



ANTIRETROVIRAL THERAPY IN NAMIBIA

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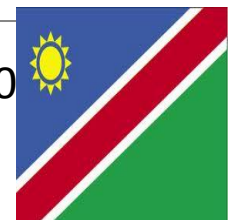
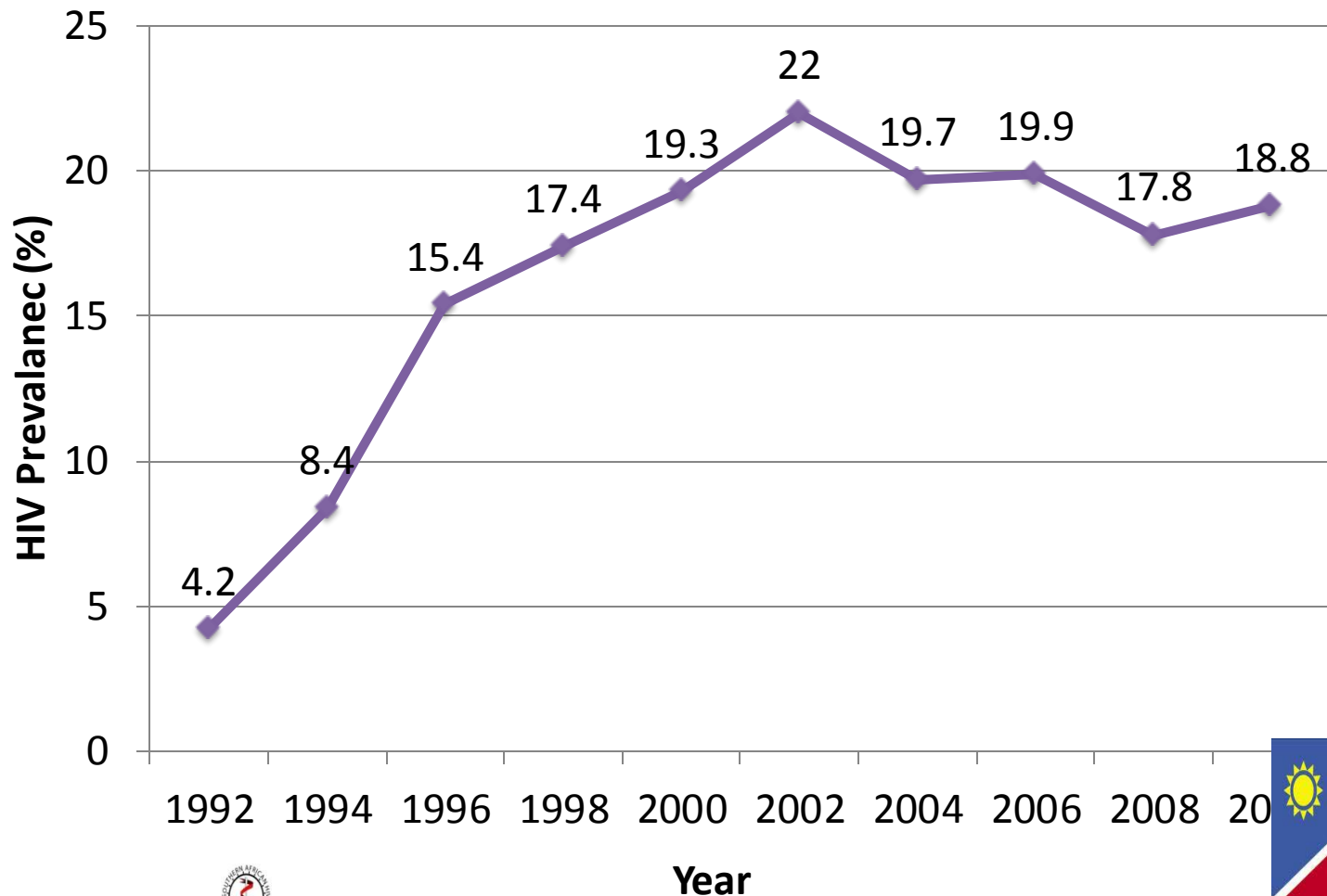


Current status in Namibia

- Population, 2.3M
- Surface area (sq. km) (thousands) 823.4
- GDP (current US\$) (billions) 12.3 GDP per capita
- growth (annual %) 3.8
- Life expectancy at birth, 62.3 years
- Mortality rate, infant 29.6 per 1,000 live births
Prevalence of HIV, 18.8% ANC Sero survey 2010



