



HIV/Aids Training

Module 4

Principals of Therapy, Adherence and
Resistance
June 2008

Adapted from and thanks to:

Foundation for Professional Development; Ashraf Grimwood; GF Jooste meetings; Prof Gary Maartens lectures; PATA conference; MIC and Department of Pharmacology UCT

Principles of therapy; adherence and resistance



SOUTH AFRICANS AND AMERICANS
IN PARTNERSHIP TO FIGHT HIV/AIDS



USAID
FROM THE AMERICAN PEOPLE

Goals of Treatment

Primary Goals

- to put as *many patients on ARVs with good adherence*
- prolong *life expectancy* & improve *quality of life*
- prevent fewer *HIV-related illnesses (Ois)*
- *models suggest that on average 15 to 40 years of life are added to an HIV infected person's life by the availability of multiple regimes*
- CD4 count should *rise* and remain above the baseline count* and VL should become and remain *undetectable*

* Note 10-20 % of patients will have a poor CD4 cell count response.

Goals of Treatment

Secondary goals

- increased uptake in Voluntary counseling and Testing (VCT)
- reduction of HIV transmission to others
- improved socio-economic status of
- households



Normative approach

- adherence is not natural
- few people do anything with absolute regularity
- most people would rather do as they please rather than do as they are told
- adults able to complete only 5 days of antibiotics ?
- “choose your patients slowly”



Sammy, pharmacist, EC, 2008





Children's adherence is even *less natural*

- the prescribing agent's contract is with a third party
 - adherence of the *second* party is dependent on performance of parties of both the *first* and the *third* part



SA National Criteria for ARV Treatment

Medical criteria:

- WHO stage 4 disease (exception: tuberculosis is not a criterion for initiating ART unless CD4 count < 200 cells/mm³) **OR**
- WHO stage 1, 2 and 3 patients with CD4 count < 200 cells/mm³.

(See Table 2 for WHO Staging.)

Psychosocial criteria:

- Demonstrated reliability, i.e. has attended three or more scheduled visits to an HIV clinic.
- No active alcohol or other substance abuse.
- No untreated active depression.
- Disclosure: It is strongly recommended that clients have disclosed their HIV status to at least one friend or family member OR have joined a support group.
- Insight: Clients need to have accepted their HIV positive status, and have insight into the consequences of HIV infection and the role of ARV treatment before commencing ARV therapy.

See page 4 ARV Treatment Protocol WC guidelines

Psychosocial criteria for ARVs

D = *demonstrated* reliability – accurate pill counts, regular clinic attendance, correct dates

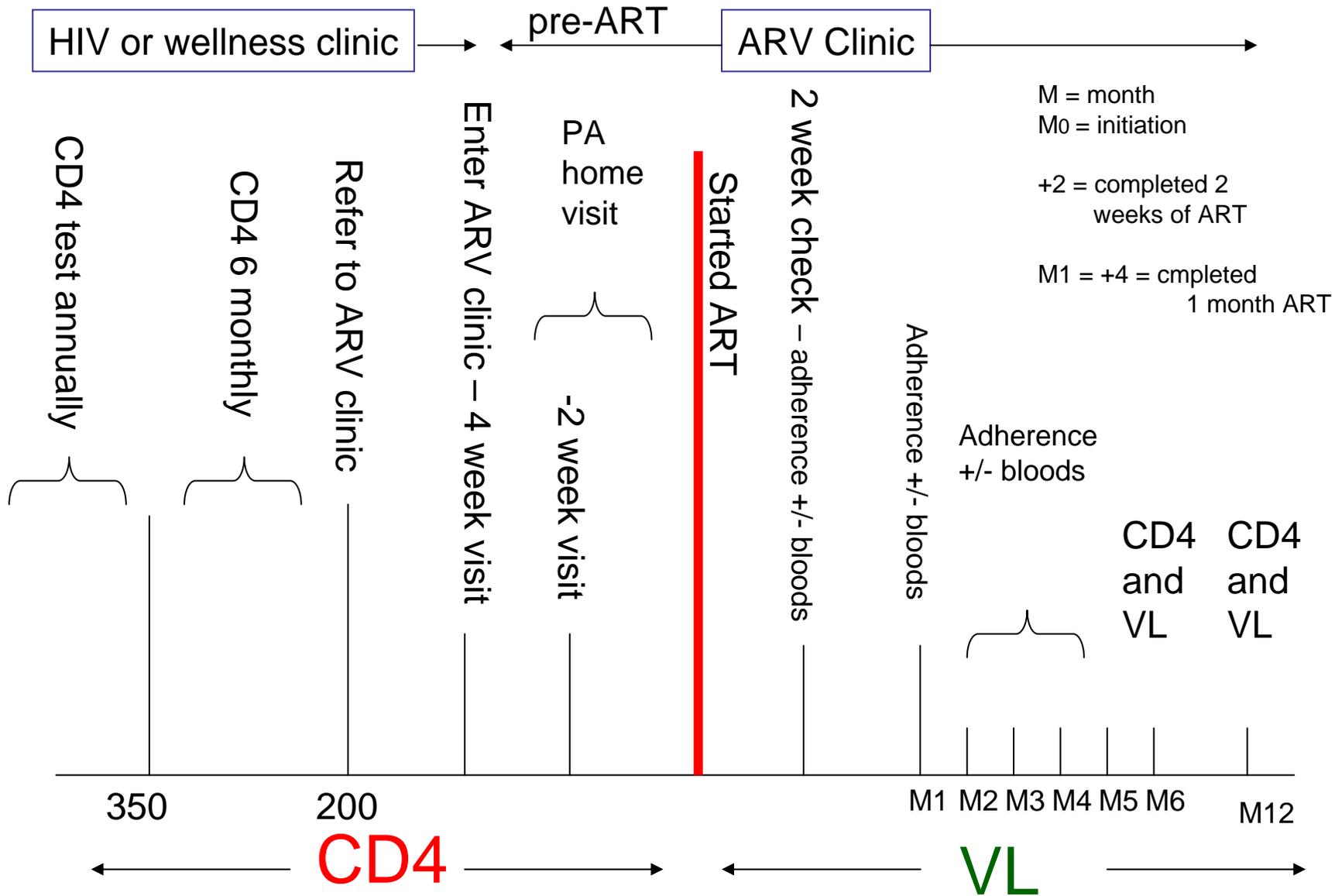
D = *drug* use and/or abuse excluded or addressed

D = *depression* excluded or treated

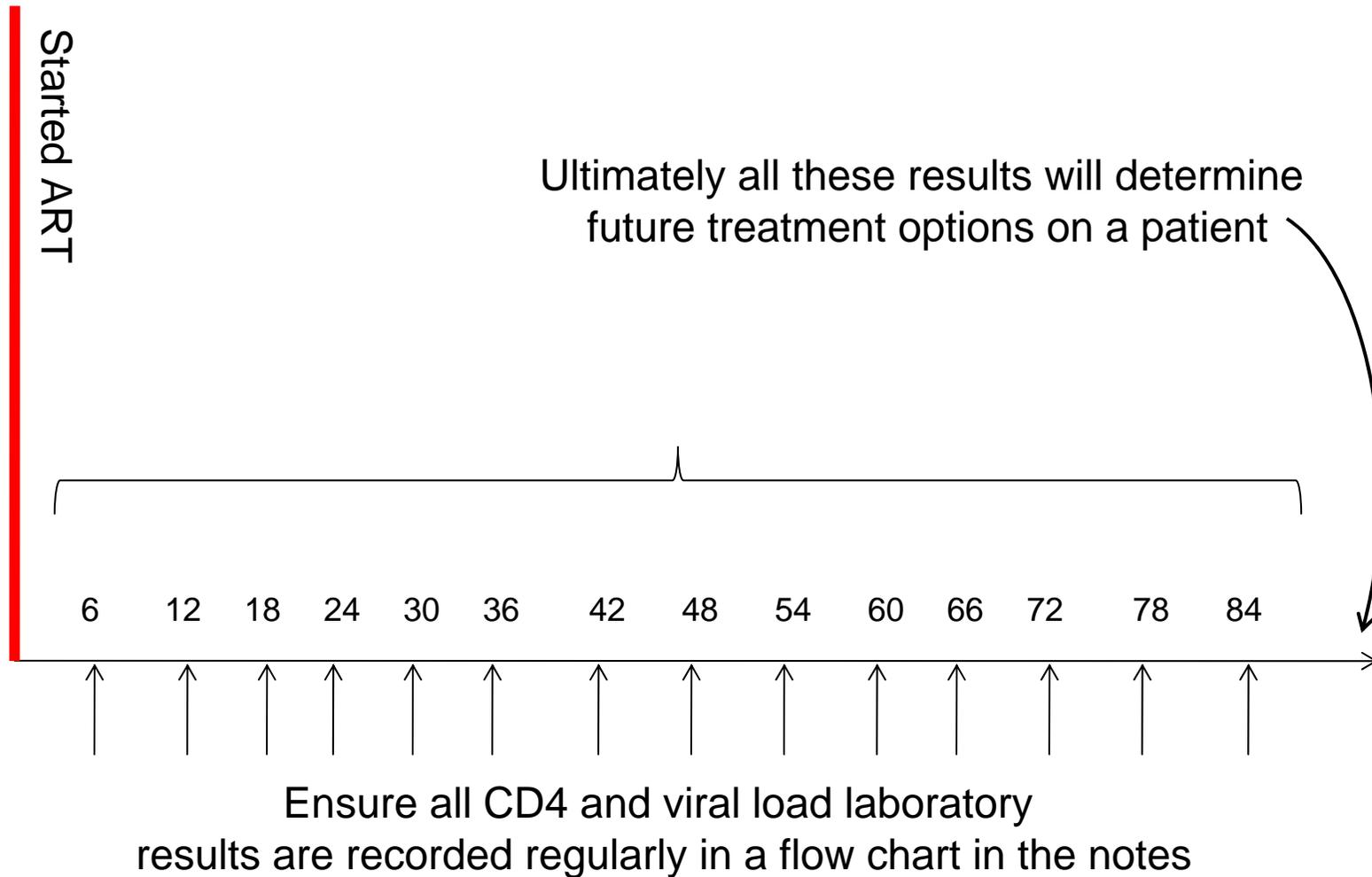
D = *disclosure* to family member or friend, good support (VCT status known)

D = good *unDerstanding* through education and counselling

Patient workup and clinic visits



Long term follow up



The 7 steps to ARV treatment

These are the 7 steps to treatment if you are HIV positive and your CD4 cell count is below 200 or you have AIDS.

Name:		Folder No.										
PREPARATION	Step 1: Voluntary Counselling and Testing (VCT) Date completed											
	<ul style="list-style-type: none"> Know your HIV status and CD4 cell count if HIV+ CD4 count <input type="text"/> <input checked="" type="checkbox"/> If CD4 cell count is less than 200 or you have AIDS you are eligible for treatment 											
	Step 2: Clinic Visit											
	<ul style="list-style-type: none"> Doctor's examination <input checked="" type="checkbox"/> Lab tests: <ul style="list-style-type: none"> Blood count <input checked="" type="checkbox"/> TB check <input checked="" type="checkbox"/> LIVER check <input type="checkbox"/> KIDNEY check <input type="checkbox"/> STI check <input checked="" type="checkbox"/> PAP SMEAR for women <input type="checkbox"/> Nutritional assessment <input checked="" type="checkbox"/> Welfare & family support evaluation <input type="checkbox"/> Contraception check <input checked="" type="checkbox"/> Arrange times for steps 3, 4 and 5 <input type="checkbox"/> 											
	Step 3: Group Education sessions											
	<ul style="list-style-type: none"> What is HIV, stages of infection <input type="checkbox"/> Healthy lifestyle, prevention <input checked="" type="checkbox"/> Treatments, adherence <input type="checkbox"/> 											
	Step 4: Therapeutic Counselling sessions											
	<ul style="list-style-type: none"> Checking treatment readiness (psycho-social assessment and understanding of HIV treatments and adherence) <input checked="" type="checkbox"/> Side-effects and what to do about them <input type="checkbox"/> 											
	Step 5: Home Visit <input checked="" type="checkbox"/>											
	<ul style="list-style-type: none"> By counsellor, community health worker or patient advocate Checking help needed for your treatment adherence 											
	REVIEW	Step 6: Treatment Readiness Assessment										
		<ul style="list-style-type: none"> Doctor reviews clinical and lab findings Clinic team reviews readiness of patient based on clinical and psycho-social feedback. Treatment plan and start date set. 										
	START	Step 7: Treatment Start-up and Follow-up Plan										
		<ul style="list-style-type: none"> See Doctor / Pharmacist / Nurse / Therapeutic Counsellor <input type="text"/> Receive medicines and check treatment instructions <input type="text"/> SET DATE FOR NEXT CHECK-UP <input type="text"/> 										

enrollment phase of 4 – 6 weeks

eligible ?

