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Appendix 1: Interim revised WHO clinical staging of HIV/AIDS for infants and children

(For persons aged under 15 years with confirmed laboratory evidence of HIV infection: HIV antibody if aged 18 months and above; virological or p24 antigen testing if aged under 18 months)

Stage I

- Asymptomatic
- Persistent generalised lymphadenopathy

Stage II

- Hepatosplenomegaly
- Papular pruritic eruptions
- Seborrhoeic dermatitis
- Extensive human papilloma virus infection
- Extensive molluscum contagiosum
- Fungal nail infections
- Recurrent oral ulcerations
- Lineal gingival erythema (LGE)
- Angular cheilitis
- Parotid enlargement
- Herpes zoster
- Recurrent or chronic RTIs (otitis media, otorrhoea, sinusitis)

Stage III

- Moderate unexplained malnutrition not adequately responding to standard therapy
- Unexplained persistent diarrhoea (14 days or more)
- Unexplained persistent fever (intermittent or constant, for longer than one month)
- Oral candidiasis (outside neonatal period)
- Oral hairy leukoplakia
- Acute necrotizing ulcerative gingivitis/periodontitis
- Pulmonary TB

- Severe recurrent presumed bacterial pneumonia
- Unexplained anaemia (<8g/dl), and or neutropenia (<500/mm³) and or thrombocytopenia (<50 000/mm³) for more than one month
- Chronic HIV-associated lung disease including bronchiectasis
- Symptomatic lymphoid interstitial pneumonitis (LIP)

Stage IV

- Unexplained severe wasting or severe malnutrition not adequately responding to standard therapy
- *Pneumocystis* pneumonia
- Recurrent severe presumed bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration)
- Extrapulmonary TB
- Kaposi's sarcoma
- Oesophageal candidiasis
- CNS toxoplasmosis (outside the neonatal period)
- HIV encephalopathy
- CMV infection (CMV retinitis or infection of organs other than liver, spleen or lymph nodes; onset at the age one month or more)
- Extrapulmonary cryptococcosis including meningitis
- Any disseminated endemic mycosis (e.g. extrapulmonary histoplasmosis, coccidiomycosis, penicilliosis)
- Cryptosporidiosis
- Isosporiasis
- Disseminated non-tuberculous mycobacterial infection
- Candida of trachea, bronchi or lungs
- Visceral herpes simplex infection
- Acquired HIV-associated rectal fistula
- Cerebral or B cell non-Hodgkin's lymphoma
- Progressive multifocal leukoencephalopathy (PML)
- HIV-associated cardiomyopathy or HIV-associated nephropathy

Appendix 2: Paediatric pain scales

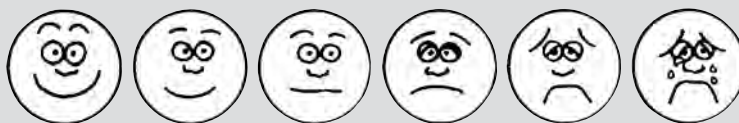
| FLACC scale for determining the intensity of pain of a child who cannot speak (under 3 years or very ill) | | | |
|--|--|---|---|
| Score | 0 | 1 | 2 |
| Face | No particular expression or smiling | Occasional grimace or frown, withdrawn, disinterested | Frequent to constant quivering chin, clenched jaw |
| Legs | Normal position or relaxed | Uneasy, restless, tense | Kicking or legs drawn up |
| Activity | Lying quietly, normal position, moves easily | Squirming, shifting back and forth, tense | Arched, rigid or jerking |
| Cry | No crying (awake or asleep) | Moans or whimpers, occasional complaint | Crying steadily, screams or sobs, frequent complaints |
| Consolability | Content, relaxed | Reassured by touching, hugging or being talked to, distractible | Difficult to console or comfort |

Each of the categories (F) Face (L) Legs (A) Activity (C) Cry (C) Consolability is scored from 0–2, which results in a total score between 0 and 10.

