Department of Health
Republic of South Africa

ADVERSE DRUG EVENTS

October 2008

Introduction

- *abbreviations* and *definitions* important
- used to monitor rollout of ART in South Africa
- at present , 550 000 patients are receiving ART
- key role in monitoring of drug safety problems
- contribute to rational and safe use of medicines
- to weigh risks and benefits (“pros and cons”) of all medicines at every level of health care

Soth African Medical Formlary SAMF 8th Edition p.613

Abbreviations

- ADE = adverse drug event
- ADR = adverse drug reaction
- LA = lactic acidosis
- PN = pereipheral neuropathy
- ALT = *alanine transa*minase (liver enzyme; broad indicator of hepatic function/dysfunction)

Abbreviations

- NRTI = nucleoside reverse transcriptase inhibitor
- NNRTI = non-nucleoside reverse transcriptase inhibitor
- PI =protease inhibitor

Serious Adverse Event

- Any adverse event that :

  a) results in death

  b) is life-threatening

  c) requires patient hospitalisation or prolongation of existing hospitalisation

  d) results in permanent disability or incapacity

  e) congenital anomaly or birth defect

Serious Adverse Event

- medical judgement should be used when deciding if other situations are serious
- for the purposes of the ART programme, an adverse event warranting a regime change is also considered serious

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National DoH ADE form - 2 pages

ARF 1

ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

(Identities of reporter and patient will remain strictly confidential)

NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE

Medicines Control Council
The Registrar of Medicines ,
Department of Health
In collaboration with the WHO International Drug Monitoring Programme

Tel : (021) 447-1618
Fax: (021) 448-6181

PATIENT INFORMATION

Name (or initials): ..... Age:..... Weight (kg) :.....
Sex:: M F DOB :..... / ..... / ..... Height (cm) :.....

ADVERSE REACTION/PRODUCT QUALITY PROBLEM

Adverse reaction[1] ☐ and/or Product Quality problem[1] ☐ Date of onset of reaction: :...../...../.....
Time of onset of reaction: .....h.....min

Description of reaction or problem (Include relevant tests/lab data, including dates):

1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reason for use

ADVERSE REACTION OUTCOME (Check all that apply)

☐ Death
☐ Disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage

☐ life-threatening
☐ hospitalisation
☐ Other.....

Event reappeared on rechallenge: Y N Rechallenge not done
Treatment (of reaction).....

Recovered: Y N
Sequelae: Y N
Describe Sequelae.....

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

2. PRODUCT QUALITY PROBLEM:

Trade Name	Batch No	Registration No	Dosage form & strength	Expiry Date	Size/Type of container

Product available for evaluation?: Y N

REPORTING DOCTOR/PHARMACIST Etc:

NAME: ..... QUALIFICATIONS:.....
ADDRESS: .....
....
Signature Date
TEL: (.....).....

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Version: MCC2003/1 3

ARF 1

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:
- medications (drugs, vaccines and biologicals)
- medical devices (including in-vitro diagnostics)
- traditional and herbal remedies
- **For Adverse Events Following Immunisation (AEFI), please follow the reporting procedure recommended by the Expanded Programme in Immunisation (EPI)**

Please report:
- adverse drug reactions to recently marketed products
- serious reactions and interactions with all products
- adverse drug reactions which are not clearly reflected in the package insert.

Report even if:
- you're not certain the product caused the event
- you don't have all the details

Report Product Quality Problems such as:
- suspected contamination
- questionable stability
- defective components
- poor packaging or labelling
- therapeutic failures

Important numbers:

Investigational Products and Product Quality Problems:
- (012) 326-4344 to fax a report
- (012) 312-0000 to report by phone

Registered Medicines and Traditional and Herbal remedies:
- (021) 448-6181 to fax a report
- (021) 447-1618 to report by phone

Adverse Events Following Immunisation:
- (012) 312 0110 to phone for information
- (012) 321 9882 to fax a report

Confidentiality: Identities of the reporter and patient will remain strictly confidential.

Your support of the Medicine Control Council's adverse drug reaction monitoring programme is much appreciated. Information supplied by you will contribute to the improvement of drug safety and therapy in South Africa.

