

Plan for the Introduction of the Inactivated Poliovirus Vaccine (IPV) in Mongolia

Annex A

Executive Summary

Mongolia has been using the oral polio vaccine (OPV) in the routine immunization program since 1965. The last case of poliomyelitis caused by wild poliovirus in Mongolia was reported in 1993. Along with the rest of the Western Pacific Region, Mongolia was declared polio-free in 2000. Since 2000, Mongolia has maintained its polio-free status. Additionally, no cases of vaccine-derived poliovirus (VDPV) have ever been reported in Mongolia. Because of the high immunization coverage and other factors (low population density, climate, geography), the risk of a VDPV emergence and spread in Mongolia is estimated to be low.

The National Immunization Program in Mongolia has been discussing the introduction of the inactivated polio vaccine (IPV) since 2010. In the national plan, “Preparedness, response measures, and prevention of importation of wild poliovirus during 2011-2015”, it was recommended that Mongolia conduct an analysis of the costs and benefits of introducing the IPV into immunization schedule. In 2012, the National Verification Committee of Mongolia reinforced this previous recommendation by recommending that the country should evaluate the impact of introducing IPV. In addition, in 2012, the WHO recommended that all countries introduce at least one dose of IPV into the routine immunization schedule in countries that are currently only using OPV. Moreover, at the meeting of the Infectious Disease and Epidemiological Committee of the MoH in 2012, the committee recommended to introduce IPV in Mongolia according to the WHO recommendation. In May 2014, the National Verification Committee discussed IPV introduction in light of the new WHO recommendations and GAVI support for IPV and recommended that the country initiate the development of an IPV introduction application to GAVI for 2014. Additionally, a NITAG meeting was organized to discuss the scientific evidence for IPV introduction.

At the National Immunization Technical Advisory Group (NITAG) meeting held on 8 September 2014, the NITAG discussed the scientific evidence and rationale for the introduction of IPV. During the discussion, the NITAG highlighted the importance of introducing IPV as part of the global endgame strategy. Furthermore, the NITAG recognized the role of IPV in preventing vaccine-derived poliovirus outbreaks following the global switch from trivalent OPV to bivalent OPV. Based on the information presented, the NITAG concluded that Mongolia should introduce IPV into routine immunization schedule to decrease the risk of an outbreak related to VDPV. It was highlighted that IPV introduction in Mongolia will prevent Type 2 VDPV cases and protect children from paralysis due to poliovirus. The Inter-agency Coordination Committee (ICC) members also discussed the IPV introduction application and agreed to submit the application to GAVI for IPV.

Mongolia intends to introduce IPV vaccine nationwide in October 2015. Before introduction, preparatory activities will include: development of a detailed IPV introduction guideline, development of training curriculum, trainings at all levels (national, district/province, and local), updating the supervision guideline, and installation of new cold chain equipment. The trainings will include IPV specific information plus other important refresher information such immunization safety and AEFI monitoring. Additionally, social mobilization activities will be conducted in order to communicate IPV introduction to the public. This will include both community posters about immunization and mass media (media advertisements and TV interviews).

The introduction of IPV in Mongolia is anticipated to be feasible. Because immunization is governed by law in Mongolia, there is a stable and accountable environment for immunization activities. In general in Mongolia, the human resource capacity is adequate and there is a sufficient number of vaccinators available to deliver routine immunizations while also sustaining high immunization coverage (>97%). To ensure sufficient cold chain capacity for IPV, Mongolia will expand the cold chain capacity at the national level by installing two new walk-in cold rooms (one in 2014 and one in 2015).

Funds to support vaccine introduction costs and immunization system strengthening activities are being requested from GAVI in the form of a vaccine introduction grant. During the period covered by this application (2015-2018), co-financing will likely not be provided by the Mongolian Government for the IPV introduction. However, Mongolia has already initiated discussions regarding the financing of the vaccine in the future once GAVI support is no longer available. The NCCD, in collaboration with the immunization advisory bodies and international organizations, will advocate to the government to include IPV in future annual budgets. It is anticipated that once GAVI support for IPV has concluded (either in 2018 or 2024), the Government of Mongolia will assume all costs related to IPV.

The main risks and challenges related to IPV introduction will be: lack of knowledge and information on IPV for healthcare workers, the growing anti-vaccine lobby, and ensuring there are enough financial resources for future cold chain equipment replacements and repairs. To mitigate the risks associated with communication, Mongolia will put emphasis on developing a strong and comprehensive communication strategy for both vaccinators and the public to address these issues. To mitigate risks associated with the financial sustainability of the cold chain, efforts will be made to advocate for inclusion of cold chain costs into the government budget in the future and/or support from international organizations from the short-term.

The Mongolian Government is committed to maintaining its polio-free status. The introduction of IPV will ensure that all Mongolian children are protected from paralysis due to poliomyelitis (wild or vaccine-related).

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1. Justification for introduction of IPV and national decision-making process

Mongolia has been using the oral polio vaccine (OPV) since 1965. The last case of poliomyelitis caused by wild poliovirus was reported in 1993. Along with the rest of the Western Pacific Region, Mongolia was declared polio-free in 2000.

In the national polio response plan, “Preparedness, response measures, and prevention of importation of wild poliovirus during 2011-2015” (approved by Health Minister order # 332), it was recommended that Mongolia began the process of evaluating the advantages and disadvantages of introducing one dose of IPV vaccine into immunization schedule. In addition, the National Verification Committee in Mongolia recommended that the country should evaluate the introduction of IPV vaccine into routine immunization in 2012. Moreover, at the meeting of the Infectious Disease and Epidemiological Committee of the MoH held in 11.May.2012, the committee recommended to introduce IPV in Mongolia according to the WHO recommendation. In May 2014, the National Verification Committee discussed IPV introduction and recommended that the country submit an IPV introduction application to GAVI in 2014.

At the most recent NITAG meeting held on 8.Sep.2014, the NITAG discussed the scientific evidence for IPV introduction in Mongolia. The NITAG noted the recent recommendations for IPV introduction from the Strategic Advisory Group of Experts (SAGE) and the Technical Advisory Group (TAG) on Immunization and Vaccine preventable Diseases in the Western Pacific Region. Furthermore, the NITAG recognized the need for IPV introduction in order to decrease the risk of a Type 2 vaccine-derived poliovirus (VDPV) outbreak following the global switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) by providing type 2 poliovirus immunity. The NITAG also discussed the immunological benefit of adding one dose of IPV. Finally, the NITAG noted that introduction of one dose of IPV into the schedule is a key step towards an all IPV schedule in the future after global polio eradication. Taking into consideration these points, the NITAG unanimously concluded that Mongolia should introduce IPV vaccine into routine immunization schedule and supported the decision to submit the IPV introduction application to GAVI. The ICC members discussed the IPV introduction application and also agreed to submit the application to GAVI during the meeting which was held in 8.Sep.2014.

The introduction of IPV in Mongolia is feasible. In Mongolia, all immunization services are governed by laws issued by the Minister of Health. This system ensures that there is a stable and accountable environment (financially and programmatically) for immunization activities. Additionally, there is commitment from the national decision-making groups such as the NITAG and ICC for IPV introduction. The strong vaccine management and cold chain as well as the sufficient number of health care workers will all contribute to the successful introduction.

