CLINICAL RESOURCE GUIDE

VERSION 1.7

SEPTEMBER 2014

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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- National Department of Health, HIV, AIDS, STI Cluster
- National Department of Health, Tuberculosis Control and Management Cluster
- U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
- Centers for Disease Control and Prevention (CDC)
- U.S. Health Resources and Services Administration (HRSA)
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PAGE 2

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PAGE 2

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PAGE 2

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PAGE 3

Clinical Resource Guide

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PAGE 3

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- Primary Care 101. National Department of Health, South Africa. 2013/14.

PAGE 3

Table of Contents

HIV TESTING AND STAGING

HIV Testing Algorithm ..... page 10
Paediatric Testing Algorithm ..... page 11
Recommended Testing Algorithm for Abandoned Children ..... page 13
Clinical Staging for Adults, Adolescents and Children ..... page 15

PHYSICAL EXAM

SOAP Card: Subjective ..... page 19
SOAP Card: Objective ..... page 20
SOAP Card: Assessment ..... page 21
SOAP Card: Plan ..... page 22
Physical Exam Checklist: Head, Eyes, Ears, Nose and Throat (HEENT) ..... page 23
Physical Exam Checklist: Cardiovascular ..... page 25
Physical Exam Checklist: Pulmonary ..... page 26
Physical Exam Checklist: Gastrointestinal ..... page 27
Physical Exam Checklist: Genito-Urinary ..... page 28
Physical Exam Checklist: Musculoskeletal ..... page 29
Physical Exam Checklist: Skin/Derm ..... page 30
Physical Exam Checklist: Neuro ..... page 31

OPPORTUNISTIC INFECTIONS/CLINICAL COMPLICATIONS IN ADULTS

Bacterial Meningitis ..... page 33
Bacterial Pneumonia ..... page 34
Cryptococcal Meningitis ..... page 36
Cryptococcal ..... page 38
Cryptosporidiosis ..... page 39
Cytomegalovirus ..... page 40
Giardiasis ..... page 42
Herpes Simplex Virus ..... page 43
Herpes Zoster ..... page 45
Intestinal Entamoeba ..... page 46
Kaposi's Sarcoma ..... page 47
Molluscum Contagiosum ..... page 48
Oral and Oesophageal Candidiasis ..... page 49
Oral Hairy Leukoplakia ..... page 50
Pneumocystis Jiroveci Pneumonia ..... page 51
TB Meningitis ..... page 53

Table of Contents

HIV TESTING AND STAGING

HIV Testing Algorithm ..... page 10
Paediatric Testing Algorithm ..... page 11
Recommended Testing Algorithm for Abandoned Children ..... page 13
Clinical Staging for Adults, Adolescents and Children ..... page 15

PHYSICAL EXAM

SOAP Card: Subjective ..... page 19
SOAP Card: Objective ..... page 20
SOAP Card: Assessment ..... page 21
SOAP Card: Plan ..... page 22
Physical Exam Checklist: Head, Eyes, Ears, Nose and Throat (HEENT) ..... page 23
Physical Exam Checklist: Cardiovascular ..... page 25
Physical Exam Checklist: Pulmonary ..... page 26
Physical Exam Checklist: Gastrointestinal ..... page 27
Physical Exam Checklist: Genito-Urinary ..... page 28
Physical Exam Checklist: Musculoskeletal ..... page 29
Physical Exam Checklist: Skin/Derm ..... page 30
Physical Exam Checklist: Neuro ..... page 31

OPPORTUNISTIC INFECTIONS/CLINICAL COMPLICATIONS IN ADULTS

Bacterial Meningitis ..... page 33
Bacterial Pneumonia ..... page 34
Cryptococcal Meningitis ..... page 36
Cryptococcal ..... page 38
Cryptosporidiosis ..... page 39
Cytomegalovirus ..... page 40
Giardiasis ..... page 42
Herpes Simplex Virus ..... page 43
Herpes Zoster ..... page 45
Intestinal Entamoeba ..... page 46
Kaposi's Sarcoma ..... page 47
Molluscum Contagiosum ..... page 48
Oral and Oesophageal Candidiasis ..... page 49
Oral Hairy Leukoplakia ..... page 50
Pneumocystis Jiroveci Pneumonia ..... page 51
TB Meningitis ..... page 53

Table of Contents

HIV TESTING AND STAGING

HIV Testing Algorithm ..... page 10
Paediatric Testing Algorithm ..... page 11
Recommended Testing Algorithm for Abandoned Children ..... page 13
Clinical Staging for Adults, Adolescents and Children ..... page 15

PHYSICAL EXAM

SOAP Card: Subjective ..... page 19
SOAP Card: Objective ..... page 20
SOAP Card: Assessment ..... page 21
SOAP Card: Plan ..... page 22
Physical Exam Checklist: Head, Eyes, Ears, Nose and Throat (HEENT) ..... page 23
Physical Exam Checklist: Cardiovascular ..... page 25
Physical Exam Checklist: Pulmonary ..... page 26
Physical Exam Checklist: Gastrointestinal ..... page 27
Physical Exam Checklist: Genito-Urinary ..... page 28
Physical Exam Checklist: Musculoskeletal ..... page 29
Physical Exam Checklist: Skin/Derm ..... page 30
Physical Exam Checklist: Neuro ..... page 31

OPPORTUNISTIC INFECTIONS/CLINICAL COMPLICATIONS IN ADULTS

Bacterial Meningitis ..... page 33
Bacterial Pneumonia ..... page 34
Cryptococcal Meningitis ..... page 36
Cryptococcal ..... page 38
Cryptosporidiosis ..... page 39
Cytomegalovirus ..... page 40
Giardiasis ..... page 42
Herpes Simplex Virus ..... page 43
Herpes Zoster ..... page 45
Intestinal Entamoeba ..... page 46
Kaposi's Sarcoma ..... page 47
Molluscum Contagiosum ..... page 48
Oral and Oesophageal Candidiasis ..... page 49
Oral Hairy Leukoplakia ..... page 50
Pneumocystis Jiroveci Pneumonia ..... page 51
TB Meningitis ..... page 53

Toxoplasmosis ..... page 55
Viral Encephalitis ..... page 57
Viral Warts ..... page 58
Wasting Syndrome ..... page 59

ANTIRETROVIRAL THERAPY

ART Initiation: Adults and Adolescents ..... page 61
ART Intitation: Children ..... page 62
1st Line ART in Adults and Adolescents ..... page 63
2nd and 3rd Line ART in Adults and Adolescents ..... page 64
1st Line ART in Infants and Children ..... page 65
2nd and 3rd Line ART in Infants and Children ..... page 66
ART Monitoring for Adults & Adolescents ..... page 67
ART Monitoring for Infants and Children ..... page 69
Treatment Failure ..... page 71
Side Effects by ARV Class ..... page 72
Lactic Acidosis Diagnosis and Management ..... page 73
Cotrimoxazole ..... page 74
Cotrimoxazole Initiation ..... page 75
Cotrimoxazole Paediatric Dosing ..... page 76

PMTCT

PMTCT Algorithm ..... page 78
PMTCT - Postnatal HIV + Diagnosis ..... page 79
Postnatal Care for Infants ..... page 80
Paediatric Negative HIV Test Result ..... page 81
Paediatric Positive HIV Test Result ..... page 82
ART Monitoring for Maternal Regimens ..... page 83
Maternal Regimens (HIV-Positive) ..... page 84
Infant Regimens (HIV-Positive Mother) ..... page 85
Nevirapine Infant Dosing Guide ..... page 86

TUBERCULOSIS

TB Symptom Screening for Adults and Children ..... page 88
Baseline Screening of TB ..... page 89
Smear Reporting ..... page 90
Xpert Diagnostic Algorithm ..... page 91
TB diagnosis using the Line Probe Assay (LPA) ..... page 93

Toxoplasmosis ..... page 55
Viral Encephalitis ..... page 57
Viral Warts ..... page 58
Wasting Syndrome ..... page 59

ANTIRETROVIRAL THERAPY

ART Initiation: Adults and Adolescents ..... page 61
ART Intitation: Children ..... page 62
1st Line ART in Adults and Adolescents ..... page 63
2nd and 3rd Line ART in Adults and Adolescents ..... page 64
1st Line ART in Infants and Children ..... page 65
2nd and 3rd Line ART in Infants and Children ..... page 66
ART Monitoring for Adults & Adolescents ..... page 67
ART Monitoring for Infants and Children ..... page 69
Treatment Failure ..... page 71
Side Effects by ARV Class ..... page 72
Lactic Acidosis Diagnosis and Management ..... page 73
Cotrimoxazole ..... page 74
Cotrimoxazole Initiation ..... page 75
Cotrimoxazole Paediatric Dosing ..... page 76

PMTCT

PMTCT Algorithm ..... page 78
PMTCT - Postnatal HIV + Diagnosis ..... page 79
Postnatal Care for Infants ..... page 80
Paediatric Negative HIV Test Result ..... page 81
Paediatric Positive HIV Test Result ..... page 82
ART Monitoring for Maternal Regimens ..... page 83
Maternal Regimens (HIV-Positive) ..... page 84
Infant Regimens (HIV-Positive Mother) ..... page 85
Nevirapine Infant Dosing Guide ..... page 86

TUBERCULOSIS

TB Symptom Screening for Adults and Children ..... page 88
Baseline Screening of TB ..... page 89
Smear Reporting ..... page 90
Xpert Diagnostic Algorithm ..... page 91
TB diagnosis using the Line Probe Assay (LPA) ..... page 93

TABLE OF CONTENTS 5

Toxoplasmosis ..... page 55
Viral Encephalitis ..... page 57
Viral Warts ..... page 58
Wasting Syndrome ..... page 59

ANTIRETROVIRAL THERAPY

ART Initiation: Adults and Adolescents ..... page 61
ART Intitation: Children ..... page 62
1st Line ART in Adults and Adolescents ..... page 63
2nd and 3rd Line ART in Adults and Adolescents ..... page 64
1st Line ART in Infants and Children ..... page 65
2nd and 3rd Line ART in Infants and Children ..... page 66
ART Monitoring for Adults & Adolescents ..... page 67
ART Monitoring for Infants and Children ..... page 69
Treatment Failure ..... page 71
Side Effects by ARV Class ..... page 72
Lactic Acidosis Diagnosis and Management ..... page 73
Cotrimoxazole ..... page 74
Cotrimoxazole Initiation ..... page 75
Cotrimoxazole Paediatric Dosing ..... page 76

PMTCT

PMTCT Algorithm ..... page 78
PMTCT - Postnatal HIV + Diagnosis ..... page 79
Postnatal Care for Infants ..... page 80
Paediatric Negative HIV Test Result ..... page 81
Paediatric Positive HIV Test Result ..... page 82
ART Monitoring for Maternal Regimens ..... page 83
Maternal Regimens (HIV-Positive) ..... page 84
Infant Regimens (HIV-Positive Mother) ..... page 85
Nevirapine Infant Dosing Guide ..... page 86

TUBERCULOSIS

TB Symptom Screening for Adults and Children ..... page 88
Baseline Screening of TB ..... page 89
Smear Reporting ..... page 90
Xpert Diagnostic Algorithm ..... page 91
TB diagnosis using the Line Probe Assay (LPA) ..... page 93

TABLE OF CONTENTS 5

Monitoring Algorithm for Bacteriologically Confirmed PTB Patients....page 95
Management of Treatment Interruption....page 96
Regimen 1: Treatment for New and Previously Treated Patients....page 98
Standard Treatment Doses for TB....page 99
Isoniazid Preventive Therapy in Adults....page 100
Isoniazid Preventive Therapy In Children....page 103
TB Diagnosis in Children....page 104
TB Treatment Regimens for Children < 8 Years of Age or < 30kg....page 106
Regimen 3A: For Uncomplicated TB With Low Bacillary Load....page 107
Regimen 3B: For Complicated TB, High Bacillary Load....page 109
Treatment for TB Meningitis....page 111

DRUG RESISTANT TUBERCULOSIS

Drug Resistant TB - Definitions....page 113
Treatment of Mono/Poly Resistant TB....page 114
Standard MDR-TB and XDR-TB Regimens....page 115
Dosing of Standard M(X)DR-TB Regmen in Adults....page 116
Dosing of Standard MDR-TB Drugs in Children < 8 years....page 119
Dosing of Additional Second-line TB Drugs in Paediatrics....page 120
Common Side Effects During MDR-TB Treatment....page 121
Management of Patients Who Default MDR-TB Treatment....page 123
Monitoring During M(X)DR-TB Treatment....page 125
Clinical Follow-Up During M(X)DR-TB Treatment....page 126

TUBERCULOSIS / HIV

Antiretroviral Treatment for Adults with Concomitant TB....page 128
Antiretroviral Treatment in Adult Patients with DR-TB....page 129
TB, HIV and STI Drug Metabolism Inducers and Inhibitors....page 130
Prohibited Drug Combinations with Specific ART....page 131
Shared Side Effects of TB and ART....page 132

SEXUALLY TRANSMITTED INFECTIONS

Male Urethritis Syndrome (MUS)....page 134
Vaginal Discharge Syndrome (VDS)....page 135
Lower Abdominal Pain (LAP)....page 137
Genital Ulcer Syndrome (GUS)....page 139
Scrotal Swelling (SSW)....page 140
Balanitis/Balanoposthitis (BAL)....page 141

Monitoring Algorithm for Bacteriologically Confirmed PTB Patients....page 95
Management of Treatment Interruption....page 96
Regimen 1: Treatment for New and Previously Treated Patients....page 98
Standard Treatment Doses for TB....page 99
Isoniazid Preventive Therapy in Adults....page 100
Isoniazid Preventive Therapy In Children....page 103
TB Diagnosis in Children....page 104
TB Treatment Regimens for Children < 8 Years of Age or < 30kg....page 106
Regimen 3A: For Uncomplicated TB With Low Bacillary Load....page 107
Regimen 3B: For Complicated TB, High Bacillary Load....page 109
Treatment for TB Meningitis....page 111
DRUG RESISTANT TUBERCULOSIS
Drug Resistant TB - Definitions....page 113
Treatment of Mono/Poly Resistant TB....page 114
Standard MDR-TB and XDR-TB Regimens....page 115
Dosing of Standard M(X)DR-TB Regmen in Adults....page 116
Dosing of Standard MDR-TB Drugs in Children < 8 years....page 119
Dosing of Additional Second-line TB Drugs in Paediatrics....page 120
Common Side Effects During MDR-TB Treatment....page 121
Management of Patients Who Default MDR-TB Treatment....page 123
Monitoring During M(X)DR-TB Treatment....page 125
Clinical Follow-Up During M(X)DR-TB Treatment....page 126
TUBERCULOSIS / HIV
Antiretroviral Treatment for Adults with Concomitant TB....page 128
Antiretroviral Treatment in Adult Patients with DR-TB....page 129
TB, HIV and STI Drug Metabolism Inducers and Inhibitors....page 130
Prohibited Drug Combinations with Specific ART....page 131
Shared Side Effects of TB and ART....page 132
SEXUALLY TRANSMITTED INFECTIONS
Male Urethritis Syndrome (MUS)....page 134
Vaginal Discharge Syndrome (VDS)....page 135
Lower Abdominal Pain (LAP)....page 137
Genital Ulcer Syndrome (GUS)....page 139
Scrotal Swelling (SSW)....page 140
Balanitis/Balanoposthitis (BAL)....page 141
TABLE OF CONTENTS 6

Monitoring Algorithm for Bacteriologically Confirmed PTB Patients....page 95
Management of Treatment Interruption....page 96
Regimen 1: Treatment for New and Previously Treated Patients....page 98
Standard Treatment Doses for TB....page 99
Isoniazid Preventive Therapy in Adults....page 100
Isoniazid Preventive Therapy In Children....page 103
TB Diagnosis in Children....page 104
TB Treatment Regimens for Children < 8 Years of Age or < 30kg....page 106
Regimen 3A: For Uncomplicated TB With Low Bacillary Load....page 107
Regimen 3B: For Complicated TB, High Bacillary Load....page 109
Treatment for TB Meningitis....page 111
DRUG RESISTANT TUBERCULOSIS
Drug Resistant TB - Definitions....page 113
Treatment of Mono/Poly Resistant TB....page 114
Standard MDR-TB and XDR-TB Regimens....page 115
Dosing of Standard M(X)DR-TB Regmen in Adults....page 116
Dosing of Standard MDR-TB Drugs in Children < 8 years....page 119
Dosing of Additional Second-line TB Drugs in Paediatrics....page 120
Common Side Effects During MDR-TB Treatment....page 121
Management of Patients Who Default MDR-TB Treatment....page 123
Monitoring During M(X)DR-TB Treatment....page 125
Clinical Follow-Up During M(X)DR-TB Treatment....page 126
TUBERCULOSIS / HIV
Antiretroviral Treatment for Adults with Concomitant TB....page 128
Antiretroviral Treatment in Adult Patients with DR-TB....page 129
TB, HIV and STI Drug Metabolism Inducers and Inhibitors....page 130
Prohibited Drug Combinations with Specific ART....page 131
Shared Side Effects of TB and ART....page 132
SEXUALLY TRANSMITTED INFECTIONS
Male Urethritis Syndrome (MUS)....page 134
Vaginal Discharge Syndrome (VDS)....page 135
Lower Abdominal Pain (LAP)....page 137
Genital Ulcer Syndrome (GUS)....page 139
Scrotal Swelling (SSW)....page 140
Balanitis/Balanoposthitis (BAL)....page 141
TABLE OF CONTENTS 6

Monitoring Algorithm for Bacteriologically Confirmed PTB Patients....page 95
Management of Treatment Interruption....page 96
Regimen 1: Treatment for New and Previously Treated Patients....page 98
Standard Treatment Doses for TB....page 99
Isoniazid Preventive Therapy in Adults....page 100
Isoniazid Preventive Therapy In Children....page 103
TB Diagnosis in Children....page 104
TB Treatment Regimens for Children < 8 Years of Age or < 30kg....page 106
Regimen 3A: For Uncomplicated TB With Low Bacillary Load....page 107
Regimen 3B: For Complicated TB, High Bacillary Load....page 109
Treatment for TB Meningitis....page 111
DRUG RESISTANT TUBERCULOSIS
Drug Resistant TB - Definitions....page 113
Treatment of Mono/Poly Resistant TB....page 114
Standard MDR-TB and XDR-TB Regimens....page 115
Dosing of Standard M(X)DR-TB Regmen in Adults....page 116
Dosing of Standard MDR-TB Drugs in Children < 8 years....page 119
Dosing of Additional Second-line TB Drugs in Paediatrics....page 120
Common Side Effects During MDR-TB Treatment....page 121
Management of Patients Who Default MDR-TB Treatment....page 123
Monitoring During M(X)DR-TB Treatment....page 125
Clinical Follow-Up During M(X)DR-TB Treatment....page 126
TUBERCULOSIS / HIV
Antiretroviral Treatment for Adults with Concomitant TB....page 128
Antiretroviral Treatment in Adult Patients with DR-TB....page 129
TB, HIV and STI Drug Metabolism Inducers and Inhibitors....page 130
Prohibited Drug Combinations with Specific ART....page 131
Shared Side Effects of TB and ART....page 132
SEXUALLY TRANSMITTED INFECTIONS
Male Urethritis Syndrome (MUS)....page 134
Vaginal Discharge Syndrome (VDS)....page 135
Lower Abdominal Pain (LAP)....page 137
Genital Ulcer Syndrome (GUS)....page 139
Scrotal Swelling (SSW)....page 140
Balanitis/Balanoposthitis (BAL)....page 141
TABLE OF CONTENTS 6

Bubo....page 142
Syphilis....page 143
Syphilis Screening of Pregnant Women....page 145
Drug Treatment of More than one STI Syndrome....page 147
Neonatal Conjunctivitis....page 149
Treatment Protocol of Asymptomatic Sexual Partner....page 151
Drug Side Effect Monitoring
Management of Efavirnez-related Central Nervous System Side Effects....page 154
AZT-Related Hematologic Toxicity....page 155
Dyslipidemia Management....page 156
Wasting and Lipodystrophy Management....page 157
Gynecomastia....page 158
Hyperlactatemia and Lactic Acidosis due to NRTI Therapy....page 159
Nausea and Vomiting....page 162
Abdominal Pain....page 163
ARV-Associated Diarrhea Management....page 164
ARV Rash Management Flow Chart....page 165
Abacavir Hypersensitivity Reaction (HSR)....page 166
Peripheral Neuropathy....page 167
Glucose Intolerance, Dibetes, and Metabolic Syndrome....page 168
Effects of ARV's on Glucose Metabolism....page 169
Tenofovir-Related Nephrotoxicity....page 170
Interpreting Blood Results: Alanine Transaminase (ALT)....page 172

Bubo....page 142
Syphilis....page 143
Syphilis Screening of Pregnant Women....page 145
Drug Treatment of More than one STI Syndrome....page 147
Neonatal Conjunctivitis....page 149
Treatment Protocol of Asymptomatic Sexual Partner....page 151
Drug Side Effect Monitoring
Management of Efavirnez-related Central Nervous System Side Effects....page 154
AZT-Related Hematologic Toxicity....page 155
Dyslipidemia Management....page 156
Wasting and Lipodystrophy Management....page 157
Gynecomastia....page 158
Hyperlactatemia and Lactic Acidosis due to NRTI Therapy....page 159
Nausea and Vomiting....page 162
Abdominal Pain....page 163
ARV-Associated Diarrhea Management....page 164
ARV Rash Management Flow Chart....page 165
Abacavir Hypersensitivity Reaction (HSR)....page 166
Peripheral Neuropathy....page 167
Glucose Intolerance, Dibetes, and Metabolic Syndrome....page 168
Effects of ARV's on Glucose Metabolism....page 169
Tenofovir-Related Nephrotoxicity....page 170
Interpreting Blood Results: Alanine Transaminase (ALT)....page 172

TABLE OF CONTENTS 7

Bubo....page 142
Syphilis....page 143
Syphilis Screening of Pregnant Women....page 145
Drug Treatment of More than one STI Syndrome....page 147
Neonatal Conjunctivitis....page 149
Treatment Protocol of Asymptomatic Sexual Partner....page 151
Drug Side Effect Monitoring
Management of Efavirnez-related Central Nervous System Side Effects....page 154
AZT-Related Hematologic Toxicity....page 155
Dyslipidemia Management....page 156
Wasting and Lipodystrophy Management....page 157
Gynecomastia....page 158
Hyperlactatemia and Lactic Acidosis due to NRTI Therapy....page 159
Nausea and Vomiting....page 162
Abdominal Pain....page 163
ARV-Associated Diarrhea Management....page 164
ARV Rash Management Flow Chart....page 165
Abacavir Hypersensitivity Reaction (HSR)....page 166
Peripheral Neuropathy....page 167
Glucose Intolerance, Dibetes, and Metabolic Syndrome....page 168
Effects of ARV's on Glucose Metabolism....page 169
Tenofovir-Related Nephrotoxicity....page 170
Interpreting Blood Results: Alanine Transaminase (ALT)....page 172

TABLE OF CONTENTS 7

HIV TESTING AND STAGING
HIV TESTING AND STAGING
HIV TESTING AND STAGING

HIV Testing Algorithm

Screening HIV test: (Finger Prick)

Screening result reactive: Subject to second confirmatory test.

Screening result non-reactive: Report as negative and provide counselling, encourage client to repeat the test three (3) months after the negative result to exclude the possibility of the window period.

Confirmatory result reactive: Report as HIV Positive and provide counselling; refer for CD4 count, TB screening. Clinical staging and Pre ART management.

Confirmatory result negative: Report as indeterminate/ discordant and explain to client. Send whole blood to lab for ELISA.

ELISA positive: Report as HIV Positive and provide counselling; refer for CD4 count, TB screening. Clinical staging and Pre-ART management.

ELISA non reactive: Report HIV Negative and provide counselling. Encourage client to repeat test three (3) months after negative result to exclude the possibility of the window period.

Source: Policy Guideline for HIV Counselling and Testing (HCT), National Department of Health, 2010

HIV Testing Algorithm

Screening HIV test: (Finger Prick)

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ELISA positive: Report as HIV Positive and provide counselling; refer for CD4 count, TB screening. Clinical staging and Pre-ART management.

ELISA non reactive: Report HIV Negative and provide counselling. Encourage client to repeat test three (3) months after negative result to exclude the possibility of the window period.

Source: Policy Guideline for HIV Counselling and Testing (HCT), National Department of Health, 2010

PAGE 10

HIV Testing Algorithm

Screening HIV test: (Finger Prick)

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Confirmatory result negative: Report as indeterminate/ discordant and explain to client. Send whole blood to lab for ELISA.

ELISA positive: Report as HIV Positive and provide counselling; refer for CD4 count, TB screening. Clinical staging and Pre-ART management.

ELISA non reactive: Report HIV Negative and provide counselling. Encourage client to repeat test three (3) months after negative result to exclude the possibility of the window period.

Source: Policy Guideline for HIV Counselling and Testing (HCT), National Department of Health, 2010

PAGE 10

HIV Testing Algorithm

Screening HIV test: (Finger Prick)

Screening result reactive: Subject to second confirmatory test.

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Confirmatory result reactive: Report as HIV Positive and provide counselling; refer for CD4 count, TB screening. Clinical staging and Pre ART management.

Confirmatory result negative: Report as indeterminate/ discordant and explain to client. Send whole blood to lab for ELISA.

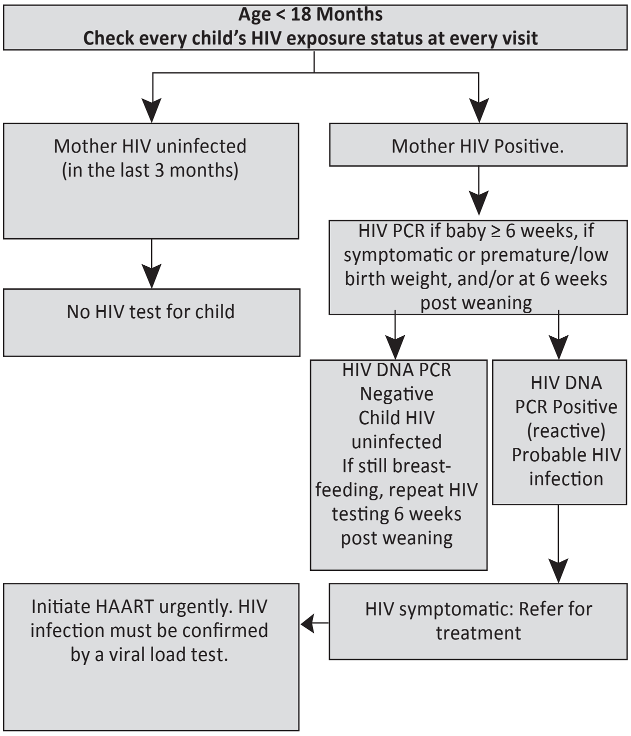
ELISA positive: Report as HIV Positive and provide counselling; refer for CD4 count, TB screening. Clinical staging and Pre-ART management.

ELISA non reactive: Report HIV Negative and provide counselling. Encourage client to repeat test three (3) months after negative result to exclude the possibility of the window period.

