Annex A. Uganda IPV introduction plan

# Executive summary of the introduction plan

Two years ago, the World health Assembly declared the completion of poliovirus eradication to be a programmatic public health emergency globally. This led to the development of the Polio Eradication and Endgame Strategic Plan that aims at eradication and containment of polio caused not just by wild viruses but also cases associated with oral polio vaccine (OPV).

To eliminate the risks associated with OPV use, the plan calls for a phased withdrawal of OPV beginning with removal of the type 2 component of OPV, which is responsible for over 95% of cVDPVs, through a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), containing only types 1 and 3) in 2016.

The end game plan includes introduction of at least one dose of IPV in routine immunization in countries using OPV by the end of 2015 prior to the tOPV-bOPV switch.

Introducing at least one dose of IPV will ensure that a substantial proportion of the population is protected against type-2 polio after OPV2 withdrawal and will also boost the immune response to OPV type 1 and 3 that are currently responsible for all polio cases.

Due to the afore said, Uganda joins this global initiative to eradicate and contain all polio disease, both wild and vaccine related through provision of potent vaccines to all children, continued surveillance activities, and prioritizing systems strengthening with focus to human resource, the health infrastructure and reinforcing community linkages for immunization services.

The country plans to introduce IPV vaccine in May 2015 into routine immunization (EPI) targeting the 0-11 months and prefers that the introduction is done nationally.

Introduction of IPV will cost US dollars 2,523,234 for central and district operational activities of which GAVI is expected to cover 1,466,147 US dollars. It is anticipated that Government and other partners will support the balance as indicated in Annex D. Government of Uganda will co-fund the vaccine cost with time but for the moment 100% contribution is expected from GAVI.

Uganda government prefers the 5 dose vial of IPV formulation. The single IPV dose in routine immunization will be administered at week 14 together with DPT3.

The birth cohort for IPV as of May 2015 is projected at 1,103,277.

The pre-implementation activities will include cold chain inventory; advocacy communication and social mobilization; review and printing of EPI data tools; capacity building/training and strengthening monitoring and support supervision.

The country will continue with preparatory activities including Central coordination and feedback meetings with EPI stakeholders, cold chain maintenance at all levels, advocacy and social mobilization and strengthening surveillance in anticipation of IPV introduction scheduled for May 2015.

The current EPI country program has adequate human resource and sufficient capacity to receive and store vaccines at National Medical stores and transport the vaccines and supplies to districts and health centres for IPV introduction throughout the country. The on-going cold chain inventory will provide better and updated data on EPI storage capacity and any identified gaps will be filled by GAVI grant for cold chain strengthening. The continuous advocacy and strong mobilization component of EPI will be put to use for IPV introduction in routine immunization

The country insists on hand washing with soap and use of ADs and safety boxes as safe injection practises. It is envisaged that similar practises will also apply for IPV immunization. The existing waste disposal methods of burning and burying will be widely used for IPV immunization on top of incineration that is available in a few Regional and District hospitals.

# Based on the past vaccine introductions Uganda does not foresee any major risks. However mechanisms will be put in place to ensure early detection and immediate corrective measures are put in place following the PCV Post Introduction Evaluation scheduled for last quarter of 2014 calendar year.

# Justification for introduction of IPV and national decision making process.

# Background information

The government of Uganda through the Ministry of Health and the Uganda National Expanded Program on Immunization (UNEPI) is committed to the provision of quality immunization services for the survival, growth and development of children. Since 2000 concerted effort has been made to revitalize and strengthen EPI performance in all districts with a target to attain at least 90% national vaccination coverage and 80% vaccination coverage in every district.

# Uganda has over the years invested heavily in a comprehensive health care system with a wide range of infrastructure, equipment and personnel as per the level of service delivery. Uganda has 112 districts with each district having a District Health Officer, Cold Chain Technician and EPI focal person. The country has 152 hospitals, 193 Health center IV, 1279 Health center III and 3605 Health center II. All hospitals, Health center IVs, Health center IIIs and some Health center IIs are equipped with operational EPI refrigerators while those without have the capacity to provide routine immunization services through outreaches.

# The Central Vaccine Store is housed within the National Medical Stores which has the capacity to store and distribute vaccines to all the districts in the country. Introduction of the new vaccine would need orientation of the National Medical Stores workforce on IPV.

Uganda is one of the signatories of the 66th World Health Assembly that endorsed the polio end game strategy where Objective two highlights the importance of introduction of at least 1 dose of IPV into the routine immunisation programs before the end of 2015 prior to the tOpV –bOPV switch. Therefore, Uganda joins this global initiative to eradicate and contain all polio disease, both wild and vaccine related through provision of potent vaccines to all children.

Following the global decisions, the Uganda government Central EPI technical committee reviewed several reference documents. The Ministry of Health and partners developed the IPV introduction proposal which was presented to several Ministry of Health (MoH) institutional framework structures (MCH technical working group and the Senior management and HPAC) that discussed and approved IPV introduction in Uganda. The proposal was then presented to Ministry of Finance, Planning and Economic Development (MoFPED) for approval.

Prior to its approval the proposal to introduce IPV was exhaustively discussed by EPI stakeholders on many occasions during the monthly technical meetings that UNEPI organises. The stakeholders included representatives of WHO, UNICEF, MCHIP, CDC AFENET, URCS, SABIN, CHAI, PATH and MACIS. The Health Policy Advisory Committee, which is the highest decision making organ of Ministry of Health (MoH) has comprehensive representation of key stakeholders.

According to the available guidelines, Uganda will not be obliged to co-finance for IPV at the time of introduction. However with time IPV immunization will be co-funded by government like any other routine vaccines.

Uganda has introduced three new vaccines since 2002: Pentavalent in 2002, HPV in fourteen districts in 2012 and PCV in 2013. The lessons learnt from previous introductions will inform decision making during the IPV introduction process.

Experience has shown that introduction of new vaccines requires timely assessment of the cold chain system to ensure adequate storage space for vaccines and dry supplies. Assessment of cold chain capacity should be physically done up to the lowest possible level, if possible using available measurements including the packaging, to ensure reliability of results.

The planning and estimation of vaccines should be done effectively to avoid stock outs after introduction. In addition, plans should be made for waste management, in particular, the disposal of used vials and sharps.

