Malawi

Internal Appraisal 2014

1. Brief Description of Process

This country appraisal was conducted for GAVI by independent technical expert, Deborah McSmith, in cooperation with the Gavi Senior Country Manager (SCM), Alison Riddle, and is based on reports and documentation supplied to Gavi by the national authorities and institutions in the country for the year 2013. It is further informed by discussions with ICC members in Lilongwe in April 2014 during a country visit by the SCM, followed by an email consultation in October 2014.

Malawi is reporting on pentavalent (Penta), pneumococcal conjugate (PCV13), and rotavirus (RV) vaccine support, and is requesting pentavalent renewal for 2015, with a change in presentation to 10 dose(s) per vial, LIQUID, plus extension of support for PCV13 and RV to 2016. The NVS programme extension request is in line with the cMYP for 2012-2016 (revised in 2013).

The country is also reporting on a carryover VIG balance for RV introduction. Activity reporting for an existing HSS grant is noticeably missing from the 2013 APR. However, a financial statement was submitted. Reporting on Malawi's HPV demonstration project is provided through a separate process.

2. Achievements and Constraints

Achievements

A key achievement in 2013 was the scaling up of the RV roll-out that began in late 2012. The related PIE revealed a relatively smooth introduction and highlighted the training of health workers, social mobilisation, and adequate levels of funding as key contributors to the success. The introduction of PCV and RV also facilitated DVD-MT and SMT training across the country.

Further activities in 2013 as reported in the APR are:

- Supportive supervisory visits
- Review meetings
- Training sessions: RED, Immunisation in Practice (IIP), DVD-MT and SMT
- An integrated measles campaign & post campaign coverage survey1
- RV PIE
- launch of the HPV demo in Sept 2013
- disease surveillance
- social mobilization during African Vaccination week

Challenges

The most significant challenges for routine immunisation are limited operational funds and a weak cold chain and logistics system – particularly at the district and health facility levels. The country describes key challenges/constraints as:

- An operational funding gap that resulted in fuel shortages leading to outreach clinic cancellations and lack of transport for supply distribution; and kerosene and gas shortages for refrigerators
- Frequent breakdown of refrigerators due to age
- A shortage of bicycles for outreach clinics

[1] Not a Gavi-supported activity.

- A shortage of M&E tools such child health passports, under one year registers, and stock books
- Data management issues
- Stock outs of OPV and 0.5mL AD syringes in early 2014 (Jan/Feb)

Coverage

Coverage across vaccines is slightly below 2013 targets and also lower than 2012 coverage (with the exception of RV, which was introduced in late 2012). Performance for Penta3 was reportedly affected by a global vaccine shortage, which especially affected immunization coverage in the first half of 2013. Despite this constraint, a national coverage of 92% is reported for Penta in 2013, with 21 of 28 districts achieving >80 percent coverage. The DTP dropout rate was 7% - only slightly higher than the 6 percent target.

As per the 2013 APR, the projected National Statistical Office district population data does not add up to the national projected population data. As a result, the number for total births in the original proposal is different from the current projected population births, similarly for the total surviving population.

The ICC minutes cite the following as contributing to lower RV coverage in 2013: age restrictions, reporting problems and stock outs. Malawi's Paediatric Association is reviewing an ICC suggestion to adjust the RV vaccine age restriction to include infants up to 12 months of age.

Equity and hard-to-reach populations

Malawi's DHS 2010 describes the DTP3 coverage estimate as 92.7% for boys and 93.4% for girls. The country reports that its only equity challenge has to do with men not taking their children for immunization. The country does not report on strategies to address this challenge.

In particular, transport constraints affect the country's ability to deliver services to hard-to-reach populations and health facilities. With UNICEF funding, the MoH is identifying hard-to-reach areas and using the REC approach to address the challenge. However, inadequate funding is a challenge to implementation.

