REPUBLIC OF RWANDA

MINISTRY OF HEALTH

EARLY WARNING INDICATORS FOR THE PREVENTION OF HIV DRUG RESISTANCE IN RWANDA IN 2007

SURVEY REPORT

December 2010

TRAC **Plus**

Center for Treatment and Research *on AIDS, Malaria, Tuberculosis and Other Epidemics*

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ACKNOWLEDGMENTS

Before presenting the results of this survey, we wish to extend our sincere gratitude and thanks to a number of people and institutions without which the present survey would not have been possible.
Our heartfelt thanks go to the WHO for activity funding and their technical advice. The national indicators monitoring could not succeed without the enthusiasm and dedication of all the participating sentinel site teams.
Our gratitude goes to the site participants from all Provinces of Rwanda who kindly facilitated data abstraction. The results of the present surveillance will enable providers to improve to strengthen health systems and improve ART programme quality. Successful implementation of an HIV drug resistance prevention and assessment strategy will provide health facilities with important information to optimize ART programmes, minimize the emergence of preventable HIV drug resistance and its transmission, and ensure the long term efficacy and durability of ART. Our gratitude also goes to all central administrative authorities who granted the authorization for carrying out field surveys. We wish to express our sincere thanks to data collectors for their individual or collective untiring effort and contribution to make the present study a success.

Dr Sabin NSANZIMANA
Acting Director of HAS unit

Contents

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Clinic
ART	Antiretroviral Treatment
CTP	Care and Treatment Project
DH	District Hospital
DR	Drug Resistance
DU	Drew University
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EPP	Estimation and Projection Package
EWI	Early Warning Indicators
FHI	Family Health International
GF	Global Funds
HC	Health Center
HIV	Human Immunodeficiency Virus
ICAP	International Center for AIDS Care and Treatment Programs
MOH	Ministry of Health
NRL	National Reference Laboratory
PIH	Partners in Health
PMTCT	Prevention of Mother to Child Transmission
STI	Sexual Transmitted Infections
TRAC Plus	**C**enter for **T**reatment and **R**esearch on **A**IDS, **M**alaria, **T**uberculosis and **O**ther **E**pidemics
TWG	Technical Working Group
VCT	Voluntary Counseling and Treatment
WHO	World Health Organization

EXECUTIVE SUMMARY

Despite the overall decrease and stabilization of HIV prevalence in the Rwandan population, there will continue to be increasing demand for ART, based on disease progression and new infections. The number of adult patients on ART increased from 8,815 in 2004 to 70,047 in 2009. [TRAC *Plus*, 2008] In this context, it is therefore necessary to have evidence-based measures to control HIV drug resistance in Rwanda and to avoid the emergence of drug resistance to the current ART regimens. As such, WHO has recommended the annual monitoring of 8 Early Warning Indicators (EWI) of HIV Drug Resistance (HIVDR) which are designed to provide evidence to guide actions to improve patient, facility and systemic factors that impact HIVDR emergence. The HIVDR EWI are: (1) ART prescribing practices, (2) Patients lost to follow-up 12 months after ART initiation, (3) Patients on appropriate first-line ART at 12 months, (4) On-time ARV drug pick-up, (5) ART clinic appointment keeping, (6) ARV drug supply continuity, (7) Patient adherence to ART and (8) Viral load suppression 12 months after ART initiation. The designated year was 2007.

The HIVDR EWI was abstracted in 13 Health Centers (HC), 13 District Hospital (DH) selected in 4 provinces and Kigali city and 1 Referral Hospital (RH). The RH was classified only for the EWI 1 because data were not recorded in the patient file.

- The first **HIVDR EWI**, about drug prescription at the initiation of ART was excellent in all health facilities. A proportion of 92.6% of sites met the WHO target which is 100%. Two health facilities initiated ART with the second line (containing Kaletra) with patients exposed to Nevirapine in the PMTCT program.
- The **HIVDR EWI 2, w**hich was to track patient loss to follow up, 9/26 (33.3%) of health facilities had 0% of patients loss to follow up at 12 months. Two sites of all 26 (7.7%) did not reach the WHO target.
- **HIVDR EWI 3a** regarding percentage of patients initiating ART at the site who are taking an appropriate first-line ART regimen 12 months later; Only one Health facility (of all 26 health facilities), switched the first-line regimen to the second-line regimen for one patient.
- **HIVDR EWI 4b** which evaluates the percentage of patients picking up prescribed ART drugs on time during their first 12 months of ART: for this indicator, only one site reached the recommended WHO target.
- **HIVDR EWI 6** which calculates the percentage of months in a designated year in which there were no ARV drug stock-outs: three health facilities out of 26 (11.1%) were not classified because they had no pharmacy files. For 24 classified health facilities, 21 (87.5%) had not experienced ARV stock-outs.