PLEASE USE ADDRESS PROVIDED BELOW- JUST FOLD IN THIRDS, TAPE and MAIL

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Geen posseël nodig nie indien in die Republiek van Suid-Afrika gepos

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DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE
PRIVATE BAG/ *PRIVAATSAK* X828
PRETORIA
0001

Version: MCC2003/1 4

Western Cape ADE form – 2 pages

Western Cape ARV Suspected Serious Adverse Drug Reaction Reporting Form

Patient Initials: _____ DOB: _____ Gender: Male | Female

Weight (in kg): _____ Height (in cm): _____

Treatment facility name: _____ Folder No.: _____

Referral Hospital name: _____ Folder No.: _____

Female patients only: Pregnant? Yes | No | Unknown

Medication history (circle suspected medicines and provide brand names where available)

Antiretroviral Medicines				Other Medication (including TB medication, herbal and traditional and over-the-counter medication)			
ARV	Dose	Date Started	Date stopped	Medicine	Dose	Date Started	Date stopped

Date ART was first commenced in this patient: _____

Adverse Event Details (Indicate with an "X" all that apply) (see back for case definitions of adverse events)

- [ ] Death — *Suspected Cause of Death:*
- [ ] Symptomatic hyperlactataemia
- [ ] Lactic acidosis
- [ ] Grade 3 or 4 transaminitis/ Symptomatic hepatitis
- [ ] Serious skin reaction
- [ ] Pancreatitis
- [ ] Neutropaenia with Neutrophil count < 0,5 *10^9cells/mm3
- [ ] Anaemia requiring transfusion
- [ ] Congenital anomaly/ Pregnancy exposure — *Specify and Describe:*
- [ ] Any other serious or unusual event — *Describe:*

Lactate level: | *Blood Gas results:*

Provide event details (including relevant signs and symptoms): Date event started: _____

Investigations (including other relevant medical history):

Management of adverse event:

Outcome	Died	Recovered	Not yet recovered	Permanent damage/ disability	Hospitalised	Regimen change - specify:
Response to rechallenge (if applicable):						
Other outcome - specify:						

Completed by: _____ Job title: _____

Signature: _____ Date completed: _____

Please include additional information that you may deem necessary in your report (use additional paper)

This report can be submitted either immediately orwith monthly reports by Fax (021) 483 6033 or emailed to pgwchivtb@gmail.com

ARV Clinic Serious Adverse Event Reporting Form
Guidelines for Reporting

Report even if:

You're not certain the product caused the event
You don't have all the details

Whom to report to:

All reports should be submitted by fax: (021) 483 6033 **OR** emailed to pgwchivtb@gmail.com

When to report:

All forms should be completed immediately and submitted with routine monthly reports

Further Information:

For further information or help with reporting contact the HIV/AIDS Hotline Tel: (021) 406 6782
Please use additional paper to include any other relevant information you deem necessary.

Important Definitions for Reportable Events

Serious Adverse Event:
Any adverse event that a) results in death; b) is life-threatening; c) requires patient hospitalisation or prolongation of existing hospitalisation, d) results in persistent disability or incapacity, e) or is a congenital anomaly or birth defect.Medical judgement should be used when deciding if other situations are serious. For the purposes of the ART programme an adverse event warranting a regimen change is also considered serious.

Symptomatic Hyperlactataemia:
Lactate>2 mmol/l in combination with one or more of the followoing symptoms: fatigue, myalgia, nausea, vomiting, diarrhoea, abdominal distension, abdominal pain, weight loss and shortness of breath

Lactic Acidosis:
Metabolic acidosis with elevated lactate (>2mmol/l)

Grade 3 or 4 Transaminitis / Symptomatic Hepatitis:
Grade 3 transaminitis: ALT 5-10 times the ULN, Grade 4 transaminitis: ALT >10 times ULN

Severe Skin Reaction:
Rash with involvement of mucosal sufaces OR systemic features including fever OR any derangement of liver or renal function.

