Optimize

ARV Transition Readiness Assessment for Country Program Managers

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Acknowledgement

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Background

OPTIMIZE, a project supported by the U.S. Agency for International Development (USAID) through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), aims to accelerate the development, testing and market introduction of optimized antiretroviral (ARV) products to support the best possible treatment outcomes for people living in low- and middle-income countries (LMIC). Optimized ARVs are those that are 1) effective, safe, well tolerated and easy to use for LMIC priority populations (including children, pregnant women and patients infected with tuberculosis (TB)), and 2) adapted to resource- and infrastructure-constrained environments (i.e. affordable, heat-stable and available in fixed-dose combinations [FDCs]). Optimized ARV products are well tolerated, have lower toxicity and a higher genetic barrier to resistance, which reduces the risk of treatment failure by supporting patient adherence and inhibiting the development of drug resistance. The resulting increase in rates of sustained viral suppression offers significant health benefits at individual and population levels by both limiting disease progression and decreasing rates of HIV transmission.

The optimization process includes a combination of global interventions to bring optimized ARVs to market rapidly and local preparations to ensure that optimized ARVs reach LMIC efficiently and effectively. At the program level, past transitions to new ARV products have often been hindered by issues such as national policy and regulatory barriers, tendering and procurement challenges, supply chain interruptions, slow uptake by prescribers, and patient apprehension. To avoid similar challenges during the transition to optimized ARV products, countries require a foundational understanding of their readiness in key domains relating to new product introduction.

How to Complete a Readiness Assessment

This ARV optimization readiness assessment is designed to analyze the capacity and readiness of a country program to appropriately introduce, manage and monitor new, optimized ARVs. As country programs are in various stages of introducing and using optimal new ARVs, this tool should be helpful in identifying areas within programs that are well equipped to manage the transition, as well as areas of focus where additional efforts may be needed.

Though the questions included may be applied to the introduction of any new ARV, it is most applicable when planning large-scale transitions for first line ART. Once a decision is made to introduce a new ARV into the national program, it may take 12 months or longer before the program is ready to begin implementation. Ideally, this tool should be completed during the early stages of planning. However, if planning or transition is already underway, review of this tool will support managers to confirm that the appropriate preparations and steps have been completed, and identify areas that were overlooked or require strengthening to ensure transition proceeds smoothly.

At the time of this writing, many countries are in the process of introducing dolutegravir (DTG) into their national programs. Additional tools and resources to support the introduction and scale-up of DTG-based regimens, including the fixed-dose combination tablet of tenofovir (TDF), lamivudine (3TC) and DTG, known as TLD, can be found at the following websites:

- **https://optimize.icap.columbia.edu**
- **https://www.newhivdrugs.org**

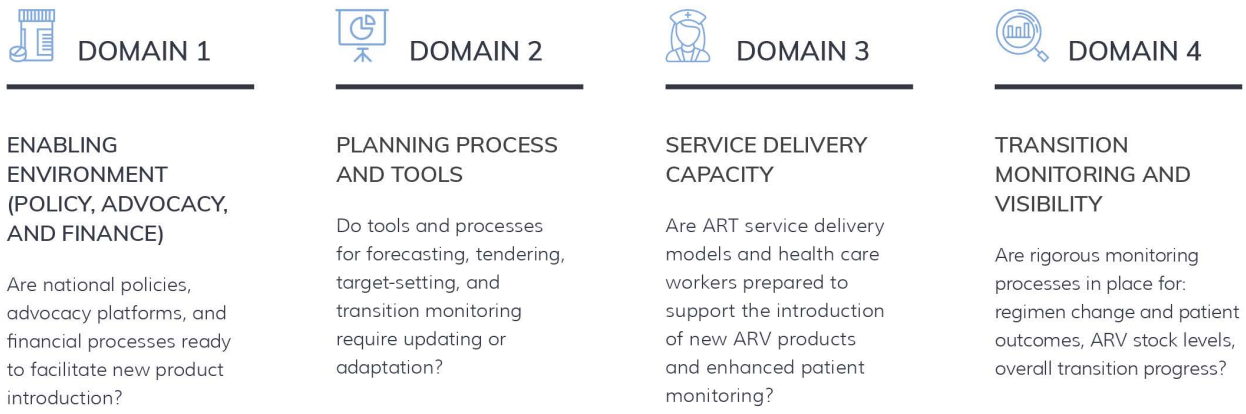
This tool is intended for use by Ministries of Health (MoH) and National ART Programs or designated representatives, to develop a national plan to transition to optimal new ARVs. As the questions included in this tool cut across a variety of disciplines, input from various departments within the MoH or other stakeholder groups may be required to complete all sections. The questions span a range of issues including treatment guidelines, country-specific clinical and programmatic considerations, financing and procurement procedures, supply chain and distribution, healthcare worker capacity building, community engagement and monitoring and evaluation.

