A Review of Antiretroviral Costing Models in South Africa

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Abstract

In the South African context of extreme polarisation and contestation on the role of antiretroviral therapy, a number of costing studies have been done over the last three years with a view to informing policy. The approaches to these studies are reviewed and key findings presented. The anticipated coverage of those in need of antiretroviral treatment is identified as a key uncertainty and major determinant of overall programme cost, perhaps outweighing differences in costing study design. Financial resources certainly exist for a treatment programme in South Africa, and issues of service capacity and readiness are identified as critical areas that have been overshadowed due to the elevation of the questions of affordability and universal access to the forefront of a highly contested and politicised policy process.

Résumé

En Afrique du Sud, où le débat s'est polarisé sur l'accès aux antirétroviraux et sur la contestation de leur rôle, plusieurs études sur les coûts de ces traitements ont été réalisées au cours des trois dernières années afin d'alimenter ce débat. Cet article décrit les approches développées dans ces études et leurs principaux résultats. Le niveau prévu de couverture des personnes qui ont besoin

d'antirétroviraux constitue la principale incertitude et le déterminant majeur du coût global des programmes, au-delà même des différences dans les modes d'évaluation des coûts. À l'évidence, des ressources existent pour un programme de traitement en Afrique du Sud mais les questions relatives à la capacité des services de santé et à leur degré de préparation sont des enjeux clés qui ont été mis au second plan. L'essentiel des débats et des controverses politiques porte sur les questions de l'accès universel et du prix des traitements.

Introduction

At the time of writing it is hoped that a National Treatment Plan that includes the provision of antiretrovirals in South Africa is imminent. If a plan does emerge, it will mark a turning point in a struggle characterised by extreme polarisation. In South Africa, marginal issues, such as the role of nutrition, and doubts about the effectiveness of treatment have dominated a debate that should rather be focused on the logistics of service delivery.

Following the announcement of the recipients of the second round of funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria, plans were on the table with secured funding for significant treatment programmes in Lesotho, Swaziland, Botswana, Namibia and Mozambique [1, 2]. At the same time, South Africa, with the largest burden and the most resources in the region, had not yet announced an antiretroviral treatment programme.

Although it is not within the scope of this paper to explore the possible reasons for this polarisation, the context is important in any discussion of costs and cost-effectiveness, as issues of cost and affordability have been utilised by both proponents and opponents to argue for and against Anti-Retroviral Therapy (ART). This paper seeks to review costing exercises undertaken in South Africa to date, and to explore common themes, approaches and deficiencies.

I
QUESTIONS BEING ASKED OF THE COSTS

Costing studies have been invoked to answer a number of different questions with respect to ART in South Africa.

Justifying the intervention

As alluded to above, one assertion has been that the intervention may not be affordable in South Africa, and that studies could assist in determining whether or not ART would be a good buy for South Africa compared to competing alternatives. The first study that sought to comprehensively cost a national intervention took this approach and concluded in 2000 that the intervention was not affordable [3]. A single intervention was modelled for a fixed estimate of the proportion of those with the potential to benefit from treatment accessing treatment, with scenarios representing different assumptions on future drug prices.

Maximising the roll-out or minimizing the cost

A further approach presupposes financial and other resource constraints and is one of economic efficiency, determining the intervention design that would yield the maximum benefit for the financial resources. One study adopting this approach has been published, where different scenarios represented different intervention options for the same numbers of people receiving treatment [4].

Calculating the resource implications

Justifiably, the major focus of current attempts to calculate the costs of treatment have tried to ascertain the financial implications for the government on the assumption of the inevitability of public sector provision of ART. The most recent studies have taken this approach, with scenarios representing different levels of coverage of those in need with one or two uniform intervention designs [5, 6].

Available resources

The above approaches are to varying degrees premised on the assumption of fixed and limited financial resources for the intervention. The assumption of costs being the limiting factor to the provision of ART requires revisiting for two reasons. The first is that in the South African context it could be argued that, at the levels of feasible provision in the next five years, sufficient resources exist. The second is that even if there were significant financial constraints, the nature of the public health catastrophe being faced would justify extraordinary

measures to find the financial resources for the intervention. Both arguments have been invoked in support of public sector ART provision, and the same cost-estimates can be utilised to argue both sides of the controversy, namely the affordability and unaffordability of ART.

