Handout: Adherence Monitoring and Client Counseling, Dispensing, and Pharmacovigilance

Pharmacists have a critical role to play in supporting the treatment process for clients on antiretroviral therapy (ART). As members of the multidisciplinary team providing care and support, pharmacists are expected to deliver key messages during medicine pick-up and dispensing to facilitate the continued participation of clients in the treatment process. Additionally, as custodians of medicines in the health care system, pharmacists are expected to lead efforts to prevent, detect, manage, and report side effects associated with antiretrovirals (ARVs), thereby improving client safety and providing vital data for decision-making.

# Part I: Pharmacovigilance

## Purpose

ARV drugs are associated with significant safety concerns of both short- and long-term side effects, including serious adverse drug reactions (ADRs). The outcomes of long-term effects are often unknown, since ARVs are typically approved through a process of priority review and fast-tracked market authorization. These undesired effects have the potential to influence clients’ willingness and ability to start or stay on treatment and may result in nonadherence and its consequences.

## Topics covered

This session covers aspects of pharmacovigilance important for the provision of HIV pharmaceutical care, as well as information on established mechanisms of reporting ADRs in the country. The following topics are covered:

* + Rationale for and history of pharmacovigilance
  + Limitations of clinical trials
  + Key terms used in pharmacovigilance
  + Why ADRs occur and the major predisposing factors
  + Common methods used in pharmacovigilance
  + In-country ADR reporting systems

## What is pharmacovigilance?

The World Health Organization (WHO) defines pharmacovigilance as the “science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem.”[[1]](#footnote-2) Pharmacovigilance focuses on investigating and monitoring ADRs after medicinal products are licensed.

## History of pharmacovigilance

Several historical events related to the use of medicines and their related undesired effects led to recognition of the need for a more deliberate system of detecting and monitoring the medicines in use in the population. Some examples include:

* + Sulfanilamide, an antibiotic initially formulated as tablets and capsules and used to treat a variety of infections, caused widespread poisoning in the 1930s. The poisoning (renal failure) resulted from the use of elixir/syrup sulfanilamide formulation, which was synthesized using diethylene glycol as a solvent. However, the solvent and not the sulfanilamide itself was identified as the problem.
  + Thalidomide was a drug used in the 1960s to manage nausea in pregnancy. Several years later, a significantly higher incidence of phocomelia in babies born of women who had been exposed to thalidomide during the pregnancy was detected.
  + In 1970, the evaluation of safety reports from drug safety committees in the United Kingdom, Sweden, and Denmark found a positive correlation between the estrogen dose in oral contraceptives and the risk of pulmonary embolism, deep vein thrombosis, cerebral thrombosis, and coronary thrombosis.

## Aims of pharmacovigilance

* **Improve client care and safety in relation to the use of medicines and all medical and paramedical interventions**

Medicines and medical products have the potential to cause harm to clients beyond the harm caused by the disease or condition being managed. Therefore, it is necessary to establish mechanisms both to prevent ADRs and manage them early when they do occur.

* **Improve public health and safety related to the use of medicines**

Adverse events can be a public health concern, especially when they affect a large group of clients, particularly those who may be vulnerable (e.g., children and those with comorbidities). Therefore, public health programs should incorporate aspects of pharmacovigilance as part of their interventions.

* **Contribute to the assessment of benefits, harms, effectiveness, and risk of medicines, encouraging their safe, rational, and more effective (including cost-effective) use**

Pharmacovigilance data provide critical information for determining the effects of medicine use in the population and inform decisions related to the selection of medicines to manage conditions based on their risk-benefit analysis.

* **Promote understanding, education, and clinical training in pharmacovigilance, and effectively communicate about it to the public**

Pharmacovigilance provides a basis for training health providers on the importance of medicines and related safety concerns in the management of medical conditions, including chronic diseases.

## Key terms in pharmacovigilance

**Adverse event:** Any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product where the causal relationship has not necessarily been established. The key point in this definition is that the event occurs after the initial administration of the medicinal product.

