SIAPS Namibia End of Project Report

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Antiretroviral therapy (ART), electronic dispensing tool (EDT), pharmacy management information system (PMIS), human resource, Ministry of Health and Social Services (MoHSS), Namibia

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We are grateful to our implementing partners for the collaboration and contributions to SIAPS' achievements.

Special appreciation goes to the USAID and US President's Emergency Plan for AIDS Relief (PEPFAR) teams in Namibia and the USA for the valuable guidance and steadfast support that enabled SIAPS to contribute to the MoHSS' fight against HIV and AIDS in Namibia.

Finally, the authors thank all SIAPS staff for their efforts in planning, implementing, monitoring, reporting, and using information to improving antiretroviral therapy (ART) and pharmaceutical services in Namibia. Your tireless efforts made a difference toward an AIDS-free Namibia.

ACRONYMS AND ABBREVIATIONS

AMR	antimicrobial resistance
ART	antiretroviral therapy
ARV	antiretroviral
Div:PhSs	Division of Pharmaceutical Services
EDT	electronic dispensing tool
EWI	early warning indicator
FESC	facility electronic stock card
HIV-DR	HIV drug resistance
HSS	health system strengthening
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
NHTC	National Health Training Center
NIMART	nurse initiated and managed ART
NMRC	Namibia Medicines Regulatory Council
PA	pharmacy assistant
PEPFAR	US President's Emergency Plan for AIDS Relief
PMIS	pharmaceutical management information system
PMS	post-market surveillance
RMU	rational medicine use
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPS	Strengthening Pharmaceutical Systems
SSV	supportive supervision visit
TB	tuberculosis
UNAIDS	United Nations program for HIV/AIDS
UNAM-SoP	University of Namibia's School of Pharmacy
USAID	US Agency for International Development
WHO	World Health Organization

SIAPS PROJECT LEGACY: 2012-2017

The University of Namibia's School of Pharmacy (UNAM-SoP) and the National Health Training Center (NHTC) have better capacity in high-quality training of pharmacy professionals.

SIAPS enhanced the capacity of the Namibia Medicines Regulatory Council (NMRC) to achieve faster registration of medicines, improve post-market surveillance of medicine quality, and ensure safety of medicines in Namibia.

Improved availability of quality pharmaceutical products and effective pharmaceutical services Stronger pharmacovigilance and better pharmaceutical care contributed to continued safety of patients on HIV and TB treatment; adherence tracking and retention in HIV care improved; and indicators for HIV drug resistance were institutionalized.

The pharmaceutical information system is now electronic and data driven and supports the MoHSS, UNAIDS, and other partners in strategic and operational decision making on ART patient services and ARV and other commodity management.

BACKGROUND

In September 2011, the USAID-funded SIAPS program took over the technical assistance activities initiated by the Strengthening Pharmaceutical Systems (SPS) program in Namibia; both programs were implemented by MSH.

Namibia has a population of more than 2.1 million people.¹ It is among the countries with the highest prevalence of HIV, with an estimated 14% of the adult population (age 15–49 years) living with HIV (MoHSS, 2013). Namibia also faced a high tuberculosis (TB) burden with a case notification rate of 529/100,000 and a TB/HIV co-infection rate of 47% in 2012.² The country's ART and TB programs were well supported and achieved universal access at the previous World Health Organization (WHO)-recommended ART initiation threshold of 350 CD4 cells/mL. With the 2013 WHO recommendation of universal ART access for people with 500 CD4 cells/mL or less, the country faced new challenges such as ensuring patients' long-term adherence to ART, retention in care, minimizing loss to follow-up, and the growing threat of HIV drug resistance (HIV-DR) and multidrug-resistant TB.

From a health systems perspective, the country had a chronic shortage of skilled pharmaceutical human resources and depended immensely on non-Namibian personnel to provide ART and other essential pharmaceutical services. Therefore, the scale-up of ART services overstretched the already strained public-sector capacity. Pharmacists did not have updated skills in pharmaceutical care for HIV and AIDS and maternal, neonatal, and child health programs. In addition, the pharmaceutical information system was largely manual and rudimentary.

