Expanded Programme on Immunization and vaccine preventable diseases surveillance review

Report of the mission
Republic of Maldives, 27 January–3 February 2013
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<table>
<thead>
<tr>
<th>Acronyms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEFI</td>
<td>adverse events following immunization</td>
</tr>
<tr>
<td>AFP</td>
<td>acute flaccid paralysis</td>
</tr>
<tr>
<td>BCG</td>
<td>bacille Calmette-Guérin vaccine</td>
</tr>
<tr>
<td>cMYP</td>
<td>comprehensive multi-year plan</td>
</tr>
<tr>
<td>DSU</td>
<td>Disease Surveillance Unit</td>
</tr>
<tr>
<td>DT</td>
<td>diphtheria–tetanus</td>
</tr>
<tr>
<td>DTP</td>
<td>diphtheria–tetanus–pertussis</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>ERC</td>
<td>Expert Review Committee</td>
</tr>
<tr>
<td>EVM</td>
<td>Effective Vaccine Management</td>
</tr>
<tr>
<td>IEC</td>
<td>information, education and communication</td>
</tr>
<tr>
<td>IGMH</td>
<td>Indira Gandhi Memorial Hospital</td>
</tr>
<tr>
<td>MFDA</td>
<td>Maldivian Food and Drugs Authority</td>
</tr>
<tr>
<td>MIS</td>
<td>management information system</td>
</tr>
<tr>
<td>MR/MMR</td>
<td>measles–rubella/measles–mumps–rubella</td>
</tr>
<tr>
<td>NCCPE</td>
<td>National Committee for Certification of Polio Eradication</td>
</tr>
<tr>
<td>NCIP</td>
<td>National Committee for Immunization Practices</td>
</tr>
<tr>
<td>NNT</td>
<td>neonatal tetanus</td>
</tr>
<tr>
<td>SIDAS</td>
<td>WHO South-East Asia Regional Office Integrated Data Analysis System</td>
</tr>
<tr>
<td>TT</td>
<td>tetanus toxoid</td>
</tr>
<tr>
<td>UCI</td>
<td>universal child immunization</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>VPD</td>
<td>vaccine preventable diseases</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Executive summary

A team comprising national and international experts reviewed the Expanded Programme on Immunization (EPI) and the system of vaccine preventable diseases (VPD) surveillance in the Republic of Maldives from 27 January to 3 February 2013.

The general objectives of the review were to assess strengths and weaknesses of the immunization service delivery at all levels of the healthcare delivery system and to review the capacity of the VPD surveillance system to detect and respond to VPD in a timely manner. In addition, the review assessed the implementation status of the recommendations of the previous EPI review conducted in 2006.

Eight of the 20 administrative atolls were selected for the review. The review teams visited regional hospitals, atoll hospitals, public health programmes, public health units and health posts. Teams conducted interviews with key informants, reviewed records/documents, observed practices, inspected physical infrastructures and verified items/stocks. Tools for data collection were based on the World Health Organization’s (WHO) common assessment tools of immunization services adapted to the Maldivian context.

The reviewers identified major strengths and areas for further improvement in all reviewed atolls with a view to formulating recommendations. The review team concluded that the Maldives has expressed its unwavering commitment for immunization as a means of protecting health of its citizens by establishing strong policies and well-defined agencies with clear mandates for implementing the EPI and VPD surveillance. The infrastructure and human resources, in general, were found to be adequate for the delivery of immunization services, including the VPD surveillance. The team underscored the high public acceptance of immunization that is corroborated by the high immunization coverage despite some isolated vaccine hesitancy. The key recommendations made by the review team were as follows:
Immunization financing

- Solicit political commitment, forge increased partnerships, improve programme efficiency and minimize programme cost for sustained immunization financing.

Planning, management and coordination of the EPI and VPD surveillance

- Strengthen horizontal coordination and cooperation between the EPI unit and the Disease Surveillance Unit (DSU).
- Develop a plan to improve technical/managerial skills of the staff, supportive supervision, monitoring and evaluation of the EPI/VPD surveillance at all levels.

Service delivery

- Introduce measures to reduce missed opportunities for childhood vaccination.

Cold chain and vaccine management

- Plan and conduct a national Effective Vaccine Management (EVM) assessment, prepare an inventory of cold chain equipment and develop a replacement plan.
- Develop and implement guidelines for vaccine stock management at hierarchical levels.

Waste management

- Orient health workers on national medical waste management guidelines and promote maximum compliance with the guidelines at all levels.

VPD surveillance

- Conduct regular and systematic programmes to orientate surveillance focal points, expatriate local health workers on national requirements of the VPD surveillance.
➢ Develop systematic, standard procedures and guidelines for collection, transport and testing of specimens for VPDs.

**AEFI surveillance**

➢ Implement measures to improve detection, recording, reporting, investigation, management and follow-up of AEFI.

