



# Participatory decision-making through the Advisory Committee on Communicable Diseases: The Sri Lankan experience

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## ABSTRACT

The paper describes how the Advisory Committee on Communicable Diseases (ACCD) in Sri Lanka addresses new challenges by ensuring participatory, collective and transparent decision-making through a broad representation of stakeholders. The Committee, which is more than 40 years old, differs from many other national immunization advisory committees, since it has a broad mandate to deal with all communicable diseases, including those for which there are no vaccines, and addresses such areas as disease surveillance and health system improvements, in addition to vaccination-related issues. The Committee has 38 members. Unlike in some countries, ACCD recommendations are legally binding for all public sector health providers. The paper provides several examples of recent recommendations and factors that influenced the Committee's decision-making, and concludes with ways the Committee can be improved.

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## 1. Introduction

Sri Lanka's Expanded Programme on Immunization (EPI), introduced in 1977 [1], achieved Universal Childhood Immunization status (coverage of more than 80%) for all EPI vaccines within 12 years. Today, the program – now called the National Programme of Immunization (NPI) – has achieved an immunization coverage rate of over 95% for all infant immunizations, resulting in an extremely low incidence of EPI-targeted diseases [2,3]. The country has also been a pioneer in the Asian region in introducing several new vaccines into its national immunization program, including Japanese encephalitis, rubella (alone or with measles), tetanus–diphtheria for older children, hepatitis B and *Haemophilus influenzae* type b (Hib). Due to the success of the program in reducing the morbidity and mortality of vaccine-preventable diseases, the Sri Lankan government has identified and earmarked the NPI as an essential area for investment for national development [4].

After ensuring high universal vaccine coverage, the focus of the program has now shifted towards improving the quality of immunization services, strengthening the vaccine cold chain, improving

*Abbreviations:* AEFI, adverse effects following immunizations; ACCD, Advisory Committee on Communicable Diseases; EPI, Expanded Programme on Immunization; GAVI, Global Alliance for Vaccine and Immunization; Hib, *Haemophilus influenzae* type b; JMOs, Judicial Medical Officers; MR, measles–rubella; MOH, Ministry of Health; NIDs, National Immunization Days; NPI, National Programme of Immunization; SNIDs, Sub-National Immunization Days; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

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the accessibility of hard-to-reach populations to vaccines, strengthening surveillance of adverse effects following immunizations (AEFI) as well as surveillance of vaccine-preventable diseases [5].

The public also has been increasingly concerned about the quality and safety of vaccines provided through the NPI. These concerns are likely the result of the low incidence of vaccine-preventable diseases in the country and the public's access to often unfounded, negative media coverage of AEFI. The nation's highly literate population (with a literacy rate of >90%) has a tendency to follow, in particular, stories in the media about serious, life-threatening vaccine-related adverse events. These developments have threatened the acceptability and credibility of the NPI.

Consequently, transparency and the collective responsibility of evidence-based decision-making that involves broad representation of key stakeholders are necessary for the continued success of the NPI. In this paper, we describe the Advisory Committee on Communicable Diseases (ACCD) which makes recommendations concerning all major changes in the NPI, including the introduction of new vaccines, and which has representation from a broad spectrum of stakeholders. The role of the ACCD in decision-making has been a key evolutionary step in the development of the country's well-regarded immunization program.

## 2. Description of the ACCD's mandate, structure and procedures

### 2.1. The overall role and mandate of the ACCD

The Advisory Committee on Communicable Diseases, established in the mid-1960s, is responsible for reviewing the status of

communicable diseases – both vaccine-preventable and those for which there are no vaccines – on a regular basis and for making all legally binding policy decisions related to their control and prevention in the country [6]. All policy decisions related to the NPI in the prevention and control of vaccine-preventable diseases come under the purview of the ACCD. Although the mandate of the ACCD has been described in several documents, the Committee does not have formal terms of reference either written in a public document or in documents given to its members.

## 2.2. Structure and composition of the Committee

The Quarantine and Prevention of Diseases Ordinance of 1897 [7], is the legal basis for the ACCD, though the act does not specifically mention the establishment of such a committee. The ACCD consists of a Chairperson, a Secretary and 36 other members. The Director General (DG) of Health Services is always the Chairperson of the Committee and the Chief Epidemiologist – who heads the Epidemiology Unit, under which the NPI is managed – serves, by designation, as the ACCD Secretary. The Secretary convenes the ACCD, prepares the agenda for the meetings, and is responsible for updating members on progress in the national implementation of the Committee's previous recommendations.