Since 2009, the MoHSS has been conducting pharmaceutical supportive supervision visits (SSVs) at public-sector health facilities. The SSVs revealed variable quality of ART and other pharmaceutical services across all levels of the public sector health system. Furthermore, there were inefficiencies in the regulation of pharmaceutical products and personnel and a dearth of local evidence on antimicrobial resistance (AMR) and HIV-DR to inform decisions on medicine selection and treatment guidelines. Due to the shortage of medical and pharmaceutical personnel, the MoHSS began rolling out the nurse initiated and managed ART (NIMART) strategy to make ART services available at primary health care facilities operated by nurses.

In response, Namibia has implemented a multifaceted approach to control the HIV epidemic that includes improving the pharmaceutical system to enhance the availability of antiretroviral (ARV) and other essential medicines to patients. SIAPS' goal in Namibia was to improve the quality and safety of pharmaceutical products and services to achieve sustained HIV epidemic control. From 2012 to 2018, SIAPS interventions focused on improving the availability of quality ARVs, other essential medicines, and pharmaceutical services to sustain more than 80% ART coverage of patients in need. SIAPS activities contributed to building the capacity of the pharmaceutical workforce for ART service delivery; the use of routinely collected patient information for making programmatic decisions, such as achieving patient retention in ART to prevent HIV-DR; designing and analyzing financing options for universal health coverage to pharmaceutical services; and strengthening the MoHSS' governance and leadership of ART services.

¹ Namibia 2011 Population & Housing Census

² MoHSS National Tuberculosis and Leprosy Programme Annual report 2012–2013

SIAPS Namibia Geographic Coverage

- From inception, SIAPS supported the MoHSS to implement interventions in all 13 (now 14) regions. Beginning in late 2015, SIAPS focused its support on the seven high-HIV burden regions (Kavango, Khomas, Ohangwena, Omusati, Oshana, Oshikoto, and Zambezi)
- Approximately 350 public and mission health facilities benefitted from health systems strengthening (HSS) technical assistance.

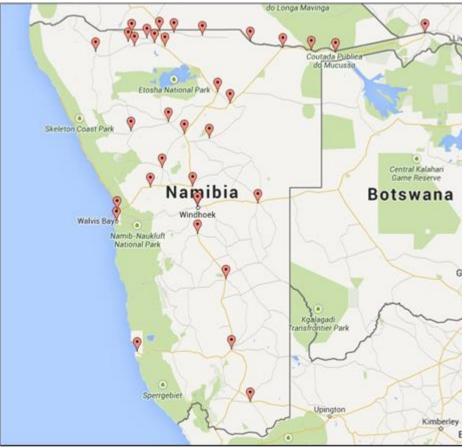


Figure 1. The main ART sites supported by SIAPS in Namibia

KEY INTERVENTIONS

SIAPS Approach

Given the Namibian context, SIAPS focused on providing technical assistance to the MoHSS to improve the quality and safety of ARVs and other essential medicines; strengthen human resource capacity in pharmaceutical management and service delivery for improved HIV and AIDS treatment outcomes; improve the availability and use of pharmaceutical service data for ART services; and strengthen the quality, efficiency, and accessibility of pharmaceutical serviceal services to attain 90% treatment coverage and 90% viral suppression.

Improved Efficiency in Registration, Regulation, and Quality Assurance of Medicines



A 2014 SIAPS-supported medicines registration application review workshop. Photo credit: SIAPS Namibia

SIAPS supported the NMRC to implement Pharmadex, which is a medicine registration software tool. The support included reconfiguring Pharmadex as a web-based system to enhance the transparency and efficiency of the registration process. SIAPS continually engaged NMRC management and staff in the redesign of processes, which resulted in the refinement of the tool to satisfy NMRC requirements. SIAPS oriented six NMRC staff on how to use the improved Pharmadex tool.