From *The FLACC: A behavioral scale for scoring postoperative pain in young children*, by S Merkel and others, 1997, *Pediatr Nurse* 23 (3), pp. 293-297. Copyright 1997 by Jannetti Co. University of Michigan Medical Center. Reprinted with permission.

<http://www.childcancerpain.org/content.cfm?content=assess13>

Faces pain rating scale



| | | | | | |
|---------|--------------------|---------------------|-----------------|-------------|------------|
| 0 | 1 | 2 | 3 | 4 | 5 |
| No pain | Hurts a little bit | Hurts a little more | Hurts even more | Hurts a lot | Worst pain |

Consists of six cartoon faces ranging from a smiling face for 'no pain' to a tearful face for 'worst pain'

Recommended age: Children as young as 3 years

Adapted from *Nursing Care of Infants and Children, 3rd ed.*, by LF Whaley and DL Wong, 1987. St Louis: Mosby. Copyright 1987, Mosby. Reprinted with permission.

<http://www.med.umich.edu/pain/pediatric.htm#ad>

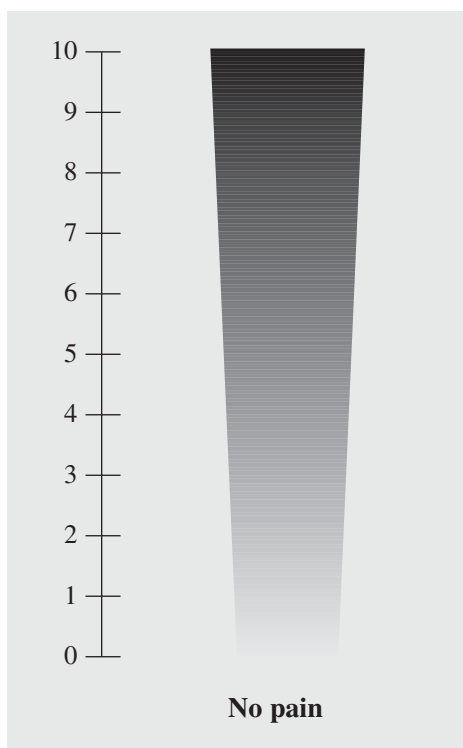
Numeric rating scale

Ask the patient to rate their pain intensity on a scale of 0 (no pain) to 10 (the worst pain imaginable). Some patients are unable to do this with only verbal instructions, but may be able to look at a number scale and point to the number that describes the intensity of their pain.

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Colour scale

This scale is a coloured stripe in which colour gradually changes from white (no pain) through shades of pink to dark red (worst possible pain). Ask the patient to point to the area on the scale that shows their level of pain. To obtain a number for documentation use the scale parallel to the colour stripe to find the number corresponding to the area where the patient points.



Word graphic scale

This scale can be used with patients as young as 6 years of age. It uses a line with words to describe pain intensity from 'no pain' to 'worst possible pain'. Show and explain the scale to the patient and then ask him or her to point (or mark) anywhere along the line that shows how much pain they have. To find a number for documentation count the black dots, starting with zero at the far left, to the area where the patient points, up to ten at the far right.

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Appendix 3A: ARV drugs and TMP/SMZ paediatric

