

Vaccine Procurement and Data Use: Understanding barriers

to data use and recommended interventions to address them.

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Abbreviations and Acronyms

BCG	Bacillus Calmette–Guérin (Tuberculosis Vaccine)
bOPV	bivalent Oral Polio Vaccine
CHAI	Clinton Health Access Initiative
COVID-19	Coronavirus Disease 2019
DQA	Data Quality Audits
DTP	Diphtheria, Pertussis (whooping cough), and Tetanus.
eLMIS	electronic Logistics Management Information System
EPI	Expanded Programme for Immunisations
EVM	Effective Vaccine Management
FIC	Fully Immunised Child
GAVI	Global Alliance for Vaccines and immunisations
GNI	Gross National Income
HCW	Healthcare Workers
HPV	Human Papillomavirus
ICC	Interagency Coordinating Committee
IPV	Inactivated Polio Vaccine
JSI	John Snow Inc
КАРВ	Knowledge, Attitudes, Practices and Beliefs
KPI	Key Performance Indicator
LMICs	Low- and Middle-Income Countries
MenA	Meningitis A
MoF	Ministry of Finance
МоН	Ministry of Health
MR	Measles-Rubella
NITAG	National Immunization Technical Advisory Group
NMS	National Medical Stores
NVI	New Vaccine Introduction
NVIP	National Vaccine and Immunisation Programme
OPV	Oral Polio Vaccine
РАНО	Pan American Health Organisation
PATH	Program for Appropriate Technology in Health
PCV	Pneumococcal Conjugate vaccine
PIE	Post Introduction Assessments
TCV	Typhoid Conjugate vaccine
TD	Tetanus Diphtheria
ТТ	Tetanus Toxoid
TWG	Technical Working Group
UNICEF	United Nations Children's fund
UNICEF SD	United Nations Children's fund Supply Division
WHO	World Health Organisations
WUENIC	WHO/UNICEF Estimates of National Immunization Coverage
YF	Yellow Fever

Executive summary

Procurement is a core function of the supply chain, and when managed and executed well, procurement systems ensure vaccine stock availability in low- and middle-income countries. While procurement is often considered the first step of the supply chain, challenges within procurement can have a much wider impact, cascading downwards and contributing to shortages and stockouts down to the health facility level. Using data to facilitate procurement improvement is therefore a key area of focus for many immunisation programmes, and identifying and resolving the barriers to data use within procurement is the focus of this document.

Through support of vaccine procurement workstreams, CHAI has identified several barriers common across multiple countries including (i) unclear procurement processes, (ii) lack of coordination between stakeholders, (iii) absence of vaccine advocacy information, (iv) a lack of a review of past procurement actions and outcomes and (v) a shortage of vaccine market evaluation. Four key interventions to mitigate and remove these barriers have been identified through learnings in three key countries: Uganda, Kenya, and Cameroon, and are recommended in addition to regular review of stock levels, consumption and planned shipments (enabled by Data Review Teamsⁱ, as discussed in previous partner guidance). These interventions are comprised of; mapping the procurement process, improving data sharing between stakeholders, creation of vaccine advocacy briefs, and embedding market intelligence within country immunisation programmes. The analysis and learning are intended to help countries facing similar gaps and challenges in identifying strategies to resolve data use barriers in procurement and hence, work towards improving t vaccine procurement.



Purpose and scope of this document

The use of data to improve the performance of immunisation supply chains has been a focus area of increasing interest as (iSC) partners look to identify means of increasing access to and use of quality data. In recent years, John Snow Inc, Village Reach, inSupply Health, and CHAI, have produced guidance documents relating to the Introduction of Data Review Teams, the Scaling of Data Review Teams, and a Theory of Change/Theory of Action for Supply Chain Data Use. These guidance documents focused on how available logistics data can be utilised to build responsive supply chains that ensure consistent availability of health products in the most efficient way. These documents also focus on how to support EPI programs to embed these practices. Within the procurement step of the supply chain cycle, it has been realised, however, that many countries are unable to harness data for improved quantification, budgeting, and supply planning - resulting in vaccine shortages. CHAI aims to build upon this previous data use work as well as utilise experiences as a supporting partner to National Immunisation Programmes, to provide insight on the common data use barriers within procurement, and provide recommended interventions to improve data use within the procurement space.

This document is intended to provide early guidance to countries, donors and implementing partners on how to resolve data use barriers in procurement. It provides recommendations on how countries can work to improve their vaccine procurement through quality data utilisation and introduces interventions for removing some of the barriers to data use that currently exist within the supply chain. The list of possible data use barriers is inexhaustible, and stakeholders are encouraged to use the logic and tools presented in this document to identify more barriers in their countries of operation and to identify relevant and practical solutions to these challenges. Countries approaching transitionⁱⁱ from GAVI financing may consider this document of particular interest as they take on greater programmatic and financial ownership of their immunisation programme, given that an estimated 38.7% of programme costs are spent on the procurement of vaccines and related consumablesⁱⁱⁱ.

Vaccine Procurement

Procurement is the process of acquiring supplies, including those obtained by purchase, donation, and manufacture^{iv}. The objective of vaccine procurement as described by the WHO is 'to receive products of assured quality at affordable prices in a timely manner'^v and may include purchasing supplies directly from national or multinational, public, and private suppliers, or use of international procurement agencies for pooled procurement. Irrespective of the procurement method, the data use requirements remain the same.

As a core part of the immunisation supply chain, procurement has wide-reaching implications on the supply chain and ultimately the ability of the programme to reduce the mortality and burden of vaccine preventable disease. Poor practices at any stage of the procurement process **(described later in this section)** increase the chance of supply shortages or gaps (i.e., not procuring enough vaccines to fulfil child, adolescent, and maternal demand for vaccines), which in turn leads to reduced immunisation coverage, increases the risk of outbreaks of vaccine preventable diseases and ultimately loss of life. A 2016 study of WHO-UNICEF Joint Reporting Forms for 73 countries, showed that 31% of national DTP stock outs were due to procurement delays, as well as 30% for BCG and 20% for OPV^{vi}. Poor procurement practices can also lead to over-purchasing, which causes cold chain challenges and ultimately wasted resources when vaccines expire before use. Effective procurement not only saves lives and improves public health but also maximises cost effectiveness (i.e. saving money on vaccines while achieving public health impact).