SIAPS trained 42 pharmaceutical staff on dossier review and medicines registration, good manufacturing and distribution practices, and quality control of medicines. This increased the pool of medicines dossier reviewers in 2014. The trainees included NMRC staff, staff of public facilities and private community pharmacies, UNAM-SoP, private importers and distributors, regional pharmacists, and other health professionals.

SIAPS provided technical support to the NMRC for intensified evaluation of applications for the registration of ARVs and other essential medicines through workshops. SIAPS funded the first intensified dossier review workshop in October 2014, at which it provided on-the-job training of dossier evaluators to follow up on the training conducted earlier that year. Subsequently, the NMRC organized additional dossier review workshops at which SIAPS provided technical assistance.

SIAPS helped streamline NMRC operations by developing and updating 56 standard operating procedures, checklists, forms, and guidelines for inspection and licensing for the Quality Surveillance Laboratory and the Therapeutics Information and Pharmacovigilance Center.

SIAPS trained three MoHSS Quality Surveillance Laboratory staff to improve medicine quality control and conduct routine tests for post-market surveillance (PMS). The three were among the 42 trained on dossier review and medicines registration, good manufacturing and distribution practices, and quality control of medicines.

Subsequently, SIAPS supported the NMRC to develop and operationalize an implementation plan and standard operating procedures as part of a PMS system. Namibia's first in-country PMS activities were conducted during the project with support from SIAPS.

In addition, SIAPS supported the Division of Pharmaceutical Services (Div:PhSs) to review the Namibia National Medicines Policy during the annual pharmacists' forum in September 2017. SIAPS technical staff facilitated group discussions and plenary sessions for 38 pharmacists and managers from 12 of Namibia's 14 regions.

Increased Number and Enhanced Pharmaceutical Management Skills of the Work Force

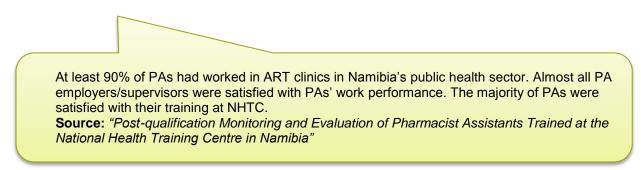
SIAPS supported UNAM-SoP and the NHTC, which together have trained 256 pharmacists, pharmacy technicians, and pharmacy assistants (PAs).

SIAPS collaborated with UNAM-SoP, the MoHSS, and other stakeholders to incorporate pharmaceutical management course content into two preservice training curricula for pharmacists, pharmacy technicians, and PAs. Five pharmaceutical management modules and training materials are now available for training on pharmaceutical supply management, pharmacoeconomics, pharmacovigilance, rational medicine use (RMU) and AMR, and pharmaceutical regulation.

Furthermore, SIAPS supported the NHTC and UNAM-SoP in setting up skills laboratories that enabled Electronic Dispensing Tool (EDT), a tool for dispensing ARVs, and facility electronic stock card (FESC) trainings at the two institutions. It also supported UNAM-SoP to develop a strategic plan to enhance pharmacist training.

SIAPS collaborated with the International Training & Education Center for Health and other stakeholders to help the NHTC develop a quality management system, competency framework, and standards for pharmacy staff to enable reaccreditation by the Namibia Qualifications Authority. The program also developed and trained Pharmacy Council staff on a framework streamlining and structuring licensure of pharmacy personnel to practice in Namibia.

SIAPS supported the NHTC to conduct its first formal comprehensive workplace assessment of NHTC PA graduates since 2007; the findings informed curriculum review for reaccreditation.



For in-service and on-the-job training, SIAPS supported the MoHSS and Div:PhSs to structure and institutionalize supportive supervision and facilitate in-service training of more than 700 pharmacy staff, nurses, TB field promoters, and medical officers on pharmaceutical electronic tools, rational medicine use, pharmacovigilance, quality assurance of medicines, and licensure of pharmacy personnel to practice in Namibia.

