

Review of financial sustainability of tuberculosis activities in Armenia

11-12 September 2017 Mission Report

Edited by Martin van den Boom, Nikoloz Nasidze and Allira Attwill



© World Health Organization [2018]

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Review of financial sustainability of tuberculosis activities in Armenia. World Health Organization; [2018]. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Contents

Abbreviations	3
Executive summary	4
Socioeconomic and geopolitical context	9
Policy and strategies pertaining to TB	9
Financing and planning	11
Medicines procurement	14
Supervision, monitoring and surveillance	15
Quality, safety and standards	16
Service delivery and linking with other interventions – health system strengthening	17
Evidence-based TB policy and practice	18
Communications and advocacy	19
Annex. Mission schedule and people met	20

Abbreviations

CCM Country Coordinating Mechanism

CSO civil society organization

FLD first-line drug

GDF Global Drugs Facility
GDP gross domestic product

HIV human immunodeficiency virus M&E monitoring and evaluation MSF Médecins Sans Frontières

MoH Ministry of Health

M/XDR-TB multidrug and extensively drug-resistant tuberculosis

NSP National Strategic Plan for Tuberculosis Prevention and Care

NTC National Tuberculosis Centre
NTP National Tuberculosis Programme

PHC primary health care

PIU Project Implementation Unit

PMDT programmatic management of drug resistant tuberculosis

SLD second-line drug
TB tuberculosis

Executive summary

The WHO Regional Office for Europe is supporting six Eastern Partnership countries to document preparedness to transition from donor- to domestically funded tuberculosis (TB) activities. As part of this work, two consultants travelled to Armenia on 11–12 September 2017 for WHO's second in-country discussions for this project. Discussions focussed on sustainability successes and challenges; triggers and enablers for transition; gaps in transition-related financial, human resource and programmatic data; and the country's existing transition plan. Findings are outlined below.

Armenia is just beginning the transition process, and does not yet have a clear transition and sustainability plan (TSP). The Global Fund to Fight AIDS, Tuberculosis and Malaria conducted a transition preparedness assessment for Armenia in 2017, and the risk posed to TB programmes during transition was categorized as "medium".¹

From a policy and legislative perspective, the Ministry of Health of Armenia (MoH) has developed the National Strategic Plan for Tuberculosis Prevention and Care (2016–2020) (NSP). The NSP presents programmatic interventions, indicators and an action plan, though it lacks financial figures and resources, and the takeover of financial responsibilities by the government is not clearly set out.

The National Assembly (Parliament) of Armenia has endorsed the Law on Medicines (2016) and clinical guidelines for prevention and treatment of TB are available, though they need updating. The National Tuberculosis Centre (NTC) developed and released new national guidelines for TB and drug-resistant TB (DR-TB) in 2016, endorsed by the MOH through Decree 2462 (5 August 2016). The new grouping of TB drugs needs to be included in the updated guidelines, to align with the new version of the WHO guidelines on programmatic management of drug resistant tuberculosis (PMDT).²

The Government of Armenia strives to provide full and equal access to essential services, including diagnosis and treatment for TB, multidrug and extensively drug-resistant TB (M/XDR-TB) and TB/HIV coinfection. However, the World Bank reports that government expenditure on health care remains insufficient at about 1.9% of gross domestic product (GDP); total health expenditure (public + private) is 4.5% of GDP and spending on health is only 7% of total government expenditure (2014).³

The Armenia Development Strategy for 2014–2025 assumes that public expenditure on health care will increase to 1.8% of GDP by 2017 and to about 2.7% by 2025. However, due to the new government's economic strategy, the health budget will be reduced.

https://data.worldbank.org/indicator/SH.XPD.PUBL.GX.ZS?end=2014&start=1995&view=chart

¹ Transition preparedness assessment report: The Global Fund programmes to fight against HIV/AIDS, tuberculosis and malaria in the Republic of Armenia (an unpublished draft was shared with the mission).

² Regional Green Light Committee for Europe Mission, Armenia, October 2016.

³ World bank health expenditure data:

Usually, a reduction in donor funding is met by an increase in domestic funding, however Armenia is facing the problematic situation whereby the Global Fund's withdrawal will be exacerbated by a concurrent reduction in the government's allocation to the health budget. Currently, Armenia has no gap in TB services, 55% of which are paid for by the government and 45% by the Global Fund. However, a significant gap will very likely appear when the Global Fund begins withdrawing in 2019.

The government does not fund second-line anti-TB drug (SLD) procurement or curative treatment programmes among target groups. This poses a significant risk for TB programme sustainability, since the amount of co-financing and self-reliance needs to be increased significantly and at pace.

