

IPV Introduction Plan

Annex A



Government of the Republic of Zambia

September 2014

INACTIVATED POLIOVIRUS VACCINE (IPV)

IPV APPLICATION TO GAVI

IPV Introduction Plan

Executive summary of the introduction plan

At the sixty-sixth World Health Assembly (WHA) in May 2013, the Ministers of Health endorsed the new Polio Eradication & Endgame Strategic Plan 2013-2018. Additionally, there was need to intensify actions to stop polio in the remaining infected countries. The Endgame Plan calls for all countries to strengthen routine immunisation programmes and replace trivalent Oral Polio Vaccine (*t*OPV) with bivalent OPV (*b*OPV) in 2016, thereby eliminating polio cases and outbreaks that may arise from the type 2 component of *t*OPV. In effort to ensure smooth transition to polio free world, the Strategic Advisory Group of Experts on immunisation (SAGE) has recommended that all countries introduce at least one dose of Inactivated Poliovirus Vaccine (IPV) into the national routine immunisation schedule before the end of 2015; which will be administered at or after 14 weeks of age (e.g. the DPT3 contact) in addition to existing OPV doses. The implementation of IPV introduction will be integrated into the existing immunisation and AFP surveillance systems.

The IPV introduction has 3 major benefits: firstly, it will reduce the risk of type 2 polio disease when *b*OPV is introduced as it has no type 2 component which is found in *t*OPV; Secondly, IPV will boost immunity against types 1 and 3 polio thereby reducing vulnerability globally to the remaining wild polioviruses and thirdly, IPV will interrupt any future type 2 outbreaks. The government has planned for operational costs related to the IPV introduction which have been factored in the cMYP 2011-2016 and micro-plan and also considered annual budget allocations for co-financing.

The IPV introduction will be a nationwide implementation in third quarter of 2015. The key milestones and activities that will precede the IPV introduction are: development of IPV introduction plan and budget; briefing of stakeholders; financial resource mobilisation; development of health worker handbook and DVD; development and implementation of communication strategy; vaccine licensure procedures and logistics management; updating of data reporting and monitoring tools; strengthening of AEFI surveillance and expert committee; orientation of vaccinators and data managers; launch ceremony and eventual introduction. Some preparatory activities commenced in second quarter 2014.

Zambia, in 2013, successfully introduced three new vaccines (PCV10, Rotavirus vaccine and Measles second dose) in the national immunisation programme. The country, in July 2014, conducted a comprehensive evaluation of the vaccine introduction processes and the EPI programme. The lessons have been documented for reference. The programme has developed an action plan to strengthen the programme in the areas related to supply chain and logistics; health work force capacity; data quality; programme monitoring and social mobilisation.

The EPI programme has considered potential health workers and community concerns and anxiety that may arise related to multiple injections. Working with partners, the Government of Zambia will be could be conducting operation research to have insight and provide strategic information in the area of programmatic practices and community response.

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

Decision making process

Zambia has made significant progress and successfully presented complete country polio free documentation to the African Regional Certification Commission (ARCC) in 2005 and continues to record no cases of circulating wild Polio virus since then. In line with the Polio Endgame Strategy and the country's commitment to increasing access to health services by expanding the number of priority programmes (such as maternal, newborn and child health), the country has planned to introduce Inactivated polio vaccine (IPV) by the end of 2015.

The National Epidemics Preparedness, Prevention, Control and Management Committee (NEPPC&MC), which is a multi-sectoral committee with membership drawn from line ministries and stakeholders, at the Ministry of Health tabled the IPV agenda and adopted the strategy to switch to IPV alongside *t*OPV and *b*OPV by 2015 and 2016 respectively.

The Inter Agency Coordinating Committee (ICC) meeting held on the 13th of May 2014 endorsed the decision to introduce the IPV into the national immunization schedule as part of the Polio End-game Strategy. This followed recommendations from the 65th World Health Assembly Session where Ministers of Health declared the polio eradication to be a programmatic emergency for global public health and called for a comprehensive polio end-game strategy. The ICC comprised major stakeholders including: academia, key ministries, Civil Society Organisations and private sector, and research institutions. Zambia does not have a National Immunization Technical Advisory Group (NITAG) but is in the process of establishing one with support from Supporting Independent Immunization and Vaccine Advisory Committees (SAVIC).

In line with global requirements, the EPI programme in Zambia presented to ICC the IPV introduction global recommendation and made emphasis that every country will have to introduce IPV into the national immunization programme by the end of 2015.

Technical and operational Feasibility

Policy Environment: The government has successfully implemented the Zambia immunisation programme because of the existence of a conducive policy environment. The availability of the Child Health Policy which includes Immunisation as a part of the Basic Health Care Package provides a platform for the delivery of immunisation services including introduction of new vaccines. The availability of the costed Comprehensive Multi Year Plan provides understanding of immunisation costing and financing.

The country has a National Polio Certification Committee as well as a National Polio Expert Committee which oversees the implementation of polio eradication activities and submits country annual updates to the African Regional Certification Commission. In addition, the presence of an accredited National Polio Laboratory continues to provide confirmation that the country has no circulating wild polio virus. The specific focus for these national polio committees is certification and containment.

