HAART Initiation in Children

Updated August 2013

Informed by:
The South African Antiretroviral Treatment Guidelines 2013
National Department of Health

Key Paediatric Guideline Updates 2013

- No separate pre-ART literacy sessions
- **All** children under 5yo are eligible for ART
- <18mo ANY VL confirms infection
- d4T should be changed to ABC <u>if the child is virologically suppressed</u>
- Children exposed to NVP for 6wks or more who are older than 3yo should be started on 3TC/ABC/**Kaletra**

CHAIN OF SURVIVAL

EARLY ACCESS

EARLY CPR

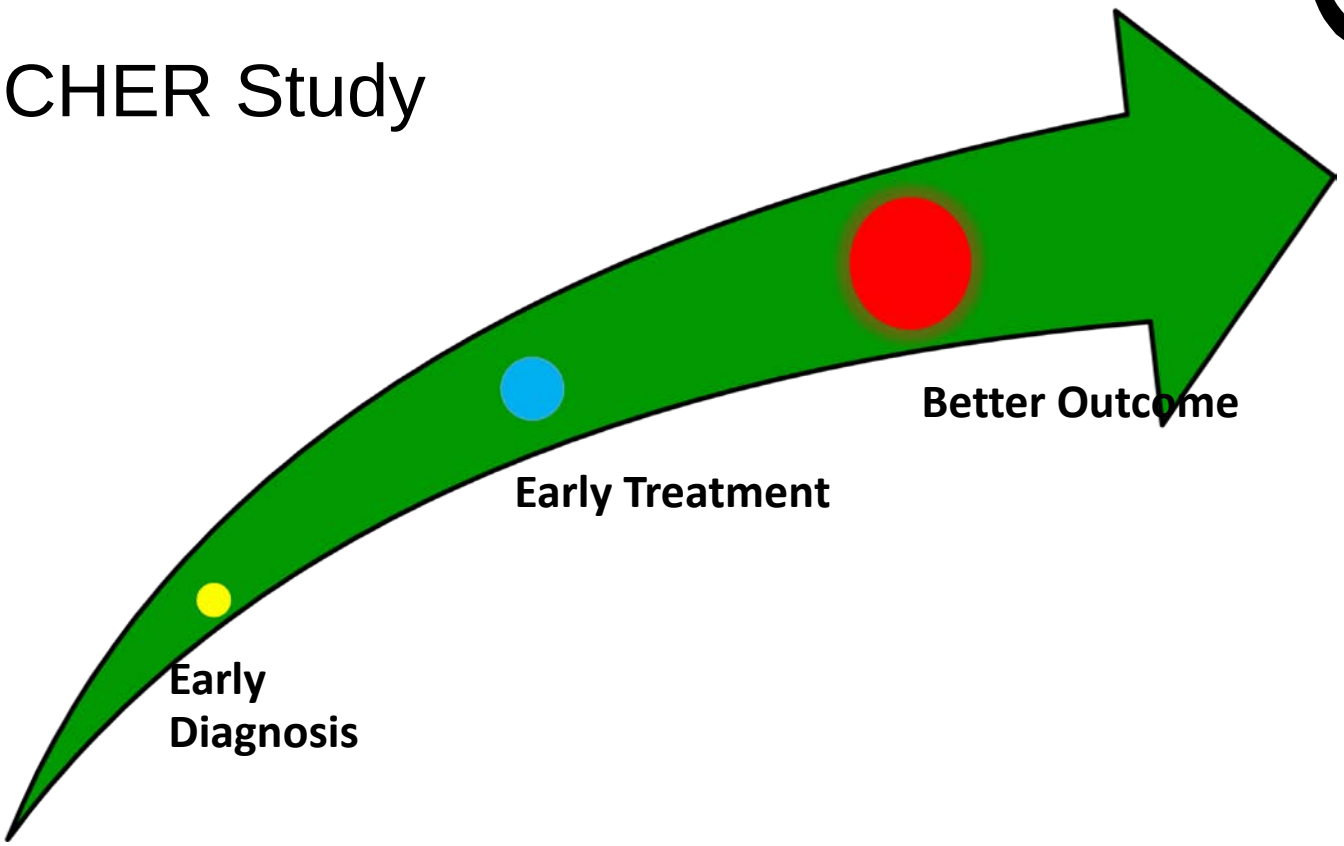
EARLY DEFIBRILLATION

EARLY ADVANCED CARE


CHAIN OF
SURVIVAL
EARLY ACCESS
EARLY CPR
EARLY DEFIBRILLATION
EARLY ADVANCED CARE
PCR
STARTING
HARTC

When To Start?

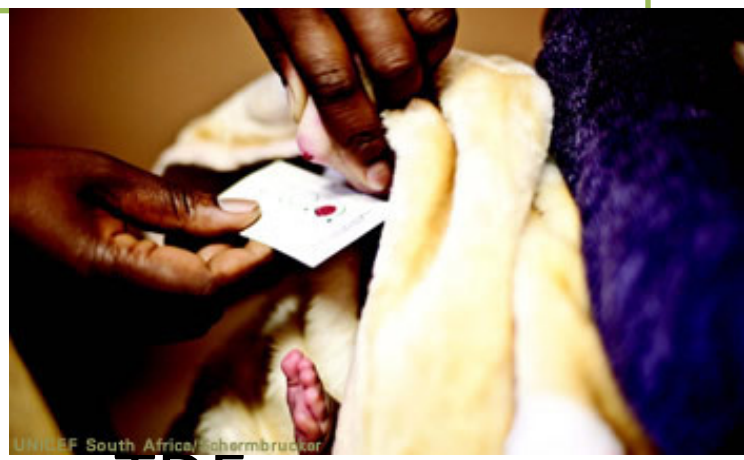
- CHER Study



Does the child have confirmed HIV infection?

- Child < 18-mo
  - **Diagnosis** requires HIV DNA PCR test
  - **Confirmation** is with a VL of any amount (NEW)
- Child >18- mo
  - **Diagnosis** is with a rapid test
  - **Confirmation** is with a second different rapid test (or ELISA)

Which baseline labs are required?



- *VL (<18-mo)
- CD4
- Hb or FBC if available
- Cr + urine dip if planning to use TDF
- ALT if jaundiced or on TB treatment
- **NB:** do not delay HAART initiation for baseline lab results

Is the child eligible for HAART?

<5 years

All HIV infected children

Regardless of WHO staging and CD4 count

>5 years

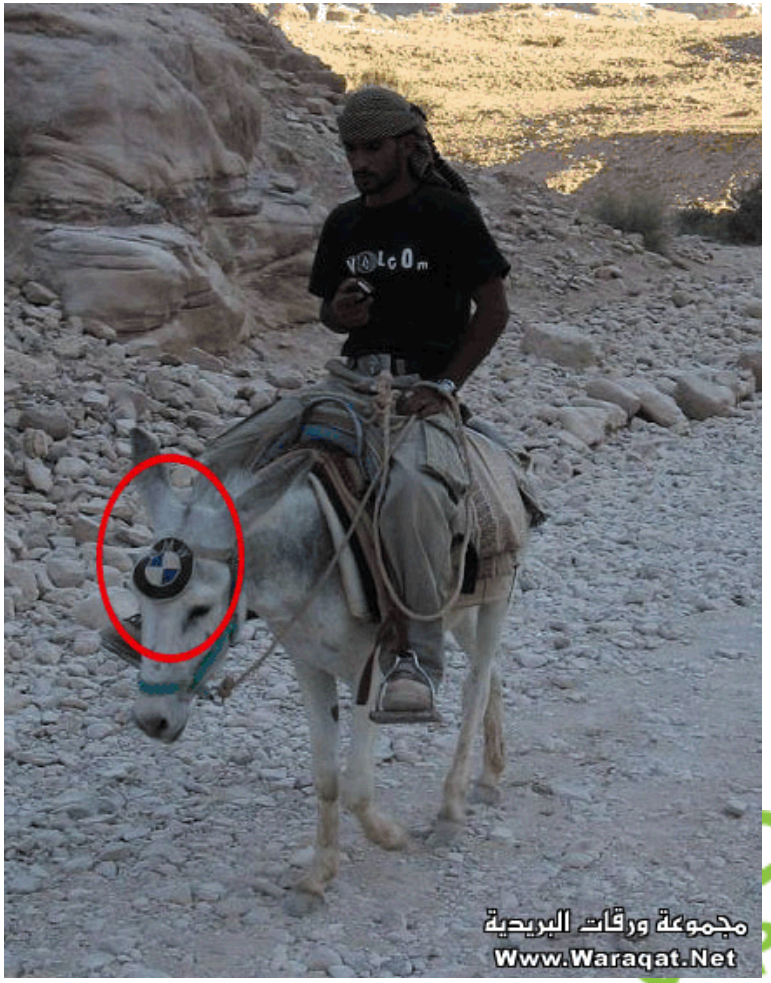
Stage III or IV

CD4 count <350

Who qualifies for fast track initiation?

Fast track: start HAART within 7 days

- Infants < 1 year of age
- CD4 Count < 200 cells/ul or < 15%
- WHO stage 4
- MDR or XDR TB



What is the baseline assessment?

- Weight, height, head circumference (<2yo)
- Developmental screen
- Screen for TB <u>disease</u> and <u>exposure</u>
- WHO Clinical Staging
- Counsel in regard to HIV readiness – do this on the same day. **NB**: <u>do not delay HAART</u> for counselling, do them concurrently

What is the TB screen for children?

- TB **Exposure**
- **Cough** (2 weeks)
- **Fever** (2 weeks)
- **Night sweats** (drenching)
- **Weight** loss or poor weight gain
- Malaise and fatigue

Staging in Children

Staging helps to determine disease progression.

1. WHO Clinical Staging
   - Relies on history and physical exam
2. Immunologic
   - Relies primarily on CD4 ct
   - When CD4 ct is low the VL and OI risk is high

NB: In children less than 5-yo staging does not determine whether they qualify for HAART.

WRHI

WHO Clinical Staging

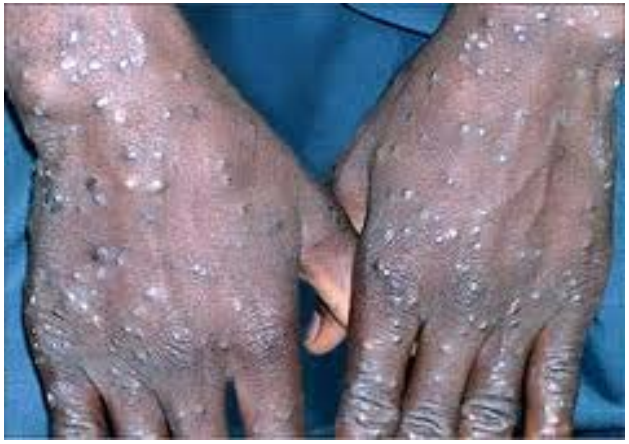
WHO Clinical Staging

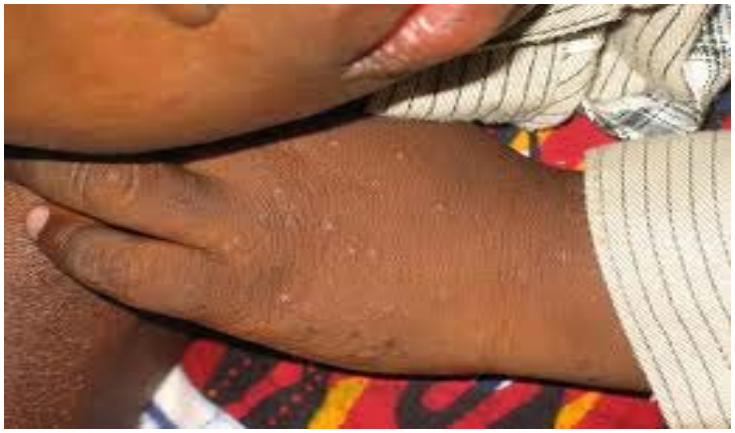
to

STAGE 1	STAGE 2	STAGE 3	STAGE 4
• No symptoms • Persistent generalised lymphadenopathy	• Unexplained persistent enlarged liver and/or spleen • Unexplained persistent enlarged parotid • Angular cheilitis • Minor mucocutaneous conditions (e.g. chronic dermatitis, fungal nail infections or warts (molluscum contagiosum)) • Recurrent or chronic respiratory tract infections (sinusitis, ear infection, pharyngitis, tonsillitis) • Herpes zoster • Recurrent oral ulcerations	• Moderate unexplained malnutrition (low weight) not responding to standard therapy • Oral thrush (outside neonatal period) • Oral hairy leukoplakia • The following conditions if unexplained and if not responding to standard treatment - Diarrhoea for 14 days or more - Fever for one month or more - Anaemia (Hb < 8 g/dL) for one month or more - Neutropaenia (< 500/mm^3) for one month - Thrombocytopaenia (platelets < 50,000/mm^3) for one month or more • Recurrent severe bacterial pneumonia • Pulmonary TB • TB lymphadenopathy • Symptomatic LIP* • Acute necrotising ulcerative gingivitis/periodontitis	• Unexplained SEVERE MALNUTRITION not responding to standard therapy • Oesophageal thrush • Herpes simplex ulceration for one month or more • Severe multiple or recurrent bacterial infections, two or more episodes in a year (not including pneumonia) • Pneumocystis pneumonia (PCP) • Kaposi sarcoma • Extrapulmonary TB • Toxoplasma • Cryptococcal meningitis • HIV encephalopathy

