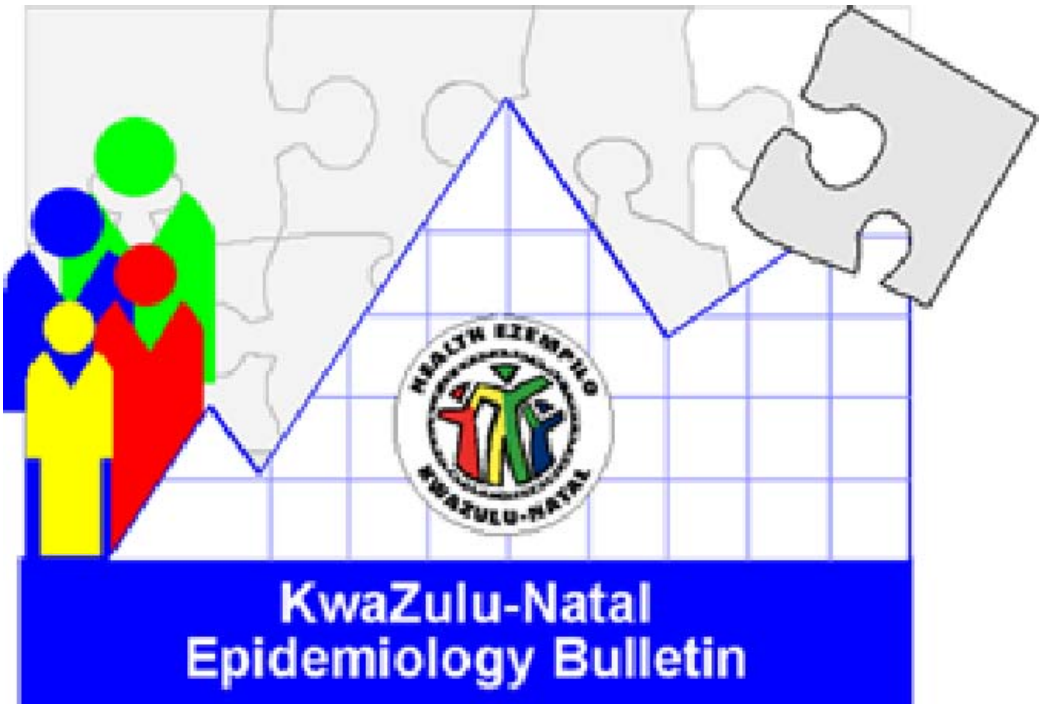

Issue 10

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Weekly Monitoring System of the Antiretroviral Therapy for HIV/AIDS in KZN

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EDITORIAL

The most severe impact of AIDS is in Sub- Saharan Africa. South Africa is now faced with the largest and fastest growing HIV epidemic in Africa and the world. Over 5 million people are currently thought to be living with HIV/AIDS in South Africa; this number is higher than in any other country in the world and is expected to double over the next decade.

The decrease in the cost of ARV has created new opportunities for more widespread use of these agents in Africa. However, there is limited experience with their use and the infrastructure needed to make them safely and effectively available remains scarce. An additional concern is that adherence to ARV, crucial to therapeutic success, may be inadequate, with resultant widespread development of ARV resistance.

The need for a robust, flexible monitoring and evaluation system to be developed whilst providing the ART Service cannot be over-emphasized. The article below aims to contextualize the current status of the ART programme, to identify and articulate the inherent frailties within the public healthcare M & E System, to highlight the achievements over the past 18 months and to discuss the challenges that affect data collection and analysis.

The recommendations take cognisance of the ongoing evolution of this programme and seek to address gaps that have been created as well as point the way forward for the coming years.

Dr Chris Jack
ART Programme Manager
DOH, KZN

TABLE OF CONTENTS

ACRONYMS & DEFINITION OF TERMS

ARV	Antiretrovirals
ART	Antiretroviral Therapy
CHC	Community Health Centres
DoH	Department of Health
KZN	KwaZulu-Natal
LFT	Liver Function Test
MYO	Month year of observation
OI	Opportunistic Infections
PYO	Person year of observation
S1	Counselling on Treatment Literacy Session 1
S2	Counselling on Treatment Literacy Session 2
S3	Counselling on Adherence
VCT	Voluntary Counselling and Testing

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Abstract

The objective of this issue of the Epidemiology Bulletin is to describe the status of the antiretroviral therapy (ART) in KwaZulu-Natal (KZN) based on the weekly indicators collected by each unit. The ART programme started in March 2004 and this is the first description of its progress in terms of coverage and outcomes. There are two data collection systems in the ART programme (a) individual patient information, which is kept on individual forms and remains at the facility; and (b) weekly indicators sent by each facility to the central level. As the data collected on individual patients have not been entered yet in electronic format, this analysis is limited to the data collected weekly by each unit.

The number of patients covered by ART has increased substantially since the start of the programme, although not all those in need receive counselling and treatment. Between March 2004 and May 2005; 77,352 HIV+ adults and children were tested for CD4 and 37,564 were found to have CD4<200. A total 13,132 started to receive ART. Because the number of eligible patients are those ones with CD4<200, these numbers might suggest that the coverage of the eligible patients with ART might be around 35%. However, after controlling for data problems the real coverage is likely to be about 51%.

Because of the different time frame in which the above patients entered and left the ART, it was necessary to estimate rates on the basis of the person year of observation. The annual interruption, mortality and side effect rates were respectively 7, 10 and 22 per 100 person years of observation.

The major problem faced by the ART programme is the under-coverage. The data suggest that counselling does not cover all patients tested for CD4 but it is mainly limited to patients diagnosed with CD4<200 and are eligible for ART. About half of the eligible patients are covered with ART, confirming the presence of a waiting list. The reasons for the low coverage, which may be due to absorption capacity, need to be investigated. There is also a need to improve the quality of the weekly indicators and to limit the data collection to the variables that are required to identify problems amenable to change through management actions.

Background

The Antiretroviral Therapy (ART) has resulted in a uniformly fatal condition being converted to a chronic disease. ART reduces the HIV replication allowing the regeneration of the patient's immune system, however the virus is not completely eradicated and the medication needs to be taken for life. Because adherence to medication is a crucial factor in reducing the development of resistance to ART, ensuring compliance and reducing the number of defaulters is of critical importance.

