

M A R C H

Lesotho Medical Association Journal

2 0 0 8



V O L U M E 6



N U M B E R 1

Lesotho Medical Association Journal

VOLUME 6; NUMBER 1 - MARCH 2008

Table of Contents

PRESIDENT'S NOTE	2
EDITORIAL	
A Giant Step	3
<i>M Mokete</i>	
CLINICAL UPDATE	
Management of Treatment Failure	4
<i>PJ McPherson</i>	
RESEARCH ARTICLES	
An Experience of Antiretroviral Therapy in Resource Limited Settings	9
<i>MIV Nagesh</i>	
Diagnosing HIV/AIDS Treatment Failure at Senkatana Centre	14
<i>A Tiam, H Osman, M Malimabe</i>	
DISCUSSION PAPER	
Decentralisation and the Health Sector in Lesotho: Issues to Consider	18
<i>K Lerotholi</i>	
HISTORICAL REVIEW	
From PHAL to CHAL and Beyond	27
<i>M Mokete</i>	

From the President's Pen

Colleagues,

Having started the new year with the opening of our website, it is with zest that we endeavor to reach the international community with the modern ways of communication as well as identify with those of our colleagues in other countries who may not have the same facilities as us but with whom we may interchange the continuance of medical expertise, which is a dynamic ever growing ambit of new diseases, new modalities of therapy and new discoveries by those in the observing forefront. As we salute our medical fraternity, we share a common hope of ever strengthening our fraternal bonds, the common ground from which we still project health care for all even before the year 2020.

Long live L.M.A.

Dr. A.M. Mojela

Editors

Dr. M. Mokete
Dr. Mohapi
Dr. Lekhanya

Instructions for Authors

The Lesotho Medical Association Journal accepts editorials, original research papers, review papers, case discussions, clinical guidelines, letters and Lesotho medical news reviews.

The author should submit both an electronic and hard copy of the manuscript to the address below:

Lesotho Medical Association Journal
Dr. Musi Mokete
P.O. Box 588
Maseru 100
musi@lesoff.co.za



Cover: Semonkong, November 2007

A Giant Step

M MOKETE, MD

The Ministry of Health has taken a giant step towards quality health in Lesotho in the year 2008. This step has resulted in the memorandum of understanding with the Christian Health Association constituting hospitals and clinics run by Lesotho Churches. The agreement with the church institutions brings a lot of relief to them as the overseas support hitherto backing them has been increasingly dry for the last two decades.

The current memorandum assures the church institutions, which were responsible for 40% of health services, of uniformity in health services provision, and raises the overall benchmarks in terms of the reorganization and reclassification of the services offered on the basis of the capacity of each institution whether Government or church related.

In point of fact, the impact on the affordability and accessibility of primary health care will be felt by the ordinary man who will get free services at the local clinics. There will still have to be very big efforts to overcome the two hour travel goal to the clinics as that is far from quality health in terms of the travel strain within the topography of Lesotho which becomes an even bigger hurdle for a very sick person who has to make a to and fro journey totalling four hours.

Yet another bold step is that of the “know your status” campaign in addressing the HIV and AIDS challenge with the people of Lesotho. This has taken off so well that we, service providers, have appreciated the ease it has made of approaching clients. It is a feather in the cap of the Government effort in combating HIV and

AIDS which should be kept up to maintain the extraordinary momentum and progress among the many countries facing the challenge of the pandemic.

A cherry on top of the cake is the ushering in of a four year family medicine specialization which will, again no doubt, boost the quality and standards of services in Lesotho. This unique programme initiated by Lesotho Government will add solid capacity for the health services in the country. It is a challenge to young physicians to join in the July 2008 and January 2009 intakes. After all, as the Chinese saying goes, “A journey of a thousand miles begins with the first step.”

Management of Treatment Failure

Adapted from a presentation given at the Annual General Meeting of the LMA on July 9, 2006

PJ McPHERSON, MD¹

¹ Queen Elizabeth II Hospital, Maseru, Lesotho

INTRODUCTION

Therapy failure occurs in three phases. In the first phase wild type virus replicates under antiretroviral therapy. This could be due to low drug potency or insufficient drug exposure. In the second phase, wild type virus is transformed to resistant virus due to selective drug pressure. In the third phase, resistant virus replicates under continued selective drug pressure.

Resistance and cross-resistance significantly limit therapeutic options (Figure 1). Certain drugs select for specific resistance mutations sometimes referred to as signature mutations characteristic of those particular drugs. For example, therapy with zidovudine, lamivudine, indinavir selects for the following mutations: 41L, 67N, 70R, 210W, 215F, 184V, 82T, 84V, 46L, 90M.

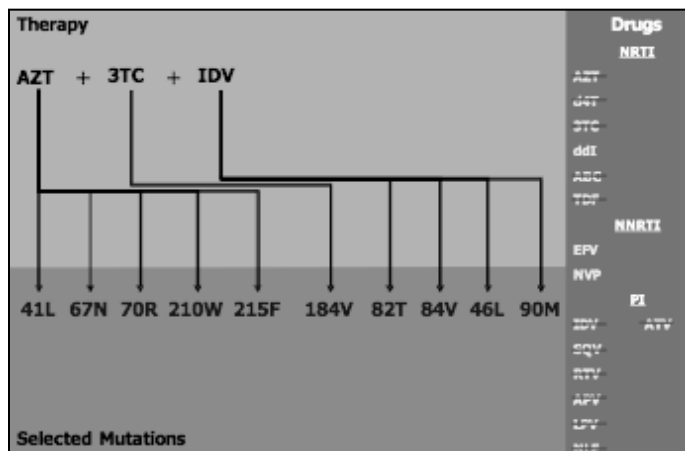


Figure 1. Resistance and cross-resistance from therapy with zidovudine, lamivudine, idinavir.

In this case resistance develops to zidovudine, stavudine and tenofovir. Lamivudine and abacavir also fall out of the available treatment options with the development of the 184V mutation. Protease inhibitors also become ineffective after the development of the four-point mutation in response to indinavir. This means that the nucleoside reverse transcriptase inhibitors, with the exception of didanosine (ddI), nucleotide reverse transcriptase inhibitor (Tenofovir) and the protease inhibitors become ineffective and cannot be used in this case.

If indinavir is replaced with an NNRTI (efavirenz) the development of 103N mutation renders both efavirenz and nevirapine ineffective (Figure 2). All treatment options are lost as all classes of drugs are rendered ineffective.

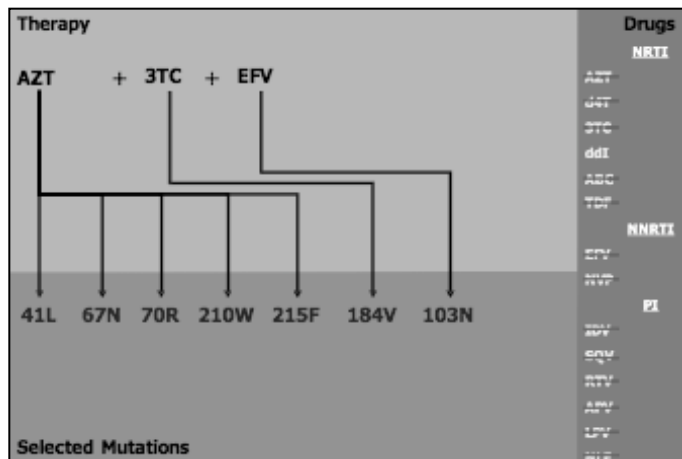


Figure 2. Resistance and cross-resistance after replacing indinavir with efavirenz.

It is however possible to develop resistance to one class of drugs while the remaining classes of drugs remain active (Figure 3).

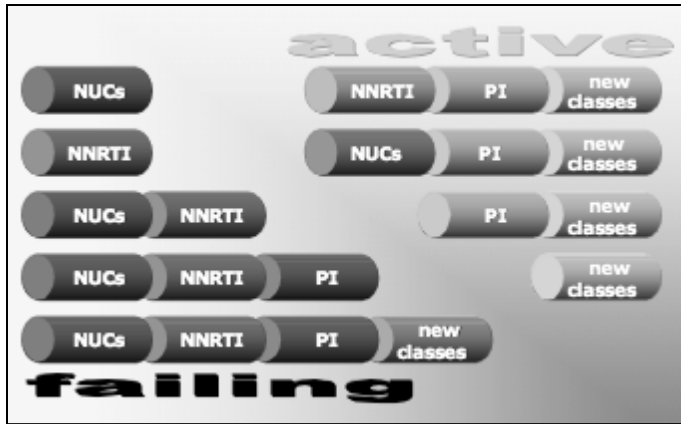


Figure 3. Frequent patterns of virologic failure.

Resistance is often associated with significant cross resistance but it does not directly drive clinical deterioration. It does, however, result in the loss of treatment options.

In the early era of “hit hard and early,” patients were put on mega-HAART which usually consisted of a combination of different classes of drugs. This resulted in serious side effects and complications a few weeks after the initiation of treatment. One patient was started on mega-HAART in 1998. Despite a marked reduction in viral load to undetectable levels, the patient developed a myocardial infarction a few weeks after the initiation of treatment with a CD4 count of 221. The patient was switched to abacavir and combivir (AZT, 3TC). The patient’s CD4 count increased to 417 despite continued viral replication. The addition of tenofovir to the regimen resulted in a further increase in CD4 count to 560 although the viral load remained the same (Figure 4). The viral mutations that developed during the course of treatment are shown below:

Genotype – 2/2001:

TAMS: 41L, 67N, 210W, 215Y
 Non-TAMS: 44D, 118I, 184V
 NNRTI: 103N
 PI: 10I, 77I

Genotype - 2/2003:

TAMS: 41L, 67N, 210W, 215Y
 Non-TAMS: 44D, 118I, 184V
 NNRTI: 103N
 PI: 10I, 63P, 77I

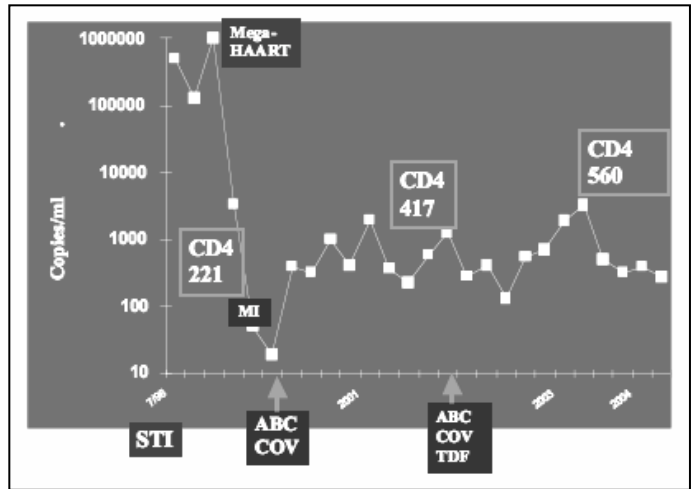


Figure 4. The effects of a patient’s course of treatment.