**Communication and advocacy**

➢ Conduct a needs assessment and plan a strategy to address the existing gaps in advocacy and communication pertinent to the EPI and VPD surveillance.
1. **Background**

The Republic of the Maldives is an archipelago in the Indian Ocean situated on the equator at approximately 7° North to 0° South latitudes and between 72° to 73° Eastern longitudes. It consists of 1192 low-lying coral islands that form a chain of about 823 km length and 130 km width within an area of 90,000 km². The land area consists of only 300 km² and 192 islands are inhabited. For administrative purposes, 26 natural atolls have been divided into 20 administrative atolls and each atoll is headed by an atoll chief.

The total population of Maldives in 2011 was 325,135 with 7478 live births. The population age distribution was as follows: (1) under 1 year – 7395 (2.3% of total population), (2) under 5 years – 30,568 (9.4% of total population), (3) under 15 years – 87,635 (27% of total population) and women of child-bearing age (15–44 years) – 79,893 (24.6% of total population) (SEAR Annual EPI Reporting Form, 2011). Population density varies significantly with geographical locations. About one third of the population lives in the capital island of Malé, while the remaining population is scattered in rural or sub-urban islands.

1.1 **Expanded programme on immunization**

Maldives has a long history of immunization. The smallpox vaccine was the first antigen used in the country, while the second antigen, oral polio vaccine (OPV), was introduced in October 1967 during the first outbreak of poliomyelitis. BCG and Cholera vaccines were used subsequently before launching the National EPI in 1976. Although the EPI programme faced a multitude of difficulties before its official launch in 1985, it was able to achieve the status of the universal childhood immunization (UCI) in 1988, 2 years ahead of the target. Since 1990, Maldives has sustained a national coverage of immunization well over 95% for all antigens, including five doses of tetanus toxoid (TT) for women of child-bearing age. In 1993, 10 years after the introduction of measles, hepatitis B vaccine was incorporated to the national EPI Schedule. The meningococcal vaccine was introduced to high-risk groups in 2004. Measles–rubella (MR) vaccine was introduced in 2006 followed by measles–mumps–rubella (MMR) in 2007.
Pentavalent diphtheria–tetanus–pertussis (DTP)-Hib-hepatitis B vaccine was planned to be introduced in 2012 on phase basis. It has already been rolled out in some atolls, while in other atolls it will be gradually introduced. The current routine immunization schedule of Maldives used in areas where DTP-Hib-hepatitis B (pentavalent) vaccine has been introduced and not introduced is shown in Tables 1 and 2, respectively.

**Table 1: Routine immunization schedule with DTP-Hib-hepatitis B (pentavalent)**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>At birth</td>
</tr>
<tr>
<td>OPV</td>
<td>At birth, 2 months, 4 months, 6 months</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>At birth</td>
</tr>
<tr>
<td>Pentavalent</td>
<td>2 months, 4 months, 6 months</td>
</tr>
<tr>
<td>Measles</td>
<td>9 months</td>
</tr>
<tr>
<td>MMR</td>
<td>18 months</td>
</tr>
<tr>
<td>TT</td>
<td>15–45 years women of child-bearing age, +1 month, +6 months, +1 year, +1 year</td>
</tr>
<tr>
<td>DT</td>
<td>5 years</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>9 months, 18 months</td>
</tr>
</tbody>
</table>

**Table 2: Routine immunization schedule without DTP-Hib-hepatitis B (pentavalent)**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>At birth</td>
</tr>
<tr>
<td>OPV</td>
<td>Birth, 4 weeks, 8 weeks, 12 weeks</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Birth, 4 weeks, 12 weeks</td>
</tr>
<tr>
<td>DTP</td>
<td>6 weeks, 10 weeks, 14 weeks</td>
</tr>
<tr>
<td>Measles</td>
<td>9 months</td>
</tr>
<tr>
<td>MMR</td>
<td>18 months</td>
</tr>
<tr>
<td>TT</td>
<td>15–45 years women of child-bearing age, +1 month, +6 months, +1 year, +1 year</td>
</tr>
<tr>
<td>DT</td>
<td>5 years</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>9 months, 18 months</td>
</tr>
</tbody>
</table>
Progress made by the EPI of Maldives since its inception was remarkable. Figure 1 shows the progress in routine immunization from 1990 to 2010. The immunization coverage has remained high for all antigens in the past two decades.

Figure 1: The National Immunization Coverage, 1980–2011 (WHO/UNICEF estimates)

The findings of the Maldives Demographic Health Survey (2009) confirmed the high immunization coverage in Maldives. The proportion of fully immunized children under 1 year of age was 88.9%. The same for BCG, DPT3, OPV3, measles and hepatitis B vaccine were 99.2%, 96.2%, 95.2%, 91.3% and 91.9%, respectively. However, it revealed some regional disparities in immunization; the percentage of children fully vaccinated was the lowest in the central region (88%) while it was the highest in the north central region (96%).