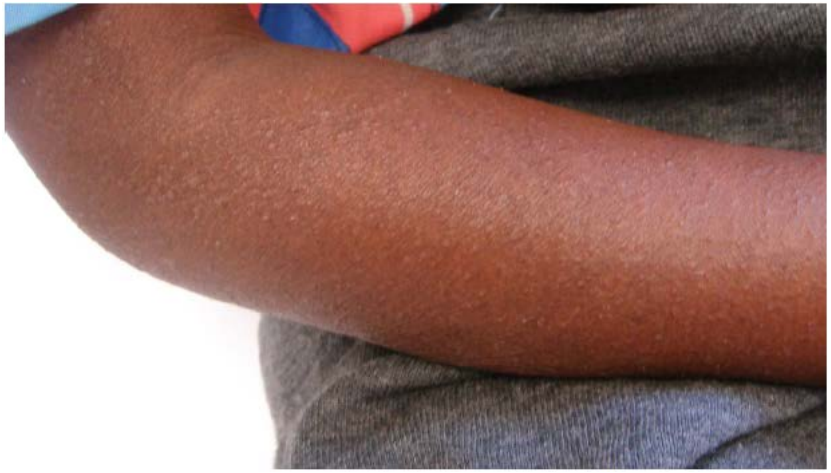
IMCI South Africa 2011, Page 44

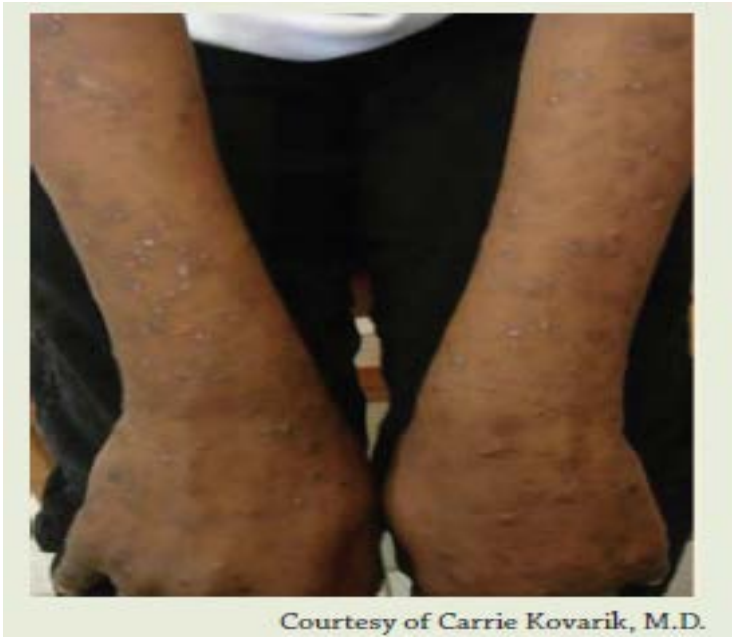
WHO Clinical Staging





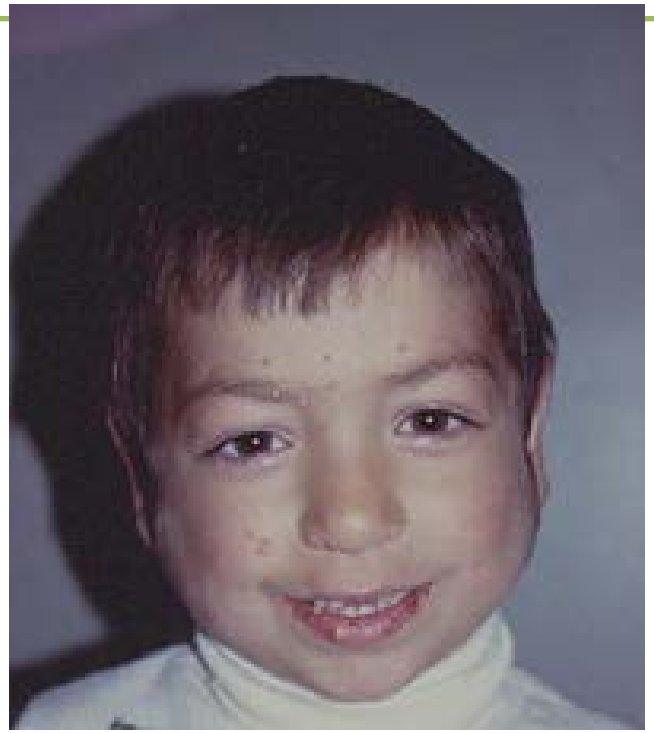
WHO Stage 2: HIV associated papular pruritic eruption





Courtesy of Carrie Kovarik, M.D.

WHO Clinical Staging

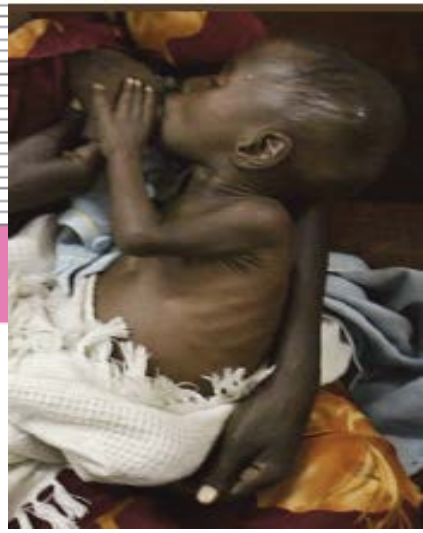


WHO Stage 2: Parotid enlargement – unexplained, persistent.
Often associated with LIP
Usually painless and bilateral
May resolve and recur

Weight-for-age GIRLS

Birth to 2 years (z-scores)

World Health Organization



Weight (kg)

3
2
0
-2
-3

Months

Birth

1 year

Age (completed months and years)

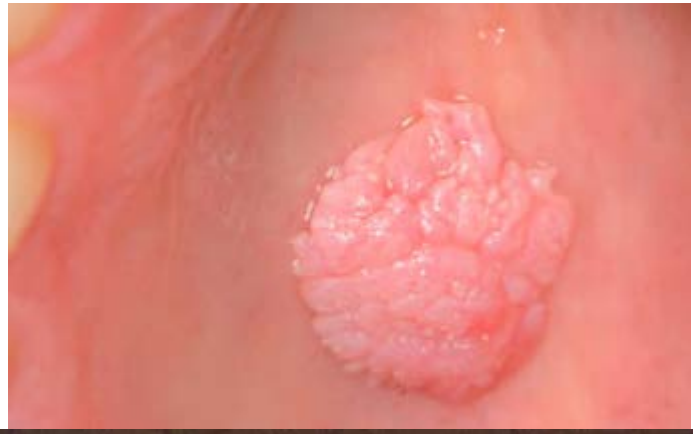
Z-score less than -2 is WHO Stage 3.

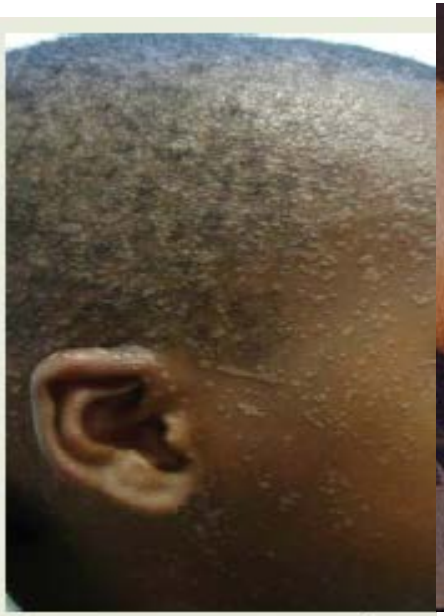
Z-score less than -3 is WHO Stage 4.

Must not be caused by poor/inadequate feeding and must not respond to standard care.

WHO Clinical Staging

WHO Stage 2: Extensive wart virus infection (HPV)
RX: HAART, tincture of time, Podophyllin, surgery, laser therapy, cryotherapy





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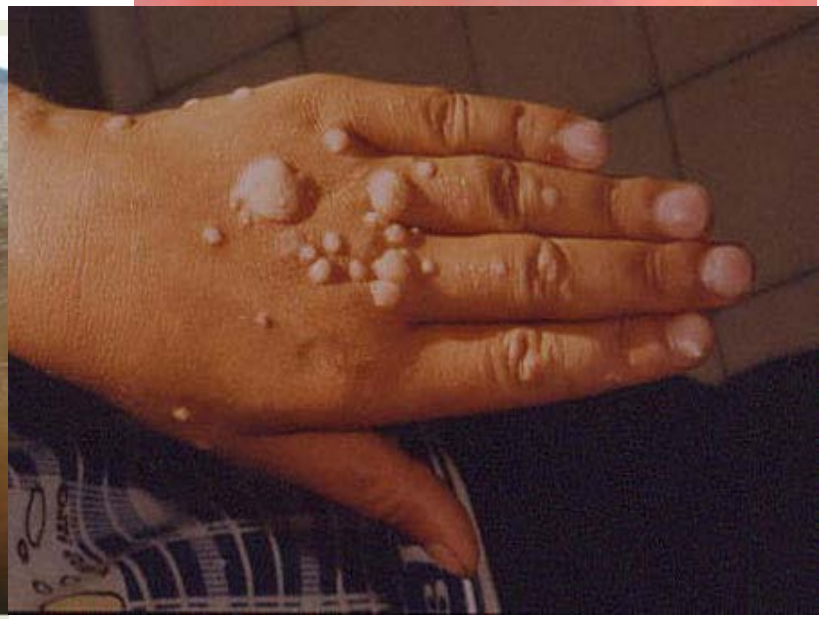
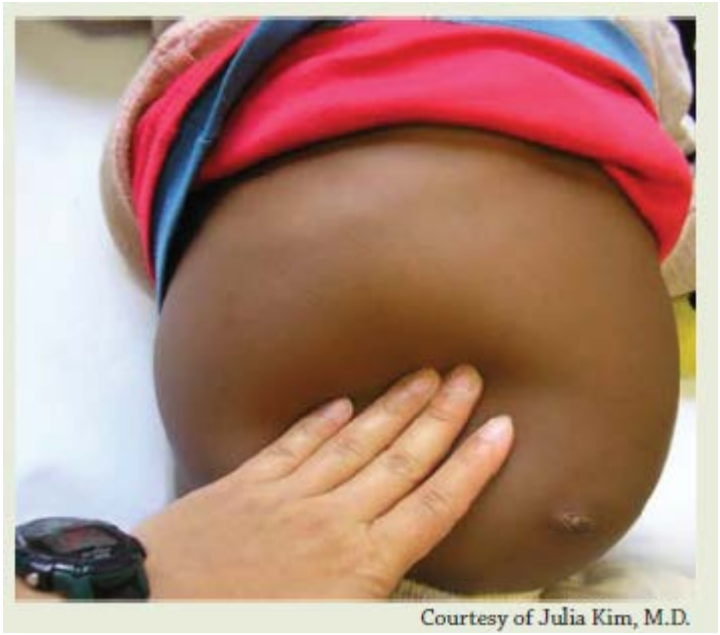


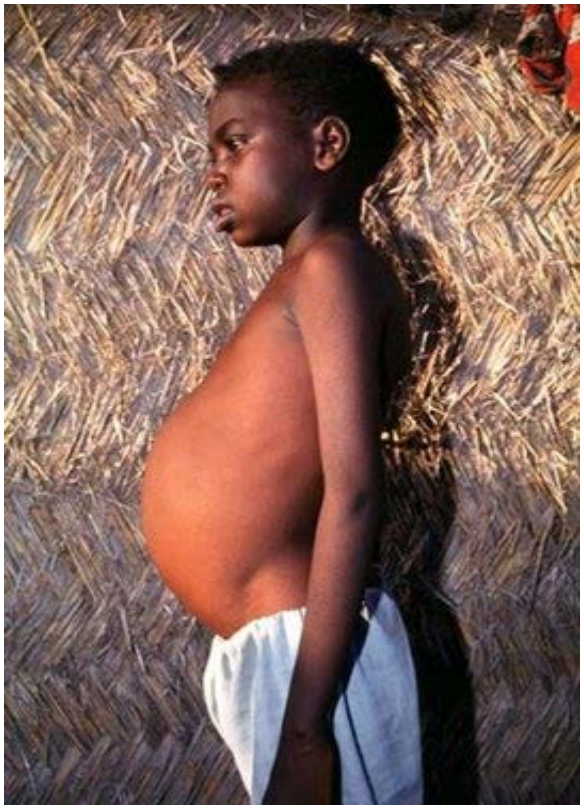
WHO Clinical Staging

Hepatomegaly

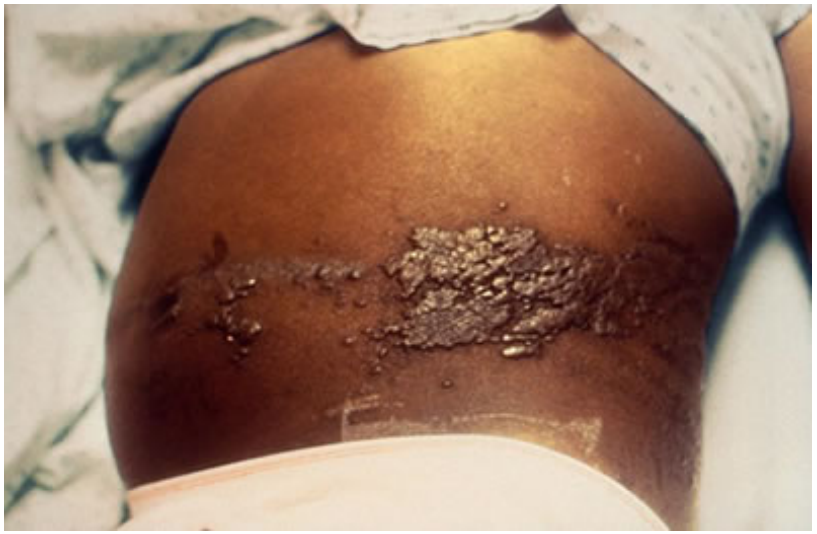


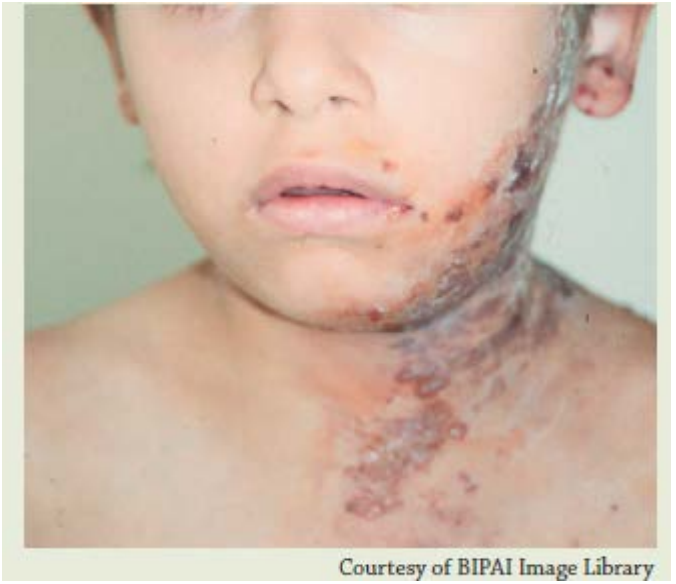
WHO Stage 2
Enlarged liver and/or spleen without obvious cause.