**Serious adverse event:** Any event that results in any of the following:

* **Death.** The client’s death was suspected to be an outcome of the adverse event.
* **Life-threatening event/reaction.** The client was at substantial risk of dying at the time of the adverse event, or use/continued use of the device or other medical product could have resulted in the death of the client.
* **Required hospitalization or prolonged current hospital stay.** Admission to the hospital or prolongation of hospitalization was a result of the adverse event.
* **Permanent or significant disability or loss of functionality.** Resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent, or permanent change, as well as impairment of, damage to, or disruption in the client's body function/structure, physical activities, and/or quality of life.
* **Associated with congenital anomalies/birth defects.** Exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
* **Required additional intervention to prevent permanent impairment/damage.** Medical or surgical intervention was necessary to preclude permanent impairment of a body function or to prevent permanent damage to a body structure, either of which was suspected to be caused by the use of a medical product.

**Side effect:** Any unintended effect of a medicinal product at doses normally used in humans and related to the pharmacological properties of the drug.

**Adverse drug reaction (ADR):** An ADR consists of the following:

* A harmful effect suspected to be caused by a drug
* “A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function”[[2]](#footnote-3)

ADRs are classified by their frequency, as shown in the table below.

|  |  |
| --- | --- |
| **Standard Categories of Frequency** | |
| Very common | ≥1/10 [≥10%] |
| Common | ≥1/100 to <1/10 [≥1% and < 10%] |
| Uncommon | ≥1/1000 to <1/100 [≥0.1% and < 1%] |
| Rare | ≥1/10,000 to <1/1000 [≥0.01% and < 0.1%] |
| Very rare | <1/10,000 [< 0.01%] |
| Frequency not known\* | Cannot be estimated from the available data |

**Unexpected adverse reaction:** A reaction that is not consistent with applicable product information or currently known characteristics of the drug.

**Signal:** Reported information on a possible causal relationship between an adverse event and a drug which was previously unknown or incompletely documented. A signal is generated when several related reports of a reaction are received and necessitate further evaluation.

**Causal relationship:** A relationship between one phenomenon or event A and another phenomenon or event B in which A precedes and causes B. In pharmacovigilance, this refers to when a medicine causes an adverse reaction, which is also known by the term “causality.”

**Causality assessment:** An evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. A causality assessment is usually made according to established algorithms.

An inherent problem in pharmacovigilance is that most case reports concern *suspected* ADRs. Adverse reactions are rarely specific to the drug, diagnostic tests are usually absent, and restarting of the same drug after having stopped it due to ADR (termed “rechallenge”) is rarely ethically justified. In practice, few adverse reactions are determined to be “certain” or “unlikely”; instead, most fall between these two extremes as “possible” or “probable.”

**Drug interaction:** A reaction between two (or more) drugs, or between a drug and a food/beverage/supplement. Interactions may also occur between a drug and a concurrent medical condition in the client. Drug interactions may be classified as:

* **Pharmacokinetic interactions**, which affect the actions of the drugs by interfering with pharmacokinetic processes, including absorption, distribution, metabolism, and elimination. These interactions may result in the slowing down or acceleration of these pharmacokinetic functions and result in either a reduction in blood levels (and a subsequent reduced pharmacological effect) or an increase in blood concentration (leading to toxicity). Most pharmacokinetic interactions are related to metabolic enzyme pathways that are shared among different drug molecules.
* **Pharmacodynamic interactions**, whichoccur through the interaction of the drugs at the site of action, where the presence of one drug interferes with the binding of the other to the active binding site.

The effects of drug interactions may be classified as types A, B, or C:

* **Type A effects**, also known as drug actions, are due to (exaggerated) pharmacological effects.
* **Type B effects**, also known as client reactions, characteristically occur in only a minority of clients and display little or no relationship to the dose.
* **Type C effects** are when the use of a drug increases the frequency of a spontaneous disease, often for unknown reasons.

## Why ADRs occur

ADRs may occur for the following reasons:

* **The effects of any medical intervention cannot be predicted with absolute certainty.**

Although knowledge of the molecular structure of a drug can provide an indication of its potential adverse effects, some drugs may exhibit inherent/unique properties that have not been experienced with previous similar molecules and, therefore, cannot be predicted.