This led to the conclusion that resistance mutations may contribute to stabilisation of a patient’s viral load and CD4 count despite viral replication because of reduced viral fitness, cross talk between mutations and maintenance of partial activity of the antiretrovirals in the presence of mutations.

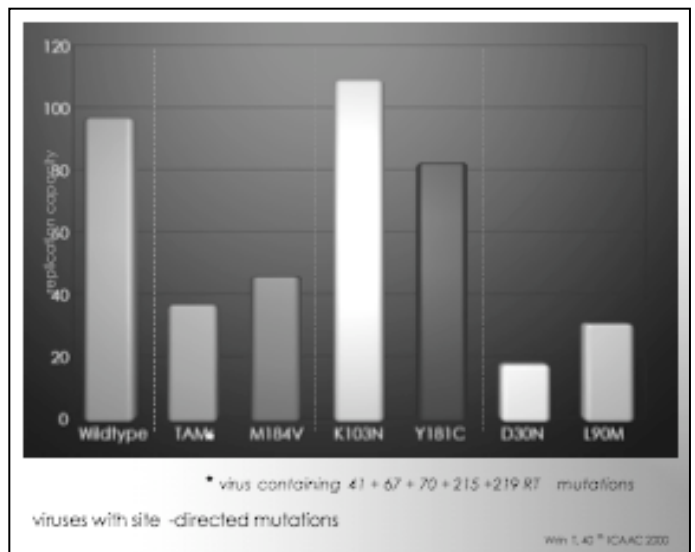


Figure 5. Certain resistance mutations markedly reduce the replicative capacity of the virus as compared to the wild type virus.

There are two mechanisms of NRTI resistance:

- Decreased NRTI binding/incorporation: This is how resistance develops to lamivudine following the development of the M184V mutation.
- Increased NRTI excision: This is how resistance develops to thymidine analogues and affects drugs like zidovudine and stavudine.

65R, 74V, 184V resistance mutations decrease AZT excision. When resistance develops to nucleoside analogues with resultant virologic failure, NNRTIs, PIs and new classes remain active (Figure 6).



Figure 6. NUC resistance in virologic failure.

The main resistance patterns are: (a) 184V, (b) 65R, (c) 67N, 70R, 219Q (+184V), and (d) 41L, 210W, 215Y (+184V).

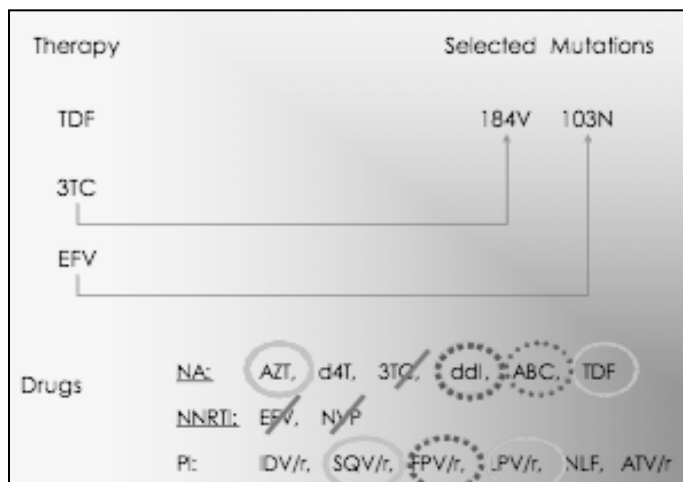


Figure 7. Resistance based switch: virologic failure with 184V

If resistance develops to lamivudine and the NNRTIs activity is maintained for the thymidine analogues, nucleotide reverse transcriptase inhibitors and protease inhibitors remain active. Zidovudine remains active in the presence of resistance to non-thymidine analogues (Figure 8). The addition of zidovudine to a failing regimen containing non-thymidine analogues stabilises the patient's CD4 count and decreases the viral load significantly.

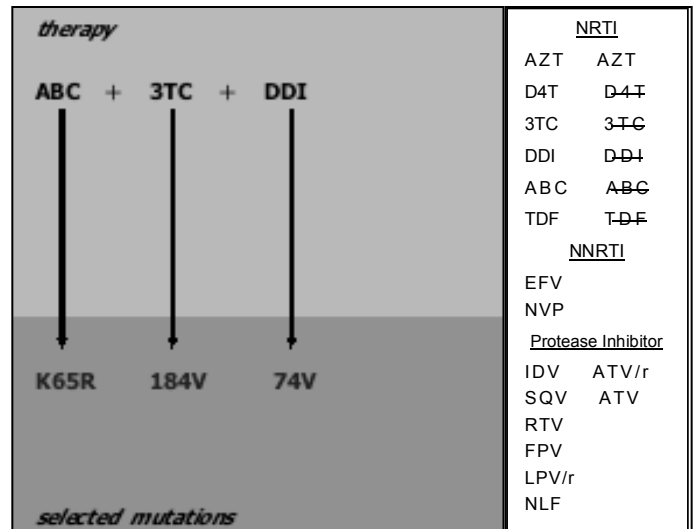


Figure 8. Resistance based switch: non-TAM resistance.

One female patient aged 45 years presented in February 2002 with CDC class B3. She was initiated on ABC, 3TC and ddI in October 2002. Virologic rebound occurred at week eight (Figure 9).

<ul style="list-style-type: none"> • Female, aged 45, ART-naive, presented 02/02 • CDC class B3 • Initial therapy: ABC, 3TC, ddI - started 10/02 • Virologic rebound occurred at week 8 				
<ul style="list-style-type: none"> • Genotype resistance test results: 				
Therapy	TAMs	Non-TAMs	NNRTI	PI
ART naive	WT	WT	WT	20R, 63P, 77I
ABC, 3TC, ddI	WT	65R, 74V, 115F, 184V	WT	63P, 77I

Figure 9. The genotype resistance test results.

The addition of zidovudine to the failing regimen reduced the viral load to undetectable levels. In the presence of the K65R mutation AZT is strengthened (Figure 10).

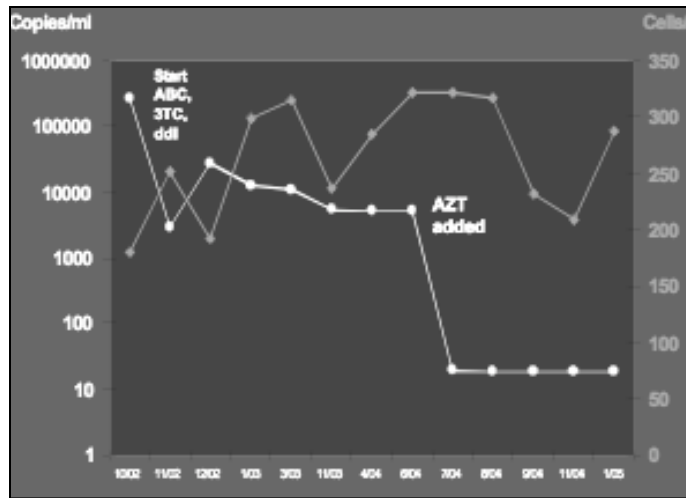


Figure 10. Viral load and CD4 count with the addition of zidovudine.

Another treatment experienced patient had used drugs from all three classes during the course of treatment. From NUC, the patient used ABC, TDF, D4T, 3TC. The patient used NVP from the NNRTI class. From PI, the patient used FOV/r, IDV, IDV/r, INV/r, LPV/r. The resistance patterns that developed during the course of treatment are below:

Date	ART	TAMs	nonTAMs	NNRTI	PI
10/99	NVP EFV IDV	-	-	-	-
12/99	STI	WT	WT	103N	10V, 36I
02/01	STI	WT	WT	WT	10V, 36I
12/01	FOV LPV/r	WT	WT	103N	10V, 36I, 54V
01/02	FOV LPV/r	WT	WT	WT	10V, 36I
03/02	FOV LPV/r	WT	WT	WT	10V, 36I, 54V
09/02	ABC DDI TDF	WT	65R	WT	10V, 36I
10/02	ABC DDI TDF	WT	65R, 184V	WT	10V, 36I
12/02	ABC DDI TDF	WT	65R, 184V, 115F	WT	10V, 36I
06/03	ABC DDI TDF	WT	65R, 184V, 115E, 74V	WT	10V, 36I

We see once again that with the addition of zidovudine to a failing regimen the viral load is reduced to undetectable levels (Figure 11).

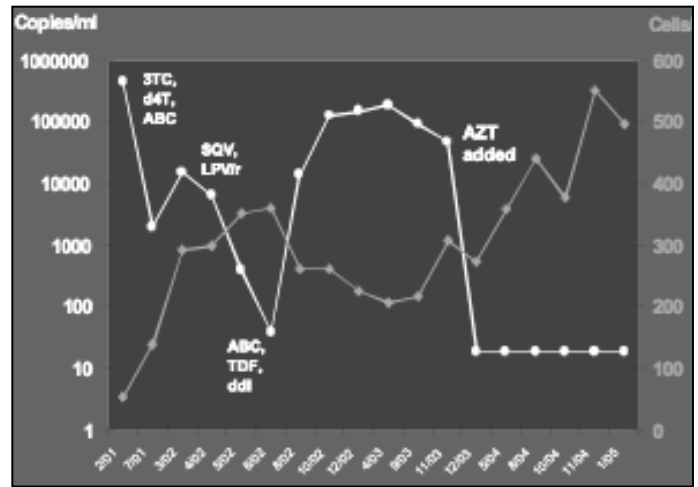


Figure 11. Viral load and CD4 count with the addition of zidovudine.

