

Strengthening Pharmaceutical Management Information Systems for the HIV Program in Ukraine: Assessment and Identification of Areas for Technical Support, September 5–20, 2011

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries and transitional economies to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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Key Words

Ukraine, HIV, procurement and supply management, pharmaceutical management information system

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ACRONYMS

AIDS	acquired immune deficiency syndrome
A.R.	Autonomous Republic (of Crimea)
ART	antiretroviral therapy
ARV	antiretroviral (medicine)
HIV	human immunodeficiency virus
HMIS	health management information system
M&E	monitoring and evaluation
MoH	Ministry of Health
MSH	Management Sciences for Health
PMIS	pharmaceutical management information system
PV	pharmacovigilance
SMT	substitution maintenance therapy
SPS	Strengthening Pharmaceutical Systems Program
TB	tuberculosis
UAC	Ukrainian AIDS Center
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	US Agency for International Development
WHO	World Health Organization

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Special gratitude is offered to the staff from the AIDS prevention and control centers and the Lavra Clinic for their tireless and exceptional cooperation during the visit.

- Crimean Republic AIDS prevention and control center (Simferopol)
- Kirovohrad municipal center for AIDS prevention and control
- Kyiv municipal center for AIDS prevention and control
- Lavra Clinic, Institute of Epidemiology and Infectious Diseases
- L'viv regional AIDS prevention and control center
- Odesa regional AIDS prevention and control center
- Odesa municipal AIDS prevention and control center

EXECUTIVE SUMMARY

The Strengthening Pharmaceutical Systems (SPS) Program received funding from the US Agency for International Development (USAID) Ukraine Mission under the SPS Ukraine Associate Award to assist the Ministry of Health and other local partners to address pharmaceutical management issues regarding the management of antituberculosis and antiretroviral therapy (ART)-related medicines and commodities. The objectives of the assessment were to evaluate existing pharmaceutical management information systems (PMIS) elements for the ART program and identify gaps and develop potential strategies for optimizing processes and tools to assure the timeliness and quality of data needed to manage medicines for HIV/AIDS. The information used to prepare this report came primarily from semi-structured interviews with key informants, observations of operations, and record keeping and reporting procedures at AIDS prevention and control centers, and document review. From September 5 to 20, 2011, the SPS team visited regional and municipal AIDS prevention and control centers in five oblasts in addition to meetings with the Ukrainian AIDS Centre (UAC) and other key stakeholders identified by the UAC. The assessment looked at four key elements structured around data collection, aggregation, and use of data and identified the information needs of the UAC to effectively manage the program, medicines, and services for patients.

Capacity: human resource capabilities, availability, and skills for collecting, interpreting, and using information for decision making. Generally, the facilities visited reported having adequate resources to manage patient loads. They identified budgetary constraints for antiretroviral (ARV) medicine procurement as the main limitations to starting more patients on ART. All sites reported that all doctors and nurses completed a formal training course (conducted by UAC) on data collection using approved forms and tools. Several users indicated that they spend a large amount of their time on data entry and data validation. With some process optimization, reduction in duplicative reporting, and automation, more time could be allocated to patient care.

Data: capture of essential data elements and quality, timeliness, and dissemination of information. Most forms and all reports seen at the centers visited are standardized, widely available, and inspected during an annual audit process. Most essential stock- and patient-related data elements are captured within existing paper-based forms and approved tools. However, the absence of an electronic database limits the capacity of facilities to efficiently manage ART scale up including the subsequent increase in volumes of products and patients and recording and reporting requirements. Sites with larger patient loads expressed a need for automated tools, and some sites have developed local solutions to fill specific gaps or to aid in data collection. One or two centers have modified the standardized UAC Excel tool, effectively creating a different version that can complicate the data aggregation process as different versions of the database are not always compatible.

Processes: critical processes for operations, implementing decisions, and providing feedback for managing ART-related pharmaceuticals and patients services. The assessment reviewed critical transactional processes in managing ART-related pharmaceuticals and patients and found that formal processes are in place for most of the key functional areas, including requisitioning, annual quantification, inventory management, and dispensing. Good stock management processes were observed at all sites visited, and stock registers, dispensing registers, and patient cards were observed to be in place; those reviewed

were up to date and regularly audited. At the sites visited, no stock-outs or expired stocks were reported. However, most sites reported an increase in the number of times that ARV stock had to be redistributed to avoid stock-outs and expiries; on average, 4–6 times in the last year. The incremental increase in the number of new patients starting treatment due to limited budgets for ARV procurement has been relatively easy to quantify. However, once the procurement bottleneck has been resolved, a more sophisticated quantification model will be required to accurately forecast ARV and other medicines needs.

Technology and infrastructure: the supporting technologies and infrastructure needed to create an enabling environment for information management to support evidenced-based decision making and effective service delivery. All sites visited were seen to have good infrastructure with Internet access and good working computers and printers. All the users were proficient with the MS Office suite, and some sites have developed local solutions in Excel to meet their specific needs. Separate Excel databases are maintained for ARV and HIV patients and for patients who receive ARVs to reduce the risk of mother-to-child transmission of HIV. Data cannot be transferred between these databases, thereby causing duplication of efforts.

UAC reported the limited ability of the MS Excel-based UAC tool to manage multiple datasets, make changes to data structures, introduce validation protocols, and enhance data security as major challenges. In addition, the lack of a common structure between different reporting systems and databases does not allow UAC to triangulate and aggregate data across systems. UAC staff strongly expressed the need for a dedicated, centralized database solution to aid analysis and decision making and increase transparency across the system.

The recommendations for improving the PMIS to enable more effective supply chain management for medicines and effective policies and other measures to assure the availability and appropriate use of medicines include the following—

- Develop a long-term strategy for managing the information needs of the UAC, the Ministry of Health, key partners, and stakeholders and secure stakeholder buy-in. The objective of the strategy is to increase transparency of, access to, and use of information, reports, and data for all stakeholders.
- Reduce the burden of data collection, validation, and aggregation at oblast ART dispensing sites and, at the UAC, by developing a web-based central data repository for the HIV program that automates data collection, validation, and aggregation.
- Explore opportunities to increase funding for ARV procurement in the immediate term to meet the needs of patients currently waiting to start ART.
- Explore the possibility of changing the distribution model from an annual delivery model to more frequent, smaller deliveries throughout the year. More frequent re-ordering and delivery will allow sites more flexibility to respond to changes in patient load and regimen profiles, improve stock management, and reduce the need for redistribution of excess or short-dated stock.
- Evaluate options for introducing dispensing and inventory management software solutions at large sites (serving more than 1000 ART patients per month) that are reaching the limits for effective paper-based systems. The software can help sites to

better manage stocks, track patient adherence, and generate reports in addition to improving data quality and reporting timeliness.

With the approval of USAID and agreement from the UAC and the State Service on HIV/AIDS and Other Socially Dangerous Diseases, SPS could provide technical assistance to the UAC to support the development of a long-term strategy for managing information on HIV and implementation of the recommendations in this report.

INTRODUCTION

The Need for Information for Managing Pharmaceuticals in HIV Programs

Public health programs, such as HIV programs, rely on the continuous availability of medicines and other pharmaceutical supplies of assured quality. Moreover, medicine availability is usually a major determinant of the utilization of health services. Ensuring an uninterrupted supply of antiretroviral (ARV) medicines and their appropriate use is critical to achieving optimal health outcomes in antiretroviral therapy (ART) services where treatment interruptions or irrational use can have serious consequences, such as treatment failure and the development of resistance.

A well-functioning pharmaceutical management information system (PMIS) that provides information for timely decision making is critical for the successful management of pharmaceutical systems supporting national ART programs. Effective pharmaceutical management requires policy makers, program managers, and providers to monitor information related to the availability of medicines and laboratory supplies, patient adherence, drug resistance, product registration, product quality issues, patient safety, financing, and program management, among others. Data on the availability and use of the required commodities needs to be routinely gathered, efficiently transmitted, appropriately analyzed, and presented in a format that is readily accessible and usable.

Managing pharmaceuticals in any setting (public or private sector) and at any level (local, regional, or national) follows a well-recognized framework (figure 1). Effective management of medicines and commodities for ART programs requires timely, accurate information to guide selection, procurement including quantification, distribution, and use of those pharmaceuticals. When combined with a system for recording and reporting on patient case management, an integrated approach to improving program and pharmaceutical management and improving health outcomes is provided.

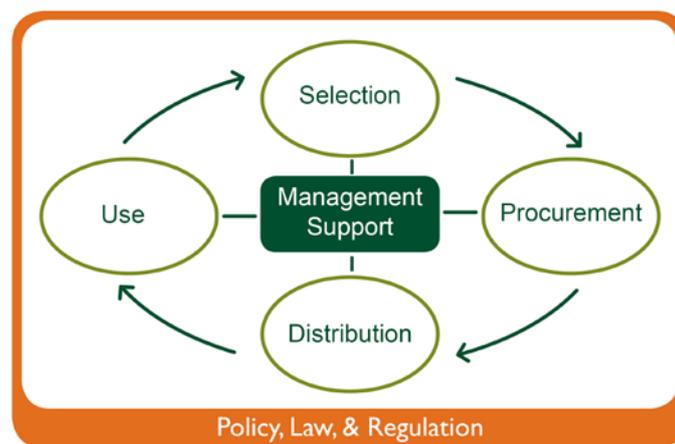


Figure 1. Pharmaceutical management framework¹

¹ Center for Pharmaceutical Management. 2011. *Center for Pharmaceutical Management: Technical Frameworks, Approaches, and Results*. Arlington, Virginia: Management Sciences for Health.

Selection involves reviewing health problems; identifying interventions and treatments; selecting individual medicines, dosages, and forms; and deciding which medicines and commodities will be available at each level of service delivery. Selection of the most appropriate medicines requires that health managers and policy makers have access to current information on common illnesses, budgetary limits, and pharmaceutical advances and receive input from doctors and pharmacists. The design of the PMIS should be flexible to accommodate frequent changes to the list of medicines and pharmaceuticals. For public health programs such as HIV and tuberculosis (TB), the need for the information system to capture data on pharmacovigilance and drug resistance to inform the revision of treatment guidelines and medicines lists is increasingly recognized. For example, the collection and analysis of data on adverse drug reactions can help identify potential safety problems and their risk factors for specific populations of patients and inform changes to treatment guidelines.

Procurement includes quantifying requirements; selecting the procurement method; managing tenders; establishing and monitoring contract terms; and assuring the quality of medicines and commodities. The availability and cost of medicines are governed by the effectiveness of the procurement system. Strong procurement processes ensure that medicines selected for purchase are reasonably priced, of assured quality, and are available in required quantities. Procurement strategies vary widely, but most processes include needs quantification, bid management, supplier selection, and quality assurance. Good procurement practices help countries ensure that the selected medicines are available for distribution to health facilities. The PMIS must be able to generate logistical information to project medicines requirements. For example, medicine consumption data at health facilities are essential to forecast quantities needed. Other information that the PMIS may contain is the list of suppliers, data on their performance, and time taken to process and deliver an order (lead time).