Source: Policy Guideline for HIV Counselling and Testing (HCT), National Department of Health, 2010

PAGE 10

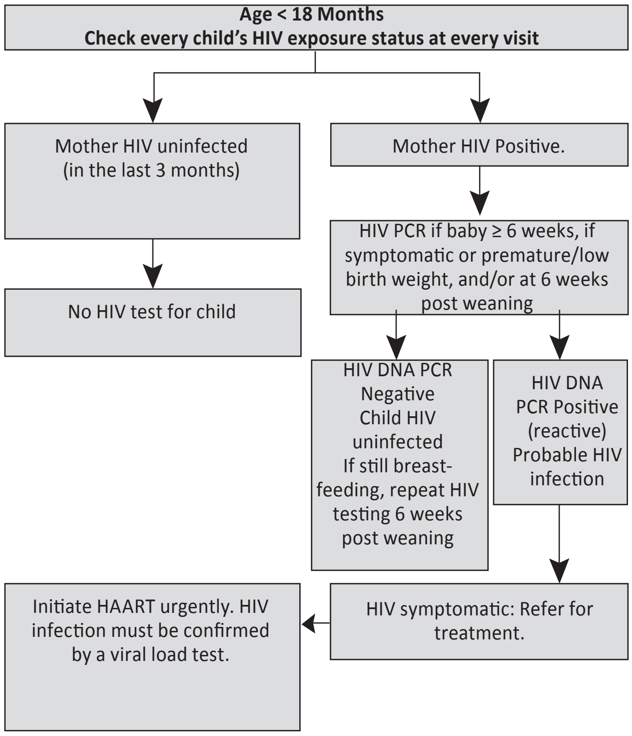
Paediatric Testing Algorithm



Source: South African Antiretroviral Treatment Guidelines. March 2013

Continued

Paediatric Testing Algorithm

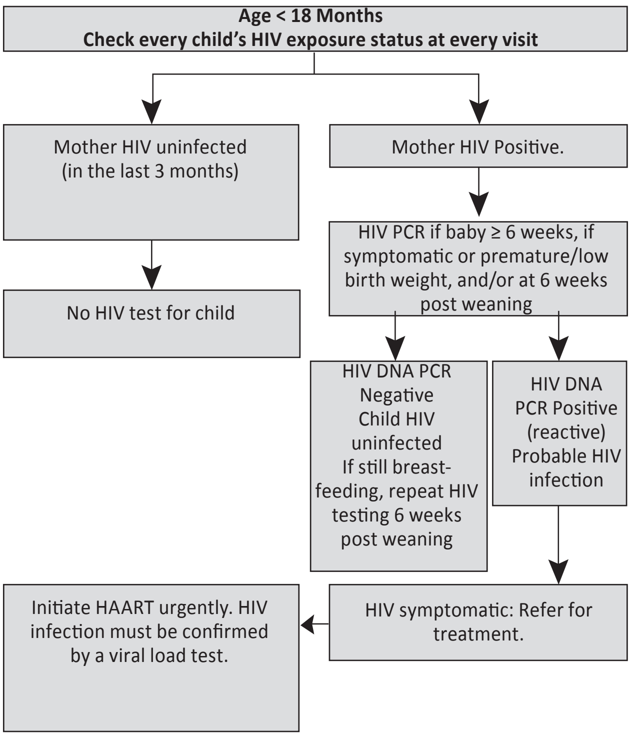


Source: South African Antiretroviral Treatment Guidelines. March 2013

Continued

PAGE 11

Paediatric Testing Algorithm

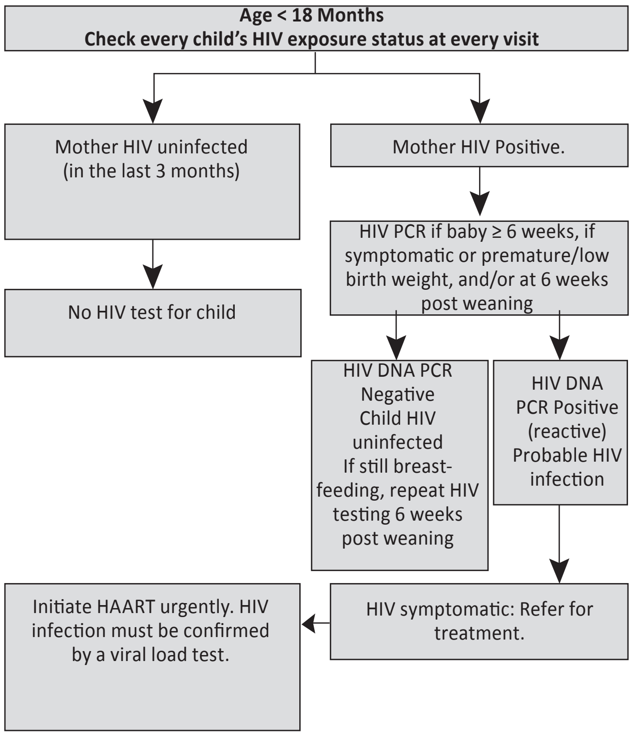


Source: South African Antiretroviral Treatment Guidelines. March 2013

Continued

PAGE 11

Paediatric Testing Algorithm



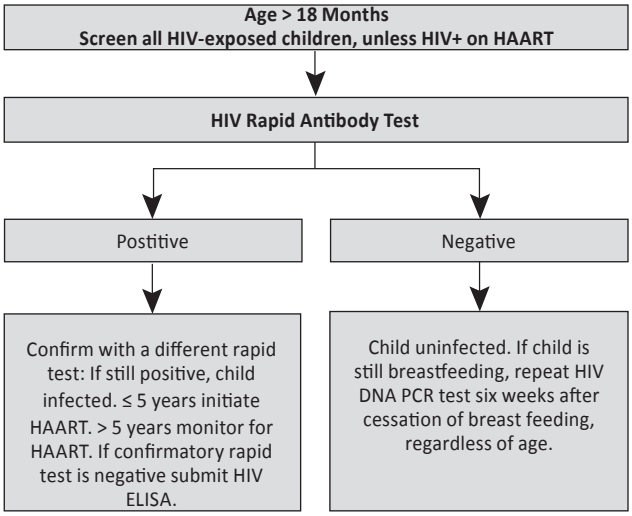
Source: South African Antiretroviral Treatment Guidelines. March 2013

Continued

PAGE 11

Paediatric Testing Algorithm

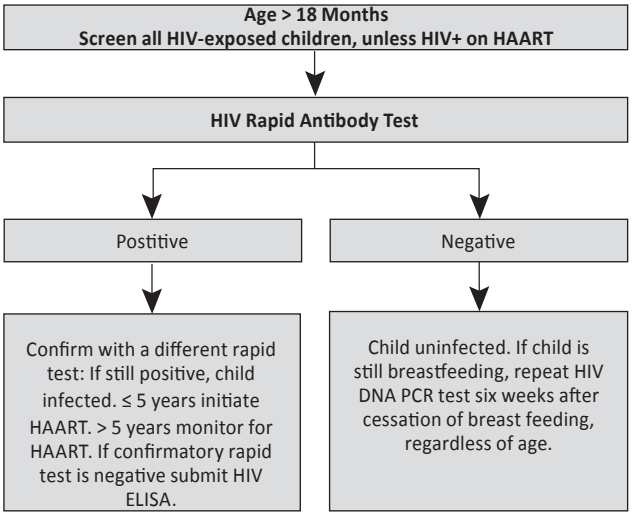
Continued



Source: South African Antiretroviral Treatment Guidelines. March 2013

Paediatric Testing Algorithm

Continued

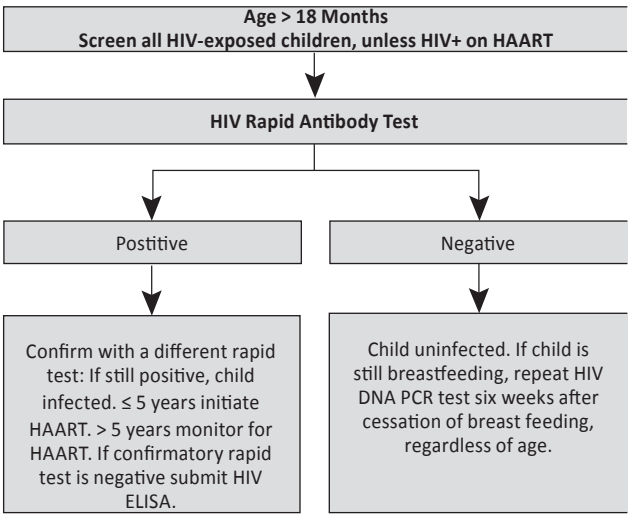


Source: South African Antiretroviral Treatment Guidelines. March 2013

PAGE 12

Paediatric Testing Algorithm

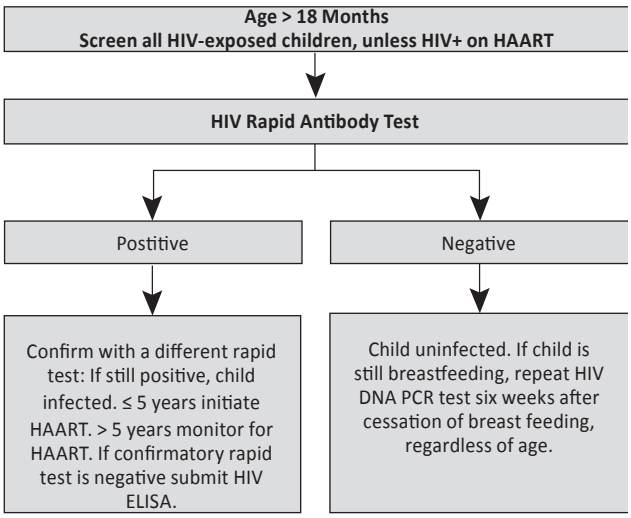
Continued



Source: South African Antiretroviral Treatment Guidelines. March 2013

Paediatric Testing Algorithm

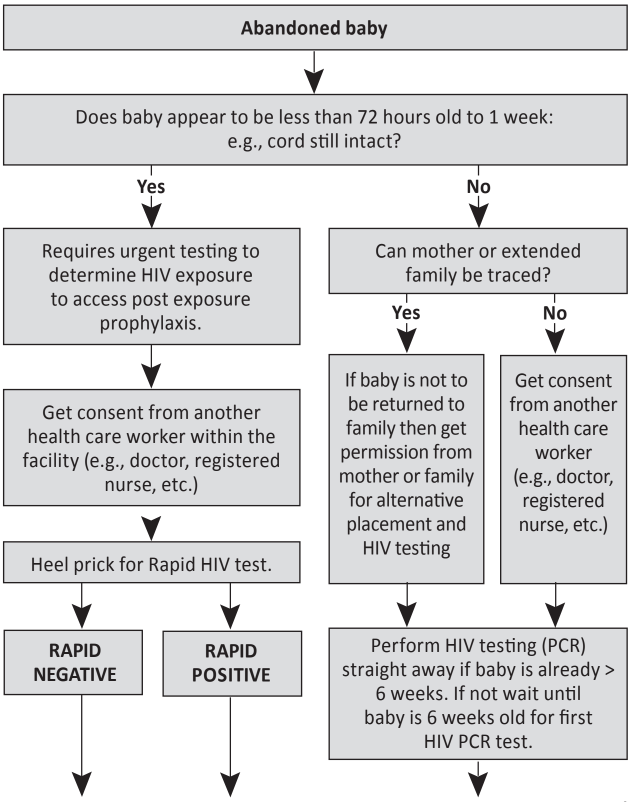
Continued



Source: South African Antiretroviral Treatment Guidelines. March 2013

PAGE 12

Recommended Testing Algorithm for Abandoned Children



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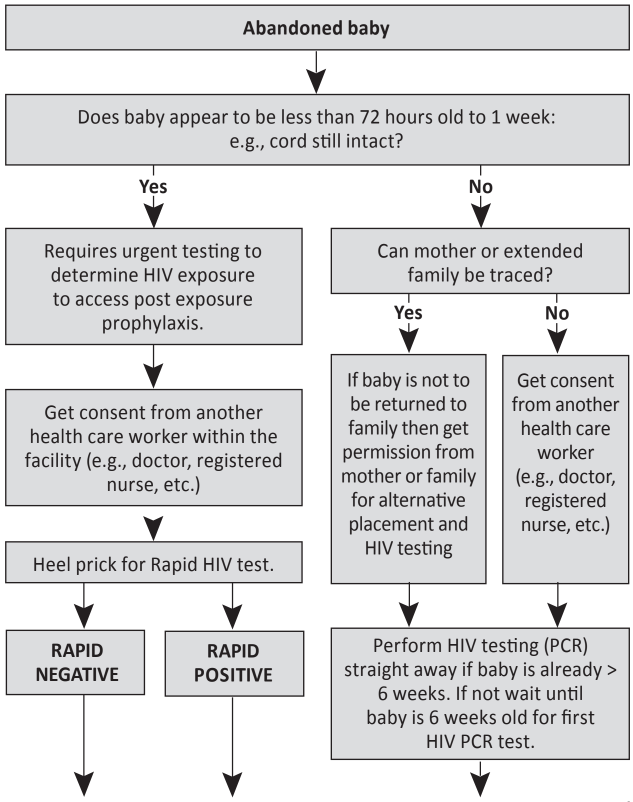
Recommended Testing Algorithm for Abandoned Children



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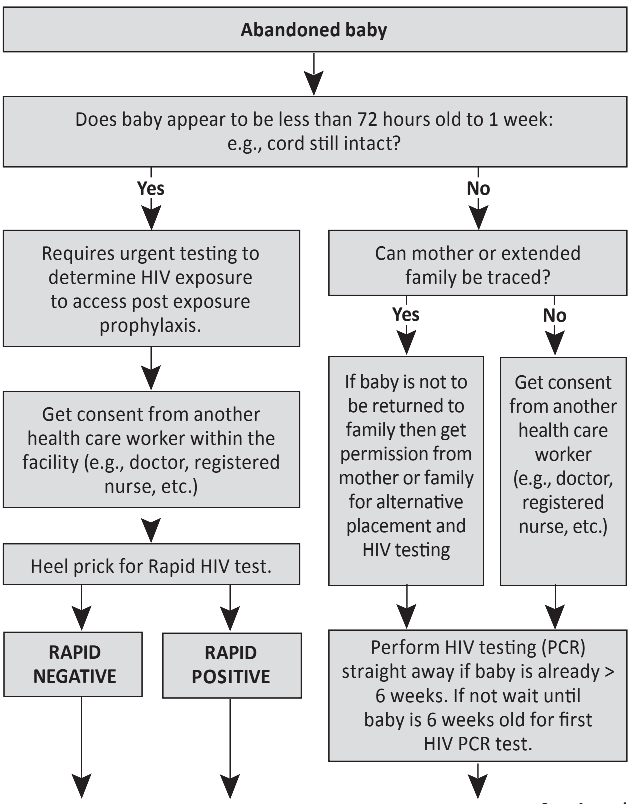
PAGE 13

Recommended Testing Algorithm for Abandoned Children



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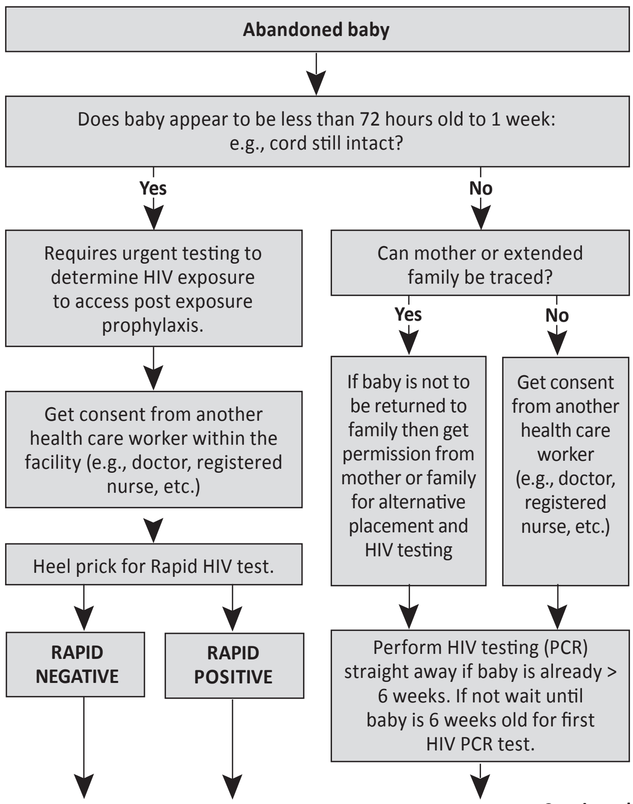
PAGE 13

Recommended Testing Algorithm for Abandoned Children



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PAGE 13

Recommended Testing Algorithm for Abandoned Children

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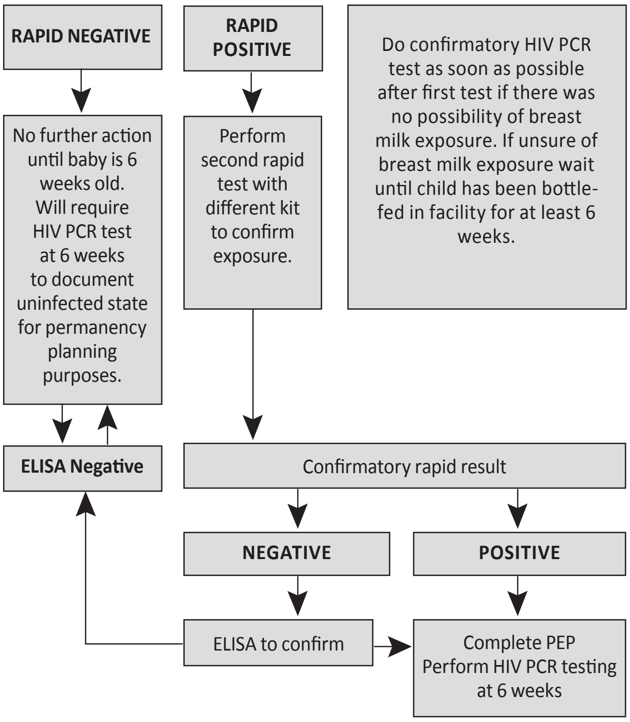

Source: South Africa National Department of Health. Policy Guideline for HIV Counselling and Testing (HCT). 2010.

Recommended Testing Algorithm for Abandoned Children

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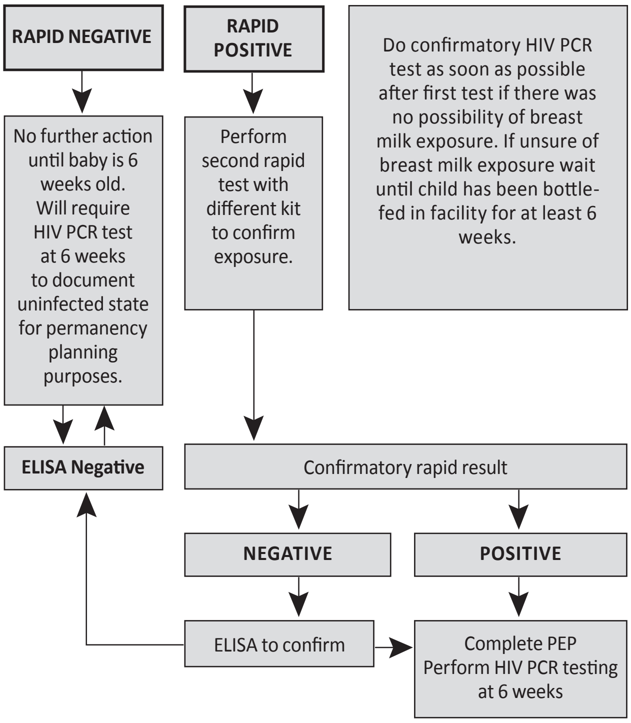

Source: South Africa National Department of Health. Policy Guideline for HIV Counselling and Testing (HCT). 2010.

PAGE 14

Recommended Testing Algorithm for Abandoned Children

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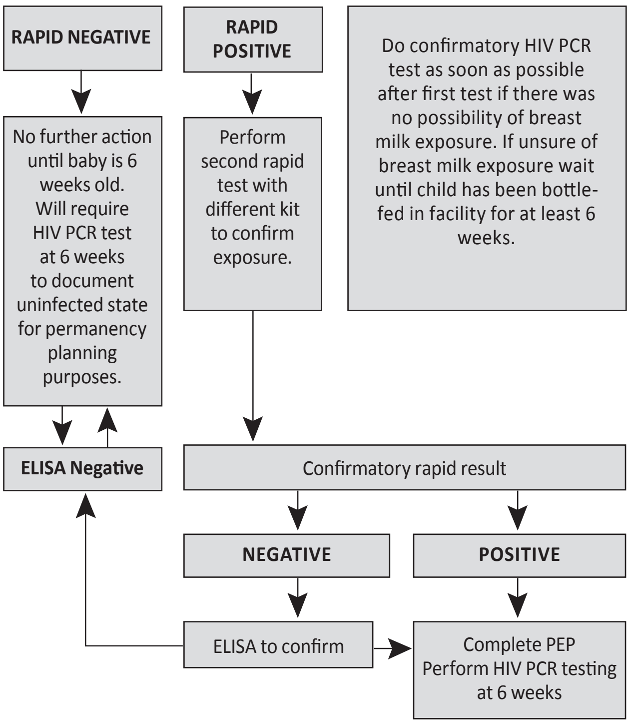

Source: South Africa National Department of Health. Policy Guideline for HIV Counselling and Testing (HCT). 2010.

PAGE 14

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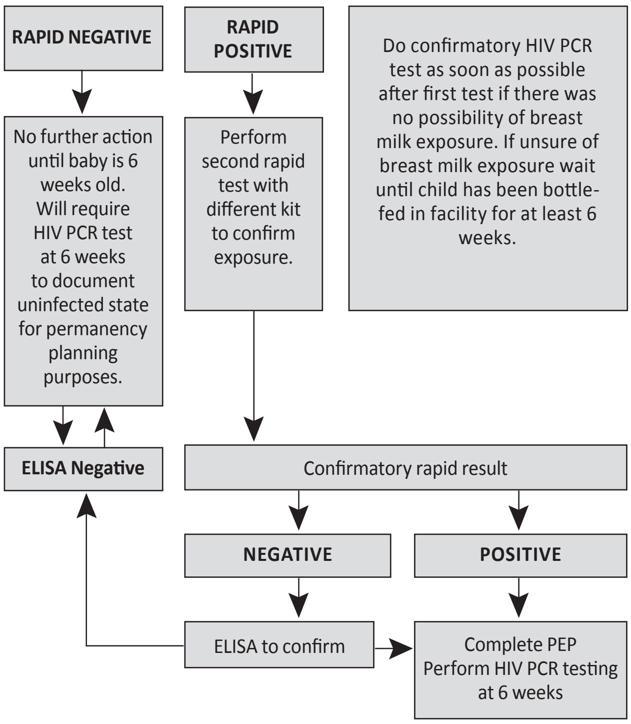

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PAGE 14

Clinical Staging for HIV Disease in Adults, Adolescents and Children[1]

CLINICAL STAGE 1

- Asymptomatic
- Persistent generalised lymphadenopathy

CLINICAL STAGE 2

- Unexplained persistent hepatosplenomegaly
- Papular pruritic eruptions
- Extensive wart virus infection
- Extensive molluscum contagiosum
- Fungal nail infections
- Recurrent oral ulcerations
- Unexplained persistent parotid enlargement
- Lineal gingival erythema
- Herpes zoster
- Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis or tonsillitis)

Source: Clinical Guidelines for the Management of HIV and AIDS in Adults and Adolescents, National Department of Health, 2010

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PAGE 15

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PAGE 15

Clinical Staging for HIV Disease in Adults, Adolescents and Children[2]

CLINICAL STAGE 3

- Unexplained moderate malnutrition not adequately responding to standard therapy
- Unexplained persistent diarrhoea (14 days or more)
- Unexplained persistent fever (above 37.5°C intermittent or constant for longer than one month)
- Persistent oral candidiasis (after first 6–8 weeks of life)
- Oral hairy leukoplakia
- Acute necrotizing ulcerative gingivitis or periodontitis
- Lymph node tuberculosis
- Pulmonary tuberculosis
- Severe recurrent bacterial pneumonia
- Symptomatic lymphoid interstitial pneumonitis
- Chronic HIV-associated lung disease including brochiectasis
- Unexplained anaemia (< 8 g/dL), neutropaenia (< 0.5 × 109 per litre)
- And/or chronic thrombocytopaenia (< 50 × 109 per litre)

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PAGE 16

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PAGE 16

Clinical Staging for HIV Disease in Adults, Adolescents and Children[3]

CLINICAL STAGE 4

- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia
- Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection or meningitis but excluding pneumonia)
- Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site)
- Extrapulmonary tuberculosis
- Kaposi's sarcoma
- Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)
- Central nervous system toxoplasmosis (after one month of life)
- HIV encephalopathy
- Cytomegalovirus infection: retinitis or cytomegalovirus infection affecting another organ, with onset at age older than one month
- Extrapulmonary cryptococcosis (including meningitis)
- Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis)
- Chronic cryptosporidiosis
- Chronic isosporiasis
- Disseminated non-tuberculous mycobacterial infection
- Cerebral or B-cell non-Hodgkin lymphoma
- Progressive multifocal leukoencephalopathy
- Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy
- HIV-associated rectovaginal fistula

Source: Clinical Guidelines for the Management of HIV and AIDS in Adults and Adolescents, National Department of Health, 2010.

Clinical Staging for HIV Disease in Adults, Adolescents and Children[3]

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PAGE 17

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PAGE 17

PHYSICAL EXAM
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SOAP Card: **S**ubjective

1. What can I do for you today? **OR**
2. What is your reason for coming to the hospital today?
3. Is this a routine follow-up or acute visit?
4. If acute visit, quickly assess for urgent care needs, if stable, proceed
- **Airway/breathing**
- **Circulation**
- **Unconscious/Convulsing**
- **Pain**
- **Fever**
5. Age, marital status, employment, social support
6. Pregnant or last menstrual period, date of last pap smear and results
7. Obstetric history (previous pregnancies and miscarriages, children alive and their ages)
8. HIV status of client, partner and children
- Last CD4 count or WHO stage?
9. Sexual History: Unprotected sex in past few months, number of partners
10. TB status
11. Review of systems
12. Medications
- Including ARVs or TB meds
- Including adherence
13. Past medical history
- Recently sick or admitted
- History of serious illness or surgery
14. Habits (smoking, drinking alcohol or abusing drugs)

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PAGE 19

SOAP Card: **O**bjective

General
- Alert or unconscious
- Dehydrated or well hydrated
- Emaciated or underweight or malnourished
- Record weight, height and BMI
- Check for JACCOL (Jaundice, Anaemia, Cyanosis, Clubbing, Oedema and Lymphadenopathy)
- Check skin rashes and lesions

Vital signs
- Respiratory rate
- Heart rate
- Blood pressure
- Temperature
- Oxygen saturation

Do a systemic examination
- HEENT (Head, eyes, ears, nose, throat)
- Cardiovascular
- Pulmonary
- Gastrointestinal
- Genito-urinary
- Musculoskeletal

Skin/Dermatological
- Neurological

Note: Pay particular attention to the system for which patient reports symptoms.

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PAGE 20

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Skin/Dermatological
- Neurological

Note: Pay particular attention to the system for which patient reports symptoms.

PAGE 20

SOAP Card: **A**ssessment

What is the patient's diagnosis?

- List all the medical problems you found under "Objective" e.g. Anaemia, jaundice, dehydration, wasting, central cyanosis, etc
- Consider differential diagnosis
- Conclude probable diagnosis

Assess Risk

- Multiple partners
- Substance use
- Cultural/religious practices
- Unprotected sex
- Adherence to medications

What is the patient's willingness to change?

SOAP Card: **A**ssessment

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PAGE 21

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PAGE 21

SOAP Card: **A**ssessment

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- Cultural/religious practices
- Unprotected sex
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What is the patient's willingness to change?

PAGE 21

SOAP Card: **P**lan

What are you planning to recommend?

- Investigations (e.g. urine, sputum and blood tests, x-rays, lumbar puncture, scan, etc.)
- Treatment and prophylaxis
- Patient education and risk reduction plan
    - Family planning
    - Condom use and distribution
    - Partner notification/counselling
    - Partner and family testing
    - Transmission reduction
    - ART Readiness Counselling
    - Adherence counselling
    - Nutrition
    - Substance Use
- Infection control (IPT, contact screening)
- Admission or referral to specialist or other facility
- Referral to community organisation/support group

SOAP Card: Plan

What are you planning to recommend?

- Investigations (e.g. urine, sputum and blood tests, x-rays, lumbar puncture, scan, etc.)
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PAGE 22

SOAP Card: Plan

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PAGE 22

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PAGE 22

Physical Exam Checklist: HEENT

Feel scalp and head for any abnormalities.

- Assess for rashes, check external ears for rashes, and drainage

Examine the face.

- Assess for rashes or skin lesions on face
- Assess for facial lipoatrophy
- Check sensation to touch on face
- Have patient raise eyebrows, wrinkle forehead, close their eyes and smile

Examine the eyes.

- Examine pupillary size and response to light and visual fields
- Look for extra ocular movements

Examine conjunctiva and inside the eyelids of both eyes.

- Assess for anaemia, jaundice, redness, discharge, lesions, swelling or discolouration

Examine the ears.

- Conduct the quick finger rub hearing test
- Assess for pain, ringing in ears and hearing loss

Examine the nose and sinuses.

Examine the mouth.

- Examine tongue, under tongue, palate, mucosal tissues, and pharynx
- Assess for lesions, sores, discolouration, exudate, skin or tissue abnormalities in the mouth
- Assess for oral candidiasis, oral hairy leukoplakia, pigmented oral lesions such as KS, HSV ulceration, and angular cheilitis.

Continued

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Continued

PAGE 23

Continued

Examine the mouth. (cont.)

- Assess for tonsil enlargement, redness or discharge in posterior oropharynx
- Assess breath for halitosis or any odour

Examine dentition and gingiva.

- Assess for ulcerative gingivitis and periodontitis
- Ask patient to show their teeth and stick out their tongue

Examine the neck.

- Ask patient to patient shrug their shoulders and turn their head from side to side
- Assess for asymmetric or rapidly enlarging lymph nodes, note size and location and whether nodes are soft, hard, red, tender, mobile or fixed, draining
- Palpate lymph nodes: pre-auricular (in front of ear), post-auricular (behind the ear), occipital (base of skull), posterior cervical (from the level of the mastoid bone to the clavicle), tonsillar (below the angle of the mandible), sub-mandibular (under the jaw on either side of the midline), sub-mental (below the chin), supra-clavicular (in the hollow above the clavicle)
- Assess for thyroid enlargement
- Examine neck for stiffness
- Palpate the carotids

Physical Exam Checklist: HEENT

Continued

Examine the mouth. (cont.)

- Assess for tonsil enlargement, redness or discharge in posterior oropharynx
- Assess breath for halitosis or any odour

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- Assess for thyroid enlargement
- Examine neck for stiffness
- Palpate the carotids

PAGE 24

Physical Exam Checklist: HEENT

Continued

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PAGE 24

Physical Exam Checklist: HEENT

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- Palpate the carotids

PAGE 24

Physical Exam Checklist: Cardiovascular

- **Examine fingers and nail beds for cyanosis and clubbing**
- **Examine lower extremities and check for oedema**
  - Assess for peripheral oedema, ulcers or discolouration
  - Check dorsalis pedis and posterior tibial pulses
- **Palpate for apex beat**
- **Feel point of maximal cardiac impulse**
- **Auscultate heart**
  - Assess rate, rhythm, arrhythmias, murmurs, extra heart sounds

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PAGE 25

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PAGE 25

Physical Exam Checklist: Pulmonary

- **Inspect anterior and posterior chest**
- **Palpate and Percuss the posterior chest**
- **Auscultate the posterior lung fields as well as right middle lobe and the lingula**
  - Note abnormal sounds including crackles or wheezes
  - Note absence of air movement (pleural effusion or pneumothorax)
- **Ask patient to lie down and listen to anterior lung fields**

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PAGE 26

Physical Exam Checklist: Gastrointestinal

- **Examine the abdomen for distension, scars**
- **Auscultate to assess for bowel sounds**
- **Palpate and Percuss the abdomen:**
  - Assess for pain, guarding, hepatosplenomegaly, abdominal masses, abnormal tenderness, rebound tenderness, and inguinal adenopathy, femoral and popliteal pulses

Physical Exam Checklist: Gastrointestinal

- Examine the abdomen for distension, scars
- Auscultate to assess for bowel sounds
- Palpate and Percuss the abdomen:
  - Assess for pain, guarding, hepatosplenomegaly, abdominal masses, abnormal tenderness, rebound tenderness, and inguinal adenopathy, femoral and popliteal pulses

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PAGE 27

Physical Exam Checklist: Genito-Urinary

FEMALE

Examine the external genitalia and anal area

- Assess for ulcers, lesions, warts, sores, swelling or discharge

Palpate inguinal and femoural nodes

- Assess for enlarged nodes and/or tenderness

Conduct bi-manual exam

- Assess for motion tenderness

Conduct internal speculum exam

- Assess for any ulcers, lesions on vaginal walls or cervix
- If needed, obtain a Papanicolaou smear
- Screen for STIs: obtain endocervical swab for gonorrhoea and chlamydia and a posterior pool swab for wet mount trichomoniasis, candida and bacterial vaginosis

MALE

Examine the penis

- Assess for any ulcers, lesions, discharge or other abnormalities, note whether circumcised

Examine the testes

- Assess for masses, swelling or tenderness

Conduct rectal exam. Examine the anal area

- Assess for lesions, sores, fissures or warts
- If needed, obtain an anal Papanicolaou smear

Palpate inguinal and femoral nodes

- Assess for enlarged nodes and/or tenderness

Physical Exam Checklist: Genito-Urinary

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PAGE 28

Physical Exam Checklist: Musculoskeletal

Examine muscle bulk

- Assess for tone and evidence of fat atrophy
- Assess for strength

Examine the joints

- Assess for enlargement, swelling, redness, warmth, deformity or tenderness

Examine for range of motion of hip and knees

- Assess for limited movement, pain or stiffness

Physical Exam Checklist: Musculoskeletal

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PAGE 29

Physical Exam Checklist: Skin/Derm

Examine entire body and scalp, axillae, palms and soles of feet, fingernails and toenails

- Assess for rashes or skin lesions on face such as seborrhoeic dermatitis
- Assess for lesions, scratches, seborrhoeic dermatitis, psoriasis, folliculitis, Kaposi's sarcoma, fungal infections, common warts, molluscum contagiosum, herpes zoster
- Assess skin turgor and note for signs of dehydration
- Assess temperature of skin
- Note any nail changes, clubbing, cyanosis or fungal infections

Physical Exam Checklist: Skin/Derm

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PAGE 30

Physical Exam Checklist: Neuro

Examine upper and lower extremity peripheral nerve function.