Splenomegaly



WHO Clinical Staging





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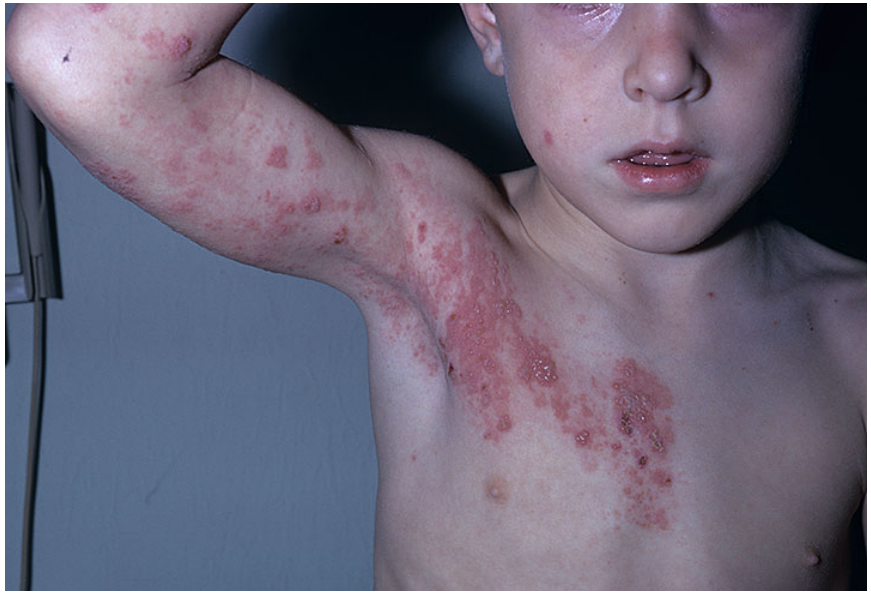
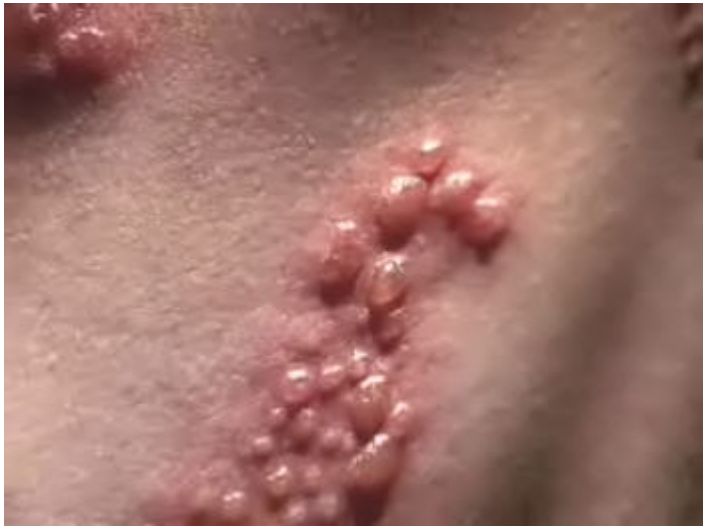
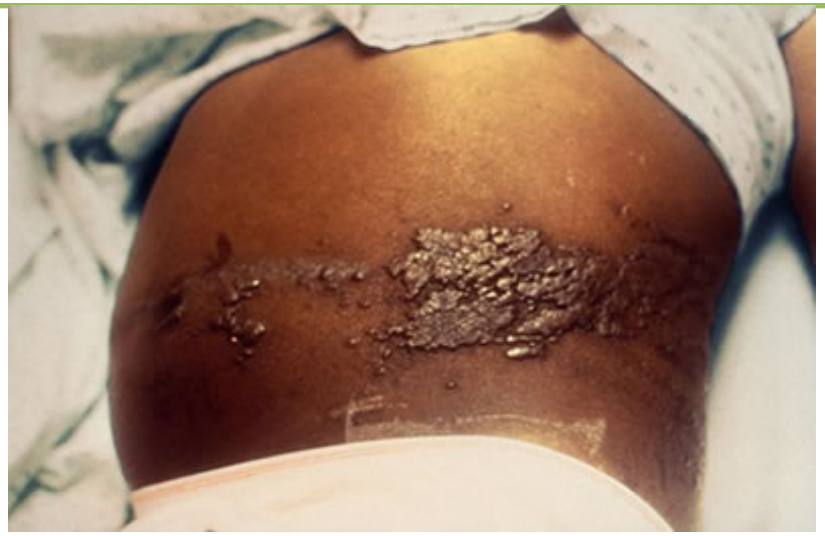


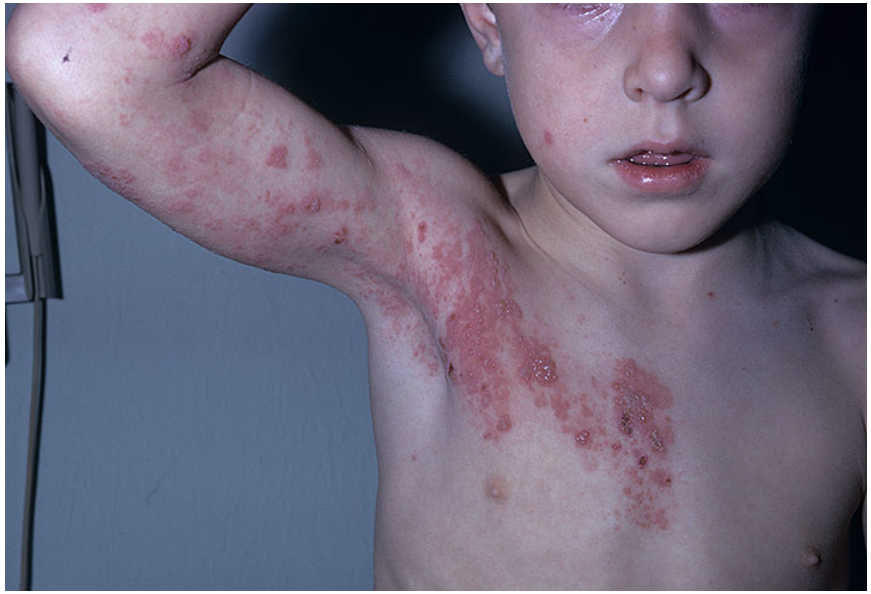


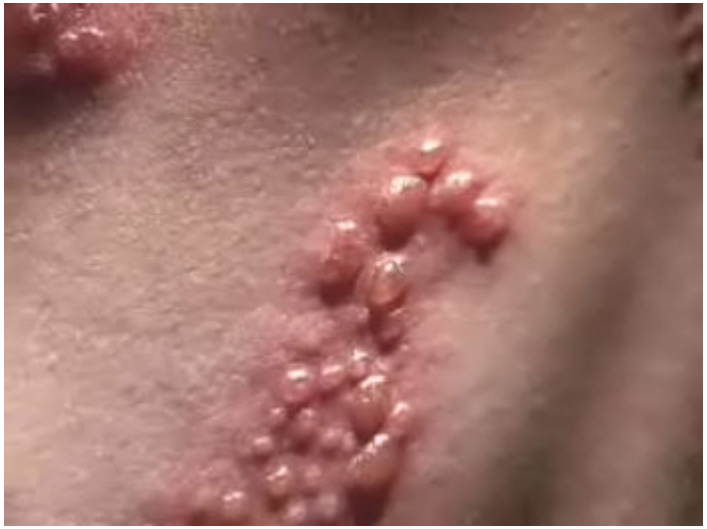
WHO Clinical Staging



WHO Stage 2: Herpes Zoster/shingles

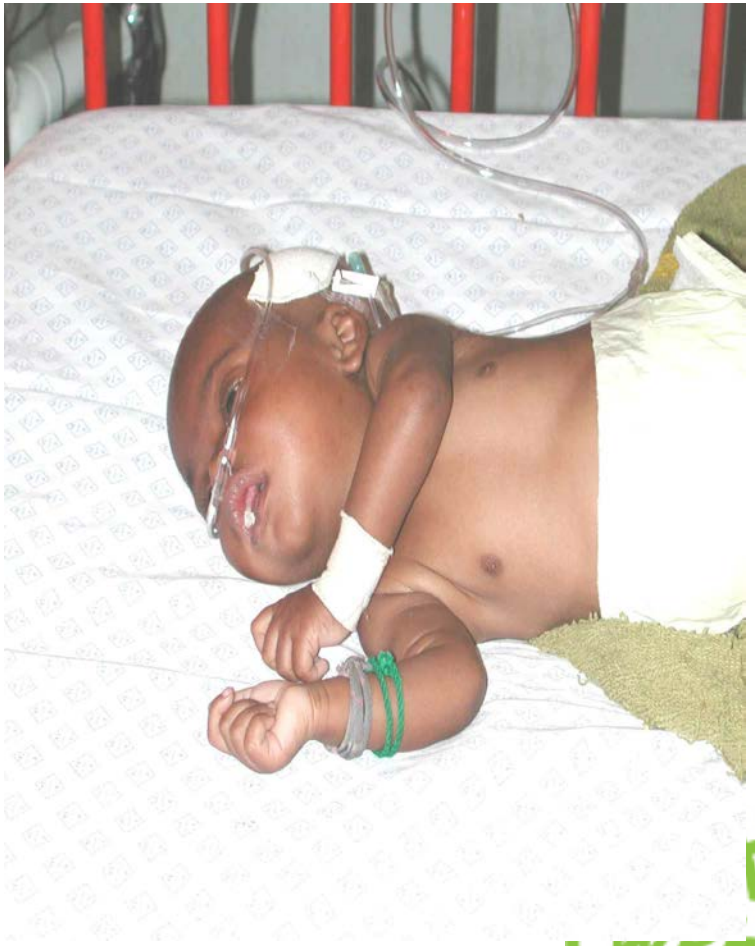
- Reactivation of VZV
- Neuralgia
- Grouped vesicular lesions, ulcers
- Herpes keratitis (eye)
- Do not cross the midline
- RX Acyclovir within 72hrs preferable





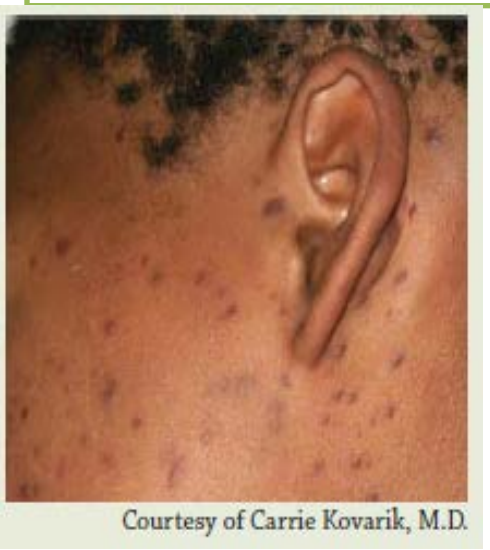
WHO Clinical Staging

- **WHO Stage 4**: PCJ (PCP)
  - High morbidity and mortality, especially in infants
  - Largely prevented by Bactrim prophylaxis
  - Cyanosis, tachypnea, dyspnea, fever, chest indrawing
  - Auscultation often unremarkable as compared to clinical picture
  - CXR: bilateral perihilar diffuse infiltrates
  - RX: HD Bactrim +/- steroid



WHO Clinical Staging

WHO Stage IV: Kaposi Sarcoma



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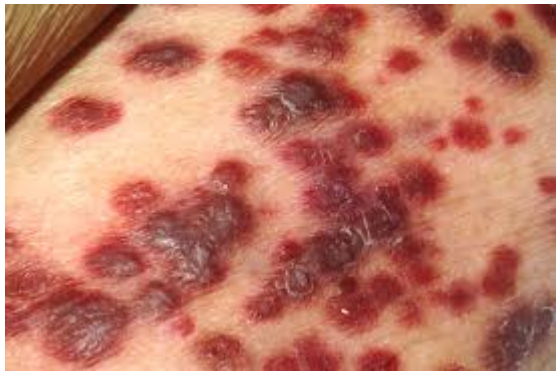
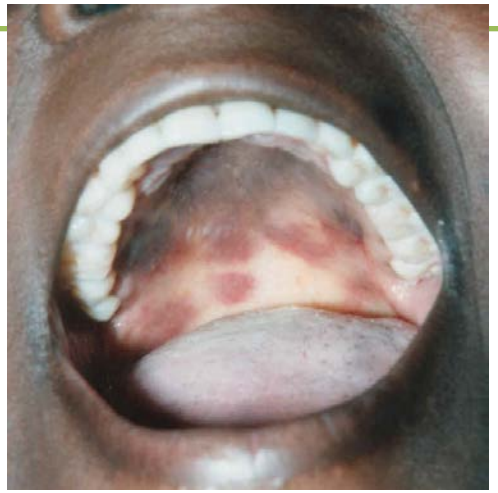
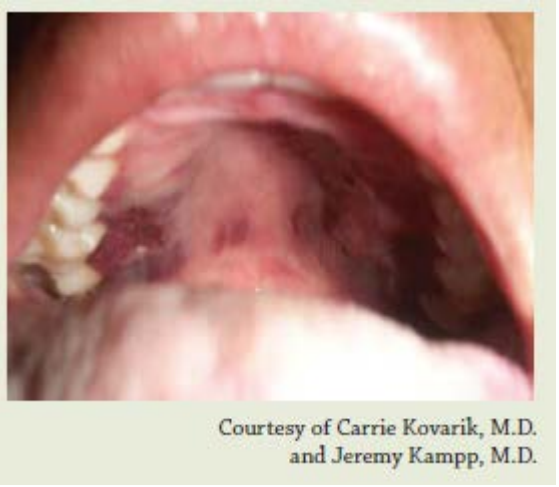
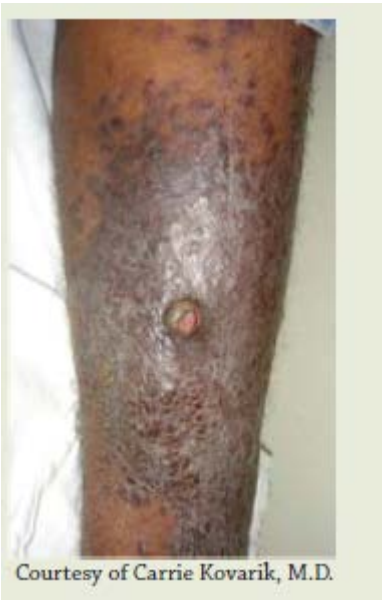






Courtesy of Carrie Kovarik, M.D.
and Jeremy Kampp, M.D.



