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Research Article

Rational medication use review: a quality assurance/improvement process for HIV/AIDS treatment programmes

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ABSTRACT

Background: A Rational Medication Use Review (RMUR) was conducted at four facilities providing antiretroviral therapy in Burundi as a simple and practical strategy for service providers and programme managers to continuously assess and monitor quality of ART services provided.
Methods: A comprehensive data collection tool was developed to systematically and retrospectively capture relevant data from randomly selected ART patient files in the four ART facilities.
Results: ART data from 157 patients receiving ART services from four facilities was extracted and analysed. WHO stage 4 AIDS defining diseases were recorded in 125 (79.6%) of the patients at the time of ART initiation. The most frequent opportunistic infections and/or co-morbidities were cryptosporidiosis (14.4%), HIV wasting (14.4%), tuberculosis (13%) and candidiasis (17.4%). 97.8% of the patients were taking concomitant medicines. A large percentage of patients (72.4%) had done a baseline CD4 test before initiation of therapy with a majority of the patients (85.8%) getting their lab results within one week of the collection of the specimens. For some patients (9%), it took up to 8 weeks to get test results. About 21.8% of the patients were hospitalized at least once while on ART and 11.2% of the hospitalized patients died.
Conclusion: " RMUR is a simple and practical strategy that can be appropriately modified to suite local settings. It offers a cost-effective and participatory method of identifying and correcting factors that may negatively impact the quality of care and desired outcomes for patients on ART.

Keywords: Rational, Medication, Use, Antiretroviral, Therapy

INTRODUCTION

The Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) pandemic poses a serious threat to public health on a global scale. The pandemic has elicited unprecedented global responses in an effort to curb its spread and provide much needed treatment and care services to affected individuals. An estimated 35.3 million people were living with HIV globally at the end of 2012. By the end of the same year , there was a commendable increase in people accessing antiretroviral therapy (ART) globally from the 1.3 million in 2005 to 10.6 million with the majority being from low and middle-income countries (9.7 million).[1,2] Sub-Saharan Africa is disproportionately affected by HIV accounting for 70% of the global burden.[3]

Access to treatment, both to mitigate the effects of the epidemic and prevent new infections, has been a major focus particularly in high burden countries.[4] With the increase in access to ART, a lifelong undertaking, focus is now shifting towards ensuring quality and evidence-informed interventions supported by sound operational research. The ultimate aim of ART is to prevent HIV-related premature death, improve patient's quality of life,[5] and, from more recent findings, prevent onward transmission.[6] As a result, governments have designed standard treatment guidelines that are meant to be used together with a trained clinician's professional judgment in order to ensure that the patient derives maximum benefit from treatment. These guidelines include pre-treatment evaluation criteria, treatment regimens to be used and when to switch therapy, recommended treatment monitoring, and the management of adverse effects among others. The guidelines are periodically reviewed as new scientific evidence emerges and it is therefore important that clinical practice and program functions be aligned with these guidelines particularly in resource-constrained countries.

There are many factors related to the medications used including , the health system, and the socioeconomic environment that may compromise treatment and affect the patient's ability and willingness to remain on treatment.[7] Some of these factors include poor antiretroviral drug supply and distribution, inadequate treatment monitoring, toxicity and side effects, cost of access to services, concomitant use of traditional and complementary medicines, stigma and discrimination.

In Treatment 2015, the Joint United Nations Programme on HIV/AIDS (UNAIDS), World Health Organization (WHO), the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund and other partners emphasize on innovation and the use of available resources and infrastructure as strategically as possible in programme planning and service delivery.[8] There is need to initiate and institutionalize quality assurance measures to regularly monitor ART services at all stages of treatment and management as well as at the various levels of the health system to ensure that factors that may negatively affect treatment outcomes are detected early and appropriate remedial measures instituted.[9]

Background

Burundi, with an estimated population of about 10.9 million,[10] reported a HIV prevalence of 1.3% among adults in 2012 with an estimated 83000 people living with HIV.[11] In 2012, estimates indicate that there were 50,000 People Living With HIV (PLWHIV) eligible for ART with only about 29000 of them receiving treatment. There were approximately 4800 deaths associated with HIV in both adults and children.[12] In response to this, the Government of Burundi, with the assistance of various partners in the health sector, has taken significant steps to improve access to ART.