Baseline bloods

Sputum results

Check PAP result

B.M.I.

Depo Provera or Nurlsterate

1 group + 2 individual = 3

Multidisciplinary meeting (MTM)

Table 3: Time events schedule (See pg 10 ARV Treatment Protocol WC Handbook)

C = counsellor; D = doctor; N = nurse

Assessment	Screening (week -4)	Education (week -2)	Commence ARV (week 0)	Week 2	Week 4	Week 8	Week 12	Monthly	3 Monthly	6 Monthly
Education / therapeutic counsellor visit	C	C	C		C	C	C	C	C	
Treatment readiness assessment		C and D	C and D							
History	D		D							
Physical exam	D		D		D	D	D		D	
Complete registers	N		N		N	N	N		N	
Safety bloods ^a		N ^a			N ^a	N ^a	N ^a			N ^a
Additional safety bloods (NVP) ^b				N ^a						
Viral load		N								N
CD4 count		N								N
Adverse events					D	D	D	N		
Adherence check ^c		N	N		N	N	N	N	D	

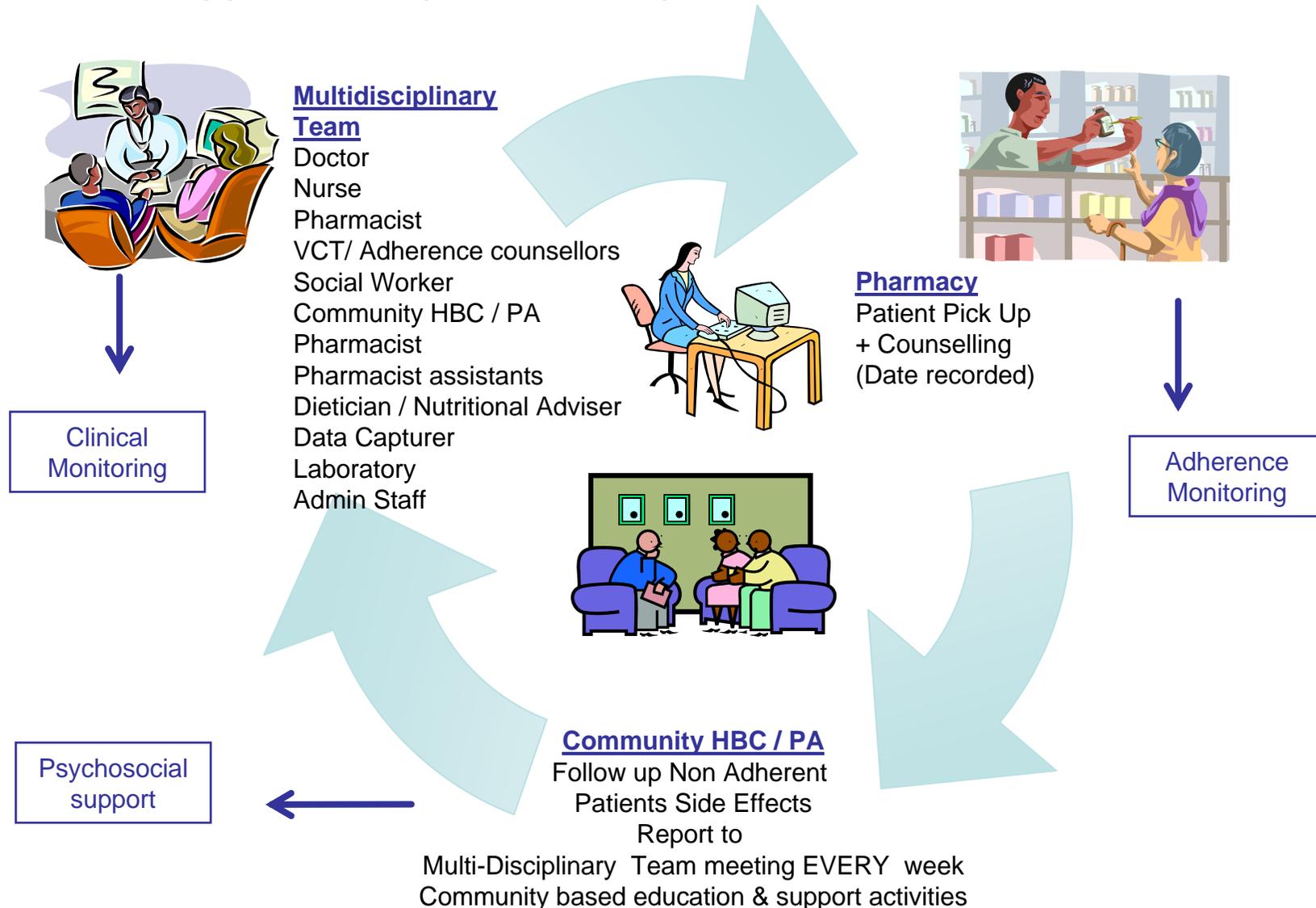
a. For details of safety bloods see 9.2. Additional safety bloods will be required in pregnancy - see 7.3.

b. For patients on NEVIRAPINE there will be an extra ALT taken at week 2.

c. Calculate monthly adherence = (tablets dispensed – tablets returned)/(tablets prescribed), e.g. (30 – 5)/28 = 25/28 = 0.9 (90%)

The Multidisciplinary Team

Holistic approach required with input from all health care team members



Documentation

- important to enter ALL relevant data
- remember there are many members working in the ARV team * Staff may be absent
- overlap with each person's responsibility so check all data complete eg. weight, ARV START date, recent blood results, next appointment date, PAP done and result entered, partner and children HIV status, contraception, counsellor notes



Each Province in SA has its own stationary



Hospital or clinic records

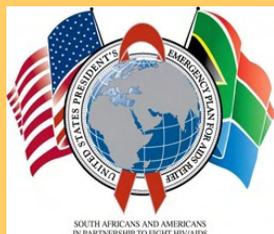


Patient's details – address and contact telephone number

Referral clinic:		Current Clinic:	
1. PATIENT DETAILS		Ensure <i>up to date</i> so community workers can do home visits and contact tracing of ARV defaulters	
<div style="border: 1px dashed black; padding: 5px;"> First name <hr/> Surname <hr/> DOB / / Sex: M / F <hr/> ID Number </div>		Folder #	
		Phone #	
		Address	
Next of kin: name, address and contact no.	Treatment supporter (treatment buddy)		Allergies: (Please write allergies in red)
	? Disclosed Tested ?		

Date of diagnosis and ARV start date

2. LONG-TERM RECORD			
<i>Use this section to maintain an ongoing summary of your patient's health. If another clinician sees this patient for the first time five years from now, s/he should be able to ascertain the major features of the clinical course from this page</i>			
Year HIV Diagnosed		ARV start date at this or transferring clinic	Transfer-in Date (ART only)
		/ /	/ /
<i>Note: Patient can only be considered transferred in if this record can be completed in full from the date of the original start. If there is prior treatment with incomplete treatment history, the patient should be considered a new patient with prior HAART exposure</i>			
ARVs prior to above start date?	NONE / PMTCT / HAART	Details	
Past medical history	Record here significant medical events that occurred before this patient record was started		



Staging = abbreviated

3. CLINICAL ASSESSMENT: FIRST VISIT AT THIS CLINIC				
<i>No. This section should be completed at first encounter with HIV + ART services to help decide whether they need HIV or ARV care</i>				
Presents from:		TB clinic / PMTCT / VCT / GP / other ART clinic / primary care clinic / in-patient / correctional / work / other		
WHO CLINICAL STAGING:				
If your patient has, OR HAS EVER HAD, any of the illnesses below, and none in stage 4 and a CD4 count >200, they need HIV care		If your patient has, OR HAS EVER HAD, any of the illnesses below, or their CD4 count is <200, they need ARV therapy		
Clinical Features		Date	Clinical Features	
WHO Stage 1	Persistent generalised lymphadenopathy		WHO Stage 4 Severe disease (AIDS)	
	Other			
WHO Stage 2	Weight loss <10% body weight			Extra-pulmonary TB
	Minor mucocutaneous conditions			Herpes simplex virus lesions > 1 month
	Recurrent URTI			Oesophageal candidiasis
	Uncomplicated herpes zoster			Pneumocystis carinii pneumonia
	Other			Kaposi's sarcoma
WHO Stage 3 Moderate disease	Weight loss >10% body weight			HIV wasting syndrome
	Diarrhoea > 1 month			HIV encephalopathy
	Oral candidiasis			Recurrent pneumonia
	Severe bacterial infections including Pneumonia			Cytomegalovirus
	Oral hairy leukoplakia			Isosporiasis / Cryptosporidiosis
	Prolonged fever		Bedridden > 50% / day for most of last month	
	Bedridden < 50% / day for most of last month		Cryptococcal meningitis	
	Pulmonary TB (current or in the last year)		Cervical cancer	
Other		Lymphoma		
			Other	
			CD4 result	

REPRODUCTIVE HEALTH											
Pregnant	Y	N	Trimester	1	2	3	Grav	Para	Pap smear result:	Date:	
Contraception			Date last used:								
none / condom / injection / pill / other											
Signs and symptoms of STI today?	1) Urethral discharge / dysuria		2) Vaginal discharge		3) Genital ulcers		4) Genital warts		5) Lower abdominal pain		
	Y / N		Y / N		Y / N		Y / N		RPR (date)	Result	Treatment completed
											Y / N
TUBERCULOSIS SCREEN											
Ever had TB before?			Y	N	If YES	Year	Extra-pulmonary or pulmonary TB			Treatment outcomes	
Current TB			Y	N	Pulmonary or extra-pulmonary	Date commenced treatment			Regimen 1 / Regimen 2 / MDR / XDR		
TB symptoms today	1) Cough > 2 wks		2) Weight loss		3) Fever		4) Night sweats		5) Haemoptysis		6) Fatigue
	Y / N		Y / N		Y / N		Y / N		Y / N		Y / N
Smear date	Culture / sensitivity date		X-ray date				Clinical indication of TB				
Result	Result		Result				Y / N				
NUTRITIONAL SCREEN (Note: If BMI is less than 18.5 must refer to dietician and nutritional programme)											
Date of assessment:			A. Weight (kg)			B. Height (meters)			C. BMI = _____		
HISTORY AND EXAMINATION:						PLAN:					
Temperature: _____ Heart Rate: _____ Respiratory Rate: _____						CD4 > 200 AND stage 1, 2 or 3 <input type="checkbox"/> CD4 < 200 OR stage 4 <input type="checkbox"/>					
						Cotrimoxazole:					
						Fluconazole:					
						Other:					
Screened for INH			Y	N	Qualifies for INH	Y	N	Started INH			
Date:					Date:			Date:			
Screened for cotrimoxazole			Y	N	Already on cotrimoxazole	Y	N	Qualifies / started			
Date:					Date:			Date:			
Screened for other / fluconazole			Y	N	Already on other / fluconazole	Y	N	Qualifies / started			
Date:					Date:			Date:			
Print name:			Signature:				Date: / /				

Evaluation for ARV's

4. CLINICAL EVALUATIONS FOR ARVs OR RE-STARTED ARVs
If ART therapy is indicated for your patient, use this section to help decide whether there are any medical contra-indications to starting

PRIOR ARV HISTORY
If your patient has ever had ARVs before, detail the period when taken, ARV changes and reasons.

