



GUIDELINES FOR THE IMPLEMENTATION OF MULTI- MONTH DISPENSING OF ANTIRETROVIRALS

This document proposes guidelines for the prescription, distribution and dispensing of pharmaceuticals using the multi-month dispensing modality within the framework of the Integrated Drug Supply Management System. These general guidelines can be applied to the processes of prescribing, distributing and dispensing antiretrovirals drugs (ARVs), as well as to other drugs and health technologies required in HIV prevention and comprehensive care for people living with HIV (PLHIV).

1. Introduction

The “Differentiated Care” strategy of the World Health Organization (WHO) recognizes the diversity of care needs for PLHIV according to four different groups, in order to adjust the way in which health programs and services can treat and serve PLHIV differently:

- The **first group** is PLHIV who are not yet on antiretroviral treatment (ART) who access care when they are well, possibly with a CD4 lymphocyte count above 500. In addition to initiating ART, these people may need complementary support to strengthen their adherence and retention on lifelong ART.

- The **second group** includes PLHIV without ART who, when seeking care, present an advanced infection. These people require a set of clinical measures and accelerated care.ⁱ
- The **third group** consists of PLHIV already on ART, but who are clinically unstable and require careful monitoring in order to provide them timely treatment as needed (medical care, increased support for treatment adherence and timely change of ART).
- The **fourth group** is those PLHIV who are clinically stable.¹ This group comprises the majority of individuals who are receiving ART. They can safely reduce the number of clinic visits, the frequency of pharmacy medication pick-ups and eventually receive ART within their community setting. This approach may decongest the overburdened clinical system and facilitate better service delivery for those patients showing more complex conditions and requiring rapid diagnosis and treatment (i.e. treatment of opportunistic infections, support for treatment adherence, viral load testing and possible changes of scheme, HIV drug resistance tests or other specialized care).

A series of measures addressed to this fourth group of stable PLHIV involve the Integrated Drug Supply Management System: multi-month dispensing of ARVs (every 3 to 6 months), dispensing through community care facilities and home delivery.

In the current crisis caused by the pandemic of the new coronavirus (SARS-CoV-2), stable people living with HIV, including adults, adolescents and children can benefit from the multi-month prescription and dispensing of antiretroviral medication (for 3 to 6 months) which will facilitate continuity of treatment, reduce the frequency of clinic visits in overburdened clinical settings, and will reduce the risk of possible exposure to the COVID-19 virus.ⁱⁱ

For the implementation of this measure, distribution and dispensing systems must be flexible and adapted to the needs of the user population in order to improve the availability of and access to antiretrovirals and to other drugs and health technologies required in the prevention of HIV and a comprehensive care delivery for PLHIV.

¹ **Clinically stable persons** are defined as those who have been on ART for at least one year and show no adverse reactions to the medication to warrant regular monitoring, have no current illness or pregnancy, are not breastfeeding currently and clearly understand the lifetime treatment adherence and show success in treatment (that is, two consecutive viral load tests below 1000 copies/ml).

Likewise, it is important to consider the current challenges in the interruption of the supply chain of pharmaceuticals and strategic supplies that has risen globally due to the COVID-19 crisis that will impact the availability and timely delivery of ARVs, diagnostic supplies and other drugs for opportunistic infections (OI). The insufficient availability of Active Pharmaceutical Ingredients (API) that generates delays in production, lengthy delivery times, deliveries on hold, limited transportation due to airport closings, movement restrictions, insufficient cargo transport and its high costs, are all aspects to be considered for the needs estimation and procurement planning.

2. Objective



Define the key guidelines to ensure the timely, continuous and sustainable access to the medication required in the multi-month prescription and dispensing of ARVs through the Integrated Drug Supply Management System

3. Requirements

- Updated regulation on prescription with recommendation of extended ARV prescription and validity for 3-6 months, especially for stable people on ART.
- Regulation on dispensing revised and adjusted to allow the extended and valid ARV dispensing for 3-6 months, especially for stable people on ART.
- Information system with tracking of patient prescription and dispensing.
- Periodic monitoring of inventory management, ensuring the local level stocks required for dispensing selected drugs for 3-6 months.
- Adequate facilities, with storage capacity, control of environmental factors, safety and other requirements defined in the "Good Storage Practices"².

²WHO good distribution practices for pharmaceutical products:

https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf

- Trained human resources, mainly in pharmaceutical care and inventory management.