However, this improved access comes with challenges related to availability of the necessary health infrastructure, human resources constraints, lack of appropriate support to the patients and patient loss to follow-up. These challenges potentially affect the quality of care, negatively impacting on treatment outcomes and patient benefits. Additionally, if left unmanaged, side effects, adverse reactions and drug interactions can lead to potentially harmful effects.

A Rational Medication Use Review (RMUR) was conducted in 2012 in collaboration with the Roads to A Healthy Future (RTHF) project and health providers as a quality assurance exercise in selected facilities providing ART services in Burundi. A RMUR is a planned, systematic, criteria-based process for monitoring, evaluating and continually improving medication use with the ultimate aim of improving treatment-related outcomes in a group of patients.[13]

It focuses on assessing and improving one or more of the steps involved in medication use (patient assessment, prescribing, preparation and dispensing, administration, patient monitoring, evaluation and reporting of medication side effects and patient education).

RMUR is a healthcare quality assurance process that is well established in developed countries and in many cases is a mandatory process for acute and long-term care facilities that provide healthcare involving medication use. The aim of the RMUR in the four RTHF-supported ART treatment sites (National Association for HIV- with HIV (ANSS) clinic in Kirundo, Kirundo Hospital, Muyinga Hospital and Kayanza Hospital) was to assess the provision of ART services at the various treatment levels in order to identify factors that may adversely affect quality of care and subsequently treatment outcomes. The ultimate aim of the review was to work with service providers and programme managers at different levels of the health care system and help them to put in place remedial measures to address the identified challenges as well as institutionalize the RMUR process.

METHODS

A comprehensive data collection tool was developed to retrospectively capture key data points from randomly selected patient files. The tool was piloted on 20 patient files to check for content appropriateness, reliability and feasibility.

The results of the pilot were circulated to the relevant stakeholders for their comments and the data collection tool was revised based on the outcomes of the pilot and input from the stakeholders. During the pilot study the location of key data in patient files was also identified.

Table 1: Drug use and quality of care indicators.

Drug use and quality of care indicators	
ART patients total - female	ART cohort WHO 4 stage parameter
ART patients total - male	ART cohort on line 1 and line 2
ART cohort age distribution parameter - male	ART: Number of visits before initiation of ART
ART cohort age distribution parameter - female	ART cohort weight measured parameter
ART pregnant women rate	ART cohort initial weight distribution parameter
ART adult cohort occupation parameter	ART cohort weight gain parameter
ART cohort annual income parameter	ART cohort weight loss parameter
ART cohort distance from facility parameter	ART CD4 baseline test done
ART cohort mode of transport parameter	ART CD4 baseline test value
ART lab value test result turn around	ART CD4 baseline test value by gender
ART patients initiated on cotrimoxazole prophylaxis	ART CD4 baseline test result above 200 - male
ART patients initiated on nevirapine	ART CD4 baseline test result above 200 – female
ART patients initiated on nevirapine desensitization	ART CD4 baseline test result less than 200 - male
ART patients received nevirapine PMTCT	ART CD4 baseline test result less than 200 - female
ART patients that received PEP	ART CD4 value after commencement of treatment
ART patients that developed TB	ART viral load tests done
ART patients that developed opportunistic infections	ART patients that developed side effects and adverse reactions
ART patients that developed an STI	ART cohort use of traditional medicines parameter
ART patients on concomitant therapy	ART dosage adjustments based on TB therapy
ART patients' average intake of none ART drugs	ART dosage adjustments based on patient's weight
ART patients' adherence to hospital appointments	ART dosage adjustments based on drug interactions
ART patients' reasons for non-adherence to hospital appointments	ART dosage adjustments based on kidney function tests
ART patients' adherence to pharmacy appointments	ART dosage adjustments based on liver functiontests
ART patients' reasons for non-adherence to pharmacy appointments	ART patients' hospital admissions
ART patients who had a pill count performed	ART patient death rate
ART dose defaulters	ART patient loss to follow up rate
ART drug stock out rate	ART patients hospital admissions rate
Patients' satisfaction with drug advice	Personnel counseling the patients

A systematic sampling approach targeting patient files that were assigned odd numbers in the institutional filing system was used. Medical records of patients that have been on therapy for at least 12 months were randomly selected. Each patient was assigned a unique number, which was used throughout the process, to maintain confidentiality. The data collected included the patient demographics, treatment history, patient treatment selection criteria, current treatment, treatment monitoring, treatment outcomes, and drug supply. Data analysis was carried out using the statistical software Epilnfo®.