The highest estimates of the potential financial burden the government could face if implementing a national treatment plan estimate this peaking at around R 20 billion (US$2.35 billion[1]) in 2015 [6], with lower expenditures before this. In the last two financial years the government has introduced adjustments to taxation that have cumulatively foregone R 30 billion (US$3.5 billion) in annual revenue [7, 8]. Geffen and Nattrass have argued that the worst case scenario would see the treatment plan constituting 2% of Gross National Product (GNP) in 2015 [6]. South Africa is currently in the process of an ambitious and costly arms procurement process of an order of magnitude that could potentially have covered the entire cost of an ART intervention. The potential affordability of the highest estimates is presented, not to justify the costs of the intervention or to argue that this is the best employment of those resources, but rather to support the view that in the likely scenario of a much more modest treatment plan than many of those being modelled, resources could be found if the political will existed. It is interesting that comparative cost effectiveness measures of alternative strategies for fighting the epidemic have not been a feature of arguments for or against ART, but rather the total financial burden of a national programme.

Costing studies

At least four separate attempts have sought to estimate the anticipated costs of a national antiretroviral treatment programme. Before considering the findings of each of these studies, it is of interest to look at the modelling approaches they had adopted.

Model topology

All of the studies to date have utilised similar deterministic approaches for estimating costs. Components include:

– demographic models to estimate the number of patients on treatment each year under different scenarios, as well as the numbers of people in each clinical stage;

1. All dollar prices reflect US$, and are calculated at an exchange rate of R 8.50 to US$1.00.

– estimates of antiretroviral medicine costs on a per-patient-per-year basis;
– estimates of the number of consultations per patient per year, and the costs of consultations;
– estimates of laboratory testing costs on a per-patient-per-year basis.

Different approaches have been used to determine numbers of individuals requiring treatment. In the case of Abt Associates Inc. [3], demographic inputs are obtained from the Doyle model, a proprietary model developed by Metropolitan Life [9]. The studies of Geffen *et al.* [6] and Abdullah [5] are based on levels of AIDS morbidity estimated by the *interventions* version of the ASSA2000 model [10]. While Boulle *et al.* [4] do not explicitly link their numbers on treatment to an external demographic model, they estimate that in 2007 the number of people starting ART in their model will be roughly 10% of the new AIDS cases estimated by the original version of the ASSA2000 model [10].

Both the Doyle model and the ASSA2000 model are combined demographic and epidemiological models, developed for the South African population. Both model the spread of the epidemic by dividing the sexually active population into four distinct risk groups, which represent different levels of sexual activity. In both cases, the sizes of the risk groups and the patterns of interaction between them are set at levels that maintain consistency with HIV prevalence data from antenatal clinics and (in the case of the ASSA2000 model) reported death data. The *interventions* version of the ASSA2000 model builds on the original ASSA2000 model by including scenarios in which antiretroviral treatment and other interventions can be modelled. Although structurally similar, the ASSA2000 and Doyle models produce significantly different results. The Doyle model produces lower estimates of HIV prevalence and AIDS morbidity at the current time, but predicts a later peak in prevalence than that estimated by ASSA2000.

Estimates of treatment effectiveness have been built into the demographic models. Three of the studies relied on the same demographic model-base (ASSA2000), where survival probability is explicitly adjusted on an individual basis for the presence or absence of ART. The survival benefit for these three studies has been assumed to be a median of 4.5 to 5 years [11].

Those studies that have attempted to provide cost-effectiveness estimates or account for cost savings have additionally costed the following under ART and no-ART scenarios:

– hospital and primary care costs for non-ART HIV management;
– costs of tuberculosis care.

Although some studies have assumed future price reductions for medicines and laboratory testing, no discounting was applied.

Four models are contrasted below (summarised in Table 1, pages 306).

Model commissioned by the National Department of Health, 2000

In 2000, the National Department of Health commissioned a study to look at the projected financial costs to the health sector as a result of HIV [3]. The demographic projections were based on a proprietary demographic model. All projected patients in WHO clinical stages 3 and 4 were considered eligible for treatment, with 80% assumed to access treatment. No explicit phase-in assumptions were apparent, and the benefit was assumed to be equivalent to a 75% reduction in mortality for those patients in clinical stages 3 and 4.