OVERVIEW

The HIV epidemic has rapidly spread across the world especially in developing countries; 67% of HIV-infected patients live in Sub-Saharan Africa [1]. Supported by various partners, the governments of these countries are scaling up antiretroviral treatment (ART) programs to face this epidemic. This rapid scale up of ART may be associated with an increase in HIV drug resistance (HIVDR) in the population if appropriate surveillance and prevention measures are not taken. Some HIV drug resistant strains will arise inevitably in patients on treatment despite good 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.

To respond to the problem of HIVDR and to attempt to minimize its occurrence, WHO has established several strategies for surveillance and monitoring of HIVDR. Among the activities proposed is the surveillance of HIV DR "Early Warning Indicators" (HIVDR EWI). Data abstraction of EWI of HIVDR was performed in ART sites country wide according to WHO guideline documents and included a phased implementation of EWI national surveillance activities. The data collection emphasized patient adherence to ART and those factors that can influence it. For the first implementation phase we have chosen 27 sites located in all 5 provinces of Rwanda, including rural and urban areas where data collection was performed using routinely available HIV program data at the site level. These results would help national HIV care and treatment decision makers and stakeholders to make evidence-based decisions and to identify appropriate program priorities in order to limit the expansion of HIV drug resistance in Rwanda.

Investigators

Investigators		
Names	**Responsibilities**	**Institutions**
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INTRODUCTION

3.1. Global expansion of ART

The human immunodeficiency virus type 1 (HIV-1) epidemic has reached pandemic proportions. The disease continues to affect humans living in all geographic areas, and sub-Saharan Africa is the most affected region with 1.9 million newly infected people in 2007, bringing to 22 million the number of people living with HIV. Two thirds (67%) of the global total of 32.9 million people with HIV live in this region, and three quarters (75%) of all AIDS deaths in 2007 occurred there [1]. Governments in the developing world have begun national roll-out and scale-up programs for the delivery of antiretroviral therapy (ART). Nevertheless, HIV drug resistance arises to some extent (even if all treatment conditions are fulfilled) because HIV is error prone during its replication, leading to the rapid development of potentially mutant viruses that are ready to be selected when drug levels fall below their effective concentrations.

In resource-limited countries the emergence of HIV drug resistance (HIVDR) may be increased by insufficient health care infrastructure and inadequately trained medical personnel, both caused primarily by lack of funds. Unless an effort is undertaken to put in place the necessary infrastructure, treatment programs may fail as a consequence of widespread HIVDR, thus greatly limiting future therapy options for patients. HIVDR is likely to be the single most important factor for determining the long term success of treatment programs. In order to enable the development of the appropriate strategies, including changing treatment regimens, it is vitally important to increase knowledge about HIVDR and its patterns as they emerge. However, few countries in the developing world have either the technical expertise or the financial resources to undertake the required monitoring and surveillance programs that would provide this essential information [2].

In recent years the rapid scale up of ART for HIV infection in resource limited countries has been identified as an international healthcare 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 in order to limit the emergence of HIV drug resistant strains.[4]

[1] **HIV DRUG RESISTANCE EARLY WARNING INDICATORS** World Health Organization indicators to monitor HIV drug resistance prevention at antiretroviral treatment sites April 2010 Update

3.2. Country background

In Rwanda, where the first cases of AIDS were confirmed in 1983 [4,5], the numbers of confirmed HIV-infected patients have increased dramatically, especially in subsequent years. By 2007, it was estimated that the number of HIV-infected persons was between 135,000 and 172,000, the number of new HIV infections was estimated at about 9,000 per year, and the adult HIV prevalence was about 2.8%. (EPP-SPECTRUM, Rwanda 2009). As in most countries of Africa, heterosexual intercourse is still the most common mode of transmission of HIV in Rwanda.