The lack of a reliable estimate of the government's final budget allocation to health makes budgeting and planning for health programmes difficult. Despite the reduced allocation to the overall health budget, an additional US\$ 1 million has been secured for 2019–2020 for HIV and TB. However, this does not mitigate the fact that the next Global Fund grant is three times smaller than that previously received. The entire TB/HIV budget is US\$ 8.3 million (US\$ 3 million for TB, and the rest for HIV). As the current Global Fund grant for TB is US\$ 9.2 million, this represents a significant reduction.

The Country Coordinating Mechanism (CCM), the national committee that coordinates funding applications to the Global Fund and country-wide activities related to TB, HIV and malaria, is yet to be integrated and it is not known what form it will take after Global Fund withdraw.

The NTC conducts supervisory visits of specialized TB services several times per year, depending on needs at service delivery level. The E-TB database collects information at NTC level, providing TB statistics to MoH authorities and partners. The functionality of this system is supported by the Global Fund.

Beyond the reductions in government and donor financing and the lack of a clear TSP, the biggest challenges facing the sustainability of Armenia's TB programme include general inefficiencies and a lack of mechanisms to support an efficient and uninterrupted supply of quality pharmaceuticals. Despite primary health care (PHC) reforms, Armenia relies heavily on expensive specialist care.

Quantification, procurement, importation and storage of first- and second-line anti-TB drugs is carried out with Global Fund support and managed by the Global Fund Project Implementation Unit (PIU) in the MoH. Losing access to the Global Fund procurement platform post-transition could have a negative impact on TB incidence, case complexity and patient outcomes.

Currently, financial incentives for PHC practitioners to conduct outpatient activities are insufficient and too many patients are unnecessarily treated by expensive specialists.

Finally, an analysis of Global Fund funding, to highlight where the most important programmatic and financial gaps may appear (in the post-transition context), has yet to be requested or conducted.

Key recommendations

Area	Action	Timeline	Responsible agency
Policy and strategies pertaining to TB	Accelerate work on Armenia's transition plan – include all aspects of TB activities supported by the Global Fund and other donors.	Q2 2018	NTP
	Clarify roles and responsibilities and timelines associated with implementing the National Strategic Plan for Tuberculosis Prevention and Care, to address expected gaps following Global Fund withdrawal and government funding reduction, and to outline accountability and define a step-wise handover process.	Q2 2018	NTP, Government of Armenia, MoH, Global Fund
	Update the clinical guidelines for prevention and treatment of TB.	Q2 2018	NTP, MoH, Global Fund
Financing and planning	Conduct an education and awareness campaign to target at-risk populations, clarifying that standard out-of-pocket payments at PHC level do not apply for TB testing or diagnosis.	Q2 2018	NTP
	Increase government expenditure on health as a percentage of GDP and as a percentage of total government expenditure.	For next budget	Government of Armenia
	Increase government expenditure on TB as a percentage of total government expenditure and as a percentage of the health budget.	For next budget	Government of Armenia
	Form an advocacy coalition to communicate to the government the enormous implications of reducing the TB budget	For next budget	Global Fund, WHO Regional Office for Europe, MSF and CSOs
	Clearly communicate a best estimate for the health allocation for the next term so government agencies and donors can plan accordingly to prevent disruption to general health and TB services.	End of Q2 2018	Government of Armenia, MoF
	Clarify the exact budget breakdown between HIV and TB funds for 2018	For next budget	Government of Armenia, Global Fund
	Develop a clear, concise brief on why a second performance indicator (related to TB patient management) is needed. This should	End of Q2 2018	NTP