The other members of the ACCD consist of academics and experts in a range of disciplines related to communicable diseases, including epidemiology; pharmacology; pharmacovigilance; vaccinology; immunology; and specific infectious diseases of importance to Sri Lanka, such as malaria, dengue, leprosy, filariasis, HIV/AIDS, and tuberculosis. In addition, there are members with expertise in health education, community medicine, maternal and child health, family health, general practice, paediatrics, microbiology, quarantine services, national drug regulation, medical logistics, and health administration. However, there are as yet no members with expertise in economics on the Committee. All experts should be either board-certified consultants in their respective fields, with a Ph.D. or MD degree or high-level health administrators in designated ministerial positions (e.g., the Deputy Director General of Health Services) to qualify for membership.

The public sector is represented on the ACCD by members from relevant agencies and departments of the Ministry of Health (MOH), as well as from public universities. Members of relevant independent professional organizations, which consist of both public and private sector professionals, such as the colleges of paediatricians, microbiologists and community medicine, represent the interests of their organization on the Committee.

In addition, two Committee seats are always allotted to representatives of the World Health Organization (WHO) and UNICEF, as key international partners in immunization. While the roles and responsibilities of these members are the same as for other members, they are also entrusted with the task of coordinating external financial and technical support through their agencies, when requested to do so by the ACCD.

Membership slots on the Committee are allocated to both designated posts and to selected agencies and organizations. In the absence of formal terms of reference, the Chairperson determines which expertise will be represented on the Committee, in consultation with other ACCD members. He then officially invites officials in certain Ministry of Health posts designated as ACCD members to join the Committee. These ministry officials remain on the Committee for as long as they remain in their jobs, after which the successor in their post replaces them on the Committee. The Chairperson also invites academic institutions, local organizations, professional associations and WHO and UNICEF (United Nations Children's Fund) to nominate suitable candidates for the Committee. These groups, which are free to nominate new rep-

resentatives to the Committee from time to time, use different methods for selecting their nominees, ranging from voting, to forming a committee to nominate a person on behalf of the organization, to selecting the candidate with the most expertise, to choosing the most senior staff person, since membership on the ACCD is considered prestigious.

Unlike in some industrialized countries, there are no representatives on the ACCD from health sector trade unions, the pharmaceutical industry, or consumer groups. The Committee also does not have *ex-officio* (non-voting) members. However, the ACCD allows any external observer, including those from the above sectors, to participate in meetings upon request, subject to approval by the Chairperson. These observers cannot participate in decision-making. In addition, the Committee is allowed to invite any relevant specialist as an external observer to give a briefing, make recommendations or participate in discussions on an issue of concern to the ACCD. Any individual, in his or her official capacity or as a citizen, may forward comments, grievances, or suggestions in writing to the ACCD to discuss during meetings.

## 2.3. Conflicts of interest

Given the substantial financial implications that recommendations of national advisory committees on immunization practices may have for the public and private sectors, as well as for vaccine manufacturers, candidates who are nominated for membership on immunization advisory committees in industrialized countries undergo careful screening for potential conflicts of interest before their names are submitted for final consideration. To ensure the integrity of the Committee in these countries, all nominees are reviewed by a steering committee [8]. This practice does not yet exist, however, in Sri Lanka. Considering the relative scarcity of experts and the financial constraints in the country, it is possible that some Committee members may also serve on boards of vaccine production companies, provide consulting or advisory services to them, or accept honoraria or travel reimbursement from a vaccine manufacturer to attend seminars or symposia.

## 2.4. Procedures of meetings

The ACCD has regularly scheduled quarterly meetings, as well as emergency meetings to address urgent or priority issues. The agenda of the quarterly meetings includes a discussion of issues remaining from the previous meeting, a situation update on immunization and priority communicable diseases in the country, and a review of the implementation and effectiveness of current prevention and control strategies, including recently enacted recommendations. The agenda also includes new issues related to communicable diseases and immunization. Time is allocated to discuss any other matter, as well as correspondence from outside agencies or individuals. The sessions may include technical presentations by relevant experts, event-based surveillance reports from various sources, research study findings, field supervision reports, AEFI investigations, or disease outbreak reports. In contrast, the agenda of emergency sessions is limited to a discussion of specific issues.