There are limited vaccine manufacturers in the market, with only 25 exporting significant quantities of WHO prequalified vaccines^{vii}. Governments can procure directly from these manufacturers - known as self-procurement, but most procure through UNICEF Supply Division, or for countries within the Americas, the Pan American Health Organization (PAHO) Revolving Fund is another option. A more detailed overview of the different procurement modalities is available in

<u>Annexes</u>

Annex A: Overview of Procurement Modalities, but the most common in LMICs is UNICEF SD due to GAVI collaboration. GAVI co-finances vaccines in LMICs, until the Gross National Income eligibility threshold^{viii} of that country is reached. After this point financial support is then gradually phased out over five years. Currently, fifty-seven LMICs rely on Gavi for vaccine financing in 2020^{ix}, and nearly one hundred countries procure through UNICEF SD^x.

In 2018, CHAI, in collaboration with EPI and partners across multiple countries, produced a review framework, to help programmes, particularly those approaching GAVI transition, better understand the disruptions and challenges pertaining to procurement, some of which concerned data. As part of this work, the procurement process was broken down into four dimensions – **governance, planning, execution, and evaluation** as outline below^{xi}.

Governance							
Objectives: enable and oversee effective vaccine procurement							
 What are the legal requirements and barriers to procurement, drug registration, and financing? Who are the main regulatory bodies involved in immunization and vaccine procurement? What are their roles? 							
	Plan		Ехе	cute	Evaluate		
Objectives: procure minimi.	e optimal quantities of the zing cost and risk of supply	right vaccines, while shortage	Objectives: execute pro order fulfillment, adj circums	Objectives: assess performance, inform			
Products	Quantities	Method	Tendering	Order management	future planning		
 How are products and their presentation chosen, do they make sense? Is government aware of full spectrum of vaccines in the market? 	• How are forecasted vaccine quantities decided and are those estimates accurate?	 Procurement mechanism (e.g., UNICEF SD, PAHO, self) Duration of tender Tendering rules (participation requirements, award criteria, contract terms) 	 Does the country provide a clear product preference profile? Is the tendering process transparent and open to suppliers? 	 How effective & accurate is the shipment plan? Is NVIP able to order vaccines in a timely & cost efficient manner? Is there access to sufficient financing? 	 Is there a regularly used system of feedback and performance measurement? How can current processes be improved? 		

Given procurement in most LMICs is co-financed by GAVI, the Vaccine Alliance and coordinated by UNICEF Supply Division acting as the international procurement agent, the high-level overview for this process has been further outlined below for reference.



- Procurement in low- and middle-income countries, typically starts with a planning phase, during which data such as population, estimated wastage and previous coverage are utilised to create a forecast of required vaccines for the upcoming procurement period. This process is led by EPI programmes and the WHO EPI Forecasting tool, is commonly used. This tool also includes a forecast of consumables such as syringes and additional vaccines for supplementary immunisation activities.
- Following the forecast, a procurement supply plan is developed. The supply plan specifies the quantities and timeframes within which vaccine stock will be delivered to countries. The supply plan is built upon the forecast and incorporates current stock on hand and projected consumption patterns to determine procurement requirements and estimated delivery dates.
- Once the forecast and supply plan are developed, they are shared by EPI with Ministry of Health leadership and GAVI for stakeholder alignment, before submission to UNICEF Supply Division (SD).
 UNICEF SD will then provide cost estimates, which need to be accepted by the Ministry of Health, Ministry of Finance, and GAVI.
- Following the cost estimate, countries must then deposit the funds to UNCIEF SD to allow the transaction to move forward. Vaccine financing is often a complex process and budget preparation, approval and disbursement timelines significantly vary country to country. Comprehensive planning is often needed to ensure the release of funding for this timeline.
- Once payment for vaccines has been disbursed, the next stage is management of orders from UNICEF SD to EPI programmes in countries. Order management is intended to, ensure that the required quantities arrive at the correct time, to avoid wastage. As a procurement agent, UNICEF SD manages the manufacturers and shipping. EPI must ensure the correct import permissions are in place for the shipment.
- The final stage is to ensure the vaccines are received correctly, and are transferred to the national store while maintaining required cold storage requirements to prevent loss of vaccine potency.

Building on recent work alongside the 2018 framework above, this document will delve further into the barriers to data use specifically and propose evidence-based solutions on **how data can be used to strengthen and support procurement**.

Key Barriers to Data Use within Procurement

Through CHAI's experience with supporting vaccine procurement in multiple countries, five common issues have been identified, encompassing both barriers to effective data use, and procurement barriers which can be addressed using data. The summaries below offer a succinct overview, but stakeholders can view these as a starting point from which to initiate discussion, rather than an exhaustive explanation. Whilst immunisation financing is a core part of the procurement process, the following barriers have not addressed the financing landscape, which has already been well evaluated. For guidance on immunisation financing for procurement, Results for Development produced Immunization Financing a resource guide for advocates, policymakers, and program managers^{xii}.

1. Procurement Processes Are Unclear

In most countries, the procurement process, particularly the stages requiring approval from multiple government agencies for the disbursement of funds, are unclear; there are often no Standard Operating Procedures and the required chronology of events is unknown. Any breakdown of the stages from quantification to vaccine arrival, tend to be classified very broadly, lacking the required country specificity. This limited definition means that country stakeholders are often unable to articulate the status of any current procurement or pinpoint exact root causes for any delays or bottlenecks. For example, when quantifying the procurement need within the planning phase, the wastage rates, population figures and coverage targets are required, and if these have not been updated (i.e. from a census or wastage study) or are unavailable when the quantification is due, the procurement quantity needs cannot be estimated, which in turn delays financing and shipment plan verification, and ultimately stock arrival.