2. Overview of IPV

2.1 Vaccine preference

The first preference for IPV presentation is the 5-dose vial. This will allow the program to minimize wastage especially in remote areas with small populations (as compared to the 10 dose vial). Another advantage of the 5-dose vial over the single dose vial is that there will be less strain on the cold chain capacity.

Table 1. IPV vaccine preferences and estimated date of introduction

Preferred IPV vaccine	Month and year of first vaccination	Preferred second presentation	Preferred third presentation
5-dose vial	October 2015	10-dose vial	1-dose vial

2.2 Country licensure status

Regulatory Approval Process

The regulatory approval process in Mongolia consists of three agencies: the Division of Pharmaceuticals and Medical Devices of MoH, the Government Agency for Specialized Inspection, and the Pharmaceutical Laboratory of the National Reference Laboratory for Food Safety. The NRA in Mongolia is partially functional and there are ongoing efforts to strengthen the capacity of the NRA. The main organization responsible for regulatory coordination is the Division of Pharmaceuticals and Medical Devices of Ministry of Health. The regulatory duties of each body are described below:

Division of pharmaceuticals and medical devices of Ministry of Health

- Development, coordination, and implementation of pharmaceutical policy
- Drug registration
- Monitoring of drug adverse events
- Permission of drug producing and importation
- Policy coordination for appropriate usage
- Monitoring and coordination of exports and importation license

Government Agency for Specialized Inspection

- Inspection of pharmaceuticals and medical devices

Pharmaceutical laboratory of National reference laboratory for Food Safety

- Testing of pharmaceuticals and medical devices

Official registration procedure for any new vaccine

Registration is conducted according to order #41 issued by Ministry of Health in 2012 “Registration order of drug and biological active production” and is show in Table 2.

Table 2. Steps required to complete the registration process

	Activity	Duration
1	Preliminary examination of documents	Within 14 days after receiving documents
2	Claiming payment for registration	Within 1 month after preliminary examination
3	Conducting laboratory testing	Within 1 month after receiving documents
4	Multiple analyses of results	Within 1 month
5	Discussion of Committee of Human drug and Committee of Pharmaceuticals and Diagnostics	Within 1 month after laboratory test result
6	Delivery of committee meeting decision	Within 10 days after the final meeting decision
7	Re-discussion of registration if committees postpone the registration	Within 2 months
8	Certificate of the registration	Within 10 days after final committee meeting

		decision
9	Input the drug registration data in to "Licensed"	Within 5 days after Certificate delivery

Registration process for IPV

IPV is a WHO pre-qualified vaccine. The process above will be followed for IPV and will take a maximum of 6.5 months. Because the procurement will be done through the UNICEF Supply Division, there is no need to get any additional licenses beyond what is described above.

Obtaining an importation license

Like all vaccines in Mongolia, an importation licenses will be obtained for IPV. To apply for the license, all necessary documents will be prepared according to Government order #219 "List of coded good with license to be imported through country border" and the Health Minister order #343 "Order for export and importation license" issued in 2011:

Steps for obtaining importation license

- Application from importer
- Examine all requested documents
- Write and ensure the importation license
- Deliver the importation license

The NCCD is experienced in obtaining importation licenses for vaccines. Following submission of the application for the importation license, the license will be available in 5 working days.

Customs procedures

The Government Agency for Specialized Inspection and Customs Authority is the agency responsible for importation at the border. If there is any issue with the vaccine at the border, they are the primary organization responsible for making decisions based on related laws.

2.3 Target Population

Total Dose requirement 2015-2018

The total dose requirement taking into account the coverage, buffer stock, wastage, and date of introduction are listed below:

Table 3. Calculation of Total Dose Requirement

	2014	2015*	2016	2017	2018
Total Births	84,567	89,641	95,019	100,721	106,764
Surviving infants	81,922	86,837	92,048	97,570	103,425
OPV3 Coverage (2013)	97%	97%	97%	97%	97%
Total Doses	NA	84,232	89,286	94,643	100,322
Wastage Factor (expected 30%)	NA	1.43	1.43	1.43	1.43
Number doses after Wastage	NA	120,452	127,679	135,340	143,460
Doses adjusted for month of introduction	NA	30,113.01	127,679	135,340	143,460
Buffer Stock for first 12 months	NA	0.25 (3 months)	0.25*0.75 (9 months)	NA	NA

Total Annual Doses	NA	37,641	151,619	135,340	143,460
Total Doses 2015-2018					468,061

*Vaccine to be introduced in October 2015. Estimate for 2015 is therefore only for 3 months
Source for population data: Annual progress report submitted to GAVI in 2013.

Injection supplies requirement

The calculation for the estimated number of injection supplies needed based on the target population included in the table below.

Table 4. Estimated number of syringes and safety boxes needed:

	2015	2016	2017	2018	Total
Target	22,322	94,643	100,322	368,484	585,770
Syringes*	24,554	104,108	110,354	405,332	644,347
Safety Boxes	223	946	1,003	3,685	5,858

*Wastage for syringes: used wastage factor of 1.1. Safety boxes calculation is 1 box per 100 target population.

Population data

The population data used is the data approved by the Ministry of Health for the Immunization fund for 2015. It is the number used to procure all routine vaccines which are paid for by the government.

The vaccine requirement was calculated using the formula

Yearly total vaccine requirement= (surviving infants with a 1.04% increase every year for population growth)*(97% DTP3 coverage in 2013) + Wastage (30% or 1.43 wastage factor) + Buffer stock (25% of total dose requirement for first year from Oct 2015 to Sept 2016). For the year 2015 the calculation is for only 3 months (total surviving infants divided by 4), as IPV will be introduced in Oct 2015.

Vaccine procurement

Vaccines are procured through two channels:through 1) UNICEF and 2) Local call for bidding of procurement services. Routine vaccines that are in the national immunization schedule (OPV, DPT, DT, HepB, MMR, and Penta) are procured through the UNICEF Supply Division. As IPV will be considered a routine vaccine in the national immunization schedule, it will be procured through the UNICEF Supply Division.

Procurement procedures

The procurement for routine EPI vaccines and GAVI supported vaccines (including the government's co-financed portion) is conducted through UNICEF SD. The UNICEF SD responds to a supply request form by sending NCCD a cost estimate. This is passed to the Ministry of Health and then forwarded by MOH to the Ministry of Finance. The Ministry of Finance then sends the necessary funds to UNICEF SD. The total lead-time required for this procedure is around two months.

3. Introduction and implementation considerations

3.1 Policy development

Mongolia will revise the immunization schedule by adding one dose of IPV to the infant schedule. No other immunization contacts will be changed due to IPV introduction. The Mongolian Government is responsible for making the change and approving the new schedule.

IPV will be concurrently administered with the third dose of Penta vaccine (DTP+HepB+HiB) and the fourth dose of OPV (see schedule below). IPV will be administered by intramuscular (IM) injection on the right thigh of children who are 4 months of age. Injection side should be opposite of Penta vaccine injection. The proposed order of injections is as follows: (1)the vaccinator should give the child 2 drops of OPV, (2)the vaccinator should prepare and inject the Penta vaccine on the left thigh, and (3) the vaccinator should inject IPV into the right thigh. The injection site disinfection method will be same as Penta which is to use a 76 percent alcohol pad before injection and the finger bandage after injection.