Distribution includes inventory management (specifically stock control); storage management; and delivery to health facilities. Effective distribution involves clearing pharmaceutical products through customs (in the case of imported products), transporting them safely, delivering them in a timely manner, keeping records, maintaining adequate stock levels, and managing available stock. Inventory management involves controlling the transfer in and out of medicines to prevent inventory from becoming too high or too low. If the inventory level is too high, a substantial portion of the medicines budget may be tied up, leaving insufficient funds for other important, perhaps lifesaving medicines or increasing the risk of expiries. If inventory is too low, services may suffer because of stock-outs or shortages of medicines. A buffer or safety stock is usually maintained to cover any unexpected increase in demand or delays in delivery. Store and facility managers monitor expiration dates, inventory levels, and storage conditions such as temperature. When distribution systems function well and are supported by good procurement practices, patients are more likely to receive the medicines they need on time and in good condition.

The logistics management information system, one component of the PMIS (figure 2) needs to be able to accurately record the movement of medicines and commodities across the supply chain; for example, all transactions that increase or decrease stock levels should be recorded. Effective inventory management requires information on what medicine is on hand, where it is in use, and how much should be ordered and when to ensure an uninterrupted supply to patients. The system should also track expiry dates to ensure that only unexpired products are distributed or dispensed. Other important information that should be tracked is

batch number and brand name so that a medicine may be traced if there is a problem with a specific medicine.

Use includes rational prescribing and dispensing and correct use of medicines by the patient. To ensure the most effective and appropriate use of medicines, patients must receive the correct dosage that best treats or manages their illness. In addition, patients should receive a supply of medicine sufficient to treat their illness at a low cost to themselves and/or to the health system. Pharmaceutical services include the provision of medicine information and counseling to promote their proper use and the monitoring of patient adherence for example, to ARV and anti-TB medicines. In addition to logistics data, the PMIS should maintain a dispensing record for each patient and generate patient-centered data on outcomes related to medicine use, such as adherence, to support patient care. Other vital information is morbidity data which can be obtained from dispensing records. In addition to informing decisions on quantification, morbidity and consumption data may be analyzed to learn about the functioning of the medicines management system and also the rational use of medicines, such as switching to second-line ART regimens at facilities in a country or region.

The activities and services described above are enabled by a strong **management support** system that includes financial, organizational, and human resource management and systems for monitoring and evaluation (M&E). In addition to consumption data, reports on various patient statistics are needed to inform management decisions, for example, to project human resource and finance needs and to plan for program scale up.

Pharmaceutical management functions rely on **policies, laws, and regulations**, which when supported by good governance, sustain the commitment to pharmaceutical supply. By establishing pharmaceutical laws and regulations, countries can set quality standards and pricing guidelines for pharmaceuticals, require licensing of pharmaceutical products, and establish production guidelines. The complexity of managing pharmaceuticals, the large number of interested stakeholders, and the value of the products make pharmaceutical systems vulnerable to mismanagement and corruption. The PMIS should comply with and support the prevailing laws. For example, it should allow for audit trails to enable transactions to be traced. Similarly, the system should be capable of generating ad hoc reports, should there be any requests from authorities. The PMIS is important for assuring transparency and providing information for oversight to enforce good governance practices.

What Is a Pharmaceutical Management Information System?

Operating an efficient pharmaceutical supply system requires relevant, accurate, and timely information exchange to ensure that staff can make sound decisions related to the selection, procurement, distribution, and use of medicines and other pharmaceuticals. But often, the information system focuses only on logistics, leaving it incomplete. Figure 2 shows the components of a comprehensive PMIS and how it links to a country's health management information system (HMIS).

The features that distinguish a PMIS from a logistics management information system include—

- Incorporation of patient-specific data in addition to logistics management information product-centered data

- The ability to triangulate consumption data with clinical and patient-specific data, for example, for quantifying medicine needs
- A focus on decision making for pharmaceutical services, not just resupply, for example, for providing medication counseling to patients
- Information on outcomes related to medicine use, such as adherence, adverse drug reactions, and pharmacovigilance, that supports pharmaceutical policy and medicine selection decisions, including individualized treatment options
- Overarching information about the pharmaceutical sector, such as data on donors, importers, and manufacturers
- Varied data sources from the whole pharmaceutical sector, not just procurement and inventory management-related activities

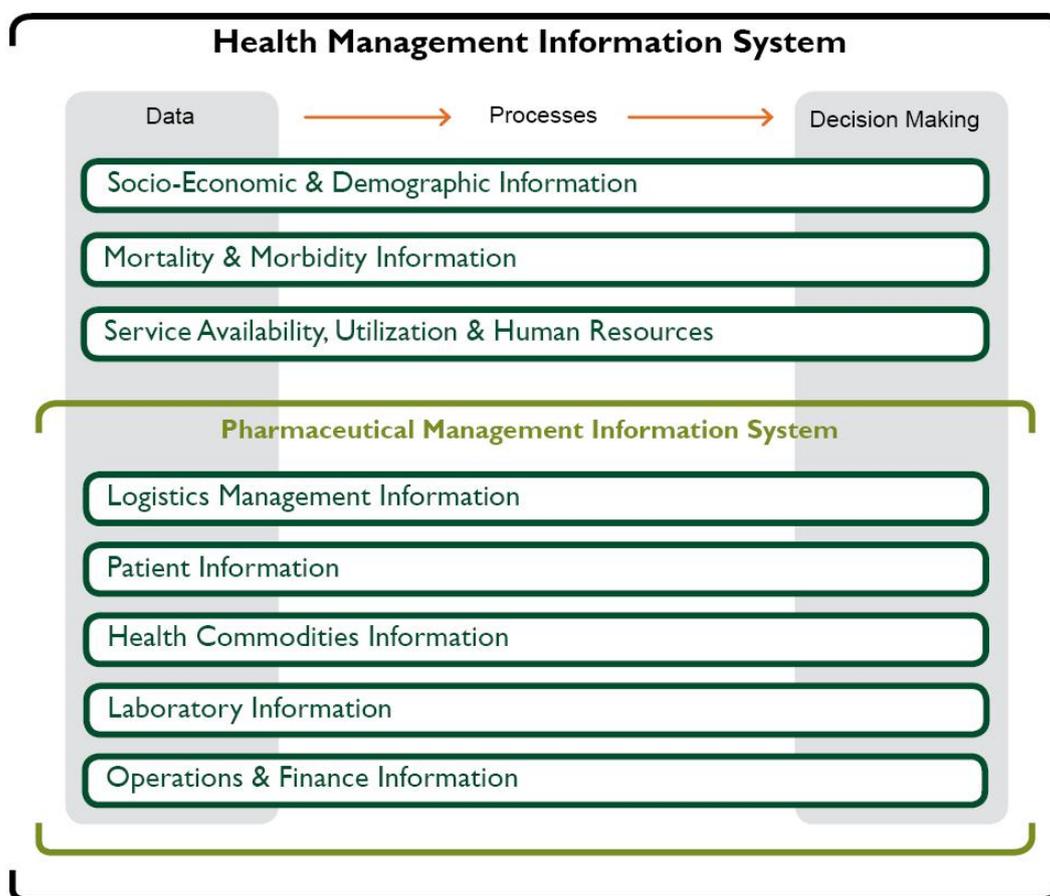


Figure 2. Components of a PMIS and linkages with a country's HMIS.²

² Adapted from the work of the Center for Pharmaceutical Management of MSH

The PMIS integrates data collection, processing, and presentation of information to help staff at all levels of a country’s health system make evidence-based decisions and measure the performance of their pharmaceutical systems as shown in figure 3. The PMIS may utilize manual and/or electronic collection devices and processing tools as part of a comprehensive strategy to ensure that both product- and patient-focused parameters are captured and that these data can inform future decisions. Information technology tools introduced (that is, computers and software) should have the potential to reduce workload, support supply chain management functions, increase the efficiency and quality of pharmaceutical services, be compatible with local technology and capacity, and be supported locally.

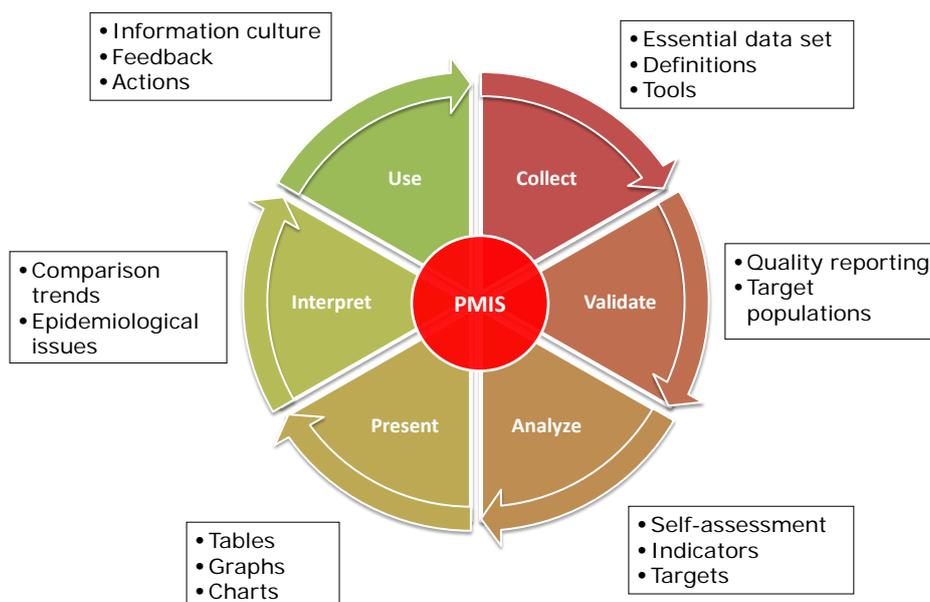


Figure 3. Key elements of the information cycle³

A well-functioning PMIS that provides information for timely and informed decision making requires—

- Human resource **capacity** to collect, interpret, and use data for decision making, supportive supervision, and monitoring system performance
- Capture and reporting of essential **data** elements; critical factors of quality and timeliness are addressed and information is disseminated to all stakeholders
- Defined **processes** for operations, implementing decisions, and providing feedback for managing pharmaceuticals and patient services
- Situation appropriate **technology** that is scalable and sustainable and enables data collection, processing, and decision-making processes.

³ Adapted from *Using Information for Action: A Manual for Health Workers at Facility Level*. The Equity Project, USAID, South Africa, as shown on page 61 of the manual *Training Module on Data for Decision-Making*, 1st Edition, April 2007. Nairobi: Ministry of Health/Division of Reproductive Health, Kenya.

BACKGROUND

The Strengthening Pharmaceutical Systems (SPS) Program has received funding from the US Agency for International Development (USAID) Ukraine Mission under the SPS Ukraine Associate Award to assist the Ministry of Health (MoH) and other local partners to address pharmaceutical management issues related to the management of TB and ART-related medicines and commodities. Objectives of technical assistance include improved PMIS to support these important public health programs, more effective supply chain management for TB and HIV/AIDS medicines and other commodities, rational use of these medicines, and effective policies and other measures to assure availability and appropriate use of quality assured medicines.

In August 2011, SPS/Ukraine staff met with representatives of the Ukrainian AIDS Center (UAC) to discuss their needs in pharmaceutical management, including strengthening the PMIS. Although there have been some efforts to address information needs in the past, these have been largely fragmented and, at present, information exchange is cumbersome and the availability of timely information for pharmaceutical management is limited. Development of a comprehensive PMIS for HIV/AIDS has also been identified as a priority under the anticipated start of the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) Round 10 grant. Therefore, addressing this need is timely, and the UAC supports SPS technical assistance to critically evaluate the current system and assist in the development of a comprehensive information systems strategy.

