The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Office of the Inspector General

Diagnostic Review of Global Fund Grants to the Republic of Azerbaijan

GF-OIG-13-007
13 March 2013

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A. EXECUTIVE SUMMARY

A.1 Introduction

1. This diagnostic review of the Global Fund grants to the Republic of Azerbaijan sought to identify and share good practices, identify key risks to which the grant programs were exposed, and make recommendations for risk mitigation. It took place from 26 September to 24 October 2012.

Four grants audited

USD 40.9 million disbursed

2. The review covered four active grants with total budget of USD 43.8 million of which USD 40.9 million had been disbursed. The Ministry of Health implemented three grant programs (HIV, TB and malaria) while the Ministry of Justice implemented one TB grant program focusing on the penitentiary sector.

Steady increase in government funding

Progress towards malaria elimination

Gap in treatment of MDR- and XDR-TB

3. The diagnostic review team observed good practices in grant implementation. These included a steady increase in government funding for the three programs, a comprehensive TB control program in prisons with a strong DOTS component and an effective national malaria control program which, has made progress towards malaria elimination through active screening and operational research studies on malaria that guided program implementation. Notwithstanding this, a number of risks were identified that may impede the successful outcome of grant programs unless mitigated. In particular, the review found a gap in the provision of treatment for multi-drug-resistant and extensively drug-resistant tuberculosis in the general population.

A.2 Key Mitigating Actions Agreed Upon

Mitigating actions agreed upon by stakeholders

4. In response to risks in the areas of program design, implementation and monitoring, the relevant stakeholders have agreed to:

(i) Develop financial sustainability plans for HIV and TB programs;
(ii) Update the national disease strategies, protocols and guidelines in line with WHO standards;
(iii) Prioritize the implementation of harm reduction interventions such as opiate substitution therapy;
(iv) Take measures to improve access to and quality of service delivery in the three disease programs;
(v) Develop and/or update standard operating procedures for laboratories and implement internal and external quality assurance; and
(vi) Finalize the TB monitoring and evaluation plan to improve quality of data.

Harmonizing procurement practices

Implementing quality assurance of pharmaceuticals

5. With regard to procurement and supply chain management, the relevant stakeholders have agreed to harmonize procurement practices in the three grants managed by the MOH, seek to secure lower prices for reagents by enhancing competition, and, in conjunction with the National Drug Regulatory Authority, develop, adopt and implement a quality assurance system for pharmaceuticals and health products.

B. MESSAGE FROM THE EXECUTIVE DIRECTOR OF THE GLOBAL FUND

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11 March 2013

Norbert Hauser
Inspector General
Office of the Inspector General
The Global Fund
Chemin de Blandonnet 8
1214 Vernier
Geneva
Switzerland

Subject: Diagnostic Review of the Global Fund Grants to the Republic of Azerbaijan

Dear Norbert

I would like to thank the Office of the Inspector General (OIG) for its thorough and insightful work on the diagnostic review of the Global Fund grants to the Republic of Azerbaijan.

The reviewed was carried out in September and October 2012 and covered four grants totaling US$ 43.8 million, of which US$ 40.9 million had been disbursed.

A diagnostic review is different from a country audit in that no overall opinions are provided and no assurance is given as to how grant funds were spent.

The diagnostic review team identified examples of good program management and practices, such as implementation of mobile laboratories with HIV testing for most at risk populations (MARPS) and decentralization of ART services, which is in process.

The review also observed a steady increase in government funding for the HIV, TB and malaria programs, a comprehensive TB control program in prisons and an effective national malaria program, which has made progress towards malaria elimination.

However, a number of risks were identified that may prevent the successful outcome of grant programs unless mitigated. The review found a gap in the provision of treatment for multi-drug-resistant (MDR) and extensively drug-resistant tuberculosis (XDR) in the general population.

A total number of 811 MDR/XDR patients were diagnosed in 2011, with only 592 enrolled in the treatment program with the Global Fund Round 7 grant support. This gap could be even higher, given that the estimated number of MDR-TB cases was more than 2,000 per year. Azerbaijan has the third highest MDR-TB rate worldwide.

Other risks identified by the Office of the Inspector General included: financial stability of national programs at the conclusion of the Global Fund grants; the appropriateness of national disease strategies in light of international guidance; quality of services and monitoring and evaluation.

The review team also observed significant unmet demand for opiate substitution treatment among injecting drug users, who are the main driver of the HIV epidemic in Azerbaijan. In response to risks identified in the review, relevant stakeholders have agreed to: develop sustainability plans for HIV and TB programs; update national disease strategies and guidelines in line with WHO standards; prioritize implementation of harm reduction interventions; improve access to and quality of service delivery in the three disease programs and finalize the TB monitoring and evaluation plan to improve quality of data.

With regard to procurement and supply chain management, the relevant stakeholders have agreed to harmonize procurement practices in the three grants managed by the Ministry of Health, seek to secure lower prices for reagents through enhanced competition and develop as well as to adopt a quality assurance system for pharmaceuticals and health products in conjunction with the National Drug Regulatory Authority.

Diagnostic reviews by the Office of the Inspector General are an essential form of quality control for the Global Fund. The Office of the Inspector General plays an indispensable role in helping us all achieve our mission of effectively investing the world's money to save lives.

Yours sincerely,

C. MESSAGE FROM THE COUNTRY COORDINATING MECHANISM

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Azərbaycanda səhiyyə sahəsində
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Ministry of Health

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06/18 **February 8, 2013**

Mr. Norbert Hauser
Inspector General
The Global Fund
Chemin de Blandonnet 8, 1214 Vernier
Geneve, Switzerland

Dear Mr. Norbert Hauser,

The Country Coordinating Mechanism on International Health Programs in Azerbaijan (CCM) hereby expresses its deep gratitude to the Office of the Inspector General of the Global Fund for its great contribution on successful implementation of the HIV, TB and Malaria programs in Azerbaijan Republic.

With the help of The Global Fund, the country could make significant improvements in fighting three diseases in the last years. Azerbaijan has expanded programs for HIV prevention and has achieved to provide anti-retroviral treatment for the people living with HIV. Tuberculosis program in the country has been strengthened and drug-resistant TB patients have been taken into strict control. The Malaria program has been successful and country is close to the elimination of this disease.

The diagnostic review mission of the OIG conducted September 26, 2012 to October 24, 2012 was helpful in preparing key findings of the Global Fund programs in Azerbaijan and their valuable recommendations will be certainly taken into consideration and implemented with a view to increase the efficiency of programs carried out in the country.

Once more, we express our deep gratitude to you and OIG team for their constructive visit to Azerbaijan and commitment to fight against HIV, Tuberculosis and Malaria and we wish to continue our fruitful cooperation in the future.

Yours sincerely,

Soltan Mammadov

Vice-Chair of CCM

D. INTRODUCTION

Diagnostic review different from audit

6. As part of its 2012 plan, the Office of the Inspector General (OIG) undertook a diagnostic review of the Global Fund grants to Azerbaijan. This review sought to:

- Identify and share good practices; and
- Identify and report the key risks to which Global Fund grant programs were exposed, and make recommendations for risk mitigation.