Grade 4 Neutropenia:
Neutrophil count less than 0.5 x 10^9/litre

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Your anonymised report will be communicated to the National Adverse Drug Event Monitoring Centre and the national HIV/AIDS pharmacovigilance units

Thank you for Reporting!

DoH National ADE form (2 pages)

ARF 1

ADVERSE DRUG REACTION
AND PRODUCT QUALITY PROBLEM REPORT FORM
(Identities of reporter and patient will remain strictly confidential)
NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE

Medicines Control Council,
The Registrar of Medicines ,
Department of Health

Tel : (021) 447-1818
Fax: (021) 448-8181

In collaboration with the WHO International Drug Monitoring Programme

PATIENT INFORMATION

Name (or initials): ..... **Age:**..... **Weight (kg) :**.....
Sex:: M F **DOB :**..... / ..... / ..... **Height (cm) :**.....

ADVERSE REACTION/PRODUCT QUALITY PROBLEM

Adverse reaction[1] ☐ **and/or Product Quality problem**[2] ☐ **Date of onset of reaction: :**...../...../.....
Time of onset of reaction: .....h.....min

Description of reaction or problem (Include relevant tests/lab data, including dates):

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1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reasons for use

ADVERSE REACTION OUTCOME (Check all that apply)

- ☐ Death
- ☐ Disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ life-threatening
- ☐ hospitalisation
- ☐ Other.....

.....

.....

.....

Event reappeared on rechallenge: Y N Rechallenge not done

Treatment (of reaction).....

.....

.....

.....

Recovered: Y N

Sequelae: Y N

Describe Sequelae:.....

.....

.....

.....

COMMENTS: (e.g. Relevant history, Allergies, Previous exposure, Baseline test results/lab data)

2. PRODUCT QUALITY PROBLEM:

Trade Name	Batch No	Registration No	Dosage form & strength	Expiry Date	Size/Type of container

Product available for evaluation?: Y N

REPORTING DOCTOR/PHARMACIST Etc:

NAME: ..... QUALIFICATIONS:.....

ADDRESS: .....

....
Signature Date

TEL: (.....).....

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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ARF 1

ADVICE ABOUT VOLUNTARY REPORTING

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DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE
PRIVATE BAG/ *PRIVAATSAK* X828
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SOUTH AFRICANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

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KZN DoH ADE form - 2 pages

From (Name of Institution) : Fax To: KwaZulu Natal Pharmaceutical Services 033 846 7280 Referring Hospital:

Serious Adverse Drug Reactions for Antretrovirals &/or Request for Authority to Purchase Antiretrovirals Drugs for Switching Regimens/Regimen 2 Drugs on Named Patient Basis

Patients Name: ID No. Gender Height cm Weight kg Pregnant: Yes No

Medication History (CIRCLE the suspected medicine and provide brand names where available)

ARV	Dose	Date Started	Date Stopped	Others (TB, Herbal etc)	Dose	Date Started	Date Stopped	Comments / notes

Adverse Events (Indicate with a tick)

Neutropaenia with neutrophil count <0.5*109 cells/mm3		Death			
Anaemia requiring transfusion	Hb:	Symptomatic Hyperlactataemia		Lactate level	
Peripheral Neuropathy		Lactic Acidosis		Bicarbonate Level	
Congenital Anomaly/Pregnancy Exposure **(Specify & Describe)**		Grade 3 or 4 transaminitis/ Symptomatic Hepatitis		pH	
		Serious Skin Reaction		Anion Gap Measure	
		Pancreatitis			

Any Other serious/unusual event (Describe)

Provide Event Details and Investigations:

Management of Adverse Event:

Outcome: Died Not yet recovered Permanent Damage Hospitalised Regimen Change Recovered

Treatment Failure

Baseline Data:	**Date**		**Viral Load**		**CD4 Count**		Date Stepped up Adherence Started
Current Data:	**Date**		**Viral Load**		**CD4 Count**		

Proposed New Regimen (to be completed by Prescriber & Pharmacist)

Required Antiretroviral Drug	Dose	PMSC Catalogue Number	Name		Phone No	Cell No	Signature
			Prescriber				
			Consultant				
			Pharmacist				
Other							

