The NEW ARV Guidelines – FAQs

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Where we were - < 2010

- 2009: Centralized doctor-led ARV program
- CD4 <200
- D4T still part of first line regimen
- 5-8% PMTCT transmission rate.

NGOs provided direct care in under-serviced areas and busy ARV units.

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April 2010 – March 2013

- 2010: "We will have the biggest ARV program in the world"
- CD4<350 for Pregnant women and TB
  - 2011: PMTCT transmission rate down to 3.5%
- TDF introduced into first line regimen
- NIMART: nurse led, clinic based ARV programs
- IYDSA shift to Technical support

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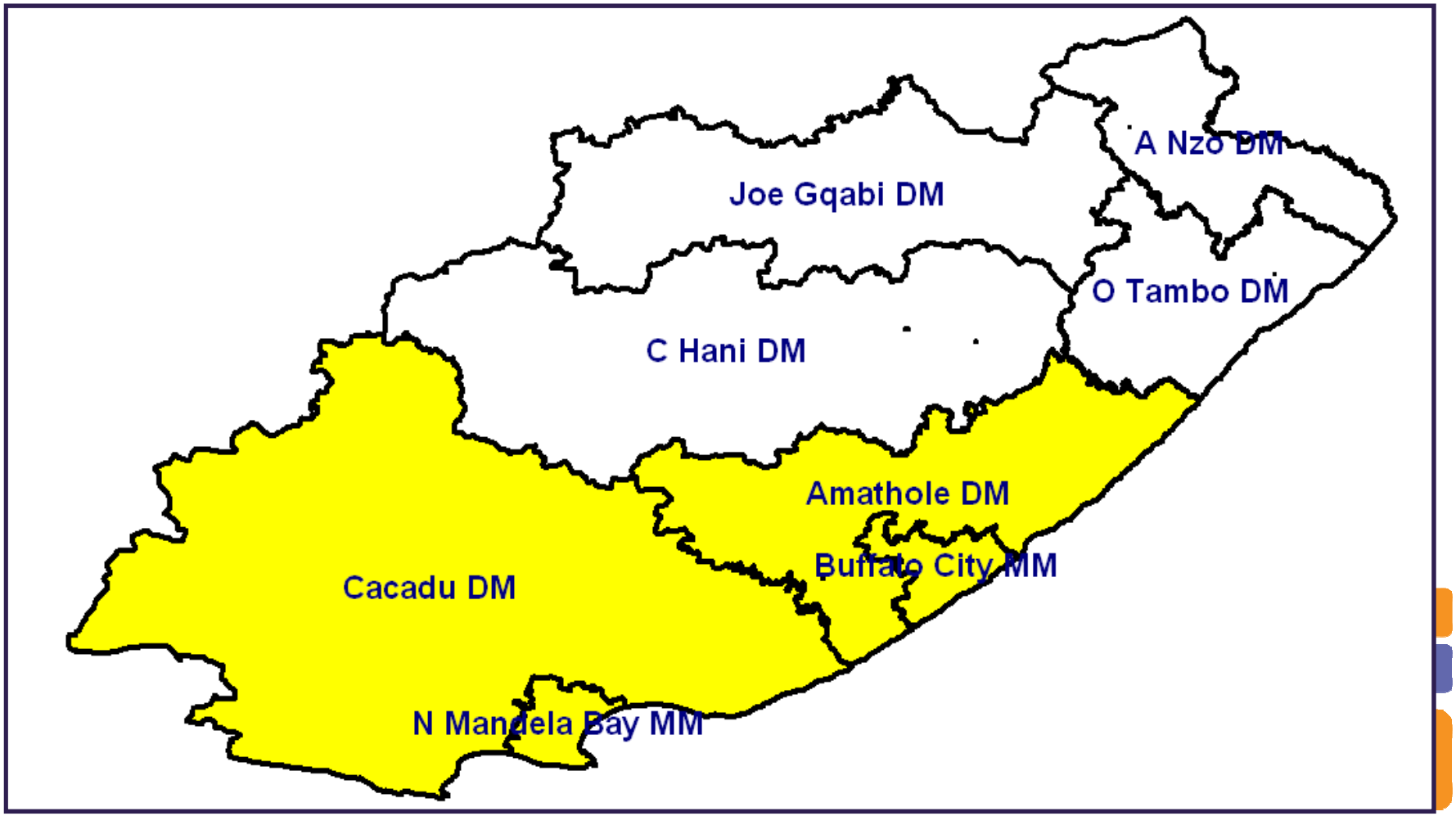

