USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

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Ensuring the Quality of Subnationally Procured MNCH Medical Products

Findings from Liberia, Nigeria, and Tanzania

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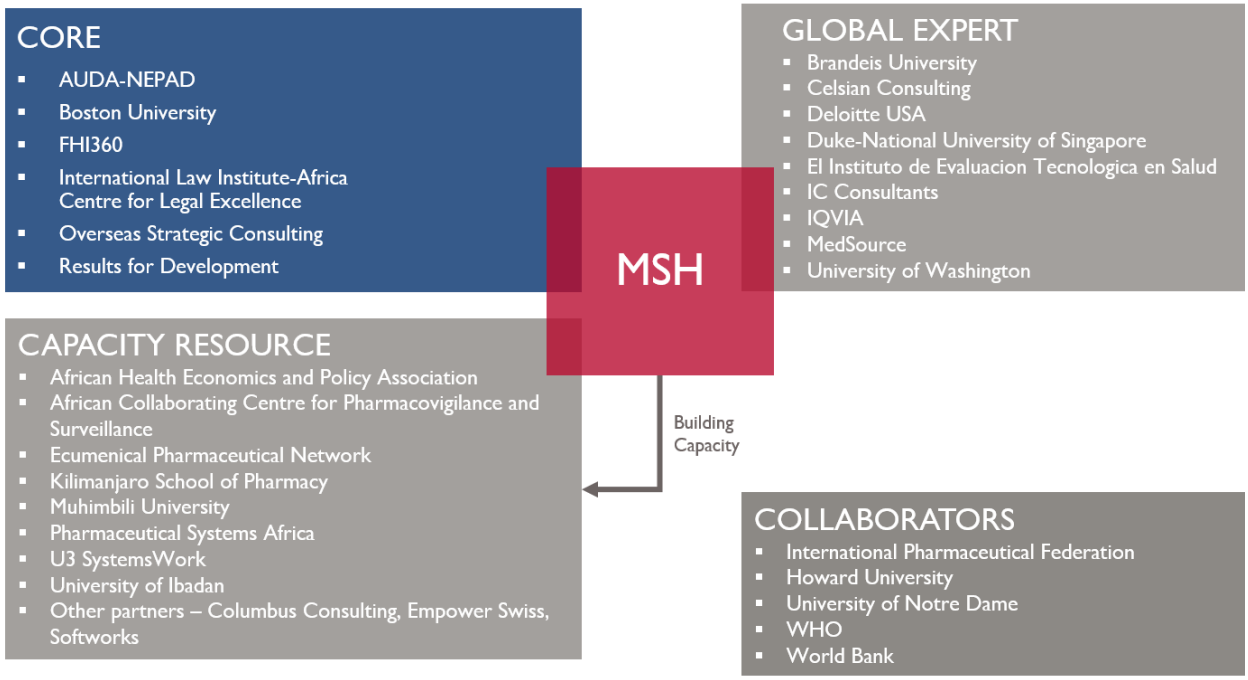
About the USAID MTaPS Program

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

The MTaPS Consortium



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ACRONYMS AND ABBREVIATIONS

CMS	central medical store
JIMSO	Jigawa State Medical Stores
MNCH	maternal, newborn, and child health
MOH	Ministry of Health
MSD	Medical Stores Department
MTaPS	Medicines, Technologies, and Pharmaceutical Services
NAFDAC	National Agency for Food and Drug Administration and Control
PBF	performance-based financing
PCN	Pharmacists Council of Nigeria
RDF	revolving drug fund
TMDA	Tanzania Medicines and Medical Devices Agency
USAID	US Agency for International Development
WHO	World Health Organization

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PROJECT SUMMARY

Program Name:		USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program
Activity Start Date And End Date:		September 20, 2018–September 19, 2023
Name of Prime Implementing Partner:		Management Sciences for Health
Contract Number:		7200AA18C00074
MTaPS Partners	**Core Partners**	Boston University, FHI 360, Overseas Strategic Consulting, Results for Development, International Law Institute-Africa Centre for Legal Excellence, NEPAD
	Global Expert Partners	Brandeis University, Deloitte USA, Duke-National University of Singapore, El Instituto de Evaluacion Technologica en Salud, IC Consultants, Imperial Health Sciences, MedSource, QuintilesIMS, University of Washington
	Capacity Resource Partners	African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 SystemsWork, University of Ibadan, University of Ghana's World Health Organizations (WHO) Pharmacovigilance Collaborating Center, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa
	Collaborators	International Pharmaceutical Federation, Howard University, University of Notre Dame, WHO, World Bank

BACKGROUND

Subnational procurement occurs for many reasons—from decentralization to averting stock-outs. However, in addition to making medicines available to achieve good health outcomes, the aim should be to procure effective quality-assured medicines at the lowest possible cost.[1] Innovative strategies to facilitate both availability and quality of medicines include financial incentives through subnational performance-based financing (PBF) schemes that can be used to purchase medicines and the establishment of a prime vendor system to facilitate subnational procurement and complement the existing public procurement system.