BASELINE SAFETY BLOODS								
Test	Date	Result	Others:	Test	Date	Result	Notes	
CD4								
Haemoglobin								
ALT								

TB WORK-UP

Symptoms suspicious of TB? Y N **If YES:** Perform TB work-up, record results in daily clinic record sheet

NUTRITIONAL ASSESSMENT

Symptoms Nausea / Vomiting / Diarrhoea / Severe loss of weight / Difficulty swallowing **Baseline BMI**

CLINICAL NOTES

CLINICAL FACTORS INFLUENCING REGIMEN CHOICE

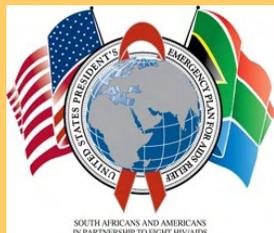
1 On TB treatment? Y / N	5 Has had more than 1 month of ARVs? (excluding PMTCT) Y / N	PLAN: ARV 1 ARV 2 ARV 3 Cotrimoxazole Fluconazole
2 Pregnant? Y / N	6 BMI > 27.5 Y / N	
3 Has severe peripheral neuropathy? Y / N	7 Other Y / N	
4 Has a history of psychiatric illness? Y / N	8 Other Y / N	

COMMENCING ARVs

Psychosocial readiness (see section 7) Y / N	Clinically ready Y / N
Regimen factors (clinical factors influencing choice) Y / N	Regimen Y / N

ASSESSMENT OF OVERALL READINESS FOR ARVs

Signature: _____ Date: / /



5. SOCIAL ASSISTANCE

Use this section to assess the need for social assistance (record the date this social assessment was made)

Lives in what sort of dwelling? (please code)		informal dwelling / formal house / hostel / other (specify)		Number of rooms:		Refrigerator:		Y	N					
Number of adults in household:		Does current partner live in household?	Y	N	Has partner been tested?	Y	N	Result:	is current partner aware of patient's HIV status?	Y	N	Is there a desire for future children?	Y	N
Own Children	Name			Other children in household										
	Year Born			Name										
In household		Y	N	Year Born										
HIV status		-/+		HIV status +/-										
General Status		own	Dead To	General Status										
Has patient disclosed HIV status		Y	N	is When:										
Source of income? (code)		Employed / grant / pension / friends or family												
Qualifies for grant		Y	N	DG	Child	Other:	Receiving grant		Y	N	Application Submitted		Y	N
Current drug use	Current alcohol use	Y	N	CAGE score	Have you ever felt you should cut down on your drinking?	Y	N	Have people annoyed you by criticizing your drinking?		Y	N	Cage Score		
Y	N	Y	N		Have you ever felt guilty or bad about your drinking?	Y	N	Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?		Y	N			
Referral		Date:		Appointment		Date:								

6. PRE-ARV COUNSELLING

Counsellors to use this section to record your patients counselling history

Session	Date / s	Counsellor / group	Tx partner attended?	Comments (e.g. motivation, level of understanding)
General HIV Education and Healthy Living				
ARVs				
Adherence Planning				
Other				

Name and contact details for treatment partner:

Patient agreed to home visit: Y N Name of community health worker: Attends a support group: Y N

What is clients understanding (in their own words) for wanting ARVs?

7. PSYCHO-SOCIAL READINESS

Date: / /

If it has been decided ARVs can safely be started (section 4) use this section to help decide if your patient is psychologically and socially prepared for ARVs.

Review and update section 5 (above) if it was completed some time before this section

IMPORTANT NOTE: The checks below are ONLY a prompt for the health care worker to check that the patient is:

a) self motivated, b) has received HIV / ARV education and c) has a degree of social support.

	Y	N		Y	N
Have they attended all the required counselling sessions? (see above)			Do they have a treatment partner?		
Have they disclosed to anyone?			Have they been attending the clinic regularly?		

If the answer to all of the above questions is YES then the patient is ready to commence ARVs



Patient appointment card



ARK appointment card

ADULT TREATMENT CARD	
Clinic:	Clinic Tel. No:
Surname:	
Name:	
Folder number:	Date of Birth:
Identity number:	
Hospital folder numbers:	
Previous treatment site(s) and folder numbers if transferred:	
Treatment start date (dd/mm/yy):	
Previous ARV treatment including PMTCT:	
Start:	Stop: Reason for change
Alergies:	
Patient advocate/Treatment buddy name:	
Patient advocate/Treatment buddy contact nos:	
NEVER BE WITHOUT YOUR TREATMENT! IN CASE OF EMERGENCY, CALL:	
.....	

Adult: 25-10-07

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Available online for free

START HERE	TCA (To Com																	
	Year																	
	Month																	
Day																		
WEEK	-4	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13
COJNSELLING	X		X		X				X				X					X
WEIGHT	X				X				X				X					X
EXAM	X				X				X				X					X
CD4	X																	
VIRAL LOAD																		
SAFETY BLOODS	X																	
ALT (NVP)							X		X				X					X
FBC (AZT)							X		X				X					X
CHO./TRIG/GLUC																		
OTHER TESTS/PAP			X															
MEDICINES/FP					X				X				X					X
RESULTS																		
Attendance Dat:																		
CD4																		
VL																		
WEIGHT																		
ART:																		
Adherence (L/M/H)																		

YEAR 1 →

ARK appointment card has space for 5 years of lab results.....

Referral letter



SOUTH AFRICANS AND AMERICANS
IN PARTNERSHIP TO FIGHT HIV/AIDS



Department of Health

National referral form

 NATIONAL COMPREHENSIVE HIV AND AIDS PROGRAMME 
TRANSFER OF ART PATIENT TO OTHER ART SERVICE POINT

Transfer to: ART Service Point: _____ District/Metro: _____ DC No.: _____ Province: _____ Tel: _____ Fax: _____ Patient's contact details: _____	Transfer from: Public sector <input type="checkbox"/> NGO/FBO/CBO <input type="checkbox"/> GP <input type="checkbox"/> Other non-public <input type="checkbox"/> Facility Name: _____ District/Metro: _____ DC No.: _____ Province: _____ Tel: _____ Fax: _____ Mail address: _____
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PATIENT IDENTIFIER

First Name: _____ Surname: _____ Date of birth:
Sex: M F Tel: _____ Current file No: _____ ID:
Parent/guardian: (if applicable) First Name: _____ Surname: _____ Tel: _____

PATIENT HISTORY

Baseline ART ART start date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Regimen 1a <input type="checkbox"/> Any child regimen <input type="checkbox"/> Regimen 1b <input type="checkbox"/> (if different to 1a or 1b) <i>Specify baseline ART regimen if not 1a or 1b:</i>	Baseline Lab (at start of ART) CD4 _____ % CD4 _____ cells/mm ³ VL _____ copies/ml ALT _____ U/l Ery _____ x10 ⁹ /l Hb _____ g/dl HCT _____ l/l Leuc _____ x10 ⁹ /l Lymph _____ x10 ⁹ /l Neut _____ x10 ⁹ /l Platelet _____ x10 ⁹ /l Gluc _____ mmol/l Cholest _____ mmol/l	Baseline clinical status (at start of ART) Weight (kg) <input type="text"/> <input type="text"/> <input type="text"/> Height (cm) <input type="text"/> <input type="text"/> <input type="text"/> WHO Clinical Stage Adult <input type="text"/> WHO Clinical Stage Child <input type="text"/>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Current ART Current regimen since: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Regimen 1a <input type="checkbox"/> Regimen 2 <input type="checkbox"/> Regimen 1b <input type="checkbox"/> Any child regimen <input type="checkbox"/> (if different to 1a/b or 2) <i>Specify current ART regimen if not 1a/b or 2:</i>	Most recent Lab CD4 _____ % <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> CD4 _____ cells/mm ³ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> VL _____ copies/ml <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ALT _____ U/l Ery _____ x10 ⁹ /l Hb _____ g/dl HCT _____ l/l Leuc _____ x10 ⁹ /l Lymph _____ x10 ⁹ /l Neut _____ x10 ⁹ /l Platelet _____ x10 ⁹ /l Gluc _____ mmol/l Cholest _____ mmol/l	Current clinical status Weight (kg) <input type="text"/> <input type="text"/> <input type="text"/> WHO Clinical Stage Adult <input type="text"/> WHO Clinical Stage Child <input type="text"/> Current prophylaxis: Cotrimoxazole No <input type="checkbox"/> Yes <input type="checkbox"/> Fluconazole No <input type="checkbox"/> Yes <input type="checkbox"/> Prophylaxis issued will last until: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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REASON FOR TRANSFER / other relevant details:

Past medical history including ARV adverse events

Transfer date: First appointment made at receiving service point: No Yes Appointment date:
Clinician's name: _____ Signature: _____ Tel: _____ Fax: _____

ACKNOWLEDGEMENT OF TRANSFER (to be completed by receiving ART service point)

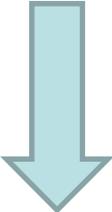
We have received the transfer notice. Received date:

Please fax mail to us: ART Assessment and Baseline form
Any previous Transfer forms ART Patient Follow Up forms/details Date of visit:

Fax/send back copy of whole form to transferring ART service point immediately after receiving it!

Clinician's name: _____ Tel: _____ Fax: _____ Clinician's name: _____

Inform all patients to advise your clinic timeously if they intend transferring to another ARV site



Discharge with **one month's** supply of ARVs and this letter

Questions, questions.....

- Condoms – “sometimes or always”, started using when ?
- PAP done – has patient obtained the result (1 – 2 months)
- REPEAT injectable contraception
- when did partner last have an HIV test
- number of pregnancies / TOP / “other children” / deaths

Traditional Medicine in SA

- 27 million South Africans (72%) from diverse backgrounds use traditional healers
- ± 150 000 diviners, herbalists, prophets, faith healers, traditional surgeons and birth attendants
- 20 000 tons of medicinal plants were consumed annually
- trade worth R 2.9 billion

Traditional Remedies

- * Herbal medications affect levels of drugs through their effect on cytochrome P450 system
- P.I.s and NNRTIs are metabolised via this pathway
- Extreme caution advised in introducing herbal drugs into routine care of HIV patients



• Ubhenjane – cure for HIV / AIDS in KZN Zebulon Gwala

• Umnwele / Unwele (Sutherlandia)

• Inkomfe (extract of African potato)

• uMakhonya – immune booster Victor Ndlovu, MCC

• Gambu – immune booster Musa Memela 2007

• Amasotsha / Amasotja MPL, Aug 2008

from R125 per month; 83 ingredients (2007)

Herbs, Foods, Traditional Medicines and ARV interactions

- | | | | |
|--------------------------|---|--------------------|---|
| • Goldenseal | x | • African potato | x |
| • Grapefruit juice | x | • Aloe vera | x |
| • Milk thistle | - | • Beetroot | - |
| • Olive oil | - | • Dagga | x |
| • Senna & laxative herbs | x | • Echinacea | ? |
| • Skullcap | x | • Garlic | - |
| • St John's Wort | x | • Ginkgo | x |
| • Sutherlandia | ? | • Siberian Ginseng | x |

200 000 traditional healers
in SA (2008); 26 million customers

Cape Times 15 May 2008

Southern African Journal of HIV
Medicine, Summer 2008 P. 56

✓	positive effects
?	unknown effect
-	no effect
X	do NOT use



Bulb/tuber/corm - immune booster



Hypoxis hemerocallidea - African potato



Lessertia frutescens

Sutherlandia (unwele / kankerbos / cancer bush) University of KZN started clinical trials in September 2007, M&G 31 August ; Prof. Nceba Gqaleni, Indigenous Health System Research, Dept. Science and Technology/ National Research Foundation

Now Available

UNAMANDLA

BHEJANE

Natural Herbs

Strongest Immune Booster Available

TB, Umkhulu, Umkhulu, i-drop, Inyongo nezinyezi.
 Am-damba, Isilume, Ukubaba Kazingwani,
 Amathamba, Isino, Isufaba, Isolo, Esentha, Is.
 Isifo Suvakhele Uvula Isihlatye, Ukugunjelwa,
 Nantwenzakazi, Isinywa Ekawusakale, Uqata Isihlatye

INKINGA YOCANS
 SUPER FIERCE IS THE ONLY ONE TO TAKE

- Strengthens and supports
- Boosts immune system
- Long acting (2-3 days)
- Low maintenance costs

Now Available







www.avert.org

Cape Times 24 November 2008



CAPE TIMES

FOUNDED IN 1876

Tikking time-bomb

ALARMING INFORMATION on the use of tik in the Western Cape came to light at a conference in the city last week.

According to the Medical Research Council (MRC), 98% of tik addicts who seek help in South Africa come from Cape Town. The highest user levels are among people younger than 19. Of the roughly 2 800 people receiving treatment for tik addiction in Cape Town, three fifths are younger than 20.

At the conference, MRC researchers cited studies which showed the link between tik (methamphetamine) use and risky sexual behaviour. Tik users, they said, were more likely to have sex while under the influence of alcohol and other drugs; they were likely to have sex at a younger age; they were more likely to have multiple sexual partners; and they were more likely to trade sex for drugs.

All of which, the MRC has warned, is leading to a rise in HIV in the province.

As one researcher put it, Cape Town is now the epicentre of two significant public health epidemics: methamphetamine use and HIV incidence.

It is tragically ironic that the Western Cape, which led the country in providing anti-retroviral drugs for those who need them, is now showing rising HIV infection rates because of the increasing use of tik.

Though both the province and the city have stepped up their programmes to tackle the tik crisis, the alarming spread of tik addiction and of HIV shows that not enough is being done.

Current treatment strategies do not meet the needs of addicts. It is time, as the MRC suggests, for the Department of Health to take the lead in a co-ordinated strategy to rid the province of the drug.

Mobile clinics and other free treatment centres, better education about the dangers of tik and about possible treatment, and an unprecedented crack-down on the producers and suppliers of the drug are needed, as well as punitive sentences for dealers to discourage the sale of tik.