The Government of Rwanda (GoR) is responding forcefully to the HIV/AIDS epidemic. HIV testing is now available in all 5 provinces in the country in more than 300 voluntary counselling and testing (VCT) sites, and results are routinely reported to MoH. HIV sentinel surveillance is routinely done every two years in 30 sentinel antenatal clinics (ANC) nationwide. The National Reference Laboratory (NRL) is certified to perform HIV confirmatory tests. In order to enhance prevention, care and treatment of HIV, as done in many countries, the GoR, in collaboration with various partners, implemented an ART program throughout the country. The number of patients on ART increased rapidly; the number of adult patients on ART increased from 8,815 in 2004 to 70,047 in 2009 [TRAC *Plus*, 2008].

In countries scaling up ART, the World Health Organization (WHO) recommends that the MoH and the National AIDS Council, or equivalent body, work with key partners to establish an HIV Drug Resistance (HIVDR) Technical Working Group (TWG). The HIVDR TWG should develop a national HIVDR prevention and assessment strategy, and make evidence-based recommendations to support HIVDR prevention.

Among the many tasks of the HIVDR TWG are the collection of HIVDR EWIs, and the implementation of surveys to assess transmission of HIVDR (primary drug resistance) and acquisition of HIVDR during antiretroviral treatment (secondary drug resistance). The collection of early warning indicators remains the priority of the WHO in this strategy of fighting against HIV DR[2]. In Rwanda, as proposed in the WHO guideline document on HIV DR early warning indicators, the HIVDR TWG has selected 5 EWIs to be collected from routinely available data in site level using data collection tools, including registers, medical records, and pharmacy refill logs.

3.3. Justification of EWI Monitoring

Despite the overall decrease and stabilization of HIV prevalence in the Rwandan population, there will continue to be increasing demand for ART, based on disease progression and new infections [EPP-SPECTRUM, Rwanda 2009]. The number of adult patients on ART increased from 8,815 in 2004 to 70,047 in 2009. [TRAC *Plus*, 2008] In this context, it is therefore necessary to have

[2] http://www.who.int/hiv/topics/drugresistance/hiv_dr_early_warning_indicators.pdf

evidence-based measures to control HIV drug resistance in Rwanda and to avoid the emergence of drug resistance to the current ART regimens. As such, WHO has recommended the annual monitoring of EWIs which are designed to provide evidence to guide actions to improve patient, facility and systemic factors that impact HIVDR emergence. Notably, these actions do not require laboratory testing.

3.4. Key Definitions

The following definitions are presented in alphabetical order:

- "**Appropriate 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 . 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.
- **"First-line ART":** The initial ARV regimen prescribed for a patient initiating ART.
- "**Incompletely dispensed"** is defined as 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**" is defined as first prescription of ART at the site in an individual who has not previously received ART at the site, with the exception of ARV drugs for prevention of mother to child transmission (PMTCT), and who has not transferred in on ART. This definition includes: treatment naïve patients; patients who have received ARV prophylaxis for PMTCT; non-naïve patients who received ART from other sources and are not recorded as transferred in.
- **"Lost to follow-up 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.

• "**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**" is defined as a regimen prescribed after clinical, immunological, or virologic failure of a first-line regimen as defined in the national guidelines. It does not include substitutions of one drug in the same class for another in a first-line regimen.

• "**Second-line ART":** A new regimen used in sequence immediately after first-line therapy, and which includes 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 stockout 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 tocks available at a higher level or in a wider geographic area.

- "**Stop**" is a complete halt of the entire ART regimen, without a restart within the "12-month date" (i.e. one calendar year after the date of ART initiation).
- "**Substitution**" is defined as change from one ART regimen to another by substituting one or more ARVs within a drug class that was already used in the original regimen. (6).
- "**Switch"** is defined as a change in an ART regimen after regimen failure. The change involves at least two new drugs; one of which is from a new ARV class. (6).
- **"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.

4. METHODS

4.1. Study design and location

4.1.1 Study Design:

The study design is a combination of cross-sectional and retrospective cohort in 27 HCs countrywide, including Kigali City and its suburbs where ART was first initiated in Rwanda.

4.1.2 Location and Sampling:

The data abstraction has been performed in 27 representative sites across the country. Site that did not have data available for abstraction were replaced with the nearest site.