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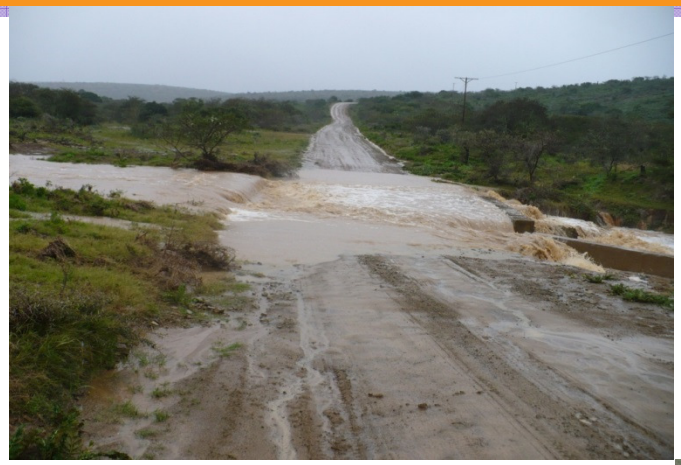

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April 2013 The New ARV guidelines

- ZERO MTC transmission
- ZERO New HIV Infections
- ZERO AIDS related deaths
- Zero discrimination

Action Framework *No Child Born with HIV by 2015*

The most dramatic changes

- Around PMTCT
- Introduction of FDC

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Guideline implementation

- Scope of Guidelines determined by NSP2012- 2016, Millennium Goals 4, 5, 6 and the NSDA
- A balance between
  - Evidence based medicine
  - Public resources
  - Feasibility of Implementation

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Fixed Dose Combination

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FDC

- Introduced into the public sector on 1st April 2013
- Tenders awarded to three companies – Cipla Medro, Aspen and Mylan
- Combination of TDF / FTC / EFV

Roll out: SA has close to 2 million patients on ART: phased approach to roll out

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Priority groups

PG 1: All HIV-positive patients newly initiating ART
PG 2: HIV-positive pregnant women and breastfeeding mothers

PG 3: Virologically suppressed patients on a d4T containing regimen
PG 4: TB co-infected patients, stable on 3TC + TDF + EFV
PG 5: Patients with co-morbidities (e.g. hypertension, diabetes), and stable on 3TC + TDF + EFV

PG 6: Patients receiving individual 3TC + TDF + EFV who request switch to FDC
PG 7: Patients receiving individual 3TC + TDF + EFV who, after counseling, agree to switch to FDC

S Afr J HIV Med 2013;14(1 Suppl):41 - 43

Case 1

A patient has been on an FDC (TDF/FTC/EFV) for a year in private practice in East London. She now presents at my clinic for ARV collection. Do I give her the FDC or do I prescribe the individual ARVs?

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Case 1: Discussion

- Does not fall into priority group 1 or 2, and therefore must be switched to the individual drugs (TDF + 3TC + EFV)
  - This patient falls into priority group 6
  - Not enough FDC available to keep this group on the FDC currently
  - Private practitioners need to advise their patients accordingly

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PMTCT Guidelines

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Case 2

A 22 year old patient is tested at the clinic and found to be 18 weeks pregnant. She is booked and receives full counselling for HIV testing.

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HIV negative test

- If negative, repeat 12 weeks after first test or at 32 weeks gestation or later
  - Consent at initial counselling includes consent for all follow up tests
  - Consider re-testing at delivery, at 6/52 post natal EPI visit, 3 monthly while breastfeeding and then at least annually
  - 3 monthly testing whilst breastfeeding should be aligned with EPI visits where possible (10wk, 6m, 12m, 18m)

HIV positive test

- If positive
  - Baseline bloods (CD4, creatinine)
  - Initiate ART with the FDC on the same day **regardless of CD4 cell count or gestational age.**
    - Do not wait for blood results to initiate
  - Exceptions: Start AZT whilst awaiting bloods
    - Ensure patient has a negative TB screen
    - Ensure no proteinuria on U-dipsticks (renal risk)
    - Active Psychiatric patients
  - Bring client back within 7 days for CD4 and creatinine results (within 2 days if GXP pending)