The study projected a total additional cost in 2010 of R 70 billion (US$8.23 billion)[2], and interpreted the intervention as unaffordable at then existing prices, as well as if significant reductions in medicine prices subsequently occurred[3]. The annual treatment costs were anticipated on a uniform per-patient-per-year basis at R 51,000 (US$6000).

A rationed approach to treatment

In late 2002, a separate study sought to explore the costs of a rationed programme, arguing at the same time the inevitability of rationing [4]. The study also sought to explore various trade-offs in programme design. Cost-effectiveness estimates were provided for the direct costs only, based on demographic estimates of life years saved (LYS). Potential savings were considered separately. All calculations were cumulative over five years of a phased intervention which was estimated to provide treatment to 10% of those becoming AIDS-symptomatic by 2007 based on mortality estimates from the ASSA2000 model.

2. Public sector only, net of cost-savings from reduced hospitalisation, outpatient visits, and tuberculosis.

3. The estimate in the event of medicine prices being 10% of the then current prices across all years was that in 2010 the additional expenditure as a result of HAART would be R 13 billion (US$1.53 billion).

Medicine prices had fallen significantly by this time, and the estimates of annual per-patient costs were substantially lower than the previous study. Additional reductions in medicine prices (34% over 5 years) were assumed. Explicit provision was made for intolerance-driven individual medicine switches impacting over time on regimen costs. Key findings included:

– the annual direct intervention cost per life-year saved, averaged over the five years, ranged from R 5,923 (US$697) to R 11,829 (US$1,392) depending on whether or not generic medicines were accessed, the inclusion of viral load testing, and the number of regimens offered;

– the annual medicine costs on first line regimens in the least expensive scenario (generic medicines) ranged from R 3,298 (US$388) to R 4,612 (US$543) in the initial projection year, depending on the duration of treatment;

– the total cost in 2007 with 107,000 patients on treatment was estimated to be R 409 million (US$48 million) in the most cost-effective scenario;

– the marginal cost per life-year saved for second line treatment at the point of virological failure was estimated to be approximately R 8,100 (US$950) for the most cost-effective scenario (36% – 39% more expensive)[4];

– the use of patented medicines instead of generic drugs increased cost per life-year saved by 53% and optimal laboratory monitoring by 45%;

– assuming no further reduction in medicine prices increased the cost per life-year saved by 23% on average over five years for the most cost-effective scenario;

– If the same health care utilisation assumptions that were utilised in the earlier study by clinical stage of illness were again applied [12, 13], the averted costs would have covered the intervention costs. The authors were however cautious about the applicability of these assumptions, and chose not to emphasise this aspect.

Treatment Action Campaign study

A group of researchers from the University of Cape Town and the Treatment Action Campaign published in late 2002 a costing study of a number of treatment interventions [6]. Details of one of the interventions, the costs of ART, are presented here.

4. Calculated by dividing the additional expenditure by the additional life years saved, on the assumption of a 60: 40 split in the survival benefit between first and second line treatment.

The ASSA2000 *interventions* model was used to provide estimates of the numbers requiring treatment as well as of effectiveness. The study included a single scenario that sought to cost the provision of ART for 90% of those projected to be clinically eligible by the year 2007, phased in over 5 years.

Medicine prices were assumed to be static over time, although a number of procurement and regimen options were considered, with provision for regimen variation provided for by a 20% factor on consultation costs to cover additional care.

Scenarios including and excluding viral load testing were developed. Limited provision was made for infrastructure expenditure and educational interventions. All costs associated with Voluntary Counselling and Testing (VLT) were included. The clinical consultation costs were calculated on the basis of assumed consultation durations, available working hours and salaries.

Key findings included:

– direct intervention costs of R 11 billion (US$1.29 billion) in 2007, peaking around R 20 billion (US$2.35 billion) in 2015. This assumes 1,257,000 and 2,483,000 people on treatment in each year respectively ;

– average annual first line medicine cost of R 4,260 (US$500), and second line cost of R 7,332 (US$863) for adults, and R 7,350 (US$865) for all regimens for children ;

– an additional 14 – 21% would need to be spent in order to include viral load testing in 2015, depending on the projected price of the test[5];

– an additional 35% would need to be spent in 2015 if patented medicines were utilised, whilst 19% of costs could be averted if first line and second line regimen costs could be reduced to R 3,600 (US$424) and R 5,400 (US$635) respectively;

– between R 6 billion and R 7 billion (US$0.70 – US$0.82 billion) could be saved through averted hospital costs by 2007;

– an additional R 1 billion (US$0.12 billion) could be saved in 2015 through averted social grants for orphans;

– the projected expenditure on hospitalisation in the absence of ART outstrips the anticipated health budget in projections, suggesting underprovision of services for HIV in general.

