Joint National/International Expanded Programme on Immunization and Vaccine Preventable Disease Surveillance Review

Democratic People’s Republic of Korea, 2–9 July 2018
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<td>AES</td>
<td>acute encephalitis syndrome</td>
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<td>AEFI</td>
<td>adverse event following immunization</td>
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<td>AFP</td>
<td>acute flaccid paralysis</td>
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<td>AFR</td>
<td>acute fever and rash</td>
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<td>ANC</td>
<td>antenatal care</td>
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<td>BCC</td>
<td>behaviour change communication</td>
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<tr>
<td>BCG</td>
<td>Bacillus Calmette–Guérin vaccine</td>
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<td>BD</td>
<td>birth dose</td>
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<td>bOPV</td>
<td>bivalent oral polio vaccine</td>
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<td>Caritas</td>
<td>German Caritas Association</td>
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<td>CCE</td>
<td>cold-chain equipment</td>
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<td>CES</td>
<td>coverage evaluation survey</td>
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<td>CHAEI</td>
<td>Central Hygiene and Anti-Epidemic Institute</td>
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<td>cMYP</td>
<td>comprehensive multi-year plan</td>
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<td>CMW</td>
<td>central medical warehouse</td>
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<tr>
<td>CRS</td>
<td>congenital rubella syndrome</td>
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<td>CSR</td>
<td>Communicable Disease Surveillance and Response</td>
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<tr>
<td>DoV</td>
<td>Decade of Vaccines</td>
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<tr>
<td>DTP</td>
<td>diphtheria, tetanus and pertussis (vaccine)</td>
</tr>
<tr>
<td>DTwP</td>
<td>diphtheria, tetanus and whole cell pertussis (vaccine)</td>
</tr>
<tr>
<td>DTP3</td>
<td>third dose of diphtheria, tetanus and pertussis vaccine</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<tr>
<td>EQAS</td>
<td>external quality assurance system</td>
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<tr>
<td>EVM</td>
<td>effective vaccine management</td>
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<tr>
<td>GAPII</td>
<td>WHO Global Action Plan</td>
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<td>GAPIII</td>
<td>WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>Gavi</td>
<td>Gavi, the Vaccine Alliance</td>
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<td>GHSSVH</td>
<td>Global Health Sector Strategy on Viral Hepatitis</td>
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<td>GISRS</td>
<td>Global Influenza Surveillance Response System</td>
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<td>GPEI</td>
<td>Global Polio Eradication Initiative</td>
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<td>GVAP</td>
<td>Global Vaccine Action Plan</td>
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<tr>
<td>HAEI</td>
<td>hygienic and anti-epidemic institute</td>
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<td>HAES</td>
<td>hygienic and anti-epidemic station</td>
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<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
</tr>
<tr>
<td>HbsAg</td>
<td>hepatitis B surface antigen</td>
</tr>
<tr>
<td>HepB</td>
<td>hepatitis B vaccine</td>
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<tr>
<td>HepB3</td>
<td>third dose hepatitis B vaccine</td>
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<tr>
<td>HepB-BD</td>
<td>hepatitis B vaccine birth dose</td>
</tr>
<tr>
<td>Hib</td>
<td><em>Haemophilus Influenzae</em> type b</td>
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<tr>
<td>HSS</td>
<td>health systems strengthening</td>
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<tr>
<td>IEC</td>
<td>information, education and communication</td>
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<td>IgM</td>
<td>immunoglobulin M</td>
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<tr>
<td>ILI</td>
<td>influenza-like illness</td>
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<tr>
<td>IMNCI</td>
<td>Integrated Management of Neonatal and Childhood Illnesses</td>
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<tr>
<td>IPV</td>
<td>inactivated polio vaccine</td>
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<tr>
<td>ITAG</td>
<td>Immunization Technical Advisory Group</td>
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<tr>
<td>IVD</td>
<td>Immunization and Vaccine Development Unit (SEARO)</td>
</tr>
<tr>
<td>JA</td>
<td>joint assessment (Gavi)</td>
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<td>JE</td>
<td>Japanese encephalitis</td>
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<tr>
<td>LMIS</td>
<td>logistics management information system</td>
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<tr>
<td>LSHTM</td>
<td>London School of Health and Tropical Medicine</td>
</tr>
<tr>
<td>MCV</td>
<td>measles-containing vaccine</td>
</tr>
<tr>
<td>MCV1</td>
<td>first dose of MCV</td>
</tr>
<tr>
<td>MCV2</td>
<td>second dose of MCV</td>
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<tr>
<td>MNTE</td>
<td>maternal and neonatal tetanus elimination</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>MoPH</td>
<td>Ministry of Public Health</td>
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<tr>
<td>MR</td>
<td>measles–rubella (vaccine)</td>
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<td>NCCPE</td>
<td>National Certification Committee for Polio Eradication</td>
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<tr>
<td>NIC</td>
<td>National Influenza Center</td>
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<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
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<tr>
<td>NMNR</td>
<td>non-measles non-rubella</td>
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<tr>
<td>NMRL</td>
<td>National Measles and Rubella Laboratory</td>
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<td>NPL</td>
<td>National Polio Laboratory</td>
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<tr>
<td>NRA</td>
<td>National Regulatory Authority</td>
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<td>NVC</td>
<td>National Verification Committee for the Elimination of Measles and Rubella/CRS Control</td>
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<tr>
<td>OPV</td>
<td>oral polio vaccine</td>
</tr>
<tr>
<td>PBF</td>
<td>performance-based funding</td>
</tr>
<tr>
<td>PCV</td>
<td>pneumococcal conjugate vaccine</td>
</tr>
<tr>
<td>Penta</td>
<td>pentavalent vaccine (composed of diphtheria, hepatitis B, <em>Haemophilus Influenzae</em> type B, pertussis and tetanus vaccines)</td>
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<tr>
<td>Penta3</td>
<td>third dose of pentavalent vaccine</td>
</tr>
<tr>
<td>PIE</td>
<td>post-introduction evaluation</td>
</tr>
<tr>
<td>PHC</td>
<td>primary health care</td>
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<tr>
<td>Polio</td>
<td>poliomyelitis</td>
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<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
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<tr>
<td>PMW</td>
<td>provincial medical warehouse</td>
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<tr>
<td>RVC</td>
<td>Regional Verification Commission for Measles Elimination and Rubella/Congenital Rubella Syndrome Control</td>
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<td>RVAP</td>
<td>Regional Vaccine Action Plan</td>
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<td>SAGE</td>
<td>Strategic Advisory Group of Experts (for immunization)</td>
</tr>
<tr>
<td>SARI</td>
<td>severe acute respiratory infection</td>
</tr>
<tr>
<td>SEA</td>
<td>South-East Asia</td>
</tr>
<tr>
<td>SEARO</td>
<td>South-East Asia Regional Office (of WHO)</td>
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<tr>
<td>SDD</td>
<td>solar driven drive</td>
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<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>SIA</td>
<td>supplementary immunization activity</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>Td</td>
<td>tetanus–diphtheria toxoid (vaccine)</td>
</tr>
<tr>
<td>tOPV</td>
<td>trivalent OPV</td>
</tr>
<tr>
<td>ToT</td>
<td>training of trainers</td>
</tr>
<tr>
<td>TTCV</td>
<td>tetanus toxoid-containing vaccine</td>
</tr>
<tr>
<td>TT2+</td>
<td>two or more doses of tetanus toxoid containing vaccine</td>
</tr>
<tr>
<td>U5MR</td>
<td>under-5 mortality rate</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>VDPV</td>
<td>vaccine derived poliovirus</td>
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<tr>
<td>VPD</td>
<td>vaccine-preventable disease</td>
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<tr>
<td>VVM</td>
<td>vaccine vial monitor</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1. **Introduction**

The Global Vaccine Action Plan (GVAP) was endorsed by the 194 Member States of the Sixty-fifth World Health Assembly in May 2012 based on an extensive consultations with Member States and multiple stakeholders. In addition to articulating a global vision for immunization and outlining key strategies, the GVAP proposes five key goals for the Decade of Vaccines (DoV) (2011–2020):¹

- Achieve a world free of poliomyelitis (polio);
- Meet vaccination coverage targets;
- Reduce child mortality;
- Meet global and regional elimination targets; and
- Develop and introduce new vaccines.

All the regions and Member States of World Health Organization (WHO) were expected to further define specific targets and develop and implement action plans that suited their current status to advance the global goals.

Due to the commitment of national Expanded Programmes on Immunization (EPIs) and multiple partners, WHO South-East Asia Region has made significant progress towards achieving these goals, as exemplified by the certification of the Region as polio free in March 2014. In addition, all countries of the Region have been validated for maternal and neonatal tetanus elimination (MNTE). The Region has also set the goals of eliminating measles and controlling rubella and congenital rubella syndrome (CRS) by 2020, as well as accelerating the control of hepatitis B and Japanese encephalitis (JE). In addition to these goals, the Regional Vaccine Action Plan (RVAP) also seeks to strengthen routine immunization systems and services, accelerate the introduction of new vaccines and related technologies and ensure adequate production and availability of safe and efficacious vaccines.²

Periodically reviewing how each country is meeting these requirements provides an insight into the status of the national EPI and allows best practices to be shared among them. A Joint Review of Integrated Disease Surveillance had been carried out in the Democratic
People's Republic of Korea in 2008 by the Communicable Diseases Surveillance and Response (CSR) Unit and the Immunization and Vaccine Development (IVD) Unit of WHO Regional Office for South-East Asia.³

A decade later, this Joint National and International EPI and Vaccine-preventable Disease (VPD) Surveillance Review conducted from 2 June to 9 July 2018 provides an opportunity to assess the progress since the last review and know the current status of the EPI in the Democratic People’s Republic of Korea, share good practices that have been developed more widely and provide recommendations for addressing the challenges faced in meeting the national, regional and global immunization goals and targets.

The EPI in the Democratic People’s Republic of Korea has achieved considerable success in preventing and controlling VPDs. The last laboratory confirmed poliomyelitis case was in 1996 and since then the country has seen significant reductions in cases of diphtheria, measles, pertussis and tetanus as compared to the period prior to the implementation of the EPI. The Democratic People’s Republic of Korea achieved MNTE prior to 2000 and was certified polio-free in 2014. The second dose of measles-containing vaccine (MCV2) was successfully introduced in 2008. Introduction of Haemophilus influenzae type b (Hib) pentavalent vaccine (diphtheria, tetanus and pertussis vaccine (DTP)–Hib–hepatitis B [HepB]) in 2012, inactivated polio vaccine (IPV) in 2015 and bivalent oral poliovirus vaccine (bOPV) in 2016,⁴ followed as per years indicated.