| Weight | | Abacavir (Ziagen®) | | Stavudine (Zerit®, d4T) | Lamivudine (Epivir®, 3TC) | | Zidovudine (Retrovir®, ZDV, AZT) | |
|-------------|-------------|------------------------|------------------|-------------------------------|---------------------------------|--------------------|--|----------------------------|
| | | 8 mg/kg twice daily | | 1 mg/kg twice daily | 4 mg/kg twice daily | | 240 mg/m twice daily | |
| Kg | | Liquid 20 mg/ml | Tablet 300 mg | Capsules 15, 20, 30 mg | Liquid 10 mg/ml | Tablet 150 mg | Liquid 10 mg/ml | Capsule 100 mg |
| 5–6.9 | | 2 ml | | | 2 ml | | 7 ml | |
| 7–9.9 | | 3 ml | | 15 mg | 3 ml | | 9 ml | 1 cap |
| 10–11.9 | | 4 ml | | 15 mg or (20 mg) | 4 ml | | 12 ml | 1 cap |
| 12–14.9 | | 5 ml | | 15 mg or (20 mg) | 5 ml | | 14 ml | 1 cap |
| 15–16.9 | | 6 ml | | 15 mg or (20 mg) | 6 ml | ½ tab | 15 ml | 2 caps |
| 17–19.9 | | 7 ml | ½ tab | 20 mg | 7 ml | ½ tab | 17 ml | 2 caps |
| 20–24.9 | | 9 ml | ½ tab | 20 mg | 9 ml | ½ tab | 20 ml | 2 caps |
| 25– 29.9 | 25– 27.9 | 11 ml | ½ tab | 30 mg | 11 ml | 1 tab ² | 24 ml | 3 caps or 300 mg tab |
| | 28– 29.9 | 12 ml | 1 tab | | | | | |
| 30–34.9 | | 13 ml | 1 tab | 30 mg | 13 ml | 1 tab | 27 ml | 3 caps or 300 mg tab |
| 35–40 | | | 15 ml | 1 tab | 30 mg | 15 ml | 1 tab | 30 ml 300 mg tab |

dosing chart for use in resource-constrained settings

| Didanosine (Videx®, DDI) | Nevirapine (Viramune®, NVP) | | | | | |
|------------------------------------|---|------------------|--------------------|------------------------|--------------------|------------------------|
| 120 mg/m twice daily | Induction dose: 4 mg/kg once daily for first 14 days, then give maintenance dose | | Maintenance dose | | | |
| | | | | | | |
| Chewable tablets 20, 50, 100 mg | Liquid 10 mg/ml | Tablet 200 mg | Liquid 10 mg/ml | Tablet 200 mg | Liquid 10 mg/ml | Tablet 200 mg |
| | 2 ml | | 4 ml | | | |
| 25 mg + 25 mg | 3 ml | | 6 ml | | | |
| 25 mg + 25 mg | 4 ml | | 8 ml | ½ tab | | |
| 50 mg + 25 mg | 5 ml | | 9 ml | ½ tab | | |
| 50 mg + 25 mg | 6 ml | | 10 ml | ½ tab | | |
| 50 mg + 50 mg | 7 ml | | 13 ml | 1 tab am + ½ tab pm | | |
| 50 mg + 50 mg | 9 ml | ½ tab | 16 ml | 1 tab am + ½ tab pm | 9 ml | ½ tab |
| 100 mg + 25 mg | 11 ml | ½ tab | 20 ml | 1 tab | 11 ml | ½ tab |
| 100 mg + 25 mg | 13 ml | 1 tab | | | 13 ml | 1 tab am + ½ tab pm |
| 3 caps or 25 mg | 100 mg + | 15 ml | 1 tab | | 15 ml | 1 tab am + ½ tab pm |

(Continued on next page)

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Appendix 3A: ARV Drugs & TMP/SMZ paediatric dosing chart for use in resource-constrained settings (Cont.)

| Weight | | Efavirenz (Stocrin [®] , Sustiva [®] , EFV) | Lopinavir/ritonavir (Kaletra [®]) | |
|---------|---------|---|---|---------------------------------------|
| | | Dose as shown once daily | <15 kg + 12 mg lop/kg ≥15 kg = 10 mg lop/kg twice daily (lop = lopinavir; r = ritonavir) | |
| Kg | | Capsules 50,100, 200 mg | Liquid 80 mg lop/ ml | Capsule 133.3/ 33.3 mg lop/r |
| 5–6.9 | | | | |
| 7–9.9 | | | 1.5 ml | |
| 10–11.9 | | 200 mg | 2 ml | |
| 12–14.9 | | 200 mg | 2 ml | |
| 15–16.9 | | 200 mg + 50 mg | 2.5 ml | 1 cap |
| 17–19.9 | | 200 mg + 50 mg | 2.5 ml | 2 caps |
| 20–24.9 | | 200 mg + 100 mg | 3 ml | 2 caps |
| 25–29.9 | | 200 mg + 100 mg + 50 mg | 3.5 ml | 2 caps |
| 30–34.9 | 30–32.9 | 200 mg + 100 mg + 50 mg | 4 ml | 3 caps |
| | 33–34.9 | 200 mg + 200 mg | | |
| 35–40 | | 200 mg + 200 mg | 5 ml | 3 caps |