HIV Prevalence Rate in Pregnant Women in Namibia 1992 - 2010



Source: MOHSS report of the 2010 National HIV Sentinel Survey, November 2010

Implementation of ARV therapy in Namibia

- ARV therapy was implemented in the Private Sector in 1997 by Government Medical Aid as approved by cabinet.
- There were no ARV guidelines
- The HIV Clinicians Society Namibia was founded by a group of doctors from both Private and state sectors.
- The initial draft guideline was made by this group in 2002 and later became the framework for the initial ARV guidelines of Namibia in 2003.
- The latest draft of Namibia guidelines is the 2010 document.
- This is the third edition



CURRENT STATUS OF ARV THERPAY IN NAMIBIA

- 80% patients in need of ART are receiving ARV Medicines
64% are women
16% are children
- Complete nation wide coverage of ART Service delivery.
- Introduction of Integrated Management of Adolescent and Adult illnesses (IMAI) strategy by MOHSS.
- Introduction of quality management program (HIV QUAL) has taken place successfully



Minimum requirement to start ARV therapy

1. Trained Medical Practitioner

To be able to assess and stage HIV positive Individual.

2. Access to Laboratory facility with minimum tests of full blood count, kidney function, HBSAg, ALT and a CD4 count.

Trained support staff especially a Nurse and a community counselor

No baseline virology studies required.



Requirement for HIV positive Adult to start on HAART therapy.

1. WHO clinical stage 3 or 4, irrespective of CD4 count *or*
2. If WHO stage 1 or 2, CD4 Count < 350 cells /mm³
3. It is anticipated that from April 2013, all pregnant women will be eligible irrespective of WHO Clinical stage or CD4 count. (Option B+)
4. All HIV/HBV Co-Infected patients with ALT $> 2X$ ULN or HBeAg-positive.



Considerations to improve HAART Adherence.

1. Assessment, Counselling and Information given 2 weeks before ARV therapy.
2. Adherence supporter encouraged but not mandatory.
3. Using the Simplest regimens.
4. Improving Provider related skills.
5. Dialogue with the community include NGOs peer educator and linkages to the TB Control program
6. Social considerations.
7. Standardised definitions of a defaulter .



Recommended HAART in Namibia in Adults

1. First line regimen: TDF 300mg + 3TC 300mg OD
plus NVP 200mg twice day.
2. HIV-TB Co-Infection: TDF/3TC/EFV
3. Chronic active TDF/3TC/NVP or
TDF/3TC/EFV

Second line

4. Second line Regimen: AZT/TDF/3TC/LPV/r.

Third line

Third line regimen: Is always to be discussed with an HIV Specialist taking into consideration results of HIV resistance testing.



Eligibility criteria for children

1. All HIV infected Infants less than 24 months age .
2. HIV infected Children between 24 – 59 months with
 - WHO Paediatric stage 3 or 4
 - or stage 1 and 2, if CD4 \leq 25%
3. HIV infected Children \geq 5 years of age.
 - WHO Paediatric stage 3 or 4
 - or WHO Paediatric stage 1 or 2 if CD4 $< 350/\text{mm}^3$.



First line regimens available for children.

1. HIV + Infants < 24 months with known prior exposure to NVP or to maternal NVP- containing HAART or PMTCT prophylaxis – LPV/r + D4T/3TC FDC
 - d4T used because there currently there is no infant AZT- containing FDC available
2. HIV + Infants < 24 months old without prior exposure to NVP and children > 24 months old but < 14kg – NVP/D4T/3TC FDC.
3. Children \geq 24 months \geq 14kg and Tanner stage I – III AZT/3TC/NVP.
 - These children can use the adult AZT-containing FDC
4. Tanner stage IV or post pubertal Adolescents TDF/3TC/NVP.



Second line Regimens in Children

1. Second line HAART for children (Tanner stage I – III)
first line: (ABC + AZT + 3TC + LPV/r)
2. Second line HAART for children Tanner stages I - III
who had PI-based first line ABC + AZT + 3TC + (NVP
or EFV).
3. The second line HAART Regimen for children who
are Tanner stage IV or V is the same as Adults.
If the first line regimen included Tenofovir, seek
advice of an HIV Specialist.