With the development of resistance to NUCs and NNRTIs only protease inhibitors and new classes of drugs remain active. The only option available in the management of such patients is a boosted double PI regimen. Boosted double PI therapy is not suitable for patients with heavy PI resistance and very low CD4 counts. When a double PI regimen is used drug interactions should be taken into consideration. If resistance develops to the reverse transcriptase inhibitors and protease inhibitors, the only option available is to use the new classes of drugs (Figure 12).

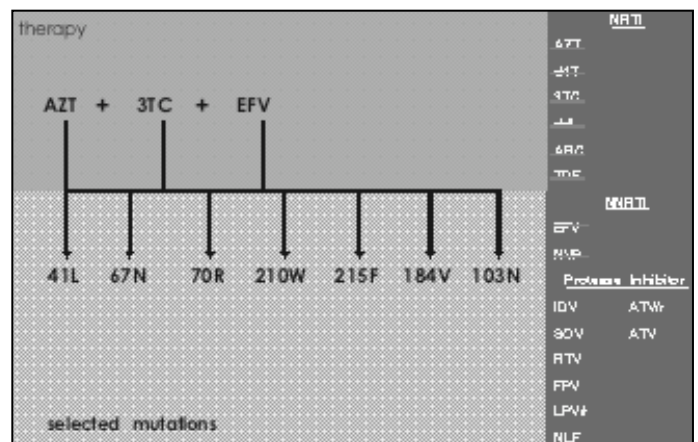


Figure 12. NUC and NNRTI resistance in virologic failure.

It follows then that new drugs and new strategies are needed (Figure 13). From trials in

treatment experienced patients it has been learned that adding two or more active and potent drugs rather than a single drug doubles the response rates. The new protease inhibitors show activity against some resistant viruses, but need to be coupled with other active drugs. The activity of new NRTIs against NRTI-resistant viruses is still uncertain. Second generation NNRTIs still have to be tested intensively in phase 2 and 3 clinical trials.

New compounds from known drug classes with significantly reduced cross resistance	
NRTIs:	Alovedine (MIV 310), DPC817 (D -d4FC), Ralvair (+/-FTC), SPD754, (DOTC)Amdoxovir
NNRTIs:	TMC 125, TMC 278, GW678248
PIs:	Tipranavir, TMC 114, GW0385
New compounds from new drug classes :	
	Fusion inhibitors
	Co-receptor antagonists
	Integrase inhibitors

Figure 13. New drugs.

In the new classes of drugs enfuvirtide is the only approved inhibitor that has shown activity in treatment experienced patients. Drugs such as CCR5, X4 antagonists and integrase inhibitors are promising, but still need extensive evaluation. They are years away from approval.

There are two strategies in the management of patients with resistant virus (Figure 14):

- Recycling strategy, which involves the use of drugs despite viral replication and resistance. The potential benefits of this strategy are the maintenance of a stable CD4 count and delayed deterioration in the clinical well-being of the patients. The potential risks are continuous viral replication, accumulation of resistance mutations and loss of treatment options.

- New drug strategy, which involves the use of new drugs or classes with optimised background. The potential benefits are viral load suppression, increase in CD4 count and improved clinical well-being. The potential risks are functional monotherapy and emerging resistance to the new drugs.

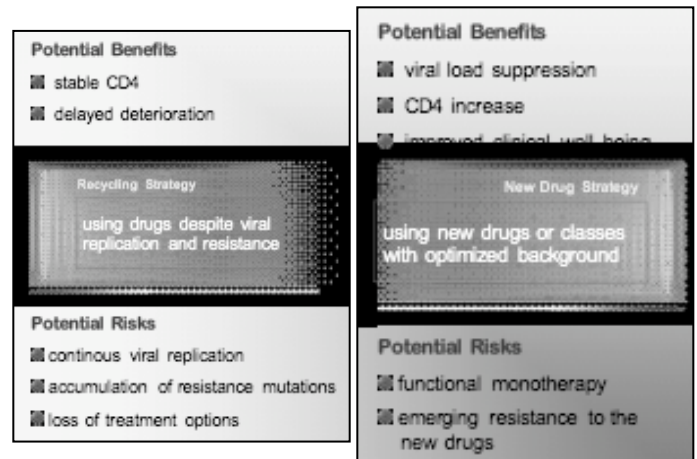


Figure 14. Strategies in the management of patients with resistant virus.

In summary, different stages of virologic failure based on resistance testing require specific treatment strategies. Different salvage strategies may be used in clinical practice:

- Switch to suppressive regimen
- Continue failing regimen
- Recycle drugs in optimised combinations
- Exploit cross talk between mutations and fitness deficiencies.

REFERENCES

1. Staszewski, Schlomo. *HIV Treatment & Research Unit. Hospital of the Johann Wolfgang Goethe University, Frankfurt, Germany.*

An Experience of Antiretroviral Therapy in Resource Limited Settings

MAJ I VENKATA NAGESH, MD, Physician¹

¹ Makoanyane Military Hospital

ABSTRACT

Background: HIV prevalence in Lesotho is very high as in other parts of sub Saharan Africa. HIV prevalence in Lesotho is 23.5%. Data on the efficacy of antiretroviral therapy in resource-limited developing countries is limited. High incidence of tuberculosis along with malnutrition and limited laboratory monitoring may decrease the efficacy of antiretroviral therapy in these settings.

Methods: We studied the efficacy of antiretroviral therapy in a cohort of patients with symptomatic HIV disease and a CD4 lymphocyte count less than 200 per cubic millimeter. The study was conducted in a peripheral hospital in Maseru, Lesotho between December 2004 and December 2006.

Results: During a 24-month period, three drug antiretroviral therapy was initiated to 255 patients who met the criteria for antiretroviral therapy. The median enrollment rate per month was 10 patients. After completion of two years, 185 of 238 (78%) were being followed up, 12 (5%) were lost to follow up and 41(17.2%) died during the study period. All the deaths occurred before 12 months of initiation of therapy. 31(75%) out of 41 deaths occurred within 3 months of starting antiretroviral therapy. The median baseline CD4 T lymphocyte count was 86 cells per cubic millimeter (interquartile range 28-111 cells per cubic millimeter). The median

increase in CD4 T-cell count after six months was 86 per cubic millimeter (interquartile range 78-190 cells per cubic millimeter). The median increase in CD4 T-cell count after twelve months was 150 per cubic millimeter (interquartile range 100-220 cells per cubic millimeter). 26 of 238 (11%) patients required a change in first line medications.

Conclusions: Antiretroviral therapy can be provided in resource-limited settings with good patient retention and clinical outcomes. Overall, the outcomes are similar to other studies in developed countries. With appropriate clinical protocols, antiretroviral therapy is a key component of HIV patient care.

INTRODUCTION

Antiretroviral therapy with three or more medications is the standard of care for patients with acquired immunodeficiency syndrome (AIDS) [1,2]. In developed countries, antiretroviral therapy decreases human immunodeficiency viral load, increases the CD4 cell count, and dramatically improves survival [3]. However, 60% of the world's population with HIV infection or AIDS lives in Sub-Saharan Africa, where high rates of co-infection with tuberculosis, tropical diseases and malnutrition together with limited laboratory monitoring, may decrease the efficacy of antiretroviral therapy.

We report the outcomes of antiretroviral therapy for the first two years in patients naïve to antiretroviral drugs, who were treated in a peripheral hospital in Maseru, Lesotho beginning in December 2004 and ending in December 2006. HIV infection primarily occurs through heterosexual transmission.

MATERIAL AND METHODS

Patients

The study was conducted between 01 Dec 2004 and 31 Dec 2006 in a peripheral hospital situated in Maseru, Lesotho. All adult HIV positive patients, naïve to prior antiretroviral therapy were started on antiretroviral therapy and included in the study. Antiretroviral therapy was initiated according to World Health Organization (WHO) and Lesotho national antiretroviral guidelines with an AIDS defining illness or CD4 T-cell count under 200 per cubic millimeter [5,6]. Of the 255 patients enrolled for therapy, 15 children under 13 years of age and two adults who had prior exposure to antiretroviral therapy were excluded from the study. The study cohort is given in Table 1.

Treatment

The first line antiretroviral regimen followed WHO guidelines as recommended by the Lesotho government [1]. The first line antiretroviral therapy regimen for adults consisted of zidovudine, lamivudine and efavirenz. Single drug substitution was permitted: stavudine could be substituted for zidovudine, nevirapine could be substituted for efavirenz and vice versa. Adherence to therapy was encouraged by home visits and peer counseling by people with AIDS, pill counts, and social support programmes.

Characteristic	Value
Adults	No (%)
Females	99 (41.5%)
Males	139 (58.5%)
Age	No (%)
13-19 years	01 (0.4%)
20-29 years	37 (15.5%)
30-39 years	104 (43.7%)
40-49 years	66 (27.7%)
> 49 years	28 (11.7%)
WHO Staging	No (%)
Stage I	43 (18%)
Stage II	40 (16.8%)
Stage III	50 (21%)
Stage IV	102 (42.8%)
Body Weight (kg)	Median (IQR)
Men	60.3 (54.4-64.5)
Women	57 (50-67.3)
CD4 T-Cell Count	Median (IQR)
Cells/mm ³	86 (28-111)
	No (%)
Pts with CD4 < 50	85 (35.7%)
Initial ART Regimen	No (%)
Zidovudine, lamivudine, efavirenz	79 (33.2%)
Zidovudine, lamivudine, nevirapine	19 (0.3%)
Stavudine, lamivudine, efavirenz	51 (21.4%)
Stavudine, lamivudine, nevirapine	89 (37.3%)

Table 1. Study cohort characteristics.

Clinical Measures

Body weight was measured at each visit. A relevant clinical examination was conducted during each visit. Laboratory monitoring included baseline CD4 T-cell count, by flow cytometry, and measurement of hemoglobin. The CD4 T-cell count was determined every 6 months. Follow up hemoglobin measurement, liver function tests and serum chemical analysis were performed if clinically indicated. The consultation frequency is determined by the clinical protocol: weekly for the first two weeks, then every two weeks until 2 months on therapy, then monthly until the first year on therapy and thereafter every 2 months. Patients are seen more frequently if clinically indicated.