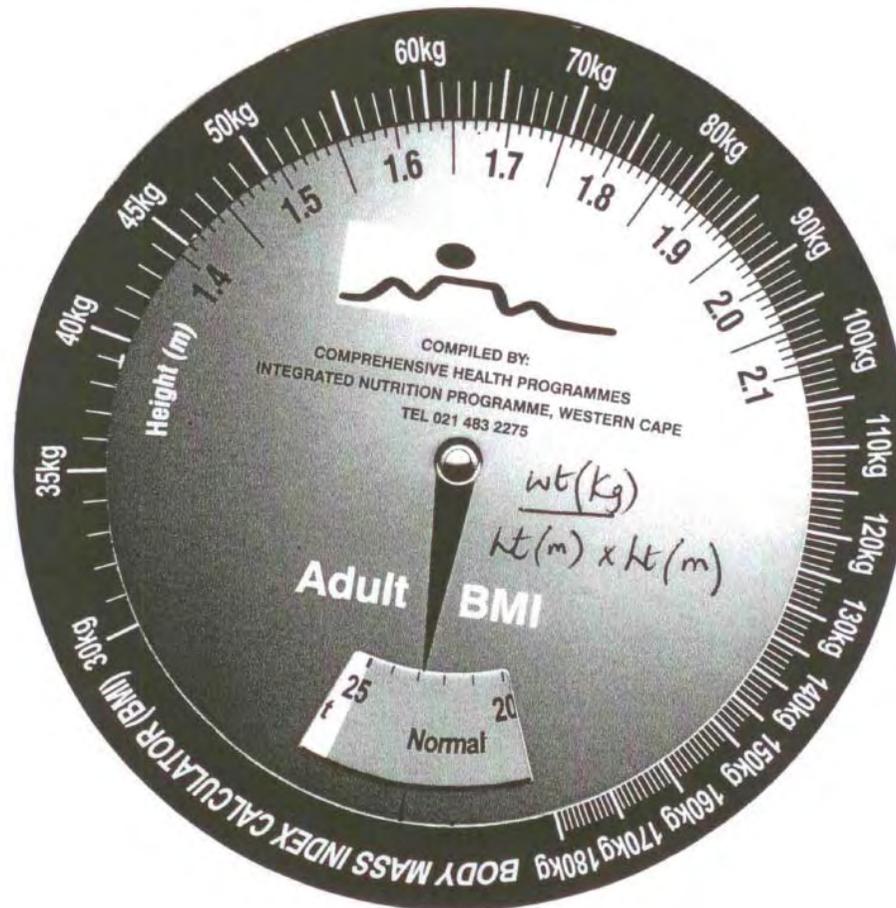
USAID
FROM THE AMERICAN PEOPLE

Nutritional Supplement Programme

- Underweight patients:
 - Paediatrics: faltering on growth charts - height and weight
 - Adults [>18 years]: BMI < 18.5
 - Supplements/month:
 - Philani porridge (1kg) = 3
 - Nutrimil shake (440gm) = 7
 - NB - registers
- Overweight patients: BMI > 28

Appointment book for Dietician

Nutritional assessment – to see dietician – check BMI – all patients must have height measured at least once.



BMI - body mass index
independent of age

Drug Adherence



- What does high adherence mean?
- < 95% associated with poor virological & immunological response
- individual case management – viral resistance
- Public Health View – increase in risk of transmission of resistant virus to *newly infected* individuals
- Health Economics Perspective – low adherence results in increased use of *second* line regimes ; also increased risk of disease progression and the cost of treating opportunistic infections



Adherence

- it describes how well (or how poorly) a patient follows a prescribed dosing regime or medical advice
- synonymous with the old term “compliance”, but *adherence* is preferred as it is more *patient centered*
- compliance implies *following orders*



Dr Venanzio Vella, Italian Cooperation

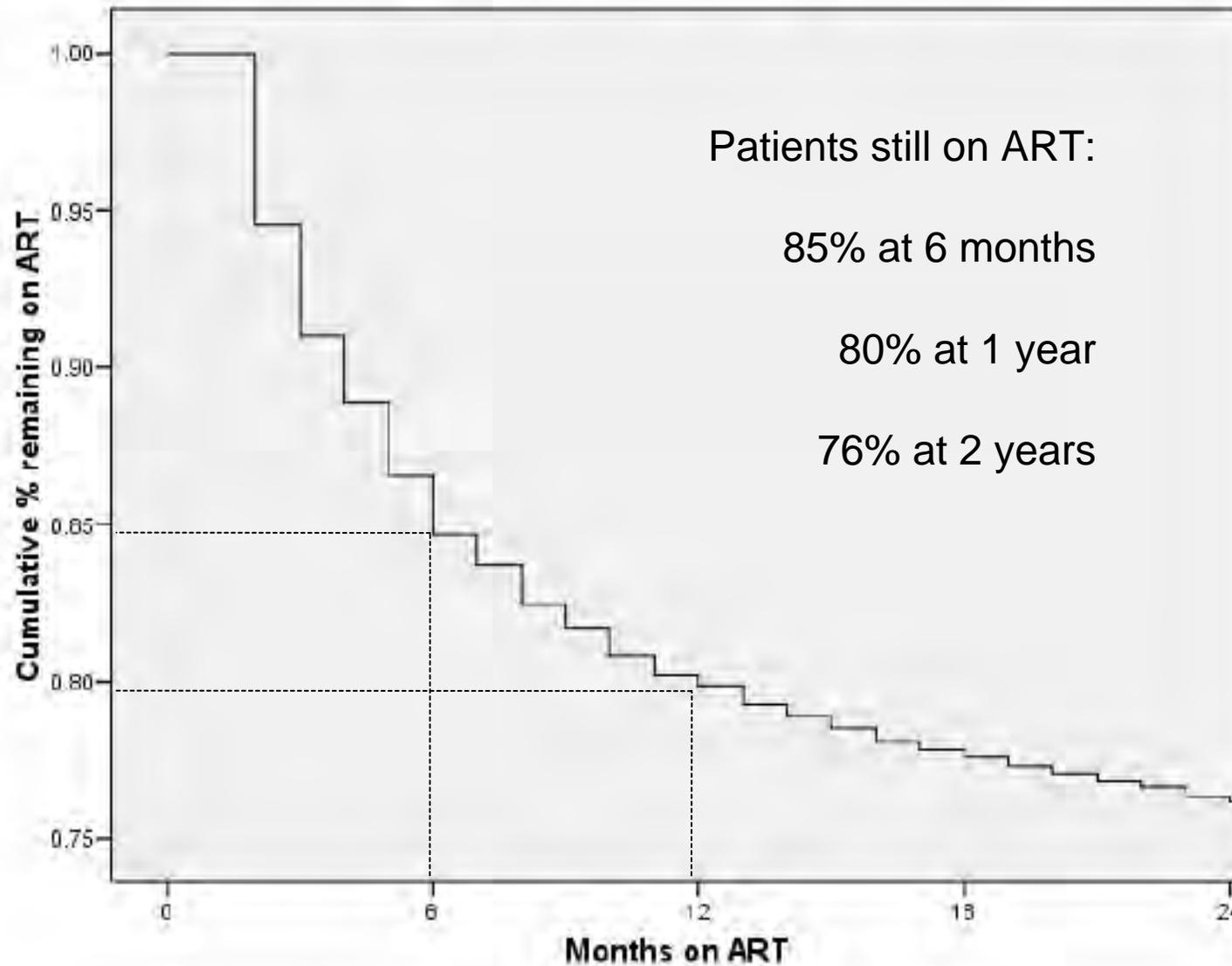
Dr Thiloshini Govender and Mr Scelo Dlamini DOH/KZN

Dr Myra Taylor, Prof Indres Moodley, Ms Verona David School of Family & Public Health and Prof Champaklal C. Jinabhai. School of Family & Public Health, Department of Community Health, University of KZN

October 2008

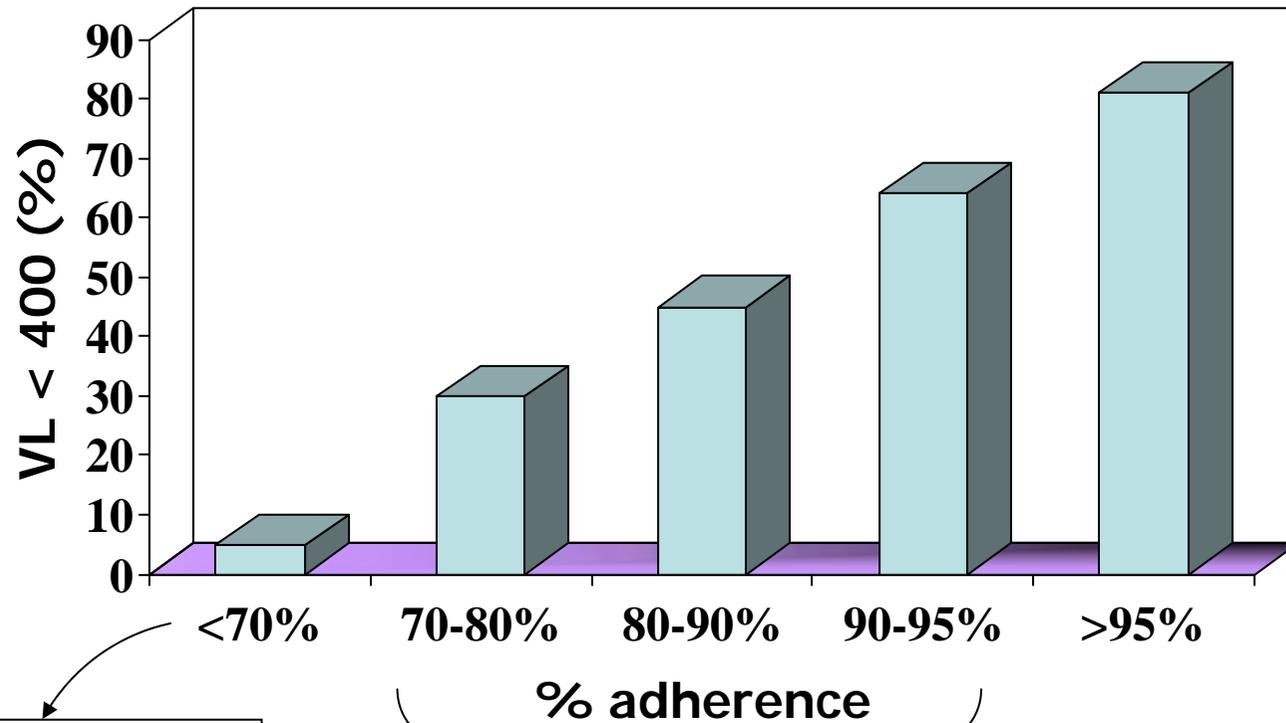
*Evaluation of Antiretroviral Therapy
Against HIV / Aids
in KwaZulu-Natal South Africa*