Some characteristics have been considered in the selection of the HIVDR EWI sites:

- ✓ Localization (urban and rural areas)
- ✓ Technical support
- ✓ Type of the health facility
- ✓ Number of the patients served at the site
- ✓ Started ART program before 2007

The denominator period was from January 2007 to December 2007 for all sites.

Data collection will be repeated annually.

Abstractors have laptops and used WHO tool Excel spreadsheets. Eight abstractors were trained at TRAC *Plus*; 2 persons per site abstracted the HIVDR EWI and 1-2 days were spent in each site. Total time for HIVDR EWI collection was about 3 weeks (November 2009).

The following are WHO HIVDR EWI:

1. ART prescribing practices,
2. Patients lost to follow-up 12 months after ART initiation,
3. Patients on appropriate first-line ART at 12 months,
4. On-time ARV drug pick-up,
5. ART clinic appointment keeping,
6. ARV drug supply continuity,
7. Patient adherence to ART and
8. Viral load suppression 12 months after ART initiation.

EWI 1 was abstracted using the register listing patients starting ARV each month in 2007

EWI 2 was abstracted using a combination of sources (ARV register, patient medical file, and patient sheet of pharmacy appointment).

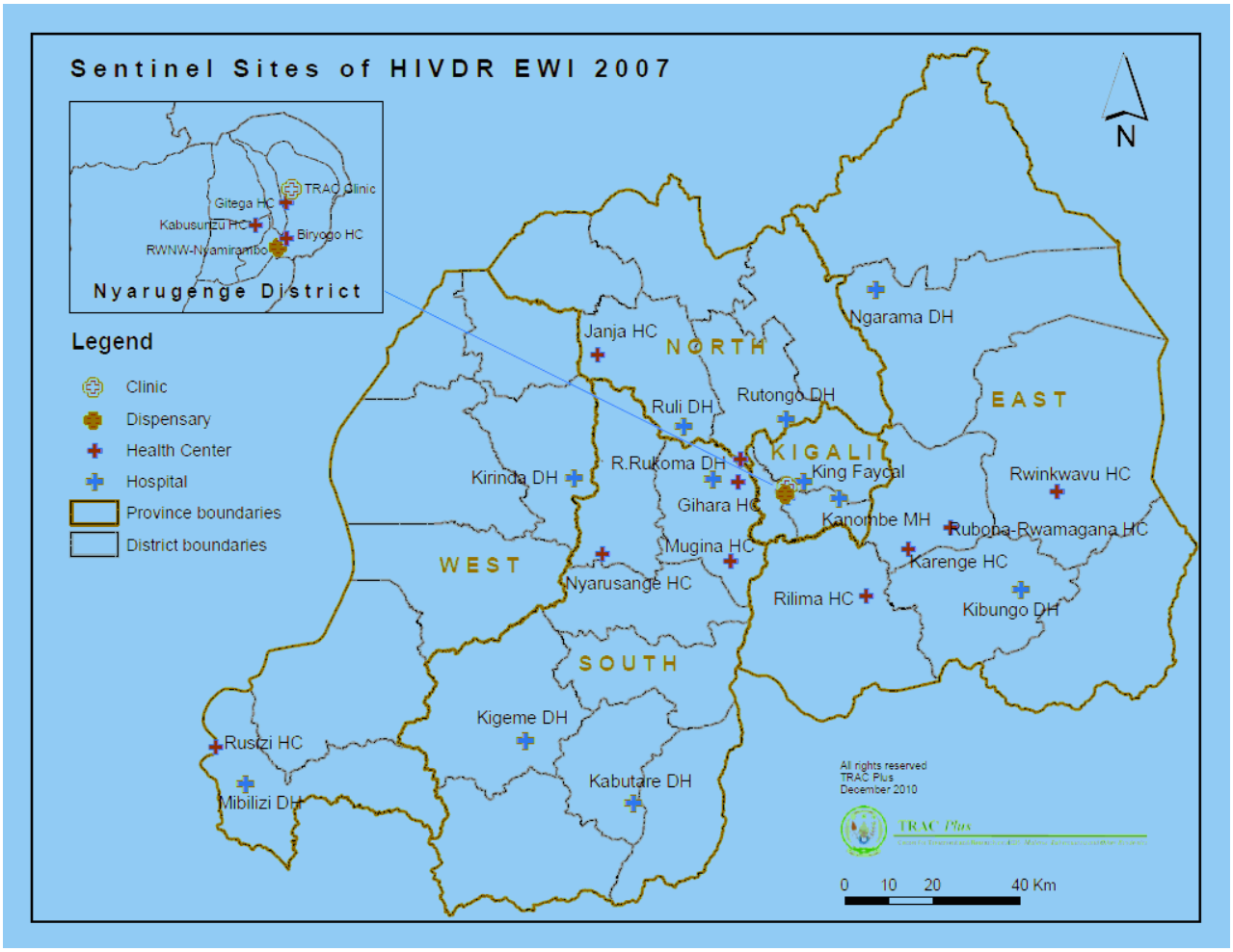
EWI 3 was abstracted using: ARV Register; patient sheet of pharmacy appointment and patient medical file.

