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
Abbreviations

- ADE = adverse drug event
- ADR = adverse drug reaction
- LA = lactic acidosis
- PN = peripheral neuropathy
- ALT = alanine transaminase (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
• 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
National DoH ADE form - 2 pages

ADVERSE DRUG REACTION
AND PRODUCT QUALITY PROBLEM REPORT FORM
NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE

PATIENT INFORMATION

Name (or initials): __________________________ Age: ____________ Weight (kg): ______________
Sex: M [ ] F [ ] DOB: ____________________ Height (cm): ______________

ADVERSE REACTION/PRODUCT QUALITY PROBLEM

Adverse reaction [ ] and/or Product Quality problem [ ] Date of onset of reaction: ____________
Time of onset of reaction: ____________

Description of reaction or problem (include relevant medical data, including dates):

MEDICINES/VACCINES/DEVICES
(includes all concomitant medicines)

[Table with columns for Date/Drug, Route/Dose, Date Administered, Date Stopped, Reason for use]

ADVERSE REACTION OUTCOME

(Select all that apply)

[Table with columns for Event component name, Treatment of reaction, Date/Drug, Route/Dose, Date Stopped, Reason for use]

Comments: [ ] (e.g. Relevant/irrelevant, Diagnosis, Treatment, Result, other medical data)

PRODUCT QUALITY PROBLEM

Product available for evaluation: [Y] [N]

REPORTING DOCTOR/PHARMACIST etc.

NAME: ________________________________ QUALIFICATION: __________________________
ADDRESS: ______________________________
TELEPHONE: ______________________________

Signature: __________________________
Date: __________________________

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

BUSINESS REPLY SERVICE

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
PRIVATE BAG PRIVADESAK X828
PRETORIA 0001

Free Mail Number: BVG2003/1

Version: MCC2003/1

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences:
• seizures (suspected toxicological)
• sudden onset convulsions (neurological)
• other seizure-like reactions
• traditional self-help therapies
• For Adverse Events Following Immunization (AEFI), please follow the reporting procedure recommended by the Expanded Programme on Immunization (EPI)

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

Report even if:
• you’re not sure the product caused the event
• you don’t have all the details

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

Your support of the Medicines 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

No postage stamp necessary if point of origin is Republic of South Africa. Envelopes already faxed are subject to the South African postal rates after this page.

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
PRIVATE BAG PRIVADESAK X828
PRETORIA 0001

Free Mail Number: BVG2003/1

Version: MCC2003/1
# Western Cape ADE form – 2 pages

## Western Cape ARV Suspected Serious Adverse Drug Reaction Reporting Form

<table>
<thead>
<tr>
<th>Patient initials:</th>
<th>DOB:</th>
<th>Gender:</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (in kg):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height (in cm):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment facility name:</td>
<td></td>
<td>Funder No:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral hospital name:</td>
<td></td>
<td>Funder No:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female patients only:</td>
<td></td>
<td>Pregnant?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Medication history (write suspected meds and provide brand names where available)

<table>
<thead>
<tr>
<th>Antivirals</th>
<th>Other Medicines (including TB medication, herbal and traditional and over-the-counter medication)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV</td>
<td>Date Stoped</td>
</tr>
</tbody>
</table>

**Date ART was first commenced in this patient:**

### Adverse Event Details (indicate with an "X" all that apply)

<table>
<thead>
<tr>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash</td>
<td></td>
</tr>
<tr>
<td>Symptomatic hypercalcitaemia</td>
<td></td>
</tr>
<tr>
<td>Leucovorin</td>
<td></td>
</tr>
<tr>
<td>Grade 3 or 4 transaminase</td>
<td></td>
</tr>
<tr>
<td>Symptomatic hepatitis</td>
<td></td>
</tr>
<tr>
<td>Dorsal skin reaction</td>
<td></td>
</tr>
<tr>
<td>Parasthesias</td>
<td></td>
</tr>
<tr>
<td>Neutropenia with Neutrophil count &lt; 0.5 x 10^9/litre</td>
<td></td>
</tr>
<tr>
<td>Anemia requiring transfusion</td>
<td></td>
</tr>
<tr>
<td>Congenital anomaly: Pregnancy exposure</td>
<td></td>
</tr>
<tr>
<td>Any other serious or unusual event</td>
<td></td>
</tr>
</tbody>
</table>