Uganda with support from CHAI is currently updating the country cold chain inventory which will support the creation of an updated expansion and improvement plan. Uganda is a beneficiary of the GAVI HSS grant a large sum of which has been committed to expansion of the cold chain.

Since the EPI program already has GAVI HSS funds to support cold chain capacity expansion both at central and district level, IPV introduction will not require major investment for expansion of the existing cold chain. Available information on the country’s cold chain indicates that it is sufficient for IPV introduction.

The upcoming EVMA will also improve capacity in effective vaccine management.

Uganda has a well functional AFP surveillance system that has informed the program to make the decision of IPV introduction. This surveillance system will provide on-going data to monitor the impact of IPV introduction and other polio eradication efforts.

In addition, there are functional sentinel surveillance sites which were developed after the introduction of pentavalent that strongly contributed to the decision making for the recent introduction of PCV. With readily available technical information, the IPV decision making is simplified.

The technical capacity of the EPI program is enhanced by functional partnership with technical agencies such as WHO and UNICEF.

The government of Uganda has committed to co-financing for Pentavalent, PCV and HPV. IPV introduction is not tagged to co-financing. GAVI funding for IPV will be available to GAVI eligible countries till 2018. Country level discussions to elicit Government commitment on future financing of IPV have commenced.

There will be continued advocacy for uptake of new vaccines including IPV. The Ministry of Health has a national advocacy and social mobilization committee that links with the Uganda Parliamentary Forum for immunization for high level advocacy. Plans are underway to involve the different advocacy committees for the IPV. Uganda has also developed a comprehensive communication strategy which has been rolled out in all districts. The communication strategy will act as an effective advocacy and social mobilization tool targeting key policy decision makers for national ownership of immunization services including new vaccines.

In addition, GAVI HSS grant will support VHTs that will strengthen communication at the peripheral level to ensure acceptability of new vaccines including IPV.

Monitoring tools (Child Health Cards, tally sheets and monthly summary forms) have been reviewed to include IPV. The health workers will be oriented on the updated HMIS data tools. GAVI HSS and other partners will support the Ministry of Health in the production and dissemination of these data tools.

Training of health workers will be conducted at all levels before IPV rollout with emphasis on justification for the new vaccine, vaccination schedule, vaccine management, filling and analysis of the monitoring tools.

Drawing from past experiences, training will be conducted in a cascade manner from national level down to the health facility level. After training, there will be follow up and general support supervision.

Funds and all training materials will be made available prior to commencement of training.

The National Coordination Committee (NCC) which brings together different immunisation players will coordinate IPV introduction activities. Feedback and monitoring of actual implementation of introduction activities will be reported regularly through the monthly EPI technical committee meetings.

# Overview of IPV

# 2.1 Vaccine preference

**Table B1. 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 | MAY 2015 | 10 Dose Vial |  |

# 2.2 Country licensure status

Uganda has a functional national regulatory authority called the National Drug Authority. It is instituted by the National Drug Policy and Authority Act 1993 of the laws of Uganda. For more information about the functions of this regulatory body please visit the web links <http://www.ulii.org/ug/legislation/consolidated-act/206> and http://www.nda.or.ug/

The National Drug Authority (NDA) guidelines for licensure of a new product will involve the under listed steps:

* Request for a dossier from the vaccine manufacturer
* Submission to NDA
* Evaluation of dossier
* Evaluation for Good Manufacturing Practice (GMP) compliance
* Registration of the vaccine

The whole process takes between three to six months before full licensure is granted.

However, the Uganda National Drug Authority (NDA) accepts expedited registration for any WHO prequalified products.

Currently there is no record with NDA for any licensed IPV in Uganda.

At the time of delivery the under listed documents should accompany the vaccine consignment at the port of entry into Uganda;

* Certificate of analysis
* Commercial invoice
* Packing list indicating all batches and expiry dates in the consignment
* Certificate of origin

Failure to provide all the above documents could cause delays in local customs processing.

In the event that the manufacture does not send documents along with the consignment then, scanned or PDF copies of each of the document can be sent to the consignee email for delivery to customs staff.

# 2.3 Target population and vaccine supply

The following table presents the target populations of children to receive a single dose of IPV together with DPT3 per year from May 2015 to 2018

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Year | 2015 | 2016 | 2017 | 2018 |
| IPV Target Population | |  | | --- | | 1,103,277 | | 1,676,850 | 1,730,509 | 1,785,885 |

Procurement and management of vaccines follows the existing vaccine procurement mechanism whereby the Government of Uganda (GOU), through the National Medical Stores (NMS), provides funds to UNICEF country office that procures vaccines from WHO pre-qualified suppliers. Similarly GAVI supported vaccines will also be procured through UNICEF as per procedure of the existing government arrangement. All this is governed by an MOU signed annually between GOU and UNICEF.

The Uganda National Drug Authority (NDA) functions that qualify compliance to GAVI requirements include:

* Functional regulatory authority
* Licensing / Marketing authorisation
* Lot by lot release
* Laboratory access
* Oversight of clinical trials
* Post Marketing surveillance

# Introduction and implementation considerations

# 3.1 Policy development

There is a draft National Immunisation Programme policy which provides for introduction of new vaccines as recommended by WHO. The policy is currently at its final stage of adoption.

For easy acceptability and sustainability, IPV will be integrated in the current routine immunization schedule and it will be administered together with Pentavalent 3, PCV3 and OPV3 at 14 weeks of age or at first contact with the eligible child.

