The Global Fund
To Fight AIDS, Tuberculosis and Malaria

10 YEARS OF IMPACT

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Our ref: OGM/GJ/JP

19 April, 2012

MESSAGE FROM THE GENERAL MANAGER AND INSPECTOR GENERAL

Audit Reports and Diagnostic Review issued by the Global Fund's Office of the Inspector General on 20 April 2012

Dear Reader:

Today the Global Fund has released three audit reports and one diagnostic review. These audits and reviews are part of the Global Fund's well established and consistent quality assurance process which seeks to ensure that grant money is used as effectively and efficiently as possible.

The reports are:

- Audit Reports: Ethiopia, Kenya and Uzbekistan;
- Diagnostic Review: Cuba.

While diagnostic reviews and audits serve similar purposes—they provide the Global Fund with an opportunity both to learn and to improve the way it does its business—there are certain important differences between them.

Audits take an historical perspective and comprehensively review grant implementation over time to substantiate whether grant funds have been used for the purpose intended and to provide assurance that grant funds are used wisely to save lives.

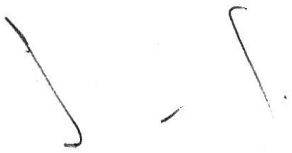
Diagnostic reviews look at the grants at a given point in time to identify the key risks to which grant programs are exposed. They provide recommendations to mitigate the risks identified.

The audit reports in the current release are 'legacy' reports, which relate to grants signed as far back as 2004 and to audits performed in 2009 and 2010. Many of the findings relate to weaknesses in grant management and oversight during the early years of the Global Fund that have been identified before, including in the High Level Panel Report and in other audit reports by the Office of the Inspector General. Many findings are already being addressed.

The diagnostic review in this release was performed in late 2011. It points to areas for improvement in managing Global Fund support. It also demonstrates solid achievements and good grant management practices.

Each report published today includes a concrete time-bound management plan of action that indicates how the findings will be addressed and the recommendations implemented. We both applaud the considerable progress that has already been made to improve grant management in response to the recommendations offered by the Global Fund's Office of the Inspector General.

Gabriel Jaramillo



John Parsons

THE OFFICE OF THE INSPECTOR GENERAL

The Global Fund to Fight AIDS, Tuberculosis and Malaria

Diagnostic Review of Global Fund Grants to the Republic of Cuba

GF-OIG-11-020
20 April 2012

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Executive Summary

Introduction

1. This diagnostic review of the Global Fund grants to the Republic of Cuba sought to identify and share good practices, identify key risks to which grant programs were exposed, and make recommendations for risk mitigation where weaknesses and gaps were found in the current risk response.

2. The review covered all three grants to Cuba totaling USD 76 million of which USD 68 million had been disbursed at the time of the review. UNDP was the Principal Recipient (PR) for all the grants. Since expenditures incurred directly by the PR are subject to UNDP's internal and external audits, they were not covered by this review, which focused on sub-recipients and service delivery.

3. There was strong evidence of successful national responses to HIV and to the effectiveness of tuberculosis control in Cuba. Many good practices were observed by the team during the course of the diagnostic review. Notwithstanding this, a number of risks were identified that may potentially impede the program unless they are mitigated. Action plans in response to the report recommendations have been prepared by the Secretariat and country and are included as Annex 2.

Key Outcomes

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

(i) Ensure that ART regimens are aligned with internationally accepted good clinical practice and are sustainable in the Cuban context;

(ii) Take actions to ensure prevention programs focus more strongly on effective harm reduction among female sex workers; and

(iii) Make improvements to the HIV indicators in the performance framework for Round 2 RCC Phase 2.

5. With regard to procurement and supply chain management, the country stakeholders have agreed to:

(i) Work to establish quality control for all pharmaceutical products, including random sampling and quality testing at different points in the supply chain;

(ii) Take actions to improve the storage conditions for condoms; and

(iii) Explore the alternatives for simplifying the procurement process for condoms with a view to reducing the overall time taken.

Message from the General Manager

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19 April, 2012

MESSAGE FROM THE GENERAL MANAGER

I would like to thank the Office of the Inspector General for its thorough and insightful work on the Diagnostic Review of the Global Fund grants in Cuba.

The review, conducted in 2011 and covering grants worth a total of USD 77 million, found strong evidence of success in efforts to prevent and treat HIV and tuberculosis in Cuba. It also identified a number of risks that may potentially limit the effectiveness of the program unless the right steps are taken.

The Secretariat, the Local Fund Agent and the Principal Recipient have already started implementing recommendations made by the Office of the Inspector General, and are working closely to monitor action on the recommendations.

I am confident that with our new emphasis on risk management and grant management, we will have appropriate procedures in place to address and resolve in a timely way the issues raised in this report by the Office of the Inspector General.

Audit reports by the Office of the Inspector General are an essential form of quality control for the Global Fund. I am grateful to the Office of the Inspector General for playing an indispensable role as we work together to achieve our mission of investing the world's money to save lives, in the most effective way possible.

Yours sincerely,

Message from the Country Coordinating Mechanism

REPÚBLICA DE CUBA
MINISTERIO DEL COMERCIO EXTERIOR Y LA INVERSION EXTRANJERA

La Habana, 23 de marzo de 2012

Sr. John Parson
Inspector General
Global Fund

Distinguished Sr. Inspector General Parson:

I appreciate you have included all the comments and amendments, requested on the Final Report for the Diagnostic Review of the Republic of Cuba.

We considered the report is objective, and recognized all the results and efforts of Cuba in the health sector, particularly in the prevention, diagnosis, and treatment of HIV/aids and tuberculosis. As you may know, all health services in Cuba are free of charge.

The diagnosis was a good exercise, where we could show the advancements gained and challenges we are facing to carried out the projects financed by the Global Fund to fight aids, tuberculosis and malaria. Nevertheless, the Country Coordination Mechanism, the Principal Recipient and the Cuban Government are fully committed to fulfill all the goals, indicators and objectives of the Grants.

As the Chair of the Country Coordinating Mechanism I assure the measures proposed in the Plan of Actions will be implemented.

Best regards,

Ileana Nuñez Mordoche
CCM Chair of Cuba

Introduction

What was the review about?

6. As part of its 2011 plan, the Office of the Inspector General (OIG) undertook a diagnostic review of the Global Fund grants to the Republic of Cuba. This review sought to:

- Identify and share good practices; and
- Identify key risks to which Global Fund grant programs are exposed and make recommendations for risk mitigation where weaknesses and gaps are found in the current risk response.

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. The fieldwork for the diagnostic review was conducted from 31 October to 16 November 2011.

8. The review covered all three grants to Cuba totaling USD 76 million of which USD 68 million had been disbursed at the time of the review. UNDP is the Principal Recipient (PR) for all the grants. Since expenditures incurred directly by the PR are subject to UNDP's internal and external audits, they were not covered by this review. A draft of the diagnostic review report was shared with the Office of Audit and Investigations (OAI) of the UNDP and the comments of the OAI have been reflected in this report.

What is the environment within which programs are implemented?

9. The Republic of Cuba has a long history of successful national responses to HIV prevention, treatment and care, and of tuberculosis control. Due to the relative international isolation of the country, information about the nature of these programs is often not well communicated.