PROBLEM STATEMENT AND OBJECTIVES

Nigeria and Tanzania both have a public pharmaceutical supply system centered around a national medical store; however, subnational entities also separately procure medicines and commodities from commercial suppliers and distributors, including those for maternal, newborn, and child health (MNCH). This is our definition of subnational procurement, and it does not include subnational entities ordering or requisitioning from central procurement entities to restock.

In Nigeria, the federal medical store primarily procures products for specific public health programs such as HIV, TB, and malaria, while the states independently procure mainly essential medicines. Tanzanian district offices facilitate procurement for primary health facilities, while higher-level facilities do their own procurement to avert stock-outs of centrally procured medical products.

Additionally, in Liberia, the World Bank initially supported the Ministry of Health (MOH) with PBF at county level in three counties and with implementing subnational procurement at the county level, similar to Tanzania, to avert stock-outs originating from the central medical store (CMS).

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program aimed to document mechanisms to ensure the quality of medicines procured at subnational levels for public-sector health care facilities in Nigeria, Tanzania, and Liberia to identify any best practices and highlight the enabling factors and challenges.

METHODOLOGY

MTaPS used a questionnaire to structure group discussions and conduct key informant interviews to learn about procurement practices and quality assurance mechanisms used for locally procured commodities. The World Health Organization (WHO) model quality assurance system for procurement agencies was a key reference, but the exercise was not a comprehensive assessment based on the model quality assurance system. In Nigeria, we interviewed key informants and conducted two group discussions in addition to reviewing documents related to PBF/results-based financing and the local procurement mechanism. The informants came from four purposefully selected states: Bauchi and Ondo

[1] WHO 2014. A model quality assurance system for procurement agencies.

states have PBF schemes, and Kaduna and Jigawa do not. The 13 Nigerian respondents played roles in their states' MOHs and other entities involved in pharmaceutical systems strengthening interventions at the national level. In addition to central- and regional-level pharmaceutical experts in Tanzania, we interviewed respondents based on their involvement in PBF in Kagera, Shinyanga, and Pwani regions and in Dodoma, which was the pilot region for the Jazia prime vendor system[2]—10 respondents in total. From the interviews, we compiled information highlighting best practices, the essential elements required to ensure quality products in subnational procurement, and areas for improvement. The data gathering was conducted over a period of six months in 2020 (March to August in Nigeria and June to August in Tanzania) and was severely hampered by COVID-19-related restrictions on travel. Most interviews were conducted by phone or e mail, thereby limiting probing, further exploration, and confirmation of the existence of documents.

In addition to MTaPS' detailed information gathering from Tanzania and Nigeria, an overview of the subnational procurement mechanism in Liberia was obtained from key informants in the country.

SUMMARY OF SUBNATIONAL PROCUREMENT PROCESSES

NIGERIA

Each state has its own specific procurement processes, which are similar but independent. The establishment of state entities specializing in pharmaceutical management has streamlined subnational procurement. Most states purchase medicines directly from local manufacturers or distributors/wholesalers by competitive bidding through open or restricted tenders to get the best prices and avoid product quality issues, such as substandard or counterfeit drugs. WHO[3] recommends using restricted tenders whenever possible to invite bids from prequalified suppliers of all health-sector goods and services; open tenders are not considered appropriate for health-sector goods as it may be difficult to determine whether products are of good quality and will be supplied in required quantities on a continuous basis. State-level regulatory agencies scrutinize these manufacturers' and wholesalers' regulatory compliance to help guarantee quality. State procurement is overseen by the state MOH. Health facilities order from the state drug management agencies or state CMS, or in some states, facilities can purchase directly from the supplier. Facilities are supposed to request prices from accredited vendors or retail pharmaceutical outlets or through annual tenders from prequalified suppliers based on an annual procurement plan, but this was not possible to verify in the study.

The respondents described the procurement process according to the national procurement law, which is domesticated at the state level with the establishment of a bureau of public procurement and the creation of the cadre of procurement officers to guide and support the procurement of goods, works, and services and ensure adherence to requisite procurement guidelines. State tender announcements are statutorily published in the national daily newspapers. Each state respondent provided specific details on procurement in their state. It was not possible to verify to what degree the standard practices were adhered to in each state.

[2] A prime vendor system is where the government contracts with one or more private-sector distributors to fill health commodity orders from regional warehouses, district stores, or health facilities.
[3] WHO 2014. A model quality assurance system for procurement agencies.

Ondo State procures MNCH commodities through the state's Abiyamo Maternal and Child Health Insurance Scheme, and health facilities order from the state CMS as needed. However, facilities can procure essential medicines directly from wholesalers as an emergency measure to avoid stock-outs. **Kaduna** State has an established procurement process that follows the national open tender system to supply all health facilities. Health facilities do not procure medicines outside of the state's central procurement system, known as the Kaduna State Free Maternal and Child Healthcare mechanism. The **Jigawa** State Medical Stores (JIMSO) centrally procures all health products using tenders to prequalified suppliers based on an annual procurement plan. The 27 local government areas order for ward-level primary health clinics directly from the three JIMSO mega-warehouses under a revolving drug fund (RDF) arrangement; health facilities in Jigawa are not allowed to procure drugs directly, but they can make emergency purchases from the JIMSO warehouses. In **Bauchi**, the state CMS procures medicines from manufacturers through licensed contractors that the Bauchi Drugs and Medical Consumable Management Agency has prequalified. Public health facilities procure from the state CMS using an RDF system; if the CMS is out of stock, facilities can purchase from Pharmacists Council of Nigeria (PCN)-approved retail pharmacy outlets.