This tool contains a two-part questionnaire. The first questionnaire (Section 1), though optional to complete, is designed to briefly examine past ARV transitions, which may have faced logistical or implementation challenges. Reflecting on historical challenges may yield lessons learned that can be applied to future transitions and help ensure that new ARVs are introduced in a timely and efficient manner. Identifying previous challenges with past ARV transitions also demonstrates the importance of careful planning and attention across all levels of the health system, from quantification and procurement to preparation of People Living with HIV (PLHIV) to ensure acceptability of new ARVs. This first questionnaire includes 17 questions querying issues related to program decision-making and implementation during the most recent past ARV transition. It is important that it is completed by, or in consultation with, stakeholders that are familiar with or were involved at the program level during the time period over which the past transition occurred. Users of the assessment should also have

reliable knowledge of decision-making and program communications about the transition, successes and challenges during implementation, including issues related to stock management and patient acceptability of new ARVs.

The second questionnaire (Section 2) queries the policies, processes and support structures that will enable the effective introduction and scale-up of new ARVs or ARV products. The 59 questions are grouped by domain (see Figure 1) and further subdivided into 15 subdomains with multiple related questions in each subdomain.

Figure 1: OPTIMIZE Transition Framework



Answers are ranked and color-coded across a scale indicating if the policy/process/structure is:

Well prepared to support transition to new ARVs
Additional consideration or time needed to support transition to new ARVs
Not yet prepared to support transition to new ARVs

Descriptive questions are also included to ensure specific information or details related to each subdomain are readily available to support the development of a comprehensive action plan to address significant gaps or challenges that are identified.

Though the aim of this questionnaire is to cover a wide range of systems and processes, it may not be all encompassing. In some cases, there may be additional relevant information to include or the scale provided may not accurately describe the current program situation. Users of the questionnaire are encouraged to include additional questions or adapt the assessment as needed.

Following completion of the assessment questionnaires, the MoH is encouraged to consider those areas that are not well prepared or are only partially prepared to support transition to new ARVs and develop an action plan to address and prioritize the identified gaps.

To assist in this process, a summary table (Section 3) is included to list key findings after review of the assessment questionnaire in Section 2. The table is structured to allow users to group findings along the three categories of transition readiness and may be used as a reference tool to guide transition planning.

As responsibility for supporting ARV transitions within the national program will be shared by a variety of stakeholders, program managers may choose to complete the assessment and/or share results of the assessment with other relevant stakeholders, including:

- Implementing partners involved in supporting the HIV Care and Treatment program
- Regional health management teams (Provincial, District, Region, or County)
- Health facility managers
- Pharmacy managers
- Healthcare workers
- Civil society of PLHIV

Section 1: Experience During the Last ARV Transition

Question	Responses
When was the last major ARV transition? What ARV or ARV product was introduced?	
Which population was the new ARV product intended for (e.g. adult first-line, pediatric first-line etc.)?	
What were the factors that influenced the decision to transition to a new ARV?	
How was the recommendation for new ARVs introduced to the program (e.g., through guideline revisions with multiple other recommendations, as a single new recommendation issued independently etc.)?	
How was the new ARV phased into the program (i.e. by specific populations or geography)?	