Table 5. Immunization schedule in Mongolia including IPV

Vaccine	Age								
	Birth	2 months	3 months	4 months	9 months	14 months	2 yrs	7 yrs	15 yrs
BCG	1 st dose								
Hep B	1 st dose								
OPV	1 st dose	2 nd dose	3 rd dose	4 th dose					
Penta		1 st dose	2 nd dose	3 rd dose					
MMR					1 st dose		2 nd dose		
DT								1 st booster	2 nd booster
Hep A						1 st dose	2 nd dose		
IPV				1 st dose					

3.2 National coordination mechanism to ensure the successful introduction

There are five organizations/bodies involved in the oversight, management, and implementation of introducing a new vaccine in Mongolia: the Ministry of Health (MoH), the National Center for Communicable Disease (NCCD), the National Immunization Technical Advisory Group (NITAG), and the National Verification Committee. The roles and responsibilities of each organization are described below.

The Ministry of Health (MoH) and the National Center for Communicable Disease (NCCD) are the main organizations responsible for the oversight and implementation of IPV introduction activities. Mongolia will introduce IPV vaccine according to order of Minister of Health #359 issued on 07.Nov.2011 "Guideline on introducing a new vaccine into immunization schedule". The Charges of MoH and NCCD according to this order are as follows:

Ministry of Health

- Discuss rationale of IPV introduction materials prepared by NCCD through NITAG members.
- Calculate expenses on IPV introduction activity and get permission from Ministry of Finance.

National Center for Communicable Diseases

- Provide management of IPV introduction activity.
- Conduct survey and surveillance of infectious disease burden and socio-economic impact relating to IPV.

- Economic efficiency and effectiveness of IPV have to be considered before IPV introduction
 - Consider other healthcare services, knowledge, and habits besides IPV in the country
 - Consider number of cases, number of complications to be prevented by IPV
 - Consider extra immunization expense per child due to IPV introduction
 - Consider difference between cost of health care service for the diseased cases and cost for IPV introduction
 - Consider sustainable finance options and supply for IPV
- Establish surveillance guideline and discuss through scientific committee of NCCD
- Consider expenditures such as vaccine supply, advocacy, training, salary for HCWs
- Conduct laboratory based IPV surveillance to determine genotype, phenotype, species of pathogen. Utilize result of epidemiology and laboratory studies of countries which have similar characteristics on socioeconomic situation.
- Introduce IPV vaccine which is prequalified or recommended by WHO.

National Immunization Technical Advisory Group (NITAG)

- Discuss new and combined vaccine introductions
- Make evidence-based decisions according to WHO recommendations
- Provide advice to the MoH and NCCD
- Advise on the development of the guideline for IPV

National Verification Committee

- Monitor implementation of WHO regional targets on vaccine preventable diseases targets and provide management
- Monitor implementation of strategic plan, government orders, any other legal documents and develop recommendations
- Develop recommendations on early warning and response measures for polio cases caused by wild poliovirus or vaccine-derived poliovirus reported in neighboring countries or local endemic poliovirus
- Monitor activity for limiting spread of infection and response measures when polio cases caused by imported wild poliovirus or vaccine-derived poliovirus have been reported

Inter-agency Coordination Committee

- Originally established in 2004 to discuss the introduction of pentavalent vaccine into routine immunization in Mongolia
- Responsible for discussing any immunization activities being implemented with the support of GAVI

3.3 Affordability and financial sustainability

Budget for IPV introduction

A detailed budget is presented in Annex D. The total estimated budget for IPV Introduction in Mongolia is \$410,819USD. Of the total cost, it is proposed that \$81,530 USD will be provided by the government, \$159,290 will be requested from WHO (for IPV and general cold chain support), \$70,000 will be requested from UNICEF, and \$100,000 USD will be requested from GAVI.

All program management related costs will supported by the government through the routine salaries of national program managers, provincial and district managers, and vaccinators.

Funds to support vaccine introduction costs and immunization system strengthening activities are being requested to GAVI in the form of a vaccine introduction grant. The activities requested to be funded by the GAVI introduction grant include: media advertisements, TV expert interviews, vaccinator training-associated costs, updating supervision guideline, developing and printing community immunization posters, cold chain equipment for the local level, training about surveillance and monitoring of AEFI, supportive supervision visits to local immunization units, a data quality assessment, and a post-introduction evaluation.

The budget estimations are based on the actual expenditure of previous immunization activities and trainings. For certain activities for which a UN approved rate was available (training activities, translation services, and local per diem), the budget was calculated based on the UN rate.

Financial Sustainability

Before 2000, all routine vaccines were funded by Japan International Cooperation Agency (JICA). At this time, the government investment in the immunization program fund was very low and only non EPI vaccines were provided by Government during this time. But in 2000, the Government Immunization fund was established. The fund was then activated in 2003, and since then the government's financial participation in immunization has steadily increased. In 2014, the government supported 93% of the cost of immunizations in Mongolia compared only 7% in 2003. Now all routine vaccines (7 types of vaccine) and the associated transportation budget (to the districts and provinces) are provided by the Government. The only external support for the procurement cost of routine vaccines is the GAVI support for a percentage of the Penta vaccine according to the co-financing agreement. It should also be noted that Mongolia received Health Systems Strengthening (HSS) and Immunization Services Support (ISS) from GAVI from 2010-2012 and 2007-2013 respectively. By next year (2015), Mongolia will be responsible for the entire financial obligation of National immunization program.

During the period covered by this application (2015-2018), co-financing will likely not be provided by the Mongolian Government for the IPV introduction. However, Mongolia has already initiated discussions regarding the financing of the vaccine in the future.

At the NITAG and ICC meetings, the need to secure government funding for IPV in the future was discussed. Both the NITAG and ICC members firmly believe in the importance of government financing of routine immunizations and have committed to working with the government to plan for future government support of IPV. These efforts will be key to ensuring that the Mongolian immunization program continues to sustain the trajectory towards financial independence from donors. The NCCD in collaboration with the immunization advisory bodies and international organizations (NITAG, ICC, MOH, WHO, UNICEF, and JICA) will immediately begin discussions with the government to include IPV in future annual budgets. It is anticipated that once GAVI support for IPV has concluded (either in 2018 or 2024), the Government of Mongolia will assume all costs related to IPV.

Because of the short time before IPV introduction, the extra-costs associated with IPV introduction at the local level were also not able to be included into the Government financial plan. Therefore, at the local level, the local hospital fund will absorb these "extra" costs of introduction. Examples of these types of extra costs including: additional injection-related supplies (alcohol pads, bandages, soap, cotton etc), additional transportation costs required to deliver the vaccine to the smallest level (soum and bagh), and the additional time required from the nurses to give an additional injection.

3.4 Overview of cold chain capacity at district, regional and central levels

Central Vaccine Store

The central vaccine store is located at the south east corner of NCCD compound in Ulan Bator city. It is one store standalone building, occupies about 300 square meters area. The building is in good condition. The climate in Ulan Bator is cold (temperatures in winter season could drop below -40C) and requires permanent heating during winter. The NCCD compound is fenced, secured and guarded continuously. The vaccine store has lockable doors and unauthorized people cannot enter it.

The Mongolian government has procured a 40m³ cold room for the Central Vaccine Store which will be installed by the end of 2014. In addition, one more cold room (40m³) will be supported by WHO and it will be installed in 2015.