The functional and well-coordinated Inter Agency Coordinating Committee chaired by the Minister of Community Development Mother and Child Health (MCDMCH) has provided a forum for forging strong partnerships which provide oversight to immunisation programming. During the recent multiple introductions of new vaccines (PCV and Measles second dose in July, and Rotavirus vaccine in November 2013), members of the ICC each brought their respective comparative advantages to the process. In addition, the country has commenced the process of establishing a National Immunisation Technical Advisory Group.

While key strategies for delivering immunisation programmes include the Reaching Every District (RED) Approach and the recently developed EPI communication strategy, these strategies need to be strengthened.

Service Delivery

Following the EVM conducted on 2011 and the development and implementation of the Vaccine Cold Chain Expansion Strategy, Zambia has continued to make great strides in expanding cold chain capacity at all levels. Government and partners mobilized financial resources to expand, replace and rehabilitate cold chain equipment in preparation for the introduction of PCV, MSD and Rota virus vaccines. Currently, there are no gaps at central, provincial, and most districts levels. However, gaps remain at health centre level; efforts are under way to address these gaps (these are highlighted in the section 3.4 below). The country also has plans to conduct the next EVM before the end of 2014.

The introduction of three new vaccines in 2013 provided an opportunity for re-training of health workers in delivering immunization. However, due to limited resources available for this activity, issues of quality were of concern. The introduction of IPV will provide further opportunity for improvement.

Introduction of two additional injectable vaccines (Pneumococcal Conjugate Vaccine and Measles second dose) and IPV as the third in two years definitely has an impact on the environment. Zambia has in place the Safe Injection Policy which has sufficiently addressed safe injection disposal needs. The country also has a functional AEFI reporting system under the Pharmacovigilance Unit in the Zambia Medicines Regulatory Authority [ZAMRA].

Data Collection

The country will review and update the data collection and monitoring tools to include IPV data elements. However, the task requires resource mobilization for production of tools and orientation of health workers. Currently, the existing partnerships such as Better Immunization Data [BID] Project will contribute to data quality enhancement.

Monitoring and surveillance of the Immunization system

The EPI programme has conducted several self-assessments including DQS [2012], an EPI coverage survey [2011], an immunization financing and costing survey [2013], a post-measles campaign survey [2012], an EVM [2011], and a KAP study [2013] and a combined PIE, in-depth EPI and surveillance review [2014]. These evaluations have provided insight to improved programming for EPI.

Vaccine procurement

The country has a dedicated budget line for cold chain through the government Medium Term Evaluation Framework to enable sustainability of the programme. In addition, the country will continue to utilize UNICEF procurement systems for IPV vaccine and related supplies

2. Overview of IPV

2.1 Vaccine preference

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
10 dose	October 2015	Single dose	-

2.2 Country licensure status

Status of NRA: The Zambia Medicines Regulatory Authority (ZAMRA) is the functional national NRA. It was established under the medicines and allied substance ACT (Number 03) of 2013 and is part of the WHO AVAREF network.

Vaccine licensure: The country will need a national vaccine licence for the implementation of the IPV in addition to the prequalification. WHO prequalified vaccines can be registered under collaborative procedure as established by WHO, i.e., expedited procedures for national registration of WHO-prequalified vaccines can be done through the available collaborative procedures. It is anticipated that this process should be completed by end of 2014.

There is no IPV registered at the moment though one product is currently under consideration.

Importation requirements: Import permit and lot releases will be required by ZAMRA for each importation

2.3 Target population and vaccine supply

Table 2: Target population estimates by year

Year	Number in target population for IPV ¹
2014	0
2015	121,544*
2016	509,045
2017	538,667
2018	568,937
Total	1,738,193

Procurement process: The country will maintain UNICEF as the institution to procure and deliver vaccines.

3. Introduction and implementation considerations

3.1 Policy development

The existing Child Health Policy has prioritised immunisation as one of the basic interventions to be provided for all Zambian children. It is under this policy guidance that immunisation services are provided. The Child Health Policy, which includes immunisation, will not be altered in any way but there will be need to alter the data collection tools, presentation of the vaccines in the immunization schedule and all monitoring tools to include IPV. The orientation of Data Collectors country-wide in the revised data collection tools will include IPV data elements. The timing of IPV administration will be aligned with the third dose of DPT which in Zambia is at or after 14 weeks of age.

Injection administration site: PCV and IPV will both be administered in the left thigh (2 cm apart), while Penta will be administered on the right thigh.

IPV schedule: IPV will be aligned to the 3rd doses of DPT and PCV which are administered at 14 weeks.

¹ If there are differences between country and WHO-UNICEF coverage estimates, the Secretariat will refer to the latter when estimating targets.

3.2 National coordination mechanism to ensure the successful introduction

See completed ghannt chart (Annex C) for the IPV introduction timeline

The Child Health Technical working group will oversee the national level management process of the introduction of IPV. This committee has sub-committees namely the service delivery, logistics and cold chain, social mobilisation and surveillance, monitoring and evaluation. The composition of these sub committees include government institutions, the UN system, other stakeholders such as Faith based organisations, civil society, professional associations, private health providers.