FOR HEAD OFFICE USE	Not Approved	Approved	Record Number	Date	Authorisation No	Signature

Comments

Western Cape ADE form – 2 pages

Western Cape ARV Suspected Serious Adverse Drug Reaction Reporting Form

Patient Initials: D.M. DOB: Date of birth Gender: Male | Female

Weight (in kg): ✓ Height (in cm): ✓

Treatment facility name: ✓ Folder No.: ✓

Referral Hospital name: ✓ Folder No.:

Female patients only: Pregnant? Yes | No | Unknown

Western Cape ADE form – 2 pages

Medication history (circle suspected medicines and provide brand names where available)							
Antiretroviral Medicines				Other Medication (including TB medication, herbal and traditional and over-the-counter medication)			
ARV	Dose	Date Started	Date stopped	Medicine	Dose	Date Started	Date stopped
nevirapine	200mg	2/4/2008	19/4/2008	None			
Date ART was first commenced in this patient: 2/4/2008							

SOUTH AFRICANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

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Anti-retrovirals
(ART / ARVs / Triple therapy / HAART)

- NRTIs
  - d4T, 3TC, AZT, ddI (TDF)
- NNRTIs
  - NVP, EFV
- PI
  - *Kaletra®*

Adverse Drug Events

1. Symptomatic hyperlactataemia
2. Lactic acidosis

NRTIs

3. Hepatitis (Grade 3 or 4)
4. Serious skin reaction

NNRTIs

5. Pancreatitis amylase
6. Neutropaenia (less than < 500 cell/mm³)
7. Anaemia requiring transfusion

NRTIs

8. Pregnancy *or* congenital abnormality NNRTI
9. Any other serious or unusual event
10. Death

Symptomatic hyperlactataemia

Lactate greater than > 2 mmol/l in combination with one or more of the following symptoms:

- –Fatigue
- –Myalgia
- –Nausea
- –Vomiting
- –Diarrhoea

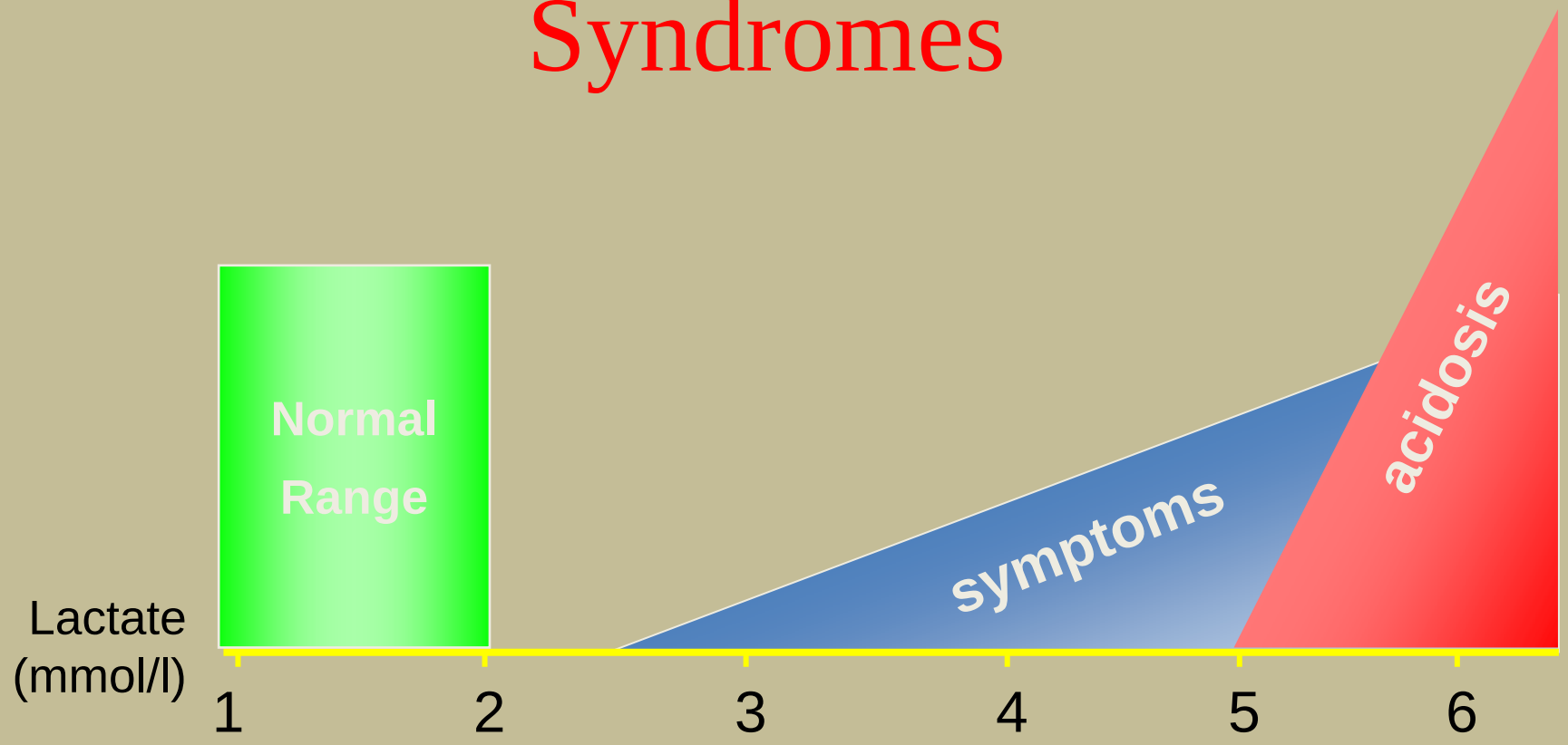
- Abdominal distention
- Abdominal pain
- Weight loss
- Shortness of breath