- Assess extraocular movements and pupil dilation
- Check sensation to pin prick and light touch
- Check ankle, achilles, patellar and plantar reflexes
- Measure vibratory sensation in toes
- Have patient stand and walk
    - Assess gait
    - Check for Romberg's sign
    - Assess cerebellar function with finger to nose and heel to shin testing
- Assess speech. Note any unusual pattern or difficulties

Physical Exam Checklist: Neuro

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PAGE 31

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PAGE 31

OPPORTUNISTIC INFECTIONS/CLINICAL COMPLICATIONS IN ADULTS

Resources for Opportunistic Infections pages unless otherwise stated:

Standard Treatment Guidelines and Essential Medicines List: Hospital Level Adults. National Department of Health, South Africa. 2012.

Primary Care 101. National Department of Health, South Africa. 2013/14.

Clinical Guidelines for the Management of HIV and AIDS in Adults and Adolescents. National Department of Health, South Africa. 2010.

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Bacterial Meningitis

Clinical Presentation: Classic presentation includes headache with stiff neck, mental status changes and high fever. Petechial rash may present with Meningococcal Meningitis. Signs include stiff neck and positive Kernig's sign.

Causative Agents: *Streptococcus pneumoniae, Haemophilus influenzae,* meningococci.

Diagnosis: Lumbar Puncture with CSF sent for gram stain and culture. Bacterial organisms present on gram stain with culture yielding bacterial pathogen. Blood cultures x 2 sent, will likely result bacteremic.

Treatment: Broad spectrum antibiotics should be initiated without delay. Usual initial treatment is Ampicillin 150-200mg/kg/day IV divided every 3-4 hours.

Once culture results available, tailor treatment based on organism.

Follow-up: Prognosis for bacterial meningitis is dependant on how quickly the empiric diagnosis is made and antibiotics are administered. Delays in diagnosis and can result in poorer outcomes than patients who are treated promptly.

Bacterial Meningitis

Clinical Presentation: Classic presentation includes headache with stiff neck, mental status changes and high fever. Petechial rash may present with Meningococcal Meningitis. Signs include stiff neck and positive Kernig's sign.

Causative Agents: Streptococcus pneumoniae, Haemophilus influenzae, meningococci.

Diagnosis: Lumbar Puncture with CSF sent for gram stain and culture. Bacterial organisms present on gram stain with culture yielding bacterial pathogen. Blood cultures x 2 sent, will likely result bacteremic.

Treatment: Broad spectrum antibiotics should be initiated without delay. Usual initial treatment is Ampicillin 150-200mg/kg/day IV divided every 3-4 hours.

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PAGE 33

Bacterial Pneumonia

Clinical Presentation: Typically a sudden onset of fever, chills, cough with sputum production, dyspnoea, and pleuritic chest pain

Causative Agent: The most common causes are *Streptococcus pneumoniae, Haemophilus influenzae and Staphylococcus Aureus.* Other frequent bacterial pathogens include *Moraxella cattharalis, Klebsiella pneumoniae, P. aeruginosa* and *Mycoplasma pneumoniae.*

Diagnosis: Clinical evaluation followed by chest radiograph with or without microbiologic testing.

Laboratory Findings: High white blood cell count. Gram stain of sputum and culture yields the diagnosis in 75% of cases

Radiographic Presentation: The classic presentation shows segmental or lobar consolidations. Infiltrates are localised in one lobe but may be more diffuse in immuno-suppressed individuals.

Treatment:

Options for uncomplicated non-severe bacterial pneumonia include amoxicillin 500mg orally three times daily for 5-10 days. Or amoxicillin/clavulanic acid 250/125 (375), orally three times daily for 5-10 days.

Treatment for severe life-threatening pneumonia is ceftriaxone 1 gram IV once at outpatient facility with referral to inpatient facility where IV antibiotics could be administered.

Continued

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PAGE 34

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Follow-up: Chest x-ray findings usually clear more slowly than clinical manifestations. Slow or incomplete resolution of pneumonia despite treatment is a common clinical problem (15%). Referral to specialized services is required.

Patient Education: Smoking cessation, Pneumococcal vaccination (if available).

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PAGE 35

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PAGE 35

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Cryptococcal Meningitis

Clinical Presentation: Gradually increasing headache with low grade fever. Additional symptoms may include nausea and vomiting, neck stiffness, confusion, seizures, focal neurologic signs with cranial nerve abnormalities, abnormal behaviour, new-onset psychiatric problems, diplopia, and unexplained blindness. Cutaneous lesions and pulmonary involvement may also be observed.

Causative agent: *Cryptococcus neoformans.* Cryptococcosis is the cause of the most common life-threatening meningitis in AIDS.

Screening: If CD4 cell count ≤ 100 send serum for cryptococcal antigen. If positive treat and start ART once induction phase completed and evidence of clinical response (after 2-6 weeks therapy).

Diagnosis: Perform lumbar puncture (LP) and measure opening pressure (a high opening pressure >200mm H_20 presents in 70% of patients). Send CSF for india ink staining, cryptococcal antigen (CRAG), bacterial gram stain and culture. Send serum for CRAG. The definitive diagnosis can be made by culture or presumptively by india ink or CSF cryptococcal antigen. A CT scan is recommended in patients with focal neurologic signs to ensure LP is safe.

Treatment:

- Initial treatment: Induction phase – Amphotericin B 1mg/kg/dose IV PLUS Fluconazole 800mg daily for 2 weeks. Consolidation phase – Fluconazole 400mg orally daily for 8 weeks. Maintenance phase – Fluconazole 200mg orally daily for life or until CD4 > 200 cells/ mm^3 for > 6 months, following at least 12 months of fluconazole therapy.

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Continued

PAGE 36

Treatment Cont.:

- Subsequent episode: Induction phase – Amphotericin B 1mg/kg/dose IV for 2-4 weeks or until CSF is sterile. Consolidation phase – Fluconazole 800mg orally daily for 8 weeks with or without weekly amphotericin B 1mg/kg. Maintenance phase – Fluconazole 400mg orally daily OR weekly Amphotericin B 1 mg/kg/dose with or without Fluconazole 400mg orally daily for life or until CD4 > 250 cells/mm^3 for > 6 months, following at least 12 months of fluconazole therapy.
- Consider alleviating raised intracranial pressure by draining not more than 20-30 ml of CSF.
- In areas where Amphotericin B is not available high doses of fluconazole are typically used for the Induction phase.

Follow-up: Re-assess daily for signs and symptoms of increased intracranial pressure. If present, repeat lumbar puncture for CSF removal.

Cryptococcal Meningitis

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PAGE 37

Cryptococcal

Cryptococcal antigen screening when CD4+ T-lymphocyte count <100 cells/µl

Positive

- Contact patient for urgent follow-up
- Screen for symptoms of meningitis*
- Check for special situations†

Symptomatic

Start fluconazole 1200 mg daily and refer immediately for lumbar puncture

Lumbar puncture (+)

Amphotericin B plus fluconazole 800 mg daily for **2 weeks** in **hospital**

Lumbar puncture (-)

Asymptomatic

Fluconazole 800 mg daily for **2 weeks** as **outpatient**

Negative

Initiate ART *No fluconazole*

***Symptomatic for meningitis if either of the following is present:**

1. Headache
2. Confusion

†Special situations include:

- Prior cryptococcal meningitis
- Pregnancy or breastfeeding mothers
- Clinical liver disease

§A lumbar puncture may be considered if available.

Fluconazole 400 mg daily for 2 months then 200 mg daily. Continue fluconazole for minimum of 1 year in total and discontinue when patient has had two CD4 counts >200 taken at least 6 months apart

Start ART after 4-6 weeks of antifungal therapy

Start ART after 2 weeks of antifungal therapy

Reference: Southern African HIV Clinician's Society Cryptococcal Antigen Screening Guideline. 2013.

Cryptococcal

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Lumbar puncture (+)
Amphotericin B plus fluconazole 800 mg daily for 2 weeks in hospital
Lumbar puncture (-)
Asymptomatic
Fluconazole 800 mg daily for 2 weeks as outpatient
Negative
Initiate ART No fluconazole
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Pregnancy or breastfeeding mothers
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Cryptosporidiosis

Clinical Presentation: Cryptosporidium can cause an asymptomatic infection, a mild diarrhoeal illness, or severe enteritis. HIV patients often report an explosive, profuse watery diarrhoea associated with malaise, nausea and anorexia and crampy abdominal pain. Malabsorption, malnutrition, dehydration, and cachexia are also observed. Chronic cryptosporidiosis confers a WHO Stage IV diagnosis.

Causative Agent: *Cryptosporidium parvum.*

Diagnosis: Microscopic identification of the oocysts in stool or tissue.

Treatment: Initiating ART is the most effective treatment. Provide supportive care including oral rehydration, nutritional supplements and loperamide or codeine.

Follow-up: As needed

Patient Education: Good hygiene, such as handwashing and proper disposal of contaminated material, and boiling or filtering water may decrease the risk of infection in immunosuppressed patients. Prophylaxis for Cryptosporidium is not routinely recommended.

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PAGE 39

Cytomegalovirus

Clinical Presentation: Most often presents with ocular and gastrointestinal signs and symptoms. Retinitis may be asymptomatic or present with rapidly progressing visual loss. Additional symptoms may be floaters, blind spots, distortion, no pain, redness and photophobia. Unilateral retinal signs with contralateral involvement developing within six months. CMV can appear on any part of the GI tract, where it produces ulcerating lesions. The oesophagus and colon are the most common sites of GI involvement. Oesophageal infection usually presents with fever and odynophagia. Lesions on the colon produce an acute colitis presenting with diarrhoea that may be bloody, often with severe abdominal pain.

Causative Agent: Cytomegalovirus, a member of the Herpes virus family.

Diagnosis: CMV retinitis visible via direct opthalmoscopy. Endoscopy shows large shallow ulcerations. Sigmoidoscopy or colonoscopy shows colitis with friable edematous mucosa and scattered ulcerations. Diagnosis is made by CMV PCR or culture directly from biopsy specimen. Systemic infection can be confirmed by viral PCR or culture of white blood cells from the buffy coat of a centrifuged specimen of blood.

Treatment: Ganciclovir is the treatment of choice, but this agent is toxic and expensive and can only be used by a specialist familiar with its use. To prevent recurrent disease commence patients on ART as soon as possible after initiating ganciclovir.

- CMV Retinitis: Ganciclovir intravitreal, 2mg once weekly (by opthalmologist)
- Initial treatment: Ganciclovir IV, 5mg/kg 12 hourly for 14 days. Specialist initiated.

Continued

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Continued

PAGE 40

Treatment (Cont.):

- Maintenance treatment: Ganciclovir IV, 5mg/kg daily until CD4 rises to >100 cells/mm3 on ART.

Note: Only patients with good clinical response should be considered for maintenance, as the cost is currently very high.

Follow-up: Side effects of most of the antiviral drugs lead to bone marrow suppression.

Patient Education: Hygienic precautions are efficient in preventing CMV infection during pregnancy.

Cytomegalovirus

Treatment (Cont.):

- Maintenance treatment: Ganciclovir IV, 5mg/kg daily until CD4 rises to >100 cells/mm3 on ART.

Note: Only patients with good clinical response should be considered for maintenance, as the cost is currently very high.

Follow-up: Side effects of most of the antiviral drugs lead to bone marrow suppression.

Patient Education: Hygienic precautions are efficient in preventing CMV infection during pregnancy.

PAGE 41

Cytomegalovirus

Treatment (Cont.):

- Maintenance treatment: Ganciclovir IV, 5mg/kg daily until CD4 rises to >100 cells/mm3 on ART.

Note: Only patients with good clinical response should be considered for maintenance, as the cost is currently very high.

Follow-up: Side effects of most of the antiviral drugs lead to bone marrow suppression.

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- Maintenance treatment: Ganciclovir IV, 5mg/kg daily until CD4 rises to >100 cells/mm3 on ART.

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Follow-up: Side effects of most of the antiviral drugs lead to bone marrow suppression.

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Giardiasis

Clinical Presentation: Giardia lamblia is an intestinal parasitic infection in which transmission occurs via the oral-faecal route. Infects the small bowel mucosa where it may be asymptomatic but usually causes diarrhoea with abdominal cramping, bloating and nausea. In severe cases it may produce malabsorption and steatorrhoea.

Causative Agent: *Giardia lamblia*

Diagnosis: Stool microscopy demonstrates Giardia ova and cysts.

Treatment: Metronidazole 400mg orally 8 hourly for 5 days. If pregnant, avoid use of metronidazole and use paromomycin 500mg orally four times daily for 7 days.

Follow-up: Relapse is common.

Patient Education: Handwashing and proper disposal of contaminated material, boiling or filtering water, and properly cooking food may decrease the risk of infection in immunosuppressed patients.

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Herpes Simplex Virus

Clinical Presentation: Recurrent herpes labialis occurs on the border of the lips. Usually starts with itching or pain followed by appearance of small vesicles. Vesicles rupture and form crusts.

Recurrent intra oral herpes usually occurs on the keratinized mucosa such as hard palate and gingival and appears as clusters of painful small vesicles that rupture and ulcerate and usually heal within a few weeks.

Clinically herpetic oesophagitis presents with extreme pain and difficulties in swallowing. Most commonly infects the oesophagus to produce multiple oesophageal ulcerations.

Genital herpes simplex presents as grouped blisters that rupture, crust and heal in a few weeks. Painful and extensive lesions usually localise in the ano-genital area, although oro-labial lesions can be seen.

HIV-infected individuals with low CD4 counts may experience chronic or extensive outbreaks.

Causative Agent: Herpes simplex virus type 1 and 2 (HSV 1 & HSV 2). The virus is transmitted by close contact.

Diagnosis: Clinical observation. Viral culture positive for HSV. Endoscopy of herpetic oesophagitis: ulcers usually multiple and small. Biopsy will show multinucleated giant cells.

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Herpes Simplex Virus

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Treatment: Treatment only shortens the healing time of individual episodes.

Oral Acyclovir 400mg 8 hourly for 7 days. Paracetamol as needed for pain.

For recurrent HSV - Acyclovir 400mg orally 8 hourly for 7 days or 800mg orally twice daily for 5 days.

For severe or refractory HSV – Acyclovir 5-10mg/kg IV 8 hourly infused over 1 hour for 5-7 days or Acyclovir 400-800mg orally 5 times a day for 7-14 days.

For disseminated HSV – Acyclovir 30mg/kg/day IV and test sensitivity of isolate to Acyclovir.

Patient Education: Recurrences may occur frequently. Condom use and partner notification should be recommended. When possible, treatment at initial symptoms of lesions is most efficient.

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Herpes Zoster

Clinical Presentation: Painful prodrome followed by erythematous papules, which quickly evolve into grouped vesicles or bullae. The skin lesions form crusts while oral lesions join together to form large ulcers. Zoster is generally limited to one dermatome, but can occasionally affect two or three neighboring dermatomes. The thoracic and lumbar dermatomes are the most commonly involved sites of herpes.

Causative Agent: Caused by reactivation of the Varicella Zoster Virus (VZV).

Diagnosis: Clinical evaluation.

Treatment:

Acyclovir limits the duration of the lesions.

Acyclovir oral 800 mg five times daily for 7 days.

Flucloxacillin oral, 500mg 6 hourly for 5 days if secondary infection.

Amitriptyline can be used for pain management. Carbamezapine is not recommended for pain management due to drug interactions with antiretrovirals.

If Zoster involves eye or nose (ophthalmic nerve) urgent ophthalmologic referral is indicated for possible IV antibiotics to prevent blindness.

Patient Education: Treatment is more efficient before the appearance of the lesions. Patients who are able to identify a prodrome should be encouraged to seek treatment.

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Intestinal Entamoeba

Clinical Presentation: Colitis with bloody diarrhoea and abdominal cramps. Asymptomatic carriers are more frequent among PLWHAs. Dissemination might be seen more in HIV-infected patients.

Causative Agent: *Entamoeba histolytica*.

Diagnosis: Microscopy of fresh stool specimen demonstrates cysts and parasites. Sigmoidoscopy may show evidence of colitis, and typical punched-out “flask-shaped” ulcers.

Treatment:

Metronidazole oral, 800mg 8 hourly for 10 days.

Followed by Paromomycin 25-35mg/kg/day orally divided in three daily doses for 7 days.

Avoid use of metronidazole in pregnancy. Loperamide is contraindicated as it may cause toxic megacolon.

Patient Education: Avoid drinking unboiled water in endemic areas. Caution consuming uncooked foods, such as fruit and vegetables that may have been washed in infected water.

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Kaposi's Sarcoma

Clinical Presentation: Lesions are multiple and can involve the skin and the mucous membranes. Cutaneous lesions occur most commonly on the trunk, the extremities and the face. Initial lesions are papular. Later the papules become nodules and plaques, and the colour changes from dark brown to violet. May affect mucous membranes, including oral palate and intestines.

Causative Agent: A cancer of the skin and the blood vessels associated with a sexually transmitted Human Herpes Virus (HHV8).

Diagnosis: Generally, lesions are recognised clinically and the diagnosis can be confirmed by biopsy.

Treatment: ART may improve localised disease. Extensive cutaneous or organ involvement will require cytotoxic chemotherapy to assist in resolving extensive disease. Referral to oncology is critical. Intralesional chemotherapy (vinblastine), local radiotherapy, liquid nitrogen cryotherapy or topical aliretinoin 0.1% gel may be effective for small skin and oral lesions.

Patient Education: Importance of starting lifelong ART. Importance of adherence to care and treatment.

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Molluscum Contagiosum

Clinical Presentation: Molluscum contagiosum presents as pearly, umbilicated papules. Extensive molluscum contagiosum is a marker of advanced HIV disease. May be extensive and involve the face, axillae and groin. The most common location is the eyelids.

Causative Agent: Molluscum Contagiosum Virus.

Diagnosis: Clinical. Consider biopsy to rule out cryptococcal skin rash or cutaneous lymphoma if clinical picture is unclear.

Treatment: Antiretroviral therapy may improve success of topical treatments. Apply tincture of iodine or 1% phenol to individual lesions. Other options include cryotherapy with liquid nitrogen, surgical excision/curettage, or electrosurgery.

Follow-up: ART Initiation

Patient Education: Do not touch molluscum bumps on other people. Treatment of the genital areas can help to prevent the spread of infection during sex. Partner notification and treatment. Counsel regarding condom use.

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Oral and Oesophageal Candidiasis

Clinical presentation: Presentation varies. Oral candidiasis may present with lesions or burning of the mouth, changes in taste, and difficulty eating spicy foods. Trouble swallowing and presentation on the posterior pharynx may indicate oesophageal candidiasis.

Causative agent: *Candida Albicans*

Candida Albicans is frequently part of the normal oral flora. Candidiasis occurs mostly in patients with a falling CD4+ count.

Diagnosis: Clinical presentation and by detection of organisms by microscopy.

Treatment: Oral candidiasis can be treated topically or systemically.

Topical Treatment for Oral Candidiasis:

- Nystatin suspension oral 100,000 iu/ml 1-2mL 4 times daily, or oral lozenges sucked 6 hourly for 10 days.
- Miconazole 2% oral gel applied twice daily for 10 days.

If no improvement, Amphotericin B lozenges 10mg 1 slowly 4 times daily, up to 8 lozenges in severe cases.

Oral Treatment for Oesophageal Candidiasis:

- Fluconazole 200mg orally daily for 14 days. The usual route is oral, but may be given IV if patient unable to swallow or is vomiting.

Follow-up: Short courses of topical therapy rarely result in adverse effects.

Patient Education: ART plays an important role in preventing recurrent disease. Discuss ART initiation.

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Oral Hairy Leukoplakia

Clinical Presentation:

- Lesions occur commonly on the lateral margins of the tongue and may be bilateral or unilateral. They appear as whitish-grey corrugations which cannot be removed. Hairy Leukoplakia lesions may also occur on the buccal mucosa as flat lesions. It has no associated symptoms.

Causative Agent: Associated with Epstein Barr Virus but actual cause is still unknown.

Diagnosis: Mainly clinical though definitive diagnosis can be made by biopsy.

Treatment:

- Hairy leukoplakia is asymptomatic and does not require treatment. It is almost always a manifestation of HIV infection and/or immunosuppression.
- Improvement in immune status with ART may resolve symptoms.

Follow-up: N/A

Patient Education: N/A

Oral Hairy Leukoplakia

Clinical Presentation:

- Lesions occur commonly on the lateral margins of the tongue and may be bilateral or unilateral. They appear as whitish-grey corrugations which cannot be removed. Hairy Leukoplakia lesions may also occur on the buccal mucosa as flat lesions. It has no associated symptoms.

Causative Agent: Associated with Epstein Barr Virus but actual cause is still unknown.

Diagnosis: Mainly clinical though definitive diagnosis can be made by biopsy.

Treatment:

- Hairy leukoplakia is asymptomatic and does not require treatment. It is almost always a manifestation of HIV infection and/or immunosuppression.
- Improvement in immune status with ART may resolve symptoms.

Follow-up: N/A

Patient Education: N/A

PAGE 50

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Patient Education: N/A

PAGE 50

Pneumocystis Jirovecii Pneumonia (PCP)

Clinical Presentation: A history of several weeks of fever and cough. Tachypnoea may be pronounced, and patients may be severely dyspnoeic. On physical exam, chest findings may be minimal. More likely to occur with CD4 count < 200 cells/mm^3.

Causative Agent: *Pneumocystis jirovecii*

Diagnosis: Mainly clinical. Lab and Chest X-ray are beneficial to rule out differential diagnosis.

Laboratory Findings:

CBC and ESR show no characteristic pattern.

Radiographic Presentation:

The classic presentation is a diffuse interstitial infiltrate, although the following presentations can be observed: abscesses, cavitations or cystic lesions, lobar consolidation, nodular lesions, effusions, pneumothorax, pneumo-mediastinum and a normal chest radiograph.

Treatment

- Cotrimoxazole 80/400mg orally 6 hourly for 21 days
  <60kg: 3 tablets
  >60kg: 4 tablets
- If vomiting, Cotrimoxazole IV, 6 hourly:
  <60kg: 240/1200mg
  >60kg: 320/1600mg
- Monitor FBC and potassium when on high dose therapy
- A corticosteroid taper should accompany initial treatment. One option is Prednisone 80mg orally twice daily x 5 days, then 40mg orally daily x 5 days, then 20mg orally daily x 5 days.

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Continued

PAGE 51

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- Maintenance therapy is Cotrimoxazole 160/800 mg (2 single strength) orally daily until CD4 > 350 cells/mm^3 on 2 separate occasions.

Follow-up: Cotrimoxazole markedly reduces hospitalisation and mortality and provides protection. Prescribe 160/800 mg (2 single strength tablets) orally once daily to patients with CD4 ≤ 350 cells/mm^3 or stage 2, 3 or 4 HIV disease (including TB). Evaluate HIV and initiate ART.

In patients with a severe sulfa allergy, rapid desensitisation to TMP/SMX or Cotrimoxazole is the preferred treatment of choice, but should occur in a closely monitored setting (as an inpatient). If this is not possible, then alternative regimens for the treatment of PCP pneumonia are clindamycin 600mg orally every eight hours plus dapsone 100 mg orally daily or clindamycin 600mg orally every eight hours plus primaquine 15 mg orally daily (exclude G6PD deficiency when giving primaquine).

Patient Education: Adherence to Cotrimoxazole prophylaxis and to ART drugs once initiated.

Pneumocystis Jirovecii
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PAGE 52

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PAGE 52

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PAGE 52

TB Meningitis

Clinical Presentation: An initial phase lasting two to three weeks characterised by malaise, confusion, headache, low grade fever and personality change. The menningitic phase follows with more pronounced neurologic symptoms such as meningismus, lingering headache and confusion, and varying degrees of cranial nerve. During the paralytic phase the pace of illness may accelerate rapidly. Confusion gives way to stupor and coma, seizures and at times hemiparesis.

- On exam neck stiffness and positive Kernig's sign.

Causative Agent: *Mycobacterium tuberculosis*

Diagnosis: Diagnosis can be difficult. Maintaining a high degree of suspicion is vital to initiate therapy.

- CSF examination: Clear CSF, elevated protein, elevated pressure, high lymphocyte count, low glucose. AFB stain or GeneXpert, and culture.
- Negative cryptococcal Antigen test.
- CT scan can show lesions like basilar arachinoditis, cerebral oedema and infarction, and presence and cause of hydrocephalus.

Treatment: The treatment is in two phases.

If New Case

Intensive Phase: 2 months with daily Isoniazid, Rifampicin, Pyrazinamide and Ethambutol. Adjuvant therapy Corticosteroids e.g. Dexamethasone IV, 12mg 12 hourly, followed by Prednisone oral, 120mg daily; after 1 week, taper dose gradually over next 6 weeks.

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PAGE 53

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Continuation Phase: Daily course of Rifampicin and Isoniazid. Discuss length of treatment with a specialist.

If retreatment case or MDR/XDR-TB refer to a specialist.

Follow-up: Assessment for pulmonary and other extrapulmonary forms of TB should take place. A social evaluation should be undertaken to assess eligibility for support grants. Within one week of hospitalisation, a plan for DOT management on discharge should be developed.

Patient Education: A health education plan should be implemented to counsel the client about TB and to develop an adherence plan to ensure treatment completion.

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PAGE 54

Toxoplasmosis

Clinical Presentation: Recognised major cause of neurologic morbidity and mortality among patients with advanced HIV disease. Transmission to humans usually occurs by eating food contaminated with cysts and oocysts, and by vertical transmission

- Toxoplasmosis causes a multifocal cerebritis and the initial symptoms are often both diffuse and focal. The symptoms are often vague and nonspecific.
- Headaches, usually dull and constant, are present in 50% of patients presenting with toxoplasma encephalitis (TE).
- Fevers occur in 40-50% of cases.
- Confusion and lethargy are common.
- Generalised or focal seizures occur in 15 to 30% of patients. Among all HIV related OIs, toxoplasmosis is the most common cause of seizures.
- Hemiparesis, hemisensory loss or other focal neurological deficits also occur.

Causative Agent: *Toxoplasma gondii*

Diagnosis:

- CT scan and MRI may display mass lesions with ring enhancement.
- Lumbar Puncture (LP) – excludes other OIs. CSF usually reveals normal glucose content, mildly raised protein, mild mononuclear pleocytosis.
- Positive antibody helps define risk but is not diagnostic.

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PAGE 55

Toxoplasmosis

Continued

Treatment:

- Cotrimoxazole 320/1600mg every 12 hours for four weeks, followed by cotrimoxazole 160/800mg every 12 hours for 12 weeks. Consider corticosteroid use if significant mass effect or midline shift on CT scan.
- Continue on cotrimoxazole 160/800mg daily until CD4 count > 250 cells/mm^3 for at least 6 months.

Follow-up: Clinical improvement precedes radiographic improvement – Neuro exam is more important than Xrays in assessing the response to therapy. Monitoring of patients includes clinical evaluations, brain CT scan, and assessment of any adverse events.

Patient Education: Patients seropositive for *T. gondii* should receive prophylaxis with cotrimoxazole.

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Viral Encephalitis

Clinical Presentation/Features: It is an acute inflammatory disorder of the brain due to direct viral invasion or hypersensitivity initiated by a virus or other foreign protein.

Causative Agents: The herpes viruses: herpes simplex 1 and 2 (HSV-1 and -2), herpes zoster (HZV), and cytomegalovirus (CMV). Each can cause a meningoencephalitis with mental status changes and focal neurologic findings.

Diagnosis: Can be difficult, especially because of the lack of availability and low yield of CSF viral cultures in this setting. Sensitive CSF PCR assays, such as HSV, have been developed. Where available, can greatly aid diagnosis.

Treatment: Acyclovir 10mg/kg IV every 8 hours for 10 days. Due to high mortality rate associated with HSV encephalitis rapid initiation is essential.

Follow-up: The prognosis for encephalitis varies. Some cases are mild and patients have full recovery. Other cases are severe, full recovery might take months, and permanent impairment or death is possible.

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PAGE 57

Viral Warts

Clinical Presentation: In most cases they appear as regular or flat warts. Rarely, they may be very extensive lesions. They are commonly found in the anogenital area, but can be found anywhere on the body, including orally.

Causative Agents: Human papilloma virus (HPV).

Diagnosis: Clinical observation biopsy.

Treatment: The goal is to eradicate all warts.

- Podophyllin resin (10-25%) in compound tincture with benzoin apply a small amount once weekly for 6-10 weeks. Limit to < 0.5mL of podophyllin or < 10 cm^2 to avoid problems with systemic absorption or toxicity. Do not use in pregnancy.
- Salicylic acid 25% ointment under a plaster at night is another option for application at base of warts.
- Other methods include: Surgical removal via tangential scissor excision, tangential shave excision, curettage, or electrosurgery or cryotherapy with liquid nitrogen or cryoprobe.
- Refer to a specialist for removal of extensive warts.

Other Methods Include: Cryotherapy, excision or injections with alpha interferon in the lesion.

Follow-up: Female patients must have regular gynaecological examinations and pap smears. Individuals who have had anal warts, should have regular rectal examinations.

Patient Education: HPV spreads by skin-to-skin contact and other close contact. Recurrence of warts may occur. Papanicolau smears are recommended for cervical cancer screening in all patients with a history of diagnosed genital HPV, which may present as viral genital warts.

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- Trichloracetic acid (TCA) or bichloracetic acid (BCA) 80–90% are another option for application at base of warts.
- Other methods include: Surgical removal via tangential scissor excision, tangential shave excision, curettage, or electrosurgery or cryotherapy with liquid nitrogen or cryoprobe.
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Other Methods Include: Cryotherapy, excision or injections with alpha interferon in the lesion.

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Patient Education: HPV spreads by skin-to-skin contact and other close contact. Recurrence of warts may occur. Papanicolau smears are recommended for cervical cancer screening in all patients with a history of diagnosed genital HPV, which may present as viral genital warts.

Viral Warts

Clinical Presentation: In most cases they appear as regular or flat warts. Rarely, they may be very extensive lesions. They are commonly found in the anogenital area, but can be found anywhere on the body, including orally.

Causative Agents: Human papilloma virus (HPV).

Diagnosis: Clinical observation biopsy.

Treatment: The goal is to eradicate all warts.

