Vaccine: X 12 (2022) 100239

Contents lists available at ScienceDirect

Vaccine: X

journal homepage: www.elsevier.com/locate/jvacx

Key lessons learned from the immunization supply chain of Malawi, an African country using EVM2.0

Ghanshyam Sethy [a], Mike Nenani Chisema [b], Lokesh Sharma [c,*], Olamide Folorunso [d], Dereje Haile [e], Zeinab Reda Berri [f], Krupal Joshi [g], Mphatso Ntenje [h], Collins Mitambo [i], Beverly Laher [j], Sanjay Singhal [k], Samuel Chirwa [l], Tedla Damte [m], Flint Zulu [n], Antoinette Eleonore Ba [n], Michelle Seidel [o], John Phuka [p]

[a] Health Specialist, UNICEF, Malawi
[b] Preventive Health Services & Program Manager-Expanded Program on Immunization (EPI), Malawi
[c] Vaccine Management Specialist, UNICEF Malawi, & Ph.D. Scholar, Jaipur National University, India
[d] Health Specialist, UNICEF Head Quarter, USA
[e] Cold Chain Specialist, UNICEF Regional Office, Nairobi, Kenya
[f] Supply Chain Contractor, UNICEF Regional Office, Nairobi, Kenya
[g] Department of Community and Family Medicine, All India Institute of Medical Science -Rajkot, Gujarat, India
[h] National Cold Chain Manager & MVIP Focal Person, Ministry of Health, Malawi
[i] Head of Research, Public Health Institute of Malawi (PHIM)-Ministry of Health, Malawi
[j] School of Global & Public Health, Kamuzu University of Health Sciences (KUHeS), Lilongwe, Malawi
[k] Department of Pulmonary Medicine, All India Institute of Medical Science, Rajkot, Gujarat, India
[l] Cold Chain Specialist, UNICEF, Cambodia
[m] Chief Health and Nutrition, Programme Health Section, UNICEF Khartoum, Sudan & PhD Scholar, LIKA UFPE, Brazil
[n] Health Specialist, UNICEF Regional Office, Nairobi, Kenya
[o] Immunization (Team Lead: Immunization Supply Chain) UNICEF Head Quarter, USA
[p] Kamuzu University of Health Sciences (KUHeS), Malawi

ARTICLE INFO

Article history:
Received 22 August 2022
Received in revised form 14 October 2022
Accepted 7 November 2022
Available online 8 November 2022

Keywords:
Vaccine
EVM2.0
Malawi

ABSTRACT

Objectives: A country's immunization system's effectiveness depends on its supply chain's efficacy. To assess the challenges of maintaining an efficient vaccine supply chain, Malawi conducted its assessment using The EVM2.0 tool (Effective Vaccine Management).

Methods: It is a cross-sectional study in which all EVM requirements were assessed between September and October 2021. Data were collected from eighty-two randomly selected sites using the site selection tool of the EVM. Data were entered into the EVM assessment tool 2.0 version 1.12 for analysis. This tool generates performance indicators and criteria scores for assessed sites, compared with a WHO minimum score of 80%.

Results: Overall criteria scores across all levels of the immunization supply chain showed a statistically significant mean difference of 5.92 ($t = 2.58$, $P = 0.02$). Comparative overall mean criteria scores across different levels of the immunization supply chain showed no statistically significant difference for primary ($p = 0.76$), sub-national ($p = 0.69$), and lowest distribution stores ($p = 0.12$). However, a substantial gap was found in the overall mean scores of the health facility's service point (SP) ($t = 4.12$, $P = 0.001$). The overall category scores across all immunization supply chain levels did not show a statistically significant difference. However, among individual category scores, Infrastructure (76 %), Equipment (67 %), Policies and procedures (62 %), Financial (47 %), and Resources (64 %) were found to be below the WHO minimum score.

Conclusion: Though the 2021 Malawi EVM assessment findings are promising, they still identified the gaps to be improved to ensure the vaccine availability in the right amount, at the right time, and at the right cost.