5. R 500 (US$59) for both viral load and CD4 cell count versus R 707.40 (US$83) for both these tests.

Western Cape Provincial Department of Health estimates

A separate study is currently being conducted under the auspices of one of the South-African provinces [5]. Results from the application of this model to a national dataset were not available at the time of writing.

The ASSA2000 interventions model was once again utilised for the demographic estimates in this study. Assuming treatment is initiated on average at the time of becoming AIDS-sick, a number of scenarios were built anticipating 20%, 50% and 90% of those in need accessing the intervention by the fifth year. Costs were varied by duration of treatment (crudely between the first six months on a regimen and treatment thereafter) to account for different monitoring and consultation frequencies, as well as regimen composition. Consensus amongst clinicians informed the choice of regimens, with first and second line regimens being available to each patient. The study did not attempt to determine cost-effectiveness ratios.

This study extends the earlier methodology [4] by including a range of starting regimens, costing a fixed intervention design that includes viral load testing and provision for first and second line treatment, and adding provision for a number of additional items such as resistance surveillance, and support for NGO's to assist in promoting adherence over and above existing counselling capacity. For each coverage scenario both generic and patented medicine prices are included with allowance for procurement, distribution and shrinkage. Further reductions in the prices of antiretrovirals are assumed, cumulatively totalling 47% reduction in 2007-2008. Key findings from the provincial dataset include:

– the major cost components of medicines, laboratory testing and consultations account for 43%, 22% and 17% of total costs in 2007-2008 respectively;

– patented medicines would increase direct intervention costs by 27% in 2007-2008 compared to WHO pre-qualified generic medicine prices.

A national task team has been established between the Ministries of Health and Finance to report amongst other things on the anticipated costs of a national treatment plan. Although the team has yet to report their findings, it is likely that similar approaches to those discussed above have been utilised. In addition, a cost-effectiveness study of a pilot public sector antiretroviral treatment programme in a peri-urban township near Cape Town should be available towards the end of 2003 [14].

II
KEY DETERMINANTS OF ANTICIPATED COSTS

The meaning of universal and progressive

What becomes immediately apparent when looking at these four studies is that the central determinant of overall resource implications is the estimated coverage and uptake. Three of the four studies included scenarios that anticipate 80% or more of those patients projected to be clinically eligible accessing ART. These scenarios are unrealistic for a number of reasons.

The need for close to perfect adherence for the individual benefit of ART, and the population risk of increased viral resistance, often lead health care professionals to suggest that eligibility has to take into account the presumed likelihood of adherence in spite of the difficulties in a priori identifying those patients who are most likely to be adherent [15]. In this context, the notion of "progressive realisation" enshrined in the South African constitution should be employed to ensure that the most marginalised in society are not systematically discriminated against in the process of responsibly scaling up services, rather than to force a dichotomous choice between rapid universal access and no access.

Geffen and Nattrass have poignantly contrasted the projected financial demand on the public health sector on account of HIV/AIDS and the total public sector health budget [6]. If estimates of optimal health service utilisation in the absence of ART are anywhere close to being accurate, it is clear from this comparison that the public health sector is significantly underproviding hospital services for those with HIV/AIDS. Many forms of implicit rationing pervade service provision in South Africa. For example, the uptake of a significant social grant for those caring for orphans is estimated to be less that 40% [6].

Perhaps most importantly, the responsible implementation of ART requires that services are progressively strengthened until they are in a position to provide the intervention. This suggests that many simpler interventions should be in place if ART is to be the final component of a comprehensive and synergistic health service response at a health district level. Some of the building blocks include adequate tuberculosis cure rates, existing HIV/AIDS treatment services that can provide a platform for identifying patients and developing treatment literacy, existing implementation of cotrimoxazole and isoniazid prophylaxis, and a well-functioning programme to prevent mother-to-child transmission of HIV. There are currently extensive human resource backlogs in public sector health provision in South Africa [16]. Even with financial resources available,

the crucial input of additional doctors and nurses may prove disconcertingly inflexible. Whatever steps are taken to set the public health system on a new footing to meet these challenges, it is unlikely that the universal coverage estimates utilised to date will be achieved.