States procure MNCH commodities for primary health care according to the federal essential medicines list, which each state adapts to its own context. Use of the essential medicines list to guide procurement is a means to not only ensure correct specification of products[2] but also keep prices down.[4] The list of medicines to procure is reviewed and approved at the state level by different committees, including Drugs and Therapeutics Committees, Drug Procurement Committees, and the Quality Control Committee, before approval by the Director of Pharmaceutical Services. Because they are essential medicines, states procure MNCH medicines, including oxytocin injection, misoprostol tablets, magnesium sulfate injection, calcium gluconate injection, methyldopa tablets, amoxicillin dispersible tablets or syrup, gentamicin and penicillin injections, oral rehydration solution, and zinc dispersible tablets or syrup. Informants reported rarely or never procuring tranexamic acid or hydralazine injection, presumably because they are not on the state essential medicines list. **Jigawa** and **Bauchi** states frequently purchase chlorhexidine 7.1% gel for public health facilities, but **Ondo** State does not as it is being procured primarily by donors and supplied directly to health facilities. However, Ondo is the only state that frequently sources and procures cephalosporins and artemisinin-based combination therapy locally as part of its list of MNCH medicines.

TANZANIA

The public and faith-based supply chain in Tanzania is mainly centralized. The government funds the Medical Stores Department (MSD) to procure and distribute health commodities and also provides funding for every health facility to purchase products directly from the MSD or its 10 zonal stores. Primary health facilities place orders directly from MSD zonal stores through the districts (district pharmacists are responsible for forwarding orders), and the MSD distributes supplies directly to health facilities, drawing down on their credits. In the case of stock-outs, facilities can use their own funds such as those attained through PBF to purchase medicines from private-sector suppliers, including from the Jazia prime vendor system. The Jazia prime vendor system is a public-private partnership strategy where

[4] MSH 2012. Managing Drug Supply 3, Chapter 18: Procurement.

the regional government contracts with one private-sector distributor to supply medical products to health facilities to complement the national MSD. Jazia, now government run, was established to address MSD stock-outs by increasing transparency and streamlining subnational procurement, which had previously been complicated and slow. Jazia was piloted in Dodoma first, followed by Shinyanga and Morogoro regions, from 2014 to 2017 before scaling it up nationally in 2018 and 2019. Although not officially allowed, regional and hospital pharmacists do occasionally procure supplies outside of Jazia when they cannot wait for delivery from a Jazia prime vendor.

While health facilities could purchase MNCH medicines locally, they have rarely been out of stock at the MSD due to a ministry directive that these products should always be available and for which the MSD receives financial performance incentives. Respondents indicated that tranexamic acid is the only MNCH medicine procured locally through prime vendors.

BEST PRACTICES

The WHO model quality assurance system for procurement agencies[5] focuses on four key activities: prequalification of pharmaceutical products and manufacturers or suppliers, purchase of products, storage of products, and distribution of products. In addition, the document refers to general requirements for procurement agencies, which include physical resources, financial systems, and documented policies and standards such as a quality manual and standard operating procedures.

The discussions in Nigeria and Tanzania focused in particular on the practices for transparent selection of vendors or wholesalers, quality checks on products post supply, and how to guarantee affordable pricing. We used the framework provided by the WHO guidance document, where appropriate, to review these practices in the two countries. The actual practices, as described by key stakeholders, in each country are described below.

Best Practice 1: Transparent Selection of Vendors

The WHO model quality assurance system[1] describes in detail how prequalification of manufacturers or suppliers should be conducted to ensure that the products supplied meet all predetermined norms and standards, maximize the use of resources, and minimize the risk of substandard products. This is achieved through, for example, use of standard procedures and clear specifications, defined responsibilities, and capacity to evaluate the information submitted in the tender. Invitation to submit expressions of interest should be open, and transparent and clear guidelines of the process should be publicly available.

NIGERIA

To ensure compliance with local procurement standards, states have committees that prequalify vendors based on technical, regulatory, and cost parameters,[6] including use of good distribution practices as validated by National Agency for Food and Drug Administration and Control (NAFDAC) state offices; compliance with NAFDAC and PCN requirements, such as PCN registration; and the

[5] WHO 2014. A model quality assurance system for procurement agencies.
[6] The public availability of the documents could not be verified, and the documents are not available on state websites.

presence of a Superintendent Pharmacist. In addition, vendors undergo PCN inspections to assess manufacturing, distributing, or warehousing practices (e.g., meeting cold chain requirements).

The process in each state is similar: vendors are selected through a rigorous bidding and prequalification process, starting with a public advertisement and moving through a series of approvals—procurement committee, quality control committee, Director of Pharmaceutical Services, and finally the Honorable Commissioner of Health. States typically update their list of wholesalers or vendors annually, although Ondo only updates the list if a need is identified.

Bauchi: The state CMS procures medicines from manufacturers through licensed contractors prequalified by the State Drugs and Medical Consumable Management Agency in the process described above. Public health facilities use an RDF system to procure from the CMS or from PCN-approved pharmacy outlets in the case of CMS stock-outs.