In Uganda, the immunization schedule is as shown in the table below;

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Vaccine/**  **Antigen** | **Dosage** | **Doses Required** | **Minimum Interval Between Doses** | **Minimum Age to Start** | **Mode of Administration** | **Site of Administration** |
| BCG | 0.05ml up to  11 months, 0.10ml after 11 months | 1 | None | At birth (or first contact) | Intra-dermal | Right Upper Arm |
| DPT-HepB+Hib | 0.5 ml | 3 | One month  (4 weeks) | At 6 weeks (or first contact after that age) | Intra-muscularly | Outer Upper Aspect of Left Thigh |
| OPV | 2 drops | 0+3 | One month  (4 weeks) | At birth or within the first 2 weeks (Polio 0) and six weeks or first contact after 6 weeks (Polio 1) | Orally | Mouth |
| PCV | 0.5ml | 3 | One Month(4weeks) | At 6 weeks (or first contact after that age) | Intra-muscularly | Outer Upper Aspect of right Thigh |
| IPV | o.5 | 1 | None | At 14 weeks (or first contact after that age) | Intra-muscularly | Left thigh 2cm below Pentavalent 3 injection site |
| Measles | 0.5 ml | 1 | None | At 9 months (or first contact after that age) | Sub-cutaneous | Left Upper Arm |
| Tetanus Toxoid | 0.5 ml | 5 | TT1 & TT2; 4 weeks TT2 & TT3; Six months TT3 & TT4; One year TT4 & TT5; One year | At first contact with a pregnant woman or women of child bearing age (15-45 years) | Intra-muscularly | Upper Arm |

Regarding IPV, the following order of injection will be emphasised during training:

* First inject DPT on the left thigh
* PCV will follow on the right thigh
* IPV will then follow on the left thigh 2cm below the injection site of DPT-HepB+Hib 3

Immunisation services are delivered as part of integrated maternal and child health interventions administered at any given opportunities including child health days and family health days. The package to the already existing health services includes:

* Routine screening for malnutrition and other illness: This done routinely in Health facility at any contact point and in outreaches. Screening is mainly done using Mid-up arm circumference tape, targeting all children under the age of 5 and pregnant mothers.
* Vitamin A supplementation: Introduced in 1999 and still on-going bi-annually targets children from 6-59 months age. The intervention has been widely appreciated at facility, outreaches and pre-primary schools
* Deworming: Children between the ages 1-14 years are targeted for this activity which also is done bi-annually at facility, outreach and schools. Deworming together with Vitamin A currently are the activities carried out by Health workers and Village health teams who mainly used in heard to reach and serve areas or where there is scarcity of trained staff
* Growth monitoring and Promotion
* Health and Nutrition education. This is routine activity done by health facility at outreach posts where different activities are to take place. It is done prior to any service like immunization, vitamin A, Deworming extra. In most cases groups are targeted for this service, however individuals have also been educated on several occasions
* Antenatal care: This is a daily activity done by a midwife at all levels of health care and at most each pregnant woman is seen at least 4 times during a single pregnancy period.
* Early infant diagnosis: All health workers have been trained in this activity and currently its being carried out in all health IIIs and on words

# 3.2 National coordination mechanism to ensure the successful introduction

There is a National Coordination Committee with membership from Ministry of Health, technical agencies, Health Development Partners (HDPs), Civil Society Organizations (CSOs), National Medical Stores (NMS), National Drug Authority (NDA), Professional bodies, Academicians, Religious and Cultural bodies, Securities agencies and technocrats from different ministries. The National Coordination Committee has sub-committees that will oversee key areas for new vaccines introduction including: Resource mobilization, Planning/Administration/Secretariat and training, Cold Chain logistic and transport; Advocacy and Social Mobilization and Surveillance. The sub-committees report the progress of their activities to the NCC.

The NCC meetings will be held monthly starting August to February then every two weeks.

# 3.3 Affordability and financial sustainability

Activities included in the budget are: preparatory meetings, training at national and lower levels, cold chain maintenance and procurement of spare parts, stationery/monitoring tools, social mobilization and communication, transportation and distribution of vaccines and supplies, implementation, surveillance and post introduction evaluation activities.

Cost estimates are derived from working figures derived from predetermined official government rates.

Quantification is based on administrative structure and functional health facilities

The Government of Uganda is funding a significant portion of the immunization costs in terms of health infrastructure, human resource cold chain equipment, transport and distribution of vaccines, supplies and logistics.

Procurement of all traditional vaccines is done by the Government of Uganda, and since 2002 the Government of Uganda has been co-financing the procurement of pentavalent vaccine and is committed to co-finance PCV10 and HPV in 2015. Donor funding has been complimenting the Government efforts.

For IPV, there is no co-financing at the beginning, however with time the Government of Uganda will consider co-financing of IPV.

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

A national cold chain assessment was conducted at National, District level and in all health facilities providing immunization in 2010. The assessment provided vital information on the number and status of cold chain equipment at all levels and was able to establish the existing gaps. Mostly the gaps established were bridged with the equipment from 2011 JICA Grant. Currently there is an ongoing comprehensive cold chain inventory which will inform the distribution of the GAVI HSS funds to procure equipment.

After the cold chain inventory and the allocation of the GAVI HSS equipment, Uganda will assess any additional needs and will mobilize additional resources.

There is routine supply of gas from the National Medical Stores to the health facilities. In addition, districts are given PHC funds for operational costs including payment for electricity tariffs. For very hard to reach facilities, the Government of Uganda with support from partners has provided solar refrigerators. GAVI HSS funds have been committed to purchase cold chain equipment for district cold chain stores and health facilities. The trained district cold chain assistants in all districts with support from the centre conduct routine maintenance and repairs on cold chain equipment.

# 3.5 Waste management and injection safety

* The Ministry of Health (MoH) has Injection safety and Healthcare Waste management Policy and Standards/guidelines. Medical Waste management is done according to the set guidelines. The Uganda National Injection Safety Task Force (UNISTAF) oversees the implementation of the guidelines.
* Waste management logistics are periodically distributed to all districts by the National Medical Stores (NMS). The logistics include safety boxes and color coded waste bins. Vaccine procurement takes into consideration provision of safety boxes and AD syringes.
* Uganda uses Auto Disabling Syringes and needles since 2007 for all health service delivery
* The current guidelines will accommodate injection safety and waste management for IPV

All vaccines and injection safety materials procured are WHO pre-qualified.

# 3.6 Health worker training and supervision

* The programme has trained health managers and services providers at the different levels of service delivery over the years on immunization. However, there is turnover of the health workforce and hence the need for continuous training. The existing health work force still needs to be oriented on IPV introduction.
* The MoH has completed training of Regional EPI/ Nutrition supervisors covering the whole country including the private sector. They will be responsible for continued on job mentoring for health workers at health facility level in immunization service delivery and any new developments including new vaccines.