Patients who had not attended services for three months and beyond the last scheduled visit and who could not be traced were considered to be lost to follow-up and statistically were considered as deaths on their last scheduled visit.

Estimates of median changes in CD4 T-cell counts were determined. Weight changes were calculated as median increases compared to baseline. Estimates of percentage of patients changing treatment were calculated as product limit estimates.

RESULTS

Enrollment

Between 01 Dec 2005 and 31 Dec 2006, HIV counseling and testing was provided to 982 patients out of which 379 (37%) were tested positive. Of the 379 patients, 255 patients (69.9%) who met the criteria for antiretroviral therapy were started on first line regimens. 15 patients who were under 13 years of age and 2 patients who had prior exposure to antiretroviral therapy were excluded from the study, as given in Table 1. The median enrollment rate per month was 10 patients. The median follow up was for 17.9 months. The baseline characteristics of the patients are given in Table 1. At the time of analysis 185 of 238 (78%) were being followed up, 12 (5%) were lost to follow up and 41(17.2%) died during the study period.

There was no difference in baseline characteristics (including age, sex, CD4 T-cell count, body weight, stage of HIV infection) between patients who were lost to follow up and who were not. The most common reason for patient being lost to follow up was that leaving Maseru to return to their rural village.

Survival

Of the 238 patients, 41 (17.2) patients died. All the deaths occurred before 12 months of initiation of therapy. 31 (75%) out of 41 died within 3 months of antiretroviral therapy. 85 (35%) of 238 started therapy with initial CD4 T-cell count of less than 50 cells per cubic millimeter, 30 patients (35%) died within 1 year. 153 (65%) of 238 patients started with initial CD4 T-cell count > 50 cells per cubic millimeter. 11 of 153 patients died within one year. 25 of 41 deaths took place in the lowest quartile of body weight for both sexes. In the review of cause of death, 10 out of 41 (25%) were classified as due to very advanced disease at the time of starting antiretroviral therapy with continued deterioration on treatment. The median CD4 T-cell count in this group was 10 cells per cubic millimeter (interquartile range of 8-15 cells per cubic millimeter) and median duration of treatment when they died was 20 days (interquartile range of 14-28 days).

CD4 T-Cell Response

The median increase in CD4 T-cell count after six months was 86 per cubic millimeter (interquartile range of 78-190 cells per cubic millimeter). CD4 T-cell count at six months was greater than base line in 169 of 186 patients (91%) and remained or decreased from baseline in 17 (9%) patients. The median increase in CD4 T-cell count after twelve months was 150 per cubic millimeter (interquartile range of 100-220 cells per cubic millimeter). CD4 T-cell count at twelve months was greater than baseline in 101 of 112 patients (90%) and remained or decreased from baseline in 11 (10%) patients. The CD4 T-cell count increased rapidly compared to the baseline in the first six months of treatment and the gain in CD4 T-cell count in subsequent intervals was lower than the first six months.

Weight Gain

The median weight gain at six months was 5 kg (interquartile range of 1.2-10 kg). At six months, 153 of 186 (82%) patients gained weight and 33 of 186 (18%) remained at the same weight or lost weight from the baseline. The median weight gain at twelve months was 7.4 kg (interquartile range of 3-17 kg). At twelve months, 98 of 112 (87%) patients gained weight and 14 of 112 (12%) remained at the same weight or lost weight from the baseline.

First Line Medication Changes

26 of 238 (11%) patients required a change in first line medications (Table 2). The main reasons for change of medications were toxic side effects. Zidovudine was changed to stavudine in 6% of patients. Stavudine was changed to zidovudine in 4.2% of patients, due to peripheral neuropathy and lipodystrophy. Nevirapine was changed to efavirenz in 9.3% of patients due to new onset tuberculosis, with the reason that it interferes with rifampicin. Hepatitis due to nevirapine was observed in one patient, but none of the patients experienced severe drug rash on nevirapine. Efavirenz was changed to nevirapine in 3% due to female pa-

	# to start on ART	# changed due to side effects	# changed due to contra-indications	% changed by 2 years ^a
Zidovudine	97	6	-	6.1
Stavudine	139	6	-	4.2
Nevirapine	107	10	7 ^b	9.3
Efavirenz	129	4	2 ^c	3
Total	238	26	9	11

Table 2. Changes in drug regimen: (a) Product limit estimate for those changing due to side effects, (b) changed due to a new episode of tuberculosis, (c) changed due to pregnancy or desire for pregnancy.'

tients resuming sexual activity with risk of pregnancy.

DISCUSSION

Antiretroviral therapy was initiated in 238 patients over a period of 2 years in a peripheral hospital in Maseru, Lesotho. This analysis is limited by the small number of patients at risk beyond one year of therapy. The one year survival was 84%. One year survival without antiretroviral therapy for adults in Lesotho is about 30% [7, 13]. Survival rate and median increase of CD4 T-cell count, in this study are comparable to those reported for patients initiating antiretroviral treatment with very low CD4 T-cell counts in two observational studies in Canada and the USA [8]. The median increase in CD4 T-cell count of 150 cells per cubic millimeter after twelve months was comparable to a similar study in Baltimore [14, 15].

The number of deaths in patients with CD4 T-cell count <50 cells per cubic millimeter (30 of 41) compared with the number of deaths (11 of 41) in patients with CD4 cell count > 50 cells per cubic millimeter, suggests better prognosis for those patients starting treatment early. Similar results were found in a study conducted in South Africa [9]. The occurrence of the large number of deaths (30 of 41) within three months of initiation of therapy are most likely due to the extreme disease advancement in many of the patients by the time they are able to access the treatment [9].

Rates of treatment changes due to adverse events were uniformly low and comparable or lower than those published for other cohorts [10]. This is a reflection of the incidence of severe adverse events in general, and demonstrates that with standardized regimens and monitoring and clinical management algo-

rithms, antiretroviral therapy can be safely demonstrated in resource limited settings [9]. The most common contraindication resulting in a treatment change was in patients who developed tuberculosis after starting antiretroviral therapy and who were switched from nevirapine to efavirenz due to concerns about the co administration of nevirapine with rifampicin. Despite the recent concern about nevirapine toxicity, <1% of the cohort who were treated with nevirapine had hepatitis. Nevirapine induced hepatitis has been associated with a CD4 T-cell count of more than 250 cells per cubic millimeter, but the count in most of our patients was less than 200 cells per cubic millimeter. The challenges involved in providing antiretroviral therapy in Lesotho include high rates of tuberculosis and limited lab facilities, which directly affect all aspects of patient care. There is a growing body of evidence which suggests that malnutrition is a critical cofactor in AIDS in resource poor countries [11, 12]. In our study, 25 of 41 (60%) deaths took place in the lowest quartile of body weight.

REFERENCES

1. WHO. *Scaling up antiretroviral therapy in resource-limited settings*. Geneva: World Health Organization, 2004.
2. Panel on clinical practices for treatment of HIV infection. *Guidelines for the use of antiretroviral agents in HIV infected adults and adolescents*. April 7, 2005. Washington, D.C.: Government printing office, 2005. Accessed 23 Dec 2006 at http://aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf.
3. Palella FJ, Dealney KM, Moorman AC, et al. *Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection*. *N Engl J Med* 1998; 338:853-860.
4. UNAIDS Lesotho HIV/AIDS Update. Accessed 25 Dec 2006 at http://www.unaids.org/en/Regions_Countries/Countries/lesotho.asp.
5. WHO case definitions for AIDS surveillance in adults and adolescents. *Wkly Epi Rec* 1994; 37:273-5.
6. Lesotho national antiretroviral guidelines.
7. Schneider M, Zwahlen M, Egger M. *Natural history and mortality in HIV positive individuals living in resource poor settings: a literature review*. UNAIDS obligations HQ/03/463871.
8. Chap KC, Yip B, Hogg RS, Montaner JS, O'Shaughnessy MV. *Survival rates after initiation of antiretroviral therapy stratified by CD4 cell counts in two cohorts in Canada and in the United States*. *AIDS* 2003; 17:1369-1375.
9. Coetzee D, Hilderbrand K, Boulle A, et al. *Outcomes after two years of providing antiretroviral treatment in Khayelitha, South Africa*. *AIDS* 2004; 18:887-995.
10. d'Arminio MA, Lepri AC, Rezza G, Pezzotti P, Antinori A, Philips AN, et al. *Insights into the reasons for discontinuation of the first highly active antiretroviral therapy (HAART) regimen in a cohort of antiretroviral naïve patients*. ICONA Study group. *Italian cohort of antiretroviral-naïve patients*. *AIDS* 2000; 14: 499-507.
11. Fawzi WW, Msamanga GI, Spiegelman D, et al. *A randomized trial of multivitamin supplements and HIV disease progression and mortality*. *N Engl J Med* 2004; 351: 23-32.
12. Fawzi WW, Msamanga GI, Spiegelman D, Hunter DJ. *Studies of vitamins and minerals and HIV transmission and disease progression*. *J Nutr* 2005; 135:938-944.
13. Post FA, Wood R, Maartens G. *CD4 and total lymphocyte counts as predictors of HIV disease progression*. *Q J Med* 1996; 89:505-508.
14. Lucas GM, Chaisson RE, Moore RD. *Survival in an Urban HIV-1 Clinic in the era of highly active antiretroviral therapy: a 5-year cohort study*. *J AIDS* 2003; 33:321-328.
15. Moore RD, Keruly JC, Gebo KA, Lucas GM. *An improvement in virologic response to highly active antiretroviral therapy in clinical practice from 1996-2002*. *J Acquir Immune Defic Syndr* 2005; 39:195-198.

Diagnosing HIV/AIDS Treatment Failure at Senkatana Centre

A. TIAM, MBChB, Dip. HIV Man (SA)¹

H OSMAN, MD¹

M MALIMABE, RNC¹

¹ *Senkatana Centre, Maseru, Lesotho*

INTRODUCTION

The development of antiretroviral therapy has been one of the most dramatic progressions in the history of medicine. Few other areas have been subject to such fast and short-lived trends. Those who have experienced the rapid developments of the last few years have been through many ups and downs [1].