Ondo: Health facilities engaged in PBF procure essential medicines from 10 accredited prime vendors, while receiving medicines for HIV, TB, and other public health programs from the federal MOH or development partners. The prime vendor selection follows the process described above; however, for this state, the Executive Governor gives final approval based on recommendations from the Honorable Commissioner of Health.

Kaduna: No public health facility in Kaduna procures medicines or commodities directly, and purchases outside the state's central system are not allowed. Because procurement has to follow an open tender system that facilities cannot guarantee locally, procurement is limited to the state level. While the procurement is annual, the state can purchase supplementary products if needed. Kaduna State publishes the call for submission of tenders and the price list for health commodities on its website.[7]

Jigawa: Suppliers go through a competitive prequalification exercise and are selected annually as part of the tender process and forwarded to the Commissioner of Health in Jigawa State for approval. State procurement occurs through a competitive tendering process of prequalified suppliers, following JIMSO's standards. Information on the procurement process, including e-registration and procurement, is available on the state's website.[8] Health facilities cannot procure medicines directly except through JIMSO.

TANZANIA

Prior to the establishment of the Jazia prime vendor system, facilities' local procurement was ad hoc. Previous local procurement data showed that some shortlisted suppliers for public health facilities were not registered by regulatory authorities as pharmaceutical dealers and sometimes had very different businesses but also supplied medicines. Such unreliable sources increased the risk of procuring poor-quality medicines. The Jazia prime vendor approach, which covers all health facilities at all levels, is based on good procurement practices and transparency that rely on qualifying the supplier before purchase. Initially, public-sector staff who benefited from a less-transparent procurement system sabotaged Jazia by delaying payments to the prime vendor or by not placing orders at all, leaving facilities without enough medicines. This was in the pilot stage, and such staff had hoped that sabotaging the system would result

[7] https://kdsg.gov.ng/procurement-of-essential-drugs-and-consumables/.
[8] http://www.jigawadueprocess.com/#.

in the government not adopting it as an official system for alternative procurement for public health facilities. As the government took up the initiative and rolled it out, it closed any opportunity to use the old system. Continuing to sabotage the system would have no purpose because there was no way to procure locally except through the prime vendor.

Choosing a regional prime vendor under Jazia follows these steps:

1. **Vendor pretender meeting** in the region. This meeting, held in the region, is intended to provide information and explanations on the operations of the prime vendor system and to offer a presentation about the upcoming tendering process. The participating vendors are informed about a possible public-private partnership contract through advertising and publishing the invitation in local mass media.
2. **Prequalification**. This process establishes a qualified pool of vendors that are legally registered and licensed, financially capable, adequately stocked with registered health commodities, able to store products appropriately (including cold chain), and have sufficient staffing and built-in quality systems.
3. **Tendering**. Jazia adheres to good procurement practices and transparent tendering procedures that comply with the Public Procurement Act.
4. **Evaluation**. The evaluation process for both prequalification and tendering is based on the criteria described in the prequalification and tender documents. After consultation with the procurement unit, the regional or facility accounting officer appoints a one-time multidisciplinary committee with the competency to evaluate based on the criteria.
5. **Due diligence**. After the evaluation, information submitted during prequalification or tendering by the highest-ranked vendor is verified. Discrepancies result in rejection in favor of the next highest-ranked vendor. The highest-ranked vendor that passes due diligence is recommended for a prime vendor contract with the respective region or hospital. The vendor's name is submitted to the tender board for adjudication and award.
6. **Contract negotiation, award, and signing**. Contract negotiations cover price (fairness, competitiveness, and reasonableness for the market); product specifications; packaging; transportation; distribution and delivery lead times; payment; and other issues. After negotiation, the tender board approves the award to the successful bidder. The legal officer of the regional or facility procuring entity prepares and ratifies the contract after the tender board's approval.
7. **Performance management**. Jazia developed a handbook[9] for the regional technical team to use to periodically monitor performance of suppliers and clients (hospitals and health facilities using the system) relative to the contract terms and to take corrective measures. It also covers monitoring for service and product quality under the contract. In addition, Jazia has high-level committees that review the procurement process

Jazia prime vendor system characteristics

- All products registered with Tanzania Medicines and Medical Devices Authority (TMDA)
- List of commodities based on essential medicines list and MSD catalog
- Fixed prices negotiated for three years
- Direct procurement by facility only if MSD notifies of a stock-out
- Delivery of commodities to the district hospital
- No limitation to size or frequency of procurement—dependent on available funds

[9] Jazia Prime Vendor System Monitoring & Evaluation Handbook For Public Health Facilities (Dispensaries, Health Centres and Hospitals) 2020.

including the National Steering Committee, national and regional technical committees, regional tender boards, and regional and council coordination teams.