To address the issue of quality of training, hands-on practical components of training, formal evaluations of training sessions will be conducted to ensure learning has occurred, monitoring to ensure all health workers responsible for vaccine handling and administration are trained, and proper timing so the training occurs immediately prior to launch will be done to avoid loss of knowledge over time. The regional support supervision teams that have been established will be facilitated to conduct quarterly support supervision to ensure continued retention of knowledge through monitoring and supervision.

The supervision will provide an opportunity to reach all health facilities, targeting all operational level health workers.

Development of IPV training materials (training manual/ field guide), and knowledge assessment tools) will be one of the activities undertaken by the Training and Secretariat Committee. Uganda will adapt the already existing WHO modules for IPV introduction. The guides will be used during the training at all levels, and will also be distributed to all health facilities and pre-service training institutions.

Uganda will utilize the existing immunization guidelines to reinforce and strengthen routine immunization good practices.

FAQs, fact sheets, training video and posters will be developed from the WHO guidelines and modules for IPV introduction for health worker training and community mobilization

* Training will be carried out in a broader aspect of Routine Immunisation to strengthen routine immunization.
* Training will be conducted in a cascaded manner from national, regional and district, health sub district and health facility level.

1. National Training of Trainers will comprise of Ministry of Health, professional bodies and Health Development Partners
2. Regional Training of Trainers; 3 members of the District Health Team per District
3. District Training of Trainers; (Health Sub District teams, District Health Team members not in the regional teams and in charges)
4. Health facility training
5. A roll-out plan to engage Private sector (Private Health Providers) in Kampala is to be supported under the National Private Sector EPI strategy.

* Training will focus on imparting skills and competencies to health workers; therefore, practical demonstration, role plays and case studies will be the main teaching methods. Uganda will prefer to have vaccines in-country to ensure that the practical sessions are hands on.
* Training will be done using power point presentations, practical demonstrations and group discussions.

It is the mandate of the program to carry out support supervision and monitoring of immunization activities to ensure adherence to the provided standards and guidelines. Support supervision is routinely conducted at least every quarter of the year.

Due to the increase in the number of supervisory units (Districts), Uganda has established EPI regional supervision teams that are responsible for support supervision and on job mentoring at health facility level. During the introduction period, the same teams will be supported to continue monitoring and ensure good immunization practices by the health workers including micro planning to reach all eligible children

Independent monitors will be sent out to all the regions in the country to oversee, provide technical support, monitor and verify the implementation process and outcomes during in the introduction period.

# 3.7 Risks and challenges

Introduction of IPV in addition to several other new vaccines (PCV, HPV) may constrain human resource considering the limited number of existing staff.

The IFMS introduced in 2013 derailed the PCV introduction and caused delay and uncoordinated release of funds to the implementers which translated into delayed implementation of introduction activities. The Ministry is monitoring performance of IFMS overtime to ensure it fulfills the purpose of streamlining funds disbursement.

The perception by health workers that parents will fear for their children on the increased number of injections should not be allowed to have any effect on routine immunization. To address this challenge, carefully thought out communication materials based on a KAP study on perception of injections and experiences from other countries will be developed. Sensitization of health workers who deal directly with parents will also be prioritized.

# Situational analysis of the immunisation programme

# 4.1 General context of the country

Uganda is located on the equator and covers an area of 241,550.7 km2, of which 18% are water bodies, with the rest being made up of plateau with numerous small hills, valleys and extensive savannah plains. It receives abundant rainfall and is rich in tillable land.

Uganda is divided into 112 districts as compared to 80 districts by end of financial year 2009/2010. The districts are further divided into 220 counties, 1261 sub-counties, 6,953 parishes and 59,092 LC1s/villages. The village forms the smallest political and administrative unit.

Uganda is governed through a decentralized system. The districts are autonomous and responsible for the health needs of the populations under their jurisdiction. The health services are also decentralized with Primary Health Care (PHC) concept as the main strategy for service delivery. Districts receive grants directly from the centre without an intervening regional tier. The Ministry of Health (MoH) has the lead role and responsibility for delivering the outputs of the Health Sector Strategic Investment Plan (HSSIP) and various other partners have defined roles to play and contributions to make. The MoH initiates policy and coordinates overall sector activities and brings together stakeholders at the central, district and community level. The stewardship function extends to the district level where by the district leadership is responsible for coordinating all the stakeholders within the district.

According to the 2002 population census by Uganda Bureau of Statistics, the population was 24.2 million: 48.5% were male while 51.5% were female; and 88% are resident in rural areas. The population growth rate is estimated at 3.2% per annum, resulting in an incremental growth of more than one million people annually. Current estimates as of mid-2012, the population stands at 34.1million persons and by the end of the HSSIP in 2014/15 will be approximately 37.9 million, increasing the average population density from 133, to 156 persons per square km.

The national literacy rate is estimated to be 73.6% and the majority of the population (88%) lives in rural areas. However, some of the districts in the north and northeast of Uganda have been affected by a prolonged period of conflict resulting in widespread insecurity and large-scale population displacement. This has had an effect on health service delivery and most of these districts have not been able to achieve the national targets for the health indicators.

It is estimated that 52% of Uganda’s population constitutes of persons under the age of 15 years, and Under 1 year at 4.3%. Over the next five years, the Ugandan population will remain a young population with 20.5% of the total population being under five, with an increase in the number of females in reproductive years from 7 million in 2009 to 8.3 million in 2014, which will put a strain on all reproductive health services.

Between 2002 and 2011 under five mortality rate declined from 156 to 90 deaths per 1,000 live births; IMR decreased from 85 to 54 deaths per 1000 live births; MMR reduced from 505 to 435 per 100,000 live births (UDHS 2011, UBOS 2012 Statistical abstract).

**The National Health System (NHS)** is made up of the public and the private sectors. The public sector includes all Government of Uganda health facilities under the MoH, health services of the Ministries of Defence (Army), Education, Internal Affairs (Police and Prisons) and Ministry of Local Government (MoLG). The private health delivery system consists of Private Not for Profit (PNFPs) providers, Private Health Practitioners (PHPs), and the Traditional and Complementary Medicine Practitioners (TCMPs). The provision of health services in Uganda is decentralised; the national level provides policy formulation, resource mobilization and strategic guidance, with districts and health sub-districts (HSDs) playing a key role in the delivery and management of health services at subnational levels. The health services are structured into National Referral Hospitals (NRHs) and Regional Referral Hospitals (RRHs), General Hospitals, Health Centre (HC) IVs, HC IIIs, HC IIs and Village Health Teams (virtual HC Is).