Table 1 above gives the key indicators that were employed in identifying and measuring the gaps in treatment and quality of care of the ART programs in the four treatment centres. These indicators included medication dispensing; treatment administration; treatment monitoring: dosage adjustments (based on age, weight, renal or hepatic function), concurrent drug use; adherence support; and prevention and management of side effects.

Ethical considerations

The aim of this RMUR was to assess the provision of ART services at the various treatment levels in order to identify factors that may adversely affect quality of care and subsequently treatment outcomes from a quality improvement perspective. This did not involve the use of questionnaires and this paper does not report on the use of experimental or new protocols and was not set up as a study or research project but is part of public health care in the HIV/AIDS programme in select towns in Burundi. It was therefore done internally with the involvement of healthcare workers in Burundi as part of an evaluation, so as to improve patient quality of care. The autonomy of the patients was protected because their identity is withheld from the authors. Consequently, neither informed consent nor ethics approval was sought or deemed necessary because this was an internal epidemiological quality improvement exercise in which it was impossible to identify the participants.[14]

RESULTS

Demographics

Data from 157 patients receiving ART from the four sites was extracted and analysed. Ninety seven (97) of patients were females and fifty seven (57) were males. Gender information was missing for three (3) patients. Patients had a median age of 36 and a mean age of 34.3 years.

Patient occupation

The patients recorded a wide variety of occupations. Three quarters of patients were subsistence farmers while 10% were students. Remainder included pensioners, electricians and nurses. Average annual income was US$ 544 ranging from US$ 224 to US$ 4624 per annum.

Distance from facility and transportation mode

Distance travelled by patients for medical services and collection of medicines ranged between a few hundred meters to more than 50 km. Only 50% of the patients lived within a 5 km radius of the treatment site. Their mode of transport was mostly walking but a few used bicycles, cars or buses to reach the facility.

Medical history review on ART initiation

WHO stage 4 AIDS defining diseases were recorded in 125 of the patients when examined just prior to ART initiation. The most frequent stage 4 conditions were cryptosporidiosis (14.4%) and HIV wasting (14.4%). Others included candidiasis, cryptococcosis and herpes simplex. Table 2 below is a summary of the WHO stage 4 symptoms that the patients presented with at the time of initiation of ART.

Table 2: WHO stage 4 conditions identified in the four treatment sites at initiation visits n = 125.

WHO S4 symptom	Frequency	Percent
Cryptosporidiosis	16	14.40%
HIV Wasting	18	14.40%
Other	9	7.20%
Candidiasis	7	5.60%
Cryptococcosis	3	2.40%
Disseminated TB	3	2.40%
Herpes Simplex	3	2.40%
Bedridden>50%	2	1.60%
Extra-pulmonary TB	2	1.60%
HIV encephalopathy	2	1.60%
PCP	2	1.60%
Delayed growth	1	0.80%
Isosporiasis	1	0.80%
Kaposi's sarcoma	1	0.80%
Cytomegalovirus	1	0.80%

Pre-ART initiation visits

96% (n=125) of the patients were given nevirapine 200-mg/day dose for 14 days upon initiation of ART. More than 95% of the patients had at least three visits prior to initiation of therapy. Less than 3% of the patients had just one pre-initiation visit. The number of pre-ART-initiation visits is summarized in table 3 below.

Table 3: Number of visits before initiation of ART.

Number of visits	Frequency	Percent
1	4	2.80%
2	1	0.70%
3	139	96.50%
Total	144	100.00%

About 95% of the patients had their weights recorded at initiation of therapy. The records of patient weights taken at the treatment initiation visit, were compared with those taken at subsequent visits. The mean and median initiation weight for this cohort of patients was 47.2 kg and 50.0 kg respectively. 76% (n=129) of the patients registered weight gain while 5.1% did not register any change in weight post-initiation. Some patients (18.9%) lost some weight during the course of their treatment.

ART regimen at initiation

Most patients at the four treatment facilities were initiated on the 1st line of therapy. More than 90% of the patients were initiated on the first-line regimen under normal dose and 7.7% were initiated on the first-line adjusted-dose regimen. There was only one patient who was initiated on the second-line of therapy.