d,
<u>d,</u>
d,
d,
е
l
)
al
aı
d,
e,
D-
ł

		2010	
		2018	
	Revise procurement law and other regulations	Engagement	NTP, Global Fund,
	to remove barriers to providing quality	should begin	WHO Regional
	assured medicines and laboratory	by Q2 2018	Office for Europe,
	consumables in Armenia.	and be agreed	GDF, MSF, USAID-
		by end Q3	Janssen
		2018	
	Clarify and outline the financial support	Q2 2018	Government of
	(salaries) for the drug management team to		Armenia
	ensure smooth continuation of activities		
	related to drug management, following Global		
	Fund withdrawal.		
Quality, safety	Develop a clear, concise brief outlining the	End Q2 2018	NTP, Global Fund,
and standards	implications and risks associated with price		WHO Regional
	fluctuations.		Office for Europe
Service delivery	Plan for government takeover of patient	Q2 2018	All relevant
and linking with	support expenses to ensure treatment		government
other	adherence and a high success rate in		departments,
interventions -	treatment outcomes, and reflect this in the		multiple cross-
health system	transition plan.		sectoral
strengthening			stakeholders
	Plan training (and re-training) sessions for all	Ongoing	NTP, Global Fund,
	actors involved in TB prevention and care and		WHO Regional
	budget appropriate finances.		Office for Europe
	Consider support for activities relating to	End Q2 2018	NTP, Global Fund,
	home care and video DOT, and reflect this in		WHO Regional
	the transition plan.		Office for Europe
	Consider active case finding activities among	Q2 2018	NTP, MoH
	vulnerable population groups, and reflect this		
	in the transition plan.		
Evidence-based	Monitor the results-based financing pilots in	Engage	NTP, MoH
TB policy and	neighbouring countries of the region, with	Curatio	
practice	regard to cost-effectiveness and affordability	immediately	
	of supply-side incentives in a similar context.	to establish a	
		date to	
		discuss	
		findings	
Communications	Provide resource mobilization and advocacy	By end Q1	WHO, Global
and advocacy		2010	F d
,	training to assist proactive CSO participation	2019	Fund.

CCM = Country Coordinating Mechanism; CSO = civil society organization; GDF = Global Drugs Facility; GDP = gross domestic product; M&E = monitoring and evaluation; MoF = Ministry of Finance; MoH = Ministry of Health; MSF = Médecins Sans Frontières; NTP = National Tuberculosis Programme; PHC = primary health care; TB = tuberculosis; USAID – United States Agency for International Development.

Socioeconomic and geopolitical context

According to the United Nations Development Programme (UNDP) Armenia ranks 84th on the Human Development Index. The population of Armenia is 3 million, 62.7% of which is in urban areas. Armenia is administratively divided into 10 *marz* (regions) plus the capital city Yerevan, which accounts for one third of the country's population.

The turbulent economic and sociopolitical difficulties observed in the 1990s affected population health, reducing life expectancy to 74.9 years (2016). However, since 2000, the country's overall situation has improved, though some health indicators still lag behind other countries in the region.⁴

Armenia's GDP per capita has gradually increased in the last decade from US\$ 5607 in 2006 to US\$ 8817 in 2016. The World Bank categorizes Armenia as a lower-middle income country.

Policy and strategies pertaining to TB

In 2014, the Government of Armenia inaugurated the Armenia Development Strategy for 2014–2025. This is a comprehensive document on all areas of government activity, which revises the Sustainable Development Programme adopted in 2008. According to the Strategy, the government plans to focus on measures for prevention of noncommunicable diseases (NCDs), through early diagnosis and treatment. In this regard, the interrelated development of outpatient and inpatient health-care services is foreseen as a key determining factor in ensuring the proper delivery and continuity of medical care. Priority areas include maternal and child health care, and cardiovascular and oncological diseases. No communicable diseases are listed as priorities.

The Strategy assumes that public expenditure on health care will increase to 1.8% of GDP by 2017 and around 2.7% by 2025. However, during the mission, colleagues from the NTP, MoH, Global Fund PIU and MoF reported that due to new the government's new economic strategy, the health budget will be reduced. The extent to which it will be cut and which programmes will be most affected are yet to be defined, though discussions are underway. It is also not clear if (or by how much) the budget for TB activities will be affected.

In 2015, the MoH developed the National Strategic Plan for Tuberculosis Prevention and Care (2016–2020), which was endorsed by the government in March 2016. The NSP presents programmatic interventions, indicators for implementation and an action plan. However, the

⁴ Global Health Observatory data: http://www.who.int/gho/countries/arm

⁵ World Bank GDP data: https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD?locations=AM

NSP lacks financial figures and resources, and the takeover of financial responsibilities by the government is not clearly set out.

Based on the NSP, a concept note was developed for a new funding model for Global Fund support. The concept note was accepted and Armenia received US\$ 9.2 million for TB activities for the implementation period October 2015 – September 2018.

Local experts conducted a transition preparedness assessment of Global Fund supported HIV and TB programmes in Armenia in 2017. Curatio International Foundation provided training on the structure and design of the assessment. Although the document has not been finalized yet, a draft of the report was kindly shared with the mission. Based on this assessment, the MoH, along with key stakeholders, will develop a plan to guide the transition from donor to domestic funding for both programmes. The transition plan was due to be released in 2018.

