HIV DRUG RESISTANCE EARLY WARNING INDICATORS

World Health Organization indicators to monitor HIV drug resistance prevention at antiretroviral treatment sites

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World Health Organization

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ACRONYMS AND ABBREVIATIONS

ART	Antiretroviral treatment
ARV	Antiretroviral (drug)
EWI	Early warning indicator
FDC	Fixed-dose combination
HIV	Human immunodeficiency virus
HIVDR	HIV drug resistance
PMTCT	Prevention of mother-to-child transmission of HIV
WG	Working group
WHO	World Health Organization

1 INTRODUCTION

In recent years, the rapid scale up of antiretroviral treatment (ART) for HIV infection in resource-limited countries has been identified as an international health-care priority. By December 2008, it was estimated that approximately four million people living with HIV/AIDS were receiving treatment in low- and middle-income countries, representing coverage of 42% of the estimated 9.5 million people in need of ART (*1*). The public health approach to scaling up ART in resource-limited settings involves the use of standardized and simplified treatment regimens that are consistent with international standards, and appropriate to local circumstances (*2*). The emergence of some HIV drug resistance (HIVDR) is inevitable in populations taking ART even if appropriate ART regimens are provided and optimal adherence to therapy is supported; this is due to the error prone nature of HIV replication, its high mutation rate in the presence of drug selective pressure, viral recombination, and because of the need for lifelong treatment.

The human and financial implications of HIV drug resistance are significant; the average annual cost of a second-line ART regimen can reach up to eight times that of a first-line ART regimen (*1*). For a patient, HIV drug resistance limits treatment options and the need for second-line regimens that are generally more difficult to take. Although the proportion of ART patients on second-line therapy continues to be low in low- and middle-income countries (less than 2%), the number and proportion of patients requiring second-line drugs will continue to rise as countries scale up ART and maintain thousands on treatment over long periods of time.

WHO has developed a Global Strategy for HIV Drug Resistance Prevention and Assessment using a public health approach (*3*). This strategy supports optimal functioning of treatment programmes to minimize emergence of preventable HIV drug resistance and to maintain the effectiveness of first- and second-line ART regimens. WHO recommends that countries adapt and implement a national strategy, based on the Global Strategy, to assess and minimize emergence of preventable HIV drug resistance.

This document describes one key element in the recommended HIVDR prevention and assessment strategy: ART site-based HIVDR early warning indicators (EWIs). These indicators are ART site factors that may be associated with preventable emergence of HIVDR, and can be acted on at the ART site or programme level. Results can inform national decision-making on ART programme planning and other HIVDR prevention measures.

This document is part of a series of guides to support country implementation of HIVDR early warning indicator monitoring. Separate guides are available for (a) EWI data abstractors, describing procedures for collecting EWI data; and (b) HIVDR working group (WG) members, to guide planning for EWI monitoring, and analysis and use of EWI results for public health action. These guides will be available in 2010 on the WHO HIVDR web site: http://www.who.int/hiv/drugresistance.

2 PURPOSE OF HIV DRUG RESISTANCE EARLY WARNING MONITORING

The purpose of implementing an HIVDR EWI monitoring system is to assess the extent to which ART programmes are functioning to optimize prevention of HIVDR. EWIs measure ART site factors known to be associated with good programme functioning and the prevention of the emergence of HIVDR. Strengthening specific aspects of ART programme delivery at the site level will minimize preventable HIVDR and promote the long-term efficacy and durability of available first- and second-line regimens.

- EWIs evaluate factors associated with HIVDR prevention without requiring laboratory testing for drug resistance.
- EWIs are monitored either at all ART sites in the country or at representative sites.
- ART site profiles, completed annually, inform the interpretation of EWI results, and guide the development of public health actions required to address them.
- EWI monitoring provides the evidence base for public health action to prevent and address HIV drug resistance.

Information collected as part of EWI monitoring includes ART prescribing practices; patients lost to follow-up after initiation of ART; patients on appropriate first-line therapy at 12 months; on-time patient appointment keeping and antiretroviral (ARV) drug pick-ups; and ARV drug supply continuity. Two optional indicators collect information on adherence, and on HIV viral load suppression at 12 months.

The WHO recommends a target for each indicator that facilities should reach to prevent emergence of drug resistance in ART patients. These targets are based on a review of the published medical literature and consensus of international experts. Individual countries may set more stringent targets, but the WHO does not recommend that countries set more lenient targets.

Monitoring EWIs can alert national ART programme managers to clinic factors that need increased support to reduce the potential for failure and the emergence of preventable resistance. Early and ongoing EWI monitoring alerts clinic and district managers to address problem areas, and may reduce the need for more costly laboratory assessments to evaluate HIVDR emergence.

Plans for EWI monitoring should be integrated into the country-level monitoring and evaluation system, in collaboration with major institutions working within the country to support and monitor ART. Implementation is most straightforward in countries where records at the majority of ART sites reflect the international agreement on the standard minimum dataset for ART records. However, EWI can be abstracted from a variety of electronic and paper-based systems.

EWI results form the basis of recommendations for quick action either at the site level or, if many sites do not meet targets, at the national ART programme level. Recommendations may include increased

training and resources for specific aspects of care, provision of targeted support for adherence, or reduction of barriers to continuous access to ARVs. Additional assessment, including operational research to clarify the source of problems and the support required to address them, may also be recommended.

3 SELECTING HIV DRUG RESISTANCE EARLY WARNING INDICATORS

It is not necessary for countries to monitor all EWIs. WHO recommends that countries monitor EWIs for which information is readily available from data currently recorded routinely at ART sites. In order to select EWIs, the HIVDR Working Group must determine which EWIs are feasible to monitor in the country, based on ART clinic and pharmacy record systems in use. This requires on-site evaluation to assess whether the relevant information is recorded in standard format. Indicators should not be selected if the appropriate data are not available.

Table 1 provides a summary of the six recommended EWIs and the two optional EWIs. Additional details on individual EWIs, including required data elements and WHO-recommended targets, are described in Section 4. Note that countries may specify more stringent national targets, but that all ART sites in a country should have the same targets.

Paediatric patients

Collection of data for most EWIs is identical for both adults and children. Most EWI are suitable for paediatric patients in their current form. However, assessment of ART regimens for paediatric populations requires additional variables, and therefore separate paediatric indicators are developed for EWIs 1 and 3a. The paediatric versions of these indicators are referred to as EWIs 1-P and 3a-P, respectively.

Please note:

- Each EWI must be monitored separately for adult and paediatric patients. The actions required to achieve the best possible HIVDR prevention may be different for children and adults (*1, 4*).
- The criteria to define ‘paediatric’ will vary according to each country’s national guidelines.

Table 1 Summary table of early warning indicators

	EWI name	EWI #	EWI purpose	Eligible patients*	Data abstraction and analysis tool available**
EWI 1	ART prescribing practices	**1**	To determine the percentage of adult patients initiating ART who are prescribed an appropriate first-line ART regimen	Patients initiating ART	Yes
		1-P	To determine the percentage of paediatric patients initiating ART who are prescribed an appropriate first-line ART regimen	Patients initiating ART	In development
EWI 2	Patients lost to follow-up 12 months after ART initiation	**2**	To determine the percentage of patients initiating ART who are lost to follow-up 12-months after ART initiation	Patients initiating ART	Yes
EWI 3	Patients on appropriate first-line ART at 12 months	**3a**	To determine the percentage of adult patients who are taking an appropriate first-line ART regimen 12 months after ART initiation	Patients initiating ART	Yes
		3a-P	To determine the percentage of paediatric patients who are taking an appropriate first-line ART regimen 12 months after ART initiation	Patients initiating ART	In development
		3b	To determine the percentage of patients initiating ART whose ART regimen was changed during the first 12 months to a regimen that includes a different drug class	Patients initiating ART	No
		• *EWIs 3a and 3b are complementary, and countries may choose to monitor both. EWI 3a should be prioritized if only one of the indicators can be monitored.*			
EWI 4	On-time ARV drug pick-up	**4a**	To determine the percentage of patients who picked up prescribed ARV drugs on time (three consecutive pick-ups)	Patients on ART	Yes
		4b	To determine the percentage of patients who picked up all prescribed ARV drugs on time during their first year of ART	Patients initiating ART	Yes
		• *EWIs 4a and 4b are complementary, and countries may choose to monitor both.* • *EWI 4a uses a sample of <u>all</u> patients on ART, and follows them for two drug pick-ups after baseline pick-up.* • *EWI 4b includes only patients <u>initiating</u> ART and follows them for the first year.*			
EWI 5	ART clinic appointment keeping	**5a**	To determine the percentage of patients who attended clinical consultations on time (three consecutive consultations)	Patients on ART	Yes
		5b	To determine the percentage of patients who attended all clinical consultations on time during their first year of ART	Patients initiating ART	Yes