Figure 37 Probability of remaining under ART in the first two years



32 delivery sites in KZN, 2835 patient records, May to Sept 2006

How much adherence is required for successful therapy

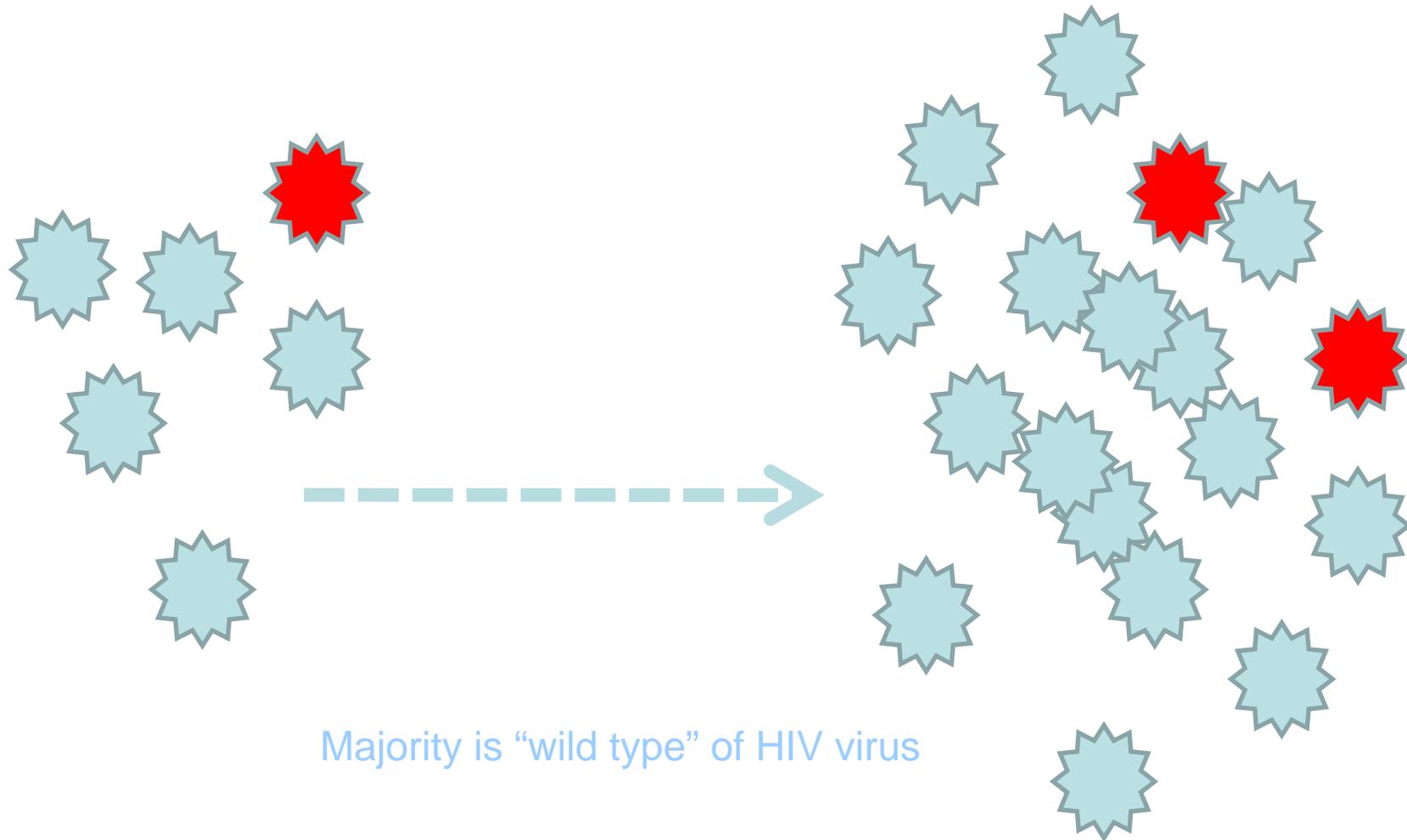


Consider stopping ARVs and re-enter patient into counselling; identify risk factors

Greatest risk of resistance developing

•D Patterson *et al*, 2000

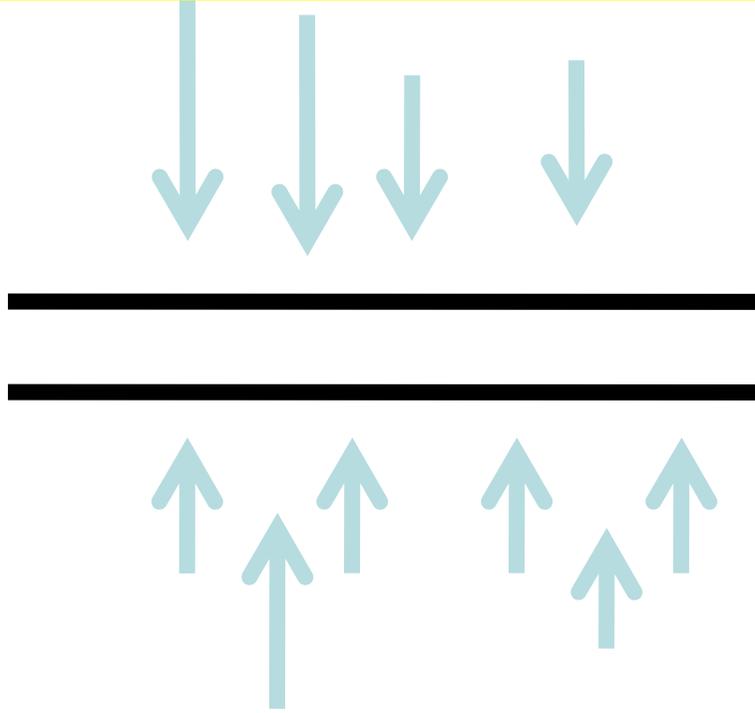
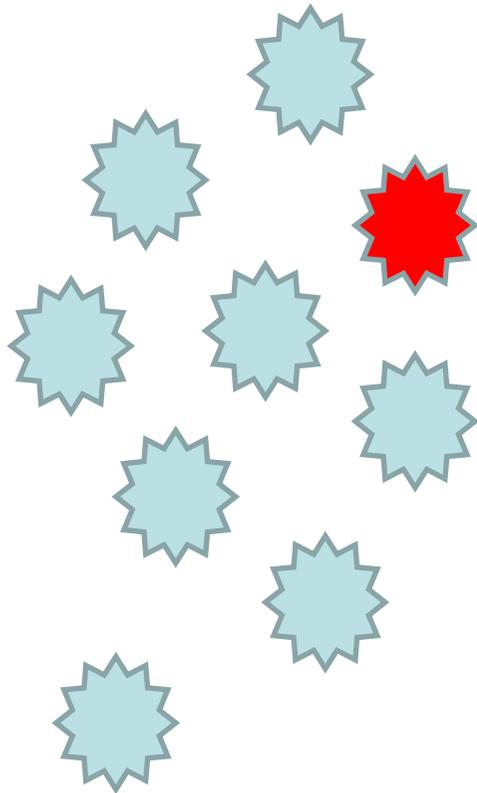
Drug resistance



Majority is "wild type" of HIV virus

No antiviral drugs leads to uninhibited viral replication

Drug resistance

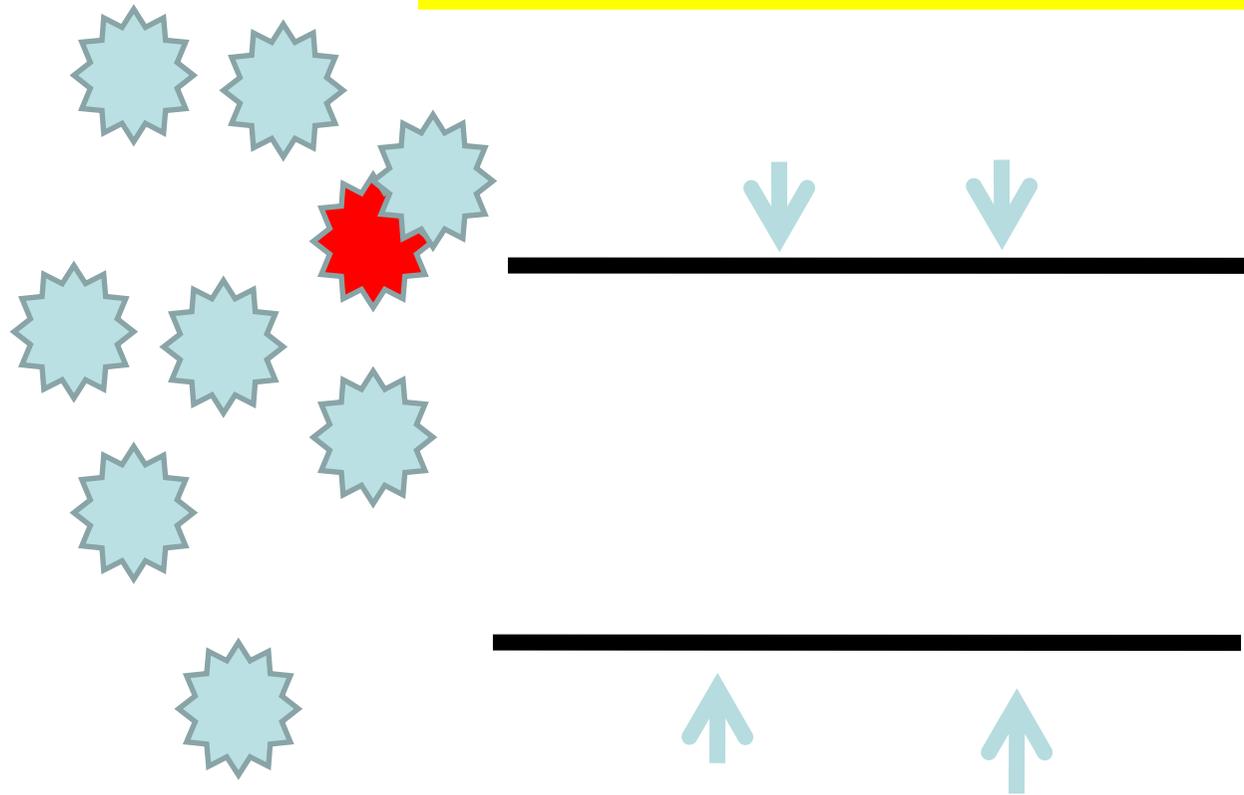


Patient's viral load remains suppressed

Drug pressure HIGH

Good adherence – patient takes > 95% of medication

Drug resistance



Poor adherence - patient non-compliant,
little drug pressure so virus can escape and continues to multiply

Drug resistance



Partial drug pressure allow some of the virus to escape and multiply
but *selects out* resistant type in preference to wild type of HIV

Poor Adherence

- an important concern is the development of resistance
- greatest risk of clinically significant viral resistance occurs after missing 11 – 30% of ARV doses ie adherence of 70 – 89%
- no resistance noted in patients with adherence < 60%
- the greatest risk is therefore in patients with *reasonably* good adherence

ADHERENCE TO LONG TERM THERAPIES: EVIDENCE FOR ACTION, W.H.O, 2003

Five dimensions of adherence:

1. Social & Economic Factors
2. Health System Factors
3. Condition Related Factors
4. Therapy Factors
5. Patient Related Factors

1. Social and economic factors

- Poor socio-economic status
- Lack of access to education
- Unemployment
- Lack of effective social support networks
- Age
- War



Lost to follow up – contributing factors and challenges in South African patients on ARVs

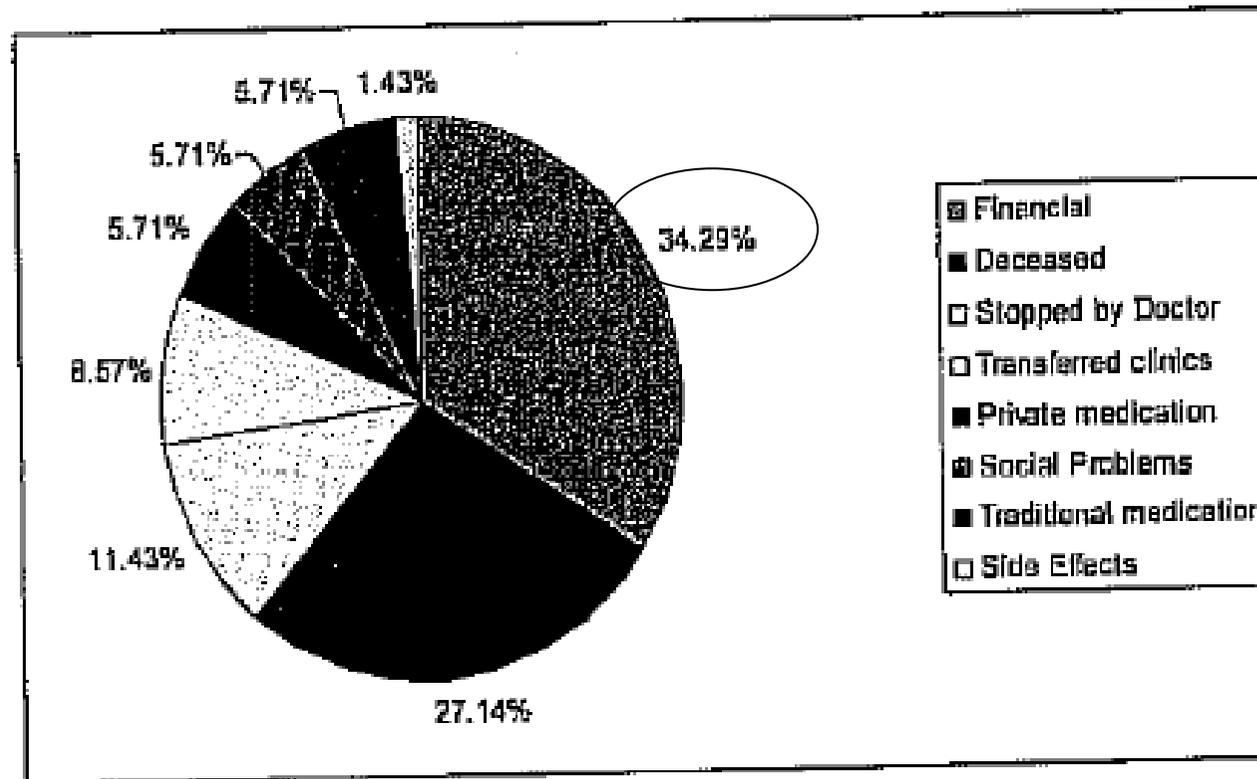


Fig. 1. Reasons given for loss to follow-up.