* **No medicine or medical intervention exists that will not have a negative, undesirable effect on someone, somewhere, at some time.**

Genetic and lifestyle differences in the population, as well as general environmental differences, present a diversity of conditions in which a drug may elicit a response. This scenario presents many possibilities for the occurrence of undesirable effects.

* **By their chemical nature, medicines produce pharmacological effects and induce physiological changes.**

Medicines are administered to elicit a predetermined desirable effect through their pharmacological effects and physiological changes. Drug effects also include some undesired effects that may occur to varying degrees within the population.

* **Information about rare adverse events may not be available until they happen.**

Clinical studies, by virtue of their limited sample size and highly selected participant inclusion criteria, may not detect rare adverse events. Additionally, the short trial period may not be enough for long-term effects to manifest themselves during the trial period. Therefore, many adverse events manifest and are detected during the period after market authorization, when the number and diversity of clients using the medicine are expanded.

Some specific potential causes of ADRs include:

* **Error in disease diagnosis.**
* **Prescription of the incorrect drug for the disease:** The disease may negatively interact with the medicine, thereby producing an undesired effect.
* **Prescription of the incorrect dose of the correct drug:** Overdosing presents an elevated risk of an adverse drug event usually related to toxicity, especially for drugs with a narrow therapeutic window.
* **Choice of the correct drug for the disease, but potentially the wrong drug for the client because of population variability:** These include genetic or ethnic predisposition, age, comorbid conditions, concurrent medications, allergies, or intolerance.
* **Choice of the appropriate drug, but without consideration of the potentially harmful interactive effects with other drugs or substances being taken by the client:** Sometimes clients have comorbid conditions that may affect the actions of the medicine, or the client may be receiving concurrent treatment for these conditions which may interact with the newly prescribed medicines.
* **Full specifications, indications, contraindications, and risks of the drug not read or fully understood.**
* **Lack of client adherence to or compliance with the health worker’s recommendations or the manufacturer’s instructions in the product information leaflet:** Educating the client is important to ensure maximum benefit of the medicine, while also informing the person of factors that may affect efficacy or increase the chances of undesired effects, e.g., diet (types of foods) or the timing of eating vis-à-vis the dosing schedule.
* **Self-medication:** Over-the-counter medicines and self-prescribed treatments are typically not documented and, therefore, may not form part of the prescriber’s evaluation process for selecting the best treatment options for the client. This may result in interactions that can potentially cause adverse effects. Concomitant use of traditional and complementary medicines is also typically not well documented and can pose a significant risk of adverse effects for some medicines.
* **Polypharmacy (increased drug interactions):** The more medicines a client takes simultaneously greatly increases the chances of drug interactions and toxicity. It is crucial that prescribers carefully consider the potential for these interactions and that pharmacists flag these risks during the dispensing process.

## Major predisposing factors for ADRs

* **Extremes of age:** The very old and the very young are more susceptible to ADRs.
* **Sex:** For some medicines, safety profiles may differ for males and females.
* **Comorbidities:** Clients who also suffer from another disease may be predisposed to experiencing ADRs (e.g., kidney and liver disease may influence metabolism).
* **Drug interactions:** Pharmacodynamic or pharmacokinetic interactions potentiate toxicity.
* **Race and genetic factors:** Genetic factors may determine the response of the body to medicines and predispose some individuals to ADRs. Pharmaco-epidemiological studies have demonstrated higher incidence of some ADRs in some population groups.
* **Prolonged treatment and amount of administered medicines**: Excessive exposure to medicines or prolonged therapy may be predisposing factors for ADRs.
* **History of allergies:** Individuals with a hyperreactive immune system may have increased chances of experiencing an ADR.
* **Multiple drug therapy (polypharmacy):** The incidence of ADRs increases with the number of drugs given due to the risk of drug interactions.

## Pharmaco-epidemiological methods used in pharmacovigilance

Several methods are used in pharmacovigilance, each having its own level of complexity and advantages and disadvantages. These methods are classified as either passive or active according to the following definitions:

* **Passive pharmacovigilance**

In passive pharmacovigilance, no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns they encounter during the process of providing clinical care. Reporting is entirely dependent on the initiative and motivation of those who do the reporting. This is the most common form of pharmacovigilance. It is commonly referred to as “spontaneous” or “voluntary” reporting.