HAART REGIMENS IN CHILDREN ON RIFAMPICIN BASED REGIMES

1. ≥ 3 years *and* weight ≥ 10 kg
 - AZT or d4T + 3TC + EFV if sexual maturity Tanner stage I-III
 - TDF + 3TC + EFV if sexual maturity Tanner stage IV/V.
2. < 3 years *or* weight < 10 kg give either
 - D4T or AZT + 3TC + ABC *OR*
 - D4T or AZT + 3TC + super-boosted LPV/r.



Post Exposure Prophylaxis

1. Low risk exposure: TDF plus 3TC fixed dose combination for 28 days within 24 hours of Exposure.
2. High Risk exposure: TDF + 3TC + LPV/r or EFV for 28 days within 24 hours of Exposure.
3. Because the background prevalence of HIV is high, there is no differentiation in management depending on whether the source is high or low HIV risk



Overview of ARV Therapy in Namibia (April – June 2012)

50 sites in Namibia give ART therapy

No. of patients on ART AS OF June 2012 108 687.

No. of Adults 90.4%

Paediatrics (<14 years old) 9.6%

Top ARV used in Namibia Public sector:

3TC + TDF fixed dose

3TC + AZT + NVP – fixed dose

NVP

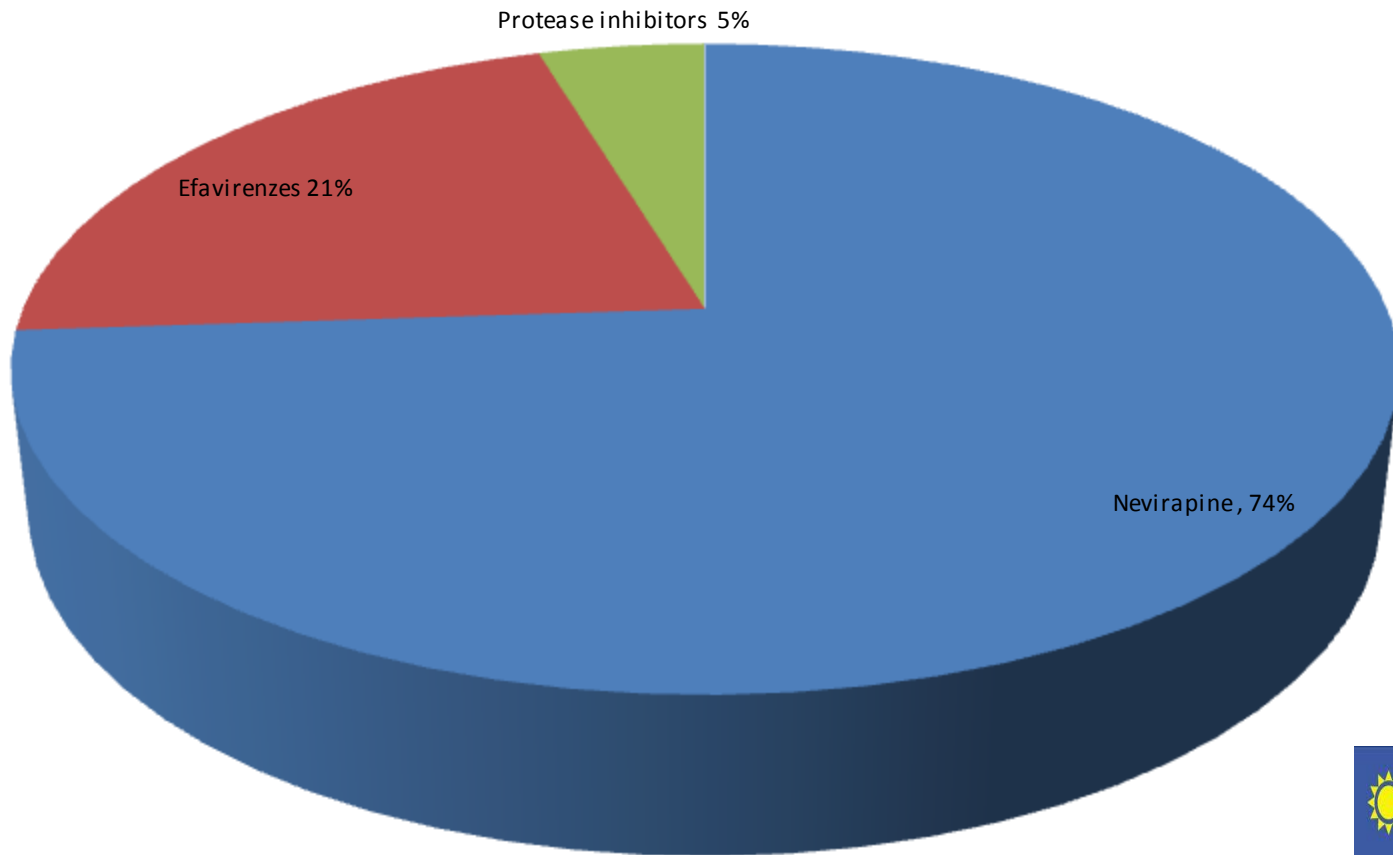
EFV

LPV/r 200/50.



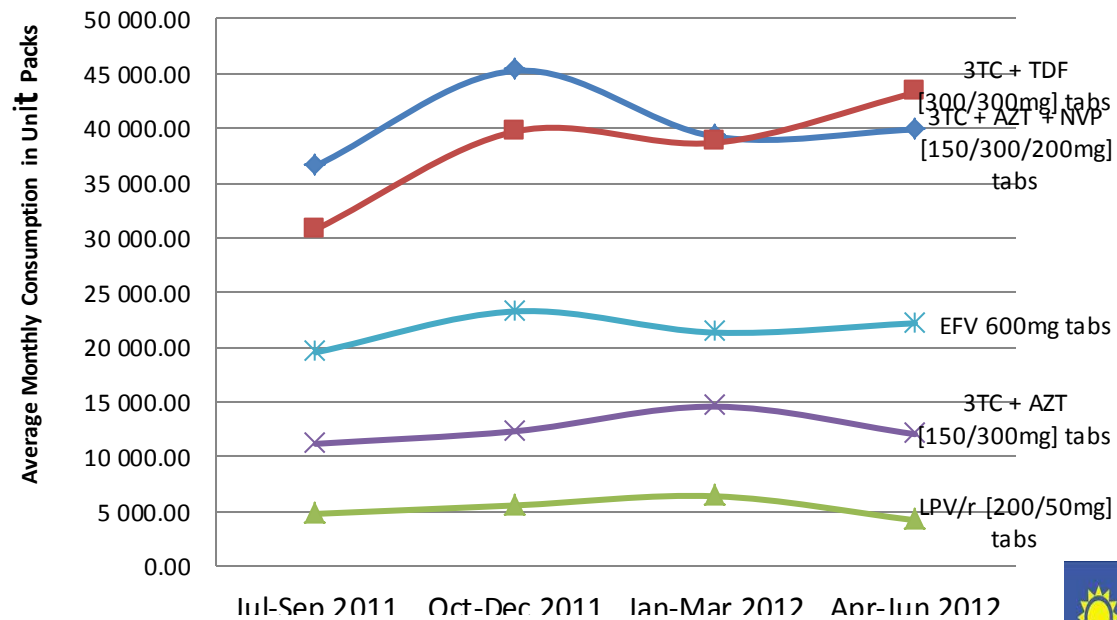
Overview of ARV Therapy in Namibia (April – June 2012)