Alongside the procurement stages being unclear, there is also limited clarity and transparency surrounding the specific roles and responsibilities of stakeholders involved, what data they require to do their role efficiently and how that data fits into the overall procurement process flow. This includes government actors outside of EPI and MOH as well as EPI partners. As a result of this, promoting accountability throughout the procurement process is a considerable challenge. When inevitable delays do occur, stakeholders are unable to identify the cause of the problem and are therefore ill-equipped to rectify any bottlenecks or take on mitigating actions in the next round of procurement. Instead, many assume that other entities are responsible for rectifying issues.

• **Data use need:** A breakdown of the steps for vaccine procurement within the country (including roles and responsibilities), status of any current procurement in process and whether procurement is currently on track.

2. Lack of coordination between stakeholders on procurement issues

Procurement planning, financing, and execution requires multiple branches of government and partners with diverse technical backgrounds to work together cohesively. It requires the input of EPI, wider maternal health colleagues, multiple departments in the Ministry of Finance, drug registration authorisation and external immunisation partners. When coordination is poor, it can lead to delays, as well as errors in procurement such as incorrect quantities. Whilst having a detailed overview of the procurement process (*see barrier 1*) provides a solid foundation, this needs to be accompanied by coordination. This includes both strong communication and collaboration between those involved, especially amongst those who are not accustomed to collaborating on a day-to-day basis.

A lack of communication could mean, for instance, that Ministry of Finance officials may not appreciate the number of doses required for one to be considered as a Fully Immunised Child (FIC) nor the implications of under-immunisation on public health outcomes. A high technical submission by the EPI may therefore not yield approval and disbursement of adequate finances, and there is need for supply chain managers to understand the bespoke approval processes in their countries and the data requirements of each decision maker. Another example is when the stock statuses of antigens are not shared amongst stakeholders, and therefore anticipated timelines are not reviewed and adjusted, so those responsible for mobilising funds for the next rounds of procurement, are unable to do so in time to avoid a stockout. Similarly, if there are finance delays, and these are not communicated back to the EPI they may waste resources planning supplementary activities, only for these activities to be cancelled due to lack of stock.

• **Data use need:** Data from EPI (e.g., stock figures, average consumption), Ministries of Health, and Ministries of Finance and procurement agents (i.e., UNICEF SD) need to be well-coordinated to influence the planning process and disbursement of funds.

3. Absence of Vaccine Advocacy Data

Governments are constantly faced with making difficult decisions regarding how to allocate finite and limited resources. As one of the most cost-effective ways to save lives, vaccines provide 'direct medical savings and indirect economic benefits such as cognitive development, educational attainment, labour productivity, income, savings and investment'^{xiii}. However, immunisation programmes are not always equipped with the data to reinforce this message against what can appear as an expensive budget line, especially in the context of the cost of procuring sufficient quantities of vaccines. As a result, vaccine budgets may be cut as they are frequently re-evaluated, or insufficient funds are allocated from the outset; this is particularly important to consider as countries transition out of GAVI support. Whilst advocacy cases are often compiled by partners for potential new vaccine introductions, they are less readily available for vaccines that already exist within a country's routine immunisation schedule.

• Data use need: Vaccine advocacy data which shows the cost-benefit analysis of individual antigens within the routine immunisation schedule, for example the cost of introducing the PCV vaccine, is considered against the reduction in disease incidence and treatment cost, as well as the improvement in those suffering from ill-health, disability, or early death. This data may also include impacts of under procurement on the vaccine system including health worker time, loss of confidence in the system due to unavailability of vaccines and other indirect costs of shortages and reductions in coverage resulting from stock outs.

4. No Review of Past Procurement

A routine and systematic review and analysis of planned procurement vs. actual procurement, would enable stakeholders to identify and assess whether required quantities of vaccines were delivered and if these deliveries occurred on time. Identifying and quantifying past procurement issues allows EPI programs and partners to develop actionable solutions for improving performance and can inform decision making for future procurement cycles. When institutionalized as part of routine operations, post-procurement reviews or audits may be conducted annually or more frequently if required. This allows procurement actions taken over a specified period of time to be reviewed against planned processes and procedures to determine compliance.

For example, if the quantity of an antigen purchased is greater or less than the quantity forecasted, why has this occurred? Financing may not have been released on time or in full, the demand may have been reduced after procurement was finalised, or the forecast may have been considered inaccurate resulting in poorly communicated adjustments, amongst other potential causes. However within most countries, procurement reviews either do not take place, or do not occur with the key decision makers in the room. Without review, it is assumed that the procurement quantities and timelines met national need, and issues are not identified or addressed.

The importance of reviewing data regularly, is true for all elements of the supply chain in order to improve wider supply chain management through data-based decision making that is able to respond to stock needs at all levels. Implementing regular data review meetings by review teams is covered in detail in *'Review Teams: A Promising Practice to Improve Data Use and Strengthen Immunization Supply Chains'*, a report produced by CHAI, JSI and VillageReach in 2018. Therefore, the implementation of data review for procurement is not covered within the intervention sections of this document.

• **Data use need:** Data related to prior procurement cycles including both forecast requirements against actual quantities and timelines. For example forecasted quantities by antigen in a particular year, actual procurement quantities, lead times for in-country processes and delivery by suppliers, funding requested, and funds disbursed for vaccine procurement etc.

As a result of continuous market intelligence, vaccine manufacturers make changes to their product formulations including the number of doses per vial and the thermostability of their products to be able to meet the challenges faced at service delivery points in LMICs. These market changes are often shared by GAVI and the WHO, however, many EPIs are unable to apply this information in a timely manner and may not have the requisite skills to develop scenarios to inform how best to leverage these market changes. For example, several countries experience high wastage rates for vaccines like the Measles-Rubella vaccine when packaged as a 10-dose vial, but may reduce wastage rates and generate cost savings by moving to a smaller 5-dose vial in service delivery points with low daily immunisation rates.