2. Health system factors

- Patient provider relationship
- Short consultations
- Inadequate patient education about illness & medication
- Lack of follow up
- Lack of community support
- Lack of training & knowledge about adherence



3. Condition related factors

Particular illness related demands including;

- Severity of symptoms
- Level of disability (physical, psychological, social)
- Rate of progression & severity of illness
- Co-morbidities e.g. depression



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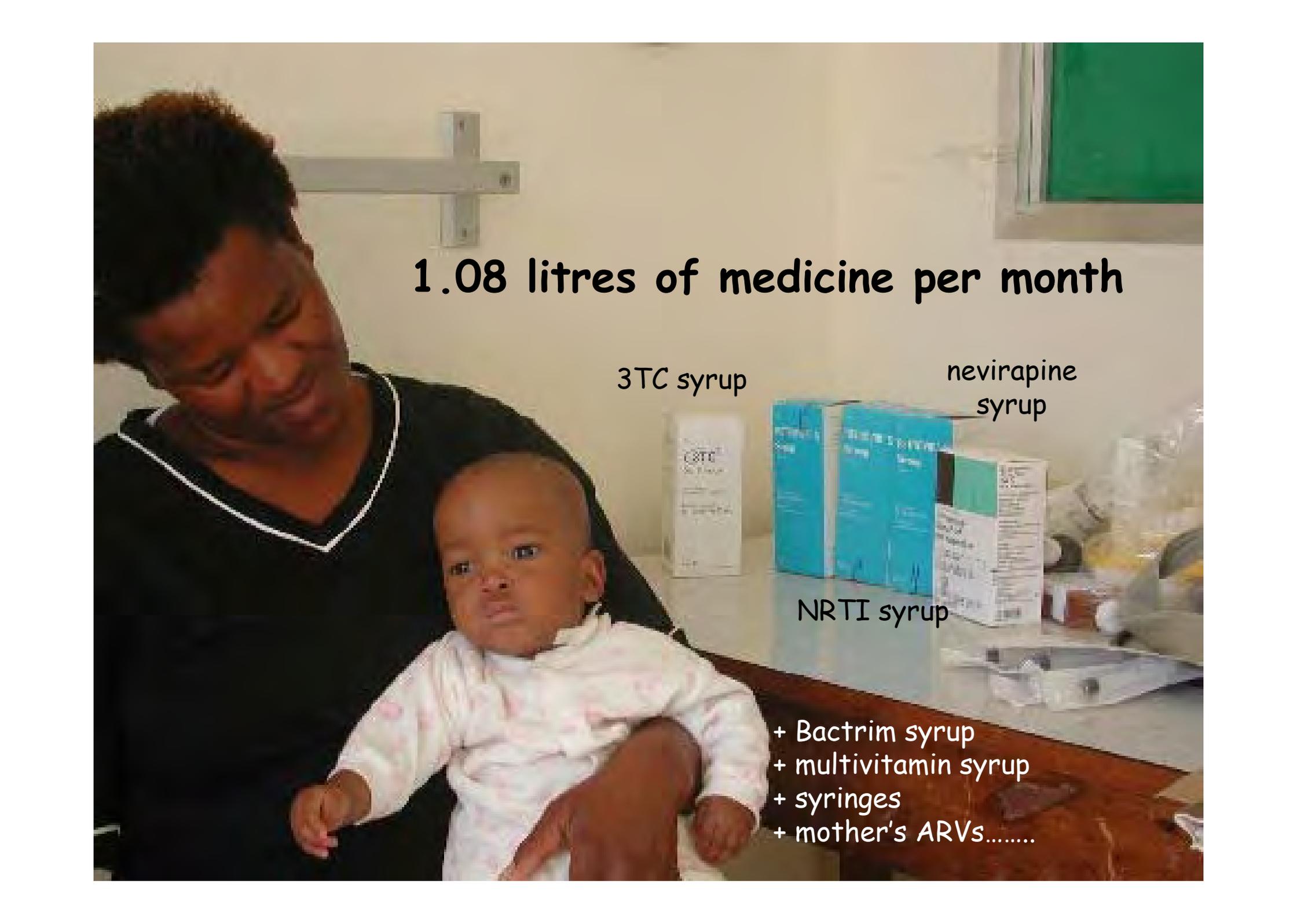
4. Therapy factors

- Complexity of the medical regimen
- Duration of treatment
- Previous treatment failures
- Immediacy of beneficial effects
- Side effects & the availability of medical support to deal with them



SOUTH AFRICANS AND AMERICANS
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A woman with dark curly hair, wearing a black top with a white collar, is holding a baby in a white patterned onesie. They are in a clinical setting. On a white counter in front of them are several boxes of medicine. The background shows a white wall with a metal cross-shaped fixture and a green board. The text '1.08 litres of medicine per month' is overlaid on the image.

1.08 litres of medicine per month

3TC syrup

nevirapine
syrup

NRTI syrup

- + Bactrim syrup
- + multivitamin syrup
- + syringes
- + mother's ARVs.....

Meticulous explanation:

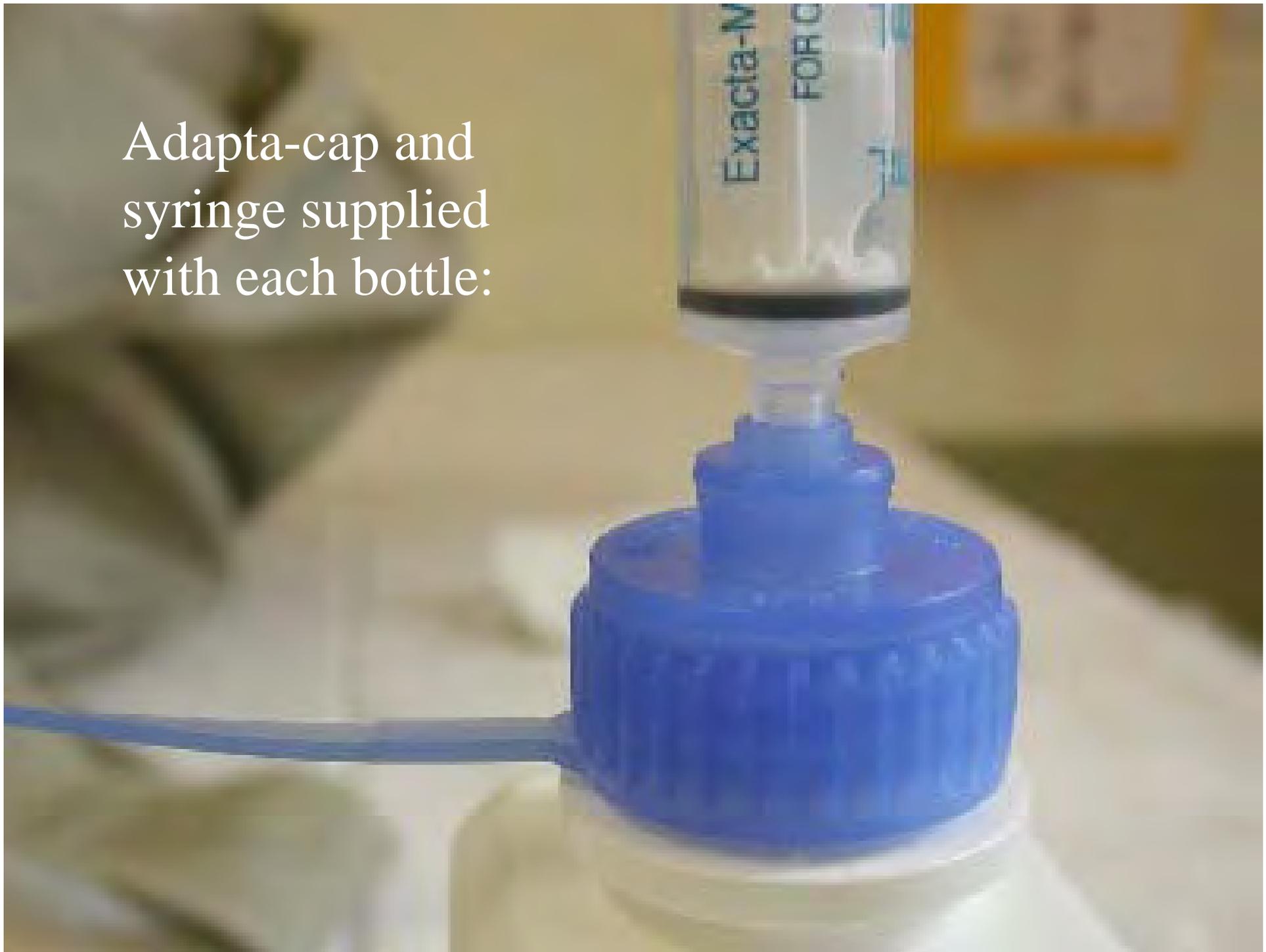


**Opening –
and closing**

Measuring



Adapta-cap and
syringe supplied
with each bottle:





'Apple' adapter

Zidovudine bottle



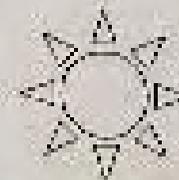
Decimal fractions:



Please tick the block every time the medicine is Taken on time with '✓'

If the medicine was not taken, mark the block with 'x'

If the medicine was taken late, mark with 'L'



	Morning Dose			Evening Dose		
	NVP	3TC	AZT	NVP	3TC	AZT
Day1	✓	✓	✓		✓	✓
Day2						
Day3						
Day4						
Day5						
Day6						
Day7						
Day8						
Day9						
Day10						
Day11						
Day12						
Day13						
Day14						
Day15	✓			✓		

	Morning Dose			Evening Dose		
	NVP	3TC	AZT	NVP	3TC	AZT
Day16	✓	✓	✓	✓	✓	✓
Day17						
Day18						
Day19						
Day20						
Day21						
Day22						
Day23						
Day24						
Day25						
Day26						
Day27						
Day28						
Day29						
Day30						

ARK Adherence Tools

The 7 steps to ARV treatment

These are the 7 steps to treatment if you are HIV positive and your CD4 cell count is below 200 or you have AIDS.

Name: _____ Folder No: _____

Step 1: Volu

- Know s
- If CD4

Step 2: Clini

- Doctor
- Lab tes
- Blood
- TB ch
- LIVER
- KIDN
- STI cl
- PAP
- Nutriti
- Welfar
- Contra
- Arrang

Step 3: Gro

- What is
- Health
- Treatm

Step 4: Ther

- Checki
- of HIV
- Side-ef

Step 5: Hom

- By cou
- Checki

Step 6: Tre

- Doctor
- Clinic t
- Treatm

Step 7: Tre

- See Doctor / Pharmacist / Nurse / Therapeutic Couns
- Receive medicines and check treatment instructions
- SET DATE FOR NEXT CHECK-UP

© ARK SA 310304

TREATMENT INFORMATION

Name:	Patient's weight:
File number:	CD4 Cell count:
Treatment commencement date:	
Patient Advocate:	



d4T

3TC

Efavirenz

WARNINGS



No Alcohol



Store in a cool, dry place



May cause dizziness/drowsiness

WARNINGS



No Alcohol



Store in a cool, dry place (DO NOT FREEZE)

TREATMENT INFORMATION

Name:	Patient's weight:
File number:	CD4 Cell count:
Treatment commencement date:	
Patient Advocate:	



AZT



3TC



Nevirapine



Remember

- ARVs do not reduce the risk of passing the virus to other people
- Do not take any other medications without first talking to your doctor.
- Do not share your ARVs with other people
- Do not skip any doses
- Keep ARVs away from children
- If you miss a dose, do not take 2 doses at once.
- Bring all your remaining pills and containers to your next appointment.

Common Minor Side Effects:

Fever, cough, dizziness, headaches, loss of appetite, nausea, mild stomach problems, trouble sleeping, tiredness/weakness, shift in body fat location.



Report to your Clinic as soon as possible if you have...

- Skin rash, with or without fever, blistering, sores in your mouth, irritated eyes, swelling, difficulty breathing, closing of your throat, swelling of your lips, tongue, or face.
- Nausea, vomiting, stomach pain, diarrhea, unusual fatigue, yellow skin or eyes, itching, clay-colored stools, or dark urine.
- Burning, numbness, pain, or tingling in the hands, arms, feet, or legs, joint or muscle aches.

