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KENYA PHARMA
Final Report

SEPTEMBER 30, 2015

This publication was produced for review by the United States Agency for International Development. It was prepared by Chemonics International Inc.

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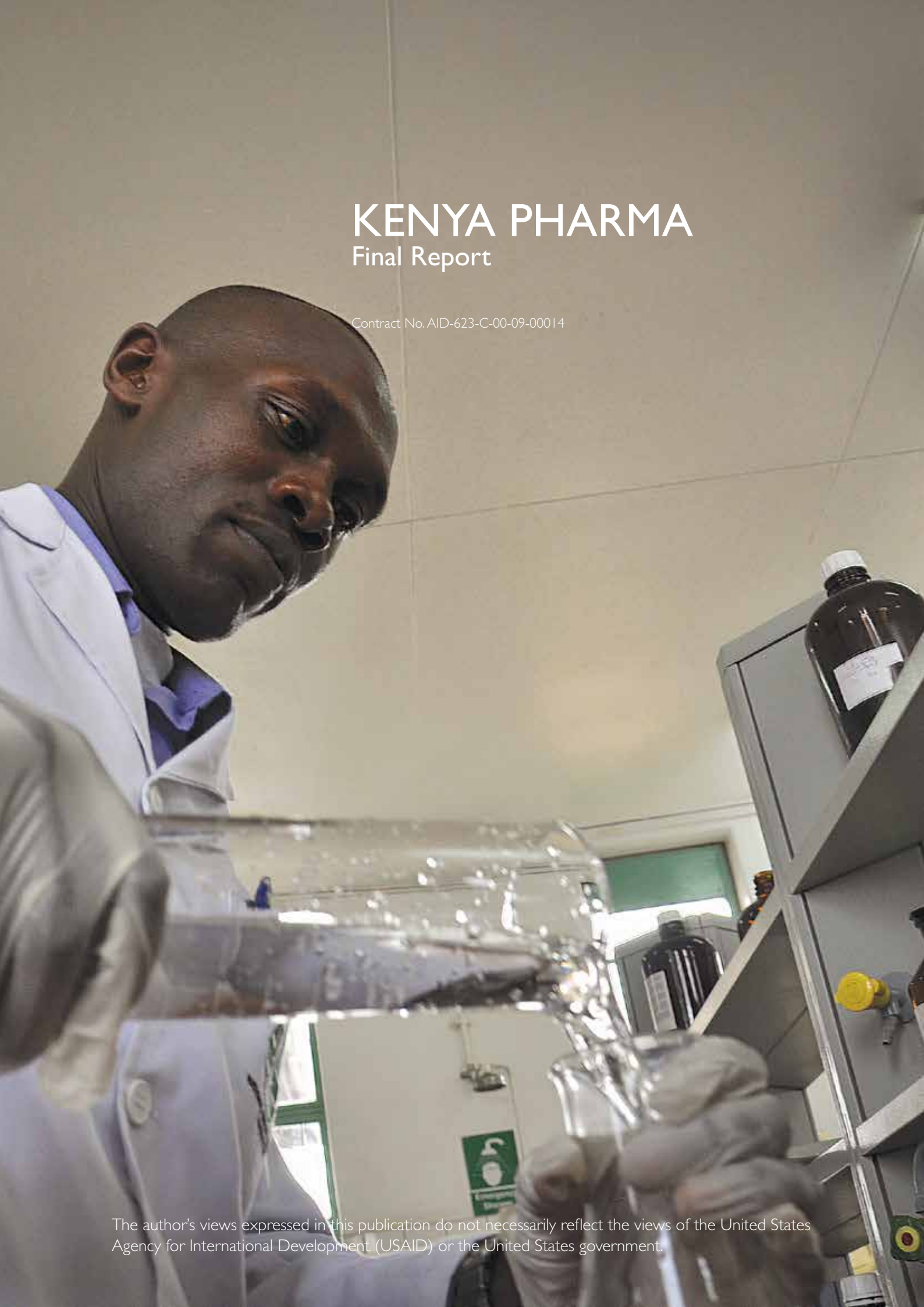
Contract No. AID-623-C-00-09-00014



Cartons packed with antiretroviral and opportunistic infection medicine at the Kenya Pharma warehouse, ready for dispatch to service delivery points.

KENYA PHARMA / TOBIN JONES

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INSIDE FRONT COVER: An analyst at the National Quality Control Laboratory conducts a test on a pharmaceutical sample.

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FRONT COVER: Patients reach out to receive medicine from a clinician who explains how the medicine should be taken.

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BACK COVER: The skipper of a *matatu* (taxi) boat and a young passenger heading to Sena Island from Mbita. This kind of public service transport is used to ferry HIV medicine to health facilities located on islands in Lake Victoria.

KENYA PHARMA / STELLA ETEMESI

A patient holding the collection of pills that he has to take in a day to manage his condition.

KENYA PHARMA / DAVID MUTUA

ACRONYMS LIST

ART	antiretroviral therapy
ARV	antiretroviral
CHMT	County Health Management Team
CSC	county support coordinator
e-SCM	electronic supply chain management system
FSR	field service representative
KEMSA	Kenya Medical Supplies Authority
LIMS	laboratory information management system
LMIS	logistics management information system
MEDS	Mission for Essential Drugs and Supplies
NASCOP	National AIDS & STI Control Programme
NOMT	National Order Management Team
NQCL	National Quality Control Lab
OI	opportunistic infection
PEP	post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	people living with HIV/AIDS
QA	quality assurance
QMS	quality management system
SDP	service delivery point
USAID	United States Agency for International Development

sustainability aspects

A patient waits to receive his monthly medicine prescription refill from the pharmacy window at Tabitha Medical Clinic in Nairobi.

KENYA PHARMA / DAVID MUTUA

EXECUTIVE SUMMARY

CREATING A SAFE, SECURE, RELIABLE, AND SUSTAINABLE PHARMACEUTICAL SUPPLY CHAIN

1.6 million Kenyans are HIV positive. The Kenyan government committed to the Joint United Nations Programme on HIV/AIDS goal of diagnosing 90 percent of HIV-positive people, treating 90 percent of those diagnosed, and virally suppressing 90 percent of those on treatment. This means providing antiretroviral (ARV) drugs to 1.3 million people. To assist in this scale-up, Kenya Pharma created a safe, secure, and reliable national pharmaceutical supply chain that is transferable to local partners for sustainability.

The consistent availability of ARVs — at health facilities and in close proximity to patients — remains a central challenge to treating HIV. For many patients, travelling to clinics is expensive and obtaining drugs carries the risk of stigma. When the supply chain is unreliable, health facilities experience stockouts, where they are forced to turn patients away or dispense only partial treatments. Patients then face a choice between another costly visit and discontinuing treatment. These patients are among the most likely to discontinue treatment, decreasing the success rates of future treatment, and increasing their risk of spreading drug-resistant viruses. To ensure that patients have consistent access to the drugs they need, Kenya Pharma created a secure and reliable supply chain that prevents stockouts, while expanding the number of service delivery points (SDPs) where patients can receive ARVs. Through a number of best practices and key interventions, Kenya Pharma eliminated

A mother and her daughter sitting in the waiting room at Tabitha Medical Clinic in the Kibera neighborhood of Nairobi.

stockouts in its supply chain. To expand access, Kenya Pharma expanded care through satellite facilities in remote areas, and in partnership with the Kenyan government, upgraded facilities to enhance access to treatment. The project and the Kenyan government collaborated on all of these interventions to ensure continuity after the project ends.

HIV treatment regimens have shifted dramatically during the project, as better ARVs have been developed and approved by the World Health Organization. The current core first-line treatment regime (a single pill containing 300 mg of Tenofovir, 300 mg of Lamivudine, and 600 mg of Efavirenz) costs $10 per patient per month, which translates to $4 million a month, or $48 million a year (excluding warehousing, distribution, and dispensing costs) to treat all 400,000 patients on Tenofovir-based regimens in Kenya. This sum requires careful management of contracting and procurement processes, as well as continual efforts to expand suppliers and reduce costs. To meet this challenge, Kenya Pharma consistently negotiated for lower prices, expanded the number of qualified suppliers, and responded quickly to changes in preferred regimens. This helped the Kenyan government expand care to more people and provide

significant savings to the U.S. government.

KENYA PHARMA'S BIGGEST SUCCESSES

Eliminating stockouts. The project's greatest success was the complete elimination of stockouts in its supply chain. Prior to Kenya Pharma, stockouts occurred in 46.6 percent of health facilities. However, through its unique interventions, the project created a secure, reliable supply chain that ensured patients always received their full prescriptions.

Improving data collection and use. Improving data and reporting on HIV/AIDS commodity use was a major project achievement and a key determinant in eliminating stockouts. Working closely with SDPs, project staff mentored SDP staff to improve data collection and reporting. Collaboration and mentorship institutionalized the importance of using data for decision-making among SDPs. This increased accurate reporting in clinics from 56 to 85 percent. In the first year, the need for emergency orders reduced from 147 to 14. Kenya Pharma incorporated data beyond the clinic level to provide data analysis for county and national commodity management teams. Data-based forecasting improved national capacity to predict commodity demands, which increased commodity security.

Building national capacity. Kenya Pharma improved national capacity to supply medicines for opportunistic infections (OIs) in HIV/AIDS patients and to provide quality-control testing. As part of the project's efforts to ensure sustainability, the project contracted with local suppliers for medicines to treat OIs and partnered with suppliers for regular reviews of their good manufacturing practices. Over time, as local suppliers' capacity grew, they became locally and regionally competitive producers of essential pharmaceuticals. This enabled the project to procure the bulk of OIs locally, promoting a virtuous cycle of increased revenue and quality production. By project close, local suppliers became well positioned to supply Kenya with its OI needs.

Kenya Pharma engaged local labs — National Quality Control Lab (NQCL) and Mission for Essential Drugs and Supplies (MEDS) — to build local capacity for quality control testing. The project purchased modern testing equipment and commissioned a laboratory information management system (LIMS) for the two labs to improve processes. Project staff also provided substantial management and technical support to the labs, improving internal policies. By the end of the project, the labs conducted quality-control testing for all of Kenya Pharma's procurements, having taken over the role from a subcontracted lab in India. This demonstrates national ownership of this step of the supply chain.