How were existing stocks of legacy ARV used? (*Check one box)*	Legacy ARVs were completely used with few expiries.	Some wastage of legacy ARVs occurred.	There was significant wastage of legacy ARVs.
Were new ARV procurement plans synchronized with planned timing for implementation? (*Check one box)*	Yes, new ARVs were delivered shortly before implementation began.	There was slight mismatch between delivery of new ARVs and anticipated start date for implementation.	No, there was significant mismatch between delivery of new ARVs and the anticipated start date for implementation.
If there was a mismatch between delivery of new ARVs and implementation, describe it here.			
Did distribution of new ARVs keep pace with the rate of transition at facility level? (*Check one box)*	Yes, distribution of new ARVs to facilities was well matched with the pace of transition.	There were some challenges in the distribution of new ARVs for a few facilities.	The rate/volumes of distribution of new ARVs to facilities were not matched to the pace of transition at the facility level resulting in expiries or stockouts at many facilities.
Was there a formal transition plan in place during the last transition with timelines and targets? (*Check one box)*	Yes, detailed transition plan developed.	Limited plan developed.	There was no formal transition plan developed.
At what pace did transition to the new ARV occur at the health facility level? (*Check one box)*	Transition occurred in line with phase-in plans and stock availability.	Transition occurred slightly faster/slower than planned, but no major stockouts or expiries experienced.	Transition did not proceed according to plans and stock availability resulting in plans and stockouts/wastage at the facility level.
During the transition period, were healthcare workers appropriately sensitized in a timely manner?	Yes, healthcare workers were appropriately trained/sensitized prior to new ARVs being introduced.	Healthcare workers received some sensitization/training, but was not sufficient.	No, healthcare workers were not well sensitized prior to the transition.

Describe training/sensitization of healthcare workers during the last transition. What worked well? What could have been improved on or where were there major gaps/ challenges?			
Were PLHIV sensitized to the new ARV and plans for transition? (*Check one box)*	Yes, PLHIV were sensitized and transition to new ARVs was well accepted.	There was incomplete sensitization of PLHIV and/or reluctance, but this did not significantly impact transition.	There was limited sensitization of PLHIV and/or poor acceptability, which had significant impact on the pace and success of transition.
Was the phase-in of the new ARV complete? (*Check one box)*	Yes, the majority of eligible populations (>90%) were transitioned and are currently on this ARV.	Most eligible populations (>75%) have been transitioned to the new ARV to date.	Transition was incomplete. Currently <75% of eligible populations have been transitioned and several legacy ARVs are still in use.
Were there other significant challenges during the last ARV transition? (*Check one box)*	Yes	Few challenges, but easily managed.	No
If “Yes”, please describe the challenges or important lessons learned from last transition.			

Section 2: ARV Transition Readiness Assessment

ARV Transition Readiness Assessment		Well placed to support transition to new ARVs	Additional consideration or time needed to support transition to new ARVs	Process not yet prepared to support transition to new ARVs
Enabling environment (policy, advocacy and finance):				
1. Policy readiness (National Care and Treatment Guidelines)	Are regimens using new ARVs included in the current ART guidelines? (*Check one box)*	Yes, guidance is available for use of new ARVs for all relevant populations.	The revision of guidance to include recommendations on the use of new ARVs is in process, or partial guidance is available on use of new ARVs in specific circumstances.	New ARVs are not included in current guidelines.
	When is the next guideline revision scheduled? (*Check one box)*	Within the next 6 months.	6-12 months	>12 months
	Is there a mechanism in place to introduce a new treatment recommendation without a complete guideline review process? (*Check one box)*	Yes	Precedent exists or consideration is being given to issuing new recommendations without formal guideline revision.	No
	To what extent do WHO Guidelines influence the decisions / recommendations included in national guidelines? (*Check one box)*	National guideline recommendations may be developed independently of WHO guidelines.	WHO recommendations are a prerequisite for inclusion in national guidelines.	WHO recommendations are a requirement in addition to local/regional evidence to update national guideline recommendations.
	To what extent do donor policies influence the decisions/recommendations to introduce new ARVs to the national program? (*Check one box)*	Donor policies heavily influence decisions to introduce new ARVs.	Donor policies do not affect the decision/recommendations to introduce new ARVs.	Donor policies may limit the decision to include new ARVs.
	Are there other new programmatic changes taking place or planned (i.e. Test and Treat, Routine Viral Load testing, Differentiated Service Delivery) that may affect the transition to new ARVs?	If yes, list the planned changes:		