No overall opinion or assurance provided

Multi-skilled team deployed in Baku and on field visits

7. A diagnostic review is different from a country audit in that no overall opinions are provided and no assurance is provided regarding how grant funds were spent. The team for the diagnostic review included technical experts in public health, financial management and procurement and supply chain management (PSM). The fieldwork for the diagnostic review was conducted from 26 September to 24 October 2012.

Review covered four active grants

8. Of the six grants made to Azerbaijan since 2005, the review covered the four active grants which totaled USD 43.8 million, with USD 40.9 million disbursed at the time of the review. The review focused on the following.[1]

USD 40.9 million disbursed

Disease	Grant Number	Total Grant Amount (USD)	Total Disbursed to October 2012 (USD)
TB[2]	AZE-708-G03-T	21,733,838	19,365,077
Malaria	AZE-708-G04-M	5,336,687	4,798,445
HIV	AZE-910-G05-H	14,292,973	14,292,973
TB	AZE-910-G06-T	2,455,175	2,455,175
	Total	**43,838,673**	**40,911,670**

Negotiations for Phase 2 of Round 9 grants for HIV and TB were in progress

9. At the time of the review, negotiations for Phase 2 of the Round 9 grants for HIV and tuberculosis were ongoing. Further, a request for continuity of essential services for TB under the Transitional Funding Mechanism of the Global Fund had been submitted by the CCM.

Low HIV prevalence country

Injecting drug use prime driver

10. Azerbaijan is a low HIV prevalence country (0.036% in the general population).[3] Injecting drug use is the prime driver of the HIV epidemic in Azerbaijan. In 2011, 62.8% of all cases of HIV infection were among Injecting Drug Users (IDU). The number of registered people living with HIV (PLHIV) was 3,600. In October 2012, 814 PLHIV were receiving ART.[4]

[1] Global Fund website, October 2012.
[2] The grant amounts are denominated in EUR and translated at the rate applicable at the specific date.
[3] Global AIDS Response Progress Report, Azerbaijan, 2012.
[4] Azerbaijan National AIDS Center data (01 October 2012).

Decentralization of antiretroviral treatment started

11. Decentralization of antiretroviral treatment services was initiated in May 2012 with the establishment of treatment centers in six out of twelve regions.

Third highest MDR-TB rate worldwide

12. The estimated incidence of all TB cases was 110 per 100,000 population.[5] During 2010, a total of 6,390 TB patients were notified (notification rate 70 per 100,000 population; case detection, all forms was 63%). The TB prevalence in prisons was estimated at over 4,000 cases per 100,000 prisoners. Azerbaijan is also among the 27 high multi-drug-resistant (MDR) TB burden countries in the world, with the third highest MDR-TB rate worldwide.

Decrease in reported malaria cases

13. There has been a steady decrease in the number of reported malaria cases from 48 cases in 2010 to two autochthonous cases in 2012 up to the time of the review. The country has developed and adopted a national Malaria Elimination Strategy and an action plan for the period 2008-2013.

14. Given the pending discontinuation of donor health programs[6] in the country, the government had been encouraged by donors to increase its funding for the national programs for the three diseases. The government has responded positively by increasing funding to support the purchase of anti-TB medicines, laboratory reagents and medicines for opportunistic infections.

[5] Global TB Control 2011, WHO report.
[6] Donors leaving the country in 2013 include USAID and the World Bank. The Open Society Institute already left in 2012.

E. GRANT IMPLEMENTATION

Principal Recipients are the Ministries of Health and Justice

15. The Principal Recipients (PRs) for Global Fund grants to Azerbaijan were the Ministry of Health (MOH) and the Ministry of Justice (MOJ). The MOH managed its three grant programs (HIV Round 9, TB Round 7 and Malaria Round 7) through the MOH Project Implementation Unit (PIU), led by a director assisted by coordinators and contracted specialists for monitoring and evaluation (M&E), procurement, and finance management.

Implementation through Sub-Recipients

16. The MOH PIU implemented the HIV, TB and malaria grant programs with technical support from three sub-recipients: The National AIDS Center (NAC), the Research Institute for Lung Disease and the National Hygiene and Epidemiology Center.

17. The MOJ implemented its grant program through a PIU led by a director assisted by a coordinator and contracted specialists in program management, monitoring and evaluation, procurement and financial management. The Main Medical Department of the MOJ implemented the program.

Distribution of health supplies by the Central Medical Stores

18. Medicines and health supplies (ARVs, first and second-line anti-TB drugs, LLINs, condoms and laboratory reagents) were procured by the MOH PIU procurement team and delivered directly to the national programs, which were responsible for distribution to health facilities.

19. Government-financed medicines and health supplies were procured and distributed to health facilities by the Central Medical Stores of the MOH (the "Innovation and Supply Center"). In addition, the government had financed laboratory reagents for TB and HIV testing, laboratory equipment, ARV medicines, and a proportion of the drugs for opportunistic infections.

25 local NGOs implemented harm reduction activities

20. A group of 25 local non-governmental organizations (NGOs), under the umbrella of the Open Society Institute—Assistance Foundation (OSI-AF) implemented harm reduction activities under the HIV program as SSRs. The NGO Support to Health was an SR that supported the MOJ TB program in its follow-up of MDR-TB patients after their release from prison.

Bank accounts maintained in EUR

21. Both PRs operated one bank account for each grant, denominated in EUR. The banks accepted payment requests in local currency from the PRs at the prevailing exchange rate on the date of the transaction. Joint signatories were required for disbursements.

Grants exempted from VAT

22. The grant programs were exempt from value-added tax.

23. The MOJ indicated that they applied the procurement regulations of the National Procurement Law (January 2002). The MOH used its own Program Operations Manual, approved by the Global Fund Secretariat and endorsed by the State Procurement Agency, to regulate procurement.

PR provided oversight over SRs

CCM strengthened through technical support from GMS

CCM also provided oversight over other health programs

24. In accordance with the Global Fund model, the Country Coordinating Mechanism (CCM) was responsible for overseeing Global Fund-supported grant programs, the Local Fund Agent (LFA) provided independent verification of program progress and financial accountability to the Global Fund Secretariat, and the Global Fund Secretariat monitored program effectiveness and managed the grants. The two PRs provided oversight over the SRs. Notable features of the oversight of the Global Fund grants to Azerbaijan were:

- The Minister of Health was the Chair of the CCM and the Vice-Chair was from the civil society sector;
- To strengthen its governance and grant oversight role, the CCM received technical support in 2011 from Grant Management Solutions and the CCM internal regulations were revised to strengthen its functioning. An oversight committee supported by technical working groups was established and has been active;
- The CCM was not restricted to oversight of the Global Fund grant programs but also discussed issues related to other health programs;
- United Nations Office for Projects Services (UNOPS) has served as the LFA since the inception of the grant programs in April 2004. It has been responsible for semi-annual reviews of programmatic and financial accountability in addition to providing services such as procurement reviews and grant assessments for grant renewals; and
- The procurement reviews carried out by the LFA had identified some of the risks detailed in the procurement section of this report. The LFA and the Global Fund Secretariat could have been more proactive in ensuring that appropriate risk mitigation measures were in place in time to address identified procurement risk.