In 2011–12, SPS is assisting the UAC, the State Service on HIV/AIDS and Other Socially Dangerous Diseases (the State Service), and other partners to systematically assess the existing PMIS for the ART program and identify a way forward for strengthening the system to improve the availability and quality of data needed for quantification and other important pharmaceutical operations, and use of the data for decision making.

Objectives of the Assessment

The assessment objectives were to—

- Evaluate existing PMIS elements of the ART program including processes, capacity, data, and technology and infrastructure
- Based on this mapping, identify gaps and develop potential strategies for optimizing processes and tools to assure timeliness and quality of data needed to manage medicines for HIV/AIDS

Methodology

The information used to prepare this report came primarily from semi-structured interviews with key informants, observations of operations, record keeping, and reporting procedures at AIDS prevention and control centers and document review. As a first step, the SPS staff adapted existing assessment tools for the goal, scope, and local context of the assessment in Ukraine. From September 5 to 20, 2011, the SPS team visited regional and municipal AIDS prevention and control centers in five oblasts to observe record keeping, aggregation,

analysis, and reporting procedures and tools and conduct interviews. Following the site visits, SPS worked with staff of the UAC to more clearly define their needs, map the challenges they face in information management, and define the scope of the technical assistance that they would like to receive from SPS to support the future scale up of the HIV program. SPS also met with other key informants identified with the UAC and reviewed key documents and tools in use during the visit. The organizations and AIDS prevention and control centers visited from September 5 to 20, 2011, are set out in table 1, and annex 1 lists individuals contains the list of persons met. The documents reviewed are listed in annex 2.

Table 1. Assessment of the PMIS for Ukraine’s ART Program September 5-20, 2011: AIDS Prevention and Control Centers and Organizations Visited

Date (all dates are 2011)	Location (oblast)	AIDS prevention and control centers and organizations visited
September 5	Kyiv	UAC
September 6		All-Ukrainian Network of People Living with HIV Lavra Clinic, Institute of Epidemiology and Infectious Diseases International HIV/AIDS Alliance in Ukraine (the Alliance)
September 7		Interagency Working Group on Monitoring & Evaluation in HIV/AIDS Meeting Pharmacovigilance unit, State Expert Committee
September 8		Joint United Nations Programme on HIV/AIDS (UNAIDS)
September 8	Kirovohrad	Kirovohrad municipal center for AIDS prevention and control
September 9	L’viv	L’viv regional AIDS prevention and control center
September 12	Odesa	Odesa regional AIDS prevention and control center Odesa municipal AIDS prevention and control center
September 13	Autonomous Republic (A.R.) of Crimea	Crimean Republic AIDS prevention and control center (Simferopol)
September 14	Kyiv	UAC
September 15		USAID debriefing
September 19		Kyiv municipal center for AIDS prevention and control
September 20		Clinton Health Access Initiative

The SPS team members for the visits were—

- Kyle Duarte, Director Systems Analysis and Software Products, MSH/Center for Pharmaceutical Management, US Office
- Helena Walkowiak, Senior Program Associate, SPS, US Office
- Valeriy Kidon, Senior Technical Advisor, SPS, Ukraine Office
- Oksana Haptyanova, Supply Chain Management Specialist, SPS, Ukraine Office
- Dmytro Moskalyk, PMIS Specialist, SPS, Ukraine Office

Caveats and Limitations

The information on which this report is based generally came from only a few sources. Due to the limited time available for the site visits and interviews, SPS staff did not have the opportunity to verify all the responses given. Moreover, because each visit was brief, access to certain information may have been limited, whether observed or collected in written or interview form. Although SPS staff made every effort to understand the information systems, processes, data collection procedures, tools, and technology being used, there may be errors due to time limitations. Ukraine is a large country and there may be some variation in the methods used to manage ARVs, recordkeeping, and recording procedures. Findings in this report should be verified as to their accuracy and representativeness, and the recommendations assessed accordingly before they are implemented.

FINDINGS

The findings of this rapid assessment are organized using the framework set out in figure 4.

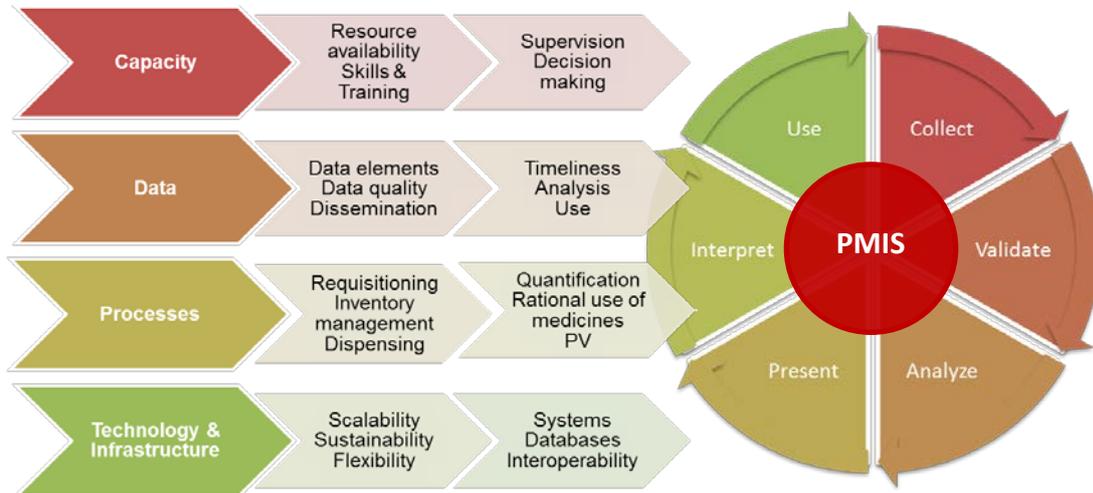


Figure 4. Framework for evaluating the PMIS for the ART program in Ukraine

The framework was used to assess the main elements of the PMIS for Ukraine’s ART program and identify UAC’s information needs to effectively manage the program, medicines, and services for patients.

The four key elements evaluated and reported are—

- **Capacity:** human resource capabilities, availability, and skills for collecting, interpreting, and using information for decision making
- **Data:** essential data elements captured and quality, timeliness, and dissemination of information
- **Processes:** critical processes for operations, implementing decisions, and providing feedback for managing ART-related pharmaceuticals and patients services
- **Technology and infrastructure:** the supporting technologies and infrastructure needed to create an enabling environment for information management to support evidenced-based decision making and effective service delivery

The findings also include a description of the ART program in Ukraine, including an outline of the flow of ARVs and pharmaceutical management information. This section concludes with a summary of discussions with the UAC staff to more clearly define their needs, map the challenges they face in information management, and define the scope of the technical assistance that they would like to receive from SPS to support the future scale up of the HIV program.

The ART Program in Ukraine

Ukraine, with its population of 45.8 million (January 1, 2011),⁴ has the most severe HIV epidemic in Eastern Europe and Central Asia. UNAIDS estimates that, in 2009, 350,000 people aged 15 or over were living with HIV with an adult prevalence rate of 1.1 percent.⁵ In 2009, 19,840 new HIV cases were registered, an increase of 5.7 percent over 2008.⁶ Although HIV cases have been registered in all 27 regions in Ukraine, HIV prevalence levels vary considerably across the country. According to MoH, Dnipropetrovsk, Donetsk, Mykolaiv, Odesa, and Kherson oblasts and Kyiv, Sevastopol, and the A.R. of Crimea reported the highest HIV prevalence rates in 2009.⁷ Injecting drug use is a significant mode of HIV transmission in Ukraine, and MoH estimates that nationally, in 2009, 36 percent of new cases were infected through parenteral transmission, predominantly of narcotics.⁸ TB-HIV co-infection is a growing problem in Ukraine with 76 percent of AIDS-associated deaths reportedly due to TB.⁹

The National Council for the Prevention of TB and HIV/AIDS of Ukraine (the National Council) coordinates the multisectoral response to HIV/AIDS, with MoH having overall responsibility for national policy, programming, and management. A deputy minister of health and the State Service oversee all aspects of the HIV/AIDS and also TB programs. The UAC is responsible for the day-to-day management of the program. The Ministry program is supported by a number of local and international donors, partners, and organizations, including region (oblast) and municipal authorities, the penitentiary system, the Global Fund, USAID, United Nations agencies, the World Bank, the National Council, the All-Ukrainian Network of People Living with HIV/AIDS (the Network), Futures Group International, the International HIV/AIDS Alliance in Ukraine (the Alliance), and other international and local nongovernmental organizations.

Ukraine began providing ART on a wide scale in six regions in 2004 under a Global Fund grant.¹⁰ At the end of 2009, 15,871 persons were receiving ART, representing 48 percent coverage of persons and 100 percent coverage of children with advanced HIV infection.¹¹ At the time of the SPS assessment (September 2011), the UAC reported that over 22,000 persons were receiving ART in Ukraine. According to MoH, 95 percent of HIV-infected pregnant women received ARVs to reduce the risk of mother-to-child transmission in 2009.¹² The delivery of HIV preventive and treatment services is provided primarily through a government network of AIDS centers and some Cabinet Dovirya (cabinets of trust which are sub-branches of the AIDS centers) at the national, regional, and municipal/district levels. Forty AIDS prevention and control centers and 737 Cabinet Dovirya were reported to be

⁴ State Statistics Service of Ukraine: population as of January 1, 2011. <http://www.ukrstat.gov.ua/>

⁵ UNAIDS 2010. Report on the Global AIDS Epidemic 2010. Geneva: UNAIDS.

⁶ Ministry of Health, Ukraine 2010. National Report on Monitoring Progress Towards the UNGASS Declaration of Commitment on HIV/AIDS: Ukraine. Reporting period January 2008 to December 2009. Kyiv: Ministry of Health.

⁷ Ibid

⁸ Ibid

⁹ Ukraine Global Fund Proposal for HIV: Round 10. Available at <http://portfolio.theglobalfund.org/en/>

¹⁰ Ministry of Health, Ukraine 2010. National Report on Monitoring Progress Towards the UNGASS Declaration of Commitment on HIV/AIDS: Ukraine. Reporting period January 2008 to December 2009. Kyiv: Ministry of Health.

¹¹ Ibid

¹² Ibid

operating throughout the country at the end of 2009.¹³ ARVs to reduce the risk of mother-to-child transmission are also provided at these centers and, in urgent cases, at maternity clinics.

Substitution maintenance therapy (SMT) services for opioid addiction and TB services in Ukraine are organized as vertical systems, each with its own management information system. SMT, using primarily methadone and buprenorphine, is provided for HIV-infected injecting drug users at narcology centers and clinics managed by the State Service for Narcotics Control, which was restructured in April 2011. As of January 1, 2010, 5,078 patients at 102 healthcare facilities in 26 regions of Ukraine were receiving SMT; of those, 2,219 were HIV-positive and 538 were receiving ART.¹⁴ Anti-TB treatment for TB-HIV co-infected patients is mostly provided at phthisiologic and pulmonologic medical facilities through the National Program for TB Control. Co-located HIV and TB services and, in some cases, SMT delivery are provide at a few AIDS prevention and control centers (including in L'viv, one of the facilities visited during the assessment).