Such scenario modelling, however, requires complex analytical skills to inform the split between procurement of 10-dose vials and 5-dose vials. This means country procurement changes, such as presentation or product switches, new manufacturers and supply recommendations may be led by partners, who may not have adequate information on the immunisation challenges at the service delivery point. Similarly, the process of evaluating the introduction of new vaccines, which often cost more, is predominantly led by partners in LMICs, who evaluate the health benefits against the pressure new vaccine introductions place on immunization systems and procurement financing. While partner support aims to alleviate some of the burden on EPIs, the role of EPI programmes within this research and decision-making process is not always clear and capacity may not be built, frustrating the goal of improving competence and independence of government institutions. This is especially critical for countries that are approaching GAVI transition, who will bear a greater proportion of the costs of procurement, as they move towards being fully self-financed. As well as financing, these forms of support may not be available following transition, either due to lack of funding or national regulations. As such, the improvement of national and global forecasting, planning and procurement capability has been identified in the Immunisation Agenda 2030^{xiv}.

• **Data use need:** Changes in vaccine product specifications and their implications on cost, cold chain capacity and wastage rates.

Recommended Key Interventions

In order to address the data use barriers outlined in the previous section, CHAI is implementing several key interventions within programme countries, to enable better data use within procurement as well as other supply chain functions. Specific country examples where these interventions have been initiated provide insight into the scale of impact that can be achieved. Whilst the below interventions will not be applicable to all countries, there will be elements of each that can be tailored and adapted to suit country context.

1. Map the procurement process and identify bottlenecks.

• Barrier(s) it helps to address:

Unclear Procurement	Lack of Stakeholder	Absence of Vaccine	No Review of Past
Processes	Coordination	Advocacy	Procurement

Procurement is a multi-faceted operation with a wide variety of stakeholders, and as outlined above, visibility across the process can be difficult to achieve. However, a first step towards increasing clarity and transparency is clearly outlining what vaccines are required (see Annex B: Procurement Snapshot Example) and creating a 'mapping' of the vaccine procurement process within countries. Mapping the vaccines procurement process from planning to post-arrival completion of the Vaccine Arrival Report enables identification of potential bottlenecks and opportunities for improvement. For each stage of the process, (see *Overview of Procurement*), the following elements need to be identified:

- The key stakeholders and what role they play in the procurement process
- The data requirements for decision making at each stage of the procurement process
- Whether the stage is part of the critical path and if it can be done in parallel with other steps in the process
- What is required to move it forward
- Estimated timescale

When breaking down the procurement process into individual steps, the more granular and detailed the step outline is, the clearer the process will be to monitor and manage (see Annex C: Key Questions When Procurement Mapping, and Annex D: Presenting Vaccine Procurement and Financing Processes). Formulating these steps into an overall 'procurement plan' provides clarity to stakeholders on the process, their roles, and the impact delays in one area will have on subsequent steps. This is intended to bring awareness to stakeholders on the linkage between their role in the process and the timely arrival of sufficient vaccines in country. For steps where confidentiality is required, notification for the key staff involved must still happen, even if steps are not widely circulated. It is also important to be realistic and identify what is actually happening within the procurement mechanism, rather than how current processes work in theory. This will enable EPI programmes to:

- identify at what stage the procurement process is at, at a given point in time.
- identify where delays and bottlenecks are occurring as and when they occur.

Following on from process mapping and problem identification, EPI programmes and partners can then work towards addressing these delays and bottlenecks. In some cases, these bottlenecks stem from lengthy and bureaucratic steps which can be removed or adapted. Through specific step by step problem identification stakeholders can isolate and pinpoint challenges which can then be tackled individually and systematically.

In the future, as supply chains mature, the mapping process may be digitised within dashboards/software systems so that there is visibility of the entire procurement pipeline and the current status of each stage. This information may then increase accountability, as it would be accessible to all stakeholders, who could manage procurement in real time, without having to contact multiple entities to gather the latest information (e.g., stock status). Digital systems may also allow for interoperability with other tools, such as DHIS2 or eLMIS systems, to reduce workload within the EPI. Whilst such systems are not yet in use, an example interface is given below, to indicate the types of key information we would wish to include within a procurement system.

Ministry of Health + New Activity		Procurement Portal					
Procurement ID	ltem	Туре	Status	Owner	Department	Due	Current Stage
Search	Search	Filter	Filter	Search	Filter	Search	Filter
<u>15938265</u>	BCG	GAVI Co- Finance	Draft in Progress	Patrick Smith	National Planning Department	30/June	Planning
<u>23987593</u>	JE	Self- Procure	In Progress	Kate Nash	Ministry of Finance	15/July	Budget Harmonisation
<u>38269434</u>	AD Needle 1.5ml	UNICEF	Overdue	Jane Doe	Ministry of Health	15/June	Costings Review
<u>39208764</u>	PCV	GAVI Co- Finance	In Progress	Sam Roberts	Pharmacy Division	18 th July	Awaiting Signoff
<u>19764223</u>	MR Diluent	UNICEF	Cancelled	Julia <u>Cakebread</u>	Presidents Office	Cancelled	Cancelled
<u>13894756</u>	Cool Boxes	UNICEF	Completed	Innocent <u>Mannee</u>	NIP	Complete	Complete

Figure 1: Sample of a Procurement Dashboard

Country Example: CAMEROON

Alongside the EPI programme, CHAI conducted quantitative analyses of procurement data such as timeliness of procurements, stock out rates of traditional and co-financed vaccines, timeliness of releasing funding for vaccine procurement and correlation between planned and actual funding disbursements. Qualitative interviews were also conducted with multiple stakeholders across the Ministry of Health and Finance, in order to evaluate current attitudes to procurement and gain insight into where the perceived bottlenecks existed. Both sets of data were then organised and synthesised into a map of the procurement process, which is currently being used to advocate for improvements within the process to reduce procurement bottlenecks.