Ulaanbaatar District Stores and Province Stores

There are 9 district vaccine stores and 21 province vaccine stores which supply the local health centres, hospitals and clinics in different parts of the Mongolia. All service delivery points use a variety of cold chain equipment among which most of the equipment are Vestfrost MK 074 and Haier HBC-70 models. Freeze tags are present at all levels, however the 30DTR (Fridge tags) are mostly expired and should be replaced.

One strength of the cold chain in Mongolia is that most of the cold chain equipment is WHO prequalified. Additionally, in 2005, 98% of vaccination units were equipped with additional cold chain equipment. The vaccine storage capacity at national level has also been improved. However, even though 98% of all vaccination units received new cold chain equipment, the majority of the cold chain equipment in each unit was still quite old, as majority of it was installed in 1993. However, between 2011-2013, 78% of all fridges at the primary (soum) and secondary (district/province) were renewed. For more detailed information on improvements to the cold chain, see the EVM improvement plan attached.

Cold Chain requirements and capacity

The detailed calculation for the cold chain capacity can be found in the attached spread sheet. Below is a summary of the calculation at each level. The capacity at the central and provincial levels are sufficient for IPV introduction. Additionally, the space available at the soum level is sufficient, but some refrigerators are no longer functional and need to be replaced.

Table 6. Central Storage Cold Chain Capacity

Volume needed including IPV (Ltr)	Total volume available starting end 2014* (Ltr)	Extra space available (Ltr)
12,687	16,815	4,128

* An additional walk in cold room of 40m³ has already been purchased by the government and will be installed at the end of 2014. Without this room the central store capacity for EPI vaccines is 10,998. Additionally, there is a cold room with the capacity of 3,663 liters that is used for non-EPI vaccines and is therefore excluded from this calculation.

Table 7. Provincial Storage Cold Chain Capacity

Province Name	Volume needed including IPV (Ltr)	Total Volume Available (Ltr)	Extra Space Available (Ltr)
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1	Arkhanangai	311	1,212	901
2	Bayan -ulgii	404	1,439	1,035
3	Bayankhongor	338	1,249	911
4	Bulgan	152	1,172	1,020
5	Gobi-Altai	204	1,365	1,161
6	Gobisumber	70	514	444
7	Darkhan-Uul	392	960	568
8	Dornogobi	221	1,331	1,110
9	Dornod	290	1,327	1,037
10	Dundgobi	132	1,276	1,144
11	Zavkhan	223	1,500	1,277
12	Orkhon	422	639	217
13	Uvurkhangai	408	1,481	1,073
14	Umnugobi	226	1,039	813
15	Sukhbaatar	180	1,296	1,116
16	Selenge	287	1,358	1,071
17	Tuv	186	1,566	1,380
18	Uvs	294	1,710	1,416
19	Khovd	347	1,568	1,221
20	Khuvsgul	483	1,970	1,487
21	Khentii	237	1,229	992

Soum Cold Chain Capacity

Soums are very small administrative levels and a single refrigerator is almost always sufficient for the cold chain. In Soums, the issue is not having enough space for vaccines but rather ensuring that each soum has a functioning refrigerator. A plan to replace 10% of the refrigerators at the soum level each year has been ongoing since 2011 as part of a ministerial order. As part of the IPV introduction grant, \$20,000 have been requested to help supplement these efforts to replace refrigerators in the Soums.

3.5 Waste management and injection safety

Waste Management

Health Minister order #359 (issued in 2011) outlines the procedures for proper waste management and injection safety in Mongolia. According to this order, any waste material (including expired vaccines, broken or damaged vaccine vials, vaccine vials without labels, vaccines with illegible labels, discolored vaccines, vaccines damaged by hot or cold storage, vaccines frozen during transportation, and opened vaccine vials) must be collected in a red bag, stored in a temporary room, and then delivered to a location where the waste can be properly disinfected and destroyed. Each health facility should establish a team responsible for managing the proper destruction of waste materials. The procedure for proper waste destruction is outlined below:

- If there is a standardized building with professionally trained staff adequately prepared to destroy waste material (i.e. the building located in a district of the capital city), following procedure should be followed:
 - Waste materials should be kept in an autoclave at 1320C (2 atmosphere press) for 30 minutes
 - The machine should break the waste material into small pieces

- The small pieces should then be disinfected and buried in a hole >2 meters deep.
- If there is no facility with professionally trained staff (i.e. facilities in the provinces and soum), the following procedure should be followed:
 - Waste materials should be kept in an autoclave at 1320C (2 atmosphere press) for 30 minutes
 - The machine should break waste material into small pieces
 - The small pieces should be disinfected, burned and buried in 30cm deep space.

The infection control team at each facility is responsible for monitoring the implementation of the waste management procedures. A report detailing each instance of waste destruction should be sent to the NCCD.

Any waste related to IPV will be treated according to Minister of Health order #359 as described above. There is therefore no need to change national policies on waste management.

Injection Safety

In 2012, the WHO guideline “Immunization Surveillance and Safety, second edition” was translated and adopted for use in Mongolia. There are on-going efforts to strengthen injection safety in Mongolia. Injection safety trainings will be incorporated into the IPV trainings.

Procurement of vaccines and injection supplies

Mongolia only procures vaccines and injection supplies that are pre-qualified by WHO. Procurement is done through the UNICEF Supply Division.

3.6 Health worker training and supervision

In general in Mongolia, the immunization delivery service is strong and there area sufficient number of vaccinators available to deliver routine immunizations while also sustaining high immunization coverage (>97%). Around 530 vaccinators work throughout the country in 417 soum hospitals and family clinics at the provincial level and 80 family clinics in the districts of UB city (except maternity hospital immunization units). Even though all vaccinators have some experience and generally have adequate knowledge to deliver immunization, some vaccinators (~40.5%) have not received professional certificate training on immunization. The National Center for Health Development, MoH has plans to professionally train new vaccinators considering a number of vaccinators will retire soon. Local clinics and health departments have also been increasingly requesting that additional “reserve vaccinators” be trained. These vaccinators would work during the leave of other vaccinators (annual and sick leave, during the training in other cities, etc).

Training materials including an IPV introduction guideline, a training curriculum, posters, and pre- and post- knowledge tests will be developed by the National Immunization Team for IPV introduction. The training curriculum will be developed by the National Immunization Team. The introduction guideline for vaccinators and doctors should include all relevant information about IPV and the process for IPV introduction. A poster for health care workers will be developed. The poster will include warnings and instructions on how to package, deliver, store, prepare, and inject IPV. Pre- and post-knowledge tests will be developed for secondary and tertiary level training and will include content on IPV and other important immunization information.

Trainings will be organized at all three health system levels and will involve all staff which participate in immunization service delivery. Before the preparation period of IPV introduction

begins, the National Immunization Team will participate in a training which will last 1-2 day(s). Following this training, the National Immunization Team will finish the preparation of all other training and IEC materials.

Next, secondary health care level (districts in Ulaanbaatar city and provinces outside of the city) trainings will start. These trainings will last approximately 2 days and will be attended by EPI managers, pediatricians and inspectors from provinces and districts. In total, there are 21 provinces and 9 districts and approximately 3 people from each province and district will attend. In order to accommodate all the participants (100-120 people), there will be three separate trainings (33-40 people at each training).