The NTC developed and released the new version of the national guidelines for TB and DR-TB in 2016, endorsed by the MoH through Decree 2462 (5 August 2016). The updated national guidelines do not match the new version of the WHO guidelines on PMDT; however, they also do not contradict current WHO policy and approaches to patient management and care. The area of misalignment relates to the lack of new groupings of TB drugs. In Armenia's case, groupings are still based on the classification of TB drugs described in the WHO compendium handbook guidelines on PMDT from 2015. 6

Recommendations

Action	Responsible agency
Accelerate work on Armenia's transition plan	NTP
 include all aspects of TB activities 	
supported by the Global Fund and other	
donors.	
Clarify roles and responsibilities and	NTP, Government of Armenia, MoH, Global
timelines associated with implementing the	Fund
National Strategic Plan for Tuberculosis	
Prevention and Care, to address expected	
gaps following Global Fund withdrawal and	
government funding reduction, and to	
outline accountability and define a step-wise	
hand-over process.	

⁶ Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. Geneva: World Health Organization; 2015 (http://www.who.int/tb/publications/pmdt_companionhandbook/en/, accessed 5 February 2018).

Update clinical guidelines for prevention and	NTP, MoH, Global Fund
treatment of TB.	

Financing and planning

The Government of Armenia strives to provide full and equal access to essential services, including diagnosis and treatment of TB, M/XDR-TB and TB/HIV coinfection. Armenia has zero out-of-pocket payments (OOPs) for TB-related services, however, standard OOPs at point of use do exist for non-TB services. The existence of these charges and a lack of understanding among at-risk groups that these OOPs do not apply to TB-services might deter patients from accessing PHC and seeking TB diagnosis. Further, the World Bank reports that government expenditure on health care remains insufficient, at about 1.9% of GDP (the world average was 5.99% in 2014; most countries in the region average 3.88–5.41%); total health expenditure (public + private) is 4.5% of GDP (the world average was 9.92% in 2014; most countries in the region average 6.13–7.81%) and spending on health is 7% of total government expenditure (the world average was 15.81% in 2014; most countries in the region average 9.55–12.54%).³

During the 2-year period spanning 2015–2016, the NTP experienced a considerable growth in funding. According to the transition preparedness assessment, the state allocations were 50–74%, which is assessed as "moderate". It should be noted that government budget does not fund SLD procurement or curative treatment programmes among target groups. This poses a significant risk for TB programme sustainability, since the level of co-financing and self-reliance needs to be increased significantly and at pace.

Usually, a reduction in donor funding is met by an increase in domestic funding, however Armenia is facing the problematic situation whereby the Global Fund's withdrawal will be exacerbated by a concurrent reduction in government allocation to the health budget. Currently, Armenia has no gap in TB services, 55% of which are paid for by the government and 45% by the Global Fund. However, a significant gap will very likely appear when the Global Fund begins withdrawing in 2019. During this mission, different agencies reported different estimates of the government's reduction in allocation to the health budget, ranging from 6–8% (MoF estimate) to 20% (NTP estimate).

Currently, the government is attempting to reduce costs and reallocate funds to capital investments, which will hopefully increase revenue in the near future and result in increased government spending capacity across the board. Until such time as these investments pay off, budget uncertainties in Armenia make planning for health programmes difficult. Beyond the prioritization of health within the overall national budget, another issue is that a reliable estimate of total government revenue (i.e. the denominator) is unknown, as is a reliable estimate of the government's final allocation to health.

The reduction in the government's allocation to the health budget is particularly problematic for planning purposes because an increase in health expenditure had been outlined by the previous government for the periods 2017–2021 and 2021–2025, as detailed in Table 1. Plans must now be changed accordingly, though what the new budget might be is not fully clear.

Table 1. Consolidated budget expenditures on health care 2012 (actual) and 2014–2025 (projected) in Armenia

Indicators	2012	2014	2017	2021	2025
	Actual		Proje	cted	
Consolidated budget expenditure on	64.8	80.6	112.0	209.2	381.7
health care, billions of drams					
% of GDP	1.6	1.7	1.8	2.2	2.7
% of consolidated budget total expenditure	6.2	6.3	6.7	7.9	9.3
Year-on-year percentage change	2.1	24.9	22.2	17.0	15.9
Real consolidated budget expenditure on health care (Index, 2012 = 100)	100	116	144	230	358
Per capita real consolidated budget expenditure on health care (Index, 2012 = 100)	100	115	142	227	355

GDP = gross domestic product.

Source: Armenia Development Strategy for 2014–2025; Annex to Republic of Armenia Government Decree No. 442 - N, 27 March 2014.