ARVs in the Public Sector-NNRTIs vs PIs March -June 2012



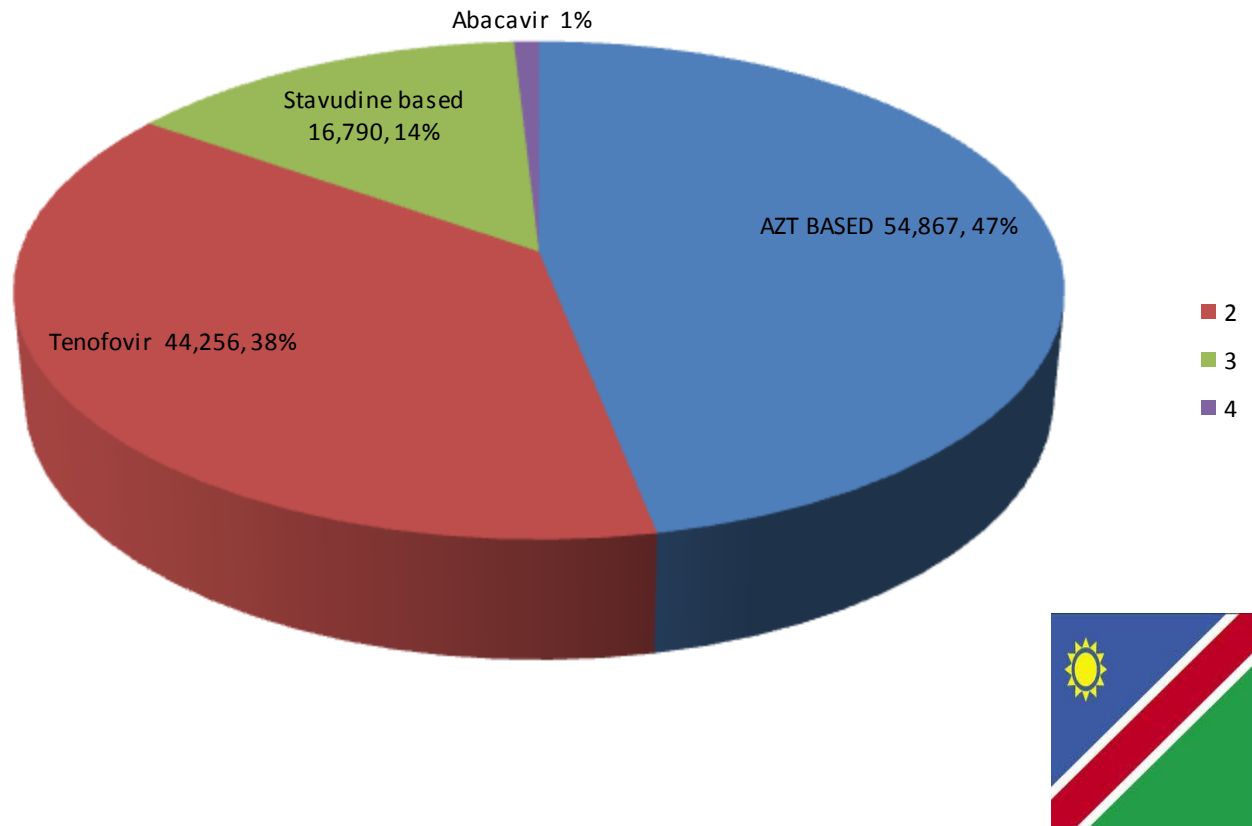
ARV IN THE PUBLIC SECTOR

Consumption Trend for the Top Five ARVs, Jul'11 - Jun'12



ARVs in the Public Sector-

Nucleoside Analogues March-June 2012



Assessment of the risk of anemia associated with zidovudine-based HAART in Namibia

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- *and*
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- *Andy Stergachis, PhD, RPh*
- *Global Medicines Program*
- *University of Washington*
- *October 2010*

Assessment of the risk of anemia associated with zidovudine-based HAART in Namibia:Background

- 2007: Namibia switched first-line treatment from d4T- to AZT-based HAART
- 2008: ~50% (22,050/43,329) of HAART users on AZT-based regimens in 2008
- 2008: Anemia in HAART users most commonly reported adverse event in 2008 (106 of 256 spontaneous ADR reports to TIPPC)
- 2009: TAC requested MSH-SPS to provide technical assistance in the adverse event monitoring of ARVs

Assessment of the risk of anemia associated with zidovudine-based HAART in Namibia: Specific Aims

Primary Aim:

To determine the incidence of and risk factors for anemia in adults on AZT-based HAART

Secondary Aim:

To demonstrate the feasibility of using automated data bases and records linkage as a sustainable platform for assessing the safety and use of HAART to help support evidence-based decision-making in Namibia

Assessment of the risk of anemia associated with zidovudine-based HAART in Namibia:Results

- Of 12,358 persons who initiated HAART between January 2007 and June 2008, 7,206 started on AZT- and 5,152 on d4T-based HAART.
- 4,746 (38%) individuals had baseline Hb values available.
 - 63% of persons with baseline Hb values were in AZT cohort.
- Total of 828 persons (6.7%) developed any anemia, and 151 persons (1.2%) developed severe anemia during follow-up.
- 293 deaths and 12 lost to follow-up.