Improved Availability and Use of Information for Decision Making

Throughout the program, SIAPS:

- Supported the MoHSS and Div:PhSs to conduct in-service training and on-the-job support of more than 700 pharmacy staff, nurses, and other cadres on the EDT, e-TB Manager, the FESC, and the pharmaceutical management information system (PMIS) dashboard. The trainings equipped health workers to implement pharmaceutical management electronic tools.
- Supported on-the-job mentoring of staff through structured pharmaceutical SSVs. The scope of the SSVs included the storage of medicines, vaccines, and clinical supplies; human resources; the status of implementation of previous SSV recommendations; inventory quantification, control, and management; PMIS; functionality of therapeutics committees; ART services; therapeutic information and pharmacovigilance activities; and quality of dispensing practices.
- Supported the adaptation of the EDT for enhanced functionality, including HIV-DR early warning indicator (EWI) monitoring; community-based ART; pre-exposure

prophylaxis; data capture; and nutrition assessment, counseling, and support product inventory management.

- Oriented MoHSS managers on the use of data from the dashboard for pharmaceutical decision making during a two-day workshop and on-the-job training during facilitybased support visits. SIAPS collaborated with the USAID-Global Health Supply Chain Program-Procurement and Supply Management to facilitate the orientation workshop, at which managers used data from the FESC to forecast and budget for pharmaceuticals for facilities in their regions.
- Provided help desk IT support for efficient use of the EDT, FESC, dashboard, and e-TB Manager.



Dr. Nunurai Ruswa (National DR-TB Medical Officer) demonstrates e-TB Manager during a training session in October 2013. *Photo credit: SIAPS Namibia staff*



Participants from different regions enter data on TB cases into the system during e-TB manager training in October 2013. *Photo credit: SIAPS Namibia staff*



SIAPS Senior Technical Advisor Mr. Samson Mwinga (left) trains health workers on mobile EDT devices at Sangwali Health Centre in the Kavango Region in October 2014. *Photo credit: SIAPS Namibia Staff*



SIAPS Senior Technical Advisor Mr. Nasser Mbaziira (right) provides on-thejob training on the mobile EDT to Ms. Priscah Sikubo (left), enrolled nurse and clinic in-charge, and Ms. Lydia Mukungo (standing), HIV/AIDS Community Counselor at Sesheke Clinic in the Zambezi Region in 2014. *Photo credit: SIAPS Namibia staff*

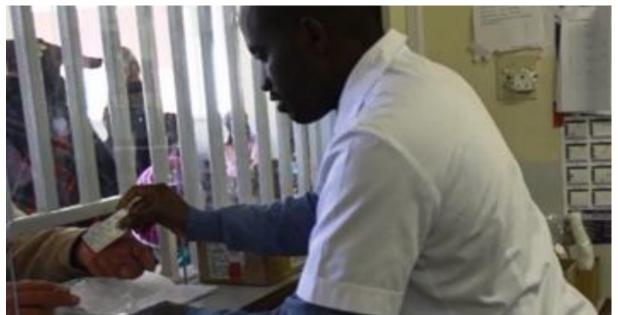
KEY ACHIEVEMENTS

Improved Efficiency in Registration, Regulation, and Quality Assurance of Medicines

- Contributed to a 46% reduction in the average number of days taken to evaluate and make a decision on a regulatory application, from 53 days in 2012 to 26 days in 2015
- Reduced the medicines registration dossier backlog from 711 applications to 100 applications over a one-year period in 2015, reflecting an 86% improvement in process efficiency

Increased Capacity for Pharmaceutical Supply Management and Services

- 256 pharmacists, pharmacy technicians, and PAs were trained in Namibia and were available to provide ART and other pharmaceutical services
- All 35 of Namibia's MoHSS hospitals, high volume health centers, and clinics have qualified pharmacy personnel



Mr. Martin Mandumbwa, a pharmacist assistant, dispenses medicines to a patient at Robert Mugabe clinic in Windhoek, Namibia. *Photo credit: SIAPS/Namibia staff, September 2015*