HIV positive

All pregant women get triple therapy ART
In fixed dose combination (FDC)

If CD4 ≤350 cells/mm³ or WHO 3/4

If CD4 >350 cells/mm³ and WHO 1/2

Lifelong ART

ART for duration of pregnancy and FOR ONE WEEK AFTER cessation of breastfeeding

p8, Figure 2: PMTCT Algorithm 1, PMTCT Guideline

FDC Prophylaxis or AZT

- Most women are eligible for FDC
  - TDF +FTC +EFV
- Active Psychiatric disease – cannot use EFV
- Active Renal disease – cannot use TDF
- If patient dx with TB – start TB treatment first and ARVs 2 weeks later

If patient does NOT qualify for FDC for treatment (CD4>350): use AZT monotherapy

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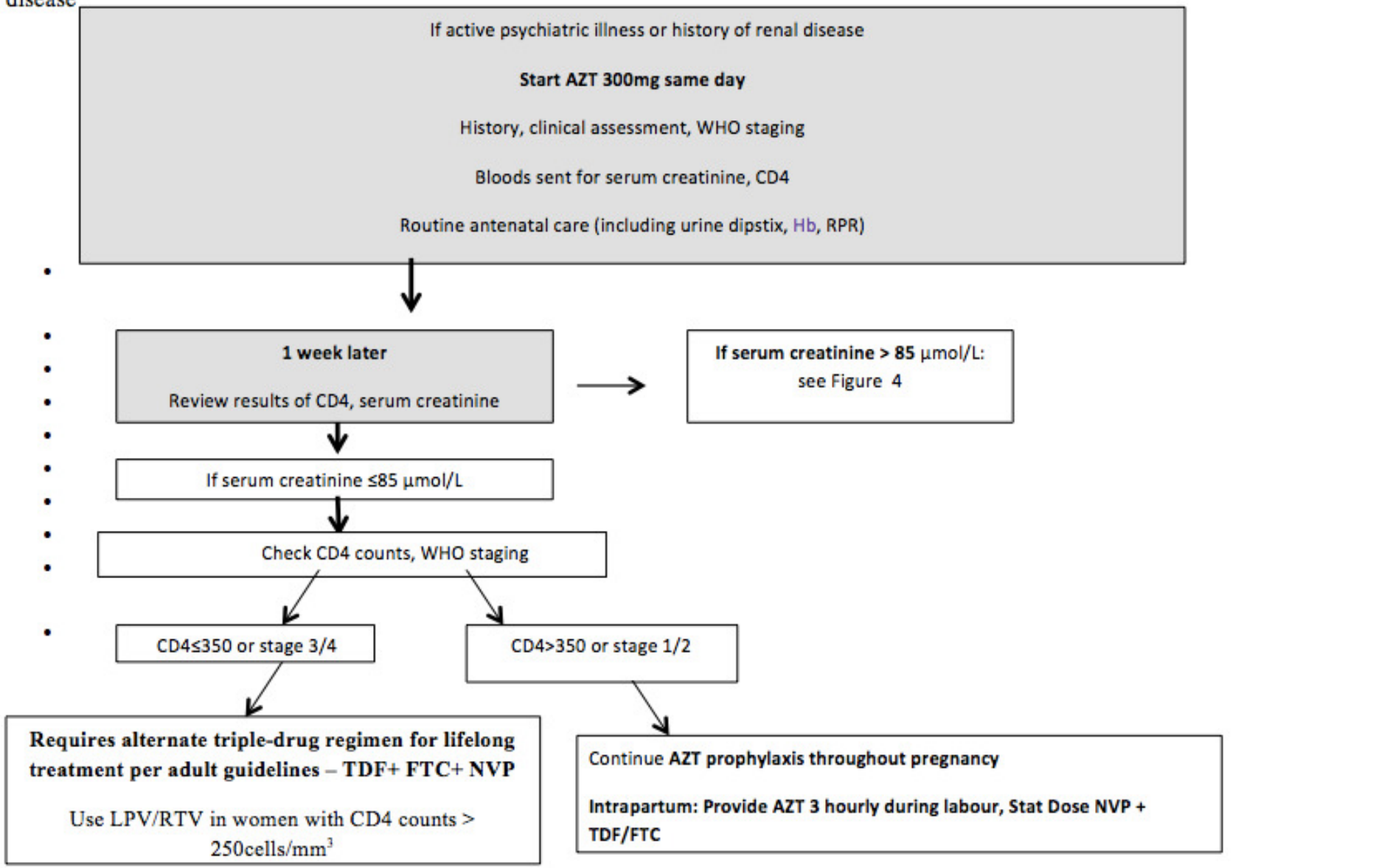
Screen for neuropsychiatric illness

