immunization investment.

In conclusion, to ensure the long-term financial sustainability of the NIP, Sri Lanka must prioritize robust domestic resource mobilization, implement cost-saving procurement strategies such as multi-year and pooled procurement, and enhance vaccine forecasting to minimize wastage. Given the limited outlook for future external funding under Gavi's strategic frameworks, strategic fiscal planning for immunization will be essential.

Annex III

List of Participants

Inauguration Session		
Ministry of Health	Hon. Dr. Nalinda Jayatissa	Minister of Health and Mass Media
	Dr. Anil Jasinghe	Secretary Health and Mass Media
	Dr. Kumara Wickremasinghe	Additional Secretary (MS)
	Dr. Asela Gunawardane	DGHS
	Dr. S.M. Arnold	DDG - PHS I
	Dr. S. Sridharan	DDG - Planning
	Dr. P. W. C. L. Panapitiya	DDG - MS I
	Dr. Ranjith Batuwanthudawa	Director - HPB
	Dr. Dedunu Dias	Director - MSD
	Dr. Vindya Kumarapeli	Director - NSACP
	Dr. Nirupa Pallewatta	Director - Anti Leprosy Campaign
	Dr. N.M.N.D. Dissanayake	Director - Public Health Veterinary Services
	Dr. S. Puvanendiran	Representing, Department of Animal Production and Health
	Dr. R.A.D.P.K. Wijesekara	Representing, Department of Animal Production and Health
Provincial Representatives	Dr. Dammika Jayalath	Provincial Director of Health Services- Western Province
	Dr. Disala Welgama	Registrar in Community Medicine - PDHS Office Sabaragamuwa
Regional Representatives	Mrs. K.M.C.D. Karunarathna	RSPHNO - RDHS Gampaha
	Mr. R. Suresh Kumara	SPHI D - RDHS Gampaha
	Mr. Chaminda Sanjeewa	SPHI - MOH Battaramulla
	Mrs. Anoma Pathirana	SPHM - MOH Battaramulla
University Representatives	Prof. R. Surenthirakumaran	Dean, University of Jaffna
	Prof. Shamini Prathapan	Representing, University of Sri Jayewardenepura
	Dr. Janaka Pushpakumara	Dean, Rajarata University of Sri Lanka
Donor Agencies Representatives	Dr. Alaka Singh	Representative, WHO
	Mr. Christian Skoog	Representative, UNICEF
Forces Representatives	Maj (Dr.) Gayathri Marasinghe	MO, Directorate of Army Preventive Medicine and Mental Health Services
	Group Captain (Dr.) T.V.S.S. Alwis	Commanding Officer, SLAF Guwanpura
	Dr. Dinesh Ariyadewa	Deputy Director, Naval Medical Services
Technical Sessions		
Family Health Bureau	Dr. Chandima Sirithunga	Director - FHB
	Dr. Sanjeewa Godakandage	Consultant Community Physician
	Dr. Gayani Gunawardhane	Consultant Community Physician
	Dr. Nadeeja Herath	Consultant Community Physician
Former Chief Epidemiologists	Dr. Nihal Abeysinghe	Former Chief Epidemiologist
	Dr. W.S. Jayakuru	Former Chief Epidemiologist

Former Directors of MCH	Dr. Chithramalee De Silva	Former Director of MCH
UN and Partner Agencies	Dr. Abner Daniel	Health and Nutrition Manager, UNICEF Sri Lanka
	Ms. Meredith Dyson	Senior Health Specialist, UNICEF ROSA
	Dr. Dhammica Rowel	Health and Nutrition Officer, UNICEF
	Dr. Manjula Kariyawasam	Immunization Consultant, UNICEF
	Miss Lakna Paramanna	Communication Officer, Communication, Advocacy and Partnership, UNICEF
	Dr. Vinod Kumar Bura	Coordinator, Immunization and Vaccine Development, WHO SEARO
	Dr. Sameera Hewage	National Professional Officer, Health Advocacy & RCCE, WHO Sri Lanka
	Dr. Reuban Samuel	Acting Public Health Administrator, WHO Sri Lanka
	Dr. Masafumi Funato	Program Manager, Middle Income Countries, Gavi
	Dr. Dayanath Ranatunga	Assistant Representative, UNFPA
ACCD/ NITAG (excluding Ex-officio members)	Prof. Narada Warnasuriya	Emeritus Professor in Paediatrics
	Dr. Ranjith Perera	Chairperson Communicable Disease Control Committee, SLMA
	Prof. Rohini Fernandopulle	Senior Professor in Pharmacology
	Dr. Palitha Abeykoon	Consultant in Public Health
	Dr. Sanath Hettige	President, College of General Practitioners
	Dr. Kosala Karunaratne	Consultant Paediatrician
	Prof. S. P. Lamabadusuriya	Emeritus Professor in Paediatrics
	Prof. Sujeewa Amarasena	Senior Professor in Paediatrics, University of Ruhuna
RCCPE & ITAG	Dr. Sunethra Gunasena	Consultant Virologist/Member- RCCPE & ITAG
NCCPE/ MRCE	Dr. Geethani Galagoda	Consultant Virologist
	Dr. Rasika Gunapala	Consultant Paediatrician
	Prof. Pujitha Wickramasinghe	Professor in Paediatrics
	Dr. P. Kumarasinghe de Silva	Consultant Physician
	Dr. B.J.C. Perera	Consultant Paediatrician
AEFI Group	Dr. Padma Gunaratne	Consultant Neurologist
	Dr. Dhammika Vidanagamage	Consultant Microbiologist
	Dr. Duminda Samarasinghe	Consultant Paediatric Cardiologist
	Prof. Asela Mendis	Consultant JMO
SLMA	Dr. Omala Wimalarathne	Consultant Vaccinologist
	Prof. Jennifer Perera	Consultant Microbiologist
MRI	Dr. Janaki Abeynayaka	Consultant Virologist
	Dr. Dhanushka Dasanayake	Consultant Immunologist
	Dr. Jude Jayamaha	Consultant Virologist
	Dr. Rajiva De Silva	Consultant Immunologist
	Dr. Kanthi Nanayakkara	Consultant Vaccinologist
	Dr. Rohitha Muthugala	Consultant Vaccinologist