The minutes of both types of sessions are circulated to all ACCD members at least two weeks before the next meeting. However, unlike in many industrialized countries, the meeting minutes are not accessible to the general public in either print form or online, nor are they officially available to anyone other than ACCD members. The minutes are provided to observers for the sessions that they attend.

## 2.5. Areas that the ACCD addresses

Unlike advisory committees on immunization practice in many countries, the mandate of the ACCD goes beyond vaccines, to include providing guidance on all types of communicable diseases and interventions for their control (Fig. 1). In addition to addressing vaccine-preventable diseases, the Committee deals with priority infectious diseases such as dengue, leptospirosis and malaria. For example, the ACCD approved the decision to integrate leprosy services provided by a centralized, vertical program into the general health services, once the prevalence of the disease was reduced to elimination level. And during a leptospirosis outbreak in 2008, the ACCD approved chemoprophylaxis with doxycycline for selected high-risk groups. In addition, the Committee has approved new guidelines for treatment of malaria and is currently assessing the feasibility of using bio-larvicides to control dengue.

In the rest of this paper, we focus on the areas that the ACCD addresses in regards to vaccines and immunization.

### 2.5.1. Disease surveillance

Staff of the Epidemiology Unit of the MOH use Sri Lanka's well-functioning passive disease surveillance system as well as special

surveillance systems for specific diseases [9] to assess the situation regarding vaccine-preventable diseases and to recommend action. With the evolving communicable disease profile in the country, the need sometimes arises to add new diseases to the disease surveillance system to facilitate decision-making. The ACCD must approve any additions to the list of notifiable diseases before official notification of the amended list is sent out in a bulletin. Mumps, meningitis and varicella are recent examples of diseases that have been added to the disease surveillance system, with approval from the ACCD, in order to inform future decisions about new vaccines against these diseases.

### 2.5.2. New vaccine introduction

The ACCD approves the introduction of any new vaccine into the NPI, after being presented with evidence related to disease burden, the vaccine's efficacy, cost-effectiveness and other relevant data. In the past few years, the ACCD has examined such evidence to recommend the introduction of the live Japanese encephalitis vaccine, SA 14-14, as a low cost, safe and effective alternative to the inactivated mouse-brain derived JE vaccine that was being used in the national program, as well as the introduction of the DPT-hepatitis B-Hib vaccine, which took place with Global Alliance for Vaccine and Immunization (GAVI) support.

- (a)
- **Strategies to control communicable diseases:**
    - Review of epidemiological data on priority communicable diseases
    - Evaluation of control and preventive strategies, including immunization
    - Introduction of new technologies, equipment and pharmaceuticals for control of communicable diseases
    - Planning and implementation of Information Education Communication (IEC) campaigns
    - Revisions of health-related laws and regulations
    - Approval of mobilizing funds from external agencies for disease control activities, including immunization
    - Revising content of and approving manuals, guidelines and handbooks on communicable disease control
    - Suggestions for introducing new and revising existing medical records, including immunization forms
    - Defining guidelines on prophylaxis (e.g., leptospirosis), post-exposure prophylaxis (e.g., human rabies), treatment schedules (e.g., TB, leprosy, HIV/AIDS) and mass prophylactic treatment (e.g., filariasis)
  - **Surveillance system improvements and expansion:**
    - Adding new diseases to the surveillance system/list of notifiable diseases
    - Improving laboratory diagnostic services for communicable diseases
  - **Approval of new vaccine introduction**
    - Introduce a vaccine universally, for targeted-populations or geographic areas only or in a phased-in manner
    - Not to introduce the vaccine

Fig. 1. Areas and types of decisions that the ACCD deals with.