Lactic acidosis

- a metabolic acidosis with an *elevated* lactate of greater than 2 mmol per litre

May occur 6 to 24 months after starting ART, may have >10kg weight gain, ♀

Hyperlactatemia – Clinical Syndromes



Compensated hyperlactatemia

- stable over time
- common

Decompensated lactic acidosis

- rapidly progressive life-threatening
- HCO < 20 mmol/l
- rare

Symptomatic Hepatitis

- Grade 3 or Grade 4 *Transaminitis*
- Grade 3 *Transaminitis* = ALT 5 to 10 times the upper limit of normal set by the NHLS laboratory
- Grade 4 *Transaminitis* - ALT more than > 10 times the upper limit of normal set by the NHLS laboratory

ALT = alanine transaminase (liver enzyme)

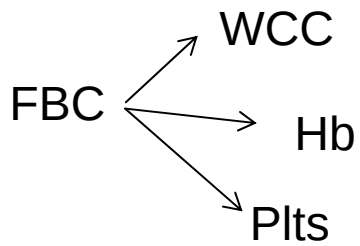
Grading of abnormal ALT

- ALT = *alanine transaminase*
- a sensitive laboratory blood test (red top tube – clotted blood) to detect abnormal liver functinon
- U.L.N. = upper limit of normal
- NHLS reference range = 0 – 40
- a result over 40 is therefore ABNORMAL