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Department of Community Medicine/ Public Health	Dr. P.A.D. Coonghe	Head and Senior Lecturer, University of Jaffna
	Prof. Janith Warnasekara	Professor in Public Health, Rajarata University of Sri Lanka
	Prof. Upul Senarath	Chair Professor of Community Medicine, University of Colombo
	Dr. Maheeka Seneviwickrama	Professor in Community Medicine, University of Sri Jayewardenepura
	Dr. Ishanka Thalagala	Senior Lecturer, University of Moratuwa
	Dr. Thilini Pannala	Senior Lecturer, University of Kelaniya
	Dr. V.P.C. Rajakaruna	Senior Lecturer, University of Ruhuna
Department of Paediatrics	Prof. D. Saraji Wijesekara	Consultant Paediatric Neurologist, University of Sri Jayewardenepura
Department of Pharmacology	Dr. Chanaka Aberathne	Consultant Nephrologist, Senior Lecture, University of Kelaniya
Department of Microbiology	Dr. K.D.D.S. Wijeweera	Lecturer Microbiology- University of Ruhuna
	Dr. Chathuri Gunasekara	Senior Lecturer and specialist in Microbiology, University of Colombo
	Prof. Veranja Liyanapathirana	Professor in Microbiology, University of Peradeniya
Professional Colleges	Dr. Kapila Jayaratne	President, College of Community Physicians of Sri Lanka
	Dr. Suntharalingam Rishikesavan	President, Sri Lanka College of Pulmonologists
	Dr. Sujatha Pathirage	President, Sri Lanka College of Microbiologists
RDHS	Dr. Indrani Malwenna	RDHS Gampaha
Provincial Epidemiologists	Dr. Dimuth Peiris	Provincial Epidemiologist - Southern
	Dr. Subha Perera	Provincial Epidemiologist - North Western
	Dr. Nirenjala Perera	Provincial Epidemiologist - Western
	Dr. Prabhath Ranasinghe	Provincial Epidemiologist - Central
	Dr. A. Lathaharan	Provincial Epidemiologist - Eastern
Regional Epidemiologists	Dr. Suranga Fernando	Regional Epidemiologist - Kandy
	Dr. Amila Chandrasiri	Regional Epidemiologist - Galle
	Dr. Niluka Gunathilaka	Regional Epidemiologist - Kurunegala
	Dr. Deshani Herath	Regional Epidemiologist - Kalutara
	Dr. Chintha Jayasinghe	Regional Epidemiologist - Polonnaruwa
	Dr. Thirumagal Sivashankar	Regional Epidemiologist - Kilinochchi
	Dr. S Sivaganesh	Regional Epidemiologist - Jaffna
	Dr. Upuli Perera	Regional Epidemiologist - Gampaha
	Dr. Roshan Rambukwella	Regional Epidemiologist - Nuwara Eliya
	Dr. Dilini Rupananda	Regional Epidemiologist - Kegalle
	Dr. Buddhika Mahesh	Regional Epidemiologist - Colombo
CMC	Dr. Chintha Jayampathi	Deputy Chief MOH - CMC
MO- Epidemiology	Dr. Kishantha Massachchi	MO Epidemiology - Kandy
MOH Team	Dr. Indika Ellawala	MOH Baththaramulla
NRMA	Dr. Ananda Wijewickrama	Chairman - NMRA
SPC	Dr. Manuj C. Weerasinghe	Chairman - SPC