Assessment of the risk of anemia associated with zidovudine-based HAART in Namibia: Characteristics of HAART Cohorts

Variable	AZT (N=7,206)	d4T (N=5,152)
% female	61.1	61.5
Mean age, years	35.7	36.7
% started their HAART regimen in 2007	43.3	89.7
Mean baseline weight, kg	56.7	53.8
Mean baseline CD4 count	157.1	155.0
% Baseline WHO stage 3 and 4	34	41
Mean baseline hemoglobin, g/dl	11.8	11.8
Hb measurements in first year of HAART, median (IQR) [‡]	2 (1-3)	2 (1-3)
Median time to first Hb measurement, days (IQR)	37 (14-70)	146 (55-258)
Mean follow-up time, years	1.26	1.76

Results

Prevalence of anemia at the start of HAART

- Of 4,852 with baseline Hb values, 672 (13.8%) had any anemia at start of HAART.
- Prevalence of anemia significantly higher in:
 - women than men (14.9% vs. 12.2%, $p=0.01$)
 - d4T cohort than AZT cohort (18.3% vs. 11.3%, $p < 0.001$)

Incidence of anemia

Cohort	Persons with baseline Hb values (n=4,746)*		Persons with no baseline Hb values (n=7,506)	
	Events	Incidence rate (per 100 PYs)	Events	Incidence rate (per 100 PYs)
Any anemia				
AZT cohort	379	11.85	84	1.45
d4T cohort	234	9.31	131	2.30
p value	0.004		0.001	
Severe anemia				
AZT cohort	73	2.28	20	0.34
d4T cohort	45	1.79	13	0.20
p value	0.5		0.16	

Abbreviations: AZT, zidovudine; d4T, stavudine; Hb, hemoglobin; PYs, person-years

* 106 individuals excluded for having severe anemia at baseline.

Risk of severe anemia: retrospective cohort analysis

- **No statistically significant difference** in the risk of severe anemia in AZT vs. d4T cohort.
 - Relative risk adjusted : 0.73; 95% CI: 0.43, 1.24
 - Adjusted for age, gender, baseline weight, CD4 count, WHO clinical stage, baseline hemoglobin, clinical status and year of starting HAART.
 - Does not take duration or timing of use into account
- **Statistically significant risk factors** for severe anemia:
 - Persons with 1 g/dl lower baseline hemoglobin had a 12% increased risk of severe anemia.
 - Persons with 1 kg lower baseline weight had a 3% increased risk of severe anemia.

Assessment of the risk of anemia associated with zidovudine-based HAART in Namibia: Nested case-control results

- Included 11 ART facilities country-wide.
- Records for 82 cases* of severe anemia and 246 persons without severe anemia (controls) abstracted.

* 82/151 cases of severe anemia

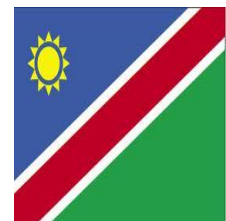
Antiretroviral treatment in the Private sector in Namibia

- 280,000 Namibians (17% of the total population) are covered by private medical insurance.
- The Medical insurance for government employees covers over 70% of all members of the private sector



