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TECHNICAL REPORT: ARV FORECAST METHODOLOGIES AND SOFTWARE FOR REPUBLICAN AIDS CENTERS IN KYRGYZSTAN, TAJIKISTAN, AND KAZAKHSTAN

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TECHNICAL REPORT: ARV FORECAST METHODOLOGIES AND SOFTWARE FOR REPUBLICAN AIDS CENTERS IN KYRGYZSTAN, TAJIKISTAN, AND KAZAKHSTAN

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The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development (USAID) or the United States Government.

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ACRONYMS

AFM	ARV Forecast and Management
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ELISA	Enzyme-linked Immunosorbent Assay
HIV	Human Immunodeficiency Virus
PLHIV	People Living with HIV
PR	Principal Recipient
QA	Quality Assurance
RAC	Republican AIDS Center
TB	Tuberculosis
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

From May 30 to June 18, 2011, the USAID Quality Health Care Project provided technical assistance to AIDS Centers in Kazakhstan, Kyrgyzstan and Tajikistan to improve ARV forecasting methodologies. A five-day, on-the-job training course was provided for staff working in Republican AIDS Centers, the Dushanbe AIDS Center in Tajikistan and the Almaty AIDS Center in Kazakhstan on the use of ARV Forecast and Management (AFM) software.

Topics covered during the training:

- A review of the National HIV diagnostic algorithms and National Reference Laboratory's monthly capacities in Kyrgyzstan, Tajikistan and Kazakhstan.
- A retrospective analysis, for the last 3 years, on the numbers of tests performed and the number of HIV confirmed cases. This indicated the average number of HIV cases that were diagnosed and their seasonal occurrence. Data were reviewed on the percentage of patients who required ART at their time of diagnosis. Training participants were shown how data on newly diagnosed patients could help forecast the percentage of patients who would have indications for treatment.
- A review of national PLHIV registration data was performed, to show how to forecast, from those who are on follow up, the number of patients who have indications for treatment. The ability to generate data on patients, disaggregated by follow-up groups, stages of HIV infection and CD4 cell counts was discussed.
- In addition to reviewing and analyzing data, the training participants installed, customized and input data using the AFM software.
- At the end of the trainings, participants undertook modeling of ARV forecasting for their country. In the Almaty AIDS Center, trained specialists used the AFM software to draft an ARV forecast for the period of January 1, 2012 to June 30, 2012. Specialists from the Kyrgyzstan AIDS Center prepared a draft ARV forecast for the period of January 1, 2012 to June 30, 2012 and submitted it to the Principal Recipient (PR). The PR then suggested that the Quality Health Care Project specialist review the forecasted quantities of ARVs and recommendations were made for finalizing an ARV order.

Findings and recommendations

1. While all three countries do ARV forecasting in some form, calculations of ARV consumption is not managed systematically to quantify and forecast ARV demands.

It is highly recommended that:

- A drug management system is adopted which shows the number of forecasted patients on treatment during a defined period of time, disaggregated by their ART regimens and by the time of their ART initiation, to allow for the accurate forecasting, management and monitoring of ARV consumption.
 - That Republican AIDS Centers in Kyrgyzstan and Tajikistan share information on ARV forecasting with oblast and rayon-city AIDS centers, and staff in the peripheral AIDS centers are appropriately trained on controlling ARV stocks.
2. A lack of ARV tab pediatric formulations, in the three countries, limits the choice of ART regimens available for children who need to be switched from liquid to tab formulations.

It is recommended to:

- Revise the range of ARVs procured and to ensure the inclusion of ARV tab pediatric formulations to ensure the availability of quality antiretroviral treatment.

3. Organize roundtable meetings with the parties responsible for ARV forecasting and procurement, to facilitate effective communication and collaboration. A workshop for specialists responsible for ARV procurement on AFM software and forecasting is also recommended.
4. Review the system of centrally warehousing and distributing ARVs in Kyrgyzstan and Tajikistan, to ensure that AIDS Centers receive the ARVs that are designated to them. Using the AFM software will support the effective management of ARV stocks in a central warehouse.