F. GOOD PRACTICES

25. The diagnostic review team observed examples of good program management and practices. The following list is not comprehensive and highlights key findings only:

HIV program:

Financial contributions from government

- The Government provided funding support for Opiate Substitution Therapy (OST) and started procuring ARV drugs (20% of national need);
- Innovative strategies for harm reduction such as mobile laboratories with HIV testing for most at risk populations (MARPs) have been implemented;
- Decentralization of ART services was in process; and
- A new law on HIV/AIDS was passed in 2010, which provides an enabling environment for the program.

TB Program:

Budget increases for TB

- The country reported a steady increase in the national budget for TB control, provided funding support for first-line anti-TB drugs for the general population and planned to start procurement of certain second-line anti-TB drugs by December 2012;

Routine testing for resistance

- TB patients were routinely tested for M/XDR-TB;
- Directly-observed treatment was conducted among M/XDR-TB patients;
- The focus had shifted from inpatient to outpatient treatment; and
- There was a comprehensive TB control program in prisons with a strong DOTS component and active screening, solid infection control and segregation of patients, no waiting list for M/XDR-TB patients, and routine follow up of released TB-affected prisoners through an NGO.

Malaria program:

Government provided over 70% of malaria funding

- The Government provided 70 to 90% of the total malaria funding, covering the cost of human resources, procurement of anti-malaria drugs and insecticides (75% of national need).
- Operational research studies were conducted, which helped to guide program implementation; and
- The country is moving towards malaria elimination and has a sound malaria policy and strong implementation record.

G. RISKS

Main risks identified:

26. The main risks identified by the OIG related to programmatic risks for HIV, TB and Malaria programs. The risks included the following: financial sustainability of the national programs at the conclusion of the grants, the appropriateness of national disease strategies in light of international guidance, program design, quality of services and M&E.

Insufficient financial resources

Risk 1: Financial resources are insufficient to ensure continuity in the provision of essential services once Global Fund grants end

Main donors leaving the country

27. Long term financial sustainability plans for HIV, TB, and Malaria programs needed to be developed. The Open Society Institute (OSI-AF) ended funding in 2012, with the remaining main donors to the health sector (USAID and the World Bank) indicating that they planned to leave the country in 2013. The only remaining external source of funding for the three diseases was the Global Fund, with the malaria grant also ending in 2013.

Large gap in treatment of M/XDR TB

28. The government of Azerbaijan covered 20% of the national need for ARV drugs. It provided for the entire demand for first-line anti-TB drugs in the general population and had allocated funds for the treatment of 400 MDR-TB patients. However, there was a gap in the provision of M/XDR-TB treatment. A total of 811 M/XDR-TB patients were diagnosed in 2011, with only 592 enrolled in the treatment program with Global Fund Round 7 grant support. This gap could be even higher given that the estimated number of MDR-TB cases was over 2,000 per year.[7]

Small budget gap in malaria program

29. With strong political commitment from the Government of Azerbaijan, and the progress towards elimination noted above, only a small gap remains in the national budget for the technical, human, and material resources to fully implement the national malaria elimination strategy.

Long term financial sustainability plan required

30. Recommendation 1: The MOH should support the development of long term financial sustainability plans particularly for the HIV and TB programs, including securing adequate budget allocation from the government at the end of the Global Fund grants. The MOJ should work with the MOH on the financial sustainability plan for TB in the penitentiary sector.

Risk 2: Some national disease strategies and guidelines have not been updated to be in line with current WHO standards

Some disease strategies and guidelines require updating

31. Some of the existing national disease strategies for the HIV and TB programs had not been updated to bring them in line with current WHO guidelines and standards.

32. In addition, there was scope to introduce a number of new

[7] Briefing on the findings and recommendations of the WHO Extensive Review of Tuberculosis Prevention, Control and Care in the Republic of Azerbaijan, 11-17 April 2012 and the WHO TB country profile report.

strategies/guidelines to improve public health care in line with WHO guidance.

33. Recommendation 2: The MOH should update the following strategies/guidelines for HIV and TB programs to ensure technically sound guidance for program implementation under the Global Fund grants:

HIV

- National BCC strategy for HIV/AIDS (e.g., focus on bridge populations such as primary sexual partners of IDUs);
- National HIV testing algorithm (e.g., introduce simple rapid testing);
- National VCT guidelines (e.g., introduce post-test counseling for positive rapid test result);
- National HIV Strategic Plan for 2013-2017 (e.g., address HIV drug resistance from both clinical and surveillance perspective); and
- National clinical guidelines for STI case management (e.g., include treatment of syphilis).

Tuberculosis

- National TB Strategic Plan 2011-2015 (e.g., include a TB/HIV component and associated action plan with detailed activities and budget);
- National protocols on surgical treatment of TB, pediatric treatment, hospitalization/discharge criteria, management of anti-TB drug side effects, management of TB/HIV co-infection; and
- National Hygiene and Epidemiology Center guidelines on infection control (e.g., revise strategy for disinfecting TB patients' homes, which contributes to stigma and discrimination).

34. Recommendation 3: The MOH should develop the following new/additional strategies/guidelines for the HIV program:

- National protocol for management of opportunistic infections among PLHIV (as part of ART clinical guidelines); and
- National guidelines for diagnosis, treatment and rehabilitation of substance abuse, including OST.

Risk 3: Some critical interventions in the disease programs are under-emphasized

Focus on IDUs needs strengthening

35. The most significant driver of the HIV epidemic in Azerbaijan was injecting drug use. In 2011, 62.8% of all cases of HIV infection were among people who use drugs, and the prevalence of HIV among people who inject drugs was 9.5% (2% to 16.7% depending on the region). There is significant unmet need for OST among IDUs: 140 clients were enrolled in OST in two sites in Baku, while the estimated number of

IDUs in the country was around 71,000 (43,736 to 98,830).[8] There was scope for the HIV program to prioritize implementation and expansion of comprehensive and large scale harm reduction activities, including the OST program, to ensure enrolment of more patients, including in the penal system.

36. There was a need for the malaria program to prioritize the strategies of vigilance and community involvement for management of foci, the development of a malaria elimination database, and the establishment of a national monitoring committee, as recommended by WHO for low and moderate endemic countries.

37. Recommendation 4: The MOH should:

- Strengthen national capacity in implementing comprehensive and large scale harm reduction activities ; support expansion of OST program by revising inclusion criteria to enroll more patients in Baku; and support the provision of technical assistance to the National Substance Abuse Treatment ("Narcology") Center; and
- Prioritize the remaining grant resources to prioritize vigilance among migrants/travelers, surveillance and certification of malaria elimination in coordination with WHO.