Antiretroviral treatment in the Private sector in Namibia

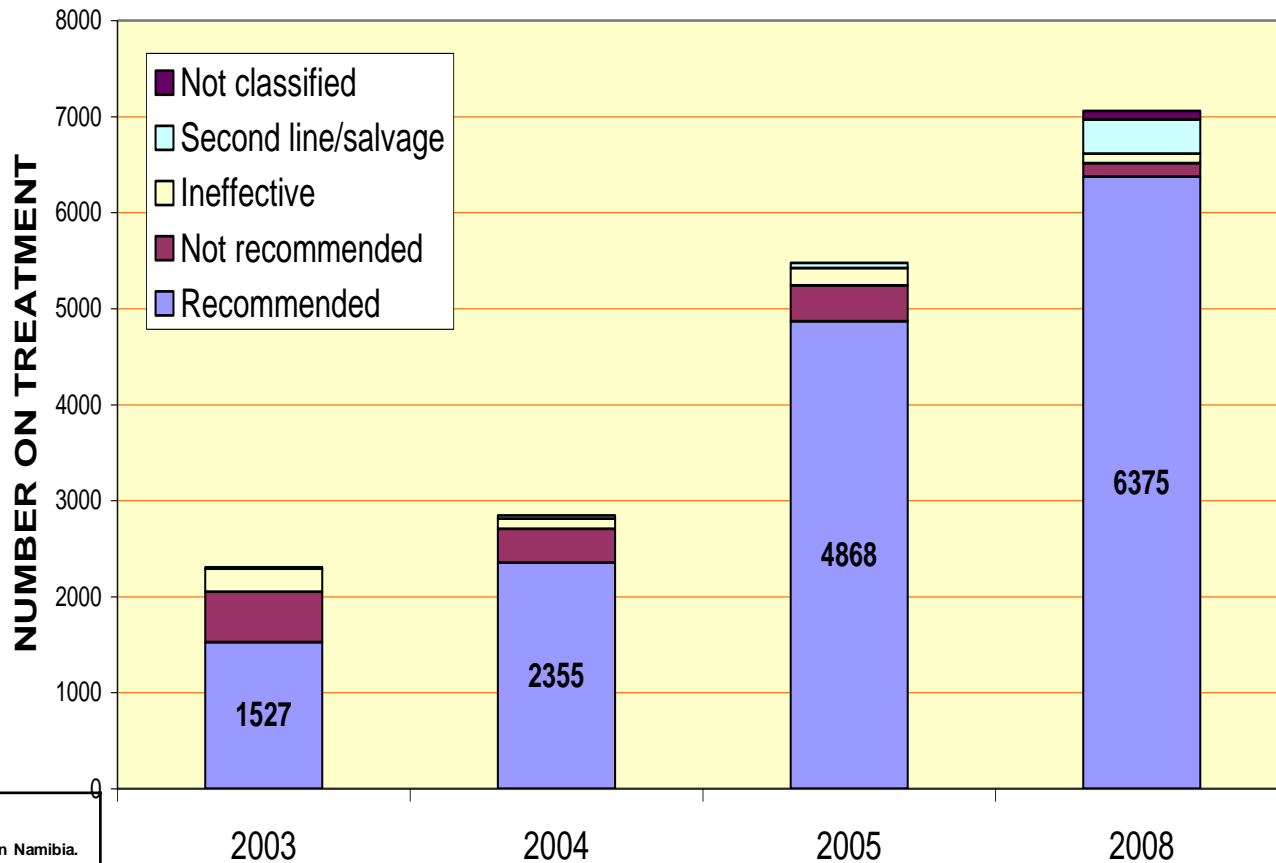
- The medical insurance companies in Namibia agreed to make anonymous data on ARV dispensing available to the Society for analysis and feedback in the years 2003, 2004, 2005 and 2008. The Society uses this information to provide feedback to the Ministries of Health and finance, and medical insurance industry. The information