2. Improve data sharing between stakeholders.

• Barrier(s) it helps to address:

Unclear Procurement	Lack of Stakeholder	Absence of Vaccine
Processes	Coordination	Advocacy

Increased data sharing between procurement partners builds upon the work that mapping the procurement process initiates. Having an end-to-end procurement map brings visibility, but unless information is routinely shared between the EPI and the other stakeholders (most often, senior leadership at the Ministry of Health, Ministry of Finance, UNICEF, GAVI) the procurement process is unlikely to meet the timeline required for the immunisation programme's upcoming needs. This information sharing should be routine and part of well-established communication expectations in order to build trust, transparency, and accountability across the procurement process. Similarly, visibility into the annual financial planning and disbursement cycle helps assist forward planning, and ensures that funds are ready and available when procurement is required

Whilst increased collaboration is an easy approach to outline, the processes required to reach this goal are often slow, with considerable effort and substantial buy-in required from all sides. This can be especially difficult to navigate within Government, given the high workloads and often siloed nature of government departments and programmes. However, procurement is often done in batches so regular sharing and collaboration does not necessarily entail weekly meetings, or time-heavy commitments. Certain aspects of the procurement process may only require an annual or bi-annual process, for example, in some countries a single annual disbursement of funds for procurement may be the norm. To initiate increased collaboration, key data for EPI programs to share may include:

- EPI calendar of activities
 - Key activities will highlight to other stakeholders where procurement surges may be required as well as when each stage of the procurement process needs to be completed in order for stock to arrive on schedule. For example, awareness of planned supplementary campaigns may require additional stock or of when
- Estimated dates of stock outs.
 - As the EPI review stock consumption within data review meetings, procurement timelines may need to be shifted if stock has not been consumed at the forecasted rate. For example, when new cohorts are included within a target population, demand may overwhelm the supply and procurement will be needed ahead of schedule.
 - Joint access to tools such as UNICEF's ViVa tool, help facilitate this sharing, and give estimated stockout dates, considering current procurement lead times^{xv}.
- Upcoming expiries.
 - Similar to stockout data, if consumption is less than forecasted then even when stock quantities are within min-max levels, approaching expiry dates need to be considered and shared to ensure procurement is triggered to maintain antigen availability. For example, an extended rainy season may lead to lower immunisation demand, but the stock will still expire, and procurement will still be required.

Information, updates, and data shared by other stakeholders may include:

- Information for budgeting and financial management
 - Transparency on the process, timelines, expectations, and limitations of the financial process would aide EPI programs in advance planning to ensure that vaccine procurement needs are included in annual government budgets and that where shortages exist these are addressed early on

- Updates on the status of funding disbursement requests
 - As illustrated in the interface example above (see Figure 1) processes to ensure continuous information sharing on the status of procurement financing requests would enable proactive management of delays, establish accountability across Ministries and Departments, and enable follow-up and revision where required.

It is important to highlight that data which is not needed or used by a stakeholder may create unnecessary information overload and lead to useful data not being utilised because it is embedded in the data 'dump'. Key information needs to be identified, and the format and users of that information must also be outlined.

Country Example: KENYA	Country Example: UGANDA
The NVIP integrated a country	Following a procurement mapping exercise, the EPI
pipeline stock tool into their eLMIS	programme sought to assess potential drivers for future
system, in order to use eLMIS data	stockouts, considering aspects such as poor forecasting and
more effectively and inform strategic	limited funding alongside wider counterparts in MoH and
procurement decisions regarding	MoF. In the early stages of the COVID-19 pandemic, the EPI
timing and quantity of procurements.	was then able to use this mapping to highlight the impact
The pipeline helped them map and	global supply delays would have upon the system.
track funding requests and order	Subsequently, the decision was taken to 'frontload' upcoming
processes to ensure sufficient lead-	vaccine procurement, which required accelerated release of
time, develop data on funding issues,	funds. Ensuring these funds through collaboration with the
and highlight issues to the broader	MoF, ensured no supply-related interruption of immunization
partner coalition.	programs throughout the first year of the crisis.

- 3. Create vaccine advocacy cases, and formats for advocacy to take place.
 - Barrier(s) it helps to address:

Absence of Vaccine	No Review of Past	Shortage of Vaccine
Advocacy	Procurement	Market Evaluation

Whilst vaccines are known to provide substantial positive return on investment^{xvi}, country specific benefits for individual antigens are usually only presented when championing the inclusion of new vaccines into the routine schedule. Key information is provided to health and finance ministries to make the case for what vaccine introduction will bring to the country, alongside the costs. By ensuring these 'advocacy cases' are produced and maintained for all routine vaccines, as well as those being considered for addition into the vaccination schedule in the future, the EPI can improve its ability to advocate for all vaccines when budgets are set and/or being re-evaluated. This would advance the aim of keeping sufficient funding available for vaccine procurement.

Key factors to consider incorporating within advocacy cases include^{xvii};

- Vaccine Factors
 - o Safety / Efficacy and Effectiveness / Indirect Effect / Vaccine Characteristics
- Disease Factors
 - Disease burden / clinical characteristics / use & cost of healthcare / alternative preventive and control measures / regional and international considerations
- Economic considerations
 - Vaccine Cost / vaccine use cost / vaccine availability and affordability / socioeconomic impact of disease / economic impact on EPI and health sector
- Health Policy and Programme Issues
 - Interaction with other disease control strategies / feasibility / impact on resources / acceptability / equity / social considerations

Any programme reviews conducted recently *e.g. EPI review, post introduction assessments (PIE), data quality audits (DQA), Effective Vaccine Management (EVM) assessments, cold chain evaluation assessment, knowledge attitudes practices and beliefs (KAPB) survey, can also be used to demonstrate the impact of the programme. As well as building vaccine advocacy cases, setting up a Vaccines Financing Sub-committee, (or incorporating one within a vaccines or supply chain technical working group (TWG) or National Immunization Technical Advisory Group (NITAG) allows the case for vaccine financing and procurement challenge resolution to be presented and may be used to secure additional resources, as part of the planning cycle. In the event of national emergencies with limited resources (e.g. the COVID-19 outbreak), funds may still have to be reallocated, but decision makers are able to make better informed decisions through access to relevant and available data.*

Key Resource: Advocacy for immunisation

Developed by PATH, John Hopkins and GAVI, this website provides ideas, resources, and guidance to advocate for strengthened commitment to vaccines and immunisation to save lives.

<u>NITAG Immunisation Policy Framework</u>: Outline's elements to consider in developing a framework for issuing immunisation related policy recommendations.

WHO Capaciti Tool: Decision support framework for assessing different presentations of vaccines.