The project centered on a sustainability model

through partnerships with local organizations and the development of a transferable supply chain model. Beginning in Year 1, the project partnered with Kenya's national coordinating institution for all HIV/AIDS care and treatment interventions, National AIDS & STI Control Programme (NASCOP). Kenya Pharma also coordinated with the Kenya Medical Supplies Authority (KEMSA), which provides pharmaceuticals and health supplies throughout the country. Kenya Pharma, NASCOP, and KEMSA engaged in a joint transition process that entailed knowledge sharing and capacity building during the last two years of the project. This enabled NASCOP and KEMSA to take over Kenya Pharma's functions, placing Kenyan institutions in control of the supply chain. To make sure these functions were transferable, the project developed a quality management system (QMS) that mapped and documented each project activity. The project worked with NASCOP and KEMSA during the transition to blend the QMS into each organization's functions and national best practices.

Expanding access through cost savings. While working to improve delivery and create a sustainable supply chain, Kenya Pharma generated substantial cost savings by building relationships with suppliers, negotiating the best prices during procurements, and expanding the supplier base to increase competition. Over the course of implementation, project staff reduced the price of one of the core first line treatment regimens (Tenofovir/Lamivudine/Efavirenz) by 50 percent, resulting in $648,500 in savings for the U.S. government. With these savings, the project procured more drugs and reached more patients, assisting the Kenyan government in working toward its ambitious treatment goals and saving Kenyan lives. This expansion of treatment availability was cited as a major contributing factor to reductions in HIV rates in Kenya from 7.2 percent to 5.6 percent over the course of the project.[1]

KENYA PHARMA'S GREATEST TOOLS

Electronic supply chain management system and field operations team. Kenya Pharma's success was driven by the combined impact of the electronic supply chain management system (e-SCM) with a field operations team that provided customer service and e-SCM support to SDPs. The e-SCM provided an electronic system for recording procurement, stock, and orders, while the field operations team supported health workers in using the tool successfully. The field team ensured health workers felt connected to the broader supply chain and encouraged a culture of data ownership among SDPs. This enabled the e-SCM's success. The two interventions supported each other to create a more successful solution than

1 Kenya AIDS Strategic Framework, 2014/2015-2018/2019

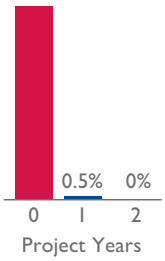
either could achieve separately. They resulted in accurate data inputs that informed all other aspects of the supply chain. This data-collection system enabled data-driven ordering and reporting and put SDPs at the center of supply chain management.

QMS. Kenya Pharma's ISO-certified QMS drove its results and sustainability. Beyond a series of documents mapping project activities, the QMS represents a method of project management that emphasizes quality in all areas and reliability in all functions. This was particularly important in controlling tens of millions of dollars of pharmaceutical procurements and effectively warehousing and distributing these drugs. Through an emphasis on following and constantly improving documented processes, staff ensured that the supply chain was secure from theft, loss, and potential breakdowns. Transferring these processes to national organizations enabled Kenyans to take ownership of the supply chain and provide a reliable source of lifesaving drugs.

RESULTS BY THE NUMBERS

0 Zero Stockouts

In the last four years of the project, there were zero stock-outs reported, with few reports of stockouts after stocks were stabilized nationally in the first year of implementation.



At baseline, 46.2 percent of SDPs experienced a stockout in the year before the project started.

Patients Served

416,711
people living with HIV/AIDS (PLHIV) treated with ARVs

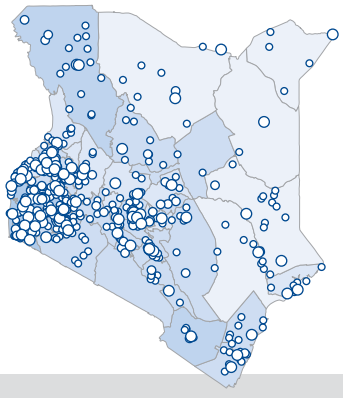
832,488
PLHIV treated for opportunistic infections (OIs)

32,269
pregnant women treated to prevent mother-to-child transmission (PMTCT)

26,066
infants treated for PMTCT

Service Delivery Points

174 ordering sites serving 785 SDPs



Warehouse employee Amos Mwangi packs medicine into a carton that will be delivered to a health facility.

KENYA PHARMA / TOBIN JONES

SECTION 1

A SUCCESSFUL MODEL FOR HIV/AIDS PHARMACEUTICAL SUPPLY CHAIN BASED ON THE BUILD, OPERATE, AND TRANSFER PRINCIPLE

BUILDING A SECURE, RELIABLE, AND SUSTAINABLE SUPPLY CHAIN

A secure supply chain has appropriate stock levels of drugs in the country to prevent stockouts and has measures in place to prevent substandard medicines from reaching consumers.

A reliable supply chain has the capability to deliver drugs when and where needed in the right quantity, quality, and price.

A sustainable supply chain is country-led and country-owned and has quantifiable deliverables and performance measures.

Kenya Pharma operated on a build, operate, and transfer model to develop a secure, reliable, and sustainable HIV/AIDS pharmaceutical supply chain (see box). The supply chain has many steps that interconnect and depend on each other: data and reporting, forecasting and quantification, procurement, quality assurance, inbound logistics, warehousing, ordering, and outbound logistics and delivery.

In Kenya, low-quality data, long processing times for orders, and a prevalence of low-quality and counterfeit drugs weakened the supply chain and overburdened health facility workers. This caused stockouts, and put lives at risk. Strengthening the supply chain required interventions at all eight interconnected steps. After building a successful supply chain, Kenya Pharma built the capacity of health-care workers, local suppliers, and local quality assurance testing labs, thus strengthening the health system. In the final project phase, Kenya Pharma transferred activities to local partners, while working closely with them to ensure that the project's achievements will continue after the project ended.

DRIVERS OF SUCCESS

There are four success drivers that run through each of the eight steps of the project's supply chain. These interventions were key to the project's outcomes.

Electronic supply chain management system. Kenya Pharma developed the e-SCM to automate the ordering process and manage data on pharmaceutical consumption in supported facilities. Data collection, reporting, and analysis are central to a successful pharmaceutical supply chain.

THE ELECTRONIC SUPPLY CHAIN MANAGEMENT SYSTEM (e-SCM): ONE SYSTEM, MANY APPLICATIONS

NASCOP

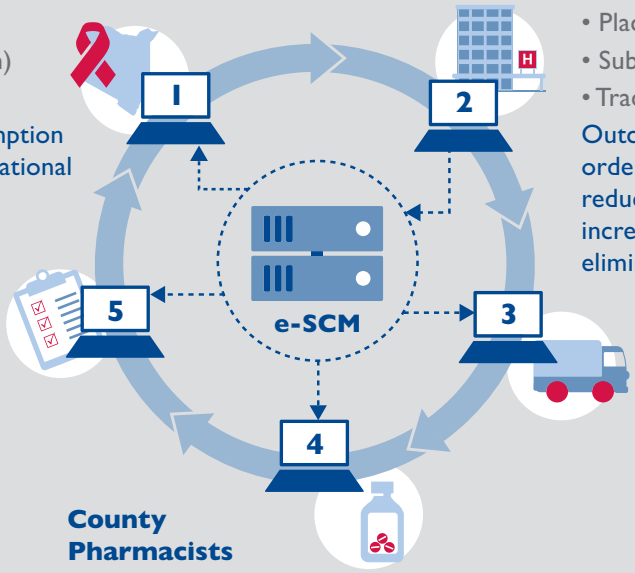
- Patient numbers
- Patient trends (i.e. regimen)
- Consumption data

Outcome: Access to consumption data enables a data-driven national quantification process for procurements.

Stakeholders

- Access to aggregated data
- Access to data for further analysis

Outcome: Increases ability to monitor and evaluate various aspects of the HIV/AIDS intervention (e.g., mother-to-child transmission, disease prevalence in counties, number of new adolescent infections).



Health Facilities

- Place orders
- Submit reports
- Track stock status

Outcome: Automated ordering and reporting reduces human error and increased transparency, eliminating stockouts.

Suppliers

- Access to procurement plan

Outcome: Able to prepare for upcoming procurements, reducing production times.

County Pharmacists

- Stock status in facilities
- Track usage per regimen
- Access to Monthly ARV Patient Summary and Consumption Data Report

Outcome: Able to access stock distribution information across county facilities, facilitating the redistribution of drugs from facilities with slow-moving commodities to others with faster turnaround.

The e-SCM translates data inputs from health facilities into information outputs throughout the supply chain.

However, prior to the e-SCM, Kenya had no widely used tracking system for health care consumption data. Most data was recorded by hand and transmitted on paper. This led to incomplete reporting and incorrect data at the national and county levels for forecasting, resulting in inaccurate forecasting, incorrect procurements, and stockouts.

The e-SCM is a cloud-based system that tracks the consumption of pharmaceuticals funded by the President's Emergency Plan for AIDS Relief (PEPFAR), as well as procurement and warehousing data. Users can connect with smartphones or any computer interface with a data connection, allowing the system to take advantage of the high cell phone penetration rates and mobile data coverage in Kenya. The system also allows users to work offline and upload data when they have

an Internet connection. Kenya Pharma developed the e-SCM in Year 1 and rolled it out to other implementing partners, NASCOP, and SDPs in Year 2. The e-SCM connects data from SDPs with national-level decision-makers on pharmaceutical procurement, promoting data-based decision-making. The e-SCM is interoperable with many local systems, allowing free flow of data, aggregation of data from multiple sources, and visibility. At the project's close, Kenya Pharma transferred the e-SCM to KEMSA for a seamless transition of supply chain management.

Health system strengthening. For Kenya to develop a sustainable, locally managed HIV/AIDS supply chain, all levels of the health system must be strong enough to respond to the demands of treating PLHIV. Kenya Pharma worked with local partners at all levels to strengthen health systems, including coordinating with national partners, utilizing local suppliers and quality assurance labs, and building capacity for data management and reporting in local health facilities.

QMS. In 2011 and 2012, the project developed a QMS to clearly document and refine processes in a way that would ultimately be transferable at the project's end. The QMS contained detailed process maps for every action associated with the supply chain, from selecting suppliers to destroying expired commodities. It also contained templates to create documents and records and included files for document and record storage. Beyond this, Kenya Pharma used the QMS as a management system in all project activities to ensure best practices were used and methods were constantly improved through regular process reviews. This unique intervention documented the processes of supply chain management to ensure high quality at every step of the supply chain, and created a clearly documented system that could be easily transferred or replicated at the end of the project.

Customer service approach. Patients receive medications from SDPs. They range from government hospitals to small field clinics. SDPs serve Kenya Pharma's primary beneficiaries: HIV/AIDS patients and their families. They also collect frontline data for all consumption information without which, a reliable supply chain is impossible. Health-care workers at SDPs are often overworked and overburdened by reporting responsibilities.