The EPI has achieved and is sustaining a homogeneously high immunization coverage across the country; this was validated by estimates from the recently concluded coverage evaluation survey (CES) held in 2017.⁵ However, in the Democratic People’s Republic of Korea context, the gold standard is reaching every child. The next step is shifting the main focus of the programme from achieving high coverage to high quality service delivery. Vaccine stock-out events were experienced in the recent past only for IPV. This was due to the global supply constraints. IPV was reintroduced on 15 May 2018 and will be administered for the two missed out birth cohorts once adequate vaccine supplies are made available.

Surveillance of VPDs with global commitment to disease control goals such as for acute flaccid paralysis (AFP), measles and rubella is in place, with staff assigned to monitor the programme in every facility and
administrative level. Reporting of the EPI target diseases (polio, measles, rubella, diphtheria, pertussis and neonatal tetanus) is mandatory and is based on clinical and/or laboratory evidence. There have been no indigenous cases of measles since 2007 and the country is ready for verification of measles elimination. Surveillance for CRS was established in three sentinel hospitals in 2015. However, the country has not yet implemented surveillance for invasive bacterial vaccine preventable diseases such as Hib, meningococcal and pneumococcal disease and for acute encephalitis syndrome (AES) due to JE.

In order to sustain universal immunization coverage, the widespread, adequate health workforce available in the country is the biggest asset of the Ministry of Public Health (MoPH). A network of around 50,000 household doctors spread across the country is engaged in providing primary health care (PHC) including immunization services. For these front-line health workers to provide quality immunization services and sustain the uptake of vaccines by parents, there is a need to improve their knowledge, skills and education pertaining to the latest developments in immunization practices.

Literacy rates in the Democratic People’s Republic of Korea are high, and thus communities are well informed on the benefits of vaccination. Vaccines are well accepted, resulting in high demand for the same. In order to sustain the demand and mitigate the effect of possible serious adverse events following immunization (AEFIs) on vaccine acceptance, the National Regulatory Authority (NRA) needs further strengthening for investigating AEFIs along with the national AEFI Investigation Committee. The current capacity of the National Control Laboratory also needs to be enhanced to ensure appropriate documentation of the potency of vaccines after receipt in the country.

The Democratic People’s Republic of Korea subscribes to the key strategic objectives of the GVAP and the global goals of the DoV (2011–2020). Furthermore, the country follows the eight goals set in the RVAP 2016–2020, which are to ensure that: (i) routine immunization systems and services are strengthened; (ii) measles is eliminated and rubella/CRS controlled; (iii) polio-free status is maintained; (iv) elimination of maternal and neonatal tetanus is sustained; (v) control of JE is accelerated; (vi) control of hepatitis B is accelerated, (vii) introduction of new vaccines and
related technologies is accelerated; and (viii) access to high quality vaccines is ensured.\textsuperscript{2}

Key national EPI objectives are stipulated in the comprehensive multi-year plan (cMYP) for immunization 2016–2020.\textsuperscript{8} The Democratic People’s Republic of Korea has had several evaluations of specific EPI components carried out in the recent past, such as: assessment of effective vaccine management (EVM) leading to the 2011 and 2015 EVM improvement plans and 2015 national Cold Chain Inventory, which is being updated regularly;\textsuperscript{9} the Gavi, the Vaccine Alliance (Gavi) Joint Appraisal (JA) in June 2016;\textsuperscript{10} the post-introduction evaluation (PIE) for pentavalent vaccine and IPV in October 2016;\textsuperscript{4} the CES in June 2017;\textsuperscript{5} a Gavi Health Systems Strengthening (HSS) evaluation in August 2017\textsuperscript{11} and a mission of the South-East Asia Regional Verification Commission for Measles Elimination and Rubella/Congenital Rubella Syndrome Control in January 2018.\textsuperscript{6} However, no comprehensive EPI and VPD surveillance review has been conducted in recent years.

In this context, this joint national/international EPI and VPD surveillance review was carried out to support implementation of the cMYP 2016–2020.

2. Objectives of the review

2.1 General objective

To review the status of the EPI and VPD surveillance including AEFI surveillance.

2.2 Specific objectives

- To provide recommendations to public health policy makers and programme managers to sustain high and equitable immunization coverage, improve immunization practices/standards and the quality of immunization data, monitoring and reporting systems.
➢ To assess progress in meeting key national, regional, and global VPD control goals with specific focus on meeting the verification level surveillance standards of measles elimination and sustaining certification standard surveillance for AFP.

➢ To review the implementation status of recommendations of the PIE (2016) with a view to identifying bottlenecks for implementation and required technical assistance.

➢ To conduct the Gavi JA 2018 as an integral part of the EPI VPD review to assess performance of Gavi supported EPI/VPD implementation in order to identify new activities for support and technical assistance in 2019.

➢ To formulate technical advice on system strengthening for proposed routine measles rubella (MR) vaccine introduction with supplementary immunization (SIA) and provide background technical information on priority areas for the new Gavi HSS-III application in 2019.

➢ To share best practices and lessons learned with the implementation of recommendations of EPI and VPD surveillance reviews in other countries.

3. Background

3.1. Geography and population

The Democratic People’s Republic of Korea is a country located in East Asia in the northern half of the Korean Peninsula. It shares borders with three countries – China along the Amnok river, Russia along the Tumen river and the Republic of Korea along the Korean Demilitarized Zone. In the Democratic People’s Republic of Korea, the State is the owner of all land and productive assets and virtually the sole provider of food, shelter, health, education and other social and economic services to all its citizens.

Life in the Democratic People’s Republic of Korea is highly structured and governed by an extensive network of institutions, committees and
coordinating bodies at all levels of society, which are responsible for overseeing all aspects of life of the people.\textsuperscript{12}

The people are ethnically homogenous and speak the Korean language. As of 2014, the population was estimated at 24.9 million (51.1% females and 48.9% males); this includes 7.6 million children, of whom 1.7 million were under the age of 5. More specifically, 21% of the population is less than 15 years of age, 66% of the population is between the ages of 15 to 59 years, and the remaining 13% is over 60 years old. As per the last census of 2008, the median age was 33.6 years. The total fertility rate was estimated at 1.91 in 2014, reflecting a decrease from 2.01 in 2008. The average annual rate of population growth has been 0.61% in urban areas, increasing at a rate of 0.75%. In contrast, the population growth has been 0.38% in rural areas. The average household size was estimated at 3.9 in 2014. Decrease of child mortality has led to an average increase in life expectancy from 69.3 years in 2008 to 72 years in 2014 (68 years for males and 76 years for females).\textsuperscript{12}

In terms of the population distribution, a majority of the country’s population resides in four provinces, with South Pyongyang having the highest population density (comprising 17% of the national population), followed by Pyongyang (14%), South Hamgyong (13%) and North Pyongan (12%).\textsuperscript{12}

Recent data from the Socioeconomic, Demographic and Health Survey (SDHS 2014)\textsuperscript{7} estimate the degree of urbanization in the Democratic People’s Republic of Korea at 61%. Pyongyang, which is the capital of the country and the seat of political, cultural and economic affairs, is the most urbanized province with more than 85% of its population living in areas classified as urban. North Hamgyong Province has the country’s second largest city and is located in the northern part of the country. It has the second highest proportion of urban dwellers (70.7%). North Hwanghae and South Hwanghae Provinces, located in the southern and least mountainous part of the country, have the lowest proportion of urban dwellers. These southern areas are largely agricultural, consisting of plains and flatlands where the population is more dispersed and less urbanized.

On the other hand, Ryanggang and Jagang provinces with their high mountain peaks have nearly two thirds of their respective populations living in urban areas. The rugged terrain in these provinces offers very limited
space for residential purposes, and a majority of the population is clustered around the few relatively flat lands that have developed into town centres.

Administratively, the country is divided into nine provinces and one municipality – the capital city Pyongyang. The provinces are divided into 210 cities or counties. The county is further subdivided into smaller geographic areas called ris and the capital county towns are called ups. The cities consist of administrative areas known as dongs. In big cities, the dongs are grouped into administrative units called districts.

3.2 Health services

The MoPH is directly in charge of the implementation of the national public health policies and is responsible for treatment, prevention and administration of central and specialist hospitals. Sub-nationally, there are health bureaus at the provincial people’s committees and Public Health Departments at the county people’s committees and ri/Dong clinics.

3.3 Infant and child mortality

All estimates agree that despite a significant increase in mortality during the mid-1990s (due to challenges facing the country during that period), there has been a significant decline in infant and child mortality between the years 1990 and 2015. The infant mortality rate is 19.7 per 1000 live births and the under-5 mortality rate (U5MR) is 24.9 per 1000 live births. Data from the United Nations Inter-agency Group for Child Mortality Estimation suggests that the Millennium Development Goal target of two thirds reduction in the U5MR was not achieved. According to the same data source, over the period 1990–2012, there has been an average annual reduction of 1.9% in the U5MR compared to 6.1% between 2000 and 2012.

Among the key drivers of this reduction in U5MR has been steady improvement in both the access to, and the quality of available health services. This has occurred since the steep decline experienced in the decade of the 1990s. This strengthening included the acceleration of the Integrated Management of Neonatal and Childhood Illnesses (IMNCI) programme, which focused on the major causes of U5MR that includes pneumonia, diarrhoea and under-nutrition, vaccination and emergency
obstetric care. For example, there has been a sharp increase in immunization coverage in terms of the third dose of DTP (DTP3) from 43% in 1998 to 94% in 2014. Thus, there are no longer any reported deaths from diphtheria, tetanus and pertussis, and the increased immunization coverage has meant a 2.5% decline in U5MR per year as reported in EPI 2015. Under-5 deaths from diarrhoea have been reduced from 15% of the total in 2009 to 5% in 2014.12

3.4 Immediate causes of child mortality

The top five causes of neonatal deaths in the Democratic People’s Republic of Korea are preterm birth, intra-partum factors, congenital defects and sepsis and hypothermia. In the post neonatal period, pneumonia and diarrhoea are the major contributors. Undernutrition has been recognized as a major underlying cause and a cofactor of both maternal and child mortality and morbidity.12 The other major contributing factor for high prevalence of pneumonia, and deaths due to the same, could be the use of coal for cooking and, heating the houses. Similarly, use of pit latrines (36.8% of households) could be a contributing factor for high prevalence of diarrhoeal diseases and mortality as a result thereof.7

3.5 Access to adequately staffed health services, facilities and information

The Democratic People’s Republic of Korea has a well-articulated and staffed health system extending from the national to the primary care level. The system serves a population estimated at 24.9 million with an annual birth cohort of approximately 345 000.