EWI 4 was abstracted using: ARV Register and patient sheet of pharmacy appointment.

EWI 6 was abstracted using the "Pharmacy Stock Form"

Sites included:

Health facility	**partner**	**province**	**Residence**	**Type**
AVEGA/Rwanda Women Network	CTP	KIGALI CITY	Urban	DISPENSARY
Rubona_Rwamagana	EGPAF	EASTERN PROVINCE	Rural	Health Center
Mugina H C	FHI	SOUTHERN PROVINCE	Rural	Health Center
Karenge HC	PIH_GF	EASTERN PROVINCE	Rural	Health Center
Rilima HC	PIH_GF	EASTERN PROVINCE	Rural	Health Center
Nyarusange HC	FHI	SOUTHERN PROVINCE	Rural	Health Center
Gihara HC	FHI	SOUTHERN PROVINCE	Rural	Health Center
Rutonde HC	GF	NORTHERN PROVINCE	Rural	Health Center
Janja HC	GF	NORTHERN PROVINCE	Rural	Health Center
Butamwa HC	MCAP	KIGALI CITY	Urban	Health Center
Gitega HC	GF	KIGALI CITY	Urban	Health Center
Biryogo HC	FHI	KIGALI CITY	Urban	Health Center
Rusizi HC	GF	WESTERN PROVINCE	Urban	Health Center
Polyclinique du Carrefour	MCAP	KIGALI CITY	Urban	Health Center
Ngarama District Hospital	EGPAF	EASTERN PROVINCE	Rural	DISTRICT HOSPITAL
Kanombe Military Hospital	DU	KIGALI CITY	Rural	DISTRICT HOSPITAL
Rutongo Hospital	GF	NORTHERN PROVINCE	Rural	DISTRICT HOSPITAL
Rwinkwavu HC	PIH_GF	EASTERN PROVINCE	Rural	DISTRICT HOSPITAL
Kirinda District Hospital	MCAP	WESTERN PROVINCE	Rural	DISTRICT HOSPITAL
Remera Rukoma HD	FHI	SOUTHERN PROVINCE	Rural	DISTRICT HOSPITAL
Ruli District Hospital	GF	NORTHERN PROVINCE	Rural	DISTRICT HOSPITAL
Mibilizi District Hospital	GF	WESTERN PROVINCE	Rural	DISTRICT HOSPITAL
Kibungo District Hospital	EGPAF	EASTERN PROVINCE	Urban	DISTRICT HOSPITAL
Kabutare District Hospital	GF	SOUTHERN PROVINCE	Urban	DISTRICT HOSPITAL
Kigeme District Hospital	FHI	SOUTHERN PROVINCE	Urban	DISTRICT HOSPITAL
TRAC *Plus* Clinic	GF	KIGALI CITY	Urban	REFERENCE CLINIC
King Faycal Referral Hospital	GF	KIGALI CITY	Urban	REFERENCE HOSPITAL



4.2 Justification of EWIs selection

WHO recommends that developing countries use the data collection tools developed by their experts in order to have uniform data and easy analysis. In Rwanda, this standardized tool was used in its electronic form, and it was completed at the site level by 2 trained data collectors from the MoH in order to save time and to minimize data input errors. After data abstraction by trained data abstractors, data validation was done by supervisors from MoH on 10% of patient records in each site.

In the context of local ART sites, 5 indicators were retained of 8 proposed indicators by WHO.