Access to and quality of services

Risk 4: Access to and quality of diagnosis, treatment, care and support services may not be assured

HIV

Limited access to ART services for initial diagnosis and treatment

38. Adherence to ART has scope for improvement, with 78.2% of adult PLHIV continuing ART after 12 months of initiation of treatment.[9] There was limited access to ART services for initial diagnostic workup and initiation of therapy and clinical monitoring as this was available only at the NAC in Baku. The process of decentralization of clinical and laboratory services to the regional AIDS centers was initiated in May 2012.

Need for improvement of ART services and harm reduction activities in prisons

39. ART service delivery in prisons was mainly the responsibility of the NAC rather than the MOJ. There had been a delay in shifting responsibilities from the NAC to the General Prison Hospital and to improvements to laboratory infrastructure, provision of laboratory equipment and training of laboratory and clinical personnel.

40. There was a need to initiate harm reduction activities including a Needle Exchange Program in prisons.

41. Recommendation 5: In order to improve access to and quality of HIV service delivery, the MOH should:

- Complete the process of on-going decentralization of ART and laboratory services to the regional AIDS centers including training of clinical and laboratory personnel. This should include strengthening technical capacity of providers in timely initiation of ART, quality clinical monitoring, management of ART side effects and drug resistance.

[8] Estimating the Sizes of Populations at Risk for HIV and AIDS, Azerbaijan, 2011
[9] Azerbaijan National AIDS Center data, October 1 2012

- The MOJ should work with the MOH to complete the process of the decentralization of ART and laboratory services to the General Prison Hospital, including training of clinical and laboratory personnel. This should include strengthening technical capacity of providers in timely initiation of ART, quality clinical monitoring, management of HIV drug resistance and ART side effects; and
- The MOJ should expand implementation of harm reduction activities to include a needle exchange program in prisons, ensuring adequate supply of necessary equipment and materials, as well as training of personnel.

DOTS implementation can be enhanced

Tuberculosis

42. DOT was implemented for MDR-TB patients but not for drug-sensitive patients. In Masali district, only one DOTS facility was functional (the district TB hospital), although there were 60 primary health care facilities in the district. Fifty-six TB patients were registered in the hospital, each receiving 10 to 15 days' stock of first-line anti-TB drugs during visits. Civil society organizations were not involved in the social support and follow-up of TB patients in the general population. The examination and chemoprophylaxis of contacts was not routinely done.

Higher number of MDR-TB patients than planned

43. Implementation of the MDR-TB expansion plan (which was in draft at the time of the review) is likely to result in the identification of markedly higher number of patients with MDR-TB diagnosis than planned under the Round 7 grant proposal, with significant implications for treatment cost and capacity.

Required treatment not available to all co-infected patients

44. Not all co-infected patients received the treatment they required. For example, in the Prison TB Hospital, only 50% of co-infected M/XDR-TB patients received ART.

45. Recommendation 6: The MOH should:

- Support expansion of DOTS implementation through integration of services into the Primary Health Care (PHC) level. The DOTS expansion should be planned and implemented in the context of on-going health care reform;
- Expand provision of social support, follow up, monitoring adherence and continuity of care services, e.g., through involvement of patronage nurses, PHC workers, community and civil society organizations;
- Ensure examination and chemoprophylaxis for TB contacts as needed, e.g., through development and implementation of guidelines;
- Finalize development of a comprehensive M/XDR-TB expansion plan including budgeted action plan to achieve universal access to M/XDR-TB prevention, diagnosis and treatment; and
- The MOJ should improve management of M/XDR-TB co-infected patients in prisons by including decentralized ART provision.

Risk 5: Quality control at national laboratory networks is not sufficient to assure satisfactory laboratory results.

46. There was scope for improvement in the management of laboratory networks for all three programs. The laboratories visited[10] did not have internal quality control (IQC) or external quality assessments (EQA); standard operating procedures (SOPs) were not available. This may compromise the diagnosis and treatment of patients.

Insufficient quality control in laboratories

47. Recommendation 7: The MOH and the MOJ should improve management of HIV, TB, and malaria laboratories by updating and/or developing SOPs and instituting IQC and EQA.

Quality of M&E data and supportive supervision can be improved

Risk 6: The quality of M&E data and of supportive supervision for effective program planning and implementation is not assured.

48. The national M&E plan for TB had not been finalized in order to guide the effective planning and implementation of the national TB program.

49. There had been a delay of more than one year in the development of the ART clinical database, which hindered adequate monitoring of ART clinical outcomes. There had been a similar delay in setting up the e-TB manager.

50. For all programs with the exception of MDR-TB, supportive supervision of program activities was *ad hoc* and not systematic. It did not include standard forms and checklists or effective arrangements for feedback, action planning and follow up.

51. Recommendation 8: The PRs (MOH and MOJ) should:

- Finalize the development of a national M&E plan for TB control in the general population and the penitentiary sector;
- Support the implementation of e-TB manager and the ART clinical database to allow for proper monitoring of clinical outcomes (including drug resistance); and
- Strengthen the routine system of supportive supervision and use of information for program management, e.g., by developing a plan or guidelines.

[10] National Reference Laboratories for TB, HIV, Malaria and TB Prison Hospital in Baku, Regional HIV laboratory in Shirvan, Regional TB laboratory in Masali, and district Malaria laboratory in Sabirabad.

High prices for reagents and CD4 tests

Risk 7: Prices for reagents and CD4 tests may not achieve best value for money.

52. The review team noted comparatively high local prices of certain reagent kits[11] and tests[12] procured from single-source local suppliers who were agents or representatives of international manufacturers.

53. Recommendation 9: The MOH should explore alternative sources/mechanisms to obtain lower prices, e.g., through direct procurement from manufacturers, attaining prices negotiated by global initiatives such as FIND or CHAI where applicable, or by using the Voluntary Pooled Procurement mechanism.

Quality of pharmaceuticals and health products not assured

Risk 8: The quality of pharmaceuticals and health products is not assured.

Quality assurance program not yet in place

54. The PRs had not yet developed a quality assurance program[13] to ensure the use of safe and effective medicines as required by the grant agreement. There was no system in place to assure quality control of pharmaceuticals and health products after distribution to peripheral facilities. The National Drug Regulatory Authority was responsible for drug registration, sampling and quality testing of pharmaceuticals at the port of entry and at various health facilities in the supply chain. However, its laboratory was not WHO-certified. Samples of pharmaceuticals and diagnostics were not routinely sent for testing in WHO-certified laboratories outside the country.

National Drug Regulatory Authority laboratory not WHO-certified

55. Recommendation 10: There is scope for the MOH to:

- Work with the National Drug Regulatory Authority to develop, adopt and implement a quality assurance system for pharmaceuticals and health products; and
- Send samples of pharmaceuticals and diagnostics for testing in WHO or ISO 17025 certified laboratories.

[11] Reagent kits (for Bactec laboratory equipment) were procured through a local supplier at two to three times the prices available through the Foundation for Innovative New Diagnostics.
[12] CD4 tests were procured for previously installed closed-type equipment. The price per test was EUR 38.
[13] Covering prequalification of suppliers, purchasing, storage and distribution standards.