Despite the reduced allocation to the overall health budget, Armenia's Global Fund team leader managed to advocate for a slight increase in TB programme funding (approximately US\$ 500 000) for 2017–2018. An additional US\$ 1 million was also secured for 2019–2020 for HIV and TB, though the exact breakdown between HIV and TB is not yet known.

While this represents a significant win for the TB programme in light of an overall health budget decrease, it does not mitigate the fact that the next Global Fund grant is three times less than that previously received. The entire TB/HIV budget is US\$ 8.3 million (US\$ 3 million for TB, and the rest for HIV), compared to the current Global Fund TB grant of US\$ 9.2 million, representing a significant reduction.

At health service level, some PHC facilities still follow the old soviet model (the refund related to outpatient activities is fixed, based on the catchment population of the facility) though all are capitation funded (not fee for service).⁷

The NTP is making a concerted effort to ensure funding is based on the quality of the service provided (not just the quantity) to incentivize PHC doctors to screen and diagnose high-risk patients and refer them on to TB specialist care. At PHC level, 1 of the 13 performance

⁷ Gillini L, Davtyan K, Davtyan H, Hayrapetyan A, Khachatryan S, Centis R et al. TB financing in East Europe promotes unnecessary hospital admissions: the case of Armenia. J Infect Dev Ctries. 2013;7(3):289–92 (https://jidc.org/index.php/journal/article/view/23493010/851, accessed 7 February 2018).

indicators is specific to TB detection: the more patients a physician detects with TB, the better their performance is ranked. However, the NTP is advocating for the inclusion of another indicator related to TB patient management, to minimize the risk of PHC physicians over-reporting incidence of TB to maximize their payment, and to ensure that every case that is reported is then tracked and managed. Essentially, this would link PHC physician payments to their management of TB patients.

At the time of the mission, the government was in the process of undergoing a health system optimization assessment, which was due to be completed by the end of 2017. The recommendations from this assessment should inform the transition plan, though no formal intention for this to happen has been stated. It is expected that the key outcome of this assessment will be to provide the government with an understanding of how to make the health-care system more cost-effective.

No meaningful breakdown or estimate of financial or programmatic gaps following Global Fund withdrawal has been produced, and the government has not expressed any intention to lead such assessment.

Other financing and planning issues that need to be addressed include the intended future of the CCM, which appears to have been given little official consideration. The major function of the CCM in Armenia is to coordinate applications for TB and HIV funding. It is not known how the CCM will be integrated after Global Fund withdraw, though stakeholders engaged during the mission expressed concern that its effectiveness will be reduced.

Recommendations

Action	Responsible agency
Conduct an education and awareness campaign to	NTP
target at-risk populations, clarifying that standard	
out-of-pocket payments at PHC level do not apply	
for TB testing or diagnosis.	
Increase government expenditure on health as a	Government of Armenia
percentage of GDP and as a percentage of total	
government expenditure.	
Increase government expenditure on TB as a	Government of Armenia
percentage of total government expenditure and	
as a percentage of the health budget.	
Form an advocacy coalition to communicate to the	Global Fund, WHO Regional Office for
government the enormous implications of	Europe, MSF and CSOs
reducing the TB budget	
Clearly communicate a best estimate for the	Government of Armenia, MoF
health allocation for the next term so government	
agencies and donors can plan accordingly to	
prevent disruption to general health and TB	

services.	
Clarify the exact budget breakdown between HIV	Government of Armenia, Global Fund
and TB funds for 2018	
Develop a clear, concise brief on why a second	NTP
performance indicator (related to TB patient	
management) is needed. This should consider both	
financial and health-related outcomes from the	
perspectives of the government, care provider and	
patient.	
Finalize a clear transition plan outlining a timeline	NTP, Global Fund, WHO Regional Office
for transitioning to a domestically financed TB	for Europe
programme.	
Consider and define the role of the CCM post-	Government of Armenia, Global Fund,
Global Fund withdrawal.	MoH, NTP
Continue advocating for PHC reforms that direct	NTP, MoH
care away from expensive specialist care.	NTP, WOR
care away from expensive specialist care.	
Consider findings from the health-care system	NTP, MoH
optimization assessment and reflect these in the	
transition plan.	
Conduct a full analysis of Global Fund funding to	NTP, MoH, Global Fund, WHO,
highlight where the most important programmatic	Government of Armenia
and financial gaps may appear.	