<u>Lives Saved Tool</u>: Mathematical modelling tool which allows users to estimate the impact of coverage change on mortality in low- and middle-income countries

Country Example: UGANDA

Government funded vaccines frequently had lower stock levels, in comparison to GAVI co-funded vaccines when reviewed by the Vaccines Financing Sub-committee made up of key UNEPI partners (NMS, WHO, UNICEF, CHAI and PATH). An advocacy case, linking stockouts of traditional government-funded vaccines with lack of funding, was composed, and an advocacy champion was identified within the sub-committee. This advocate was a key component, leading critical engagement with the Uganda Ministry of Health, the Ministry of Finance, alongside other key stakeholders in the health financing space and was able to reinforce the committee's experience with vital data to back up the funding case. In the 2019/20 financial year, Uganda increased its funding for procurement of traditional vaccines by 130%, which has been sustained since.

4. Increase Market Intelligence In-Country

• Barrier(s) it helps to address:

Absence of Vaccine	No Review of Past	Shortage of Vaccin
Advocacy	Procurement	Market Evaluation

Vaccines market information is constantly changing and whilst product selection is supported by GAVI and partners, countries must increasingly champion their own procurement choices. Choices such as product selection will change over time based on evolving supply (e.g. more competition) and demand (e.g. less donor support). These choices need to be data-driven, and evidence based, requiring market awareness to be embedded within government immunisation programmes as well as the wider Ministry of Health. Presentation switches, such as switching from 5-dose to 10-dose vials, and product switches, by selecting a different manufacturer's vaccine, are often under-considered by EPI countries, despite the cost saving potential they offer through reduced procurement expenditure, as well as the wider programmatic impacts on wastage and cold chain requirements. Institutional responsiveness can be increased through clear country processes to review product selection (who, how, when, with what data)

Market analysis includes identification of:

- Potential options for new vaccines and routine product switches
- Which vaccines support country objectives and have highest health impact
- Feasibility of procurement decisions, including financing needs of vaccines for immediate and longer term (co-financing plans and future needs as a country moves towards GAVI graduation)
- New Vaccine Introduction (NVI) strategy and/or framework within multi-year plans

By conducting internal evaluations of the vaccine market governments would be able to recognise savings, identify technical barriers, and ensure that correct, relevant information is getting into the hands of decision-makers. If possible, review market intelligence alongside the vaccination programme performance annually, as part of midterm review(s) or alongside the multi stakeholder dialogue. For the EPI to benefit from increased market awareness, steps taken to incentivise reviews and product switches, one such option would be to ensure any money saved through switches remains within the EPI.

Embedding market intelligence is a slow process, and may be a long-term goal for some countries. However those approaching GAVI transition will need to identify means of ensuring that they are able to finance their required vaccines within the available national immunisation procurement budget and being able to plan with a forward-looking perspective is vitally important towards this goal.

RESOURCES: Market Intelligence for Action: GAVI Transition's impact on Vaccine Procurement and the critical role of market intelligence Market Intelligence Resources for Vaccine Product Choice and Price Market Intelligence Resources for Product Access and Implementation Strategies

Country Example: KENYA

Product selections are reviewed alongside public market intelligence resources within the NITAG made up of the government and multiple partners. An application for the introduction of Typhoid conjugate vaccine (TCV) into the routine schedule has been submitted to GAVI. A switch from10-dose vials (MR-10) to 5-dose vials (MR-5) is currently being considered following an analysis of cost savings and strong Health Care Worker (HCW) support.

Further discussion and analysis on the introduction of HPV and Rotavirus vaccines are planned by the NITAG.

Conclusion

The increased use of appropriate data within, and to inform improvements in, the procurement process has the potential to make a significant improvement to the performance and output of immunisation programmes. Whilst many barriers to data use in procurement currently exist, including those outlined in this document, governments, donors and implementing partners can mitigate these barriers through several key and specific recommendations and strategies.

Through mapping the procurement process, programmes and governments can create specific milestone reports and indicators to monitor progress of procurement actions and help identify the status of future procurement at any point, and utilise this information to identify bottlenecks and increase accountability for the resolution of bottlenecks. The mapping can then further be used as a basis for increasing coordination between the relevant stakeholders within the process, and identifying the data which must be shared. In addition to improved data sharing, optimising available data to create and strengthen the case for financing and procurement improvements, can enable stakeholders to better advocate for vaccine procurement. Advocacy for procurement needs can be further strengthened when awareness and capacity of vaccines market data is instilled within EPI. Although this is a longer-term approach to addressing data barriers within procurement, it is particularly relevant for changes of product and presentation in procurement.

Together these recommendations can be viewed as multifaceted interventions which will not solve all procurement problems, but provide a starting point for tackling procurement issues through data. For these reasons, we encourage interested country officers and stakeholders to leverage this document alongside other recent materials in data use, and immunisation procurement financing for a holistic approach to procurement strengthening.

SUGGESTED RESOURCES FOR FURTHER READING

- <u>Immunization Data: Evidence for Action</u>: A Realist Review of What Works to Improve Data Use for Immunization Evidence from low- and middle-income countries
- <u>Introduction of Data Review Teams:</u> A Promising Practice to Improve Data Use and Strengthen Immunization Supply Chains
- <u>Scaling of Data Review Teams:</u> A Promising Practice to Improve Data Use and Strengthen Immunization Supply Chains
- <u>Theory of Change/Theory of Action for Supply Chain Data Use</u>: A Conceptual Framework for Program and Supply Chain Managers is a conceptual, planning, and prioritization resource to instill, scale, and sustain data use at all levels of a health supply chain
- Immunization Financing: A resource guide for advocates, policymakers, and program managers

Country Overviews

Cameroon



Overview:

- EPI schedule: BCG, bOPV, Penta, PCV-13, Rota, IPV, Yellow Fever, HPV, MR, and Td
- Central immunisation programme conducts a forecasting workshop, using the standard UNICEF population-based forecasting methodology, based on data from the national statistics agency with support from UNICEF, CHAI and WHO.
- MOH, Ministry of Economy, and Ministry of Finance meet to agree on a workplan, discuss EPI financing needs, make decision on total amount for purchase of vaccines. A further review is taken by the financial controller who will grant access to the funds.
- Both traditional and GAVI supported vaccines are procured through UNICEF SD.
- EPI prepares a programme forecast for the upcoming year on an annual basis every September. This forecast estimates vaccines need, considering population figures, wastage, and programme targets.
- The existing stock inventory and average monthly consumption are used to project the end of year closing balance for antigens, to create a suggested supply plan for the year.
- Once the forecast is validated, UNICEF and Gavi work towards implementing the supply plan. The primary challenge in implementation is usually mobilization of funds.