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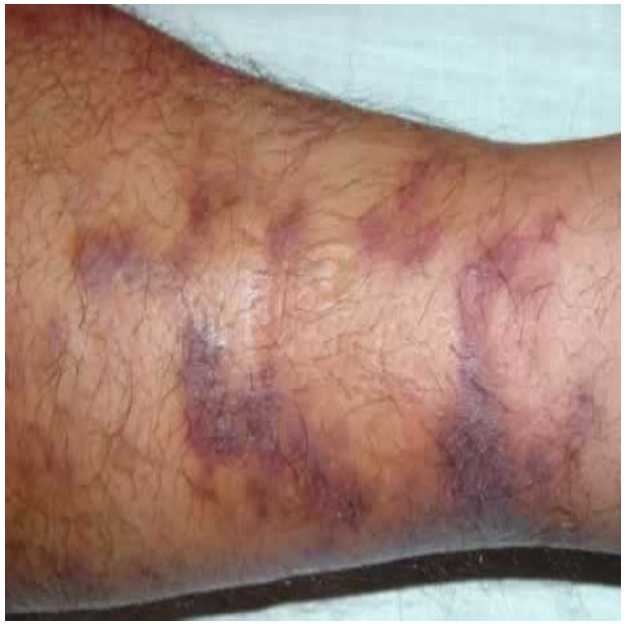
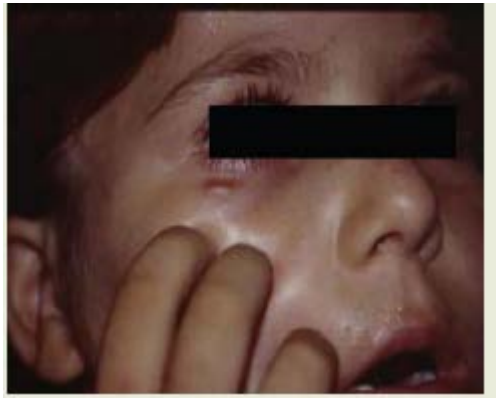


WHO Clinical Staging

- Vascular neoplasm associated with HHV8
- Skin or oropharynx but may be disseminated and involve any organ
- Pink, purple, red, brown lesions
- Initially flat but may develop into

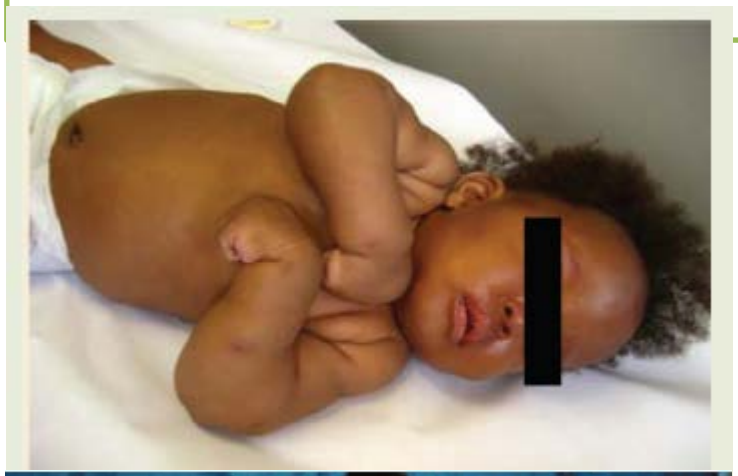
patches, papules, plaques, nodules

tumors



- Clinical diagnosis, may be confirmed by biopsy
- Can be associated with IRIS

WHO Clinical Staging

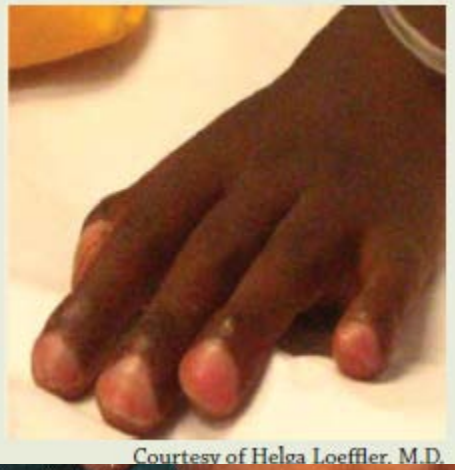


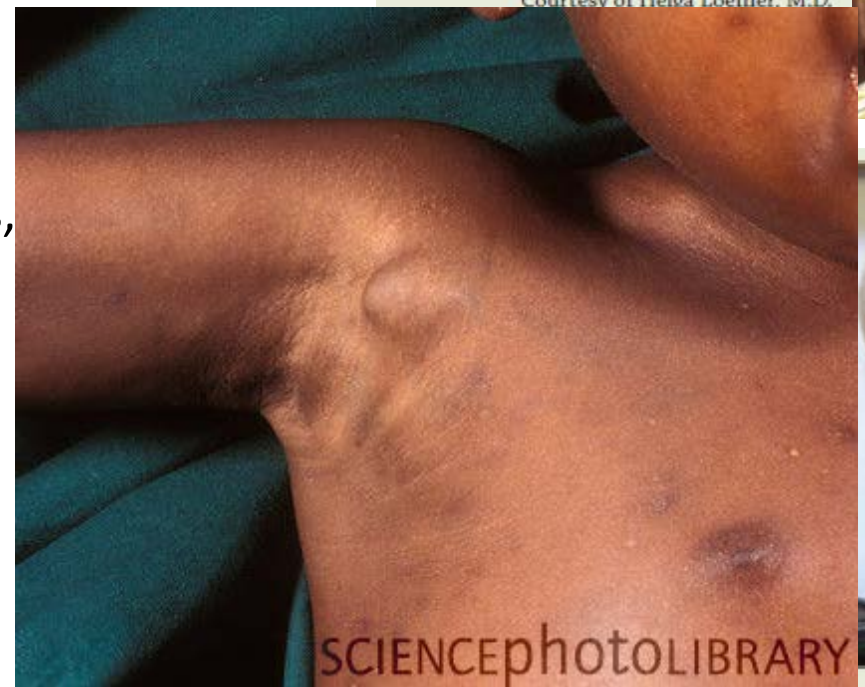
- **WHO Stage 4:** HIV Encephalopathy
- At least 2 of the following progressing over at least 2 months with no other cause:
  - Failure to attain or loss of milestones/intellectual ability
  - Progressive impaired brain growth
  - Acquired symmetric motor deficit accompanied by paresis, pathological reflexes, ataxia, gait disturbances
- HAART and PT/OT help

WHO Clinical Staging

WHO Stage 3: "Symptomatic LIP"

- CXR – bilateral, diffuse, reticulonodular infiltrates with mediastinal LAD
- Caused by lymphoid cell proliferation in lungs and organs
- Symptoms- cough, tachypnea, low O2 sats, exercise intolerance
- Treatment– antibiotics for infections, bronchodilators, oral steroids
- Difficult to differentiate from TB.





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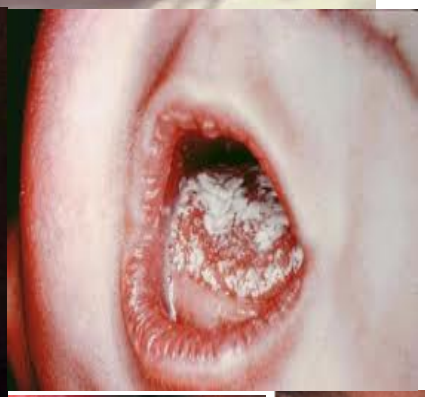
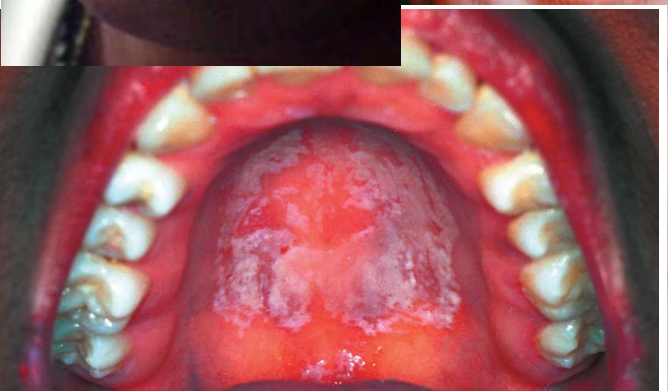
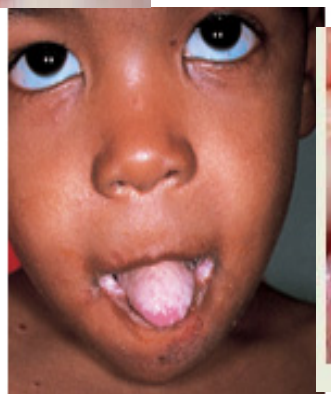




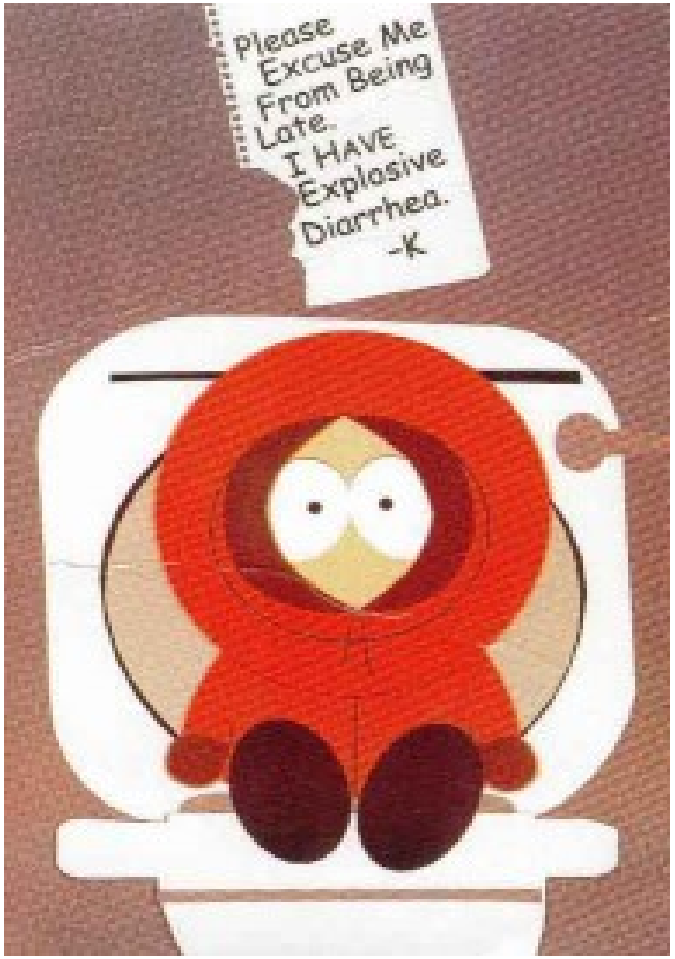


Courtesy of I-TECH Public Image Library

Stage 3: Oral Thrush

- Suggestive of HIV outside of 6-8 weeks of life
- **Qualifies children less than 15yo for HAART initiation**
- Associated with progression of HIV disease
- Median time of survival between diagnosis and death is 3.4 years with no intervention in children
- Treatment**: HAART**, topical and systemic antifungals is recommended

WHO Clinical Staging



- **Stage 3: Persistent Diarrhea** – >14 days
- 3+ loose stools/day
- Associated with an **11-fold** increased risk of death
- Treatment – Nat'l Paeds HIV guidelines 2010 pp. 49-52, WHO guidelines
- Qualifies children <15yo for HAART: ask about this during history, qualifies for HAART

What have we done so far?

- Make the diagnosis
- Start HAART early!
- Confirm the diagnosis
- Send BL labs and determine eligibility
- Perform BL assessment
- Stage clinically and immunologically

What are the Paeds Regimens?

First Line Regimen	
All infants and children under 3 years (or < 10kg)	ABC + 3TC + LPV/r
Children ≥ 3 years (and ≥ 10kg)∞	ABC + 3TC + EFV
Currently on d4T-based regimen	Change d4T to ABC if Viral Load is undetectable If Viral load >1000 copies/ml manage as treatment failure If Viral load between 50 – 1000 copies/ml – consult with expert for advise

∞ Children ≥ 3 years and exposed to NVP for 6 weeks or longer (PMTCT) should be initiated on ABC + 3TC + LPV/r

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Tastes horrible!! Monitor Chol/Trig annually

NB: double dose when on TB Rx or add Ritonavir

This regimen can be daily dosed

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Currently on d4T-based regimen	Change d4T to ABC if Viral Load is undetectable If Viral load >1000 copies/ml manage as treatment failure If Viral load between 50 – 1000 copies/ml – consult with expert for advise

NEVER change one drug in a failing regimen

∞ Children ≥ 3 years and exposed to NVP for 6 weeks or longer (PMTCT) should be initiated on ABC + 3TC + LPV/r

ANTIRETROVIRAL DRUG DOSING CHART FOR CHILDREN 2012

Compiled by the Child and Adolescent Committee of the SA HIV Clinicians Society

Double-dose if on TB rx or add Ritonavir

Can be daily dosed (also ddI).