Best Practice 2: Quality Checks of Medical Products

ROLE OF REGULATORY AND CIVIL SOCIETY BODIES

In Nigeria, the role of the NAFDAC and PCN in quality assurance and compliance with statutory requirements greatly contributes to local procurement of quality-assured medicines. Examples include PCN's requirement for good distribution practices and accreditation of wholesaler premises as prequalification criteria for selection and NAFDAC's market authorization/product registration. Supervision and oversight from the states' drug management agencies and MOH departments of pharmaceutical services contribute as well; therefore, strengthening these state-level systems is important to ensure quality. Additionally, ward health management committees and facility management committees, with active participation from civil society, supervise and monitor the supply of medicines, determine pricing, and hold public health facilities accountable for delivering quality health and pharmaceutical services and products. For example, Jigawa State has a due process and a project monitoring bureau[10] that allows citizens and civil society organizations to monitor implementation of government contracts.

Similarly in Tanzania, the TMDA and Pharmacy Council have a number of quality assurance mechanisms in place, including product registration and pre-approval before importation, registration of suppliers, routine site inspections of local suppliers and retail pharmacies in collaboration with local governments, and laboratory testing of samples of imported medicines.

VISUAL/PHYSICAL INSPECTION

In Nigeria, visual checks of medicines, whether procured by the state or facilities, include NAFDAC registration number, expiry dates, packaging materials, batch/lot numbers, manufacturing dates, labeling, addresses of the manufacturer/importer/distributor, and physical examination. SMS verification[11] is also used where available to confirm a product's NAFDAC registration number. Each state has slightly different product inspection procedures either on receipt or as part of regular supervision, but all include routine organoleptic testing (appearance, color, and odor).

Although subnational entities in Tanzania rely on TMDA and Pharmacy Council processes to ensure quality products, hospitals and primary health facilities have goods receiving committees that are responsible for physically examining facility-procured products to detect any signs of poor quality and confirm the TMDA registration number on the outer and inner packaging. The members of the goods receiving committee are from the council health management team or regional health management team and include the hospital pharmacist and the procurement person, and they use a standard checklist developed as one of the standard operation procedures.

[10] http://www.jigawadueprocess.com/#.

[11] SMS verification of medicines is a national scheme that uses mobile authentication based on scratch codes to verify product authenticity of the NAFDAC registration number. The sender receives a text message stating whether the product is genuine or suspected as fake. It currently only is functional for antimalarials and antibiotics.

QUALITY TESTING

It is impossible for facilities to quality test all products procured locally, but a strong regulatory authority with an effective post-market quality surveillance program helps safeguard the public from poor-quality medicines. Both countries justify their subnational risk-based testing approach in this way.

In Nigeria, **Ondo** State tests random samples of medicines using a TruScan™ handheld analyzer[12] during inspections. **Jigawa** State is trying to acquire a Minilab™[13] for quality control testing.

Kaduna only randomly tests suspect products based on physical testing (e.g., damaged or discolored), whereas **Jigawa** and **Bauchi** do not conduct any testing, assuming that products from a prequalified vendor are of adequate quality. Respondents in **Kaduna** and **Ondo** did not report any failed products, perhaps highlighting the importance of supplier prequalification as part of the quality assurance strategy.

TMDA has a post-market surveillance program that includes routine sampling of specific products from wholesalers, pharmacies, and health facilities, which are either submitted to the TMDA laboratory or tested in the field using TMDA's 33 regional Minilabs, as well as a risk-based approach to test suspect products using the Minilabs. Every health facility is encouraged to send suspect products for Minilab quality screening at the regional level and then for TMDA laboratory confirmatory testing, if necessary. The failure rate of product testing by the TMDA was reported to be only 5%.

The cost of local-level testing must be considered when including it as part of the post-market surveillance quality assurance strategy. Minilabs, which use thin-layer chromatography testing, cost approximately $6,000 per kit (including shipping).[14] Reference samples range from $42 for a set of gastrointestinal medicine samples to more than $900 for antimicrobial samples. According to the NAFDAC, for an additional $2,000, a purchaser can get the reagents and reference samples replenished if they are used up within 12 to 18 months of purchase of the Minilabs. The TruScan handheld analyzer,[15] which uses Raman spectroscopy for noncontact analysis (e.g., through plastic bags, blister packs, and clear gel caps) costs approximately $50,000 according to the NAFDAC.

Best Practice 3: Affordable Prices Guaranteed

The states' competitive bidding processes in Nigeria help ensure value since they buy directly from manufacturers or major distributors in large quantities, which gives them more negotiating power; moreover, states negotiate prices with vendors who then maintain contracted prices until the next tender, usually for one year. State drug management agencies also promote price competitiveness by sharing price lists with their customers. For example, Kaduna State, with support from the Bill and Melinda Gates Foundation, undertook a supply chain baseline cost of medicines and health commodities assessment aimed at improving supply chain process and setting the standards for pricing of health commodities in the state.[16]

[12] A hand-held analyzer that detects the presence or absence of active pharmaceutical ingredients.
[13] https://www.gphf.org/en/minilab/.
[14] https://www.gphf.org/en/minilab/factsheet.htm, including shipping.
[15] https://www.thermofisher.com/order/catalog/product/TRUSCANGP#/TRUSCANGP.
[16] https://kdsg.gov.ng/story-of-the-kaduna-state-public-health-supply-chain-transformation-project-sctp/.