10. Since the beginning of Global Fund support to Cuba, the country has obtained three grants, two for supporting the response to HIV, and one for tuberculosis. Because of the low disease burden and the classification of the Republic of Cuba as a middle income country, Cuba is, under current regulations, not eligible to submit further proposals to the Global Fund.

11. The current Global Fund grant portfolio for the Republic of Cuba is as follows[1]:

Round/ Disease	Grant Number	Program Start/ End Date	Total Grant Amount	Total Disbursed	% Disbursed
R2 HIV	CUB-202-G01-H-00	1-Jul-03/ 31-Dec-11	36,224,962	35,269,140	97%
R6 HIV	CUB-607-G02-H	1-Oct-07/ 31-Dec-12	32,661,139	26,289,944	80%
R7 TB	CUB-708-G03-T	1-Jan-09/ 31-Dec-13	6,883,212	6,360,299	92%
		Total	75,769,313	67,919,383	

12. The Round 2 HIV grant will complete its first phase of the RCC grant extension at the end of December 2011. The agreement for the second three-year phase was under negotiation at the time of the OIG diagnostic review. There are no further pending grants or negotiations.

13. There is overwhelming evidence of highly successful national responses to HIV and to the effectiveness of tuberculosis control in Cuba. This is reflected in the levels and trends of epidemiological indicators of HIV prevalence and tuberculosis incidence. It is supported by service indicators such as ARV treatment coverage, survival rates of people on ART and tuberculosis treatment success rates.[2] And it is underpinned by encouraging indicators of social and behavioral change documenting increasing use of condoms, increasing

[1] Source: Global Fund database accessed 25 October 2011

[2] According to the MINSAP HIV database, 12,960 people were living with HIV in November 2011, 6,489 of them on ART. The 2011 WHO tuberculosis report estimated the tuberculosis burden (all forms) in 2010 to be between 540 and 2,500 patients with a mean estimate of 1,400. Raw data obtained by the OIG team from the National Health Information System (not yet verified by the TB Program) indicate that in 2010 a total of 847 patients were started on anti-tuberculosis treatment.

social inclusion of people living with HIV and increasing tolerance of sexual diversity.

Statistics on HIV and tuberculosis in Cuba

HIV prevalence among young people aged 15 to 24	2007	2009
	0.03%	0.02%
People aged 15 to 49 who know their HIV status	2006	2009
	52%	55%
Proportion of infants born to HIV positive mothers who are HIV positive	2007	2009
	3%	2%
Proportion of adolescent girls (15-19) who used a condom during last sexual intercourse	2006	2009
	78%	81%
Proportion of people living with HIV who are satisfied with health care at peripheral level	2007	2009
	64%	79%
Proportion of people who started ART in 2002 still on ART in 2010	2010	
	94%	
Tuberculosis cases (all forms) notified per 100,000 population	2006	2010
	6.9	7
Treatment success rate for smear positive tuberculosis	2008	
	88%	
Proportion of sputum microscopy slides with concordant results on quality control by the National Reference Laboratory (2,207 slides)	2010	
	99.3%	

Sources: UNGASS Report 2009; ONEI: HIV indicator surveys 2006 and 2009; ONEI: Survey of People living with HIV 2007 and 2009; MINSAP: Epidemiological Report HIV/STI 2010; MINSAP: TB Report 2008-2010; WHO: TB Database (accessed Nov 2011)

Grant Implementation and Good Practices

Who is responsible for implementing the program?

14. The UNDP grant administration team works very closely with the National Project Office (ONP), an office of the Ministry of Foreign Trade and Investment (MINCEX), as its counterpart for grant administration and program coordination. The National HIV and TB programs provide technical assistance and support on program coordination. The National Statistic and Information Office (ONEI) is responsible for data collection, analysis and reporting of programmatic results. There are a total of 30 Sub-Recipients (SRs) responsible for implementing the program activities.

What made it hard to implement the program?

15. The United States embargo against Cuba has been in force since the 1960s and is the most enduring trade embargo in modern history. This embargo limits American businesses[3] from conducting business with Cuban interests. In September 2011, President Barack Obama extended the embargo through to September 2012. There is thus a risk that fund transfers to Cuba could be blocked due to U.S. Government sanctions, which could result in non-execution of program budget and non-implementation of program activities.

16. This has implications for Global Fund grants to Cuba. For example, the funds requested for the quarter ended September 2010 were blocked by the bank responsible for the transfer as a result of the U.S. Government sanctions on Cuba. These funds were eventually released approximately six months later after the Global Fund obtained an OFAT license for this purpose. It is important to acknowledge that on this occasion lengthy program disruption was mitigated by the UNDP advancing its own funds. Recommendations made to address risk have been included in Annex 2 under Risk 1.

How were grant funds managed?

17. Many of the usual finance risks considered in OIG reviews relate to the PR's management of funds (bank accounts, payments, etc.) and also the accounting systems and records. These areas were not included in the scope of our review. Also, out of scope were PR salaries and administration costs (see paragraph 8).

18. Program expenditure by SRs was found to be well controlled. The ONP continuously monitored SR budget execution, reviewed all SR expenditures, and maintained financial records for the program. The primary financial records for the grant programs were maintained by the PR; the ONP reconciled its financial records to those of the PR on a quarterly basis. Procurement was undertaken based on formally established procedures. Program funds were managed by the PR. All SR expenditures and EMED procurements were reviewed by the PR, with all payments being made directly by

[3] All U.S. citizens and permanent residents wherever they are located, all people and organizations physically in the United States, and all branches and subsidiaries of U.S. organizations throughout the world.

the PR. The LFA, PR and ONP performed quarterly financial and programmatic reviews of the grant programs.

What good practices were observed during this diagnostic review?

19. The following is a list of good practices that were observed by the OIG team in the course of the diagnostic review. Since the review focused on the examination of pre-identified risks, this list is neither exhaustive nor systematic. These good practices may serve as lessons for other countries receiving Global Fund support.

a) All Global Fund-supported programs in Cuba are implemented by Government staff and volunteers. There are no human resource costs (salaries or incentives) in any of the three grants, except for the salary costs of UNDP. This is to a large part assured by an extensive engagement of volunteers.

b) Among the very large number of volunteers associated with the HIV and tuberculosis program, people living with HIV play an important role through the "Línea de apoyo a las personas con VIH" organized with support of the CNP at the national, provincial and municipal level. People living with HIV are represented in all important decision forums related to the national response.

c) The national strategy for HIV testing and counseling is cumbersome and is not designed to deliver rapid results. It is, however, very carefully designed to maximize the reliability and quality of testing and counseling, and it has wide coverage with over 2 million people tested in the first 10 months of 2011[4]. At the same time, the Ministry of Public Health (MINSAP) is very cautious in introducing more efficient rapid HIV testing systems that rely on imported technology. This concern for sustainability is a good practice that characterizes many public health programs in Cuba.