* **Active pharmacovigilance**

Active pharmacovigilance is safety surveillance in which active measures are taken to detect adverse events. This is done through deliberate follow-up of clients once treatment has commenced and may continue beyond the end of treatment to detect any late or long-term effects.

## Spontaneous reporting

A spontaneous report is an unsolicited communication by health care professionals or consumers that describes one or more ADRs in a client who was given one or more medicinal products and that does not derive from a study or any organized data collection scheme.

When this method targets a defined group of clients and involves reporting specific safety concerns suspected to be related to a medicine, it is referred to as *targeted spontaneous reporting*.

### Features

* Most common form of pharmacovigilance
* No measures taken to systematically follow up with clients to record any ADRs they have experienced
* Reporting dependent on initiative of those who do the reporting, resulting in underreporting of ADRs compared to actual incidence
* Difficult to estimate rates and frequencies of ADRs with this method
* May lead to warnings and changes in product information leaflets

## Cohort event monitoring

Cohort event monitoring (CEM) is a prospective, observational cohort study of adverse events associated with one or more medicines. A CEM program is essentially an observational study of a new medicine in the early post-marketing phase which is conducted in normal clinical practice; however, it can also be used for older medicines.

### Features

* Prospective pharmacovigilance surveillance system
* Usually applied to new medicines in routine clinical practice during early post-marketing phase
* Records all medicine-related events regardless of severity, including medication errors, problems due to poor storage conditions, poor quality or counterfeit medicines, and drug interactions
* Total of 10,000 enrolled clients needed to reach 95% likelihood of witnessing rare events caused by the medication

## Sentinel site reporting

A sentinel surveillance system is used when high-quality data are needed about the safety of a specific drug or treatment regimen that cannot be obtained through a passive system. Selected reporting units with a high number of clients on the treatment—and, therefore, a high probability of encountering adverse events—good laboratory facilities, and experienced, well-qualified staff are responsible for identifying ADRs and reporting on certain diseases.

### Features

* Used when high-quality data are needed about a disease or treatment that cannot be obtained through passive methods
* Conducted in locations with a high probability of seeing cases of the particular disease(s)
* May not be as effective for detecting rare diseases or adverse events occurring outside the sentinel site locations

## Reporting of ADRs

### Benefits

* **Helps identify rare ADRs:** Clinical trials and the initial period of medicine use following market authorization are characterized by a low number of research participants and clients. As a result, rare ADRs may not manifest during this period. However, rare ADRs may occur once there is more widespread use.
* **Prevents medicine tragedies:** From a historical perspective, the population impact of negative effects related to the use of a medicine could have been much lower if there had been systems in place to enable early identification of these negative effects.
* **Detection of counterfeit and substandard medicines when health care personnel are alert to unexpected and apparently inexplicable adverse reactions or lack of effect**: The problem of substandard and counterfeit medicines is a growing global challenge affecting the health and well-being of a significant portion of the population. Pharmacovigilance reports assist regulatory authorities to identify and manage these products in the market, thereby contributing to safety.
* **Leads to improvement of labeling information:** The findings of pharmacovigilance studies which are informed by reported case studies and which generate related signals serve to improve the quality of client and health provider information. In turn, this improves medicine prescription decisions and prevents unnecessary harm to clients.
* **Contributes to the development of a database on ADRs that would serve as a useful and relevant educational source**

### Who should report ADRs?

The responsibility for reporting suspected ADRs lies not only with clinicians, but also with health workers and clients. These include:

* All health workers in both the private and public sectors as part of their professional responsibilities
* Manufacturers and distributors/marketing authorization holders, whose adequate surveillance and reporting are a regulatory responsibility for maintaining market authorization
* Members of the public
* Public health programs involving the use of medicines or health products, including research institutions, nongovernmental organizations, and other partners, which should incorporate pharmacovigilance to enhance client safety.