- **EWI 5** which is related to ART clinic appointment keeping was not applicable, because in file patient this indicator is not systematically encoded.
- **Optional EWI 7**, which is pill counting, was not applicable in several ART sites, because many of them do not count remaining pills of ART.
- **Optional EWI 8**, which is viral load suppression 12 months after ART initiation, was not applicable in current ART settings context. This is not a biological indicator of ART monitoring in Rwanda.

4.3 General objective of HIVDR EWI monitoring

The main purpose of HIVDR EWI monitoring system was to assess the extent to which ART programs are functioning to optimize prevention of HIVDR

4.4. Specific objectives

- To assess the initial prescribed ART in selected sites in 2007
- To determine the percentage of lost to follow up in selected sites in 2007
- To assess the retention on first-line ART at 12 months after treatment initiation in 2007
- To determine the ppercentage of patients picking up all prescribed antiretroviral (ARV) drugs on time in 2007
- To determine the ppercentage of months in 2007 without any ART stock out
- Make recommendations based on findings

Overview of 5 selected indicators

EWI 1. ART prescribing practices

Percentage of patients initiating ART at the site in 2007 who are initially prescribed, or who initially pick up from the pharmacy, an appropriate first-line ART regimen.

Numerator: number of adult patients initiating ART during the selected time period who are prescribed an appropriate first-line ART regimen in 2007.

Denominator: number of adult patients initiating ART at the site during the selected time period

WHO target: 100%

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

Percentage of patients initiating ART at the site in 2007 who were lost to follow-up during the 12 months after starting ART.

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., and who are not known to have transferred out or to have died.

Denominator: number of adult patients initiating ART at the site in 2007.

WHO target : ≤ 20%

EWI 3. Patient still on first-line ART at 12 months

Percentage of patients initiating ART at the site during the selected period who are taking an appropriate first-line ART regimen 12 months later.

Numerator: number of adult patients initiating ART at the site during the selected period 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 during the selected period, excluding the patients who transferred out during the 12 months after initiating ART. Patients who died, stopped ART, switched to second-line ART, or were lost to follow-up must be included in the denominator.

WHO target: ≥ 70%

EWI 4. On-time ARV drug pick-up

Percentage of patients who picked up all prescribed ARV drugs on time during their first 12 months of ART.

Numerator:

Number of patients who picked up all prescribed ARV drugs on time during their first year of ART.

Denominator: number of patients initiating ART in 2007.

WHO target: ≥ 90%

Note:

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).

EWI 6. ARV drug supply continuity

Percentage of months in 2007 without any ART stock out.

WHO target: 100%

Numerator: number of months in 2007 in which there were no stock-out days of any ARV drug routinely used at the site;

Denominator: 12 months (Jan 2007-Dec 2007).

5. RESULTS

In consideration of levels, 13 Health Centers, 13 District Hospitals and 1 Reference hospital participated in data abstraction. All indicators collected in 2009 are concerning adult patients and the designated period was 2007 (From January to December 2007). The numerator is the number of patients concerned by the indicator after 12 months of treatment initiation. The denominator after 12 months is number of patients who are still in the ART program in the site after 12 months of ART initiation.