- Efavirenz may be contraindicated in active psychiatric illness
- Any woman with an **active** psychiatric illness should not receive an EFV-containing antiretroviral regimen **without consultation**
- Mild depression is not a contraindication to efavirenz

Figure 3 : PMTCT algorithm 2: Initiation of antiretrovirals during pregnancy in women with active psychiatric illness or history of renal disease



Use of nevirapine

- Only consider NVP in patients with a baseline CD4 count <250 cells/mm^3 in women (<400 cells/mm^3 in men)
- Note: pregnancy puts patients at a higher risk for NVP toxicity
- Counsel patient well on early symptoms of toxicity and ensure adequate follow up

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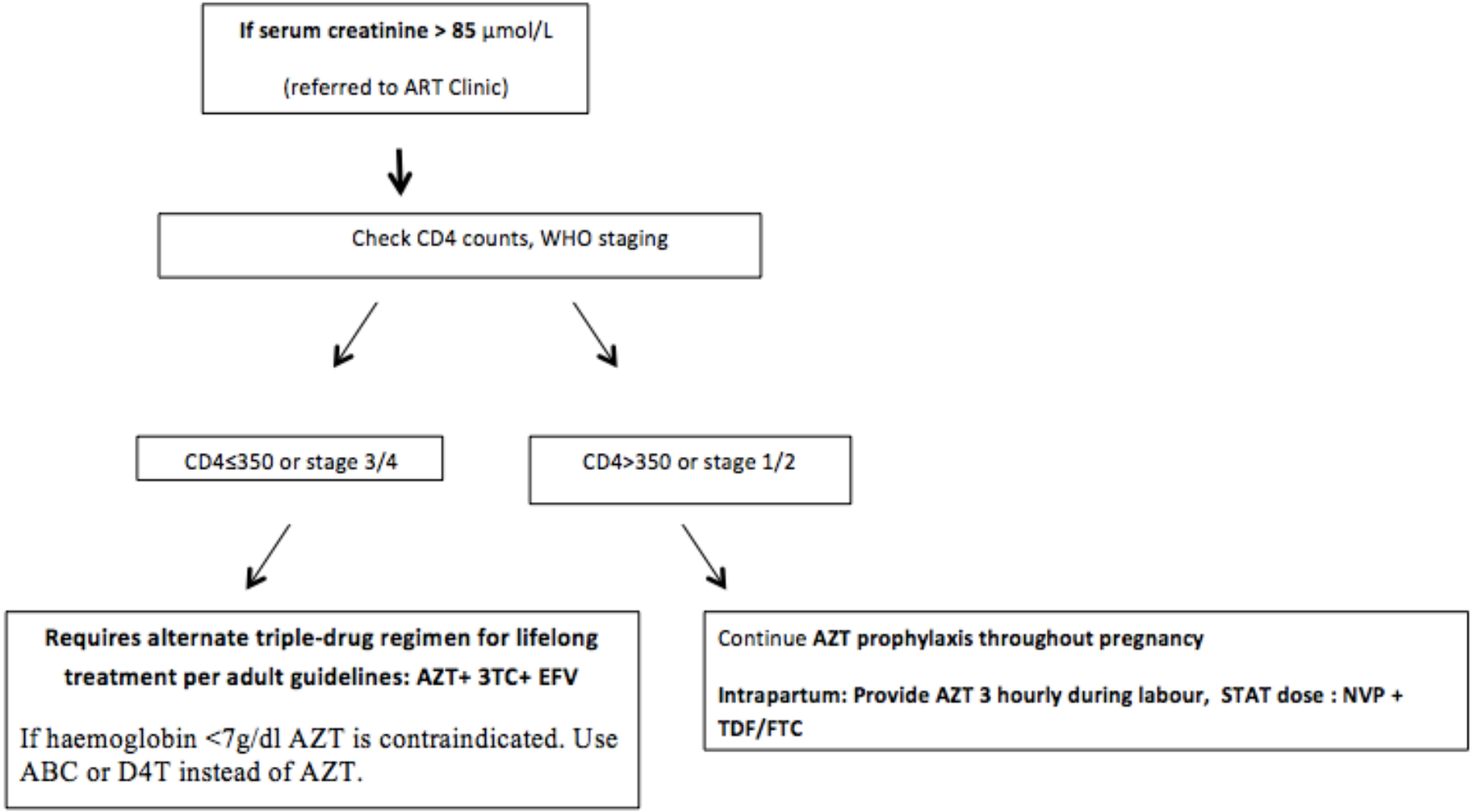
Screen for renal disease