Table 1. Summary of price influencing strategies in Nigeria and Tanzania

Nigeria	Tanzania
■ States purchase directly from manufacturers or major distributors ■ Large volume for the whole state ■ Price negotiated and fixed for one year	■ Minimum of two vendors prequalified ■ Price fixed for three years in contract with vendor ■ Prices to patients are fixed

Under Jazia, the region pools procurement through one contract with one prime vendor, which allows for bulk purchase price negotiation and prices fixed for the three-year contract period, although each district council orders from the prime vendor independently. In addition to being fixed, prices are transparent to the purchaser. To guarantee price competition, two prequalified vendors are the minimum for bidding on a tender. Prices to the patient on products bought locally are set by the regional health management team, district health management team, or council health management team, depending on the facility. The mark-up sustains facility RDFs. Before the prime vendor system, prices to patients changed often due to fluctuations in the local market and always-changing suppliers. Price instability was difficult for facility staff to explain to patients and eroded their trust.

CASE STUDY ON LIBERIA

The pharmaceutical framework contract in Liberia was established in 2019 to allow three counties (Gbarpolu, Rivercess, and Sinoe), where a PBF strategy was in place, to procure specific MNCH essential medicines from selected private wholesalers to top off stocks when they are under supplied in the quarterly requisition process due to stock-outs or low availability at the CMS.

The pharmaceutical framework agreement between the counties/MOH and the pharmaceutical wholesaler defines fixed prices for a list of essential medicines, inclusive of delivery to the county depot within 10 days of receiving the purchase order, and stipulates that all medicines should be registered by the Liberia Medicines and Health Products Regulatory Authority. The approach respects the national supply chain system:

- Counties submit pharmaceutical orders quarterly to the CMS using standard procedures.
- Upon receipt of pharmaceuticals from the CMS, the counties note the pharmaceuticals received in lower quantities than ordered and can place orders to the approved pharmaceutical wholesaler for under-supplied pharmaceuticals if they are on the list of essential medicines and supplies of the framework agreement. Sometimes the counties have to prioritize what they purchase, according to their available budget
- Quality of medicines procured through the framework agreement is monitored as part of the national post-market surveillance system through risk-based sampling and testing at the national quality control lab. County staff have been trained in visible checks of quality and risk-based sampling. An approach of peripheral quality testing using Minilabs is being expanded but is currently only in place in the border counties and not the three counties with the framework agreement.
- Verification of adherence to the framework agreement is carried out by a third-party national verification agency on a quarterly basis, specifically confirming the following:
  - Counties place quarterly orders to the CMS and orders are completed correctly
  - Orders to the approved pharmaceutical wholesaler are only made when the CMS has insufficient supplies to supply the county (e.g., stocked-out or nearly out of stock)
  - The County Health Team only procures from the preapproved wholesaler at the negotiated fixed prices using the approved list

The number of facilities in the three counties with stock-outs of tracer medicines decreased from 100% in 2019 to 68% in the fourth quarter of 2019 and decreased further to 20% in the third quarter of 2020. This mechanism has reduced stock-outs while ensuring quality medicines are procured at a reasonable price.

DISCUSSION

IMPACT OF SUBNATIONAL PROCUREMENT ON AVAILABILITY

Key informants indicated that they felt the redesign in some Nigerian states of the local procurement mechanism that allows the state CMS to procure from prequalified vendors (including manufacturers) has increased the availability of essential drugs, especially in health facilities that can procure directly from the CMS. The four states reported that key MNCH commodities, such as oxytocin, amoxicillin, and oral rehydration solution, were available with no facility stock-outs in the previous three months.

In Tanzania, the MSD's fulfillment rate had decreased to 60% between 2013 to 2015, and estimates suggested that about 40% of facilities' requirements were covered through local procurement. Jazia has substantially improved the availability of health commodities in public health facilities. In the initial pilot region of Dodoma, the mean availability of tracer medicines in the region increased from 69% in 2014 to 94% in 2018.[17] In the three early implementing regions (Dodoma, Morogoro, and Shinyanga), a similar increase in availability of health commodities in facilities was noted—from between 45% and 60% to between 80% and 90% after Jazia was introduced. As the strategy was scaled into other regions, similar estimates of increases in availability at the facility level were observed. In Kagera, for example, availability increased from 60% before Jazia to 85% in 2018 during the Jazia roll-out phase and then more recently to 98% (estimate for 2019–2020 after Jazia was at scale nationwide). Now that Jazia is scaled up nationwide, the three regions studied (Kagera, Pwani, and Shinyanga) estimated availability at the facility level over the previous year to be more than 80%.

ENABLING FACTORS

Other factors in Nigeria that have strengthened local procurement and product quality assurance include supervision of the supply chain by the NAFDAC, PCN, and state MOH departments of pharmaceutical services, which has improved vendors' reliability and regulatory compliance. Also, state governments' and development partners' efforts to strengthen health facilities' pharmaceutical systems, including improving storage capacity and conditions, building capacity of staff on inventory management, and standardizing logistics management information systems through the scale up of mSupply software in many states as an electronic logistics management information system, has helped to maintain the quality of locally procured medicines. In both countries, facilities' procurement of health commodities relies on their financial resources. PBF schemes have provided a reliable source of funding for facilities in Nigeria and Tanzania to purchase medicines locally. In Tanzania, other funding sources for facilities include the National Health Insurance Fund, Community Health Fund, Basket Fund,