Medicines procurement

TB medicines, including new TB drugs, are provided free of charge to all TB and DR-TB patients in Armenia, regardless of immigration status. Shortages in drug supply have not been observed. Procurement of first-line TB drugs (FLDs), SLDs and ancillary medicines, as well as laboratory consumables, is performed through the GDF, with funding from the Global Fund grant. Quantification, procurement, importation and storage of the FLDs and SLDs is carried out with Global Fund support and managed by the Global Fund PIU in the MoH. The NTC is responsible for selection, forecasting, drug ordering and distribution directly to TB facilities, including the prison sector. Procurement of new TB drugs is also donor-dependent, relying on the following sources of funding: the endTB project implemented by MSF, the Global Fund grant and the USAID-Janssen bedaquiline donation programme.

Procurement of FLDs was envisaged by the government and budgeted for in 2016, however, this did not happen due to a lack of registered pharmaceutical companies in Armenia, and the lack of quality-assured TB medicines in the local market. Currently, the Global Fund PIU is undertaking steps to assess the possibility of purchasing TB medicines from a single provider

(the GDF). The government's plan to gradually increase funding for procurement of TB drugs is not specified in any document or strategic paper.

Recommendations

Action	Responsible agency
Formally agree upon the post-transition	NTP, Global Fund, WHO Regional Office
procurement platform.	for Europe, GDF, MSF, USAID-Janssen
Develop a transition plan to clearly define to what	Global Fund and WHO
extent and over what time the government will	
increase responsibility for TB drug procurement.	
Revise procurement law and other regulations to	NTP, Global Fund, WHO Regional Office
remove barriers to providing quality assured	for Europe, GDF, MSF, USAID-Janssen
medicines and laboratory consumables in Armenia.	
Clarify and outline the financial support (salaries)	Government of Armenia
for the drug management team to ensure smooth	
continuation of activities related to drug	
management, following Global Fund withdrawal.	

Supervision, monitoring and surveillance

In 2014, the national TB prevention and care programme merged with the Republican Tuberculosis Dispensary to form the National Tuberculosis Centre (NTC). As a result of this merger, the NTC gained strengthened roles in TB policy development and implementation, and in the coordination of work among all stakeholders in the TB system, including M&E.

The NTC is the national centre (referral hospital) for TB clinical management, and is also responsible for the supervision of specialized TB services, mentoring TB medical personnel, and monitoring the quality of services, including field supervision and routine data collection and reporting on TB. Supervision is conducted by a dedicated M&E team, which consists of four people. Supervision visits are complex, and include treatment, drug and laboratory components. Each TB inpatient and outpatient unit at *marz* level is receives supervisory visits several times during the year, depending on their needs. In addition to central level supervision, the heads of health departments in each *marz* are responsible for coordination of TB activities in their region.

Currently, M&E team salaries and all expenses related to monitoring visits are paid by the Global Fund. The M&E team is an important unit in Armenia's NTP and provides reliable data to the MoH and Global Fund. According to the NTP manager, Dr Armen Hayrapetyan, salaries for M&E unit staff will be ensured by the government (NTC), after planned structural changes occur in the NTC.

The electronic information system (E-TB database), collects information at NTC level, gathered by the M&E team. It provides TB statistics to MoH authorities and partners, and the functionality of the system is supported by the Global Fund.

Recommendations

Action	Responsible agency
Ensure supervision visits continue after Global	Global Fund, WHO, MSF, Government
Fund withdrawal – added to NSP.	of Armenia
Plan remuneration for the M&E team and reflect	Government of Armenia
this in the transition plan.	
Calculate and consider expenses related to	NTP, MoH
monitoring and supervision visits (per diem,	
transportation, vehicle maintenance etc.) and	
reflect this in the transition plan.	
Calculate and consider expenses related to	NTP, MoH
uninterrupted functioning of the E-TB database	
and reflect this in the transition plan.	

Quality, safety and standards

Significant risks are involved in rapid transitions to national-led procurement of effective and affordable drugs and diagnostics, and the Government of Armenia requires significant assistance to mitigate potential harm caused by changing policies on national procurement.

The risks facing the government are not limited to losing access to the Global Fund's procurement platform post-transition; they extend to losing access to the guarantee of and consistency in prices paid for anti-TB drugs, which could have a serious impact on the volume and quality of drugs the government is able to procure. In turn, this could have a negative impact on TB incidence, case complexity and patient outcomes.

While the government has access to the Global Fund's procurement platform, the price and quality of drugs remains consistent. However, Armenia is too small to demand a high number of suppliers to compete for their business, meaning it is likely that market forces will result in the government paying higher prices for drugs, post-transition. On a positive note, the Law on Medicines (2016) states that WHO prequalification is mandatory.