| Nelfinavir (Viracept®) | Trimethoprim/sulfamethoxazole TMP/SMZ (Septrain®, Bactrim®, various) | |
|---------------------------|---|--|
| 60 mg/kg twice daily | 4 mg/kg once daily (for prophylaxis against opportunistic illnesses; dose for treatment of bacterial and protozoal infections are higher than listed here) | |
| Tablet 250 mg | Liquid 8 mg/ ml | Single-strength (SS) tablet 80 mg TMP/ 400 mg SMZ |
| 2 tabs | 3 ml | |
| 2 tabs | 4 ml | ½ SS tab |
| 2 tabs | 5 ml | ½ SS tab |
| 3 tabs | 7 ml | 1 SS tab |
| 3 tabs | 8 ml | 1 SS tab |
| 4 tabs | 9 ml | 1 SS tab |
| 5 tabs | 11 ml | 1 SS tab |
| 5 tabs | 14 ml | 2 SS tabs |
| 5 tabs | 17 ml | 2 SS tabs |
| 5 tabs | 20 ml | 2 SS tabs |

Appendix 3B: Paediatric ARV and co-trimoxazole dosing

Paediatric dosing in resource-constrained settings

Developed collaboratively by:

1. Global AIDS Program, Division of HIV/AIDS Prevention National Center for HIV, STD & TB Prevention, Centres for Disease Control and Prevention (CDC), Atlanta, Georgia, USA
2. Home-based AIDS Care Program, Tororo, Uganda Global AIDS Program, CDC Uganda, Entebbe, Uganda
3. Baylor International Pediatric AIDS Initiative Baylor College of Medicine, Houston, Texas, USA
4. The MTCT-Plus Initiative Columbia University Mailman School of Public Health, New York, New York, USA

Abacavir – Tablets may be swallowed whole, or crushed and dispersed in water or into a small amount of food and immediately ingested.

Stavudine – Capsules may be opened and dispersed in water or into a small amount of food and immediately ingested. Stavudine capsules are not recommended for use in children <7 kg since dose size from smallest capsule is stable at room temperature for 24 hours or under refrigeration for 30 days. In settings where households do not have access to refrigeration, the oral solution should not be used. In the event that 15 mg capsules are not available, consider giving the 20 mg capsule to children in the 10–16.9 kg range. Though these may result in doses higher than the recommended 1 mg/kg dose, higher doses than this have been used in clinical trials and were generally well tolerated. However for children <10 kg a capsule size larger than 15 mg is not advised.

Lamivudine – Tablets are not scored, but can be divided into two equal halves with a pill splitter in the pharmacy. Tablets may be crushed and dispersed in water or onto a small amount of food and immediately ingested. Oral solution should be used in children <15 kg since accurate dosing with tablets is not practical in smaller children. Oral solution is stable at room temperature. The dose changes from ½ to 1 tablet as a child enters this weight range; however, lamivudine has few adverse effects and this dose should be generally well tolerated.

Zidovudine – Capsules may be opened and dispersed in water or onto a small amount of food and immediately ingested. Tablets may be crushed and dispersed in water or onto a small amount of food and immediately

ingested. Oral solution should be used in children <7 kg since accurate dosing with capsules is not practical in smaller children. Oral solution is stable at room temperature. Weight-based doses were determined by using body surface area values calculated from typical heights for weight.