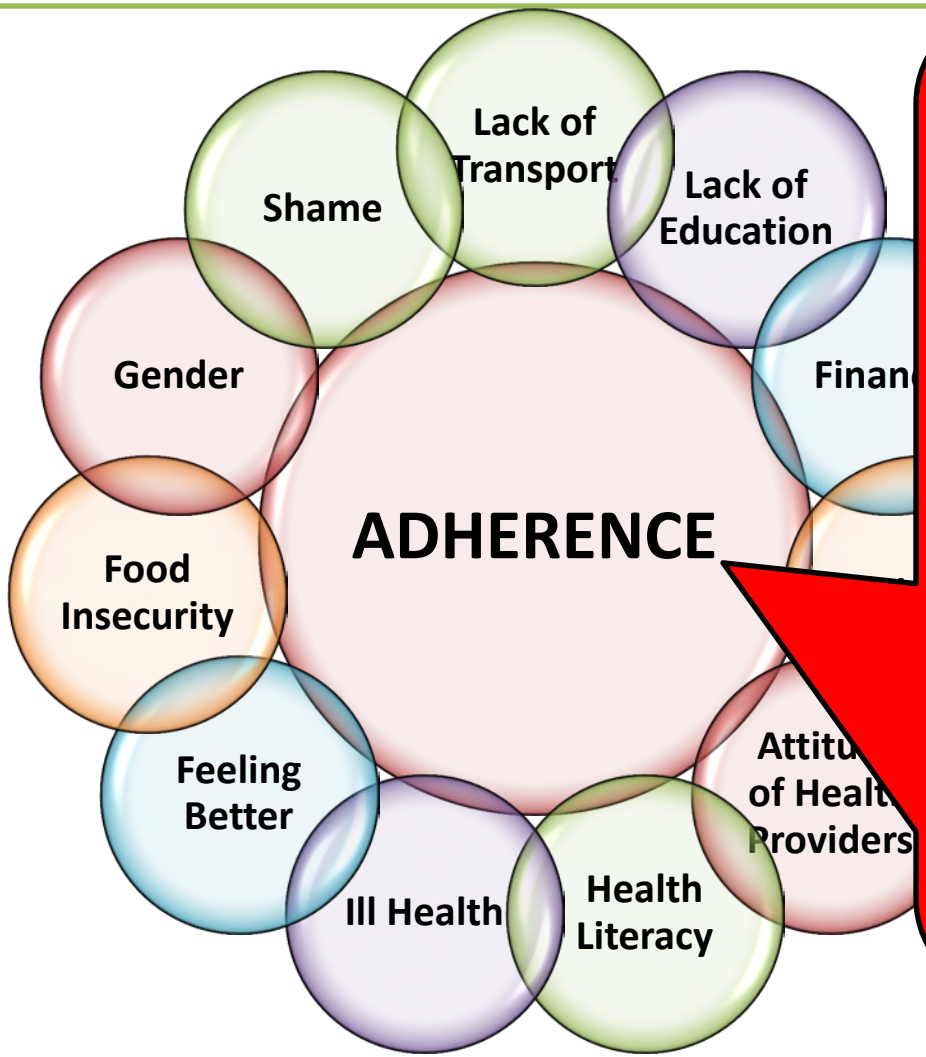
	Abacavir (ABC)		Lamivudine (3TC)		Efavirenz (EFV)	Lopinavir/ritonavir (LPV/rtv)	Ritonavir boosting (RTV)	Stavudine			
Target Dose	8mg/kg TWICE daily OR ≥10kg: 16mg/kg ONCE daily		4mg/kg TWICE daily OR ≥10kg: 8mg/kg ONCE daily		By weight band ONCE daily	300/75mg/m²/dose TWICE daily	ONLY as booster for LPV/ TWICE daily (0.75xLPV dose bd)	1mg/kg/dose TWICE daily	180-240mg/m²/dose ONCE daily	160 (after	
Available Formulations	Sol 20mg/ml Tabs 300mg (not scored)		Sol. 10mg/ml Tabs 150mg (scored) 300mg		Caps 50,200mg Tabs 50, 200, 600mg (not scored)	Sol. 80/20mg/ml Adult Tabs 200/50mg, Paeds Tabs 100/25mg	Sol. 80mg/ml	Sol. 1mg/ml Caps 15, 20, 30mg	Tabs 25,50,100mg (dispersible in 30ml water) Caps 250mg EC	Tab	
Wt. (kg)	Currently available tablet formulations of abacavir, efavirenz, LPV/rtv and AZT are film-coated and must be swallowed whole and NOT chewed, divided or crushed										Wt. (kg)
<3	Consult with a clinician experienced in paediatric ARV prescribing for neonates (<28 days of age) and infants weighing <3kg										<3
3-3.9	2ml bd		2ml bd		Avoid using when <10kg or <3 years: dosing not established	*1ml bd	1ml bd	6ml	Avoid	5ml bd	6ml bd
4-4.9											
5-5.9	3ml bd		3ml bd			*1.5ml bd	1.5ml bd	7.5mg bd: open 15mg capsule into 5ml water: give 2.5ml	100mg od: (2x50mg tabs)		
6-6.9									125mg od: (1x100mg + 1x25mg tabs)		9ml bd
7-7.9	4ml bd		4ml bd					10mg bd: open 20mg capsule into 5ml water:		8ml bd	
8-8.9											1 cap bd OR 12ml bd
9-9.9											
10-10.9	Choose only one option:		Choose only one option:		200mg nocte (1x200mg cap/ tab)	2ml bd	1.5ml bd	15m cap			
11-13.9	6ml bd	12ml od	6ml bd	12ml od							
14-16.9	8ml bd	1 tab od OR 15ml od	1/2x150mg tab bd OR 8ml bd	1x150mg tab od OR 15ml od	300mg nocte: (200mg cap/tab + 2x50mg cap/ tab)	Choose one option: -2.5ml bd -100/25mg paeds tabs 2 bd -200/50mg adult tabs: 1 bd	2ml bd				2 caps am 1 cap pm OR 15ml bd
17-19.9											
20-24.9	10ml bd	20ml od	1x150mg tab bd OR 15ml bd	2x150mg tab od OR 1x300mg tab od OR 30ml od		Choose one option: -3ml bd -100/25mg paeds tabs: 2 bd -200/50mg adult tabs: 1 bd	2.5ml bd				2 caps bd OR 20ml bd
25-29.9	1x300mg tab bd	2x300mg tabs od	1x150mg tab bd	2x150mg tabs od OR 1x300mg tab od	400mg nocte: (2x200mg caps/ tabs)	Choose one option: -3.5ml bd -100/25mg paeds tabs: 3 bd -#200/50mg adult tabs: 1 bd + 100/25mg paeds tabs 1 bd	3ml bd	30mg bd	250mg od: (2x100mg + 1x50mg tab) OR 1x250mg EC cap od	1 tab bd	1 tab bd
30-34.9						Choose one option: -4ml bd -100/25mg paeds tabs: 3 bd -#200/50mg adult tabs: 1 bd + 100/25mg paeds tabs 1 bd					
35-39.9						Choose one option: -5ml bd -200/50mg adult tabs: 2 bd	4ml bd				
>40					600mg tab nocte						>40

od = once a day
bd = twice a day

* Avoid PLV/rtv solution in any full term infant <14 days of age and any premature infant <14 days after their due date of delivery (40 weeks post conception) or obtain expert advice.
# Children 25-34.9kg may also be dosed with LPV/rtv 200/50mg adult tabs: 2 tabs am; 1 tab pm

Weight (kg)	3-4.9	5-9.9	10-13.9	14-29.9	≥30
Cotrimoxazole Dose	2.5ml od	5ml od	5ml od	10ml or 1 tab od	2 tabs od
Multivitamin Dose	2.5ml od	2.5ml od	5ml od	5ml od	10ml or 1 tab od

What factors influence adherence?



- Adolescence
- Drug side-effects
- Drug palatability
- Chemist error
- Drug stock-outs
- Social issues
- Mental health
- Holiday travel
- Disclosure not done
- Vulnerable child
- High pill burden
- BD dosing

When should ARVs be changed?

Toxicity/Adverse Events

- Short-term side-effects
- Long-term side-effects

Drug interactions

Treatment failure

- Clinical
- Virological
- Immunological

How do I monitor treatment response?

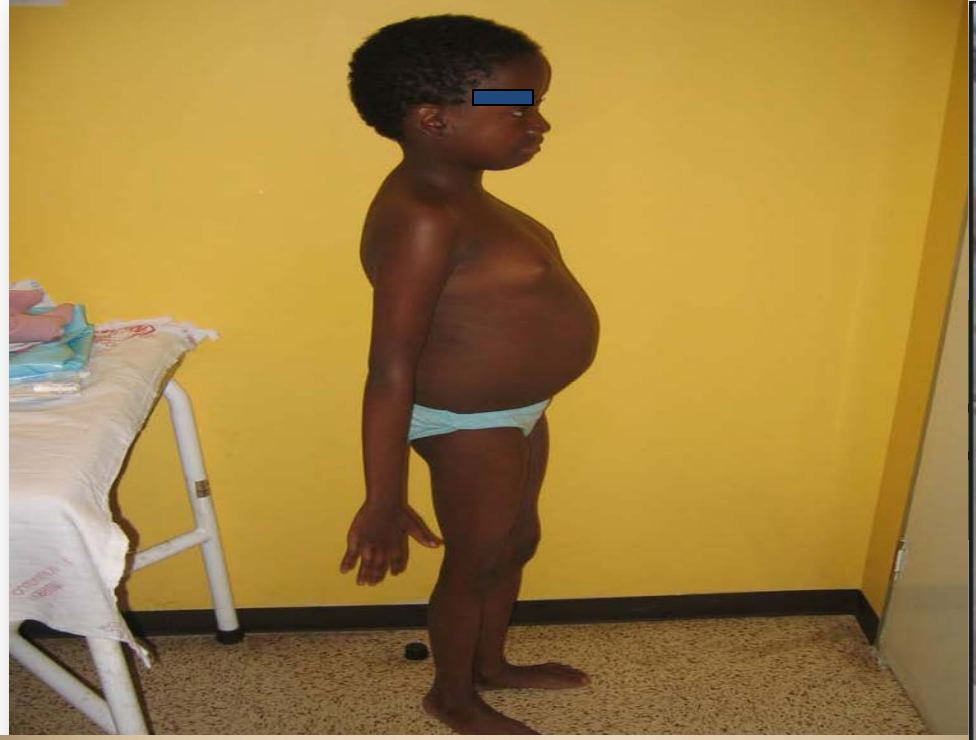
On ART	Purpose
Height, weight, head circumference (<2yrs) and development	To monitor growth and development stages
Clinical assessment	To monitor response to ART and exclude adverse effects
CD4 at 1 year into ART, and then every 12 months	To monitor response to ART, stop cotrimoxazole prophylaxis as per national guideline
VL at month 6, 1 year into ART, then every 6 monthly in children < 5 years / 12 monthly in children 5 years to 15 years	To monitor viral suppression response to ART To identify treatment failure and to identify problems with adherence

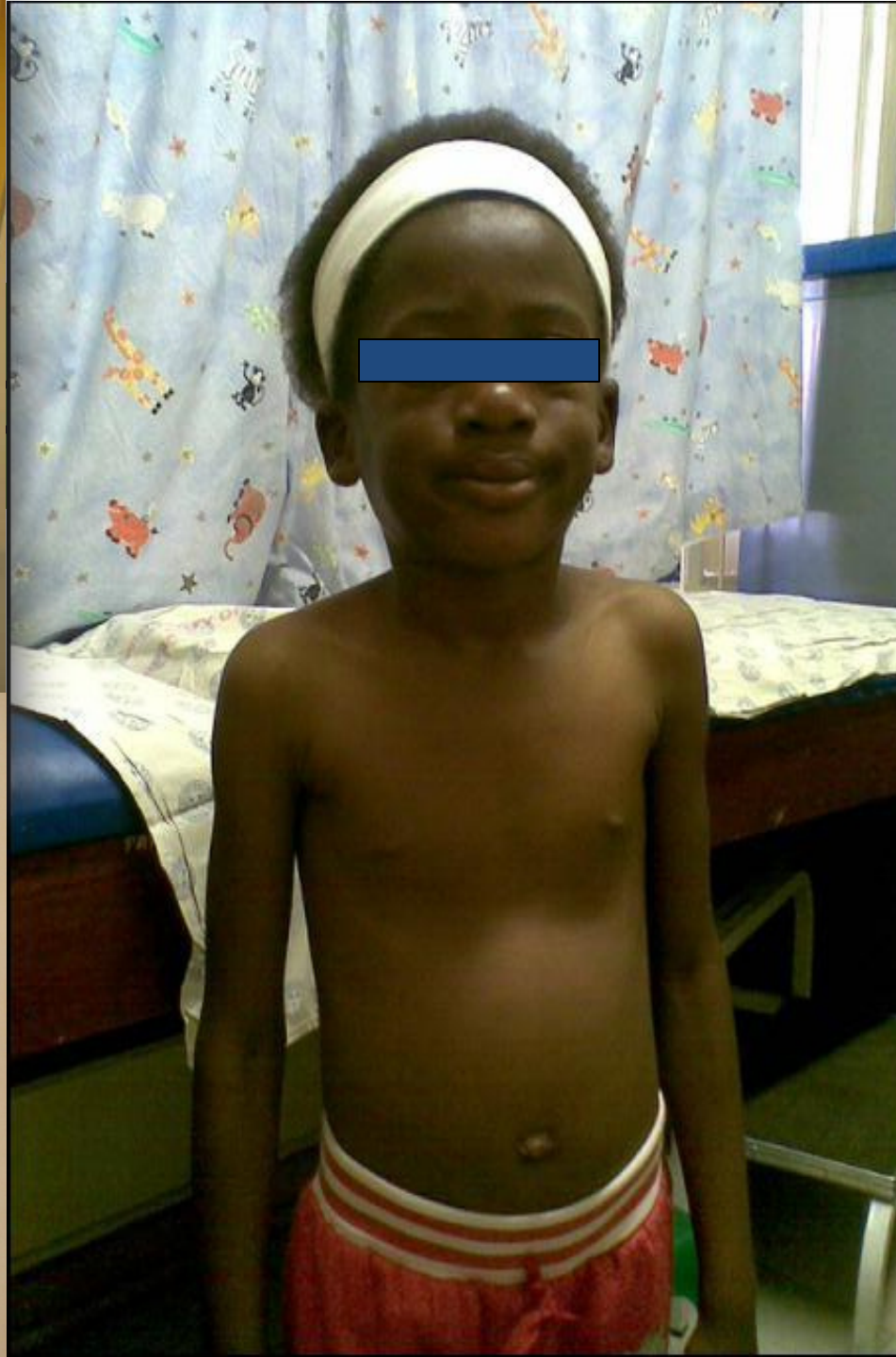
How do I monitor treatment response?