Improving coverage of ART for persons who need it is a priority for MoH and its partners. At the time of the SPS visit, key informants estimated that 9,000 to 12,000 persons were waiting to start ART, but were unable to do so because of lack of funding for ARV procurement. Key informants and partners cited the lack of funding for ARVs as the main limitation to scaling-up the ART program in Ukraine. Currently the procurement of ARVs is funded primarily through the state budget and also a Global Fund Round 6 grant. Of the 15,871 persons receiving ART at the end of 2009, treatment for 14,468 was funded from the state budget.¹⁵ The recently awarded Global Fund Round 10 grant for HIV includes funds for the procurement of ARV medicines. The UAC is one of the three principal recipients under this grant, and proposed UAC responsibilities include the procurement of medicines and commodities, including ARVs. However, it is anticipated that the procurement role of UAC will only be initiated in phase II of the grant.

Under the Round 10 proposal¹⁶ it is planned that 23,033 persons will receive ART by the end of the program, which represents 23.3 percent of the estimated 98,874 persons that will be in need of ART in Ukraine by 2016. This target is additional to the number planned to receive ART funded from the state budget. Under the current National AIDS Program Operational Plan (2011–2013), the aim is to provide 40,000 patients with ART by 2013.¹⁷ Other strategies to facilitate scale up of HIV treatment and care include decentralization of ART services, expansion of SMT provision, and improved prevention, diagnosis, and treatment of TB in persons living with HIV.¹⁸ Critical to the success of these interventions is the provision of timely and reliable information to inform program planning, implementation and monitoring. The development of a comprehensive PMIS for HIV/AIDS has been identified as a priority area under the anticipated start of the Global Fund Round 10 grant.

¹³ Ibid

¹⁴ Ibid

¹⁵ Ukraine Global Fund Proposal for HIV: Round 10. Available at <http://portfolio.theglobalfund.org/en/>

¹⁶ Ibid

¹⁷ UNAIDS 2009. Comprehensive External Evaluation of the National AIDS Response in Ukraine. Kyiv: UNAIDS.

¹⁸ Ministry of Health, Ukraine 2010. National Report on Monitoring Progress Towards the UNGASS Declaration of Commitment on HIV/AIDS: Ukraine. Reporting period January 2008 to December 2009. Kyiv: Ministry of Health.

Organization of the ARV Supply System in Ukraine

As mentioned above, ARV medicines are currently procured using two main sources of funding: the Global Fund Round 6 grant and domestic budget. Since 2009, the ARVs funded by the Global Fund are procured by the Network following Global Fund and World Health Organization (WHO) mandated procurement processes and guidelines. State-funded procurements are managed by MoH Department for Maintenance of State Programs and Tender Procedures (the Procurement Department). State procurement of ARVs follows the Government of Ukraine procurement processes and guidelines. Regardless of funding source, all shipments of ARVs are inspected and subject to standard quality assurance processes at the time of receipt. The ARVs are then distributed by local distributors (Ukrvaccina for state-procured ARVs and Ukrmedpostach for ARVs procured with Global Fund monies) to the oblast-level AIDS prevention and control centers. These centers then redistribute the medicines to ARV dispensing sites in their oblast or region.

Procurement is based on an annual supply plan and ARVs are delivered in bulk shipments. Due to the lack of storage space at central levels for Ukrvaccina, these bulk deliveries are then immediately pushed down to the oblasts according to an annual distribution plan approved as a MoH order. The oblast-level centers receive their annual allotment of ARV medicines in one delivery as the medicines become available to the distributor. Therefore, the oblasts may receive several products at once or in staggered shipments. The task of accurately determining quantities needed and stock management, including the availability of reliable data to inform these decisions, is critical to avoid stock-outs and expiries.

In Ukraine, ARV quantification is performed annually by oblast-level centers using data that are locally collected, aggregated, and analyzed, and then reviewed and finalized by the UAC at national level. ART scale up is determined by the available funding and so the forecasts prepared by the oblasts are generally based on consumption data and allow for only a modest increase in new patients. Because of the lengthy procurement process, oblast-level centers quantify needs 12 to 18 months in advance, and existing procurement processes allow little flexibility to subsequently adjust quantities to accommodate changes in demand based on actual scale-up and new patient profiles. UAC has set up a system for redistribution of ARV medicines to avoid shortages and expiries between oblasts, and oblast-level centers make their own arrangements for redistributing stock within their region.

The flow of ARVs and information within the ART program in Ukraine as depicted in figure 5 is based on a review of key documents and information gathered during the assessment.

Table 2 provides a description of the AIDS prevention and control centers visited by the SPS team during the assessment.

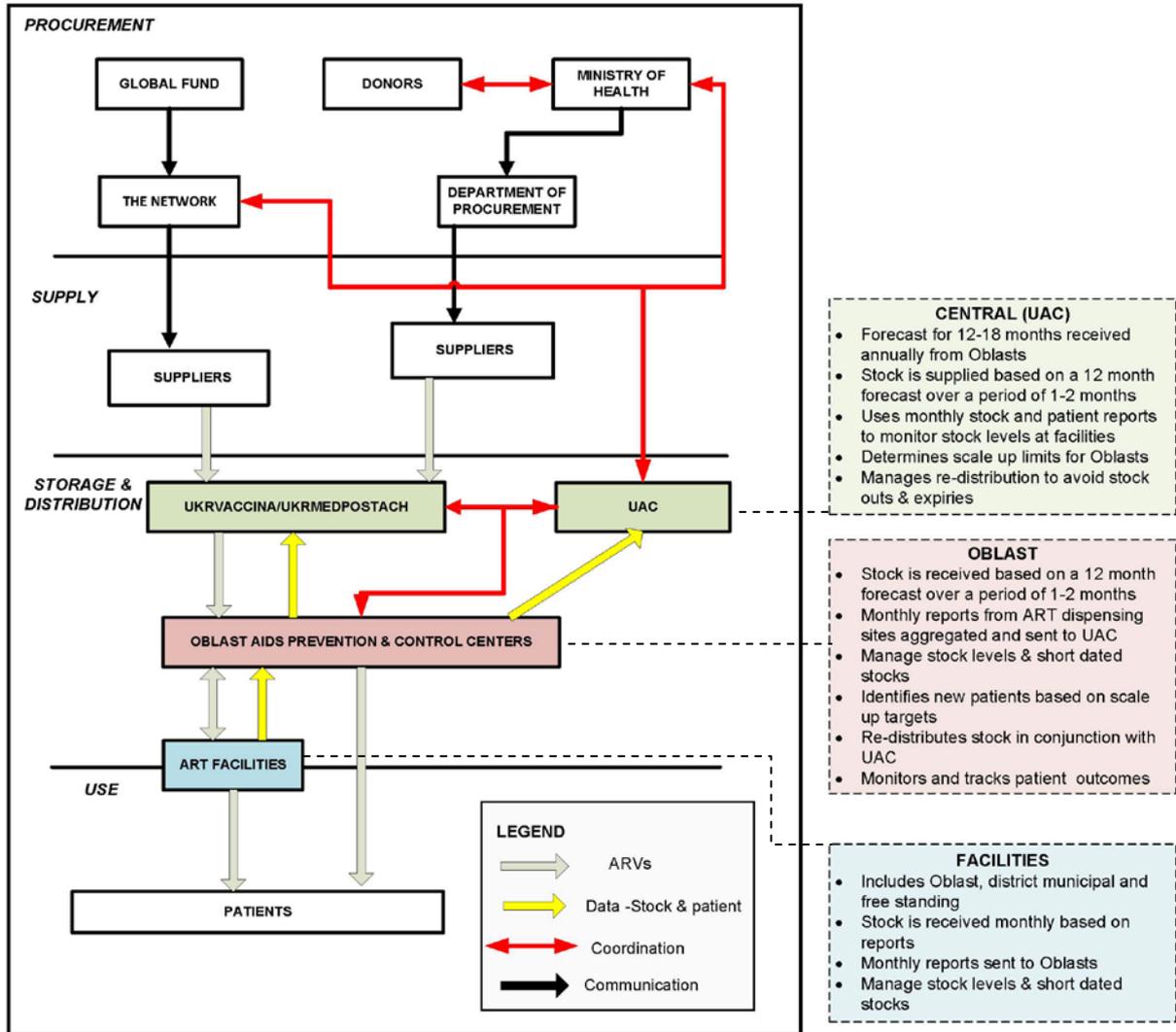


Figure 5. Flow of ARVs and information in the ART program in Ukraine

Table 2. Description of the AIDS Prevention and Control Centers Visited

Oblast	Unit visited	Facility type	Number of lower-level facilities that the center supplies with ARVs	Co-located SST
Kyiv	Kyiv municipal center for AIDS prevention and control	Structural unit of Kyiv municipal clinic hospital administratively reporting to Kyiv municipal health care board of Kyiv municipal state administration	2 cabinets	Yes
Kirovohrad	Kirovohrad municipal center for AIDS prevention and control	Self-maintained health facility administratively reporting to Kirovograd regional health care board of Kirovograd regional state administration	0	No
L'viv	L'viv oblast AIDS prevention and control center	Self-maintained health facility administratively reporting to L'viv oblast health care board of L'viv oblast state administration	0	Yes
Odesa	Odesa oblast AIDS prevention and control center	Self-maintained health facility administratively reporting to Odesa oblast health care board of Odesa oblast state administration	6 units	No
Odesa	Odesa municipal AIDS prevention and control center	Self-maintained health facility administratively reporting to Odesa municipal health care board of Odesa municipal state administration	8 cabinets	No
A.R. of Crimea	Crimea Republic AIDS prevention and control center (Simferopol)	Self-maintained health care facility administratively reporting to the Ministry of health care of the Autonomous Republic of Crimea	6 lower level units	No

ART PMIS Assessment Observations from Site Visits: Capacity

Table 3. Capacity: Site-Specific Findings

Site	Number of patients on ART	Human resource availability	Skills and training	Supervision and decision making
Kyiv municipal center	<ul style="list-style-type: none"> 1,813 patients including 110 pediatric patients 341 reportedly waiting to start ART; of these, 10 are waiting for medicines to become available 	<ul style="list-style-type: none"> Three staff members are involved in generating reports – chief of the center, the epidemiologist, and staff responsible for M&E 	<ul style="list-style-type: none"> Not all staff have been trained on using data collection tools Have developed an Excel-based tool to assist with data collection 	<ul style="list-style-type: none"> Reports are used for data analysis and decision making regarding stock management and redistribution
Kirovohrad municipal center	<ul style="list-style-type: none"> 206 patients 40 patients reportedly waiting to start ART 	<ul style="list-style-type: none"> Data collection and entry and reporting are primarily the responsibility of the acting chief doctor (currently vacant), the accountant, the two doctors, and the nurse in charge of ARV stock management and dispensing Staff report spending a large percentage of their time (up to 25 percent for some) recording and entering data and generating reports 	<ul style="list-style-type: none"> All staff reported to be trained on using data collection tools in Kyiv (regular trainings are held 4-5 times a year) Have been trained to use UAC Excel-based tool to generate reports 2 doctors and 1 nurse reportedly trained in stock management Have developed an Excel-based tool to monitor appointments 	<ul style="list-style-type: none"> Reports are used to review facility performance and discuss issues with staff Receive regular supervisory visits from UAC (4-5 times per year); UAC reviews reports with clinic staff as part of visit Reports are used for data analysis and decision making regarding stock management and redistribution
L'viv oblast center	<ul style="list-style-type: none"> 320 patients in the region including 31 children (as of July 1, 2011)¹⁹ Target for 2012 is 74 new patients 	<ul style="list-style-type: none"> 7 doctors, 1 nurse for dispensing and stock management, and the 1 nurse for SMT all have data collection responsibilities Data analysis and reporting are chiefly the responsibility of the head of the clinical department; have an M&E department that generates the report ART center staff state that reporting is a significant burden 	<ul style="list-style-type: none"> All staff reportedly trained on using data collection tools in Kyiv (regular trainings held 4-5 times a year) Trainings focus on data collection and validation Other than time burden, no challenges reported in generating reports; staff are reported to be well trained and experienced 	<ul style="list-style-type: none"> Receives regular supervisory visits from UAC and also State Service; UAC reviews reports and number of patients on ART and planned as part of visit Reports are used for data analysis and decision making regarding scale up, annual quantification, and stock management and redistribution