Five classes of drugs are currently available: nucleoside and nucleotide analogs (NRTIs or “nukes”), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitor T-20 and integrase inhibitors. Over 20 drug products have now been licensed, including formulations of both individual and combined antiretroviral agents [2]. As good as this may sound, HIV is genetically unstable with many mutations developing for some drugs even before patients are exposed to them. This is coupled with the requirement for very stringent adherence to treatment as a prerequisite of treatment success [2,3].

MATERIALS AND METHODS

This study was carried out during the period of June 2004 to May 2007 at Senkatana Centre for adult HIV/AIDS treatment/care. All the cases were managed at Senkatana Centre by our

team. Most cases were referred to the centre by various ART centres (private/public) around the country and from the Republic of South Africa. We have decided to review these cases to show how patients with treatment failure should be diagnosed and managed. In this research, patients' charts were reviewed and important aspects of history, physical examination, investigation and treatment collated.

The inclusion criteria was for all patients initiated on second line regimen as defined by the national guidelines at Senkatana and were still being monitored at the centre at the time of review. Exclusion criteria included those who have been transferred out or withdrew consent to be treated at the centre.

RESULTS AND OBSERVATIONS

Among the 24 patients reviewed in this study, 18 (75%) were female and 6 (25%) were male. Patient ages ranged from 26 to 54 years with an average of 38.3 years and a median age of 39 years. 15 (62.5%) patients were ARV experienced (i.e. they were referred to Senkatana already on treatment) while 9 (37.5%) were ARV naïve (i.e. they were initiated on treatment for the first time at Senkatana).

Initial clinical evaluations showed that 3 (12.5%) patients were in stage I, 7 (29.2) were in stage II, 12 (50%) were in stage III and 2 (8.3%) were in stage IV. At treatment failure, 1 patient (4.2%) was in stage I, 5 (20.8%) were in stage II, 9 (37.5%) were in stage III, 5 (20.8%) were in stage IV and 4 (16.7%) were not staged (Table 1).

WHO stage	At enrollment (%)	At treatment failure (%)
1	3 (12.5%)	1 (4.2%)
2	7 (29.2%)	5 (20.8%)
3	12 (50%)	9 (37.5%)
4	2 (8.3%)	5 (20.8%)
No staging	-	4 (16.7%)

Table 1. Distribution of patients among WHO AIDS stages

Review of opportunistic infections at enrollment showed that 10 (41.7%) had tuberculosis irrespective of site affected, 2 (8.3%) had chronic diarrhoea, 1 (4.2%) had oral thrush, 1 (4.2%) had an unclassified OI, and 10 (41.7%) had no OI (Table 2).

Opportunistic Infections	At enrollment (%)	At treatment failure (%)
Tuberculosis	10 (41.7%)	6 (25%)
Diarrhoea	2 (8.3%)	-
Oral Thrush	1 (4.2%)	-
Wasting Syndrome	-	7 (29.2%)
Others	1 (4.2%)	1 (4.2%)
None	10 (41.7%)	10 (41.7%)

Table 2. Frequency of opportunistic infections.

CD4 at initial evaluation ranged from 1 to 273, with a mean of 90, median of 67, and mode of 65. Meanwhile, at diagnosis of treatment failure, CD4 ranged from 5 to 381, with a mean of 126.42. A subanalysis of patients with virologi-

cal treatment failure showed a CD4 count range of 1 to 194 with a mean of 58.4 at initial evaluation and a range of 5 to 381 at diagnosis of virological treatment failure with a mean of 106.2 cells/ml. Current CD4 ranged from 190 to 932 with a mean of 483.9cell/ml.

Viral loads were carried out on 15 patients at initial evaluation and values ranged from 51 to 207,189 copies/ml with a mean of 55,776 copies/ml. At diagnosis of treatment failure, viral loads ranged from 1,135 to > 500,000 copies/ml. Current viral loads recorded for the 24 patients were all <50copies/mls, which is classified as undetectable (Gold Standard).

The duration of first-line therapy ranged from <1month for those with clinical failure such as grade 4 hypersensitivity reaction to 67 months for other types of treatment failure. However, focusing on virological treatment failure, patients were on treatment from 13 to 67 months averaging 31 months.

Considering our classification of treatment, 16 (66.7%) patients had virologic treatment failure, 7 (29.2%) had clinical failure and 1 (4.2%) had immunological failure (Table 3). A subanalysis of patients with clinical failure showed that 6 (85.7%) had Steven Johnson’s syndrome and 1 (14.3%) had grade 4 transaminitis. All the patients with clinical failure were initiated on nevirapine, were female and 2 (28.6%) had CD4 counts >250.

Failure Type	No. (%)
Virologic Treatment Failure	16 (66.7%)
Clinical Treatment Failure	7 (29.2%)
Immunological Treatment Failure	1 (4.2%)

Table 3. Frequency of treatment failure type.

DISCUSSION

The introduction of HAART into HIV management led to tremendous reductions in HIV-related morbidity and mortality. The more than 20 antiretroviral agents and combination products approved for the treatment of HIV infection allow clinicians many options for initial therapy [3]. However, in resource strained settings such as ours, options are still very limited. Currently, the first line combination in Lesotho is from two sub-classes of reverse transcriptase inhibitors: nucleoside/nucleotide analogue reverse transcriptase inhibitors (NRTIs) and non nucleoside reverse transcriptase inhibitors (NNRTIs). In our study all patients were initiated on these combinations (Table 4). Treatment failure can be virological, immunological or clinical.

First Line	No. (%)
Stavudine + lamivudine + nevirapine	14(58.3%)
Stavudine + lamivudine + efavirenz	5(20.8%)
Zidovudine + lamivudine + nevirapine	2(8.3%)
Zidovudine + lamivudine + efavirenz	3(12.5%)

Table 4. Frequency of first line drug combinations

Virological treatment failure being the most significant treatment failure is said to occur when: (1) there is sustained increase in VL >5000copies/ml, (2) a decline in VL <1log₁₀ (10fold) 6-8 weeks after initiation of HAART, and (3) a sustained rise in VL >0.6log₁₀ from its lowest point or a return to 50% of pre-Rx value [3-5].

Immunological treatment failure is described as the absence of an increase or a decrease in the CD4 cells in patients receiving HAART. It is difficult to predict the rise in CD4 count in pa-

tients on HAART. Some studies showed a median increase of 21.2 cells/ml per month in the first 3 months followed by 5.5 CD4 cells/ml in subsequent months (Le Moing 2002).

Clinical treatment failure is defined as development of an AIDS-associated condition, major treatment complications such as grade 4 drug reactions or even death in patients on HAART. In our study population, Steven Johnson Syndrome was the most common cause of clinical treatment failure. Of importance, all patients with SJS were female and were treated with nevirapine. However, this should take into consideration IRIS [4-7]. Table 3 shows these various types of treatment failure.

Note: Non-adherence to treatment is the most common cause of treatment failure.

Management of Patients with Virological Treatment Failure

ARV resistance is a rapidly evolving field, and requires expertise in dealing with many situations. Much of the information we have on ARV resistance is from populations in the developed world where clade B is the biggest problem, while in most of Africa, clade C is the commonest infection [8].

All patients referred to our centre with suspicion of virological treatment failure are evaluated clinically and given a full medical history and clinical examination. In the history, emphasis is laid on ARV history, adherence, and co-infections such as tuberculosis. Patients are subsequently staged. Adherence counselling is carried out and continued throughout the evaluation period. Investigations include a routine HIV test in addition to which, there is need for viral load to confirm the diagnosis; a lipid profile is also done. In the western world

where facilities are available, resistance testing is also routinely done. In our centre, this is only very rarely done. All results are then reviewed and patients are initiated on second line regimen (Table 5).

Second line Regimen	No. (%)
zidovudine + didanosine + kaletra	11 (45.8%)
abacavir + didanosine + kaletra	6 (25%)
stavudine + lamivudine + kaletra	7 (29.2%)

Table 5. Frequency of second line drug combination

RECOMMENDATIONS AND CONCLUSIONS

HIV medicine remains one of the most challenging fields of medical practice. Furthermore, treatment failure constitutes a major challenge for those working in this speciality. It is also challenging for the patients because the first line treatment is the simplest combination with fewer pills daily. Economically, it is also cheaper.

This study has reviewed 24 cases of treatment failure. Of importance, virological treatment failure may be associated with resistance mutations which can either be transmitted at primary infection or as a super infection. Adherence remains the key to prevention of treatment failure.

We recommend a cross-sectional study be carried out across the country to assess the virological treatment successes. This will give a clear picture of what is going on, so that an epidemic treatment failure can be averted.

REFERENCES

1. Ho DD, Neumann AU, Perelson AS, Chen W, Leonard JM, Markowitz M. Rapid turnover of plasma-virions and CD4 lymphocytes in HIV-1 infection. *Nature* 1995; 373:123-6. <http://amedeo.com/lit.php?id=7816094>.
2. Andries K, Azijn H, Thielemans T, et al. TMC125, a novel next-generation NNRTI active against nonnucleoside reverse transcriptase inhibitor-resistant HIV type 1. *Antimicrob Agents Chemother* 2004; 48: 4680-6. <http://amedeo.com/lit.php?id=15561844>.
3. Brilliant J, Klumpp K, Swallow S, Cammack N, Heilek-Snyder G. In vitro resistance development for a second-generation NNRTI: TMC125. *Antivir Ther* 2004, 9:S20.
4. Cane P, Chrystie I, Dunn D, et al. Time trends in primary resistance to HIV drugs in the United Kingdom: multicentre observational study. *BMJ* 2005; 331: 1368. Abstract: <http://amedeo.com/lit.php?id=16299012>.
5. Castagna A, Danise A, Menzo S, et al. Lamivudine monotherapy in HIV-1-infected patients harbouring a lamivudine-resistant virus: a randomized pilot study (E-184V study). *AIDS* 2006; 20: 795-803. Abstract: <http://amedeo.com/lit.php?id=16549962>.
6. Cohen C, Steinhart CR, Ward DJ, et al. Efficacy and safety results at 48 weeks with the novel NNRTI, TMC125, and impact of baseline resistance on the virologic response in study TMC125-C223. Abstract TUPE0061, 16th International AIDS Conference 2006, Toronto.
7. World Health Organization. Scaling up antiretroviral therapy in resource-limited settings: treatment guidelines for a public health approach 2006 revision. World Health Organisation 2006; Geneva.
8. Blower S, Bodine E, Kahn J, McFarland W, The antiretroviral roll out and drug-resistant HIV in Africa: insights from empirical data and theoretical models. *AIDS*: 2005 Jan 3;19(1):1-14.