Achieving and sustaining high immunization coverage dramatically decreased the incidence of VPD in Maldives. No indigenous polio cases have been reported since 1978. One imported polio case was found in 1994. No cases of diphtheria and pertussis have been reported for decades. The last four cases of neonatal tetanus (NNT) were reported in 1994.
VPD detected in and the acute flaccid paralysis (AFP) surveillance indicators for Maldives from 2002 to 2011 are given in Tables 3 and 4.

**Table 3**: Vaccine preventable diseases reported in Maldives, 2002–2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Polio</th>
<th>Diphtheria</th>
<th>Pertussis</th>
<th>Total tetanus</th>
<th>Neonatal tetanus</th>
<th>Measles</th>
<th>Rubella</th>
<th>Mumps</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>926</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>2003</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>77</td>
<td>81</td>
<td>ND</td>
</tr>
<tr>
<td>2004</td>
<td>ND</td>
<td>0</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>37</td>
<td>ND</td>
<td>44</td>
</tr>
<tr>
<td>2005</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1395</td>
<td>3</td>
<td>5410</td>
</tr>
<tr>
<td>2006</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>47</td>
<td>0</td>
<td>5349</td>
</tr>
<tr>
<td>2007</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>20</td>
<td>ND</td>
<td>341</td>
</tr>
<tr>
<td>2008</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>ND</td>
<td>114</td>
</tr>
<tr>
<td>2009</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>71</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>2011</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>69</td>
<td></td>
</tr>
</tbody>
</table>

ND=No data  
Source (WHO/UNICEF Joint Reporting Form)

**Table 4**: Performance indicators of AFP surveillance, 2002–2011

<table>
<thead>
<tr>
<th>Indicator</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wild polio</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AFP rate</td>
<td>3.28</td>
<td>0.97</td>
<td>0</td>
<td>0.97</td>
<td>1.04</td>
<td>0</td>
<td>0</td>
<td>4.4</td>
<td>4.53</td>
<td>3.4</td>
</tr>
<tr>
<td>Non-polio AFP rate</td>
<td>3.28</td>
<td>0.97</td>
<td>0</td>
<td>0</td>
<td>1.04</td>
<td>0</td>
<td>0</td>
<td>4.4</td>
<td>4.53</td>
<td>3.4</td>
</tr>
<tr>
<td>% Adequate stool collection rate</td>
<td>25</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>50</td>
<td>50</td>
<td>33</td>
</tr>
<tr>
<td>Total stool samples collected</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>% non-polio Enteroviruses (NPEV)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Primary result reported within 14 days</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

1 For 2012 data, see the IVD VPD Weekly Bulletin (source: data as of 5 June 2012).
2 Number of discarded AFP cases per 100 000 children under 15 years of age.
3 Per cent with two specimens 24 hours apart and within 14 days of paralysis onset.
4 2001–2007 data includes percentage of the primary result reported within 28 days.
2. Purpose and methodology of the review

2.1 Context

Justification

The WHO Regional Office for South-East Asia has been assisting Member States in strengthening the EPI and VPD surveillance. As an integral part of this process, Member States are encouraged to conduct periodic internal reviews of the EPI and VPD surveillance. These internal reviews are complemented by joint national/international EPI and VPD surveillance reviews. The last joint national/international review of such a magnitude was conducted in Maldives in 2006.

The 2006 review made significant recommendations to the immunization programme. The review prioritized following recommendations for implementation: (1) to establish an expert group to develop national EPI guidelines and outline policies and procedures; (2) to review the existing immunization schedule; (3) to standardize procedures for collection, transport and testing for suspected measles cases; (4) to integrate vitamin A distribution system with routine immunization services; and (5) to develop a national multi-year plan for in-service EPI training. Since the last review, the ministry of health has undertaken a multitude of actions to improve the EPI and VPD surveillance. Further in the post-review period, national activities were decentralized and the MMR vaccine was incorporated into the National EPI schedule. Hence, a joint national/international review at this juncture enables follow-up of the implementation of recommendations of the last joint review.

Parallel to these developments, the South-East Asia Region has been free of polio since January 2011 and the certification of polio-free status is due in February 2014. With the significant progress made towards polio eradication in the Region, it is important that all Member States achieve surveillance standards and documentation. In this context, assessing strengths and gaps in surveillance standards, laboratory and outbreak response capacity and verifying polio-free status in Maldives is vital. A joint national/international review enables the verification of the polio-free status and the identification of strengths and gaps in Maldives. Furthermore, at a
time when the South-East Asia Region is embarked upon a mission to eliminate measles, a joint national/international review will also facilitate appraisal of the country capacity in detection, confirmation, reporting and response to measles cases.

A comprehensive review of the EPI and VPD surveillance would also help in assessing the impact of decentralization in Maldives on the EPI.

2.2 Objectives of the review

Specific objectives of the review

(1) To assess strengths and weaknesses of immunization service delivery at all levels of the health-care delivery system.

(2) To analyse the managerial and administrative capacity for immunization and surveillance at the central, regional, atoll, sub-atoll and island levels.