- Podophyllin resin (10-25%) in compound tincture with benzoin apply a small amount once weekly for 6-10 weeks. Limit to < 0.5mL of podophyllin or < 10 cm^2 to avoid problems with systemic absorption or toxicity. Do not use in pregnancy.
- Trichloracetic acid (TCA) or bichloracetic acid (BCA) 80–90% are another option for application at base of warts.
- Other methods include: Surgical removal via tangential scissor excision, tangential shave excision, curettage, or electrosurgery or cryotherapy with liquid nitrogen or cryoprobe.
- Refer to a specialist for removal of extensive warts.

Other Methods Include: Cryotherapy, excision or injections with alpha interferon in the lesion.

Follow-up: Female patients must have regular gynaecological examinations and pap smears. Individuals who have had anal warts, should have regular rectal examinations.

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PAGE 58

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PAGE 58

Wasting Syndrome

Clinical Presentation: The involuntary weight loss of 10% of baseline body weight plus either chronic diarrhoea (two loose stools per day for more than 30 days) or chronic weakness and documented fever (for 30 days or more, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that would explain the findings.

Causative Agent: The cause is not well understood. Hypermetabolic state and gradual weight loss due to gastrointestinal disease with diarrhoea are likely associated.

Diagnosis: Clinical signs and symptoms.

Treatment: Opportunistic infections should be treated if possible. Caloric intake should be optimized; dietitians can help patients maximize caloric intake.

Follow-up: Evaluate HIV situation. ART initiation according to guidelines.

Patient Education: Monitor the weight. Maintain the intake of nutritious foods. Immediately seek treatment for any serious diarrhoea.

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PAGE 59

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PAGE 59

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PAGE 59

ANTIRETROVIRAL THERAPY
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ART Initiation: Adults and Adolescents

CD4 count ≤ 350 cells/µl irrespective of clinical stage

OR

Irrespective of CD4 Count

- All patients with TB/HIV (drug sensitive or resistant TB)
- Pregnant and breastfeeding women who are HIV positive
- WHO stage 3 or 4

REQUIRE FAST TRACK (ART initiation within 7 days of eligibility):

Pregnant women eligible for lifelong ART (initiate same day)

OR

Patients with very low CD4 (≤ 200 cells/µl)

OR

Patients with Stage 4, CD4 irrespective of CD4

OR

Patients with TB/HIV (including M(X)DR-TB) comorbidity with CD4 < 50

(Cryptococcal meningitis - defer ART for at least 14 days; TB meningitis – defer ART for 8 weeks after starting TB treatment)

PATIENTS with CD4 > 350, Not yet eligible for ART:

- Wellness programme for regular follow-up, 6 monthly CD4
- Screen for IPT eligibility according to IPT guidelines
- Counsel on nutrition, contraceptive and annual Pap Smear
- Advise on HIV prevention to sexual partners and children

Source: The South African Antiretroviral Treatment Guidelines, March 2013; National Tuberculosis Management Guidelines, 2014.

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PAGE 61

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PAGE 61

ART Initiation: Children

Confirmed HIV Diagnosis **AND**:

- All children less than 5 years of age, irrespective of CD4
- Children ≥ 5 years to 15 yrs with clinical stage 3 or 4 or CD4 ≤ 350 cells/µl

REQUIRE FAST TRACK:
(Start ART within 7 days of being eligible)

- Children less than 1 year of age
- WHO Clinical Stage 4
- MDR or XDR TB
- CD4 count < 200 cells/µl or < 15%

Source: The South African Antiretroviral Treatment Guidelines, March 2013.

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PAGE 62

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PAGE 62

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PAGE 62

1st Line ART in Adults and Adolescents

All new patients needing treatment, including pregnant women	**TDF + FTC (or 3TC) + EFV FDC PREFERRED**	Replace EFV with NVP in patients with significant psychiatric co-morbidity or intolerance to EFV or where the neuro-psychiatric toxicity of EFV may impair daily functioning
Adolescents	**ABC + 3TC + EFV**	If eligible, at 18 years an adolescent must be switched to FDC
Contraindication to TDF	**AZT + 3TC + EFV (or NVP)**	Renal disease or the use of other nephrotoxic drugs e.g. aminoglycosides
Contraindication to TDF and AZT	**d4T + 3TC + EFV (or NVP)**	Renal disease and anaemia or the use of other nephrotoxic drugs e.g. aminoglycosides
Contraindication to TDF, AZT, and d4T	**ABC + 3TC + EFV (or NVP)**	Renal disease, anaemia, peripheral neuropathy, the use of other nephrotoxic drugs
Currently on d4T based regimen	**TDF + FTC (or 3TC) + EFV FDC PREFERRED**	Mandatory if patients experience toxicity or who are at high risk of toxicity (high BMI or pregnant). Switch to TDF if virally suppressed and normal CrCl, even if tolerated.

Source: The South African Antiretroviral Treatment Guidelines, Final, March 2013.

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Contraindication to TDF, AZT, and d4T	**ABC + 3TC + EFV (or NVP)**	Renal disease, anaemia, peripheral neuropathy, the use of other nephrotoxic drugs
Currently on d4T based regimen	**TDF + FTC (or 3TC) + EFV FDC PREFERRED**	Mandatory if patients experience toxicity or who are at high risk of toxicity (high BMI or pregnant). Switch to TDF if virally suppressed and normal CrCl, even if tolerated.

PAGE 63

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Contraindication to TDF, AZT, and d4T	**ABC + 3TC + EFV (or NVP)**	Renal disease, anaemia, peripheral neuropathy, the use of other nephrotoxic drugs
Currently on d4T based regimen	**TDF + FTC (or 3TC) + EFV FDC PREFERRED**	Mandatory if patients experience toxicity or who are at high risk of toxicity (high BMI or pregnant). Switch to TDF if virally suppressed and normal CrCl, even if tolerated.

PAGE 63

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Contraindication to TDF, AZT, and d4T	**ABC + 3TC + EFV (or NVP)**	Renal disease, anaemia, peripheral neuropathy, the use of other nephrotoxic drugs
Currently on d4T based regimen	**TDF + FTC (or 3TC) + EFV FDC PREFERRED**	Mandatory if patients experience toxicity or who are at high risk of toxicity (high BMI or pregnant). Switch to TDF if virally suppressed and normal CrCl, even if tolerated.

PAGE 63

Source: The South African Antiretroviral Treatment Guidelines, Final, March 2013.

2nd and 3rd Line ART in Adults and Adolescents

2ND LINE	
Failing on a tenofovir (TDF)- based 1st line regimen.	**Zidovudine (AZT) + Lamivudine (3TC) + Lopinavir/ritonavir (LPV/r)** Patients with anaemia and renal failure switch to ABC
Failing on a stavudine (d4T)- based 1st line regimen.	**Tenofovir (TDF) + Lamivudine (3TC) OR (FDC) + Lopinavir/ritonavir (LPV/r)**
Dyslipidaemia or diarrhea associated with LPV/r	**Switch Lopinavir/ritonavir (LPV/r) to Atazanavir/ritonavir (ATV/r)**
3RD LINE - Specialist referral for all patients failing a 2nd line regimen	
Expert and genotype resistance testing based decision and supervised care.	Most likely regimen: **Raltegravir/Darunavir/Etravirine** adjusted according to genotype interpretation. Should be managed by expert and take into account prior exposure and predictable mutations. Drugs will be managed centrally.

Source: The South African Antiretroviral Treatment Guidelines, March 2013

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Failing on a stavudine (d4T)- based 1st line regimen.	**Tenofovir (TDF) + Lamivudine (3TC) OR (FDC) + Lopinavir/ritonavir (LPV/r)**
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PAGE 64

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PAGE 64

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PAGE 64

1st Line ART in Infants and Children

All infants and children under 3 years or < 10 kg	**Abacavir (ABC) + Lamivudine (3TC) + Lopinavir/ritonavir (LPV/r)**
Children over 3 years and > 10kg	**Abacavir (ABC) + Lamivudine (3TC) + Efavirenz (EFV) If exposed to NVP for 6 weeks or longer should start on Abacavir (ABC) + Lamivudine (3TC) + Lopinavir/ritonavir (LPV/r)**
Currently on stavudine (d4T) based regimen	**Check viral load. If undetectable, change Stavudine (d4T) to Abacavir (ABC) If viral load > 1000 copies/ml manage as treatment failure If viral load 50-1000 copies/ml consult with an expert**

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PAGE 65

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PAGE 65

2nd and 3rd Line ART in Infants and Children

Failed first line Protease Inhibitor (PI)-based regimen	**Recommended 2nd line regimen**
Failed ABC + 3TC + LPV/r	**Consult with expert for advice**
Failed d4T + 3TC + LPV/r	
Failed unboosted PI-based regimen	
Failed first line NNRTI based regimen ***Discuss with expert before changing**	**Recommended 2nd line regimen**
Failed ABC + 3TC + EFV (or NVP)	AZT + 3TC + LPV/r
Failed d4T + 3TC + EFV (or NVP)	AZT + ABC + LPV/r
Failing any 2nd line regimen	**Refer for specialist opinion. Regimen will be based on genotype resistance testing, expert opinion and supervised care. 3rd line ART managed centrally.**

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2nd and 3rd Line ART in Infants and Children

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PAGE 66

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PAGE 66

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PAGE 66

ART Monitoring for Adults & Adolescents

At Initial Diagnosis of HIV	Purpose
Confirm HIV result with rapid antibody test	Ensure that national testing algorithm has been followed
CD4 on the same day if HIV positive and WHO clinical staging	To assess eligibility for ART To assess eligibility for fast-tracking
Ask if pregnant, planning to conceive, or breastfeeding	To identify women who need ART for life or ART for PMTCT
Screen for TB symptoms using Screening Tool	To identify TB/HIV co-infected
Hb or FBC if requires AZT Creatinine if requires TDF ALT if requires NVP	To detect anaemia or neutropaenia, detect renal insufficiency and exclude liver disease
Cryptococcal Antigen if CD4<100	To detect possible infection early and provide prophylaxis or treatment
At Routine Follow-Up Visits if not yet eligible for ART	**Purpose**
Repeat CD4 at 6 months	To see if they have become eligible for ART
WHO clinical staging at every visit	To see if they have become eligible for ART
Screen for TB symptoms and assess for IPT eligibility	To identify TB/HIV co-infection and prevent TB activition and transmission
Offer prevention for HIV positives	To prevent HIV transmission and reinfection. To prevent STIs.

Continued

ART Monitoring for Adults & Adolescents

At Initial Diagnosis of HIV	Purpose
Confirm HIV result with rapid antibody test	Ensure that national testing algorithm has been followed
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Ask if pregnant, planning to conceive, or breastfeeding	To identify women who need ART for life or ART for PMTCT
Screen for TB symptoms using Screening Tool	To identify TB/HIV co-infected
Hb or FBC if requires AZT Creatinine if requires TDF ALT if requires NVP	To detect anaemia or neutropaenia, detect renal insufficiency and exclude liver disease
Cryptococcal Antigen if CD4<100	To detect possible infection early and provide prophylaxis or treatment
At Routine Follow-Up Visits if not yet eligible for ART	**Purpose**
Repeat CD4 at 6 months	To see if they have become eligible for ART
WHO clinical staging at every visit	To see if they have become eligible for ART
Screen for TB symptoms and assess for IPT eligibility	To identify TB/HIV co-infection and prevent TB activition and transmission
Offer prevention for HIV positives	To prevent HIV transmission and reinfection. To prevent STIs.

Continued

PAGE 67

ART Monitoring for Adults & Adolescents

At Initial Diagnosis of HIV	Purpose
Confirm HIV result with rapid antibody test	Ensure that national testing algorithm has been followed
CD4 on the same day if HIV positive and WHO clinical staging	To assess eligibility for ART To assess eligibility for fast-tracking
Ask if pregnant, planning to conceive, or breastfeeding	To identify women who need ART for life or ART for PMTCT
Screen for TB symptoms using Screening Tool	To identify TB/HIV co-infected
Hb or FBC if requires AZT Creatinine if requires TDF ALT if requires NVP	To detect anaemia or neutropaenia, detect renal insufficiency and exclude liver disease
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PAGE 67

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Continued

PAGE 67

ART Monitoring for Adults & Adolescents

Continued

On ART	Purpose
CD4 at 1 year on ART	To monitor immune response to ART
VL at month 6, 1 year on ART, and then every 12 months	To identify treatment failures and problems with adherence
ALT only if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity
FBC at month 3 and 6 if on AZT	To identify AZT toxicity Refer if Hb < 8 g/dl
Creatinine at month 3 and 6, 1 year then every 12 months if on TDF	To identify TDF toxicity Refer if eGFR < 60 ml/min
Fasting cholesterol and triglycerides at month 3 if on LPV/r	To identify LPV/r toxicity
Screen for TB and assess for IPT eligibility	To identify TB/HIV co-infection and prevent TB activation and transmission

Source: The South African Antiretroviral Treatment Guidelines, March 2013

ART Monitoring for Adults & Adolescents

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PAGE 68

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PAGE 68

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PAGE 68

ART Monitoring for Infants & Children

At Initial Diagnosis of HIV	Purpose
Verify HIV status	Ensure that national testing algorithm including HIV DNA PCR and HIV viral load (RNA) for infants and children less than 18 months has been followed
Document weight, height, head circumference (<2yrs) and development	To monitor growth and development and identify eligibility for ART
Screen for TB symptoms using Screening Tool	To identify TB/HIV co-infection or IPT eligibility
WHO Clinical Staging	To identify ART eligibility
CD4 Count	Children < 5 years - baseline but do not wait to start ART. If > 5 years, to identify ART eligibility and start cotrimoxazole per guidelines
Hb or FBC if available	To detect anaemia or neutropaenia
At Routine Follow-up Visits (Not ART eligible)	**Purpose**
Document weight, height, head circumference (<2yrs) and development	To monitor growth and development and to see if they have become eligible for ART
Check that CD4 has been done in the last 6 months	To identify ART eligibility
WHO Clinical Staging	To identify ART eligibility
Screen for TB symptoms and TB contacts	To identify TB/HIV co-infection or IPT eligibility

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PAGE 69

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PAGE 69

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Source: The South African Antiretroviral Treatment Guidelines, Final. March 2013.
Continued
PAGE 69

ART Monitoring for Infants & Children

At initiation of ART (Baseline)	Purpose
Hb or FBC	If < 8g/dl start ART and refer to specialist
CD4 count (if none in last 6 months)	Baseline assessment
Cholesterol + Triglyceride if on PI-based regimen	Baseline assessment
Creatinine and urine dipstix if on TDF regimen	If abnormal refer to specialist
ALT (if jaundiced or on TB treatment)	To assess for liver dysfunction
On ART	**Purpose**
Height, weight, head circumference (<2 yrs) and development	To monitor growth and development stages
Clinical assessment	To monitor response to ART and exclude adverse effects
CD4 at 12 months then every 12 months	To monitor response to ART, stop cotrimoxazole prophylaxis per guidelines
VL at month 6, 12 months into ART, then 6 monthly if < 5 years/12 monthly if 5-15 years	To monitor viral suppression response to ART. To identify treatment failure and problems with adherence
Hb or FBC at month 1, 2, 3 and then annually if on AZT	To identify AZT-related anaemia
Cholesterol + Triglycerides 12 monthly 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 LFTs and refer to specialist
Screen for TB symptoms and TB contacts	To identify TB/HIV co-infection or IPT eligibility

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PAGE 70

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PAGE 70

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PAGE 70

Treatment Failure

Viral Load	Response
>1000 copies/mL	Check for adherence, compliance, tolerability and drug-drug interaction and assess for psychological issues. Repeat VL test 2 months later
If remains >1000 copies/mL	Change regimen to 2nd line therapy

Virologic Failure: Results when the viral load is not completely suppressed, leading to resistance. Defined as a 1-log (10 fold) increase in the lowest recorded viral load. Virologic failure will be noticeable before immunologic or clinical failure.

Immunologic Failure: Results from resistance stemming from the viral load not being completely suppressed. Defined as a 30% drop from the highest value or a return to pre-baseline or lower. This is the second indicator of treatment failure.

Clinical Failure: The viral load is no longer completely suppressed, which results in immune suppression and clinical symptoms may once again become evident. This is the last of the three to become evident. Sometimes difficult to differentiate from an adverse event, drug-drug interaction or IRIS.

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Side Effects by ARV Class

Protease Inhibitors	Nucleoside Reverse Transcriptase Inhibitors (NRTIs)	Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)
Metabolic Disorders • Hepatotoxicities • Hyperglycemia, insulin resistance • Lipid abnormalities • Fat redistribution **Drug Interactions** **GI Intolerance** **Bone Disorders** **CYP450 3A4 Inhibition**	**Nausea** (All) **Headache** (All) **Anaemia** (AZT) **Renal Toxicity** (TDF) **Peripheral neuropathy** (D4T/DDI) **Fat redistribution** (all, except TDF) **Pancreatitis** (DDI > D4T) **Lactic acidosis, fatty liver** • D4T + DDI > D4T > ZDV • Rare with ABC, TDF, 3TC and FTC	**Side effects:** **Rash** (EFV , NVP) **Hepatotoxicity** (NVP) **Dizziness, vivid dreams and other central nervous system** (EFV) **Across the class** • Cross Resistance

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PAGE 72

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PAGE 72

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PAGE 72

Lactic Acidosis Diagnosis and Management

Clinical Presentation: Symptoms are non specific and include: Abdominal pain, shortness of breath, nausea, vomiting, weight loss, muscle pain.

Causative Agent: NRTIs especially didanosine and stavudine.

Diagnosis: Elevated LDH, ALT/AST and CPK. Low bicarbonate level and a widened anion gap (Sodium-Chloride + bicarbonate) >13.

Treatment: Stop ARV drugs and correct acidosis using IV fluids to diminish the risk of hypovolaemia, oxygen.

Moderate:

- Lactate 5-10 with moderate symptoms
- Moderate metabolic acidosis with standard bicarbonate 15-20
- Stop ART and observe as inpatient for 1-2 days
- Give oral vit Bco and Thiamine
- Oral or IV fluids
- Exclude sepsis and OIs
- Recheck lactate and discharge for outpatient follow-up if clinically stable
- Recommence ART (regimen without d4T nor ddl) when lactate is normal

Severe:

- Lactate >10 without metabolic acidosis or significant acidsosi with standard bicarbonate <15
- Admit to high care and Stop ART
- IVI Thiamine and Vit Bco and $NaHCO_3$ if profound acidosis
- IVI fluids and broad spectrum antibiotics
- Do septic search (blood and urine cultures)
- Ventilation if respiratory fatigue occurs
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PAGE 73

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PAGE 73

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PAGE 73

Cotrimoxazole

Group: Antibiotic

Formulation:

Tablet: 80/400 and 160/800 mg (forte) trimethoprim/sulfamethoxazole (TMP/SMX)
Syrup: 1 ml with 8/40 mg
Ampules: 80/400 mg

Clinical Information:

Prophylaxis: 160/800mg (2 single strength tablets) orally once daily.

See PCP Card for PCP treatment dosages.

Renal insufficiency: halve dose with creatinine clearance of 15-50 ml/min. Manufacturer recommends avoiding if creatinine clearance < 10 ml/min.

Dosage and Administration:

PCP prophylaxis: 80/400 mg qd or 160/800 mg TMP/SMX 3 x/week.

PCP therapy: 5mg/kg (based on trimethoprim) po or iv every 8 h for 21 days, therefore usually 4 to 5 ampules a 80/400 mg every 8 h.Toxoplasmosis prophylaxis: 1 tablet (160/800 mg) qd.

Adverse Effects: Allergic response including rash, possible. In case of mild allergy, treatment can be continued. In high doses, anaemia, neutropenia, thrombocytopenia, nausea, vomiting, headache, elevated transaminases.

Drug Interactions: Cotrimoxazole can increase levels of anticoagulants and phenytoin and reduce the efficacy of oral contraceptives.

Comments/Warning: Caution with sulfonamide allergy! Oral suspension for children can be used for desensitization: increase the dose slowly over six days from 12.5, 25, 37.5, 50 and 75 to 100% of the 480mg tablet dose

Cotrimoxazole

Group: Antibiotic

Formulation:

Tablet: 80/400 and 160/800 mg (forte) trimethoprim/sulfamethoxazole (TMP/SMX)
Syrup: 1 ml with 8/40 mg
Ampules: 80/400 mg

Clinical Information:

Prophylaxis: 160/800mg (2 single strength tablets) orally once daily.

See PCP Card for PCP treatment dosages.

Renal insufficiency: halve dose with creatinine clearance of 15-50 ml/min. Manufacturer recommends avoiding if creatinine clearance < 10 ml/min.

Dosage and Administration:

PCP prophylaxis: 80/400 mg qd or 160/800 mg TMP/SMX 3 x/week.

PCP therapy: 5mg/kg (based on trimethoprim) po or iv every 8 h for 21 days, therefore usually 4 to 5 ampules a 80/400 mg every 8 h.Toxoplasmosis prophylaxis: 1 tablet (160/800 mg) qd.

Adverse Effects: Allergic response including rash, possible. In case of mild allergy, treatment can be continued. In high doses, anaemia, neutropenia, thrombocytopenia, nausea, vomiting, headache, elevated transaminases.

Drug Interactions: Cotrimoxazole can increase levels of anticoagulants and phenytoin and reduce the efficacy of oral contraceptives.

Comments/Warning: Caution with sulfonamide allergy! Oral suspension for children can be used for desensitization: increase the dose slowly over six days from 12.5, 25, 37.5, 50 and 75 to 100% of the 480mg tablet dose

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Syrup: 1 ml with 8/40 mg
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Prophylaxis: 160/800mg (2 single strength tablets) orally once daily.

See PCP Card for PCP treatment dosages.

Renal insufficiency: halve dose with creatinine clearance of 15-50 ml/min. Manufacturer recommends avoiding if creatinine clearance < 10 ml/min.

Dosage and Administration:

PCP prophylaxis: 80/400 mg qd or 160/800 mg TMP/SMX 3 x/week.

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PAGE 74

Cotrimoxazole Initiation

Infants

- Cotrimoxazole is initiated at 4-6 weeks in all infants exposed to HIV.
- Initiate in HIV-infected children ≤ 5 years old or children >5 with clinical stage 2,3,4 or CD4<15% or <200 cells/mm^3.
- The first PCR is done at 6 weeks. If positive, continue cotrimoxazole.
    - If exclusively formula fed, stop when PCR is negative and infant is clinically HIV-negative and exclusive formula feeding is expected to continue.
    - If breast fed, stop when PCR is negative ≥ 6 weeks after full cessation of breast feeding and infant is clinically HIV-negative.
- Any HIV-infected child at high risk for bacterial infections or malaria.
- Any HIV-infected child with previous PCP infection.
- Initiate in all HIV-infected children less than 12 months of age as soon as possible after HIV diagnosis.

Adults

- Cotrimoxazole prophylaxis is recommended for all HIV adults with clinical stage 2,3,4 or CD4 < 200 cells/mm^3.
- Cotrimoxazole should be continued in all patients on ART until CD4 count is > 200 cells/mm^3.
- Pregnant women should continue on Cotrimoxazole prophylaxis as the benefits outweigh the small risk to the foetus.

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PAGE 75

Cotrimoxazole Paediatric Dosing

Age or Weight of Child	Dose	Suspension (200 mg SMX/40mg TMP/5mL)	Single tablet strength (400 mg SMX/80 mg TMP)	Double strength tablet (800 mg SMX/160 mg TMP)
<6 months or <5kg	100 mg SMX/ 20 mg TMP	2.5 mL	¼ tablet	–
6 months-5 years or 5-15 kg	200 mg SMX/ 40 mg TMP	5 mL	½ tablet	–
6-14 years or 15-30 kg	400 mg SMX/ 80 mg TMP	10 mL	1 tablet	½ tablet
>14 years or >30 kg	800 mg SMX/ 160 mg TMP	–	2 tablets	1 tablet

Source: Guidelines for Management of HIV in Children, Second Edition, National Department of Health, 2010

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PAGE 76

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PAGE 76

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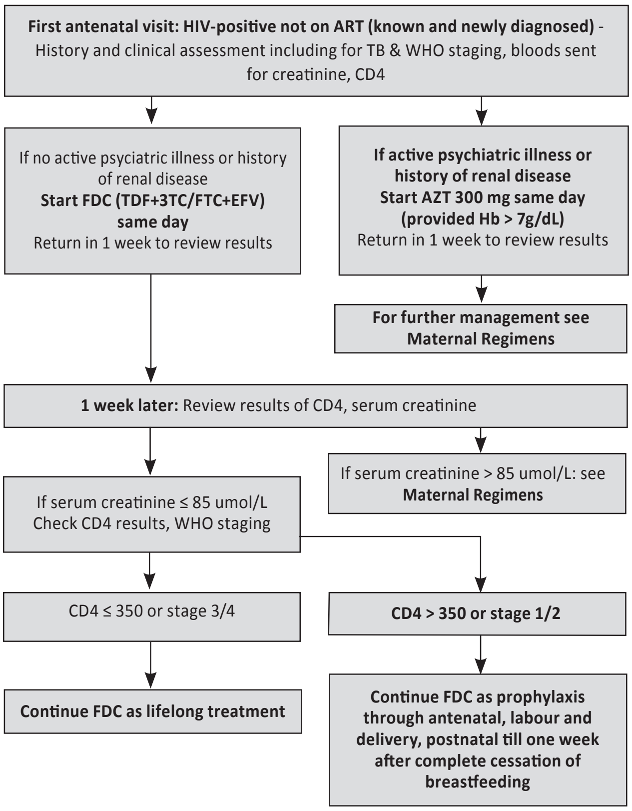
PAGE 76

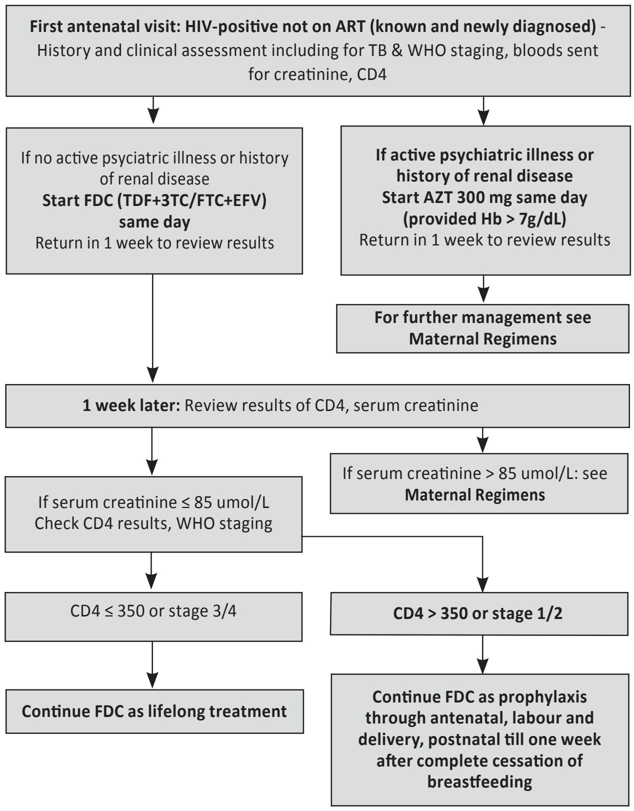
PMTCT
PMTCT
PMTCT

PMTCT Algorithm



Source: The South African Antiretroviral Treatment Guidelines, March 2013

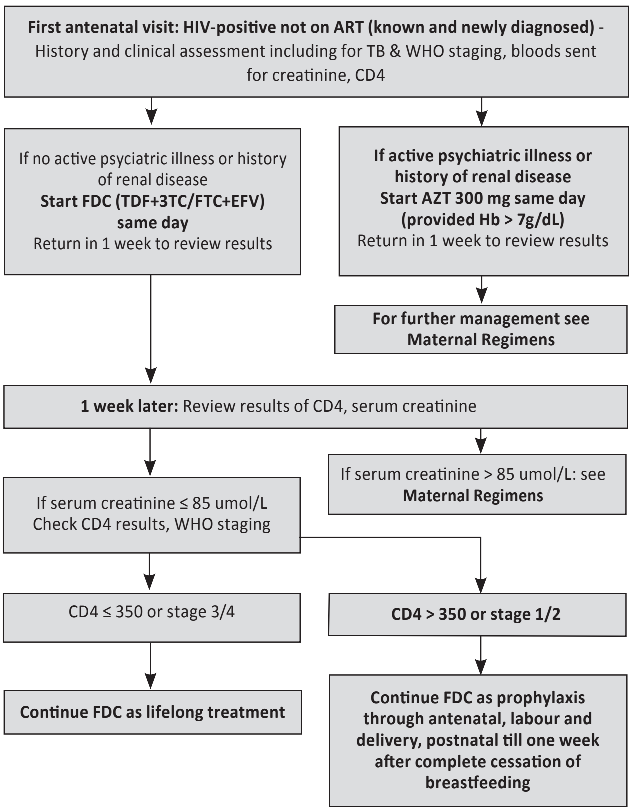
PMTCT Algorithm



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 78

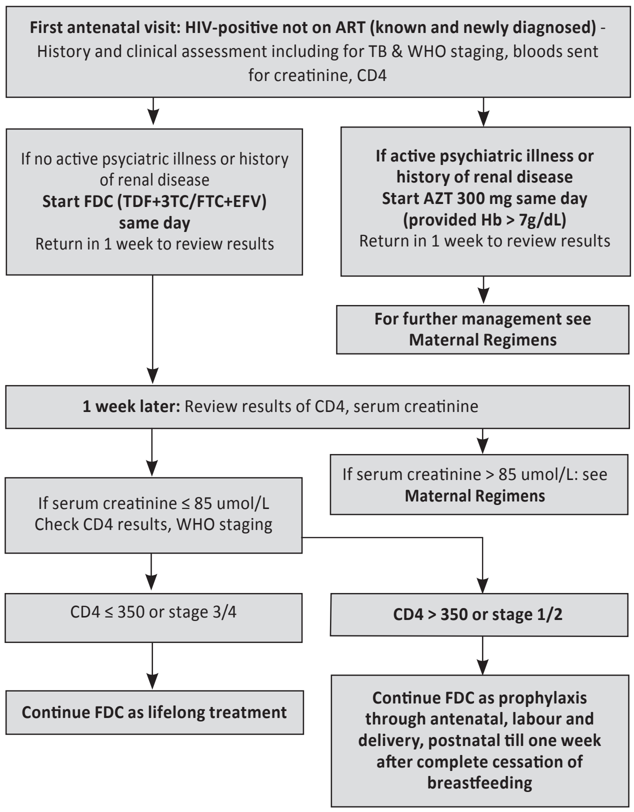
PMTCT Algorithm



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 78

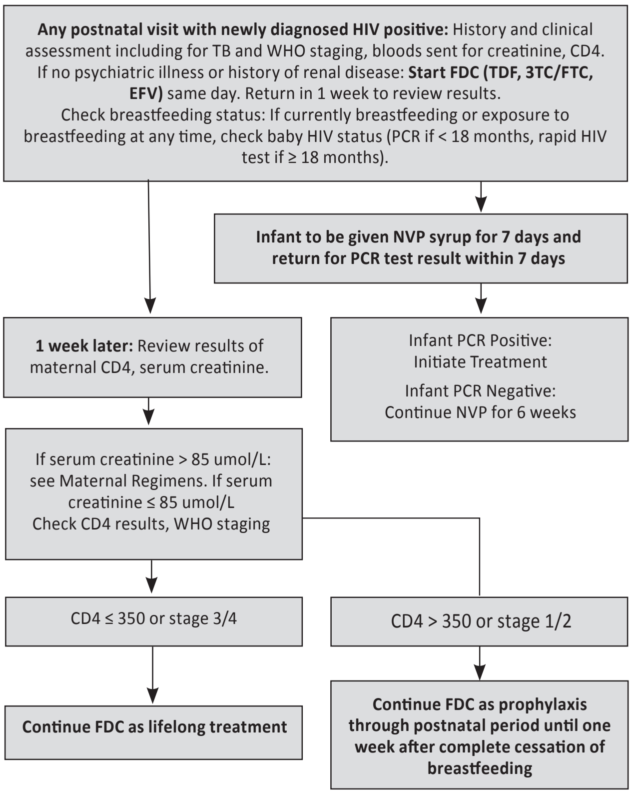
PMTCT Algorithm



Source: The South African Antiretroviral Treatment Guidelines, March 2013

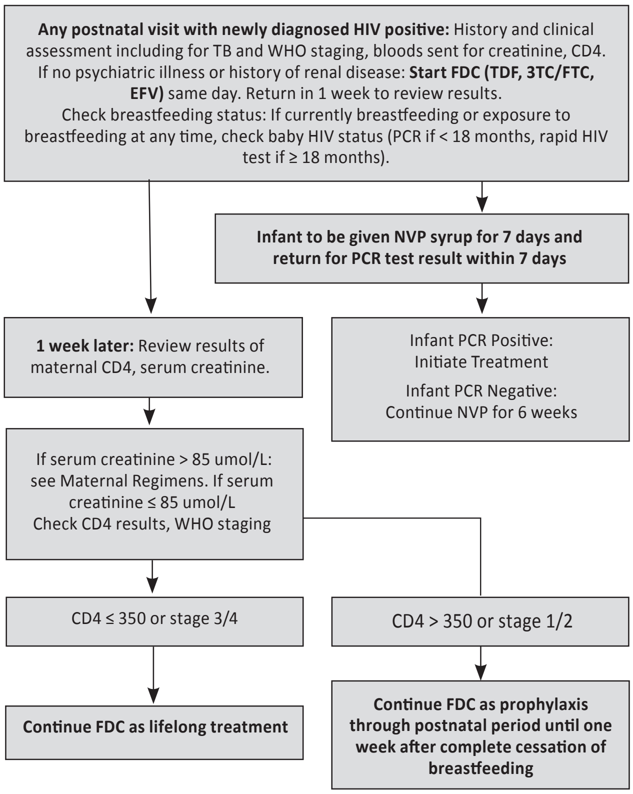
PAGE 78

PMTCT - Postnatal HIV + Diagnosis



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PMTCT - Postnatal HIV + Diagnosis