Didanosine – Must use 2 tablets with each dose to provide adequate antacid to buffer stomach acid to allow absorption. The tablets may be dispersed in water before administering. Alternatively, the tablets may be chewed and swallowed. Must be administered on an empty stomach at least 30 minutes before or 2 hours after eating. Oral suspension requires addition of antacid and water and is stable at room temperature for only 24 hours or under refrigeration for 30 days. In settings where households do not have access to refrigeration, the oral suspension should not be used. If taken with indinavir, the drugs must be separated by one hour. Weight-based doses were determined by using body surface area values calculated from typical heights for weight.

Nevirapine – Tablet is scored and may be divided into equal parts. Tablet may be crushed and dispersed in water or onto a small amount of food and immediately ingested. Oral solution is stable at room temperature. Nevirapine induction dose is 4 mg/kg once daily for 14 days. If no rash develops, it is followed by a maintenance dose of 7 mg/kg twice daily for children <8 years old, or 4 mg/kg twice daily for children >8 years old. Consider using liquid for the induction dose in children in this weight range to give a more precise dose. If using tablets for children in this weight range, this chart suggests 1 tablet in the morning and ½ tablet in the afternoon to yield a dose that approximates that of the liquid. The half-life of nevirapine is long enough that the fluctuation in drug levels from this staggered dose is considered clinically acceptable.

Efavirenz – Capsules may be opened and dispersed in water or onto a small amount of food and immediately ingested. Oral solution is stable at room temperature. Dose for oral solution is greater than that for capsules or tablets. The dose and pharmacokinetics of the oral solution are not as well established as with the capsules and tablet. Thus, although the liquid may be available in some areas, it is advisable to use the capsule or tablet forms when possible.

Lopinavir/ritonavir – Dose is calculated based on lopinavir component. Capsules may NOT be opened or crushed and must be swallowed whole, but may be used for children who can swallow capsules. Capsules or oral solution should be taken with food. Capsules and oral solution must be refrigerated until dispensed. After removal from refrigeration, capsules and

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oral solution are only stable for 60 days at room temperature (up to 25°C). Where temperatures are expected to exceed 25°C, the feasibility of dispensing smaller amounts and giving more frequent refills should be considered (for example, no more than monthly supplies dispensed at one time). Lopinavir/ritonavir is not recommended for children <6 months old. The amount of solution has been rounded up to the nearest ½ ml from manufacturer's recommendation for easier measurement. In the 17–19.9 kg range, two capsules twice daily would result in a dose that is 40–60% higher than recommended, however, using only one capsule twice daily would result in a dose that is 20–30% lower than recommended. Consider liquid for children in this weight range.

Nelfinavir – Tablets may be crushed and dispersed in water or onto a small amount of food and immediately ingested. Must be taken with food to improve absorption. Oral powder for administration requires complicated administration technique that may not be practical in resource-poor settings. Doses for children <2 years of age are not well established. The dose listed for children <10 kg is within a range of up to 75 mg/kg twice daily. This has been used for small children by some clinicians.

Indinavir – Capsules may be opened and dispersed in water or onto a small amount of food and immediately ingested. Must be taken on an empty stomach (1 hour before or 2 hours after a meal). Patients must drink lots of water during the day while taking indinavir to prevent development of kidney problems. If taking didanosine, the drugs must be separated by one hour. Weight-based doses were determined by using body surface area values calculated from typical heights for weight.

Trimethoprim/sulfamethoxazole – Recommendations for prophylaxis against opportunistic infections for HIV-infected children are to give 5 mg/kg twice daily for 3 consecutive days/week. Considering the dosage strength of the TMP/SMZ suspension and in efforts to support medication adherence, dosing children once daily every day of the week may be simpler. The dose of 4 mg/kg is an easy conversion from the child's weight to the mls of suspension because the 8 mg/ml dosage strength of the TMP/SMZ suspension allows the dose to be calculated as ½ ml of suspension per kg. Doses are higher for treatment of bacterial and protozoal infections and other sources should be consulted.