- Renal Risk:
  - diabetes or hypertension
  - a previous kidney condition requiring hospitalisation
  - ≥2+ proteinuria on urine dipstix testing
- **A serum creatinine of >85 µmol/L is considered abnormal in pregnancy**
- If patient history/ U-dipstix suggests renal disease, dispense AZT at 1st ANC visit and review with creatinine result at 7 days

Figure 4: PMTCT algorithm 3: Initiation of antiretrovirals during pregnancy in women with serum creatinine > 85 μmol/L:



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Case 3

I have a 24 year old pregnant patient with a creatinine of 90 µmol/L and a CD4 of 180 cells/mm^3. She is 22 weeks pregnant and weighs 76kg. As indicated in the guidelines, I cannot give TDF and will be giving her AZT + 3TC + EFV. Do I adjust the dosages of the ARVs?

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Pregnant women already on ART

Does one change the following stable pregnant women on ART to FDC?

- A patient on TDF + 3TC + EFV
- A patient on d4T + 3TC + EFV
- A patient on AZT + 3TC + EFV or TDF + 3TC + NVP
- A patient on TDF, 3TC and Aluvia

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Case 3

- Any pregnant patient with possible renal disease MUST be referred to a doctor
  - investigated and monitored
- Doctors may still use the Cockcroft- Gault formula (creatinine clearance) to adjust the applicable ARV dosages in renal disease
  - Use ideal or baseline weight in the calculation
  - **All** medication excreted by the kidneys must have the dose adjusted according to the creatinine clearance level

EFV in Pregnancy?

- EFV still has a FDA pregnancy class D classification
- Risk with EFV of congenital defects: 2.7%
  - NVP: 2.5%
  - AZT: 3.3%
- 2011 Pregnancy register: 17 / 623
- Although reassuring, numbers still too small to change FDA classification.

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The Infant

- Three phases where we intervene
  - Use FDC in all women during pregnancy
  - 6 weeks Post Exposure prophylaxis to the infant: daily NVP
  - FDC to all breast feeding mothers

Regular HIV testing of mother during pregnancy and breast feeding

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Monitoring bloods FDC - Pregnant women

- Creatinine (lifelong and prophylaxis)
  - Baseline, 3 months, 6 months, 12 months then annually
- CD4
  - Lifelong: baseline and at 1 year
  - Prophylaxis: baseline and 6 months after FDC stopped
- VL (only if on lifelong)
  - 6 months, 12 months and then annually

Discontinuing FDC (prophylaxis)

- If breastfeeding, continue until 1 week after cessation of breastfeeding
- If woman chooses not to breastfeed
  - Assess WHO and baseline CD4 count was >350
  - Send HBsAg
  - **Baby still gets 6/52 NVP syrup**
- Always check HBsAg BEFORE DISCONTINUING
  - If HBsAg positive, DO NOT discontinue FDC: woman qualifies for LIFELONG ART (p31, PMTCT guideline)

ADULT ARV guidelines

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ART Eligibility

- CD4 count ≤350 cells/mm^3 irrespective of WHO clinical stage
- WHO stage 3 or 4 irrespective of CD4 count
- Irrespective of CD4 count
  - All types of TB
  - All pregnant and breast feeding women

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Standardised ART regimen A adults: 1st line

Category	Recommended regimen
All new patients eligible for treatment, including pregnant women	**TDF + (FTC / 3TC) + EFV** or FDC formulation
Contraindications to EFV	TDF + (FTC / 3TC) + NVP
Contraindication to TDF	AZT+ 3TC + EFV (or NVP)
Contraindication to TDF and AZT	d4T + 3TC + EFV (or NVP)
Contraindication to TDF, AZT and d4T	ABC + 3TC + EFV (or NVP)
Currently on d4T based regimen	TDF + FTC / 3TC + EFV FDC preferred