Strengthened Capacity of Institutions in Preservice Training of Pharmaceutical Human Resources

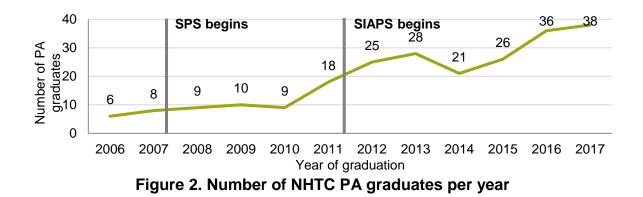


USAID Country Representative Brian Fink (fourth from right) with 36 PA graduates and NHTC/MoHSS representatives in 2016

- Pharmaceutical management content is now incorporated in two preservice training curricula for pharmacists and PAs
- Five pharmaceutical management modules and training materials are now available for training on pharmaceutical supply management, pharmacoeconomics, pharmacovigilance, RMU and AMR, and pharmaceutical regulation at the UNAM-SoP



Pharmacy students take their oath on the eve of the UNAM-SoP graduation in 2015



Enhanced Availability and Use of ART and Pharmaceutical Information for Decision Making

- More than 80 public health facilities are using the EDT for ARV dispensing, ART patient monitoring and reporting, and eliminating the burden of manual data entry and data gaps
- More than 30 integrated management of adult and adolescent illnesses and primary health care facilities are using the mobile EDT for NIMART services
- All 13 designated regional drug-resistant TB treatment centers are using e-TB Manager
- Improved visibility of pharmaceutical and ART data through the use of the pharmaceutical information dashboard, which was implemented at more than 50 health facilities countrywide (*www.pmis.org.na*)
- PMIS quarterly feedback reports reduced the variability of ARV regimens by keeping appropriate medicines stock levels to avoid stock-outs that would have led to regimen alterations
- Data from SIAPS-supported tools are used in the national forecasting, supply planning and budgeting of HIV and other commodities



US Ambassador to Namibia H.E. Thomas Daughton (left), and Minister for Health and Social Services Dr. Bernard Haufiku (middle) launch the new Pharmaceutical Information Dashboard at Windhoek Central Hospital, Namibia, on June 23, 2016. On the right is Dr. Evans Sagwa, SIAPS Namibia Country Director.



Mr. Daughton (seated) unveils the FESC at Okatana Health Center on July 13, 2017. Looking on (from right to left) are Oshana Regional Governor Clemens Kashuupulwa, PEPFAR Country Director Lela Baughman, Dr. Sagwa, and SIAPS Senior Technical Advisor, Bayobuya Phulu.

Improved Pharmaceutical Service Delivery and Patient Safety

- Regular monitoring and analysis of HIV-DR EWIs through SIAPS' technical assistance contributed to a reduction in ART patients lost to follow-up from 21% in 2013 to 4% in 2015
- Institutionalized ART adherence monitoring using the ARV pill-pick up EWI data from the EDT
- Improved compliance to treatment guidelines through an informative assessment of the use of standard treatment guidelines and reporting on ART regimens in the ART guidelines
- Spontaneous adverse drug reaction reporting to the Therapeutics Information and Pharmacovigilance Center by health facilities, complemented by active medicine safety surveillance was implemented
- An AMR advocacy and intervention model and a call to action statement were developed by the MoHSS and partners in 2013; the model has guided AMR advocacy and containment interventions in Namibia. A paper on antimicrobial sensitivity patterns of cerebrospinal fluid isolates in Namibia and implications for empirical antibiotic treatment of meningitis was published.
- The fifth and sixth editions of the national essential medicines list were updated with SIAPS technical assistance



MoHSS Deputy Permanent Secretary Dr. Norbert Forster and USAID/Namibia Mission Director Ms. Elzadia Washington display copies of the national essential medicines list (fifth edition) during the launch of the document in Windhoek. Looking on is MoHSS Deputy Director for Pharmaceutical Services Ms. Jennie Lates. *Photo credit: MSH staff, October 2012*