Baseline and follow-up CD4 counts

A large percentage of patients (72.4%) had done a baseline CD4 test before initiation of therapy compared to 22.4% who did not. In 5.1% of the patients, it could not be ascertained from the records if an initial CD4 count had been done. Two thirds of the male patients and about half of the female patients were initiated on ART when their baseline CD4 count was below 200. The baseline CD4 count was below 100 in 20% of the patients and between 101 and 150 in 21% of the patients. A total of 58.2% of the reviewed patients had initiation CD4 count below 200. About 29% of the patients had a baseline CD4 count between 200 and 350. Only 5.1% of the patients had a baseline CD4 count above 350. Figure 1 below illustrates the baseline CD4 cell count. None of the patients had been checked for viral load during the course of therapy.

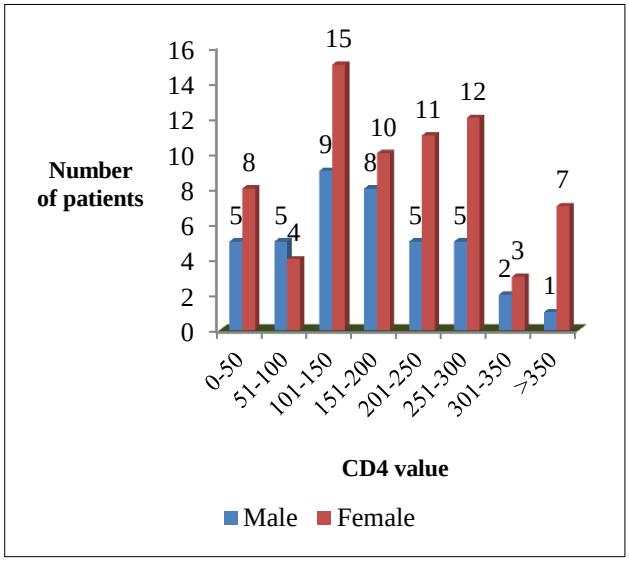

Figure 1: Baseline CD4 count of patients initiated at the four FHI supported treatment sites in Burundi.

Data showed that 95.48% of the patients had an increase in CD4 count 12 months after ART initiation. The CD4 measurement increased to a value of between 201 and 300 in 16.7% of the patients and to above 300 in 24.2% of patients. Only 4.5% recorded a decrease in CD4 value.

Lab results turn-around time

Most of the patients (85.8%) got their lab results within one week of the collection of the specimens. For some patients (9%), it took up to eight weeks to get their test results (Table 4).

Table 4: ART lab value test results turn around.

LBV lead times	Frequency	Percent
No data	2	1.50%
1 week	115	85.80%
2 weeks	3	2.20%
8 weeks	12	9.00%
8-12 weeks	2	1.50%
Total	134	100.00%

Dosage adjustment

Dosage adjustment was carried out to factor in anticipated serum drug concentration changes that may result from concurrent TB treatment, body weight changes, altered kidney function, and liver function in 66.7%, 7.7%, 0.6% and 2.0 % of the patients respectively (Table 5).

Table 5: Dosage adjustments.

Parameter	% of patients with adjusted dosage
Dosage adjustment based on TB therapy	66.7% (n=6)
Dosage adjustment based on patient's weight	7.7% (n=156)
Dosage adjustment on kidney function (Creatinine levels)	0.6% (n=154)
Dosage adjustments based on liver function	2.0% (n=153)

ART *patients hospital admissions rate and outcomes*

Twenty-two percent (22 %) of patients were hospitalized at least once while on ART. Of the sampled patients, 11.2% were recorded as deceased. Five patients were lost to follow-up after discharge while four had transferred to other facilities. 82.9 % of the patients were at the time of the review (Table 6).

ART health personnel involved in adherence counselling

At the ANSS Clinic in Kirundo, patient adherence counselling was performed by nurses while in Kayanza, counselling was done by nurses, doctors and other clinicians. In Kirundo and Muyinga Hospitals, patient counselling was done by the doctors and nurses.

Table 6: ART patient outcomes.