Grade 1	Grade 2	Grade 3	Grade 4
40 -100	100 -200	200 - 400	More than 400

Differential count – neutrophils

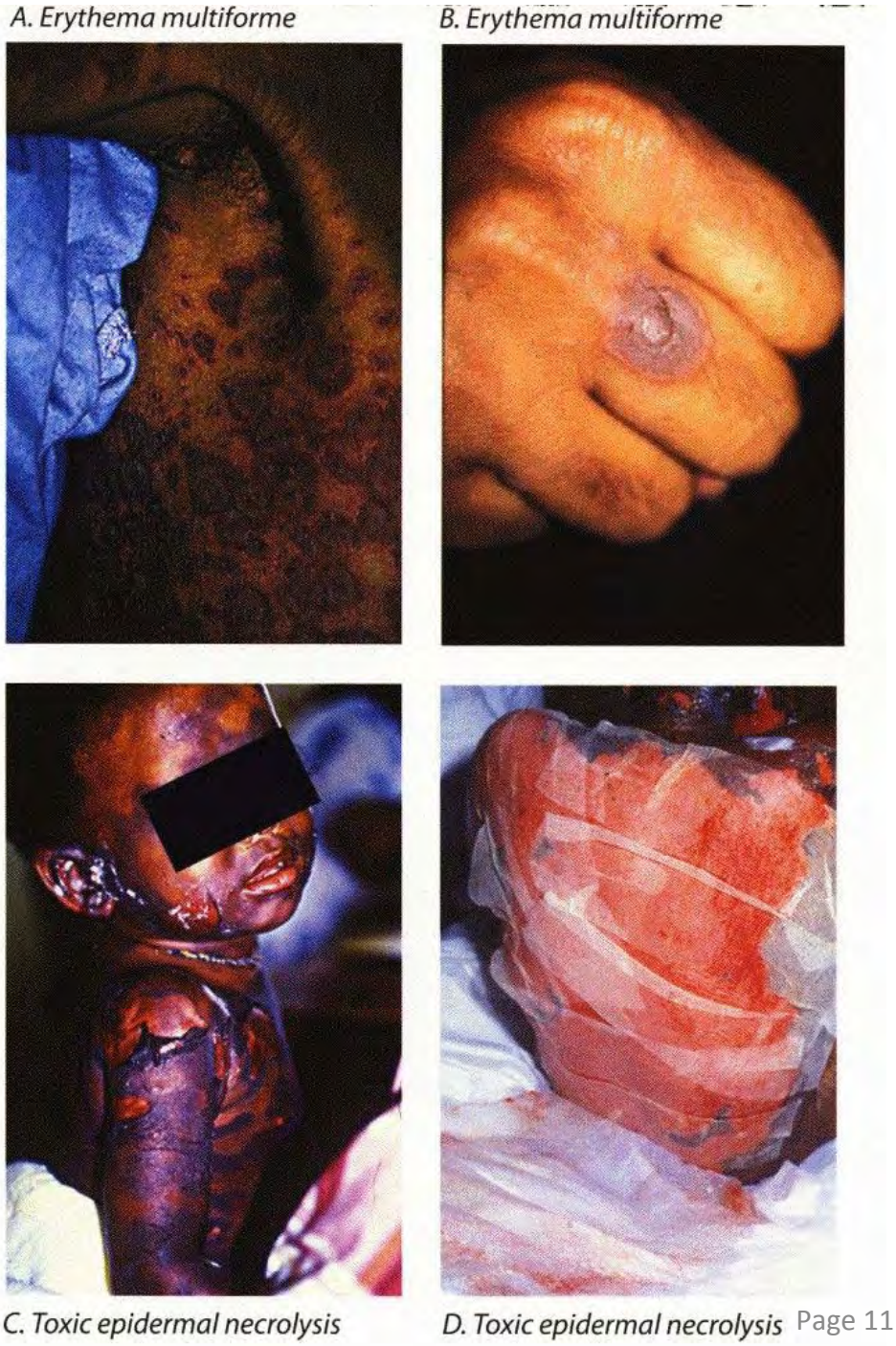
- expressed as a percentage (%) of the total white cell count (WCC)
- e.g.total WCC = 2.3 x 10^9 /L (2300)
- neutrophil percentage = 12%
- absolute neutrophil count = 2300 x 12/100 = 276



Grade 1	Grade 2	Grade 3	Grade 4
1000 to 1500	750 to 1000	500 to 750	Less than 500

Severe skin reaction

- Rash with involvement of the mucosal surfaces OR systemic features including fever OR any derangement of liver or renal function (abnormal liver enzymes or abnormal U&E)