Kenya Pharma took a customer-service approach to addressing SDP problems by deploying field service representatives (FSRs). SDPs required reliable information on when their orders were received and filled, and when to expect delivery. They needed assistance processing quality assurance issues and placing emergency commodity requests if they had forecasting errors and low stocks. FSRs connected facilities with organizations mandated to assist them with requests outside of Kenya Pharma's scope, such as

STEPS TO A SUCCESSFUL SUPPLY CHAIN

1 Reporting

- Received consumption data and orders from SDPs
- Input data into e-SCM for reporting to partners
- Facilitated reporting by SDPs and provided customer service on commodity issues
- Provided information via e-SCM on:
  - SDP profiles
  - Project statistics (national, provincial, and district)
  - Project reports and updates

2 Forecasting and Quantification

- Gathered consumption data to determine regimen usage trends
- Monitored policy trends
- Followed available in-country resources
- Developed forecasts for procurements
- Developed procurement plan

3 Procurement

- Liaised with forecasting and quantification on the procurement plan
- Prepared tenders and evaluated offers
- Managed subcontracts, including production and payments
- Conducted market research
- Updated e-SCM with weekly status of procurements

4 Quality Assurance

- Conducted sampling
- Conducted analysis
- Reviewed reports from laboratories
- Inspected drugs upon arrival
- Conducted post-distribution surveillance
- Responded to field issues
- Disposed of expired goods
- Inspected manufacturing plants
- Reported annually

5 Inbound Shipments

- Obtained clearance at country of origin
- Prepared import declaration fee waivers
- Reserved cargo space and shipped commodities
- Ensured clearance at port of entry
- Tracked shipments

6 Warehousing

- Received and inspected products
- Stored commodities properly
- Managed inventory information
- Maintained up-to-date stock information on e-SCM

7 Ordering

- Received orders from SDPs (via courier, phone, e-mail, e-SCM, or fax)
- Rationalized and approved orders
- Picked and packed drugs for shipment
- Liaised with shipping agent to schedule routes and consolidate deliveries
- Maintained order profiles for each SDP on e-SCM

8 Delivery

- Sent order previews for delivery planning
- Picked commodities up at warehouse
- Tracked shipments
- Delivered commodities to SDPs
- Updated project information monthly on e-SCM

* Conducted M&E for evidence-based decision making at all steps.

computer problems and Internet outages, as these issues were integral to the successful last mile of the supply chain.

Kenya Pharma's approach to SDP customer service, facilitated by FSRs, data analysts, and the e-SCM, built a culture of data ownership and use that ensured accurate data inputs, reduced the burden on health-care workers, created visibility of inputted data, and contributed to eliminating stockouts.

The customer-service approach also created a culture of communication and trust. SDPs trusted FSRs to work with them and support their needs. Patients trusted the SDPs to always have their regimens in stock, and county and national players were confident that they had accurate data for procurement decision-making.

THE EIGHT STEPS IN A SUCCESSFUL SUPPLY CHAIN

Data and reporting. Accurate data, reporting, and visibility formed the foundation of Kenya Pharma's successful supply chain. SDPs reported patient numbers and commodity consumption patterns to inform forecasting and quantification and to analyze consumption against commodity orders. Ensuring timely and accurate reporting was a major project accomplishment. Through the e-SCM and field operations team, Kenya Pharma improved reporting accuracy from 56 to 85 percent by the project's end.

Health facilities used the e-SCM to enter patient treatment data and commodity consumption, track the status of stocks available at a facility, and place orders. This data was stored in a cloud-hosted database from which project data quality analysts reviewed reports and orders and rationalized them to ensure data accuracy. The e-SCM enabled FSRs to respond quickly to data inaccuracies, while also emphasizing data ownership in the health facilities.

Kenya Pharma added analytics to the e-SCM, providing users with quick access to dashboards that track patient numbers, regimen usage, and stock levels within individual facilities across counties or the country. These analyses allowed data-driven forecasting and quantification. They also enabled county and national governments to make informed decisions on regimen preferences and identify areas with greater or lesser need for prioritized services, which increased overall efficiency.

The e-SCM also integrated with other systems to synchronize reporting and data analysis. The project incorporated systems created by the Clinton Health Access Initiative and Management Sciences for Health to record day-to-day dispensing of drugs, patient management, and facility inventory management systems. This simplified health-care workers' reporting mechanism. The e-SCM also connected to the national reporting platform, the district health information system, and the Kenyan government's supply chain agency, KEMSA. These linkages led to a seamless

INTERCONNECTIONS IN THE SUPPLY CHAIN

Forecasting and quantification depends on quality data from the e-SCM, which in turn depends on the SDPs' ability to ensure that accurate and timely information is available on commodity use patterns.

flow and visibility of data across the various stakeholders and supply chain actors that helped strengthen antiretroviral commodity management in the country.

The field operations team supported SDPs to build capacity and data ownership. In the early stages of the project, FSRs regularly visited SDPs and helped them conduct stock takes. As the supply chain stabilized and SDP capacity grew, FSRs then mentored SDPs in tracking and reporting data through the e-SCM. Later, as SDPs became more capable of ordering, FSRs shifted from regular visits to needs-based visits, while remaining available for support 24 hours a day, seven days a week. In support of the government's effort to devolve health responsibilities to the county level, FSRs transitioned to county support coordinators (CSCs) and built the capacity of county government staff to continue their work with SDPs. The project also hired data quality analysts to review reports and commodity orders, rationalize them, and ensure that orders are accurate. Together, the CSCs and data quality analysts developed county fact sheets based on the data received and analyzed that they share with the County Health Management Teams (CHMTs).

Forecasting and quantification. Forecasting is the process of determining the projected commodity requirements over a defined period through the review of national policies, guidelines, and standard treatment protocols, and reviewing project treatment targets against numbers of patients on treatment, scale-up plans, and appropriate regimen mix. This process depends on complete and accurate historical data (see box). Assumptions that mirror project growth are developed in cases where insufficient data is available, or in situations where treatment protocols are likely to change.

When forecasting was not coordinated, and consumption data was poor or not reported, procurement quantities were inaccurate, resulting in under- or oversupply of pharmaceuticals. Kenya Pharma ensured accurate forecasting and quantification by organizing coordinated forecasting between departments and across institutions and improving data quality and timeliness. Forecasting accuracy averaged 94 percent over the life of the project.

Kenya Pharma rationalized demand from SDPs with known numbers of patients and standard treatments during quantification every quarter. Between quarterly quantification, the project performed monthly procurement planning, which involved staff from all departments reviewing stock levels of every commodity in the supply chain. Staff compared current levels with forecasts to determine if stock levels were sufficient to respond to SDP orders. Consumption could change in unpredictable ways. Frequent pipeline monitoring provided project staff the flexibility to respond to unexpected changes in commodity uptake. When stocks

TECHNICAL COORDINATION: SITTING TOGETHER FOR ACCURATE FORECASTING AND ORDERING

A strong supply chain depends on strong communication and coordination between technical departments that work together. Team collaboration was an important aspect of Kenya Pharma.

were low, the project initiated emergency procurements to ensure commodity security.

To strengthen the national supply chain system, Kenya Pharma incorporated NASCOP and KEMSA into its monthly procurement and supply planning meetings. NASCOP recognized the role that monthly procurement planning played in preventing stockouts in the project's supply chain and partnered with Kenya Pharma to turn this into a national best practice. To prepare for project end, NASCOP began hosting the planning meetings in the first quarter of 2014, while project staff remained in control of the meetings and forecasting tools. By the third quarter of 2014, NASCOP had taken over leadership of monthly procurement planning, utilizing the project's tools and recording these meetings as a national best practice.

Procurement. Over the course of its implementation, Kenya Pharma procured 50 to 60 percent of all ARVs consumed in Kenya and 100 percent of medications for OIs. The project used clearly articulated and carefully documented procurement procedures aimed at transparency, while ensuring that suppliers met international quality standards.

KENYA PHARMA / STELLA ETEMESI

Kenya Pharma's quality assurance officer, Benjamin Kioko (right), takes a random sample of a pack of medicine during a good manufacturing practice audit conducted at Universal Inc. in Nairobi. Universal was one of Kenya Pharma's local suppliers of OI medicine.

The QMS guided the procurement process, ensuring that every step followed organizational policy and international best practices. Procurements were frequently valued at millions of dollars, highlighting the necessity for strong controls. A hundred percent of procurements adhered to organizational and international standards over the life of the project. To improve supplier competition, Kenya Pharma expanded the supplier base and developed a system of price negotiations with suppliers. Project staff determined the "reference price" from the lowest quoted price from previous procurements, other procurement agencies, or internationally published prices. The reference price provided a benchmark in negotiations, which staff asked suppliers to match. Through this process, the project realized cost savings of $1,277,377.

Kenya Pharma partnered with local suppliers — Universal, Cosmos, and Regal — to strengthen local capacity for manufacturing OI medicines. The project supported local suppliers through procurement contracts and regular performance reviews and management from the project's procurement team. Kenya Pharma used 100 percent batch testing to ensure that all procurements met quality assurance standards, while they worked towards meeting international standards for pharmaceutical manufacturing. The project also worked with the manufacturers to put in place mechanisms to ensure adherence to good manufacturing practices. Kenya Pharma used scheduled and ad hoc inspections to encourage suppliers to consistently improve their standards. Suppliers reinvested revenue from the project's procurement contracts to build

UPDATING EQUIPMENT

Kenya Pharma procured two HPLCs and a dissolution tester for MEDS and three types of lab equipment for NQCL, expanding their capacity and modernizing facilities.

- *Seven high-performance liquid chromatography machines.* These machines separate product ingredients for product identification. This procurement replaced outdated equipment whose frequent breakdowns and high maintenance costs increased costs and reduced reliability.
- *Dissolution testers.* A dissolution tester enables the lab to test a tablet formulation's absorption in the body. A product failing dissolution testing means it will not be available in the body, meaning treatment will not be realized. As most HIV/AIDS medicines are in tablet form, this enhancement substantially increased lab capacity.
- *Microbiology isolator.* This allows NQCL to test the sterility of products within an enclosed space, rather than sterilize an entire laboratory room. It significantly decreased needed bench space and allowed multiple users, thus reducing turnaround times. The isolator also mitigates environmental degradation by ensuring all waste is sterilized before disposal.

their global standardization and competitiveness.

Pharma also worked with local suppliers to lobby for the elimination of taxation rules that targeted pharmaceutical components, which prevented local suppliers from competing with importers. This successful effort enabled local suppliers to produce pharmaceuticals at globally competitive prices, allowing the project to continue local procurements.