- (b)
- **Improvements in specific aspects of immunization** (examples):
    - Cooperating with the private sector to improve its delivery of EPI and AEFI reporting
    - Training and delivery of emergency kits to manage anaphylactic reactions to vaccines
    - Recommendations to enhance cold chain logistics
  - **Changes in immunization strategies:**
    - Adding supplemental immunization activities (campaigns) for priority vaccines
    - Changes to the vaccination schedule
    - Immunization strategies for special, vulnerable groups (e.g., internally displaced populations, tsunami victims)
  - **Addressing immunization-related safety issues and concerns:**
    - Ordering investigations for severe AEFI
    - Decisions regarding suspension and reintroduction of vaccine use pending investigations
    - Mandating the use of a standardized autopsy protocol to investigate suspected immunization-related deaths
    - Providing advice to the national regulatory authority on appropriate tests to be conducted for toxicity and sterility of vaccines suspected of having safety problems

**Fig. 1.** (Continued).

### 2.5.3. Immunization strategies

Reviewing existing immunization strategies is another function of the ACCD. For example, following a large measles outbreak that occurred from October 1999 to November 2000 in Sri Lanka, the ACCD approved the recommendation of the Epidemiology Unit to initiate a country-wide measles catch-up campaign and to add a second measles dose to the immunization schedule in the form of measles–rubella (MR) vaccine at the age of three years. Similarly, the decision to conduct National Immunization Days (NIDs) and Sub-National Immunization Days (SNIDs) for polio eradication was supported by the ACCD. Following the mass displacement of people in the recently concluded civil war, the ACCD took timely measures to approve immunization guidelines for the internally displaced population. Immunization guidelines were also developed for victims of the Asian tsunami that occurred in 2004.

### 2.5.4. Addressing immunization-related safety concerns

The ACCD foresees impending threats to the NPI and suggests measures to overcome them. Following the death in 2009 due to anaphylaxis of a child who had just received rubella vaccine, the Committee recommended an island-wide training on the detection and early management of anaphylaxis for Medical and Nursing Officers who provide vaccination services in outreach clinics, with the support of anaesthesiologists. The Committee also decided to have emergency kits for the management of anaphylaxis delivered to all immunization clinics in the country.

On certain occasions, the ACCD recommends new legal requirements. One example was the recent recommendation to make the performance of post-mortems for vaccine-related deaths compulsory in order to determine the definitive cause of death.

In addition, the Committee has recommended that the Epidemiology Unit, in collaboration with the Directorate of Private Sector Health Development of the MOH, start working closely with private sector institutions to improve immunization services, cold chain maintenance and AEFI reporting in the private sector.

On occasion, the ACCD has made recommendations to withhold vaccines temporarily or permanently from the NPI for safety reasons, as well as recommendations to reintroduce them following investigations. In 2008, the Committee recommended that the NPI suspend the introduction of the DPT-hepatitis B-Hib vaccine, following several cases of hypotonic hypo responsive episodes (HHE), which resulted in five deaths [10]. Rubella vaccine was also placed on hold for a brief period, following a series of suspected cases of hypersensitivity among vaccine recipients and one death. Recommendations to reintroduce both the DPT-hepatitis B-Hib and rubella vaccines after independent investigations were also made by the ACCD [11]. The reassurance resulting from the Committee's recommendations to the panicked public, the media and resistant trade unions has helped restore the public's confidence in these vaccines, as well as the credibility of the NPI.

To deal with such cases, which have started to negatively impact the NPI, the ACCD approved the establishment of an Expert Committee on AEFI. This sub-committee has become a critical arm of the ACCD in determining the role of vaccines in reported cases of severe AEFI and in making recommendations to minimize adverse events. The sub-committee analyzes reported cases of severe adverse events and deaths possibly linked to vaccination, initiates further detailed investigations, reviews these investigation reports as well as independent investigations, and issues appropriate recommendations.

As an example, during the recent spate of deaths among recipients of DPT-hepatitis B-Hib vaccine, an emergency session of the ACCD was convened to determine how to address the continued occurrence of deaths and cases of severe AEFI. The ACCD assigned the Expert Committee on AEFI the task of conducting an assessment of all deaths and cases of severe AEFI that were temporally associated with the DPT-hepatitis B-Hib vaccine and that had been primarily investigated by NPI managers. For exceptionally complex cases, members from the AEFI Expert Committee conducted field investigations to determine causality. The Expert Committee first recommended that the current batch of vaccine be replaced with a new batch, in case the adverse events were due to the particular batch being used. These recommendations were carried out, but as more surveillance data came in showing the continued occurrence of adverse events among children who had received vaccines from the second batch, the Expert Committee recommended to the ACCD that the vaccine be withdrawn from the program until a final determination could be made about the role of the vaccine in these adverse events. The ACCD approved these recommendations—a decision that was not easy to make as opinions among Committee members were divided. Finally, based on majority opinion, the ACCD approved the recommendation to revert back to the old schedule of giving DPT and hepatitis B as separate vaccines, without the Hib vaccine, for the time being.