Next, the district/province EPI managers and other individuals who attended the secondary level training will train the local level vaccinators and doctors from 417 soum hospitals and 80 family clinics. The trainings at every level will include information specific to IPV, AFP surveillance, and vaccine introduction procedures, as well as refresher information on general immunization topics (surveillance, vaccine safety, AEFI, and cold chain).

Supportive Supervision

EPI managers conduct routine supportive supervision for all immunization activities at the local level. Following IPV introduction, normal routine supervision will be conducted plus a few additional visits at both the local and National level. In addition, the inspectors of the local inspection agencies do routine supervision on health system functions at their respective level. The inspectors who attend the training meeting will conduct additional supportive supervision on IPV introduction in addition to the EPI managers who will be present.

3.7 Risks and challenges

Possible risk and challenges	Plan to address
A. Financial:	
<ol style="list-style-type: none"> Potential increase in the cost for supply of cold chain for new vaccine and repairing service cost for old cold chain equipment Immunization activity cost (especially petrol expenditure needed to reach difficult-to-reach population) Increase in the general expenses of immunization services (work load of vaccinators, extra supplies, etc.) due to increase in number of injections per child 	<p>To address the potential financial risks, supplementary funds for cold chain equipment, petrol cost, and cost for additional IEC activities have been included in budget for the vaccine introduction grant. Additionally, if needed, National Immunization Program will discuss with the government and international organizations regarding potential funds for additional cost.</p>
B. Programmatic:	
<ol style="list-style-type: none"> Need to improve the skill level of healthcare workers (especially vaccinators) Increased workload for vaccinators due to additional injection shot 	<ol style="list-style-type: none"> Conduct supportive supervision at vaccinator level <ol style="list-style-type: none"> Avoid increasing the workload of vaccinators by training new vaccinators Give incentive to vaccinators for immunizing difficult-to-reach children

<p>3.Lack of information about new vaccine and injection shot by physicians and nurses</p>	<p>3. Organize training on introducing new vaccine for physicians and nurses. Emphasize the importance of good communication in trainings.</p>
<p>4.Old, broken, or insufficient cold chain equipment in some remote areas/soums.</p>	<p>4. Evaluate and expand capacity of cold chain at local level and strengthen local capacity to maintain cold chain</p>
<p>5. Actual wastage might be higher than calculated wastage (especially in rural areas)</p>	<p>5.1 Assess wastage 5.2 Organize vaccine delivery effectively and efficiently</p>
<p>6.Number of injections per child will increase which might lead to a need for additional injection supplies</p>	<p>6. Increase number of safety boxes, disinfectants, alcohol pads, and other immunization supplies</p>
<p>7.Children might miss IPV dose due todrop out (Drop out mainly happens in Mongolia because of internal migration, difficulties in traveling to rural areas in winter because of heavy snow, mother’s forgetting the date of next visit, and difficulties because of poverty)</p>	<p>7.1 Include discussions on drop out into weekly and monthly planning sessions 7.2Conduct qualitative assessment of coverage data and supportive supervision</p>
<p>8. Occurrence of co-incident adverse event taken as adverse event of IPV</p>	<p>8. Ensure physicians conduct high-quality examinations. Continue to strengthen AEFI system and risk communication</p>
<p>9.May take long time to get new immunization documents,schedule, and immunization cards approved through normal channels</p>	<p>9.Work with government to get quick approval for new immunization documents, schedules, and cards</p>
<p>C. Mobilization of community</p>	
<p>1. Community might hesitate and/or refuse to get injection of IPV since Mongolia has been declared polio free</p>	<p>1.1 Organize expanded IEC and advocacy activity to community 1.2. Respond to negative information about immunization, improve risk communication, and partner with pediatricians, education sector specialists and journalists 1.3.Improve the quality of AEFI information and reporting from local to national level 1.4. Train physician and doctors to respond suspected AEFI case</p>
<p>2. The anti-vaccination lobby is growing in Mongolia</p>	<p>2.1 Assess the reasons of vaccine hesitancy through research/survey</p>

2.2 Develop communication strategy with UNICEF to counter anti-vaccine lobby

4. Situational analysis of the immunisation programme

4.1 General context of the country

General context of the country

Mongolia is located in central Asia. It borders Russia to the north and China to the south, east, and west. Ulaanbaatar is capital city and 46 % of the population resides in Ulaanbaatar. As of August 2014, the total population is estimated to be 2,969,098 (National Statistical Office of Mongolia). In terms of population, Mongolia is the least dense country in the world.

Mongolia has extreme continental climate and most of the country is hot in summer and very cold in winter time. The average temperature in January is -30 °C, making it the coldest capital city in the world.

Administratively, Mongolia is divided into two parts: the capital city districts and provinces. The Capital City districts and the provinces are considered to be at the same administrative level. The Capital city is divided into districts and sub-districts. The provinces are divided into soum and bagh. In the Capital city, there are 9 districts and 152 sub-districts (National statistical office of Mongolia). In the rest of the country, there are 21 provinces, 339 of soum, and 1568 of bagh.

59% of the total population is under age of 30. Since 2006, the number of births per year has increased and is greater than was previously estimated. The number of births in 2013 was 79,371 compared to 45,326 in 2005 (National statistical office of Mongolia).

Overview of the health system

The vision of the Ministry of Health of Mongolia is to strive to ensure the availability, accessibility, affordability and equity of quality healthcare services for all Mongolians. Healthcare is provided through a needs-based health system which specifically addresses the health issues affecting vulnerable groups (particularly the poor). The Ministry of Health is also responsible for regulating and enhancing the health sector's human resource capacity. The ultimate goal of the Ministry of Health is to promote social and economic development through poverty alleviation.

Currently there are about 1500 health facilities including government facilities and private facilities. These facilities provide healthcare services at 3 levels. The primary care level consists of hospitals in soum and family health centers in districts. The secondary level consists of hospitals in districts and hospitals in provinces. The tertiary level includes national research centers, professional institutions, and clinics.

There were 16 central or specialized hospitals, 5 Regional Diagnostic and Treatment Centers, 20 province and district hospitals, 8 district PHCs, 6 rural general hospitals, 39 Inter-soum hospitals, 271 soum health centers, 221 family health centers, 179 private hospitals and 851 private clinics delivering health services to Mongolia population in 2012.

As of 2012, there were 43.6 thousand employees in the health sector's state and private facilities. 24.7% of total number of employees was in primary health care, 18.1% were in the secondary level, 18.4% were in the tertiary level, 12.6% were in private sector and 26.2% were

in maternity hospitals and other health facilities. Out of all employees, there were 8.5 thousand doctors, 1.4 thousand pharmacists, 16.8 thousand allied health professionals (including 9.9 thousand nurses) and 12.3 other workers. There were 30.3 physicians per 10 000 population, 37.6 nurses and midwives and 59.4 mid-level health professionals in Mongolia, 2012.

As a result of the implementation of comprehensive efforts against infectious diseases, Mongolia has been declared free from smallpox and poliomyelitis. Furthermore, in 2014, Mongolia was certified as measles free. In 1993, the Mongolian government established the National immunization program.

The National Program for Combating Infectious Diseases was developed and approved by the Mongolian government in 2002. This was the framework used to guide all infectious disease related efforts until 2010. Subsequently, a sub-program on vaccine preventable infectious diseases was approved as part of the revised National Program for Combating to Infectious Diseases in 2011-2015. As part of this program, Mongolia intends to introduce new vaccines into the routine immunization schedule over the next few years (including IPV).