1. OBJECTIVES

- Provide on-the-job training for the staff of Republican AIDS centers in Kyrgyzstan, Tajikistan and Kazakhstan on ARV drug forecasting and ARV stock management, in order to avoid treatment interruptions and to increase adherence.
- Install software and train staff on the use of the ARV forecasting and management (AFM) software in Republican AIDS Centers in Kyrgyzstan, Tajikistan and Kazakhstan.

I.1 EXPECTED OUTCOMES

The introduction of country specific ARV forecasting and management systems in Kyrgyzstan, Tajikistan and Kazakhstan will be undertaken in stages.

First stage – Introduce and install AFM software in the Republican AIDS Centers in Kyrgyzstan and Tajikistan and in Almaty AIDS Center in Kazakhstan. Provide on-the-job job training for staff at these centers.

- The utilization of AFM software will allow for the proper management of ARV stock in medical institutions and improve the system of ordering and prescribing ARVs. AFM software will help prevent unexpected stock-outs and stock wastage because of drugs expiring; prevent the uncontrolled use of ARV stock; assist in forecasting quantities of ARV stock and improve the efficiency and time required forecasting ARV supplies.
- AIDS center staff who participate in the training, will understand how to collect the data needed and to estimate the number of patients likely to require ART initiation.

Follow up and evaluate the usage of the software by the AIDS Centers at the end of Stage One. If implementation has been successful, discuss with the Principal Recipient and national stakeholders, how to expand the system nationally.

Second stage:

- All staff who are responsible for ARV provision in the three countries' AIDS Centers are trained, are able to estimate the number of patients requiring ARV initiation, and can forecast their ARV stock needs.

I.2 GOALS

- To accurately forecast ARV quantities so they reflect patients' needs.
- Consumption of ARVs in countries, that utilize the software will become controlled and used for quantification in order to maximize therapeutic benefit and cost-effectiveness.
- To minimize overstocking and overspending on ARVs by implementing the AFM software system.
- To significantly reduce ARV wastage, because stock has reached its use-by expiry date.

Direct benefits for PLHIV will be:

- ✓ A reduction in interruptions to patients' antiretroviral treatment because of ARV stock outs.
- ✓ Improved adherence and adherence support by physicians.
- ✓ More people with advanced HIV receiving treatment: without increasing funds for ARV procurement.
- ✓ The extension in the use of first-line treatments at 6, 12 and 24 months after initiation.
- ✓ Increased time of survival at 6, 12, 24, 36, etc. months after initiation of treatment

2. ARV FORECAST AND MANAGEMENT SOFTWARE

The basic Russian version of the ARV Forecast and Management Software (AFM) was introduced and installed in the Republican AIDS Centers of Kyrgyzstan and Tajikistan and in Almaty AIDS Center in Kazakhstan. Specialists responsible for ARV forecasting, stock management and distribution were trained in the use of the software.

The software allows planners to calculate quantities of ARVs to be procured: taking into account what is available in stock and what has already been given to patients. If unit prices are entered, the AFM software calculates the cost of the drugs that have been ordered.

The software is equipped with three types of adjustable alarm systems to alert users to:

- ✓ **The time to initiate an ARV forecast and place an order,**
- ✓ **To place an emergency order if stocks of a particular drug are running low,**
- ✓ **To warn that a patient is about to run out of his/her drugs, so they can be contacted to let them know they need to pick up more ARVs.**

Manager-level control of the software protects the database and stock against undesirable changes or errors that might be made by users.

After completing the forecast process, the calculations (the number of patients by ARV regimens and ART initiation by months) can be exported into Excel and printed. This allows physicians to follow their patients' use of ARV by time and regimen and follow the schedule they have prescribed for their patients.

Approved forecast results easily can be printed out as an ARV order that can be presented for procurement.