2006

ark
absolute return for kids

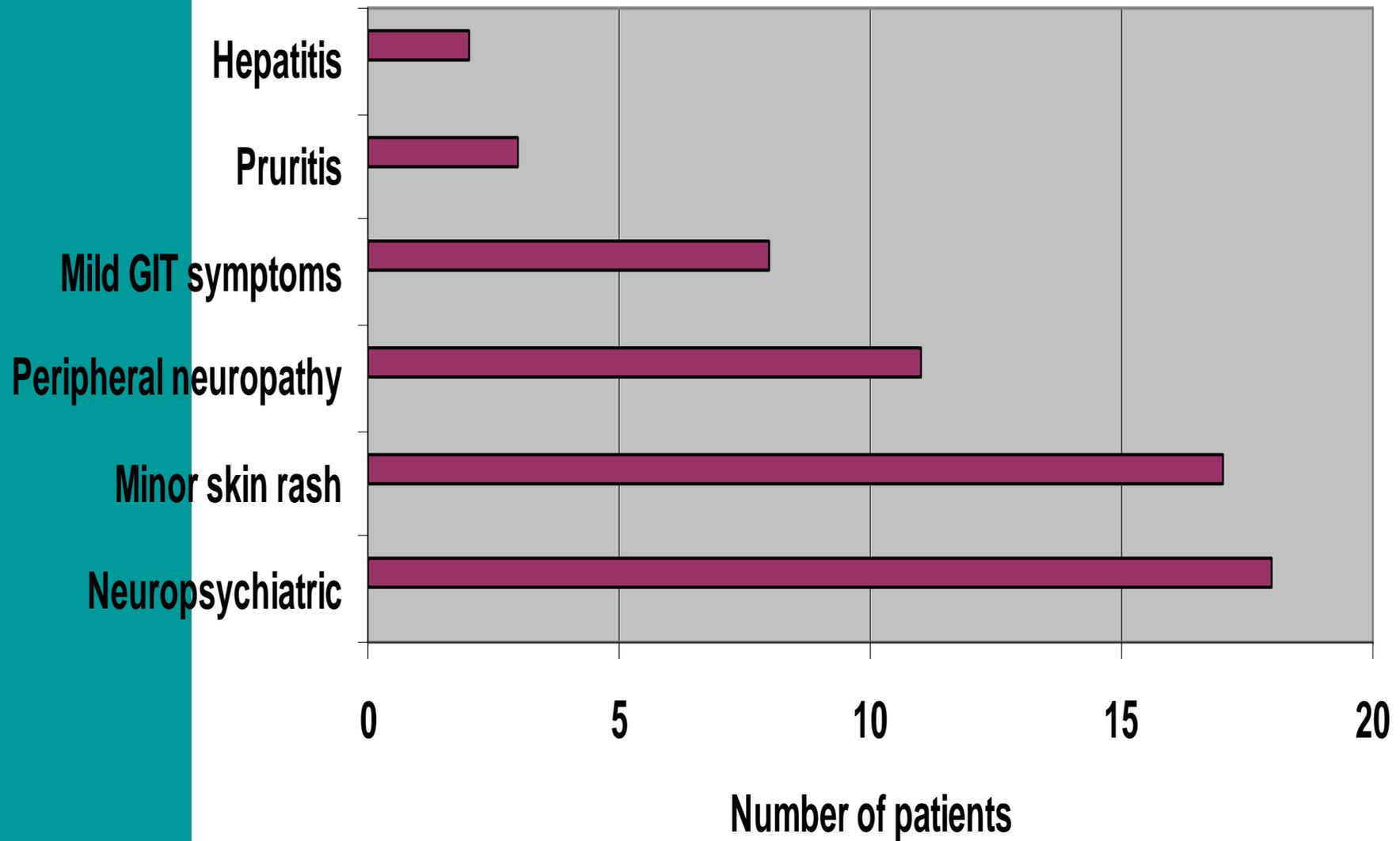


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Side effects – naïve patients



5. Patient Related Factors

- Resources
- Knowledge
- Attitudes
- Beliefs
- Perceptions & expectations of the patient
- Stigma - disclosure



Step up adherence

- less than 80% adherence
 - poor attendance
 - or a detectable viral load > 400
- re-educate
- re-explain
- give adherence tools eg pill box, tick sheet
- ask about drug or alcohol use/abuse
- refer to a counsellor
- see patient *more* frequently eg 2 weekly
- arrange a home visit by P.A.

CHECK !

Treatment fatigue !

Adherence



Cecilia Makiwane
Panorama 1981



CMH, Eastern Cape

April 2008 - 4 clusters (Bisho) 45
Kms



www.avert.org

A caregiver ?

- her child needs A CAREGIVER who will be responsible for giving the ARV's twice daily till he is old enough to be responsible on his own
- monthly transport to and from the ARV clinic
- disclosure to child of his own status ?

Calculating adherence

% Adherence =

$$\frac{(\text{pills remaining at last visit} + \text{pills issued at last visit}) - \text{pills remaining now}}{(\text{number of pills taken each day} \times \text{number of days passed since last visit})} \times 100$$

e.g. Visit date:

Tuesday 2nd May:

Efaverinz: 2

Stavudine: 4

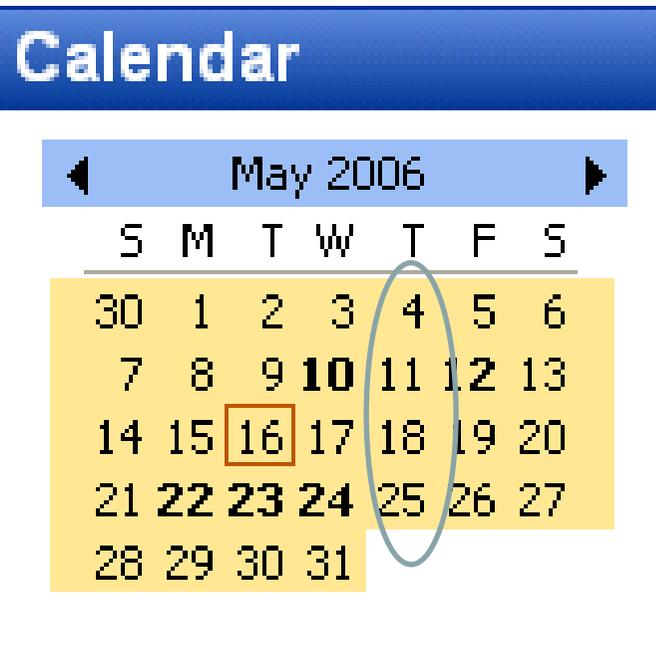
Lamivudine: 4

Wednesday 31 May:

Efaverinz: 6

Stavudine: 6

Lamivudine: 8



EVERY

28 DAYS

Reasons cited for non-adherence

- | | |
|---------------------------|-----|
| • Just forgot | 66% |
| • Away from home | 57% |
| • Busy with other things | 53% |
| • Change in routine | 51% |
| • Fell asleep | 40% |
| • Problems with the times | 40% |
| • Felt ill | 28% |
| • Side effects | 24% |
| • Depressed/overwhelmed | 18% |
| • Too many pills | 14% |
| • Others must not notice | 14% |
| • Felt drug was harmful | 12% |



ADHERENCE TO LONG TERM THERAPIES:

EVIDENCE FOR ACTION W.H.O. REPORT, 2003

- patients need to be supported not blamed
- the consequences of poor adherence are poor health outcomes & increased health care costs
- improving adherence enhances patient safety
- improving adherence might be the best investment for tackling chronic conditions effectively
- health systems must evolve to meet new challenges
- a multi-disciplinary approach towards adherence is needed

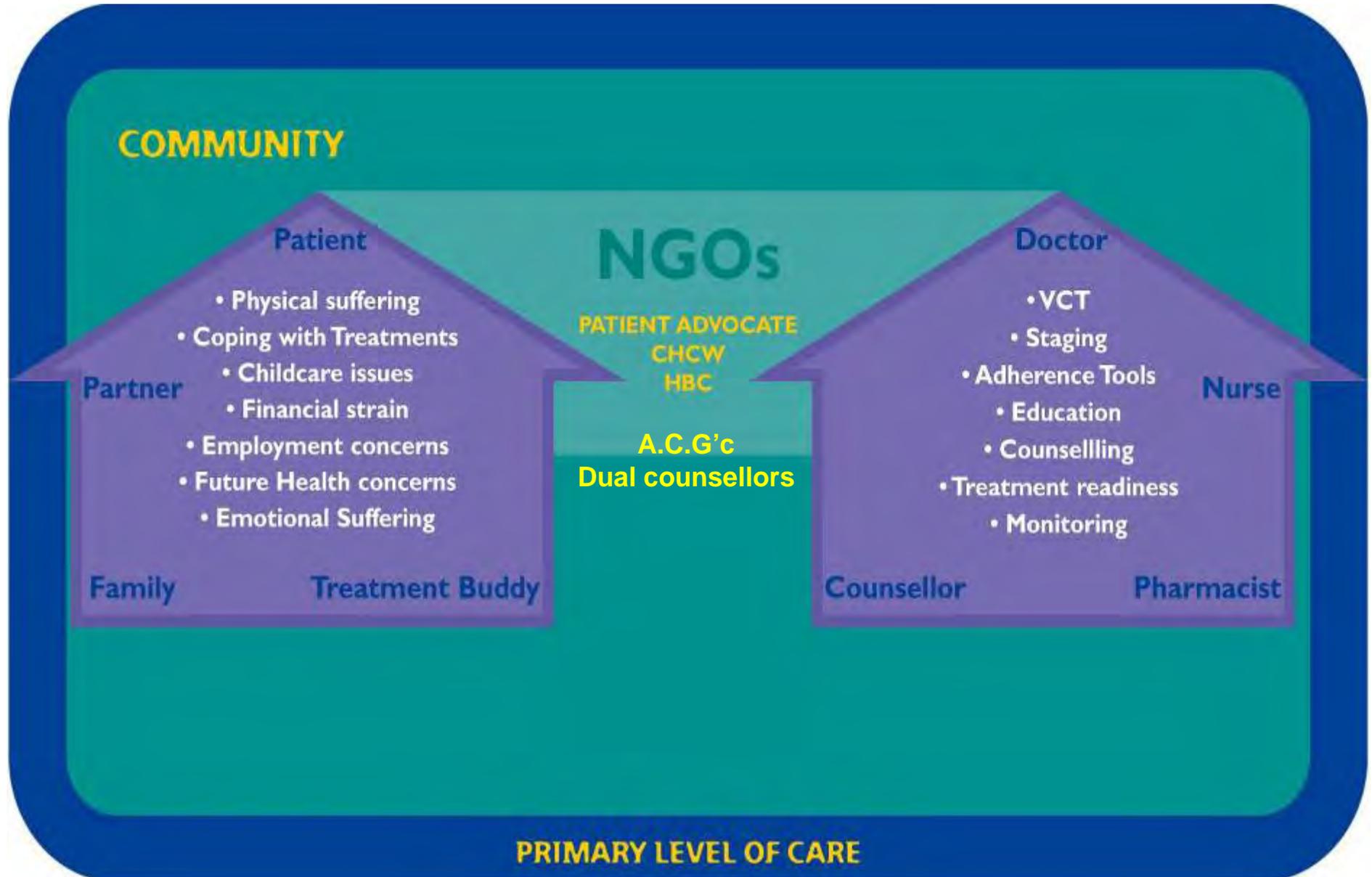
Factors influencing adherence

Table 1: Factors influencing adherence

Factors	Promote Adherence	Reduce Adherence
Patient factors	<p>Motivated patient</p> <p>Good understanding of HIV disease and therapy</p> <p>Education given in patient's home language prior to and during therapy</p> <p>Participation in a support group</p>	<p>Alcoholism</p> <p>Depression</p> <p>Poor understanding of the disease or therapy</p> <p>Non-disclosure of HIV status (to close family/friends)</p>
<i>Disease factors</i>	Late or symptomatic HIV disease	Early, asymptomatic disease
<i>Therapy factors</i>	<p>Small number of tablets</p> <p>Few adverse events</p>	<p>Large number of tablets</p> <p>Severe or ongoing minor adverse events</p>

¹ Adapted from Wilson D et al. Oxford Handbook of HIV Medicine.

ARK SA ARV Adherence Programme



Why ART fails ?

- Ask to the patient to *think* about *why* the current treatment failed ?
 - adherence
 - prior resistance
 - drug absorption problem
 - interference by other drugs eg TB drugs
 - combination* of these factors

Resistance - definition

- HIV is resistant to a drug if it keeps multiplying rapidly while you are taking ARV's. Changes (mutations) in the virus cause resistance
- HIV mutates almost every time a new copy is made. Not every mutation causes resistance. The “wild type “ virus is the most common form of HIV. Anything different from the wild type is considered a mutation.

Selective pressure

- HIV is error prone (no checking for errors unlike all human cells)
- an ARV drug will not control the virus that is resistant to it. It can “escape” from the drug. If you continue taking the drug, the resistant virus will multiply fastest. This is called “selective pressure”.