Patient outcome	Frequency	Percent
Deceased	17	11.20%
Lost to follow up	5	3.30%
Alive and on treatment at facility	126	82.90%
Transferred	4	2.60%
Total	152	100.00%

ARV stock outs

Two of the four facilities reported having had stock outs of first-line ARVs such as Triomune® (Stavudine, lamivudine and nevirapine) for a period of up to three months, abacavir for one month and Duovir® (Lamivudine and zidovudine) for 15 days.

ART co-morbidities while on HAART

Table 7 lists the reported co-morbidities with some of the patients suffering from more than one ailment either concurrently or at different times during treatment. TB was diagnosed in 13% of the patients after ART initiation while Candidiasis (C. albicans) was reported in 17.4 % of the patients. No STIs were documented in the patient files reviewed.

Table 7: Reported ART opportunistic infections.

Name of OI	Frequency	Percent
Abscesses	1	4.3%
Meningitis	1	4.3%
Cryptosporidiosis	1	4.3%
Cough	1	4.3%
Vaginal ulceration	1	4.3%
Otitis media	1	4.3%
Meningitis	2	8.7%
Shingles	2	8.7%
Diarrhoea	3	13.0%
Pneumonia	3	13.0%
Pulmonary tuberculosis	3	13.0%
Candida albicans	4	17.4%
Total	23	100.00%

*Some of the patients presented with more than one opportunistic infection

Side effects and adverse reactions

Various side effects were reported during the course of treatment with the most significant being anaemia reported in 24% of all patient files reviewed. Some of the patients experienced more than one episode of the side effects. These side effects are listed in table 8. Two-thirds

of the side effects (n=20) were reported to the hospital personnel. In 15% (n=20) of the patients who experienced the side effects, it resulted in longer hospital stay.

Table 8: Side effects and adverse reactions experienced.

Side effects experienced	Frequency	Percent
Tinnitus	1	4.00%
Lactic acidosis	1	4.00%
Lypodystrophy	1	4.00%
Physical asthenia	1	4.00%
Neuropathy	1	4.00%
Joint pains	1	4.00%
Diarrhoea	1	4.00%
Renal insufficiency	1	4.00%
Paresthesia	2	8.00%
Hepatotoxicity	2	8.00%
Dizziness	2	8.00%
Allergy to nevirapine	2	8.00%
Skin eruptions	3	12.00%
Anaemia	6	24.00%
Total	25	100.00%

*Some of the patients presented with more than one side effect

Concomitant use of traditional and other medicines

Results showed that 58.2% of the patients reported that they had never used traditional medicines while 2% said they had used traditional medicines for treating their condition. There was no record of any traditional medication use in 39.9% of the cases. However 97.8% of the patients were taking other medicines in addition to their ART regimen. On average each patient took two additional non-ARV drugs.

Treatment and appointment adherence

Most patients (87.9%) attended all their medication refill appointments while 17 patients did not attend on time. Thirteen (13) patients missed their refills, some by as long as five months, while 10.7% of the patients missed their medicines for more than three days. The main reasons recorded for non-adherence to treatment included lack of time, absence of care givers, inadequate faith in the treatment, and distance from the treatment facility.

Reasons given for non-adherence to pharmacy appointments included 1) sharing of medication; 2) lack of time to collect the medication; 3) debilitating sickness that made it impossible to come to the pharmacy 4) long distance to treatment facility.

DISCUSSION

The provision of ART is a complex undertaking requiring the input of both clinicians and non-clinicians at the various stages of the treatment process. There are many social, health and economic factors that can potentially affect quality of care during the different levels of HIV treatment. As more people get on treatment, there is need to strengthen the quality aspects of both the clinical and programme aspects of HIV treatment to ensure that the patients and communities derive maximum benefit from treatment. Continuous quality monitoring, involving a multidisciplinary approach, should therefore be a critical component of ART service provision and would enable programme managers detect issues that may compromise outcome and patients' quality of life. Sound operational research is also critical in developing appropriate evidence to inform practice and policy decisions.

HIV testing and ART initiation

At the time of the survey, the Burundi HIV treatment guidelines recommended initiation of ART in patients with a CD4 count below 200. Patients who present early for HIV care and treatment before the immune system has been severely compromised respond better to ART and this enables them to resume their socioeconomic activities sooner. It also reduces the risk of HIV transmission to sexual partners especially when their immune systems are relatively healthy.[15,16] In women, this also presents an opportunity to prevent mother-to-child transmission. From the survey, 20% of the patients had ART initiation at CD4 counts below 100 indicating severely compromised immunity. There is need to intensify community and hospital-based HIV testing to detect those infected early and link them to care and treatment services as appropriate.