3. Governance

ICC

The EPI Technical Working Group that is part of the larger health sector coordination structure functions as the ICC in Malawi. ICC membership includes MOH EPI, CHAI, SSDI – Communication, Health Education Services, JSI-MCHIP, WHO, UNICEF, and three CSOs: Malawi Health Equity Network (MHEN), Health Rights and Education Programme (HREP), and Eye for Development (EFD). In its current form, the ICC is focused on operational issues and is used as a forum for workplanning and problem-solving. Issues and recommendations are then channelled to the Health Sector Review Group as part of the SWAp structure. The ICC met three times in 2013. It endorsed the 2013 APR (late submission) in July 2014, however signatures are missing.

HSCC

An HSS technical working group also exists in Malawi but was non-functional in 2013. Previously, the HSS committees for Gavi and the Global Fund were merged, but the committee became defunct when GF funding came to an end. However, there are plans to reconstitute it in 2014. It includes stakeholders from EPI, TB, malaria, HIV, planning, HR, finance, procurements, and other relevant departments in the MoH.

NITAG

A NITAG is in development and is expected to become operational in 2014.

4. Programme Management

Malawi has a new cMYP for 2015 to 2016 and is adjusting its NVS requests to match this plan. The country undertakes an annual review of the EPI Programme and monitors RI on a monthly

basis. The annual EPI workplan is developed from the cMYP and the Health Sector Strategic Plan (HSSP).

The Gavi Secretariat has no specific concerns about the timeliness of new vaccine introductions in Malawi and PIE results reinforce this assessment. However, a key challenge to programme management is high staff turnover at the district level. There is a continual need for training, and the limited capacity leads to under-utilization of funding in some instances. In response, Malawi is revising its EPI Field Manual to be used as reference material for programme management at the district level. There is also a need for capacity building at the central level to improve program and financial management in the EPI Programme.

The country's main programme delivery objectives for 2014/2015 are to sustain:

- High routine immunization coverage
- High quality surveillance on AFP, measles and NNT; and
- High awareness on the importance of immunization.

Priority actions for 2014/2015 are:

- Improve documentation and data management
- Improve health worker capacity at all levels
- Implement nationwide Zero Stock Outs campaign
- Finalize and disseminate EPI Policy
- Further improve cold chain capacity at all levels
- Advocate for sufficient funding
- Strengthen advocacy and social mobilization activities
- Finalize and disseminate EPI communication strategy
- Sustain safe injection practices and waste management.
- Introduce measles second dose vaccine
- Introduce Inactivated Polio Vaccine
- Introduce of Fridge Tag2
- Conduct temperature monitoring study

5. Programme Delivery

The EPI programme currently provides measles, Penta3, OPV, BCG, PCV13, RV and TT vaccines. Penta was introduced in 2002, PCV13 in 2011, and RV in 2012. The country is approved to conduct a dual introduction of MSD and IPV in January 2015.

Malawi reported no postponed deliveries or vaccine stock outs in 2013. There were minor discrepancies between doses approved in the GAVI decision letter and doses received. However, Malawi did experience short shipments of Penta vaccine due to a global shortage in 2013, mainly in the first six months. Also, due to a stock out of OPV and 0.5mL AD syringes in January/February 2014, the EPI Programme requested a buffer stock of 500,000 OPV doses for the National Vaccine Store from UNICEF.

Injection safety and surveillance

The country has an injection safety policy that includes incinerators and the 'burn and bury' method. It also conducts sentinel surveillance and special studies for RV and pediatric bacterial meningitis, with results from surveillance/special studies pending.

However, Malawi has no national dedicated vaccine pharmacovigilance capacity, national AEFI expert review committee, institutional development plan for vaccine safety, nor risk communication strategy. Malawi does not share vaccine safety data with other countries.

Data management

The use of computerized monitoring of vaccine management has rolled out to districts. Currently, the Stock Management Tool (SMT) is used at the national vaccine store, all regional vaccines stores, and all district vaccine stores.