Under the management of the MoPH, the country has an extensive network of more than 130 central and provincial hospitals (tertiary care), more than 1600 county/ri hospitals (secondary care) and more than 6200 polyclinics (primary care) at ri (rural county) and dong (urban county) levels. At the grass-roots level, a household doctor (section or family doctor) provides preventive and curative health care to around 130–140 households. There are about 50 000 household doctors in the country.12

Despite its high coverage, the Democratic People’s Republic of Korea’s health system has several shortcomings, including ageing
infrastructure, lack of transport, irregular electricity, lack of heating, unsanitary and irregular water supply, lack of quality (and sufficient) medicines and other equipment and a limited operational budget. For example, the Maternal and Neonatal Needs Assessment 2013–2014, jointly undertaken by the United Nations Children’s Fund (UNICEF), the United Nations Population Fund (UNFPA) and MoPH revealed that the quality of service provided in ri hospitals is a major area in need of improvement to ensure maternal and neonatal survival and well-being during pregnancy and delivery. Electricity is a particularly serious issue, with frequent power cuts and no backup generators. Most of the medical instruments and equipment are out of date, resulting in poor quality of care.\textsuperscript{12}

In 2017, the country’s Multi Indicator Cluster Survey conducted by the Government’s Central Bureau of Statistics with assistance from UNICEF showed that 1 in 5 children are stunted, although the national rate of stunting – an indication of chronic or recurrent malnutrition – has dropped significantly from 28% in 2012 to 19% in 2017. The survey results also showed significant differences in the nutritional status of children in different parts of the country – in the capital Pyongyang, 10% of children were affected by stunting, while in Ryanggang Province some 32% of children were affected.\textsuperscript{14}

Another significant challenge in the context of the Democratic People’s Republic of Korea is not having an effective referral system. Even though there is a substantial network of health facilities, movement between facility levels is often compromised by a range of barriers relating to limitations of transport, roads and communications systems, which are exacerbated by extreme weather conditions in the winter season. There are no ambulances or other vehicles for emergency referrals at ri-level hospitals, and when emergencies do occur hired vehicles, bicycles, animal-drawn carts or stretchers are used to transport the patient to the hospital for care. This situation is compounded by a lack of exposure of the health workforce to international standards and practices, and underinvestment in the development of updated curricula and methods at training institutions both centrally and in the provinces for medicine, midwifery, and nursing.\textsuperscript{12}

Despite these challenges with the referral system, there have been improvements to networking across the health system in recent years. The telemedicine network in the Democratic People’s Republic of Korea covers all areas of the country through an optic fibre connecting the central and all
provincial levels. This system is beneficial as more than 80% of the country is mountainous and difficult to access. Based on the achievements and experience of this telemedicine system, the MoPH plans to expand the scope and application of telemedicine services and to update the existing health information system, including application of an e-health information system throughout the country.\(^\text{12}\)

### 3.6 Expanded programme on immunization

The EPI is coordinated through the Central Hygiene and Anti-Epidemic Institute (CHAEI), which provides technical guidance to hygiene and anti-epidemic stations (HAES) at provincial and county levels. The vaccines are supplied from the Central Medical Warehouse (CMW) at the national level to provincial and county medical warehouses.

The service delivery system is supported by an extensive network of health facilities. There are 1694 county and ri hospitals and 6263 ri clinics and polyclinics. The facilities are run by over 200 000 trained health staff who are engaged in immunization service delivery. Household doctors are responsible for provision of all PHC services, including immunization and disease surveillance in their catchment areas or sections.\(^\text{4}\)

In each ri, immunization services are delivered through the fixed facility mode on set immunization days; while in counties, immunization services are provided through more than 12 000 immunization posts including 7008 PHC units, 433 county level clinics/hospitals, and 130 central and provincial level hospitals and specialized hospitals.

Monthly immunization sessions are held at fixed sites on a fixed day (eleventh or twelfth of each month) throughout the country simultaneously, with an additional 1–2 days for defaulter tracking. The PIE conducted following the introduction of pentavalent vaccine in 2016 found that local-level micro planning for immunization service delivery did not exist.\(^\text{4}\)

### 3.7 Cold chain and vaccine management

The national cold store at the CMW is equipped with walk-in cold rooms and walk-in refrigerators. All provincial cold stores have walk-in cold rooms. The county level cold stores are equipped with ice-lined refrigerators, deep
freezers and in some places, solar driven drive (SDD) refrigerators. Some of the ri hospitals are equipped with SDD refrigerators and the plan was to equip all 1200 ri hospitals throughout the country with SDD refrigerators by 2017. Passive vaccine carriers are in use at ri and dong clinics during immunization sessions. Temperature monitoring is done by using fridge tags, available at all levels.12

For reporting and monitoring of immunization supplies and logistics, including vaccines, an electronic reporting system is used from provinces to the national level, while the paper-based reporting system operates from ris/dongs to counties and from counties to provinces.

Vaccine transportation from the CMW to provincial medical warehouses (PMWs) is carried out quarterly using refrigerated and insulated vehicles; and from PMWs to county medical warehouses it is carried out monthly using insulated vehicles. From county medical warehouses to ris/dongs, vaccines are transported on the day or the previous day of vaccination in vaccine carriers/cold boxes with icepacks, using bicycles and vans.12

The EVM assessment 20159 has shown substantial improvement since the previous assessment in 2011. The following key areas of improvement have been noted:

➢ The cold chain capacity has improved at the ri level and other supply chain levels. Since the last EVM assessment, more than 200 new refrigerators have been procured.

➢ Fridge tags have been introduced countrywide in 2014. This has improved the quality of temperature monitoring at all levels. Planned preventive maintenance of cold-chain equipment at county medical warehouses is being practiced.

Nationally and provincially, the EPI is situated within a network of HAESs that manage a wide range of communicable disease control programmes (Fig. 1).
In order to give the desired thrust to the EPI, the Government has developed the cMYP 2016–2020 with the following key objectives:

- Achieve measles elimination, rubella and CRS control by 2020.
- Sustain >98% routine coverage for the third dose pentavalent vaccine (Penta3) by 2020.
- Sustain 98% coverage for the first and second doses of measles containing vaccine (MCV1 and MCV2) by 2020.
- More than 80% of counties to achieve DTP3/Penta3 coverage of more than 95%.
- Maintain the disparities in provincial DPT3/Penta3 coverage at lower than 1%.
- Maintain MNTE, remain polio-free and implement the Polio Eradication and Endgame Strategic Plan 2013–2018 (Polio Endgame) as recommended by the Strategic Advisory Group of Experts (SAGE).
- Reduce hepatitis B seroprevalence in the under-5 years’ cohort to less than 2% by 2020.
Joint National/International Expanded Programme on Immunization and Vaccine Preventable Disease Surveillance Review

➢ Introduce new or underutilized vaccines: MR, pneumococcal conjugate vaccine (PCV), Rotavirus (RV) and JE vaccine.

➢ Reduce incidence of rotavirus diarrhoea, pneumonia and meningitis due to Hib disease, JE and CRS.

Currently, the EPI in the Democratic People’s Republic of Korea provides the following vaccines in the national immunization schedule: Bacillus Calmette–Guérin (BCG), HepB birth dose (BD), oral poliovirus vaccine (OPV), IPV, pentavalent vaccine (composed of diphtheria, HepB, Haemophilus Influenzae type B, pertussis and tetanus vaccines/DTP–Hib–HepB), measles containing vaccine (MCV) and tetanus–diphtheria toxoid (Td) vaccine (for pregnant mothers). All vaccines used in the EPI are WHO prequalified and supplied through the UNICEF supply division.

The immunization schedule followed in the country is given in Table 1.

Table 1: Immunization schedule

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Dose 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>At birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HepB</td>
<td>At birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPV</td>
<td>6 weeks</td>
<td>10 weeks</td>
<td>14 weeks</td>
</tr>
<tr>
<td>IPV</td>
<td>14 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pentavalent (diphtheria, tetanus, whole cell pertussis–Hib–HepB)</td>
<td>6 weeks</td>
<td>10 weeks</td>
<td>14 weeks</td>
</tr>
<tr>
<td>MCV</td>
<td>9 months</td>
<td>15 months</td>
<td></td>
</tr>
<tr>
<td>Td</td>
<td>Third and fourth month of pregnancy (irrespective of the parity)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>6 to 59 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.8 VPD surveillance

Oversight or preventive health care and integrated disease surveillance is conducted by the CHAEI at national and provincial levels. CHAEI has numerous sections including an information section that receives reports from the provinces, epidemiology section for outbreak investigations, microbiology and virology laboratories (polio, measles, influenza, and avian
influenza) and malaria, parasitology, food safety and other sections that support disease surveillance.

The disease surveillance assessment in 2008 revealed that all infectious diseases are considered for immediate notification in case of an outbreak. Regular data collection is based on immediate, weekly and monthly reports from ris/dongs to counties to the provinces and from the provinces to the central level. According to the national health authorities, case definitions are available at all levels.

In addition to national data reporting requirements, the Democratic People’s Republic of Korea reports surveillance data to the global VPD surveillance networks coordinated by WHO. In April 2006, using the existing communicable disease surveillance system, the Democratic People’s Republic of Korea began monthly reporting to WHO Regional Office for South-East Asia on the aggregate number of VPDs and AEFIs. In 2015, the country introduced case-based surveillance for measles and rubella and weekly reporting of measles case-based data including laboratory results. Also reported weekly are AFP cases and polio laboratory reports.

Prior to this, the National Measles and Rubella Laboratory (NMRL) had initiated monthly reporting of measles and rubella serology (immunoglobulin M [IgM]) results in 2005. Additionally, the MoPH conducts influenza-like illness (ILI) and severe acute respiratory infections (SARI) surveillance. There are 42 ILI sentinel sites and 12 SARI surveillance sentinel sites. WHO supports three sentinel sites with funds and logistics for conducting surveillance. The National Influenza Laboratory has been designated as a national influenza centre (NIC) by the Global Influenza Surveillance Response System (GISRS). The NIC reports laboratory data monthly to the global data-sharing platform of the GISRS.

4. Data collection

In this review, data collection was mainly done by visiting the selected central level institutions and institutions in the five selected provinces. The international review team consisted of nine team members, drawn from a variety of agencies including WHO (3), UNICEF (3), Gavi (2) and an independent consultant.
There was a total of four (one central and three provincial) teams. The three provincial teams visited selected institutions in the five selected provinces. Each had one or two international members accompanied by a national member and sub-national members. A meeting of the international review members was held on 1 July 2018 to discuss the final arrangements for the review.

On 2 July 2018, the team met WHO and UNICEF representatives and MoPH officials to discuss the review plan, methodology and tools. From 3 July 2018 onwards, the four groups started visiting the selected provinces and reviewing the EPI/VPD surveillance system in the country using the assessment guide developed.

National and provincial officials accompanied the teams to the respective provincial offices, met officials of the provincial health departments and visited the nearest hospital for the review of VPD surveillance.