In special circumstances like the DPT-hepatitis B-Hib vaccine issue, the ACCD requests external technical assistance to inform recommendations. WHO, for instance, was invited to carry out an independent assessment of causality in the DPT-hepatitis B-Hib and rubella vaccine incidents. The WHO assessment provided an unbiased, second opinion for the Committee to consider. The Committee discussed the findings from both the Expert Committee on AEFI and the WHO assessments – both of which found no conclusive evidence that the DPT-hepatitis B-Hib vaccine caused the deaths – before recommending that the NPI reintroduce the vaccine. Though the decision was not unanimous, the discussions that took place between the Expert Committee on AEFI and WHO further strengthened the capacity of the ACCD to arrive at practical, evidence-based conclusions regarding the future course of action for this vaccine. A similar process was used to respond to the rubella incident, which helped the ACCD to counter the widely held belief among the public and health worker trade unions that it was not anaphylaxis but the inferior quality of the vaccine that caused the death of the child.

#### 2.5.5. Health system improvements

The ACCD can also recommend health system improvements that will help ensure the success of immunization and other disease control measures. As demonstrated during the DPT-hepatitis B-Hib incident, one drawback in investigating deaths among vaccine recipients in Sri Lanka was the absence of a definitive cause of death, even for deaths in which post mortems had been performed. This was attributed to the fact that Judicial Medical Officers (JMOs), forensic experts who perform autopsies and determine cause of death in homicide cases, conducted these post mortems, but had not been trained to look for pathological causes. The ACCD was able to rectify this by mandating that consultant JMOs use a standardized autopsy protocol when conducting post mortem examinations of all deaths suspected to be immunization-related.

### 3. The process of making recommendations related to the introduction of new vaccines

#### 3.1. Data requirements

A summary of the data required and questions to be answered before the ACCD makes a recommendation about a new vaccine is shown in Fig. 2.

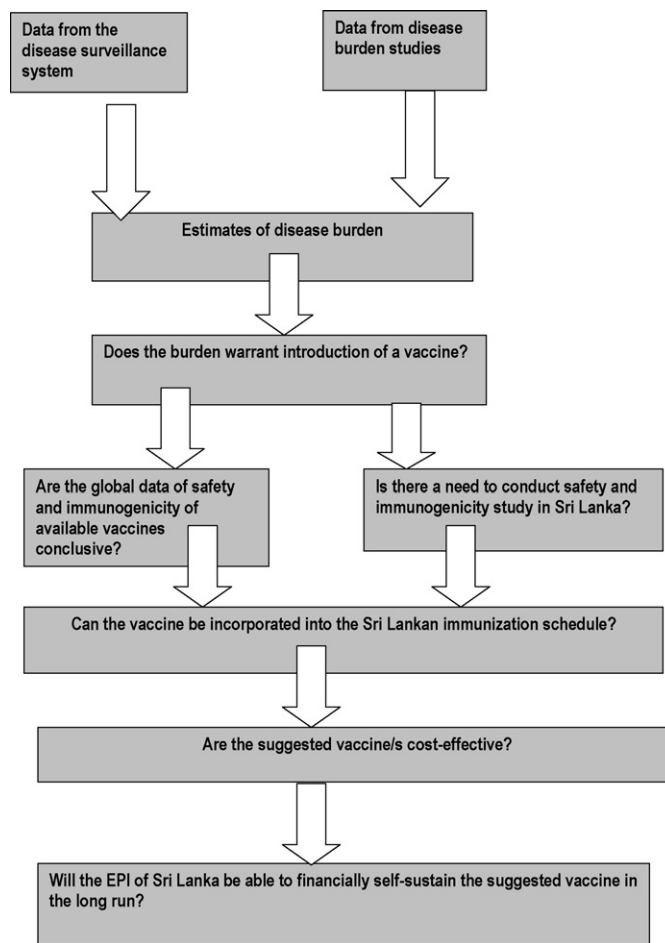


Fig. 2. Required data and considerations of the ACCD in making decisions about the introduction of a new vaccine.