d) The youth program of the National Center for Sexual Education (CENESEX) and the Ministry of Education supported by the Global Fund focuses on adolescents aged 12 to 19. Although it is an HIV prevention program, the thematic foci are sexual rights, gender equality, respect of sexual diversity, and prevention of sexual violence. The program addresses the main social drivers of HIV vulnerability. In a society where the immediate personal risk of HIV infection for most young people remains low, this focus on social vulnerability is highly appropriate.

e) The programs for men who have sex with men (MSM) supported by the Global Fund have a broad spectrum of activities with foci on the promotion of human rights and the respect of sexual diversity. The program has significantly decreased the stigmatization of homosexuality in Cuban society and has stimulated a social and

[4] National Health Information System, November 2011

political dialogue on sexual rights that is unprecedented in Latin America.

f) The national information systems for HIV and for tuberculosis provide comprehensive and reliable data almost in real-time. The information systems for tuberculosis and for HIV case detection are entirely integrated into the national health information system providing reliable weekly data. The HIV treatment information system is managed by the National AIDS Program at the central level, but integrated into the health information system peripherally. It provides a complete set of data in real time that allows any type of analysis, from cohort survival to the actual consumption of anti-retroviral drugs.

g) Therapeutic decisions for the use of antiretroviral medications are based on a responsive system of treatment committees meeting weekly at the provincial and central level to decide on the treatment plan of each patient individually based on clinical and laboratory evidence.

h) The National Statistics and Information Office conducts biennial behavioral surveys on issues relevant to HIV prevention and social support among the general population and among specific groups such as MSM and people living with HIV. The surveys are comprehensive, the questionnaires are of high quality and the sample sizes are large. They provide reliable serial data on social and behavioral trends and are used to guide prevention and social support programs.

i) There is regular, permanent and cross-functional communication between all layers of the Cuban health system. Examples are regular feedback through telephone calls and cross-sectoral meetings of programs and logistics with clinicians and warehouse management staff regarding matters such as supply of condoms, laboratory reagents and medicines. During our review, many examples were noted where weaknesses in existing systems were mitigated by this communication, for example, missing data or inaccuracies in condom distribution monitoring reports were quickly identified and corrected.

j) There are many online information portals that are widely used, which make consolidated and frequently updated data available:
   - The MINSAP “Registro informatizado de VIH” is a complete database of all people living with HIV in Cuba that is updated on a weekly basis.
   - The SIDATRAT database of IPK contains detailed medical records of more than 90% of people on ART in Cuba.
   - The EMCOMED Mistral and Comedics database includes stock

and consumption data of all pharmacies country-wide.

- The Cuba national formulary database is a registry of all drugs registered for use in Cuba by category and health facility level.
- The pharmacovigilance database of CECMED.

k) The supply management and distribution system of ARVs and other medicines, managed by the storage and distribution company for pharmaceuticals (EMCOMED), incorporates good pharmaceutical distribution and warehouse practices. It is a pull system with weekly orders, working with buffer stocks of 30 and 60 days, including minimum and maximum stock levels. It is combined with an online logistics management information system that is only paper-based at the level of the smallest pharmacies. The online portal provides real-time stock and consumption information by health facility, product and province.

l) EMCOMED has an agreement with the national passenger bus service ASTRO to provide emergency delivery service of small packages within 24 hours countrywide, thereby assisting with deliveries of ARVs to avoid stock-outs. Laboratory samples, for example for CD4 determination, are transported daily to the nearest laboratory in the same manner, assuring that results are received within three days.

m) The national drug regulatory authority (CECMED) provides quality control and certification of the warehouses and trucks used for medicines according to good pharmaceutical distribution and warehousing practices.

Is oversight adequate?

20. No significant risks were noted with regard to oversight[5]. The constitution and functioning of the CCM is well documented in statutes and regulations. Independent external audits are conducted annually and there is formal follow up of the implementation of audit recommendations. The LFA has been PwC throughout the grant programs in Cuba and there has been continuity in the key LFA personnel for financial oversight. The LFA's performance in Cuba, as captured in the Global Fund LFA Performance Evaluation Tool, is rated as "above average" for the region of Latin America and the Caribbean. One challenge for the LFA, however, is the fact that the LFA is not based in-country and has to travel from Argentina for verification visits. Further, the LFA did not have a proper understanding of certain program issues; for example, the assertion by the LFA that Cuba did not have a standard ART protocol[6] was shown to be incorrect by the results of the diagnostic review. This would suggest that the LFA's review of programmatic issues could be strengthened.

[5] However, kindly note the caveat in paragraph 8.
[6] RCC Phase 2 Request Assessment Report, page 66; 15th April 2011.

Risks

What risks did the diagnostic review team identify?

21. Notwithstanding the many good practices outlined above, the OIG noted a number of risks that may potentially impede the very strong program observed unless they are mitigated. None of these risks seriously threaten the achievement of overall objectives.

22. A number of risks were identified in the areas of program design, implementation and monitoring. They are primarily in three areas: (i) The use of outdated antiretroviral treatment protocols based on short-term cost considerations that could in the longer term increase the overall cost of HIV treatment to the Cuban health system; (ii) Prevention programs that (despite many exemplary approaches) miss the opportunity of effective harm reduction among female sex workers; and (iii) Systems for monitoring and evaluation of Global Fund grants that are parallel to effective national systems and do not add value to national M&E and health information systems.

23. Procurement and supply chain management of pharmaceutical products and supplies required for program implementation have well established control systems to mitigate risk. Nonetheless, the following risks were identified in the supply chain: (i) The procurement process shows a systematic delay in the procurement of condoms; (ii) Some warehouses have improper storage conditions for condoms; and (iii) No random sampling and quality testing of pharmaceutical products at different points in the supply chain.

24. These risks are discussed further below. Recommendations and action plans for risk mitigation have been included as Annex 2.

What were the risks related to the HIV program?

1. Antiretroviral first line treatment failure

25. According to the MINSAP HIV database[7], 1,832 people with HIV receive one or two drugs that are no longer recommended for antiretroviral treatment because of toxicity and adherence problems (Stavudine and Indinavir). This represents 28% of all patients on ART in Cuba and 36% who are on a national first-line treatment protocol. This is due to the limited range of locally produced drugs and the application of a policy that prioritizes treatment protocols with nationally produced drugs. Some of these regimes require that patients take up to 18 tablets per day. Review of pharmacy records by the OIG team indicates that there are significant adherence problems in some locations[8]. Removing these two drugs from the first line treatment protocol requires a more

[7] 11 November 2011
[8] For example, in Santa Clara

aggressive introduction of two drugs, namely Tenofovir and Efavirenz that are currently procured in limited quantities with Global Fund support. These two drugs are not costly (each currently costs about USD 100 per patient per year) and prices are falling. The OIG mission was told that they are "in the pipeline" for local production.

2. Antiretroviral treatment toxicity

26. According to the MINSAP HIV database[9], more than 1,600 people living with HIV are on a first- or second-line ART protocol that includes Stavudine 40 mg. This drug was withdrawn from the international market because of severe dose-related toxicity. While there is a general recommendation to completely phase out the use of Stavudine, there is an immediate recommendation to reduce the dosage of Stavudine from 40 to 30 mg[10].