Vaccine management

The most recent EVM assessment was conducted in November/December 2012 and shows an improvement over the 2009 results. In the 2009 assessment, Malawi scored 77%, and fully implemented 76% of the recommendation, with partial implementation of 18 percent. In 2012, the country had an average performance of 87%, with scores of 100% for vaccine arrival process, storage capacity, and maintenance and repair. Areas needing improvement related to: temperature monitoring, dry storage and shelving, and problems with wastage rate calculations. The country reports that only three of 34 activities in the improvement plan are not implemented.

Post introduction evaluations

A PIE for RV introduction was completed in 2013. According to the APR, highlights of the findings include:

- While approximately 2,500 health workers were trained during PCV13 introduction, for RV more than 13,000 health workers were trained and the training period was increased from 1 to 2 days.
- Introduction plans for regions and districts were developed.
- Adequate reference materials and technical guidelines were provided for trainings at all levels.
- Adequate resources were mobilized from MCHIP, UNICEF, CHAI, WHO and local NGOs within districts for trainings, social mobilization, programme management, monitoring and supervision.

6. Data quality

Malawi has no significant discrepancy between DTP3 administrative data and WHO and UNICEF co verage estimates (2013) (see Annexes A & B). The last reported survey covered the 2009 cohort. The county is preparing for a demographic household survey (DHS) in 2015.

The country reports activities to improve data quality since 2011 as:

- DQSA in 2012 (8 districts) and 2014 (21 remaining districts)
- Training of district and zonal level managers in DVD-MT and SMT
- Supportive supervisory visits
- Training of health workers in Immunization In Practice (IIP) and zero stock out
- RED trainings
- Review meetings with EPI focal personnel.

Malawi also plans to conduct coordination meetings with HMIS and train health workers in data management.

A DQSA in March 2014 found some over reporting of data in all the antigens assessed after aggregating at the national level, with the accuracy ratio for all antigens ranged from 85% to 92%. With regard to quality monitoring, the strong components at both district and health facility levels were recording at 86% and 65% respectively, while computerized archiving (37% district) and reporting components (41% health facility) were the weakest.

7. Global Polio Eradication Initiative

Malawi is a polio-free country, with its last case occurring in 1992. While the GPEI is not active in the country, Malawi will introduce one dose of IPV into routine immunisation in early 2015 while maintaining two OPV doses (as per cMYP 2015-16).

8. Health system strengthening

Malawi did not provide reporting on HSS activities in 2013, despite submitting a financial statement showing HSS expenditures totalling US$130,320.00 from a previous HSS grant (2007-2010). The

country holds a balance of US$1,290,240.00 from the previous grant of US$11,343,000, which is fully disbursed. Outstanding activities include: construction of a new regional cold store in the north, procurement of bicycles, and procurement of fridges.

During an SCM visit in April 2014, the country reported numerous delays in procurement activities but expected activities to re-start in the coming weeks. An update from the country is required.

Malawi was provisionally approved for a new HSS grant in 2013, but the grant is on hold pending the resolution of a Gavi cash program audit that took place (See Section 10).

9. Use of non-HSS cash grants from Gavi

CSO support

Malawi is not reporting on CSO A or B support.

Campaign support

Malawi is not reporting on campaign operational support.

ISS support

Malawi reports an expenditure of US$162,996 for 2013, but does not providing any reporting on activities completed with ISS funds.

Vaccine introduction grants

Malawi carried over a balance of US$223,033 from the 2012 RV VIG, and used US$162,996 in 2013. Funds were used to conduct supportive supervision, the RV PIE, revision of EPI program documents including the EPI manual, and the training of health workers in DVD-MT and SMT.

10. Financial management

A Gavi FMA was last conducted in 2010, and a cash program audit (CPA) was conducted in early 2013. The CPA examined a sample of transactions covering income and expenditure from 2008-2013 for all grants. The sample represented 68 percent of reported expenditure (MK 1.670 Billion or approximately US$4 million).