¹⁹ Information received from UAC (September 2, 2011)

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Assessment and Identification of Areas for Technical Support, September 5-20, 2011*

Site	Number of patients on ART	Human resource availability	Skills and training	Supervision and decision making
Odesa oblast center	<ul style="list-style-type: none"> • 2,385 patients in the oblast; approximately 300 served by oblast center • 180 pediatric patients in oblast 	<ul style="list-style-type: none"> • 24 doctors provide ART care in the oblast • Four staff members are involved in preparing the annual quantification, including data review, validation, and analysis; takes 1-2 days to prepare • For monthly reporting, takes one specialist doctor one working day to input data and generate the reports 	<ul style="list-style-type: none"> • All staff reportedly trained on using data collection tools in Kyiv (regular trainings held 4-5 times a year) 	<ul style="list-style-type: none"> • Perform regular supervisory visits to ART dispensing sites in oblast (2 per year); visit includes reviewing and validating reports • Receives regular supervisory visits from UAC • Reports are used for data analysis and decision making regarding scale up, annual quantification, and stock management and redistribution
Odesa municipal center	<ul style="list-style-type: none"> • 1034 patients including 81 children • Target for 2012 is 150 new patients 	<ul style="list-style-type: none"> • 10 staff involved in data collection and entry • Inventory reports are generated by chief nurse and the senior nurse responsible for ART stock management 	<ul style="list-style-type: none"> • All staff reportedly trained on reporting in Mykolaiv 	<ul style="list-style-type: none"> • Receives regular supervisory visits from oblast staff; in addition, staff consults with oblast doctors every day by telephone specifically on switches • Reports are used for decision making regarding starting new patients, stock management, and redistribution
Crimea Republic center (Simferopol)	<ul style="list-style-type: none"> • According to UAC, 1,673 patients reportedly on ART July 1, 2011 in the Republic • 137 pediatric patients reportedly on ART July 1, 2011 in the Republic • 1,300 patients reportedly waiting to start ART 	<ul style="list-style-type: none"> • 76 ART staff including 3.5 dedicated ART doctors and 3 pediatric doctors • Deputy chief doctor prepares the monthly report for UAC; takes half a day to prepare • Three staff take an estimated 5 days per month to collect and follow up on data to prepare the monthly report for UAC 	<ul style="list-style-type: none"> • All staff reportedly trained in reporting • Developed an Excel-based tool to assist with tracking expiry dates 	<ul style="list-style-type: none"> • Perform regular supervisory visits to ART dispensing sites (aim for 4 per year); visit includes following up on reports and training if needed; also call sites to follow up on reports and data • Reports are used for data analysis and decision making regarding scale up, annual quantification, and stock management including redistribution

Summary of Findings: Capacity

Facilities report that, in general, they have adequate resources to manage patient loads and that currently the main limitation to starting more patients on ART are budgetary constraints for ARV procurement. The goal under the current National AIDS Program Operational Plan (2011–2013) is to provide 40,000 patients with ART by 2013. Even well-staffed centers will require more automation of data collection, processing, and reporting if accuracy and timeliness are to be maintained.

In addition to the staff responsible for dispensing and store management, most of the ART centers visited reported that medical staff spent considerable time on data recording as part of their duties. The chief or deputy chief of the center are generally responsible for generating the monthly reports with support from other staff. A few staff felt that they spent a large percentage of their time on data collection and reporting. With some optimizations in processes, technologies, and reports as discussed in the next section on data, staff would be able to dedicate more time to patient care.

All sites visited report that doctors and nurses must complete a formal training course, organized by UAC, before they begin providing ART services to patients (doctors study ART patient care and reporting and nurses study patient care and, where relevant, dispensing, stock management, and data capture and reporting). These training workshops are held multiple times throughout the year, and all sites report that their doctors and nurses attend regular refresher trainings.

The workshops include training on data collection using approved forms and data validation processes to crosscheck patient statistics with consumption and regimen reporting. Senior staff also receive training on reporting and data analysis for the annual quantification of needs and how to use data to avoid stock-outs and expired stocks.

The centers visited report that most of their staff is skilled in using computers and specifically MS software applications such as Excel. At some of the sites, staff has developed Excel-based tools to aid the tracking of expiry dates and data collection. Some centers also have experience in using databases and dedicated software solutions.

All facilities report that they receive routine supervisory visits from the UAC and are given regular feedback on their performance. Measures of performance include stock management indicators, such as the number of stock-outs and number of expired products, and treatment indicators, such as number of patients lost to follow up. Oblast-level centers that oversee ART dispensing sites also perform regular supervisory visits; in oblasts with a large numbers of patients and numerous ART dispensing sites, these visits are seen as critical to resolving discrepancies in reporting.

All the centers report using the data they collect to inform operations and decision making at their own facilities. Some examples given are using data to decide on the number of new patients to start on ART and which regimens to use; redistributing short-dated stock; and developing the annual ARV forecast.

ART PMIS Assessment Observations from Site Visits: Data

Table 4. Data: Site-Specific Findings

Site	Data elements	Quality and timeliness	Understanding, dissemination, and use of data
Kyiv municipal center	<ul style="list-style-type: none"> • Most essential stock-related and patient-related data elements are captured • Most forms and all reports are standardized, government-approved format and templates • Developed an Excel-based tool to aid data capture 	<ul style="list-style-type: none"> • Cabinets that dispense ART report every month and reports are received in a timely manner • With approximately 7,000 HIV positive patients including almost 2,000 on ART, staff report that the paper-based record system is breaking down • Use UAC tool for generating monthly reports • Center dispenses three-months supply of ARVs to patients that are adherent but the UAC tool is based on monthly dispensing; as a result, UAC tool projections of stock on hand are inaccurate 	<ul style="list-style-type: none"> • Staff state that data is used for reporting, monitoring cabinet performance, ARV expiry dates, and to inform redistribution • Staff want to 'see' (virtually) the stock status across sites to enable more visibility for planning and redistribution purposes
Kirovohrad municipal center	<ul style="list-style-type: none"> • Most essential stock-related and patient-related data elements captured • Most forms and all reports are standardized, government-approved format and templates • Developed an Excel-based tool to monitor appointments 	<ul style="list-style-type: none"> • Use UAC tool for generating monthly reports • All reports produced are reported to be validated • All dispensing records reported to be validated 	<ul style="list-style-type: none"> • Recording and reporting data reported to take up to 25 percent of staff time • Staff demonstrated good understanding of data validation, interpretation, and use • Staff report that the data is used for reporting, monitoring performance at the center, stock status, and expiry date and also to inform the annual quantification and planning for redistribution
L'viv oblast center	<ul style="list-style-type: none"> • Most essential stock-related and patient-related data elements are captured • Most forms and all reports are standardized, government-approved format and templates • Performance indicators are monitored 	<ul style="list-style-type: none"> • Center staff said that reports are generated in a timely manner • Use UAC tool for generating monthly reports; generating reports not reported to be a problem • Site has dedicated experienced staff that focus on reporting 	<ul style="list-style-type: none"> • Staff demonstrated a good understanding of data validation, interpretation, and use, and also of reports required and interpretation of indicators such as ART utilization trends, stock status, and expiry date monitoring

Findings

Site	Data elements	Quality and timeliness	Understanding, dissemination, and use of data
Odesa oblast center	<ul style="list-style-type: none"> • Most essential stock-related and patient-related data elements are captured • Most forms and all reports are standardized, government-approved format and templates 	<ul style="list-style-type: none"> • Reports from lower level ART dispensing sites received monthly. Lower level ART sites send in paper forms (report that no computers available currently) • All reports reported to be validated • All dispensing records reported to be validated • Staff report that validation and aggregation of data is time consuming • Use UAC tool for generating monthly reports 	<ul style="list-style-type: none"> • Staff report that aggregation of data is very time consuming; validation and generation of monthly reports takes doctors away from seeing patients • Preparation of the annual forecast is reported to be extremely labor intensive • Staff demonstrated a good understanding of data validation, interpretation, and use
Odesa municipal center	<ul style="list-style-type: none"> • Most essential stock-related and patient-related data elements captured • Most forms and all reports are standardized, government approved format and templates • Monitors performance indicators 	<ul style="list-style-type: none"> • Staff report that they work hard to ensure reports are sent out in a timely manner • Use UAC tool for generating monthly reports • Staff report that generating reports is not a problem; stock availability from oblast is their primary concern 	<ul style="list-style-type: none"> • Staff demonstrated a good understanding of data validation, reports required, and interpretation of indicators
Crimea Republic center (Simferopol)	<ul style="list-style-type: none"> • Most essential stock-related and patient-related data elements captured • Most forms and all reports are standardized, government-approved format and templates • Developed an Excel-based tool to assist with tracking expiry dates 	<ul style="list-style-type: none"> • Reports from lower level ART dispensing sites are received monthly; staff report that lower-level sites do not have computers, and submit paper reports; budget constraints often result in reports being physically carried to the A.R. center rather than by fax, resulting in delays • Use UAC tool for generating monthly reports • All reports received are vetted by the oblast staff and then entered manually into the UAC Excel-based reporting tool for submission; center reports that three staff spend approximately 5 days per month vetting all reports 	<ul style="list-style-type: none"> • Staff demonstrated a good understanding of data validation, interpretation, and use • Data validation challenges indicate that staff at oblast facilities need more training; automation of reporting at lower level sites also needed

Summary of Findings: Data

Most forms and all reports seen at the centers visited are standardized, widely available, and inspected during an annual audit process. Most essential stock- and patient-related data elements are captured.

Some sites have developed local solutions, for example, Excel tools to fill specific gaps or aid in data collection. One or two centers have modified the standardized UAC Excel tool, effectively creating a different version. Because the UAC tool is based on monthly dispensing, projections of stock on hand produced by the tool are inaccurate at centers that dispense a three-month supply of ARVs to patients that maintain good adherence.

ART centers must prepare reports for different stakeholders and, as a result, several staff identified duplicative reporting as a concern and requested simplification and consolidation in the number of different reports required.

Staff at the oblast and municipal centers that supply ARVs to lower-level sites report that the paper-based reporting system presents data validation challenges. Staff is not easily able to identify and verify variances in paper-based reports over different reporting periods. A few staff also attributed data quality problems to the workload at lower-level ART dispensing sites. Data quality problems impede the validation and aggregation process, and some staff felt that more time is spent on validation than on analysis.

Two oblast-level centers that have large numbers of patients on ART managed at several sites report that data quality issues make it difficult to accurately track stock-on-hand at some lower-level sites. Closer supervision and focused trainings may be needed to improve data quality and in the long term, automation of reporting at lower-level sites.

Oblast-level centers enter data from paper-based reports into the UAC Excel tool. Staff report that this process is cumbersome and time consuming. The sites are open to optimization of this process. Optimizing data aggregation by introducing dedicated computer solutions would provide staff with additional time to focus on monitoring the data quality of records and reports at lower-level ART dispensing sites.