Drug reactions - blisters

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

A. Stevens Johnson Syndrome

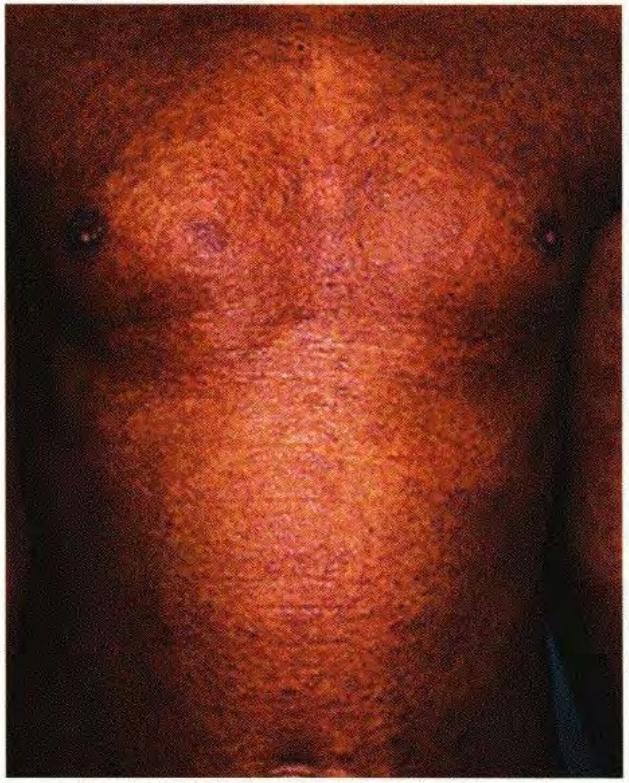
B. Stevens Johnson Syndrome

C. Stevens Johnson Syndrome

Drug reactions - blisters

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

A. Morbilliform drug rash



B. Morbilliform drug rash

Papulosquamous conditions

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

Drug reactions – HIV patients

- HIV patients have a higher incidence of drug reactions (*100 x* normal population)
- offending *drugs* include co-trimoxazole, anti-tuberculosis medication, ART especially NNRTIs (NVP and EFV), anti-convulsants and NSAIDs
- drug reactions due to NNRTIs occur in 9 – 32% of patients but only 6 – 7 % will require discontinuation

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

Drug reactions – HIV patients

- *Timing* – usually occurs after 8 to 21 days, but may be up to 6 weeks
- *Morphology* of the rash can vary including:
  - morbilliform
  - targetoid
  - blisters
  - hand, foot and mouth mucosal lesions (conjunctival, oral and genital erosions)

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
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Drug reactions – HIV patients

- the most severe form of skin drug reactions are *Stevens Johnson Syndrome* (SJS) ie blistering of the skin with involvement of two or more mucosal surfaces and
- *Toxic Epidermal Necrolysis* (TEN) which causes extensive blistering with stripping of the skin
- both have a high mortality (up to 60%) and require referral to hospital to prevent death from septicaemia and end-organ failure

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

Drug reactions – management

1. *Stop* offending drug
2. Topical antibacterials and *Jelonet*® to denuded areas
3. Maintain *hydration*
4. *Analgesia*
5. Glycothymol mouthwash for SJS and TEN
6. Chloromycetin *eye* ointment, normal saline eye washes
7. Screen for *septicaemia*
8. Refer to *tertiary* unit (ICU)

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

Hypersensitivity syndrome

- occurs with NNRTIs (NVP) as well others (anticonvulsants, sulphur and antiTB drugs)
- presents as a morbilliform or urticarial rash
- associated with fever (>40°C), arthritis, hepatitis, eosinphilia
- rash occurs 4 – 6 weeks after introduction of the drug

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

Hypersensitivity reactions - management

- stop offending drug
- For mild reactions:
  - moderate potency of topical steroids
  - oral antihistamines:
    - phenergan 25mg two times daily
    - chlorphenramine 4mg three times daily
  - avoid topical antihistamines
- Monitor liver function

A clinical atlas of skin conditions in HIV / AIDS – an illustrated management guide for health care Professionals
Dr C N Dlova and DR A Mosam

Neutropaenia

- Neutrophil count less than 0.5×10^{9} per litre

Western Cape ADE form – 2 pages

Adverse Event Details (Indicate with an "X" all that apply) (see back for case definitions of adverse events)