### What aspects of ADRs should be reported?

* Suspected reactions, including minor ones (for “new” medicines)
* All serious, unexpected, or unusual ADRs, in the case of established or well-known medicines
* Observation of any increased frequency of a given reaction
* Suspected ADRs associated with drug-drug, drug-food, or drug-food supplement interactions
* ADRs occurring in special cases or conditions, such as when medications or other substances are used or abused during pregnancy and lactation
* ADRs attributed to an overdose or medication error
* Cases of product quality concerns, including nonresponse, therapeutic ineffectiveness, or suspected pharmaceutical defects

### How should an ADR be reported?

This section should be discussed as per the country-specific reporting protocols.

# Part III: ADHERENCE MONITORING AND CLIENT COUNSELING

## Purpose

Adherence to ART is critical to achieving viral suppression, preventing the development of opportunistic infections and drug resistance. This session describes the importance of adherence, its implications on treatment, and the activities/interventions pharmacists can undertake during the dispensing process to assess the client’s adherence and support/reinforce adherence messages.

## Topics covered

* Adherence and its importance for successful outcomes
* Link between adherence, resistance, and future treatment options
* Factors associated with nonadherence
* Methods for measuring adherence
* Methods and strategies to improve adherence
* Counseling for adherence problems

## Definition of adherence

Adherence is the extent to which a client’s behavior coincides with the prescribed health care regimen as agreed upon through shared decision-making between the client and the health care provider.

The treatment of long-term/chronic conditions requires clients to understand the disease (in this case, HIV) and the process for treating it, to be highly motivated and feel involved in the decision-making.

## Why is adherence counseling important?

Adherence counseling plays an essential role in treatment, for the following reasons:

* **Helps clients develop an understanding of the disease, its treatment, and potential challenges**

Proper understanding of the disease, its treatment, and the potential challenges of treatment allows clients to make the psychosocial and behavioral decisions needed to facilitate favorable treatment outcomes. When a client has a better understanding of the disease, they are more likely to follow through with the treatment decisions as agreed upon with their clinicians and other HIV care providers.

* **Prepares clients to initiate treatment**

Given that treatment is a lifelong process, adequate preparation is necessary before starting it to set the stage for the treatment process. During this stage, the potential or actual factors that may influence adherence are explored. These include current health status, socioeconomic background, and perceptions of illness and treatment. Treatment information is provided at this stage and covers what treatment entails, including the potential side effects, and the importance of adherence.

* **Provides ongoing support for clients to stay on treatment, with good adherence over the long term**

Once a client begins treatment, regular monitoring and reinforcement of adherence are necessary to ensure sustained optimal behavior. Clients are likely to encounter several challenges that may influence their ability and willingness to stay on treatment, thereby negatively affecting adherence. These include side effects, pill fatigue/pill holidays, and stigma. Early identification of these challenges ensures that they can be addressed early, before they adversely affect adherence and, ultimately, treatment outcomes.

* **Helps clients develop good treatment-taking behaviors**

For most clients on ART, especially those who are stable or who do not have severe disease, treatment involves self-care as a major component. Clients have limited and more intermittent contact with health providers and, therefore, are responsible for monitoring a major part of their treatment process. Adherence counseling assists clients to understand the implications of behavior on treatment outcomes and encourages clients to adopt behaviors that increase the chances of favorable outcomes.

* **Helps clients set treatment goals**

## Forms of nonadherence

Several forms of nonadherence may manifest in clients on ART:

* **Failure to take the correct number of pills at the appropriate frequency**

It is important for clients to take the correct amount of medicines at the appropriate frequency to ensure that optimal therapeutic levels are maintained in the blood in order to achieve viral suppression. When clients miss scheduled doses or take fewer pills than directed, subtherapeutic levels that do not have the desired effect on viral replication may result.

* **Missed appointments for clinical consultation, counseling sessions, laboratory testing, ARV refill pick-up**

Regular clinical and laboratory monitoring is essential in ART to ensure that the clinicians have a good understanding of the treatment effectiveness or disease progression. This enables them to make any necessary changes to treatment early. When clients miss scheduled ARV refill pickups, this signifies potentially missed doses, which affects treatment outcomes.

* **Taking treatment “holidays”**

Clients may decide to stop taking their medicines for a period of time due to several reasons, including pill fatigue. This is referred to as a “treatment/pill holiday.”