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	Have recommendations for the use of new ARV been considered in the context of other programmatic changes?	Yes	Recommendations for the use of new ARVs in the context of new programmatic changes are under consideration.	No
	Is there additional data/evidence that is needed prior to the introduction or scale-up of new ARVs in the program to all populations?	No, sufficient evidence exists to introduce and scale up new ARVs to all populations.	Currently available evidence is sufficient to introduce new ARVs to the national program, but there may be additional evidence anticipated that could change some recommendations and scale up in some populations.	Yes, additional global/regional clinical and/or operational evidence is required to scale use of ARV's to all populations.
	If additional evidence is required, describe specific questions or areas of concern.			
2. Financial requirements and resources	What are the current major funding sources for ARVs (Domestic, Global Fund, PEPFAR, other) and are there funding streams specific for particular populations (e.g. pediatrics) or lines of therapy (e.g. third-line)?			
	Is there an anticipated future funding gap for ARVs?	No	Yes, but transitioning to less expensive ARV products will mitigate funding gap.	Yes, significant funding gap may preclude transition to new ARVs.
	If there is a funding gap, in which financial year or over what time period is the gap anticipated to last?			
3. New ARV Procurement	Have manufacturers submitted dossiers for registration of the new ARVs under consideration?	Yes, new ARVs have been registered in country.	Dossier(s) for new ARVs submitted and under review.	No dossiers submitted.

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	What is the average timeline and process for registering a new ARV product in country?	<6 months	6-12 months	>12 months
	Is there a waiver or expedited process in place for registration of essential new drugs?	Yes	No, but exceptions may be made for extraordinary circumstances.	No
	Have new ARVs been listed in essential procurement documents including the national essential medicines list (if required)?	Yes	A plan is in place or a process is ongoing to update essential procurement documents.	No
	Have new ARVs been included in the most recent procurement cycle?	Yes	Planned	No
	Over what timeframe could a new ARV be included in the procurement process?	< 3 months	3-12 months	12 months
4. Demand Generation	Is there a formal strategy to generate awareness and demand for new ARV drugs amongst the community?	Yes, an awareness campaign is ongoing to generate demand in the community.	No formal strategy is in place, but there has been some sensitization and the community has some awareness of new ARVs.	No community awareness or demand generation activities are planned or being implemented and there is limited awareness of new ARVs.
	Is there a formal strategy to generate awareness and demand for new ARV drugs amongst healthcare workers?	Yes, healthcare workers have been well sensitized and aware of new ARVs.	No formal strategy is in place, but healthcare workers have some awareness of new ARVs.	No demand generation activities are planned and healthcare workers have limited awareness of new ARVs.

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Operational Planning and Preparation				
5. ARV quantification at the national and sub-national levels	How frequently is the supply plan reviewed and updated?	Routinely reviewed and updated based on monthly facility reports and as ARV deliveries are received.	Quarterly	Annually or semi-annually
	Have new ARVs been included in the national quantification plan?	Yes	Not yet, but a revised quantification is planned and will include new ARVs.	No
	Has forecasting for new ARVs accounted for existing stock and minimizing excess stock?	Yes	Yes, but there is some concern about excess stock or expiries of existing stock.	No
	Has forecasting for new ARVs been planned in accordance with anticipated order delivery dates, distribution timelines and implementation start dates?	Yes	Yes, but there is some uncertainty about timelines for order delivery and/or readiness for implementation.	No
	Has the necessary level of buffer stock been defined and agreed upon?	Yes, the level of buffer stock planned will cover at least two supplier delivery periods with sufficient flexibility to account for unpredictable rates of transition.	The level of buffer stock planned will cover less then two supplier delivery periods and lack of flexibility may slow the rate of transition.	No
	Does forecasting for new ARVs account for necessary buffer stock?	Initial orders build stock up (including buffer stock) to maximum level within 3 months.	Initial orders build stock up (Including buffer stock) to maximum level within 6 months.	Initial orders do not build stock up to maximum level.