These sub-committees will undertake the tasks of finalising the budgets, timelines, adaptation of training materials, development of communication strategies and materials, review of data collection and monitoring tools as well as follow on evaluations under the guidance of ICC.

3.3 Affordability and financial sustainability

See completed budget and financing (Annex D) for the IPV introduction timeline

Estimates of costs: The sources of information used to estimate the costs are the cMYP (2011-2016), micro-planning and population projections from the Zambia Census of Population 2010. Actual immunization expenditure data from micro-planning and the Immunisation Financing and Costing study of 2012 were used.

Table 3: Identification of the non-vaccine operational costs for IPV introduction

	Cost Category	TOTAL COST US\$	Government support	Possible Partners' support*		Existing GAVI HSS funding	Requested GAVI VIG
			Amount US\$	Name	Amount US\$	Amount US\$	Amount requested US\$
1	Program management and coordination	19,646		UNICEF	19,646	0	
2	Planning and preparations	-				0	
3	Social mobilization, IEC and advocacy	238,340				0	238,340
4	Other training and meetings	979,520	829,520	UNICEF	150,000	0	
5	Document production	204,935	162,866			0	42,068
6	Human resources and incentives	-				0	
7	Cold chain equipment	-				0	
8	Transport for implementation and supervision	396,903	220,877			0	176,026
9	Immunisation session supplies	-				0	
10	Waste management	-				0	
11	Surveillance and monitoring	-				0	
12	Evaluation PIE	51,140		WHO	51,140	0	
13	Technical assistance (in kind)	-				0	
14	Data management	103,565				0	103,565
15	Other (Vehicle Maintenance)	25,407	25,407			0	
	Total	2,019,456	1,238,670		220,786	0	560,000

Trend of immunisation financing: For the period, 2014 to 2018 cMYP, the projected costs of funding by category involving shared and direct costs for the EPI programme amounting to UDS2.5 billion, indicated in the table above. Direct costs related to EPI programme accounts for 9% only. The main components funded by the programme are at 64% and 27.4% for Vaccine supplies and logistics and Service delivery respectively.

The additional operational costs for IPV introduction have been taken into account in the existing government budget lines and partnership.

Table 4: Summary of baseline year (2012) expenditures and projected costs (2014-2018), by category

	2012	2014	2015	2016	2017	2018	TOTAL 2014-2018
Vaccine Supply and Logistics (routine only)	\$ 24,134,509	\$ 25,950,340	\$ 26,930,504	\$ 27,869,169	\$ 29,385,240	\$ 32,014,254	\$ 142,149,506
Service Delivery	\$ 11,235,175	\$ 11,592,979	\$ 11,852,925	\$ 12,136,248	\$ 12,378,973	\$ 12,644,836	\$ 60,605,961
Advocacy and Communication	\$ 221,000	\$ 153,000	\$ 166,464	\$ 106,121	\$ 227,311	\$ 276,020	\$ 928,916
Monitoring and Disease Surveillance	\$ 656,325	\$ 703,154	\$ 737,299	\$ 773,103	\$ 810,514	\$ 850,010	\$ 3,874,080
Programme Management	\$ 3,463,783	\$ 1,381,176	\$ 2,129,406	\$ 2,177,319	\$ 1,225,018	\$ 1,277,617	\$ 8,190,536
Supplemental Immunization Activities (SIA) (includes vaccine and operation costs)	\$ 9,072,315	\$ 472,949	\$ 491,717	\$ 3,679,822	\$ 538,781	\$ 301,068	\$ 5,484,336
TOTAL Direct Costs	\$48,783,107	\$40,253,598	\$42,308,315	\$46,741,781	\$44,565,837	\$47,363,805	\$221,233,336
Shared Health Systems Costs	\$ 443,968,392	\$ 452,887,424	\$ 461,945,173	\$ 471,184,076	\$ 480,607,758	\$ 490,219,913	\$ 2,356,844,344
GRAND TOTAL	\$ 492,751,499	\$ 493,141,022	\$ 504,253,487	\$ 517,925,857	\$ 525,173,595	\$ 537,583,718	\$ 2,578,077,679

Co-financing: In the initial year of introducing the vaccine, no co-financing mechanisms will be employed. Co-financing mechanisms will be employed in the subsequent years. The Government, as in previous years, will provide the co-financing.

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

Adequacy of cold chain storage capacity: There are four supply chain levels: Primary, Sub-National, Lowest Distribution and Service Delivery. The National Vaccine Store gets its supplies from manufacturers twice a year. The National Vaccine Store further distributes to 10 provinces using mainly cold boxes on a quarterly basis. Districts then collect their supplies from provincial vaccine stores on a monthly basis. The lowest distribution level, [health facilities] also collects from the district level on a monthly basis.

The country undertook a major cold chain expansion from 2011 and has continued to implement this expansion plan. The central level capacity is currently 55,000 litres and the 66,786 litres at provincial level. The table below summarises the supply intervals at various levels of the cold chain system.