* **Failure to make necessary lifestyle changes**

Some lifestyle changes are required for clients on ART, including no longer smoking and using/abusing alcohol and other substances, eating a healthy diet, and exercising. The failure to make these changes may compromise treatment.

## Consequences of poor adherence

Poor adherence adversely affects individuals and has negative consequences from a public health and health economics perspective.

### For the individual

**Treatment failure:** This consists of a progressive increase in viral load, continued damage to the immune system, development of opportunistic infections and, subsequently, death.

**Drug resistance:** Suboptimal therapeutic levels result in the virus developing resistance to the drugs. The ease with which drug resistance may develop differs by drug class and individual drug, with some drugs being more highly susceptible.

**More complex treatment, more toxicity:** Drugs and regimens used to treat drug-resistant strains of the virus are usually more complex and expose clients to a greater chance of toxicity and adverse events.

**Increased chances of progression to advanced disease:** Drug resistance results in progressive advancement of the disease process, leading to advanced HIV disease and consequent development of an AIDS-defining illness.

### For public health

**Transmission of resistant virus (subsequent ART failure):** Clients who develop a resistant strain of the virus are likely to transmit the resistant strain to their sexual partners (or to the child, in the case of an HIV-infected pregnant woman). This has serious consequences for the health of the population and the treatment program.

**Increased morbidity and mortality:** Drug resistance results in treatment failure, increased morbidity (from opportunistic infections), and death from AIDS-related illnesses.

### For health economics

**Negative impact on the established cost effectiveness of ART:** Management of drug-resistant HIV requires the use of more complex, usually more expensive, drug regimens.

## Methods for measuring adherence

Measuring adherence is a critical component of adherence monitoring and support, as it allows for the early detection of adherence challenges and informs the formulation of strategies to address any identified challenges.

Several methods are used to assess/measure adherence, and each has its own advantages and disadvantages. It is worth noting that none of the methods are 100 percent accurate, and not all are applicable in all settings. Pharmacists should identify the most feasible combination of methods and use them to develop the best possible interpretation of each client’s adherence.

### Health provider assessment

In this method, health providers use physical and clinical parameters to assess whether clients are responding to treatment. They may ask, “How is the client’s general well-being? Have any previously identified problems been resolved?” The appearance of opportunistic infections may also signify poor adherence.

This method for assessing adherence is simple, cheap, and does not require a structured tool. However, it is subjective (i.e., depends on the health provider’s perspective), and the assessment may be influenced by the client-provider relationship.

### Client self-report

In the client self-report method, the health provider asks the client if they have missed any doses during a defined period (usually in the recent past) and, if so, how many doses they have missed.

This strategy is simple and inexpensive, and it allows the health provider to make a qualitative assessment if the client provides the number of doses missed during the specified period. However, its usefulness depends on the client’s ability to recall missed doses, and there is the possibility that the client may not be truthful, particularly if the person fears consequences from the health provider. The accuracy of the information the client provides may depend on the established client-provider relationship.

### Pill counts

This method requires clients to return to the facility with the medicine container. The health provider then counts the remaining pills and compares the amount to the number of pills the client is expected to have (as a balance) on the day of the visit.

This method is simple, inexpensive, and objective, and it allows for quantitative calculation of adherence. However, the results may be influenced by “pill dumping” (i.e., when the client disposes of some pills to create the impression that they were taken) or pill sharing (i.e., with other clients). It is also not easy to verify whether the client actually swallowed the medicine and if the client took the pills at the correct time.

### Use of pharmacy records

This method involves review of the client’s ARV pick-up records at the pharmacy to assess historical trends. Serial/habitual lateness of picking up ARVs (many days past the scheduled pick-up dates) indicates that the client may have been without medication for a number of days and, therefore, not taking the required doses, equating to poor adherence.

Where there is a good record system, this method provides an objective assessment of adherence. However, it does not allow for adherence to the dosing schedule to be assessed. In cases where pill sharing is taking place (with a spouse, family, or friends), picking up medications on time does not necessarily mean that the client is taking the medicines as scheduled.