Proposed approach for advocacy and containment of AMR in Namibia – July 2013

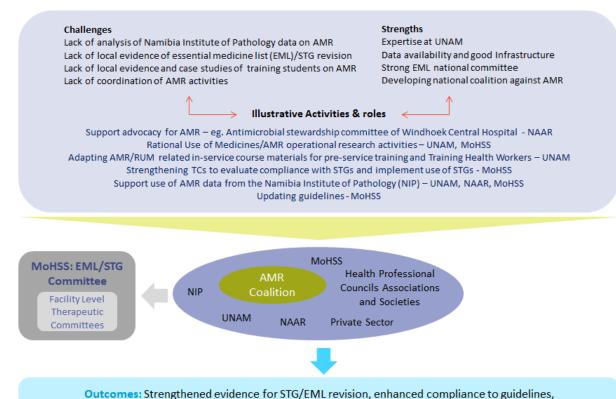


Figure 3. Model for containment of antimicrobial resistance and advocacy for rational medicine use, July 2013

improved adherence to ARVs and anti-TB medicines, reduced risk of AMR Overall Outcome: AMR institutionalized and coordinated



AMR/RMU forum participants at a call to action celebration on July 24, 2013. Photo credit: SIAPS Namibia staff

LESSONS LEARNED

- A holistic approach to pharmaceutical capacity building contributed in a sustainable way to alleviating the human resource constraints that Namibia faced in the early stages of ART rollout.
- Innovative electronic data collection tools deployed for use at remote ART sites aided ART decentralization and patient access to much-needed ART services, closer to where patients live.
- MoHSS' active leadership and targeted, collaborative training of pharmacy staff and other health workers accelerated results achievement.
- On-the-job mentoring, follow up, and continuous training minimized the negative impact of high staff turn-over and aided continuity of quality pharmaceutical services despite HR constraints.
- Political goodwill and support for the program enabled the implementation of interventions.
- The Namibian Government's readiness to create positions and absorb trained personnel is essential for institutional HR development.
- Stakeholder involvement at all phases of project implementation is essential for ownership and continuity of interventions.
- Continuous engagement of stakeholders in monitoring the progress of interventions helped address some challenges and strengthened project successes.
- SIAPS' continued technical assistance to stakeholders and trained health care workers enhanced the use of acquired skills for implementation of post-training actions.
- The dissemination of monitoring and evaluation information created opportunities for sharing SIAPS experiences across regions and generated action for improving services.
- Technical activity interventions need to incorporate pharmaceutical leadership development to support follow-up of recommendations.

SUSTAINABILITY AND COUNTRY OWNERSHIP

SIAPS collaborated with key local governmental stakeholders and other partners to ensure that supported interventions were implemented in partnership for continuity. In FY15–FY17, SIAPS developed guidance documents, including manuals on structured pharmaceutical SSVs, medicine use evaluations, EDT installation and user guides, e-TB Manager, the dashboard, and the FESC. These documents will guide MoHSS stakeholders for continuity of processes. For human resource capacity for pharmaceutical services, SIAPS enhanced the capacity of two local training institutions (NHTC and UNAM-SoP) through joint activity implementation and development of materials on pharmaceutical management that the two institutions can continue using for pre- and in-service training of pharmaceutical personnel.

As at March 2018, all technical activities had been transitioned to the Namibian Government, USAID implementing partners, and or local implementers.