Major problems of ART are access and compliance. Because of the limited access, in December 2003, the World Health Organisation (WHO) published a policy document outlining a plan to bring ART to 3 million people in developing countries by the end of 2005, the '3 by 5' initiative. Although ART programmes have become more widespread (Barnett & Whiteside: 338), according to the latest estimates from UNAIDS for 2005 only 970,000 patients were covered with ART against an estimated 6.5 million in immediate need. ART requires a high level of adherence (e.g. $\geq$ 95%) to maintain a durable suppression of viral load (Bangsberg *et al.*, 2000; Montaner *et al.*, 1998 & Paterson *et al.*, 2000). It is therefore extremely important that any facility involved in distributing ART ensures adherence and trace defaulters.

When ART was introduced in South Africa, a review of the healthcare facilities was undertaken to assess their resource base and suitability to provide this service (accreditation). The accreditation consisted of several steps to assess a clinical site's readiness to administer ART as defined by the National Department of Health's Operational Plan of 19 November 2003. Potential ART sites were assessed according to minimum standards, which included infrastructure, data capability and personnel. A strengthening plan was implemented to ensure that the sites falling below the minimum standards were following the guidelines.

In KwaZulu-Natal (KZN), the ART rollout programme started in March 2004 and involved the regimens outlined in Table 1 below. Regimen 1a is dispensed to all adult patients excluding females who still intend to bear children as well as male shift workers for whom regimen 1b is used. Regimen 2 is given as a second line drug when regimen 1a and 1b fail. There are two paediatric regimens till the age of 3 years and two other regimens for older children.

After the accreditation of the initial 8 sites, the ART programme was gradually expanded and by May 2005 there were 49 sites distributing ART. In addition, clinics falling under most of these facilities were also included in order to reduce the workload as well as to increase accessibility.

Table 1: ART regimens for adults and children			
Adults patient regimen			
Regimen 1a	**Regimen 1b**	**Regimen 2**	**Special Regimen**
• Lamivudine (3TC) • Stavudine (d4T) • Efivarenz (EFV)	• Lamivudine (3TC) • Stavudine (d4T) • Nevirapine (NVP)	• Didanosine (ddI) • Zidovudine (AZT) • Lopinavir/otonavir (LPV/r)	• Any combination of treatment as a replacement of drugs from 1a or b
Paediatric patient regimen			
Regimen 1		**Regimen 2**	
<3yrs	**>3yrs**	**<3yrs**	**>3yrs**
• Lamivudine (3TC) • Stavudine (d4T) • Kaletra	• Lamivudine (3TC) • Stavudine (d4T) • Efivarenz (EFV)	•Didanosine (ddI) •Zidovudine (AZT) •Efivarenz (EFV)/ Nevirapine (NVP)	• Didanosine (ddI) • Zidovudine (AZT) • Kaletra

Objectives

The aim of this issue of the Epidemiology Bulletin is to describe the patient information system of the ART programme and to analyse the information collected by the weekly reports between March 2004 and May 2005.

Introduction

There are two separate information systems for the ART rollout in KZN. The first one is based on individual information collected through patient forms, as outlined in Table 2 below. The second system is based on weekly indicators, which are aggregated through a weekly status report form that is submitted to the Epidemiology and Health Indicator Unit of the DoH. The weekly form summarizes the status of the weekly activities and has been modified to facilitate the compilation of the required information and to meet the requirements of the National Department of Health. Both data collection systems are described although the present analysis deals only with the data collected through the weekly form.

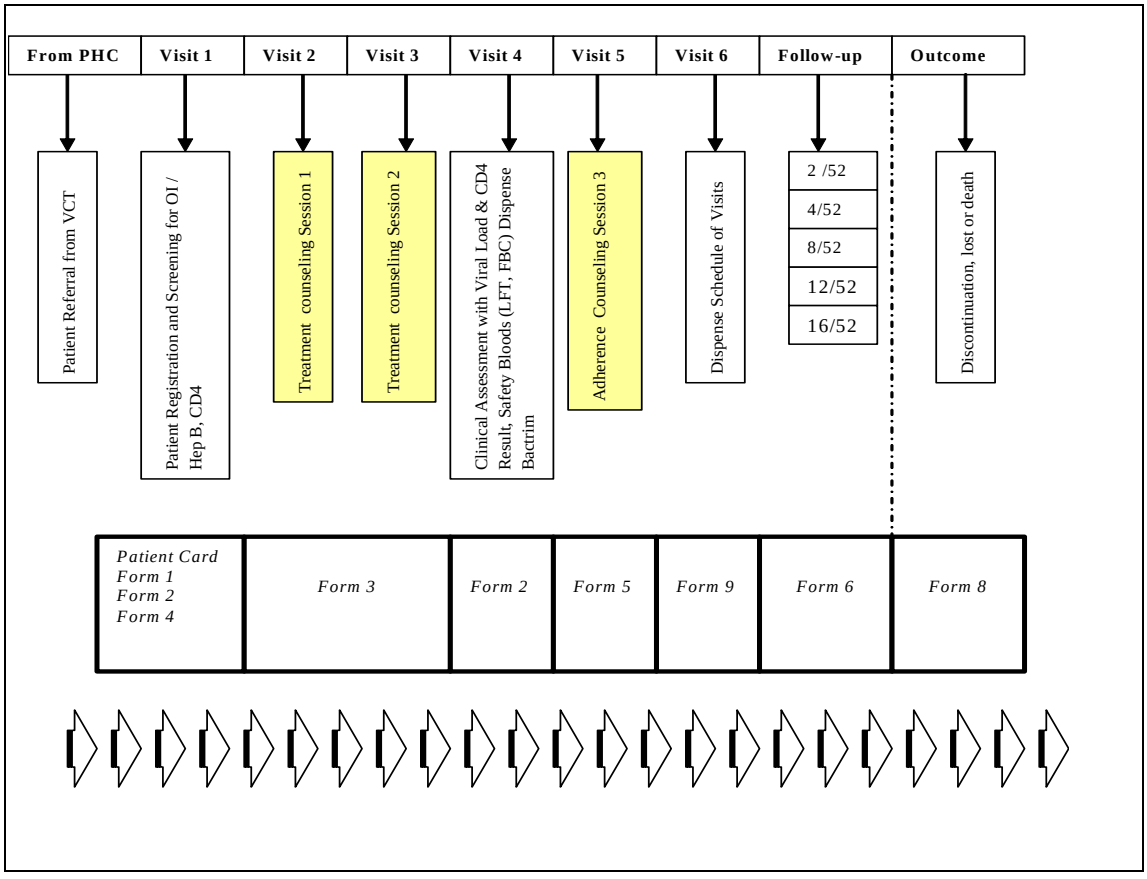
Table 2: Adult and Paediatric patient forms	
Adults	**Paediatrics**
Form 1: Adult Patient Registration	Form 1: Paediatric Patient Registration
Form 2: Adult Baseline Clinical Examination	Form 2: Paediatric Baseline Clinical Examination
Form 3: Adult Patient Counselling form	Form 3: Paediatric Patient Counselling form
Form 4: Adult Baseline Laboratory Results	Form 4: Paediatric Baseline Laboratory Results
Form 5: Adult initiation/change of treatment	Form 5: Paediatric Prescription form
Form 6: Adult Patient follow-up	Form 6: Paediatric patient follow-up
Form 7: Adult Patient transfer form	Form 7: Paediatric inter-hospital transfer form
Form 8: Adult Patient Exit form	Form 8: Paediatric Patient Exit form
Form 9: Checklist	Form 9: Paediatric Checklist
Adult visit summary	Paediatric visit summary