AFM software allows users to generate up-to-date reports on:

- ✓ **The quantity of drugs in an institutions' warehouse,**
- ✓ **The number of patients on each regimen.**

However, there are some limitations in the basic version of the AFM Software: it does not monitor the expiry period of drugs in the central warehouse, as it only manages the stock in the institution where it is installed.

3. FINDINGS AND RECOMMENDATIONS

3.1 KYRGYZSTAN

Findings

1. There is a lack of up-to-date data for:
 - The number of newly diagnosed patients who have indications for immediate ART initiation at the time of receiving their HIV diagnosis,
 - The number of patients by HIV stages or by follow up groups,
 - The number of children on ART by age groups (this is necessary to accurately calculate quantities of syrups and the time to shift to tab forms of ARVs),
 - The number of patients on each ART regimen, by oblast.
2. AIDS Center staff were unable to present the calculations for their last ARV forecast for the period: July 1, 2011 – December 31, 2011. The lack of this data will affect the accuracy of the next forecast period: January 1, 2012 - June 30, 2012, which should be completed by end June 2011.
3. The physicians responsible for ART initiation in the Republican AIDS Center did not know:
 - The quantity of ARVs in stock,
 - The period of time for which the stock had been calculated,
 - The number of patients for whom the stock was calculated, by ART lines and regimens,
 - The approximate shipment date for the most recently ordered ARVs.

Given that this was the case for the Republican AIDS Centers, it is likely that responsible staff at Oblast AIDS Centers are also operating without this information.

4. The stock of ARVs in the Republican AIDS Center was not managed efficiently. The Republican AIDS Center is responsible for managing ARV stock for 8 AIDS centers. The existing system of managing the stock will not prevent stock outs (which is likely given the quantities of some ARVs) or overstocking and expiry of ARVs.
5. The calculation of national data for the number of patients needing treatment, the quantity and type of ARVs to be procured are calculated by the Republican AIDS Center, without consultation with physicians working in the regions. They do not seek out information from the doctors who are responsible for following up patients on their plans for changing the drugs or regimes (due to side effects etc.).
6. The data for children is calculated for age range 0-18 years, which makes it almost impossible to accurately forecast pediatric formulations (ARV dosages for children aged above 6 years or >35kg are the same as for adults).

Recommendations

Generally, forecasts that are based on demographic, morbidity or target data alone, will tend to overestimate drug requirements because they do not take into account the actual volume of services being provided, or the quantities of commodities being dispensed.

- Incorporate data on the actual number of patients being treated, the actual quantities of drugs dispensed and the actual quantities of commodities used into the forecast.
- Collect and analyze crucial information (on the number of HIV positive people requiring treatment and the quantities and type of ART needed) to monitor and forecast effectively. (Training participants affirmed that collecting such information would be feasible and required little additional effort).

Excel templates were developed and presented to training participants for the collection of the following data:

1. The number of tests performed in the Republic and the number of people tested (these figures exist but had not been analyzed). It is recommended that monthly data collection be added to the template in order to analyze curve trends and seasonality.
2. The number of HIV diagnosed cases and the number of diagnosed patients who have indications for ART initiation. Such data will allow for estimations (from those who've been diagnosed) on the number of expected patients needing ART in the future. It is recommended that this data be collected at the end of each month.
3. The number of patients by follow-up groups, subdivided by those on ART. If possible, make differentiation of subgroups by CD4 cell counts. It is recommended that this data be collected every quarter.
4. The number of children on ART by age groups in order to accurately calculate quantities for children's formulations and process for shifting from adult to child formulations of ARVs.
5. The number of patients on each ART regimen by oblast.

Having all these data will make it possible to apply a combination of morbidity-based¹ and adjusted consumption methodologies² to forecast the estimated number of patients requiring ART. The initial choice of ARV regimens is influenced by many factors, for example, a patient's previous ARV drug history, co-existing infections or conditions, provider prescribing patterns and drug availability. Drugs within a regimen can be adjusted periodically, based on the changing needs of patients such as side effects; changing body weight; pregnancy or pregnancy planning; HIV/TB co-infection; treatment failure and drug resistance. Regimens can also be changed to meet the special needs of pediatric patients. Forecasts also need to account

¹ In the *morbidity-based methodology*, the estimation of commodity needs is based on the application of standard treatment guidelines, testing algorithms, or other treatment protocols to the projected number of patients expected to receive treatment or services within the forecast period. The projected number of patients to be forecasted may be based on demographic data, morbidity data, service statistics data, program targets, or a combination of those data.