4. Responsible units

- Drug Supply Management Unit
- National and local Pharmacotherapy Committees
- National and local HIV/AIDS programs
- Comprehensive Care Services
- Pharmaceutical Services
- Community partners involved

5. The Comprehensive Supply System

The Integrated Drug Supply Management System is governed by the national rules and regulations in force and the needs for medicines and other health technologies of the population served. This information allows defining the appropriate structure for each of the system processes (selection, needs estimation and procurement, storage, distribution, dispensing and rational use), with a mission to achieve the access and availability of medicines and other quality health technologies, to contribute to the solution or the control of health problems efficiently.ⁱⁱⁱ

“The success of community ART supply models depends on having sufficient and reliable resources and support, including a flexible and reliable supply of pharmaceuticals, access to good quality clinical care, a reliable monitoring system that can track patients from the community to the medical office and vice versa, and a team of non-professional health workers with national support.”ⁱ

6. Guidelines for the implementation of multi-month prescription, distribution and dispensing (MMD) of pharmaceuticals in the Integrated Drug Supply Management System processes

6.1 Regulatory aspects

- a. Review and update the drug prescription standard procedures for people living with HIV and the criteria for multi-month prescription.
- b. Review and adjust the procurement standard procedures in order to ensure purchase authorization and budget in advance (if possible, 1 year in advance). This allows the process of needs quantification and the subsequent purchase order to begin with enough time in advance for the supply chain to start up and deliver the drugs on the expected dates.
- c. Review and update standard procedures for placing emergency re supply orders, if necessary.
- d. Define the list of medications that can be prescribed and dispensed for several months.
- e. Define the number of months to prescribe and dispense, taking into account the estimated number of people covered by organization, the existing stocks of medicines, procurement budgets, storage capacity and dispensing capacity at local level.
- f. Define the user recommendations (i.e. adequate preservation, right use, safety and inventory control).

6.2 Needs estimation

- a. Revise the needs projections in terms of the number of people that will be included in the dispensing model, treatment schemes, and safety stock at the central and local levels to allow implementation of the multi-month prescription and dispensing model.
- b. Check that the safety stock level corresponds to the amount of drugs required during the replenishment lead time at each level. In case of international procurement, it is recommended to have a minimum safety stock of 6 months.
- c. Make regular evaluations of the actual demand with respect to the estimates made for the same period (For example: the needs estimation for a product in the month of January 2020 was 120.000 tablets and the actual consumption that month was 116.800; the difference between the two figures was 96.6%. This concludes a high precision in the estimation of needs. When results are obtained outside the difference +/- 5%, the cause must be investigated so as to improve the estimation process, when it applies).

- d. Monitor monthly the indicator “Absolute error between ARV consumption and estimation”, in order to make the necessary changes in a timely manner.
- e. Include alternative ARV pharmaceutical packages in suitable quantities for the MMD modality; for instance, 90-tablet bottles, particularly for most used fixed-dose combination treatments.

6.3 Procurement

- a. Analyze the data on local and international suppliers, prices, availability, capacity and timelines required for the supply.
- b. Develop a procurement plan that includes: needs estimation in units per pharmaceutical form, current stocks, amounts in transit, national and international prices, prioritization and delivery dates.
- c. Constantly monitor the implementation of procurement schedules, to avoid shortages due to delays in purchase deliveries. This monitoring requires timely intervention.
- d. Maintain constant communication with the national and international procurement mechanisms used by the country to monitor possible contingencies caused by the global impact of the COVID-19 pandemic.
- e. Develop contingency plans with supply alternatives, including risk mitigation due to external market causes.

6.4 Storage

- a. Evaluate the storage capacity at every level, mainly those closest to the patients (local), with the capacity to store the amounts required in the multi-month dispensing (3-6 months).
- b. Apply the requirements of Good Storage Practices, prioritizing actions that prevent loss of quality of the medicines (i.e. temperature and humidity control, avoid direct light).
- c. Update the inventory control registration tools.