Individual patient forms

The individual forms are designed to improve the management of each patient during the different components of care. The data collected on the individual forms in Table 2 aim at monitoring the pathway followed by the individual patient (Figure 1). The process starts with the HIV positive patient being referred from any health service to the ART clinic. The referred patient has to provide a South African identity document (in the case of adult patients) or a birth certificate (for children) in order to be registered. Pregnant women without an identity document may use the Prevention of Mother to Child Transmission barcode.

The patient is then registered and followed up through the individual forms depicted in Figure 1. Having filled in Form 1, the patient undergoes various screening tests to measure CD4 and liver functions (LFT); and to diagnose TB, opportunistic infections (OI) and Hepatitis B. Before the CD4 results are received, the patient should attend treatment literacy sessions 1 and 2 in the second and third visit. A patient with CD4 count less than 200 or with advanced stage of AIDS, according to the World Health Organisation staging is enrolled into the ART programme. After the eligible patients have attended adherence counselling and have been reviewed by the clinician, they begin ART and are followed up through a series of laboratory tests. A patient booking system is used to manage the large number of patients requiring ART and a waiting list is maintained for those qualifying for treatment.

Figure 1 Patient pathway for antiretroviral rollout in KwaZulu-Natal



Although the individual patient forms were designed and distributed to all facilities that are currently rolling out, data have not been entered yet in electronic format. The staff filling the individual forms include administrative clerks for Forms 1 Form 7, counsellors for Forms 2, 5 and 6; clinicians for forms 3 and 8 and the clinician together with the clerks for Forms 4 and 9. The backlog of patient information to be captured is quite substantial whilst the number of patients enrolling into the programme is increasing daily. Attempts have been carried out to speed up the transfer of the information in electronic format in a few hospitals. A pilot project on Medicom system was carried out at Greys Hospital from the last quarter of 2004 and was further installed for use at Edendale, King Edward VIII and Mahatma Gandhi Memorial Hospitals. The installation and use of the system was suspended at the above-mentioned new sites due to technical problems and limited local technical support.

The individual paper forms have been affected by problems. Site staff has expressed concerns about the excessive number and different types of forms that need to be filled. Furthermore, when the individual forms were changed, some sites have continued to use the older ones because they were considered more user-friendly. The existence of different sets of forms is likely to complicate the data entry.

Weekly Status reporting

ART Service Points summarize the information from their registers into the "Weekly Status Report" form. The form (see Annex) contains information about the weekly number of patients being screened and counselled, beginning ART, having side effects, discontinuing and dying. The deadline for faxing the forms to the Epidemiology and Health Indicator Unit is every Tuesday. The data are captured in a Microsoft Access database developed by the Epidemiology and Health Indicator Unit, which produces descriptive statistics for the ART programme manager and the National Department of Health.

Methodology

The weekly data analysed in this issue covers the period between March 2004 and May 2005. Queries were generated in the MS Access database to extract the information related to CD4s screened, CD4 less than 200, patients initiated on treatment, patients developing side effects, patients discontinuing or interrupting treatment, patients lost to follow up and dying. Frequency statistics were produced to provide a description of the progress of the rollout programme and to discuss the limitation of the data derived from the weekly forms. Because the patients entered and left the ART programme at different points in time, the rates for death, interruption and side effects were based on the person month of observation (PMO) and person year of observation (PYO). The number of PMOs was estimated according to the patients reported to be under ART each month. This number was updated each month by adding up the patients surviving the previous month to the new patients enrolled during that month and by taking into account that the patients leaving ART during the month were on average exposed for half of the time. For example, the 12,322 PMO in May 2005 was derived by: (10,092+2311-(161/2)) where 10,092 were the patients surviving the month of April 2005; 2,311 were the

new patients enrolled under ART in May 2005 and 161 were the patients who left the programme in May 2005 because of deaths, interruption and lost to follow up and therefore contributed an overage of 0.5 month each. The total PMOs were used as denominator for the monthly rates of deaths, interruptions and side effects. The total PMOs divided by 12 provided the denominator for the rates per PYO. Because each PYO is equivalent to a person who was under ART for a whole year, the use of PYOs as denominator takes into consideration that patients entered and left the programme at different points in time and can be used to estimate the yearly rates for mortality, termination and side effects.

Results

From the initial 8 sites accredited in March 2004, the sites distributing ART reached the number of 49 in May 2005. Each ART site is composed of one hospital, and some community health centres (CHCs) and clinics within the catchment area of the hospital. The data from clinics are incorporated into the weekly forms of the hospital to which they belong, while the CHCs report independently as standalone ART sites. For example clinics linked to Edendale Hospital should ideally send their data to Edendale Hospital, which integrates them into its weekly forms, while Imbalenhle CHC reports on its own.