Of the sampled expenditure, Gavi was unable to validate certain expenditure, classified as follows:

a) Partially documented – MK190m (US$0.6M) – For the future, MoH to ensure proper and adequate support documents are in place for all expenditure charged to Gavi grants,
b) Ineligible – MK 122m (US$0.5) – GoM to reimburse Gavi,
c) Irregular – MK 41m (US$0.13) – MoH to ensure adequate controls are put in place to avoid future irregular expenditure.

The audit established that, to a large extent, incomplete information was maintained to substantiate programme expenditure and the nature of the issues identified showed that the requirements of Gavi's Transparency and Accountability Policy (TAP) were not generally applied.

Consequently, Gavi suspended further cash-based support to Malawi pending the implementation of the audit recommendations. The Gavi audit team will return to Malawi in October 2014 to assess progress and determine next steps. In the interim, all NVS cash-based support is channeled through WHO and UNICEF, including pending VIGs for MSD and IPV. Further HSS support is contingent on completion of the audit recommendations.

11. NVS targets

Further discussions on Malawi's rotavirus and PCV targets are required. Malawi's 2014 targets are significantly higher than approved targets (660,293 vs 641.871) for 100% coverage. 2015 targets are also for 100% coverage (675,317). However, this is more than a 10% increase between 2013 and 2015 (20% increase between 559,464 and 675,317), which is contrary to Gavi policy.

Malawi has also not calculated a drop-out rate for either vaccine. Targets likely need to be adjusted downward unless the country has a thorough justification. The Secretariat is following up with the Ministry of Health.

Overall, EPI in Malawi has performed well since its establishment in 1979. In the late 1980's, the country attained coverage of 80 percent and above for all antigens. High coverage has been sustained overall, except when there was a global vaccine shortage or when there was a change in the recommended statistical proportion of children under 1. However, coverage decreased slightly in 2013, and the reasons need to be carefully examined before the planned introductions of IPV in 2014/15 and MSD in 2015. The cMYP indicates that the country also plans to introduce MR combination vaccine around 2016.

Malawi has consistently demonstrated capacity to perform well in terms of coverage, however challenges that relate to the age of vaccine storage equipment (eg, frequent breakdown of refrigerators due to aging equipment) are of concern for planned additional vaccine introductions. The cMYP emphasizes cold chain expansion, rehabilitation and management; and replacing and maintaining transport equipment (vehicles, trucks, motorcycles, boats and bicycles) as priority activities.

12. EPI financing and sustainability

Malawi is in the low co-financing group for Gavi support and well-performing. The country's co-financing contributions in 2013 totalled US$ 1,200,000.

Gavi financial support is reported in the national health sector budget. In September 2013, a corruption scandal enveloped the national government and resulted in many donors freezing support to the health SWAp. As a result, the EPI program faced shortfalls in operational funds and resources to purchase traditional vaccines in early 2014. Selected donors (Norway and Germany) have since stepped in with discrete funding to bridge the gap. Per ICC minutes, the EPI program has requested MK1.8 billion (US$444,444) for the 2014-2015 fiscal year for purchase of vaccines but the Ministry has not yet communicated the funding allowance for EPI.

Malawi requests technical assistance for financial sustainability strategies, resource mobilisation for immunisation, and financial management. The country is a Gavi priority in terms of immunisation financing support. An immunisation financing assessment was carried out in September 2013.

13. Renewal recommendations

Topic	Recommendation
NVS	Approve renewal of Penta3 for 2015, with a change in presentation to 10-dose vial
NVS	Approve Programme Extension of support for PCV13 and RV to 2016

14. Other recommended actions

Topic	Action Point	Responsible	Timeline
APR	Country to provide ICC member signatures for the July 2014 meeting endorsing the 2013 APR.	Country	
NVS	Country to justify >10% increase in targets for PCV and RV, or revise downward.	Country	
HSS	Country to provide HSS 1 activity reporting for 2013.	Country	
ISS	Country to report on the use of ISS funds totalling US$162,996 in 2013.	Country	
PFO	Country to implement all cash program audit recommendations.	Country	
PFO	Gavi to update FMA pending CPA conclusion.	Gavi/PFO	
IFS	Alliance to provide technical assistance for EPI financing, resource mobilisation, and financial mgmt.	Alliance	