Drug interaction

Management of HIV is associated with a high use of pharmacologically active agents both in the management of HIV infection and the associated co-morbidities.[17] Additionally, in the developing countries particularly, there is a high degree of self-medication and use of traditional medicines. This scenario presents a challenge of drug interactions that may affect treatment outcomes and potentially lead to toxicity.[18] It is therefore crucial that the ART providers deliberately and continuously monitor the use of other medications and the possible implications on treatment, and educate the patient and care-givers appropriately.

Side effect and adverse reaction reporting and management

Antiretroviral drugs (ARVs) have a wide range of documented and emerging side effects that can have varying influence on the patient and the treatment process.[19,20] Side effects have been known to account for a number of hospital admissions, prolong hospital stays as well as significantly influence treatment adherence. ART-related side effects have also been documented as some of the leading reasons why patients on ART delay

or stop taking their medicines.[21] In this review, 12.82% (n=156) of the patients reported having experienced side effects while on therapy with some of the patients having experienced more than one side effect. The side effects experienced in 75% (n=20) of the patients were reported to the hospital personnel. Twenty percent (n=15) of the patients who experienced the side effects had an increase in hospital stay and 66.7% (n=15) required additional drug therapy to manage the Adverse Drug Reactions (ADR). It is critical that mechanisms are put in place to detect the side effects early and help the patient appropriately manage them to reduce associated morbidity and mortality as well as prevent adversely affecting adherence. A RMUR can be used to establish systems and protocols to detect ADRs early and ensure that they are managed appropriately.

Adherence

High levels of adherence to ART are crucial for achieving optimal viral suppression, reducing chances of drug resistance, prolonging life, improving quality of life and health of PLHIV[22,23] as well as achieving the HIV prevention benefits of ART.[24] Data from the review show that 10.7% of the patients defaulted from therapy by more than three days while thirteen (13) patients missed their refill dates with some defaulting from therapy for as long as five months. There are several factors that affect a patient's potential for adherence. During the review, these were assessed through analysis of the patients' attendance to clinical and pharmacy refill appointments, as well as pharmacy based adherence assessment strategies. Risk drivers to non-adherence identified related to the medication (side effects, dosage regimen), health system (patient education, provider relationship, distance from health facility), and socioeconomic factors (cost of transportation, stigma, social support). These factors should be assessed during all visits and should be used to inform the design of the patient adherence support system.

ART drug supply

Since ART is a life-long undertaking, consistent availability of antiretroviral drugs is an important component of ART treatment management as it ensures that medicines are available to the patient at all times. The challenges of drug supply and distribution have been experienced in many country programs particularly in developing countries. These may be attributed to inadequate financing and poor drug forecasting.[25] At Muyinga and Kirundo Hospitals stock outs were reported of triomune® 30 for a period of three months, abacavir for one month, and duovir® for 15 days. It is important that the supply system both at the programme and health facility level is closely monitored to ensure that stock-outs are avoided and emergency measures are put in place to manage them as and when they occur. Innovative strategies to support drug financing and distribution including strategic partnerships with the private sector need to be considered. Additionally there should be dedicated personnel responsible for drug supply and distribution that should receive the necessary training.

CONCLUSION

With appropriate modification and customization to respond to the needs of individual ART centres or programmes, a Rational Medication Use Review is a simple and practical strategy for programme managers to continuously assess and monitor provision of ART and can be targeted at various levels of the health system. It offers a cost-effective method of identifying any factors that may be negatively affecting the quality and desired treatment outcomes and enables prompt correction and thereby ensure continuous improvement of the quality of treatment and treatment-related outcomes.

Limitations of the review

The study was based on data that was obtained from hospital or clinic patient files which were not properly designed to capture all the necessary information for this review. Secondly, the inclusion criteria used in this review targeted only those files assigned to patients that had been on therapy for a period of at least one year and does not include patients that may have died shortly after initiation of therapy, defaulted because of medication side effects a few months into therapy as well as patients lost to follow up. Finally, there was limited laboratory data thereby making it difficult to ascertain whether therapy needed to be tailored to the individual needs based on weights, renal function and liver function.

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