The functions of the National health system are contained in the National Development Plan (NDP) 2010/2011-2014/2015); which is Uganda’s Comprehensive Development Framework that guides the implementation of the second National Health Policy (NHP) 2010/2011-2014/2015 and the National Health Sector Strategic and Investment Plan 2010/2011-2014/2015. The NHP focuses on health promotion, disease prevention, early diagnosis and treatment of diseases. It specifically prioritises effective delivery of the Uganda National Minimum Health Care Package (UNMHCP), more efficient use of available health resources, strengthening public and private partnerships for health and strengthening of health systems. The HSSIP provides the medium term strategic framework for health, and highlights what government intends to pursue in regard to attaining the health goals for the country.

**The Uganda National Expanded Programme on Immunization (UNEPI**) is located in the Department of National Communicable Disease Control within the Directorate of Clinical and Community Services. The UNEPI has a managerial structure to ensure efficient service delivery; the organogram of the UNEPI is illustrated in Figure 1.

The **vision** of UNEPI is to ensure that the Ugandan population is free of vaccine-preventable diseases.

The **mission** is to contribute to the overall objective of the HSSIP in reducing morbidity, mortality and disability due to vaccine preventable diseases, so that they are no longer of public health importance.

The **goal** of the programme is to ensure that every child and high-risk group is fully vaccinated with high quality and effective vaccines against the target diseases according to recommended strategies.

The targeted diseases for infants, as of 2013, are tuberculosis, poliomyelitis, diphtheria, pertussis, tetanus, measles, hepatitis B, and *Haemophilus influenzae* type b (Hib), pneumococcal pnuemonae infection. Vaccination against the Human Papilloma Virus (HPV) is currently in 14 districts targeting girls 10 – 12 years. The programme plans to scale up country wide Human Papilloma Vaccination in 2015. Plans are underway to introduce Rotavirus Vaccine in 2016.

The programme has four major areas of focus:

1. Strengthening routine immunization;
2. Conducting supplemental immunization activities to achieve global targets of polio eradication, elimination of maternal and neonatal tetanus, and accelerated measles control;
3. Sustaining a sensitive disease surveillance system within the Integrated Disease Surveillance and Response framework.
4. Introduction of new vaccines in the routine schedule and also expand the vaccination beyond the traditional target group

Immunization is a countrywide programme covering all districts of Uganda. The MoH/UNEPI is responsible for policy, standards and priority setting, capacity building, coordinating with other stakeholders and partners, resource mobilisation, procurement of inputs such as vaccines and injection safety materials, monitoring and technical support supervision to the districts. The districts and health sub-districts are responsible for planning, management and delivery of EPI services through the implementation of the overall district health plan. The community is involved in mobilization and bringing the children for immunization. Immunization is part of the PHC and is integrated into the child survival activities at the district and health facility levels

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

**Table B2. Trends in national vaccine coverage**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trends of national vaccine coverage (percentage)** | | | | |
| **Vaccine** | **Vaccine Used 2013** | **Target population**  **(number by age and sex,**  **if available) 2013** | **Coverage reported (JRF)** | |
| **Most recent year-2013** | **Previous year-2012** |
| BCG | 1,608,116 | 1706689 | 94% | 82% |
| OPV 3 | 1,507,910 | 1513147 | 99% | 82% |
| DTP 1 / Penta 1 | 1,607,045 | 1513147 | 106% | 89% |
| DTP 3 / Penta 3 | 1,469,684 | 1513147 | 97% | 78% |
| Measles 1 | 1,471,484 | 1513147 | 97% | 82% |

Immunization in Uganda is implemented within the health system and there are barriers that affect access to services and hence cause equity problems.

Geographic barriers include hard-to-reach areas due to physical barriers e.g. eastern and south western region which are mountainous and hilly terrain coupled with poor road network. This has caused inequalities in distribution of human resources, in most cases qualified health workers will not be willing to work in these areas. The GOU has put in place strategies to address this gap which include: Attain and retain the right HRH numbers and skills mix in the health sector through advocacy for annual increases in recruitment to increase the proportion of skilled positions in order to improve quality health services delivery in those areas. The Uganda Parliamentarian Immunization Forum is spearheading this activity; Use evidence to advocate for appropriate remuneration of health workers; Provide decent and safe accommodation for health workers at health facilities especially in hard to reach areas through GAVI HSS; some local governments have put in place a mechanism provide incentive schemes for attraction and retention of health workers in hard-to-reach areas while addressing the gender and human rights aspects

The program has over the years faced resistance to uptake of vaccination, mainly from some religious sects which deny their members from accessing social services like immunization and education. This has majorly been observed in the eastern part of the country. There are some isolated cultural and traditional myths and belief in herbs to be preventing immunizable diseases. However the communication strategy is addressing this problem.

An inter-play of geographical, socio-economic and cultural factors that have created socio-dynamics of "Hard-to-convince" communities resulting in under-served areas particularly in urban and peri-urban settings where there is high health seeking patterns and preference for private sector health services. This is coupled with a hugely migratory population that seeks care in the private sector facilities most of which are not actively involved in provision of quality immunisation services. Thus MOH/UNEPI has directly partnered with the Federation for Private Health Professionals a national Umbrella Organisation to engage private health facilities that are also strategically located in high concentrations in the urban/peri-urban settings to increase immunisation coverage and scale up surveillance reduce under/un-immunised children and also target the respective "Hard-to-Convince" communities.

# 4.3 Findings from recent programme reviews

According to the findings of the reviews and several assessments in the recent past (2010 UNEPI Review, 2011 Effective Vaccine Management Assessment, 2012 UNICEF/WHO Joint Mission Assessment) the root causes for the low immunization performance seem to relate to stagnating funding, health sector reform, human resource issues and a general lack of prioritization of the routine immunization program.