	EWI name	EWI #	EWI purpose	Eligible patients*	Data abstraction and analysis tool available**
		• *EWIs 5a and 5b are complementary, and countries may choose to monitor both.* • *EWI 5a uses a sample of <u>all</u> patients on ART, and follows them for 2 clinic consultations.* • *EWI 5b includes only patients <u>initiating</u> ART and follows them for the first year.*			
EWI 6	ARV drug supply continuity	**6a**	To determine the percentage of months in a designated year in which there were no ARV drug stock-outs	N/A	Yes
		6b	To determine the percentage of months in a designated year in which there were no ARV drug stock-outs (provides more detailed information than 6a)	N/A	Yes
		6c1	To determine the percentage of patients on ART whose regimen was stopped, modified, or incompletely dispensed at the pharmacy due to ARV stock-outs in a 12-month period	Patients on ART	No
		6c2	To determine the percentage of patients initiating ART at the site whose regimen was stopped, modified, or incompletely dispensed at the pharmacy due to ARV stock-out during the first 12 months of ART	Patients initiating ART	No
		• Countries may choose to monitor either EWI 6a or 6b. EWI 6b provides more detailed information on frequency and duration of stock-outs. • EWIs 6c1 and 6c2 assess the extent to which stock-outs affect patient care, and are only feasible in countries whose standardized patient records specifically include stock-out as a reason for a change in regimen.			
Optional EWI 7	Patient adherence to ART	**7a**	To determine the percentage of patients who demonstrate 100% ART adherence by pill count	Patients initiating ART	No
		7b	To determine the percentage of patients who demonstrate 100% ART adherence by another standardized adherence measure	Patients initiating ART	No
Optional EWI 8	Viral load suppression 12 months after ART initiation	**8**	To determine the percentage of patients initiating ART at the site whose viral load is <1000 copies/ml after 12 months of ART	Patients initiating ART	No

* Eligible patients are described in Section 7.1 (see table 2).

** A set of data abstraction and analysis tools for EWI monitoring is available through WHO. See Appendix IV.

4 DESCRIPTION OF HIV DRUG RESISTANCE EARLY WARNING INDICATORS

This section provides a description of the basic elements of each early warning indicator. Countries should only select EWIs that can be abstracted from the current ART record systems. If national ART programmes are updating their record system for other purposes, consideration should be given to incorporating relevant data elements that would support monitoring additional indicators.

4.1 EWI 1. ART prescribing practices

EWI 1. Percentage of adult patients *initiating ART at the site who are initially prescribed, or who initially pick up from the pharmacy, an *appropriate first-line ART regimen* (cross-sectional)** (*5, 6*)
Suggested target: 100%
Definition of numerator and denominator: • **Numerator:** number of adult patients *initiating ART at the site* who are prescribed, or who initially pick up from the pharmacy, an *appropriate first-line ART regimen*. • **Denominator:** number of adult patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**
Considerations: • EWI 1 is used to assess *first-line ART* regimens among adult patients. EWI 1-P is used to assess *first-line ART* regimens among paediatric patients.
Data elements abstracted for each eligible patient: • A *patient identifier*; • The *date of ART initiation* at the site (either as an ART prescription or an ARV drug pick-up); • The ART regimen initially prescribed (or ARV drugs initially picked up); • HIV type (i.e., HIV-1, HIV-2, or HIV-1/2 co-infection) – to be abstracted only in countries where HIV-2 diagnosis is recorded in the medical record and is considered in regimen selection.
Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis: 1. Patients for whom any of the following crucial information is missing: • Patient ID • *ART initiation date* • Initial ART regimen

* Words or phrases shown *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

EWI 1 - P. Percentage of paediatric patients *initiating ART at the site who are initially prescribed, or whose care-giver initially picks up from the pharmacy, an *appropriate first-line ART regimen* (cross-sectional)** (*7*)

Suggested target: 100%

Definition of numerator and denominator:

- **Numerator:** number of paediatric patients *initiating ART at the site* who are prescribed, or whose care-giver initially picks up from the pharmacy, an *appropriate first-line ART regimen*.
- **Denominator:** number of paediatric patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 1-P is used to assess *first-line ART* regimens among paediatric patients.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (either as an ART prescription or an ARV drug pick-up);
- The ART regimen initially prescribed (or ARV drugs initially picked up), including dose of the drugs and number of doses/day;
- Patient's age and weight at ART initiation (or at closest date within 3 months before ART initiation);
- PMTCT regimens that were used for both the mother and the child;
- HIV type (i.e., HIV-1, HIV-2, or HIV-1/2 co-infection) – to be abstracted only in countries where HIV-2 diagnosis is recorded in the medical record and is considered in regimen selection.

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients for whom any of the following crucial information is missing:
   - Patient ID
   - *ART initiation date*
   - Initial ART regimen
   - ARV formulation and strength
   - Daily dose
   - Weight of child
   - Age of child

* Words or phrases marked *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

4.2 EWI 2. Patients lost to follow-up 12 months after ART initiation

EWI 2. Percentage of patients *initiating ART at the site who are *lost to follow-up* 12 months after ART initiation (cohort)** (*8–19*)

Suggested target: ≤20%

Definition of numerator and denominator:

- **Numerator:** number of patients *initiating ART at the site* who, during the first 12 months after ART initiation, did not attend a clinical consultation and did not pick up ARV drugs within 90 days (≤90 days) after the date of their last missed appointment, or within 90 days (≤90 days) after the last ART *run-out date*.
- **Denominator:** number of patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- If possible, countries should abstract the data for this indicator from medical and pharmacy records. The use of both types of records will ensure correct identification of patients '*lost to follow-up*'.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (either as an ART prescription or ARV drug pick-up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The '15-month date' (i.e. 15 months after the *date of ART initiation*);
- The date of the last clinical consultation attended on or before the '12-month date';
- The date of the last scheduled or expected clinical consultation missed on or before the '12-month date' (if applicable);
- The date of the first clinical consultation attended between the '12-month date' and the '15-month date' (if any);
- The date of the last ARV drug pick-up on or before the '12-month date';
- The ART regimen picked up at the last drug pick-up on or before the '12-month date' including number of days (or strength and pill number/volume dispensed);
- The date of the first drug pick-up between the '12-month date' and the '15-month date' (if any);
- The date of *transfer out* on or before the '15-month date' (if applicable);
- The date of *death* on or before the '15-month date' (if applicable);

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* prior to 12-month date
2. Patients who *died* prior to 12-month date
3. Patients for whom any of the following crucial information is missing.
    - Patient ID
    - *ART initiation date*
    - The record must include one of the following:
        - the date of the last clinical consultation attended on or before the '12-month date' (if this date is within 90 days of 12 month date); **or**
        - the date of last scheduled/expected clinical consultation missed; **or**
        - the date of last ARV pick-up before the 12-month date **and** the number of days of ARV drugs picked up.

* Words or phrases marked *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

4.3 EWI 3. Patients on appropriate first-line ART at 12 months

EWI 3a. Percentage of adult patients *initiating ART at the site who are taking an *appropriate first-line ART regimen* 12 months later (cohort)** (*20–21*)

Suggested target: ≥70%

Definition of numerator and denominator:

- **Numerator:** number of adult patients *initiating ART at the site* who are on an *appropriate first-line ART regimen* (including *substitutions* of one *appropriate first-line regimen* for another) 12 months after ART initiation.
- **Denominator:** number of adult patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 3a is used to assess *first-line ART* regimens among adult patients. EWI 3a-P is used to assess *first-line ART* regimens among paediatric patients.
- EWI 3a and 3b are complementary and countries may choose to monitor both. 3a should be prioritized if only one of the two indicators can be collected.
- Countries can abstract data for these indicators from medical records (drugs prescribed) or pharmacy records (drugs dispensed). Both types of records should be used if possible.
- Patients who *died*, *stopped* ART or *switched* to a *second-line ART* regimen in the first year after ART initiation are included in this sample because these outcomes may reflect quality of care.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (either as an ART prescription or an ARV drug pick-up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The date of the last clinical consultation attended on or before the '12-month date';
- The ART regimen prescribed at the last clinical consultation on or before the '12-month date', including number of days prescribed, or pill number and strength (mg) and pills/day prescribed;
- The date of the last ARV drug pick-up attended on or before the '12-month date';
- The ARV drugs picked up at the last pick-up on or before the '12-month date', including number of days dispensed, or pill number and strength (mg) and pills/day dispensed;
- The date of *transfer out* on or before the '12-month date' (if applicable);
- The date of *death* on or before the '12-month date' (if applicable);
- The date ART was *stopped*, without a restart, on or before the '12-month date' (if applicable);
- HIV type (i.e. HIV-1, HIV-2, or HIV-1/2 co-infection) – to be abstracted only in countries where HIV-2 diagnosis is recorded in the medical record and is considered in regimen selection.