ANNEX 1: Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZN	Azerbaijan New Manat (local currency)
CCM	Country Coordinating Mechanism
DOTS	Directly Observed Treatment Short- course
EUR	Euro
EQA	External Quality Assurance
HIV	Human Immunodeficiency Virus
IDU	Injecting Drug User
IQC	Internal Quality Control
LFA	Local Fund Agent
M&E	Monitoring and Evaluation
MARP	Most-at-risk population (for HIV infection)
MDR	Multi-drug resistant (tuberculosis)
MOH	Ministry of Health
MOJ	Ministry of Justice
NAC	National AIDS Centre
NGO	Non-governmental Organization
OIG	Office of the Inspector General (of the Global Fund)
OSI-AF	Open Society Institute-Assistance Foundation
OST	Opiate Substitution Therapy
PHC	Primary Health Care
PIU	Project Implementation Unit
PLHIV	People Living with HIV/AIDS
PMTCT	Preventing Mother-to-child-transmission
PR	Principal Recipient
PSM	Procurement and supplies management
SR	Sub-Recipient
STI	Sexually-transmitted Infection
TB	Tuberculosis
USD	United States Dollar
WHO	World Health Organization
XDR	Extensively drug-resistant (tuberculosis)

ANNEX 2: Recommendations and Management Action Plan

Risk	Recommendation	Response and Action Plan		Responsible Parties	Due Date
		Global Fund Secretariat **(Responsible for ensuring that the recommendation is implemented)**	**Country Coordinating Mechanism and Principal Recipients** **(Responsible for the actual implementation of the recommendation)**		
1. Financial resources are insufficient to ensure continuity in the provision of essential services once Global Fund grants end	<u>*Recommendation 1*</u> *The MOH should support the development of long term financial sustainability plans particularly for the HIV and TB programs, including securing an adequate budget allocation from the government at the end of the Global Fund grants. The MOJ should work with the MOH on the financial sustainability plan for TB in the penitentiary sector.*	The Secretariat agrees with the recommendation and will follow up on its implementation. The long-term program sustainability is in the Secretariat's focus, which is evidenced in the Secretariat's communication to the CCM, MOH and MOJ, for example in the joint letter from Global Fund and USAID to the CCM in the summer of 2012 on the shortage second-line TB treatment that played a positive role in increasing the governmental allocation for this budget line. As the OIG report notes, the increase of governmental funding for national programs is a positive trend that is already in place. It has to be strengthened further on a systematic basis and the Secretariat will support the MOH and MOJ in this work – for example, the Secretariat already provided description of the principles of a financial sustainability plan development and several examples of such plans.	HIV: Azerbaijan HIV/AIDS National Strategic Plan 2013-2017, along with its action plan and detailed budget will be used as the basis for preparation of financial sustainability plan. It is planned to get approved version of the financial sustainability plan till the end of 2014. TB: The financial sustainability of TB Control Program will be based on the following policy documents: - The National TB Strategy for 2011-2015 adopted by the MOH on September 21, 2010 (Prikaz #72) - The National TB Control Program for 2011-2015 approved by the Cabinet of Ministers on November 26, 2010 (resolution N. 226), and further adopted by the MOH (Prikaz 10, dd. January 12, 2011). Both documents outline main steps for reducing socio-economic burden associated with TB in Azerbaijan by 2015 through strengthening TB services, integration of PHC and enhancing capacity of healthcare workforce.	National AIDS Center (NAP)/PIU/CCM MoH / MoJ	End of 2014 End of 2014

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			The financial sustainability plan will be approved by the end of 2014. MMD of MoJ In order to avoid services interruption at the end of the Global Fund grants the MoJ and MoH are going to support mutual partnership on financial resources allocation. Thus, joint action plan and budget for "MDR and XDR-TB prevention and control in Azerbaijan for the 2013-2015 years period" was developed in close collaboration; Financial Gaps for Transitional Funding Mechanism and Round 9 TB Project extension were analyzed. MMD MoJ will secure an adequate budget allocation from the government for continuation of TB Control interventions based on the National TB Strategy at the end of the Global Fund grant through development of a sustainability plan and supporting budget request to the Ministry of Finance in April 2014. The plan will be approved by the end of 2014.	MoH / MoJ	End of 2014
2. National disease strategies and guidelines are not currently in line with WHO	*Recommendation 2* *The MOH should update the following strategies/guidelines for HIV and TB programs to ensure technically sound guidance for program implementation under the Global Fund grants:*	The Secretariat agrees with the recommendation and will follow-up on its implementation.	HIV: • As a current BCC strategy on HIV/AIDS developed in 2006 is focused mostly on MARPs, it will be updated to include bridge population as well. • Existing HIV testing algorithm will be revised to reflect using of rapid tests in mobile units, at VCT	UN Joint Team on AIDS (UNAIDS / UNFPA/UNICEF)	September 2013 November

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standards	 <u>*HIV*</u> • *National BCC strategy for HIV/AIDS (e.g., focus on bridge populations such as primary sexual partners of IDUs);* • *National HIV testing algorithm (e.g., introduce simple rapid testing);* • *National VCT guidelines (e.g., introduce post-test counseling for positive rapid test result);* • *National HIV Strategic Plan for 2013-2017 (e.g., address HIV drug resistance from both clinical and surveillance perspective); and* • *National clinical guidelines for STI case management (e.g., include treatment of syphilis).* <u>*Tuberculosis*</u> • *National TB Strategic Plan 2011-2015 (e.g., include a TB/HIV component and associated action plan with detailed activities and budget);*		points, at delivery time in maternity homes and etc. It will be done by the National AIDS Center with the WHO technical assistance. • National VCT guidelines will be updated by the National AIDS Center with the WHO technical assistance by the end of November 2013. • HIV drug resistance has been included into the revised HIV NSP 2013-2017. The amended NSP is going to be approved by the MoH and the Cabinet of Ministers of Azerbaijan Republic, respectively. • STI treatment protocols will be updated with the technical assistance of WHO. Medicines for STIs treatment will be purchased using the GF funds only upon approval of this protocol. TB: • Although TB/HIV component is an integral part of the National TB strategy the component will be broadened with detailed activities and budget included • It should be emphasized that all TB clinical protocols will be reviewed by WHO and aligned with its recommendations. After WHO desk review National	National AIDS Center/WHO National AIDS Center/WHO National AIDS Center/ UNAIDS Republic STI Dispensary/ WHO NTP, RILD, MOH, WHO MOH, RILD PHRC, WHO, PIU	2013 November 2013 June 2013 November 2013 June 2013 October