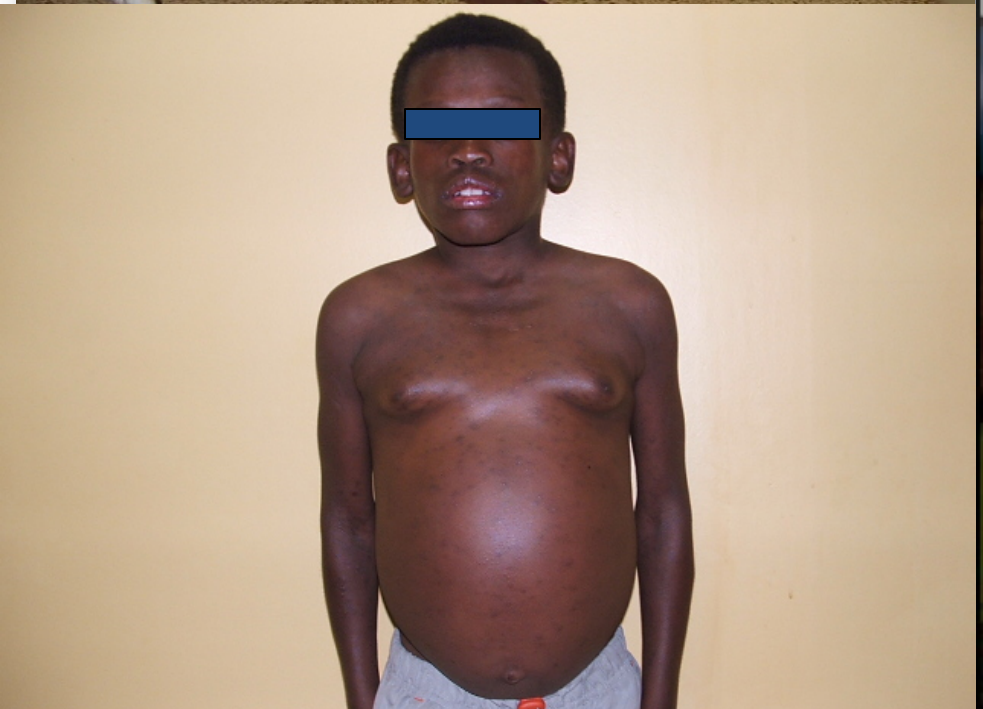
On ART	Purpose
Hb or FBC at month 1, 2, 3 and then annually if on AZT	To identify AZT-related anaemia
Cholesterol + Triglyceride at 1 year and then every 12 months if on PI based regimen	To monitor for PI-related metabolic side-effects
Clinical drug-related adverse events	To identify drug-related adverse events If develops jaundice or rash on EFV or NVP do Liver function test and refer to specialist

Common Side-Effects

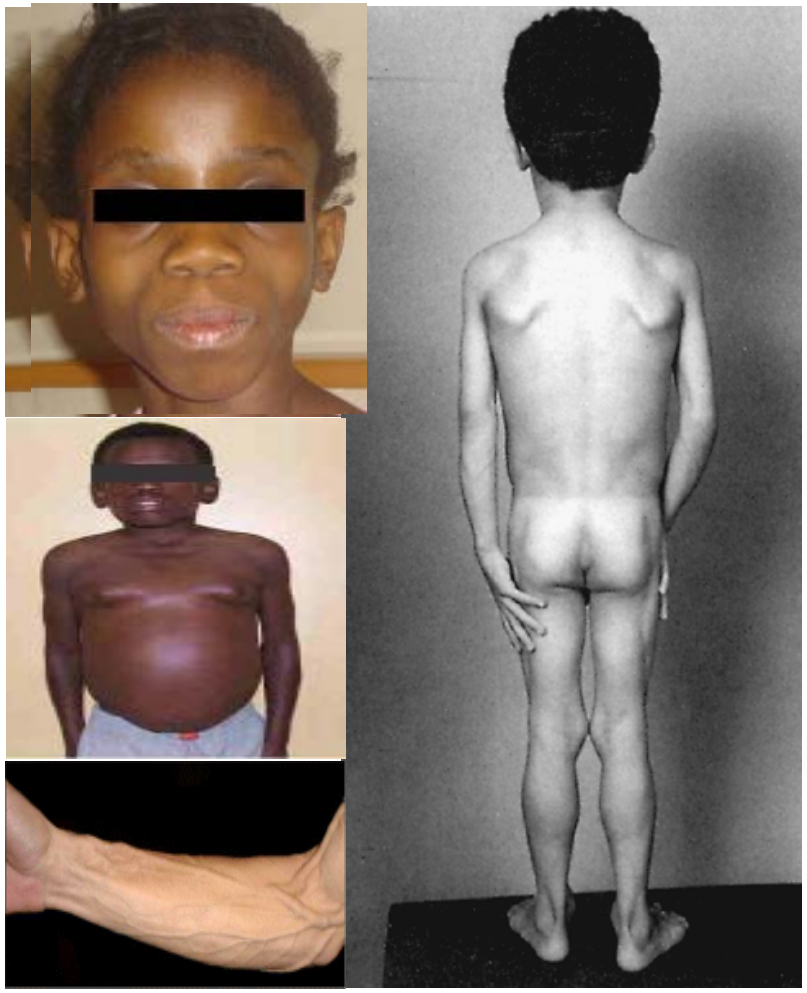
- NRTIs: GIT, HA, lactic acidosis with hepatic steatosis and lipodystrophy (esp. d4T)
- AZT: anaemia and neutropenia
- ddI: pancreatitis
- d4T: lipodystrophy, PN, LA, hepatic steatosis







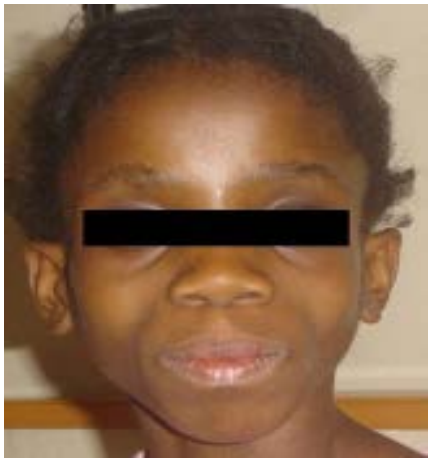
Lipodystrophy



- NB: Don't only look at the face!
- Thin and muscular arms and legs with prominent muscles and veins
- Thin face and buttocks
- Enlarged abdomen
- Enlarged breast and buffalo hump may be seen after puberty

Lipodystrophy

- Most commonly caused by d4T, ddI and less commonly AZT and can cause life-long stigma and poor adherence
- Caregiver may notice changes
- Increases the risk of heart disease and diabetes in future
- Monitor glucose, chol, TG annually
- TREATMENT: Change most likely drug



ASAP if **VL is lower than detectable levels.** For example, change d4T to ABC or TDF based on child's age and weight. ***Never*** **change only one ARV if VL is >400!**

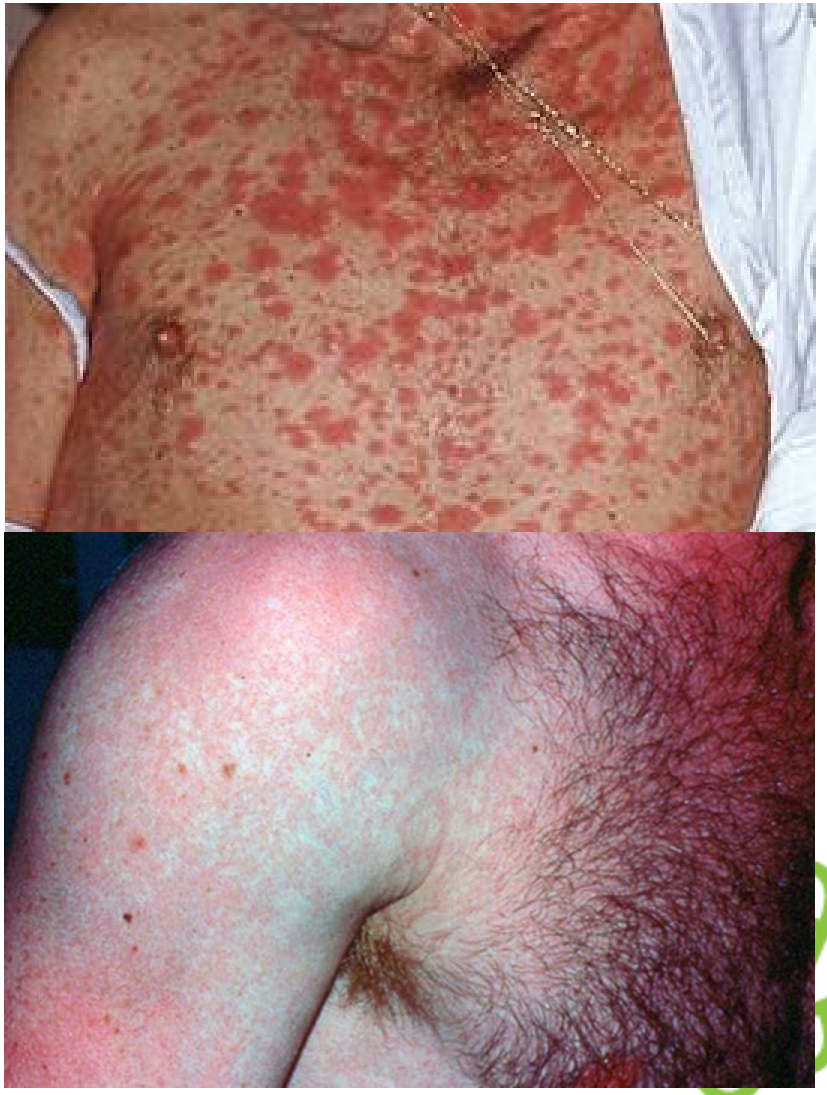
Common Side-Effects: Kaletra/Aluvia

- Kaletra
  - Tastes like battery acid
  - GIT – N/V/D, **<u>hyperlipidemia</u>,** increased risk for MI

- Aluvia
  - Many older children do not tolerate the 200/50 but do tolerate the 100/25

Common Side-Effects: ABC

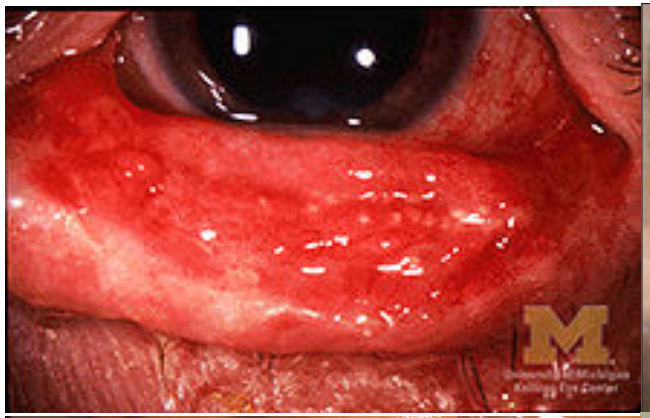
- Usually 1st 2-6 wks (90%)
- >>in Caucasians with HLA-B*5701
- Dx – 2+ symptoms:
  - Fever (78%)
  - Rash (66%) - +/- itching
  - GIT (46%)
  - Constitutional- (46%)
  - Respiratory (6%)
- Symptoms usually worsen after taking the medicine
- NEVER re-challenge with ABC after this reaction - may be fatal

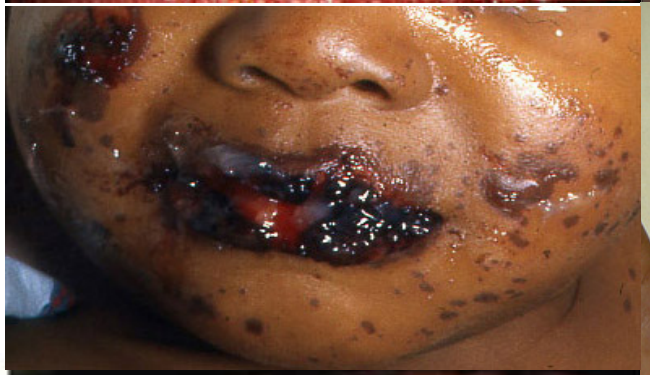


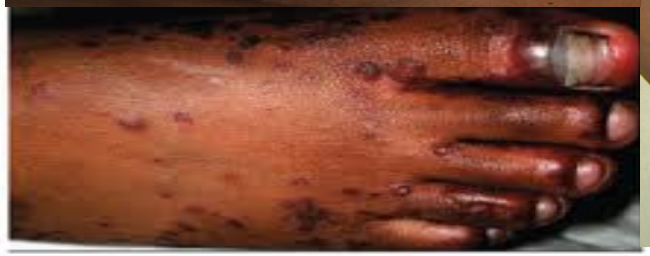
Common Side-Effects: NNRTIs

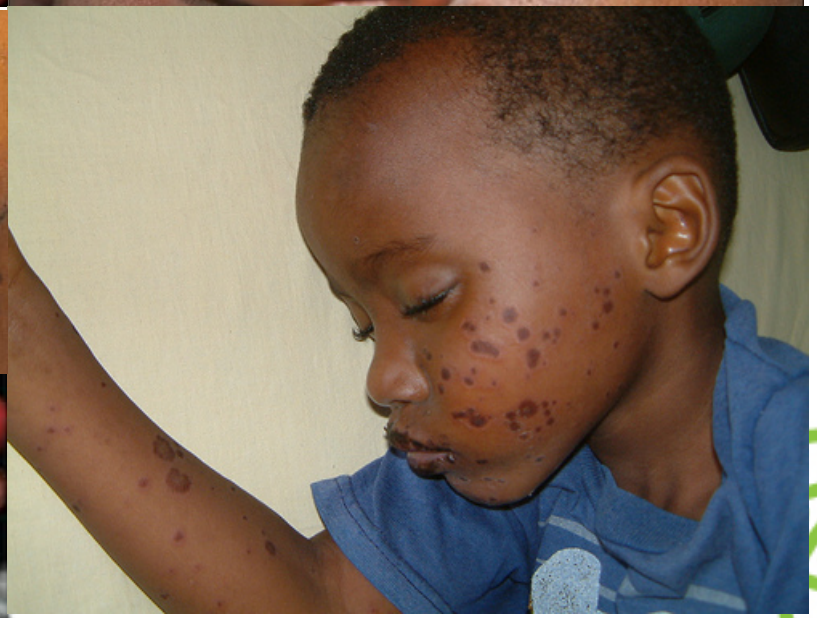
- Rash: mild to life-threatening
- Low genetic barrier to resistance
- NVP- potentially fatal skin and liver hypersensitivity reaction
- EFV: dreams, decreased concentration and exacerbations of psyche disorders such as depression and psychosis - usually resolve and better if taken on empty stomach b/c decreases absorption of EFV.

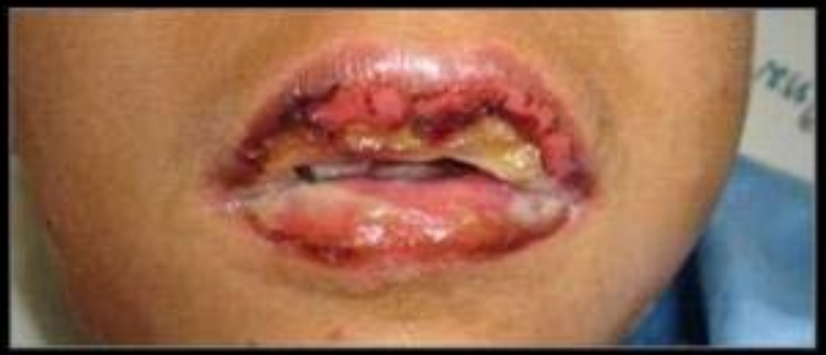
What is this rash?