Figure 2 shows that, with the exception for the initial period, most of the facilities have regularly submitted their data. At the beginning of the ART rollout, the proportion of facilities sending the weekly forms declined in the second month. The lower compliance during the initial months was due to the fact that there were changes in the weekly form and in the data requirements. Attempts were made to solve this problem but some sites were unable to obtain some of the data required by the new weekly form. Another problem was that even when reporting improved after April 2004 these reports were received after several weeks from the deadline. Most delays in submission were reported to be due to high levels of workload at facility level. Because only a few units were involved in the first few months, overall completion between March 2004 and May 2005 was in the order of 96% and therefore the initial under-reporting has not had substantial consequences.

Figure 2 Proportion of reports received

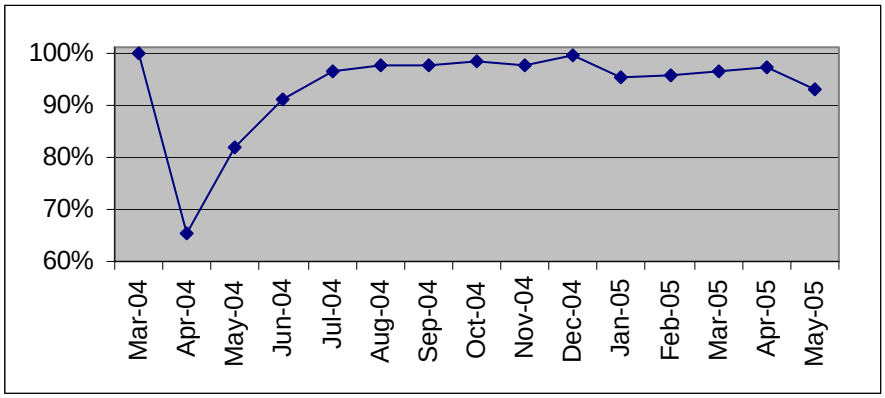
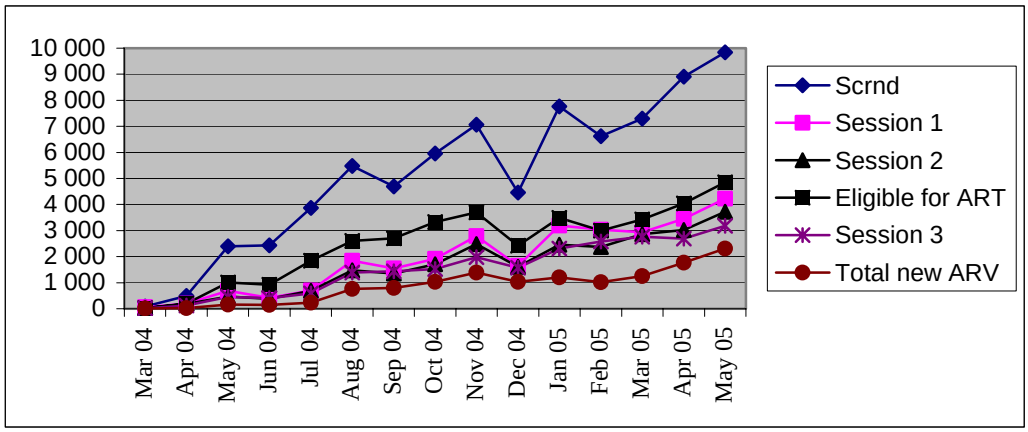


Figure 3 shows the trends in the indicators of the ART programme between March 2004 and May 2005. The number of patients who were screened for CD4, underwent counselling sessions 1, 2 and 3 and were enrolled under ART has substantially increased between March 2004 and May 2005. The irregular fluctuations are not so much due to irregularity of reporting but to the fact that in such a monitoring system it is inevitable to have some reliability problems related to the reported data. However, even with these limitations, the data from the weekly indicators are critical to quantify the increasing workload. The patients screened for CD4 per month have gradually increased from 81 to 9,837, and the patients starting ART per month have increased from 11 to 2,311 between March 2004 and May 2005.

Figure 3 Number of new patients per month



Although coverage has gradually increased there are still many eligible patients who are not under ART. Figure 3 shows that the line related to the new patients per month that are considered eligible according to CD4<200 was above the lines for counselling and ART, suggesting the presence of under-coverage.

Table 3 shows the cumulative numbers of patients covered with ART between March 2004 and May 2005. A total of 13,132 adults and children were treated with ART and the majority were women, which might be due to the fact that women are traditionally more in contact with the health care system. While proportionally more males were assigned to Regimen 1a, females were equally covered by Regimen 1a and 1b. There was no difference between male and female children both in terms of total numbers on ART and type of regimen.

Between June 2004 and May 2005, the interruption and the mortality rates were relatively stable. Figure 4 shows the monthly rates for side effects, deaths and interruptions starting from June 2004. The rates related to March-May 2004 are not shown because they were affected by wide fluctuations, which were the likely result of the initial small numbers and the higher unreliability of the reporting system in the first few months of the ART programme. Between June 2004 and May 2005 the average monthly default and mortality were relatively stable at respectively around 0.8 and 0.6 per 100 person months of observation. On an annual basis, the rate per

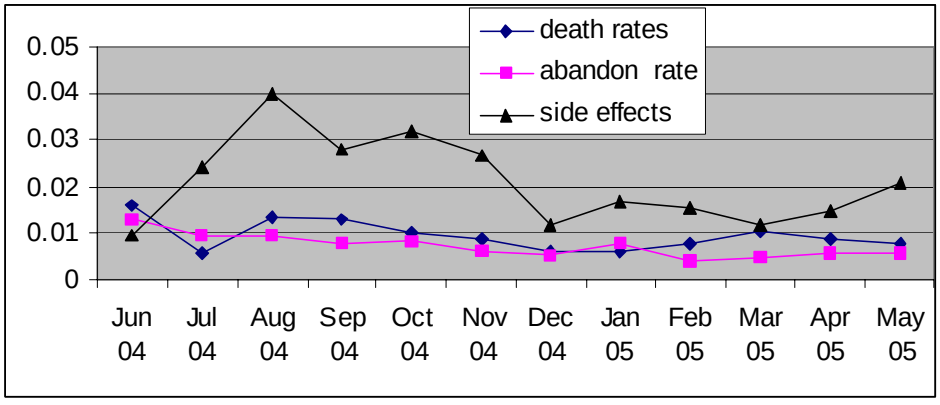
person year of observation was about 7% for interruption and about 10% for mortality.