* Corresponding author at: Vaccine Management Specialist, UNICEF Malawi, & Ph.D. Scholar, Jaipur National University, India.
E-mail address: lokesh.l85@gmail.com (L. Sharma).

https://doi.org/10.1016/j.jvacx.2022.100239
2590-1362/

Background

The effectiveness of a country's immunization system, and indeed the entire health system, depends mainly on the efficiency of its supply chain to deliver needed public health commodities. The unique nature of vaccines, which requires temperature-specific storage and distribution, makes the immunization supply chain unique [1]. The EVM (Effective Vaccine Management), launched by WHO and UNICEF in 2010, is the flagship immunization supply chain quality management approach that benchmarks country (end to end) supply chains against global standards. With the EVM initiative, countries can assess their immunization supply chain (recommended every 3–5 years), highlight gaps, define improvement plans and monitor improvement activities' implementation, to improve supply chain and overall immunization program performance [2]. An improved mobile EVM (the EVM 2.0) was launched in 2019, after almost a decade of implementing the original EVM tool. While the previous EVM only evaluated nine vaccine management criteria, the more robust EVM2.0 (utilized in Malawi in 2021) covers 13 criteria. Moreover, EVM2.0 can do a targeted assessment [3].

Malawi's Ministry of Health (MoH) and Expanded Programme on Immunization (*EPI*) has long used the EVM as a strategic tool for improving the country's immunization program - conducting two EVM Assessments (EVMAs) using the original EVM tool in 2012 and 2016. After that, in 2021, Malawi's MoH conducted its third assessment using the new EVM 2.0 tool. The main aim was to highlight the vaccine supply chain strengths and progress and identify improvement opportunity areas across the country's supply chain levels and functions.

Material and methods

(a) Study setting: The assessment was conducted between September and October 2021 in Malawi using the new EVM 2.0 tool, with technical support from UNICEF (United Nations Children's Fund), WHO (World Health Organization), and other technical partners. Malawi is a landlocked country in Southern Africa, sharing borders with Tanzania to the north, Zambia to the west, and Mozambique to the east, south, and southeast. The country is divided into three regions (north, center, and south) with 28 administrative districts.

One Primary level (PR) Vaccine store receives vaccines directly from an international manufacturer, distributor, or local vaccine manufacturer. The primary level (PR) vaccine store, the National Vaccine Store (NVS), is located in Lilongwe and receives vaccines from international suppliers bi-annually. There are two functional Sub-National level vaccine stores (SN): the North Regional vaccine store at Mzuzu and the South Regional vaccine store in Blantyre. There is one other regional sub-national level vaccine store, i.e., the central vaccine store, which is not fully functional. These Regional Vaccine Stores receive vaccines from the NVS. In Malawi, there are operational district vaccine stores (OD), the lowest distribution level vaccine store (LD) that receives vaccines from the SN/PR level monthly. The health center facilities are the service points (SP) that receive vaccines monthly from their ODs for immunization services.

(b) Study Design and EVM tool: It is a cross-sectional study that employed EVM 2.0 Tool Version 1.12 in English, and all the EVM requirements were assessed.

(c) Sampling: Eighty-two sites were randomly selected through the site selection tool of EVM: 1 PR, 3 SN, 20 LD, and 58 SP (Table 1).

(d) EVM training: A core group from the MoH and UNICEF received a one-day remote country manager's orientation and a five-day remote EVM training. The core group conducted a face-to-face EVM assessor's training (including a detailed review of the EVM questionnaire) to prepare EVM assessors for data collection. Assessors were allocated to the eighty-two selected sites. Data were collected between September 19th and September 25th, 2021.

Table 1
Random selection of various sites in Malawi.

Site selection completion date	18/06/2021
Site selection performed by	External Partner: Zainab Rida Berry
Confidence	85
Precision	5
No. of SPs per LD	1
Total active locations	931
Total locations excluded	0
Total locations selected	82
Total PR	1
Total SN	3
Total LD	20
Total SP	58
Location inclusion percentage	8.8 %

(e) Data collection, cleaning, and approval: From September 19th to September 25th, 2021, a total of nine teams of 35 assessors from various fields participated in the data collection, examining 82 locations (1 PR, 3 SN, 20 LD, and 58 SPs). During data collection, assessors (and their supervisors) communicated issues experienced with the EVM tool to the UNICEF Regional Office (RO) focal point, who, in collaboration with WHO and UNICEF Headquarters, provided timely solutions. After completing the data collection, the in-country team, with RO and a consultant's support, reviewed the data for the omission, errors, and gaps and ensured consistency across inputs before signing off/approving the questionnaires. Three Sub National (Regional) Vaccine Stores were randomly selected in the sampling frame, out of which one was not fully functional; hence it was removed (Table 2). Similarly, out of 58 SPs, two were not functional and hence removed at the time of assessment (Table 2).