Distribution of HIVDR EWI by Health Facilities, 2007

Health facility	**Type**	**Number of files recorded**	**% EWI 1**	**% EWI 2**	**% EWI 3**	**% EWI 4**	**% EWI 6**
			T: 100%	T: ≤20%	T: ≥70%	T: ≥90%	T: 100%
AVEGA/Rwanda Women Network	DISPENSARY	34	100	0	100	71	100
Biryogo H C	Health Center	100	99.0	14	99	83	100
Butamwa HC	Health Center	22	100	5	100	33	100
Gihara HC	Health Center	41	100	25	100	88	100
Gitega HC	Health Center	56	100	4	100	86	100
Janja HC	Health Center	52	100	0	100	70	83
Karenge HC	Health Center	17	100	0	100	65	100
Mugina H C	Health Center	21	100	5	100	80	100
Nyarusange HC	Health Center	59	100	11	100	86	100
Polyclinique du Carrefour	Health Center	43	100	8	97.7	52	100
RILIMA HC	Health Center	50	100	0	100	58	100
Rubona HC	Health Center	5	100	0	100	80	100
Rusizi HC	Health Center	36	100	17	100	54	100
Rutonde HC	Health Center	5	100	0	100	44	
Kabutare District Hospital	DISTRICT HOSPITAL	99	100	29	100	63	100
K M Hospital	DISTRICT HOSPITAL	94	100	0	100	66	100
Kibungo District Hospital	DISTRICT HOSPITAL	100	100	1	100	77	100
Kigeme DH	DISTRICT HOSPITAL	143	100	16	100	68	100
Kirinda District Hospital	DISTRICT HOSPITAL	100	100	16	100	68	100
Mibilizi District Hospital	DISTRICT HOSPITAL	99	100	16	100	75	100
Ngarama District Hospital	DISTRICT HOSPITAL	75	100	0	100	84	100
Remera Rukoma HD	DISTRICT HOSPITAL	74	100	3	100	82	
Ruli District Hospital	DISTRICT HOSPITAL	31	100	0	100	97	100
Rutongo Hospital	DISTRICT HOSPITAL	76	100	9	100	44	58
Rwinkwavu HC	DISTRICT HOSPITAL	87	100	6	100	80	100
TRAC *Plus* Clinic	REFERENCE CLINIC	54	96.3	17	95.8	37	57
K Fl Referral Hospital	REFERENCE HOSPITAL	28	100				
% of ART sites meeting the WHO target			**92.6**	**92.3**	**100**	**3.8**	**87.5**

The table above illustrates the performance of participant sites according to 5 HIVDR EWI applicable to the designated period (2007).

- The first **HIVDR EWI**, about the drug prescription at the initiation of ART was excellent in general. However, two sites, Biryogo HC and TRAC *Plus* clinic, prescribed inappropriate first line regimens. In 2007, in Biryogo HC one prescription was Kaletra containing regimen, and in TRAC *Plus* clinic, two regimens were Kaletra containing regimens. Those regimens were given to women who were previously exposed to single dose Nevirapine. Two women were twice exposed to single dose Nevirapine; the other one was once exposed to single dose of Nevirapine. A proportion of 92.6% of sites met the WHO target which is 100%.
- The **HIVDR EWI 2, w**hich is to track patient loss to follow up, 9/27 (33.3%) Health facilities had 0% of patients loss to follow up at 12 months. These sites are: AVEGA/Rwanda Women Network, Janja HC, Kanombe Military Hospital, KARENGE HC, Ngarama District Hospital, RILIMA HC, Ruli District Hospital, Rubona and Rutonde HC. In terms of percentages, 6/13 (46.2%) of HC and 3/13 (23.1%) of District Dospitals had 0% lost of follow up. Some health facilities could be emphasized: King Faycal Referral Hospital which does not complete the patient file, in worse case, could have 100% of loss to follow up because that indicator does not exist in that health facility, but it was classified only for the EWI 1. Kabutare District Hospital had 29% lost of follow up and Gihara HC with 25% lost of follow up.
- **HIVDR EWI 3a** concerning percentage of patients initiating ART at the site who are taking an appropriate first-line ART regimen 12 months after the initiation date. Only one Health facility, Polyclinique du Carrefour, switched the first-line regimen to the second-line regimen for one patient, of all 26 health facilities. Once again King Faycal Referral Hospital was not classified because there was no data for this indicator.
- **HIVDR EWI 4b** which evaluates the percentage of patients picking up prescribed ART drugs on time during their first 12 months of ART; for this indicator, only one site reached the recommended WHO target (≥ 90%). In Ruli District Hospital 97.0% of patients on ART picked up prescribed medications on time. However, it is difficult to interpret if the reason for not respecting the pharmacy appointment is due to availability of pills in hand or if it is a true drug stock out. In almost all sites, patients had reserve pills which could avoid their running out.
- **HIVDR EWI 6** which calculates the percentage of months in designated year in which there were no ARV drug stock-outs, the designated years was 2007. For this indicator, three health facilities (11.1%) were not classified because they had no pharmacy files. These sites were: King Faycal Referral Hospital, Remera Rukoma DH and Rutonde HC. For classified health facilities, 87.5% had not ARV stock-outs, three health facilities

(12.5%) had months of ART stock-outs. At the national level this target was reached at 96.0%; it would be reached at 100% according to WHO guideline.

- **Percentage of ART sites meeting the national target:**

  For **HIVDR EWI 1**, 92.6% of sites met the WHO target. We point out that 2 sites prescribed Kaletra containing regimen as initial ART first-line, involving a total of 3 patients.