All HIV naive patients initiated on treatment must be initiated on FDC based regimen unless there are documented contraindications

Use NVP based regimen in patients with significant psychiatric comorbidity, intolerance to EFV and where the neuropsychiatric toxicity of EFV may impair daily functioning, e.g. shift workers

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Standardised ART regimen adults: 2nd line

Category	Recommended regimen
Failing on a TDF-based 1st line regimen	AZT + 3TC + LPV/r
Failing on a d4T -based 1st line regimen	TDF + 3TC / FTC and LPV/r
Dyslipidaemia or severe / intolerable diarrhoea associated with LPV/r	Switch LPV/r to ATV/r

Management of virological failure:

-If plasma HIV RNA >1000 copies/mL

-Check for adherence, compliance, tolerability and drug- drug interaction

- Assess psychological issues

-Continue with first line treatment.

- Repeat VL test 2 months later

-If plasma VL confirmed >1000copies/mL

- change regime to second line therapy, provided adherence >80%

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Standardised clinical monitoring: **At initiation**

- WHO clinical staging
- Screen for pregnancy
- Screen for TB symptoms

- CD4 count / HB / Creat
- If considering NVP – ALT
- CrAG if CD4 <100 cells/mm^3

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Standardised clinical monitoring: Patients on ART

- CD4 at 1 year on ART
- VL at month 6 and 1 year on ART and then every 12 months
- ALT only if on NVP and develops rash or symptoms of hepatitis
- HB or FBC at month 3 and 6 if on AZT
- Creatinine at month 3 and 6, 1 year then every 12 months if on TDF
- Fasting cholesterol and triglycerides at month 3 if on LPV/r

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ART considerations in older patients or those with co-morbidities

- Co morbidities can affect ART regimen selection and tolerability
- Examples
  - High cholesterol → avoid lipid-elevating regimens
  - Cardiovascular disease → may consider avoiding abacavir
  - Diabetes → may avoid tenofovir or boosted PIs
  - Fragile bones → avoid tenofovir
  - Renal failure → avoid fixed-dose combinations; consider avoiding tenofovir

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Guidelines for initiating ART in TB/HIV co-infected patients

Clinical scenario	Recommendation
CD4+ count <50 cells/mm^3	Start ART within 2 wks of starting TB therapy
CD4+ count ≥50 cells/mm^3 with clinical disease of major severity*	Start ART within 2-4 wks of starting TB therapy
Other patients with CD4+ count ≥50 cells/mm^3	Can delay ART initiation until 2-8 wks after starting TB therapy
Drug-resistant TB	Start ART within 2-4 wks after confirmation of resistance, initiation of second-line TB therapy
HIV-infected pregnant women with active TB	Start ART as early as feasible

***Low Karnofsky score, low body mass index, low hemoglobin, low albumin, organ system dysfunction, extent of disease**

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Guidelines for initiating INH in HIV positive patients

NB: Revisions to policy will be phased in. Continue with current policy until systems are in place for **Mantoux** testing

	Pre- ART(CD4 >350)	on ART
TST not done*	IPT for 6 months	IPT for 6 months
TST negative	IPT for 6 months	IPT for 12 months
TST positive	IPT for 36 months	IPT for 36 months

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Apparently no one considered the

sun when designing this wall.....

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Case4: Problem

A pregnant HIV positive women presents at the clinic. Her baseline urine dipstick is NAD and she is otherwise well. You initiate her on FDC, take the creatinine and CD4, and ask her to return a week later.

When she comes back her creatinine is normal but her **CD4 is 86 cells/mm^3**. As her CD4 is <100 cells/mm^3, you test for **Cryptococcal Antigen (CrAg), which is positive.**

Should you continue FDC? Should you start fluconazole?

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For the doctor: CrAg positive

- Continue the FDC in all cases
- asymptomatic in the first trimester of pregnancy
  - do not initiate fluconazole due to adverse effects on the foetus
  - counsel the patient to report any symptoms suggestive of cryptococcal meningitis IRIS ASAP
    - headache, confusion, fever, neck stiffness
  - initiate fluconazole after first trimester of pregnancy
- asymptomatic in the second/third trimester of pregnancy
  - initiate fluconazole as per the CrAg algorithm.
  - counsel the patient to report any symptoms suggestive of CM IRIS ASAP
- symptomatic for cryptococcal meningitis
  - urgent LP and treat for CM accordingly

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Reference: Prof Gary Maartens, Western Cape HAST

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Infant And Children ARV guidelines

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ARV Eligibility

- All children <5 years old irrespective of CD4 count
- Children >5: CD4 <350 or WHO Stage 3 & 4

Children <1 years old must be initiated in 7 days of HIV test.