Expert Panels	Dr. LakKumar Fernando	Consultant Paediatrician
	Prof. Hemantha Senanayake	Consultant Obstetrician and Gynaecologist
	Dr. Lilani Karunanayake	Consultant Microbiologist
	Prof. Neelika Malavige	Professor in Immunology, University of Sri Jayewardenepura
	Prof. Asvini Fernando	Consultant Paediatrician
	Dr. N.S.Hettiarachchi	Consultant Paediatrician
	Dr. Jayantha Weeraman	Consultant Paediatrician
	Dr. Kanishka Karunaratne	Consultant Obstetrician and Gynaecologist
	Dr. Sanjeewa Kularatna	Associate Professor, Health Services and Systems Research, Duke-NUS Medical School, Singapore
	Dr. Mahika Karavita	Consultant Microbiologist- NIID
	Dr. D.A.M. Dassanayake	Registrar in Medical Administration
	Dr. K.M.H. Perera	Registrar in Medical Administration
	Dr. DMAK Dissanayake	Registrar in Medical Administration
	Dr. Savithri Kellapatha	SMO-OPD- LRH

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Epidemiology Unit	Dr. Hasitha Tissera	Chief Epidemiologist
	Dr. Thushani Dabrera	Deputy Chief Epidemiologist
	Dr. Hathshya Munasingha	Consultant Epidemiologist
	Dr. Thilanga Ruwanpathirana	Consultant Epidemiologist
	Dr. Athula Liyanapathirana	Consultant Epidemiologist
	Dr. Sashimali Wickramasinghe	Consultant Epidemiologist
	Dr. Chinthana Perera	Consultant Epidemiologist
	Dr. Nimal Gamagedara	Consultant Epidemiologist
	Dr. Harendra Dassanayake	Consultant Epidemiologist
	Dr. Sudath Peiris	WHO Consultant
	Dr. Pramil Liyanage	Consultant Health Informatics
	Dr. Prabha Abeykoon	Acting Consultant Community Physician
	Dr. Kumudu Weerakoon	Acting Consultant Community Physician
	Dr. Jinadari Amarasena	Acting Consultant Community Physician
	Dr. Hemal Chandrasena	Acting Consultant Health Informatics
	Dr. Aruni Hathamuna	Senior Registrar in Community Medicine
	Dr. Anoma Marasinghe	Senior Registrar in Community Medicine
	Dr. Helanka Wijayatilake	Senior Registrar in Community Medicine
	Dr. Indumini Gunatilake	Senior Registrar in Community Medicine
	Dr. Gobica Piriyananth	Registrar- Health Informatics
	Dr. Madhava Dharmadasa	Registrar in Medical Administration
	Dr. Sheron Perera	MO Health Informatics
	Dr. Mojitha Fernando	MO Health Informatics
	Dr. Alinda Perera	Medical Officer
	Dr. Sankesha Kariyawasam	Medical Officer
	Dr. Nirmani Dissanayake	Medical Officer
	Dr. Nadeeka Sandanayake	Medical Officer
	Dr. Marthani Balasubramaniam	Medical Officer
	Dr. Chamila Balasuriya	Medical Officer
	Dr. Chamila Abeywickrema	Medical Officer
	Dr. Thushanthi Wijesinghe	Medical Officer
	Dr. Charuhashini Sivapirashanth	Medical Officer
Comperes	Dr. Dakshila Galappatti	Registrar in Community Medicine
	Dr. Dhivya Nathaniel	Registrar in Community Medicine
Moderators	Dr. Jayantha Liyanage	Former Regional Advisor- Immunization System Strengthening, WHO- SEARO
	Dr. Ananda Amarasinghe	Former Team Coordinator- VPD and Immunization- WHO Representative Office for Papua New Guinea
Rapporteur	Prof. Nuwan Wickramasinghe	Chair Professor of Community Medicine, Rajarata University of Sri Lanka

Former Chief Epidemiologists

Dr. P. Arumaynayagam	1959-1967
Dr. N.P.M Mendis	1967-1976
Dr. P.U. de la Motte	1976-1980
Dr. A.V.K.V de Silva	1980-1986
Dr. R.L. de Sylva	1986-1991
Dr. (Mrs) W.S. Jayakuru	1991-2000
Dr. T.A. Kulatilake	2000-2003
Dr. M.R.N. Abeysinghe	2003-2008
Dr. Paba Palihawadana	2008-2016
Dr. Sudath Samaraweera	2019-2021
Dr. Samitha Ginige	2021-2024

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+94 112 695 112 / +94 112 681 548

Epidemiology Unit, Ministry of Health
231, De saram Place, colombo 10

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