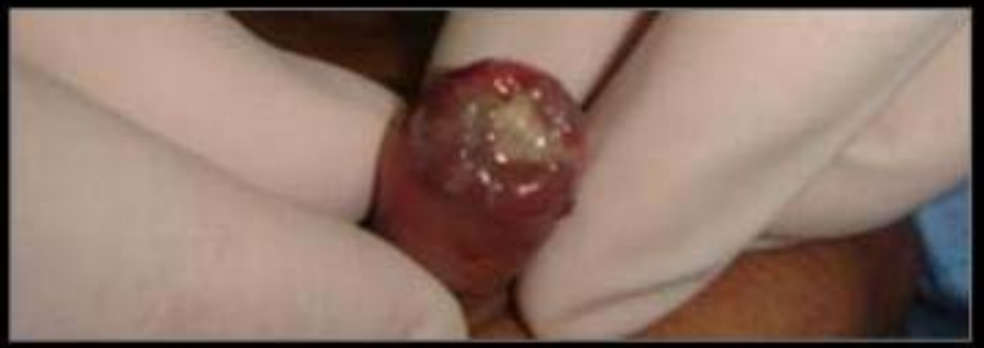


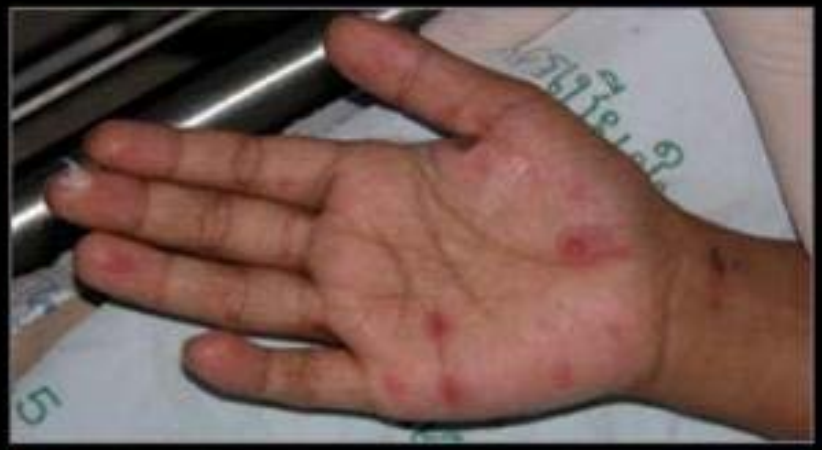


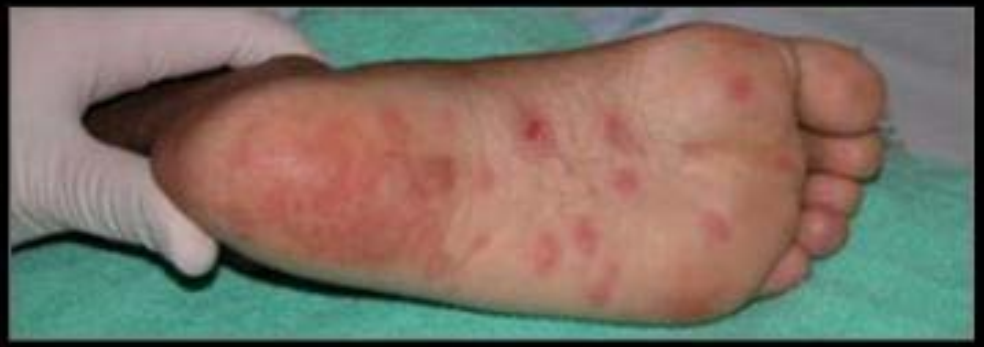


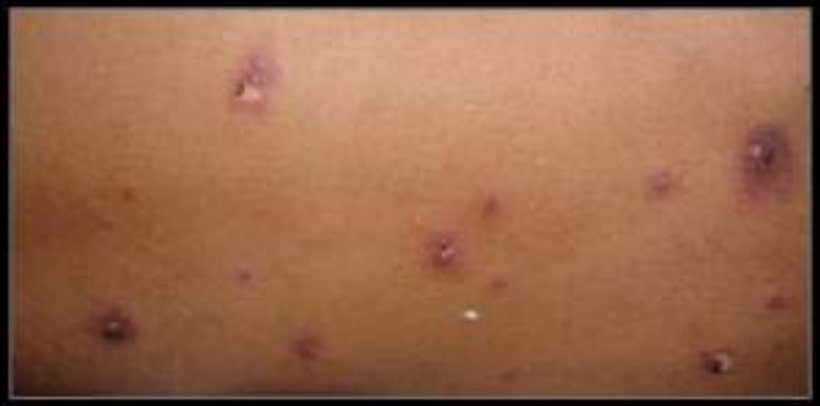












* Associated with NVP, Bactrim, EFV, Lop/rit in that order
*Minor skin rash associated with NNRTIs does not involve the eyes or mouth
*Can be fatal and progress to TEN if not diagnosed early

Picture credit: Dr. V. Sirisanthana

What is the care plan for children who do not qualify for HAART?

- Review 3 monthly
  - WHO Clinical Stage (largely from history)
  - Screen for TB, give IPT
  - Check weight, height, head circumference
  - Check CD4 6 monthly

What about Children on d4T?

Dr. Aaron Motsoaledi
Minister of Health 2009 – 201?
Champion in the fight against HIV in South Africa

- d4T is associated with many serious side-effects such as PN, LD, LA, hepatic steatosis
- Change from d4T to ABC or AZT or TDF in children who are virologically suppressed
- **DO NOT** change one drug in a patient with a VL > 400

TDF and FDC in Adolescents

TDF 300 mg daily

- ≥15 years-old
- > 35kg
- > Tanner stage 2
- eGFR is ≥80

FDC=TDF, FTC, EFV

- >40kg (EFV) + TDF rules

What about TB co-infection?

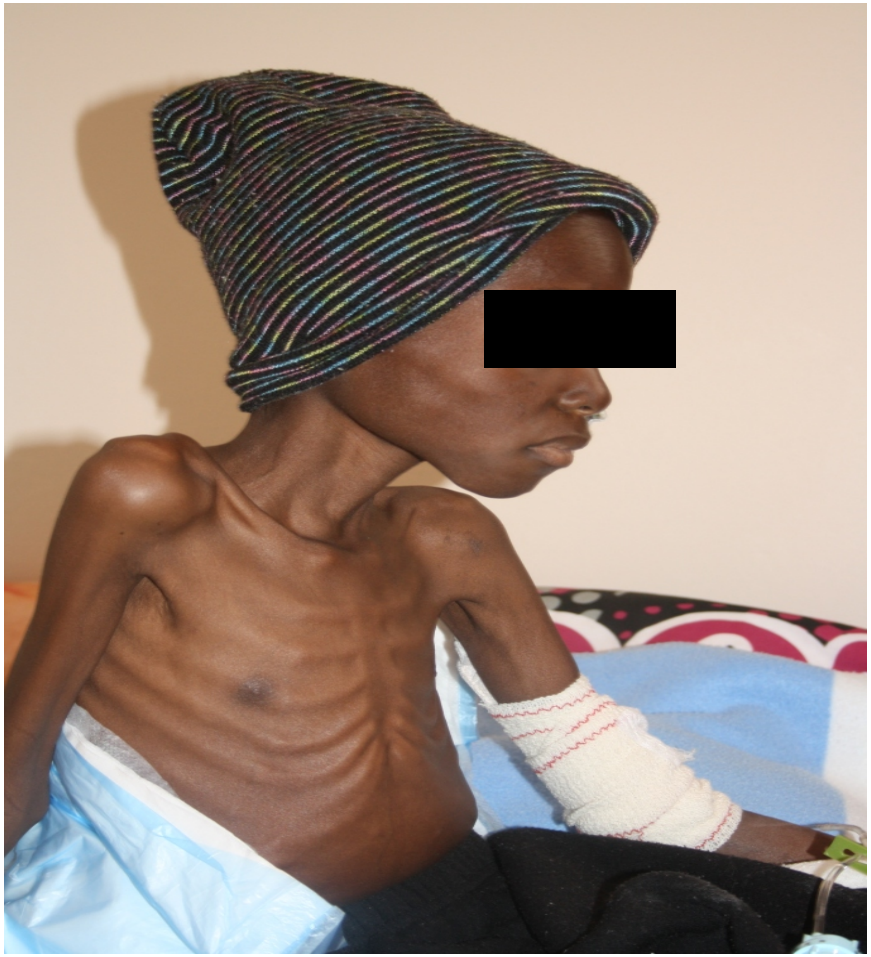
Key points to remember:

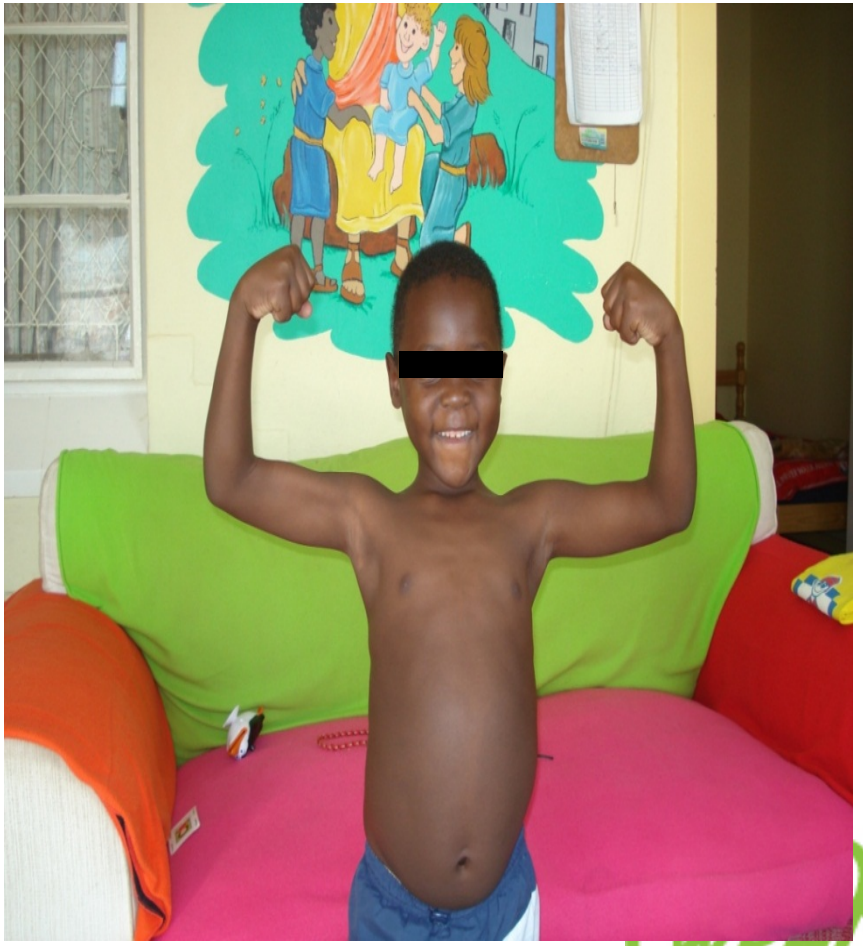
- If TB treatment started first then can start HAART in 2 weeks
- If on Kaletra/Aluvia then remember to double-dose this drug or add Ritonavir if available

What have we done so far?

- Reviewed paeds regimens
- dd-Kaletra & Aluvia or add Ritonavir if on TB rx
- DO NOT change one drug if the VL is >400
- Daily dose ARVs if possible
- Get eligible kids off d4T
- Monitoring labs
- Common ARV side-effects
- Wellness care for children

That's Ayoba!





Case SM

- 10 month old girl:
  - 3 admissions for chest infections
  - Milestones delayed-sat 8 months
  - Oral thrush, hepatosplenomegaly, generalized lymphadenopathy
  - Weight = 7.9kg 3rd centile, height = 71cm 10th centile
  - CD4 count = 166 (6%), VL = 295 000 copies/ml

What treatment would you institute?

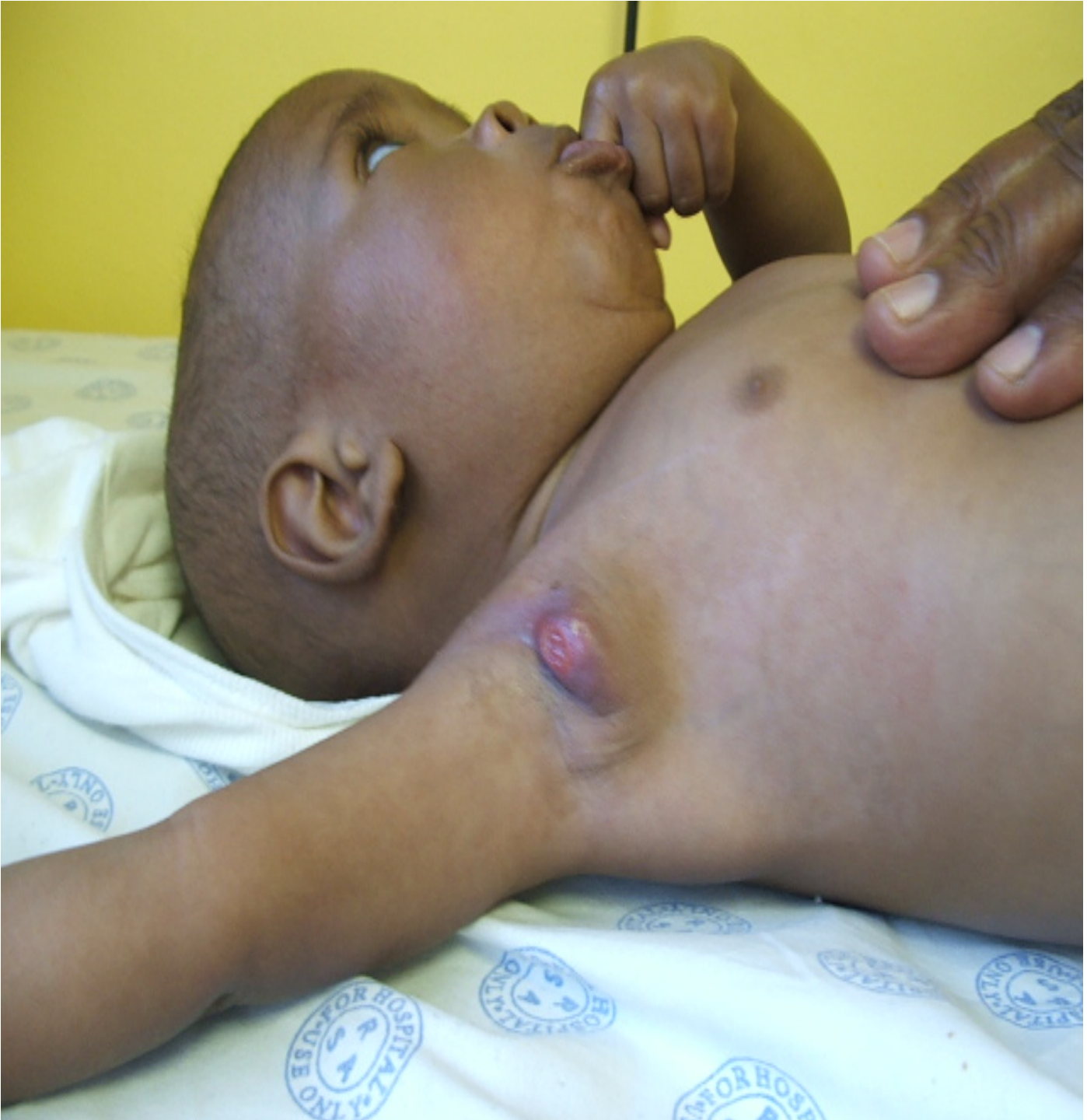
SA Guidelines (1st line)

<3yrs

ABC+3TC+Kaletra

>3yrs

ABC+3TC+Efavirenz



1 month after starting ART

Case SM continues…

- *After 1 month of treatment an enlarged right axillary lymph node is noticed*

- What is the diagnosis?
- What investigations should you do?
- How would you manage this case?