Organizational structure of National Immunization Program

Immunization services are provided at all levels of health system. The Immunization program is regulated mainly by the Law of Mongolia on Immunization and other relevant policy legislation.

National Center for Communicable Disease (NCCD) is the main body that organizes immunization activities at the national level. NCCD assesses immunization achievement based on surveillance of vaccine preventable disease and laboratory surveys. NCCD also plans outbreak responses, plans prevention activities to limit the spread of disease, orders vaccines, stores vaccines, and transports vaccines to local units. Moreover NCCD is responsible for managing and supporting local immunization units and overseeing the implementation of the Immunization law.

National Verification Committee, National Immunization Technical Advisory Group, Inter Agency Coordinating Committee and professional committees manage overall immunization policy, recommend new vaccine introductions, and facilitate international collaboration between civil society, donor organizations, and NCCD.

The national EPI managers provide support for policy development and decision making procedures at Ministerial level. At the sub-national Health Departments (21 provinces and 9 districts) there is an epidemiologist who is responsible for NIP implementation (EPI manager) and an assistant-doctor who is in charge for vaccine cold chain logistics. At health facility level, every general practitioner involves into immunization service apart from a designated vaccination nurse. All level maternal hospitals or wards have a designated vaccination nurse to provide birth dose of routine vaccination for newborn infants in a timely manner.

National routine vaccines are delivered completely free-of-charge to the target population. In Mongolia, Children under 0-15 are given 7 vaccines that provide protection against 11 different infectious diseases. There are 518 immunization units in Mongolia. Immunization services are divided into 3 categories: routine, voluntary, and epidemiologically linked.

The first poliomyelitis cases were reported in 1962-1963 and the oral polio vaccine (OPV) was included into routine immunization schedule in 1965. During 1965-1983 a pellet shaped vaccine of poliovirus produced in Russian Federation was used for routine immunization. Since 1983, a liquid oral vaccine (OPV) against poliovirus has been administered according to WHO

recommendation. In 1982, the last large outbreak of polio was reported and in 1993 the last two cases of polio were reported. In 2000, Mongolia was declared free from polio.

Oral polio vaccine is given to children at age of within 24 hours of birth, 2, 3 and 4 month. Supplementary immunization activities (SIAs) were conducted several times in 1994, 1995, 1996, 1997, 1998, and 2010 in selected areas of Mongolia. In 2010, the first dose coverage during the nationwide OPV campaign reached 91.9% (203393 / 221415) and second dose coverage was 94.1% (208253 / 221415). Since 2001, nationwide coverage of OPV in the routine immunization schedule has been consistently more than 95%.

4.2 Geographical, economic, policy, cultural, gender and social barriers to immunization

Table 8. Trends in vaccination coverage

Trends of national vaccine coverage (percentage)				
Vaccine	Vaccine Used	Target population (number by age and sex, if available, 2013)	Coverage reported (JRF)	
			Most recent year, 2013	Previous year, 2012
BCG	Japan	79,780	99.13 %	98.82%
OPV 3	Belgium	77,008	97.88 %	96.74 %
DTP 1 / Penta 1	Korea	75,523	98.24 %	97.27 %
DTP 3 / Penta 3	Korea	77,316	97.61 %	96.72%
HPV 1	USA (Gardasil)	14,063	Pilot	Pilot
HPV 3	USA (Gardasil)	14,063	Pilot	Pilot
Measles 1	India (MMR)	73,250	97.05 %	98.83 %
Measles 2	India (MMR)	63,610	96.68 %	98.31 %
PCV 1	--	--	--	--
PCV 3	--	--	--	--
Rota 1	--	--	--	--
Rota 2 or 3	--	--	--	--

Immunization for the entire population is the responsibility of the government according to Immunization law of Mongolia issued on 20.April.2000. The cost for vaccines including routine and epidemiologic-linked to prevent infectious disease, limit the spread, eliminate diseases is paid by Mongolian government. Therefore there are no major barriers related to age, sex, culture, and economy for vaccination in Mongolia.

However, since 1990 Mongolia has been undergoing a major socio-economic transition which has led to an increase in internal migration, intensive urbanization, and an increase in the mining industry. An increase in unofficial mining has led to high migration within the country. As of 2013, the total population was 2.9 million. 67.9% of the population resides in the capital city, which demonstrates the high migration within the country. In the capital city 60% of the residing population lives in gher squares (Mongolian traditional house). 32% of the total population lives in rural areas and most of them have a nomadic or semi-nomadic lifestyle.

People who live near mining areas have been determined to be a risk group for immunization because:

- Poverty rates are higher in these populations
- They have not been registered in any administrative level
- Children of poor families usually work

It is difficult for healthcare workers to reach these populations to provide health care services because they are not registered. Unregistered people live in both in urban and rural areas.

4.3 Findings from recent programme reviews

Recent major accomplishments of the immunization program

Since 2005, all health facilities have began to use auto disabled syringes and safety boxes for routine immunization. This has greatly improved the safety of immunization practices in Mongolia.

In the past few years, many activities have been conducted to strengthen the cold chain and vaccine management. In 2008, a central vaccine storage room with all required cold chain equipment was established with the financial support of UNICEF according to the WHO standard. Additionally, the Multilog cold chain and vaccine supply monitoring system were introduced at the central level. The Multilog system simplified and improved the monitoring of all cold storage at the national level. In 2009-2010, the Vaccine supply and stock management (VSSM) software was introduced at both the national and provincial/district levels. The installation of the VSSM led to a decrease in shortages. Vaccine transportation has been improved. The vehicles with cooling equipment were purchased and are used specifically for vaccine transportation at National level. The vaccine transportation cost to district and province is paid by Government immunization fund which secures sustainable funding for transportation.

In last 3 years, refresher trainings targeted towards district and provincial epidemiologists to improve knowledge on immunization were organized using short-term consultants and trainers from international organizations. For example, trainings on VSSM, Vaccine management, and AEFI were designed and implemented.

Since 1993, no cases of polio have been reported in Mongolia. Since 1999 no neonatal tetanus cases have been reported. Since 2004, there have been no cases of diphtheria and pertussis reported. Additionally, since 2009, there have been no reported cases of measles in Mongolia. These achievements demonstrate the success and strength of the national immunization program.

Another achievement has been the steady increase in government financing for the immunization program. Since 2011, nearly all routine vaccine costs have been paid by government. The pentavalent vaccine is currently co-financed by the government and in the future the government will assume full responsibility for the cost of the vaccine.

Feasibility of IPV introduction

The introduction of IPV in Mongolia is anticipated to be very feasible. Because immunization is governed by law in Mongolia, there is a stable and accountable environment for immunization activities. Also, decision-making and advisory process have recently been improved by establishing a National immunization Technical Advisory Group (NITAG) which is responsible for give evidence based on recommendations of decision makers. Important immunization issues are regularly discussed and implemented by the ICC, Infectious diseases' professional

advisory committee at NCCD, and NITAG. There is a full commitment from these national decision-making groups for IPV introduction. The strong vaccine management system and cold chain as well as the sufficient number of health care workers will all contribute to the successful introduction.