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6. Drug distribution and management	In the last reporting period, how many facilities reported ARV stock status?	100%	70-99%	<70%
	Are there challenges with current visibility of facility stock levels?	There is good visibility into current levels of stock at all facilities.	There is visibility into current levels of stock at some facilities, but not all of them.	There is poor visibility into facility level stocks.
	Is there a system to track on-time ARV distribution to regional medical stores?	Yes	Partial system in place	No
	Is the distribution system equipped to manage an influx of new ARVs, including additional deliveries to ensure adequate buffer stocks are available at the facility level?	Yes	Some concerns exist about the capacity of the distribution system to manage new ARVs.	The distribution system is not well equipped to manage new ARVs or make additional deliveries.
	How many facilities have adequate storage space for maximum stock required for new products and adequate stocks to meet demand for legacy ARVs during the transition period?	>85%	65-84%	<65%
	Is there a system to support and track the last-mile distribution to all dispensing facilities?	Yes	A partial system is in place or is inconsistently applied.	No
	If yes, please describe. If no, is last-mile distribution a significant challenge in the program?			
	Are there any anticipated challenges with the future visibility of facility stock levels?	No	Unclear	Yes

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	If “Unclear” or “Yes”, describe anticipated challenges.			
	Is there reliable visibility into stock levels at non-facility-based distribution sites?	Yes	No, non-facility-based ART distribution sites in place or have limited/incomplete visibility.	Limited or unreliable visibility into stock levels at non-facility-based distribution sites.
	Is there a system in place for facilities to request urgent or emergency deliveries before a stockout occurs?	Yes, formal system in place to enable out-of-cycle orders.	Informal system in place for out-of-cycle orders.	No urgent out-of-cycle orders may be placed.
7. Preparation of health worker cadres for transition	Are facility healthcare workers aware of program plans for introduction of new ARVs?	Yes, healthcare workers are sensitized and aware that new ARVs are or will be available.	Sensitization of facility healthcare workers on program plans for new ARVs is incomplete or is still being planned.	No, sensitization for facility healthcare workers on program plans for new ARVs has not yet occurred and/or has not yet been planned.
	Are pharmacy managers aware of program plans for the introduction of new ARVs?	Yes, pharmacy managers are aware that new ARVs are or will be available.	Sensitization of pharmacy managers on program plans for new ARVs is incomplete or still being planned.	No, sensitization on program plans for new ARVs for pharmacy managers has occurred and has not yet been planned.

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	Are counselors (including lay counselors) sensitized and aware of program plans for introduction?	Yes, counselors have been sensitized and counseling materials on new ARVs are available.	Sensitization of counselors and development of counseling materials on new ARVs have not yet occurred but are planned.	No sensitization or counseling materials have been planned or developed on new ARVs.
	Are local or facility health managers equipped to support the introduction of new ARVs?	Yes, sensitization of health managers has occurred and operational guidance has been developed for health managers to support the introduction of new ARVs.	Health managers are sensitized on the introduction of new ARVs, but no operational guidance has been provided to them.	No, health managers have not yet been sensitized or prepared for the introduction of new ARVs and no operational guidance has been developed.
	Are community health workers prepared to support the introduction of new ARVs?	Yes, sensitization of community healthcare workers has occurred.	Sensitization of community healthcare workers has not yet occurred, but has been planned.	No sensitization of community healthcare workers has been planned.
Service Delivery Support				
8. Training of facility-based healthcare workers for transition	Have training materials and other supportive job aids been updated to include information about new ARVs to healthcare workers?	Yes, healthcare worker trainings are ongoing and new job aids have been disseminated.	Updating of training and other communication materials is in process, but no trainings have occurred and/or job aids have not yet been disseminated.	Training materials and supportive job aids have not yet been updated.
	Briefly describe updates that have been made, planned or will be needed to inform healthcare workers about new ARVs.			

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9. Training of pharmacy managers and staff to manage new ARV stocks	Have training materials or supportive job aids been updated to include guidance for pharmacy managers and pharmacy staff to manage new ARV stocks and appropriately dispense?	Yes, updates have been made to ensure pharmacy managers and staff are equipped to manage and dispense new ARVs. Trainings are ongoing and guidance has been disseminated.	Updates to training materials and supportive job aids for pharmacy managers and dispensers have been made, but no trainings or dissemination has occurred.	Training and supportive job aids for pharmacy managers and staff to manage and/or dispense new ARVs have not yet been updated to include new ARVs.
	Briefly describe any updates that have been made, planned or may be needed to prepare pharmacy managers and dispensers to manage and dispense new ARV stocks.			
10. Prescribing and dispensing guidance within DSD models of care for stable patients	If differentiated service delivery models (DSDM) including spacing of clinical appointments, multi-month prescribing and/or community ART dispensing are being implemented, is a plan in place for how new ARVs will be prescribed and dispensed through these models?	Yes, planning and clear guidance on how new ARVs are to be introduced, prescribed and dispensed in the context of new DSDM have been developed.	No such service delivery models are being implemented in the program or planning for introduction of these models is currently underway.	No specific plans or guidance have been developed to consider how new ARVs will be prescribed/delivered in the context of DSD models.