3. Long-term sustainability of antiretroviral treatment

27. The Global Fund grants currently finance all imported antiretroviral drugs in Cuba. The grants will end in December 2014 following Phase 2 of the Round 2 RCC grant that has not yet been signed. According to current regulations, Cuba will no longer be eligible to submit proposals to the Global Fund.

4. Outreach HIV testing campaigns with delayed confirmatory testing

28. Under the title "Hazte la Prueba", MINSAP is conducting a mobile campaign of rapid HIV testing in bars and at public events that are believed to be frequented by persons at risk of HIV infection. Several different test systems have been procured. They were evaluated by the National AIDS Research Laboratory and have been selected on the basis of having 100% sensitivity and at least 99.5% specificity. Persons who test positive at outreach sites are advised that these are preliminary results. They are referred to a health center to undergo standard HIV counseling and testing. In two provinces where the OIG team collected information about outreach testing, no false positive results were reported this year among more than 3,000 tests. Nonetheless, there is a real risk that false positive results will occur and give rise to psychological distress.

[9] 11 November 2011.
[10] "Antiretroviral Therapy for HIV Infection in Adults and Adolescents: Recommendations for a public health approach" (2006 revision) WHO.

5. Additional food supplements providing low value for money

29. People with chronic illnesses, including people living with HIV, receive special nutritional supplements as part of the food rations provided by the Government. These supplements are delivered through regular food distribution channels. In addition, the Global Fund supports the distribution of a limited number of further food supplements for people living with HIV (currently 18 liters of cooking oil per year, plus canned sausages when available). These supplements are distributed monthly at designated distribution sites. Since cooking oil is in short supply in Cuba and has a high price on the open market, the supplement is very popular. People living with HIV interviewed by the OIG generally defended the food supplementation program. However, they acknowledged that the current subsidy made very little difference in their daily diet. When asked about priorities, all of them ranked the need for more effective and convenient ARV drugs much higher than continued food supplementation. Furthermore, some of the current nutritional challenges faced by people living with ARV are related to the use of drugs such as Indinavir and Didanosine which should no longer be included in first line ART.

6. The lack of a harm reduction program for female sex workers

30. The Global Fund supports the program for HIV prevention among "people who practice transactional sex" (PPST) through both HIV grants with a total contribution of about USD 100,000 per year. The program implements prevention activities in environments where there is a high likelihood that sex is being traded for money or goods. It also targets people who are in some way linked to these environments, such as hotel workers and owners, police officers, and prisoners. Targeting condom promotion to environments where casual sexual contacts are highly prevalent is a sensible approach to HIV prevention. But it does not constitute a program for specific harm reduction among sex workers. In a survey, about 1% of women reported that they have at one time exchanged sex for money[11]; this is acknowledged to be an under-estimate. It is reasonable to assume that a core among them do this regularly enough to be considered sex workers. Harm reduction among this group requires a more specific focus than the general HIV prevention activities that characterize the PPST program currently. It is likely that there is a similarly small group of sex workers among the population of transsexuals, transvestites and MSM[12]. The programs of CENESEX and the HSH[13] Project specifically provide intensive peer support to this

[11] ONEI: HIV behavioral survey 2009
[12] In the ONEI behavioral survey of 2009, 2.7% of men declared that they had exchanged sex for money at one time. The proportion among them who had sex with another man is, however, not known. The total number of MSM in the sample is too small to make this type of sub-analysis.
[13] MSM

population. Nothing comparable is currently available for female sex workers.

7. Inappropriate indicator definition in the HIV Round 2 RCC grant performance framework

31. The Phase 1 grant performance framework of the HIV Round 2 RCC grant includes several Global Fund "top ten indicators" reporting the number of people reached and/or the number of people trained. As of June 2011, three of these indicators reached performance scores that exceeded the target by 300% to 1,400%. The LFA has identified this as a risk[14]. In the proposed Phase 2 framework, a mechanism is included to avoid "double counting" by eliminating the inclusion of persons in training programs that have already been trained on the same subject. This would require a cumbersome monitoring mechanism better avoided in programs for social and behavioral change. Behavior change and social change programs require frequent and repeated re-enforcement. "Training" of peer educators, people living with HIV, or MSM, should be more extensive than attending a workshop. Training is an opportunity to stimulate on-going discussions and mutual support to build self-confidence and to internalize attitudes and behaviors. Repeated training of the same people is part of the methodology.

8. Continuity of Vigor and Vigor Max condom brands

32. The Vigor, Vigor Max and Momentos condom brands were created as part of the national strategy for the social marketing of condoms designed to increase condom use. Both Vigor and Momentos are sold in packets of three. The Vigor condom contains more lubricant than Momentos, which results in greater resistance. A market survey indicated that Vigor is the preferred brand[15]. Vigor Max is sold in packets of two and includes a separate sachet of lubricant, which makes it specifically suitable for anal sex. Given that MSM are most at risk of HIV infection in Cuba, this product is important for prevention.

33. The Momentos brand is funded by the Government and supplied to all pharmacies in Cuba. The Vigor and Vigor Max brands are funded by Global Fund grants and distributed to selected pharmacies as well as to bars, restaurants and cafes. All three brands are sold at 1 Cuban Peso per packet. Based on 2009 condom costs, the government subsidy for Momentos was 0.80 Cuban Pesos per packet[16]. The comparable subsidy[17] for the Vigor and Vigor Max

[14] HIV Round 2 RCC Training Plan for 2011
[15] MINSAP/Population Services International validation study of condom brands 2005.
[16] 2010 CNP Report to MINSAP
[17] The hypothetically subsidy, if these condoms had been financed by the Government instead of the Global Fund.

brands would have been 2.00 and 2.75 Cuban Pesos respectively (250% and 344% higher than for Momentos). This gives rise to the risk that these brands might not be sustainable after the end of the Global Fund grants.

34. Current Global Fund grant agreements provide for continued funding for the procurement of Vigor condoms for national distribution until the end of 2012 under the Round 6 grant, and until the end of 2014 under Round 2 RCC for distribution in the provinces of Havana, Artemisa and Mayabeque only. Vigor Max is currently only distributed in Havana and there is no budgetary provision for scale-up to national level.

What were the risks related to the TB program?

1. Inadequate infrastructure in tuberculosis laboratories

35. During visits to tuberculosis laboratories in two polyclinics in Villa Clara and Sancti Spíritus, and to provincial tuberculosis laboratories in Ciego de Ávila and Havana (Municipio Plaza), the OIG review team noted several deficiencies in infection control and biosecurity related to laboratory infrastructure. The rooms in the polyclinics in which sputum slides were prepared had no ventilation or extraction fan. Major equipment supplied to the two provincial laboratories could not be installed because of a lack of space or because it did not fit through the doors. In Ciego de Ávila the equipment is temporarily installed in a room that has no door. In Havana the security hood could not be installed.