Table 5: Vaccine stock levels and supply interval at different levels

Stock	Location of vaccine stores			Service-delivery levels
	National	Province	District	
Safety stock, months	3	1	1	0.5
Supply period, months	3	3	1	1
Maximum stock level, months	6	4	2	1.5

Addressing capacity gaps: It is anticipated that with the current on-going efforts to improve cold chain capacity, the introduction of IPV will not pose major challenge on the system. There are currently on-going efforts to expand and improve the cold chain and logistics systems for vaccine management. These include the procurement of cold chain equipment for the national and provincial levels which have significantly increased capacity at national level (five 40m³ walk-in cold rooms and stand by generator already functional).

For the provincial level four 40m³ and four 30m³ Walk in Cold Rooms (WICR) with stand by generators already functional, over 130 district level equipment fridges, while 400 health

facility fridges have already been procured and plans are underway for training and installation of the equipment in six of the ten provinces by the end of 2014. Two additional trucks are in the process of being procured to supplement the fleet of transport.

There are additional efforts with funding already committed for the procurement of additional vaccine fridges through established government budget line for cold chain and support from Elmer Philanthropies in 2015. The Government, World Bank and CIDRZ will procure an extra at least 500 additional refrigerators which will result into an additional 90,000 litres at district level and 8,628 litres at health facility level.

All of the provincial vaccine stores have adequate cold chain capacity both for the negative and positive temperatures except for Lusaka, Muchinga and the North western Provinces which need an additional 5,056 litres and 846 litres respectively. Muchinga will require 73 litres of negative cold chain capacity.

However, the procurement of these additional cold rooms for the three aforementioned provincial vaccine stores are underway and expected by the end of 2015 through government funds. There is an on-going cold chain replacement being undertaken by the Ministry of Community Development Mother and Child and partners such as CIDRZ and JICA that will greatly improve the cold chain capacity to meet the needs of the program at the district and health facility levels.

Power supply and cold chain maintenance: The procurement of the 5 National Cold Rooms and 8 Provincial cold rooms with accompanying standby generators has already incorporated the issue of power supply. In order to address the challenge of power supply at the health facility level, funds have been mobilised through the Vaccine Cold Chain expansion to replace and also procure additional solar vaccine fridges alongside the required spare parts for the maintenance of the existing as well as new equipment. Funding has already been secured through the JICA supported and Elmer Philanthropies cold chain support.

In addition, the National Cold Chain workshop is being rehabilitated and refurbished this year through Elmer support funding through the Centre for Infectious Diseases Research in Zambia (CIDRZ). The rehabilitation of this workshop which is also a national training workshop for provincial and district level technicians will result in improved cold chain management of equipment.

The Ministry of Finance through the treasury authority has dedicated a budget for cold chain procurement and management.

3.5 Waste management and injection safety

Injection safety and waste management: With the introduction of new vaccines, the Ministry of Community Development Mother and Child Health is aware that there will be an increase in the waste generated. Therefore, there is a need to strengthen guidelines for waste disposal and encourage burn and bury. Where incinerators are available they will be used and if not available the burn and bury principle will be used. Disposable safety boxes and AD syringes will continue to be used to ensure injection safety and safe disposal of waste. The guidelines for strengthening these processes will be integrated in the training manuals and field guides for health workers.

Procurement of injection safety related devices: The country will procure WHO pre-qualified devices using bundling approach through UNICEF procurement system.

3.6 Health worker training and supervision

Capacity building - health workers: The health system in Zambia operates with existing structures at various levels in the provision of vaccine programmes. In order to efficiently introduce IPV, the implementation will be absorbed within the existing structures. Further, IPV introduction will be preceded by the development of an IPV handbook and training DVD and countrywide orientation of frontline health workers.

The introduction of IPV will require training at all levels across the different sub-specialties. The training will be conducted in a cascade manner at national, provincial and district management levels in the various disciplines relating to vaccine management and staff supervision.

One health worker from each of the health facilities in the country will be trained for the introduction of IPV to contain training costs while maintaining the quality of training. All districts will be provided with adequate training materials to conduct cascade on-site orientation within each health facility. This approach will reduce training time and preclude removing staff from the facilities during the introduction phase.

In order to strengthen supervision, checklists will be adapted and district supervising teams will be trained on their use. A budget for supportive supervision has also been developed which will encourage early mentorship and correction of training gaps. Communicating about IPV vaccine and its benefit is critical for encouraging parents/care givers to vaccinate their children. As such health workers need to communicate appropriately and re-assure parents about the safety of the vaccine and address any concerns they may have. Therefore health workers will also need to be trained on interpersonal communication skills as well as on risk communication.

Programme management: Management at the provincial and district levels have existing supportive supervision programme, onsite mentorship and performance assessment activities which are conducted at respective sub-levels on a quarterly basis. These resources will help to back-stop any gaps that may arise as a result of shortfalls in programme specific monitoring and supervision due to limited resources.

Training materials: The Ministry of Community Development Mother and Child Health will adapt existing generic training materials from WHO and other sources, working through the child health technical working group/ sub-committees which are composed of membership from the Ministry of Health, Ministry of Community Development, and Mother and Child and Partners including Civil Society Organisations.

These materials will include various aspects of the vaccine, e.g., AEFIs, FAQs, and fact sheets. In addition training videos and other print materials will be produced. A pre- and post-test for the training will be integral part of the training process. A complete package of training materials will be distributed at each service delivery level. Communication materials will also be developed.