Appendix 4: ARVs for children – side effects and adverse events

| Side effects and adverse events of ARVs in children | | |
|---|-------------------------|---|
| Class | Drug | Side effects/adverse events |
| NRTI | Zidovidine (Retrovir®) | Anaemia, granulocytopenia, myopathy, lactic acidosis |
| | Didanosine ddI (Videx®) | Common: abdominal pain, nausea and vomiting Uncommon: pancreatitis, peripheral neuropathy, lactic acidosis |
| | Stavudine (Zerit®) | Common: headache, rash, gastrointestinal Uncommon: pancreatitis and peripheral neuropathy, lactic acidosis |
| | Abacavir (Ziagen®) | Hypersensitivity reaction (with or without rash) – may be fatal in adults and children |
| | Lamivudine (3TC) | Common: headache, fatigue and abdominal pain Uncommon: pancreatitis and peripheral neuropathy, lactic acidosis |
| | NNRTI | Nevirapine (Viramune®) |
| Efavirenz (Stocrin®) | | Skin rash CNS – Sleep disturbance, confusion, abnormal thinking. Teratogenic in primates |
| PI | Ritonavir (Norvir®) | Nausea, vomiting, diarrhoea Hypercholesterolaemia and hypertriglyceridaemia |
| | Nelfinavir (Viracept®) | Diarrhoea Can exacerbate chronic liver disease Hypercholesterolaemia and hypertriglyceridaemia |
| | Kaletra® | Nausea, vomiting, diarrhoea Hypercholesterolaemia and hypertriglyceridaemia |

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Appendix 5: Grading of adverse events

| Feature | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|----------------------------------|-------------------|---|---|---|
| Haematology | | | | |
| Haemoglobin (g/dL) Age >2 yrs | 10–10.9 | 7–9.9 | <7.0 | Cardiac failure 2° to anaemia |
| Absolute neutrophil count | 0.750 – 1.2 | 0.400–0.749 | 0.25–0.399 | <0.250 |
| Platelets (cells/mm) | | 50 000–75 000 | 25 000–49.999 | <25 000 or bleeding |
| Gastro-intestinal | | | | |
| Bilirubin | 1.1–1.9 x N* | 2.0–2.9 x N | 3.0–7.5 x N | >7.5 x N |
| AST | 1.1–4.9 x N | 5.0–9.9 x N | 10.0–15.0 x N | >15.0 x N |
| ALT | 1.1–4.9 x N | 5.0–9.9 x N | 10.0–15.0 x N | >15.0 x N |
| GT | 1.1–4.9 x N | 5.0–9.9 x N | 10.0–15.0 x N | >15.0 x N |
| Pancreatic Amylase | 1.1–1.4 x N | 1.5–1.9 x N | 2.0–3.0 x N | >3.0 x N |
| Abdominal pain | Mild | Moderate No Rx needed | Moderate Rx needed | Hospital and Rx |
| Diarrhoea | Soft stools | Liquid stools | Liquid stools + mild dehydration, bloody stools | Severe dehydration or hypotensive shock |
| Constipation | Mild | Moderate | Severe | Distention + vomiting |
| Nausea | Mild | Moderate | Severe, little oral intake | Unable to take any food or fluid for >24 hrs |
| Vomiting | <1 episode/day | 1–3 episodes/day or duration >3 days | >3 episodes/day or duration >7 days | Intractable vomiting |
| Allergic/dermatological | | | | |
| Allergy | Itch without rash | Itchy rash | Mild urticaria | Severe urticaria Anaphylaxis, angioedema |
| Drug fever | | 38.5–40.0°C | >40°C | Sustained fever: >40°C >5 days |
| Cutaneous | | Diffuse maculopapular rash dry desquamation | Vesiculation, ulcers | Exfoliative dermatitis, Steven-Johnson or E. multiforme, moist desquamation |