In the mornings, the teams visited the hospitals to understand immunization service delivery and VPD surveillance. In the afternoons, the teams met selected provincial/ri/dong staff to review EPI implementation while the national team visited the CMW and CHAEI. In the afternoons, they also visited either the provincial or the county medical warehouses. At the medical warehouses, the teams met all the relevant officials from the province/county/ri.

### 4.1 Methods of data collection

The review teams used a number of methods to collect data and information:

- Desk reviews including reviewing EPI/VPD reports, surveillance data and immunization coverage data;
- Interviews with relevant stakeholders including health officials and health facility staff. Topics discussed included planning, implementation, the supervision and monitoring mechanism, feedback mechanism and capacity building initiatives;
- Data examination for data quality and consistency, where possible;
Visits to hospitals and hygienic and anti-epidemic institutions to assess immunization service delivery, VPD surveillance and related aspects;

Review of the roles of national advisory and oversight bodies, e.g. NITAG, National Verification Committee for the Elimination of Measles and Rubella/CRS Control (NVC) and National Certification Committee for Polio Eradication (NCCPE).

4.2 Selection of the provinces, counties, ris/dongs and institutions for site visits

The MoPH selected provinces/counties/ris/dongs and facilities for site visits in consultation with WHO and UNICEF Country Offices for the Democratic People’s Republic of Korea. One team focused on the city of Pyongyang and the central coordination of the EPI. During the central level visits, a few members representing the national committees were met but it was not possible to have discussions with all members of the respective committees.

The following provinces were visited:

- South Hamyong
- North Hwanghae
- Kangwon
- South Pyongan
- Nampo City (Nampo Province)

4.3 Tools for the review

In consultation with national officials of the MoPH, the team leader together with the core members of the review team had developed the checklists to review the required data at each facility visited. The list of required information was sent to each site prior to the expected visit. The tools were translated to the Korean language prior to the review.
5. Preparation of the review reports

Each review team prepared their feedback on key findings and observations from the review and visits to health facility and other institutions, as under:

➢ A short report (2–3 pages) summarizing the background, outlining successes and challenges and finishing with recommendations. The report was in line with the review objectives.

➢ A brief summary using 3–4 power point slides, similar in format to the review reports.

In addition, key designated technical experts in the review team were asked to provide a brief 1–2-page summary of the key recommendations for specific technical areas. This summary also followed the same formats as above.

A debriefing with the MoPH and WHO/UNICEF representatives was held on 9 July 2018 and the findings of the review and recommendations were presented.

6. Findings

The MoPH in the Democratic People’s Republic of Korea is responsible for the overall national health programmes, including immunization. The system of health management is based on centralized planning models. All health services are provided through a network of government health facilities at national, provincial, county and ri/dong levels. There is no private sector for delivery of health services. The country has a clear, programmatic vision for immunization services that is reflected in the cMYP 2016–2020, describing how to achieve GVAP and RVAP goals.

There is good ownership of the programme and an appropriate national focus on immunization with sufficient resources and infrastructure. Health staff was found to be committed and well trained, with relatively low turnover. There is access to all families and every child through household doctors with well-demarcated catchment areas consisting of approximately 130 households in each. This has facilitated provision of
near universal access for all people to benefit from all vaccines in the national schedule.

6.1 Reaching WHO South-East Asia Regional Vaccine Action Plan goals

6.1.1 Maintaining the polio free status

The Democratic People’s Republic of Korea has been maintaining its polio-free status since 1997 and is actively implementing the Polio Endgame of the Global Polio Endgame Initiative (GPEI), in alignment with Goal 3 of the RVAP 2016–2020.

The national and sub-national OPV coverage has been maintained at >98% in 2017. A single dose of IPV at 14 weeks of life along with the third dose of pentavalent vaccine was introduced into the national vaccination schedule in May 2015.\(^4\)

The IPV introduction was followed by switching over from trivalent OPV (tOPV) to bOPV (Sabin Type 1+3) in April 2016. Due to the global IPV shortage, the vaccination could not be given for two birth cohorts.

As in June 2018, the annualized national level coverage for bOPV was 98.5%, with variance at the county level of 94% to 100%. In May 2018, IPV was re-introduced with a plan for covering missed cohorts in 2019.

The country continues active AFP surveillance with high implementation coverage and also zero reporting from 7954 sites in the country, achieving high completeness (>98%) and timeliness (>98%). From 2001 to 2014, the non-polio AFP rate reached the operational target of 2/100 000 children under 15 years of age. Since then there has been a slight reduction in 2015, 2016 and 2017 (1.72, 1.83 and 1.59 per 100 000, respectively) but rates still meet the certification standard. It was reported at the time of the review that for the year 2018 (up to the end of June 2018) the annualized non-polio AFP rate had reached 2/100 000 children under 15 years of age. However, the non-polio AFP rates calculated for the provinces were not available to the review team at the time of the review. All AFP cases reported in 2016-2017 were found to be fully immunized with OPV.\(^15\)
Adequate stool samples had been collected from all AFP cases up to 2015 (100%), with figures in 2016 and 2017 at 98% and 97%, respectively. AFP surveillance has been supplemented by collection and testing of stool samples from contacts of AFP cases. No wild poliovirus and vaccine derived poliovirus (VDPV) has been detected in active AFP and supplemental polio surveillance activities.15

Laboratory testing of polioviruses is only undertaken at the National Polio Laboratory (NPL). In 2017, 95% primary culture reports were issued within 14 days and the non-polio enterovirus isolation rate was 14%. The laboratory reported that in some provinces, specimen transportation had been delayed, specifically during the rainy season and in winter. The list of laboratory supplies required has been identified and submitted for procurement through WHO as a part of the 2018 procurement plan. Once the supplies reach the NPL, refresher training will be arranged and accreditation pursued.

The Democratic People’s Republic of Korea completed Phase 1 poliovirus laboratory containment under the previous Global Action Plan Second Edition (GAPII) prior to Regional certification in March 2014. This had the involvement of the MoPH, Ministry of Agriculture, Ministry of Armed Forces, Ministry of Environmental Protection, Ministry of Public Security, the National Academy and its Biological Academy and the Veterinary Institute of the Agricultural Academy. There is currently no private laboratory sector in the country. The GAPII survey included a total of 801 biomedical laboratories but none were identified with wild poliovirus and/or VDPV infectious or potentially infectious materials.15

Stool specimens, environmental specimens and Sabin2 type viruses for laboratory diagnosis collected at the time of tOPV use were autoclaved and incinerated and all the processes were documented with the WHO field survey mission in April 2016. As such, there is no laboratory that keeps Sabin type 2 infectious and potentially infectious materials in the country. The current requirements of the WHO Global Action Plan to minimize poliovirus facility-associated risk (GAPIII) are being met.

The national outbreak preparedness and response plan has yet to be updated incorporating the latest standard operating procedures (SOPs) of the GPEI and fulfilling other global requirements.
6.1.2 Elimination of maternal and neonatal tetanus

Due to its strong immunization programme and high rates of institutional delivery rates in urban and rural areas, it has been assumed that the Democratic People’s Republic of Korea achieved MNTE before 2000 when the WHO validation process began. Following validation of MNTE in the whole WHO South-East Asia (SEA) Region in May 2016, the WHO Regional Director presented recognition to all Member States at the Regional Committee Meeting held in Colombo, Sri Lanka in September 2016.

The Democratic People’s Republic of Korea has maintained a very high antenatal care (ANC) coverage of 93.9% pregnant women attending ANC services four times during pregnancy, and 6.1% of mothers visiting ANC services one to three times during 2017. The institutional delivery rate in 2017 was 90.1% and the skilled birth attendance was 100%. From 2007 to 2017, the TT2+ coverage has been in the range of 96.5–98.7%.

In the country’s continued efforts to maintain MNTE, the current WHO position on tetanus vaccines provides opportunities to review the current immunization schedule, identify gaps and consider revisions of the national schedule to optimize protection against tetanus for both genders in a life-cycle approach.

WHO recommends a 3-dose primary vaccination series with Td followed by three booster doses. The 3-dose primary series should begin as early as 6 weeks of age, with subsequent doses given with a minimum interval of 4 weeks between doses. The three booster doses should preferably be given during the second year of life (12–23 months), at 4–7 years, and at 9-15 years of age. Ideally, there should be at least 4 years between booster doses.16

There are currently no booster doses given after the primary dose series. All pregnant mothers receive two doses of Td during the third and fourth month of pregnancy irrespective of their parity. There are plans to introduce tetanus toxoid containing vaccine (TTCV) booster doses once local production is available.
6.1.3 Elimination of measles and control of rubella and CRS

Since 1966, the Democratic People’s Republic of Korea has been immunizing children and adults against measles with a domestic measles vaccine. A WHO prequalified vaccine was introduced as MCV1 in the national immunization schedule in 1997. The Government declared a measles outbreak in 35 out of 205 counties on 16 February 2007. In response to the outbreak, a nationwide SIA was launched in two phases covering a total target population of 16,123,376 in the age group of 6 months to 45 years. The reported coverage was 99%.

Subsequently, in 2008, the Democratic People’s Republic of Korea introduced MCV2 in addition to the existing MCV1 in the national immunization schedule at the age of 15 months. Introduction of MCV1, a wide age range SIA reaching a coverage of around 99%, subsequent introduction of MCV2 and both MCV1 and MCV2 doses achieving a near universal coverage have all contributed to building a high population immunity against measles infection in the country.\(^6\)

UNICEF, taking the lead along with WHO, supported a joint national and international CES using the WHO recommended new methodology in 2017. The CES reported that the estimate for MCV1 and MCV2 based on health facility records were 99.2% (95% confidence interval [CI] \(<\pm1\%\)) and 97.9% (95% CI 96–98.6%). The success of the strategies used has been demonstrated by the report of the last indigenous transmission of measles infection having been reported in 2007, with no cases thereafter.\(^5\)

In the first half of 2018, all provinces reported an annualized MCV2 coverage of \(>97.3\%\). The country has applied for Gavi support for MR introduction in October 2019, which will be preceded by an MR SIA for children from 9 months to under 15 years of age. Subsequently, the MR vaccine will replace measles vaccine in the immunization schedule.

The national MCV1 and MCV2 coverage from 1980 to 2016 is given in Fig. 2.
With MR introduction still to come into the EPI, it is assumed that population immunity levels for rubella, contrary to that for measles, are very low. The proportion of the population immune to rubella has predominantly acquired through natural rubella infections. In 2016, the MoPH conducted a SIA with MR in collaboration with the German Caritas Association (Caritas) targeting a population of 3 million (SIA coverage figures not available); this population may have achieved higher immunity to rubella depending on the coverage and the vaccine effectiveness. However, a significant child and adolescent population and an absolute majority among women in the childbearing age group (15–49 years) are susceptible to rubella infections. The latter group is at the highest risk of having babies born with CRS.