Building local production and capacity built national sustainability in the supply chain, improved commodity security by reducing procurement turnaround times, and simplified processes such as manufacturer inspection. By the project's end, Kenya Pharma procured the majority of OIs from Kenyan manufacturers. This continued the virtuous cycle of local suppliers investing in their own capacities becoming more competitive and ensuring sustainability.

The e-SCM provided information to manufacturers on upcoming procurements. This enabled them to prepare for upcoming procurements, reduce production times, and improve supply chain responsiveness. This strong relationship with manufacturers also assisted the project in negotiating better prices, which saved money and enabled the project to expand pharmaceutical coverage through larger procurements.

Quality assurance (QA). Kenya Pharma tested nearly 3,500 samples during implementation, and ensured high-quality products at each stage of the supply chain through a multilevel QA program. The project put in place an independent testing mechanism that inspected and sampled commodities for testing by subcontracted labs independent from manufacturer analysis results. The project experienced 100 percent QA accuracy, limiting recalls to two instances and product rejections to three. There were zero product recalls in the final year of the project. Scheduled post-market surveillance followed up on potential degradation of commodities after distribution to SDPs with 100 percent compliance recorded.

At the start of the project, Kenya Pharma subcontracted with Vimta labs in India and two local labs, MEDS and NQCL, for testing of procurement and post-market surveillance samples. At first, local capacity was insufficient and Vimta completed the majority of testing. This required shipping samples of local procurements to India for testing.

Kenya Pharma worked closely with NQCL and MEDS to build their capacity for QA as a necessary component of a Kenyan pharmaceutical supply chain. Support to the local labs included providing equipment (see box), a laboratory information management system, continual demand for services, and regular, detailed management feedback. The project also contributed to mechanisms of improvement on

service delivery, compliance, collaboration, and sustainability.

In Year 5, MEDS and NQCL began routine self-assessments. In preparation for quarterly reviews, they began approaching Kenya Pharma with perceived weaknesses and took ownership of outcomes. Through Kenya Pharma's facilitations, the labs have adopted a collaborative approach where they jointly discuss and agree to test results and analysis methods. This collaboration was further strengthened by the labs developing a memorandum of understanding that defined their future engagement in terms of sharing information, analyzing samples, and engaging government and other stakeholders. NQCL and MEDS now have an average testing turnaround time of 14 days, significantly less than the 21 days stipulated in their contracts. Building the capacity of MEDS and NQCL enabled the project to seamlessly shift all QA testing to the Kenyan labs in Year 5 of the project.

The project scheduled post-market surveillance visits to SDPs to ensure proper handling and storage of commodities to prevent deterioration during storage. The project also put in place scheduled supplier audits to ensure their consistent adherence to good manufacturing distribution practices. There were also ad hoc supplier inspections arising from complaints or detected noncompliance (quality or non-quality).This resulted in reduction of noncompliance incidences and quick resolution of reported complaints.

Inbound logistics. Kenya Pharma partnered with DHL Excel Supply Chain Kenya Ltd to undertake inbound logistics transportation of pharmaceuticals from suppliers to the project's warehouse in Nairobi. Documenting shipments and meeting required turnaround times are key aspects of pharmaceutical supply chain reliability. Working with DHL and Phillips Healthcare Services, the project created work processes that ensured coordination of the imports approval, supplier handover of shipments, shipping, custom clearance, and warehouse receipt processes, which led to reliable shipping times. Shipments from manufacturers met required turnaround times and were evaluated monthly. Kenya Pharma initially utilized air shipments to move drugs from manufacturers in India and the Netherlands. While air shipments were less economical than sea shipments, they enabled the project to build up stocks in the country and stabilize the supply chain by shortening procurement shipping times. As the supply chain stabilized and emergency procurements became less common, Kenya Pharma transitioned to sea shipments, significantly reducing inbound logistics costs, while meeting procurement timelines. During implementation, the project met its goal of 80 percent of procurements arriving at the central warehouse on time.

Warehousing. Strong warehouse controls and procedures are essential to minimizing wastage, tracking commodities in the supply chain pipeline, performing

KENYA PHARMA / TOBIN JONES

A DHL staffer delivers a carton of Kenya Pharma commodities to Mbeere District Hospital. DHL was subcontracted by Kenya Pharma to deliver commodities to SDPs.

QA, and ensuring fast, reliable turnaround times on SDP orders. Kenya Pharma used 100 percent physical checks on incoming shipments to ensure suppliers adhered to contract requirements and reported missing or damaged commodities to suppliers for replacement. Biannual stock taking and reconciliation ensured that commodities in the warehouse matched commodity records. Ensuring that stock records were accurate in terms of amount and location enabled Kenya Pharma to process orders in two to three days for fast, customer-oriented turnaround. The QMS included processes for all aspects of warehouse management to ensure best practices were followed and provided a transferable model to local partners.

Ordering. SDPs placed commodity orders through the e-SCM monthly. Every order was reviewed by a data quality analyst to ensure that commodities ordered matched patient records and regimen-use trends. Field teams followed up with SDPs when discrepancies arose. This system ensured that the ordering process was accurate and the correct amounts of pharmaceuticals reached the SDPs.

The ordering system emphasized the importance of accurate ordering in the prevention of stockouts. It built the capacity of SDPs to place accurate and timely orders. In the 12 months prior to project startup, 147 emergency requisitions were necessary due to inaccurate quantification by the ordering facilities. Kenya Pharma reduced this to 14 emergency requisitions within the first year of the project. Over the last four years of the project, 99.88 percent of SDPs were adequately stocked with all commodities.

Kenya Pharma adopted the order rationalization exercise in 2010. Upon receipt of each SDP order, project data analysts reviewed consumption data from that SDP against its reported patient numbers and resupply quantities. This analysis was done in coordination with the SDP staff responsible for consumption data reporting to ensure that adequate commodities were issued and the order was accurate. This exercise served to remind SDP staff to use available data for decision-making, and to provide an avenue for constant communication between the project and SDPs. Toward the end of the project, NASCOP identified order rationalization as a best practice, and in February 2015 established the National Order Management Team (NOMT), which will continue this activity after the project ends. Kenya Pharma hosted and supported the team until August 2015, when NASCOP established a national office to host them.

Outbound logistics and delivery. One route consolidated delivery increased predictability of shipments for SDPs, while reducing delivery costs and adverse environmental impact. When Kenya Pharma started, it made ad hoc deliveries of drugs to SDPs, sending commodities as they were ordered. This was in response to low stocks at SDPs. However, as stocks stabilized and SDPs became able to keep three months of commodities on hand, the project shifted to consolidated deliveries. Regular deliveries helped SDPs plan for future orders, reduced delivery costs, and mitigated the project's environmental impact.

Fast outbound shipment ensured that SDPs received pharmaceuticals on time, regardless of whether they were regular shipments or emergency orders. Kenya Pharma subcontracted DHL Excel Supply Chain Kenya for outbound shipment, delivering drugs from the warehouse in Nairobi to SDPs. Working with DHL, the project achieved fast outbound shipment and delivery. Average turnaround from the time an order was dispatched from the central warehouse to the time it was delivered to the SDP was two to three days, and 99 percent of SDPs received their orders within four days.

Kenya Pharma delivered pharmaceuticals to SDPs in 46 of the 47 counties in Kenya, regardless of insecurity, remote locations, and logistical complications. Through DHL, the project partnered with specialized local delivery agents to transport drugs safely in remote, challenging, and unstable areas. Deliveries to northern arid lands typically required private drivers, while deliveries to the islands required passenger boats and special packaging to protect commodities from the elements. Delivery to remote or insecure interior areas were not consolidated due to low populations and greater distances between SDPs.

KENYA PHARMA / MARTIN MUTUA

Benta is an orphan who was brought up at the Cottolengo Center. She now lives on her own, and continues to collect her monthly prescription of life-saving medicine from the center. Behind her, the "tree of life" holds the names of infants who have sero-converted thanks to Kenya Pharma's medicine.

SNAPSHOT
ARVs Provide Hope for HIV-Positive Orphans

At the Cottolengo Center, the lives of vulnerable children and infants have been changed by pharmaceuticals delivered by Kenya Pharma. The center received a monthly delivery of ARV and OI medicines from Kenya Pharma. The Cottolengo Center serves children who are either affected or infected with HIV and is currently home to 83 children, ranging from nine months to 23 years of age.

Benta used to live at the Cottolengo Center. Born in Kajulu village in Kisumu County, Benta was brought to the center as a three-year-old HIV-positive orphan. Benta was extremely ill in her first years at the center. Her caregivers feared she would not survive. At the time, the center did not have access to affordable ARVs.

Kenya Pharma's monthly ARV deliveries had an enormous impact on the center's ability to treat the children in its care. "In the early days we used to lose so many of our kids because ARVs were not easily available," said Sister in Charge Mercy Muthoni. "Most of the kids would not live beyond 10 years. But now the drugs are available and we have a reliable supply; we've seen a big difference. The mortality rate has reduced…we have only lost five little ones in the last three years."

Benta was one of Cottolengo's pioneer ARV treatment recipients. She started ARV treatment in 2001 when the drugs were still extremely expensive. In 2009, Cottolengo began receiving PEPFAR-funded drugs through the Kenya Pharma supply chain. Access to HIV medicines marked a turning point in Benta's life. ARV and OI drugs enabled her to survive childhood and strengthened her immune system to overcome OIs, including six separate tuberculosis infections. At 23 years old, Benta moved out of the center, but she continues to receive her medicines from Cottolengo because she can rely on it to have her treatment available.

Today, Benta is planning a future. She lives on her own, works as a hairdresser, and hopes to own her own beauty parlor. "If it wasn't for these medicines, I would have been long gone. But I am able to enjoy life and do things like other people."

ARVs at the Cottolengo Center have a profound impact on its youngest wards. Infants born HIV positive can undergo sero-conversion to negative status if they receive ARVs in the crucial early days of life. "We've achieved 95 percent sero-conversion," says Sister Mercy. Her office is adorned with a drawing of a tree of life with the names of children who have sero-converted. Twenty-eight of those names belong to infants who received drugs supplied by Kenya Pharma. There are now too many names to fit them all on the tree.

Dr. Hezekiah Chepkwony, the director of NQCL, shows off a new microbiology isolator, with Dr. Khadijah Kassachoon, the principal secretary for health.

KENYA PHARMA / STELLA ETEMESI

SECTION 2

BUILDING A SUSTAINABLE MODEL FOR SEAMLESS TRANSITION TO LOCAL PARTNERS

Kenya Pharma operated on a sustainability model from Year 1, coordinating with national and county forecasting mechanisms (see box on next page), investing in national capacity to manufacture and test commodities, and building data capture and reporting at the clinic level. All of this was supported through the development of a QMS designed to document all of the project's processes for eventual transfer.