² The adjusted consumption methodology is an adaptation of the consumption-based methodology that uses the consumption data of one or more facilities that have reliable data and extrapolates from that data to estimate the quantities of commodities needed at other, similar facilities for which no data or unreliable data exist. Again, this methodology requires the availability of timely and accurate consumption data on quantities of drugs dispensed to patients or quantities of commodities used at one or more service delivery sites.

for patients on non-standard ARV drug regimens, such as patients who are not treatment-naïve, or may have entered the program already on ART, as well as patients on individualized salvage therapy.

It is recommended to conduct ARV forecasting and procurement reviews every 6 months. A timetable for ARV forecasts, orders and deliveries was drafted and presented to the Global Fund PR.

Challenges

Current challenges to the efficient management and forecasting of ARV stock are: high staff turnover, a lack of experienced personnel and the low capacity of trained staff at the Republican AIDS Center. Forecasting for the current period appears to have been particularly ad-hoc, with little attention paid to real need, or to what was already in stock.

Additional Findings

While the findings and recommendations presented below, relating to HIV diagnostics in Kyrgyzstan, are not directly linked with the objectives of this consultancy; they *do* have an impact on accurately estimating new HIV cases and forecasting ARV stock.

For the period: January 1, 2010 – April 31, 2011, 1,258 HIV confirmatory tests were performed in Kyrgyzstan and 801 of them were eventually identified as being HIV positive³ (63.7%). Monthly observations revealed some lower values, 25% in May 2010 and some higher values, 100% in October 2010. So approximately 4 people out of 10 had false positive results based on initial ELISA testing.

In general the first assay should have the highest sensitivity, whereas the second and third assays should have a similar or higher specificity. As assays have continued to improve in terms of quality and performance, it is now common that the assays used, have high sensitivity and specificity. The number of initially discordant results should not exceed 5%. If it does, quality assurance procedures should be checked and/or a new testing algorithm should be validated and adopted.

A large study of HIV testing in 752 U.S. laboratories reported a sensitivity of 99.7% and specificity of 98.5% for enzyme immunoassay, and studies in U.S. blood donors reported specificities of 99.8% and greater than 99.99%. With confirmatory Western blot, the chance of a false-positive identification in a low-prevalence setting is about 1 in 250 000 (95% CI, 1 in 173 000 to 1 in 379 000).

The specificity rate given here for the enzyme immunoassay screening test, indicates that out of 1,000 positive HIV test results, about 15 of these will be a false positive. Confirming the test result (i.e., by repeating the test, if this option is available) could reduce the likelihood of a false positive to about 1 out of 250,000 tests.

Additional Recommendations

External consultancy and support is needed to review and assess the supply of HIV laboratory test kits including: product selection, transportation, warehousing, distribution to laboratories and storage condition at final destination.

³ Data provided by Kyrgyzstan Republican AIDS center.

In order to guarantee reliable and quality HIV test results, there is a need to introduce quality assurance (QA) procedures for specimen collection, testing, reporting and utilization of obtained data.