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	• *National protocols on surgical treatment of TB, pediatric treatment, hospitalization/discharge criteria, management of anti-TB drug side effects, management of TB/HIV co-infection; and* • *National Hygiene and Epidemiology Center guidelines on infection control (e.g., revise strategy for disinfecting TB patients' homes, which contributes to stigma and discrimination).*		protocols on TB surgical treatment, paediatric treatment, management of side effects, and management of TB/HIV co-infection will be approved by the MOH. • Hospitalization/discharge protocol was incorporated into TB guidelines approved by the MOH on December 30, 2012. • The National Infection Control guidelines were developed in close collaboration with WHO and aligned with all WHO recommendations. The document was approved by the MOH on December 30, 2012.		2013 Done Done
	<u>*Recommendation 3*</u> *The MOH should develop the following new/additional strategies/guidelines for the HIV program:* • *National protocol for management of opportunistic infections among PLHIV (as part of ART clinical guidelines); and* • *National guidelines for*	The Secretariat agrees with the recommendation and will follow up on its implementation. Furthermore, following the OIG review additional funds for technical assistance on drug abuse treatment/rehabilitation including OST, were incorporated in the	HIV: • National protocol on OIs management will be developed by the National AIDS Center with a technical assistance of WHO. Medicines for OIs treatment will be purchased using the GF funds only upon approval of this protocol. National guidance on Diagnosis, Treatment (including OST) and Rehabilitation of Narcological Diseases will	National AIDS Center/WHO Republic Narcological Center / UNODC/ WHO	30 August 2013 30 December 2014

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	diagnosis, treatment and rehabilitation of substance abuse, including OST.	Phase 2 of the Round 9 HIV/AIDS grant.	be developed by the Republic Narcological Center with technical assistance of UNODC and WHO (for clinical management part of protocol).		
3. Critical interventions in the disease programs are under-emphasized	*Recommendation 4* *The MOH should:* • *Strengthen national capacity in implementing comprehensive and large scale harm reduction activities ; support expansion of OST program by revising inclusion criteria to enroll more patients in Baku; and support the provision of technical assistance to the National Substance Abuse Treatment ("Narcology") Center; and*	The Secretariat agrees with the recommendation and will follow up on its implementation. The Secretariat acknowledges the importance of expansion of the OST program – it was communicated to the CCM in the Phase 2 Round 9 HIV/AIDS Pre-assessment report. The MOH is planning to expand the OST program using national funding. However, following the OIG review, the additional funds were allocated for technical assistance on drug abuse treatment/rehabilitation into the Phase 2 of the Round 9 HIV/AIDS grant.	HIV: • Since extension period the PIU has been working towards strengthening of national capacity of harm reduction projects to address recommendations provided by international HR experts, improve quality of services and increase coverage of beneficiaries; One of the recommendations given by HR Experts was strengthening capacity of NGOs through uniting of few small NGOs in one big. This idea was delivered to NGOs and as a result, a number of organizations have jointly prepared and submitted proposals for the 2nd phase of the GF Grant. The other recommendation given by experts was increasing number of MARPs covered by one outreach worker. This suggestion was also taken into consideration and found its reflection in the requirements set in the announcement for HR projects for the Phase 2. Introducing mobile units with possibility of HIV testing for MARPs was another example of strengthening of harm reduction projects in the country. This experience is going to be continued and scaled up in Phase 2. During the Phase 2 it is planned to continue strengthening the capacity of NGOs through conducting onsite trainings by mentors, as well as providing possibility of gaining	PİU / MoH	Ongoing

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			international experience via study tours, strengthening of HRN Secretariat and establishing of Expert Board. The Republic Narcological Centre (RNC) will define: 1) ways to increase enrolment of patient into OST; 2) areas where technical assistance needed and submit the developed plan till 30 March. Needed financial support can be provided by the GF HIV Grant.	RNC	April 2013
	• *Prioritize the remaining grant resources to prioritize vigilance among migrants/travelers, surveillance and certification of malaria elimination in coordination with WHO.*	The Secretariat has already been working with the CCM and the MOH on reviewing the remaining activities of the Round 7 Malaria grant in order to reallocate funds to emphasize and move towards obtaining the certificate on malaria elimination. While this re-allocation has to be completed by the end of first quarter of 2013, some newly suggested activities are already approved by the Secretariat and being implemented.	• The RCHE in coordination with WHO office is developing new guidelines for increasing vigilance among migrants and travelers. The document is going to be submitted to the MOH to the end of second quarter; • Part of grant resources (or accumulated savings) could be reallocated for training of managers tourist companies (or staff members of health insurance companies) on malaria and other infectious diseases prevention (vigilance among travelers and population) the trainings are expected to be included into the Grant Closure Plan and have to be approved by the GF Secretariat; • The country will apply for receiving malaria free status certification from WHO. Since the country is interested in receiving the Certificate, part of activities is expected to be financed by the Government. Currently an expert from abroad has been invited and	RCHE PIU/ RCHE PIU/ RCHE PIU/	Second quarter of 2013 Third and fourth quarter of 2013 Second quarter of 2013

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			has developed all SOPs for National Reference Laboratory. Later on the SOP-s for NRL will be discussed with all partners and finally it will be approved by RCHE and MOH. • The country has proper disease surveillance system –EIDSS, which incorporates infectious diseases data collection from every health facility. However, data interpretation capacity of local health authorities is very weak, and that is malaria WG suggests additional trainings for the category. Therefore, in order to improve diseases surveillance mechanisms and data interpretation skills of the district health authorities' additional training for the category needs to be carried out. The trainings could be organized by GF financial support from project savings if they accumulated. The activity will be communicated with the GF secretariat and if approved, the training will be organized in third or fourth quarter of the year 2013.	RCHE PIU/	Third and fourth quarter of 2013
4. Access to and quality of diagnosis, treatment, care and support services may not be assured	*Recommendation 5* *In order to improve access to and quality of HIV service delivery, the MOH should:* • *Complete the process of on-going decentralization of ART and laboratory services to the regional AIDS centers including training of clinical*	The Secretariat agrees with the recommendation and will follow up on its implementation. The decentralization of ART and laboratory services, which is ongoing and positively appraised by OIG in the report, has been strongly supported by the	HIV: • National AIDS Center will ensure that 6 ART units with its laboratory network established with a purpose of ART decentralization in the country in Phase 1 will be fully functional till the end of 2013 to provide	National AIDS Center/WHO	30 December 2013

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	and laboratory personnel. This should include strengthening technical capacity of providers in timely initiation of ART, quality clinical monitoring, management of ART side effects and drug resistance. • *The MOJ should work with the MOH to complete the process of the decentralization of ART and laboratory services to the General Prison Hospital, including training of clinical and laboratory personnel. This should include strengthening technical capacity of providers in timely initiation of ART, quality clinical monitoring, management of HIV drug resistance and ART side effects; and* • *The MOJ should expand implementation of harm reduction activities to include*	Secretariat as a measure to ensure greater access to services. The increase of technical capacity providers both in civilian and penitentiary sector is part of the Phase 2 Round 9 HIV/AIDS grant. The Secretariat will continue the advocacy for full expansion of the harm reduction program in the penitentiary sector. The letter to Minister of Justice and a visit of MOJ officials to harm reduction facilities in Switzerland in summer 2012 was a step towards this goal. The funds for needle exchange in	quality ART management and its clinical and laboratory monitoring. Strengthening technical capacity of providers through trainings on ART will be continued in Phase 2. MMD of MoJ • ART and HIV Laboratory Services decentralization successfully implemented with the state and GF support. Laboratory personnel were trained; the necessary equipment for immune-enzyme tests and CD4 cells detection has been procured, installed and launched in the Penitentiary Treatment Institution Laboratory. • Virus load equipment currently is installed; Laboratory reagents and maintenance materials order was developed and submitted to the Principal Recipient. Once TI Laboratory is supplied with necessary laboratory reagents and maintenance materials, virus load detection test will be produced by MMD, as well. According to the "Fight with disease caused by the human immunodeficiency virus" (May 11, 2010) law of Azerbaijan Republic, HIV positive diagnosis should be confirmed/registered on the permanent basis by the Reference Laboratory and cannot be decentralized. • HIV patients (out-patient) registration, ART	MMD of MoJ MMD of MoJ	Done As soon as procured by PR goods will be available. Anticipated date (March, 2013)