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 79

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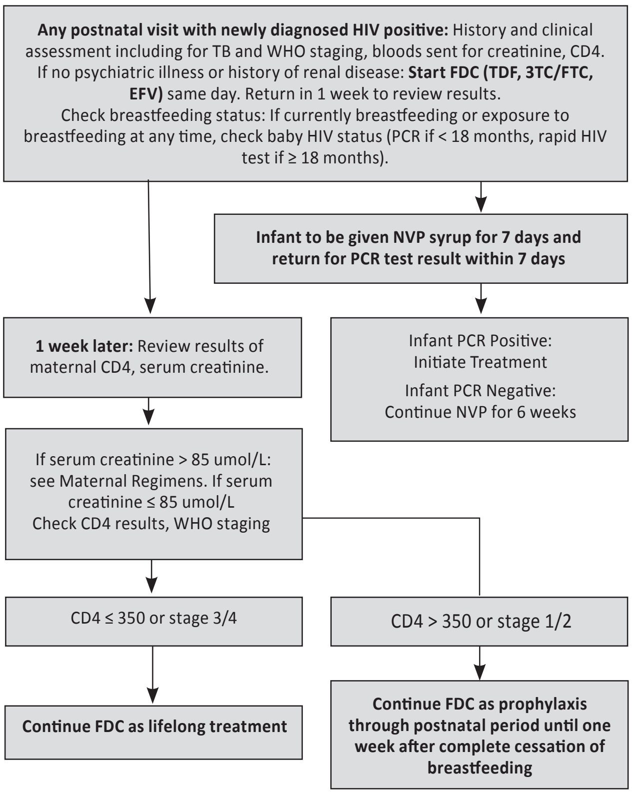

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PAGE 79

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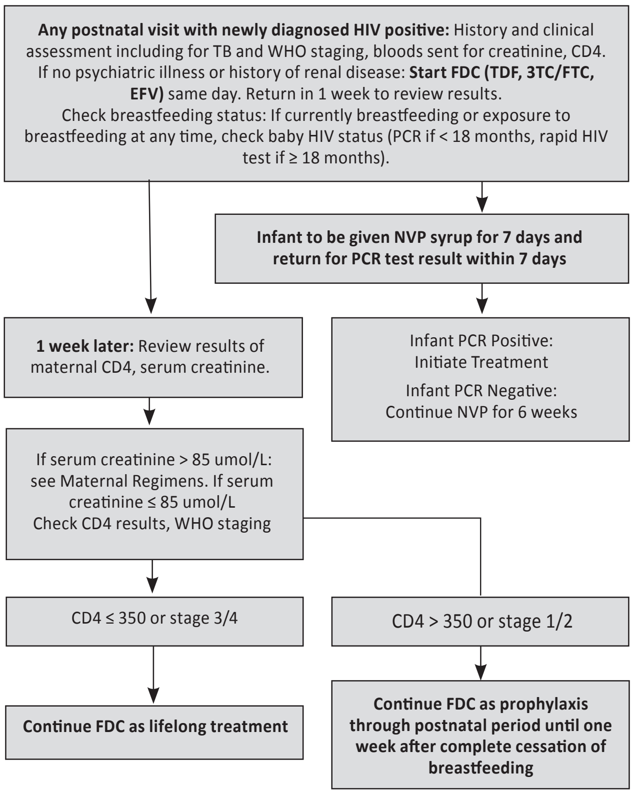
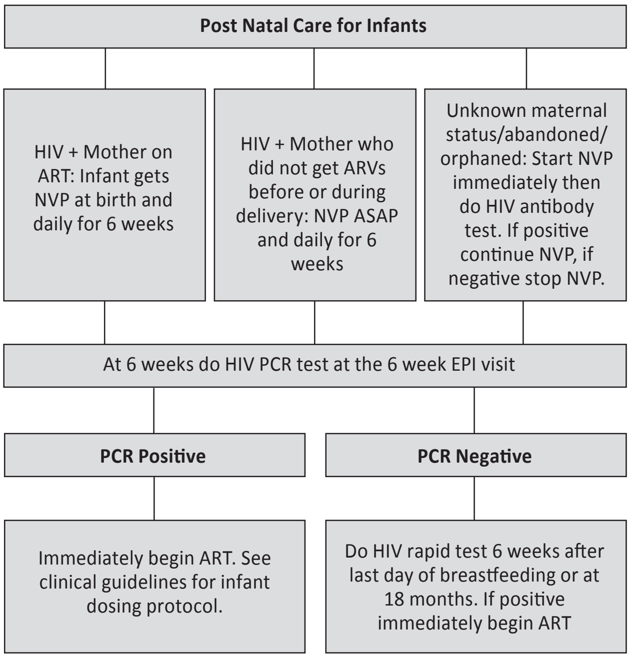


Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 79

Post Natal Care for Infants



Source: The South African Antiretroviral Treatment Guidelines, March 2013

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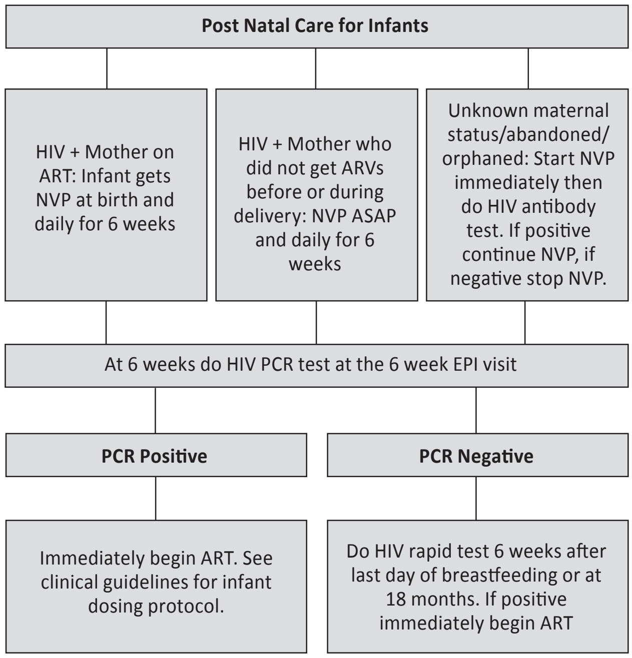
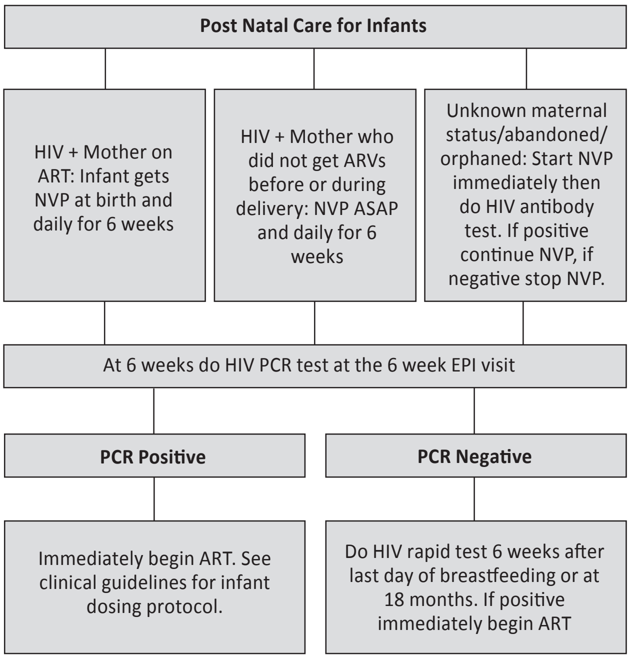


Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 80

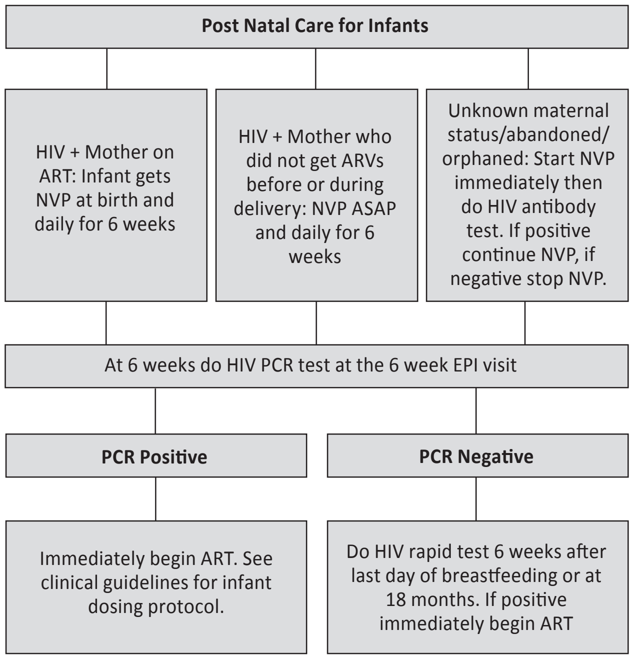
Post Natal Care for Infants



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 80

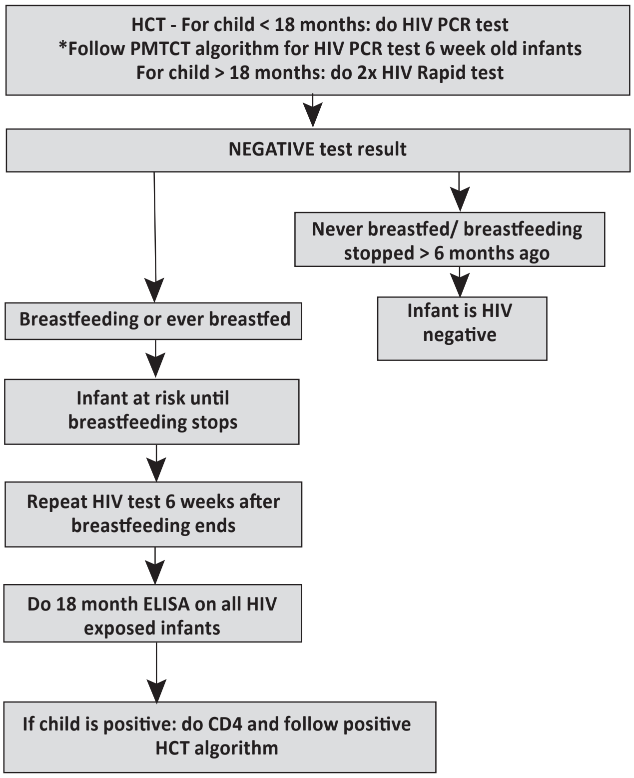
Post Natal Care for Infants



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 80

Paediatric Negative HIV Test Result



Source: The South African Antiretroviral Treatment Guidelines, March 2013

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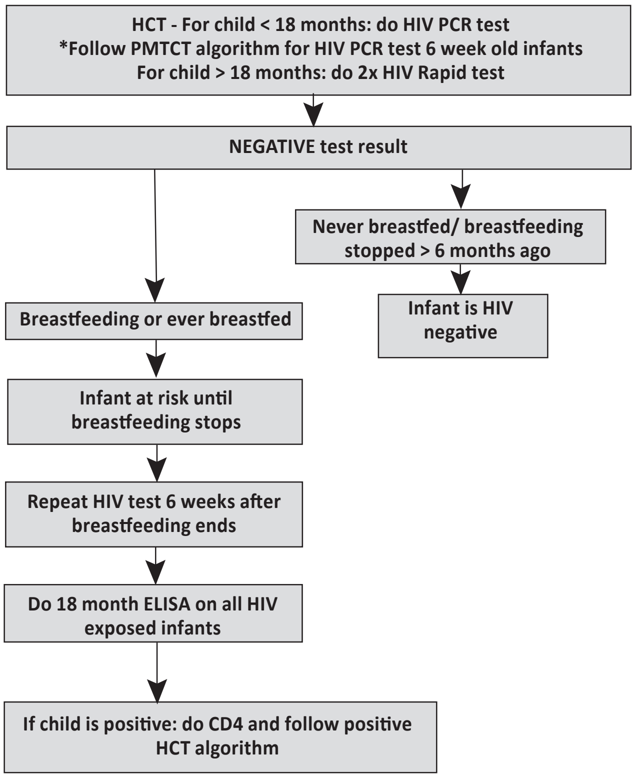
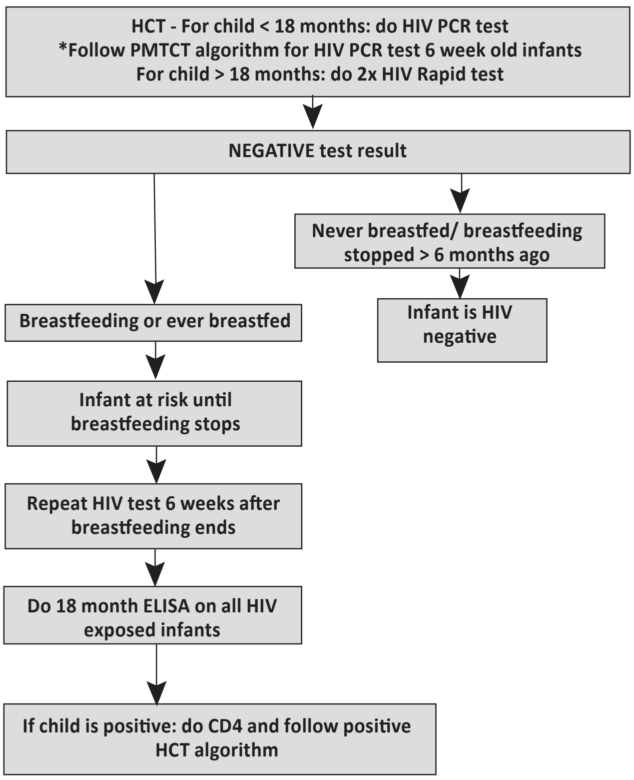


Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 81

Paediatric Negative HIV Test Result



Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 81

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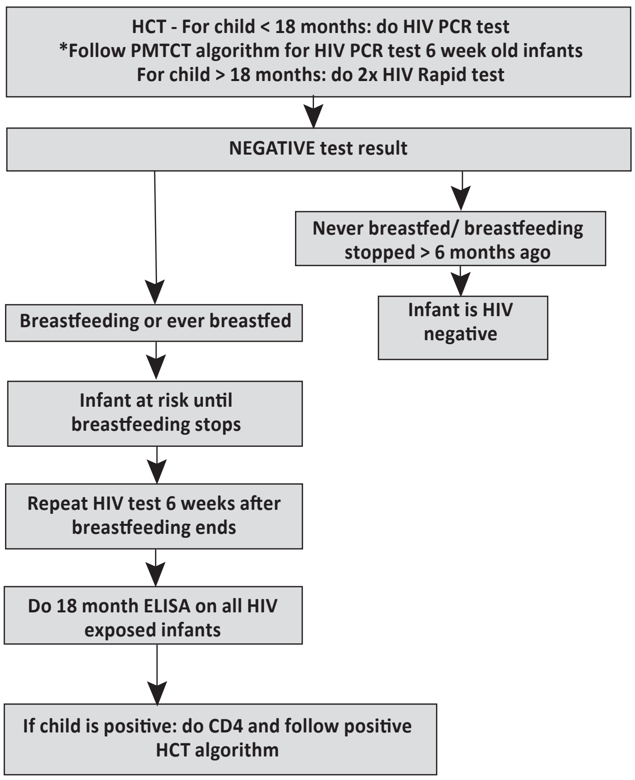

Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 81

Paediatric Positive HIV Test Result

HCT - For child < 18 months: do HIV PCR test
***Follow PMTCT algorithm for HIV PCR test 6 week old infants**
For child > 18 months: do 2x HIV Rapid test

↓

POSITIVE test result

Child < 5 years
Do CD4 test & WHO Staging

Child ≥ 5 years
Do CD4 test & WHO Staging

- CD4 ≤ 350 or stage 3/4 → Start ART within 2 weeks
- CD4 > 350 or stage 1/2 → Enroll in wellness program & begin Cotrim

Start ART within 2 weeks

Begin adherence counselling for caregiver or patient/ weight, height & development monitoring/nutrition counselling/ FBC or HB/ give Cotrim

Child < 3 years or Child < 10 kg or Child > 3 years exposed to NVP > 6 weeks
1st Line:
ABC+3TC+LPV/r

Child > 3 years and Child > 10 kg
1st Line:
ABC+3TC+EFV

Child on d4T regimen:
Switch d4T based on 1st Line Paediatric ART tables

Follow up tests

Routine: Test CD4 at 12 months on ART, then every 12 months. Test viral load at 6 months, 12 months, then 6 monthly if < 5 years and 12 monthly if 5-15 years

Non-routine: Hb or FBC at month 1, 2, 3, then annually if on AZT. If on LPV test for cholesterol + triglyceride. If on TDF test for creatinine + urine dipstix. If jaundiced or TB test for ALT. **At every check up screen for: TB, weight, height, head circumference (<2 years) and side effects.

Source: The South African Antiretroviral Treatment Guidelines, March 2013

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Child on d4T regimen: Switch d4T based on 1st Line Paediatric ART tables
Follow up tests
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PAGE 82

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Source: The South African Antiretroviral Treatment Guidelines, March 2013
PAGE 82

ART Monitoring for Maternal Regimens

For women taking	Monitoring if on lifelong ART therapy	Monitoring if on ART prophylaxis
TDF + 3TC/FTC + EFV (FDC)	Creatinine at 3, 6, 12 months post-initiation	Creatinine at 3, 6, 12 months post-initiation
	VL at 6, 12 months post-initiation; CD4 at 12 months post-initiation	CD4 at 6 weeks post-partum and 6 monthly
AZT only	N/A	Hb at 1, 2, 3, and 6 months post-initiation
Other triple drug regimens	Per adult ARV guidelines	

Source: The South African Antiretroviral Treatment Guidelines, PMTCT, 12.3.2013.

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PAGE 83

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PAGE 83

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AZT only	N/A	Hb at 1, 2, 3, and 6 months post-initiation
Other triple drug regimens	Per adult ARV guidelines	

Source: The South African Antiretroviral Treatment Guidelines, PMTCT, 12.3.2013.

PAGE 83

Maternal Regimens (HIV-Positive)

All women at first antenatal visit (any gestational age)	**FDC initiated immediately**	If FDC ontraindicated, start AZT immediately and review within 1 week
Currently on lifelong ART	**Continue the ART regimen if the woman is on a compatible regimen (EFV, 3TC, TDF) to change to FDC**	Check a VL when pregnancy diagnosed
2nd antenatal visit (1 week later)		
Creatinine ≤ 85µmol/l	**Continue FDC**	
Creatinine > 85µmol/l	**AZT + 3TC + EFV If CD4 ≤ 350 AZT in pregnancy**	Refer for renal disease If Hb < 7g/dl use d4T instead of AZT
EFV contraindicated (active psychiatric illness)	**CD4 ≤ 350: TDF + FDC + NVP CD4 > 350: AZT in pregnancy**	Substitute LPV/r for NVP in women with CD4 counts > 250 but < 350
AZT in pregnancy or tests HIV positive in labour	**sdNVP + sd TDF + FTC + AZT 3 hourly in labour**	**Begin FDC after delivery if breastfeeding. Assess ART eligibility**

Source: The South African Antiretroviral Treatment Guidelines, March 2013

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Creatinine ≤ 85µmol/l	**Continue FDC**	
Creatinine > 85µmol/l	**AZT + 3TC + EFV If CD4 ≤ 350 AZT in pregnancy**	Refer for renal disease If Hb < 7g/dl use d4T instead of AZT
EFV contraindicated (active psychiatric illness)	**CD4 ≤ 350: TDF + FDC + NVP CD4 > 350: AZT in pregnancy**	Substitute LPV/r for NVP in women with CD4 counts > 250 but < 350
AZT in pregnancy or tests HIV positive in labour	**sdNVP + sd TDF + FTC + AZT 3 hourly in labour**	**Begin FDC after delivery if breastfeeding. Assess ART eligibility**

Source: The South African Antiretroviral Treatment Guidelines, March 2013

PAGE 84

Maternal Regimens (HIV-Positive)

All women at first antenatal visit (any gestational age)	**FDC initiated immediately**	If FDC ontraindicated, start AZT immediately and review within 1 week
Currently on lifelong ART	**Continue the ART regimen if the woman is on a compatible regimen (EFV, 3TC, TDF) to change to FDC**	Check a VL when pregnancy diagnosed
2nd antenatal visit (1 week later)		
Creatinine ≤ 85µmol/l	**Continue FDC**	
Creatinine > 85µmol/l	**AZT + 3TC + EFV If CD4 ≤ 350 AZT in pregnancy**	Refer for renal disease If Hb < 7g/dl use d4T instead of AZT
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PAGE 84

Infant Regimens (HIV-Positive Mother)

Mother on lifelong ART or antenatal prophylaxis received	NVP at birth and then daily for 6 weeks	If mother is breastfeeding and not virally suppressed (late booking or AZT mono-therapy) continue NVP until 1 week post breastfeeding cessation
Mother not on ART before or during delivery and tests HIV + post delivery	NVP as soon as possible and daily for 6 weeks	Assess ART eligibility as soon as possible
Unknown maternal status because orphaned or abandoned	Give NPV immediately (unless rapid HIV test result available within 2 hours) Test infant with rapid test. If + continue NVP for 6 weeks. If - discontinue.	Follow up at 6 weeks with HIV DNA PCR
Mother on AZT regimen (due to contraindication to FDC)	NVP at birth and then daily for 6 weeks	Test infant at 6 weeks with HIV DNA PCR. If - and breastfeeding continue NVP until 1 week post breastfeeding cessation

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PAGE 85

Nevirapine Infant Dosing Guide

Drug	Birth Weight	Dose	Quantity
NVP syrup (10mg/ml)	< 2.0 kg	2mg/kg (first 2 weeks) 4mg/kg (next 4 weeks)	0.2 ml/kg 0.4 ml/kg
	Birth to 6 weeks 2.0-2.5 kg birth weight	10 mg/d	1 ml
	Birth to 6 weeks at or > 2.5 kg birth weight	15 mg/d	1.5 ml

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PAGE 86

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TUBERCULOSIS
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TB Symptom Screening for Adults and Children

Adults:

- **Do you have a cough? (>2 weeks or any duration if HIV+)**
- **Have you had a fever for more than 2 weeks?**
- **Do you have drenching night sweats?**
- **Have you lost weight? (>1.5kg unexplained weight loss)**

Children:

- **Does the child have a cough > 2 weeks that is not improving on treatment?**
- **Has the child had a fever for more than 2 weeks?**
- **Has the child lost weight or failing to thrive? (check *Road to Health Card*)**
- **Is the child always tired or less playful than usual?**

Other questions for adults and children:

- Have you had close contact with someone with TB?
- Has anyone in your family been diagnosed with TB recently?
- Is blood present in your sputum?
- Do you have shortness of breath? For how long?
- Have you lost your appetite?
- How long have you been feeling weak and tired?
- Have you worked in a mine?
- Have you previously been treated for TB?
- Do you know your HIV status?
- Do you have diabetes?

(Questions in bold are most essential)

Not all those with TB will have a cough; therefore, a high index of suspicion is required, particularly in people who are HIV positive who may only have one of the above symptoms.