Case KL

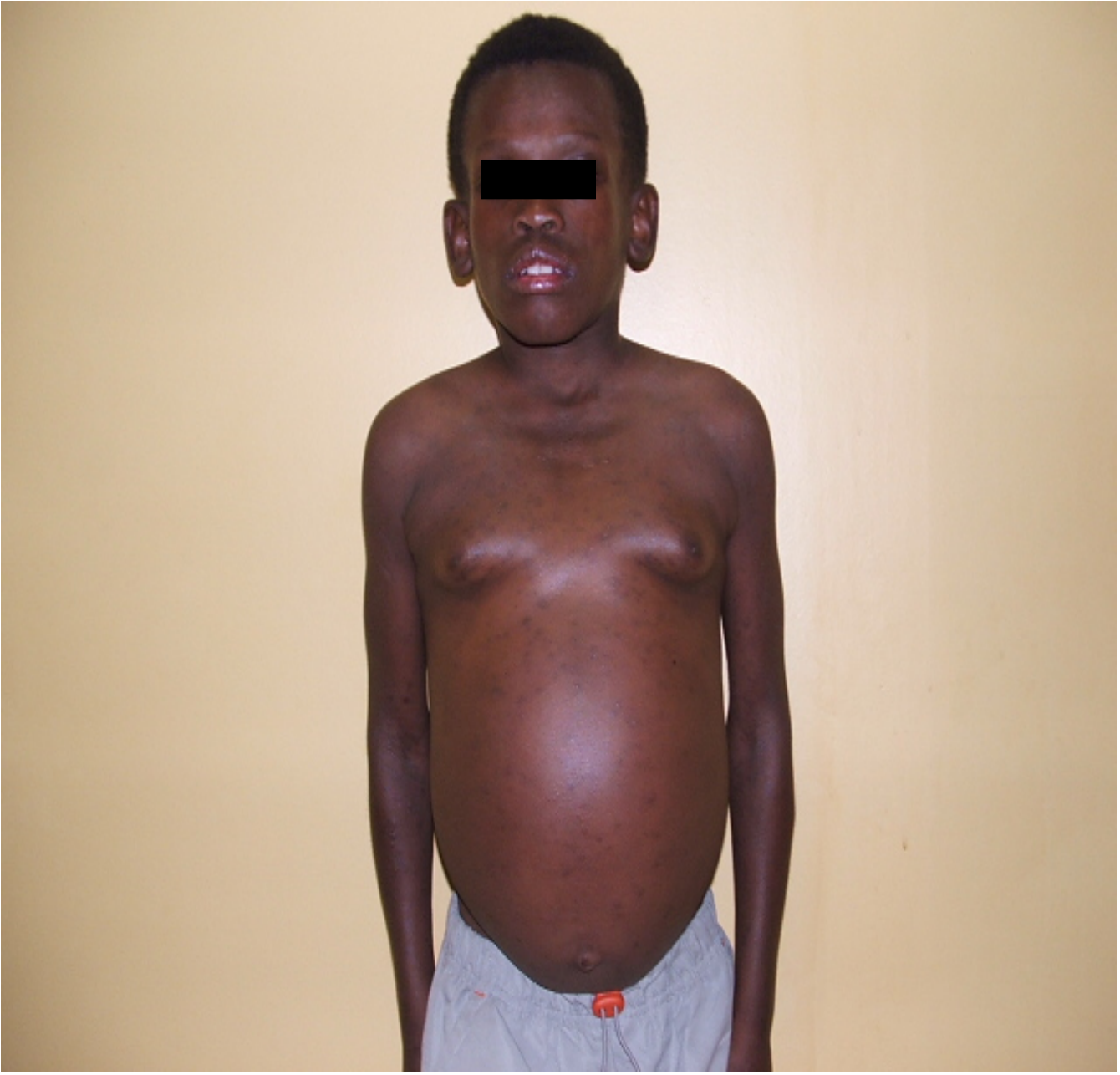
- 2008:

10 year old boy:

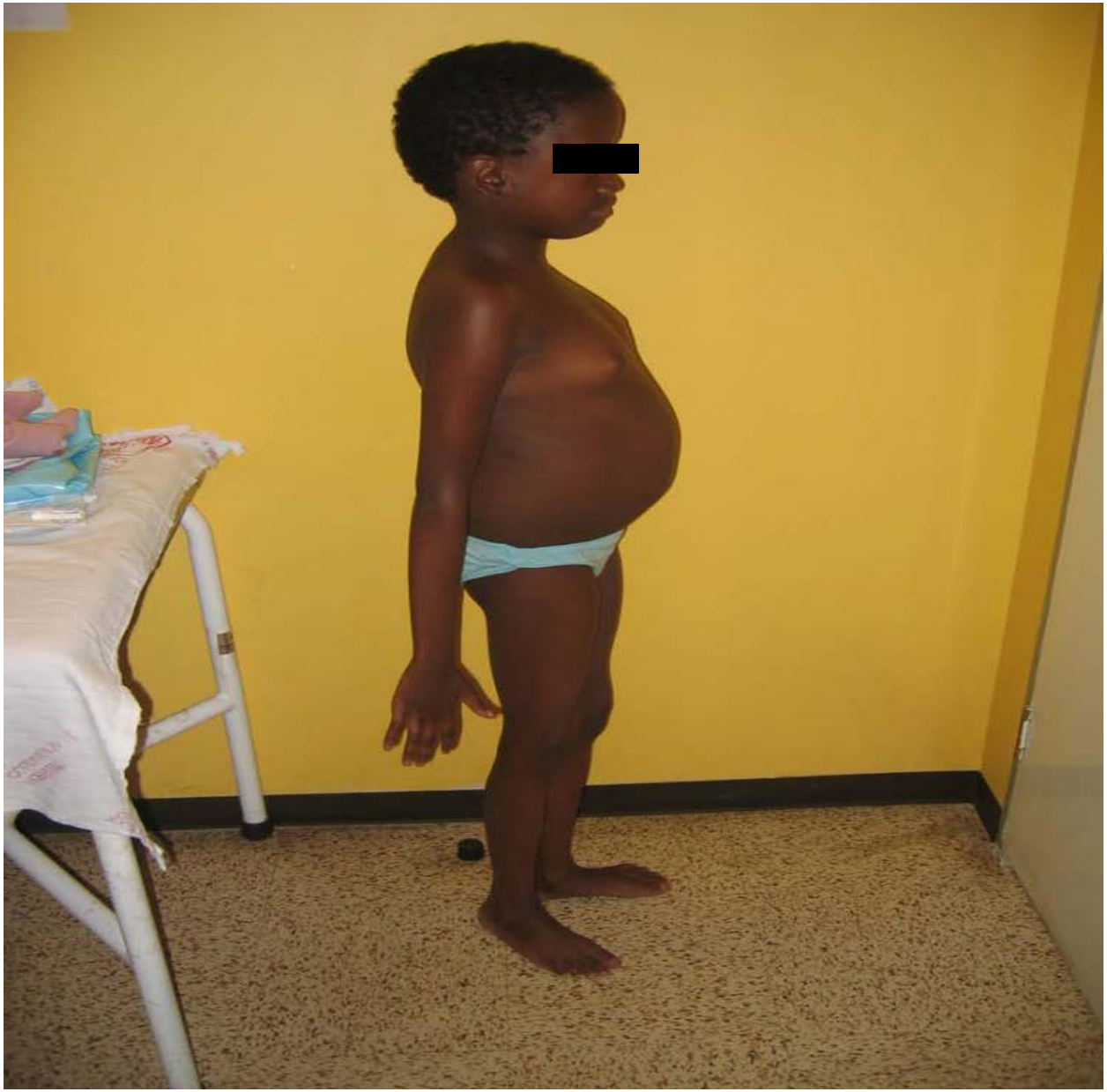
- WHO Stage IV (cryptococcal sepsis);
- CD4% = 1.64% (65), VL > 750 000
- LIP + cor pulmonale, 6 months PTB Rx completed x 2 months.
- Started on HAART (3TC, d4T, EFV)

2012: 14 years

- Much healthier, happier child.
- CD4% = 11.5% (404), VL < 25
- "Skinny" arms and legs
- Granny reported abdominal distension: Abdo sonar no



After 4 years of HAART



Case KL – cont...

- What is the diagnosis?
- Do you want to do any further investigations?
- How should he be managed further?

Case SM

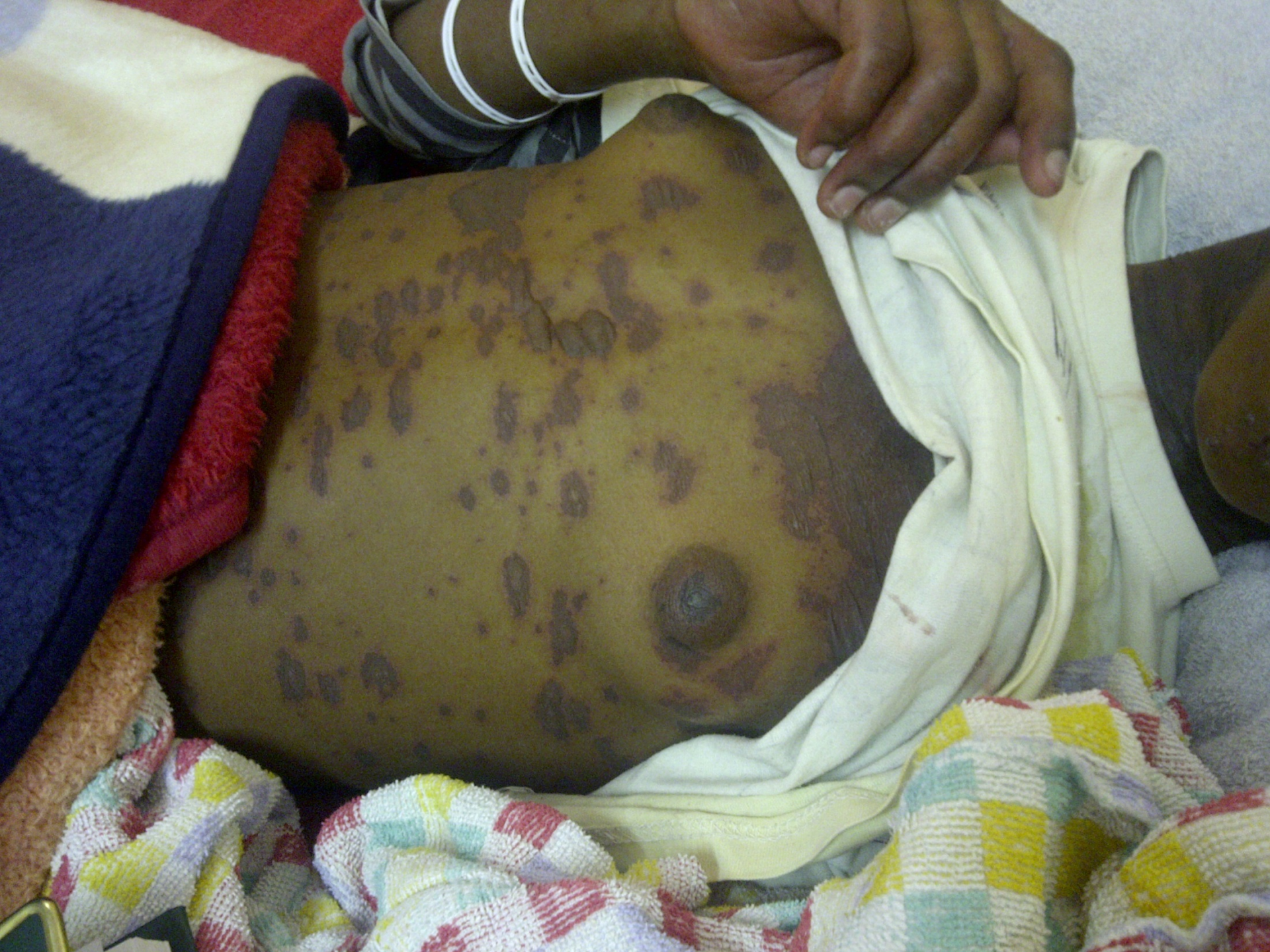
- Presented to clinic in April 2008
- Mom recently demised of HIV related disease
- SM tested HIV+ at the clinic
- Started on TB treatment
- Clinically:
  - Underweight for age
  - Generalised LAD; HSM
  - WHO stage 3
- CD4 203 (16%) VL 15 000
- FBC/ALT normal

SM continued

- Did very well on ART (D4T/3TC/EFV)
- Good adherence
- Completed TB treatment
- Virally suppressed at 6 months
- Increasing CD4 and % (Cotrimoxazole stopped)
- Developed lipodystrophy in 2010 (gynaecomastia, peripheral wasting)
- Changed from D4T to ABC
- Well until 2013

In July 2013

- CD4 count 834 (25%) VL LDL
- Changed from EFV to NVP
- Presented 3 weeks later…….



Comments					
INR					
PTT p					
PTT c					
ESR					
CRP	165				
Na	129				
K	4,9				
Cl	89				
CO_2	22				
Urea	8,6				
Creat	68				
Ca (corr)	2,26				
Mg	0,97				
Phos	1,28				
Total bili	22				
Dir bili	18				
Total prot	75				
Albumin	43				
ALP	359				
GGT	251				
ALT	80				
AST	95				

DATE		DATE		DATE	
Glucose		Trig		ANA	
HbA1c		Cholesterol		ds DNA	
LDH		HDL-cholest		ENA	
Uric acid		LDL-cholest		RF	
Sputum MC&S					

Diagnosis?

- Necrotic targetoid papules/plaques
- Blistering neck
- Urethritis
- Conjunctivitis

- Stevens Johnson Syndrome
- ? Drug resposible

Management…

- ART stopped
- Admitted for supportive care
- IVI fluids
- Analgesia
- Prednisone
- Chloromex
- Bactroban

What should we do about his ART???

Thank you


UNITED STATES AGENCY
USAID
INTERNATIONAL DEVELOPMENT
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FROM THE AMERICAN PEOPLE


UNITED STATES PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF
SOUTH AFRICANS AND AMERICANS
IN PARTNERSHIP TO FIGHT HIV/AIDS


WRHI