(f) Data analysis: Data were entered into the EVM assessment tool 2.0 version 1.12 for analysis. This tool generates performance indicators and criteria scores for assessed facilities after entering the necessary data for each assessed supply chain location. Each criterion is given a score out of a maximum score of 100 % and compared with a minimum score of 80 %, set by WHO, to be considered effective.

(g) Statistical analysis: Data were compiled and analyzed using Microsoft Excel 2010 (Microsoft Corporation, Redmond, Washington, USA). Descriptive statistics (mean ± standard deviation with 95 % confidence interval (CI)) were calculated for quantitative data like Comparison of EVM Criterion and Category score-2021 of Malawi country with global WHO minimum score of 80. The Shapiro-Wilk and Kolmogorov-Smirnov tests were the normality tests. Depending upon the results from normality tests, a non-parametric test (Mann-Whitney U test) or parametric test (Student's t-test) was done to compare the Malawi EVM criterion score with WHO EVM criterion score and Malawi EVM Category score with WHO EVM category score. The p-value < 0.05 was taken as the statistical significance for all analyses.

Results

Criteria Scores: Comparative criteria scores across different levels of the immunization supply chain during EVM 2021 and WHO minimum criteria score are depicted in Table 3 and Fig. 1.

An unpaired *T*-test was done to find the difference between the 2021 EVM score and WHO minimum score. Before applying the *t*-

Table 2
Assessed sites of the sampling frame.

	Site selection	Assessed	Difference	% Assessed
Total locations assessed	82	79	3	96.3 %
Total PR assessed	1	1	0	100.0 %
Total SN assessed	3	2	1	66.7 %
Total LD assessed	20	20	0	100.0 %
Total SP assessed	58	56	2	96.6 %

Table 3
Comparison of EVM Criterion score-2021 data with WHO score.

	Criteria	WHO score	PR	SN	LD	SP	All over
E1	Vaccine arrivals	80	70	**NA**	**NA**	**NA**	**70**
E2	Temperature management	80	77	84	90	81	**83**
E3	Storage and transportation capacity	80	58	61	75	77	**67**
E4	Facility infrastructure and equipment	80	84	76	73	77	**77**
E5	Maintenance and repair	80	82	72	69	67	**72**
E6	Stock management	80	84	91	83	60	**79**
E7	Distribution of vaccines and dry goods	80	81	77	76	72	**76**
E8	Vaccine management	80	100	100	91	67	**88**
E9	Waste management	80	92	86	72	79	**82**
M1	Annual needs forecasting	80	86	99	81	61	**81**
M2	Annual work planning	80	81	75	65	46	**65**
M3	Supportive supervision	80	71	98	71	58	**73**
M4	iSC performance monitoring	80	61	60	63	49	**58**
95 % Confidence interval		–	**73.62–87.38**	**81.76–80.50**	**70.05–81.45**	**58.78–73.56**	**71.24–79.76**
Normality		–	**0.96**	**0.93**	**0.94**	**0.93**	**0.98**
P-VALUE		–	**0.83**	**0.42**	**0.60**	**0.44**	**0.98**
Unpair T-test		–	**0.30**	**0.39**	**1.64**	**4.12**	**2.58**
P-value		–	**0.76**	**0.69**	**0.12**	**0.002**	**0.02**