Findings from previous program reviews

Reviews of the national immunization program were conducted by the Ministry of Health of Mongolia, WHO, Asian Development Bank, UNICEF, JICA, and GAVI in 1997, 2000, 2002, and 2004. Since 2004, no international reviews of the entire program have been conducted. Instead, focused reviews of different aspects of the immunization program have been conducted. For example, in 2006, a data quality self-assessment was conducted by WHO. In 2010, an assessment of the Immunization law was conducted. In 2011 and 2012, an EVM assessment was conducted.

Overall, these reviews concluded that the national immunization program in Mongolia is strong, and the recommendations from these reviews became the rationale for policy changes and the basis for subsequent improvement plans. For example, the immunization law was developed and approved in 2000 following a recommendation from a review.

Mongolia has developed many legal documents to help implement recommendations on combatting vaccine preventable diseases. For example, in 2011, the Mongolian government approved a new national program on combating for infectious diseases. An activity plan for implementing this national program specifically for the period 2011-2015 was developed and approved by Minister of Health and National Development and Innovation Committee issued by joint order #261/101 in 2011. The immunization law is critical as it creates a system to ensure financial commitment from the government for immunization.

Recently identified areas for improvement

In Mongolia, issues related to immunization program are regularly discussed by the different immunization advisory committees and recommendations are made. Often, the immunization law is modified to incorporate these improvements. Below are some of the key challenges and subsequent improvement actions that have been taken in Mongolia:

1. Recommendation: Improve the implementation of clause 15.2 of the immunization law: "Transport vaccines with temperature monitoring device /fridge tag/, vaccine documents in licensed vehicles".
In order to implement this recommendation, order number 122 of the Minister of Health was issued. The new order gave an updated and more detailed explanation for transportation.
2. Recommendation: Increase the Government's financial contribution for cold chain and replace and renew cold chain equipment to prepare for the introduction of new vaccines such as Hepatitis A and HPV.
To implement this recommendation, a Cold Chain Equipment Supply Plan 2012-2015 was developed and approved by minister order #359. The plan has been implemented nationwide and the following percentage of the national cold chain equipment were replaced every year: 30% of cold chain equipment in 2011, 50% in 2012, 4% in 2013, 10 % in 2014. In addition, a new cold room with volume of 40 m³ will be established to central vaccine storage rooms and its cost provided by Government. Finally, one additional cold room with same capacity has approved by WHO, and it will be installed in

2015.

3. Recommendation: Improve funding at local level as there is currently insufficient funds for per diem and petrol costs at the local level which leads to a decrease in immunization activities in difficult-to-reach populations living in remote areas.
This recommendation is being implemented through the Reaching Every District Strategy (developed in 2010 and approved by #154 ministerial order in 2011). Immunization workers and directors are currently analyzing barriers to immunization and requesting funds for general outreach health services packages which also include immunization.
4. Recommendation: Strengthen the safety of immunization activities by improve AEFI reporting, surveillance, and response.
To implement this recommendation, Ministerial order #217 was issued in 2012. Also, the procedures for vaccine waste management for vaccines was clarified through minister order #359 in 2011.
5. Recommendation: Update the Response protocol for wild poliovirus
To implement this recommendation, the preparedness plan on prevention and response to an importation of wild poliovirus was developed in 2010 and approved.
6. Recommendation: The NITAG recommended that a specific procedure should be followed to evaluate the introduction of any new vaccine. The process should include surveillance to help evidence-based decision making for the introduction of new vaccines
The recommendation was implemented by developing the procedures for the introduction of new vaccines (approved by order#359 Minister of Health in 2011).

Resource constraints in implementing the recommendations

Among the recommendations from program reviews and advisory bodies, some recommendations difficult to implement due to a variety of factors. These include:

- Doctors and nurses are have heavy workloads and find it difficult to fulfill all immunization duties at both the primary and secondary level. Additionally, small amount of salaries and lack of incentives has resulted in a high rate of health care worker turnover.
- Vaccine wastage rate for birth dose of BCG and Hepatitis B within 24 hours is high in the remote areas
- The strength of the anti-vaccination lobby is increasing
- Despite improvements, there is still insufficient funding to repair cold chain equipment at all levels, and currently the government tends to rely on international organization's supports to procure some of the equipment. In additionally there is only one engineer responsible for repairing cold chain equipment for the entire country level

Lessons Learned from Previous New Vaccine Introductions

In September 2005, the pentavalent vaccine (DTP+HepB+Hib) was introduced and in September 2009 the MMR vaccine was introduced into national immunization schedule in Mongolia. In 2012-2013, Mongolia introduced the Hepatitis A vaccine into the routine immunization schedule in a phased manner. In addition, the H1N1 was administered to 723,625 persons aged 6-65 according to National plan of delivering pandemic influenza vaccine and

immunization. Lastly, in 2012 Mongolia did a pilot introduction of the HPV vaccine in 2 districts and in 2 provinces.

During each vaccine introduction, many lessons were learnt and these lessons were incorporated in each subsequent introduction.

The Pentavalent vaccine was introduced from 2005-2008 in phases across provinces. This structure allowed the experiences from each phase to inform the planning for the next phase. Some of the key lessons learned were:

- The guideline and training materials were sufficient. Lots of effort was required documents used for immunization training material.
- Immunization staff at all levels were fully trained. During training, staff had the opportunity to practice how to inject the penta
- Many activities including AEFI surveillance and immunization safety were improved by approving more detailed Minister orders related to these issues
- Cold chain and immunization units provision were strengthened by introducing penta. All problems related to cold chain and safety immunization were discussed during penta and decided practically by adding usage of safety box and auto disabled syringes.
- Vaccine presentation has a large influence on the cold chain requirements. Lessons learnt from Penta and MMR underscored the importance of this decision.
- Mongolia has also become more experienced in how to initiate and complete all procedures needed to amend the Immunization Law and change the National immunization schedule.

4.4 Stock management

Primary store has a computerized stock management system in use. VSSM 4.7 (Vaccines and Supplies Stock Management). The software is a WHO Vaccine Software is designed especially to record crucial for immunization information on vaccine stock management, as VVM status, lot, batch numbers, expiry dates etc. The software package is supported by the software developer (WHO). Stock records backed up every week.

At NCCD vaccine arrivals and vaccine dispatches are recorded and stock balances are updated within one working day of the transaction. Standard forms (ledger) are used at all levels. The stock records for vaccines and diluents record the key information for all vaccines including vaccine type, presentation, manufacturer, batch number, expiry date, quantities, and VVM status.

Routine reports on internal vaccine distributions, with summary of the details of each and every transaction are included.

Country has also introduced a vaccine requisition system which uses vaccine requisition forms for ordering, receiving, and using vaccines regularly, on monthly basis at all levels. The stock records ensure that the vaccine is issued according to the 'earliest-expiry-first-out' (EEFO) principle in National Vaccine Store (NVS). A recent analysis of the NVS system has indicated that the stock control system (which is designed to record wastage) is being used and staff knew that expired and damaged vaccine should be clearly labeled and stored out of the cold chain until final disposal.

Stock management for IPV will be monitored same as other routine vaccines as described above.

Table 9. Mongolia minimum and maximum storage policies

Level	Minimum (months)	Maximum (months)
PR (Central stores)	3	6
LD (province)	1	2
LD (districts of UB)	0.25	1.25
SP (Health Facility)	0.25	1.25

District Stores and Province Stores are generally responsible for vaccine collection from the Central Vaccine Store located at the NCCD. NCCD is only responsible for sending vaccines if the vaccines must be shipped by air. In this case, the NCCD sends vaccine to the local airport. District stores collect vaccine every month from the Central Store. Province stores collect vaccine every 3 months directly from central store.