NATIONAL OVERSIGHT AND MANAGEMENT: NASCOP

NASCOP is the national coordinating institution for all HIV/AIDS care and treatment in Kenya. From the beginning of the project, Kenya Pharma staff participated in pharmaceutical coordination groups like the two-pager process and commodity security meetings. NASCOP led these processes while Kenya Pharma provided information and implemented meeting decisions. Kenya Pharma also incorporated NASCOP into supply chain best practice exercises, such as monthly procurement planning and order management meetings, and in the final year transferred the coordination of these meetings to NASCOP.

Kenya Pharma participated in monthly technical working groups and commodity security meetings, providing market intelligence and sharing best practices from the supply chain. Project field staff reported on emerging trends and developments in health facilities gathered during their regular activities in the field.

Kenya Pharma convened monthly procurement planning meetings to bring together

SUPPORTING DEVOLUTION AND COUNTY OWNERSHIP

FSRs became CSCs at the time of devolution in Kenya. In their new role, CSCs assisted the decentralization of pharmaceutical commodity management in two ways: through support of county-level stakeholders and through the upgrading of SDPs.

Decentralization created a new set of stakeholders in the CHMTs. CHMTs include county pharmacists, health directors, and ARV coordinators who are responsible for commodity security in the counties. The CSCs worked closely with CHMTs, producing monthly county fact sheets with performance indicators, including reporting rates, patient numbers and changes, and stocks available. From these snapshots, the CSCs produced action items to close any gaps.

NASCOP also charged counties with increasing the number of SDPs as part of decentralization. This process intended to reduce the distance between SDPs and patients and reduce the cost and time patients spent acquiring their regimens. Kenya Pharma assisted in this process by assessing potential future SDPs and working with them to begin using the e-SCM to place orders and monitor drug consumption to avoid stockouts. This activity was critical to making ARVs more available and accessible to PLHIV in Kenya.

NASCOP, KEMSA, and Management Sciences for Health to review national stock status. Participants reviewed the procurement pipeline and made decisions about commodities to be procured and deliveries that needed to be fast-tracked or delayed to avoid stock shortages or overages. This activity ensured that there was one national procurement planning and tracking tool maintained across the separate pipelines of Kenya Pharma and KEMSA. This exercise helped the country review the national commodity status and instructed KEMSA and Kenya Pharma warehouses on how to respond to SDP orders. The exercise also facilitated inter-pipeline transfers of commodities from one warehouse to another.

NASCOP first hosted the meetings in its offices in 2014, and began leading the meetings and procurement planning process in 2015. By the time of transition, NASCOP staff had experience working with Kenya Pharma's procurement planning tools, coordinating between supply chain stakeholders and making determinations on emergency and delayed procurements.

In 2014, Kenya Pharma invited NASCOP and KEMSA to the order management planning meeting and demonstrated the model as one of the key pillars in ensuring timely order processing. In 2015, NASCOP, USAID, and KEMSA adopted the Kenya Pharma order management planning model and constituted the NOMT. Kenya Pharma hosted the NOMT from its inception and provided it with access to phones, airtime, and printers, enabling it to carry out activities relating to order rationalization.

The NOMT represented a shift to coordinating a single national supply chain between KEMSA and Kenya Pharma's pipelines. It jointly rationalized orders for both pipelines as they were received in the e-SCM or in KEMSA's LMIS. The NOMT reviewed stocks available in KEMSA and Kenya Pharma warehouses to determine the target buffer level for each commodity and to provide guidance on the commodities to be transferred to KEMSA from Kenya Pharma.

The NOMT worked to ensure that all SDPs received seamless service during the transition period. One challenge the NOMT faced was the delay of delivery of orders to facilities leading to overlapping order cycles and late reporting. The team evaluated the order processing timelines and made recommendations to ensure timeliness at all stages.

As Kenya Pharma transitioned activities to NASCOP, project staff worked with NASCOP to document the best practices central to Kenya Pharma's strong and reliable supply chain. Staff worked with NASCOP and the QMS to determine which processes were most important for incorporation into national best practices,

KENYA PHARMA / GEORGE OSULO OF KENYA AIDS RESPONSE PROGRAM (KARP)

A patient talks to a doctor at St. Monica's Hospital about his condition.

and then documented and transferred them. Documenting these processes ensured that knowledge and processes were institutionalized and can be replicated, even with the frequent staff turnover often experienced in government organizations.

PROCUREMENT, DISTRIBUTION, AND CUSTOMER SERVICE: KEMSA

KEMSA is a constitutionally mandated institution for procurement and distribution of lifesaving medicines to health-care facilities throughout Kenya. It was important to coordinate with KEMSA from the project's beginning as the two organizations had significant overlap in their mandates. Kenya Pharma, KEMSA, USAID, and NASCOP worked together to divide SDPs between Kenya Pharma and KEMSA's separate supply chains to prevent double supply and enable both groups to remain responsive to health facilities' needs. KEMSA's Global Fund procurements were limited to annual processes, frequently causing gaps. Therefore, Kenya Pharma and KEMSA created a pharmaceutical-sharing agreement that allowed Kenya Pharma to provide drugs to KEMSA. This helped fill gaps in KEMSA's supply chain when short-term forecasts shifted, and allowed both organizations to coordinate on ensuring commodity security. KEMSA and Kenya Pharma partnered in national technical meetings and monthly procurement planning meetings to provide national coverage for all HIV/AIDS commodities.

KEMSA's scope of work extends beyond HIV/AIDS pharmaceuticals, requiring a separate electronic system from

the e-SCM. Kenya Pharma adapted the e-SCM to interface with KEMSA's LMIS to reduce the burden of reporting for health facilities. During the transition, KEMSA agreed to take over the e-SCM and incorporate it into the functions of its LMIS. This allowed SDPs to continue reporting with minimal interruptions, supporting a seamless transition between the two supply chains.

After Kenya Pharma identified KEMSA as their transition partner for supply chain management, project staff began working to prepare KEMSA for procuring commodities under PEPFAR. Procurement rules and regulations under PEPFAR differ substantially from the Global Fund and government of Kenya approach that KEMSA follows. Kenya Pharma staff inducted KEMSA on PEPFAR-supported pharmaceutical procurements, including sharing document templates of all procurement supporting documents. The project hosted knowledge-sharing sessions with KEMSA and NASCOP in 2014. Beginning in 2015, KEMSA and NASCOP staff started taking over project functions, and some of their staff co-located in the Kenya Pharma offices to continue aligning processes to accommodate project best practices in procurement and order management planning processes. Also in 2015, KEMSA and Kenya Pharma staff reviewed the QMSs utilized by each organization to reconcile differences. This process ensured that KEMSA adopted Kenya Pharma's QMS processes without disrupting KEMSA's existing systems. KEMSA adopted Kenya Pharma's stock and procurement tracking tool to facilitate tracking procurements and identifying commodities that require resupply.

Kenya Pharma supported KEMSA in preparation for their debut ADS 312 assessment by USAID. The project reviewed KEMSA processes, developed recommendations, and shared best practices to prepare KEMSA for the assessment. Kenya Pharma staff also introduced KEMSA to the performance evaluation of labs, creating an opportunity for continual engagement of these institutions after the project ended.

KEMSA also took over Pharma's role in delivering pharmaceuticals to SDPs and providing customer service to health facilities. In 2015, CSCs mentored KEMSA field staff in customer service and data quality analysis to enable them to take over these functions. Prior to this shift, KEMSA field staff had focused on sales and marketing. The mentorship program ensured that the customer service function will continue after Kenya Pharma phased out.

KENYA PHARMA / TOBIN JONES

An analyst at NQCL reviews the results of a sample analysis against reference specifications.

SNAPSHOT
Developing a Sustainable QA System

QA is one of the key pillars of a successful pharmaceutical supply chain. Prior to Kenya Pharma, local labs had inadequate testing infrastructure, which led to commodity distribution prior to testing. To build sustainability and local ownership, Kenya Pharma partnered with NQCL, a Kenyan government-owned QA lab, and MEDS to build capacity of their labs and boost the country's capacity to test pharmaceuticals. Through a subcontract with NQCL, the project built a strong relationship with the lab. Kenya Pharma upgraded and installed new equipment for NQCL, developed a LIMS, improved internal accountability to build a culture of high performance and productivity, and supported the lab to invest revenues for future growth. Kenya Pharma extended similar support to MEDS, providing two ultra-high-performance liquid chromatography systems and a dissolution tester.

LIMS. Pharma partnered with Strathmore University and both QA labs to develop a LIMS to streamline the process of sample documentation, compiling and comparing post-analysis certification and required signatures. The system now provides status reports on all samples submitted to the labs, enabling them to track samples in its system, which has improved customer service, transparency, and the timely release of test results.

Developing internal accountability. Kenya Pharma provided management support to NQCL and MEDS through quarterly subcontractor performance reviews. Along with improving laboratory and business practices, these meetings improved the business relationship between NQCL and MEDS, which initially viewed each other as competitors, but now function as collaborating institutions. The two laboratories now compare notes on testing protocols, which enhances learning.

QA capacity and local ownership. Building the Kenyan government's ability to perform QA testing represents an important shift in the ownership of the QA system for pharmaceuticals. Local QA testing reduces analysis time, increases post-market surveillance, and ensures safe medicines for patients.

Victor Okoth (seated), the regional manager for the Nairobi and Central regions, instructs the pharmacy staff of Mukuru Kwa Rueben FBO Clinic on how to access and use the e-SCM.

KENYA PHARMA / STELLA ETEMESI

SECTION 3

QUALITY MANAGEMENT SYSTEM

In 2011 and 2012, Kenya Pharma developed a QMS to clearly document and refine processes for transfer at project conclusion. The QMS contains detailed process maps for every supply chain action, from selecting manufacturers to destroying expired commodities. The QMS provides templates to create documents and records, as well as files for document and record storage. The QMS also serves as a management system for every project activity, ensuring best practices are used and methods are constantly improved through regular process reviews.

Documenting for quality. Documenting all project processes ensured quality in three ways. First, documenting processes required staff to think critically about them and examine opportunities for improvement. Second, the QMS created standards for high project performance by embedding international standards and Kenya Pharma's evaluation criteria into process maps that dictate project action and hold staff accountable to the highest possible standard. Finally, regular process review placed an emphasis on improvement, creating a mechanism to review and refine processes.

The QMS documentation and monitoring process fostered a culture of improvement. For example, in reviewing procurement processes, staff recognized that a standard procurement process took 180 days. Although this timeframe worked in normal circumstances, emergency procurements required faster turnaround. Staff created special procedures for emergencies to ensure that drug procurement occurred as quickly as possible and stockouts were

averted. The review of QMS processes and the emphasis on staff improvement through the QMS allowed for this process refinement.