The government needs help demonstrating that they are at risk of poor quality and/or price fluctuations which could cripple their NTP performance.

Recommendation

Action Responsible	le agency
--------------------	-----------

Develop a clear, concise brief outlining the	NTP, Global Fund, WHO Regional Office
implications and risks associated with price	for Europe
fluctuations.	

Service delivery and linking with other interventions – health system strengthening

The MoH has overall responsibility for TB prevention and care in Armenia, though the NTC has shared responsibility for implementation of the NTP. The NTC is the leading institution in Armenia responsible for TB policy and methodology development, monitoring and evaluation of NTP performance, and provision of medical care and services.

Inpatient TB services are provided upon referral to the TB hospital, which is situated on the site of the NTC and has 170 beds. Armenia has a further four TB units in general hospitals, with a total of 300 beds. Outpatient TB services are provided in nine polyclinics in Yerevan, each with one TB officer and one nurse, and 50 TB booths across the country.

Laboratory services are conducted by 24 laboratories, 6 of which are in Yerevan. The national reference laboratory is located at the NTC. Armenia has a well-functioning courier service organized for specimen transportation from smear collection to laboratories. The transportation system is established and maintained with Global Fund grant support. The country has 24 Gene Xpert MTB/RIF platforms installed countrywide, the majority of which are in PHC facilities.

The NTC developed and released updated national guidelines for TB and DR-TB in 2016, endorsed by the MoH. Training of TB and PHC staff on TB prevention and care issues has been organized with Global Fund support. More than 600 doctors working at PHC-level were trained in the year spanning 2016–2017.

The NTP is responsible for providing care and social support through funding available from the Global Fund grant. Currently, this includes 16 000 Armenian drams for drug-sensitive TB patients and 26 000 drams for DR-TB patients each month. In addition, transportation expenses (200 drams) are provided to cover facility visits.

To make care more patient-centred and improve adherence to therapy, options for delivering directly observed treatment, short-course (DOTS) to DR-TB patients are available in urban and rural settings. Most patients present for treatment at their closest PHC facility (59 TB booths) in the regions and in Yerevan. PHC is typically provided by a network of first-contact outpatient facilities involving urban polyclinics, health centres, rural ambulatory facilities and FAPs (Feldsher–Acusher Posts, outpatient posts staffed by health assistants and midwives), depending on the size of the population in a particular community. According to government norms, a physician at the PHC-level serves a population of 1200–2000 adults and a paediatrician

typically covers 700–800 children.⁸ Currently, financial incentives for outpatient activities for PHC practitioners are insufficient. It is foreseen that a system of payment will be introduced that is based on the number of patient visits that a doctor receives. Home-based care is available across the country for all patients on TB therapy, especially those being treated with new TB drugs. For these patients, a TB booth nurse conducts home visits. MSF introduced directly observed treatment via video (Video DOT) in Armenia in 2016, which is becoming more available in urban and rural areas. The work of and linkages with "Tuberculosis Regional Eastern European and Central Asian Project (TB-REP)" shall be further intensified and capitalized upon.

The Armenian Red Cross Society is involved in TB case finding among at-risk populations. This activity is supported by the Global Fund.

Recommendations

Action	Responsible agency	
Plan for government takeover of patient support	All relevant government departments,	
expenses to ensure treatment adherence and a	multiple cross-sectoral stakeholders	
high success rate in treatment outcomes, and		
reflect this in the transition plan.		
Plan training (and re-training) sessions for all	NTP, Global Fund, WHO Regional Office	
actors involved in TB prevention and care and	for Europe	
budget appropriate finances.		
Consider support for activities relating to home	NTP, Global Fund, WHO Regional Office	
care and video DOT, and reflect this in the	for Europe	
transition plan.		
Consider active case finding activities among	NTP, MoH	
vulnerable population groups, and reflect this in		
the transition plan.		

Evidence-based TB policy and practice

In neighbouring Georgia, a TB-specific results-based financing pilot project is being conducted by Curatio International Foundation in partnership with the London School of Hygiene and Tropical Medicine. The project seeks to address supply-side issues by motivating TB health-care workers to promote TB treatment.

The project is developing a costing and cost-effectiveness analysis of interventions to assess health-care worker incentives. The pilot study has 10 controls and 10 intervention units for outpatients only, and will be assessed over a 4-year period. Intervention will start in 2018 and

⁸ Richardson E. Armenia: Health system review. Health Systems in Transition. 2013;15(4):1–99 (http://www.euro.who.int/ data/assets/pdf file/0008/234935/HiT-Armenia.pdf, accessed 23 January 2018).

follow patients for a 2-year treatment period plus follow-up, and will allow time for changing the intervention.