### Important Definitions for Reportable Events

#### Serious Adverse Event:

Any adverse event that a) results in death; b) is life-threatening; c) may result in 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 this ART programme, an adverse event meeting a significant change in health condition is also considered an adverse event.

#### Symptomatic Hypercalcitaemia:

Lactate-3 month in combinations with one or more of the following symptoms: fatigue, myalgia, nausea, vomiting, diarrhoea, abdominal distension, abdominal pain, weight loss and dryness of breath

#### Lactic Acidosis:

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

#### Grade 3 or 4 transaminase | Symptomatic Hepatitis:

Grade 3 transaminase: ALT 5-10 times the ULN; Grade 4 transaminase: ALT >10 times ULN

#### Severe Skin Reaction:

Rash with involvement of mucosal surfaces or systemic features including fever OR any disarrangement of fever 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 anonymized report will be communicated to the National Adverse Drug Event Monitoring Centre and the national HIV/AIDS pharmacovigilance units.

Thank you for reporting!
ADVERSE DRUG REACTION
AND PRODUCT QUALITY PROBLEM REPORT FORM
 Mahmoud Administration of the
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

PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Name (or initials):</th>
<th>Age:</th>
<th>Weight (kg):</th>
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</thead>
<tbody>
<tr>
<td></td>
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<thead>
<tr>
<th>Sex:</th>
<th>DOB</th>
<th>Height (cm):</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ADVERSE REACTION/PRODUCT QUALITY PROBLEM

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>Date of onset of reaction:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>and/or Product Quality problem</th>
<th>Time of onset of reaction:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>hour, minute</td>
</tr>
</tbody>
</table>

Description of reaction or problem (Include relevant tests/lab data, including dates):
1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

<table>
<thead>
<tr>
<th>Trade Name &amp; Batch No. (Asterisk Suspected Product)</th>
<th>Daily Dosage</th>
<th>Route</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Reasons for use</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

ADVERSE REACTION OUTCOME (Check all that apply)

<table>
<thead>
<tr>
<th>Death</th>
<th>Disability</th>
<th>congenital anomaly</th>
<th>required intervention to prevent permanent impairment/damage</th>
<th>life-threatening</th>
<th>hospitalisation</th>
<th>Other</th>
<th>Event reappeared on rechallenge:</th>
<th>Recovered:</th>
<th>Sequelea:</th>
<th>Describe Sequelea:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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<td>N</td>
<td>N</td>
<td>N</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rechallenge not done</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Treatment (of reaction): ..........................................................................................

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

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Batch No</th>
<th>Registration No</th>
<th>Dosage form &amp; strength</th>
<th>Expiry Date</th>
<th>Size/Type of container</th>
</tr>
</thead>
</table>

Product available for evaluation?:  Y  N

REPORTING DOCTOR/PHARMACIST Etc:

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

ADDRESS: ..........................................................

..........................................................

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

..........................................................