Table 3 Number of patients starting ART between March 2004 and May 2005

Adults							
	Males	**%**	**Females**	**%**	**TOTAL**	**%**	
Regimen 1a	2 982	80.9%	3 985	47.9%	6 967	58.0%	
Regimen 1b	679	18.4%	4 264	51.2%	4 943	41.2%	
Regimen 2	11	0.3%	21	0.3%	32	0.3%	
Special Regimen	15	0.4%	50	0.6%	65	0.5%	
	3 687	**100%**	**8 320**	**100%**	**12 007**	**100%**	
Paediatrics							
		Males	**%**	**Females**	**%**	**TOTAL**	**%**
<3yrs Regimen	Regimen 1	125	22.3%	110	19.4%	235	20.9%
	Regimen 2	9	1.6%	6	1.1%	15	1.3%
>3yrs Regimen	Regimen 1	420	75.0%	445	78.8%	865	76.9%
	Regimen 2	6	1.1%	4	0.7%	10	0.9%
	TOTALS	**560**	**100%**	**565**	**100%**	**1 125**	**100%**

The weekly monitoring system is unlikely to provide reliable estimates of the frequency of side effects. In the weekly form, the number of side effects is recorded according to four grades, however the monthly frequency of the four grades had such a high variation that was not usable. Therefore, it was decided to plot the monthly rates for all the four grades of side effects, which although had a lower variation, showed still a wide monthly fluctuation especially between June and November 2004. The overall annual rate for any side effects was around 22 per 100 person years of observation, which is relatively low for such a toxic therapy. Besides the overall under-estimation, the main problem of the reporting of the number of any side effects is its high unreliability when it is disaggregated by site. If each site is considered, the weekly variation of the number of side effect reported is so wide that it cannot be used for any monitoring purpose. Therefore, this type of indicator should be left out of the weekly forms and its frequency should be analysed through the data collected through the individual forms.

Figure 4 Monthly outcome rates



Reliability of the data related to coverage

Because one major objective of setting up such a monitoring system is to estimate coverage, this section deals with some potential problems related to coverage estimation. The coverage is obtained by dividing the number of counselling session for adherence (S3) and the number starting ART by the number of eligible patients. The numbers related to the patients who have undergone S3 or have started ART can only be counted once because these events happen once. However, this may not be always the case for the number of eligible patients because this is derived by counting the number of "patients with CD4<200". Although the criteria of the recording system is to count only the numbers of "new patients" at their first CD<200 each week, this does not exclude the possibility that this number consist of all the tests which in a given week resulted in CD4<200. In the first case, the number will consist of patients counted only once, in the second case the number will also include patients who are already under ART and who are re-tested in the follow up visits. Therefore it will be possible to have clinics correctly reporting only the new patients with CD4<200, and other clinics reporting all CD4<200 tests which will result in an inflation of the number of "eligible patients" and an underestimation of coverage.

A variable interpretation of the above criteria across units will create lack of comparability in coverage. For the clinics that are correctly reporting only the new CD4<200 there are no problems, because the coverage is derived by dividing the number of S3 and ART (numerator) by the number of patients newly diagnosed with CD4<200 (denominator). In other words both the numerator and the denominator will be based on individual patients, which have been counted once. For the clinics, incorrectly reporting all the CD4<200, including the patients already under ART and who are re-tested in the follow up visits, the coverage will be under-estimated because the denominator will be inflated by patients who are counted more than once.

Figure 5 and 6 provide an example of what might have happened because of the different interpretation of the above reporting criteria. Figure 5 shows the proportion of eligible patients, which were covered with ART by district. Sisonke and uMzinyathi had more than 100% coverage because the number of patients starting ART was higher than the number of eligible patients. Most of the other districts had coverage in the order of 40%-80% while Zululand, eThekwini and uThungulu had a lower coverage.

Figure 5 Coverage of eligible patients with ART

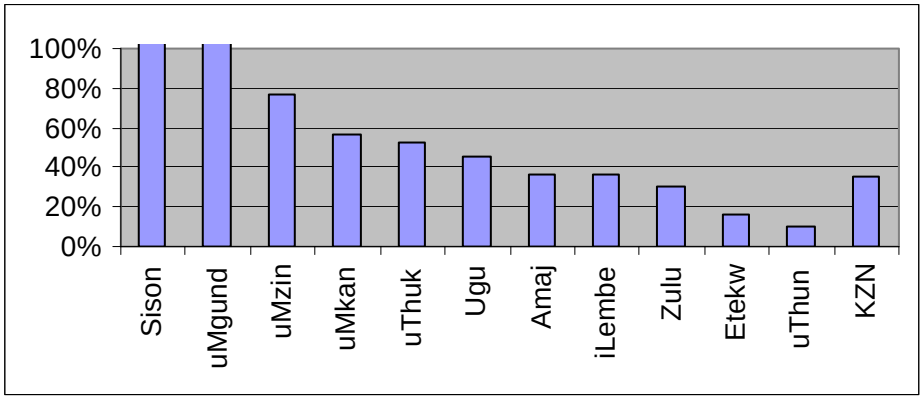
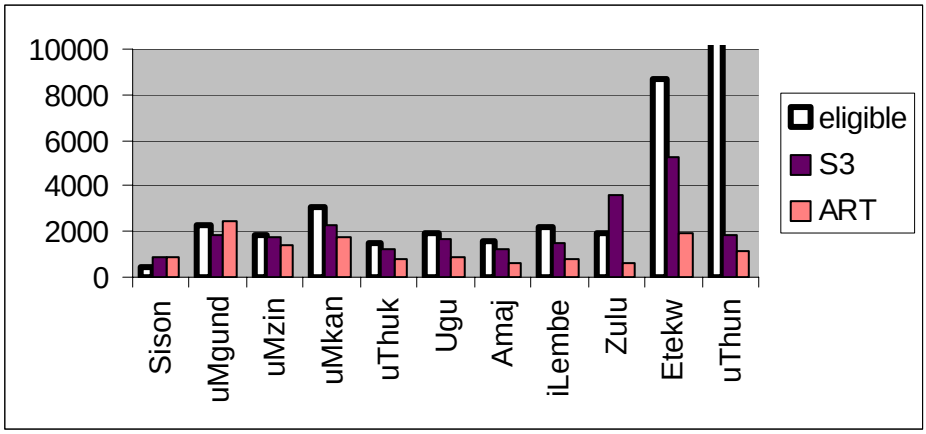