Staff at centers that oversee lower-level ART dispensing sites said that they routinely analyze reports to monitor regimen changes at these sites. The identification of unauthorized regimen changes have reportedly led to reluctance in decentralizing patient care decisions on regimen changes down from the oblast level in some cases.

All centers report that they use the data generated to actively monitor shelf-life of ARVs and to plan for redistribution of stock as needed to avoid expires and stock-outs. None of the centers visited reported any stock-outs or expires of ARVs in the last year.

ART PMIS Assessment Observations from Site Visits: Processes

SPS reviewed critical transactional processes in managing ART-related pharmaceuticals and patients, including the forms and tools used to capture data for the key functional areas set out below.

Requisitioning

- Staff at the oblast-level centers report that the annual requisitioning process is standardized and well-defined.
- Oblast-level centers visited quantify ARV needs annually for an 18 month period.
- Standardized ARV annual distribution processes are also reported to be in place.

Inventory Management

- ARV stock-outs in last year: none reported at the six centers visited.
- ARV expiries in last year: none reported. Staff at all six centers visited report that they closely monitor ARV expiry dates. In two centers, staff has developed Excel tools to enable them to better track expiry dates of ARV products in stock.
- Good stock management processes were observed at all sites visited including receiving, put-away, and general housekeeping. Stock registers, dispensing registers, and patient cards were observed to be in place, and those reviewed were up to date and regularly audited.
- Staff at all sites visited report that they conduct monthly and quarterly stock counts and issue stock using the first-expiry-first-out system. Temperature monitoring and recording in storage areas were reported, and in centers where the storage areas were visited, were observed to be in place.
- Staff report they are aware of and follow defined processes to manage damaged products (all damaged products are returned immediately).
- All oblast-level centers in conjunction with the UAC actively redistribute short-dated ARV stocks to avoid stock-outs and to meet patient loads.

Dispensing and Patient Services

- Updated patient cards and patient registers for HIV (register number 510-2/0) and for ART (register number 510-3/0) were seen at all centers visited.
- Staff report that good patient follow-up processes have resulted in low loss to follow-up rates (reported at approximately 1 percent).
- Staff at centers report that they monitor adherence and missed appointments. At some oblast-level sites, dedicated staff (social workers) is available to follow-up on missed appointments.

Rational Use of Medicines and Pharmacovigilance

- Oblast-level centers report that they approve new patients and regimens for all ART dispensing sites in the oblast.

- Staff report that they monitor patient adherence to ARVs, mainly through self-reporting by the patient. Some centers also use record review and pill identification to monitor ARV adherence.
- Some centers have developed Excel/paper forms to enable them to monitor appointments due and attended.
- Staff report active redistribution of ARV stocks to avoid treatment interruptions and to meet needs for new patients.
- Staff at all centers were aware of a form for reporting adverse drug reactions and report that they follow a defined process for reporting adverse events. However, in most cases staff reports indicate that the number of actual reports submitted to MoH in the last year was low.
- Staff were not aware of a standard form for reporting quality issues.

Data for Decision Making

- Staff report active use of data, reports, and indicators to manage stocks and patient loads.
- Oblast performance is monitored by the UAC using standardized reports.
- ARV quantification is performed annually using data that is locally collected, aggregated, and analyzed.
- At several oblast-level centers, staff report that regimens for new patients are selected according to data on ARV availability to prevent stock-outs.

Supervision

- Separate reports are produced for Global Fund patients and ARV stock (report number 729) and state-funded patients and ARV stock (report number 136). Both stock status reports are submitted monthly.
- Centers reported regular visits by MoH and state officials to monitor regional site performance, data quality, and adherence to orders and guidelines.
- Oblast-level centers follow up with lower-level ART dispensing sites to monitor data quality and adherence to treatment guidelines and reporting requirements.
- Staff at all centers report that they receive regular audit visits from several agencies to check stock accuracy and that all documents are updated and cross-checked (by signatures verifying stock counts in registers and patient cards).
- Staff at Odesa oblast center reported the use of standard forms to check prescriptions and stock levels.

Summary of Findings: Processes

Formal processes are in place for most of the key functional areas, including requisitioning, annual quantification, inventory management and dispensing. Standardized forms and tools are in place, although some centers have developed tools to better track expiry dates of ARV products, patients waiting to start ART, and adherence to appointments.

Although detailed standard operating procedures are not used, formal processes are in place, many times supported by written instructions (for example, on how to make an entry in a register).

All the centers visited reported using indicators and routine reports to track ARV stock levels and expiry dates, avoid treatment interruptions, and monitor the potential for starting new patients on ART, including identifying the regimens to use. None of the six centers visited reported any ARV stock-outs or expiries in the last year.

All sites visited reported an increase in number of instances where they had to redistribute stocks to avoid stock-outs and expires in the last year as compared with the previous year (three centers reported redistributing stock 4-6 times in the last year). Facility managers reported that, over the last couple of years, ARV procurement bottlenecks have led to an increasing amount of redistribution between facilities to avoid stock-outs.

Most sites felt that regular supervision by both MoH staff and oblast staff is essential to identify data errors and to ensure compliance to orders. All the centers visited reported receiving regular audit visits to monitor stock accuracy and that stock and patient registers are kept updated.

For oblast-level centers, annual forecasting with static data for a period of 18 months is not very accurate, and the existing processes allow little flexibility to accommodate changes in demand based on projected scale-up and new patient profiles.

According to the UAC, approximately 9,000 to 12,000 patients are waiting to start ART and, under the current National AIDS Program Operational Plan (2011-2013), the aim is to provide 40,000 patients with ART by 2013. Scale-up to meet this demand will necessitate automation, specifically a web-based central data warehouse to provide transparency and granularity of data required to effectively scale up services.

For SMT, a separate vertical supply management system is in place for methadone and buprenorphine products, and, with the exception of a few ART centers where services are co-located, dispensing of ART and SMT happens at different facilities. Formal processes that incorporate close monitoring and routine cross-checking are followed for SMT, and standardized recording and reporting tools are used to generate reports which are submitted through a separate system to MoH.

ART PMIS Assessment Observations from Site Visits: Technology and Infrastructure

Table 5. Technology and Infrastructure: Site-Specific Findings

Site	Resources	Systems	Support	Infrastructure
Kyiv municipal center	<ul style="list-style-type: none"> • 4 computers • 2 printers 	<ul style="list-style-type: none"> • UAC Excel tool, in addition to local Excel-based tools developed by center and paper-based back up • Cabinets use paper-based tools • Specialized epidemiology software (EpiAIDS) 	<ul style="list-style-type: none"> • Local resources used for maintenance and support • All users proficient 	<ul style="list-style-type: none"> • Reliable power supply, Internet connections, and phone lines • Old computers; urgently in need of new machines to run newer versions of MS Windows or more current applications • Staff reported proficiency with databases and familiarity with web-based systems
Kirovohrad municipal center	<ul style="list-style-type: none"> • 10 computers • 5 printers • Internet >56K 	<ul style="list-style-type: none"> • UAC Excel tool and paper back up 	<ul style="list-style-type: none"> • Local resources used for maintenance and support • All users trained 	<ul style="list-style-type: none"> • Reliable power supply, Internet connections, and phone lines • Storage conditions and space are reaching limits and require some investment in upgrades • Staff report that the laboratory facilities are in need of improvement/upgrade
L'viv oblast center	<ul style="list-style-type: none"> • Networked • 13 computers • 7 printers • Internet >56K 	<ul style="list-style-type: none"> • UAC Excel tool and paper-based back up • Databases of ARV and HIV patients and patients who receive ARVs to reduce risk of mother-to-child HIV transmission are separate and unconnected; data cannot be transferred between these databases 	<ul style="list-style-type: none"> • Local resources used for maintenance and support • All users trained 	<ul style="list-style-type: none"> • Reliable power supply, Internet connections, and phone lines • Adequate storage conditions and space
Odesa oblast center	<ul style="list-style-type: none"> • 2 computers • 2 printers • Internet >56K (older models) 	<ul style="list-style-type: none"> • UAC Excel tool and paper-based back up • Most lower-level sites use paper-based tools 	<ul style="list-style-type: none"> • Local resources used for maintenance and support • All users trained 	<ul style="list-style-type: none"> • Reliable power supply, Internet connections, and phone lines • Staff reported proficiency with databases and familiarity with web-based systems • Storage space is inadequate
Odessa municipal center	<ul style="list-style-type: none"> • 8 computers • 5 printers • Internet >56K 	<ul style="list-style-type: none"> • UAC Excel tool and paper-based back up 	<ul style="list-style-type: none"> • Local resources used for maintenance and support • All users trained 	<ul style="list-style-type: none"> • Reliable power supply, Internet connections, and phone lines • Old computers (>7 yrs) need to be updated/replaced • Adequate storage conditions and space
Crimea Republic center (Simferopol)	<ul style="list-style-type: none"> • 2 computers • 2 printers • Internet >56K 	<ul style="list-style-type: none"> • UAC Excel tool and paper-based back up • Lower level sites use paper-based tools 	<ul style="list-style-type: none"> • Local resources used for maintenance and senior staff provide support • All users trained 	<ul style="list-style-type: none"> • Reliable power supply, Internet connections, and phone lines • Storage space is inadequate

Summary of Findings: Technology and Infrastructure

With the exception of Kyiv, all centers visited had working computers and a good supporting infrastructure. The newer sites are better equipped with updated/new computers and printers. Smaller sites tend to have older computers that are sub-optimal for running the latest MS office products and web-based applications. All computer equipment is inventoried and locally maintained using local facility budgets. Kyiv municipal center said budgetary constraints meant they could not support license fees for dedicated software solutions.

Almost all users are reported to be proficient in the MS office suite of products, and computers are used extensively at the centers visited. All these centers use the UAC Excel-based tool for reporting. The UAC tool was originally introduced in Ukraine by Médecins Sans Frontières and was further developed with financial support from the Network. The tool is used primarily for reporting on stock management, including expiry dates, and patient profiles for ART services. Over the years, the Alliance and other partners have modified the Excel tool to meet new reporting requirements. The tool is currently managed by the UAC and has been institutionalized and is officially used by all ART sites. As the tool is developed in MS Excel, there are some limitations and constraints. Some sites have made modifications to the tool which can result in inconsistencies when aggregating across several different spreadsheets. As noted earlier, the tool's logic is based on monthly dispensing, and the dispensing of larger quantities can distort the projections of stock-on-hand generated by the tool.

Separate Excel databases are maintained for ARV and HIV patients and patients who receive ARVs to reduce the risk of mother-to-child transmission. Data cannot be transferred between these databases, thereby causing duplication of effort to keep all databases updated.

A few users were aware of the potential of extracting more information from all the data that is being collected. However, existing tools limit the potential of ad-hoc analysis and custom queries.

Most users clearly reported the need for more robust reporting systems and more sophisticated solutions, and some requested increased visibility into data across sites. The existing paper-based systems limit scale-up capacity; for example, tracking over 7,000 patients via patient cards and paper records is cumbersome and error prone, resulting in duplication and inaccurate data recording. Extensive reporting burdens drive the needs for automation and process improvement.

As most sites report that they keep minimal buffer/safety stocks, any variance in demand can quickly impact stock availability. Paper-based systems have a lag time before such variances can be identified, leaving little time for staff that must ensure there is no interruption of treatment to respond.

The existing infrastructure at all sites can support more sophisticated technology. However, adopting new technologies and solutions may require approval to modify the current legal and administrative requirements for paper-based systems and for acceptance of digital reports, for example PDF formats and online forms for requisitioning ARVs.