(3) To assess strengths and weaknesses of current vaccine distribution mechanisms and cold chain management.

(4) To assess the status of injection safety and waste management for sharps.

(5) To review immunization policies, schedules, financing and programme sustainability.

(6) To review the capacity of the central surveillance system including the laboratory support as applicable to detecting and responding to VPD in a timely manner.

(7) To document the capacity for surveillance and management of adverse events following immunization.

(8) To assess training needs for immunization managers, surveillance staff and basic health workers (vaccinators) at all levels.

(9) To review the role of the private sector and non-governmental organizations, as providers of routine immunization services in the context of decentralization of the health system.

(10) To assess communication strategies, including advocacy, partnership, social mobilization and their implementation.
To review the role of national coordination and advisory bodies involved in immunization, polio eradication, measles elimination and adverse events following immunization (AEFI).

To review roles and responsibilities of immunization programme stakeholders.

To review roles and responsibilities of the surveillance network.

2.3 Methodology of the review

The review was conducted from 27 January to 3 February 2013, at central, regional, atoll, sub-atoll and island levels. The reviewers included nine international professionals representing the Member States (India, Indonesia, Myanmar, Nepal, Sri Lanka and Thailand), WHO, United Nations Children's Fund (UNICEF), United States Centers for Disease Control and Prevention, and the senior national staff of the Maldivian Ministry of Health. The international professionals were specialists in EPI, cold chain, vaccine management, injection safety, VPD/AEFI surveillance and programme management. A total of eight teams was formed to conduct the review in the archipelago. One central team concentrated in the capital island of Malé and the corresponding atoll.

The review consisted of four components:

(1) a briefing session of 1 day for all participants;
(2) field work of 4 days in selected atolls and in Malé;
(3) a session of 1 day for reviewing and consolidating results of the eight teams and preparing the review report for the de-briefing session;
(4) de-briefing session to the Honourable Minister of Health, ministry officials and other national and international stakeholders.

The central team visited the health protection agency, the largest private hospital in Malé, Indira Gandhi Memorial Hospital (IGMH), including the national measles reference laboratory at the IGMH and a few health centres around Malé. They interviewed key government officials, medical specialists, health staff involved in the EPI and VPD surveillance, reviewed functions of the National Committee for Immunization Practices
(NCIP), National Certification Committee for Polio Eradication (NCCPE), the National Expert Review Committee (ERC) and the national measles laboratory.

At the atoll level, teams visited regional hospitals, atoll hospitals, public health programmes, public health units and health posts. They interviewed medical consultants and other hospital-based health workers, public health workers involved in the EPI and VPD surveillance, island/atoll council members, religious dignitaries, parents and the general public. They reviewed records, documents, returns, feedbacks, guidelines pertinent to the EPI and VPD surveillance, looked for investigation reports of VPD outbreaks and AEFI. They inspected physical infrastructures and verified items or stocks. They further observed practices and mock displays of practices and conducted small-scale community surveys. They used structured data collection tools based on WHO’s common assessment tools of immunization services adapted to suit the Maldivian context. These included tools for assessing health facilities and public health units and public health programmes, and an open-ended interviewer guide for additional data collection. The tools captured information on the following broad technical areas: (1) planning and management; (2) immunization service delivery; (3) cold chain and vaccine management; (4) monitoring and evaluation; (5) human resources; (6) AEFI and VPD surveillance; and (7) advocacy and communication.

**Selection of sites**

Of the 20 administrative atolls, 8 (40%) were selected for the review. The atolls were selected in consultation with national counterparts in such a manner that they represented the archipelago. Selection of atolls was also based on the population density. List of team members is given in Annex 1. The atolls selected for the review are given in Annex 2.

Within selected atolls, all regional/atoll hospitals and a sample of health facilities (health posts, health centres and public health units) were reviewed. All the eight teams (including the central team) reviewed 17 health centres, 4 atoll hospitals, 3 regional hospitals, 1 health post, 2 private hospitals and 1 tertiary care hospital (IGMH).
Limitations of the review

- While the review was carried out in 8 of the 20 administrative atolls, within an atoll, facilities reviewed were restricted to the regional/atoll hospital and, in most cases, two other facilities due to time and logistics constraints.

- There were significant geographical variations in monitored aspects related to the EPI and VPD surveillance. The report includes findings that were common in all or majority of the reviewed atolls.

- Given that immunization sessions are held often once a month, appraisals of most of the practices were based on interviews and mock displays rather than observing real practices.

3. Findings and recommendations

3.1 Immunization financing

In Maldives, expenditures on routine and optional vaccines are exclusively financed by the government. Aligning with this, the Maldives Government has reserved a separate line item in the national budget for the procurement of vaccines and injection supplies for the EPI. However, the declining financial allocations, relative insufficiency of funds due to rising programme cost and the cost of new vaccines are threatening the financial sustainability of the national EPI. Unlike many other Member States in the Region, Maldives is unable to reduce the vaccine cost by negotiating concessionary prices due to absence of an economy of scale.