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PAGE 88

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PAGE 88

Baseline Screening of TB

Investigations		Recommended Frequency
Microscopy	All patients	Baseline, 7 weeks and 23 weeks
Height	All patients	Baseline
Weight	All patients	Baseline and monthly
Body mass index	All patients	Baseline
HIV test	Patients with unknown HIV status or have not tested in the past year	Baseline
Blood glucose	Urine glucose and ketones (All patients)	Baseline
	Blood glucose (symptomatic patients)	Baseline and monthly for diabetic patients
Pregnancy test	Women of child bearing age, presenting with history of amenorrheoa and not on contraception	Baseline
Alcohol use screening	Patients with a history of alcohol use	Baseline
Liver funtion tests	In patients with a history of liver disease, excessive alcohol use	Baseline
Serum creatinine	In pathents with a history of kidney desease	Baseline, monthly
Chest x-ray	Patients with concomitant lung disease and those with a history of working in the mines	Baseline, end of treatment

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PAGE 89

Smear Reporting

ZN Staining		Auramine Staining	
Number of Bacilli Seen on a Smear	**Results Reported**	**Number of Bacilli Seen on a Smear**	**Results Reported**
No AFB per 100 oil immersion field	0	No AFB on slide	0
1-9 AFB per 100 oil immersion field	Scanty	<1 AFB per field	+
10-99 AFB per 100 oil immersion field	+	1-9 AFB per field	++
1-10 AFB per 1 oil immersion field (min 50 fields)	++	10-99 AFB per field	+++
>10 AFB per 1 oil immersion field (min 20 fields)	+++	>100 AFB per field	++++

Source: National Tuberculosis Management Guidelines, 2014

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PAGE 90

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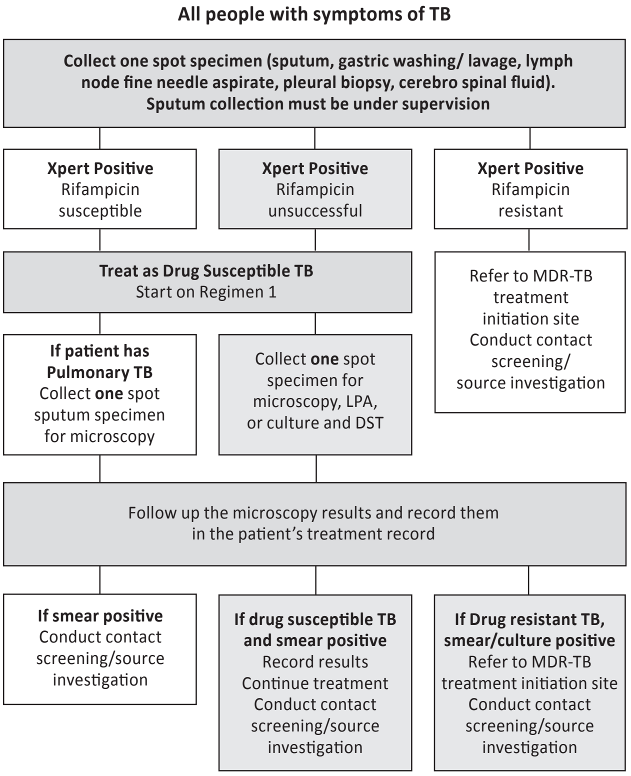
PAGE 90

Xpert Diagnostic Algorithm



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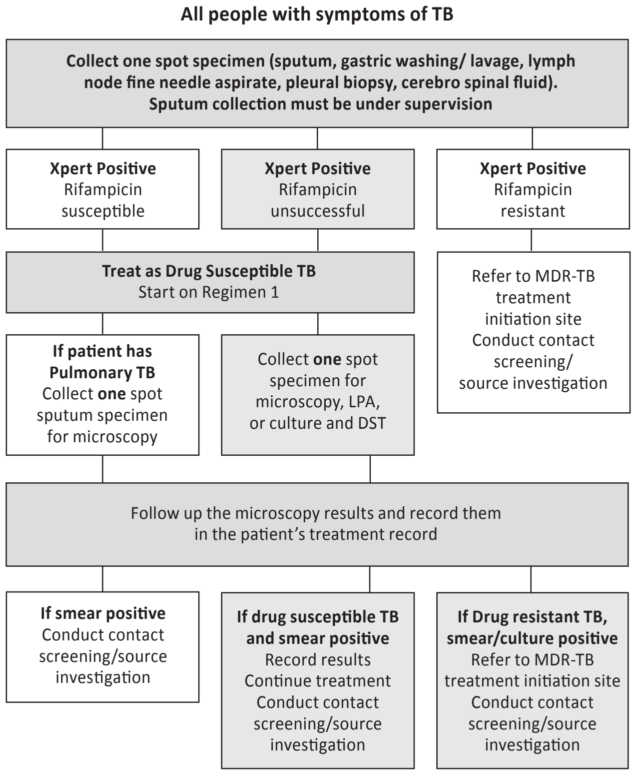
Xpert Diagnostic Algorithm



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PAGE 91

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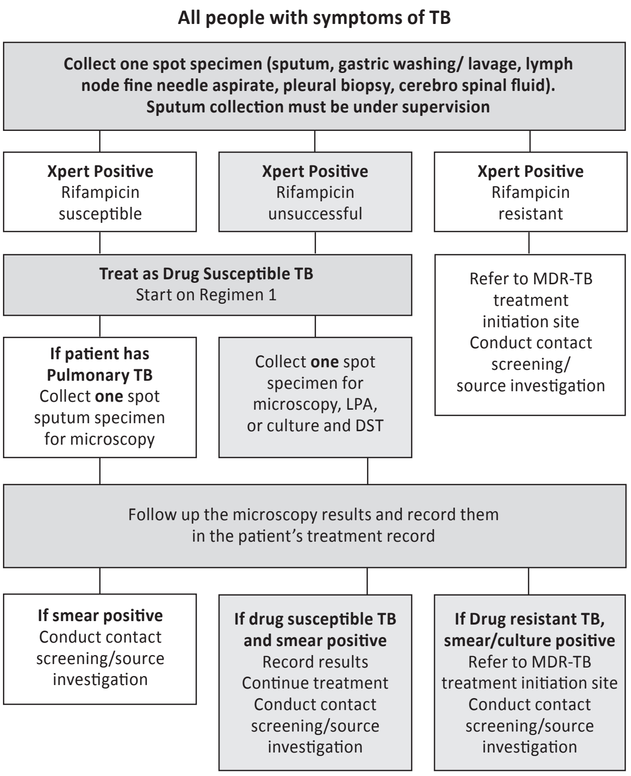

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PAGE 91

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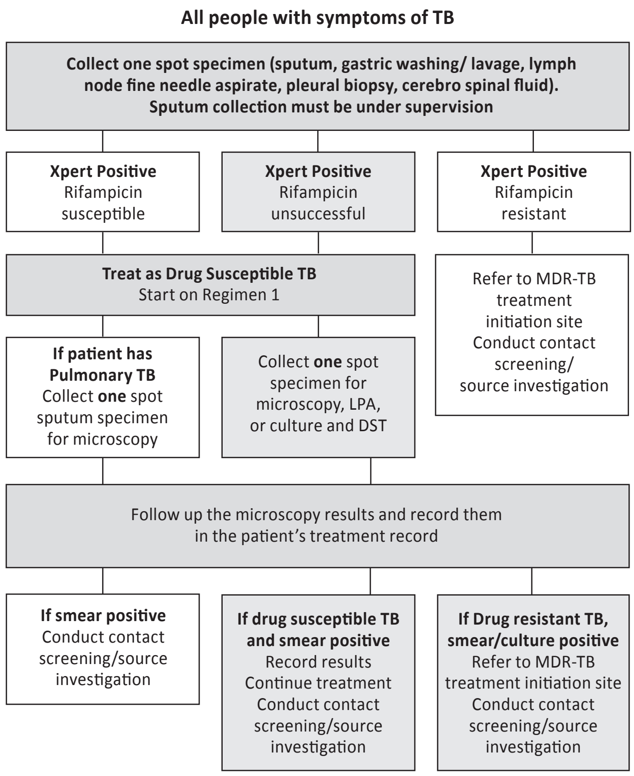

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PAGE 91

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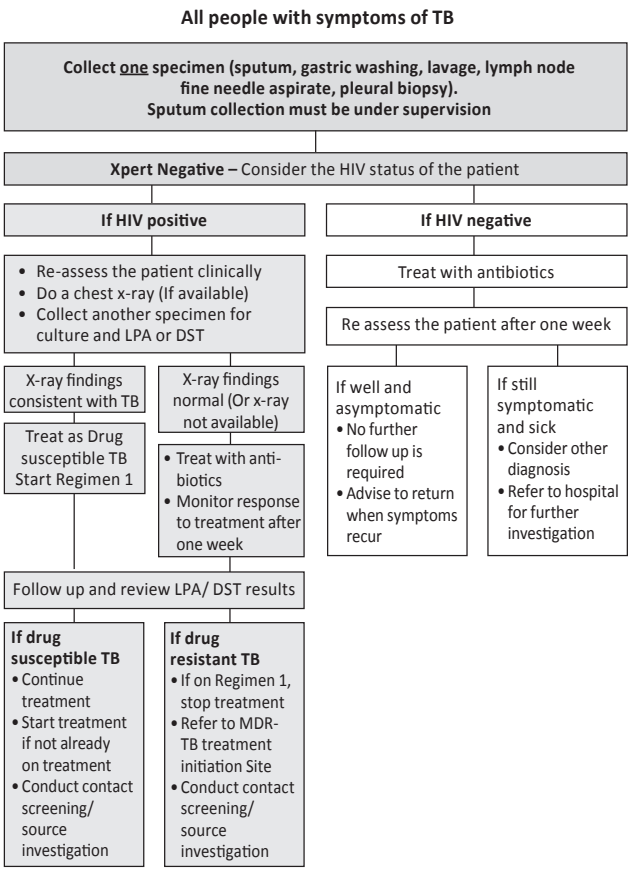

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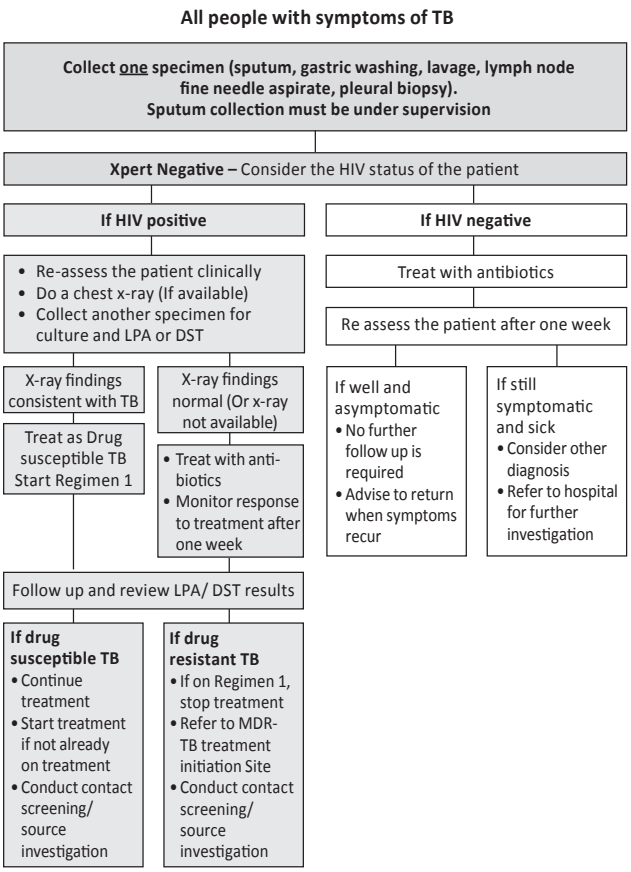

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All people with symptoms of TB
Collect one specimen (sputum, gastric washing, lavage, lymph node fine needle aspirate, pleural biopsy). Sputum collection must be under supervision
Xpert Negative – Consider the HIV status of the patient
If HIV positive
If HIV negative
• Re-assess the patient clinically
• Do a chest x-ray (If available)
• Collect another specimen for culture and LPA or DST
Treat with antibiotics
Re assess the patient after one week
X-ray findings consistent with TB
X-ray findings normal (Or x-ray not available)
If well and asymptomatic
• No further follow up is required
• Advise to return when symptoms recur
If still symptomatic and sick
• Consider other diagnosis
• Refer to hospital for further investigation
Treat as Drug susceptible TB Start Regimen 1
• Treat with anti-biotics
• Monitor response to treatment after one week
Follow up and review LPA/ DST results
If drug susceptible TB
• Continue treatment
• Start treatment if not already on treatment
• Conduct contact screening/ source investigation
If drug resistant TB
• If on Regimen 1, stop treatment
• Refer to MDR-TB treatment initiation Site
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TB Diagnosis Using the Line Probe Assay (LPA)

The LPA test may be used on high risk patients where rapid diagnosis of MDR-TB or Isoniazid resistance is required. One spot sputum specimen should be collected for smear microscopy, if AFB positive then another specimen must be collected for LPA. If smear microscopy is AFB negative, another smear for culture and LPA must be collected.

Interpretation of the LPA Results

Result	Action
Smear microscopy results are AFB positive	The LPA test will be conducted on the second specimen and the results should be back within 5 – 7 days, therefore the patient should be given a return date within 7 days. If the results confirm drug resistant TB the patient should be counselled and arrangements for referral to the local MDR-TB Unit made to ensure treatment initiation as soon as possible. If the results confirm drug sensitive TB, the patient should be counselled and started on TB treatment immediately.
Smear microscopy results are negative	If DR-TB is strongly suspected then a second specimen for culture must be collected for culture and LPA. Whilst waiting for results, chest x-rays may be conducted to support the diagnosis. If clinical and x-ray findings are suggestive of TB, the patient may be started on Regimen 1 and the results reviewed as soon as available and patient managed appropriately.

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PAGE 93

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Continued

PAGE 93

TB Diagnosis Using the Line Probe Assay (LPA)

Result	Meaning	Action
MTB complex detected	MTB was isolated from the specimen therefore the patient has bacteriologically confirmed TB	Review susceptibility results and treat accordingly
MTB complex not detected	MTB was not isolated from the specimen	This result does not completely exclude TB
Rifampicin and Isoniazid susceptible	Patient has drug susceptible TB	Treat with Regimen 1
Rifampicin and Isoniazid resistant	Patient has multi drug resistant TB (MDR-TB)	Treat with Category IV
Rifampicin resistant and Isoniazid susceptible*	Patient has Rifampicin mono resistance (RR-TB)	Treat with Category IV
Rifampicin susceptible and Isoniazid resistant	Patient has Isoniazid mono resistance	Treat with first line drugs RHZE for6 months

* Isoniazid resistance is more complex genetically than rifampicin resistance. The LPA can "miss" isoniazid resistance (i.e. report a false isoniazid susceptible result). In most laboratories, if the LPA shows rifampicin mono resistance, the isoniazid susceptibility will be tested on phenotypic drug susceptibility testing for confirmation.

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Result	Meaning	Action
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MTB complex not detected	MTB was not isolated from the specimen	This result does not completely exclude TB
Rifampicin and Isoniazid susceptible	Patient has drug susceptible TB	Treat with Regimen 1
Rifampicin and Isoniazid resistant	Patient has multi drug resistant TB (MDR-TB)	Treat with Category IV
Rifampicin resistant and Isoniazid susceptible*	Patient has Rifampicin mono resistance (RR-TB)	Treat with Category IV
Rifampicin susceptible and Isoniazid resistant	Patient has Isoniazid mono resistance	Treat with first line drugs RHZE for6 months

* Isoniazid resistance is more complex genetically than rifampicin resistance. The LPA can "miss" isoniazid resistance (i.e. report a false isoniazid susceptible result). In most laboratories, if the LPA shows rifampicin mono resistance, the isoniazid susceptibility will be tested on phenotypic drug susceptibility testing for confirmation.

PAGE 94

TB Diagnosis Using the Line Probe Assay (LPA)

Result	Meaning	Action
MTB complex detected	MTB was isolated from the specimen therefore the patient has bacteriologically confirmed TB	Review susceptibility results and treat accordingly
MTB complex not detected	MTB was not isolated from the specimen	This result does not completely exclude TB
Rifampicin and Isoniazid susceptible	Patient has drug susceptible TB	Treat with Regimen 1
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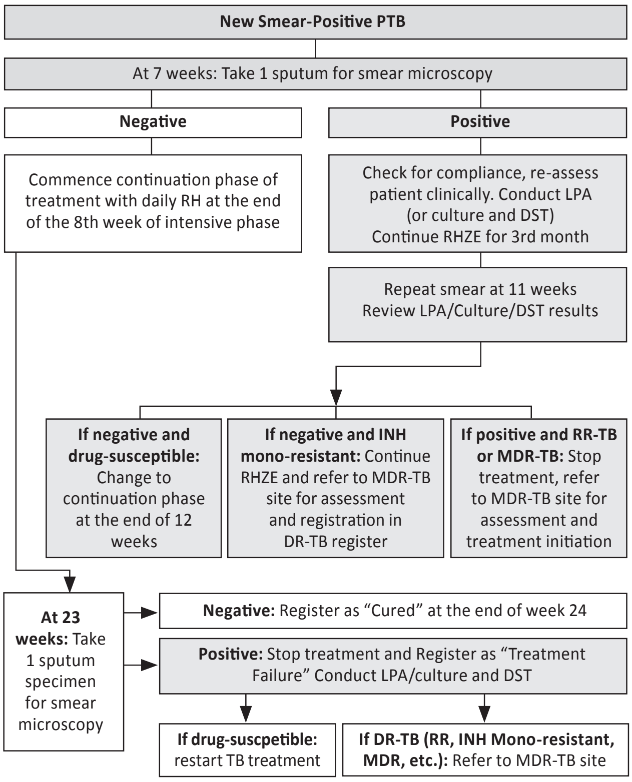
PAGE 94

Monitoring Algorithm for Bacteriologically Confirmed PTB Patients



Source: National Tuberculosis Management Guidelines. Department of Health, 2014.

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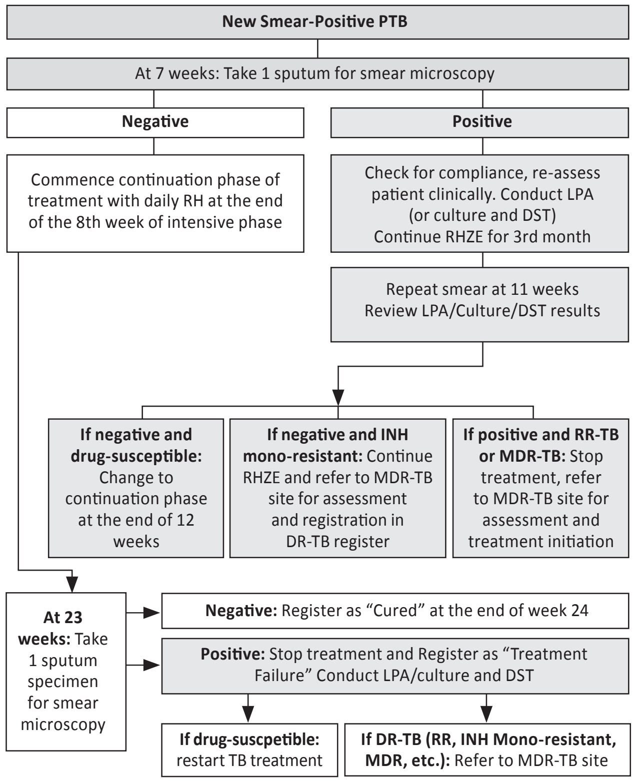

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PAGE 95

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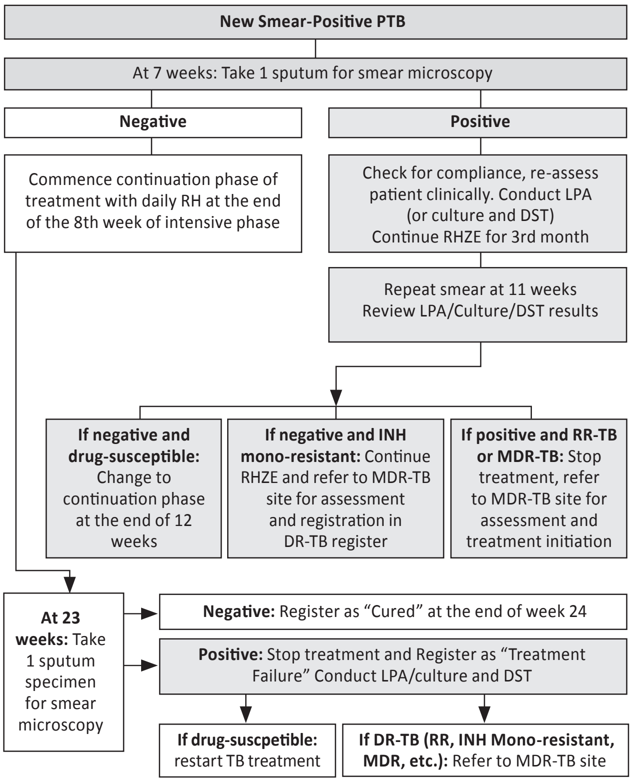

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PAGE 95

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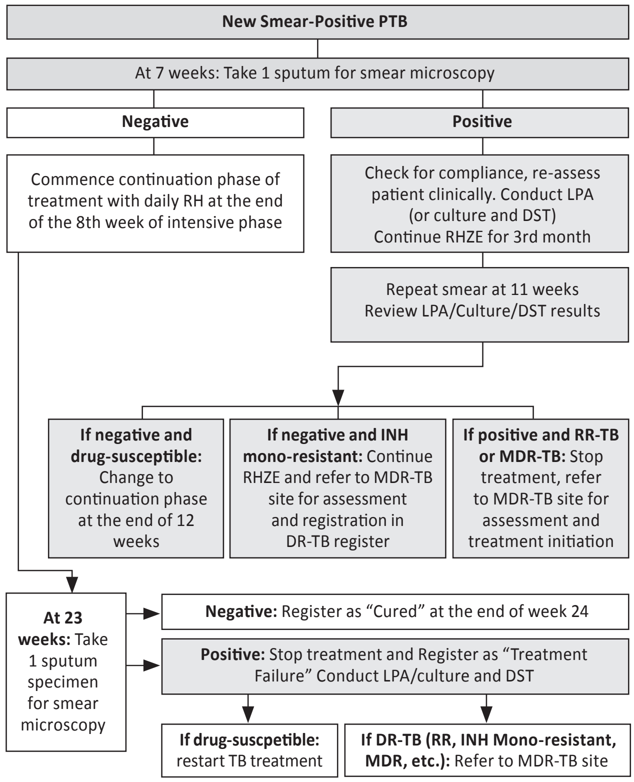

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PAGE 95

Management of Treatment Interruption

If The Patient Interrupted Treatment For Less Than 1 Month
1. Trace the patient 2. Establish the cause for interruption of treatment 3. Address the problem or concerns/ counsel patient 4. Continue treatment and add the missed doses at the end of the treatment phase • If the interruption occurred during the intensive phase, the duration of this phase must be extended by the number of days that the patient did not take treatment. • If the interruption occurred during the continuation phase, the duration of this phase must be extended by the number of days that the patient did not take treatment.

If Patient Interrupts Treatment 1 – 2 Months			
Action 1		**Action 2**	
1. Trace the patient 2. Establish the cause for interruption of treatment 3. Address the problem or concerns/ Counsel patient 4. Collect sputum specimen for Xpert 5. Continue treatment and review results of the tests	If Xpert positive and Rif sensitive	• Continue treatment and add the missed doses at the end of the treatment phase	Monitor as usual until treatment is completed
	If Xpert positive and Rif resistant	• Stop treatment • Register patient as "RR-TB" • Refer to the MDR-TB treatment initiating site for further management	Follow up to ensure the patient has been successfully referred

Continued

Management of Treatment Interruption

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Continued

PAGE 96

Management of Treatment Interruption

If Patient Interrupted Treatment For Two Months Or More (Lost To Follow Up)			
Action 1		**Action 2**	
1. Trace the patient 2. Establish the cause for interruption of treatment 3. Address the problem or concerns/ Counsel patient 4. Collect sputum specimen for Xpert 5. Do not start treatment, wait for the results	If Xpert positive and Rif sensitive	• Register as "Treatment after loss to follow up" • Restart Regimen 1	Monitor as usual until treatment is completed
	If Xpert positive and Rif resistant	• Register patient as "RR-TB" • Refer to the MDR-TB treatment initiation site for further management	Follow up to ensure the patient has been successfully referred

Management of Treatment Interruption

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PAGE 97

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PAGE 97

Regimen 1: Treatment for New and Previously Treated Patients

Regimen 1: For Adults and Children Older Than 8 Years or Weighing More Than 30kg			
Pre-treatment body weight	Intensive Phase 7 days a week for 2 months	Continuation phase 7 days a week for 4 months	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30-37 kg	2 tabs	2 tabs	
38-54 kg	3 tabs	3 tabs	
55-70 kg	4 tabs		2 tabs
> 70kg	5 tabs		2 tabs

R-Rifampicin, H-Isoniazid, Z-Pyrazinamide, E-Ethambutol

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PAGE 98

Standard Treatment Doses for TB

Adults and Children > 8 years / > 30kg TB Drug Dosages		
Essential TB drug (abbreviation)	**Dose mg/kg**	**Dose range mg/kg**
Rifampicin (R)	10	8-12
Isoniazid (H)	5	4-6
Pyrazinamide (Z)	25	20-30
Ethambutol (E)	15	15-20
Streptomycin (S)	15	12-18

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PAGE 99

Isoniazid Preventive Therapy in Adults

- HIV-positive adults and adolescents (including pregnant women) with NO symptoms of TB disease are eligible for IPT screening.
- Exclude TB with sputum Xpert in patients with ANY of the TB symptoms in the TB screening tool, prior to considering IPT.
- Tuberculin Skin Test (TST) is required in all adults and adolescents. If TST is not available, IPT should be continued for 6 months for pre-ART patients and 12 months for patients on ART. All efforts should be made to perform TST within a month of starting IPT
- Any patient who becomes eligible for ART who has never had IPT before should be assessed for IPT eligibility once stable on ART.
- If patient is TST negative, re-screen annually until TST positive at which point 36 months of IPT should be given. IPT is currently not recommended beyond 36 months.
- Standard dose:
  - Isoniazid (INH): 5 mg/kg/day (maximum 300 mg per day)
  - Vitamin B6 (pyridoxine): 25 mg per day to be given with INH to all adults/adolescents on IPT

Source: Guidelines for Isoniazid Preventive Therapy, 2014

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Continued

PAGE 100

Isoniazid Preventive Therapy in Adults

Continued

Reading the Tuberculin Skin Test		
Immune Status	**HIV positive, malnourished, severe illness**	**Others (including previous BCG)**
Diameter of induration in positive test	≥ 5 mm	≥ 10 mm

Provision of IPT for HIV Positive Patients		
TST negative	**Pre-ART**	**On ART**
TST negative	No IPT	IPT for 12 months
TST positive	IPT for 36 months	IPT for 36 months
*Pregnant women on ART for PMTCT are considered "On ART"		

Source: Guidelines for Isoniazid Preventive Therapy, 2014

Continued

Isoniazid Preventive Therapy in Adults

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PAGE 101

Isoniazid Preventive Therapy in Adults

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PAGE 101

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PAGE 101

Isoniazid Preventive Therapy in Adults

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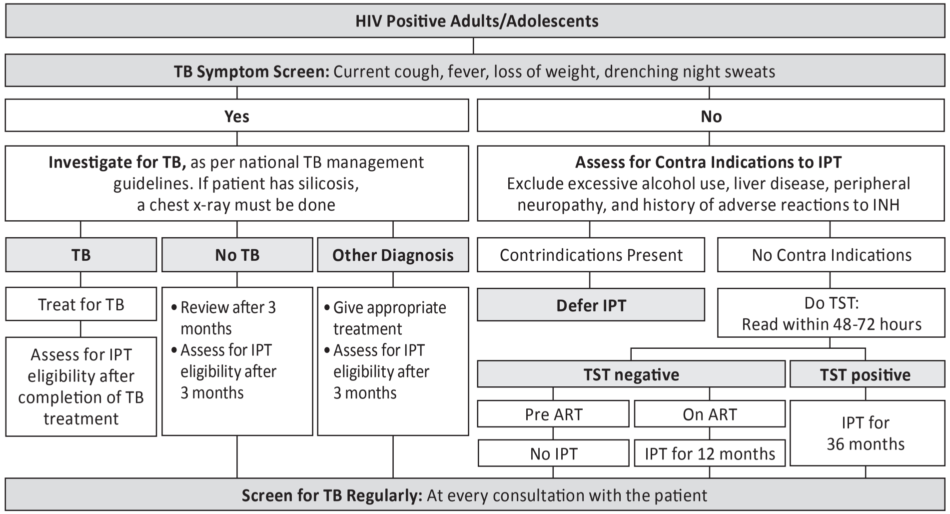

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Isoniazid Preventive Therapy in Adults

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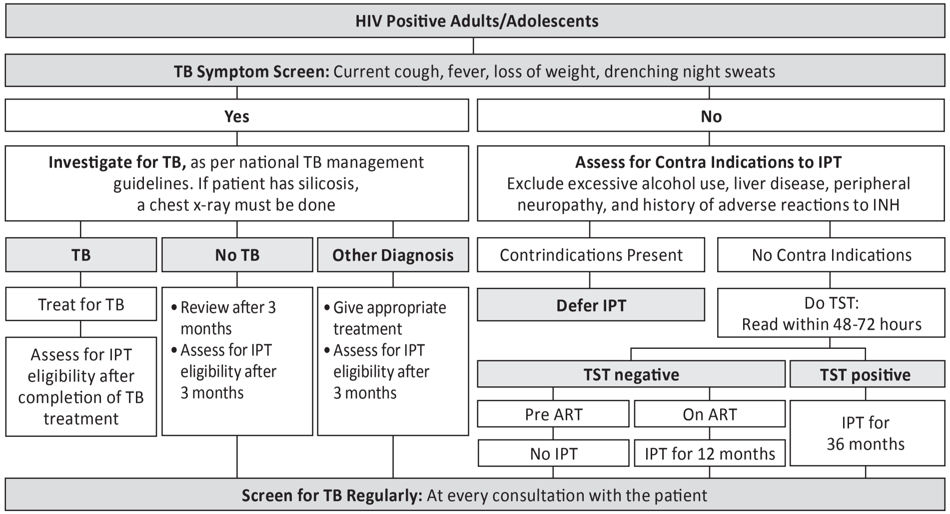

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Isoniazid Preventive Therapy in Adults

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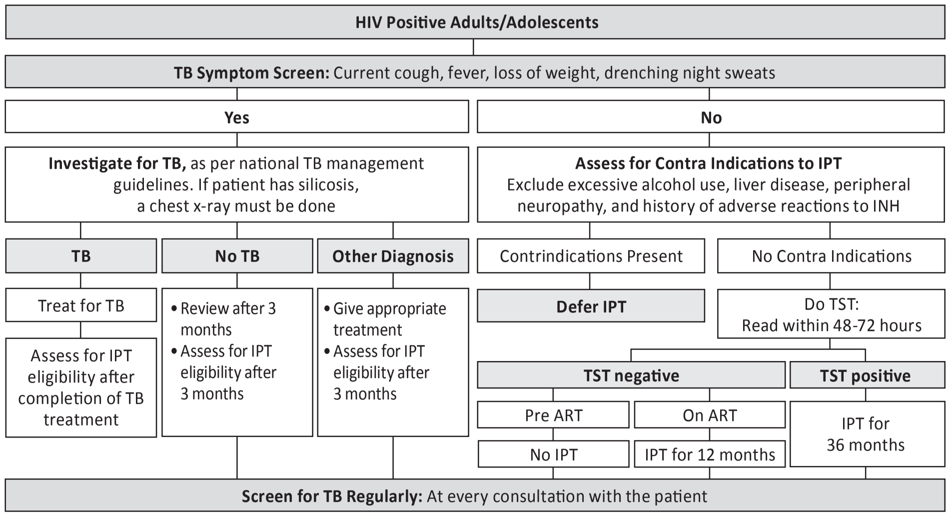

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Isoniazid Preventive Therapy in Adults

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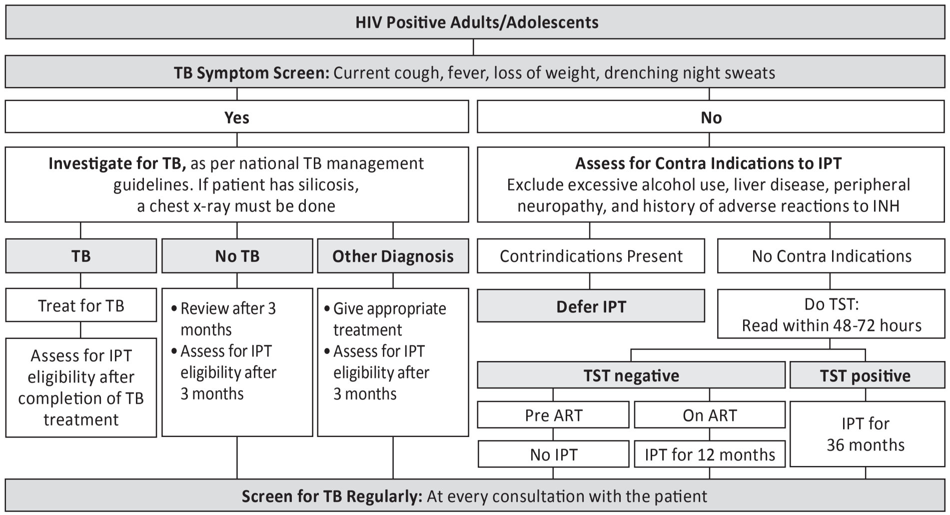

Source: Guidelines for Isoniazid Preventive Therapy, 2014

Isoniazid Preventive Therapy In Children

- Where a possible or confirmed TB contact has been identified and once active TB disease has been excluded, the following children should receive 6 months of INH preventive therapy:
  - All children under 5 years of age
  - All HIV-infected children up to 15 years of age
- Children who are re-exposed to a case of active TB disease following completion of 6 months of IPT must receive a repeat course of IPT (for 6 months), once active TB disease is excluded
- Pre-exposure IPT is not recommended for any child irrespective of HIV status

Weight band (kg)	Daily INH 100mg tablet
2 – 3.4	¼ tablet
3.5 – 4.9	½ tablet
5 – 7.4	¾ tablet
7.5 – 9.9	1 tablet
10 – 14.9	1 ½ tablets
15 – 19.9	2 tablets
≥ 20	3 tablets