SIAPS IMPLEMENTATION PARTNERS AND STAKEHOLDERS

- MoHSS/Government of the Republic of Namibia at the national, regional, district, and health-facility levels
- MoHSS Directorate of Special Programs
- MoHSS Directorate of Tertiary Health Care and Clinical Support Services
- MoHSS Directorate of Primary Health Care
- MoHSS Regional health directorates
- MoHSS Division Pharmaceutical Services and subdivision: National Medicines Policy Coordination
- MoHSS Division Quality Assurance
- MoHSS National Health Training Center
- MoHSS National Tuberculosis and Leprosy Program
- MoHSS Division: Pharmaceutical Control and Inspection
- MoHSS Namibia Medicines Regulatory Council
- MoHSS Health facilities
- MoHSS Central Medical Store
- MoHSS Multi-Regional Medical Depots in Rundu and Oshakati
- USAID
- WHO
- Centers for Disease Control and Prevention
- Joint United Nations Program on HIV/AIDS (UNAIDS)
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- Management Sciences for Health: Supply Chain Management System project
- Namibia Institute of Pathology
- The Health Professions Council of Namibia
- Pharmaceutical Society of Namibia
- The Pharmacy Council of Namibia
- The University of Namibia's School of Medicine
- UNAM-SoP
- International Training & Education Center for Health
- Namibia University of Science and Technology
- Tufts University
- University of Washington
- Namibian Association of Medical Aid Funds
- PEPFAR implementing partners in Namibia:
 - IntraHealth
 - KNCV Tuberculosis Foundation
 - Namibia Planned Parenthood Association
 - Project HOPE
 - Society for Family Health
 - o Tonata
 - USAID Global Health Supply Chain Program Procurement and Supply Management
 - Walvis Bay Corridor Group

RESOURCES

Consolidating SIAPS' Five-Year Support to the Ministry of Health and Social Services for Strengthening Pharmacovigilance in Namibia. Available at: <u>http://siapsprogram.org/publication/altview/consolidating-siaps-five-year-support-to-the-ministry-of-health-and-social-services-for-strengthening-pharmacovigilance-in-namibia/english/</u>

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Community-based Group ARV Dispensing Improves ART Services in Namibia.

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Mazibuko GN, Sagwa E, Kagoya HR, Kibuule D, Rennie T, Mavere T, Lates J. (2014). Incorporating pharmaceutical supply management modules in the pre-service curriculum of the BPharm program, of the University of Namibia, School of Pharmacy. *Journal of Pharmaceutical Policy and Practice*, 7 (Suppl 1), P12. http://doi.org/10.1186/2052-3211-7-S1-P12

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ANNEX

Toward Building a Resilient Pharmaceutical System in Namibia: Pictorial Highlights

From the USAID-SIAPS Namibia End of Project Event in Windhoek, Namibia, March 14, 2018



(left to right) Ms. Dinah Tjipura, SIAPS Senior Manager; Mr. Robert Rhodes, Acting Country Representative of USAID/Namibia; Mr. Axel Tibinyane, Director: Atomic Energy & Radiation representing the Minister of Health & Social Services, MoHSS; and Mr. Lazarus Indongo, Deputy Director, Pharmaceutical Services, MoHSS



Mr. Robert Rhodes, Acting Country Representative of USAID/Namibia gives his remarks



Panelists (left to right) Prof. Timothy Rennie, Associate Dean, School of Pharmacy, UNAM; Mr. Stephen Tjiuoro, CEO, NAMAF; and Ms. Karen Brockmann, President, Pharmacy Council of Namibia laugh at a joke during the panel discussion



Mr. Wuletaw Churfo, ART Logistic Pharmacist, MoHSS, makes remarks on information systems during a panel discussion on building a resilient pharmaceutical system in Namibia



Mr. Bayobuya Phulu, SIAPS Senior Technical Advisor, explains pharmaceutical care in service delivery during the SIAPS solutions marketplace



Ms. Rosalia Indongo (right), TB/HIV Advisor | USAID Namibia and SIAPS Namibia Activity Manager presents at the pharmaceutical governance thematic table during the SIAPS solutions marketplace



Mr. Samson Mwinga (left), SIAPS Senior Technical Advisor, and Mr. Stanley Stephanus (right), SIAPS IT Specialist, explain SIAPS-supported electronic tools and information systems during the SIAPS solutions marketplace



SIAPS Namibia staff at the event