For the most part, storage space for ARVs was observed to be getting close to capacity in many centers visited. If the desired amount of scale is to be achieved, more storage space will be needed.

By increasing the frequency of deliveries, smaller quantities delivered more frequently would enable most storage space issues to be resolved. However, this change would require modification of the procurement and distribution procedures currently in place.

ART PMIS Assessment: General Findings from Site Visits

Staff report that the lack of funding for ARV procurement is currently the main limitation to scaling-up access to ART at all the centers visited.

The existing paper-based system limits the capacity of oblast and municipal centers and their decentralized ART dispensing sites to quickly scale-up treatment and efficiently manage the subsequent increase in volume of products, patients, and reporting requirements.

Reports from staff indicate that approximately up to 25 percent of human resource time is taken up with generating reports, thereby reducing the amount of time staff has to focus on patient care and improving treatment outcomes and scaling up related activities. The duplication of reports for different funding sources and to different stakeholders only adds to the burden of data collection, processing, and reporting. As discussed under the capacity section, as ART dispensing sites add more patients, the reporting burden will increasingly impact service quality, given the limitations of the current data management system and the UAC Excel-based tool.

As a result of well-trained staff and strong, well-defined processes for managing medicines and service delivery, the majority of key parameters needed for managing operations, monitoring performance, and planning are collected. However, the current Excel- and paper-based systems have limited potential to extrapolate, triangulate, and cross-reference the data to allow staff to perform ad-hoc analysis and respond to custom queries.

Standard best practices in key pharmaceutical management processes (stock management, dispensing, and requisitioning) were observed to be in place at the centers visited. Although detailed standard operating procedures are not widely used, formal processes are in place, many times supported by written instructions (for example, on how to make an entry in a register). In addition, staff is aware of the existence of orders (official documents) that identify what forms and reports are mandated and approved for use in data collection.

During the past year, the limited budgets for procurement of ARVs have resulted in incremental increases in new patients starting on ART, which are relatively easy to quantify. Once this bottleneck is addressed, however, to achieve scale-up targets, a more sophisticated model will be required to accurately forecast ARV and other medicine and commodity needs. The model will need to address multiple real-life scenarios that could play out, for example, a focused HIV testing and awareness campaign that could lead to a rapid and exponential increase in the number of patients who will need to start on ART. As managers have not had the opportunities to test their quantification models and tools and develop scale up assumptions for more complex scenarios, the capacity to manage quantification for scale up may need to be strengthened.

Discussions with the Ukraine AIDS Center

After the site visits were completed, SPS met with the director and key staff from the UAC to define more clearly their needs and map the challenges they face in information management. SPS also solicited inputs from the UAC on strategies underway or planned that address some of these gaps. Discussions were initiated on the potential scope of the technical assistance that the UAC would like to receive from SPS to support the future scale up of the HIV program. The key points from these discussions are summarized below.

The UAC tool is based on MS Excel and therefore has a limited ability to manage multiple datasets, make changes to data structures, introduce validation protocols (version controls), enhance data security, and reduce vulnerability to viruses.

Sites need to report the same information in different forms (and formats) to the different stakeholders. For example, to the Global Fund, they report on SMT use by people living with HIV and specifically those that receive ART, and on treatment of HIV-TB co-infected individuals. However, there is no common structure between these reporting systems (forms and mainly Excel-based tools) and program performance indicators. This fragmentation results in unlinked and separate databases that make data triangulation difficult. The data cannot be easily aggregated across systems and shared between stakeholders, for example, to generate reports on program performance for the Global Fund and procurement data for the Network. This rigid database structure also limits the ability for ad-hoc analysis and data triangulation across different data sets, for example, determining how many women between the ages of 15 and 30 are pregnant and receiving ART.

The UAC and partners lack information and evidence to support budget proposals and advocacy efforts, for example, on the number of persons living with HIV who meet the criteria for initiating ART to justify funding increases for ARV procurement.

The director and staff strongly expressed the need for a dedicated, centralized database solution to aid analysis and decision making and increase transparency across the system. For the system to be sustainable, the director recognizes and strongly emphasized that the UAC must be directly involved in the design, development, and implementation of the new system to build capacity within the UAC. The UAC will work with the State Service to convene a steering committee to oversee these processes.

An important design element is to align UAC database structures with MoH and other key stakeholders. The director stressed the importance of stakeholder coordination in designing the proposed system. UAC would like to leverage indicators and information to drive coordination between the key partners that support the UAC to improve effectiveness and efficiency.

The UAC shared the figures shown in annex 3 that map out the information flow between institutions and partners and the data collection and reporting system for generating M&E indicators. As the figures show, data collection follows a defined methodology and uses standardized data collection tools across several vertical institutions for program financial and statistical reporting. The indicators and data are reported to different governmental stakeholders in addition to the UAC. It is clear that the design of a central database will need to be modular, flexible, and scalable to meet the reporting requirements of the various stakeholders.

Legislation is in place that regulates the collection, storage, and analysis of personal data dealing with health and sets out requirements for ensuring confidentiality. The database design will need to take these requirements into account.

The UAC is looking to SPS to work with the principle partners to create a strategic vision for a technological solution for collecting, saving, and transmitting data and developing a long-term strategy for managing information on HIV.

RECOMMENDATIONS

The study objectives were to use a rapid assessment approach and systems perspective to review the existing PMIS elements of Ukraine's ART program including processes, capacity, data, and technology, and, based on this mapping, identify gaps and develop potential strategies for optimizing processes and tools to assure timeliness and quality of data needed to manage medicines and supplies. The recommendations below were developed from the analysis of observations made during site visits and key informant interviews. The recommendations are broadly organized into those for the central level and those for the facility level (oblast, municipal, and district/cabinet).

Central-Level Recommendations

- Develop a long-term strategy for managing the information needs of the UAC, MoH, key partners, and stakeholders and secure stakeholder buy-in for the long term
- Reduce the burden of data collection, validation, and aggregation at oblast ART dispensing sites and, at the UAC, by developing a web-based central data repository (data warehouse) for the HIV program that automates data collection, validation, and aggregation
 - The goal of this system will be to increase access to and use of information and also to simplify the generation and sharing of regular reports, indicators, and ad-hoc analyses across service delivery sites, partners, and government institutions.
 - The system will increase transparency; provide more visibility across ART dispensing sites, including real-time information on ARV medicine stocks-on-hand; utilize dashboards to monitor site performance metrics, stock status, and patient loads; and provide valuable information to enable the UAC to justify the need for resources to meet scale-up targets, including for ARV procurement.
 - The system should utilize new technologies to enable data collection by using data forms, allow the importing of data with different formats (for example, Excel [xls], flat files [csv], or xml), and also permit the importing of data from different systems and databases. Figure 6 shows the proposed conceptual design for such a centralized data repository.
 - The system design should ensure that it is scalable (can accommodate increases in sites, patients, and partners), flexible (allows changes to data structures and in processes such as the quantity of ARVs dispensed), and modular (allow phased implementation). It is important to ensure that the development is done using open source tools and knowledge transfer from the vendor to the UAC to ensure sustainability of the system.
 - To further support sustainability, the UAC should be directly involved in the design, development, and implementation of the new system to build capacity within the institution.

- Given the importance of stakeholder commitment and coordination, the UAC should work with the State Service to establish a steering committee comprised of key stakeholders to ensure stakeholder needs are understood, their commitments are clearly defined, and met; prioritize functionality; manage “scope creep”; and steer this initiative forward.

With the approval of USAID and agreement from the UAC and the State Service, SPS could provide technical assistance to the UAC to support the development of the long-term strategy for managing information on HIV and to support the design and initial phase of implementation of the web-based central data repository. This support is discussed further in the next section.

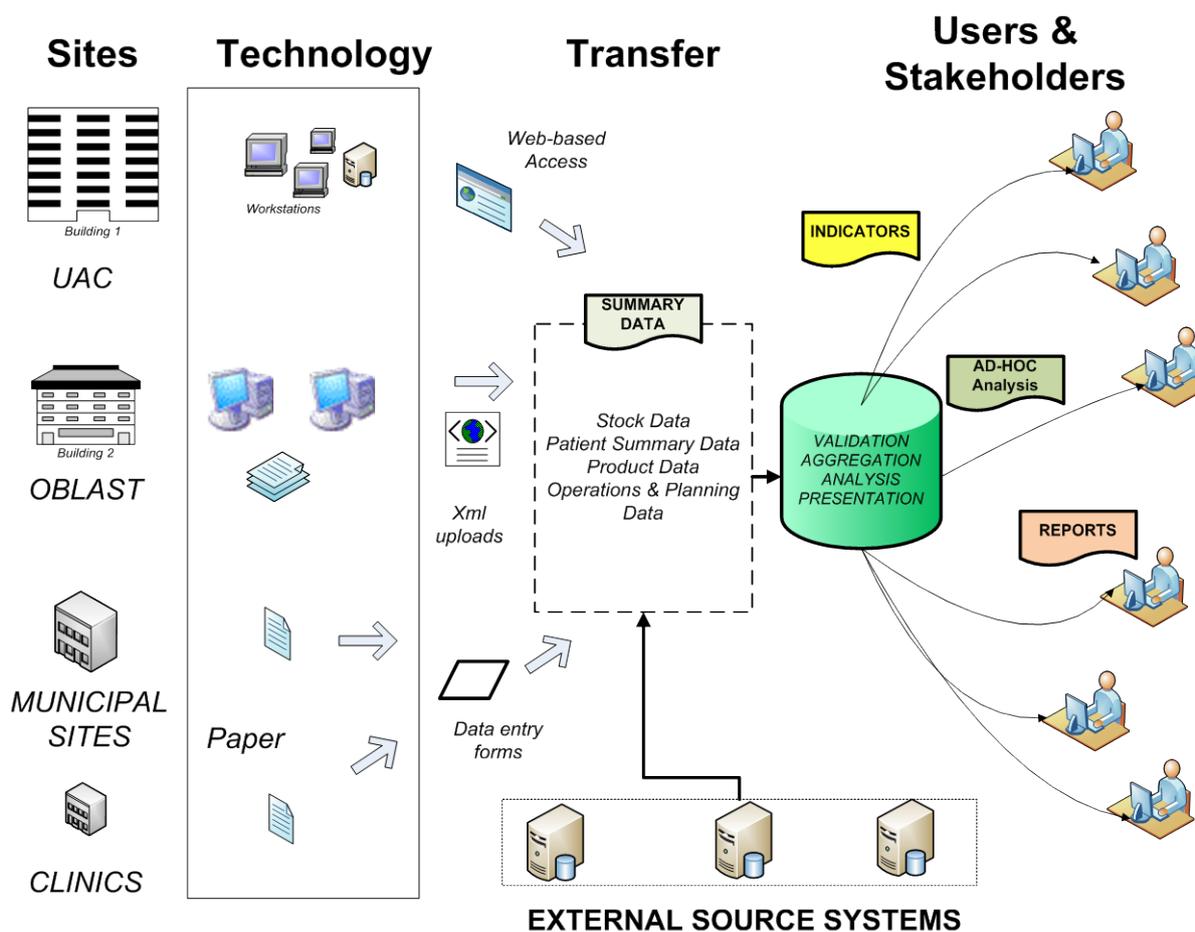


Figure 6. Proposed conceptual design for the centralized data repository

Additional central-level recommendations include—

- Explore opportunities to increase funding for ARV procurement in the immediate term to meet the needs of patients currently waiting to start ART.
- Explore the possibility of changing the distribution model from an annual delivery model to more frequent smaller deliveries throughout the year. More frequent re-ordering and delivery will allow sites more flexibility to respond to changes in patient

load and regimen profiles, improve stock management, and reduce the need for redistribution of excess or short-dated stock.