Viral loads

Viral load testing remains disproportionately expensive, adding between 19% and 45% to the direct cost or cost-effectiveness estimates in two of the studies [4, 6].

Regimens

The above studies have varying degrees of detail in how the medicine costs are calculated. Perhaps even more important than the current cost estimate for medicines is the anticipated change in prices over time. There is no consensus on the reasonableness of assuming future price reductions beyond the best currently available generic prices. Even the most optimistic of the above models assumes that the annual cost for first line treatment will not fall below the oft-quoted target of $200 per year [17].

Consultation costs

The relative efficiency of clinical consultations for ART compared to other services at either primary care facilities or hospitals remains unknown. Three of the four reviewed studies have made assumptions for consultation costs in the absence of data. This is one area where the results of costing exercises currently being conducted in parallel with public sector ART pilot projects will improve the precision of estimates, in spite of the pilot nature of the projects.

III
KEY DETERMINANTS OF ANTICIPATED BENEFITS

Knock-on

One of the reasons for the inclusion of near-universal coverage estimates in treatment plans, is that if the population benefit is quantified only as an aggregate of the benefits to individuals on ART, it is only these scenarios that demonstrate

significant shifts in morbidity and mortality at a population level. There is no shortage of persuasive arguments on the importance of treatment in increasing the uptake and effectiveness of other HIV/AIDS interventions. The extent to which these still apply at much lower levels of coverage is uncertain. The arguments that a significantly rationed ART programme will retain these effects disproportionate to the rationing are central to supporting a rationed approach. Examples of these effects include the presumed increase in uptake of VCT, the reduction of stigma and denial, and the provision of hope in an increasingly desperate health care setting. It is unlikely that these effects will ever be able to be attributed to treatment programmes from a research perspective, as the introduction of programmes parallels the changing nature of the epidemic which in itself is likely to have enormous effects on the same parameters.

Component effects

The demographic modelling underpinning three of the studies has also attempted to quantify the population level impact of VCT associated with ART [11]. The additional testing required to enrol patients into ART programmes has been assumed to deliver independent benefits in line with those that have been seen with VCT alone. It is uncertain if these effects would be constant as the uptake increased. These effects result in infections averted and mortality and morbidity reductions many years later. To include the reductions in morbidity and mortality on account of these requires long-term projections with increasing uncertainty. These "component effects" have not to date been included in the benefit side of a cost-effectiveness comparison.

Non-ARV treatment costs

The difficulty in applying utilisation assumptions from cohort studies to whole population modelling exercises has already been demonstrated on the basis of the implausibility of the cost estimates this generates. It is also likely that the increasing pressure on services is constantly changing the service levels offered to those seeking care for HIV, with reducing lengths of stay in hospitals, higher admission thresholds, increased reliance on home-based care and reduced access to care.

Conclusions

This paper has demonstrated the range of work done to date on anticipating the costs of a national antiretroviral treatment programme in South Africa. A number of common determinants of cost across all of the studies have been identified. The key assumption on the projected extent or size of the programme has been highlighted and discussed.

Although projected costs have been utilised to argue both for affordability and unaffordability, it is argued here that other constraints are more likely to limit a future programme in the coming years. The politically contested role of ART may have led to an overemphasis on the use of cost estimates as justification for policy choices in a context where some of the key determinants of these estimates are subject to immense uncertainty. On the premise that a programme is desirable and inevitable, and that the projected costs are relevant mostly in facilitating financial planning, it is important for the debate on costs to shift to one of economic efficiency. South Africa would gain more by focusing on different dimensions of provision, with a keen sense of capacity at all levels, than on the affordability of universal access.

An argument frequently offered in response to the lack of capacity to deliver ART at the projected levels of need, is that the introduction of ART can be used to build health systems, rather than being limited by them. If true, this requires more attention being focused on health system issues and roll-out strategies. This is certainly the major challenge for South Africa.