- If you stop taking the drug, there will be no selective pressure. The wild type will now multiply the fastest. Although resistance tests will not detect any resistance, it might come back if you re-start the same drugs.
- Note: If resistance testing is performed, it must be done **WHILE** the patient is on the failing drugs. Resistance testing is **NOT** the same as monitoring of drug levels which evaluate compliance.

Resistance

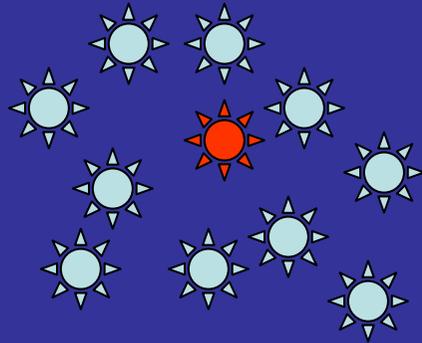
- PRIMARY means that patient has acquired (sexually / blood transfusion) an HIV that is not sensitive to ARV's from initiation of HAART
- SECONDARY means that the patient has acquired resistance to HAART over time as a natural process
- “Treatment fatigue”??



Drug resistance

- initial studies of the use of antiretroviral (ARV) therapy as monotherapy showed only transient clinical and immunological response
- it was recognised that the transient nature of the response was due to the development of viral resistance against the ARV
- dual therapy resulted in an improved and more prolonged virological response, but this still diminished over time
- Highly Active Antiretroviral Therapy (HAART) regimens containing three or more agents are capable of producing prolonged virological suppression

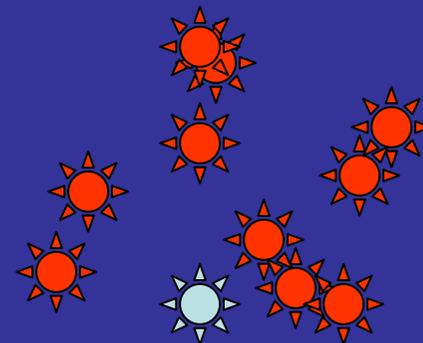
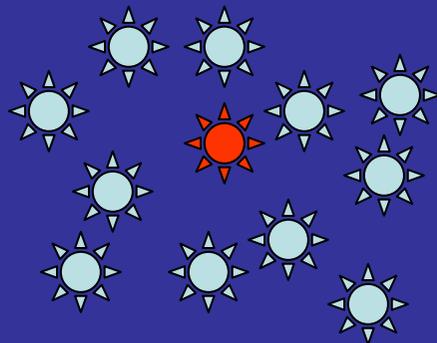
NVP and selection of NNRTI resistance



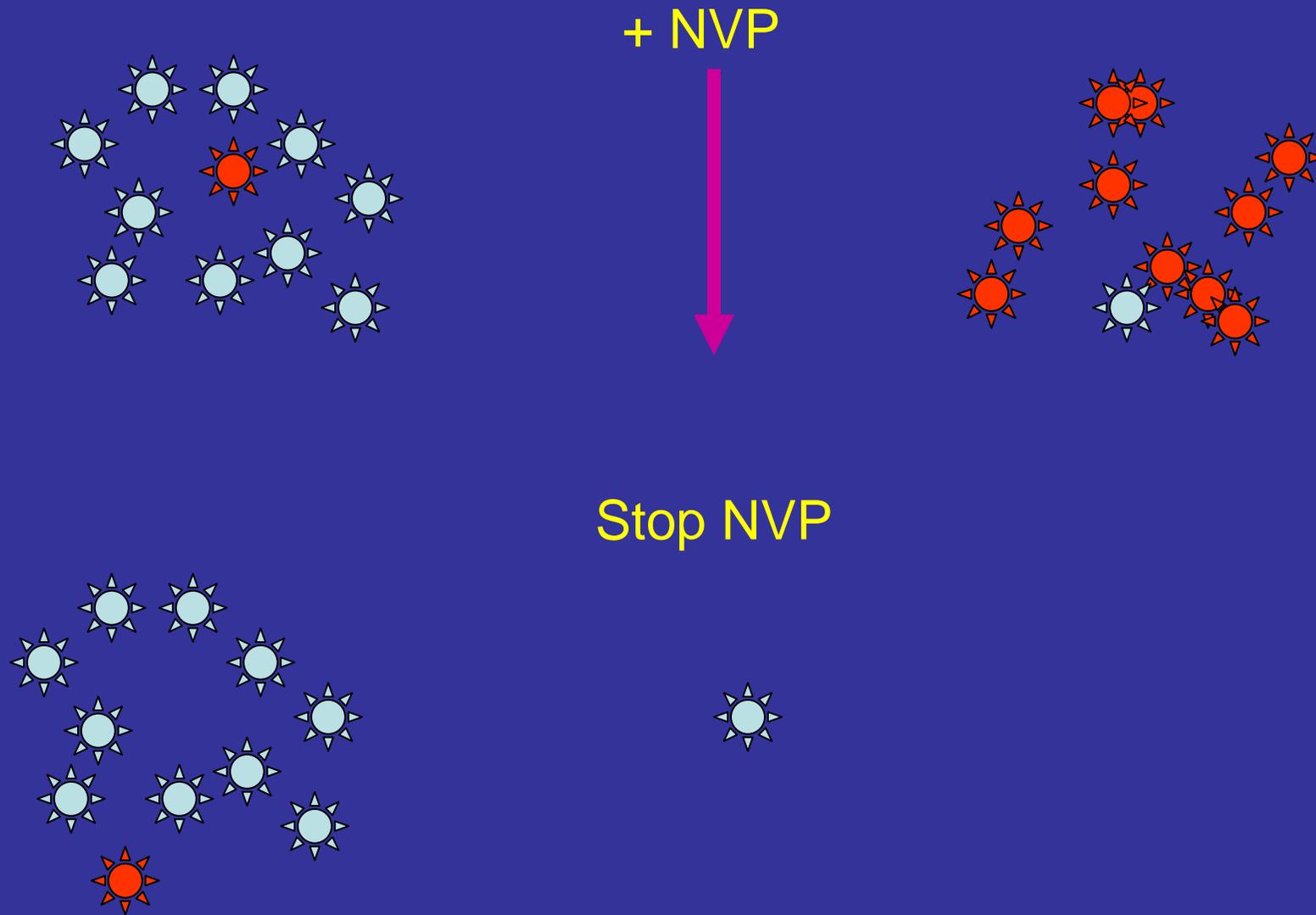
No drug



+ NVP



NVP and “fading” of NNRTI resistance



Mechanism of Resistance

- ARV resistance occurs as a result of mutations in the HIV genome that affect the ARV target binding sites
- the HIV reverse transcriptase enzyme is *error-prone* due to a lack of proof-reading capability, generating approximately 1 mutation in each newly produced virus.
- in the presence of ARV drugs, mutations conferring resistance are the fittest due to applied selection pressure.



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Mechanism of resistance

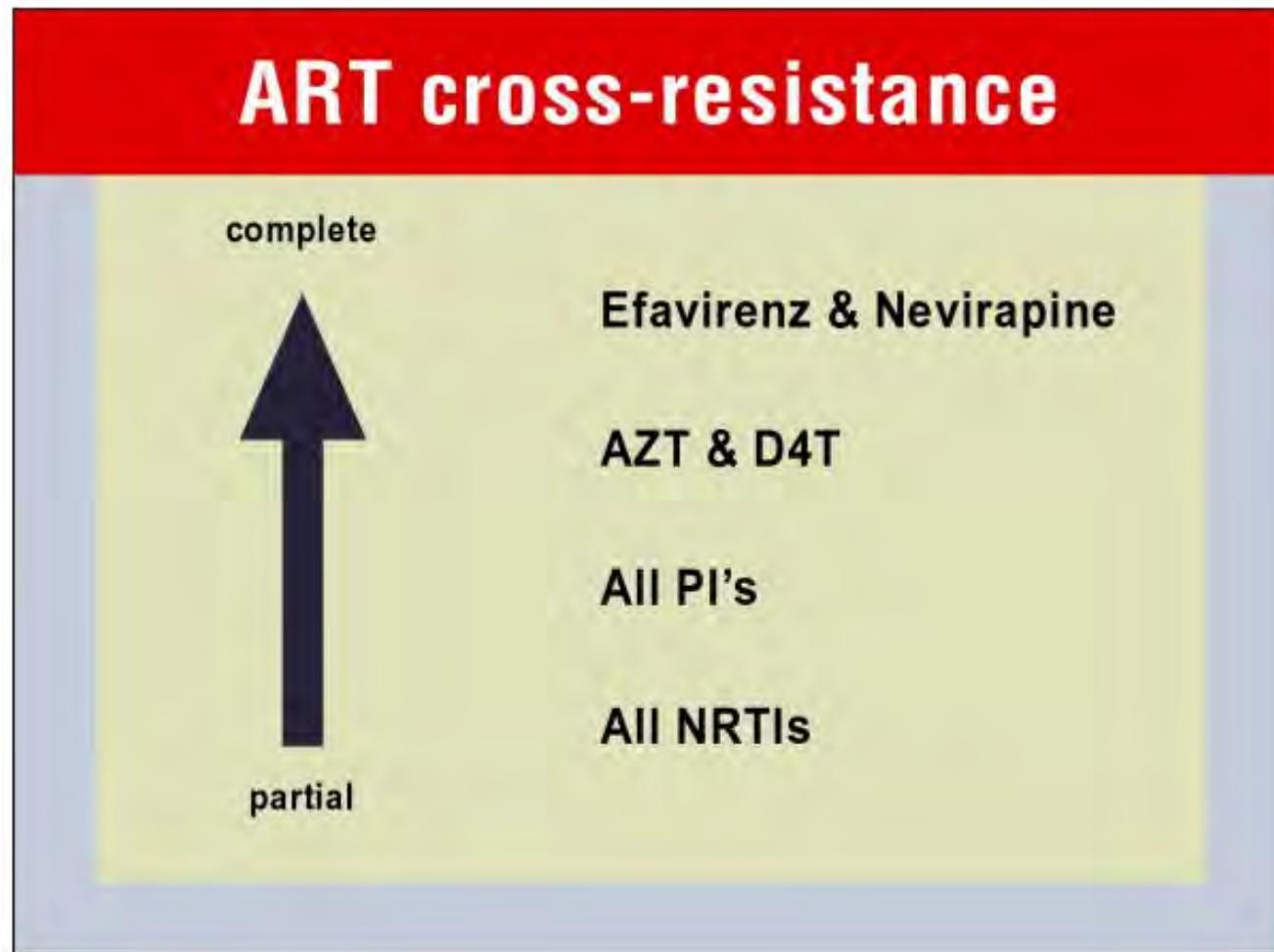
- Combination ARV therapy (HAART) that is powerful enough to suppress HIV replication prevents the development of resistance
- **low genetic barrier to resistance**: develop high levels of resistance as a result of a single mutation - RAPID
eg NNRTI and Lamivudine (however even if resistant on genotyping lamivudine still lames other drugs)
- **high genetic barrier to resistance**: Cumulative mutations are required for high level resistance – SLOW
eg PI's and most NRTI's

Types of Cross Resistance

- Complete Cross-resistance
 - Efavirenz resistance confers complete resistance to Nevirapine.
- Class Resistance
 - The accumulation of multiple mutations can lead to resistance of an entire class (eg. Certain combinations of mutations against NRTIs can lead to class resistance).
- Cross-Class resistance
 - Mutations affecting PIs and NRTIs typically occur when patients continue to take therapy as the viral load steadily rises towards pre-treatment baseline values (occurring slowly over many months or even years).



Cross Resistance



Resistance to NRTI's

- it is important to note that AZT and ddl are from the SAME class of drugs as d4T and 3TC
- AZT and ddl can be used as part of Regime II as they have only *partial resistance* to HIV



Signs of Resistance

- increasing viral Load:
 - concurrent infection
 - non-adherence
 - resistance
- can be confirmed with:
 - *Phenotyping* : virus grown in media with increasing concentrations of drugs to determine M.I.C.
(minimum inhibitory concentration)
 - *Genotyping* : sequencing of genes determines known viral mutations
 - both expensive

Golden rules

- Chart **WEIGHT** of every patient at every visit:
 - loss of weight may point to infection with Tuberculosis *or* development of hyperlactataemia *or* other infection
 - weight gain points to good response to ARV's and / or Tuberculosis treatment

Golden rules

- Generally, the viral load should always be < 400 copies per ml after the first 6 months in treatment naïve patients (unless they have primary resistance). If it is raised, it is usually due to poor ARV adherence.



Department of Health
Republic of South Africa



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