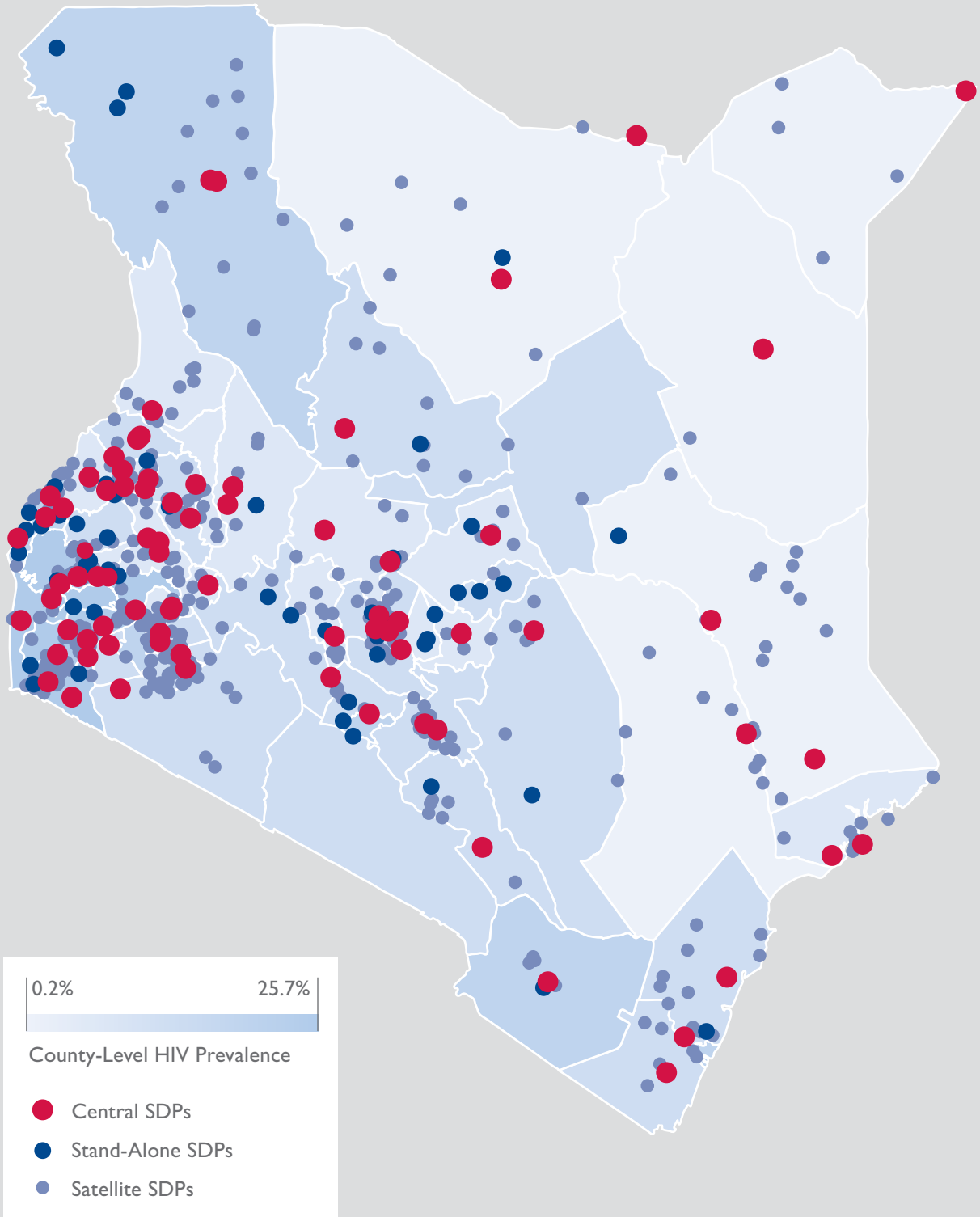
Breaking apart silos. All staff participated in QMS documentation and audit processes. They worked together to develop the project's quality policy and design each process documentation. The entire staff collaborated on interactive process mapping and review sessions, promoting organizational openness, staff collaboration, and technical learning. This system allows staff at different supply chain points to better understand each other's roles and how their contribution connects to other elements of the supply chain.

Transferring systems for sustainability. The QMS aimed to provide process documentation for the eventual transfer of Kenya Pharma to local ownership. Through documenting work, the project developed a detailed set of instructions for operating a successful supply chain. After three years, Kenya Pharma transferred the instructions to local partners and the full transition occurred in the project's last year. Staff worked with NASCOP and KEMSA staff to incorporate the QMS within their systems.

Driving QMS success. Institutionalization and management commitment drive QMS success. Using the QMS enhanced project work and reduced administrative burdens, enabling staff buy-in. Management modeled QMS use and demonstrated its importance to daily project activities, reviewing project success through the QMS and highlighting its relevance for staff.

WHERE WE WORKED

Kenya Pharma served health facilities, called SDPs, in 46 out of 47 counties through a network of central SDPs serving themselves and satellite sites as well as standalone sites. Kenya Pharma's presence correlated to overall HIV burden rates across the country.



A pharmacy technologist unpacks medicine received from Kenya Pharma in the clinic's well-stocked pharmacy store.

KENYA PHARMA

SECTION 4

MAJOR ACHIEVEMENTS AND PROJECT IMPACT

Kenya Pharma's greatest achievements relate to improved health outcomes and the elimination of stockouts. The project has improved reporting and use of data and built local health systems for sustainability. It also achieved a significant gender impact (see box on the next page).

Increased access to ARVs improved outcomes for PLHIV. Improving treatment outcomes and quality of life for PLHIV represents Kenya Pharma's most important development impact. Approximately 1.6 million people in Kenya live with HIV. In 2014, 800,000 people received treatment, and 410,000 of those people received regimens through Kenya Pharma. Over the course of the project, Kenya Pharma saved $1,277,377 through negotiated prices and $1,478,420 through re-tendering, expanding the number of qualified suppliers and bulk purchases. This money was channeled to increase the quantities of pharmaceuticals procured and extend the reach of drugs to more PLHIV. By reaching more people with more timely treatment, the project improved HIV/AIDS treatment and the quality of life of PLHIV and their families.

Distance between patients and SDPs constitutes a major barrier to pharmaceutical access. Travelling long distances is a major expense and can require patients and caregivers to miss an entire day of work. Some patients must choose between making the journey and feeding their families. The correlation between HIV burden and high poverty areas compounds this issue, limiting resources for accessing care. Kenya Pharma collaborated with NASCOP to bring treatment closer to patients, increasing the number of clinics dispensing

GENDER IMPACT

Women represent the majority of PLHIV in Kenya, with the Kenya AIDS Indicator Survey 2012 reporting prevalence in women 64 percent higher than in men (6.9 versus 4.2 percent), resulting in a substantially feminized patient profile for the project. Women are also more likely to be caregivers for PLHIV, assisting in collecting ARV regimens and OI medications. These labor costs are reduced through expansion of SDPs that bring pharmaceuticals closer to patients and their caregivers. Improved access to treatment leads to reduced labor required for care and increased health of patients. Finally, the provision of adult post-exposure prophylaxis (PEP) is primarily provided to women reporting sexual violence. When taken correctly, PEP reduces the possibility of post-exposure sero-transmission of HIV by 80 percent. Kenya Pharma procured PEP commodities provided by the facilities, reducing the harmful health impact of sexual violence.

ARVs and OIs and thus reducing the burden of travel on patients and caregivers. The Kenya Pharma field team also worked with clinic staff, building their capacity to report accurate consumption and to place correct and timely orders, thus ensuring well-stocked clinics.

Uninterrupted supply of HIV pharmaceuticals equals zero stockouts. Given the difficulty of reaching health facilities, facilities must remain constantly well-stocked and ready to provide treatment. When a stockout occurs and patients are turned away from clinics, they become the most likely patients to discontinue treatment, increasing morbidity and mortality and risk of infection transmission to partners and children. In Kenya Pharma's baseline study, 46.2 percent of SDPs had experienced a stockout in the previous 12 months. By the end of Year 2, 0 percent of SDPs experienced a stockout. Over the course of the project, 2 percent of facilities ever experienced a stockout of OI drugs and only 0.5 percent experienced a stockout of ARVs.

Kenya Pharma achieved zero stockouts by adopting specific measures at each stage of the supply chain to reduce stockout incidents. Accurate data reporting fed into regular and data-driven forecasting and quantification, ensuring that procurement anticipated upcoming gaps and could respond accordingly. Efficient procurement and inbound shipping ensured availability of adequate stocks in country and efficient warehousing practices ensured quick and reliable packaging of commodities for orders. SDPs placed accurate orders using a data-driven, electronic ordering system, and they received the drugs they needed thanks to efficient warehouse and outbound shipping procedures for rapid commodity delivery. Project policies set high standards for stocks on hand in the project's warehouse and in SDP storerooms, and careful coordination with partners and suppliers further reduced the risk of stockouts.

Data-driven decision-making. High-quality data plays a central role in pharmaceutical supply chain functioning. Kenya Pharma created a culture of data ownership among SDPs to ensure high-quality data entered the system. The project worked with national- and county-level ART commodity management teams to encourage data-driven decision-making.

Health facilities dispensed HIV/AIDS drugs to patients and collected important data on consumption rates, stock levels, and patient complaints. Accurate forecasting for pharmaceutical procurements depended on this information. Kenya Pharma worked with health facilities to develop data collection and reporting capabilities. This initiative had two components: the e-SCM and the field operations team. Working closely with health facilities, the field operations team supported SDPs to report accurately using the

KENYA PHARMA / STELLA ETEMESI

Warehouse staff put together basic care and prevention package kits for delivery to SDPs at the project warehouse in Nairobi.

e-SCM and to input valuable data into forecasting systems.

In 2012, project staff discussed the need to support SDPs in delivering accurate data with NASCOP and Provincial Health Management Teams, the precursors to CHMTs prior to devolution. NASCOP agreed to partner on a data quality audit that sampled 44 SDPs. Staff developed a data trend analysis from the audit and confirmed weaknesses in SDP reporting. Kenya Pharma shared these data trends with SDPs and provided on-the-job mentoring to SDP staff, focusing on the correlation between data and decision-making. Staff also held monthly data discussions with SDPs and shared data trend analysis available on the e-SCM.