2. Poor alignment of indicators in the tuberculosis grant performance framework

36. The National Tuberculosis Program has a performance framework that includes seven impact indicators and 23 "operational indicators" in four categories: (i) Case detection; (ii) Diagnosis; (iii) Treatment outcome; and (iv) Laboratory performance. The Global Fund performance framework (TB Round 7 Phase 2) has a performance framework with five outcome indicators and 15 process indicators. Only five of these 20 grant performance indicators can be directly derived from national indicators. Although there are some gaps in the national monitoring system that justify the inclusion of additional indicators in the grant performance framework, these indicators should be limited so that parallel grant monitoring structures are not required. While tuberculosis program monitoring is integrated in the National Health Information system at an exemplary level, the grant performance framework has necessitated the establishment of an entirely independent monitoring system located at the National Statistics and Information Office. This system does not generate information that is of use to the country. This increases the cost of grant implementation. On the other hand, despite significant support of the Global Fund grant to the laboratory network, for instance, laboratory performance is

not monitored in the grant performance framework although it is tracked very well by the national health information system.

What were the risks related to Procurement and Supply Management?

1. Improper storage conditions for condoms

37. The storage and distribution company for medical consumables (EMSUME) is responsible for the storage and distribution of all medical consumable products for the public health system, such as bandages, syringes and condoms. During site visits, the OIG team observed examples of improper storage conditions and weak warehousing practices at three EMSUME locations out of seven visited. In particular:

- Central warehouse (El Cotorro): Vigor Max condoms were stored in a sea cargo container outside, with storage temperatures exceeding the maximum of 30°C recommended. Vigor condoms were found in two separated locations with just one stock card.
- Artemisa: The warehouse has open access to birds, and possibly rodents, which creates a hygiene risk. There is limited space to separate outgoing shipments. One case was observed of stock card adjustment being made a number of days before the stock was shipped.
- Matanzas: The warehouse has open access to birds and possible rodents. There was evidence of water damage to Vigor condoms and an error in condom product codes.
- None of the warehouses visited monitored the temperature of stores.
- None of the warehouses visited stacked boxes in defined clusters to facility easy stock counts.
- None of the provincial warehouses visited used pallet racks.

38. The storage and distribution system should be optimized to maintain the quality according to the recommended maximum storage temperature and good warehousing practices. In particular, storing condoms outdoors in shipping containers should be avoided as the temperatures inside containers can be substantially above ambient temperatures, resulting in faster deterioration. Condoms stored for 120 days (4 months) at 50°C will have their shelf life reduced by 3 years[18].

2. No random quality testing of antiretroviral medicines at different points in the supply chain

39. For ARVs, the manufacturer is responsible for quality analysis by batch and must submit a certificate of analysis, a certificate of WHO Good Manufacturing Practice pre-qualification, and a summary

[18] WHO/UNAIDS/UNFPA/FHI Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010, p.102.

of the product characteristics. The national drug regulatory authority (CECMED), in coordination with EMCOMED, monitors the safety and quality of medicines by conducting quality analyses of specific batches in cases where a "notification of suspected failure of quality or therapeutic effects"[19] has been received. However, no random samples of pharmaceutical products are obtained at different points in the supply chain to verify if the product meets the required quality standard and product specifications.

40. The Global Fund policy on quality assurance of pharmaceutical products requires: "In collaboration with NDRAs, PRs must ensure that random samples of FPPs are obtained at different points in the supply chain - from initial receipt of the FPPs in-country to delivery to end-users/patients - for the purpose of monitoring the quality of such FPPs (including quality control testing)"[20].

3. Delays in the procurement process of condoms

41. The procurement process for condoms has been troubled by delays. An analysis of the last six purchase orders, from February 2008 to September 2010 demonstrates this. For these six purchase orders:

- The average time from the date the order was issued by the SR, until the PR issued the purchase order to UNFPA was 3.4 months.
- The average time from the date the purchase order was issued to arrival of the product in a Cuban port was 7.6 months.
- The average total delivery time from date the order was issued by the SR until arrival of the product in Cuba was 11 months.

Delivery time for Condoms 2008-2011

Date order issued by SR	Months until PR issues request for bid	Months from order until Purchase Order to UNFPA (a)	Months from Purchase Order to delivery (b)	Total delivery time until port (a+b)
12/02/08	1.4	3.0	4.6	7.6
24/12/08	1.2	3.5	5.6	9.1
15/01/10	0.4	4.9	7.6	12.5
9/10/09	0.7	3.7	5.9	9.6
28/09/10	1.0	2.8	11.0	13.8
29/09/10	0.9	2.7	11.0	13.7
	Average	**3.4**	**7.6**	**11.0**

[19] Notification online: http://www.cecmed.sld.cu/Docs/VigPC/Med/Boleta_Cal_Efect.htm
[20] Global Fund policy on Qualify Assurance of pharmaceutical products, 10 Nov. 2009

42. The analysis of the procurement and distribution planning of Vigor and Vigor Max condoms showed that all six purchase orders arrived later than planned. During field visits, the OIG team observed stock-outs of Vigor condoms of up to five months duration in seven out of twelve provincial warehouses and five out of ten pharmacies visited[21]:

Visit Date	Location	Period of Stock Out
08/Nov/2011	Ciego de Ávila (EMSUME store)	May and Jun 2011
08/Nov/2011	Ciego de Ávila (EMCOMED store)	May to Sep 2011
09/Nov/2011	Camagüey (EMSUME store)	May and Jun 2011
07/Nov/2011	Villa Clara (EMSUME store)	May and Jul 2011
08/Nov/2011	Sancti Spíritus (EMSUME store)	Nov to Dec 2010
07/Nov/2011	Pinar del Rio (EMSUME store)	May to Sep 2011
07/Nov/2011	Pinar del Rio (EMCOMED store)	May to Sep 2011
10/Nov/2011	Matanzas (Five Pharmacies)	Nov 2011

43. UNFPA has been used since 2006 as a single source supplier for condoms, operating under a long-term agreement (LTA) with UNDP. Given this arrangement, there is scope to simplify the procurement process for condoms, and thereby reduce the overall time needed.

44. The work-plan indicator that the CNP uses to monitor stock outs of condoms at sales points takes into account all stock outs experienced, including those of just one day in duration. Given that there is weekly resupply to sales points it would be more useful to only measure stock outs of more than seven days. This would result in measurement of the number of sales points that have missed at least one resupply, and thereby facilitate follow up of delays in the supply chain.

4. Annual procurement of small quantities can result in higher prices

45. EMED currently follows an annual procurement cycle and in some cases invites pre-qualified suppliers to submit a bid for the same products each year. EMED has not been using LTAs because the Global Fund budget is monitored and released on an annual basis. The increased volume agreed through LTAs could result in: reduced prices due to economies of scale; reduced workload for procurement staff due to a quicker process for placing orders; and a better level of service by suppliers. An LTA is an intention to buy,

[21] Due to time limitations, the OIG team did not establish the exact cause of each stock out noted. Delay in procurement was, however, cited as the cause of stock outs of social marketing condoms noted during the annual grant audit for 2010 [management letter for audit of ID 00059615 and ID 00074618], whereas delays in distribution of condoms were noted for the 2008 and 2009 grant audits [management letters for the audit of ID 00048105 and ID 00058109].

not a legal contract for the agreed volume and price. It can therefore be implemented alongside the annual budget cycle of the Global Fund.