To formulate policy recommendations regarding the introduction of new vaccines, the ACCD requests a set of data from the Epidemiology Unit. The Unit then appoints a working group, consisting of experts from Ministry of Health agencies, major hospitals, universities and the private sector, to help gather and analyze relevant data concerning the disease and vaccine in question. The Epidemiology Unit may also request technical or financial support from international partners for the collection or analysis of data, in the form of, for instance, an expert, such as a health economist, financing to conduct a local clinical trial, or laboratory training for surveillance studies.

The compilation of data on the burden of the disease in question in Sri Lanka is a necessity before the ACCD can approve the introduction of any new vaccine. For certain diseases, the existing disease surveillance system provides sufficient data, while for many new vaccine-preventable diseases for which local epidemiological information and surveillance mechanisms are inadequate, the ACCD recommends that methodologically sound disease burden studies be conducted in the local population. The study of invasive Hib disease conducted in Colombo district with financial assistance from the Hib Initiative provided critical support to the ACCD in its decision to recommend the introduction of Hib vaccine into the NPI in 2008. The Committee also commissioned the Epidemiology Unit to conduct local disease burden studies of human papillomavirus (HPV) (with financial support from UNFPA), invasive pneumococcal disease (with support from GAVI's PneumoADIP), and rotavirus (with support from the International Vaccine Institute (IVI)), to inform decisions about the introduction of these vaccines in the future.

Data on appropriate vaccines, their immunogenicity, efficacy and safety profiles are also required by the ACCD before recommending the introduction of a new vaccine. As a government policy, the ACCD will approve only WHO pre-qualified vaccines for use in the NPI. As such, they demand methodologically sound, credible vaccine efficacy and safety data from other countries, and it is the duty of the epidemiologists as managers of the NPI to provide the Committee with this information. In addition, in recent years, the ACCD has required that safety and immunogenicity studies for some new vaccines be conducted in the Sri Lankan population before a recommendation for their introduction can be made. Before the Committee would make a decision to replace the inactivated mouse-brain JE vaccine with the live, low cost SA 14-14-2 vaccine from China, it recommended that a study to assess the safety and immunogenicity of the vaccine be carried out among Sri Lankan children. While the ACCD realizes that conducting local studies delays the introduction of a new vaccine and incurs additional costs, it felt compelled to recommend this study because of scepticism in the medical community about existing data on the safety and immunogenicity of the live JE vaccine. The Committee recommended the switch to the live vaccine in 2009 based on the positive results of the local study.

Since the NPI is mainly a self-funded program with many competing priorities, its managers have started to look at results of economic analyses of new vaccines before making decisions about their introduction, with the support of external economists (e.g., from universities). A cost-effectiveness study was conducted before introducing the live JE vaccine, and a similar study is underway for the pneumococcal conjugate vaccine, while another has been planned for rotavirus vaccine. In addition, NPI staffs assess the financial sustainability of introducing any proposed new vaccine, examining options for financing available through the Finance Ministry and donor agencies. In seeking possible funding sources, they also calculate potential cost savings from reducing vaccine wastage through implementation of an open vial policy, by switching to lower cost vaccines (e.g., from the mouse-brain derived to the live JE vaccine), or other cost saving measures. As an MOH policy, the ACCD will not recommend that a vaccine be introduced into the NPI if the country cannot sustain its financing, even if co-financing (through GAVI) or full donor support are available for a limited period of time. Therefore, the situation never arises in Sri Lanka in which the ACCD makes a recommendation that the Ministry of Finance determines is not financially feasible.

### 3.2. *The annual Immunization Stakeholders' Forum*

Since different professionals may hold different views regarding whether and how a new vaccine should be introduced, and since their opinions can be critical to the success of the vaccine's introduction, the next step, after data are gathered and analyzed by a working group, is to discuss the introduction of the vaccine at an annual Immunization Stakeholders' Forum. The purpose of the Forum is to seek a wider, national consensus on the decision to introduce the new vaccine and to identify potential areas of concern and obstacles to its introduction. The Forum is attended by administrators and technical experts from the Ministry of Health and academia, as well as representatives from professional medical organizations, the national drug regulatory authority and international agencies, such as WHO and UNICEF.