Figure 6 helps to understand how some of the above coverage rates might have been created because of different interpretation of the reporting criteria. Each district has three bars indicating respectively the total numbers of eligible patients, S3 and ART. Because of the rationale mentioned in the previous paragraphs, while there is no doubt that for each district, the second and third bar (S3 and ART) are related to number of new patients, while the first bar might be related to the number of eligible patients (first CD4<200) but it might also represent the number of tests with CD4<200. Looking at each district, the three bars of Figure 6 allow to identify the following patterns:

(a) For Sisonke and uMgungundlovu the first bar (eligible patients) is lower than the third one (ART) and this could be due to under-reported number of eligible patients or extra coverage to patients who were not eligible. These two possibilities caused coverage higher than 100%.
(b) For eThekwini and uThungulu the first bar (eligible patients) is several times higher than the third bar (ART) and this is likely to be related to the already mentioned problem of reporting the number of all tests with CD4<200 instead of the number of new CD4<200.
(c) For uMzinyathi, uThukela, Ugu, and Amajuba, the number of eligible patients is very similar to the number of S3, suggesting that the first bar indeed represents new CD4<200 and not number of tests CD<200. For uMkhanyakude and iLembe the number of eligible patients is slightly higher than the number of S3, which might be a genuine sign of undercoverage for counselling or it may be due to slight over-reporting of eligible patients. Zululand had an unusual high reporting of S3 compared with the number of eligible patients, while the number related to ART was very low, suggesting that there may be problems with the data.

Figure 6 Eligibles, S3 and ART by districts



The above situation can be summarized into three different patterns of reporting, which are better clarified by examining the monthly numbers of eligible S3 and ART. The first reporting pattern is shown in Figure 7, which represents the aggregated monthly numbers for both Sisonke and uMgungundlovu. It can be noticed that the eligible patients are related to new patients with CD4<200 because the monthly

numbers of eligible patients are very similar to the numbers of S3. The fact that at every month, there is a consistent higher number of patients starting ART compared with the number of eligible patients and S3 suggests over-reporting of ART. This caused the overestimation of coverage shown in Figure 5 for these districts.

Figure 7 Likely under-reporting of eligible patients

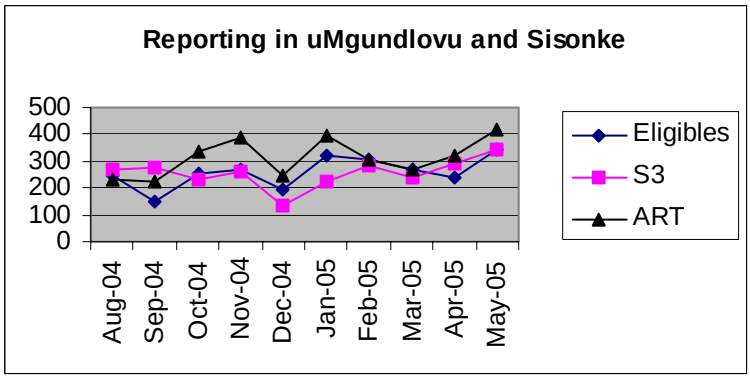


Figure 8 Likely over-reporting of eligible patients

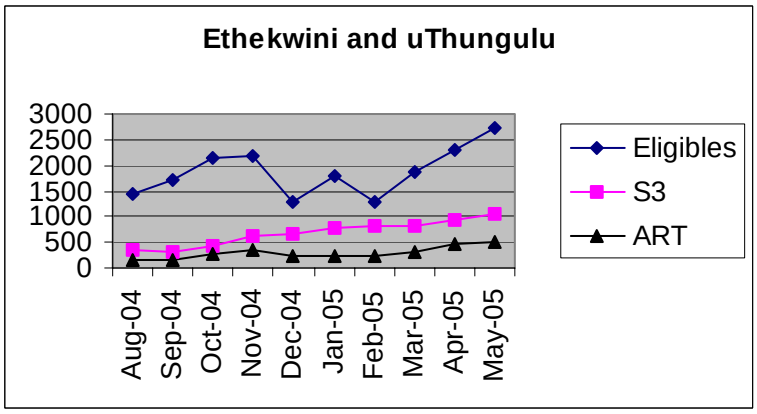
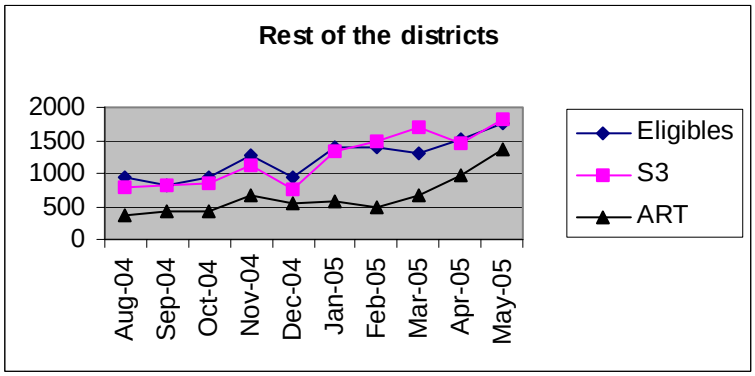


Figure 9 Likely reliable reporting of eligible patients



The second reporting pattern, shown in Figure 8, represents the combined monthly reports from eThekwini and uThukela. The fact that the number of eligible patients is several times higher than the number of S3, suggest the possibility that these numbers are not related to the new CD4<200 but to the total CD4<200 including the repeated tests conducted on already recruited patients during the follow up visits. This is also suggested by the exponential increase of the number of `eligible patients` after February 2005. This created the under-estimation of coverage for these two districts shown in Figure 5.