Laboratory confirmed rubella cases and MR SIA coverage for various years is given in Fig. 3.
Fig. 3: Laboratory confirmed rubella cases reported from 2002 to 2016 and MR SIA coverage of 2015 – 2016 reaching 99.8%

Measles and rubella surveillance was established in the Democratic People’s Republic of Korea in 2006 using 7954 sites spread over the entire country. CRS surveillance was introduced in 2015 in 222 sites at provincial and county levels. Up to 2017, the clinical case definition for measles for collection of samples for laboratory investigations was: “any person in whom a clinician suspects measles infection, or any person with fever and maculopapular rash (i.e. non-vesicular) and cough, coryza (i.e. runny nose) or conjunctivitis (i.e. red eyes)” or for suspected rubella (when fever, maculopapular rash and cervical, suboccipital or postauricular adenopathy or arthralgia/arthritis are diagnosed) was used. This is contrary to the elimination level surveillance standards recommended by WHO Regional Office for South-East Asia (SEARO) in alignment with the verifying framework of the measles elimination phase.6

The last laboratory confirmed rubella case was reported in 2012. Fig. 3 indicates that there were around 500 laboratory confirmed rubella cases reported each year from 2002 to 2004. Since then there was a decrease in numbers of laboratory confirmed cases until 2012. Beyond 2012 there have been no laboratory confirmed rubella cases. However, these data have to be interpreted with limitations in the sensitivity of integrated measles and rubella surveillance as indicated by the low non-measles and none-rubella discarded rate.6
Although no rubella cases have been reported since 2012, the CRS incidence in the Democratic People’s Republic of Korea has gone up slightly from 30 suspected CRS cases in 2016 (in a cohort of 342,884 live births in 2016) to 33 in 2017. The above surveillance data too are a proxy indicator of susceptibility of pregnant women to rubella. These reported cases are consistent with the numbers of CRS cases derived based on the expected rate of suspected CRS cases in the country, which is >1 per 10,000 live births as reported by the NVC report, Democratic People’s Republic of Korea for 2016. The above reported suspected CRS cases are an underestimate, given that CRS surveillance is limited to the provincial and country level hospitals. They are syndromic as not all suspected cases are subject to serological investigations.

Surveillance performance indicators are given in Tables 2 and 3.

Table 2: Surveillance performance indicators for measles and rubella, 2012–2016 reported by the MoPH as per respectively existing surveillance standards
Table 3: *Measles and rubella surveillance performance indicators in 2015 – 2017 when elimination level standards are applied* *

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>suspected cases with fever and rash</td>
<td>504</td>
<td>511</td>
<td>505</td>
</tr>
<tr>
<td># suspected cases with serum sample collected</td>
<td>132</td>
<td>73</td>
<td>106</td>
</tr>
<tr>
<td>% suspected cases with serological testing</td>
<td>26%</td>
<td>14%</td>
<td>21%</td>
</tr>
<tr>
<td>% serum sample received in laboratory within 5 days of sample collection</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>% serum sample with serology result within 4 days of sample receipt in the laboratory</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Discarded non measles non-rubella rate per 100,000 population</td>
<td>2.07</td>
<td>2.10</td>
<td>2.08</td>
</tr>
<tr>
<td>% provinces meeting discard rate of 2 or more per 100,000 population</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
</tr>
</tbody>
</table>

* Performance indicators were calculated by the mission members of the Regional Verification Commission (RVC) during their visit to the Democratic People’s Republic of Korea in January 2018 using available data and having applied elimination level measles–rubella standards in line with the verifying framework of measles elimination.

In 2017, a total of 505 suspected measles/rubella cases were reported, of which 106 blood specimens were tested but none tested positive for measles or rubella. In the first half of 2018, a total of 259 fever and rash cases were reported with blood specimens taken from all and tested as recommended by the RVC. None tested positive.

However, this is almost equal to the total number of measles and rubella cases separately reported in 2017 and it creates some doubt as to whether the hygienic and anti-epidemic doctors use the current case definition of “fever and maculopapular rash” or, as previously, apply the separate case definitions for measles and rubella cases but taking the blood samples from all. The case reporting, sample collection and laboratory testing for all suspected measles and rubella cases met all required timelines in 2017. However, the sub-national discard rates for non-measles and non-rubella cases were not available at the national level.

The provinces reported having switched to fever and rash surveillance based on the recommendation of the RVC mission in January 2018 and as
per the new five-year national strategic plan on measles elimination and rubella/congenital rubella syndrome control (2018-2022). Measles–rubella surveillance indicators were up to date and exceeded targets of the non-measles and non-rubella discard rate (2/100,000 population). However, CRS surveillance indicators were not available and staff had further guidance requirements on sample collection from contacts and healthy children.

### 6.1.4 National Measles and Rubella Laboratory

The NMRL in Pyongyang is part of the global and SEA regional measles and rubella laboratory networks and is accredited by WHO. The last accreditation was performed in 2016. The NMRL participates annually in the external quality assurance system (EQAS) conducted by WHO. In 2017, the NMRL scored 100% in the EQAS proficiency test. A major challenge for the NMRL is the shortage of test kits to perform serological tests for all suspected fever and rash cases when the switchover is made to elimination-level fever and rash surveillance with 100% serological investigations.

Performance of the NMRL for 2012–2016 is given in Table 4.

### Table 4: Performance of laboratory surveillance, 2012–2016

![Table 4](image)

### 6.1.5 Accelerating hepatitis B control

The goal of hepatitis B immunization in the Democratic People’s Republic of Korea is to reduce the prevalence of chronic hepatitis B virus (HBV) infection among children born after vaccine introduction and is measured by the prevalence of hepatitis B surface antigen (HBsAg).
RVAP 2016–2020 explicitly includes accelerated control of hepatitis B as one of its goals. Key strategies include sustained high coverage with the third dose of hepatitis B vaccine (HepB3) at national and district levels, birth dose introduction, catch-up immunization for children and vaccination for high-risk adults. In 2016, the Regional Immunization Technical Advisory Group (ITAG) recommended reducing the prevalence of chronic hepatitis B among children 5 years of age to ≤1% by 2020 as target of hepatitis B control through immunization. This is in line with morbidity reduction targets in the Global Health Sector Strategy on Viral Hepatitis (GHSSVH), 2016–2021 (endorsed by the World Health Assembly) and the Regional Action Plan for Viral Hepatitis in South-East Asia 2016–2021 (endorsed by the Regional Committee Meeting of WHO Regional Office for South-East Asia).

Several studies using convenience samples suggest that HBV infection is highly endemic in the Democratic People’s Republic of Korea. The National Hepatitis B Prevention Institute Strategic Work Plan (2009–2013) suggested the prevalence of chronic hepatitis B to be 12%. The National Hepatitis Programme has been set up and expanded to 210 counties and over 4000 ris/dongs as of 2017. The system consists of hepatitis preventive institutes at national, provincial and county levels where hepatitis B laboratory diagnosis and treatment are provided. Suspected cases of hepatitis are referred to county hepatitis preventive institutes for testing by ri/dong clinics and hospitals.

6.1.6 Hepatitis B immunization

Hepatitis B vaccine, including the birth dose, was introduced nationwide in 2003. This was replaced by tetravalent vaccine (DTP–HepB) in 2006 and by pentavalent vaccine in 2012, with high immunization coverage being sustained (Fig. 4). The coverage of the hepatitis B birth dose (HepB-BD) has been over 97% since 2008 and the HepB3 coverage has been over 93% since 2009. In 2016, all 210 counties reported HepB3 coverage of over 95%. A national catch-up immunization targeting children born between 1994 and 2004 was carried out during 2010–2012 by the MoPH with support from Caritas. The MoPH reported that 99.2% children in the eligible age group had received three doses of HepB.
As many countries (including the Democratic People’s Republic of Korea) do not have sero prevalence data of HBV infections, especially not on a nationally representative scale, WHO commissioned the London School of Hygiene & Tropical Medicine (LSHTM) to generate estimates of the prevalence and incidence of HBV infection. LSHTM investigators conducted a systematic review of all biomarker surveys that estimate the prevalence of HBsAg in the general population before implementation of vaccination, and in children under-5 years of age after vaccination.

To generate estimates in countries and territories without empirical data, modellers extrapolated the available data using mathematical models on the basis of geographical proximity to countries that had data, and income levels. In the absence of better data, the prevalence of HBsAg among children under-5 years of age was used as a surrogate indicator of the cumulative incidence of chronic HBV infection at 5 years of age. This represents a slight variation from the core indicator of the monitoring and evaluation framework of the GHSSVH on viral hepatitis.17

The United States Centers for Disease Control and Prevention (CDC) also examined the hepatitis B vaccination data from 1992 to 2015 in the SEA Region, reviewed the literature on chronic HBV infections of pre- and post-vaccine introduction periods, focused on studies among children and young adults and used the Goldstein model to estimate the total number of chronic HBV infections, i.e. percentage of persons HBsAg positive in
countries lacking nationally representative sero-surveys after nationwide HepB introduction. Results of the modelling are given in Fig. 5 and suggest that HBsAg prevalence in the Democratic People’s Republic of Korea has been significantly reduced in vaccinated children.

**Fig. 5: Modelling results of HBsAg estimates in SEA countries including the Democratic People’s Republic of Korea**

![Bar chart showing HBsAg estimates](chart.png)

It is evident that the Democratic People’s Republic of Korea has maintained high coverage with the HepB-BD since its introduction. Administering the HepB-BD was further strengthened in 2015 by supplying a total of 1000 SDD refrigerators to level hospitals. The national CES conducted in 2017 found HepB-BD and HepB3 coverage to be 98.2% and 97%, respectively among 12–23 month-old infants.

As per the national immunization schedule, the HepB-BD has to be given to all neonates within the first 24 hours of delivery. The Pyongyang Maternity Hospital where approximately 20 000 births occur every year implements a protocol to provide HepB-BD vaccination within 2 hours after birth.
A nationwide SIA has been done in 2010–2011 with three doses of HepB targeting children 6–17 years of age. Currently, the MoPH is discussing with WHO on the initiation of a special project to vaccinate health-care workers with HepB, considering them as a high-risk group. A nationally representative HBsAg sero-survey among children born after vaccine introduction is planned for 2019 with technical assistance from WHO with a view to assessing Democratic People’s Republic of Korea reaching the regional hepatitis B control target.