Annex 1: Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CCM	Country Coordinating Mechanism
CECMED	National drug regulatory authority
CENESEX	National Center for Sexual Education
CNP	National Center for the Prevention of STI and HIV
EMCOMED	Storage and distribution company for pharmaceuticals
EMED	Government entity responsible for procurement for grant programs
EMSUME	Storage and distribution company for medical consumables
FPP	Finished Pharmaceutical Product
HIV	Human Immunodeficiency Virus
IPK	Pedro Kouri Institute for Tropical Medicine
LFA	Local Fund Agent
LTA	Long-Term Agreement
M&E	Monitoring and Evaluation
MINCEX	Ministry of Foreign Trade and Investment
MINSAP	Ministry of Public Health
MSM	Men who have Sex with Men
OFAC	The Office of Foreign Assets Control of the Department of the Treasury (U.S.)
OIG	Office of the Inspector General (Global Fund)
ONEI	National Statistics and Information Office
ONP	National Project Office (of MINCEX)
PPST	Persons who practice transactional sex
PR	Principal Recipient
PSM	Procurement and Supply Management
RCC	Rolling Continuation Channel (for Global Fund grants)
SIDATRAT	Online treatment management system
STI	Sexually Transmitted Infection
TB	Tuberculosis
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNGASS	United Nations General Assembly Special Session (on HIV/AIDS)
U.S.	United States
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

Annex 2: Recommendations and Action Plan

Risk	Recommendation	Comments and Agreed Actions	Responsible Party	Due Date
General				
1. Delays in Funds Transfer There is a risk that fund transfers to Cuba could be blocked due to U.S. Government sanctions, which could result in non-execution of program budget and non-implementation of program activities.	Recommendation 1 The Global Fund Secretariat should monitor the disbursements made to Cuba and inform the CCM immediately should any transfer be blocked. This will allow for coordinated measures to be taken on a timely basis to ensure the continuity of the grant programs.	Global Fund Secretariat Comment: The Global Fund Secretariat is in constant communication with the CCM and will continue following up on this issue.	Global Fund Secretariat	Completed
HIV				
2. First-Line Treatment Failure The risk of continuing the use of Stavudine and Indinavir, or of significant delays in phasing them out, is the emergence of drug resistance and the need to move to expensive third line drugs earlier in the course of therapy. In the long run, this will generate costs to the Cuban health care system that are higher than the additional investment that would be required now for an accelerated introduction of Tenofovir and Efavirenz in first line treatment protocols.	Recommendation 2 The MINSAP should change the current first line treatment protocol to eliminate Stavudine and Indinavir and instead include Efavirenz and Tenofovir. In the development of the Phase 2 budget and procurement plan for the HIV Round 2 RCC grant, the Global Fund Secretariat should support this change, even if this would require an increase in the ARV procurement budget of the grant.	Country Comment: The recommendation is technically coherent and had already been analyzed by the National AIDS Technical Committee. During the update of national guidelines in December 2011, now in final review process before publishing, Indinavir was withdrawn as a first-line ARV and it will be explicit that d4T is not a preferred regime. The definitive solution to this recommendation will be developed taking into account the related financial analysis to ensure the sustainable introduction of Efavirenz and Tenofovir once the projects are completed.	Dr. María Isela Lantero Department Head STI/HIV /AIDS MINSAP Dr. Daniel Pérez, IPK	Second half 2012 Presentation of results to the CCM and send report to the Global Fund

		Measurement: submit for approval to the National AIDS Technical Committee the result of the comprehensive analysis performed by national experts together with research institutions and industry, with subsequent submission to the competent state authorities for approval.		
3. ART Toxicity The use of Stavudine in the 40 mg formulation causes severe toxicity and harm to patients.	Recommendation 3 In addition to the recommendation to phase out the use of Stavudine in the medium to long-term, the Government of Cuba should take immediate action to reduce the dosage formulation of Stavudine from 40 to 30 mg.	Country Comment: The recommendation is correct, and the first working contacts with industry had already made. We are able to move forward on this recommendation and reformulate the d4T 40mg dose and produce a 30mg dose until we have another alternative nucleoside analogue as recommended by all international standards. Measurement: revitalization of the work with research institutions and industry, and define schedule for compliance with this recommendation.	Dr. María Isela Lantero Department Head STI/HIV /AIDS MINSAP Dr. Daniel Pérez, IPK	Second half 2012 Presentation of results to the CCM and send report to the Global Fund
4. ART Sustainability There is a risk that after 2014, many patients in Cuba will be on expensive 2nd and 3rd line ARVs which the Government will not be able to afford unless there is continued international assistance. The risk is difficult to assess because future	Recommendation 4 The MINSAP should, as quickly as possible, phase out the use of Indinavir in first line treatment regimes in order to increase the options of using affordable protease inhibitor drugs in second line treatment regimes. This would decrease the cost of second line treatment. At the same time, MINSAP should explore the possibility to initiate ART earlier in	Country Comment: The recommendation is technically correct. During the update of national guidelines in December 2011, now in final review process before publishing, Indinavir was withdrawn as a first-line ARV Measurement: Assess the number	Dr. María Isela Lantero Department Head STI/HIV /AIDS MINSAP Dr. Daniel Pérez, IPK	Second half 2012 Presentation of results to the CCM and send report to the Global Fund

development of the prices of these drugs is uncertain, as is the capacity of the Government of Cuba to invest in the procurement of the drugs. The main concern is about expensive Protease Inhibitors such as Tipanavir and Darunavir, and Fusion Inhibitors such as Enfurvitide which at current price levels cost between USD 700 to 1,000 each per patient per year.	the course of HIV infection, for instance among asymptomatic patients with CD4 counts between 350 and 500. This would boost HIV prevention, reducing the need for ARV procurement in the long term. The Global Fund should support these changes through the HIV Round 2 RCC grant.	of people who would need to be treated as a result of the change in the criteria for initiation of ART, along with the costs and medication needs according to strata of priority. Present to the National AIDS Technical Committee and submit for approval by the appropriate government bodies.		
5. VCT and Outreach In a population with low HIV prevalence, the positive predictive value of a test with 99.5% specificity is low. Even in the so-called "high risk environments",[22] you could expect that one in four positive test results could be falsely reactive. The fact that this has not been observed is no reason to ignore this risk. Although there are multiple safeguards in the counseling and support process, there is a significant risk of causing psychological distress among people who are falsely identified as having a reactive test result. This could be effectively mitigated by introducing a two-stage rapid testing algorithm in outreach	Recommendation 5 The MINSAP should consider applying a two-step rapid testing algorithm in the outreach campaigns "hazte la prueba" by adding a highly specific on-site confirmatory test.	Country Comment: The recommendation is theoretically correct. After reviewing the recommendation and considering that so far there have been no false positive cases in the entire universe of rapid tests performed in the campaigns "Hazte la Prueba" for the moment we believe that it is not pertinent that Cuba implement alternative strategies from WHO, with more than a screening test, which would increase program costs, and thereby limit program scope. Moreover, Cuba has additional confirmatory tests that constitute the gold standard for confirmatory diagnosis of HIV infection. We will, however, maintain this observation for consideration in the future.	N/A	N/A

[22] According to information provided to the OIG mission in 2 provinces, about 3,600 outreach tests were performed in 2011 with 40 positive results.