- Evaluate options for standardizing reporting formats and identify common data elements across programs such as HIV and TB, and donors to simplify reporting and information sharing.
- Develop job aids and work instructions to guide pharmaceutical management operations, reinforce best practices, and support on-the-job training.
- Although quantification is currently reported to be working well, as the scale-up of ART accelerates, this will result in an increase in the number of regimens in use and switching rates, and will require more complex demographic segmentation. A more sophisticated quantification process and tools will be needed to model these complex scenarios and derive an accurate forecast.

Facility-Level Recommendations

- The UAC and oblasts should evaluate options for introducing dispensing and inventory management software solutions at large sites (serving more than 1,000 ART patients per month) that are reaching the limits for effective paper-based systems. The software can help sites to better manage stocks, track patient adherence, and generate reports in addition to improving data quality and reporting timeliness.
- Plan and budget for the replacement of old computers that are sub-optimum for running the latest MS office products and web-based applications.
- Use Internet access to send digital reports in place of paper ones, where possible. Building in validation and aggregation rules will greatly reduce the time spent on these tasks at the oblast level.
- Implement strategies to improve data quality at decentralized sites, including more frequent supportive supervision and one-on-one training and mentoring.
- Strengthen communication between facilities to facilitate the redistribution of stocks within the oblasts. Strategies may include developing processes to share monthly reports on short-dated stocks and/or reports on impending stock-outs.
- Encourage staff to document and submit reports of adverse drug reactions. Reporters should be requested to report all events irrespective of their opinion about relatedness or unrelatedness to the medicine taken by the patient. Establish a process for staff to report suspected poor product quality.
- Identify additional storage space for ARVs and ART-related medicines and supplies at sites that are close to capacity.

NEXT STEPS

The next steps as agreed in meetings with the UAC and USAID are set out below.

The goal of the proposed SPS technical approach is to provide technical assistance to the UAC and other key stakeholders to develop interventions to strengthen data collection, analysis, interpretation, and use that enable evidence-based decision making for managing ART services and ARV medicine management at all levels of health system. SPS proposes to work with the UAC and partners to build capacity locally for designing, developing, implementing, and sustaining a locally appropriate system. The SPS approach is to capitalize and build on existing information systems and resources with the aim to put in place a workable system in 2–3 years that can serve as a platform for future expansion and development.

The follow up activities are—

- SPS will present a summary of these findings and recommendations for comment and feedback to the State Services and at the next Interagency Working Group meeting, if appropriate.
- SPS will then work with the UAC, the State Service, and other stakeholders to reach consensus on next steps.

With the approval of USAID, and pending agreement from stakeholders, the proposed initial activities for SPS support are to—

- Develop a long-term strategy for managing the information needs of the UAC, MoH, key partners, and stakeholders
- Define a strategy to develop a locally sustainable, centralized data repository that facilitates data triangulation and the synthesis and integration of information
- In conjunction with the UAC, hold a stakeholder meeting to discuss the strategy and incorporate stakeholder inputs to refine the strategy and ensure that it is locally relevant and responds to prioritized needs
- Work with the State Service and the UAC to convene a steering committee involving key stakeholders; work with the steering committee to outline the key functions and features of the system and to define the scope and anticipated SPS technical assistance
- Work with the key stakeholders/partners to develop high-level technical specifications for the proposed PMIS solution and project plan
- Begin developing module one of the PMIS based on a phased development plan agreed with partners and USAID

The illustrative timeline for the development of the locally sustainable, centralized data repository is set out in figure 7.

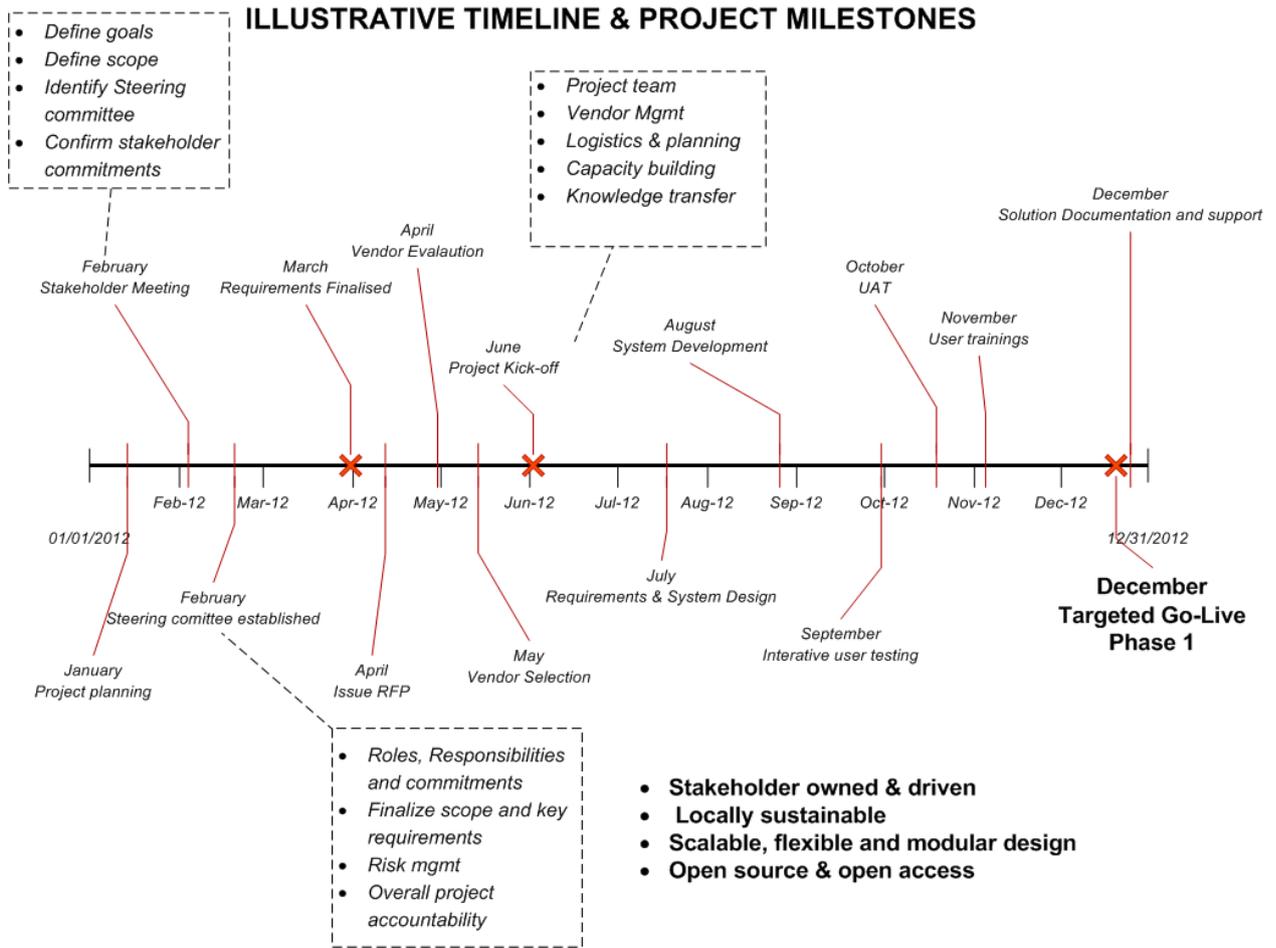


Figure 7. Illustrative timeline and project milestones

An important step of this activity is reaching agreement with stakeholders on the commitments, roles and responsibilities, scope, and strategy for developing the centralized data repository. This step is of particular importance, given the number of partners and the various information systems and data sources that will ultimately need to be linked together.

ANNEX 1. LIST OF PERSONS MET

USAID/Kyiv, Office of Health and Social Transition

- Alina Yurova, SPS AOTR
- Marina Blumina
- Judy Chen
- Tetiana Rastrigina
- Volodymyr Shevchenko
- Erica Vitek

UAC, Ministry of Health of Ukraine

- Natalia Nizova, Director
- Yulia Kordukova, Specialist, Treatment Department
- Yevgeniy Shyder, Databases Development Specialist
- Olexandr Zhyhinas, Deputy Head, Program Activities Monitoring and Evaluation Center

The State Service on HIV/AIDS and Other Socially Dangerous Diseases

- Olena Ieshchenko, Acting Head of the State Service
- Marina Zelenska, Head of HIV/AIDS Department of the State Service

The State Expert Center, Ministry of Health of Ukraine

- Olena Matvieieva, Head, Postregistration Surveillance Board

All-Ukrainian Network of People Living with HIV

- Nataliya Salabai, Head of Monitoring and Evaluation Team
- Lyudmila Shumylo, Senior Monitoring & Evaluation Specialist

Clinton Health Access Initiative

- Irina Grishayeva, Country Director

International HIV/AIDS Alliance in Ukraine

- Sergyi Filippovych, Associate Director, Treatment
- Vlad Volchkov, Health Products Manager
- Iryna Malykh, Head of Procurement and Supply Management Team

UNAIDS

- Ani Shakarishvili, Country Coordinator in Ukraine
- Alexey Ilitskiy, Monitoring & Evaluating Advisor

Lavra Clinic, Institute of Epidemiology and Infectious Diseases, Kyiv

- Svitlana Antonyak, Head of HIV Department, Hromashevsky Institute of Epidemiology and Infectious Diseases, National Academy of Sciences (Lavra Clinic)
- Konstantin Rakitko

Kirovohrad municipal center for AIDS prevention and control

- Valentyna Lazareva, Acting Chief Doctor, Infectious Diseases
- Valentyna Trivoy, Chief Accountant
- Natalia Trivoy, Economist

L'viv regional AIDS prevention and control center

- Mariana Sluzhynska, Acting Chief Doctor
- Oksana Kutynska, Chief Monitoring &Evaluating
- Olena Pavlyshyn, Doctor Infectionist
- Ivanka Svyst, Pharmacy Nurse
- Yuri Dasho, Doctor SMT

Odesa regional AIDS prevention and control center

- Stanislav Servetskiy, Chief Doctor
- Irina Soroka, Deputy Chief

Odesa municipal AIDS prevention and control center

- Vitaliy Novosvitny, Chief Doctor
- Victoria Ryhzkova

Crimea Republic AIDS prevention and control center (Simferopol)

- Yuliya Myhaylyk, Deputy Chief Doctor

Kyiv municipal center for AIDS prevention and control

- Oleksander Yurchenko, Chief Doctor, Kyiv City Clinic N 5
- Alina Kharytonyuk, Deputy Chief Doctor

ANNEX 2. LIST OF DOCUMENTS REVIEWED

Global Fund: Ukraine Grant Portfolio. Country Statistics and Grant Portfolio. Available at <http://portfolio.theglobalfund.org/en/Country/Index/UKR>

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UNAIDS 2009. *Comprehensive External Evaluation of the National AIDS Response in Ukraine*. Kyiv: UNAIDS. Available at http://www.un.org.ua/files/20090522_ee_en_5.pdf

ANNEX 3. UAC FLOW CHARTS: DATA COLLECTION FOR MEASURING M&E INDICATORS