6.1.7 Accelerating JE control

The southern areas of the country, where malaria is prevalent, are considered to be at risk for JE; this includes South Hwanghae, North Hwanghae, Kangwon, Nampo City, South Pyongan and the southern part of South Hamgyong. Locally produced JE vaccine is being given to children in high-risk areas at 12 months of age since the past several years, and the reported coverage is 95%. SIAs with JE vaccine have been conducted in these areas in 2009–2010 and again with support from Caritas in 2014 for the age groups of 12–23 months and 4–6 years, covering a population of 1.5 million and achieving 99.5% coverage.

Since 2009, only a few suspect JE cases have been reported every year and there have been no reports of JE cases in the last 3 years. JE has been included as a target disease for surveillance in the national VPD surveillance programme. However, it is still not integrated with the WHO AES/JE surveillance network.

6.2 Review of immunization system components

6.2.1 Immunization coverage

In the five provinces visited by the review teams, routine vaccine coverage was all reported as over 95% by antigen in the past 5 years based on the national immunization schedules (except for IPV). IPV was introduced in April 2015 but interrupted from May 2016 onwards due to the global vaccine supply shortage. The vaccine was re-introduced in May/June 2018 and it is planned to also immunize missed birth cohorts in 2019.
In the 2017 CES, immunization coverage with documented valid doses given prior to 12 months of age was >90% for all provinces except South Pyongan (89.1%, 95% CI 81.1–94%) and Kangwon (78.2%, 95% CI .1–86.9%). Coverage for valid, documented doses given before 12 months of age was significantly higher than the national coverage (92.5%, 95% CI 90.6–94%) in South Hwanghae (99.2%, 95% CI 94–99.9%) and significantly lower in Kangwon Province (78.2%, 95% CI 66.1–86.0%).

National reported vaccination coverage for the period 2007–2017 is given in Table 5. National vaccination coverage of valid doses of vaccines administrated by 12 months of age, based on health facility records is given in Table 6.

Table 5: Reported vaccination coverage (in percentage), 2007–2017

<table>
<thead>
<tr>
<th>Year</th>
<th>BCG</th>
<th>Penta1</th>
<th>Penta3</th>
<th>HepB-BD</th>
<th>IPV</th>
<th>MCV1</th>
<th>MCV2</th>
<th>OPV3</th>
<th>TTCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>96</td>
<td>93</td>
<td>92</td>
<td>97</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>97</td>
</tr>
<tr>
<td>2008</td>
<td>97</td>
<td>93</td>
<td>92</td>
<td>97</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>96</td>
</tr>
<tr>
<td>2009</td>
<td>98</td>
<td>94</td>
<td>93</td>
<td>99</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>98</td>
<td>97</td>
</tr>
<tr>
<td>2010</td>
<td>98</td>
<td>94</td>
<td>93</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>98</td>
</tr>
<tr>
<td>2011</td>
<td>98</td>
<td>95</td>
<td>94</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>2012</td>
<td>98</td>
<td>97</td>
<td>96</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>2013</td>
<td>98</td>
<td>94</td>
<td>93</td>
<td>99</td>
<td>99</td>
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<td>99</td>
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<tr>
<td>2014</td>
<td>98</td>
<td>94</td>
<td>93</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
<td>99</td>
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<tr>
<td>2015</td>
<td>97</td>
<td>97</td>
<td>96</td>
<td>97</td>
<td>99</td>
<td>98</td>
<td>97</td>
<td>99</td>
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<tr>
<td>2016</td>
<td>97</td>
<td>97</td>
<td>96</td>
<td>98</td>
<td>25</td>
<td>99</td>
<td>98</td>
<td>99</td>
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<tr>
<td>2017</td>
<td>98</td>
<td>98</td>
<td>97</td>
<td>98</td>
<td>25</td>
<td>99</td>
<td>98</td>
<td>99</td>
<td>98</td>
</tr>
</tbody>
</table>

Source: WHO and UNICEF estimates of national immunization coverage, May 2018 revision (draft)
# Country official estimates
Table 6: National vaccination coverage – valid doses, vaccinated by 12 months of age, based on health facility records

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Coverage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>97.2</td>
</tr>
<tr>
<td>Q2</td>
<td>98.2</td>
</tr>
<tr>
<td>Q3</td>
<td>99.8</td>
</tr>
<tr>
<td>Q4</td>
<td>99.8</td>
</tr>
<tr>
<td>Q1</td>
<td>99.1</td>
</tr>
<tr>
<td>Q2</td>
<td>72.1</td>
</tr>
<tr>
<td>Q3</td>
<td>98.6</td>
</tr>
<tr>
<td>Q4</td>
<td>98.6</td>
</tr>
<tr>
<td>Q1</td>
<td>97</td>
</tr>
<tr>
<td>Q2</td>
<td>99</td>
</tr>
</tbody>
</table>

Source: CES 2017

6.2.2 Vaccine supply, cold chain and logistics

Vaccines and supply chain logistics are managed through a network of central, provincial and county medical warehouses with dedicated staff. There were no major vaccine supply, cold chain or logistic issues detected during the visit to the CMW in Pyongyang or to the respective provincial and county medical warehouses and ri hospitals. The CMW receives vaccine shipments twice a year, which are distributed to the provincial level quarterly.

The vaccine forecasting performed at the national level is effective and meets the annual demands of the country. MoPH facilitates the customs clearing processes for incoming vaccines shipped by UNICEF. There was no evidence of any stock-outs at any of the levels visited in the recent past except for IPV, which had global supply constraints.

Vaccine stock levels are given in Table 7.
Table 7: Vaccine stock levels at the end of June 2018

<table>
<thead>
<tr>
<th>Item</th>
<th>Vial size</th>
<th>Balance of last month</th>
<th>Received during this month</th>
<th>Out during this month</th>
<th>Present stock as of last day of the month</th>
<th>Required for the second quarter</th>
<th>Required for the third quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 BCG</td>
<td>20 d</td>
<td>106 500</td>
<td>17 260</td>
<td>89 240</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 HepB</td>
<td>1 d</td>
<td>594 150</td>
<td>160 000</td>
<td>91 180</td>
<td>862 970</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 bOPV</td>
<td>10 d</td>
<td>216 260</td>
<td>30 300</td>
<td>185 960</td>
<td>35 000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 IPV</td>
<td>5 d</td>
<td>9420</td>
<td>9420</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 MCV</td>
<td>10 d</td>
<td>118 320</td>
<td>24 300</td>
<td>94 020</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Td</td>
<td>10 d</td>
<td>128 464</td>
<td>21 528</td>
<td>106 936</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 DTP- Hep B +Hib</td>
<td>1 d</td>
<td>228 430</td>
<td>225 700</td>
<td>229 930</td>
<td>224 200</td>
<td>400 000</td>
<td></td>
</tr>
</tbody>
</table>

D – dose/s
Source: Central Medical Warehouse, Pyongyang, July 2018

The CMW has sufficient cold-chain capacity for all vaccines currently in use in the national EPI schedule. A national cold-chain inventory has been prepared in 2015 and is being updated bi-annually. The 2016 PIE for pentavalent vaccine and IPV confirmed that the country has a well-functioning cold-chain system. The CMW has four 40 m$^3$ cold rooms and two 20 m$^3$ cold rooms, all of which are functioning well. However, the country may need to increase the central and provincial level cold chain storage capacity, if decisions will be taken to introduce any more new or under-utilized vaccines. This need was highlighted during the visit to the central medical warehouse in Pyongyang.

There is a plan to replace the two 20 m$^3$ cold rooms currently in the CMW with two 40m$^3$ cold rooms soon and shift the two 20 m$^3$ cold rooms to the provincial level. There are 600 SDD refrigerators expected through UNICEF with Gavi support, waiting for the exemption certificate from the United Nations (UN) Sanctions Committee.
At the CMW, temperature monitoring is carried out using Multilog-2 (currently not utilizing the automatic SMS function) and supported by the use of FT-2. This could be made more beneficial if an automatic SIM card function were introduced and could become an effective way to inform the cold-chain technicians in a timely manner with an alarm system by way of an SMS. The provincial and lower levels were found to have an extremely effective temperature monitoring process during the review. Both electronic and manual temperature monitoring systems are used at lower levels as a precautionary step.

The CMW has a generator to cater to an electricity failure; however, it is manually operated and there is a person in-charge to look after the system providing a 24 hours service. The medical warehouses at all levels visited in the five provinces had voltage stabilizers and back-up electric generators which could be used during grid electricity failures encountered that are beyond the control of MoPH. Frequent interruption of electricity was a common finding at the county and ri levels visited by the review teams.

With Gavi support through its HSS funds, the vaccine distribution system is being strengthened through the provision of new cold-chain equipment and vehicles at all levels. This is expected to help improve the low score attributed to the “distribution” component (E7) in the EVM assessment conducted in 2015.

A national waste management plan and guidelines have been developed, and during the time of the review, the provincial level training was ongoing. Sharp wastes are temporarily placed in safety boxes. Filled safety boxes are disposed through incineration at facilities where incinerators are available.

The CMW is developing a logistic management information system (LMIS); the software has already been developed under the Gavi performance-based funding (PBF) support and a database is currently being prepared. An external consultant is being hired to review/update the guidelines, SOPs and tools and to build the capacity of relevant staff in managing it. The hardware procurement is being done through WHO with Gavi HSS support. At the CMW premises, a tent is used for dry storage; a move to a permanent structure is planned under the next tranche of Gavi PBF support.
The PMWs maintain sufficient vaccine supply for 3 months, with vaccine shipments received quarterly from the CMW. PMWs make use of 10 m³ cold rooms with generators and voltage regulators. The cold rooms are monitored with both Multi-log 2 and FT-2. All logs confirmed temperature management within the correct range for the past 60 days (at the time of the review), with no alarms. Vaccines from the provincial stores are transported to the county medical warehouses using a 5-ton refrigerated truck.

The county medical warehouses maintain enough supply for 3 months, with vaccine shipments received quarterly from the PMW. County medical warehouses make use of SDD refrigerators for storing vaccines and use cold boxes for transportation. Vaccines are transported using a combination of motorbikes and tricycles/minivans. SDD refrigerators, installed by the provincial technicians, have been well maintained with FT-2 tags and manual records confirming that the required temperature is maintained, with no alarms during the past 60 days (at the time of the review). The SDD refrigerators were clean and dry with vaccines packed appropriately according to heat/freezing sensitivity levels.

The ri level receives monthly shipments of vaccines from the county medical warehouse on the day prior to the established immunization day. The volume shipped is based on the monthly plan prepared by the immunization doctor in consultation with the household doctors.

Vaccines are not stored at the ri level during the period outside of the established immunization day. Unused vaccines are returned to the county medical warehouses for storage. The ri hospital maintains a SDD refrigerator which was well-managed, clean, dry and FT-2 logs confirmed that temperature was maintained within the correct range for the past 60 days.