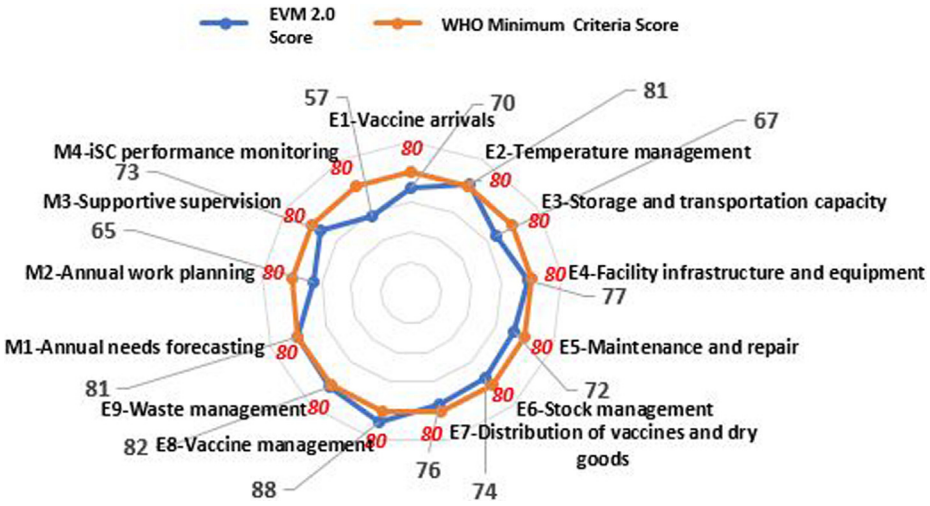

Fig. 1. Overall EVM2.0 Criteria scores across different levels of immunization supply chain in Malawi.

test, we checked for data distribution which showed that our data followed a normal distribution (Shapiro Wilks test was not significant in all criterion scores).

Overall criteria scores across all levels of the immunization supply chain (iSC) show a mean Difference of 5.92, which was a statistically significant difference (t = 2.58, P = 0.02) score across all criteria, with improvement required in Vaccine arrivals (70 %), Storage and transportation capacity (67 %), Facility infrastructure and equipment (77 %), Maintenance and repair (72 %), Stock management (74 %), Distribution of vaccines and dry goods (76 %), Annual work planning (65 %), Supportive supervision (73 %), iSC performance monitoring (57 %). The difference in the overall mean scores was not statistically significant for primary (p = 0.76), sub-national (p = 0.69), and lowest distribution stores (p = 0.12). A substantial gap was found in the health facility's service point (SP) compared to the WHO standard score (t = 4.12, P = 0.001).

Category Scores: Comparative category scores across different levels of the immunization supply chain during EVM 2021 and WHO minimum category scores are depicted in Table 4 and Fig. 2.

The overall category scores across all immunization supply chain levels show no statistically significant difference. Among individual category scores, Infrastructure (76 %), Equipment (67 %), Policies and procedures (62 %), Financial (47 %), and Resources (64 %) were found to be below the WHO minimum score (Table 4).

Table 4
Comparison of EVM Category score-2021 data with WHO minimum score.

	Category	WHO score	PR	SN	LD	SP	All over
C1	Infrastructure	80	83	81	79	63	**76**
C2	Equipment	80	71	53	69	78	**67**
C3	Information technology	80	81	86	86	93	**86**
C4	Human resources	80	100	98	89	79	**91**
C5	Policies & procedures	80	36	87	76	63	**62**
C6	Financial resources	80	96	61	42	20	**47**
	OUTPUT	80	65	71	67	57	**65**
	PERFORMANCE	80	97	90	85	77	**87**
95 % Confidence interval		–	**79.81–82**	**61.42–86.83**	**47.89–84.61**	**59.70–84.30**	**65.50–91.25**
Normality		–	**0.89**	**0.86**	**0.88**	**0.96**	**0.93**
P-VALUE		–	**0.25**	**0.13**	**0.19**	**0.83**	**0.60**
Unpair T-test		–	**0.18**	**1.09**	**1.77**	**1.53**	**0.29**
P-value		–	**0.85**	**0.29**	**0.09**	**0.16**	**0.77**

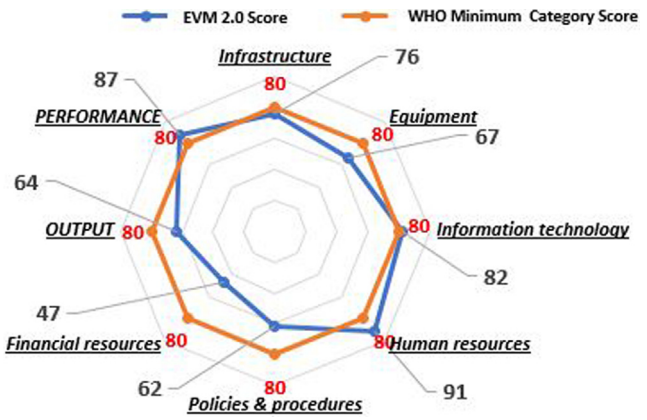

Fig. 2. Overall EVM2.0 Category scores across different levels of immunization supply chain in Malawi.