Decentralisation and the Health Sector in Lesotho: Issues to Consider

Taken from a discussion paper by the Capacity Project on potential constraints to successful decentralisation in the health sector

KELLY LEROTHOLI, MD¹

¹ *Capacity Project*

BACKGROUND

The intention with the decentralisation process undertaken by the Ministry of Health and Social Welfare (MOHSW) is to conform to the policy direction outlined by the Ministry of Local Government (MOLG) in the mandate conferred upon it (i.e., the Ministry of Local Government) by Government.

The expectation(s) with regard to the MOHSW is that with the onset of decentralisation, the district shall become the administrative and political centre for service delivery. Furthermore, the district shall incorporate the Health Service Areas and be headed by a District Administrator (DA). This DA will, in effect, constitute a representation of central government at the district level¹. The political system at the district level shall be headed by the District Council which consists of elected councillors. Health and Social Services shall be devolved to the DA's office. This devolution shall include all attendant resources whether human, financial, or otherwise. The district hospitals shall remain under the jurisdiction of the central level MOHSW. The terms of reference (TOR) further recognise that the process of decentralisation, in the

MOHSW, shall proceed smoothly only if the MOHSW is structured in line with the new dispensation, wherein the central level is charged with the responsibility for: policy development, strategic planning, development and implementation of the legislative framework, supervision and support of district services, and ensuring the quality of services delivered through its monitoring and supervision roles. In addition, the central level should also have the responsibility for liaising and interacting with other national and international partners. The district, on the other hand, shall have the responsibility for the planning, management, implementation, and monitoring and evaluation of the health and welfare services that shall fall within their jurisdiction. These shall be undertaken in consultation with the political and administrative structures at the district level (i.e., the office of the DA).

The intention with this discussion paper is to set out for the MOHSW those issues that are going to be critical to the eventual success or failure of the process of decentralisation where the Ministry is concerned.

¹ This is a distinction that is important to understand given the prevailing misconception in some quarters regarding the role of the DA in the context of Local Authorities.

THE ISSUES

Decentralisation of political and administrative power is becoming an increasingly prevalent component of health sector reform in all parts of the world. This transfer of power away from the centre is often combined with efforts to reform outdated and cumbersome civil service structures. In the majority of instances where decentralisation has been attempted, the wider implications of decentralisation, particularly for human resources planning, training and management are generally poorly researched and inadequately understood.

Decentralisation is a term that is used to describe the different means/arrangements of power sharing. These "arrangements" can range from the transfer of limited administrative responsibility from a central Ministry of Health to local offices all the way up to the creation of new governmental structures which then become the entities responsible for providing health and other services. The implications of decentralisation of human resources for health are greatly influenced by the degree to which political or administrative power is transferred, how the new roles are defined, what skills are available at the local level, and what administrative linkages exist between different management levels, and between the central health authority and the other central government offices that influence resource allocation. Finally, they are also influenced by the degree of political will to make decentralisation work.

A recent trend has been to have decentralisation implemented as part of health sector reform. Health sector reform aims to improve the performance of the sector, and ultimately, the health of people, through a conscious process of setting sectoral priorities and policies,

and then reforming the way health services are structured and financed to fit with the revised policies and priorities. The resultant changes in organisational structures and institutions have fundamental human resource implications. It therefore goes to follow that the success of health sector reform in reaching the goals set for it will depend greatly on the amount of thought and preparation that the human resource (HR) issues have been given.

Two key areas have to be considered with regard to the preceding. These are (1) human resource issues that emerge as a part of the process of transferring power to lower management levels, and (2) human resource domains where problems arise as a result of the way in which the decentralised management systems are structured.

DECENTRALISATION AND THE HEALTH SECTOR IN LESOTHO

In 2005, the MOHSW developed a strategy for the decentralisation of the services provided by the sector. The strategy was intended to enable the MOHSW to deliver on the obligations set forth by the Local Government Act. A key objective of the strategy is to ensure a well functioning district health system that facilitates the implementation of the Health Sector Reform Programme.

Within the strategy document four key elements have been defined in order to adequately and appropriately address the issue of decentralisation in the health and social welfare sector. These four elements are discussed below:

- (1) **Services:** Decentralisation dictates that the services to be decentralised or provided by the decentralised structures

must be clearly defined. They form the substance to be decentralised. For Lesotho, the core services have been defined in the Essential Services Package.

- (2) **Spatial Decentralisation:** This refers to the issue of "Districts" versus "Health Service Areas". The strategy adopts the ten (10) district-approach as has been adopted for the overall Local Government system. It also acknowledges the reality that health service catchment areas cut across district boundaries.
- (3) **Administrative Structures:** Decentralisation requires a revision of the present structures for the health and social welfare sector wherein there is an inordinate degree of focus on the central level. To that end the strategy revises administrative structures in the sector such that the primary focus for services provision shifts to the district level. It also emphasises the role of the district health management team (DHMT) in managing and coordinating district level health and social welfare activities; and that of the central level in setting policies and ensuring that services are provided in an equitable manner throughout the country. In this area the strategy also defines the links with Local Government and foresees a functional relationship between the district health system and Local Government structures at that level.
- (4) **Functions:** The strategy recognises that decentralisation will take place only if a radical/different approach is taken with regard to functions, roles, responsibilities, and decision-making authority. These are defined in the strategy for all levels of

health services provision (i.e., central, district, and unit).

PHASES ENVISAGED FOR DECENTRALISATION

The approach adopted is that of incremental change. That is to say, the decentralisation shall take place in a phased manner. This approach recognises that the GOL has to allocate sufficient technical and fiscal capacity in order to enable the entrenchment of decentralisation and the attendant tenets of Local Government. This presents serious challenges to the resource capacity that the nation currently offers. This is deemed to be justification enough for GOL to adopt a phased or incremental approach to decentralisation. For the MOHSW the incremental/phased approach is as follows:

- (1) **In the first phase, 2004-2007,** the aim is to decentralise/de-concentrate powers and responsibilities within the health and social system². This phase is envisaged to take at least 4 years, noting that phases will overlap. The focus is on strengthening competencies of the district level management and the central level to perform their new roles and tasks³. The competencies building will be implemented first in the three pilot districts of Berea, Mohale's Hoek and Thaba-Tseka, and then expanded to the other districts. The process of competencies building is led by the decentralisation component of the overall health sector reform. Further, the other seven health sector reform components need to pilot, test and revise the recently developed mechanisms and pro-

² For the Health and Social Welfare Sector, this means Establishing and providing resources for the District Health Management Teams

³ A strong and competent Human Resources Department will be crucial in this regard. All efforts should be undertaken to ensure that the HRD is adequately strengthened.

cedures for the decentralized system to function properly. They include new systems and procedures in planning, financial management, human resources management, provision of quality services through for example the use of the new clinical guidelines, monitoring and evaluation of the services, etc. Each reform component is responsible for its work, however, all efforts are made in a coordinated manner. An important part of this first phase is to re-structure and re-capacitate the central Ministry of Health and Social Welfare. The role and tasks will change drastically and new competencies need to be developed.

- (2) **The second phase** will take place once the local government elections have been held and the local government institutions have been established. This includes sensitisation of the councillors and members of committees on social and health issues and close co-operation with them and the district health management team. At this phase, responsibility of service provision remains within the health and social welfare sector (MOHSW). The phase coincides with the first phase and is envisaged to start around October 2004 provided that the Councils are in place.
- (3) **The third phase**, envisaged to take place during 2007-2016, involves gradual shifting of responsibilities and powers to the local government institutions from the health and social sector of the government. The local government structures will take over the responsibility of provi-

sion of social and health services to their people. It is too early to envisage the speed and the extent of the change, since much depends on the capacity of the local governments to undertake responsibilities in health and social service provision and also on the willingness of and pressure put to the central level to decentralise. The process will be gradual and will take several years and should have reached its targets by the year 2016, as are the plans of the Government in the overall decentralisation process.

In the Lesotho scenario it will be necessary that any discussion related to human resources (HR) issues that emerge as a part of the process of transferring power to the lower levels; and to HR domains where problems arise as result of the way in which decentralised management systems are structured be preceded by a consideration of two factors that constitute key prerequisites for the successful implementation of health and social welfare services in the country. These are discussed in the sections below.

ENGENDERING AN UNDERSTANDING OF HEALTH SERVICES DECENTRALISATION IN THE MINISTRY OF LOCAL GOVERNMENT

The need for this undertaking has been brought about by the realisation that the role of the DHMT within the district-level functions is not understood in the same manner by the headquarter level staff of the Ministry of Local

Government (MOLG) and that Ministry's representatives at the district level. For example, the fact that the DHMT is to be a local government structure and is therefore directly answerable to the district council in its home district is a situation that is not clear to the district administrator's office in a significant number of districts.⁴ This is a situation that has been verified by the offices of the Coordinators of Decentralisation in both the MOHSW and the MOLG.

Addressing/correcting the scenario described requires that the MOLG undertake an in-house sensitisation exercise that would have as its main aim the sensitisation of the district-level structures of the MOLG as to their envisaged roles and responsibilities vis-à-vis health services provision in the districts. This process should constitute a detailed briefing that clearly articulates the structures, functions, roles, and responsibilities that will have been defined for the district-level services provision structures.

ENGENDERING AN UNDERSTANDING WITHIN THE MOHSW

As with the MOLG above, there is as yet no uniform understanding within the different levels of the MOHSW regarding the implications of the process of decentralisation for the Ministry. In addition, the knowledge of the contents and dictates of the Local Government Act and its amendments is minimal. This seems to be the case at all levels of management within MOHSW.

Secondly, the MOHSW has articulated a De-

centralisation Strategy, ostensibly to devise a means of ensuring that the Ministry is able to deliver on its responsibilities as implied/defined within the Local Government Act. The knowledge of this strategy is also not widespread to the extent that it should in the Ministry.