Progress Areas:

- Comprehensive mapping of the procurement process, including qualitative interviews, to identify bottlenecks.
- Breaking procurement requests into smaller, more regular sums and transfer of funds, since there is less bureaucracy around smaller amounts.

Future Focus:

- Streamlining the procurement process, in order to remove bureaucratic loops in the system.
- Increase advocacy for vaccine procurement, to limit vaccine budget lines converted into something else for national emergencies which penalises immunizations and leads to deaths and epidemics.
- Inform budget planning for traditional, government funded vaccines.

¹ "Cameroon | Gavi, the Vaccine Alliance." <u>https://www.gavi.org/programmes-impact/country-hub/africa/cameroon</u>. Accessed 4 Jun. 2021.

Кепуа

	Immunisation Context ²				
KENYA	 Live Births Per Year: 1,631,470 Under-Five Mortality Rate: 49 per 1000 live births Epidemics Risk: Polio Risk Tier 1 Under-immunized Children: 115,136 Zero-Dose: 43,176 (2019) DTP3 Coverage: 92% (WUENIC 2019) 				

Overview

- Kenya provides nine vaccine formulations through a National Vaccine and Immunisation Programme (NVIP): IPV, Pentavalent, PCV, Rotavirus, YF, BCG, MR, TD & HPV.
- Procurement is led by NVIP, and supported by UNICEF, CHAI, GAVI, WHO, County NVIP and MoF. The National Forecast group provides a vaccine forecast annually, with input from the county.
- Procurement of both traditional and GAVI supported vaccines through UNICEF, whilst non-EPI vaccines and antisera are procured through local tendering.
- The national level maintains a maximum and minimum stock level at the regional level and plans procurements in relation to the maximum and minimum national stock levels. i.e. once the minimum is reached, the procurement mechanism is triggered.
- Vaccine selection process
 - 1. NVIP declares intent (usually with support from development partners)
 - NVIP evaluates products based on the following criteria (with technical support from partners)
 (i) Serotypes (ii) Presentation (CC primary) (iii) Ease of use
 - 3. NVIP makes a final decision
 - 4. ICC rubber stamps decision

Progress Areas:

- The central and county levels of Government are improving the forecasting and planning process for the vaccines supply and immunization consumables through improved process and coordination.
- The EPI are currently identifying public market intelligence resources, for product considerations in the following areas: MR 10/5 dose switch, Typhoid product selection, and either HPV, PCV, or Rotavirus product switch.
- The Ministry is embarking on training immunization system managers at the county level on improved data handling, analysis, and planning interventions. This will be through activities planned in the HSS as well as Ministry of Health training to improve data management at county level.
- Developed a procurement and supply-chain dashboard to drive quarterly Logistics Working Group meetings and bring critical KPIs to the attention of NVIP.

Future Focus:

- The NVIP has the capacity to make educated decisions due to Kenya's strong research base, development partnerships, and extensive experience with NVIs. However the NVIP does not regularly review all available vaccines in market or in pipeline; often new product developments are prompted by partner orgs. Processes involved with NVI selection can be daunting i.e. cold chain and service delivery implications.
- Under fulfilment relative to forecasts, investigating if this because the forecasts are inaccurate (i.e. over-estimate population or reach), or because of a lack of financial liquidity to buy all vaccines.
- Looking to improve the accuracy of wastage rates; especially for more vaccines where they may be underestimated.

² "Kenya | Gavi, the Vaccine Alliance." <u>https://www.gavi.org/programmes-impact/country-hub/africa/kenya</u>. Accessed 4 Jun. 2021.

Uganda

		Immunisation Context ³				
UG	ANDA	 Live Births Per Year: 1,812,193 Under-Five Mortality Rate: 55 per 1000 live births Epidemics Risk: Polio Risk Tier 2 Under-immunized Children: 110,352 Zero-Dose: 15, 765 DTP3 Coverage: 93% (WUENIC 2019) 				

Overview

- Uganda currently has 9 antigens in the schedule: BCG, OPV, TD IPV, Pentavalent, PCV, Rotavirus, HPV and MR. The traditional vaccines (bOPV, TD, MR, BCG) are funded by the Government of Uganda and the rest are co-financed by both GAVI and the Government of Uganda.
- Annual forecasting and supply planning is done using the UNICEF Forecasting tool and is led by the EPI and the National Medical Stores, supported by partners like UNICEF, WHO and CHAI.
- NMS is then responsible for the procurement and delivery of the vaccines, this is a relatively new process change (2012), and prior to this procurement was led by the EPI.
- The resource envelope for immunization has increased fourfold since 2012 to a total of US\$ 85.6 million in 2016 and is mainly attributed to new vaccine introduction and the lift of the ban of Gavi funding to Uganda in 2012^{xviii}.

Progress Areas:

- Conducted a procurement finance analysis to identify and quantify the relationship between procurement financing and operations, and service delivery outcomes.
 - Secured additional funding to procure government-funded vaccines (BCG, bOPV, MR, Td) through advocacy efforts. All Government funds were released for FY 2020/21
 - Map and track funding requests and order processes to ensure sufficient lead-time, develop data on funding issues, and highlight issues to broader EPI/partner coalition.
- At the onset of COVID-19 pandemic, supported the MOH-UNEPI to frontload all shipments ahead of global shutdowns, thereby averting in-country shortages of vaccines.

Future Focus:

- Increase visibility into when stock replenishment will be required, to ensure procurement process is instigated early enough, and avoid future stockouts.
- Support budgetary planning for future financial years considering any planned NVI required to introduce YF, MenA and HepB birth dose coming years.
- Set up a Vaccines Financing Sub-committee, (or incorporate into TWG) to build a case for additional resources: advocate for additional funds for the procurement of traditional vaccines to prevent nationwide stock-outs and potential service interruptions.