Ministry of Health has stream lined management of the program that enabled harmonization of support of EPI partners

* The National Medical Stores assigned with the delivery of vaccines and logistics and since July 2013 there has reduced stock out of vaccines at District stores
* The upcoming cold chain inventory will identify gaps in the system and will inform management on objective corrective measures
* Recruitment of health workers by the government to address the shortage of staff
* Training and mentoring of health workers in the different aspects of immunization. EVM training was conducted for mid-level managers in all Districts
* A national communication strategy was developed and rolled to all the districts in the country. GAVI ISS funds have been disbursed to Districts to support implementation of the communication strategy plans
* Improved advocacy for immunization e.g Uganda Parliamentarians Immunization Forum
* Capacity has been built by creation of 15 regional EPI support supervision teams
* The Ministry of Health is reviewing and updating Health Management Information Systems tools including immunization data collection tools to cater for new vaccines

The table below gives a summary of the main issues contributing to the declining immunization coverage trends.

**Bottleneck Analysis of Routine Immunization in Uganda**

| *Challenges* | *Details* |
| --- | --- |
| Program Management, Supervision and Political Will | Funding shortfalls (outlined below) have been exacerbated by the decentralization of the government structure, which shifted the financing of the program costs, as well as supervision and management of health and immunization services to the districts. Districts however lack both the financial and management capacity to assume these responsibilities |
| Immunization Financing | The decline in immunization coverage parallels trends in government and donor support for routine immunization.   * Funding for routine immunization from the Ministry of Health has remained essentially flat for the past 5 years. However, the percentage of the MoH budget for EPI has decreased by more than half from 7.7% in 2006/7 to 3.6% in 2009/10. * At the same time, funding from partners for Primary Health Care (PHC) remains grossly inadequate at all levels of the system. Funding for operational cost is unpredictable and inadequate to carry out planned regular and outreach services, particularly at district level. |
| Social Mobilization | * Advocacy/communication/mobilization activities are primarily promoted during periodic immunization events, such as Child Health Days and immunization campaigns. A recent KAP suggested that there is potential for more effective health promotion with expansion of Village Health Teams, radio, print media, TV and nationwide mobile phone coverage. * Utilization of health services by the community is limited though 72% of households in Uganda live within five kilometers from a health facility (Uganda National Health Policy, 2010) |
| Supply Chain and Logistics (SC&L) including information systems | * Uganda conducted an EVM assessment in July 2011. Storage capacity was found to generally be adequate at all levels and all facilities have WHO compliant equipment installed. * Though there is adequate storage capacity to introduce pneumo vaccines without the need for further CCL expansion, there may be a need for additional cold storage expansion prior to Rotavirus vaccine introduction (planned for 2015). * The current arrangement of monthly distribution of vaccines and supplies to 112 districts has overstretched the program operational costs. 75% of the Immunization Program total operational budget is spent on procurement of gas and clearance of vaccines ((EPI Review, 2010) |
| Monitoring & Evaluation | * Inadequate supplies of Child Health Cards and critical recording and coverage monitoring tools, infrequent and inadequate supervision at all levels, and lack of monitoring in districts and all health facilities has been identified as a major problem (EPI Review, 2010) |
| Service Delivery, Human Resource Capacity, and Training | * Staff shortages and weak supervision (driven by funding shortfalls) - Only 51% of the approved positions at national level in the public sector are currently filled. There are however, variations among districts with some districts particularly in northern Uganda with only 35% of their posts filled (MoH, 2008). Shortage of critical staff has greatly compromised the delivery of quality health services. The main reasons for the many vacancies include insufficient training capacity and unattractive remuneration * The implementation of the RED strategy in Uganda began in 2003, but field assessments indicate that the approach is not implemented according to guidelines all of which is contributing to the gaps in immunization coverage. * Use of data for planning and monitoring immunization activities continues to be limited and supportive supervision, particularly at the health facility level, is generally inadequate. |

Following the Bottleneck Analysis of Routine Immunization in Uganda, the program developed a CIP 2012/13 that was implemented**.**

In February 2014, an external UNICEF/WHO mission carried out a desk review of the 2-year revitalization plan and made key recommendations and priority areas that the program is currently implementing. The team took note of progress made through concerted effort of the MOH with support of partners and donors, to address core challenges in the various components of the program, a number of critical strategic areas remain to be reinforced in order to sustain the gains achieved. To that effect, Uganda is recommended to focus on the priority action points in 2014, including addressing the data quality issues identified.

* Limited resources available for training of OPL health workers. Training for introduction of IPV will provide an opportunity to train OPL health workers.
* Limited resources available for community mobilization activities.
* There is an EPI communication strategy that has been disseminated to the district level. The IPV introduction plan will help to disseminate this communication strategy to lower level health workers during IPV trainings so that routine immunization utilization is improved.
* Suboptimal Data management that has been compounded by limited availability of HMIS tools, capacity to compile, analyse and utilize data at point of collection. Data Quality Improvement action plan has been developed to address the identified gaps
* Constrained human resource despite the recent recruitment. This needs on-going advocacy and lobbying.

In 2002, pentavalent vaccine was introduced in the country, and in 2013 PCV was introduced. Several lessons were learnt and these will be considered to ensure smooth introduction of IPV into routine immunization program.

Introduction process in terms of training, logistics, vaccine distribution, social mobilization and monitoring tools of Pentavalent was smooth

|  |  |
| --- | --- |
| Lesson learnt | Action to be taken |
| Delayed release of funds delays the training and negatively affects the quality of training. This was due to the change in the cash transfer system which required a new Integrated Financial Management System (IFMS). | Early planning to address unnecessary delays at all levels. This should be done three months before the launch. |
| Lack of vaccines for demonstration during training also affects the quality of training | UNICEF supply division through GAVI will be contacted to ensure availability of IPV in country before training is initiated in country |
| Delayed availability of vaccines for people to start the actual vaccine administration immediately after the training leads to knowledge and skills loss | Training will commence immediately the vaccine has arrived preferably at the Central Vaccine Store |
| Inadequate preparation of phased introduction led to vaccine stock outs in Districts | The national launch should happen when all Districts have already been trained so that there is one uniform day of the official launch. |

# 4.4 Stock management

At the Central Vaccine Store there is a computerized stock management system that is updated regularly and shared with partners which is managed by National Medical Stores at national level.