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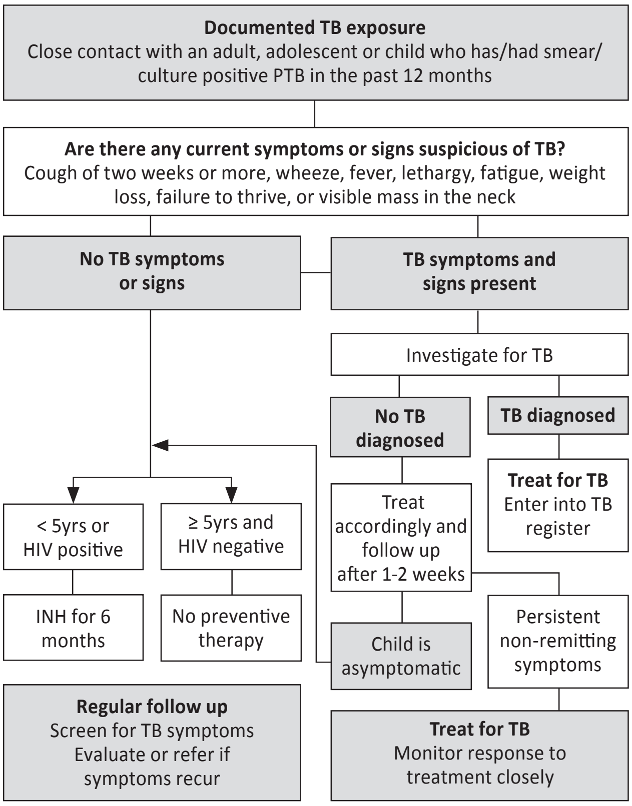
PAGE 103

TB Diagnosis in Children



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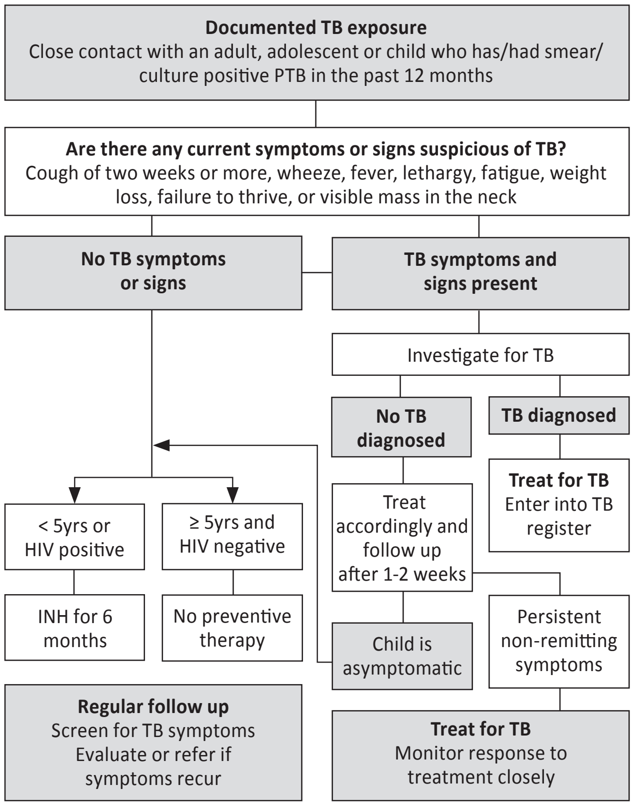
TB Diagnosis in Children



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PAGE 104

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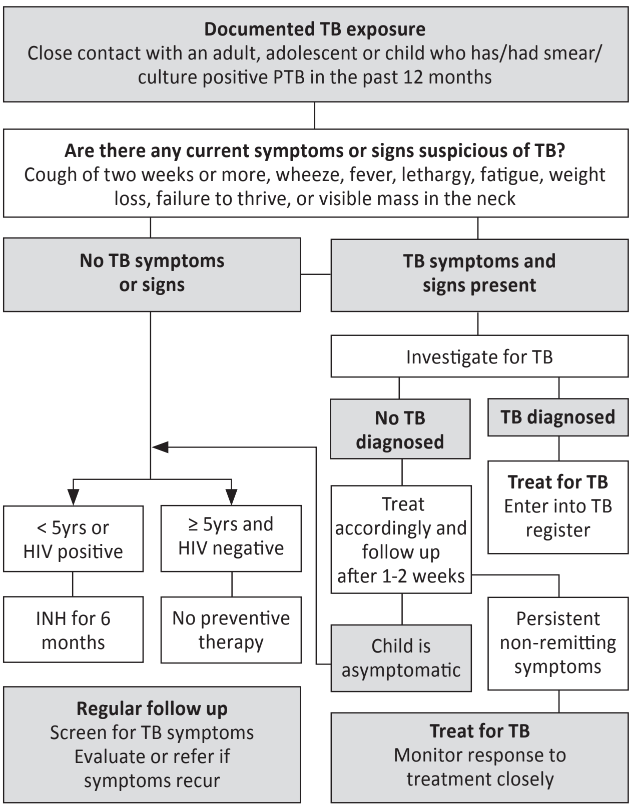

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PAGE 104

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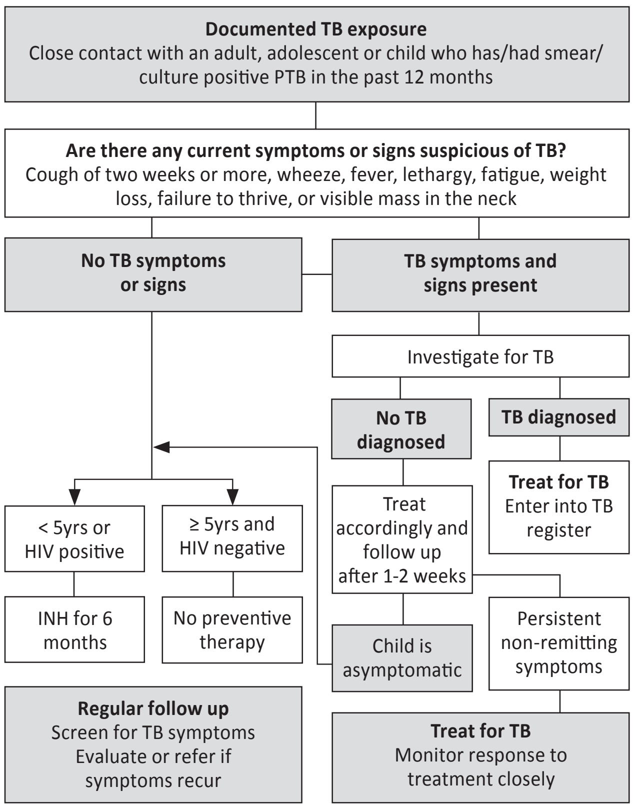

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PAGE 104

TB Diagnosis in Children

Continued

Scenario	Regard as TB Case if the Following Exist
History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)	Symptoms of TB **AND** An abnormal chest x-ray suggestive of TB
Symptoms of TB	History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux) **AND** An abnormal chest x-ray suggestive of TB or positive smear or culture by gastric aspirate/sputum
No Chest X-ray available	Symptoms of TB **AND** History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)

Note: The diagnosis can be confirmed by collecting a gastric aspirate or sputum for smear and culture.

Source: SA National TB Guidelines, 2009; Guidelines for the Management of TB in Children, 2013

TB Diagnosis in Children

Continued

Scenario	Regard as TB Case if the Following Exist
History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)	Symptoms of TB **AND** An abnormal chest x-ray suggestive of TB
Symptoms of TB	History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux) **AND** An abnormal chest x-ray suggestive of TB or positive smear or culture by gastric aspirate/sputum
No Chest X-ray available	Symptoms of TB **AND** History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)

Note: The diagnosis can be confirmed by collecting a gastric aspirate or sputum for smear and culture.

Source: SA National TB Guidelines, 2009; Guidelines for the Management of TB in Children, 2013

PAGE 105

TB Diagnosis in Children

Continued

Scenario	Regard as TB Case if the Following Exist
History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)	Symptoms of TB **AND** An abnormal chest x-ray suggestive of TB
Symptoms of TB	History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux) **AND** An abnormal chest x-ray suggestive of TB or positive smear or culture by gastric aspirate/sputum
No Chest X-ray available	Symptoms of TB **AND** History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)

Note: The diagnosis can be confirmed by collecting a gastric aspirate or sputum for smear and culture.

Source: SA National TB Guidelines, 2009; Guidelines for the Management of TB in Children, 2013

PAGE 105

TB Diagnosis in Children

Continued

Scenario	Regard as TB Case if the Following Exist
History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)	Symptoms of TB **AND** An abnormal chest x-ray suggestive of TB
Symptoms of TB	History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux) **AND** An abnormal chest x-ray suggestive of TB or positive smear or culture by gastric aspirate/sputum
No Chest X-ray available	Symptoms of TB **AND** History of exposure to infectious TB case **OR** Confirmed infection (positive Mantoux)

Note: The diagnosis can be confirmed by collecting a gastric aspirate or sputum for smear and culture.

Source: SA National TB Guidelines, 2009; Guidelines for the Management of TB in Children, 2013

PAGE 105

TB Treatment Regimens for Children < 8 Years of Age or < 30 kg

Regimen	Definition	Initial Phase Daily Treatment	Continuation Phase Daily Treatment
Regimen 3A	Uncomplicated TB with low bacillary load (Eg. minimal lung parenchyma involvement, intrathoracic disease, TB lynphadenitis, TB pleural effusion)	RHZ for 2 months	RH for 4 months
Regimen 3B	Complicated TB, high bacillary load (Smear-positive or extensive pulmonary TB, all other forms of extrapulmonary TB such as spinal or osteoarticular TB or abdominal TB)	RHZE for 2 months	RH for 4 months
TB Meningitis	For treatment of TB meningitis - consult a paediatrician	HRZ + Ethionamide for 6 to 9 months	
MDR-TB	Confirmed R resistance or R+ H resistance or contact with known MDR-TB case	See MDR-TB standardised regimen. Substitute moxifloxacin for levofloxacin if < 8 years. Consult with expert	
XDR-TB	Confirmed XDR-TB or contact with known XDR-TB case	See XDR-TB standardised regimen Consult with expert	

Source: Adapted from SA NDOH National Tuberculosis Management Guidelines, Guidelines for the Management of Tuberculosis in Children, 2014, and Drug-Resistant Management Guidelines, 2014/2011.

TB Treatment Regimens for Children < 8 Years of Age or < 30 kg

Regimen	Definition	Initial Phase Daily Treatment	Continuation Phase Daily Treatment
Regimen 3A	Uncomplicated TB with low bacillary load (Eg. minimal lung parenchyma involvement, intrathoracic disease, TB lynphadenitis, TB pleural effusion)	RHZ for 2 months	RH for 4 months
Regimen 3B	Complicated TB, high bacillary load (Smear-positive or extensive pulmonary TB, all other forms of extrapulmonary TB such as spinal or osteoarticular TB or abdominal TB)	RHZE for 2 months	RH for 4 months
TB Meningitis	For treatment of TB meningitis - consult a paediatrician	HRZ + Ethionamide for 6 to 9 months	
MDR-TB	Confirmed R resistance or R+ H resistance or contact with known MDR-TB case	See MDR-TB standardised regimen. Substitute moxifloxacin for levofloxacin if < 8 years. Consult with expert	
XDR-TB	Confirmed XDR-TB or contact with known XDR-TB case	See XDR-TB standardised regimen Consult with expert	

Source: Adapted from SA NDOH National Tuberculosis Management Guidelines, Guidelines for the Management of Tuberculosis in Children, 2014, and Drug-Resistant Management Guidelines, 2014/2011.

PAGE 106

TB Treatment Regimens for Children < 8 Years of Age or < 30 kg

Regimen	Definition	Initial Phase Daily Treatment	Continuation Phase Daily Treatment
Regimen 3A	Uncomplicated TB with low bacillary load (Eg. minimal lung parenchyma involvement, intrathoracic disease, TB lynphadenitis, TB pleural effusion)	RHZ for 2 months	RH for 4 months
Regimen 3B	Complicated TB, high bacillary load (Smear-positive or extensive pulmonary TB, all other forms of extrapulmonary TB such as spinal or osteoarticular TB or abdominal TB)	RHZE for 2 months	RH for 4 months
TB Meningitis	For treatment of TB meningitis - consult a paediatrician	HRZ + Ethionamide for 6 to 9 months	
MDR-TB	Confirmed R resistance or R+ H resistance or contact with known MDR-TB case	See MDR-TB standardised regimen. Substitute moxifloxacin for levofloxacin if < 8 years. Consult with expert	
XDR-TB	Confirmed XDR-TB or contact with known XDR-TB case	See XDR-TB standardised regimen Consult with expert	

Source: Adapted from SA NDOH National Tuberculosis Management Guidelines, Guidelines for the Management of Tuberculosis in Children, 2014, and Drug-Resistant Management Guidelines, 2014/2011.

PAGE 106

TB Treatment Regimens for Children < 8 Years of Age or < 30 kg

Regimen	Definition	Initial Phase Daily Treatment	Continuation Phase Daily Treatment
Regimen 3A	Uncomplicated TB with low bacillary load (Eg. minimal lung parenchyma involvement, intrathoracic disease, TB lynphadenitis, TB pleural effusion)	RHZ for 2 months	RH for 4 months
Regimen 3B	Complicated TB, high bacillary load (Smear-positive or extensive pulmonary TB, all other forms of extrapulmonary TB such as spinal or osteoarticular TB or abdominal TB)	RHZE for 2 months	RH for 4 months
TB Meningitis	For treatment of TB meningitis - consult a paediatrician	HRZ + Ethionamide for 6 to 9 months	
MDR-TB	Confirmed R resistance or R+ H resistance or contact with known MDR-TB case	See MDR-TB standardised regimen. Substitute moxifloxacin for levofloxacin if < 8 years. Consult with expert	
XDR-TB	Confirmed XDR-TB or contact with known XDR-TB case	See XDR-TB standardised regimen Consult with expert	

Source: Adapted from SA NDOH National Tuberculosis Management Guidelines, Guidelines for the Management of Tuberculosis in Children, 2014, and Drug-Resistant Management Guidelines, 2014/2011.

PAGE 106

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Children up to 8 years or < 30kg

Body Weight (kg)	Intensive Phase (2 months)			Continuation phase (4 months)	
	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL	Pyrazinamide 500mg	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL
2-2.9 kg	½ tablet	1.5 mL	expert advise on dose	½ tablet	1.5 mL
3-3.9 kg	¾ tablet	2.5 mL	¼ tablet	¾ tablet	2.5 mL
4-5.9 kg	1 tablet	3 mL	¼ tablet	1 tablet	3 mL
6-7.9 kg	1½ tablets		½ tablet	1 ½ tablets	
8-11.9 kg	2 tablets		½ tablet	2 tablets	
12-14.9 kg	3 tablets		1 tablet	3 tablets	
15-19.9 kg	3½ tablets		1 tablet	3½ tablets	
20-24.9 kg	4½ tablets		1½ tablets	4½ tablets	
25-29.9 kg	5 tablets		2 tablets	5 tablets	

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.
Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.
Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Continued

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Children up to 8 years or < 30kg

Body Weight (kg)	Intensive Phase (2 months)			Continuation phase (4 months)	
	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL	Pyrazinamide 500mg	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL
2-2.9 kg	½ tablet	1.5 mL	expert advise on dose	½ tablet	1.5 mL
3-3.9 kg	¾ tablet	2.5 mL	¼ tablet	¾ tablet	2.5 mL
4-5.9 kg	1 tablet	3 mL	¼ tablet	1 tablet	3 mL
6-7.9 kg	1½ tablets		½ tablet	1 ½ tablets	
8-11.9 kg	2 tablets		½ tablet	2 tablets	
12-14.9 kg	3 tablets		1 tablet	3 tablets	
15-19.9 kg	3½ tablets		1 tablet	3½ tablets	
20-24.9 kg	4½ tablets		1½ tablets	4½ tablets	
25-29.9 kg	5 tablets		2 tablets	5 tablets	

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.
Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.
Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Continued

PAGE 107

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Children up to 8 years or < 30kg

Body Weight (kg)	Intensive Phase (2 months)			Continuation phase (4 months)	
	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL	Pyrazinamide 500mg	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL
2-2.9 kg	½ tablet	1.5 mL	expert advise on dose	½ tablet	1.5 mL
3-3.9 kg	¾ tablet	2.5 mL	¼ tablet	¾ tablet	2.5 mL
4-5.9 kg	1 tablet	3 mL	¼ tablet	1 tablet	3 mL
6-7.9 kg	1½ tablets		½ tablet	1 ½ tablets	
8-11.9 kg	2 tablets		½ tablet	2 tablets	
12-14.9 kg	3 tablets		1 tablet	3 tablets	
15-19.9 kg	3½ tablets		1 tablet	3½ tablets	
20-24.9 kg	4½ tablets		1½ tablets	4½ tablets	
25-29.9 kg	5 tablets		2 tablets	5 tablets	

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.
Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.
Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Continued

PAGE 107

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Children up to 8 years or < 30kg

Body Weight (kg)	Intensive Phase (2 months)			Continuation phase (4 months)	
	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL	Pyrazinamide 500mg	Rifampicin/ Isoniazid 60,60	Pyrazinamide 150mg* or 150mg/3mL
2-2.9 kg	½ tablet	1.5 mL	expert advise on dose	½ tablet	1.5 mL
3-3.9 kg	¾ tablet	2.5 mL	¼ tablet	¾ tablet	2.5 mL
4-5.9 kg	1 tablet	3 mL	¼ tablet	1 tablet	3 mL
6-7.9 kg	1½ tablets		½ tablet	1 ½ tablets	
8-11.9 kg	2 tablets		½ tablet	2 tablets	
12-14.9 kg	3 tablets		1 tablet	3 tablets	
15-19.9 kg	3½ tablets		1 tablet	3½ tablets	
20-24.9 kg	4½ tablets		1½ tablets	4½ tablets	
25-29.9 kg	5 tablets		2 tablets	5 tablets	

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.
Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.
Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Continued

PAGE 107

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Continued

Children > 8 years or > 30 kg and adolescents

Pre-treatment Body Weight kg	Intensive Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 – 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5years and 12.5mg for children <5years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Continued

Children > 8 years or > 30 kg and adolescents

Pre-treatment Body Weight kg	Intensive Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 – 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5years and 12.5mg for children <5years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 108

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Continued

Children > 8 years or > 30 kg and adolescents

Pre-treatment Body Weight kg	Intensive Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 – 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5years and 12.5mg for children <5years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 108

Regimen 3A: For Uncomplicated TB With Low Bacillary Load

Continued

Children > 8 years or > 30 kg and adolescents

Pre-treatment Body Weight kg	Intensive Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 – 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

*For each dose, dissolve 150mg dispersible (1 tablet) in 3ml of water to prepare a concentration of 50mg/mL (150mg/3mL). Only PZA 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

Children who are malnourished or HIV positive: Pyridoxine 25mg daily may be given for children >5years and 12.5mg for children <5years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 108

Regimen 3B: For Complicated TB, High Bacillary Load

(All other forms of severe TB: extensive pulmonary TB, spinal or osteo-articular TB or abdominal TB.)
Children up to 8 years and < 30kg

Body Weight (kg)	Intensive Phase (2 months)				Continuation Phase (4 months)
	Rifampicin, Isoniazid 60,60	Pyrazinamide 500mg	Pyrazinamide 150mg* or 150mg/3mL	Ethambutol 400mg tablet OR 400mg/8mL** solution	Rifampicin, Isoniazid 60,60
2-2.9 kg	½ tablet	expert advice on dose	1.5 mL	1 mL	½ tablet
3-3.9 kg	¾ tablet	¼ tablet	2.5 mL	1.5 mL	¾ tablet
4-5.9 kg	1 tablet	¼ tablet	3 mL	2 mL	1 tablet
6-7.9 kg	1½ tablets	½ tablet		3 mL	1½ tablets
8-11.9 kg	2 tablets	½ tablet		½ tablet	2 tablets
12-14.9 kg	3 tablets	1 tablet		¾ tablet	3 tablets
15-19.9 kg	3½ tablets	1 tablet		1 tablet	3½ tablets
20-24.9 kg	4½ tablets	1½ tablets		1 tablet	4½ tablets
25-29.9 kg	5 tablets	2 tablets		1½ tablets	5 tablets

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Footnotes continued on next page

Continued

Regimen 3B: For Complicated TB, High Bacillary Load

(All other forms of severe TB: extensive pulmonary TB, spinal or osteo-articular TB or abdominal TB.)
Children up to 8 years and < 30kg

Body Weight (kg)	Intensive Phase (2 months)				Continuation Phase (4 months)
	Rifampicin, Isoniazid 60,60	Pyrazinamide 500mg	Pyrazinamide 150mg* or 150mg/3mL	Ethambutol 400mg tablet OR 400mg/8mL** solution	Rifampicin, Isoniazid 60,60
2-2.9 kg	½ tablet	expert advice on dose	1.5 mL	1 mL	½ tablet
3-3.9 kg	¾ tablet	¼ tablet	2.5 mL	1.5 mL	¾ tablet
4-5.9 kg	1 tablet	¼ tablet	3 mL	2 mL	1 tablet
6-7.9 kg	1½ tablets	½ tablet		3 mL	1½ tablets
8-11.9 kg	2 tablets	½ tablet		½ tablet	2 tablets
12-14.9 kg	3 tablets	1 tablet		¾ tablet	3 tablets
15-19.9 kg	3½ tablets	1 tablet		1 tablet	3½ tablets
20-24.9 kg	4½ tablets	1½ tablets		1 tablet	4½ tablets
25-29.9 kg	5 tablets	2 tablets		1½ tablets	5 tablets

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Footnotes continued on next page

Continued

PAGE 109

Regimen 3B: For Complicated TB, High Bacillary Load

(All other forms of severe TB: extensive pulmonary TB, spinal or osteo-articular TB or abdominal TB.)
Children up to 8 years and < 30kg

Body Weight (kg)	Intensive Phase (2 months)				Continuation Phase (4 months)
	Rifampicin, Isoniazid 60,60	Pyrazinamide 500mg	Pyrazinamide 150mg* or 150mg/3mL	Ethambutol 400mg tablet OR 400mg/8mL** solution	Rifampicin, Isoniazid 60,60
2-2.9 kg	½ tablet	expert advice on dose	1.5 mL	1 mL	½ tablet
3-3.9 kg	¾ tablet	¼ tablet	2.5 mL	1.5 mL	¾ tablet
4-5.9 kg	1 tablet	¼ tablet	3 mL	2 mL	1 tablet
6-7.9 kg	1½ tablets	½ tablet		3 mL	1½ tablets
8-11.9 kg	2 tablets	½ tablet		½ tablet	2 tablets
12-14.9 kg	3 tablets	1 tablet		¾ tablet	3 tablets
15-19.9 kg	3½ tablets	1 tablet		1 tablet	3½ tablets
20-24.9 kg	4½ tablets	1½ tablets		1 tablet	4½ tablets
25-29.9 kg	5 tablets	2 tablets		1½ tablets	5 tablets

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Footnotes continued on next page

Continued

PAGE 109

Regimen 3B: For Complicated TB, High Bacillary Load

(All other forms of severe TB: extensive pulmonary TB, spinal or osteo-articular TB or abdominal TB.)
Children up to 8 years and < 30kg

Body Weight (kg)	Intensive Phase (2 months)				Continuation Phase (4 months)
	Rifampicin, Isoniazid 60,60	Pyrazinamide 500mg	Pyrazinamide 150mg* or 150mg/3mL	Ethambutol 400mg tablet OR 400mg/8mL** solution	Rifampicin, Isoniazid 60,60
2-2.9 kg	½ tablet	expert advice on dose	1.5 mL	1 mL	½ tablet
3-3.9 kg	¾ tablet	¼ tablet	2.5 mL	1.5 mL	¾ tablet
4-5.9 kg	1 tablet	¼ tablet	3 mL	2 mL	1 tablet
6-7.9 kg	1½ tablets	½ tablet		3 mL	1½ tablets
8-11.9 kg	2 tablets	½ tablet		½ tablet	2 tablets
12-14.9 kg	3 tablets	1 tablet		¾ tablet	3 tablets
15-19.9 kg	3½ tablets	1 tablet		1 tablet	3½ tablets
20-24.9 kg	4½ tablets	1½ tablets		1 tablet	4½ tablets
25-29.9 kg	5 tablets	2 tablets		1½ tablets	5 tablets

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Footnotes continued on next page

Continued

PAGE 109

Regimen 3B: For Complicated TB, High Bacillary Load

Continued

Children > 8 years or > 30kg and Adolescents

Pre-treatment Body Weight (kg)	Initial Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 - 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

* For each dose, dissolve 150mg dispersible (1 tablet) in 3mL of water to prepare a concentration of 50mg/mL (150mg/3mL). Only Pyrazinamide 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

**For each dose, crush 400mg (1 tablet) to a fine powder and dissolve in 8ml of water to prepare a concentration of 400mg/8mL. Discard unused solution.

***The continuation phase may be prolonged to 7 months in slow responders and children who are HIV positive . In children who are malnourished or HIV positive Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Regimen 3B: For Complicated TB, High Bacillary Load

Continued

Children > 8 years or > 30kg and Adolescents

Pre-treatment Body Weight (kg)	Initial Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 - 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

* For each dose, dissolve 150mg dispersible (1 tablet) in 3mL of water to prepare a concentration of 50mg/mL (150mg/3mL). Only Pyrazinamide 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

**For each dose, crush 400mg (1 tablet) to a fine powder and dissolve in 8ml of water to prepare a concentration of 400mg/8mL. Discard unused solution.

***The continuation phase may be prolonged to 7 months in slow responders and children who are HIV positive . In children who are malnourished or HIV positive Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 110

Regimen 3B: For Complicated TB, High Bacillary Load

Continued

Children > 8 years or > 30kg and Adolescents

Pre-treatment Body Weight (kg)	Initial Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 - 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

* For each dose, dissolve 150mg dispersible (1 tablet) in 3mL of water to prepare a concentration of 50mg/mL (150mg/3mL). Only Pyrazinamide 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

**For each dose, crush 400mg (1 tablet) to a fine powder and dissolve in 8ml of water to prepare a concentration of 400mg/8mL. Discard unused solution.

***The continuation phase may be prolonged to 7 months in slow responders and children who are HIV positive . In children who are malnourished or HIV positive Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 110

Regimen 3B: For Complicated TB, High Bacillary Load

Continued

Children > 8 years or > 30kg and Adolescents

Pre-treatment Body Weight (kg)	Initial Phase (2 months)	Continuation Phase (4 months)	
	RHZE (150,75,400,275)	RH (150,75)	RH (300,150)
30 - 37	2 tablets	2 tablets	
38 – 54	3 tablets	3 tablets	
55 – 70	4 tablets		2 tablets
>71	5 tablets		2 tablets

* For each dose, dissolve 150mg dispersible (1 tablet) in 3mL of water to prepare a concentration of 50mg/mL (150mg/3mL). Only Pyrazinamide 150mg or 500mg tablets may be given at a time depending on availability but NOT both.

**For each dose, crush 400mg (1 tablet) to a fine powder and dissolve in 8ml of water to prepare a concentration of 400mg/8mL. Discard unused solution.

***The continuation phase may be prolonged to 7 months in slow responders and children who are HIV positive . In children who are malnourished or HIV positive Pyridoxine 25mg daily may be given for children >5 years and 12.5mg for children <5 years may be added to the treatment.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 110

Treatment for TB Meningitis

	Duration	Dosage	Maximum daily dose
Rifampicin	6 months if there are concerns about ongoing disease, prolong for another 3 months. Consult with a specialist.	20 mg/kg as a single daily dose	600 mg
Isoniazid		20 mg/kg as a single daily dose	400 mg
Pyrazinamide		40 mg/kg as a single daily dose	2000 mg
Ethionamide		20 mg/kg as a single daily dose	1000 mg

The recommended treatment duration is 6 months but if there are concerns about clinical progress, the treatment can be prolonged by another 3 months to 9 months in total. Consult a paediatrician.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

Treatment for TB Meningitis

	Duration	Dosage	Maximum daily dose
Rifampicin	6 months if there are concerns about ongoing disease, prolong for another 3 months. Consult with a specialist.	20 mg/kg as a single daily dose	600 mg
Isoniazid		20 mg/kg as a single daily dose	400 mg
Pyrazinamide		40 mg/kg as a single daily dose	2000 mg
Ethionamide		20 mg/kg as a single daily dose	1000 mg

The recommended treatment duration is 6 months but if there are concerns about clinical progress, the treatment can be prolonged by another 3 months to 9 months in total. Consult a paediatrician.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 111

Treatment for TB Meningitis

	Duration	Dosage	Maximum daily dose
Rifampicin	6 months if there are concerns about ongoing disease, prolong for another 3 months. Consult with a specialist.	20 mg/kg as a single daily dose	600 mg
Isoniazid		20 mg/kg as a single daily dose	400 mg
Pyrazinamide		40 mg/kg as a single daily dose	2000 mg
Ethionamide		20 mg/kg as a single daily dose	1000 mg

The recommended treatment duration is 6 months but if there are concerns about clinical progress, the treatment can be prolonged by another 3 months to 9 months in total. Consult a paediatrician.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 111

Treatment for TB Meningitis

	Duration	Dosage	Maximum daily dose
Rifampicin	6 months if there are concerns about ongoing disease, prolong for another 3 months. Consult with a specialist.	20 mg/kg as a single daily dose	600 mg
Isoniazid		20 mg/kg as a single daily dose	400 mg
Pyrazinamide		40 mg/kg as a single daily dose	2000 mg
Ethionamide		20 mg/kg as a single daily dose	1000 mg

The recommended treatment duration is 6 months but if there are concerns about clinical progress, the treatment can be prolonged by another 3 months to 9 months in total. Consult a paediatrician.

Source: SA NDOH Updated TB Treatment Protocols for Children, 2014

PAGE 111

DRUG RESISTANT TUBERCULOSIS
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DRUG RESISTANT TUBERCULOSIS

Drug Resistant TB - Definitions

Mono-Resistance:

Resistance to **ONE** first-line drug (Rifampicin, Isoniazid, Pyrazinamide or Ethambutol)

Rifampicin Resistance (RR):

Resistance to Rifampicin, with our withou resistance to other TB medicines. This may be mono, poly, multi, or extensive drug resistance.

Poly-Resistance:

Resistance to **TWO** or more first-line drugs, but **NOT** both Isoniazid and Rifampicin

Multi-Drug Resistance (MDR):

Resistance to at least **BOTH Isoniazid and Rifampicin**

Extensive-Drug Resistance (XDR):

Resistance to **Isoniazid and Rifampicin PLUS a fluoroquinolone** (ciprofloxacin, levofloxacin, moxifloxacin) **PLUS** one or more **2nd line injectable drug** (kanamycin, amikacin or capreomycin).