³ "Uganda | Gavi, the Vaccine Alliance." <u>https://www.gavi.org/programmes-impact/country-hub/africa/uganda</u>. Accessed 4 Jun. 2021.

<u>Annexes</u>

Annex A: Overview of Procurement Modalities

Currently available		Description
, procurement m	nodalities	
Self- procurement (Bilateral -		 National priorities and policies support investments/exclusive sourcing in domestic manufacturing. This can lead to limitations in product availability and delays in introductions Most non-GAVI MICs choose to manage their own tender process
suppliers)	sourcing	and access a wide range of suppliers; they prefer to retain autonomy over procurement. Requires strong in-house negotiation capabilities and access to market intelligence.
UNICEF (a form of international pooled procurement)		• Many countries (GAVI or not) procure through UNICEF They gain from greater efficiency from pooled procurement (e.g., low prices, wide selection of products) but their in-house negotiation, regulatory, and product switch capabilities can sometimes be limited due to this process due to a decreased focus on building internal capabilities
Regional pooled procurement (e.g., PAHO Revolving Fund)		 Gains from streamlined regulatory, financial, and operational mechanisms: greater efficiency gain from pooled procurement (e.g., low prices, wide selection of products) Currently, PAHO RF is the only functional regional pooled procurement mechanism. Note: PAHO have a 'most-favoured nation' (MFN) agreement with suppliers whereby they must offer the lowest price globally to PAHO. GAVI was granted an exception to this for HPV, PCV, Rota
Hybrid		 UNICEF & domestic: used by countries where policy promotes domestic procurement, with exceptions for products not available domestically & policy allowing single-source procurement, e.g., Vietnam External & domestic sourcing: used by countries where policy promote domestic procurement, with exceptions for products not available domestically and policy preventing procurement via UNICEF SD, e.g., India Pooled procurement & self-procurement external or domestic: e.g., Brazil – local manufacturer and PAHO

Annex B: Procurement Snapshot Example

Vaccine	Туре	Supplier	Method	Gavi Support	Price/ dose	UNICEF price/ dose	Safety	Notable characteristics	Presentation	Assessment of current procurement status by antigen
Domestic										
BCG	Routine	IVAC	Domestic order	No	\$0.06	\$0.16	WHO- Govt certificate	No VVM	20-dose	Lower price & same presentation as UNICEF SD
DTP	Routine	IVAC	Domestic order	No	\$0.10	\$0.17	WHO- Govt certificate	No VVM	20-dose	Lower price & same presentation as UNICEF SD
Td	Routine	IVAC	Domestic price	No	\$0.30	\$0.11	WHO- Govt certificate	No VVM	10-dose	Higher price but same presentation as UNICEF SD
International Tender										
DPT- HepB- Hib (Penta)	Routine	Serum & Bio-E	Tender & UNICEF SD	20% co- financing on UNICEF SD procurement	\$1.20	\$1.20	WHO PQ'ed	International product	1-dose	Same price & good international product from strong, sustainable supplier
IPV	Routine	Sanofi	Tender	Yes, fully funded until 2025	\$2.00	\$2.00	WHO PQ'ed	International product	10- 5- and 1- dose	Fully funded by Gavi until 2025; Gavi policy unknown after 2025
Tech transfer										
Measles- Rubella (MR)	Routine	Serum - POLYVAC	Domestic order	No	\$0.65	\$0.64	WHO PQ'ed	G <u>ood clinical</u> <u>trial results</u>	10-dose	Same price & good international product from strong, sustainable supplier.

Annex C: Key Questions When Procurement Mapping

Topic area	Key questions
Overarching	 What is the end-to-end process by which vaccines are financed and procured?
capabilities /	Which units within the government are involved?
processes	 What level of priority is immunization afforded within the government?
	How are vaccine procurement priorities and strategies aligned and communicated
	across relevant actors within the Vietnamese government?
	What technical capabilities can the government utilize to support decision making
	and execution in vaccine procurement?
Financing	What funding sources does the MOH use for immunization financing and how much
	does each source provide? What percentage of the MOH's immunization budget is
	currently covered by Gavi?
	 What sources of funding will replace Gavi funding following transition?
Demand	 How does sub-national and national-level data inform vaccine demand forecasts?
forecasting	 How does demand forecasting inform tendering strategy / process (for both self-
	procured and UNICEF SD-procured vaccines)?
	 How often are forecasts adjusted? How often are these communicated with
	suppliers and UNICEF SD?
	 Are vaccines forecasts based on funding availability or based on need?
Market	 How does the MOH inform itself of global vaccine market dynamics (e.g., supply,
intelligence	demand, gaps, supplier reputations)?
	How does global vaccine market intelligence inform product selection, new vaccine
	introduction plans, and/or tendering strategy/process?
	 Does the MOH use benchmark pricing to inform price targets? Where does this data
Delievend	come from?
Policy and	 How do global immunization policy and TPP recommendations inform the MOH's upgeting product and procentation proferences?
regulation	vaccine product and presentation preferences:
	 How do domestic clinical and delivery experiences inform product and presentation preferences?
	 What clinical and registration standards (e.g. WHO PO registration in Vietnam) are
	required for vaccines procured for the public market?
Tendering	What steps and timelines are involved in the vaccine tendering process?
	What criteria are used to select vaccines in the tendering process? How are they
	weighed against each other?
	 What tendering and procurement processes and standards are communicated with
	suppliers and other stakeholders? How are they communicated?
	 How long do tenders last for various vaccines?
	• Is there any communication around tendering with other Gavi or ASEAN countries?
	How does the MOH decide whether to procure a given vaccine directly or through
	UNICEF SD?
Order /	• Does the MOH/MOF have difficulty paying suppliers and/or UNICEF SD on time and
procurement	in agreed-upon amounts for vaccines? If yes, how often and why?
agency /	 How does the MOH communicate with suppliers and UNICEF SD regarding
supplier	manufacturing timelines and changes to demand?
management	 How does the MOH monitor and assess suppliers and UNICEF SD on performance?
	Does this performance factor into tendering decisions?
	 Who conducts the customs clearance and related paperwork for internationally
	procured vaccinations?

Annex D: Presenting Vaccine Procurement and Financing Processes



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