The Forum consists of several sessions on global advances in vaccines, and for any new vaccine under consideration, there are presentations on a needs assessment for the vaccine, economic considerations, and proposed vaccination strategies. The presentations are followed by panel discussions, working group sessions and group presentations. The Forum concludes with a plenary discussion, during which a consensus is reached on the introduction of the

vaccine into the NPI. On occasion, Forum participants recommend that a new working group be formed to gather additional evidence and analysis about particular concerns and issues raised during the meeting. If the Forum recommends the introduction of the vaccine, NPI managers then develop the strategies to introduce the new vaccine into the program. Once these recommendations are made by the Immunization Stakeholders' Forum, they are submitted to the ACCD for approval.

### 3.3. *Deliberations of the ACCD*

All of the steps involved in considering the introduction of a new vaccine, including the collection and analysis of data and the holding of the annual Forum, simplify the decision-making process for the ACCD. However, even at this stage, the Committee may appoint a new working group to further clarify important issues regarding, for instance, the epidemiology of the disease, the type of vaccine, or its safety profile. The sessions of the ACCD are always interesting, with heated arguments and counter arguments made by clinicians and academics on the one hand, and epidemiologists and health administrators on the other. Following these discussions, which can last several hours, the analysis and presentations of the working groups, and a discussion of their recommendations, the ACCD reaches a consensus on its position regarding introduction of the new vaccine, as opposed to taking a vote, as in some countries [12]. The Committee may recommend that the vaccine be introduced universally (throughout the country), be targeted for high-risk populations only, or that the introduction be phased in. The Committee may also recommend that the vaccine not be introduced at this time.

### 3.4. *Implementation of ACCD recommendations*

Once the Committee reaches a consensus on a recommendation, these recommendations become legally binding for the Ministry of Health. The Deputy Director General (Public Health), on behalf of the DG of Health Services, oversees the implementation of these recommendations. The MOH then prepares guidelines, based on these recommendations, which are disseminated to relevant ministry officials and health workers in the form of a government circular. Once the recommendations are published in the circular, all health officials – at both the national and provincial levels – are obligated to implement them. The Regional Directors of Health Services are responsible for the technical implementation of the guidelines at the local level. ACCD recommendations that require changes in the law must be approved by the cabinet before being implemented. Papers are prepared and submitted to the Cabinet of Ministers through the Minister of Health for approval. Legal officers of the MOH liaise with the Attorney General's office to plan their implementation.

The ACCD also follows the progress in implementing its recommendations and any issues that have arisen in subsequent meetings.

## 4. **Factors influencing decisions about vaccines and the immunization program**

Immunization is consistent with the national policy in Sri Lanka of universal free health care for all [5,13] and has been identified as a priority area for investment [4]. These social and fiscal government policies are positive factors influencing decisions about vaccinations and the immunization program. At the same time, political and societal pressure is mounting on government health officials concerning immunization-related matters, given that policy makers, trade unions and the public consider the NPI a precious asset and the pride of the nation that should be protected and

preserved at any cost [14]. As a result, while the policies of successive governments have been instrumental in making the national immunization program a success [13,15], the active and critical role played by opposition political parties and health worker trade unions have influenced the decision-making process and have helped improve the quality of the program.

For example, following the death from anaphylactic shock of a school girl who had just been vaccinated against rubella in 2009, health worker trade unions demanded that the date of manufacture, along with the expiry date, be printed on all vaccine vials used by the public sector in Sri Lanka, even though WHO labelling guidelines do not require this. The ACCD subsequently made a policy recommendation that all future vaccines used in the NPI must carry the date of manufacture and the expiry date on the vial itself. In addition, after two separate incidents of death following rubella vaccination, opposition parties raised questions about the transparency of vaccine procurement, and representatives of the ACCD were summoned before a parliamentary select committee to answer their queries. The influence of political parties has therefore made the decision-making process for immunization more transparent and accountable in Sri Lanka.