Training plan: IPV training will be offered in a cascaded manner starting with Training of Trainers at the national level through the province and district to the health centre staff. The training content will include integrated approaches to injection safety and other vaccine handling practices, as well as AEFI communications.

Supervision plan - before, during and after introduction: In order to maintain high quality IPV implementation, it is necessary to develop a strong supervision plan at all levels of care. As such, a pre-implementation supervisory checklist will be adapted, printed and distributed. Through the cascade training of health workers, orientation to this checklist will be conducted. Supervision of the implementation of IPV will continue following introduction to ensure adherence to guidelines.

3.7 Risks and challenges

The programme anticipates implementation challenges which may include community and healthcare worker acceptance of multiple injections at a single visit. There are also concerns from health workers on providing multiple injections to the child at one time and how the care-givers will accept it. To understand the concerns of both the care-givers and health workers, the country is conducting a multiple injection study in 2014, findings of which will be used to design and tailor appropriate communication messages and use credible sources of information to reach care-givers with information.

IPV introduction may also be affected by availability of adequate frontline health workers to provide continuous service with minimal disruptions due to an increased number of vaccines to be offered at once. Extensive community awareness campaigns as well as staff capacity building will be conducted to address this concern.

Timely reporting of data may be another factor that would affect the monitoring of IPV implementation and could ultimately result in a delayed submission of the annual progress report and the Joint Annual Reporting Form. The Ministry of Community development Mother and Child Health is in the process of cascading Quality Improvement through Data Use (QIDU) training to all staff at all levels to improve the quality of data and local use of the data to improve health services. In addition, Zambia will receive support through the Bill and Melinda Gates Foundation (Better Immunization Data) to improve the quality of data, beginning initially with one province and cascading to all provinces over a period of 4 years.

4. Situational analysis of the immunisation programme

4.1 General context of the country

Country Context: Zambia is a Lower Middle Income Country and since 2006, the country has been implementing Vision 2030, which aims at transforming into a prosperous middle-income nation by 2030. Over the past 5 years, the country recorded major improvements in macro-economic performance, with the average annual economic growth rate of above 5 percent. However, these improvements have not yet significantly impacted the socio-economic well-being of the population, the majority of whom are poor and vulnerable. The projected population of the country is about 14.6 million (2014) with an annual population growth rate of 2.8%.

Zambia has a high burden of disease, which is mainly characterised by high prevalence and impact of communicable diseases, particularly, malaria, HIV and AIDS, STIs, and TB, as well as high maternal, neonatal and child morbidities and mortalities. The country is also faced with a rapidly rising burden of non-communicable diseases, including mental health, diabetes, cardio-vesicular diseases and violence.

According to the 2007 Zambia Demographic and Health Survey (ZDHS), it is evident that years of investment in primary health care services have yielded positive results in select indicators such as Maternal Mortality Ratio (MMR) whereby maternal deaths were reduced from 729 deaths per 100,000 live births in 2002 to 591 in 2007; Under-Five Mortality Rate (U5MR) reduced from 168 per 1000 live births in 2002 to 119 in 2007; and Infant Mortality Rate (IMR) reduced from 95 to 70 deaths per 1,000 live births, respectively. In the same period between 2002 and 2007, Neonatal Mortality Rate (NMR) reduced from 37 to 34 deaths per 1,000 deaths per 1000 live births. HIV prevalence in adults, aged 15 to 49 years, was reduced from 16.1% to 14.3%.

Health System: In the health system, the main providers of health care services include public health facilities under the Ministry of Community Development Mother and Child Health, Ministry of Defence, Ministry of Home Affairs and the Churches Health Association of Zambia (CHAZ) which is a faith based umbrella organisation that oversees many faith based clinics and hospitals spread across the country, predominantly in rural and hard-to-reach areas. The majority of the workforce is employed and remunerated through the MoH. Other providers in the formal system include private-for-profit clinics, diagnostic centres, hospitals and drug sellers.

According to the Health Facility Listing of 2012, the country has a total of 1,958 health facilities country-wide. Of these facilities, 6 are Level 3 Hospitals, 24 are Level 2 Hospital and 81 are level 3 hospitals. A total of 409 are Urban Health Centres while 1131 are rural health centres and 307 are health posts. Out of the total reported health facilities, 1,592 are Government-owned, 116 are mission-owned and 250 are privately owned.

In the health system, the lowest level facility is a health post, intended to cater to a population of 500 households (3,500 people) in rural areas and 1,000 households (7,000 people) in the urban areas, or to be within reach within a 5 kilometre radius for sparsely populated areas. The next level is the health centre (HC) out of which Urban HCs are intended to serve a catchment population of 30,000 to 50,000 people while Rural HCs are to serve a catchment area with a population of about 10,000 people. Level 1 hospitals serve a population of between 80,000 and 200,000 while Level 2 hospitals or general hospitals serve a catchment population of between 200,000 and 800,000. Level 3 or central hospitals serve a catchment of above 800,000 people.