Recommendations

- Advocate policy-makers to solicit political commitment for financial sustainability of the EPI.

- Identify and implement measures to improve programme efficiency and minimize the programme cost.

- Forge and increase partnerships for immunization with traditional and non-traditional development partners.
3.2 Planning, management and coordination of the EPI and service delivery

National level

Immunizing all children in Maldives has been recognized as a major government policy. The policy states that immunization is a basic right of the children in the country. The high priority accorded is reflected in the policy statement that the government regards children as one of the most important assets of the nation, and therefore every effort should be made to promote the welfare and full development of their potential for quality of life irrespective of gender and socioeconomic status.

The recently enacted Public Health Act (2012), which includes the provisions for protecting and promoting public health, controlling the risk to public health, promoting the control and prevention of infectious diseases, currently forms the legal basis for organization and delivery of routine, optional and emergency immunizations. Moreover, the school entry requirements (1994) have made it compulsory to have all childhood vaccines completed for the entry of children to schools.

A comprehensive multi-year plan (cMYP) for setting priorities and mobilizing and using resources effectively throughout the implementation of the EPI is available for the 5-year period from 2009 to 2013. It describes the national goal and objectives of immunization. This guiding document of planning, management and coordination of the EPI lists out strategies and activities pertinent to immunization planned for the period of concern. The country has established and sustained a long-standing partnership with WHO and UNICEF to support the EPI.

Nonetheless, given the recent enactment of the Public Health Act (2012), there is a need for developing new or adjusting existing policies for immunization to suit the aforementioned act. Despite the availability of strong policies, there is a current gap in the communication of national policies to the subnational focal points that affects effective translation of these policies to action at the subnational level. Given that there are only three technical persons at the national level to implement the EPI, it is essential to ensure adequate human resources at the EPI unit and enhance their technical capacity. On the basis of the fact that the VPD surveillance
comes under the purview of the DSU, the review team identified the urgent need for an effective mechanism for close, horizontal coordination between the EPI unit and the DSU than it is at present.

**Subnational level**

The review team noted the existence of a remarkable “*culture of vaccination*” in the reviewed atolls. This observation was supported by the sustained high immunization coverage and low dropout rates during record reviews. Given the target population for immunization service delivery, the review team opined that the existing human resources at the great majority of reviewed atolls were adequate for the management of the EPI. The information elicited suggested that the proficiency in correct administration of vaccines (injection technique) by the health staff was high and auto-disabled syringes were universally being used for administration of EPI vaccines. The other notable observation was the commendable maintenance of all records and returns pertinent to immunization enabling retrieval of accurate information. The manner in which the Child Health Development Card is maintained in duplicates is exemplary and helps retrieval, verification of individual immunization status of children for management and school entry purposes.

While appreciating these strengths, it is not the practice to update the immunization status of children who have been vaccinated at a health centre outside the resident island in clinic registers including the duplicate copy of the Child Health Development Card retained at the health centre. The reviewers also highlighted that there were many instances of missed opportunities for childhood immunization and high wastage of vaccines coming under the open vial policy. Another shortcoming was the non-existence of a systematic mechanism to track the immunization status of the mobile population despite well maintenance of records and returns pertinent to immunization. Though it may be considered insignificant at this stage, the review highlighted some isolated vaccine hesitancy which, to the credit of the EPI, is being recorded in a central vaccine hesitancy database.
Recommendations

- Provide adequate human resources and introduce measures to enhance the technical capacity of the new and existing professional staff at the EPI unit.
- Strengthen horizontal coordination and cooperation between the EPI unit and the DSU of the health protection agency.
- Finalize the draft EPI training manual for health workers and disseminate it to health workers to improve the quality of immunization services.
- Plan and conduct activities to impart middle level managerial skills to health staff at the subnational level:
  - introduce measures to reduce missed opportunities for vaccination;
  - reintroduce the standardized preparation of the list of beneficiaries of vaccination (children eligible for vaccination).

3.3 National vaccine regulatory function

Maldivian Food and Drugs Authority (MFDA) functions as a central institution (the highest level of health-care delivery) functioning under the ministry of health. It is the national drug regulatory authority. The MFDA approves the use of only pre-qualified vaccines. In addition to the routine vaccines used in the EPI, MFDA approves the use of optional vaccines in consultation with the national EPI. Currently, the seasonal influenza vaccine and meningococcal vaccine for pilgrims over 15 years and yellow fever vaccine for travellers over 18 years are falling under the category of optional vaccines approved by the MFDA in consultation with the EPI. The MFDA has a mandate to display flexibility in fast-track licensing of other vaccines contingent upon the need of a rapid deployment in emergency situations. The inter-sectoral committee on the advice of the technical committee, especially in epidemic or pandemic situations, facilitates through the representatives of the MFDA and Maldives custom service fast-track approval and clearance of these vaccines for public use. For further effective functioning of the delivery of immunizations with the highest quality, potency and safety, the review underscored the urgent need for
Further strengthening the technical capacity of the staff of the MFDA and the customs on ensuring potency of vaccines, vaccine storage requirements and issues pertinent to clearance.