In addition, in recent years, intensive media interest and coverage (both print and electronic) have dramatically influenced the decision-making process related to immunization and have led to changes in the implementation of the immunization program. Following the death from anaphylaxis mentioned above, the media brought into focus the lack of anaphylaxis management kits at health clinics and the absence of a Medical Officer or Nurse authorized to administer drugs to manage anaphylaxis. This media attention and the resulting national dialogue led the ACCD to recommend that all guidelines related to immunization of children at clinics be revised, to stipulate which personnel must be present during vaccination sessions and to require that all health clinics carry anaphylaxis management kits. The ACCD also mandated new stricter and more transparent procedures for the procurement of vaccines.

The availability of technical support for evidence-based decision-making and funding from non-traditional sources, such as the GAVI Alliance, GAVI's accelerated vaccine development and introduction programs (e.g., the Hib Initiative, the Rotavirus Vaccine Program, PneumoADIP), UNFPA and others, have also played a vital and praiseworthy role in influencing the national immunization program [16].

The ever-expanding role of the nation's primary health care staff in improving the national AEFI surveillance system has also led to an increased focus among immunization program managers on immunization safety and evidence-based decision-making related to vaccination safety issues. Finally, one cannot underestimate the important role of literate, vigilant parents in the success of the immunization program by having their children immunized on time and accepting the newly introduced vaccines.

## 5. Remaining issues, challenges and potential solutions

Growing public concerns about vaccines in Sri Lanka have increased the need to rely on evidence and to be transparent at every step, from gathering data to monitoring vaccine side effects at the local level. Participatory decision-making in the ACCD and in the Immunization Stakeholders' Forums has been used to make informed decisions about which new vaccines to introduce and to maintain the credibility of the NPI. However, there are still some areas that need further improvement in the long term.

One area is the lack of formal written terms of reference for the ACCD, as exist in many countries with vaccine advisory committees [12]. It is appropriate and timely that written terms of reference

for the ACCD be prepared and made public. In addition, though transparency is enhanced by having representation of a range of stakeholders, the public has not shown much interest in following the decision-making process and has not demanded access to its proceedings. However, the media has played a major role in questioning the validity of decision-making when the safety of a vaccine has been in question. This has led program managers to sensitize the media prior to any changes in the EPI schedule or the introduction of a new vaccine. Making proceedings of ACCD meetings accessible to the public, including the media, is therefore worth considering for the future to ensure transparency and to pre-empt misinformation or the spread of rumours.

Similarly, since trade unions in the health sector have significant influence in health-related matters due to their bargaining power, mechanisms are also needed to ensure that they are properly informed of the decision-making process related to the NPI. These measures can include organizing meetings with trade union representatives to discuss a new ACCD decision and reporting back to the ACCD on their concerns. Representatives of trade unions should also be made more aware of the fact that they can participate as external observers in ACCD meetings upon request.

While ACCD membership now includes a wide range of experts and stakeholders, health economists should be included on the Committee to ensure that financial and economic aspects of immunization are considered systematically. At present, many economic studies are conducted because of the personal interest of a handful of epidemiologists, with support from international health economists. The lack of health economists in Sri Lanka is a key obstacle to their inclusion on the ACCD; however, this situation should improve over time if postgraduate courses on Community Medicine add a health economics module to its curriculum and if post-doctoral community medicine trainees are encouraged to study health economics during their mandatory training overseas.

It is widely recognized that having ACCD members declare conflicts of interest is critical to ensure transparency in the eyes of the general public [17], especially given the mounting criticism of doctors having financial interests in pharmaceutical companies, including those that produce vaccines [18]. Since the ACCD has, at present no rules regarding conflict of interest, it is advisable that conflict of interest guidelines be developed and implemented in the future.

## 6. Conclusion

In conclusion, as in many developed countries, Sri Lanka has witnessed in recent years a growing reluctance among some people to accept vaccines, a similar scepticism among some in the medical profession – due to rare adverse events and a low incidence or even disappearance of EPI-targeted diseases [19] – and aggressive, negative media campaigns that question the credibility of its national immunization program. Despite the limitations mentioned above, the ACCD has risen to these challenges by broadening its representation to include a range of stakeholders, and by being more transparent in its decision-making. This process will further evolve, and the adaptability of the Committee to changing situations will determine the future success of the NPI and its contribution to the national development of Sri Lanka.

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## Conflict of interest statement

The authors state that they have no conflict of interest.

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