3.2 TAJIKISTAN

Findings

1. Monthly updated data from Oblast/Rayon AIDS Centers are collected and analyzed regularly by the Tajikistan Republican AIDS Center. Reporting forms from the Republican AIDS Center's follow up department contains the following information that will allow for the forecasting of new patients requiring ART and ARVs quantification:
 - Data on the number of patients that have indications for ART initiation at the time of receiving their HIV diagnosis. This data is necessary for forecasting the number of diagnosed patients who will need ART.
 - The number of patients who are in follow up groups, disaggregated by HIV stages and CD4 cell count. These data are necessary for forecasting the number of patients who will need ART from those who are on follow up.
 - The number of children on ART disaggregated by age groups and by ART regimens. These data are necessary for accurate quantification of liquid and tab ARV formulations.
 - The data on the number of patients on ART disaggregated by ART lines, regimens, and institutions where they receive treatment. These data are necessary to accurately forecast the number of patients and quantification of ARVs and to prepare distribution lists.
2. Patient forecasting and ARV quantification is done by specialists in the Republican AIDS Center based on retrospective analysis of data and modeling the numbers for the Oblast/Rayon/City AIDS Centers.
3. Despite the well-implemented mechanism for forecasting the number of patients who will need ART, there is limited information flow from the Republican AIDS Center to the Oblast/Rayon/City AIDS Centers. This makes it difficult for specialists working at the lower levels to see how ARV stock quantities have been calculated and be able to manage their stock consumption.
4. A review of the last ARV order, presented by AIDS Center specialists, revealed that in some cases there are discrepancies between the number of ARVs ordered and those that are supplied. Any changes in quantities, dosages and packaging of drugs, without consulting with the specialists responsible, will create difficulties in distributing the drugs; in choosing an ART regimen for new patients and will increase the likelihood of drugs being wasted.
5. A lack of ARV tab pediatric formulations in the drugs that are procured limit options for ART regimens for children who need to be switched from liquid to tab formulations.
6. ARV drugs are distributed from the central warehouse to follow up departments in health institutions and then to patients. Physicians who work in the follow up departments manage ARV stock levels and expiry dates: there is no pharmacy in the institutions.

Recommendations

The system in the Tajikistan Republican AIDS Center for forecasting the number of patients who will need ART is well organized. The necessary data for accurate stock forecasts are collected and analyzed. The recommendations presented below mostly relate to ARV quantification, procurement, storage and distribution.

1. It is strongly recommended that all the data related to patients' forecasts and ARV quantification be shared with the specialists at the Oblast/Rayon/City AIDS Centers. Information shared should include each AIDS Center's calendar for putting patients on ARVs, in order allow specialists to manage consumption of the drugs.
2. Assess and revise the current system of storing and distributing ARVs so that it is a unified, efficient system. In the current system, Oblast AIDS Centers receive part of their ARVs from a central warehouse and part from the warehouse of the Republican AIDS Center: such a system makes stock control and distribution difficult.
3. Discuss with national stakeholders the possibility of including a pharmacist in the staff of AIDS Centers and establishing pharmacies in AIDS institutions. This would enable patients to receive their ARVs from the institution's pharmacy and the pharmacist would control and manage stock, reducing the likelihood of wastage and expiring drugs.
4. Revise the range of ARVs being procured and increase the range of drugs being ordered, including tab pediatric formulations to ensure quality antiretroviral treatment.
5. Organize a roundtable meeting with the parties responsible for ARV forecasting and procurement, to facilitate effective communication and collaboration.
6. A workshop for specialists responsible for ARV procurement on AFM software and forecasting is also recommended.

3.3 KAZAKHSTAN

Findings

1. Forecasts for patients and ARV quantification in Kazakhstan is done by AIDS Centers at the oblast level. ARVs for AIDS Centers are paid for under the budget of the oblast health care departments. However, these figures are reported and analyzed at the central level by specialists from the Republican AIDS Center. Using this system of planning and forecasting for ARV stock in the Republic means that data are generated at the peripheral level and then aggregated at the central level by the Republican AIDS Center. Such a process allows the specialists responsible for antiretroviral treatment to be more flexible and accurate when they calculate their ARV orders.
2. The implementation of “electronic surveillance” through the ARV forecasting software in the country will allow specialists responsible for ARVs forecasts to obtain the data needed to accurately calculate ARV stock.
3. The range of ARV tab pediatric formulations are limited in the country so physicians’ options in choosing regimens and switching from liquid to tab formulations are restricted.