**Recommendations**

- Plan activities to enhance the capacity of the staff of the MFDA on ensuring efficacy of vaccines, vaccine storage requirements and issues pertinent to clearance.
- Design and conduct a sensitization programme/s for the custom officers on storage requirements of vaccines and sustenance of their potency till clearance.

### 3.4 National coordination and advisory bodies

A standing NCIP is available with terms of references. It acts as the main technical advisory body for policy guidance to the EPI. A national AEFI committee does not exist and its purviews have been assigned to the NCIP. The Chairperson of the NCIP during the review opined the need for strengthening the NCIP and identified specific areas where strengthening is required. An NCCPE and an ERC are functional in the country. The NCCPE prepares an annual update for the certification of poliomyelitis, prepares a report to the regional certification committee for polio eradication and appraises the risk of importation of poliomyelitis into Maldives. It is chaired by a medical specialist. The ERC reviews and classifies AFP cases regularly and monitors the certification process. This committee consists of two senior consultants in Paediatrics and one government and one independent medical officer.

**Recommendations**

- Initiate activities to strengthen the technical capacity of the NCIP.
- Expand the engagements of the EPI with relevant national multi-sectoral committees, partners and professional associations in matters pertaining to the EPI.
3.5 Cold chain and vaccine management

National level

The review highlighted that the cold storage capacity at the central cold stores is adequate for the vaccines currently used in the EPI. However, though the possibility of introducing new and underutilized vaccines in future has been considered in the cMYP, the gaps of the cold chain storage capacity for future introductions of new and underutilized vaccines were not recently appraised. The current central cold store is congested and poorly ventilated. The storage capacity for EPI products has been reduced by non-EPI products stored in the central cold stores. Non-adjacent location of the dry storage and cold storage facilities impedes the smooth delivery of dry and cold EPI items. The inventory of the cold chain equipment has not been recently updated. The ice pack freezer was found to be non-functional. A noteworthy observation was the establishment of a system based on short message service to alert temperature fluctuations. A backup generator is not available for the maintenance of the electricity supply in an event of power failure. Reviewers were of the opinion that the currently available staff are inadequate for the maintenance of the cold chain related activities in the central cold stores.

Subnational level

The review teams observed that the cold chain equipment was available at the subnational level and a great majority of them were in functional condition. The available cold storage capacity was adequate for storing currently required amount of vaccines in reviewed facilities. The monitoring and recording of temperature were being carried out on a regular and accurate basis. One exceptional finding was that the management of diluent is exemplary in reviewed areas. It was encouraging to note that stock management records were maintained for diluents similar to vaccines. Notwithstanding these encouraging features, reviewers also observed that there were instances of incorrect storage of vaccines, in particular freeze-sensitive vaccines, and storage of reagents and other pharmaceuticals in refrigerators where vaccines were stored. The stock requisitions were not based on any scientific methods resulting in avoidable expirations of items. Currently, a systematic mechanism does not exist to report cold chain
equipment breakdowns to the next level for appropriate actions. Nor do they have contingency plans. Plans for repairing and maintaining cold chain equipment were not strong.

**Recommendations**

- Introduce measures to strengthen the central cold stores of the EPI.
- Plan and conduct an effective vaccine management (EVM) assessment.
- Conduct training programmes for the health staff on vaccine management.
- Prepare an inventory of cold chain equipment and develop a replacement plan.
- Provide adequate human resources required for the maintenance of the cold chain of vaccines.
- Develop guidelines for vaccine stock management at hierarchical levels and thresholds for the minimum stock, maximum stock and buffer stocks that can be stored at any given time at each level of service provision.
- Discourage the storage of non-EPI products with EPI products in cold chain equipment.

**3.6 Monitoring and evaluation**

The review team noted that the technical capacity of the existing staff at the EPI unit and the DSU is adequate for monitoring and evaluation of the EPI and VPD surveillance. A well-established and well-functioning management information system (MIS) for EPI exists in Maldives. Regular and timely flow of the management information currently through the existing MIS from the subnational level to the national level is an advantage for regular and systematic monitoring of the EPI, including the VPD surveillance, from the national level. Number immunized is easily obtainable for the calculation of immunization coverage through the existing system of immunization records. Several data sources exist to obtain denominator figures. These multiple sources complement accuracy of the denominator figures.
Nevertheless, the immunization coverage is neither calculated nor monitored at island and regional levels. It is performed at the national level.

It was observed that the insufficient availability of human resources at the EPI unit and the DSU does not permit initiating actions based on the analysis of management information and conducting supportive supervision at the subnational level. It is further complicated by the current, insufficient financial provisions for subnational activities. All the review teams highlighted that monitoring and evaluation of the EPI including the VPD surveillance were not features of routine activities at either the reviewed atoll or island levels. The public health staff at the reviewed atolls were found to be short of skills pertinent to monitoring and evaluation. During the review, feedback on monitoring and evaluation was not found on either central or subnational levels by any review team.