  About **HIVDR EWI 2**, among classified sites for this indicator, 90.3% had ≤ 20% (The WHO target) of lost to follow-up. Two sites had more than 20% of patients lost to follow up.

  Concerning the **HIVDR EWI 3**, among classified sites, 100% of sites had ≥ 70% (The WHO target) of the patients still on an appropriate first-line ART regimen 12 months after ART initiation.

  About **HIVDR EWI 4** only one (3.8%) of classified sites reached the WHO target (≥ 90%).

  For the **HIVDR EWI 6**, for classified health facilities, 87.5% had no ARV stock-outs and reached the WHO target (100%).

Data validation results:

The data validation was done by doing data abstraction on 10% of eligible randomly selected patients records in all 27 sentinel sites by TRAC *Plus* staff and data abstractors. We made sure that data validation performed by the data abstractors was conducted in different sites from where they were involved in the EWI abstraction. For 5 HIVDR EWI abstracted, all 10% (393 patients' files) were compared with the records from data abstractors and matched with data of the survey; except 3 files patient in which the pills count (EWI 7) was not the same as the data abstraction report. But this indicator (EWI 7) was not considered because it was not systematic in almost sites.

Discussion

Regarding the EWI 1, all sites prescribed an adequate ART regimen. Two sites out of 27 did not prescribed the National first line regimen for a clinical reason according to the history of the patients. According to the EWI 2, again 2 sites among 26 classified sites did not reach the WHO target, the reason for this failure could be either the lack of patient follow up or the patient file which are not updated.

The percentage of patients who continued the initial treatment after 12 months (EWI 3) was satisfactory in 2007.

The EWI 4 shows that almost all sites did not reach the WHO target. We cannot conclude that patients in all sites experienced ART stock out. The explanation for this situation is that patients who are not lost to follow up had extra pills on hand which can cover for a few days after the appointment date. About the continuity of ART drugs in the pharmacy at the site level (EWI 6), 3 sites out 27 sites do not have an official system of drug procurement. For other sites which experienced stock out, when a molecule was not available in a health facility, it was replaced by another according to the national guidelines**.** Sometimes there was a stock out, for example of a combined treatment molecule (Duovir-N for example), which could be replaced by separate molecules or the other molecules of the same class; but there was a period of TDF stock out in some sites and patients switched TDF to AZT or another molecule of the same class. The other possibility to avoid stock out for patients at the site level, in case of stock out of a molecule in one site, there was an arrangement with the nearest site to borrow the missing molecule and these molecules was not recorded in pharmacy forms.

Conclusion:

The ART prescription was a success in all 27 considered sites; however some sites experienced a high rate of patients lost to follow up. The first line regimen was considerably preserved beyond the WHO norms.

The **HIVDR EWI4b** which evaluates the percentage of patients picking up prescribed ART drugs on time, the analysis of data abstraction showed that, except one site, all remaining sites were under the target recommended by WHO.

The stock out of ART is still a reality in some sites and was observed in 3 sites out of 24 classified sites.

Abstraction of some HIVDR EWI was not applicable, including the respect of clinic appointment. The pill counting (HIVDR EWI7) is not common in many Health Facilities and the viral load testing (HIVDR EWI8) was not performed as a biological routine monitoring.

6. Recommendations:

1. All sites are requested to complete the patient file for a good follow up of patients; otherwise it will be difficult to monitor HIV DR.
2. The HIVDR EWI5 of ART appointment keeping is not an optional indicator; it must be filled in all patient files.

3. The pharmacy form in the patient file must be correctly filled because it may help to understand the adherence of the patient. It could indicate whether or not a patient had a treatment interruption during a period.
4. HIVDR EWI2 regarding the rate of patients lost to follow up: Even though the target suggested by WHO was ≤ 20%, this target is very high; health facilities must do their best to have the fewest patients lost to follow up rate. In order to minimize the risk of HIV drug resistance in our population, the percentage of lost of follow-up must be as low as possible.
5. HIVDR EWI4, the percentage of patients picking up prescribed ART drugs on time was low in all sites except one. Health providers must educate and encourage patients on ART to respect their clinical and drug pick up appointments.
6. ART stock-out at sites level must be avoided. For some sites which do not have pharmacy forms, or which had them but not completed, should keep them correctly completed.