The third pattern of reporting shown in Figure 9 is the combined monthly numbers from the rest of the other districts. In this case the monthly numbers of eligible patients are very similar to the numbers of S3 and therefore they are likely to be related to new patients with their first CD4<200. The slope of the monthly increases in the number of new ART is very similar to the slope of the increase of S3 and eligible patients, reinforcing the impression that the number of eligible patients are new CD4<200. If only this last group of districts is used, the ART coverage is around 51% compared with 35% if the whole sample of KZN is used. Therefore, when the numbers are limited to the most reliable districts, the coverage of ART slightly increases but it is still limited to about half of the eligible patients.

The above figures show that the assumptions that the number of CD4<200 represents eligible patients might not be true for all the sites. For example, the number of eligible patients in eThekwini and uThungulu was several times greater than the number of S3 and ART patients. This is likely to have been created by the reporting of all the CD4<200, including the already recruited patients who have been retested several times during the follow up visits. This situation, besides providing an unlikely very low coverage for these two districts, bring down the coverage for the whole province because of the false high number of eligible patients contributed by eThekwini and uThungulu. This situation impairs the achievement of the major objective of the weekly monitoring system, which is to show how many eligible patients are covered with ART.

Discussion

The weekly monitoring system has been set up to check the progress of the ART programme in terms of workload, coverage and impact. Between March 2004 and May 2005, there were 77,352 CD4 tests, 37,564 CD4<200 and 13,132 patients who started ART. In terms of impact, the frequency of interruptions, side effects and mortality was respectively 7, 22 and 10 per 100 person years of observation. Although the exact estimate of coverage of the eligible patients with ART is affected by reliability problems, it is likely that about half of the eligible patients have been covered with ART.

The function of such a monitoring system is to warn about potential problems but it does not have sufficient information to diagnose the causes of the problems and the relative solutions. The first function of such a monitoring system is to identify which clinics may have unreliable reporting so that these clinics can be visited to find out reasons and suggest correction of the reported data. It is only after the data are checked that it is possible to identify the clinics with lowest coverage and the highest

frequency of default, side effects and mortality to find reasons and take actions. In this context, the monitoring system should have a managerial focus, and each variable being collected should envisage specific actions. Such a system of data collection is not suitable to collect information to achieve epidemiological objectives such as to test certain hypotheses. Such an epidemiological focus should be reserved for the second type of information system that is actually collecting detailed information on individual patients.

The first priority is to clarify the objective of the present weekly monitoring system. If the system was conceived with a management objective in mind, the questions to be asked should include the following: (a) is the information linked to action ? And (b) Was any action taken as a consequence of the weekly indicators?

Management objectives

The reply to the first question depends on the clarity of the objectives behind the data collection. If the initial objective was to monitor coverage of eligible patients with ART, the numerator should have consisted of new patients started on ART and the denominator should have consisted of new CD4<200. As shown by the Annex, the present weekly form contains the "No. of patients screened CD4" and "Patients with CD4<200". Although the intention may well have been to collect new CD4<200 only, as already shown in the last section of the results some units may have interpreted this information as related to new patients but other clinics may have included re-tested patients too. To avoid this potential problem, the weekly forms should specify "new patients screened", "new patients with CD4<200", "repeated CD4 tests" and "repeated CD4<200" among ART patients coming back for follow up visits. In case this is not possible, the priority should be to collect the number of new CD4 and new CD4<200.

The indicators related to the outcomes are critical to assess the impact of the ART but they should be interpreted taking into account the difficulty in obtaining this information. Reporting side effects through the weekly form is not realistic because of their high variation, especially if the numbers are disaggregated by site. Other problematic variables are the number of patients who discontinue, restart or are lost to follow up. Last but not least, mortality is likely to be under-estimated in those sites experiencing a high default rate because it is a challenge to obtain information on the deaths of these patients, if the supporter or the patient is not reachable.

Any information not related to management actions should be reserved to the data collected on the individual modules. Although the introduction of the disaggregated paediatric information could have its own justification on the epidemiological point of view, any analysis for hypothesis testing should be limited to the individual modules. Furthermore, the analysis has not found any difference between male and female children and between children of different age groups. Therefore, the information on the weekly form could be limited to the number of total children under treatment without disaggregation by age and gender.

The quality of the data should be routinely checked and corrected. The central level should identify outliers so that the clinics can be contacted to recheck their numbers. The units with a weekly variation exceeding several times the provincial variation

could be singled out as likely outliers. The technique was already described for the hospital information system in Issue 9 of the Epidemiology Bulletin and the Epidemiology Unit could apply it to the data of the weekly monitoring system.

Once the reliability of the data has been checked and corrections have been carried out, the data can be used to identify clinics with low coverage or high frequency of negative outcomes. Because such information system is an early warning system it does not have sufficient information to identify reasons behind problematic clinics and extra data will be required to find out the causes and the solutions.

Way Forward

Although the weekly reports are regularly submitted, they should be timelier. With the exception for the first few months, submission has not been a problem but the reports have not been submitted on time. This may defeat the purpose of using the data as an early warning system of impending problems.

The major problem remains the reliability of the submitted data. The wide fluctuations seen in the monthly numbers suggest that the aggregation of numbers at the end of each week is not always done consistently and it may lead to over and under counting of individual variables. This may be related to the above-mentioned problems of unclear definitions leading to misclassification. There is a need to verify how consistently the data capturers apply the definitions for all these variables.

A major challenge, that is very common in many monitoring systems, is the lack of interest and incentives in reporting. Involving the staff at the periphery in gathering information to produce indicators that should be used to improve programme's activities is not simple. The theoretical assumptions behind the data collection do not always work as planned because staff may be overworked and may not consider this extra task as a priority. It has to be considered that gathering statistics at the end of each week is likely to be seen as a bureaucratic imposition from the top, which is not a felt need at the periphery.

Aggregating data requires time, incentives, interest and a standardized method. If these elements are missing, it is likely that the staff will take the short cut and will put numbers on the forms that do not always reflect real data. This attitude may be reinforced by the infrequent use of the indicators for action and the lack of feedback to make the periphery aware that the data are leading to solutions to improve programme's activities.

The Epidemiology Unit and the Management of the ART programme will have to tackle the above problems in a pragmatic way. Management should revisit the objective of the data collection to review how the present information has been recently used for action and how this led to improvement of activities. Some indicators may not be negotiable because they are requested from the national level but the provincial level should focus their attention and energy on improving primarily the indicators required for action.