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* prior to 12-month date
2. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - This EWI allows for classification based on either clinical or pharmacy information. One of the following combinations of information is required:
     - 'date of last clinical consultation attended', 'last ART regimen prescribed' **and** 'number of days of ART prescribed at the last clinical consultation attended'; **or**
     - 'date of last ARV drug pick-up', 'ARV drugs picked-up at last ARV drug pick-up', **and** 'number of days of ARV drugs picked-up at the last drug pick-up'.

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

EWI 3a-P. Percentage of paediatric patients *initiating ART at the site who are taking an *appropriate first-line ART regimen* 12 months later (cohort)** (*20, 22*)

Suggested target: ≥70%

Definition of numerator and denominator:

- **Numerator:** number of paediatric patients *initiating ART at the site* who are on an *appropriate first-line ART regimen* (including *substitutions* of one *appropriate first-line regimen* for another) 12 months after ART initiation.
- **Denominator:** number of paediatric patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 3a is used to assess *first-line ART* regimens among adult patients. EWI 3a-P is used to assess *first-line ART* regimens among paediatric patients.
- For paediatric populations, EWI 3a-P and 3b are complementary and countries may choose to monitor both. 3a-P should be prioritized if only one of the two indicators can be collected.
- Countries can abstract data for these indicators from medical records (drugs prescribed) or pharmacy records (drugs dispensed). Both types of records should be used if possible.
- Patients who *died*, *stopped* ART or *switched* to a *second-line ART* regimen in the first year after ART initiation are included in this sample because these outcomes may reflect quality of care.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (either as an ART prescription or an ARV drug pick-up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The date of the last clinical consultation attended on or before the '12-month date';
- The ART regimen prescribed at the last clinical consultation on or before the '12-month date', including number of days prescribed, or pill number and strength (mg) and pills/day prescribed, or liquid volume (ml) and strength (mg/ml) and dose/day prescribed;
- Patient's age and weight at time of last clinical consultation or drug pick-up on or before the 12-month date (or at closest date within 3 months of that event);
- The date of the last ARV drug pick-up attended on or before the '12-month date';
- The ARV drugs picked up at the last pick-up on or before the '12-month date', including number of days prescribed, or pill number/volume and strength (mg) and pills/day or dose/day dispensed;
- The date of *transfer out* on or before the '12-month date' (if applicable);
- The date of *death* on or before the '12-month date' (if applicable);
- The date ART was *stopped*, without a restart, on or before the '12-month date' (if applicable);
- HIV type (i.e. HIV-1, HIV-2, or HIV-1/2 co-infection) – to be abstracted only in countries where HIV-2 diagnosis is recorded in the medical record and is considered in regimen selection.

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* prior to 12-month date
2. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - Initial ART regimen
   - Weight and age of child
   - This EWI allows for classification based on either clinical or pharmacy information. One of the following combinations of information is required:
     - 'date of last clinical consultation attended', 'last ART regimen prescribed' **and** 'number of days of ART prescribed at the last clinical consultation attended'; **or**
     - 'date of last ARV drug pick-up', 'ARV drugs picked-up at last ARV drug pick-up', **and** 'number of days of ARV drugs picked-up at the last drug pick-up'.

* Words or phrases shown *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

EWI 3b. Percentage of patients *initiating ART at the site whose initial ART regimen was changed during the first 12 months to a regimen that includes a different drug class (cross-sectional)** (*20–21*)

Suggested target: 0%

Definition of numerator and denominator:

- **Numerator:** number of patients *initiating ART at the site* whose initial ART regimen was changed to a regimen that includes a different drug class during the first 12 months after ART initiation (including *switches* for regimen failure and *substitutions* for toxicity).
- **Denominator:** number of patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 3b monitors any change to a regimen that includes a different drug class. This includes *switches* to *second-line ART* regimens (due to regimen failure), and *substitutions* of drugs in a new class (due to toxicity).
- EWI 3a and 3b are complementary and countries may choose to monitor both. 3a should be prioritized if only one of the two indicators can be collected.
- Countries can abstract data for these indicators from medical records (drugs prescribed) or pharmacy records (drugs dispensed). Both types of records should be used if possible.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (either as an ART prescription or an ARV drug pick-up);
- The ART regimen initially prescribed (or ARV drugs initially picked up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The date of the last clinical consultation attended on or before the '12-month date';
- The ART regimen prescribed at the last clinical consultation on or before the '12-month date';
- The date of the last ARV drug pick-up attended on or before the '12-month date';
- The ARV drugs picked up at the last pick-up on or before the '12-month date';

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - This EWI allows for classification based on either clinical or pharmacy information. One of the following combinations of information is required:
     - 'date of last clinical consultation attended' **and** 'last ART regimen prescribed'; **or**
     - 'date of last ARV drug pick-up' **and** 'ARV drugs picked-up at last ARV drug pick-up'.

* Words or phrases shown *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

4.4 EWI 4. On-time ARV drug pick-up

EWI 4a. Percentage of patients who picked up prescribed antiretroviral (ARV) drugs *on time (cross-sectional)** (*14, 23–29*)

Suggested target: ≥90%

Definition of numerator and denominator:

- **Numerator:** number of patients who have picked up all their prescribed ARV drugs *on time* for two consecutive drug pick-ups after a baseline pick-up.
- **Denominator:** number of patients who picked up ARV drugs on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.

Considerations:

- EWIs 4a and 4b are complementary, and countries may choose to monitor both.
- EWI 4a uses a sample of all patients (including those initiating ART and those who have been on ART for longer periods of time), and follows them for 2 drug pick-ups after a baseline pick-up.
- EWI 4b includes only those initiating ART and follows them for the first year.**

Data elements abstracted for each eligible patient:

- A patient identifier;
- The date of the first ARV drug pick-up ('baseline pick-up');
- The dates of the two consecutive ARV drug pick-ups after the 'baseline pick-up' ('pick-up 1' and 'pick-up 2');
- The ART regimen, including number of days, or pill number/volume and strength (mg) and pills/day or dose/day dispensed at 'baseline pick-up' and the subsequent ARV drug pick-up ('pick-up 1');
- The date of *transfer out* after 'baseline pick-up' (if applicable);
- The date of *death* after 'baseline pick-up' (if applicable);
- The date of ART *stop* after 'baseline pick-up' (that is, a recorded decision by the patient or physician that ARV should be *stopped*, if applicable).

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* between baseline pick-up date and baseline pick-up *run-out date*.
2. Patients who *died* between baseline pick-up date and baseline pick-up *run-out date*.
3. Patients who *stopped* ART, without a restart, between baseline pick-up date and baseline pick-up *run-out date*.
4. Patients for whom any of the following crucial information is missing.
    - Patient ID
    - Date of baseline ART pick-up
    - Number of days of ARVs picked up at baseline ART pick-up
    - Date of first ARV drug pick-up after baseline
    - Number of days of ARVs picked up at first ARV drug pick-up after baseline.

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

EWI 4b. Percentage of patients *initiating ART at the site who picked up all prescribed ARV drugs *on time* during their first 12 months of ART (cohort)** (*14, 23–29*)

Suggested target: ≥90%

Definition of numerator and denominator:

- **Numerator:** number of patients *initiating ART at the site* who picked up all their ARV drugs *on time* during the first year of ART, or until they were classified as *transferred out*, *dead*, or as having *stopped* ART.
- **Denominator:** number of patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWIs 4a and 4b are complementary, and countries may choose to monitor both.
- EWI 4a uses a sample of all patients (including those initiating ART and those who have been on ART for longer periods), and follows them for 2 drug pick-ups after a baseline pick-up.
- EWI 4b includes only those initiating ART and follows them for the first year.
- EWI 4b provides two measures of *on-time drug pick-up*. The first is a conservative measure that does not take into account 'left-over' pills (buffer stocks) remaining with the patient. The second calculation assumes that patients maintain and use buffer stocks of their ARV drugs.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (preferably initial ARV drug pick-up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The dates of each ARV drug pick-up attended on or before the '12-month date';
- The ART regimen, including number of days dispensed, or pill number/volume and strength (mg) and pills/day or dose/day dispensed, at each drug pick-up on or before the '12-month date';
- The date of *transfer out* on or before the '12-month date' (if applicable);
- The date of *death* on or before the '12-month date' (if applicable);
- The date of ART *stop*, without a restart, on or before the '12-month date' (if applicable).

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* between the date of first ARV drug pick-up and the first *run-out date*.
2. Patients who *died* between the date of first ARV drug pick-up and the first *run-out date*.
3. Patients who *stopped* ART, without a restart, between the date of first ARV drug pick-up and the first *run-out date*.
4. Patients for whom any of the following crucial information is missing.
    - Patient ID
    - *ART initiation date*
    - Dates of all drug pick-ups in the first 12 months
    - ART regimen dispensed at each drug pick-up
    - Number of days of ART picked up (for each ARV drug pick-up).