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	a needle exchange program in prisons, ensuring adequate supply of necessary equipment and materials, as well as training of personnel.	the penitentiary sector are also incorporated in the Phase 2 of Round 9 HIV/AIDS grant but their release is conditioned to the MOJ permission to start the distribution.	prescription, monitoring and ART side effects management is currently implemented in decentralized manner by MMD MoJ. • At the present time management is carried out empirically in Penitentiary System. Within the savings from GF Round 9 HIV Project and possible state resources, MMD aims to introduce ART drug resistance detection equipment to the TI Laboratory. • MMD MoJ is planning to revise existing Round 9 HIV Project Training Plan and ensure necessary training sessions for strengthening technical capacity of staff involved to HIV Program implementation and laboratory personnel. • 80% of ART drugs and Laboratory reagents is a subject to be covered by MoJ budget in PS starting from 2013 as an input to decentralization of ART and laboratory services. • Within the Round 9 HIV Project harm reduction activities frame four needle exchange devices have been procured; two implementation sites in PS were identified for a pilot invention. In this regard, training session by an international expert was conducted for MoJ personnel. The issue of injectors and needles exchange as a Harm Reduction Program in PS Institutions is under discussion in MoJ.	MMD of MoJ PIU/MMD, MoJ PIU/AIDS Center, MoH PIU/MoH MMD of MoJ MMD of MoJ MMD of MoJ	Done 2014 Once a year (3 times) during the 2 phase Done Pilot will be implemented by October 2013 The rest is

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					ongoing
	Recommendation 6 *The MOH should:* • *Support expansion of DOTS implementation through integration of services into the Primary Health Care (PHC) level. The DOTS expansion should be planned and implemented in the context of on-going health care reform;* • *Expand provision of social support, follow up, monitoring adherence and continuity of care services, e.g., through involvement of patronage nurses, PHC workers, community and civil society organizations;* • *Ensure examination and chemoprophylaxis for TB contacts as needed, e.g., through development and implementation of*	The Secretariat agrees with the recommendation and will follow-up on its implementation.	A. National TB Strategy is the key policy document outlining the principles of integration of TB and PHC services To enforce integration of TB and PHC services, the Ministry of Health has issued a number of orders and instructions relevant to TB control at the PHC / rayon level including: • A recent MOH Order No. 70 from 19 September 2012 "On approval of model regulations and job descriptions for employees working in medical institutions subordinated to the Ministry of Health" assigns new responsibilities to PHC providers in terms of infection diseases control, including the responsibilities to carry out direct observation of TB treatment, defaulters' and contacts' tracing. • Introduction of Family Medicine Institute for PHC in the frame of the Health Sector Reform projected supported by the World Bank. Currently the NTP with the support of Abt Associates is working with the Department of Family Medicine on the introduction of TB case finding, case management (with focus on DOT) and prevention protocols in the postgraduate curriculum for family doctors with special emphasis on practical issues related to collaboration between the	NTP, RILD, Post-graduate Institute, Abt Associates,	Done September 2013-

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	guidelines; • *Finalize development of a comprehensive M/XDR-TB expansion plan including budgeted action plan to achieve universal access to M/XDR-TB prevention, diagnosis and treatment; and* • *The MOJ should improve management of M/XDR-TB co-infected patients in prisons by including decentralized ART provision.*		general health services and specialized TB services. It is expected that TB module will be incorporated into the curriculum by September 2013. • A system of certification of doctors was introduced in Azerbaijan in January 2011. This system mandates the doctors of all specialties (and, in the nearest future, nurses) to pass an examination to certify the professional knowledge and hence confirm the vocational qualifications. TB-related questions are part of this test, and the NTP will continue working with the MOH department responsible for certification in further upgrading this part for testing of PHC providers, to accommodate for the new requirements. In line with the MOH strategy, the certification of all physicians and nurses will be finalized by 2015. B. Azerbaijan TB law issued in 2000 ensures social support (employment, accommodation, benefits and etc.) to all TB patients. On December 30, 2012 the MOH adopted ACSM Strategy for 2013-2017 with aim to facilitate involvement of PHC workers, community and civil society organizations in follow up, patronage and adherence monitoring. The launch of ACSM activities is expected by July 2013. C. TB prevention clinical protocol was approved by the MOH in April 2012. It should be emphasized that TB	NTP, MOH, NGOs, other donors	December 2015 July 2013

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			case finding, treatment and prevention protocols were incorporated into TB guidelines adopted on December 30, 2012. D. A comprehensive M/XDR-TB expansion plan including budgeted action plan has been developed with technical assistance of WHO/EURO. The final version of the plan will be translated and submitted to the Ministry of Health by mid-February 2013. It's expected that the plan will be approved by March 2013. MMD of MoJ: • All detainees in PS are provided with qualitative HIV diagnostics and ART. After OIG review, as a result of individual educational sessions with psychologists and educational activities on HIV among prisoners, the number of HIV/TB co-infected patients attracted to ART was increased on 30%.	WHO, NTP, RILD, PIU MMD of MoJ	Done March 2013 Done
5. Quality control at national laboratory networks is not sufficient to assure	*Recommendation 7* *The MOH and the MOJ should improve management of HIV, TB, and malaria laboratories by updating and/or developing SOPs and instituting IQC and EQA.*	The Secretariat agrees with the OIG recommendation and will follow-up on its implementation.	HIV: • National AIDS Center and MMD of the MoJ will develop SOP for HIV labs by 30 September 2013 and ensure executing IQC and EQA by the end of 2014 year. Needed financial support will be provided by the GF HIV Grant as soon as mechanism for both IQC and	National AIDS Center, MMD of MoJ/WHO	December 2014

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satisfactory laboratory results			EQA is elaborated. TB • SOPs for TB labs have been already developed by WHO and EXPAND-TB experts. At the moment translation of the SOPs to Azeri language under the discussion with WHO/EURO. After the translation WHO country office will submit the document to the MOH for approval. IQC and EQA are integral part of SOPs. The adoption of SOPs is expected by April 2013. Malaria • SOPs for Malaria have been developed by WHO consultant. They are now being translated, after they will be submitted to the MoH. MMD of MoJ: • In a view of recommendations similarity given to MoH and MoJ regarding TB and HIV Reference Laboratories, relevant activities carried out in collaboration with MoH. The MoJ TB Laboratory staff is currently working on "Standard Operations Procedure" document, submitted by TB Reference Laboratory adaptation of the PS context. As soon as primary version of "Standard Operations Procedure" document is elaborated by HIV Reference Laboratory	 NTP, NRL, WHO PIU / RCHE For TB Lab MMD, MoJ For HIV Lab AIDS Center, MoH	 April 2013 June 2013 June, 2013 30 December 2014

