Optimize

Checklist to Guide Optimal ARV Introduction

As antiretroviral therapy (ART) programs advance toward the World Health Organization (WHO) Treat All and UNAIDS Fast Track targets, ensuring timely access to "optimized" antiretroviral (ARV) products – those that are effective, safe, tolerable, acceptable and affordable – is more critical than ever before. New, optimized ARVs are anticipated to provide more effective treatment outcomes while yielding significant cost savings.

While all countries adhere to their own policies and decision-making norms, there are a common set of processes and milestones when introducing new ARV products to a country program. This includes the creation of an enabling environment, planning and preparation for introduction and scale-up, support for service delivery and monitoring of the transition process.

Past transitions to new first-line ARV regimens in low- and middle-income countries (LMICs) have met with a variety of logistical and implementation challenges including stock-outs, drug expiries, inappropriate prescribing and resistance to change among healthcare workers and patients. Lessons learned from the past transitions such as the phase-out of d4T and introduction of the fixed-dose combination (FDC) of tenofovir, lamivudine and efavirenz (TLE) have demonstrated the importance of planning and coordination at global, national and subnational levels to avoid similar challenges as programs rapidly introduce new optimal ARV products.

This checklist is focused on the various activities country programs need to consider and plan for to ensure successful transition once a country has decided to introduce a new ARV. It is designed to serve as a reference guide for HIV program managers to navigate the complex set of questions, variety of stakeholders and array of activities needed to ensure timely and effective introduction of new ARVs into a public health program. See the reverse of this page for the checklist.

The checklist is divided into five sections, which concentrate on activities tied to the implementation of a new product introduction policy decision:

1 — **OVERALL MANAGEMENT AND COORDINATION**

Focuses on developing a process through which decision making and planning are managed and coordinated.

2 — **ENABLING ENVIRONMENT**

Ensures that new ARVs are available for procurement, policies and guidance are in place to ensure appropriate use, and funding is available to support introduction and scale-up.

3 — **PLANNING AND PREPARATION**

Supports the development of detailed plans to train healthcare workers, sensitize patients and the community of people living with HIV (PLHIV), ensure stock is available to support rollout, and update the tools and registers needed for monitoring and evaluation.

4 — **SERVICE DELIVERY SUPPORT**

Delineates the activities required at the service delivery level to generate demand, support appropriate prescribing and dispensing, address provider and patient questions, and address bottlenecks and challenges.

5 — **TRANSITION MONITORING AND VISIBILITY**

Underlines the critical role of ongoing monitoring of the transition process, with emphasis on both evaluation of patient outcomes and supply chain systems.

Checklist of All Activities

1 — OVERALL MANAGEMENT AND COORDINATION

- ☐ Identify key stakeholders and establish a new product introduction coordinating mechanism
- ☐ Design a phase-in strategy including: 1) initial introduction; 2) scale-up plan; and 3) associated timelines for uptake
- ☐ Develop master list of activities to prepare, implement and monitor all aspects of transition and identify a responsible individual or group to lead each activity
- ☐ Communicate transition plan, roles, and responsibilities to stakeholders
- ☐ Conduct routine tracking of transition progress against established targets

2 — ENABLING ENVIRONMENT

- ☐ Define new product value proposition and rationale for phase-in plan to disseminate throughout health system
- ☐ Allocate funds for new product procurement, uptake activities, and monitoring
- ☐ Update HIV Care and Treatment guidelines on new product use including eligible populations, contraindications and alternative regimens, and laboratory monitoring requirements. Also include rationale and plans for phase-in process as appropriate
- ☐ Ensure product(s) are registered for use and listed in essential procurement documents and the essential medicines list
- ☐ Update/develop national and subnational forecasts and procurement plans to incorporate new products
- ☐ Develop and communicate policy on existing stocks that are being replaced with new product(s) throughout healthcare system (this may include usage until stocks are exhausted, or destruction of stocks as appropriate)
- ☐ Initiate new product procurement processes and align introduction plans with projected order delivery dates

3 — PLANNING AND PREPARATION

- ☐ Conduct situational assessment of current landscape and analyze capacity of the current health system to appropriately manage and use the product
- ☐ Develop provider education/sensitization and rollout plans
- ☐ Define patient and community education and sensitization strategy and rollout plan including general sensitization through platforms such as local media, or targeted sensitization for PLHIV
- ☐ Revise patient monitoring and stock tracking tools (paper and/or electronic)
- ☐ Develop and field test new data capture tools, job aides and communication materials to ensure completeness and feasibility
- ☐ Share sensitization plans and new materials with implementing partners for integration into local campaigns and programs

4 — SERVICE DELIVERY SUPPORT

- ☐ Educate/sensitize providers with SOPs for clinical management, revised documentation processes and facility-level stock management guidelines
- ☐ Educate/sensitize patients and community on transition rationale and benefits of new ARV product
- ☐ Develop guidance on new ARV introduction within differentiated care settings and within other programs in the health sector (e.g. tuberculosis, maternal and child health)
- ☐ Conduct ongoing supportive supervision and mentorship of clinical and pharmacy management staff involved in new product introduction activities
- ☐ Utilize early feedback from implementers to respond to challenges, clarify miscommunications, and adjust phase-in plan as appropriate

5 — TRANSITION MONITORING AND VISIBILITY

- ☐ Establish intensified patient monitoring program, including pharmacovigilance and pregnancy surveillance (as appropriate)
- ☐ Conduct intensified stock monitoring of new products to ensure uptake meets expected targets
- ☐ Review clinical and stock data routinely to ensure uptake proceeds according to phase-in plan and identify signals which may indicate unexpected challenges
- ☐ Identify and assess service delivery challenges to provide corrective instruction or to inform further phase-in plans
- ☐ Disseminate results and lessons learned from pilot introductions, demonstration projects, or other operations research to advance thinking and build capacity at local, national, and global level

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Publication was made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID) under the terms of cooperative agreement #AID-OAA-A-15-00069. The contents are the responsibility of ICAP and do not necessarily reflect the views of USAID or the United States Government.