A refrigerated “Isuzu NKR55E2” truck is used to transport vaccines from the central store to the province stores and to district stores. These trucks are also used to transport vaccines from customs to the Central Store. The trucks are equipped with “Thermo King” refrigeration units. During a test run, the refrigeration units functioned properly and maintained a temperature of +2°C to +8°C. The vehicle and the refrigeration units are in good condition. The refrigeration unit is powered by the main engine and has a standby electrical power system that can be plugged into a main supply. NCCD and other stores equipped with the necessary power adapter for the refrigerated truck. The vehicle is equipped with a thermometer which can be read in the driver's cabin at the screen of monitor. There is also a temperature recording device, which can produce hard copy output.



Table 10. Vaccine delivery modes from NCCD to Provinces and distances

District or province	Name	Distance from UB	Mode
District	Bagakhangai	In city	Road
District	Baganuur	In city	Road
District	Bayangol	In city	Road
District	Bayanzurkh	In city	Road
District	Chingeltei	In city	Road
District	Khan-Uul	In city	Road
District	Nalaikh	In city	Road
District	Songinokhairkhan	In city	Road
District	Sukhbaatar district	In city	Road
Province	Arkhangai	453	Road
Province	Bayankhongor	630	Air
Province	Bayan-Ulgii	1,636	Air
Province	Bulgan	318	Road
Province	Darkhan-Uul	219	Railway or Road
Province	Dornod	655	Air

Province	Dornogobi	463	Railway or Road
Province	Dundgobi	260	Road
Province	Gobi-Altai	1,001	Air
Province	Gobisumber	230	Railway or Road
Province	Khentii	331	Road
Province	Khovd	1,425	Air
Province	Khuvsgul	671	Air
Province	Orkhon	371	Railway or Road
Province	Selenge	311	Railway or Road
Province	Sukhbaatar	560	Road
Province	Tuv	43	Road
Province	Umnugobi	553	Air
Province	Uvs	1,336	Air
Province	Uvurkhangai	430	Road
Province	Zavkhan	984	Air

Transportation from province and districts to the Health facility level

Primary health care facilities are responsible for collecting vaccine from province stores by traveling to the facilities stores once per month. In order to transport the vaccines, all facilities are equipped with vaccine carriers and icepacks.

IPV will be transported in the same way as all other routine vaccines as described above.

5. Monitoring and evaluation

5.1 Updating of monitoring tools

The following is a list of monitoring materials and documents which will be updated, printed, and delivered to health facilities:

- Checklist of supportive supervision for health care workers
- Reporting format on immunization coverage
- Surveillance reporting format
- Immunization cards

After introduction, a quality assessment for immunization coverage and EVM will be conducted. Additionally, following introduction Mongolia will conduct a post-introduction evaluation. This evaluation will specifically be designed to identify the major success and major challenges of the introduction. This information will then be used during the planning of other new vaccines in Mongolia in coming years. There is no barrier related to gender equality in Mongolia. Therefore Mongolia does not have plans to change the reporting forms to collect data on sex.

5.2 Adverse Event Following Immunisation (AEFI) monitoring and reporting

Any suspected case of AEFI is investigated according to order #217 of the Health Minister. The healthcare worker who first diagnoses the suspected case of AEFI must report it to the next level health care provider/immunization officer within 24 hours and then the immunization officer must report it to NCCD. Then, the information on the suspected case of AEFI should be sent to the MoH. Investigation of the case of AEFI must begin as soon as possible and information on

the health situation of the child and detailed vaccine information of both before and after birth should be collected. Causality of AEFI case should be determined and response measure against AEFI should be conducted in timely manner. Mongolia does not directly agree or disagree with any rumors about AEFI following vaccination. Information on immunization will be delivered through media channels.

There is no AEFI Expert Review Committee in Mongolia. In the case of severe AEFI case, a team consisting of professional specialists from different medical disciplines should be established according to order # A/92 issued by the General Director of NCCD.

Surveillance and monitoring for an AEFI case related IPV will be conducted according to order #217. A doctor who examined a child health situation before vaccination should conduct an active survey on a vaccinated child for 3 days. Weekly notification of any AEFI cases should be sent to NCCD, analyzed, and delivered to MoH.

6. Advocacy, communication, and social mobilisation

Members of the primary Immunization advisory groups in Mongolia (NITAG and ICC) will sensitize political and decision makers about the need and importance of IPV. Additionally, sensitization materials will be developed and distributed to decision makers with specific knowledge on IPV and the general polio situation.

The National center for communicable Diseases of Mongolia, MoH will lead all communication strategy on IPV introduction. Additionally, they will collaborate with the communication teams at the Center for Health Development of MoH, WHO, and UNICEF. Many types of IEC materials will be developed by NCCD officers and the Ministry of Health will ensure the quality of the materials.

The following eight types of IEC materials will be developed or updated: an IPV introduction guideline, posters, immunization booklet (updated), TV spots, live TV interviews, newspaper articles, reminder for mothers, and immunization certification (update).

1. *Introduction guideline*: The introduction guideline is the main material to be used for training. This guideline should include all information about IPV and all processes of IPV introduction.
2. *Posters*: Posters are very basic education materials for vaccinators and doctors. Two types of posters for healthcare workers and parents will be prepared. They will include important warnings and instructions for packaging, delivering, storing, preparing to vaccinate and injecting. The parent's poster should include knowledge about IPV introduction benefits to the population and contribution to the Global Polio Endgame Strategy and should be given to the community.
3. *Immunization booklet*: a regularly published immunization booklet directed towards parents and the community is currently used in Mongolia. This immunization booklet is updated every 1-2 years. When it is next updated, it will include information about IPV benefits, IPV introduction, and more.
4. *TV spot*: because media advertisements have proven to be important communication methods, Mongolia will organize 30 second TV spots for IPV targeted to the general public

5. *Expert TV interviews*: live interviews with high-level experts will broadcast on TV at peak time through famous national networks. The national immunization technical advisory group (NITAG) members and officers of Ministry of Health will support the TV interviews.
6. *Newspaper articles*: an article about IPV introduction will release through daily newspapers and websites.
7. *Reminder message*: a reminder message about the date of one additional single dose of IPV vaccine will be send to all mothers who have a child aged 3 months.
8. *Immunization certification*: the immunization certificate which is given to all children will be updated by adding additional information about the IPV dose.

Launch Ceremony

A national launch ceremony at the 15th anniversary of Polio free Mongolia will be held at the District Health Department of UB city. Minister of Health/Vice Minister of health, main international partners (WHO, UNICEF, and JICA), and some other important decision-makers will help plan and attend the National Launch ceremony. The national launching of IPV introduction will be used as an opportunity to advertise the achievement of Mongolia's ability to maintain polio-free status for 15 years. At the ceremony, it will also be highlighted that introducing IPV will further strengthen Mongolia's efforts to maintain polio-free and Mongolia's role in helping the world reach the Global polio eradication goal. At the same time, each province health department also will organize a launching ceremony for IPV introduction and the 15th anniversary of Polio-free status at local level. Influential individuals responsible for the public health policy implementation from the province governance and head of the Health department will invited to the ceremony at the district and provincial level.