Health Priorities: The national priorities as outlined in the National Health Strategic Plan 2011-2016 are classified into two categories: public health and health system. The public health priorities are further identified as: primary health care services; Maternal, Neonatal and Child Health; Communicable diseases; Non Communicable Diseases; Epidemics control and public health surveillance; Environmental health and food safety; and Health Service Referral Systems. The Health System priorities on the other hand have been identified as: Human Resources for Health (HRH), Infrastructure and Equipment, Health Information, Health Systems Governance, and Essential Drugs and Medical Supplies.

Structure of the EPI Programme: At the national level, the EPI through the Child Health Unit is responsible for facilitating policy formulation; setting immunisation practices and standards through development of EPI guidelines; supporting capacity-building process, provision of vaccines and other programme logistics; facilitating linkages with other stakeholders and partners; resource mobilisation; monitoring and technical support; and supervision to districts.

At provincial level, the provincial level is responsible for supportive supervision of districts under their jurisdiction; planning and management of district service delivery; and ensuring that districts achieve optimal levels of performance. Provinces support distribution of vaccine and other supplies to districts including holding of buffer stocks.

At district level, this level is responsible for planning and management of district service delivery; ensuring a regular supply system to facility level; offering supportive supervision to health facilities; ensuring adequate mobilisation of the community effective reporting; and monitoring.

At health facility level, this level is responsible for immunisation services delivery as an integrated package with larger involvement of the community through the neighbourhood health committees; ensuring all necessary equipment and supplies are in place, including adequate stock levels of vaccines and a functioning cold chain; ensuring effective reporting; and monitoring.

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

Table 6: Trends in national vaccine coverage

Trends of national vaccine coverage (percentage)				
Vaccine	Vaccine Used	Target population (number by age and sex, if available)	Coverage reported (JRF)	
			Most recent year 2013	Previous year 2012
BCG	20 dose vial	653,131	82%	81%
OPV 3	20 dose vial	653,131	74%	69%
DTP 1 / Penta 1	1 dose vial	653,131	86%	84%
DTP 3 / Penta 3		653,131	79%	76%
Measles 1	10 dose vial	653,131	80%	85%
Measles 2		326,566	26%	No Data
PCV 1	2 dose vial	326,566	81%	No Data
PCV 3		326,566	48%	No Data
Rota 1	1 dose tube	326,566	34%	No Data
Rota 2 or 3		326,566	15%	No Data

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

Geography:

Zambia is a landlocked country with a total area of 752,618 square kilometres of which 9,220 km² is water. Zambia has a tropical climate with a rainy season that runs from October/ November to March/ April. The terrain is mostly plateau with some hills and mountains. The country has big rivers and swamps which get flooded in the rainy season and cause barriers to health access.

Economic Environment:

The population of Zambia has rapidly grown and the average life expectancy at birth has also increased, thus placing an increasing burden on the national economy, particularly the country's capacity to keep pace with health-related needs. While the population is increasing, the country on the other hand is experiencing high levels of unemployment and weak socio-economic status of the population, which have implications on the health status of the population. Income inequity among the population has remained high, with the Gini Coefficient at 0.57 in 2004 (a drop from 0.66 in 1998).

High poverty levels (67% in 2006) and poor access to safe water and sanitation also remain serious factors on health. The classification of Zambia as a low-Middle income country has resulted in the reclassification by GAVI as an intermediate country. Per this reclassification, Government is expected to increase investments in financing immunization. For increased domestic resources, the Ministry of Community Development Mother and Child Health (MCDMCH) will need to strengthen advocacy with the national treasury.

Policy: The existing Child Health Policy has prioritised immunisation as one of the basic interventions to be provided for all Zambian children. It is under this policy guidance that immunisation services are provided. National Immunization Policy will not be altered in any way as a result of IPV introduction, but there will be need to alter the data collection tools, presentation of the vaccines in the immunization schedule and all monitoring tools. The timing of IPV administration will be aligned with the third dose of DTP which in Zambia is at or after 14 weeks of age.

Social and Cultural: Zambia has a multi-cultural society, characterised by different racial and ethnic groups, religious and traditional groupings, urbanisation, and increasing access to the internet and other sources of information, with significant potential for promoting good health. However, there are some social, cultural and religious beliefs and practices that negatively affect health. These include cultural practices, such as sexual cleansing of surviving spouses, unsafe traditional male circumcision procedures, early marriages for female children, gender discrimination in favour of males, and risky traditional health practices.

Additionally, there are certain religious sects which discourage immunization hence health seeking behaviour generally is low. Health workers attitude is a barrier for utilization of immunization services. Families and communities have an important role in shaping the character and behaviours of the people.

Gender: Zambia has made commitments towards promoting gender equality in support of MDG 4 and SADC targets. With regard to education, the Gender Parity Index (GPI) for primary education improved from 0.90 in 1990 to 1.01 in 2009. However, for secondary level education decreased from 0.92 in 1990 to 0.87 in 2009, and for the 15-24 years old population it stagnated at 0.8 from 2003 to 2005. Regarding women's representation in parliament, despite the increase from 3.8% in 1991 to 14% in 2009, the country scored low against the target of 30%.

The gender barrier predominantly affects women who when they engage in economic activities to support their families do not prioritize health seeking behaviour, especially immunization, but would rather concentrate on income generating activities. To address this barrier, in line with the ministry vision, the programme will intensify outreach in order to reach the communities where these women live.