Recommendation

Action	Responsible agency
Monitor the results-based financing pilots in	NTP, MoH
neighbouring countries of the region, with regard	
to cost-effectiveness and affordability of supply-	
side incentives in a similar context.	

Communications and advocacy

The CCM is vital for including CSOs in decision-making and communicating advice to decision-makers, and it is the only platform fulfilling this role in Armenia. The Global Fund is providing technical assistance to CSOs to help them advocate more effectively. Despite this, the CCM/CSO relationship is not well balanced, though this extends beyond CCM and TB to all CSO engagement in Armenia. CSO participation requires further assistance to motivate and enable CSOs to proactively engage and thereby fulfil their potential.

Recommendation

Action	Responsible agency
Provide resource mobilization and advocacy	WHO, Global Fund.
training to assist proactive CSO participation in TB	
policy-making.	

Annex. Mission schedule and people met

Mission schedule

Financial Sustainability Assessment Mission Yerevan, Armenia, 11–12 September 2017

Mission Members: Allira Attwill, health economist, WHO consultant; Dr Nikoloz Nasidze, WHO consultant

Date	Time	Meeting	Place
11 September 2017	10:00-12:30	Dr Armen Hayrapetyan,	NTC, Abovyan City,
		National Tuberculosis Centre	Kotayk Region,
		(NTC) Director, NTC key staff	Armenia
	12:30-13:30	Lunch	
	14:00-15:30	Hasmik Harutyunyan, Global	Ministry of Health,
		Fund Program Coordination	Government
		Team Manager	building 3
	16:00-17:00	WHO Country Office	9 Alek Manukyan
			Str.
12 September 2017	10:00-11:00	Ministry of Finance	Melik Adamyan Str.
	11:30-12:00	State Health Agency	Nork
	12:30-14:00	Lunch	
	14:30-15:30	Drug Regulatory Agency	Komitas 49/a

People met during the mission

Gayane Ghukasyan, WHO Country Office in Armenia
Armen Hayrapetyan, Director, National Tuberculosis Centre
Aram Manukian, Deputy Director, National Tuberculosis Centre
Hasmik Harutyunyan, Global Fund Program Coordination Team Manager
Lilit Khachatryan, M&E Specialist, Global Fund Coordination Team
Zhora Asatrian, Ministry of Finance, Adviser to Head of Department of Programmatic Budget
Re-planning

Tsaghik Vardanyan, Head, State Health Agency Arsen Davtyan, Financial Specialist, State Medical Agency

The WHO Regional **Office for Europe**

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States

Andorra

Armenia

Austria

Azerbaijan

Belarus

Belgium

Bosnia and Herzegovina

Bulgaria Croatia

Cyprus

Czechia Denmark

Estonia

Finland

France

Georgia

Germany

Greece

Hungary

Iceland

Ireland

Israel Italy

Kazakhstan

Kyrgyzstan

Latvia

Lithuania

Luxembourg

Malta

Monaco

Montenegro

Netherlands

Norway

Poland Portugal

Republic of Moldova

Romania

Russian Federation

San Marino

Serbia

Slovakia Slovenia

Spain

Sweden

Switzerland

Tajikistan

The former Yugoslav Republic of Macedonia

Turkey

Turkmenistan

Ukraine

United Kingdom

Uzbekistan

World Health Organization Regional Office for Europe

UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark

Tel: +45 45 33 70 00 Fax: +45 45 33 70 01

Email: eurocontact@who.int Website: www.euro.who.int

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

Member States

Albania

Andorra

Armenia

Austria

Azerbaijan

Belarus

Belgium

Bosnia and Herzegovina

Bulgaria

Croatia

Cyprus

Czechia Denma<u>rk</u>

Estonia

Finland

France

Georgia

Germany

Greece

Hungary

Iceland

Ireland

Israel Italy

Kazakhstan

Kyrgyzstan

Latvia

Lithuania

Luxembourg

Malta

Monaco

Montenegro

Netherlands

Norway Poland

Portugal

Republic of Moldova

Romania

Russian Federation

San Marino

Serbia

Slovakia

Slovenia Spain

Sweden

Switzerland

Tajikistan

The former Yugoslav Republic of Macedonia

Turkey

Turkmenistan

Ukraine

United Kingdom

Uzbekistan

World Health Organization Regional Office for Europe

UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark

Tel: +45 45 33 70 00 Fax: +45 45 33 70 01

Email: eurocontact@who.int Website: www.euro.who.int