**Recommendations**

- Motivate central-level health professionals at the EPI and DSU to analyse available management information and surveillance data for evidence-based decision-making and provide feedback for improving performance at the subnational level.
- Develop plans to improve supportive supervision, monitoring and evaluation of the EPI at all levels.
- Develop a systematic plan to impart skills on monitoring and evaluation including supportive supervision to the public health staff managing EPI at the central and subnational levels.

### 3.7 Waste management of injection syringes, vaccine vials and ancillary items

The national EPI has given attention to safe disposal of vaccine vials, injection syringes and other wastes generated in delivery of immunization services. According to this, national guidelines have been formulated for medical waste management. However, the review teams observed that the compliance with the national guidelines on medical waste management has been challenging at the subnational level. The central monitoring of the waste management practices has been extremely difficult given the complexity of geographical location of islands. Reviewers highlighted that
the practices of disposal of injection syringes, vaccine vials and other medical wastes pertinent to immunization were not uniform and varied from place to place. Some reviewers observed that some available incinerators were non-functional. Though open burning in a pit in a controlled manner has been allowed in guidelines when incinerators were not available, some practices in this regard were noted to be leading to environmental pollution and potentially threatening to the health of inhabitants of some islands. However, one noteworthy observation was the widespread use of safety boxes and the practice of segregation of medical wastes. Even in the case of using safety boxes, some reviewers had observed improper use of safety boxes compromising the injection safety of the health staff.

**Recommendations**

- Orient health workers on National Medical Waste Management Guidelines and promote compliance with the guidelines to the maximum at all levels.
- Provide and promote use of incinerators in all health facilities where feasible.

### 3.8 Surveillance of AEFI

The EPI has established a national network of AEFI surveillance. National guidelines are available in this regard. Definitions of reportable AEFI, mechanisms for reporting and responsibilities of reporting are well defined and in place in the guidelines. The reporting instructions and formats for monthly reporting of severe AEFI are available at the institutional levels of reviewed atolls. Though the reporting was regular, all the teams reported that it had been the practice of predominantly zero reporting for the past 3 years. This raised doubt about the sensitivity of the AEFI detection system, given the non-reporting of at least high fever which is a reportable serious adverse event that should be reported according to the current guidelines. Further, the review teams highlighted that there was no recording system of AEFI in existence at the clinic, institutional levels and during house visits that could lead to missing potential AEFI cases. Therefore, given this low sensitivity of case detection at the moment, reviewers were of the opinion that the EPI needs to consider if they should focus on reporting mild,
moderate and severe AEFI, for the purpose of increasing the sensitivity of the surveillance system with subsequent investigations being focused on severe AEFI. Even for a few cases where severe AEFIs had been reported, there were no investigation reports. At the national level, a national AEFI committee does not exist and the functions of such a committee are looked after by the NCIP. Though, the occurrence of a fatal, immediate post-vaccination reaction could be significantly low theoretically given the absolute number of vaccinations performed in Maldives per annum, review team focused on the lack of preparedness of the staff for such an event that could occur due to chance. Such an event could potentially have a significant impact on the EPI of Maldives. The reviewers underscored that the EPI should revisit AEFI surveillance with an enhanced focus on AEFI detection recording, reporting, investigation, management, and follow-up and feedback procedures. It is also essential to mention that the majority of the subnational health staff of reviewed areas had not been exposed to training on AEFI surveillance.

**Recommendations**

- Finalize and share the current draft AEFI guidelines with the health staff at all levels.
- Revisit the overall AEFI surveillance strategy and introduce measures to improve detection, recording, reporting, investigation, management and follow-up of AEFI.
- Plan and conduct training activities for the health staff on AEFI surveillance and management.

### 3.9 Vaccine preventable disease surveillance

In Maldives, an integrated system of communicable disease surveillance including the VPD surveillance exists. The communicable disease control division of the centre for community health and disease control has overall responsible for communicable disease surveillance. Thus, the VPD surveillance also comes under their purview. AFP, measles, diphtheria, pertussis, tetanus, neonatal tetanus, viral hepatitis, mumps, rubella and meningitis are VPDs relevant to the antigens used in the national EPI schedule in Maldives subject to surveillance. Yellow fever, encephalitis and varicella infections are also notifiable diseases, though these vaccines are
not used for local residents. Case-based investigations are expected to be performed for all VPDs. Instructions for notifications and case investigations are available in the case notifying forms, and 2008 version of a manual on case definition for notifiable diseases is available as a guideline for health workers. At the subnational level, reviewers observed that daily reporting formats and case investigation forms were available and used for surveillance. Moreover, daily reporting of notifiable diseases occurred at the facility level and at the regional level. These data were entered into the WHO South-East Asia Regional Office Integrated Data Analysis System (SIDAS). However, SIDAS was underutilized for data analysis at the subnational level.