campaigns by adding a highly specific confirmatory test. Less than 20 confirmatory tests would be required for each 1,000 screening tests procured. This would not require a large investment and would eliminate unwarranted psychological distress.				
6. Food Supplementation The risk of continuing the program of Global Fund subsidized food supplementation is the use of Global Fund resources for a program that is not sustainable and for which there is little evidence of benefit. The investment in this program is not only the approximately USD 600,000 used annually for the procurement of food, but the considerable system costs of distribution and monitoring carried by the Government of Cuba. In terms of value for money, this program is not justifiable. There is a strong consensus among health personnel and among people living with HIV that there are greater priorities for the allocation of limited resources.	Recommendation 6 In the negotiation of the phase 2 agreement of the Round 2 RCC grant, the CCM and the Global Fund Secretariat should remove the support of food subsidies and reassign the savings to other priority program areas, especially for a faster change to more effective and better tolerated first line antiretroviral treatment.	Global Fund Secretariat Comment: The Secretariat discussed this issue during Phase 2 review and support for food subsidies was kept in the signed grant agreement as it was included in the original proposal. Country Comment: The recommendation will be evaluated. We will base a decision on an analysis of the results of several studies in the country. The analysis of ART will be considered independently of the issue of food subsidies, because treatment decisions must be sustainable for the country and not just for the two years that this recommendation refers.	Dr. Georgina Zayas, INHA Dr. Daniel Pérez, IPK Dr. Myrna Villalon, National Coordinator PVS Dr. María Isela Lantero Department Head STI/HIV /AIDS MINSAP	Second half 2012 Presentation of results to the CCM and send report to the Global Fund

7. Harm Reduction for Female Sex Workers The associated risk is a risk of omission. While the PPST program generates some benefits, it is neither targeting nor achieving harm reduction among female sex workers in Cuba. There is a high level of uncertainty about the profile of sex work in Cuba. But as long as the program is preoccupied with reaching larger and larger numbers of "people associated with transactional sex" it will not be able achieve the necessary depth to acquire this knowledge and to develop an appropriate response.	Recommendation 7 Under Objective 1 of the HIV Round 2 RCC grant, the CNP should develop a better understanding of the profile of female sex work in Cuba and implement an appropriate harm reduction program. This may require technical assistance from experienced organizations in the region, some of which has already taken place. For instance, the CNP has had consultation with the Centre for Integrated Training and Research (COIN) in the Dominican Republic. Research and evidence-based programming with regard to female sex workers is a primary component of COIN's work. http://www.coin.org.do/Idioma/english/history.html	Country Comment: In Cuba, so called sexual work is not acknowledged as an occupation, thus national law in line with ILO Conventions and resolutions do not accept this as a profession or trade. Pimping is prohibited by law. Nevertheless we agree there is a need to carry out preventive work with women and men who practice commercial or transactional sex. Measurements: a. - Extend the exchange of experience with organizations in the region with experience in working with women who practice commercial or transactional sex. b. - Conduct qualitative research in our context and use the results to inform the work with this vulnerable group.	Dr. Ochoa Rosaida Director CNP	a. - Second Semester 2012 b. - First Quarter 2013 Presentation of results to the CCM and send report to the Global Fund
8. HIV Indicators The risk of introducing a tool to avoid "double counting" in training activities is the addition of a very costly process, mostly in terms of opportunity costs incurred by the grant sub-recipients and implementing organizations. Besides being costly, it risks undermining the very objective of these training programs, namely to strengthen sustainable and self-supporting	Recommendation 8 When finalizing the HIV Round 2 RCC Phase 2 performance framework, the Global Fund Secretariat, in conjunction with the PR, should abandon the proposal to eliminate re-training and repeat contacts from performance reporting of training and mobilization indicators. Repeated trainings and contacts should instead be encouraged. If it is really necessary to count and report numbers of people reached or trained, then the counts should be based on the number of contacts rather than on the number of persons.	Country Comment: The indicator "number of contacts" is already considered in the RCC. This recommendation is thus considered closed.	N/A	N/A

networks of people who are affected by HIV or who are at risk of contracting HIV.				
9. Condom Brand Continuity Maintaining the Vigor and Vigor Max brands of condoms in the market after the end of Global Fund grant support will most likely require a higher level of government subsidy than is currently provided for the government brand, Momentos. This creates the risk that the Vigor and Vigor Max brands may disappear which could have a negative impact on condom use among people who have established brand loyalty, and would result in the loss of the more resistant condom brands, including the brand specifically suitable for anal sex.	Recommendation 9 The National Program for STI and HIV should conduct a study of brand preference for Vigor and Vigor Max condoms and of purchasing behavior among key groups targeted by HIV prevention programs. This evaluation should provide the necessary evidence to reach a decision about future subsidies and market pricing of these condom brands after the end of Global Fund support.	Country Comment: Agreed. Measurement: Develop a proposal for sustainability of the VIGOR and VIGOR MAX brands for analysis by the AIDS Technical Committee, and referral to the authorities of the Ministry of Public Health with a view to achieving sustainable future imports.	Dr. Rosaida Director CNP Dr. María Isela Lantero Head of Department STI/HIV/AIDS MINSAP Director MEDICUBA	Second half 2012 Presentation of results to the CCM and send report to the Global Fund
	Recommendation 10 As it will be difficult to generate sufficient evidence and reach an informed decision within the remaining time of the Global Fund Round 6 HIV grant, the CCM should consider negotiating with the Global Fund to continue country-wide support for the marketing of Vigor condoms as part of the Round 2 RCC grant until this grant ends in December 2014.	Country Comment: Agreed. Measurement: From the results of the measurement listed in Recommendation 9, communicate to the CCM the response of the MINSAP authorities and, if not made sustainable by the Cuban state, develop a proposal to the Global Fund.	Dr. Rosaida Director CNP Dr. María Isela Lantero, Head of Department STI/HIV/AIDS MINSAP Director MEDICUBA	Third quarter of 2012 Presentation of results to the CCM and send report to the Global Fund
Tuberculosis				
10. Laboratory Infrastructure Several small or temporary deficiencies in infection control and biosecurity related to laboratory infrastructure, when taken in combination, indicate a non-negligible risk of occupational exposure to tuberculosis among laboratory	Recommendation 11 The MINSAP should review the infrastructure of tuberculosis laboratories at all levels and inform the relevant authorities about structural issues that expose laboratory staff to the risk of infection. Measures to address these issues will have to be negotiated individually on the local (provincial or municipal) levels.	Country Comment: The recommendation is suitable and both the PNCT and the IPK laboratory will work on possible solutions, according to maintenance plans and investments of local governments in the provinces.	Directors of CPHM and Dr. Ernesto Montoro, IPK	September 2012. Submission to CCM of the plan of action, with the date of inclusion in the

staff at different levels.		Action: The IPK reference laboratory and the heads of all provincial laboratories will develop an action plan to solve the problems, including tasks that must be incorporated into the maintenance plans of the provinces. In the case of the laboratories of the provinces of Havana (Plaza) and Ciego de Avila (CPHEM), minimum improvements to their infrastructure should be undertake to achieve optimal functioning of biological safety cabinets purchased with project financing. In all other laboratories performing smear, should be improved the conditions of ventilation (exhaust fans) should be improved to lower the risk of infection for workers. <u>Global Fund Secretariat Comment:</u> In the approved budget for phase 2 of this program there is a total of US $ 96,221 (years 4 and 5) allocated for the improvement of infrastructure of TB laboratories. The Secretariat will work with the PR to consider budget implications. Any costs which go beyond the approved budget will have to be financed by other sources identified by the PR and CCM.		maintenance plans of the provinces.