### Drug level monitoring

This requires the availability of laboratory facilities to determine blood levels for therapeutic drug monitoring. This infrastructure is unlikely to be available in most ART settings and, therefore, its usefulness on a large scale is limited. This method is objective but expensive (requires laboratory infrastructure), and it may be influenced by the drug’s pharmacokinetics.

### Electronic drug monitoring (EDM)/medication event monitoring (MEMS)

This method involves a device used to monitor medication adherence. The medication event monitoring system (MEMS) is a cap that fits on standard medicine bottles and records the time and date each time the bottle is opened and closed. EDM has the advantages of being objective and providing information on the timing of doses over long periods. However, it does not detect pill dumping, and the technology is expensive.

## Strategies and tools to enhance adherence

Potentially nonadherent clients should be identified and their barriers addressed during counseling before they are prescribed ARVs for the first time.

It is crucial to identify factors that may affect clients’ adherence prior to initiation of treatment in order to anticipate the challenges or barriers they may experience. This enables health workers to educate and counsel each client on the potential effects of these barriers on their treatment and assist them to develop strategies to make any changes deemed necessary. Some barriers include existing substance abuse of drugs and/or alcohol, psychosocial issues, gender-based violence, and stigma.

* **Intensified adherence counseling and support for newly initiated clients**

Newly initiated clients require more intensified adherence monitoring and support as they navigate the initial period of treatment. During the initial phase, clients are likely to experience side effects associated with the ARVs or consequences of immune reconstitution. These may affect their willingness to stay on treatment, as the medicines may be making them feel worse.

* **Identification of an adherence partner/buddy or a peer educator**

Social support during treatment is crucial. Clients may identify an individual or confidante who can accompany them on their treatment journey, provide psychosocial support, and remind them to take their medicines and attend scheduled appointments. These treatment supporters may be friends, family, or community workers assigned to the treatment and support program.

* **Provision of continuous adherence counseling during all contact between clients and health providers (multidisciplinary responsibility)**

All health providers who have contact with clients during the course of treatment have the responsibility to provide continuous adherence support as part of a multidisciplinary approach to ART. During the ARV dispensing process, pharmacists should monitor adherence, provide adherence support, and help identify any adherence challenges clients may be experiencing, as well as identify and monitor any side effects.

* **Intensified adherence support/counseling for clients with adherence challenges**

Clients who experience adherence challenges during treatment, whether related to the medicines or other psychosocial factors, need to be identified early and provided with more intensified adherence support. Adherence counselors, pharmacists, and community health workers who interact with clients in the community can provide this support.

* **Reminders for appointments and drug pick-up**

Most adherence issues are related to the failure to keep scheduled appointments for clinical consultations, laboratory tests, or medicine pick-up. Many programs have incorporated reminder strategies that preempt missed appointments by reminding clients via text message, telephone calls, or assigned case managers.

* **Early identification and tracking of defaulters**

To ensure that clients avoid extended periods without taking their medicines, an early warning system is needed to alert health providers when clients have missed appointments and trigger the established mechanisms for tracing defaulting clients and bringing them back to care.

* **Linkages to community support structures (support groups)**

Community involvement is a crucial component of ART. Various community support structures are available to support adherence, including community ART clubs/groups, community case managers, and peer supporters.

* **Differentiated service delivery (DSD)**

Many treatment programs have adopted DSD models that group clients according to need, ensuring that barriers to treatment are reduced and that health providers are able to concentrate on clients who require more intensive care. Multi-month scripting (MMS) and dispensing (MMD) have been adopted to reduce how often clients have to pick up ARV refills, thereby reducing the chance of missed doses. Based on stock, clients can pick three, four, or six months of ARVs at a time.

* **Reducing challenges to access (distance to health facility, waiting time) through community distribution of ARVs**

The use of private pharmacies to dispense ARVs for stable clients allows clients to pick up their medicines at more convenient locations and times, as well as avoid long waiting times.

1. World Health Organization (WHO). 2016. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. 2nd edition. Geneva: WHO. [↑](#footnote-ref-2)
2. WHO. 1975. Requirements for adverse reaction reporting. Geneva: WHO. [↑](#footnote-ref-3)