Discussion

Vaccines are very labile, and proper storage and handling are crucial in maintaining potency and preventing waste [4–6]. The Effective Vaccine Management (EVM) Initiative aims to improve vaccine supply chains so that effective vaccines are available when needed. The EVM tool assesses each aspect of the vaccine supply chain so that areas that need improvement can be identified [2]. It was launched by the WHO and UNICEF in 2010 [7]. A revised version, the EVM 2, was launched in 2019 [8].

Developing countries face several challenges in managing vaccine supply systems, compounded by the introduction of newer vaccines. An assessment by WHO-UNICEF has revealed that many low- and middle-income countries (LMICs) face regular vaccine stockouts due to an inefficient supply chain [9]. India conducted the national EVM assessment in 2018 at 145 sites. India achieved only the recommended 80 % score only in the E3 criteria, i.e., Storage and transportation capacity [10]. An EVM assessment was done in the rural Tolan district of Ghana in 2017. Out of the nine, only five criteria were assessed. However, the WHO minimum target of 80 % was not achieved for any criteria [11]. The EVM assessments conducted by India and Ghana were with the original EVM tool, while Malawi is the first country to use the EVM 2.0 tool for the 2021 EVM assessment for its vaccine supply assessment.

In Malawi, the overall EVM criterion score was 75 (71.24–79.76), lower than the WHO minimum criteria score of 80 %, similar to other developing countries. Malawi has achieved the WHO recommended minimum scores of at least 80 % only in temperature management, vaccine management, waste management, and annual needs forecasting criteria. The need for improvement was identified in the areas of iSC performance monitoring, annual work planning, storage, and transport capacity, vaccine arrivals, maintenance and repairs, supportive supervision, stock management, distribution of vaccines and dry goods, and facility infrastructure and equipment. The overall EVM category score was 87 (65.50–91.25). The recommended 80 % or more score was achieved only in information technology and human resources. Infrastructure, equipment, policies and procedures, and financial resources have identified the need for improvement.

Various studies have shown that system redesigning in response to the constraints identified in the underperforming iSC by EVM assessment can help in improving efficiencies and reliability of iSC performance and vaccine coverage [12–13]. A modeling study using scenarios from three countries (Guinea, Madagascar, and Niger) to analyze the impact of immunization supply chain redesigning showed that country-specific changes to the bottlenecks identified in the supply chain using EVM assessment would help to improve efficiency [14]. A study from the Western Cape Province of South Africa revealed that private outsourced vaccine supply chain segments might perform better than those managed by the government [15]. A scoping review on interventions to increase the distribution of vaccines in Sub-Saharan Africa concluded that system redesign and outsourcing vaccine logistics could improve the performance of vaccine supply chains in Africa [16]. Similarly, Nigeria has made significant progress in its vaccine supply performance by identifying outsourcing direct, customized deliveries and private sector-led vaccine distribution [17].

Though the 2021 Malawi EVM assessment findings are promising, they indicate a need to bridge the gaps identified so that vaccines are available in the right amount, at the right time, and the right cost. A study on the return on investment from childhood immunizations in low-income countries showed a net return of 16 times the cost invested [18]. Hence it is important to channelize the resources and investments in the right direction to improve the vaccine supply chain management and help Malawi build a world-class immunization supply chain network.

Limitation of the study

The apparent limitation of this study is that we could not find any previous assessment reports using the EVM2.0 tool in the literature to compare.

Conclusion

The Malawi 2021 EVM assessment using the EVM2.0 tool has identified areas that need improvement. The country needs to

make every effort to fulfill the minimum suggested standard for each criterion to improve the country's immunization supply chain. Developing and implementing a complete continuous quality improvement procedure is the need of the hour so that the vaccines are available in the right amount, at the right time, and at the right cost.

The results of an EVM assessment alone will not be sufficient to meet these goals. It is of utmost importance to develop and implement a complete continuous quality improvement procedure. As part of the national vaccination program, Malawi is dedicated to the three-step method of analyzing, planning, and implementing change. It is prudent to ensure that the three-step EVM methodology covers current, future, and predicted supply chain difficulties, particularly those associated with launching new vaccines.