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11. Mentorship and supportive supervision	Is there a national/centralized level mentorship/supervision strategy being implemented that can provide additional capacity building support for healthcare workers using national tools and consistent messages?	Mentorship and supervision is being implemented using national tools.	Mentorship and supervision is implemented inconsistently (i.e. variability across the tools and messages used by implementing partners).	Mentorship and supervision is not being well implemented.
	Have mentorship and supervision tools been updated to build capacity on the use of new ARVs?	Yes, national mentorship and supervision tools have been updated to include use of new ARVs.	Updates to tools are planned or in process or some partners have incorporated guidance on use of new ARVs.	No, mentorship and supervision tools have not been updated to incorporate guidance on use of new ARVs.
Transition Monitoring and Visibility				
12. Patient level data collection	Have patient data collection systems (registers, clinic visit cards, EMRs) been updated or guidance developed to enable documentation of new ARV use in patient clinical records?	Yes, patient data collection systems have been updated and/or clear guidance has been developed for healthcare workers to document use of new ARVs.	Updates to data collection tools or guidance for documentation of new ARVs are planned or in process.	No, data collection tools have not yet been updated or guidance has not yet been developed on documentation of new ARV use in patient clinical records.
	Do existing data collection tools allow for systematic (i.e. automated) aggregation and tracking of patient outcomes by ARV regimen and formulation?	Yes	Data aggregation must be done manually or is incomplete.	No

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	Do existing data collection tools allow for systematic (i.e. automated) aggregation and tracking of outcomes for priority sub-populations (pregnant women, TB patients, adolescents)?	Yes	Data aggregation must be done manually or is incomplete.	No
13. Stock monitoring systems	Are there systems in place to monitor the rate of ARV consumption at facility level?	Yes, there is clear visibility into the consumption of ARVs and available stocks at the facility level.	There is some visibility into the rate of consumption.	No, there is limited visibility into the rate of ARV consumption at facility level.
	How often are facilities required to report on ARV commodities?	Monthly	Quarterly	Facilities do not report on ARV commodities.
	Are there systems in place for healthcare workers or pharmacy managers to report stockouts or drug expiries at the facility level?	Yes, there is a system in place for real time or rapid reporting of drug stockouts/expiries.	Local/regional systems are in place for healthcare workers or pharmacy managers to report stockouts, but data is not aggregated or analyzed at national level on a regular/timely basis.	There is no systematic way for healthcare workers or pharmacy to report stockouts or drug expiries at the facility level.
	Describe systems in place for tracking stock levels at facility level and/or addressing issues of stockouts or drug expiries.			
14. Tracking of transition progress	Are there indicators that are routinely collected that can be used to track transition progress (number of patients initiated or transitioned to new ARVs) at the national level?	Routinely collected data is sufficiently available at the national level to track the number of patients initiated or transitioned to new ARVs.	Routinely collected data is available at the facility and/or subnational level on the number of patients transitioned to new ARVs, but data is not aggregated in a timely way at the national level.	No, routinely collected data currently does not allow for tracking of transition progress.

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	Describe how transition progress will be monitored or if monitoring of transition may be challenged at the national level.			
15. Toxicity monitoring	Are there systems in place for healthcare workers, patients and the public to report adverse drug reactions?	Yes	System in place but not well utilized.	No
	Describe the process including body responsible, for monitoring reports of adverse drug reactions, or describe challenges that limit the reporting of adverse drug reactions.			
	Do current ART training materials establish clear protocols for management and reporting of adverse drug reactions?	Yes	General training materials exist for reporting adverse drug events but these have not been incorporated into ART training.	No
	Has the national program included indicators to track rates of treatment limiting toxicity?	Yes	A plan is in place to revise national indicators in line with WHO recommendations on indicators to track drug toxicity.	No

Section 3: Summary Table

Category	Next steps/Comments
Process not yet prepared to support transition to new ARVs	
Additional consideration or time needed to support transition to new ARVs	
Well placed to support transition to new ARVs	

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