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ARV Regimens

First Line Regimen	
All infants and children under 3 years (and <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 advice

∞ 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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2nd line regimens

2nd line regimen	
Failed 1st line protease inhibitor (PI) based regimen	
Failed 1st line PI based regimen	***Recommended 2nd line regimen***
ABC + 3TC + LPV/r	**Consult with expert for advice***
D4T + 3TC + LPV/r	
Unboosted PI based regimen	
Failed 1st line NNRTI based regimen (discuss with expert before changing)	
Failed 1st line NNRTI based regimen	***Recommended 2nd line regimen***
ABC + 3TC + EFV (or NVP)	AZT + 3TC + LPV/r
d4T + 3TC + EFV (or NVP)	AZT + ABC + LPV/r

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Advice for the expert

Recommended 2nd line regimen under expert advice	
ABC + 3TC + LPV/r	No previous daily NVP for PMTCT AZT + 3TC + EFV* + LPV/r * Use NVP if <3 years or <10kg Previous Daily NVP for PMTCT Treat with 3rd line regimen
d4T + 3TC + LPV/r	No previous daily NVP for PMTCT AZT + ABC + EFV* + LPV/r * Use NVP if <3 years or <10kg Previous Daily NVP for PMTCT Treat with 3rd line regimen
Previously on a regimen with unboosted PI (e.g. RTV alone), or with rifampicin while on LPV/r	Must be managed by an expert on basis of genotype resistance testing to confirm PI susceptibility

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3rd line

Third line regimens	
Failing any 2nd line regimen	Refer for specialist opinion – Regimen based on genotype resistance testing, expert opinion and supervised care. Access to third line ART will be managed centrally by the NDOH Most likely: Raltegravir / Darunavir / Etravirine

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Investigations at dx

- Document weight and height (head circumference <2years old)
- Screen for TB
- WHO staging

- Baseline CD4 & HB or FBC
- **HIV Viral load**
- Cholesterol and TG if on LPV/r regimen
- (creatinine if using TDF, ALT if using NVP)

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Monitoring: 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 - 15 years	To monitor viral suppression response to ART To identify treatment failure and to identify problems with adherence

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Monitoring: adverse events

On ART	Purpose
Hb or FBC at month 1, 2, 3 and then annually if on AZT	To identify AZT-related anaemia
Cholesterol and 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 tests and refer to specialist

Case 5

A sexually active 17yr old is found to be HIV positive and eligible for ARVs.
Which regimen would you initiate?

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Case 5: Discussion

ABC +3TC + EFV

- TDF is not the preferred treatment in adolescents
  - may predispose to hypophosphataemia and osteoporosis in adolescents (rare complication)
  - TDF and FDC are not licensed for use <18 years of age in SA
- ABC is therefore first choice in all children and adolescents under 18 years of age
- Children at age 18 can be changed to FDC if
  - virally suppressed
  - no risk factors **and**
  - ONLY once the DOH has extended FDC to other priority groups
    - this patient does not fall into priority group 1 or 2 so will not yet be eligible for FDC when she turns 18

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For the doctor

- Some **doctors** would consider TDF if
  - approaching 18 years
  - past Tanner Stage 2
  - weighs >35 kg
  - ie, TDF can be used if the child is physically mature enough
- FDC is NOT licensed for children <18 years old
  - ABC based regimen must be used when ART is initiated by NIMART trained nurses

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Case 6

A 16 year old pregnant teenager presents at the clinic. Which regimen do I use?