4.3 Findings from recent programme reviews

4.3.1 EPI Review: The in-depth EPI and Surveillance review of 2014 showed that:

Immunisation system environment had the following strengths:

- Supportive political environment, emphasizing community development and child health issues (MCDMCH, MoH)
 - Minister launch campaigns, new vaccines
 - Dedicated budget for monthly outreach sessions, cold chain, cards
 - Cabinet memo for supporting immunization campaigns
 - Government supports lab surveillance facilities
- Zambia pays for all traditional vaccines; co-finance new vaccines through GAVI (procurement through UNICEF)

- Growing infrastructure (road works) & additional health posts improve access to health services - including immunizations
- National Health Strategic Plan for the years 2011-2016 and the updated & aligned Comprehensive Multi Year Plan (cMYP) 2011-2016 is available.
- A framework for a bottom-up planning system exists and includes integration of health activities (to optimize resources including staff)
- Strong links to community structures (availability of head count data) provides opportunities to greatly improve program performance
- Motivated and dedicated staff with high profile immunization champions

4.3.2 Immunisation Financing and Costing Study: The immunisation financing and costing study 2012 by Health and Development Africa of South Africa revealed that government contributes significant financing to the programme and that this is key for sustainability.

4.3.3 Effective Vaccine Management Assessment (EVMA) 2011: The Effective Vaccine Management (EVM) results indicated that the vaccine supply chain in Zambia has a number of strengths which included excellent practices at all levels in the supply chain and in line with most major EVM indicators. The on-going efforts highlighted in section 3.4 are being implemented for cold chain capacity at all levels will ensure adequate capacity for current and future programme need.

Actions undertaken include procurement and installation of automated walk-in cold rooms with accompanying standby generators. Temperature monitoring devices were also procured for vaccine fridges at lower levels where manual temperature monitoring system has continued. Guidelines for management of cold chain including temperature monitoring have been developed but are yet to be printed and disseminated.

In order to strengthen stock management processes, the ministry employed logisticians for EPI commodities in late 2013. This led to the institutionalization of the stock management tool which is updated regularly, as well as the development of stock management tools for lower levels.

4.3.4 Community mobilisation during campaigns: The 2012 post measles survey revealed that the main source of information about the campaign was the health worker, followed by the radio/television. However, it noted that these sources may not be the ideal sources in populations with limited access to health facilities and radio/television given the high poverty level in Zambia. School-going children and traditional leaders should be widely used to disseminate information on campaigns.

Status of implementation of recommendation from previous assessments:

4.3.5 Data Quality Improvement: The immunisation coverage survey of 2011 revealed coverage performance of above 90% for most of the antigens. National results obtained from the survey showed weighted fully immunised children (FIC) crude coverage (card plus history) of 81.1% whereas the crude rate by card only was 67.2%. The findings will provide direction on future Health Workers training in EPI programme quality related aspects.

The 2012 DQS report highlighted the need to improve the quality of the transmission of data between levels. Archiving of paper based recording for specified periods

requires strengthening and plans are underway to address data issues with support through Better Immunisation Data (BID) project.

Overcoming resource constraints: There is a need for financial and human resources. To address these challenges, the programme is advocating increased budgetary allocation from government and partners. The programme will continue to explore opportunities for leveraging resources through integration of services.

NUVI lessons learnt: Building on the platform of previous introduction of new vaccines in 2013, the EPI programme has drawn a number of lessons such as Immunization service delivery is best implemented in an integrated approach with other primary health care services. The critical role played by community members and volunteers in immunization service delivery taking up various roles such as in:

- Social mobilisation
- Health Education
- Head count & recording
- Defaulter tracing

is essential.

4.4 Stock management

The Stock Management Tool adapted from WHO is used to monitor the use of vaccines. This has improved the stock control system at the national store. The vaccine distribution follows the 'Earliest Expiry–First Out' principle. There are plans to introduce an electronic vaccine management system at the provincial and district levels whilst the manual system will continue to run side by side.

All vaccine arrivals and vaccine dispatches are recorded and stock balances are updated within two working days of the transaction. The stock records for vaccines and diluents record the key information for all vaccines: vaccine type, presentation, manufacturer, batch number, expiry date and quantities. Furthermore the location is indicated in the stock record system. The stock management system provides routine reports on internal vaccine distributions and reports summarize the details of each and every transaction.

There is a stock policy that has been implemented at all levels used to control either a stock–out or overstocking in order avoid breaching safety regulations or maximum stock levels, as well as to predict future trends in order to control the stock levels. There is a periodic (at least once every three months at primary level) physical inventory of vaccine, diluents, syringes and safety boxes to ensure the accuracy of data record.

The Stock Management Tool is used to monitor the use of vaccines, and has improved the stock control system at the national store. The vaccine distribution follows the 'Earliest Expiry–First Out' principle. An electronic vaccine management system will be introduced at provincial and district levels whilst the manual system will continue to run side by side. There are neither records of damaged vaccines nor an internal review of the vaccine loss/damages records.

Transport system for vaccine delivery: The budget for distribution of vaccines and supplies to all levels has been factored in the operations costs for the introduction The central level

store is responsible for the collection of vaccine from the port of entry to the store, and further dispatching vaccine to provincial stores as required.