Signature  Date

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

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

BUSINESS REPLY SERVICE
BESIGHEIDSANTWOORDDIENS
Free Mail Number:
Vryposnommer: BNT 178

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID
REGISTRAR OF MEDICINES
REGISTRATEUR VAN MEDISYNE
PRIVATE BAG/ PRIVAATSAK X828
PRETORIA
0001
### KZN DoH ADE form - 2 pages

<table>
<thead>
<tr>
<th>Form (Name of Institution):</th>
<th>Fax To: KwaZulu Natal Pharmaceutical Services 033 846 7280</th>
<th>Referring Hospital:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Adverse Drug Reactions for Antiretrovirals &amp;/or Request for Authority to Purchase Antiretrovirals Drugs for Switching Regimens/Regimen 2 Drugs on: Named Patient Basis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients Name:</th>
<th>ID No.</th>
<th>Gender</th>
<th>Height cm</th>
<th>Weight kg</th>
<th>Pregnant: Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Medication History (CIRCLE the suspected medicine and provide brand names where available)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>AADV</th>
<th>Dose</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Others (i.e. Herbal etc)</th>
<th>Dose</th>
<th>Date Started</th>
<th>Date Stopped</th>
<th>Comments / notes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Adverse Events (Indicate with a tick)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Neutropenia with neutrophil count &lt;0.5 x 10^9 cells/mm³</th>
<th>Uraemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaemia requiring transfusion</td>
<td>Hb: Symptomatic Hyperlactataemia</td>
</tr>
<tr>
<td>Periapexia</td>
<td>Lactic Acidosis</td>
</tr>
<tr>
<td>Congenital Anomaly/Pregnancy Exposure (Specify &amp; Describe)</td>
<td>Metabolic Acidosis</td>
</tr>
<tr>
<td>Grade 3 or 4 transaminases</td>
<td>Symptomatic Hepatitis</td>
</tr>
<tr>
<td>Severe Skin Reaction</td>
<td>Anion Gap Measure</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any Other serious/unusual event (Describe)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Provide Event Details and Investigations:</th>
<th>Management of Adverse Event:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Outcome:</th>
<th>Died</th>
<th>Not yet recovered</th>
<th>Permanent Damage</th>
<th>Hospitalised</th>
<th>Regimen Change</th>
<th>Recovered</th>
<th>Treatment Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Data:</td>
<td>Date</td>
<td>Viral Load</td>
<td>CD4 Count</td>
<td>Date Stopped up Adherence Started</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Data:</td>
<td>Date</td>
<td>Viral Load</td>
<td>CD4 Count</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposed New Regimen (to be completed by Prescriber/Physician)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Required Antiretroviral Drug</th>
<th>Dose</th>
<th>PMSC Catalogue Number</th>
<th>Name</th>
<th>Phone No</th>
<th>Cell No</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber</td>
<td>Consultant</td>
<td>Pharmacist</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>FOR HEAD OFFICE USE</th>
<th>Not Approved</th>
<th>Approved</th>
<th>Record Number</th>
<th>Date</th>
<th>Authorisation No</th>
<th>Signature</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western Cape ARV Suspected Serious Adverse Drug Reaction Reporting Form</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Patient Initials:</strong> D.M.</td>
</tr>
<tr>
<td><strong>DOB:</strong></td>
</tr>
<tr>
<td><strong>Date of birth</strong></td>
</tr>
<tr>
<td><strong>Weight (in kg):</strong></td>
</tr>
<tr>
<td><strong>Height (in cm):</strong></td>
</tr>
<tr>
<td><strong>Gender:</strong></td>
</tr>
<tr>
<td><strong>Treatment facility name:</strong></td>
</tr>
<tr>
<td><strong>Referral Hospital name:</strong></td>
</tr>
<tr>
<td><strong>Folder No.:</strong></td>
</tr>
<tr>
<td><strong>Female patients only:</strong></td>
</tr>
<tr>
<td><strong>Pregnant?</strong></td>
</tr>
</tbody>
</table>
### Medication history (circle suspected medicines and provide brand names where available)

<table>
<thead>
<tr>
<th>Antiretroviral Medicines</th>
<th>Other Medication (including TB medication, herbal and traditional and over-the-counter medication)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV</td>
<td>Medicine</td>
</tr>
<tr>
<td>nevirapine</td>
<td>Dose</td>
</tr>
<tr>
<td>200mg</td>
<td>Date Started</td>
</tr>
<tr>
<td>2/4/2008</td>
<td>Date stopped</td>
</tr>
<tr>
<td>19/4/2008</td>
<td>None</td>
</tr>
</tbody>
</table>