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Case 6: Discussion

- This is NOT defined in the new guidelines
- FDC is not yet licensed in SA for use in children <18 years
  - cannot be prescribed by NIMART nurses to pregnant teenagers
- If the child is pregnant and under 18 years the following is recommended:
  - If CD4 <350 cells/mm^3: ABC + 3TC + EFV
  - If CD4 >350 cells/mm^3 and does not qualify for lifelong ART: AZT monotherapy
- ALL OF THESE CASES MUST BE DISCUSSED WITH A DOCTOR AS LEGISLATION MIGHT CHANGE IMMINENTLY

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Key Messages

- FDC roll out – GO SLOW and stick to priority groups.
- HIV negative pregnant women – test every 12 weeks
- ALL pregnant women are eligible for FDC irrespective of CD4 count
- Centralized procurement of drugs for salvage therapy

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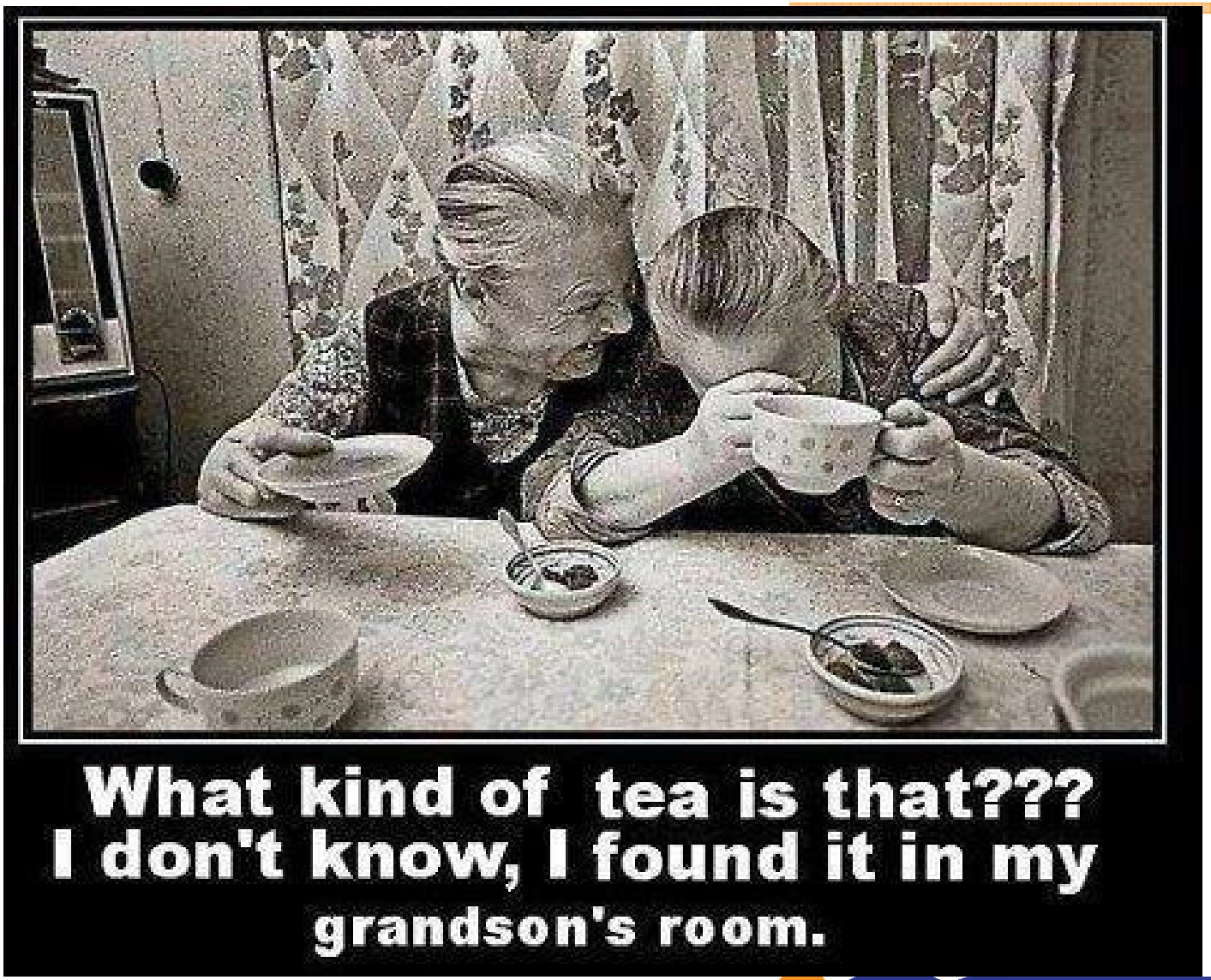

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