11. TB Indicators The Round 7 tuberculosis framework significantly increases the cost of grant implementation without generating any associated benefit. This cost is often indirect and hidden. It is more likely to be carried by the national budget than by the grant. It is a cost that could be minimized if the grant performance framework were better aligned to the national framework. Furthermore, there is a risk of sustainability. The mechanisms created to monitor indicators that are meaningless to the national program have no sustained benefit. Finally, there is the risk that the Global Fund investment is not adequately monitored. Nearly half of the Global Fund grant in phase 1, approximately USD 1.6 million, was spent on equipment for 344 laboratories. The purpose of this investment was to improve laboratory performance. The national health information system has several good indicators to monitor laboratory performance. Instead, the Global Fund is simply tracking inputs by counting the "number and percentage of reinforced laboratories".	Recommendation 12 The OIG does not recommend revision of the performance framework of the tuberculosis grant in Cuba because the grant is in its final implementation phase. However, the OIG recommends that the Global Fund Secretariat should in future be more vigilant in its grant negotiations to avoid the signature of grant agreements that include performance frameworks that are so poorly aligned with national systems. Older frameworks can be significantly improved during the negotiation of phase 2 agreements.	Global Fund Secretariat Comment: The recommendation is taken into consideration.	Global Fund Secretariat	Completed

Procurement and Supplies Management				
12. Condom Storage Improper storage conditions of condoms could result in a decreased quality and an increased risk of failure of the condoms.	Recommendation 13 EMSUME should improve storage conditions at the central and provincial warehouses by: a) Applying the international guideline for supply of condoms: "WHO/UNAIDS/UNFPA/FHI Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010" and ensuring that all the recommended conditions for storage of condoms are implemented at all warehouses and condoms are not stored in ad-hoc storage areas, such as sea cargo containers. b) Providing each store with a thermometer and register temperatures periodically. c) Applying Good Warehousing Practices, by: o Implementing areas for receiving and distributing. o Using separate stock cards per product, per store location. o In case of space constraints, implement pallet racks to increase warehouse capacity. o Ensuring storage areas are kept free of birds and rodents by closing ventilation holes with screens or grates.	Country Comment: Agreed. Measurement: a.1-The PR will consider the details regarding the procurement process. a.2-CECMED will respond with the quality control plan for the sampling of products. b and c.- Incorporate current action plans on improving the conditions of storage, and the recommendations of the diagnostic review.	Dr. Rosaida Ochoa, Director CNP Dr. Diego Álvarez Dopazo, Director	a. - First Semester 2012 b and c. - First Semester 2012. Action Plan reworked and submitted to the CCM and Global Fund
13. Quality Testing Due to a lack of quality control after the pre-shipment quality control test, carried out under responsibility of the manufacturer, there is a risk of providing sub-standard condoms and pharmaceutical products to	Recommendation 14 The Global Fund Secretariat should encourage the PR to collaborate with CECMED to ensure that the requirements of the Global Fund Quality Assurance Policy for Pharmaceutical Products (as amended and restated on 14 December 2010) are met, in particular: "that random samples of finished pharmaceutical	Global Fund Secretariat Comment: According to the Grant Agreement, the PR is responsible of the quality of health products procured with Global Fund resources. With regards to testing samples in laboratories, the laboratory should comply with the Global Fund QA	Dr. María Isela Lantero, Chief PN MINSAP Dr. Daniel Pérez, IPK Dr. Pérez	Second quarter 2012 Submission for approval to the Global and the LFA of the governing

the end-user.	products (FPPs) are obtained at different points in the supply chain - from initial receipt of the FPPs in-country to delivery to end-users/patients - for the purpose of monitoring the quality of such FPPs (including quality control testing)".	policy. Country Comment: These processes have been worked in the organization, and will be the responsibility of the national health authority. There is already a draft document that is under review. It is an effort of the country to establish quality control for all medicines, similar to the system that already exists for vaccines. Investments are planned over a two-year timeframe. While all testing is not being conducted in the country, the CECMED will send samples to a laboratory.	Cristía, Director CECMED Dr. Carlos Cortés, UNDP	document for quality control
14. Procurement Delays Delays in the procurement and delivery process of condoms can result in limited supply and stock-outs at sales points.	Recommendation 15 The Global Fund Secretariat should explore with the PR the opportunities to simplify and speed up the procurement process for condoms procured under the LTA with UNFPA, with the objective to reduce the time required from when the CNP places the order until the purchase order is issued to UNFPA. It is also important to ensure that delivery terms are met by UNFPA.	Global Fund Secretariat Comment: The PR is responsible to engage the most adequate procurement methods in line with the Global Fund PSM Policies and Good Procurement Practices, and ensure the best possible services. The PR is also responsible to plan adequately the procurement process in order to avoid delays in implementation. Country Comment: Agreed. The PR to explore alternatives.	UNDP	Immediate
	Recommendation 16 The CNP should change its internal work-plan indicator to measure stock outs of condoms at	Country Comment: The recommendation will be followed up in the reports	Lic. Mildred Iglesias, ONEI	Second Semester 2012.

	sales points from 1 day to a minimum of 7 days, in order to measure the number of sales points that have missed at least 1 resupply, thereby facilitating follow up on delays in the supply chain.	beginning the second semester of the on-going RCC year. We are doing this because we need to introduce changes in the guidelines throughout the country, looking to produce consistent reports. This indicator is a country indicator and not a performance framework indicator. For Round 6 this recommendation would need to be negotiated with the Global Fund Secretariat, as in this Project this indicator is reported to them. This recommendation, however, is not feasible as Round 6 will close by the 31 December 2012.	Dra. Rosaida Ochoa, Director CNP Dr. Rafael Iglesias, CNP	
15. Procurement Quantities Annual procurement of small quantities of products that are procured every year can increase prices and procurement workload.	Recommendation 17 EMED should explore alternative procurement solutions under the HIV Round 2 RCC grant in order to identify the products that are bought regularly in relatively small quantities (such as some laboratory reagents). For procurement of the identified products, EMED should aim to combine the quantities for 2013 and 2014, and invite pre-qualified suppliers to submit bids for an open Purchase Order or LTA. If required, EMED should seek technical assistance from UNDP for the establishment of these procurement instruments.	Country Comment: A study of procurement for years 4 to 6 of RCC has already been initiated for the reagents and other products, considering sources and risks. Once completed, if open Purchase Order or LTA is considered convenient, the Secretariat will be consulted to determine whether this is relevant given the Global Fund staggered funding commitment policy.	Dr. Mirta Villanueva, ONP Dr. Carlos Cortés, UNDP Mrs. Limay Deler, EMED	First half 2012 Presentation of results to the CCM and send report to the Global Fund