Antiretroviral treatment in the Private sector in Namibia

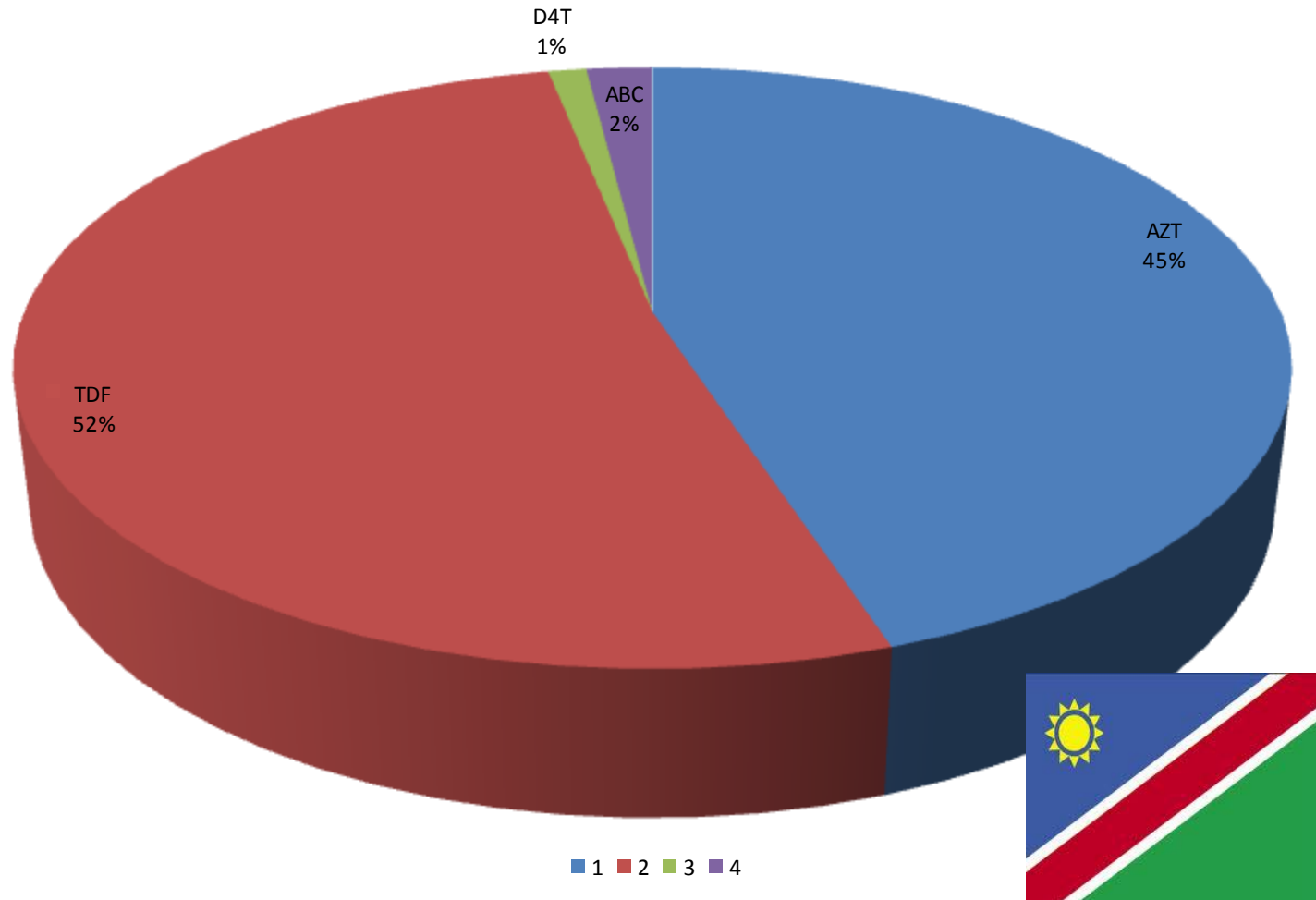
- Cross sectional ARV dispensing for the last quarters of 2003, 2004, 2005 and the second quarter of 2008 were compiled and analysed.
- ART regimens were compared with the most recent national and international guidelines and classified into
 - recommended (NNRTI-based and boosted PI-based),
 - not recommended (non-boosted PI-based or d4T/ddI containing regimens),
 - ineffective (dual therapy) and second line or salvage regimens.

Antiretroviral treatment in the Private sector in Namibia



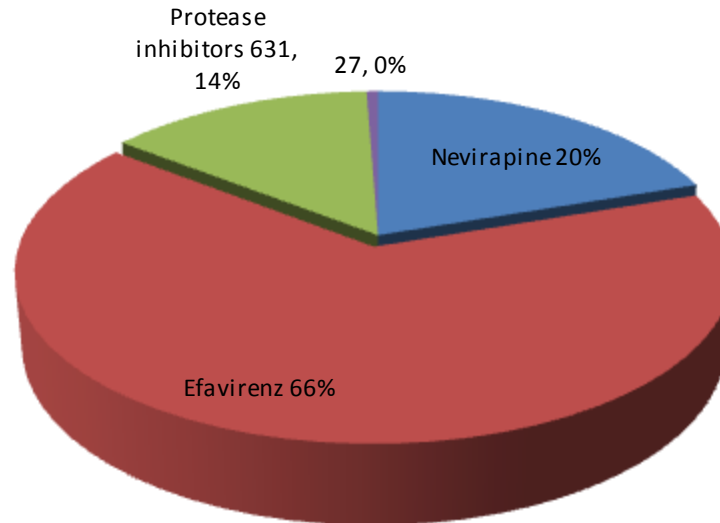
Antiretroviral treatment in the Private sector in Namibia

NUCLEOSIDE ANALOGUES IN THE PRIVATE SECTOR 2012



Antiretroviral treatment in the Private sector in Namibia

Nevirapine Efavirenz -Protease inhibitors DARUNAVIR Private Sector



Antiretroviral treatment in the Private sector in Namibia

- The available data give an accurate picture of the significant contribution of the private sector to ART access in Namibia.
- Adherence to recommended ARV regimens has overall improved. There is a significant increase in second line regimens.
- Standard protocols for analysing ARV dispensing could identify practices in need for training and supportive supervision.
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