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

4.5 EWI 5. ART clinic appointment keeping

EWI 5a. Percentage of ART patients who attend clinical consultations *on time (cross-sectional)** (*28, 30–33*)

Suggested target: ≥80%

Definition of numerator and denominator:

- **Numerator:** number of patients who attended two consecutive scheduled or expected clinical consultations, after a baseline consultation, *on time*.
- **Denominator:** number of patients who attended a clinical consultation on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWIs 5a and 5b are complementary, and countries may choose to monitor both.
- EWI 5a uses a sample of all patients (including those initiating ART and those who have been on ART for longer periods of time), and follows them for two scheduled or expected clinical consultations after a baseline consultation.
- EWI 5b includes only patients initiating ART and follows them for the first year.
- EWI 5a and 5b can be monitored only in countries where scheduled appointments are recorded in advance, or fixed intervals are used for scheduling patient visits (e.g. every 28 days), so that 'expected' appointment dates can be recorded.
- Note that EWI 5a should not be collected at sites where no distinction can be made between attendance by the patient or a surrogate (treatment 'buddy', partner, relative, etc.)
- "On time" as it relates to appointment-keeping is defined as a patient attending a clinical consultation either on the "same day" or "within seven days" of the scheduled or expected consultation. Countries select one of these two definitions and apply it consistently at all sites.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The date of first clinical consultation attended ('baseline clinical consultation');
- The dates of the two consecutive clinical consultations scheduled or expected following the 'baseline clinical consultation';
- The dates of the two consecutive clinical consultations attended after the 'baseline clinical consultation' (i.e. 'clinical consultation 1' and 'clinical consultation 2');
- The date of *transfer out* between 'baseline clinical consultation' and 2nd scheduled or expected clinical consultation (if applicable);
- The date of *death* between 'baseline clinical consultation' and 2nd scheduled or expected clinical consultation (if applicable);

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* before the date of first scheduled or expected clinical consultation after baseline consultation.
2. Patients who *died* before the date of first scheduled or expected clinical consultation after baseline consultation.
3. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - Date of baseline clinical consultation
   - Dates of subsequent clinical consultations attended
   - Dates of scheduled/expected follow-up appointments for each consultation attended.

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

EWI 5b. Percentage of patients *initiating ART at the site who attended all scheduled or expected clinical consultations *on time* during the first 12 months of ART (cohort)** (*28, 30–33*)

Suggested target: ≥80%

Definition of numerator and denominator:

- **Numerator:** number of patients *initiating ART at the site* who attended all their scheduled or expected clinical consultations *on time* during their first 12 months of ART, or until they were classified as *transferred out*, *dead*, or as having *stopped* ART.
- **Denominator:** number of patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWIs 5a and 5b are complementary, and countries may choose to monitor both.
- EWI 5a uses a sample of all patients (including those initiating ART and those who have been on ART for longer periods of time), and follows them for two scheduled or expected clinic consultations after a baseline consultation.
- EWI 5b includes only those initiating ART and follows them for the first year.
- EWIs 5a and 5b should be monitored only in countries where scheduled appointments are recorded in advance, or fixed intervals are used for scheduling patient visits (e.g. every 28 days), so that 'expected' appointment dates can be recorded.
- Note that this EWI should not be collected at sites where no distinction can be made between attendance by the patient or a surrogate (treatment 'buddy', partner, relative, etc).
- "On time" as it relates to appointment-keeping is defined as a patient attending a clinical consultation either on the "same day" or "within seven days" of the scheduled or expected consultation. Countries select one of these two definitions and apply it consistently at all sites.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (preferably the ART prescription date);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The dates of all clinical consultations scheduled or expected after ART initiation, and on or before the '12-month date';
- The dates of all clinical consultations attended after ART initiation and on or before the '12-month date';
- The date of *transfer out* on or before the '12-month date' (if applicable);
- The date of *death* on or before the '12-month date' (if applicable);
- The date of ART *stop*, without a restart, on or before the '12-month date' (if applicable).

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* before the date of first scheduled or expected clinical consultation after ART initiation.
2. Patients who *died* before the date of first scheduled or expected clinical consultation after ART initiation.
3. Patients who *stopped* ART before the date of first scheduled or expected clinical consultation after ART initiation.
4. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - Dates of all clinical consultations attended in the first 12 months of ART
   - Dates of scheduled/expected follow-up appointments for each consultation attended.

(Note that patients who *transfer out*, *die* or *stop* ART after first scheduled or expected clinical consultation after ART initiation are classified based on consultations attended until that event.)

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

4.6 EWI 6. ARV drug supply continuity

The national HIVDR WG may choose to collect one or more of these indicators to assess drug supply continuity.

EWI 6a. Percentage of months in a designated year in which there were no ARV drug *stock-outs (cross-sectional)** (*34–36*)
Suggested target: 100%
Definition of numerator and denominator: • **Numerator:** number of months in the designated year in which there were no *stock-out* days of any ARV drug routinely used at the site. • **Denominator:** 12 months.
Considerations: • Countries may choose to monitor either EWI 6a or 6b. EWI 6b provides more detailed information on frequency and duration of *stock-out*, but may not be feasible at all sites. • Methods of abstracting data for EWI 6a should be developed in conjunction with staff implementing the ARV drug supply monitoring system at the site. • A separate evaluation is performed for each ARV drug routinely used at the site.
Data elements abstracted: • Months in which there was a *stock-out* of any ARV drug routinely used at the site.
Data analysis - exclusion factors: • For each ARV drug or fixed-dose combination (FDC), either the month(s) in which there was a *stock-out*, or confirmation that there was no *stock-out* during the year, must be recorded.

EWI 6b. Percentage of months in a designated year in which there were no ARV drug *stock-outs* (cross-sectional) (*34–36*)
Suggested target: 100%
Definition of numerator and denominator: • **Numerator:** number of months in the designated year in which there were no *stock-out* days of any ARV drug routinely used at the site. • **Denominator:** 12 months.
Considerations: • Countries may choose to monitor either EWI 6a or 6b. EWI 6b provides more detailed information on frequency and duration of *stock-out*, but may not be feasible at all sites. • Additional calculations can be made using data collected for EWI 6b, including total *stock-out* days in a specified period, longest period of *stock-out*, etc. • Methods of abstracting data for EWI 6b should be developed in conjunction with staff implementing the ARV drug supply monitoring system at the site. • A separate evaluation is performed for each ARV drug routinely used at the site.
Data elements abstracted: • Start date and end date of each *stock-out* of any ARV drug routinely used at the site.
Data analysis - exclusion factors: • For each ARV drug or fixed-dose combination (FDC), either the start date and end date of each *stock-out*, or confirmation that there was no *stock-out* during the year, must be recorded.

* Words or phrases shown *in italics* are defined in Appendix I.

EWI 6c1. Percentage of patients on ART whose regimen was *stopped, *switched*, *substituted*, or *incompletely dispensed* at the pharmacy due to ARV *stock-out* in a 12 month period (cross-sectional)** (*34–36*)

Suggested target: 0%

Definition of numerator and denominator:

- **Numerator:** number of patients whose regimen was *stopped*, *switched*, *substituted* or *incompletely dispensed* at the pharmacy due to *stock-out* during a 12-month period, or until they were classified as *transferred out*, *dead*, or as having *stopped* ART for other reasons.
- **Denominator:** number of patients on ART on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 6c1 and 6c2 may be used only in cases where reasons for ART *substitution*, *switch*, *stop* or *incompletely dispensed* ART regimens are recorded in a standard format, and if 'ARV drug supply shortage' or equivalent, is one of the standard reasons captured on patient records.
- EWI 6c1 is generally feasible only at sites with electronic records.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The '12-month date' (i.e. one year after the *sample start date*);
- The dates of ARV drug pick-up;
- The date(s) of ART *stop* due to *stock-out* (if applicable);
- The date of ART *switch* or *substitution* due to *stock-out* (if applicable);
- The date when the ART regimen was *incompletely dispensed* due to *stock-out* (if applicable).

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - Dates of ARV drug pick-up
   - Dates on which ART was *stopped*, *switched*, *substituted* or *incompletely dispensed* (if applicable), or confirmation that none of these events occurred, must be recorded.