	Death	*Suspected Cause of Death:*
	Symptomatic hyperlactataemia	
✓	Lactic acidosis	
	Grade 3 or 4 transaminitis/ Symptomatic hepatitis	
	Serious skin reaction	
	Pancreatitis	
	Neutropaenia with Neutrophil count < 0,5 *10^9cells/mm3	
	Anaemia requiring transfusion	
	Congenital anomaly/ Pregnancy exposure	*Specify and Describe:*
	Any other serious or unusual event	*Describe:*

Lactate level:	*Blood Gas results:*
6.8 mmol/l	**pH and bicarb**

usually from a hospital with a blood gas machine

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Provide event details (including relevant signs and symptoms):	Date event started: _____
Investigations (including other relevant medical history):	
Management of adverse event:	

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Outcome	Died	Recovered	Not yet recovered	Permanent damage/ disability	Hospitalised	Regimen change - specify:
Response to rechallenge (if applicable):						
Other outcome - specify:						

Completed by: _____ **Job title:** _____

Signature: _____ **Date completed:** _____

Please include additional information that you may deem necessary in your report (use additional paper)

This report can be submitted either immediately orwith monthly reports by Fax (021) 483 6033 or emailed to pgwchivtb@gmail.com

Guidelines for reporting

- ART clinic serious ADE reporting form to be completed even if you are *not certain* the product caused the event
- report even if you *don't have ALL* the details
- WHO: Fax: 021 – 483 6033 or email to pgwchivb@gmail.com
- WHEN : complete immediately and submit monthly

Guidelines for reporting

- the ADE form does not constitute an admission that medical personnel or the product caused or contributed to the event
- your anonymous report will be communicated to the National Adverse Drug Event Monitoring Centre and the National HIV / AIDS Pharmoco-vigilance units

Substitution with tenofovir (TDF)

- in WC, a motivation form needs to be completed
- it does NOT replace the adverse drug event form
- in WC, upon completion, ADE form must be faxed to 021 – 483 9921

MOTIVATION FOR TENOFOVIR USE

Date of Submission / /

Facility : _____

Prescribing clinician: _____

Contact number: _____

Email address: _____

Signature: _____

Patient Details

Folder number: _____

Surname: _____

First name: _____

Date of birth: / /

Gender: M ☐ F ☐

ARV Start Date: / /

Current regimen: | | | |

☐ Symptomatic Hyperlactataemia — lactate result | date taken

☐ Severe adverse events on both Zidovudine and Stavudine

☐ Hepatitis B Antigen positive — When test was done / /

☐ Cosmetically significant lipoatrophy

N.B. This motivation **does not** replace an Adverse Event Form, if not yet submitted please complete and fax to 021 483 9921

Planned regimen: | | | |

Notes:

Send to: HIV/AIDS Pharmacist
Fax: 021 483 9921
Email: Hmoeng@pgwc.gov.za

Date of Review / /

Western Cape TDF motivation form

SOUTH AFRICANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

USAID FROM THE AMERICAN PEOPLE

MOTIVATION FOR TENOFOVIR USE

Date of Submission	/ /

Facility : _____

Prescribing clinician: _____

Contact number: _____

Email address: _____

Signature: _____

Patient Details

Folder number: _____

Surname: _____

First name: _____

Date of birth: / /

Gender: M ☐ F ☐

ARV Start Date: / /

Current regimen:

- ☐ Symptomatic Hyperlactataemia

lactate result	date taken

- ☐ Severe adverse events on both Zidovudine and Stavudine
- ☐ Hepatitis B Antigen positive

When test was done	/ /

- ☐ Cosmetically significant lipoatrophy

N.B. This motivation **does not** replace an Adverse Event Form, if not yet submitted please complete and fax to 021 483 9921

Planned regimen:

Notes:

Send to: HIV/AIDS Pharmacist
Fax: 021 483 9921
Email: Hmoeng@pgwc.gov.za

Date of Review	/ /

Summary – ADE forms

- ensure as much detail out the patient is put on the form
- ensure stationary (blank forms) are kept at every ART site (ART clinic and pharmacy)
- ensure collected and forwarded regularly
- have a central collection point (? one person responsible each month)

THANK YOU FOR REPORTING

Department of Health
Republic of South Africa

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