Finally there has been a plethora of studies and consultancies taking place within the MOHSW that all in some-way-or-other have (or will have) a bearing on how health services are provided in a decentralised health system.

The following are being suggested as a means of addressing the above:

- (1) **Decentralisation and the MOHSW:** It is suggested that the MOHSW invite the MOLG, specifically the Decentralisation Unit, to come and give a brief on Decentralisation, the Local Government Act, and the implications contained therein for the MOHSW. This meeting should be mandatory for all levels of management within the Ministry.
- (2) **MOHSW Decentralisation Strategy:** Following from the above, the MOHSW should undertake a process of reviewing the Decentralisation Strategic Plan as a means of assessing whether-or-not it will enable the ministry to undertake the role defined for it within the Local Government Act.

If the remedial measures suggested above are undertaken as has been suggested, this would go a long way towards creating an environment conducive to both the articulation of a structure for the MOHSW as well as the im-

⁴ An additional point of concern in this regard is that within the MOHSW the understanding is that the DHMT is to constitute a part of the District Administrator's office. Given that this office constitutes a representation of Central Government in the district, having the DHMT as a part of the DA's office would then mean that the DHMT is a representation of Health-HQ at the district level. This would preclude the DHMT from being a part of any implementation in the district and would in effect relegate it to having oversight responsibility for policy, and monitoring and evaluation.

plementation thereof.

HR ISSUES EMERGING AS A PART OF THE PROCESS OF DECENTRALISATION

Decisions about new roles and responsibilities under decentralisation must be followed by the definition of new organisational structures, and terms and conditions of service at both the central and peripheral levels, and by the reallocation of staff between these two levels. Four important HR considerations emerge in this regard. These are:

- (1) The adequacy of available information on human resources
- (2) The complexity of transferring human resources
- (3) The impact of professional associations, unions and registration bodies on the design and implementation of management structures and jobs
- (4) The morale and motivation of health staff.

Adequacy of Available Information on Human Resources

Decisions on human resources will only be sound if they are based on appropriate and timely information. Access to reliable and easily accessible data on staff is crucial to any decision about their allocation.

Basic personnel data, such as a health worker's name, professional qualifications, and age, are more likely to be available than data (or accurate information) on the type and level of position they occupy or the cost of employing them. Information on lower level staff is usually incomplete or even missing. Even where the information is available in some form, considerable time and effort may be needed to

verify its accurateness and completeness. Data on training intakes and outputs are often incomplete and inaccurate, particularly since they come from multiple sources with different schedules of updating and quality control.

Complexity of Transferring Human Resources

The transfer of human resources to local control is a far more complex process than the hand-over of facilities or equipment. There is a much wider range of issues in this regard than there is with equipment and/or facilities. Key decisions that need consideration are listed below:

- (1) Modifying or creating new organisational structures and positions at the central and local levels, and specifying the linkages between them
- (2) Revising job descriptions and reporting relationships
- (3) Defining new processes for personnel management
- (4) Deciding how to reallocate existing staff to new organisational structures
- (5) Transferring personnel records and staff
- (6) Mediating if the new employer refuses to accept the transfer

Dealing with individual staff members who will not or cannot transfer.

Impact of Professional Associations, Unions and Registration Bodies

Health workers' associations, unions, and registration bodies are a very powerful force in the design and implementation of decentralised management structures and jobs. A common fear of the members of health workers' associations and unions is that decentralisation will jeopardise their tenure and substantially reduce their salaries and benefits. As a result, professional registration bodies may be reluc-

tant to approve innovations that successful decentralisation demands, such as the reallocation of responsibilities between professional cadres, re-profiling of jobs, or changes in the training curriculum and level of entry.

Morale and Motivation of Staff

Issues of morale and motivation of health workers loom very large during the initial period of decentralization, when new structures, roles, and responsibilities are defined and staff transfers implemented. Uncertainty over their own professional futures and legitimate concern about the impact of decentralization on the quality of health services combine to make this a time of high anxiety for health workers. This anxiety may force some of them to seek employment in the private sector or even outside the country. The loss of morale and motivation can also result in the initial withdrawal of health managers, particularly those at the central level, from planning for decentralization. If these managers fail to engage actively in the early debates over decentralization, they miss an important opportunity to influence the detailed design of new structures and roles when these are still subject to change.

Collaborative relationships between central and local staff may become frayed where a considerable difference of opinion exists about the advisability of decentralization or the speed with which it is being implemented. Central-level staff may be reluctant to hand power to local staff, seeing them as ill-prepared for their new responsibilities. Local staff, in turn, may be eager to gain a bigger say in the management of health services, and resent the slow pace of reforms. Jealousy over perceived individual gains and losses from decentralization may further damage relations between individual staff members.

HR ISSUES ARISING AS A CONSEQUENCE OF DECENTRALISATION

Decentralization is a complex process, frequently undertaken with some urgency and in a highly political environment. Such pressures of implementation can force decisions that in retrospect prove detrimental to guaranteeing equitable, efficient, and competent staffing of health services. The lack of a comprehensive assessment of the human resource implications of decentralization has been a frequent finding in those countries where decentralization has been attempted. In this section, the key human resource domains where problems arise are identified.

CONCLUSIONS

For current and future HRH initiatives, joining efforts behind a common agenda is needed. To keep the momentum going and consolidate the gains already made, it is important to build on existing efforts and continuity and avoid reinventing the wheel.

In the short-term development of HRH, the focus should be on technical aid corps, and bilateral support between GOL and other SADC governments. In the long-term development, the focus should be to review and upgrade remuneration packages to be in line with those of neighboring countries. Finally, the human resources development strategic plan must include a very strong monitoring and evaluation component at the central and district levels in view of decentralization.

Organizational Structures, Roles and Responsibilities

Successful decentralization requires that the new organizational structures, roles, and responsibilities be clearly defined, form a functional whole, and be acceptable to the health

staff. Difficulties usually arise for several reasons. First, the definition of organizational structures, roles, and responsibilities may be unclear or inappropriate in view of health sector needs. Second, the roles and responsibilities may conflict with each other. Third, the organizational structures and allocation of roles and responsibilities may be disputed. Fourth, these organizational changes may be inadequately communicated below the central level or change so frequently that no one is clear on the current status. The organizational structures, roles, and responsibilities of the intermediate, regional level appear to be the hardest to define clearly.

The allocation of roles and responsibilities can be disputed for a number of reasons. Personality conflicts, mistrust, professional pride, or jealousy can all arise in the course of implementing decentralization. A frequent problem area is the relationship between hospital directors and local health managers. Hospital directors in most countries are senior physicians. Considerable resentment may be caused by making these doctors, in the post-decentralisation organisational structure, subordinate to a local health manager who is junior in age and experience.

Viability of Coordinated Health and Human Resource Development

Health services and health personnel planning, production, and management must be well coordinated with each other. There is a real danger, however, that if adequate care is not taken when new organizational structures are designed and powers allocated, decentralization can jeopardize this coordinated development of health services and their staffing.

First, coordinating the development of health services with that of human resources to oper-

ate those services requires both reliable data on the numbers, skills, and geographic distribution of health personnel and the capacity to use these data for human resources planning. Decentralization, unfortunately, has the potential to fragment human resource databases by transferring the responsibility for maintaining staff records to decentralized units that lack the necessary systems and skills. This reduces considerably the national capacity for coherent human resources planning.

Second, if decentralization isolates national-level decision making on health and human resources development from local-level staffing decisions, the ensuing lack of coordination and conflict have potentially serious consequences for the equitable, affordable, and competent staffing of health facilities. For example, local aspirations are almost certain to take precedence over the greater national good when a decentralized level is given both considerable freedom to decide how it intends to develop and staff its health services and the means to generate revenue to pay for such services. The situation is further complicated if the health workers who transfer take their civil service position with them.

Third, the coordination of health and human resources development can be threatened by decentralization-induced difficulties in career development. Such difficulties can arise either through hindrance to career mobility that decentralization can bring about or from a lack of access to continuing education. Particularly in countries where health workers come under a local government, decentralization can severely restrict the access to career opportunities beyond the administrative area in which the staff work. A transfer to a post in another administrative area may require a resignation from the current post and an accompanying loss of benefits. In addition, staff development

opportunities may be restricted because some lower level units have little or no capacity to mount a program of in-service training for local health staff or because the central level fails to allocate attractive overseas training opportunities equitably.

Ensuring Technical and Managerial Competence

Ensuring the technical and managerial competence of health workers through the turbulence of decentralization is a major challenge. The transfer of power raises several complex issues, which alone and/or in combination jeopardize the competence with which health workers discharge their new post-decentralization duties.

The first issue is a shortage of skilled staff. The new organizational structures and staffing levels may require a quantity of technically trained health staff, especially managers, which the country simply does not possess. In

some countries, the shortage is made worse by the reluctance of highly skilled health workers, such as doctors, to move out of the capital city. In countries, where expatriate staff is recruited for government positions to compensate for this shortage, these workers face both considerable obstacles to maintaining the technical quality of their work, such as their limited knowledge of local languages and culture, and potentially also resentment by some of their national colleagues.

While the numbers of central and peripheral-level managers may be sufficient, these managers may not be equipped with the requisite set of skills for their post-decentralization roles. For example, it is important to take cognizance of the fact that central officials must possess skills in policy-making and monitoring, while lower-level officials need more operational and entrepreneurial skills.

From PHAL to CHAL and Beyond

Presented at the CHAL Annual General Meeting (5-6 November 2007)

'MUSI MOKETE, MBCHB

INTRODUCTION

In 1972 whilst attending a WHO conference in Geneva, I was part of the Lesotho delegation that met a Malawian delegation part of which was a reverend gentleman who was a member of the Malawi Private Health Association. Among many other discussions that we shared, I found that they had a situation very much similar to the one which we had in Lesotho, namely: missionary health institutions (hospitals and clinics), operating in partnership with Government, that organised themselves as the Malawi Private Health Association and share resources and ideas in spite of their different religious denominations. They found it cheaper to buy drugs and other necessary hospital materials in bulk together and share. The ideas were very attractive and the reverend gentleman was informally invited to Lesotho. Like a true Christian, he honoured his promise and made a visit to Lesotho the following year in 1973.