* Words or phrases shown *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

EWI 6c2. Percentage of patients *initiating ART at the site whose regimen was *stopped*, *switched*, *substituted*, or *incompletely dispensed* at the pharmacy due to ARV *stock-out* during the first 12 months of ART (cohort)** (*34–36*)

Suggested target: 0%

Definition of numerator and denominator:

- **Numerator:** number of patients *initiating ART at the site* whose regimen was *stopped*, *switched*, *substituted*, or *incompletely dispensed* at the pharmacy due to *stock-out* during the first 12 months of ART, or until they were classified as *transferred out*, *dead*, or as having *stopped* ART for other reasons.
- **Denominator:** Number of patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 6c1 and 6c2 may be used only in cases where reasons for ART *substitution*, *switch*, *stop* or *incompletely dispensed* ART regimens are recorded in a standard format, and if 'ARV drug supply shortage' or equivalent, is one of the standard reasons captured on patient records.

Data elements abstracted for each eligible patient:

- A patient identifier;
- The *date of ART initiation* at the site (either as an ART prescription or an ARV drug pick-up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The date(s) of ART *stop* on or before the '12-month date' due to *stock-out* and the name(s) of ARV drug(s) *stopped* (if applicable);
- The date of ART *switch* or *substitution* on or before the '12-month date' due to *stock-out* and the name(s) of ARV drug(s) *switched* or *substituted* (if applicable);
- The date when the ART regimen was *incompletely dispensed* on or before the '12-month date' due to *stock-out* and the name(s) of the ARV drug(s) of the regimen that was *incompletely dispensed* (if applicable).

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - Dates on which ART was *stopped*, *switched*, *substituted* or *incompletely dispensed* (if applicable), or confirmation that none of these events occurred, must be recorded.

* Words or phrases shown *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

4.7 Optional early warning indicators

Two EWIs are considered optional because they are currently feasible in a small number of countries.

Optional EWI 7. Patient adherence to ART

EWI 7a. Percentage of patients *initiating ART at the site who demonstrate 100% adherence by pill count (cross-sectional)** (*19, 28, 37–38*)

Suggested target: ≥90%

Definition of numerator and denominator:

- **Numerator:** the number of patients who demonstrate that 100% of each of their ARV drugs has been taken as prescribed according to a pill count.
- **Denominator:** number of patients initiating ART whose adherence was assessed by pill count performed by a provider or pharmacist, on or before the '12-month date', or until they were classified as *transferred out, dead,* or as having *stopped* ART. Sampling continues of patients initiating ART on or after the *EWI sample start date* until the full sample size is reached.**

Considerations:

- EWIs 7a and 7b should only be monitored if physical pill counts (7a) or other standardized adherence measure (7b) are systematically performed by a provider or pharmacist, using the same methodology, for all patients who pick up drugs.
- Provider estimates and patient self-reports that are not based on pill counts or other standardized adherence measure should not be used for this indicator; these estimates do not provide useful data for analysis on a population-wide basis as they are not collected in a standardized format.

Data elements abstracted:

- A patient identifier;
- *Art initiation date*;
- The '12-month date' (i.e. One year after the *date of art initiation*);
- The last ARV pick-up or clinic appointment date when pill count was assessed (on or before the '12-month date');
- The art regimen assessed (list of ARV drugs or fixed-dose combinations)
- The percentage of pills taken for each of the ARV drugs or fixed-dose combinations (separate pill counts must be performed for each ARV or fixed-dose combination, unless a fixed-dose combination containing all ARVs is used)

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - Percentage of pills taken

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

EWI 7b. Percentage of patients *initiating ART at the site who demonstrate 100% adherence by standardized adherence measure (cross-sectional)** (*19, 28, 37–38*)

Suggested target: ≥90%

Definition of numerator and denominator:

- **Numerator:** the number of patients who demonstrate that 100% of their ART regimen has been taken as prescribed according to a standardized adherence measure.
- **Denominator:** number of patients initiating ART whose adherence was assessed by standardized adherence measure performed by a provider or pharmacist, on or before the '12-month date', or until they were classified as *transferred out, dead,* or as having *stopped* ART. Sampling continues of patients initiating ART on or after the *EWI sample start date* until the full sample size is reached.**

Considerations:

- EWIs 7a and 7b should only be monitored if physical pill counts (7a) or other standardized adherence measure (7b) are systematically performed by a provider or pharmacist, using the same methodology, for all patients who pick up drugs.
- Provider estimates and patient self-reports that are not based on pill counts or other standardized adherence measure should not be used for this indicator; these estimates do not provide useful data for analysis on a population-wide basis as they are not collected in a standardized format.

Data elements abstracted:

- A patient identifier;
- *ART initiation date*;
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The last ARV pick-up or clinic appointment date when adherence was assessed by standardized measure (on or before the '12-month date');
- The ART regimen assessed;
- The percentage of pills taken (based on complete regimen, not individual ARVs)

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - *ART initiation date*
   - Percentage of pills taken

* Words or phrases shown *in italics* are defined in Appendix I.
** Sampling is described in Section 7.1.

Optional EWI 8. Viral load suppression 12 months after ART initiation

EWI 8. Percentage of patients *initiating ART at the site whose viral load is <1000 copies/ml after 12 months of ART (cohort)** (*6–7, 39–41*)

Suggested target: ≥70%

Definition of numerator and denominator:

- **Numerator:** number of patients *initiating ART at the site* who are still taking ART at 12 months and who have a viral load of <1000 copies/ml.
- **Denominator:** number of patients *initiating ART at the site* on or after the designated *EWI sample start date*. Sampling continues until the full sample size is reached.**

Considerations:

- EWI 8 should be collected only in countries where viral loads are performed routinely for all ART patients at 12 months after ART initiation at >75% of sites.
- *Deaths* are included in the denominator because a *death* before 12 months may be the result of a treatment failure; these patients are assumed to have a non-suppressed viral load at 12 months.
- Patients who *switch* to a *second-line ART* regimen before 12 months are included in the denominator, allowing an assessment of whether the *second-line regimen* successfully suppressed virus replication.

Data elements abstracted for each eligible patient:

- a patient identifier;
- The *date of ART initiation* at the site (either as ART prescription or ARV drug pick-up);
- The ART regimen initially prescribed (or ARV drugs initially picked up);
- The '12-month date' (i.e. one year after the *date of ART initiation*);
- The date of the last clinical consultation attended on or before the '12-month date';
- The ART regimen prescribed at the last clinical consultation on or before the '12-month date', including number of days, or pill number/volume and strength (mg) and pills/day or dose/day dispensed;
- The date of the last ARV drug pick-up attended on or before the '12-month date';
- The ARV drugs picked up at the last pick-up on or before the '12-month date', including number of days, or pill number/volume and strength (mg) and pills/day or dose/day dispensed;
- The date of blood collection for HIV viral load test closest to the '12-month date' (and between 11-15 months after ART initiation);
- HIV viral load test result (copies/ml);
- The date of *death* on or before the '12-month date' (if applicable);
- The date of *transfer out* on or before the '12-month date' (if applicable).

Data analysis - exclusion factors: Information is abstracted on consecutive eligible patients, including those with missing data. However, the following patients are excluded from EWI analysis:

1. Patients who *transferred out* prior to 12 month date, unless a viral load was recorded at/after 11 months.
2. Patients for whom any of the following crucial information is missing.
   - Patient ID
   - Date of blood collection for viral load
   - Viral load test result

* Words or phrases shown *in italics* are defined in Appendix I.

** Sampling is described in Section 7.1.

5 SELECTING EARLY WARNING INDICATOR SITES

Once the HIVDR Working Group determines which EWIs will be monitored, data abstraction should be piloted in a subset of ART sites. The pilot sites do not have to be representative of all ART facilities in the country, but should include different sites using each of the country's important medical record-keeping systems, if possible. After piloting has been completed, the national HIVDR strategy should include a plan to move to a representative process. In order to be representative, HIVDR EWIs should be collected from either:

- all ART sites in the country; or
- representative sentinel sites.

If EWIs will not be monitored at all ART sites, the HIVDR WG should formally develop a method for selecting representative sites to ensure that monitoring data will be useful to country planning processes. Important selection factors generally include levels of available technology, patient population size, geographic representation, and a representative mix between rural, semi-urban, and urban sites. The selected sites should also represent other key factors that the national HIVDR WG regards as important (e.g. partner institutions involved at the sites; HIV exposure categories and sex distribution; ethnic and cultural groups; economic status of patients; and barriers to access such as cost or distance travelled to obtain care).

If children are treated primarily at paediatric ART sites, the national HIVDR WG should consider selecting one set of representative sites for adult patients and a separate set of representative sites for paediatric patients.

Records assessment. Records must be assessed at each site to ensure that data will be of adequate quality and completeness for EWI monitoring. Available records should be reviewed to determine the best source(s) of information for each EWI. Consistency and completeness of information across different record systems (including paper and electronic systems in both the pharmacy and clinic) also should be assessed for a sample of patients. Site selection should not be limited to those facilities with excellent records. However, the data in each site selected should be adequate to abstract the patient information required for EWI monitoring. Sites for which poor data quality or incomplete data would limit the value of EWI monitoring should be provided support to improve their systems, and be reconsidered for EWI monitoring in the future.