6.5 Distribution

- a. Document and implement the Good Distribution Practices recommended by WHO³.
- b. Plan the integrated distribution for MMD; ensure dispensing all the medication to the patients in the event they require treatment for other pathologies in addition to HIV (prophylaxis for opportunistic infections, treatment of chronic illnesses, etc.).
- c. Distribute the MMD model delivery along the entire year so that a patient only has 2-4 contacts a year with the health center. A uniform and timely patient distribution throughout the year would prevent spikes in the distribution and collapsing the capacities.
- d. Make regular revisions of the medicines for the multi-month dispensing and the scope of patients enrolling in this modality to ensure timely supply.
- e. Develop the order of medicines for the MMD modality in a timely manner from the local level to upper levels. The order is directed to the regional or central level, based on the periodicity defined by the MMD, establishing the amounts required by the products to be prescribed and dispensed for various months by the number of patients (Example: 3-month consumption = pharmaceutical units required monthly for each treatment scheme x the # of patients to be served x 3 months).
- f. Include in the order for local level sufficient quantity to cover the lead time consumption (this can be an additional 1 to 2 months of the average monthly consumption).

6.6 Rational use (prescription)

- a. Share with the prescribing doctors or nurses the list of drugs approved for the multi-month prescription and dispensing.
- b. Define the criteria for patient inclusion in the MMD model and share with the prescribing doctors or nurses of the institution.
- c. Share the standard procedure for medical prescription, including:
 - i. Prescription format, where in addition to the patient identification information, it must contain the medication required (generic name), concentration, pharmaceutical form, method of administration, and daily dose. Moreover, it should specify the amount required for the number of months stipulated. Example: if the daily dose is 1 table and the prescription is for 3 months, the quantity is ninety (90) tablets.
 - ii. Criteria for patient inclusion in the MMD model.

³WHO good distribution practices for pharmaceutical products:

https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf

- iii. Patient treatment adherence monitoring and control.
- d. Training of medical, pharmaceutical and nursing staff and patients.

6.7 Rational use (dispensing)

- a. Dispensing is a pharmaceutical professional act, in response to a medical prescription. In this act, the patient is informed and oriented on the proper use; emphasis is made on compliance with the dosage regimen, the effect of food, interaction with other medicines, recognizing potential negative reactions and storage conditions of the product^{iv}. However, many countries have a deficit of pharmaceutical staff to handle the various modalities or alternatives in the application of the dispensing process, which requires the constant training of other medical staff and members of civil society and other community organizations.

7. Alternative dispensing modalities in the community

There are different modalities for ARV dispensing that have been implemented with the participation of the civil society, peers or volunteers, facilitating the delivery of medication at home or in community sites close to the user population. Therefore, the guidelines presented below include different alternatives for community and home dispensing. In the context of the COVID-19 epidemic, it is essential that all necessary infection prevention and control measures are adopted for the safety of the providers and users of these community or home dispensing services.^{v vi}

7.1 Dispensing in public network health services and in community services

- a. Have the list of medicines and users who will be served, including the multi-month prescription and dispensing modality (define the number of months: 2 to 6 months).
- b. Verify that the prescription is complete and legible, in compliance with the country's regulations.
- c. Confirm that the total amount prescribed for each medicine corresponds to the daily dose for the number of months specified.
- d. Verify with the patient the information provided in the prescription and the drugs that were actually dispensed.
- e. Specify the duration of the medication dispensed and the date of the next delivery.
- f. Register in the information system the data required for dispensing control: name of the patient, medicines and amounts prescribed, medicines and amounts dispensed by date of delivery.

- g. If an automated information system is not available to track each patient, the use of a patient pharmacy card/record is recommended, containing the following information: the medicines and amounts prescribed, the medicines and amounts dispensed, prescription date, dispensing date, next delivery date.
- h. Train patients on the required activities for the proper use of the medication, preservation and storage, keeping it out of the reach of children, what to check before use, the importance of not interrupting treatment.

7.2 Home delivery

Home delivery of the prescribed medication must be carried out by the public health services of the Ministry of Health public network, or in coordination with civil society organizations, with previous patient authorization. Some countries have developed regulations with specific requirements for home delivery, as is the case of Colombia⁴.

Recommendations for the public health services or civil society organizations:

- a. Generate the required procedures to ensure the programming and implementation of home delivery, with monitoring and supervision.
- b. Ensure that the human resources responsible for the transport and home dispensing are qualified and trained on the handling and preservation of the medication and provide information to the client on its rational use.
- c. If hiring an external agency for home dispensing is required, draft a contract or a legal document with the profile and qualification requirements of the persons involved in the activities, requirements for the transport vehicles to ensure preservation and custody of the medication, requirements of the records to be completed in order to evidence dispensing of the medication and the frequency of delivery. In addition, include monitoring and evaluation parameters, such as delivery times, patient surveys on service satisfaction and establishing follow-up meetings.
- d. Ensure confidentiality of patient identification information, home address and all other information provided in the procedure.
- e. Make a delivery schedule, by route, adapted to the capacity in place and to the coverage of patients to be served.
- f. Inform patients in advance the scheduled delivery date and make changes if necessary, as long as the treatment is not affected due to a lack of supply.