The government structures encouraged SDPs to improve their data entry, reviews, and submission. Consultative reviews with project staff further engaged SDPs as partners in data entry. SDPs began using trend analysis to track performance and correct errors, thus improving data quality. This approach supported the importance of data accuracy at both the national and clinic levels. Witnessing how accurate data inputs increased timely receipt of drugs, health-care facilities strengthened their commitment to collect and report accurate data. This deepened a data ownership culture in which SDPs took responsibility for producing accurate and timely reports. As SDPs have taken ownership of data tracking and reporting, accuracy increased from 56.6 percent in the project's baseline to 85 percent in the project's final year.

At the national and county levels, Kenya Pharma introduced data to the forecasting and

quantification process. Through access to the e-SCM, NASCOP and CHMTs viewed data across national and county spreads. The project also shared data-based forecasting tools to help create a culture of data-driven decisions. NASCOP adopted Kenya Pharma's forecasting and procurement planning tools as a national best practice to determine current and future project requirements. The NOMT used data from SDPs to make decisions on order replenishments and buffering levels at the facilities.

Strengthened national capacity. Building sustainability into the supply chain allowed for Kenya Pharma's success. The project worked with partners on every level of the supply chain from national-level decision-making with NASCOP to procurement, distribution, and customer service with KEMSA, to building local manufacturing and QA testing capabilities, and to building the capacity of SDPs for work with data on patient trends.

At the highest level of supply chain implementation, NASCOP manages national forecasting of ART commodities. Through the national procurement committee and the NOMT, Kenya Pharma institutionalized project tools as national best practices. In Year Five, NASCOP requested that Kenya Pharma staff sit with them to capture QMS processes as national best practices to institutionalize best practices within the national supply chain. NASCOP identified procurement planning and order management planning meetings as key best practices in Kenya Pharma and incorporated them into a national commodity management strategy.

Kenya Pharma worked with KEMSA to prepare for PEPFAR commodities procurements. Kenya Pharma compared its QMS process maps with KEMSA's and worked with KEMSA staff to edit their procedures to reflect best practices from Kenya Pharma's supply chain and to institutionalize these processes. Kenya Pharma also mentored KEMSA staff in customer service of SDPs, working closely with KEMSA's sales representative staff to shift their approach from sales and marketing to customer service, with support for accurate data reporting and ordering at facilities.

Kenya Pharma's investment in local suppliers and QA testing increased national capacity to produce and test drugs domestically, increasing the security and reliability of the supply chain while reducing overall costs.

The documentation of all project activities in the QMS created a replicable system through which Kenya Pharma developed a secure, reliable, and sustainable supply chain model and eliminated stockouts. Engaging with transition partners, the project transmitted these practices to them and encouraged the continued use of best practices following project conclusion.

KENYA PHARMA / GEORGE OGILLO OF KENYA AIDS RESPONSE PROGRAM (KARP)

Dorcas picks up her monthly prescription of medicine from the pharmacy at St. Monica's Hopsital in Kisumu.

SNAPSHOT
ARVs Central to Patient Health in Nyanza

St. Monica's Hospital in Kisumu began receiving ARVs and OI medications from Kenya Pharma's supply chain in 2010. Kisumu East, located in Nyanza Province, has one of the highest HIV prevalence rates in the country, with infection rates around 15 percent, above the national average of 5.6 percent. With such a high prevalence rate among its patients, the regular supply of HIV commodities at St. Monica's was vital for sustaining and improving the lives of its patients on HIV prevention, treatment, and care services. St. Monica's consistently provided these services to PLHIV in the last five years thanks to the reliable monthly supply of ARVs and OI medicines delivered by Kenya Pharma. The state of health of patients enrolled on ARV therapy at St. Monica's pays testament to treatment availability and improved patient outcomes.

George is one of those patients. He has a large family with two wives and seven children. Although George was diagnosed as HIV-positive about seven years ago, both his wives and all of his children are HIV negative. His family's status is aided by the fact that George has been on ARV and OI treatment since 2009. George knows that the medicines have kept him healthy, protected his wives from getting infected, and ensured his children born since his infection have been born free of the virus. The treatment has also allowed him to continue farming and rope-making, activities through which he supports his family. Fully aware of the impact HIV medicines have had on his life, George now works with St. Monica's community outreach team, supporting HIV-positive individuals and encouraging others to get tested and enroll in treatment.

Dorcas is a 55 year-old HIV-positive widow living in Kisumu with five children. Before enrolling as an ARV treatment client at St. Monica's, she suffered frequent abscesses and a CD4 count of 79. Almost 11 years later, Dorcas is an active middle-aged woman supporting her family with a small farm. She also serves as a community health volunteer, helping others in her community overcome HIV. The medicines she receives have prolonged her life and enabled her to improve the lives of others.

Because of Kenya Pharma's reliable supply of medicines to St. Monica's pharmacy, the hospital did not experience commodities stockouts after 2009, and never had to turn a patient away due to shortages of ARVs or OIs. According to Joel Wanda, the pharmacist in-charge at the hospital, the reliability of the Kenya Pharma supply chain greatly contributed to the positive health outcomes seen in patients. "Kenya Pharma services have been very good. I have ordered and received my commodities in good time, which translates to availability of medicines to my patients every time they show up."

Harris Ayoo is one of the warehouse personnel responsible for handling thousands of cartons of medicine that pass through the Kenya Pharma warehouse before they are dispatched to health facilities around the country.

KENYA PHARMA / TOBIN JONES

SECTION 5

BEST PRACTICES AND RECOMMENDATIONS

BEST PRACTICES

We highlight seven best practices below that were key contributors to Kenya Pharma's success. These should be adopted as best practices in implementing an HIV/AIDS pharmaceutical supply chain, and have already been incorporated into Kenyan best practices in coordination with NASCOP.

Customer service model. Kenya Pharma operated with a customer service model centered on meeting the needs of SDPs as the primary clients of the supply chain. SDPs represented the supply chain to end-use beneficiaries and connected beneficiaries to the supply chain. As a best practice, Kenya Pharma instituted a number of activities to support a customer service-oriented and demand-driven supply chain:

Regular SDP visits to follow up on e-SCM use, accurate data tracking and reporting, and proper commodity storage. The SDPs experienced high staff turnover, which required frequent visits. Regular SDP visits were important for gathering and sharing information that centered the supply chain on patient needs. The project's focus on data over sales supported the needs of SDPs, while assisting them in ordering the drugs they needed.

Data quality analysis of every SDP order including review and follow up where there are problems. Consistent order review was essential to ensuring order accuracy. Discussions between data quality analysts and SDP staff generating data helped SDP staff understand the importance of their role and improved data capture.

Follow up on issues reported by SDPs. These issues included

flagging patient issues with QA and highlighting clinic problems outside of the supply chain mandate, such as facility infrastructure or computer problems. Following up on these issues assured SDPs of their role in the supply chain and resolved problems that affected the reliable supply of pharmaceuticals.

Electronic supply chain management system. Electronic stock management was a key driver of Kenya Pharma's successes. The e-SCM reduced the burden of reporting on overworked clinic staff by reducing the time required to report and providing a flexible platform for facilities with infrastructure challenges or in remote locations for which reporting data in traditional ways can be costly, time consuming, or impossible. The e-SCM also enabled multiple stakeholders to access important data for forecasting, quantification, procurement, and manufacturing processes, enabling the entire supply chain to communicate and analyze data effectively.

Monthly procurement planning. This is an essential best practice for tracking commodities and preventing stockouts. Even with quality data, shifts in pharmaceutical consumption can occur quickly and rapid responses are sometimes necessary. Kenya Pharma instituted monthly procurement planning using a checklist of all pharmaceuticals in the supply chain. The project performed this monthly to track levels of every drug in the pipeline and to prepare for quarterly procurements or initiate emergency procurements if needed. Beginning in 2013, Kenya Pharma coordinated with NASCOP, KEMSA, and Management Sciences for Health to create national monthly procurement planning meetings. Recognizing the importance of monthly planning as a best practice for commodity security, NASCOP took over these meetings in 2014.

Monthly order management planning. Kenya Pharma performed monthly order management. In this process, orders submitted from each SDP were rationalized by data quality analysts, who followed up with SDPs if the orders were not accurate. This activity was key in ensuring that SDPs were adequately stocked each month. Monthly order management helped the project hold SDPs accountable for the accuracy of their orders while ensuring that the correct amounts of medicines were delivered from the warehouse and SDPs were adequately stocked, preventing stockouts.

In the last year of the project, the order management team transitioned into the NOMT, which included staff from Kenya Pharma, KEMSA, and NASCOP. The NOMT reviewed orders from all facilities in Kenya, merging those previously supported by Kenya Pharma with those supported by KEMSA for a single, national supply chain. Incorporating the supply chains was an essential step in Kenya

KENYA PHARMA / STELLA ETEMESI

A pharmacist at Nairobi Women's Hospital fills out a customer feedback form.

Pharma's transition of activities to local partners. Project staff shared their order management tools and mentored NASCOP and KEMSA staff in fulfilling the order management role. The NOMT embedded this best practice into Kenyan institutions.

Data-driven decision-making. Data-driven decision-making is important at the SDP level and the forecasting level. The combined use of the e-SCM and FSRs prompted SDPs into data ownership.

The combined use of the e-SCM and the field operations team that supported the e-SCM at the health facilities was a key best practice for driving data ownership and data-driven decision-making. While the e-SCM provides an electronic system for recording procurement, stock, and dispensing, the field operations team supported health workers in using the tool successfully, while ensuring that they felt connected to the broader supply chain and took on a culture of data ownership that enables the e-SCM to be a successful tool. The data quality team reviewed every SDP report and order, following QMS-prescribed checklists to determine that reported consumption and stock levels match with patient numbers. Where the data is

reported inconsistently, data analysts follow up with facilities to discuss the data and reconcile discrepancies. This culture of communication and support on e-SCM-reported data generates data ownership in health facilities that see the value of the data they generate and understand that their reports are analyzed and utilized in forecasting and quantification.

Kenya Pharma was able to funnel this data into monthly procurement planning and order management meetings where information on actual stock levels in the SDPs and throughout the supply chain pipeline can inform regular and emergency procurements and commodity sharing. Beginning in 2014, NASCOP used data reported by SDPs through the e-SCM for its national forecasting, as well as monthly procurement meetings and Kenya Pharma's quarterly quantification and procurements. The use of reliable data had a significant impact on the security of the supply chain as the correct amounts of pharmaceuticals were procured.

RECOMMENDATIONS

Kenya Pharma successfully achieved its goals. However, the project encountered external and internal challenges that should be addressed in future projects. This section discusses these challenges and recommendations for USAID and the project's transition partners.