Site profile. Standardized information on each EWI monitoring site should be documented to support interpretation of EWI results and planning of public health actions. WHO recommends that a site profile be filled in for each EWI site at least annually. For the first year in which EWIs are monitored, a profile should be filled in for both the current year and the previous year. If a site characteristic has changed since the previous profile, the month in which the change took place should be noted. A recommended site profile template is provided in Appendix II.

6 PREPARING AN HIVDR EARLY WARNING INDICATOR MONITORING PLAN

Each national HIVDR WG should develop an EWI monitoring plan that includes the following elements.

1. The strategy used for selecting representative sites (or pilot sites for the pilot phase).
2. A list of the sites where EWI monitoring will be initially performed, the areas of the country in which the sites are located, relevant demographic information on the patient populations served, and the percentage of patients receiving ART in the country who are treated at these sites. For each site the plan should specify whether the site is managed by the national ART programme, a partner, or a combination of both. The partner(s) should be listed.
3. A brief description of the electronic or paper medical records, registers and pharmacy record systems that will be used at each site for EWI data abstraction. There is no need to describe forms or modules that will not be used for EWI monitoring.
4. A list of the EWIs that will be monitored and the corresponding national targets.
5. For each site, the sample sizes required for each EWI, based on the number of patients (a) initiating or (b) on ART at the site in the year for which data will be abstracted (see Section 7.1).
6. The EWI sample start date, that is the date of past clinic events (either 'initiated ART' or 'on ART') used as the beginning of patient sampling (see Section 7.1.1).
7. For each EWI, the field(s) or variable(s) in each medical record system that will be used for the denominator, and the method used to obtain the information.
8. For each EWI, the field(s) or variable(s) in each medical record system that will be used for the numerator, and the method for abstracting the information.

For sites with electronic record systems, include a copy of the file structure or data entry screens for electronic medical records, registers and pharmacy systems as an appendix to the plan, and circle the relevant fields for the numerators and denominators of each EWI.

For sites with paper-based systems, include a copy of the relevant paper forms as an appendix to the plan and mark the relevant fields from which the numerator and denominator will be abstracted.

7 OPERATIONAL ISSUES IN HIVDR EARLY WARNING INDICATOR MONITORING

This section briefly describes the basic operational elements for EWI monitoring. These elements are described in detail in the companion guidance: *WHO HIV drug resistance early warning indicators: data abstraction manual*, and *Monitoring WHO HIV drug resistance early warning indicators: planning and analysis manual*, which will be available in 2010 on the WHO HIVDR website: http://www.who.int/hiv/drugresistance.

7.1 Sampling plan for HIVDR early warning indicator monitoring

The sampling strategy is based on calculating a minimum sample size for each indicator at each site, based on the number of eligible patients for each EWI. There are two types of 'eligible patients' -- those that *initiated ART* for the first time, and those that *were on ART* (which includes both patients initiating ART and those on ART). Table 2 presents the definition of eligible patients, by EWI.

Table 2 Definitions of 'eligible patients'

Early warning indicator	Eligible patients
1 and 1-P 2 3a and 3a-P 3b 4b 5b 6c2 7a and 7b 8	Patients **initiating** ART
4a 5a 6c1	Patients **on** ART *(includes patients initiating ART, continuing ART and transferring in on ART)*

- For EWIs 1, 1-P, 2, 3a, 3a-P, 3b, 4b, 5b, 6c2, 7a, 7b and 8, the number of eligible patients at each site is the number of patients who initiated ART during the 12-month period to be monitored. That is, if the EWI sample start date is in 2008, the sample size is based on the number of patients who initiated ART at the site in 2008.
- For EWIs 4a, 5a and 6c1, the number of eligible patients at each site is the number of patients on ART during the 12-month period to be monitored, regardless of whether they initiated ART in that year or in a prior year. The simplest method to arrive at this number is to use the number of patients on ART at the site at the midpoint of the year. An alternative method is to take the

number on ART on 1 January of the selected year, add this number to the number on ART on 31 December of the selected year, and divide by two. This simple calculation will give you the mean number of patients on ART during the year.

Using the annual number of eligible patients (Table 2), the sample size can be calculated using Table 3.

Table 3 Sample size by annual number of eligible patients

Annual number of 'eligible patients' at the site *Eligible patients for each EWI defined in Table 2*	**Number to be sampled at the site (sample size)**
1–75	All
76–110	75
111–199	100
200–250	110
251–299	120
300–350	130
351–400	135
401–450	140
451–550	145
551–700	155
701–850	160
851–1600	175
1601–2150	180
2151–4340	200
4341–5670	210
5671–10000	215
>10000	Consult WHO

Note that separate sample size calculations must be made for each group of eligible patients (those *initiating ART* and those *on ART*) at the site. The sample size for EWIs based on *patients initiating ART* will be lower than those for EWIs based on *patients on ART*.

The sample sizes in Table 3 are the **minimum** sample sizes required to achieve a 95% confidence interval of ±7%. If greater numbers can be abstracted, a more precise estimate will be obtained. Methodology for the sample size calculation is described in Appendix III.

- **EWIs 6a and 6b.** The denominator is 12 months and the sampling table is not applicable.
- **Paediatric patients.** Sample sizes should be calculated separately for adult and paediatric patients at sites where both adults and paediatrics receive ART.
- **Electronic medical records.** For countries with electronic medical records from which data may be directly downloaded and calculations made based on a computer program, WHO recommends monitoring each EWI based on all eligible patients for the calendar year at each site.

Normally EWI should be monitored annually. However, countries with adequate resources may choose to monitor EWI more frequently, for example by month or quarter, provided that the sample size used for each time period does not fall below the minimum required sample size (Table 3).

Countries may choose to integrate EWI monitoring into other routine programme monitoring and evaluation activities, which have random sampling strategies that differ from the sampling methodology presented by the WHO. In such cases, the country should consult the regional HIVDR focal point and the WHO HIVDR team at Headquarters (Geneva) to discuss options and feasibility.

WHO guidance on sampling was modified in November 2009

WHO revised its guidance on sampling in EWI monitoring in November 2009 to include the use of a minimum sample size for each indicator.

- *Under previous sampling guidance, countries selected EWI denominator periods rather than absolute number of patients (sample size).*
- *The new sampling guidance significantly decreases the burden of data abstraction and supports the calculation of narrower confidence intervals.*
- *The WHO discourages continued use of the former sampling strategy.*

7.1.1 Starting month and time periods for data abstraction

The purpose of EWI monitoring is to provide evidence to improve facility, district and national programmes. Monitoring should therefore be scheduled to best fit into district or national programme planning cycles.

There are two dates that the HIVDR Working Group must establish.

1. The "EWI sample start date", that is, the date designated as the start of patient sampling. Patients attending a clinical consultation to initiate ART or to evaluate their progress on ART, or patients picking up their ART at the pharmacy, on or after this date make up the site sample. Data are abstracted on consecutive patients until the required sample size is achieved. It is important that the same sample start date be used for all participating sites in a country. However, the abstraction eligibility date may be different for different EWI.

2. The date on which data abstraction will begin, that is, the date on which data abstractors will go to the sites to physically abstract the data.

These two dates are related. The EWI sample start date must take into account (a) the minimum follow-up period, which is 12–15 months, and (b) the rate of patient accrual in the sample. The rate of patient accrual will be slower for smaller sites where required sample sizes are a relatively large proportion of the patient population.

- For EWIs 1, 1-P, 2, 3a, 3a-P, 3b, 4b, 5b, 6c2 and optional EWIs 7a, 7b and 8, data are abstracted on consecutive patients *initiating ART* on or after a specific day of the selected year, until the required sample size is achieved.
- For EWIs 4a, 5a and 6c1, data are abstracted on consecutive patients *on ART* on or after a specific day of the selected year (usually 1 January), until the required sample size is achieved.
- Sample sizes are site-specific and may vary depending on whether the EWI is based on patients *initiating ART* or patients *on ART*. Abstraction continues until the sample size for the EWI at the site is achieved, regardless of the number of months of data it takes to reach it.
- For EWIs 6a and 6b, data should be abstracted on stock-outs over a one-year period for each ARV drug in routine use during the full 12 months. Generally, the abstraction will be done for the 12 months of a calendar year.

7.2 Data abstraction from ART sites

Paper-based medical records. If paper-based records are in place, abstractors trained under the national HIVDR strategy should abstract the data at each site. Generally, data will be abstracted retrospectively, once per year. If possible, countries should combine the EWI data abstraction with other indicator and patient monitoring programmes taking place in the country. EWI monitoring may also be used as, or combined with, a quality assurance assessment of record-keeping at ART sites.