6.2.3 Cold-chain management

All teams reported that vaccines were well stored in warehouses, electric refrigerators and SDD refrigerators, adhering to the proper storage principles and bundling of vaccines with injection supplies. All vaccine vial monitors (VVMs) inspected were good and vaccines were in usable stages. No vaccine freezing issues or any expired vaccines stored in the cold rooms or refrigerators were observed.
A FT2 device was being used in each refrigerator checked during the field visits. However, due to the inadequacy of computers (even at county level), its values (e.g. continuous temperature records) may not be yet fully realized through regularly checked electronic records of continuous temperature monitoring through computers. The value of VVMs and the shake-test was understood at all levels.

In addition, there have been some gaps in the adequacy of the cold chain and further equipment are needed at some places. These are partially being addressed through UNICEF procurement, which is underway. Re-analysis of the cold-chain inventory is required to identify further unmet needs at all levels.

It has been identified that lack of adequate heating during the harsh winter could be an issue, due to two reasons:

- At the ri level, heating of the immunization rooms in winter is critical for both preservation of vaccines and the health of infants. The ri clinics reported that temperatures may drop to \(-15^\circ\) C and electricity supply in winter can be as limited as 2–4 hours in a day. Currently, coal heaters are being used, but coal supply is an issue in winter and the burning of coal is not ideal in a closed environment.
- Heating is also critical for the vaccine storage areas at the county medical warehouses.

Heating needs are progressively being addressed through WHO procurement, initially of 300 heaters, although delivery is delayed while obtaining the UN Sanctions Committee clearance.

Transport was also identified as an issue at all levels, with a need for additional trucks for the provincial warehouses, motorbikes/tricycles at the county level and motorbikes at the ri level.

### 6.2.4 Immunization service delivery

The immunization programme is effectively organized, managed and guided by relevant national policies and protocols. Immunization services in the Democratic People’s Republic of Korea are provided through a network of government health facilities at national, provincial, county and ri/dong
levels. Front-line immunization services are provided through health facilities at ri/dong clinics. Immunization services are provided on a “fixed day, fixed-site” basis. There is no outreach approach to service delivery. Vaccination takes place using a “one day per month” schedule simultaneously in the provinces, with another 1–2 days added for vaccinating defaulters.

In recent years, with the funding support through Gavi HSS grants, the cold-chain systems in the country have been extended to ri level hospitals with SDD refrigerators installed in them. This has led to increased level of quality assurance in provision of immunization services. During field visits, the review teams observed that where available, SDD refrigerators are being put to good use and carefully maintained at both county and ri levels, with both continuous temperature monitoring (through Fridge-tag 2) and temperature motoring sheets (checking and recording temperature twice per day) in place.

An extensive household doctor network serves as a strong foundation for the public health system. This was seen in every province visited and plays a significant role in guaranteeing universally high coverage of vaccination. Household doctors, who effectively connect communities and public health systems, are responsible for identifying and registering pregnant women and new births, informing communities and families of scheduled health services including vaccination, following up on any vaccination defaulters, and timely detecting and reporting of communicable diseases including VDPs.

Teams also observed that the programme is efficiently managed with clear roles and responsibilities, chains of command and flows of information sharing and communications. The frontline health workers and communities/families are informed of the importance of vaccinations and actions needed from each to ensure timely and complete vaccination for children.

Filled immunization cards and monthly immunization data reports were observed in all health facilities visited (self-made monthly report seen in one health facility); the teams noted that different health facilities appear to apply different formats of immunization registers.
In the Pyongyang Maternity Hospital, where 20,000 births are delivered annually, it was impressive for the review team to observe well-equipped obstetric wards, special care units for premature babies and vaccination units. The HepB-BD is provided within 2 hours of birth and BCG is provided on the second day after birth. The hospital submits vaccination data to the CHAEI monthly.

Regular structured and cascaded training including training of trainers (ToTs) for the county level (mid-level) is conducted at the provincial level by the national EPI staff. A similar type of training is being carried out by the provincial staff at county level. Regular, ongoing and monthly orientation of EPI staff at ri level is conducted. This opportunity has been well used to provide staff with refresher training on key immunization-related topics every month at all levels. This platform is being used to orient new staff that is not exposed to cascading training provided earlier on different subjects. Similarly, the CMW staff conducts training for cold-chain technicians on cold room and SDD refrigerator installation and maintenance of cold-chain equipment, including the use of FT-2 and multi-log 2 at the national level followed by other levels.

Supervisory visits are done by the provincial staff to the county level quarterly, and review meetings are conducted at the county level for the ri level staff monthly. However, a standard or tailored checklist for supervision is not being used. An evaluation of county performance is conducted by the provincial level staff quarterly, while the county evaluates ri doctor skills and knowledge every 2 months.

Provincial and county plans are in place for the MR campaign and IPV catch up for two missed cohorts through the routine programme.

**6.2.5 AEFI surveillance**

Cases are documented in an AEFI register recording vaccination, type of reaction, temperature, treatment and outcome. Cases are monitored in the AEFI room until released or transferred to the county hospital. Cases are reported by phone to the county level and a list is provided monthly to the county HAES. There was an apparent lack of standardized recording and reporting of AEFI. All levels would benefit from standard registers for recording all aspects of AEFI identification and follow up. In all provinces visited, the teams from the health bureaus and HAESs emphasized that AEFI
surveillance is one of the challenges they face. This is largely due to lack of communication tools/devices for rapid communications when immediate response and obtaining guidance from the higher level for immediate action is needed.

6.2.6 Waste management

Waste from immunization sessions at the ri level is stored in safety boxes and returned, along with unused vaccines, for disposal at the county level. In the districts that were under review at the county level, one hospital had an incinerator, while another one had a homemade incinerator that has been constructed by the hospital workers. A review of waste management practices at all levels, in accordance with current waste management guidelines, would be useful in recommending a uniform system of disposal of immunization waste in all districts.

6.2.7 Record keeping/immunization cards

Record keeping is robust at all levels. At the ri level, one ri used a printed register and another used a hand-drawn register; however, the same information was recorded in a standard format. The administrative coverage data is submitted monthly in a timely manner from ri to country, county to province and province to the central level.

6.2.8 Adequacy of human resources

No significant gaps in human resources were identified; however, turnover is an issue among vaccinators. Most vaccinators work for 2 to 3 years after graduation, and then some leave due to marriage, pregnancy or other reasons. This highlights the importance of regular training, supportive supervision and performance evaluation.

6.2.9 Existence of micro-plans

Micro-plans were in evidence at both ris. These are prepared by the immunization doctor, based on information from household doctors. The plan is reviewed each month with the county staff prior to the monthly immunization day.
6.2.10 Adequacy of communication strategies and behaviour change communication (BCC)

The human resource capacity appears to be adequate and knowledgeable to perform the different communication strategies.

A range of information, education and communication (IEC) materials were displayed at clinics/hospitals in the immunization room and other areas. Household doctors also maintain laminated information cards on immunization for educating parents about each vaccine during immunization days. IEC materials were also apparent in the obstetrics department of county hospitals.

6.2.11 VPD surveillance

The surveillance indicators of AFP and measles and rubella detection reflect the level of sensitivity of the current VPD surveillance system of the Democratic People’s Republic of Korea in detecting outbreaks or clustering of cases. The epidemiological and laboratory data generated in the influenza outbreak and response launched to it at the beginning of 2018 could be considered as a proxy measure of the ability of the system to detect and respond to any VPD outbreak.

The functioning of the VPD surveillance system could be further verified by its ability to detect communicable diseases by household doctors in their field activities and the epidemic response by the hygienic and anti-epidemic doctors at different levels.

The five-year national strategic plan on measles elimination and rubella/CRS control plan was updated in February 2018 and entails shifting the reporting of suspected cases of measles and rubella to cases of “fever and rash” to enable reaching the surveillance standards of verification of measles elimination. The case definition was broad and used as “fever with a maculopapular rash”. However, a specific outbreak preparedness plan is yet to be developed.
6.3 Surveillance at province, county and ri/dong levels

During the interactions with the officers from the provincial and county level and visits to relevant institutions in the five provinces, the review teams observed a high level of performance of the VPD surveillance system across different levels. These include both passive and active surveillance, targeting AFP, acute fever and rash (AFR), neonatal tetanus, pertussis and diphtheria. The staff is aware of the need for reporting VPDs, and any communicable disease will have to be notified within 72 hours of detection. WHO standard definitions for AFP and AFR were in use.

The teams saw well-kept records for zero reporting and active surveillance over the years. Overall, there is good understanding of AFP surveillance, including case definition and steps required to be undertaken once an AFP case is detected. While AFR surveillance has been adapted into VPD surveillance, the rationale as a surveillance sensitivity indicator is not yet fully understood across all levels.

From the discussions, the review team has learnt that there is close coordination between the epidemiologists from relevant HAESs and hospitals (through a disease control and prevention unit, which coordinates relevant departments) for disease notification and case investigation and follow up. Laboratory results of suspected cases of concern, e.g. AFP and AFR, are fed back to county and ri levels based on national surveillance guidelines. There are rapid response teams in place, not only in HAESs, but also in hospitals (composed of a team of multi-disciplinary experts, which includes laboratory expertise) at provincial and county levels. In provinces visited, no VPD outbreaks have been reported in recent years except in South Hamyong province where an influenza outbreak occurred. One of the key challenges highlighted during the discussions was to ensure regular supplies for specimen collection for AFP and AFR cases.

The provincial health bureaus and the county health departments provide the administrative guidance in operating the different functions by diverse categories of staff at various levels. The staff at the provincial and county HAESs provide the technical support to the field staff for detection, investigation and reporting of VPDs and liaise with the central level staff. The provincial laboratory provides the guidance on provincial laboratory requirements and liaises with the national laboratory for technical guidance.
in terms of ensuring standards of collection, transportation of samples and their quality assurance.

The following challenges were observed:

➢ Human resource capacity at the county HAES for epidemiological investigations is inadequate.
➢ Facilities for computerized data management are not available at HAESs at the county and ri levels. As a result, data analysis at the ground level and display of surveillance data visually does not occur.
➢ Transport facilities for sample collection and dispatching them to the next level and logistics support for sample collection is reported to be inadequate.
➢ As there are no frequent outbreaks occurring, there is a need for simulation exercises of outbreak preparedness and response plans at regular intervals.

7. **Data analysis**

7.1 **Case definitions/reporting**

➢ Zero reporting is done for AFP, measles and neonatal tetanus.
➢ Case-based data reporting is done for AFP, measles and rubella.
➢ The province conducts active surveillance. There are active surveillance hospitals that should be attended every week by an officer from the HAES. In addition to that, the household doctors actively look for any communicable disease during their visits to the community and inform suspected communicable diseases that are subject to notification.