Annex A
Malawi baseline and annual targets, 2013 APR

Number	Achievements as per JRF		Targets (preferred presentation)					
	2013		2014		2015		2016	
	Original approved target according to Decision Letter	Reported	Original approved target according to Decision Letter	Current estimation	Previous estimates in 2013	Current estimation	Previous estimates in 2013	Current estimation
Total births	668,801	668,801	682,962	687,604	697,650	703,641		719,825
Total infants' deaths	40,985	40,985	41,091	27,311	41,178	28,324		28,789
Total surviving infants	627816	627,816	641,871	660,293	656,472	675,317		691,036
Total pregnant women	668,801	668,801	697,650	687,604	697,650	703,641		719,825
Number of infants vaccinated (to be vaccinated) with BCG	668,801	648,515	682,962	687,604	697,650	703,641	713,119	719,825
BCG coverage	100 %	97 %	100 %	100 %	100 %	100 %	100 %	100 %
Number of infants vaccinated (to be vaccinated) with OPV3	627,816	574,599	641,871	660,293	656,472	675,317	671,720	691,036
OPV3 coverage	100 %	92 %	100 %	100 %	100 %	100 %	100 %	100 %
Number of infants vaccinated (to be vaccinated) with DTP1	668,801	619,984	668,801	687,604	697,650	703,641	671,720	719,825
Number of infants vaccinated (to be vaccinated) with DTP3	627,816	575,576	641,871	660,293	656,472	675,317	671,720	691,036
DTP3 coverage	100 %	92 %	100 %	100 %	100 %	100 %	100 %	100 %
Wastage*[1]* rate in base-year and planned thereafter (%) for DTP	5	5	5	10	5	10	5	9
Wastage*[1]* factor in base-year and planned thereafter for DTP	1.05	1.05	1.05	1.11	1.05	1.11	1.05	1.10
Number of infants vaccinated (to be vaccinated) with 1 dose of DTP-HepB-Hib	668,801	619,981	641,871	687,604	697,650	703,641		
Number of infants vaccinated (to be vaccinated) with 3 dose of DTP-HepB-Hib	668,801	575,576	641,871	660,293	656,472	675,317		
DTP-HepB-Hib coverage	107 %	92 %	100 %	100 %	100 %	100 %		0 %
Wastage*[1]* rate in base-year and planned thereafter (%)	25	5	5	10	5	10		
Wastage*[1]* factor in base-year and planned thereafter (%)	1.33	1.05	1.05	1.11	1.05	1.11		1
Maximum wastage rate value for DTP-HepB-Hib, 10 dose(s) per vial, LIQUID	25 %	0 %	25 %	25 %	25 %	25 %	0 %	25 %
Number of infants vaccinated (to be vaccinated) with 1 dose of Pneumococcal (PCV13)	668,801	617,443	641,871	660,293		675,317		691,036
Number of infants vaccinated (to be vaccinated) with 3 dose of Pneumococcal (PCV13)	668,801	576,286	641,871	660,293		675,317		691,036