Electronic medical records. If electronic records are in place, a programme to abstract data for EWI monitoring should be guided by experts from the national HIVDR WG. Generally, it is not feasible to obtain EWI information from summary reports already produced by those systems; feasibility may be limited by varying definitions of an indicator (for example, different timeframes for defining 'lost to follow-up'), or varying methods of applying a definition. If electronic medical record systems are used to produce EWIs, validation procedures that use abstraction from paper records should be set up.

Data abstraction procedures are described in the companion guidance: *WHO HIV drug resistance early warning indicators: Data Abstraction Manual*, which will be available in 2010 on the WHO HIVDR website: http://www.who.int/hiv/drugresistance. WHO tools for data abstraction and analysis also are available through WHO.

7.3 Data quality assessment

Assessment of data quality should be implemented throughout the EWI monitoring process. During the monitoring process, data quality assessment provides crucial information for ensuring that the

right data are collected in appropriate ways. After the data are analysed, data quality assessment gives programme managers a measure of the confidence that should be placed in the data produced, and how fit the data are for use in operations, planning and decision making. These assessments are particularly important for countries or facilities collecting EWI information for the first time.

Three elements of data quality should be considered in the assessments: data reliability, data completeness and data consistency.

Data reliability: This element assesses the reliability of data abstraction for each indicator. Assessing the quality of abstraction early in the monitoring process will identify problems that can be addressed through additional support or training for abstractors.

Data completeness: While some missing data is anticipated, a large percentage of missing information in patient records at any facility, or for any EWI, presents challenges for achieving the required sample size and for interpreting the results. The site selection process should include an assessment of the completeness of the clinic record systems for information relevant to EWI monitoring (see Section 5). Monitoring completeness of data should also take place during the data abstraction period, and as part of data assessment prior to analysing and interpreting the results.

Data consistency: This refers to consistency of patient information across different record systems within the same facility. Clinic and pharmacy records are the primary sources of information used for EWI monitoring. Some facilities use both paper based and electronic systems for clinic and pharmacy records. The records assessment process includes evaluating the consistency of information across these information sources (see Section 5); this is a crucial step in assessing which sources provide the most accurate information, and in ensuring that correct data are used for monitoring EWI.

While data quality assessments are designed to address the data used for EWI monitoring in particular, they also identify strengths and weaknesses of existing record systems in the participating clinics. Incompleteness and inconsistency of data generally indicate more systemic problems in record keeping that should be addressed. Thus the results of data quality assessments can help inform changes that will improve patient monitoring systems and clinic practice.

8 PREPARING A COUNTRY REPORT ON HIV DRUG RESISTANCE EARLY WARNING INDICATORS

As part of an annual national report on the HIV/AIDS epidemic, data on the HIVDR EWIs should be monitored, analysed and published. Results should be used to strengthen the national response to the epidemic. The report for each ART site should be used to optimize its performance. An ART site that does not meet one or more EWI targets may require increased support in the form of additional resources, training or staff.

The introduction to the annual EWI report should include information on the ART sites from which the indicators have been collected, and information about data collection for each EWI, including how numerators and denominators were calculated. Table 4 provides an example of a summary table for EWI results.

Results should be evaluated both to identify sites that fail to meet targets for several indicators (e.g. Site 9 in Table 4), and indicators whose target is not met at many sites (e.g. the on-time drug pick-up indicator in Table 4). More information may be required to determine the type of additional support needed at specific sites or the programme changes required at many sites.

Results of EWI monitoring may be used to support evidence-based recommendations for in-depth surveys, programme changes, or requests for additional support.

Table 4 Example of an early warning indicator summary table

Site	Percentage of months with no ARV drug stock-outs (2009) Target: 100%	Percentage of appropriate initial ART regimen prescriptions Target: 100%	Percentage of patients initiating first-line ART lost to follow-up 12 months later Target: ≤20%	Percentage of patients on ART attending all clinical consultations on time Target: ≥80%	Percentage of patients on ART picking up all ARV drugs on time Target: ≥90%
1	12/12 (100%)	144/145 (99%)	2/145 (1%)	140/ 160 (88%)	145/ 160 (91%)
2	10/12 (84%)	122/130 (94%)	6/130 (5%)	100/145 (69%)	131/145 (90%)
3	10/12 (84%)	75/75 (100%)	14/75 (19%)	68/ 100 (68%)	79/ 100 (79%)
4	12/12 (100%)	100/100 (100%)	9/100 (9%)	88/ 120 (73%)	99/ 120 (83%)
5	12/12 (100%)	179/180 (99%)	6/180 (3%)	166/ 200 (83%)	166/ 200 (83%)
6	10/12 (84%)	145/145 (100%)	9/145 (6%)	141/ 160 (88%)	150/ 160 (94%)
7	12/12 (100%)	130/130 (100%)	19/130 (15%)	111/ 145 (77%)	121/ 145 (83%)
8	12/12 (100%)	144/145 (99%)	26/145 (18%)	118/175 (67%)	138/175 (79%)
9	11/12 (92%)	101/110 (92%)	25/110 (23%)	88/ 130 (68%)	83/ 130 (64%)
10	12/12 (100%)	75/75 (100%)	4/75 (5%)	59/100 (59%)	81/100 (81%)
…	…	…	…	…	…
152	12/12 (100%)	40/40 (100%)	3/40 (8%)	34/ 110 (31%)	47/ 110 (43%)
153	12/12 (100%)	158/160 (99%)	33/160 (21%)	144/ 180 (80%)	171/ 180 (95%)
154	12/12 (100%)	110/110 (100%)	14/110 (13%)	100/130 (77%)	114/130 (88%)

It is also recommended that a further summary table be created that shows the target for each indicator and the percentage of sites that meet it (Table 5).

Table 5 Example of a summary table of targets and outcomes

Early warning indicator	Indicator target	Number of sites that meet the indicator target (% of sites that meet target) n=154 ART sites
Percentage of months with no ARV drug stock-outs	100%	149/154 (97%)
Percentage of appropriate initial ART regimen prescriptions	100%	146/154 (95%)
Percentage of patients initiating first-line ART, lost to follow-up at 12 months of ART	≤20%	151/154 (98%)
Percentage of patients on ART keeping all clinical appointments on time	≥80%	145/154 (94%)
Percentage of patients on ART picking up all ART drugs on time	≥90%	95/154 (62%)

APPENDIX I GLOSSARY OF SELECTED EARLY WARNING INDICATOR TERMS

The following definitions from Chapter 4 (description of indicators) are presented in alphabetical order.

Term	Definition for purposes of EWI monitoring
APPROPRIATE FIRST-LINE ART REGIMEN	An ART regimen that meets one or both of the following definitions: • standard regimen listed in national ART guidelines and used according to those guidelines; • regimen recommended in the WHO treatment guidelines (*2*). In each country, the national HIVDR WG defines 'appropriate regimens' according to national and international norms.
DATE OF ART INITIATION	The date of first drug pick-up (for countries using pharmacy records for data abstraction) or date of first ARV prescription (for countries using medical records for data abstraction).
DEATH	A report of death in the patient's medical record, for which a date (at least month/year) is recorded. This may be based on a formal death certification or on a report from a person/caregiver who knew the patient.
EWI SAMPLE START DATE	The date designated as the start of the sampling. Patients attending a clinical consultation to be initiated on ART or for their progress on ART to be evaluated, or patients picking up their ART at the pharmacy, on or after this date make up the site sample. • This is NOT the date that abstraction starts. • The sample start date is fixed by the HIVDR Working Group.
FIRST-LINE ART	The initial ARV regimen prescribed for a patient initiating ART.
INCOMPLETELY DISPENSED	An ARV regimen dispensed at the pharmacy that falls under either of the following conditions: • fewer ARV drugs were dispensed than were prescribed (e.g. only two out of three ARV drugs were dispensed); or • all the prescribed ARV drugs were dispensed, but the quantity of one or more drugs was less than the number of doses prescribed, or insufficient to cover the expected pick-up interval.
INITIATING ART AT THE SITE	A patient who has not previously received ART at the site, and who has not transferred in on ART. This definition includes: treatment naïve patients; patients who have received ARV prophylaxis for PMTCT; and non-naïve patients who received ART from other sources and are not recorded as transferred in.
LOST TO FOLLOW-UP (LTFU) AT 12 MONTHS	A patient who missed a scheduled clinical consultation or ARV drug pick-up in the first 12 months of therapy and who did not return to the ART site or pharmacy within (that is, ≤) 90 days after the last missed clinical consultation or missed drug pick-up, and for whom there is no information to classify the patient as "dead", "stop", or "transfer out". Patients who return during the 12-month period are not classified as LTFU. • For patients who cannot be classified as LTFU (using the above definition) at 12 months, the follow up period must be extended until the patient is seen at the site **or** to the 15 month date, whichever is earliest. • Patients whose transfer, ART or death status is unknown and who meet the 'LTFU' definition are considered 'LTFU' despite that some may have died or be attending another clinic.