Maintaining a six-month buffer on all medicines in country. In Years 3 and 4, a new tax on imports passing through the port in Mombasa prevented the project from clearing medicines through customs efficiently. In some cases, commodities remained in port in excess of six months. Kenya Pharma's policy of maintaining six months of stock in country enabled the project to prevent stockouts while the project coordinated with partners and the Kenyan government to find a way to continue imports efficiently. As unexpected external factors present a threat to the supply chain's integrity, it is recommended that USAID works closely with KEMSA and NASCOP to maintain a six-month buffer supply of all medicines after Kenya Pharma closes.

Continuing support for transition partners and extending transition times. The transition process took longer than Kenya Pharma and its partners anticipated for the following reasons. First, the transition required cultural shifts within partner organizations, which took longer than expected. Kenya Pharma designed a transition process based on the handover of processes and policies. These processes are well documented in the QMS, and Kenya Pharma and its partners agreed that a 14-month transition period was sufficient. However, these processes required complex changes to the organizational approaches NASCOP and KEMSA use to manage the supply chain. It took considerable time for the staff to adjust to the new procedures and for policies to be institutionalized. This

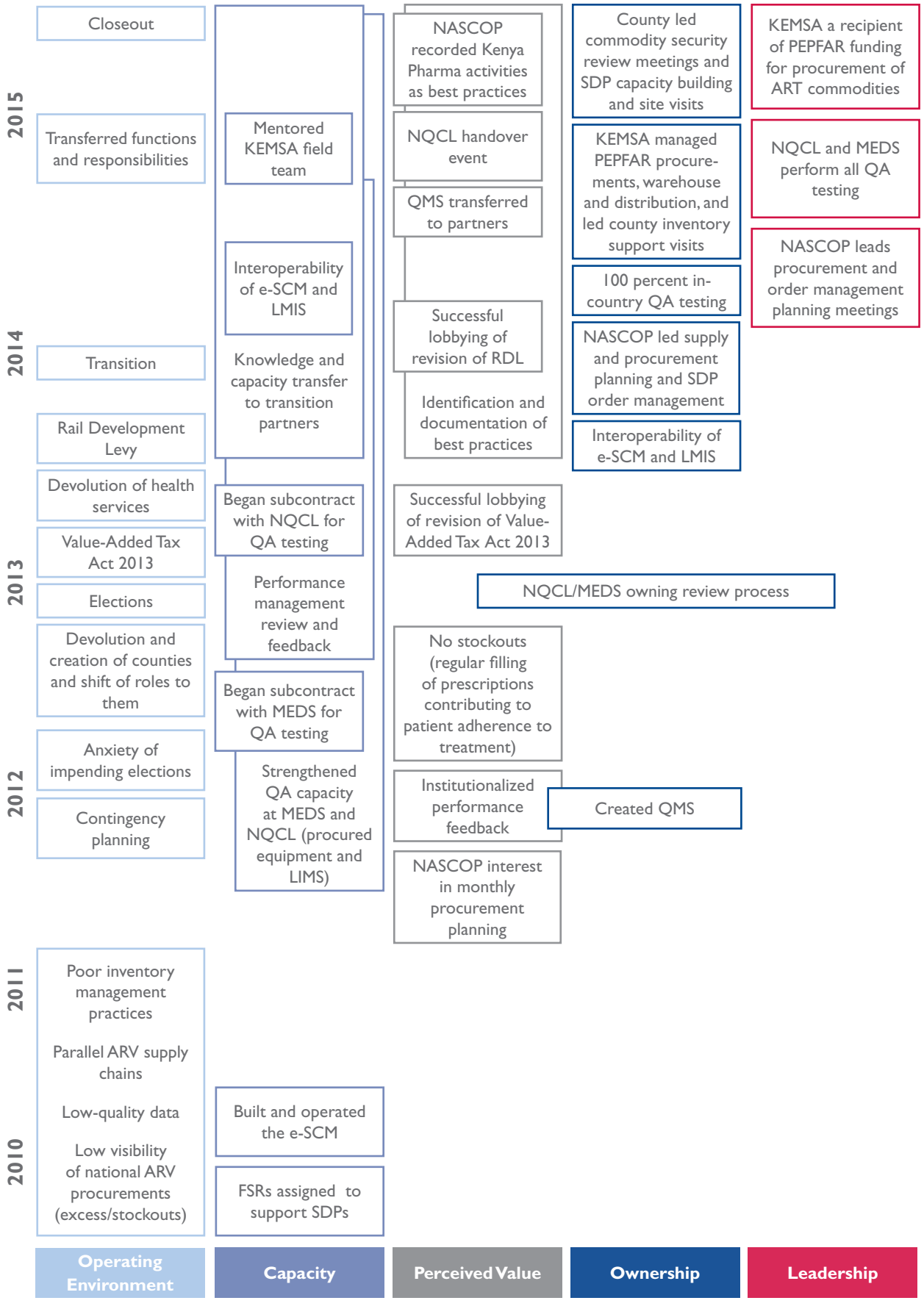
resulted in delaying transition milestones. From the project's experience, a sustainable transition model should take no less than three years to allow for culture change and recommends this timeframe for future projects.

Future projects should assess where each county is in the devolution process and provide sufficient time and support to implement activities. The supply chain transition took place during the devolution process. With many roles in the health system transitioning from the central government to devolved units at the county level, NASCOP and KEMSA took on new responsibilities to support the CHMTs. This complicated the transition process and extended the timelines, as all partners adjusted to new roles.

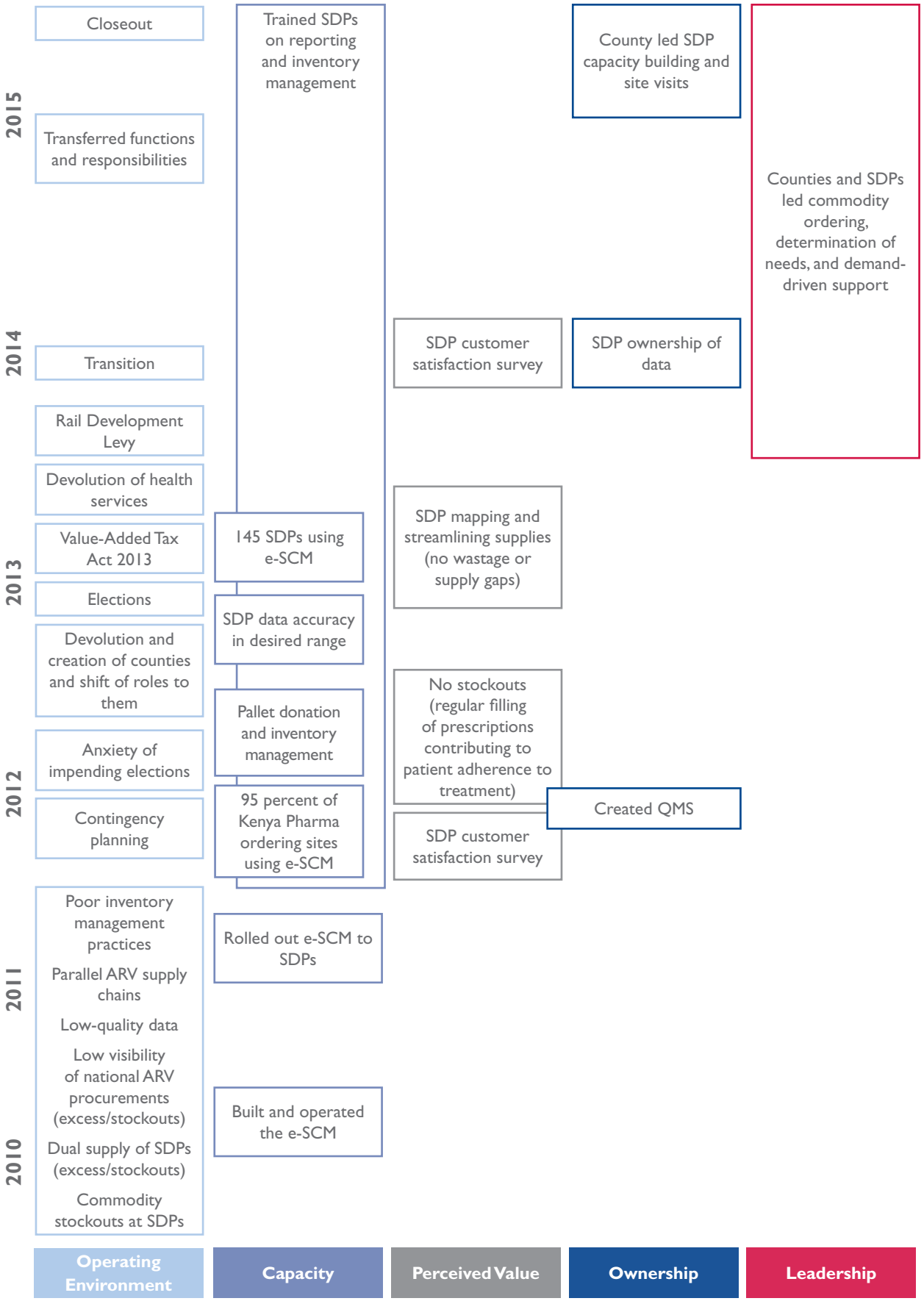
Delayed transition milestones removed the period of changeover where Kenya Pharma intended to provide support and emergency procurements. Kenya Pharma continued regular procurements into the last months of implementation. The project closed before KEMSA completed its first independent PEPFAR procurement, and Kenya Pharma was unable to support KEMSA in this process. Therefore, Kenya Pharma strongly recommends that USAID continues to provide technical and financial support to all transition partners, including KEMSA, NASCOP, QA labs, SDPs, and local suppliers to ensure that the transition is complete. The project's experience showed that transition processes must be central to project activities to ensure sustainability. Kenya Pharma recommends that upcoming projects demonstrate their sustainability and transition models from project startup.

Diversifying supply base and strengthening health systems. ARVs are currently provided by a narrow base of approved suppliers. This places a bottleneck on ART supply and increases global prices. The current price of recommended first-line treatment is $10 per patient per month. This translates to $4 million per month, or $48 million per year, to treat 400,000 patients on Tenofovir-based regimens in Kenya — and that's before shipping, warehousing, and distribution costs. The monetary cost of treating HIV presents an enormous burden for host and donor governments. Building the capacity of local suppliers to manufacture ARVs will reduce these costs and diversify sources of ARVs. Additionally, strengthening procurement, warehouse, and order management systems will eliminate redundancies and pharmaceutical waste. This is another necessary step to reducing costs and enabling Kenya to reach its ambitious treatment goals.

BUILDING PROJECT SUSTAINABILITY — NATIONAL LEVEL



BUILDING PROJECT SUSTAINABILITY — COUNTY AND SDP LEVEL



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