7.2 **Completeness and timeliness of reporting**

Completeness and timeliness were assessed for all VPDs. Weekly zero reporting is available when no cases are detected. For AFP, measles and
rubella/CRS, the completeness and timeliness are in the range of 98.6–99.5%. However, these indicators are relatively lower for suspected diphtheria, pertussis and tetanus cases, in the range of 94.7–97.3%. The reason for this difference is more importance being given to measles/rubella and AFP surveillance as compared to other communicable diseases when the limited numbers of anti-epidemic doctors at HAESs are overwhelmed with active surveillance.

7.3 Investigation

➢ Surveillance is aimed at: maintaining the polio-free status, elimination of measles, rubella and CRS control, maintaining MNTE and monitoring HBV and JE/AES.

➢ As per the presented data for January 2017-June 2018, samples have been collected at 100% for AFR (since January 2018) as well as AFP cases (for the latter two stool samples collected within 24-48 hours apart following diagnosis). However, collecting samples for contacts of AFP cases and healthy children in the community is an area for further strengthening in the province.

➢ AFP surveillance indicators have been calculated for the provinces and they indicate that AFP surveillance is sensitive enough to detect the expected number in the provinces. The results of the expert review committee classification of AFP cases were available. However, the policy of collecting stool samples from the contacts of AFP cases and healthy children in the community was not known to the staff. Some environmental samples are collected by central level staff.

➢ Provinces have switched to case-based AFR surveillance. For obvious methodological reasons, the non-measles non-rubella (NMNR) discard rate was less than 2/100 000 population in 2015 and 2016. The NMNR discard rate reached 2.34/100 000 population by the end of June 2018 (after annualizing 6 months’ data).

➢ There were no surveillance indicators including laboratory investigation results compiled for enrolled suspected CRS cases at the CRS sentinel sites. It was revealed during discussions that
anti-epidemic doctors had to travel extensive distances to collect samples, and that transport facilities from county to ri level were limited.

➢ Though there are sentinel surveillance sites for CRS in the provinces, there were no laboratory confirmed cases. The CRS surveillance indicators (epidemiological and laboratory) were not available. Currently, the Democratic People’s Republic of Korea CRS data are not reported to the WHO global network.

➢ The serological investigation rate for fever and rash cases was 100% in 2017. As per the presented data, adequate investigations have been performed within 48 hours of notification, and specimens have been received at the laboratory within 5 days of collection for all enrolled cases in 2018.

➢ No acute encephalitis cases have been reported during the last 3 years.

➢ At provincial level and below, two or more doses of TT vaccine (TT2) coverage of pregnant women and the percentage of deliveries with trained birth assistance were not available for comments. However, discussions suggested that the large majority of deliveries occur in health facilities and pregnant mothers are offered two doses of TT in each pregnancy irrespective of the parity.

➢ Hepatitis B surveillance data was not available with the HAESs as it is conducted as health facility-based surveillance under the hepatitis control programme.

➢ Provincial and county HAESs are well placed to establish, coordinate and conduct sentinel surveillance of rotavirus diarrhoea and invasive bacterial diseases. However, the addition of rotavirus and invasive bacterial disease sentinel surveillance will overwhelm the anti-epidemic doctors. This would be due to: (i) the insufficient number of anti-epidemic doctors currently present at the provincial and county HAES levels; (ii) their current work load; and (iii) the distance they must travel to investigate reported cases of VPDs in the community and for active and passive surveillance sentinel sites.
➢ The county hospitals visited by reviewers currently conduct acute encephalitis surveillance. Hospital doctors have the capacity to test cerebrospinal fluid. Therefore, extending the current acute encephalitis syndromic surveillance to acute meningoencephalitis syndrome is feasible. The same county hospital setting can be used to conduct sentinel rotavirus diarrhoea surveillance by enrolling hospitalized patients for diarrhoea.

The following needs were highlighted during the discussions:

➢ Development and availability of National guidelines and SOPs for conducting rotavirus diarrhoea and invasive bacterial diseases sentinel surveillance;

➢ Training for clinicians and nurses at county hospitals and anti-epidemic doctors on rotavirus diarrhoea and invasive bacterial diseases surveillance including epidemiological data management;

➢ Information and communication technology equipment for data management, not only for rotavirus diarrhoea and invasive bacterial diseases surveillance, but also for other integrated VPD surveillance;

➢ Logistics and supplies for collection of specimens;

➢ Transport facilities and equipment required for specimen transfer to the provincial or national laboratory;

➢ Support for printing surveillance data collection forms and data reporting forms;

➢ Training for laboratory staff at the county hospitals if rapid diagnostic tests (RDTs) are to be used in hospitals, and for the provincial laboratory staff if RDTs, cerebrospinal fluid testing and cultures are to be implemented.

### 7.4 Record keeping

The maintenance of surveillance data (laboratory and epidemiological) for measles–rubella and AFP surveillance is being done as per the national
standards. However, computerized reporting is done only from the provincial level to the national level.

7.5 Analysis of data at different levels for immediate action

Data analysis occurs at the provincial and county HAES levels. Surveillance indicators were available at the provincial and county level HAESs.

7.6 Process of reporting to higher levels/feedback to lower levels

All suspected communicable diseases detected are reported to the next higher level within 72 hours. This applies to reporting from the provincial level to the national level as well.

South Hamyong Province experienced an influenza outbreak in the beginning of 2018. Nearly 35,000 cases were detected in a period of 4 months. Apart from this, no other VPD outbreaks or clustering of cases have occurred in the recent past.

The response measures to this outbreak of influenza included:

- active search and identification of cases of influenza-like illness, referral of severe cases and cases among high-risk groups to hospitals for appropriate case management; and
- social mobilization and sensitization of the community on preventive measures through health workers and volunteers.

8. Conclusions

- The Democratic People’s Republic of Korea is on track to achieve the RVAP 2016–2020 goals. The National CES conducted in June 2017 has clearly indicated that the country has achieved more than 95% coverage for all antigens in the national immunization schedule.

- Sustaining polio-free status: Reintroduction of IPV took place in May 2018 and plans to provide vaccination for missed-out cohorts are under way. AFP surveillance is being implemented
and the operational target of >2/100 000 for the under-15 years population is being pursued. Environmental surveillance is being conducted in selected places.

- The MoPH is taking actions to **eliminate measles and control rubella and CRS**. A five-year national strategic plan for measles elimination and control of rubella and CRS has been developed and measures are being implemented to acquaint field staff with “fever and rash surveillance” as opposed to the previously used separate reporting of suspected measles and rubella cases. All fever and rash cases are now tested to identify measles and rubella as well as non-measles and non-rubella cases. A MR SIA will be conducted in 2019 as planned followed by routine MR introduction in place of the currently used measles vaccine.

- **Maintaining MNTE**: There is a need to introduce booster doses of TTCV. While the MoPH has plans to introduce booster doses the local production of vaccine is in place, partners need to explore opportunities for support.

- **Accelerating JE control in high-risk areas**: While there have been no JE cases in the past 3 years developing a national plan for accelerated control of JE is required.

- **Accelerated control of hepatitis B**: To validate the assumption of the status of low prevalence of hepatitis B in children following very high vaccination coverage since HepB3 and HepB-BD introduction conduct of a nationally representative seroprevalence survey is planned.

However, a few challenges remain and need to be addressed promptly to maintain the success the country has achieved in VPD elimination and control so far:

- Strengthening VPD surveillance to maintain the required levels of national indicators, i.e. non-polio AFP >2/100 000 for the under-15 years of age population, non-measles non-rubella discard rate >2/100 000 and CRS >1/100 000.

- Providing quality supervision for VPD case investigation.
Providing adequate support for sample collection in distant areas.

Improving data management capacity at the central level as well as at lower levels in order to maximize utilization of data that is generated by routine reporting and promoting utilization of local data for immediate public health action.

Providing regular refresher training for maintaining high standards of surveillance and making the staff understand the commitments the country has made for achieving regional and global goals.

Completing the development of LMIS and its implementation at all levels.

Providing adequate support for transportation of vaccines and other logistics from PMWs to county medical warehouses and further to the ri level due to inadequate transport facilities.

Maintaining a continuous supply of electricity through generators for vaccine stores and selecting and supplying appropriate cold chain equipment.

Heating immunization rooms especially during harsh winter seasons through providing heaters.

Ensuring that EPI-related national committees have optimum functioning capacity to monitor the activities implemented by the EPI programmes in achieving the set objectives, and support introduction of new vaccines and technologies appropriate to the country and the programme.

9. Recommendations

9.1 Vaccine supply chain and logistics

Set a target date for the completion of development of LMIS and its implementation at all levels.

Develop a plan for vaccine distribution and supervision of implementation of EPI and VPD surveillance activities according
to the monthly immunization clinic plan in each province and estimate the vehicle requirement.

➢ Use the automatic SMS alert feature of Multilog-2.
➢ Provide a heating system for cold-chain equipment rooms and immunization clinics during winter.

9.2 Immunization service delivery

➢ Strengthen functions of relevant national committees to oversee programme activities; this includes:
  - NITAG
  - NVC for Measles Elimination and Rubella/CRS Control
  - National Committee for AEFI
  - NCCPE.
➢ Define specific provincial outbreak preparedness and response activities for polio/circulating VDPV and measles and rubella cases within the overall national outbreak response plans.
➢ Stagger immunization session days by counties across a province to allow for more supervisory visits.
➢ Use standardized checklists given by MoPH and partners for field supportive supervision and monitoring.
➢ Develop a national cold-chain equipment (CCE) deployment and comprehensive national CCE repair/maintenance plan for further strengthening of the cold chain.
➢ Conduct disease–burden and cost–benefit analysis studies for rotavirus and pneumococcal diseases.
➢ Implement WHO SAGE recommended schedules for TTCV.

9.3 VPD/AEFI surveillance

➢ Update VPD surveillance guidelines in line with WHO regional guidelines.
➢ Develop SOPs for surveillance of AFP, AFR and CRS and monitoring and evaluation plans so that global SOP requirements are met.

➢ Conduct re-training of relevant staff as per updated national surveillance guidelines.

➢ Implement all planned activities in relation to measles elimination and rubella/CRS control by 2020 as per the new National Strategic Plan.

➢ Develop AES/JE surveillance to be at par with the regional AES/JE surveillance network.

➢ Increase the number of anti-epidemic doctors (AEDs) at county HAESs, or train household doctors in timely conducting case investigations and sample collections.

➢ Provide materials for adequate sample collection and transportation from ri level to the provincial and national levels.

➢ Support computerized surveillance data management at county HAESs.

➢ Analyse all AEFI data by minimum core variables; collect detailed information and conduct causality assessment for severe AEFIs with involvement of a strengthened national AEFI committee.

➢ Conduct national/provincial joint supportive supervision and monitoring of HAESs/sentinel hospitals with establishment of a log system for supervisory notes.

10. References


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