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			it will be adapted to the PS context as well.	and MMD, MoJ	
6. The quality of M&E data and of supportive supervision for effective program planning and implementation is not assured.	<u>*Recommendation 8*</u> *The PRs (MOH and MOJ) should:* • *Finalize the development of a national M&E plan for TB control in the general population and the penitentiary sector;* • *Support the implementation of e-TB manager and the ART clinical database to allow for proper monitoring of clinical outcomes (including drug resistance); and* • *Strengthen the routine system of supportive supervision and use of information for program management, e.g., by developing a plan or guidelines.*	The Secretariat agrees with the recommendation and will follow up on its implementation. The Secretariat is monitoring the development of a national M&E plan for TB and implementation of e-TB manager and these products are at final stages of development (e-TB manager was extended nationwide on December 30, 2012). The Secretariat also recognizes the importance of the ART clinical database and, as per MOH request, has increased the financial allocation for this activity in the Phase 2 of the Round 9 HIV/AIDS grant. The existing grants also have activities on strengthening of national M&E capacity and the Secretariat is monitoring the implementation of these activities.	HIV: • HIV-related M&E software including ART database with drug resistance will be developed by the National AIDS Center by the end of 2013 year. • MMD, MoJ plans to allocate resources within the 9th round of the HIV sub-project to ensure the regular ART clinical base filling as such a console version will be presented by the OR. As a remote operator and sub-project coordinator hardware consoles purchased previously will be used. A protocol of interaction and information interchange shall be discussed with the PR. • M&E unit of the National AIDS Center (NAP) will develop guidelines for supportive supervision and a united plan for such visits of National AIDS Center, MMD of the MoJ, SRIOG and so on. TB: • The National M&E plan developed with technical assistance of WHO expert and will be finalized and submitted to the MOH by February 2013. The plan will be approved by March 2013.	National AIDS Center MMD, MoJ PIU/MoH National AIDS Center PIU, MOH, MOJ, WHO, Abt Associates PIU, MOH, MOJ;	December 2013 December 2013 November 2013 March 2013 February

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			• PIU/MoJ will make sure already existing M&E plan for Penitentiary sector would be incorporated into the National one.	NTP	2013
7. Prices for reagents and CD4 tests may not achieve best value for money	<u>*Recommendation 9*</u> *The MOH should explore alternative sources/mechanisms to obtain lower prices, e.g., through direct procurement from manufacturers, attaining prices negotiated by global initiatives such as FIND or CHAI where applicable, or using the Voluntary Pooled Procurement mechanism.*	The Secretariat agrees with the recommendation and will follow up on its implementation. Azerbaijan has standardized the laboratory equipment it uses for HIV. The HIV laboratory equipment procured with grant resources is, therefore, the same equipment which the government has procured generally. Azerbaijan has procured "closed" laboratory systems which require that a specific brand of reagent and/or test is procured. Although this tends to limit competition and create dependency on a single manufacturer, this practice does not run contrary to the Global Fund's policies on the procurement and supply management of health products. • Closed systems generally provide the highest quality and are typically easier to manage. Manufacturers also tend to provide on-going servicing and maintenance, but only if the specified reagents and/or tests are used. • Open systems require a robust QA system, which includes a good	As per previous experience manufacturers forward PIU requests to local distributors/, representative offices and further communcation and pricing laying on them. But taking into consideration OIG recomendations procurement team will proceed with international announcements on relevant web pages (Dgmarket, UN web page etc) and send direct requests to manufactures in order to obatin best prices. As well as using of VPP and other mechanisms will be discussed and evaluated .	PIU MoH	Ongoing

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		validation mechanism and continuous reagent QA monitoring, to ensure the selected commodities are of high quality. The QA requirements present additional costs for open systems despite the potentially lower cost of the reagents and/or tests. In addition, in open systems there are often challenges in having the manufacturer of the machine provide servicing and maintenance if reagents and/or tests from another manufacturer are being used. • The Global Fund's Quality Assurance Policy for Diagnostics reflects that, when determining the lowest possible price, the "Total Cost of Ownership" should be considered. In Azerbaijan, the reagents and/or tests are being procured through the official local distributor of these goods. Furthermore, the Secretariat has agreed with the PIU, and will monitor the implementation, on the following actions to try and achieve lower prices for these reagents and tests: • The PIU will place international announcements on relevant web pages (Dgmarket, UN web page etc); and			

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		• The PIU will send direct requests to manufacture(s) in order to try and obtain the lowest possible prices. In addition, the Secretariat is exploring the option of Azerbaijan procuring these products through the VPP mechanism. Preliminary discussions with the VPP team, however, indicate that that the VPP prices may be the same or only marginally lower. More precise information will be available in February-March 2013. Finally, the Secretariat is including in the Phase 2 grant agreement of the Round 9 HIV/AIDS grant provisions requiring the country to proactively explore opportunities for obtaining lower prices for these reagents and tests. The Secretariat will monitor the progress made by the PR in their fulfillment.			
8. The quality of pharma-ceuticals and health products is not assured	<u>*Recommendation 10*</u> *There is scope for the MOH to:* • *Work with the National Drug Regulatory Authority to develop, adopt and implement a quality assurance system for pharmaceuticals and health*	The Secretariat agrees with the recommendation and will follow up on its implementation. In the recently negotiated Phase 2 agreements for the Round 9 HIV/AIDS and TB grants (fall 2012) the Secretariat is including conditions requiring that "by no later than 15 August 2013, the	A Working Group (WG) on Strengthening of Quality Assurance mechanism development has been established and initial discussions were carried out. The working group member representing Innovation Center has informed us that they have obtained ISO 17025 certificate for their laboratory which allow to use the laboratory during quality assurance process. They were	PIU MoH	End of March 2013

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	products; and • *Send samples of pharmaceuticals and diagnostics for testing in WHO or ISO 17025 certified laboratories.*	Principal Recipient shall provide evidence, in form and substance satisfactory to the Global Fund, that it has strengthened Quality Assurance activities at all levels in the supply chain where necessary to ensure that pharmaceuticals are periodically randomly sampled and tested in a laboratory accredited by the WHO Prequalification Program or certified pursuant to ISO 17025 in accordance with the Global Fund Quality Assurance policy." As of December 2012, an ISO 17025-certified laboratory was identified and MOH is working on development of Quality Assurance procedures. The Secretariat is monitoring progress made by the PR in fulfilling the condition on the basis of guiding principles available in "Guidance for Reinforcing and /or Establishing Pharmaceutical Quality Control Systems and Related Stock Management Activities in Countries Supported by the Global Fund" made available to the PRs.	requested to prepare and submit price list for required laboratory examinations. Based on obtained information the WG will proceed with Quality Assurance protocol development. It is expected that protocol will be finalized by end of March 2013 with immediate implementation upon approval.		