Key elements to ensure quality of medicines procured subnationally

- Clear, step-wise procedures and guidelines on subnational procurement clarifying roles and responsibilities
- Established list of products that can be procured subnationally based on the essential medicines list
- Requirement that only products with a valid market authorization are procured
- Prequalified suppliers selected through a restricted tender according to pre-established and transparent criteria
- Prices fixed in the agreement for at last one year if not two or three
- Adequate funding for facilities procuring locally
- A robust post-market surveillance system with risk-based sampling

[17] Wiedenmayer K, et al., 2019. Jazia prime vendor system- a public-private partnership to improve medicine availability in Tanzania: from pilot to scale.

and user fees. Recognizing that the public supply system periodically faces constraints and that facilities have different funding levels, facilities also now receive direct funding from the government's Direct Health Facility Financing program to top off supplies through Jazia. In Nigeria, in addition to providing a source of funding for subnational purchases, the state medical stores and health facilities' improved financial documentation and reporting under PBF have significantly enhanced facilities' local medicine purchases. For example, proper documentation and reconciliation of medicine dispensing and costs have facilitated pharmaceutical-sector planning, and facilities have generated additional operational funds.

In Tanzania, the MSD's slow response in confirming stock-outs often delayed health facilities' approval to procure locally. Jazia guidelines now require the MSD to respond within 24 hours, which the MSD has generally followed. This allows facilities to order quickly from the prime vendor to prevent stock-outs. For MNCH products, the government's directive to the MSD of no stock-outs, combined with financial performance incentives, has helped ensure product availability, averting the need for subnational procurement of those items. However, the central-level system falters occasionally, and the district then has to prioritize procurement of MNCH medicines because the no stock-out directive for any MNCH medicine applies to all levels of the health system. The clear government directive allowing local purchase in the case of MSD stock-outs as well as the availability of approved local suppliers who deliver to the district hospital facilitates the supply process.

In Tanzania, different accountability mechanisms were found to be important in the success of Jazia.[18] These included financial accountability through the use of health facility bank accounts and financial and inventory audits; performance accountability using key indicators; and procedure accountability through adherence to standard operating procedures, supervision, and coaching. Jazia's performance monitoring mechanism ensures that only the best performers are chosen as prime vendors.

CHALLENGES AND POSSIBLE SOLUTIONS

The challenge of managing procurements at the local level was mentioned by respondents in both countries, and the lack of an automated system for subnational procurement tendering was cited as a gap. Tracking data on performance of accredited vendors and product quality would increase competition and quality of vendors and products. Data on subnational procurement, including consumption, is needed to monitor local procurement effectively and increase transparency, and it could better inform the total budget for health commodities.

Sufficient local financing is needed to support subnational procurement. In Tanzania, delayed payment to the prime vendors is a serious problem that could compromise Jazia; prompt payment keeps prices as low as possible.[19] In response, some prime vendors are demanding cash up front, which is contrary to their contracts. The government should monitor payments and investigate and mitigate delays. Additionally, because of excessive debt with their prime vendors, some facilities purchase outside of the Jazia system. If left unchecked, facilities will likely return to previous local procurement practices, which lacked transparency and invited corruption.

[18] Kuwawenaruwa, et al., 2020. The role of accountability in the performance of Jazia primer vendor system in Tanzania. Journal of Pharmaceutical Policy and Practice. 13:25.
[19] MSH 2012. Managing Drug Supply 3, Chapter 18: Procurement.

IMPACT OF COVID-19 IN NIGERIA

Key informants in Nigeria offered insights on how COVID-19 had affected procurement of essential medicines and commodities. The pandemic produced unstable and very high currency exchange rates as well as increased demand for personal protective equipment and other consumables such as hand sanitizers that depleted fixed budget allocations. Product prices skyrocketed; for example, the cost of a pack of examination gloves increased more than 300% from about ₦1,000 to about ₦3,500 between April and July 2020. These increases were due to a number of factors:

- Inability of local pharmaceutical companies to produce at full capacity because of border closures that blocked shipments of active pharmaceutical ingredients; similarly, slower imports created scarcity of some products
- Demand and therefore prices for personal protective equipment and commodities used to manage COVID-19, such as hydroxychloroquine, chloroquine, and vitamin C
- Higher transportation costs
- Interruptions in the global production and logistic supply chain, resulting in shortages of and higher prices for test kits and testing chemicals/materials

As a result, uncertified manufacturers seized the opportunity to produce substandard products such as hand sanitizers that lack the minimum percentage of alcohol.

Kaduna and Ondo states reported that the cost of conducting routine physical tests increased but did not disrupt testing frequency; however, Ondo State tested fewer products and conducted fewer supervisory visits because of restrictions on movement and precautionary measures against COVID-19.

IMPLICATIONS FOR COUNTRIES SETTING UP OR IMPLEMENTING SUBNATIONAL PROCUREMENT

The procurement function plays a central role in the supply of safe, effective, quality-assured medical products that maximize health program outcomes. Therefore, WHO and other multinational partners recommend that entities involved in any procurement activity develop and implement a quality assurance system based on a model focusing on prequalification of products and manufacturers [suppliers], purchasing, storage, and distribution of pharmaceutical products.[20] Procurement quality assurance is an all-encompassing concept that cuts across all procurement activities, and it is resource intensive. Therefore, its design and implementation can be done in phases.