Recommendations

1. Discuss with national stakeholders the possibility of including a pharmacist in the staff of AIDS Centers and establishing pharmacies in AIDS institutions. This would enable patients to receive their ARVs from the institution’s pharmacy and the pharmacist would control and manage stock, reducing the likelihood of wastage and expiring drugs.
2. Revise the range of ARVs being procured and increase the range of drugs being ordered, including tab pediatric formulations to ensure quality antiretroviral treatment in the country.
5. Explore and discuss mechanisms for ARV stock to be transferred from one Oblast AIDS Center to another, if drugs are urgently required. This will protect against stock outs and wastage due to drugs expiring.
3. Analyze and maximize use of large spectrum of data from all AIDS Centers to ensure increased accuracy of the forecasting process of the number of patients for whom quantification of ARVs drugs will be done.

2. ANNEX 1: TRAINING SCHEDULE

Training Schedule

Kyrgyzstan: May 30 - June 3, 2011

Tajikistan: June 6 -10, 2011

Kazakhstan: June 13 – 17, 2011

Day 1		
09:00-13:00	<ul style="list-style-type: none"> - Review of National HIV diagnostic algorithms and mechanisms - Review of National statistical data and mechanisms related to PLHIV registration (numbers, sex, age groups, etc.). - Number of PLHIV available on follow up - Review of existing methodologies on estimation of PLHIV numbers in the country 	Aram Manukyan, National Consultant and training participants
13:00-14:00	Lunch	
14:00-18:00	<ul style="list-style-type: none"> - Review of reference laboratory's capacities (monthly) and number of tests performed monthly during the last 2-3 years - Retrospective analysis for 2-3 years of the number of tests performed vs. HIV confirmed cases, number of confirmatory tests performed vs. HIV confirmed cases - HIV early diagnosed cases 	Aram Manukyan, National Consultant and training participants and RAC lab staff
Day 2		
09:00-13:00	<ul style="list-style-type: none"> - Analysis of PLHIV "dispenser" groups on follow up (numbers, age groups, existence of planning mechanisms and timeline for patients follow up, observation and testing) - Review of existing ARV drugs in stock 	Aram Manukyan, National Consultant and training participants + RAC pharmacist or person in charge of institution pharmacy/ARV stocks
13:00-14:00	Lunch	
14:00-18:00	<ul style="list-style-type: none"> - Review and analyze drug distribution mechanisms from institution pharmacy - Review of existing and preferred ARV regimens and number of patients on ART by ARV regimens - Mechanisms for selection of ARV regimens (National guideline vs. practice) 	Aram Manukyan, National Consultant and training participants + RAC pharmacist or person in charge of institution pharmacy/ARV stocks
Day 3		
09:00-13:00	<ul style="list-style-type: none"> - Software installation and calibration 	Aram Manukyan, National Consultant and person who will manage this software at Republican AIDS

		Center
13:00-14:00	Lunch	
14:00-18:00	- Basic data input	National Consultant and person who will manage this software at Republican AIDS Center under supervision of Aram Manukyan
	- Drafting recommendations for synchronizing ARVs management and distribution processes	Aram Manukyan and National Consultant
Day 4		
09:00-13:00	- Basic data input	National Consultant and person who will manage this software at Republican AIDS Center under supervision of Aram Manukyan
	- Drafting recommendations for synchronizing ARVs management and distribution processes	Aram Manukyan and National Consultant
13:00-14:00	Lunch	
14:00-15:30	- Presentation discussion and finalization of recommendations	Aram Manukyan, National Consultant and training participants
15:30-18:00	- Software introduction	Aram Manukyan
Day 5		
09:00-13:00	- Practical training (modeling situation, running software, forecasting and ARVs order preparation) - Answers and questions	Aram Manukyan
13:00-14:00	Lunch	
14:00-17:00	- Practical training (stock management, patients management, adherence control, preparation of reports)	Aram Manukyan
17:00-18:00	- Vision of further developments and expectations	National consultant and training participants

ANNEX 2: BIBLIOGRAPHY

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