Pneumococcal (PCV13) coverage	107 %	92 %	100 %	100 %	0 %	100 %		100 %
Wastage*[1]* rate in base-year and planned thereafter (%)	5	1	5	5		4		4
Wastage*[1]* factor in base-year and planned thereafter (%)	1.05	1.01	1.05	1.05	1	1.04		1.04
Maximum wastage rate value for Pneumococcal (PCV13), 1 dose(s) per vial, LIQUID	5 %	5 %	5 %	5 %	5 %	5 %	0 %	5 %
Number of infants vaccinated (to be vaccinated) with 1 dose of Rotavirus	668,801	559,464	641,871	660,293		675,317		691,036
Number of infants vaccinated (to be vaccinated) with 2 dose of Rotavirus	668,801	524,830	641,871	660,293		675,317		691,036
Rotavirus coverage	107 %	84 %	100 %	100 %	0 %	100 %		100 %
Wastage*[1]* rate in base-year and planned thereafter (%)	5	1	5	5		4		4
Wastage*[1]* factor in base-year and planned thereafter (%)	1.05	1.01	1.05	1.05	1	1.04		1.04
Maximum wastage rate value for Rotavirus, 2-dose schedule	5 %	5 %	5 %	5 %	5 %	5 %	0 %	5 %
Number of infants vaccinated (to be vaccinated) with 1st dose of Measles	627,816	571,670	641,871	660,293	656,472	621,292	671,720	624,700
Number of infants vaccinated (to be vaccinated) with 2nd dose of Measles		0		0	656,472	562,913	671,720	590,257
Measles coverage	100 %	0 %	100 %	0 %	100 %	83 %	100 %	85 %
Wastage*[1]* rate in base-year and planned thereafter (%) *{0}*		0		0	25	25	25	25
Wastage*[1]* factor in base-year and planned thereafter (%)	1	1	1	1	1.33	1.33	1.33	1.33
Maximum wastage rate value for Measles second dose, 10 dose(s) per vial, LYOPHILISED	0.00 %	40.00 %	0.00 %	40.00 %	0.00 %	40.00 %	40.00 %	40.00 %
Pregnant women vaccinated with TT+	528,353	438,892	553,199	553,199	579,050	579,050	527,708	604,653
TT+ coverage	79 %	66 %	79 %	80 %	83 %	82 %	74 %	84 %
Vit A supplement to mothers within 6 weeks from delivery	234,080	234,080	239,037	239,037	244,178	244,178		249,306
Vit A supplement to infants after 6 months	1,301,017	207,205	1,329,203	343,802	1,360,123	365,893	N/A	388,706
Annual DTP Drop out rate [(DTP1 – DTP3) / DTP1] x 100	6 %	7 %	4 %	4 %	6 %	4 %	0 %	4 %

Annex B
WHO and UNICEF Estimates of National Immunization Coverage for DTP3, 2013

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Estimate	64	84	89	93	99	87	91	93	93	97	96	89
Estimate GoC	••	•	•	•	•••	•	•	•	•	•••	••	••
Official	64	84	89	93	100	87	91	93	93	97	96	89
Administrative	64	84	89	93	84	87	91	93	102	98	96	92
Survey	NA	82	NA	86	NA	NA	NA	93	NA	NA	NA	NA

Annex C
Malawi overall expenditures and financing for immunization, 2013 APR

Expenditure by category	Expenditure Year 2013	Source of funding						
		Country	GAVI	UNICEF	WHO	CHAI	MCHIP	NA
Traditional Vaccines*	2,711,499	2,711,499	0	0	0	0	0	0
New and underused Vaccines**	22,705,500	1,100,000	21,605,500	0	0	0	0	0
Injection supplies (both AD syringes and syringes other than ADs)	0	0	0	0	0	0	0	0
Cold Chain equipment	0	0	0	0	0	0	0	0
Personnel	0	0	0	0	0	0	0	0
Other routine recurrent costs	1,003,586	0	242,661	0	0	435,111	325,814	0
Other Capital Costs	0	0	0	0	0	0	0	0
Campaigns costs	1,118,288	51,429	0	364,634	702,225	0	0	0
NA		0	0	0	0	0	0	0
Total Expenditures for Immunisation	27,538,873							
Total Government Health		3,862,928	21,848,161	364,634	702,225	435,111	325,814	0

* Traditional vaccines: BCG, DTP, OPV (or IPV), Measles 1st dose (or the combined MR, MMR), TT. Some countries will also include HepB and Hib vaccines in this row, if these vaccines were introduced without GAVI support.