Date ART was first commenced in this patient: 2/4/2008
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
3. Hepatitis (Grade 3 or 4)
4. Serious skin reaction
5. Pancreatitis
6. Neutropenia (less than < 500 cell/mm³)
7. Anaemia requiring transfusion
8. Pregnancy or congenital abnormality
9. Any other serious or unusual event
10. Death
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

Symptomatic hyperlactataemia
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

Normal Range

Lactate (mmol/l)
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 function
- U.L.N. = upper limit of normal
- NHLS reference range = 0 – 40
- a result over 40 is therefore ABNORMAL

<table>
<thead>
<tr>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 -100</td>
<td>100 -200</td>
<td>200 - 400</td>
<td>More than 400</td>
</tr>
</tbody>
</table>
Differential count – neutrophils

• expressed as a percentage (%) of the total white cell count (WCC)
• e.g. total WCC = 2.3 x 10⁹ /L (2300)
• neutrophil percentage = 12%
• absolute neutrophil count = 2300 x 12/100 = 276

<table>
<thead>
<tr>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 to 1500</td>
<td>750 to 1000</td>
<td>500 to 750</td>
<td>Less than 500</td>
</tr>
</tbody>
</table>
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
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
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
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 )
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
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)
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
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
Neutropaenia

• Neutrophil count less than $0.5 \times 10^9$ per litre
### Western Cape ADE form – 2 pages

<table>
<thead>
<tr>
<th>Adverse Event Details (Indicate with an &quot;X&quot; all that apply)</th>
<th>Suspected Cause of Death:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Lactate level:</td>
</tr>
<tr>
<td>Symptomatic hyperlactataemia</td>
<td>Blood Gas results:</td>
</tr>
<tr>
<td>Lactic acidosis</td>
<td><strong>6.8 mmol/l</strong></td>
</tr>
<tr>
<td>Grade 3 or 4 transaminitis/ Symptomatic hepatitis</td>
<td><strong>pH and bicarb</strong></td>
</tr>
<tr>
<td>Serious skin reaction</td>
<td>usually from a hospital with a blood gas machine</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td></td>
</tr>
<tr>
<td>Neutropaenia with Neutrophil count &lt; 0.5 *10^9 cells/mm³</td>
<td></td>
</tr>
<tr>
<td>Anaemia requiring transfusion</td>
<td></td>
</tr>
<tr>
<td>Congenital anomaly/ Pregnancy exposure</td>
<td>Specify and Describe:</td>
</tr>
<tr>
<td>Any other serious or unusual event</td>
<td>Describe:</td>
</tr>
</tbody>
</table>

(see back for case definitions of adverse events)
<table>
<thead>
<tr>
<th>Provide event details (including relevant signs and symptoms):</th>
<th>Date event started:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigations (including other relevant medical history):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Management of adverse event:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Outcome</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Response to rechallenge (if applicable):</td>
</tr>
<tr>
<td>Other outcome - specify:</td>
</tr>
<tr>
<td>Completed by:</td>
</tr>
<tr>
<td>Job title:</td>
</tr>
<tr>
<td>Signature:</td>
</tr>
<tr>
<td>Date completed:</td>
</tr>
</tbody>
</table>

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

This report can be submitted either immediately or with 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](mailto: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 Pharmaco-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

**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 lipodystrophy

**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:** hmoeno@pgwc.gov.za

**Date of Review:** 

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:  

<table>
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<tr>
<th>Symptomatic Hyperlactataemia</th>
<th>lactate result</th>
<th>date taken</th>
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<tr>
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<td>Hepatitis B Antigen positive</td>
<td>When test was done</td>
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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