⁴ Resolution 1604 of 2013. Republic of Colombia. Ministry of Health and Social Protection. "That establishes the guidelines to be considered to comply with the exceptional mechanism of medication delivery in a period no longer than 48 hours, at the place of residence or work of the member ..."

- g. Inform patients what documents are needed for home delivery. Example: patient identification document (original) and medical prescription. If the patient is absent or in the case of a minor, the medication can be delivered to another responsible adult, who will also have to show the documents listed above as well as his/her identification card.
- h. Ensure the prescribed medicines are listed in the correct amounts.
- i. Ensure the proper packaging of the listed medicines. Example: dark resistant bag, with a legible label showing the patient identification, address and telephone.
- j. Make records to document the dispensing at the right address and to the authorized person (adult, with required documentation). The record must include: patient identification, prescription date, date and time of home delivery, identification of the person receiving, signature of the person receiving and a space for comments. In the case of any inconveniences that prevent the delivery, the issue must be specified or if the patient has any observations.
- k. Ensure the dispensing with adequate information that promotes a rational use by the patient (mainly recommendations on the preservation of the medicines). When the dispensing is made by pharmaceutical professionals, information should be provided on possible drug interactions, adverse reactions and treatment adherence.
- l. Update the information system with delivery date, medicines and amounts delivered, identification information of the person receiving the medication and any issues that came up. The treatment health team should have access to this information.

7.3 Considerations on human resources and the dispensing process

- a. Ensure training and education of the staff on good distribution practices for pharmaceuticals.
- b. Execute correctly the procedure established by the health services provider.
- c. Ensure the tracking of the pharmaceuticals throughout all the activities.
- d. Ensure appropriate transportation: to preserve the integrity and safety of the medication, protection against extreme temperatures, humidity, light or possible contaminants and keeping preservation conditions at all times, complying with the technical specifications of the manufacturers.
- e. Ensure the safekeeping and safety of the medicines during transport.
- f. The transportation vehicles must be in good technical and mechanical condition.
- g. During the medication dispensing, confirm that the identification document corresponds to the patient, provide authorized information and make the required registration.

7.4 User considerations

- a. If in agreement, authorize the proposed date and address for home dispensing or arrange another date or place.
- b. Be present on the scheduled date for the dispensing; or in case of an unexpected event, secure the presence of an adult with the required documentation.
- c. Verify the label information on the exterior package of the pharmaceuticals.
- d. Sign in acceptance, and if not in agreement, write on the space for comments the observation or disagreement.
- e. Report issues or disagreements immediately to the health services provider.

8. Information System

- a. The information system must facilitate the collection of dispensing data at the time of patient care delivery, in some cases from the prescription and also during the dispensing. When a software is used for the medical prescription, it should be customized to allow the multi-month prescription and dispensing. The system should register data by patient as average monthly consumption, considering and correcting the distortion given by the dispensing made only in some months, to avoid errors in inventory replacement and the risk of stock outs.
- b. The information system should be nominal, by patient, and should capture the unsatisfied demand. This would facilitate making the orders or requests for medicines from the local level with complete and good quality information (for instance, the real demand defined by consumption given by the dispensing of medication plus the amounts prescribed and not dispensed).
- c. If an automated information system is not available, the institution must ensure at least the use of Kardex or stock cards by product, with daily update. It is also recommended to use individual patient cards with dates, medicines and amounts prescribed and dispensed and next dispensing date (whether in a health facility, community center or home delivery).

9. Evaluation and adjustments to the dispensing model

From the central level, it is important to do systematic monitoring of the demand behavior compared with the needs estimation. It is also advisable to conduct an analysis of the existing gaps and establish interventions to mitigate the impact at the local level.

The local level must conduct a weekly review of the stock and compare it with the needs for the following week. This will allow a timely intervention, thus avoiding shortages and implementing the necessary measures for improvement.

When implementing MMD and alternative dispensing modalities at the community level it is critical to monitor key WHO-recommended person-centred care indicators related to adherence, retention and viral suppression to assess the impact and effectiveness of the intervention.^{vii}

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