To my surprise when he came as a guest of Government, I was asked to take him around the country to see whether his ideas could take root. I took him to Morija and introduced him to Dr. Ted Germond, with whom I had previously lamented the duplication and sometimes triplication of health services in Lesotho. For example Motsekua clinic (RCC), Matelile clinic (LEC), and Malealea clinic (GOL), were serviced by different Medical Practitioners from their respective principal authorities despite

being along the same route. That was not cost-effective because one medical practitioner could have serviced the same clinics without interfering with their loyalties. Ted Germond and I took the visitor to the three health clinics in a Government vehicle. We shared many ideas, in particular the idea of health service areas. For those of us who had seen the dissipation of many similar clinics with comparable services throughout the country the HSA idea was the solution.

Our next port of call was St Joseph's Hospital in Roma where we initially met with some resistance since support from Miserior (a German Charity) was still strong. Similar resistance was met from Maluti, which still benefited from the help from the USA. Pressure from the declining overseas help and common Lesotho challenges of expensive health care brought missionary authorities together and thus the Private Health Association of Lesotho (PHAL) was born and registered in 1974.

PHAL IS BORN

The charter members of the Private Health Association of Lesotho were the Lesotho Evangelical Church (LEC), the Anglican Church of Lesotho (ACL), the Roman Catholic Church (RCC), and the Seventh Day Adventist (SDA). The first charter members were joined after 1980 by the Assemblies of God, the Bible

Covenant and, still later, for a short period by the Methodist Church. At the time, it was established that “the principal objective of the association shall be to develop the highest level and widest distribution of Health Services in Lesotho through mutual cooperation of all members and coordination with Government of Lesotho and especially her Ministry of Health and Social Welfare.”

CHALLENGES OF THE SEVENTIES

Challenges of the seventies were, in fact, challenges of previous years; some were still outstanding, others a little improved. Doctor patient ratio was 1:17000 and Lesotho’s population was nearing one million. PHAL had eight hospitals and Government had nine with 40% of the patient/clients being looked after by PHAL. The terrain of the country was still invidious. Staff needed upgrading. Cooperation was a necessity.

Thus the advent of PHAL was a blessing whatever the teething problems. Health service areas were mapped out throughout the country with the help of Government and cooperation of all involved, thus reducing travelling expenses for service delivery and buying time for other activities. A Hawaiian group including medical practitioners from the USA broached the idea of nurse clinicians to Lesotho Government, who would be (after appropriate training) a bridge between the doctors (medical practitioners) and staff nurses as they were then designated. They would relieve the doctor shortage and screen patients so that services could be more cost-effective. The idea took root, training was begun and nurse clinicians offloaded doctors both in some Government and PHAL institutions

By 1978 we went to the Alma Ata conference in Russia wherein primary health care principles were declared with health for all by the year 2000 based on accessibility and affordability of the services. The declaration fell on fertile ground because PHAL and Government were already in the second gear. At the same time Medicus Mundi – an organization of the European Volunteer Doctors particularly German and Dutch had been attracted to Lesotho following the 1972 WHO conference at which the PHAL idea was suggested in their Aachen conference. They boosted the working health teams and brought in a fresh look towards the very basic pillar of services namely quality of services for all especially in the periphery. That vindicated, to some extent, the main objective of PHAL “to develop the highest level and widest distribution of services in Lesotho through mutual cooperation of all members and coordination with the government.”

At the end of the seventies, Lesotho doctors, in particular PHAL doctors, had learned to be specialists in generality. Nurse anaesthetists were trained in Mozambique under a WHO programme, but unfortunately were all taken by Government as more candidates were no longer trained. At the 1979 AGM (Annual General Meeting) of PHAL, the then Minister of Health said “It is my own belief that the era of cooperation, coordination and integration in health care has only begun and that the Government and PHAL will need each other even more in the future than in the past.” Then Lesotho primary health care services had become a model for many other African countries including South Africa which was at its worst Apartheid era. A common buying policy from the Lesotho Pharmaceutical Corporation (LPC) had been established with its distributing arm, the National Drug Service Organisation, and PHAL had bought shares in LPC.

THE EIGHTIES

PHAL had gone through teething problems and adjustments to the new situation. To ease the process the constitution had been looked into and amended a number of times for regulatory mechanisms. However the main objective was not lost. The eighties brought about the campaigns of extended immunization programmes, which in fact brought Lesotho to high pinnacles of efficiency in immunizations worldwide among the developing countries.

At the AGM's of PHAL, continued concern about capacity building recurred. Joint workshops and seminars continued. Through the PHAL secretariat, hospitals shared technical help to repair and upgrade utilities as well as teaching and workshops for the local technical staff. That tradition continues up to date.

The secretariat stabilized thanks to the foundations laid by Ted Germond, temporarily followed by Foose, Pekeche, Makara, and Petlane, which were later consolidated by the long-serving Secretary General, Mrs. Nchee, and sustained by Mrs. Ntholi and her team. Successive Boards of Trustees kept the trust of stakeholders, the clients, the heads of churches and cooperation with the Government on an even keel. We salute them.

Capacity was built slowly at the secretariat to be able to cope with management of human resources efficiently and effectively, hence the continued support of donors at national and international levels. By 1986 the first case of HIV was recorded and it spread like bushfire with its resultant AIDS.

THE NINETIES

The wear and tear of institutional structures became evident. Finances also dwindled as the population increased and HIV and AIDS caught up with the reluctant acceptance of the fact that, yes, HIV was with us and AIDS was a sequela.

To meet the challenges of the nineties Government had to be placed on the alert, hence the development of memoranda of understanding which brought about salary assistance for qualified nursing staff, and later doctors. But these could not be sustained as agreements had not been concluded between Government and PHAL. Technicalities became hurdles.

The African Development Bank funded the renovation of Government Hospitals in the nineties, but formalities delayed the continuance of the same programme for the mission hospitals by 1996. However Irish Aid, which was indeed a great boon and a shot in the arm, helped to develop the infrastructure of the PHAL schools of nursing, including other necessary additional buildings.

On the 14th of April in 1997, the Private Health Association of Lesotho was officially registered as the Christian Health Association of Lesotho (CHAL). On the 16th of April, letters were written to all to announce the new change. The constitution whilst evolving through the amendments still kept the same objective of quality health for all. The vision and mission statements were more elaborate, distinct and clear, "with a total commitment to quality health care provision." This time the word Christian Health Association, instead of Private Health Association, defined the Association better and more transparently. It defined

what the Association, in fact, had been and what it is, as the acronyms had previously been influenced by what we had copied from Malawi. The new definition enabled CHAL to ward off other encroachments in terms of membership applications, which had hitherto left an assailable grey area. "In pursuit of this mission, the Christian Church in a non profit making manner, is committed to see to it that quality health services reach those who have least access (families and communities), through appropriate technologies, in the spirit of mutual trust and cooperation as a tangible expression of Christ's vision to love our neighbours as ourselves."

THE NEW MILLENNIUM

The new millennium ushered in many new developments:

- (1) Consolidation of the constitution to adjust to the new century.
- (2) The expiry of the memorandum of understanding of the nineties as well as its emergency replacement by Supplementary Emergency Financial Facility (SEFF) before any further agreements would be made between Government and CHAL.
- (3) Sorting out the legal requirements of valuation of health institutions as well as their proprietorship -- a big hurdle indeed, a new but legitimate requirement in business terms for efficiency. This difficulty was overcome thanks to the input of Irish Government Aid.
- (4) The health reform programme, which added stress to all Heads of Churches, CHAL, Board of Trustees and the entire CHAL membership. Decentralisation and Local Government control of the health institutions reorganises some health service areas in terms of local government

administration, which is an adjustment for CHAL.

- (5) The requirement of reclassification of hospitals according to services they offer and what government will offer to match the 20% contribution by CHAL health institutions in order to reach the same standard of service provision through the whole country to promote equity.
- (6) Contributions of the Millennium Challenge Corporation for upgrading the hospitals, clinics and health centers for improved service delivery
- (7) Acquisition of a site for CHAL, which has been stalled for 3 years at Government secretaries' office after Cabinet's approval. Building would provide a home for CHAL for comfortable and productive work. Currently Dr. Phooko has been contacted to facilitate the process.

All the above hurdles necessitated a memorandum of understanding between Government and CHAL for a "way forward." The process was protracted and stressful, as all of us know because of the many concerns expressed at different levels which were eventually ironed out to enable the ceremonial hallmark of signing of the memorandum of understanding in February 2007 followed by another lengthy process leading to the signing of the Letter of Intent by the heads of Churches and Government on the 5th of October 2007. Thanks is owed to the joint task team.

CHAL has been kept afloat for all the difficult years due to a great extent from contributions of the Lesotho Government, Irish Aid, UNICEF, World Vision, Bristol Myers Squibb, the Global Fund programme and many others. All have been able, through the diligent governance of the Secretariat, to effect revolutionary hospitals, health centres, clinics, programmes, exemplary orphans and vulnerable children

(OVC) activities, successful HIV and AIDS responses, home based care programmes, and formidable positive groups of people living with AIDS as demonstrable transparent outcomes to national and international support. This fulfills the 1979 prophecy of the Minister of Health in 1979 who said, "It is my own belief that the era of cooperation, coordination and integration in health care has only begun and that the Government and PHAL will need each other even more in the future."

What remains now for all parties is to complete all the remaining exercises of continuous review, upgrading the institutions for certification and accreditation in order to meet the health needs of all citizens. CHAL, according to its constitution, has committed itself totally to quality health care provision with emphasis on peri-urban and rural areas. In the spirit of mutual trust and cooperation it will express Christ's vision to love our neighbours as our-

selves. Further it strategically aims "to strengthen the CHAL Secretariat in order that it performs the intended functions both short term and long term through the partnerships with member institutions, Government of Lesotho and other stakeholders."

Brothers and sisters in Christ let us put all our hands on the deck for the fulfillment of CHAL's mission, our mission, Christ's vision and command. For this long journey of CHAL, with the light of hope beaming at the end of the tunnel, we need a pause, a site, for the erection of a stone (Eben Ezer) of thanks to the Lord for having carried us this far. A building, a home for CHAL from which productive work will be intensified as we keep repeating, "Lord what would you have us do?" and like Samuel say, "speak Lord thy servant heareth." Thank you for your attention.

This page intentionally left blank