Ethics approval: This study was approved by the National Health Sciences Research Committee with an IEC number 444/08. Permission to conduct and publish this study was obtained from the concerned authority.

Contributor statement: All authors were involved in the planning, implementation, and assessment of the EVM2.0. KJ and SS were involved in data analysis and interpretation of results. KJ, SS, and LS drafted the original manuscript with editing and final approval from all the authors.

Funding: JF has received a grant of 85000$ from UNICEF to implement the EVM assessment of Malawi (Grant No. SC180020) in August 2021.

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] Chiodini J. Safe storage and handling of vaccines. Nursing Standard, 2014;28:45–52.
[2] WHO & UNICEF. Achieving immunization targets with the comprehensive, effective vaccine management (cEVM) framework (Vol. 2) 2014.
[3] Effective Vaccine Management (EVM) assessor guide. https://www.technet-21.org/media/com_resources/trl/6094/multi_upload/EVMAssessorGuidev1.01EN.pdf.
[4] Rao S, Naftar S, Baliga S, Unnikrishnana B. Evaluation, awareness, practice and management of cold chain at the primary health care centers in coastal India. J Nepal Paediat Soc 2012;32:19–22.
[5] Bankole AM, Olusegun KK, Marian NB, Iboma G, Adebowale AO, Lukeman AJS, et al. The impact of health facility monitoring on cold chain management practices in Lagos, Nigeria. J Public Health Epidemiol 2010;2:78–81.
[6] Oyefolu AOB, Nwaeke AC, Audu RA, Akinyemi KO, Salu OB, Muller CP, et al. Evaluation of measles vaccine cold chain in Lagos State, Nigeria. African J Clin Exp Microbiol 2007;8:1–7.
[7] WHO/UNICEF joint statement. Achieving immunization targets with the comprehensive effective vaccine management (cEVM) framework. Available at WHO UNICEF statement.pdf. Last accessed on 13th July 2022.
[8] Effective Vaccine Management - technical resources. https://www.technet-21.org/en/topics/evm.
[9] WHO/UNICEF joint statement. Achieving immunization targets with the comprehensive effective vaccine management (EVM) framework. Available at WHO-IVB-16.09-eng.pdf. Last accessed on 24th July 2022.
[10] Government of India. National EVM Assessment 2018. NCCVMRC-NIHFW & UNICEF. Available at National_EVM_Assessment_Report_2018.pdf (nhm.gov.in). Last accessed on 13th July 2022.
[11] Osei E, Ibrahim M. Kofi Amenuvegbe G. Effective Vaccine Management: The Case of a Rural District in Ghana. Adv Prev Med; 2019. p. 5287287.
[12] Prosser W, Jaillard P, Assy E, Brown ST, Matsinhe G, Dekoun M, et al. System redesign of the immunization supply chain: experiences from Benin and Mozambique. Vaccine 2017;35:2162–6.
[13] Prosser W, Folorunso O, McCord J, Roche G, Tien M, Hatch B, et al. Redesigning immunization supply chains: results from three country analyses. Vaccine 2021;39:2246–54.
[14] Prosser W, Spisak C, Hatch B, McCord J, Tien M, Roche G. Designing supply chains to meet the growing need of vaccines: evidence from four countries. J Pharm Policy Pract 2021;14:80.
[15] Lydon P, Raubenheimer T, Arnot-Krüger M, Zaffran M. Outsourcing vaccine logistics to the private sector: the evidence and lessons learned from the Western Cape Province in South-Africa. Vaccine 2015;33:3429–34.
[16] Vouking MZ, Mengue CMA, Yauba S, Edengue JM, Dicko M, Dicko HM, et al. Interventions to increase the distribution of vaccines in Sub-Saharan Africa: a scoping review. Pan Afr Med J 2019;32:14.
[17] Sarley D, Mahmud M, Idris J, Osunkiyesi M, Dibosa-Osadolor O, Okebukola P, et al. Transforming vaccines supply chains in Nigeria. Vaccine 2017;35:2167–74.
[18] Ozawa S, Clark S, Portnoy A, Grewal S, Brenzel L, Walker DG. Return On Investment from childhood immunization in low and middle-income countries, 2011–20. Health Aff (Millwood) 2016;35:199–207.