The calculation of peak capacity is based on the principle that vaccine deliveries take place at fixed intervals as stated in national EPI policy: three monthly arrivals at provincial stores; monthly arrivals at district stores and health centres; a one month safety stock for provincial and district stores; and a half-month safety stock for health centres.

Vaccine distribution to provinces takes place every three months. A well formulated distribution plan is shared with the receiving stores, and a distribution monitoring system helps monitor performance in terms of frequency and timeliness, in order to ensure vaccine availability at each receiving store. Additionally, there is a system of receiving the stock available at provincial stores prior to setting the quantity to be distributed, based on the available stock at hand and the maximum stock level policy.

Currently, there are two ten-ton trucks that are used for distribution; an additional two 20-ton trucks are being procured. This additional truck will reduce the frequency with which each individual truck has to travel to the provinces. The introduction of IPV will not have any negative impact on stock management or distribution. Funds have already been allocated for drivers, DSA and fuel for distribution purposes.

5. Monitoring and evaluation

5.1 Updating of monitoring tools

The country has planned to review and update the data collection, monitoring, supervision tools and children-under-5 cards to capture the data elements for IPV. The child health technical working group through the guidance of ICC will review and print the tools. The cost of review and production has been incorporated in the country CMYP and IPV introduction plan.

Sex aggregation data: Zambia's health information system does not collect sex-disaggregated immunisation data. There are currently no plans to introduce this data element. Previous coverage surveys have shown no significant difference in gender disaggregated coverage for various antigens (ZDHS, 2007).

5.2 Adverse Event Following Immunisation (AEFI) monitoring and reporting

The Zambia Medicines Regulation Authority (ZAMRA) has been leading the pharmacovigilance systems for AEFI conditions that could arise from administration of vaccines. This approach was strengthened from the legacy of measles campaigns and is now being utilised for routine immunisation.

AEFI Expert Review Committee: Though there have been no reported AEFIs from the routine immunisation programme, a team of experts who are part of the child health technical group has been tasked with conducting a follow-up in the event of an AEFI. There is need to activate this team existence during non-campaign times.

Monitoring of AEFI: There is a strong surveillance system for vaccine preventable diseases (VPD) that includes AEFI monitoring. AEFI monitoring and reporting is incorporated into the EPI Manual and HMIS /Surveillance forms. The AEFI notifications are transmitted from the health facility through the system up to national level and ZAMRA. A subsequent investigation determines whether a particular vaccine is the cause of the AEFI condition, or the AEFI is the result of a programmatic error or even coincidence.

6. Advocacy, communication, and social mobilisation

Advocacy: High level advocacy meetings for stakeholders will be utilised, to include televised discussions by experts. Politicians will be engaged through the health parliamentary forum and will include ministerial statements by the Ministry of Health and Ministry of Community Development Mother Child Health. The Ministers responsible for the health sector activities will co-host several advocacy events that will target various stakeholders such as media houses, partners and civil society organisations. These events will be forerunners and culminate into the IPV launch and eventual introduction.

The Ministry responsible for traditional affairs and chiefs will be targeted to advocate for the polio Endgame process in the country. Programme communication will be conducted through the health sector hierarchy working with line ministries at various levels including the local political system such as the influential District Commissioners.

Development of communication strategy: The country has planned to update the EPI Comprehensive communication strategy to include IPV aspects. A detailed communication plan will be developed with activities, timelines and budget. In this regard, communication technical assistance through available advocacy toolkits and guidance from global communication experts will enhance the knowledge management in the communities. The social mobilization and communication committee will be responsible for guiding and implementing as well as monitoring the social mobilization and communication activities.

Zambia plans to conduct a study to understand the concerns of care-givers and health workers on multiple injections. Findings from this study and from past studies on communications will be used to develop key messages and communication material as well as to decide on which communication channels to use. Social mobilization will be done through mobilizing professional associations such as medical associations, NGOs, CBOs, religious leaders and teachers etc. Orientations will be provided to various agencies and community engagement will be ensured from the micro-panning to implementation of communication plans.

Development of IEC materials: The country has planned for materials development workshops that will include media houses to provide perspectives and insight on immunisation. Population-based anthropological studies have been planned to document live experiences from the community.

Tailored and targeted messages and communication material will be developed, pre-tested and finalized. Frequently Asked Questions (FAQs), fact sheets, posters and audio visual material will be developed and disseminated to inform care-givers about the importance and benefit of IPV vaccination and to motivate them to vaccinate all their children. Reach of radio is high in Zambia. Radio messages will be developed in all major languages and broadcast through more than 35 radio stations in the country. TV spots will also be used for specific messages. Social media will also be used to maximize the reach of communication messages. Interpersonal communication will be a key channel to complement the messages being disseminated through mass media. Community health workers and neighbourhood health committees and safe motherhood committees will be mobilized to disseminate messages about IPV.

National Launch: The Minister of Community Development Mother and Health will launch the IPV introduction. This will be a collaborative effort aligned with other Government ministries (e.g., the Ministry of Health or the Ministry of Local Government and Housing), and other immunization partners.