This conclusion must however be tempered with the acknowledgement that simply because South Africa can find the financial resources to begin a programme now does not excuse the system of global Apartheid that makes treatments for HIV and other diseases an extreme financial burden for those countries most affected by them [18].

Table 1: Comparison of four costing studies. All prices in South African Rands.

	National Department of Health (2000)	Rationed approach (2002)	Treatment Action Campaign (2003)	Western Cape Department of Health (2003)
Demographic model	Doyle	Aligned with ASSA2000	ASSA2000	ASSA2000
Definition of clinical eligibility	Everyone in stages 3 and 4	At the onset of AIDS	At the onset of AIDS	At the onset of AIDS
Coverage of those projected to be clinically eligible for ART	80% of all in clinical stages 3 and 4	10% by 2007	90% by 2007	20, 50 and 90% by 2008
Phasing in	No	Yes, over 5 years	Yes, over 5 years	Yes, over 5 years
Modelling period	2000 - 2010	2002-2007	2002- 2015	2003-2015
Adults/Children	Both	Adults	Both	Both
Scenarios and sensitivity analyses	Uniformly reduced medicine prices	First line only; two regimens; no medicine price reductions; with and without viral loads; increased survival benefit; generic/patent	With and without viral loads; uniformly different medicine price structures	Generic/patent; different levels of coverage of need
First line annual medicine costs (adults)	R 44,000	R 4,612 - R 15,288	R 4,260	R 3,744
		R 8,933 - R 15,288	R 7,332	R 8,913
Initial first line regimen (adults)	Not stated	d4T / 3TC / NVP	AZT / 3TC / NVP (generic)	d4T / 3TC / NVP (55%) or EFV (45%)
Assumed medicine price reductions over time	Scenarios of uniform reductions across all years of between 10% and 90%	34% reduction by 2007	No change, but a scenario presented with lower prices across the whole study	47% by 2008
Impact of patented medicine prices over generic medicines	Not explicitly calculated	53% increase in cost per LYS in most cost-effective scenario	35% increase in direct costs in 2015	27% increase in direct costs in 2007-2008
Regimen variation	Uniform regimen	Uniform starting regimen with explicit assumptions on individual medicine changes	Uniform costs, but 20% factor on consultation costs to cover changes	Variable starting regimen, with explicit provision for within-regimen changes

Viral loads included	Not explicit - R 3,500* per year for monitoring	Increased baseline cost-effectiveness ratio by 45% in a scenario which included more frequent CD4 cell counts as well as viral loads	Increased direct costs by 14 - 21% in 2015	Included in all scenarios
Basis of clinical consultation costs	Not explicit	Cost per visit based on current primary care per consultation costs with a cost factor of 1.5	Explicit calculation of clinical costs based on consultation durations and salaries	Cost per visit based on current primary care costs with a cost factor of 1.5. Counselling considered already-funded
Other components included	None	Pre-ART treatment costs to ensure feeder services at a ratio of three people in treatment for each person started on ART	VCT component fully costed, with limited costing of infrastructure and educational campaigns	Pre-ART treatment costs to ensure feeder services at a ratio of three people in treatment for each person started on ART, resistance monitoring, and adherence support services

Direct costs in 2007/2008	R13 billion* to R 70 billion* additional cost (number on treatment unclear, but at least 80% of those projected to be in stages 3 and 4)	R 409 million in 2007 (107,000 on treatment)	R 11 billion* in 2007 (1,257,000 on treatment)	Estimates from model applied to national demographic data not yet available
Maximum direct costs (note the different projection periods)	R 70 billion in 2010	R 409 million* in 2007 (107,000 on treatment)	R20.3 billion* in 2015 (2,483,000 on treatment)	

Cost-effectiveness calculations for direct costs only	Not done	Cumulative over 5 years, R 5,923 to R 11,829 per life-year saved depending on scenarios	Not done	Not done
Savings in the health sector as a consequence of treatment	The direct costs quoted above are additional to other HIV-related health sector expenditures and already account for averted costs	Averted hospital, primary care and tuberculosis treatment fully cover the most cost-effective scenario if those accessing ART are assumed to have optimally utilised services in the absence of ART	Up to R 10 billion per year could be saved from the time of full phase-in through averted hospitalisations and social grants for orphans	

**Rate of R 8.50 to US$1.00.*

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