There are standards recommended by the WHO model quality assurance system, some of which were seen applied in Nigeria, Tanzania, and Liberia, that countries can take into consideration when setting up or planning improvements in their central or subnational procurement operations to ensure a reliable supply of quality-assured products.

Prequalification of suppliers and pharmaceutical products

- Selection of suppliers should be conducted according to documented criteria and specifications, such as compliance with good distribution practices and adherence to standard operating procedures in a transparent process that is publicly documented.
- The suppliers are assessed to determine whether the products meet the predetermined norms and standard of safety, quality, and efficacy and whether the supplier is able to consistently supply quality-assured products.

[20] The WHO model is available at https://apps.who.int/iris/handle/10665/69721.

- Subnational procurement should be restricted to registered medicines on the national essential medicines list to ensure the appropriateness and quality of medicines, and only products that are registered by the national medicine regulatory authority should be procured.

Purchase of products

- Purchase of medical products through a restricted tender of prequalified suppliers ensures their quality and should be the method utilized whenever possible.
- Guidelines/standard operating procedures with clear roles and responsibilities for local procurement of medicines ensures that all parties understand the process, and they should be based on adapted international best practices and local circumstances. Dissemination of these guidelines promotes transparency and enables active engagement of vendors.
- While the volumes of subnational procurement may not be as large as a national procurement and prices may be higher, policies that enable implementation of price influencing strategies such pooling or price negotiation contribute to affordability of medical products

General requirements or enablers

- A guaranteed source of local financing is needed to sustain procurement at the subnational level. While subnational procurement is not only relevant in a context where there is PBF, as in some of the contexts studied, health facilities with an off-budget income stream such as PBF or RDF systems have an advantage in addressing their health commodity needs through subnational procurement.
- A system should be put in place to discourage any procurement outside the prime vendor system, such as in the case of debt with prime vendors, to avoid having the prime vendor system fail and local procurement reverting to inadequate practices of procurement of medicines of doubtful quality and higher price.
- The principles of quality assurance should be applied to the whole process of procurement. An established post-marketing surveillance strategy to monitor quality should be risk based for best use of resources[21] and because quality testing beyond physical inspection and the use of screening tools is rarely feasible to apply widely at the subnational level. Innovations play an important role in quality assurance, such as Nigeria's SMS verification of registration status, and technological advances such as TruScan and Minilabs can be considered should resources allow augmenting the post-marketing surveillance strategy.

In Nigeria, the subnational procuring entity is the state for distribution to health facilities, and in two of the four states studied the health facility can also procure directly. In Tanzania, the health facilities procure directly from the prime vendor through a regional contract, complementing regular government supply. The district usually receives orders from primary health facilities, verifies them, and forwards them to the prime vendor. Facilities pay their bills through their individual facility accounts. This

[21] Nkansah P, et al., 2017. Guidance for Implementing Risk-Based PostMarketing Quality Surveillance in Low- and Middle-Income Countries. U.S. Pharmacopeial Convention. The Promoting the Quality of Medicines Program.

partnership with the private sector facilitated procurement of additional supplies, ensuring transparency and accountability from the beginning, and has been rolled out nationwide.[22]

The following specific recommendations can be derived from the practices observed in Nigeria, Tanzania, and Liberia.

- While guidelines/standard operating procedures for subnational procurement of medicines are in place, automation would facilitate compliance with standard procedures.
- Capacity, through coaching and supervision, should be built in subnational procurement; for example, enhancing the skills of facility, administrative, and management staff to improve the procurement process and generate and use procurement information for informed decision making.
- A government-sustained strategy of RDF mechanisms through results-based financing and/or PBF could be considered to improve the availability of medical products through subnational procurement by facilities to complement the state procurement. A cost benefit analysis would generate useful lessons to inform potential scale up.
- Further expansion of successful innovations in quality assurance, such as the use of TruScan and Minilabs, should be considered to augment the post-marketing surveillance strategy.
- Performance monitoring of a set of key performance indicators is important for the accountability of suppliers as well as to monitor the performance of the subnational procurement mechanism and adjust and correct as needed. In the case of Tanzania, computerizing and centralizing the data on subnational procurement from any regional prime vendor would provide the government with actual data on consumption of health commodities and the total budget for health commodities in the country in addition to increasing transparency in local procurement.
- In Tanzania, delayed payment is a serious problem that if left unattended will negatively affect the Jazia prime vendor system. The government should set up mechanisms to monitor the payment system and investigate any delayed payment to prime vendors.
- Some facilities purchase outside the prime vendor system, such as in the case of excessive debt with their prime vendors. If this is left unchecked, facilities are likely to go back to the previous system of local procurement, leading to lack of transparency and probably corruptive tendencies again. A system should be put in place to justify any procurement outside the prime vendor as it is the case for the MSD.
- The involvement of civil society organizations and the public for monitoring appropriate implementation of the procurement process should be encouraged where possible.

[22] Wiedenmayer K, et al., 2019. Jazia prime vendor system- a public-private partnership to improve medicine availability in Tanzania: from pilot to scale.