At the district and lower levels, stock management is done manually using a Vaccine and Injection Materials Control Book.

|  |  |
| --- | --- |
| Foreseeable issues | How to be addressed |
| Since it is a 10 dose vial, there may be wastage | Hasten community mobilization for both static and outreach posts to reduce the high wastage rate |
| The current VIMCB not adequately updated by health workers | Mentorship during support supervision of OPL health worker to ensure completeness regular updating of the VIMCB |

* Vaccines are received centrally by National Medical Stores (NMS) and stored at the National Vaccine Store
* National Medical Stores (NMS) gets vaccine and other logistics requirements’ estimates from districts
* Bundled vaccines and their logistics are delivered monthly by refrigerated vaccine trucks to all District headquarters (District Vaccine Stores, DVS).
* The Health Sub District (HSD) vehicle collects the vaccines from the District Vaccine Stores (DVS) and distributes to the respective health facilities but some are also kept at the Health Sub District (HSD) Vaccine Stores (Sibir refrigerator, ice liners and the RCW refrigerators)

IPV will be integrated in the above transport system with other vaccines already in the routine immunization program

# Monitoring and evaluation

# 5.1 Updating of monitoring tools

The Ministry of Health resource centre is in the process of updating all data collection tools and the immunization program (tally sheets, HMIS 105 and child register) submitted all the necessary revisions taking into consideration the new vaccines including IPV.

All health workers will be trained on the updated data collection tools to ensure quality of data

The updated tools will be printed by UNICEF and distributed by the National Medical Stores (NMS) with the rest of other vaccines and supplies.

UNEPI is currently working with the Federation for Private Health Professionals to adapt, and distribute EPI monitoring and supervision tools particularly for utilisation by private sector facilities.

The current HMIS tools already capture data by gender.

# 5.2 Adverse Event Following Immunisation (AEFI) monitoring and reporting

In Uganda, AEFI surveillance was established in 2003 in preparation for the mass measles campaigns. A Global Post Marketing Surveillance Network was established in 2008 to strengthen AEFI Surveillance that has since evolved into the network of Global Vaccine Safety Initiative. In AFRO, Uganda and Senegal are part of this network. One of the activities of this network is capacity building in countries with special focus on AEFI monitoring, investigation, causality assessment and response.

A baseline assessment of the vaccine safety system was conducted in September 2009 in Uganda, and an advanced course on Adverse Event Following Immunization (AEFI) monitoring and causality assessment took place in Uganda in August 2011.  The World Health Organization (WHO) - Uppsala Monitoring Centre (UMC) pharmacovigilance tool for Individual Case Safety Report (ICSR) management was adopted by Uganda. A WHO visit to monitor the status of the National Regulatory Authorities took place in September 2011, during which the national institutional development plan, comprising of post-marketing activities with surveillance of AEFI, was reviewed and updated.

The routine HMIS tools have a component of AEFIs including the weekly reports within the IDSR framework. Post-marketing surveillance for adverse events will be emphasized in all training sessions and reporting through the weekly reports, case based data and monthly HMIS reports will be closely monitored. Plans are underway to establish at least two sentinel sites to support active surveillance for AEFIs in 2014. Reporting tools for AEFIs were printed and distributed to all health facilities. The National Drug Authority is responsible for entering all information into the national pharmacovigilance centre. The same channels are used to investigate any rumours related to vaccination. National guidelines are available highlighting key action points and responses to all reported and investigated AEFIs.

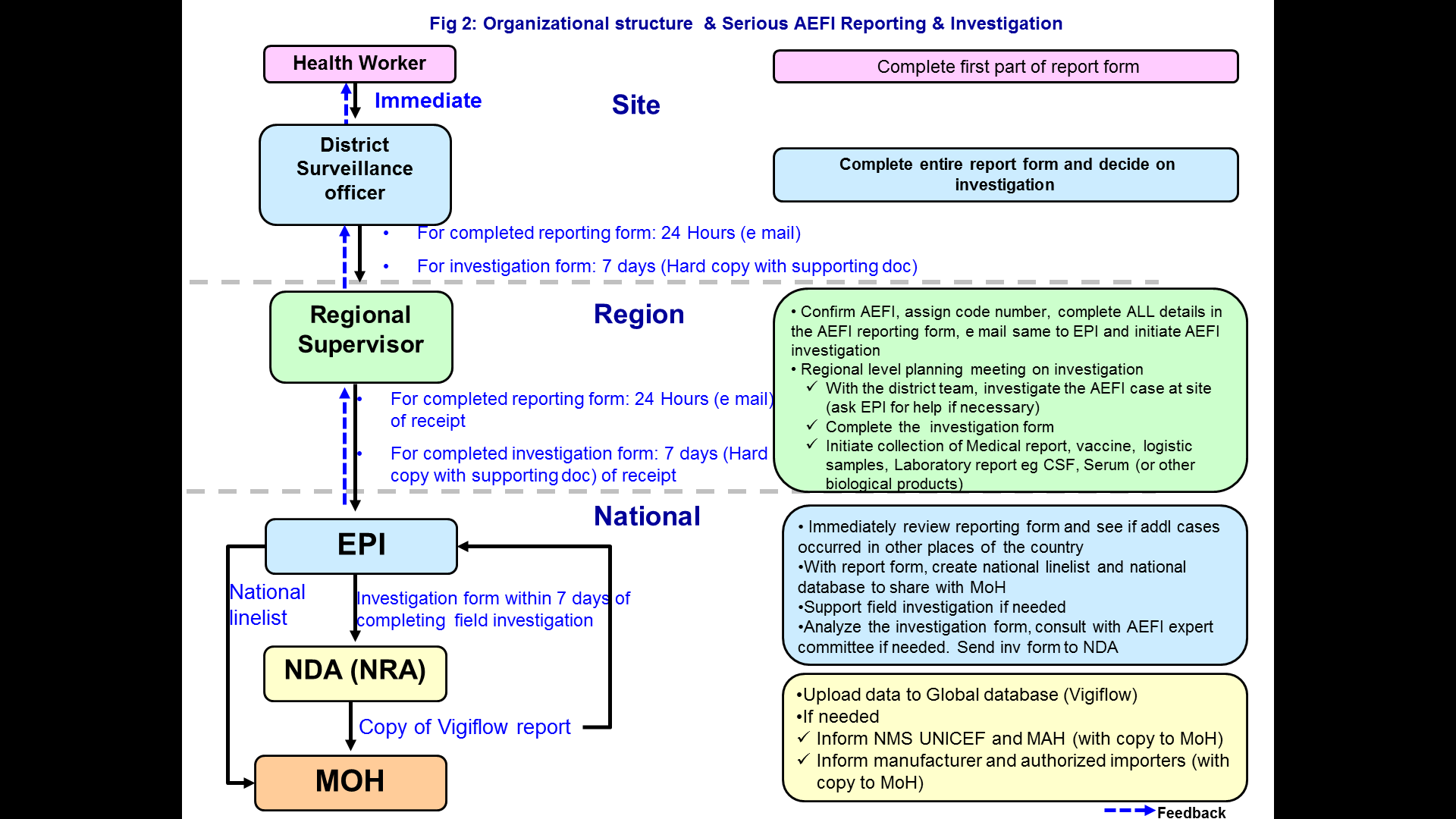
In Uganda, the National Expert Committee namely “The Expert Committee for Case Review and Causality Assessment” committee was established in August 2012 with the mandate to provide technical assistance for the timely classification and assessment of causal association between the vaccine and the AEFI and provide specific recommendations on vaccine safety issues. It consists of six members with varied expertise namely paediatrician, physician, pharmacists, microbiologist, clinical epidemiologist and communication expert. The members were trained for 5 days by WHO/AFRO on the basics of vaccine pharmacovigilance and causality assessment. These members were officially nominated by the Director General of Health services, are independent and completely free of government and industry conflict of interest. The committee is responsible for assessing the causes of serious AEFIs, AEFI clusters and AEFI of special interest; provides technical expertise for serious AEFI management and provides recommendations for appropriate corrective action.