Therefore the first decision should be to identify which indicator should be prioritized. For example, it may be difficult to justify the permanence of four different types of

side effects or disaggregated information on children into gender and age groups if this never led to any specific action and it is unlikely that it will be used for specific action in the future.

Reliability of reporting does not depend on training only but on several other factors. In June and July 2005, a training workshop on monitoring and evaluation was held with all the ART hospital clinics in KwaZulu-Natal to address the above problems. However, training per se is insufficient to improve the system if motivation to collect indicators will continue to be low and if the staff will continue to feel that the statistics they produce is not linked to the potential improvement of their working conditions, such as more resources according to workload.

Another problem is the lack of a standard way to aggregate the weekly data. Leaving up to each clinic the decision on what method to use to aggregate the numbers at the end of each week is likely to lead to inefficiencies and inconsistencies. The aggregation should be based on a standardized paper register in which each row would represent a new patient and each column would represent the variables that will be ticked. At the end of the week, this information could be transferred in an Excel spreadsheet to provide the summary of the weekly numbers. The Excel files could then be electronically transferred to the Epidemiology Unit, reducing the workload and reducing the mistakes.

The Epidemiology Unit should device a method to identify clinics reporting unlikely weekly numbers. As already mentioned, for each variable the weekly variation of the numbers reported by each unit could be compared with the overall provincial variation. This could be based on the same method introduced in Issue 9 of the Bulletin to identify outliers for the hospital information system. The outlier clinic should then be contacted to find out what are the reasons and requested to validate the numbers reported.

In conclusion, the current weekly monitoring system should be treated as an interim warning system. Although very useful to monitor progress in several indicators, the system should be streamlined according to the steps described in the previous paragraphs including:

- Revisit the objectives of the weekly system and focus the efforts in improving the indicators that can lead to specific actions;
- Compile guidelines on how the data should be collected and validated, and utilize the Facility Information Officers to ensure that the data are captured accordingly;
- Develop a standardized format for the data aggregation at clinic level;
- Monitor the quality of the submitted data, identify outliers and contact the units submitting problematic information for prompt correction; and
- Use the indicators to identify clinics with low coverage and frequency of negative outcomes to verify the reasons and suggest specific actions.

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Issue 9. Epidemiology Bulletin. Hospital utilization in Kwa-Zulu-Natal in FY03/04-FY04-05. DOH. March 2005.

ANNEX - WEEKLY FORM

FAX COMPLETED FORM TO 033-345 3527

ARV ROLLOUT PROGRAM

Department of Health
330 Longmarket Street
Pietermaritzburg, 3201
Phone: 033 - 395 3070
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Weekly Status Report (Version 5)

Facility: _____ Start Date of Treatment Site: / / 20

Project Manager: _____

District (*Tick*): Ugu ☐ uMgungundlovu ☐ uThungulu ☐ uThukela ☐ Sisonke ☐ iLembe ☐ eThekwini ☐ uMkhanyakude ☐ uMzinyathi ☐ Amajuba ☐ Zululand ☐

Reporting Period: Monday - / / 20 to: Friday - / / 20

ADULT PATIENT INFORMATION

No. of patients screened CD4: M ☐ F ☐ Patients with CD4 < 200: M ☐ F ☐

No. of patients in treatment readiness assessment phase:

Session 1: ☐ Session 2: ☐ Session 3: ☐

No. of patients started on ARV this week (*as per report period*):

Regimen 1a:	M		Regimen 1b:	M	
	F			F	
Regimen 2:	M		Special Regimen	M	
	F			F	

TOTAL No. OF PATIENTS ON ARV FROM START DATE:

Regimen 1a:	M		Regimen 1b:	M	
	F			F	
Regimen 2:	M		Special Regimen	M	
	F			F	

No. of women enrolling whilst pregnant		No. of women falling pregnant on treatment					
No. of patients developing side effects:	Grade 1		Grade 2		Grade 3		Grade 4	

No. of patients restarting treatment *(after discontinuation/interruption)*:	M	Explain:
	F	Explain:
No. of patients discontinuing/interrupting ART:	M	Explain:
	F	Explain:
No. of patients on treatment lost to follow-up:	M	Explain:
	F	Explain:
No. who died this week before Treatment:	M	Explain:
	F	Explain:
No. who died this week while on Treatment:	M	Explain:
	F	Explain:

PAEDIATRIC PATIENT INFORMATION (children less than or equal to 14 years)

Date started on paediatric patients ARV treatment: / / 20 Caregivers counselled this week: M ☐ F ☐

Paediatric patients screened this week:	M		Paediatric patients eligible for ARV:	M		Patients from PMTCT (Nevirapine exposed):	M	
	F			F			F	

Paediatric patients started on ARV this week:

Regimen 1	d4T+3TC+ LPV/r (<3yrs)	M		Regimen 2	ddI+AZT+EFV/ NVP (<3yrs)	M	
		F				F	
	d4T+3TC+EFV (>3yrs)	M			ddI+AZT+ Kaletra (>3yrs)	M	
		F				F	

TOTAL No. OF PAEDIATRIC PATIENTS ON ARV FROM START DATE:

Regimen 1	d4T+3TC+LPV/r (<3yrs)	M		Regimen 2	ddI+AZT+EFV/ NVP (<3yrs)	M	
		F				F	
	d4T+3TC+EFV (>3yrs)	M			ddI+AZT+ Kaletra (>3yrs)	M	
		F				F	

Paediatric patients developing side effects:	Grade 1		Grade 2		Grade 3		Grade4	

Paediatric patients restarting ART *(after discontinuing / interrupting)*:	M	Explain:
	F	Explain:
Paediatric patients discontinuing / interrupting ART:	M	Explain:
	F	Explain:
Paediatric patients on treatment lost to follow-up:	M	Explain:
	F	Explain:
Paediatric patients who died before treatment:	M	Explain:
	F	Explain:
Paediatric patients who died while on treatment:	M	Explain:
	F	Explain:

FIO: _____ Filled in by: _____ Date: / / 20

Weekly Status Report Form *KwaZulu-Natal* *Updated on: 3/11/2005*