| Feature | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|-------------------------------|---|--|---|
| Nervous system | | | | |
| Mental status or behaviour | Changes with normal function | Changes requiring drugs or other therapy: or mild lethargy, sedation, or somnolence that resolves with rest | Changes not improved with drugs or other therapy: or onset of confusion, memory loss, lethargy, sedation, or somnolence not resolved by rest | Delirium, obtundation, coma or psychosis or Grade 3 toxicity with no response to dose reduction |
| Neuropathy/ lower motor neuropathy | None | Mild transient paresthesia | See below** | See below*** |
| Other | | | | |
| Clinical symptoms not otherwise specified above | No therapy, monitor condition | May require minimal intervention and monitoring | Requires care or possible hospitalisation | Requires active medical intervention, hospitalisation or hospice care |

* N = normal

** Persistent or progressive paresthesias, burning sensation of feet or mild dysesthesia, no weakness, mild tendon reflex changes, no sensory loss.

*** Onset of significant weakness, decrease or loss of DTR, sensory loss in stocking-glove distribution, multiple cranial nerve involvement; bladder or bowel dysfunction, fasciculations, respiratory embarrassment from chest wall weakness, Grade 3 features not resolving on drug dose reduction.

Appendix 6: Guidelines for adverse drug reaction (ADR) reporting

National Pharmacovigilance Programme

The Medicines Control Council (MCC) has a responsibility to ensure the safety, efficacy and quality of all medicines used by the South African public. The National Pharmacovigilance Programme is co-ordinated by the MCC and has two dedicated Units responsible for the monitoring of the safety of medicines. The National Adverse Drug Event Monitoring Centre (NADEMC) in Cape Town monitors the safety of all registered medicines in South Africa. In addition, a focused surveillance unit at MEDUNSA is responsible for monitoring the safety of antiretroviral (ARV) medicines and complementary medicines. The unit at MEDUNSA is also responsible for monitoring the safety of unregistered medicines used during clinical trials.

What is pharmacovigilance?

Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). The goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health.

What is an ADR?

The Medicines Control Council (MCC) defines an adverse drug reaction (ADR) or adverse reaction as a response to a medicine which is noxious and unintended, including lack of efficacy. It can occur at any dosage and can also result from overdose, misuse or abuse of a medicine.

Who should report ADRs?

All health-care workers, including doctors, dentists, pharmacists, nurses and other health professionals are encouraged to report all suspected adverse reactions to medicines (including vaccines, X-ray contrast media, traditional and herbal remedies). This is especially important when the reaction is not in the package insert, is potentially serious or clinically significant.

What happens to a report?

All ADR reports are entered into a national ADR database. Each report is evaluated to assess the causal relationship between the event and the medicine. A well-completed adverse drug reaction/product quality form submitted could result in any of the following:

- Additional investigations into the use of the medicine in South Africa
- Educational initiatives to improve the safe use of the medicine
- Appropriate package insert changes to include the potential for the reaction
- Changes in the scheduling or manufacture of the medicine to make it safer

The purpose of ADR reporting is to reduce the risks associated with the use of medicines and to ultimately improve patient care.

Will reporting have any negative consequences on the health worker or the patient?

An adverse drug reaction report does not constitute an admission of liability or that the health professional contributed to the event in any way. The outcome of a report, together with any important or relevant information relating to the reaction, will be sent back to the reporter as appropriate. The details of a report are stored in a confidential database. The names of the reporter or any other health professionals named on a report and the patient will be removed before any details about a specific adverse drug reaction are used or communicated to others. The information is only meant to improve the understanding of the medicines used in the country.

Is the event possibly an ADR?

The following factors should be considered when an adverse drug reaction is suspected:

1. What exactly is the nature of the reaction?
(Describe the reaction as clearly as you can, and where possible provide an accurate diagnosis.)