The committee is supported by a secretariat that comprises of UNEPI, NDA and WHO. A causality assessment guideline is available that guides the members during their meetings. This is complemented by field visits as need arises.

The AEFI system has been structured to ensure that there are channels for both routine reporting as well efficient and immediate reporting of severe and serious AEFI. The same channels will be utilized for IPV and these include:

1. Weekly and Monthly routine reporting of all AEFI: this includes reporting and line listing of all AEFIs from the level of health worker up to the national level through monthly progress reports of HMIS. All AEFIs identified in any week or month are reported through the existing disease surveillance systems and then submitted to the national level through DHIS2 on a monthly basis or MTRAC on a weekly basis.
2. Reporting and investigation of serious AEFI: All serious AEFI are immediately (within 24 hours of detection), notified by the first person who identifies the event to the nearest health facility by quickest means of communication e.g. telephone, messenger etc. Notification is followed up with a report in the AEFI reporting form by the health worker (tools already distributed to health facilities). The district or the regional focal person immediately constitutes an investigation team to initiate an investigation to determine the cause of the AEFI and in turn notifies UNEPI by phone or email. In case laboratory investigation is required, any specimen collected is accompanied by completed AEFI laboratory request form. Appropriate action is taken as per national guidelines regarding any reported AEFI and these depend on the type of AEFI e.g. if it is an immunization error, capacity building of concerned health facility is immediately done or intensification of focused support supervision.

The following organogram summarises the reporting channels for all identified AEFIs.



# Advocacy, communication, and social mobilisation

Advocacy, communication, public awareness and education about IPV as an additional vaccine are critical to the success of the Polio End Game Strategy. In the recent past (2013), the country introduced PCV (10) into the routine immunisation schedule and similarly, the service providers and the community were prepared accordingly.

Advocacy to mobilize support for this new vaccine will target key decision makers at national, district and sub-county levels in the country. This will be done through; briefs and advocacy dialogue meetings with: MPs, Ministers of Health and Finance, Planning and Economic Development, Directors and other senior officials within the Ministry of Health, health professionals with interests in immunization, Medical Professional Bodies (Uganda Paediatrics Association, Uganda Medical and Dental Council, Allied Health Professionals and Uganda Nurses and Midwives Council), District leaders, politicians, religious leaders, cultural leaders, civil society organizations and private practitioners as partners in mobilization.

Service organisations like Rotary International whose global challenge is ‘end Polio Now’ will be the key allies and advocates throughout the process.

Currently, a National Advocacy, Social Mobilisation and Communication strategy for immunisation services in Uganda is now in place. The development of this strategy was informed by a formative research conducted country wide plus other review reports. By the end of 2013, this strategy was rolled out to all districts to guide them implement strategies to generate demand for immunisation services and also promote utilisation of EPI services including new vaccines.

However, for IPV introduction into routine, a rapid assessment will be done to assess people’s perceptions towards the introduction of IPV (in light of the polio eradication initiative) and their acceptability of an extra injection to the child versus the benefits. These results will inform the process of updating the communication strategy, materials design and development.

Introduction of an injectable vaccine poses a challenge of convincing stakeholders at various levels and which calls for a need to package messages with clear justification.

Development of messages and materials will be based on the existing communication strategy and the available literature on IPV. The process will entail the following key activities:

* + - * Develop an advocacy and communication plan of action
      * Develop, design, pre-test and mass produce health promotion materials and messages for both print and electronic media in the various local languages
      * Air Radio and TV Programmes and print media
      * Monitor all messages and materials being circulated.

It is important to note that the key message areas will highlight the following among others: safety of the vaccine; reasons for introduction of IPV; benefits of IPV in light of polio eradication; the schedule; advantages of IPV like that of posing no risk of vaccine associated paralysis and that it triggers an excellent protective immune response in most people.

Anything that is new and very important needs to be launched. Therefore, a national launch will be done and used as an opportunity to rejuvenate immunisation services in the country. It is envisaged that this launch will ride on existing and already known child survival strategies like the Child Days Plus and the African Vaccination Week which fall in April of every year. Efforts will be made to have a high level dignitary preside over the function. Later, districts will be encouraged and supported hold follow up mini launches in their respective districts.

As a way of enhancing grass root mobilisation, community meetings will be conducted to promote community dialogue prior to IPV introduction. Village Health Teams will be brought on board and will be expected to play a crucial role in raising community awareness of the new vaccine, distributed appropriate messages/ materials and also encourage parents to complete the immunisation schedule. It is envisaged that all these activities will move in synergy and complement each other.

Use of the Uganda Junior League that uses the power of sports to mobilize communities will boost the mobilization efforts.