At the facility level, reviewers noted that the medical specialists, medical officers and nursing officers who are predominantly expatriates have not been sensitized to the national requirements of disease surveillance, including VPDs. In addition, local surveillance focal points have been unidentified and, in cases of having identified focal points, they have been untrained in the VPD surveillance. In most cases, the notifications were based on the clinician’s diagnosis. But the clinician’s diagnosis did not take into consideration the suspected or probable case definitions. This was a result of their unawareness of national requirements for disease surveillance. Reviewers were of the opinion that there was a likelihood of VPD cases being missed at the facility level and as such the current surveillance practice was considered to be less sensitive to capture VPDs. Reviewers highlighted that there was no active surveillance mechanism in operation for AFP, measles and NNT cases. There were occasions of a few VPD cases in facility databases that were not notified to the central level. Though the numbers were small, these missed cases will have a significant impact on performance indicators, given the small population of the Maldives. All reviewers found that the national guidelines to help health workers collect and transport laboratory specimens for key VPDs were not available. The observed tendency of dependence of the subnational staff on the national level to initiate investigations and collect laboratory specimen and the lack of preparedness for response at the subnational level without central involvement could be reflected in sub-optimal surveillance performance indicators in future. It may be a reason for sub-optimal rate of adequate collection of stool samples in AFP cases observed in 2009–2011 (Table 4).
**National laboratory for measles and AFP**

The laboratory in the IGMH has been conditionally accredited. The central review team remarked that the measles/rubella laboratory has been underutilized. This was further corroborated by observations of the teams that visited atolls. According to them, the peripheral staff were neither ready to send specimens for verification of fever rash cases nor aware of the procedures pertinent to sending specimens. The polio reference laboratory is in Colombo, Sri Lanka, and specimens are processed and transported to Colombo.

**Recommendations**

- Strengthen the VPD surveillance focusing on the following areas:
  - updating and sharing existing guidelines on the VPD surveillance with all levels;
  - identifying surveillance focal points and enhancing their technical capacity as well as that of other health staff involved in the VPD surveillance;
  - planning and conducting regular and systematic programmes to orientate current and all future expatriate doctors and nurses on national requirements of disease surveillance;
  - implementation and regular monitoring of active case detection of AFP, NNT and measles;
  - developing systematic, standard procedures and guidelines for collection, transport and testing specimens for VPDs, strengthening laboratory support and implementation at the subnational level;
  - strengthening collaboration with secondary- and tertiary-level hospitals to enhance the VPD surveillance.

**3.10 Communication and advocacy**

Republic of Maldives has recognized advocacy and communication as an important aspect, and accordingly activities have been planned under different strategies in the cMYP (2009–2013). Technical guidance on
communication has been elaborated in the draft EPI manual. The review underscored the availability of national prototypes of communication and advocacy materials pertinent to immunization. The reviewers highlighted the excellent support currently being rendered by the community, religious leaders, media, academic institutions and professional associations. However, it has to be underlined that opportunities are available for further engagement with media, medical professionals and professional organizations in communication and advocacy pertinent to immunization, given the evolving nature of issues surrounding the mature EPI of Maldives. The interviews revealed that the funding is a limiting factor for designing programmes and producing information, education and communication (IEC) materials in adequate quantities.

The review teams were impressed by the display of IEC materials carrying positive messages in relation to EPI and VPDs at visited health centres and hospitals. The other remarkable observation was the strong interpersonal communication between the health staff and the parents during the service delivery.

**Recommendations**

- Establish and sustain interactions with the local media on important aspects related to EPI.
- Organize regular meetings with the atoll/island councils, religious leaders and community leaders to advocate, sensitize important aspects related to EPI and solicit their support to sustain the achievements of the EPI.
- Plan and conduct awareness programmes targeted at the community to bridge the existing information gaps pertinent to EPI, including AEFI and VPDs.
Annex 1

Deployment of review teams and atolls visited

<table>
<thead>
<tr>
<th>Team</th>
<th>International team member</th>
<th>National team member(s)</th>
<th>Atolls/ regions visited</th>
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<tbody>
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Annex 2

Atolls selected for the review
WHO assists Member States of the South-East Asia Region to periodically review their surveillance systems and national immunization programmes. These reviews provide an insight into the strengths and limitations of the national immunization programmes. Additionally WHO encourages countries to identify strategies to harness strengths and utilize the available resources to improve the quality of immunization and disease surveillance. In this regard, a joint national and international review was conducted in the Republic of Maldives to review the Expanded Programme on Immunization (EPI) and Vaccine Preventable Diseases (VPD) surveillance in January 2013.

This report summarizes the findings of the review in terms of current major strengths and areas for further improvement in the national EPI and VPD surveillance system. The report also details recommendations for the consideration of the Government of Maldives for further strengthening EPI and VPD surveillance with a view to achieving national goals for immunization.