Term	Definition for purposes of EWI monitoring
ON TIME CLINIC APPOINTMENT KEEPING	"On time" as it relates to appointment-keeping is defined as a patient attending a clinical consultation either on the "same day" or "within seven days" of the scheduled or expected consultation. Countries select one of these two definitions and apply it consistently at all sites. • Appointment-keeping refers to appointments with a clinical provider. Appointments for drug pick-ups and laboratory tests without an accompanying clinical consultation should not be included. • A proxy/caregiver cannot attend an ART clinical consultation on behalf of a patient. If a proxy attends the appointment, this is classified as a missed appointment. • The word 'expected' pertains to ART sites where there is no formal appointment system.
ON TIME PICK-UP OF ARV DRUGS	A patient pick-up of ARV drugs on or before the date the previously dispensed drugs would have run out if they had been taken according to schedule. For EWI monitoring purposes, an on-time ARV drug pick-up made by a proxy/caregiver counts as an on-time ARV drug pick-up.
RUN-OUT DATE	The date on which ARV drugs dispensed at the last ARV drug pick-up would have been finished if taken as prescribed.
SECOND-LINE ART	A new regimen used in sequence immediately after first-line therapy, and which includes a change in at least one class of drug.
STOCK-OUT	Any occurrence of zero stock of a routinely-used ARV drug at the site at which the patient routinely picks up ARVs. • Although some countries define it differently, for the purpose of EWI monitoring, stock-out is defined at the site level, because any stock-out at that level creates a barrier to patient access to medications and increases the chance of treatment interruption. We note that some countries define stock-out based on stocks available at a higher level or in a wider geographic area.
STOP	A complete cessation of any ARV drug, during the first 12 months of ART, in a patient who has not restarted ART. Stops can be the result of a patient decision or a decision by the clinical team. • A patient who has stopped ART for a period of time during the first 12 months after ART initiation, but restarted first-line ART before the 12 month date, should not be classified as "stop".
SUBSTITUTION	A change in an ART regimen after toxicity. • For the purpose of EWI monitoring, substitution involves drugs within the same drug class as used in the original regimen.
SWITCH	A change in an ART regimen after regimen failure. • For the purpose of EWI monitoring, 'switch' involves a change to a different drug class than was used in the original regimen.
TRANSFER OUT	A patient whose ART is being provided at another identified ART delivery site, and who was still on first-line ART at the time of transfer. If the individual is known to be receiving ART at another site and this transfer has been recorded in the medical records, the participant meets the definition for transfer out.

APPENDIX II ANTIRETROVIRAL TREATMENT SITE PROFILE

1. Site identification

Site Name:	
Profile Date (day/month/year):	

2. Site key data

District:	
City or Area:	
Clinic Ownership (public, private, NGO, etc.)	
Number of years this site has provided ART	

3.a Number of HIV care patients at clinic

Description	Patient count
Total number of HIV patients served by clinic	
Average number of patients seen in clinic per day	
Number of HIV+ patients currently on ART	
Number of patients who initiated an ART regimen in the previous year	
Number (or approximation) of patients who plan to initiate an ART regimen in the next 12 months	

3.b Description of the method used for determining eligibility for ART:

4.a Staff

Average number of HIV care providers (nurses, physicians, clinical officers) working during the clinic days:	
Total number of ARV dispensing staff (pharmacists and other staff if applicable):	
Total number of staff prescribing ARV:	

4.b Education/training level for HIV care providers

Qualifications for:	
Routine HIV care providers:	
Staff initiating ART:	
Number of staff trained/refreshed in ART patient management in the last 12 months	
Number of staff trained/refreshed in ART patient records/M&E in the last 12 months	

4.c Roles of staff

Number of each staff category carrying out each role:

	Nurse	**Clinical Officer**	**Physician**	**Pharmacist**	**Expert patient**	**Other**
Initiate ART						
Dispense ARVs						
Prescribe ART						
Adherence Counselling						
Routine HIV Care						
Other (specify)						
Other (specify)						
Other (specify)						

4.d Supervision to the ART clinic

Date of last supervision to the site	
Designation of supervisor	
Frequency of supervisory visits to the site (monthly/quarterly/biannually)	
Is feedback (verbal or written) provided by the supervisors after a visit?	

5.a Drug regimens

List of first- and second-line ARV drugs used	
First-line ARV drugs:	
Second-line ARV drugs:	

5.b ARV dispensing locations

ARV dispensing locations:	

6 Lost to follow-up procedure

Detailed description of the process in place at the clinic to handle those participants who miss an appointment before classifying them as 'lost to follow-up':

7 Cost incurred by patient at the ART clinic

Service	Cost incurred by the patient (currency)
Registration at the clinic	
Clinic appointment	
First-line ARV drugs per month	
Second-line ARV drugs per month	
Pre-therapy laboratory investigation (except CD4 count testing)	
CD4 count testing	
Viral load testing	
HIV drug resistance testing	
Pharmacy dispensing fee	

8 Transport and waiting times

Note: The information for questions in Section 8 will be subjective; it may be helpful to ask three or more clinic staff to arrive at consensus, including the receptionist or other appropriate clinic staff.

8.a Transport

Most common mode of transport (please select one):	Car	☐	Bicycle	☐
	Bus	☐	Walking	☐
	Taxi	☐	Other	☐

8.b Distance travelled (kilometres)

	Distance (km)
The distance to the nearest location served by this site	
The distance to the furthest location served by this site	

8.c Waiting time (minutes)

	Waiting time (minutes)
The shortest amount of time patients wait upon arrival prior to being seen at the clinic	
The longest amount of time patients wait upon arrival prior to being seen at the clinic	
The average amount of time patients wait upon arrival prior to being seen at the clinic	
The shortest amount of time patients wait at the pharmacy to pick up their ARV drugs	
The longest amount of time patients wait at the pharmacy to pick up their ARV drugs	
The average amount of time patients wait at the pharmacy to pick up their ARV drugs	

9 Opening hours

9.a ART clinic opening hours

Time period	Opening time (HH:MM)	Closing time (HH:MM)	Number of hours open
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Weekdays*			
Weekends*			
Every day*			
Unknown			
Other			

* use these rows if the opening hours are the same for every week day or for every weekend day.

ART clinic: total hours open per week:	

9.b ART pharmacy opening hours

Time period	Opening time (HH:MM)	Closing time (HH:MM)	Number of hours open
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Weekdays*			
Weekends*			
Every day*			
Unknown			
Other			

* use these rows if the opening hours are the same for every week day or for every weekend day.

ART pharmacy: total hours open per week:	

APPENDIX III SAMPLE SIZE CALCULATIONS FOR EARLY WARNING INDICATOR MONITORING

The formula used to calculate the sample size for monitoring WHO HIVDR EWI is in two parts. The first equation calculates a sample size for large populations. The second equation applies a finite population correction factor. This formula produces samples that will allow a 95% confidence interval of ±7% if the true proportion of patients meeting the target for the indicator is 50%.

Equation 1 (large population sample size):

$n_0 = Z^2 * p * (1-p) / e^2$

Where:

Z = 1.96

p = 0.5 (that is, 50% is assumed as the "true prevalence" of the proportion of patients meeting the target, because this gives the most conservative estimate of the sample size required)

e = precision = 0.07 (based on the confidence interval of ±7%)

Equation 2 (finite population correction factor):

$n = n_0 / (1 + ((n_0-1)/N))$

Where:

N = population size of the eligible individuals at the site

APPENDIX IV DATA ABSTRACTION AND ANALYSIS TOOLS FOR EARLY WARNING INDICATOR MONITORING

A set of data abstraction and analysis tools for EWI monitoring is available through WHO. These tools are designed to be used during the data abstraction phase at the site, as well as during the subsequent analysis performed centrally by national HIVDR WG staff.

EWI data abstraction and analysis tools are Excel-based. They can be used as spreadsheet files (electronic tools) if computers are available for EWI monitoring and data abstractors are trained to transfer information from medical and pharmacy records directly into a database. The tools can also be printed out as paper-based forms for manual data recording.

Each WHO electronic tool has a built-in system of functions that automatically calculates the specific EWIs once complete data are entered. If data are abstracted onto paper forms at the sites, they can later be entered in the electronic tool to perform analyses.

Tools are currently available for the following indicators: 1, 2, 3a, 4a, 4b, 5a, 5b, 6a and 6b.

Data abstraction procedures are described in the companion document *WHO HIV drug resistance early warning indicators: data abstraction manual*, which will be available in 2010, also on the WHO HIVDR website: http://www.who.int/hiv/drugresistance.

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