Source: South Africa National Tuberculosis Management Guidelines, 2014

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Source: South Africa National Tuberculosis Management Guidelines, 2014

PAGE 113

Treatment of Mono/Poly Resistant TB

Drug resistance pattern	Suggested regimen	Minimum duration	Comments
H	Regimen I or II intensive phase for full duration (except for H). In practice it is easier to use fixed dose combinations, but these are not available for children < 8 years for this purpose. Treat with R+Z+E single doses.	6 – 9 months based on symptomatic response to treatment, weight gain, and sputum culture combination. A minimum of 6 months treatment after culture conversion is adequate.	Monitor the patient with sputum smear microscopy and culture on monthly basis throughout treatment. Monthly clinical assessment required. Refer to MDR TB expert if patient is not responding well to treatment.
R (+/- any other 1st line drug than H)	Standardised MDR-TB regimen PLUS INH	18 months after culture conversion	These patients will need confirmation of diagnosis if diagnosed through GXP; however, LPA is a confirmatory diagnosis.
Poly-resistant TB cases			Refer to MDR-TB expert for regimen based on resistance pattern and history of anti-tuberculosis drugs used.

Source: Management of Drug-Resistant Tuberculosis Policy Guidelines, Updated Jan 2013

Treatment of Mono/Poly Resistant TB

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PAGE 114

Standard MDR-TB and XDR-TB Regimens

MDR-TB

<u>Intensive phase:</u> **Km(Am)-Mfx-Eto-Trd-Z**

Kanamycin (Amikacin) - Moxifloxacin - Ethionamide - Terizidone - Pyrazinamide

Minimum duration of 6 months; continue for 4 months after culture conversion

<u>Continuation phase:</u> **Mfx-Eto-Trd-Z**

Moxifloxacin - Ethionamide - Terizidone - Pyrazinamide

Continuation phase ends 18 months after culture conversion

XDR-TB

<u>Intensive phase:</u> **Cm-Mfx-Eto-Trd-Z-PAS-Clofazimine**

Capreomycin - Moxifloxacin-Ethionamide-Terizidone-Pyrazinamide-PAS-Clofazimine

Minimum duration of 6 months; continue for 4 months after culture conversion

<u>Continuation phase:</u> **Mfx-Eto-Trd or Cs-Z-PAS/Clofazimine**

Moxifloxacin-Ethionamide-Terizidone or Cycloserine-Pyrazinamide-PAS/Clofazimine

Continuation phase ends 18 months after culture conversion

Source: South Africa National Guidelines. Management of MDR-TB Policy Guidelines, 2011

Standard MDR-TB and XDR-TB Regimens

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Intensive phase: Km(Am)-Mfx-Eto-Trd-Z
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Minimum duration of 6 months; continue for 4 months after culture conversion
Continuation phase: Mfx-Eto-Trd-Z
Moxifloxacin - Ethionamide - Terizidone - Pyrazinamide
Continuation phase ends 18 months after culture conversion
XDR-TB
Intensive phase: Cm-Mfx-Eto-Trd-Z-PAS-Clofazimine
Capreomycin - Moxifloxacin-Ethionamide-Terizidone-Pyrazinamide-PAS-Clofazimine
Minimum duration of 6 months; continue for 4 months after culture conversion
Continuation phase: Mfx-Eto-Trd or Cs-Z-PAS/Clofazimine
Moxifloxacin-Ethionamide-Terizidone or Cycloserine-Pyrazinamide-PAS/Clofazimine
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PAGE 115

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Intensive phase: Cm-Mfx-Eto-Trd-Z-PAS-Clofazimine
Capreomycin - Moxifloxacin-Ethionamide-Terizidone-Pyrazinamide-PAS-Clofazimine
Minimum duration of 6 months; continue for 4 months after culture conversion
Continuation phase: Mfx-Eto-Trd or Cs-Z-PAS/Clofazimine
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PAGE 115

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Continuation phase: Mfx-Eto-Trd or Cs-Z-PAS/Clofazimine
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PAGE 115

Dosing of Standard M(X)DR-TB Regimen in Adults

MDR-TB Standardized Treatment Regimen for Adults and Children > 8 Years — Intensive Phase: Treatment taken at least 6 times weekly for at least 6 months, guided by TB culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
Kanamycin	15-20mg/kg	500-750mg	1000mg	1000mg
Moxifloxacin	400mg	400mg	400mg	400mg
Ethionamide	15-20mg/kg	500mg	750mg	750-1000mg
Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

MDR-TB Standardized Treatment Regimen for Adults and Children > 8 Years — Continuation Phase: Treatment taken at least 6 times weekly for at least 18 months following culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
Ethionamide	15-20mg/kg	500mg	750mg	750-1000mg
Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Moxifloxacin	400mg	400mg	400mg	400mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

Pyridoxine 150 mg (max 200 mg) daily to paitents on Terizidone. Levofloxacin if not tolerating Moxifloxacin at 750 mg for patients < 51 kg and 1000 mg if > 51 kg

Continued

Dosing of Standard M(X)DR-TB Regimen in Adults

MDR-TB Standardized Treatment Regimen for Adults and Children > 8 Years — Intensive Phase: Treatment taken at least 6 times weekly for at least 6 months, guided by TB culture conversion				
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MDR-TB Standardized Treatment Regimen for Adults and Children > 8 Years — Continuation Phase: Treatment taken at least 6 times weekly for at least 18 months following culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
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Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Moxifloxacin	400mg	400mg	400mg	400mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

Pyridoxine 150 mg (max 200 mg) daily to paitents on Terizidone. Levofloxacin if not tolerating Moxifloxacin at 750 mg for patients < 51 kg and 1000 mg if > 51 kg

Continued

PAGE 116

Dosing of Standard M(X)DR-TB Regimen in Adults

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Ethionamide	15-20mg/kg	500mg	750mg	750-1000mg
Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Moxifloxacin	400mg	400mg	400mg	400mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

Pyridoxine 150 mg (max 200 mg) daily to paitents on Terizidone. Levofloxacin if not tolerating Moxifloxacin at 750 mg for patients < 51 kg and 1000 mg if > 51 kg

Continued

PAGE 116

Dosing of Standard M(X)DR-TB Regimen in Adults

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Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

MDR-TB Standardized Treatment Regimen for Adults and Children > 8 Years — Continuation Phase: Treatment taken at least 6 times weekly for at least 18 months following culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
Ethionamide	15-20mg/kg	500mg	750mg	750-1000mg
Pyrazinamide	30-40mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
Moxifloxacin	400mg	400mg	400mg	400mg
Terizidone	15-20mg/kg	750mg	750mg	750-1000mg

Pyridoxine 150 mg (max 200 mg) daily to paitents on Terizidone. Levofloxacin if not tolerating Moxifloxacin at 750 mg for patients < 51 kg and 1000 mg if > 51 kg

Continued

PAGE 116

Dosing of Standard M(X)DR-TB Regimen in Adults

Continued

XDR-TB Standardized Treatment Regimen — Intensive Phase: Treatment taken daily for at least 6 months, guided by TB culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
Capreomycin	15-20mg/kg	500-750mg	1000mg	1000mg
Moxifloxacin	400 mg	400mg	400mg	400mg
Ethionamide	15-20 mg/kg	500mg	750mg	750-1000mg
Terizidone	15-20 mg/kg	500mg	750mg	1000mg
Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
Clofazimine	3-5 mg/kg	200mg	300mg	300mg

Continued

Dosing of Standard M(X)DR-TB Regimen in Adults

Continued

XDR-TB Standardized Treatment Regimen — Intensive Phase: Treatment taken daily for at least 6 months, guided by TB culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
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Moxifloxacin	400 mg	400mg	400mg	400mg
Ethionamide	15-20 mg/kg	500mg	750mg	750-1000mg
Terizidone	15-20 mg/kg	500mg	750mg	1000mg
Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
Clofazimine	3-5 mg/kg	200mg	300mg	300mg

PAGE 117

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Dosing of Standard M(X)DR-TB Regimen in Adults

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Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
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PAGE 117

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Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
Clofazimine	3-5 mg/kg	200mg	300mg	300mg

PAGE 117

Continued

Dosing of Standard M(X)DR-TB Regimen in Adults

Continued

XDR-TB Standardized Treatment Regimen — Continuation Phase: Treatment taken daily for at least 18 months following culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
Moxifloxacin	400 mg	400mg	400mg	400mg
Ethionamide	15-20 mg/kg	500mg	750mg	750-1000mg
Terizidone	15-20 mg/kg	500mg	750mg	1000mg
Pyrazinamide	30-40 mg/kg	1000-1750mg	1750-2000mg	2000-2500mg
PAS	150 mg/kg	8000mg	8000mg	8000mg
Clofazimine	3-5 mg/kg	200mg	300mg	300mg

Source: South Africa National Guidelines. Management of MDR-TB Policy Guidelines, 2011

Dosing of Standard M(X)DR-TB Regimen in Adults

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XDR-TB Standardized Treatment Regimen — Continuation Phase: Treatment taken daily for at least 18 months following culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
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PAGE 118

Dosing of Standard M(X)DR-TB Regimen in Adults

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PAGE 118

Dosing of Standard M(X)DR-TB Regimen in Adults

Continued

XDR-TB Standardized Treatment Regimen — Continuation Phase: Treatment taken daily for at least 18 months following culture conversion				
Drug	**Dose (<33kg)**	**Dose (33-50kg)**	**Dose (51-70 kg)**	**Dose > 70kg**
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PAGE 118

Dosing of Standard MDR—TB Drugs in Children < 8 Years

Dosing of Standard MDR-TB Drugs in Children < 8 Years				
Drug	**Formulation**	**Range (mg/kg)**	**Frequency**	**Maximum daily dose**
Amikacin	Vials: 500 mg, 1 g	15 – 22.5	Once Daily	1g
Levofloxacin (for children under 8 years)	Tablets: 250, 500, 750 mg	7.5 – 10	Once Daily	
Ethionamide	Tablets: 250 mg	15 – 20	2x daily initially aim for 1x daily	1g
Terizidone	Capsules: 250 mg	10 – 20	Once daily	1g
Pyrazinamide		30 – 40		

NB: Ethambutol may be given at the dosage of 20-25 mg/kg

Source: Guidelines for the Management of Tuberculosis in Children 2014

Dosing of Standard MDR—TB Drugs in Children < 8 Years

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Terizidone	Capsules: 250 mg	10 – 20	Once daily	1g
Pyrazinamide		30 – 40		

NB: Ethambutol may be given at the dosage of 20-25 mg/kg

Source: Guidelines for the Management of Tuberculosis in Children 2014

PAGE 119

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Pyrazinamide		30 – 40		

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PAGE 119

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Terizidone	Capsules: 250 mg	10 – 20	Once daily	1g
Pyrazinamide		30 – 40		

NB: Ethambutol may be given at the dosage of 20-25 mg/kg

Source: Guidelines for the Management of Tuberculosis in Children 2014

PAGE 119

Dosing of Additional Second-line TB Drugs in Paediatrics

Dosing of Additional MDR/XDR TB Drugs in Paediatrics				
Drug	**Formulation**	**Daily dose mg/kg/day**	**Frequency**	**Maximum daily dose**
Streptomycin	Vials: 500 mg, 1g	15 – 30	Once Daily	1g
Kanamycin	Vials: 500 mg, 1g	15 – 30	Once Daily	1g
Capreomycin	Vials: 1g	15 – 30	Once Daily	1g
Moxifloxacin (for children older than 8 years and adults)	Tablets: 400mg	7.5 – 10	Once Daily	
Prothionamide	Tablets: 250 mg	15 – 20	Twice daily	1g
PAS	PAS granules 4g packets	150	Twice daily	12g

Source: Guidelines for the Management of Tuberculosis in Children, 2014

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PAGE 120

Common Side Effects During MDR-TB Treatment

Drug	Complaint/Side Effect
Aminoglycosides	Hearing loss, Vestibular toxicity, Hypokalemia, Hypomagnesemia, Rash
Amikacin	Ototoxicity*: dizziness and hearing loss, Renal failure*
Capreomycin	Hearing loss, Vestibular toxicity, Hypokalemia, Hypomagnesemia, Rash
Fluoroquinolones	Seizures, Headache, GI complaints, Rash
Clofazimine	GI complaints, Rash
Cycloserine	GI complaints, Behavioural Changes including depression and anxiety*, Rash, Peripheral neuropathy, Seizures*, Headache*, Psychosis
Ethambutol	Visual changes, Rash, Headache
Ethionamide	GI complaints (nausea, anorexia)*, Hypothyroidism*, Hepatotoxicity*, Behavioural Changes, Rash, Peripheral neuropathy*, Headache
Isoniazid	Hepatotoxicity, Behavioural Changes, Visual changes, Rash, Bone Marrow Suppression, Peripheral neuropathy, Seizures, Headache
Linezolid	Visual changes, Rash, Bone Marrow Suppression, Peripheral neuropathy

Continued

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Continued

PAGE 121

Common Side Effects During MDR-TB Treatment

Continued

Drug	Complaint/Side Effect
Para-Aminosalicylic Acid	GI complaints, Hyperthyroidism, Hepatotoxicity, Rash
Pyrazinamide	Hepatotoxicity, Rash
Rifampicin	Hepatotoxicity, Rash, Bone Marrow Suppression
Rifabutin	Visual changes, Rash

** Most common*

Source: South Africa National Guidelines. Management of MDR-TB Policy Guidelines, 2011

Common Side Effects During MDR-TB Treatment

Continued

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PAGE 122

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PAGE 122

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* Most common

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PAGE 122

Management of Patients Who Default MDR-TB Treatment

Patient on MDR-TB treatment for at least one month

Interruption of two or more months

Return smear positive

- Patient was on treatment for less than 3 months
- Restart new treatment using their previous resistance profile
- Patient was on treatment for 3-6 months
- – Conduct culture and DST
  – Restart previous treatment regimen
  – Adjust regimen when DST results are available

Return smear negative

- Patient was on treatment for less than 3 months
- Restart new treatment using their previous resistance profile
- Patient was on treatment for 3-6 months
- – Restart the patient with the injectable until two consecutive negative cultures
  – Treatment should be given for minimum of 24 months after initial conversion

Continued

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Continued

PAGE 123

Management of Patients Who Default MDR-TB Treatment

Continued

Patient was on treatment for more than 6 months	Patient was on treatment for more than 6 months
– Conduct culture and DST – Start completely new treatment regimen	If the patient was off the injectable at the time of interruption and has no evidence of clinical deterioration, restart oral medication only (continuation phase)

Source: South Africa National Guidelines. Management of MDR-TB Policy Guidelines, 2011; Adapted from the PIH Guide to the Medical Management of Muldtidrug-Resistant Tuberculosis International Edition, Partners in Health, 2003

Management of Patients Who Default MDR-TB Treatment

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PAGE 124

Management of Patients Who Default MDR-TB Treatment

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PAGE 124

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PAGE 124

Monitoring During M(X)DR-TB Treatment

Monitoring	Recommended Frequency
Sputum smear	At baseline, monthly
TB culture	Baseline, monthly until conversion then at least every other month
Drug Susceptibility Testing	On admission and if no improvement (patient TB culture positive on treatment) within 3-6 months
Liver Function Tests	Every 1-3 months if on Pyrazinamide or at risk/symptoms of hepatitis (children: if symptomatic, every 6 months if on ART)
Serum Creatinine	Baseline, monthly while on injectable
Serum Potassium	Monthly while receiving injectable
TSH	Baseline, every 6 months if receiving ethionamide and/or PAS, monthly monitoring for signs of hypothyroidism (children: every 2 months)
HIV and Pregnancy Tests	Baseline and repeat as indicated
Chest X-ray	Baseline, every 6 months, at treatment completion, when requested by clinician (children: every 2-3 months during intensive phase)
Lung CT-Scan	When indicated

Source: South Africa National Guidelines. Management of MDR-TB Policy Guidelines, 2011

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PAGE 125

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PAGE 125

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PAGE 125

Clinical Follow-Up During M(X)DR-TB Treatment

Clinical Follow-Up	Recommended Frequency
Evaluation by Clinician (if outpatient)	At baseline and at least monthly until culture conversion, then at least every 2-3 months
Weight	At baseline, weekly during intensive phase, then monthly
BMI	Baseline, then monthly
Height	Baseline
Side Effects Monitoring	On-going
Signs and Symptoms of hypothyroidism	Monthly
Audiometry	Baseline, monthly during injectable, 3 months after injectable stopped
Eye Test	Baseline, when indicated

Source: South Africa National Guidelines. Management of MDR-TB Policy Guidelines, 2011

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PAGE 126

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PAGE 126

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PAGE 126

TUBERCULOSIS / HIV
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TUBERCULOSIS / HIV

Antiretroviral Treatment for Adults with Concomitant TB

TB develops while on ART	TB diagnosed before starting ART
Continue ARV therapy throughout TB treatment **First-line regimen.** Patient can remain on regimen they are taking. **Second-line regimen should be changed to the following:** Lopinavir/ritonavir should be doubled to 4 tablets (800/200mg) 12 hourly while patient on rifampicin-based TB treatment Monitor LFT monthly Reduce Lopinavir/ritonavir to standard dose 2 weeks after rifampicin portion of TB treatment completed	**First line ART regimen as follows:** 1. Tenofovir 300mg daily 2. Lamivudine 300mg daily 3. Efavirenz 600mg at night (Combined as FDC) **CD4 < 50 cells/µl:** Fast track - start ART within 2 weeks after starting TB treatment **CD4 > 50 cells/µl:** Start ART within 2-8 weeks after starting TB treatment **Patients with TB meningitis (irrespective of CD4 count):** Defer ART until 8 weeks after starting TB treatment

Source: National Tuberculosis Management Guidelines 2014

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PAGE 128

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PAGE 128

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PAGE 128

Antiretroviral Treatment in Adult Patients with DR-TB

HIV positive patient diagnosed with DR-TB

Patient on ART at time of diagnosis

Start DR-TB treatment immediately

Continue ART throughout DR-TB treatment

Antiretroviral therapy:

1. If patient on Tenofovir, Lamivudine and Efavirenz or Nevirapine; stop Tenofovir and switch to Zidovudine or Stavudine during injectable phase.
2. Tenofovir to be re-introduced in continuation phase

Patient not on ART at time of diagnosis

Start ART irrespective of CD4 cell count once DR-TB treatment is tolerated preferably within first month of treatment

First-line therapy for adults:

1.Zidovudine 300mg po bd
OR Stavudine 30mg po bd

AND

2. Lamivudine 300mg po daily

AND

3. Efavirenz 600mg at night
OR Nevirapine 200mg every 12 hours

Remember: Patients on MDR-TB or XDR-TB treatment and ART are taking a large number of tablets. Do pre-emptive counselling to improve adherence.

Nevirapine may be given because MDR-TB patients do not receive Rifampicin.

Cycloserine or Terizidone and Efavirenz have been shown to cause central nervous system toxicity and psychiatric disturbances.

Source: South Africa National Department of Health. Managment of Drug-Resistant Tuberculosis. Policy Guidelines, August 2011.

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PAGE 129

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PAGE 129

TB, HIV and STI Drug Metabolism Inducers & Inhibitors

	TB	ART and treatment for other HIV related conditions	STI treatment
Inducers	Rifampicin Rifabutin	Nevirapine Efavirenz Phenobarbitone Carbamezapine Phenytoin	None
Inhibitors	Isoniazid	Protease Inhibitors Fluconazole Ketoconazole Cimetidine Diltiazem Verapamil Fluoxetine Itraconazole Omeprazole Grapefruit Juice	Ciprofloxacin Clarithromycin Erythromycin

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PAGE 130

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Inducers	Rifampicin Rifabutin	Nevirapine Efavirenz Phenobarbitone Carbamezapine Phenytoin	None
Inhibitors	Isoniazid	Protease Inhibitors Fluconazole Ketoconazole Cimetidine Diltiazem Verapamil Fluoxetine Itraconazole Omeprazole Grapefruit Juice	Ciprofloxacin Clarithromycin Erythromycin

PAGE 130

TB, HIV and STI Drug Metabolism Inducers & Inhibitors

	TB	ART and treatment for other HIV related conditions	STI treatment
Inducers	Rifampicin Rifabutin	Nevirapine Efavirenz Phenobarbitone Carbamezapine Phenytoin	None
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PAGE 130

Prohibited Drug Combinations with Specific ART

Agent by class	Agents prohibited with lopinavir/ritonavir	Agents prohibited with ritonavir	Agents prohibited with NVP and EFV
Anti-arrhythmic agents	Fleicanide Propafenone	Amiodarone Fleicanide Propafenone Quinidine	
Anti-histaminics	Astemizole Terfenadine	Astemizole Terfenadine	
Anti-infectives			Systemic Ketoconazole
Cholesterol lowering agents	Simvastatin		
GI motility	Cisapride	Cisapride	Cisapride
Psychiatric medications	St. John's Wort (Hypericum perforatum)		St. John's Wort (Hypericum perforatum)
Sedative/hypnotics	Midazolam Triazolam	Midazolam Triazolam	Midazolam Triazolam

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PAGE 131

Shared Side Effects of TB and ART

Side-Effects		
Nausea and Vomiting	Didanosine, Zidovudine, Protease inhibitors	Pyrazinamide
Hepatitis	Nevirapine, Efavirenz, Protease inhibitors (especially when dose is increased to overcome rifampicin induction)	Rifampicin, Isoniazid, Pyrazinamide
Peripheral Neuropathy	Stavudine, Didanosine	Isoniazid
Rash	Nevirapine, Efavirenz	Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, Streptomycin
Renal Toxicity	Tenofovir	Aminoglycosides (Kanamycin, Amikacin, Streptomycin), Rifampicin
Neuropsychiatric	Efavirenz	Isoniazid

*TB therapy carries significant side-effects and attention by the health care worker. Attention to this is as important as with ART

Source: Clinical Guidelines for Management of HIV and AIDS in Adults and Adolescents, National Department of Health, 2010

Source: National Tuberculosis Management Guidelines 2014

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PAGE 132

SEXUALLY TRANSMITTED INFECTIONS

STI Screening Checklist

- Ask all patients (ages 15-49 years) the following questions:
- Do you have any genital discharge?
- Do you have any genital ulcers?
- Has your partner(s) been treated for an STI in the last 8 weeks?

All patients with an STI

- Educate and counsel regarding potential importance of treatment adherence
- Explain the risk of transmission between partners and discuss methods for preventing and reducing the risk of transmission, including abstinence or condom use until treatment completion
- Promote consistent condom use, demonstrate condom use, provide condoms
- Stress the importance of partner treatment, issue one notification slip for EACH sexual partner
- Offer Provider Initiated HIV Counselling and Testing to patient and all partners
- Counsel men regarding male medical circumcision and women regarding family planning

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Male Urethritis Syndrome (MUS)

Patient complains of urethral discharge or dysuria

↓

Take history and examine. Milk urethra if no visible discharge. Emphasise HIV testing

↓

If discharge and/or dysuria present, treat with:
Cefixime, oral, 400 mg single dose*
AND Doxycycline, oral, 100 mg twice daily for 7 days

↓

Ask patient to return in 7 days if symptoms persist → If symptoms persist: Unprotected intercourse or poor adherence?

If Yes:
Repeat treatment

If No:
Treat with: **Metronidazole 2g immediately as a single dose**
Ask patient to return in 7 days if symptoms persist

If Improved:
Discharge patient

If Not Improved:
Treatment failure – Refer

People who are penicillin allergic may also react to cephalosporins.
**If severe penicillin allergic, i.e. angioedema, anaphylactic shock or bronchospasm: Ciprofloxacin, oral, 500 mg single dose.*
If no response after 48 hours – refer.

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PAGE 134

Vaginal Discharge Syndrome (VDS)

Patient complains of abnormal vaginal discharge/dysuria or vulval itching/burning.

↓

Has patient been sexually active in the last 3 months?

If Yes: Is abnormal discharge or vulval itching/burning confirmed?

↓

If Yes: Is there Lower abdominal pain or pain on moving the cervix?

If Yes: Use lower abdominal pain flowchart

If No, treat with:
Cefixime, oral, 400 mg single dose*
AND **Doxycycline, oral, 100 mg 12 hourly for 7 days**
AND **Metronidazole, 2 g immediately as a single dose**
In pregnancy during breast feeding treat with:
Cefixime, oral, 400 mg single dose
AND **Amoxicillin, oral 500 mg 8 hourly for 7 days**
AND **Metronidazole, 2 g immediately as a single dose**

If No: Consider vaginal candidiasis and/or bacterial vaginosis.
Treat with:
Metronidazole, oral 2 g immediately as a single dose
AND **Clotrimazole, vaginal pessary 500 mg inserted immediately as a single dose**
OR Clotrimazole, vaginal cream, with applicator for 7 days, twice daily

Continued

Vaginal Discharge Syndrome (VDS)
Patient complains of abnormal vaginal discharge/dysuria or vulval itching/burning.
Has patient been sexually active in the last 3 months?
If Yes: Is abnormal discharge or vulval itching/burning confirmed?
If Yes: Is there Lower abdominal pain or pain on moving the cervix?
If Yes: Use lower abdominal pain flowchart
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Continued
PAGE 135

Vaginal Discharge Syndrome (VDS)

Continued

If vulval oedema/curd-like discharge, erythema, excoriations present, treat for candidiasis by adding:
Clotrimazole, vaginal pessary, 500 mg inserted immediately as a single dose
AND if vulval irritation:
Clotrimizole, vaginal cream applied thinly to vulva twice daily and continue for 3 days after symptoms resolve. (Maximum 2 weeks).
Ask patient to return in 7 days if symptoms persist.

Patient returns in 7 days

Has the patient had:
Unprotected intercourse *or* poor adherence?

If Yes:
Repeat treatment

If No:
Treatment failure – Refer

People who are penicillin allergic may also react to cephalosporins.

**If severe penicillin allergic, i.e. angioedema, anaphylactic shock or bronchospasm: Ciprofloxacin, oral, 500mg single dose*

If no response after 48 hours-refer

**Pregnant and penicillin allergic: Replace Amoxicillin, oral with Erythromycin, oral, 500mg 6 hourly for 7 days*

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PAGE 136

Lower Abdominal Pain (LAP)

Sexually active patient complains of lower abdominal pain with or without vaginal discharge.

Take history (including gynaecological) and examine (abdominal and vaginal). Emphasise HIV testing.

Check to see if any of the following are present:
Pregnancy
Missed/overdue period
Recent delivery, abortion or miscarriage
Abdominal guarding and/or rebound tenderness
Abnormal vaginal bleeding
Abdominal mass
Fever > 38° C

If Yes:
Refer all patients for gynaecological or surgical assessment.
Severely Ill Patients:
Set up an IV line and treat shock if present. If referral is delayed > 6 hours, give:
Ceftriaxone, IV, 1 g
PLUS **Metronidazole, oral, 400 mg**

If No, check for:
Lower abdominal tenderness with or without vaginal discharge

Are there:
Nitrites in urine and no cervical motion tenderness?

If Yes:
Treat as a UTI

If No:
Continued on back

Continued

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If Yes:
Treat as a UTI

If No:
Continued on back

Continued

PAGE 137

Lower Abdominal Pain (LAP)

Continued

If No, treat with:
Ceftriaxone, IM, 250 mg single dose*
AND **Doxycline, oral, 100 mg 12 hourly for 14 days**
AND **Metronidazole, oral, 400 mg 12 hourly for 14 days**

Review in 2 to 3 days or earlier if no improvement

If No Improvement:
Refer all patients for gynaecological or surgical assessment.
Severely Ill Patients:
Set up an IV line and treat shock if present. If referral is delayed > 6 hours, give:
Ceftriaxone, IV, 1 g
PLUS **Metronidazole, oral, 400 mg**

If Improved:
Complete treatment

People who are penicillin allergic may also react to cephalosporins.

**If severe penicillin allergic, i.e. angioedema, anaphylactic shock or bronchospasm: Ciprofloxacin, oral, 500 mg 12 hourly for 3 days.*

Advise patient to return if no improvement within 2-3 days for referral.

Pregnant/Breastfeeding refer.

Lower Abdominal Pain (LAP)

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**If severe penicillin allergic, i.e. angioedema, anaphylactic shock or bronchospasm: Ciprofloxacin, oral, 500 mg 12 hourly for 3 days.*

Advise patient to return if no improvement within 2-3 days for referral.

Pregnant/Breastfeeding refer.

PAGE 138

Genital Ulcer Syndrome (GUS)

Patient complains of genital sore or ulcer with/without pain.

↓

Take sexual history and examine. Emphasise HIV testing.

↓

Was patient sexually active within the last 3 months?

If Yes, treat with:
Benzathine Penicillin,* IM, 2.4 MU immediately as a single dose
AND **Erythromycin, oral, 500 mg 6 hourly for 7 days**
AND **Acyclovir, oral, 400 mg 8 hourly for 7 days**
AND Pain relief if indicated
Review after 7 days or earlier if necessary

↓

Are ulcer(s) healed or clearly improving?

If Yes:
Discharge patient

If No:
Emphasise HIV testing.
If no improvement, refer!

If No:
Consider genital herpes.
Emphasise HIV testing.
Treat with:
Acyclovir, oral, 400 mg 8 hourly for 7 days

**People who are penicillin allergic. Severe penicillin allergic, i.e. angioedema, anaphylactic shock or bronchospasm.*

Men and non-pregnant women: Replace Benzathine Penicillin with doxycycline 100 mg twice daily x 14 days

Pregnant women: Increase Erythromycin, oral, 500mg 6 hourly x 14 days

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Scrotal Swelling (SSW)

Sexually active patient complains of scrotal swelling/pain.

↓

Take history and examine. Emphasise HIV testing.

Scrotal swelling or pain confirmed?

If Yes: Are testes rotated and elevated *or* is there history of trauma *or* is there other nontender swelling not thought to be due to sexual activity?

- **If Yes**
  - ↓ Refer for surgical opinion. **Refer urgently if suspected torsion!**
- **If No:** Treat with: **Ceftriaxone, IM, 250 mg single dose*** AND **Doxycycline, oral, 100 mg 12 hourly for 14 days**
  - Review after 7 days or earlier if necessary.
    - **If NOT Improved** → Refer for surgical opinion. **Refer urgently if suspected torsion!**
    - **If Improved:** Complete treatment and discharge patient.

People who are penicillin allergic may also react to cephalosporins.

**If severe penicillin allergic, i.e. angioedema, anaphylactic shock or bronchospasm: Ciprofloxacin, oral, 500 mg 12 hourly for 3 days.*

If no response after 48 hours – refer.

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PAGE 140

Balanitis/Balanoposthitis (BAL)

Patient complains of soreness/itching of glans, inability to retract foreskin, malodour.

↓

Take history and examine. Emphasise HIV testing.

↓

Retract foreskin, clean with water filled syringe and dry.

Foreskin cannot be retracted
Complicated case, **refer!**

Re-examine

↓

If Symptoms Are Confirmed
Treat with:
Instruction on retraction of foreskin when washing
Daily washing with water, avoid soap while inflamed
Clotrimazole cream 2 x daily for 7 days
Perform urinalysis for glycosuria. If positive, refer.

Ask patient to return in 7 days if symptoms persist

If symptoms persist:
Was there poor adherence to Clotrimazole?

→ **If No:**
Treatment failure, **refer!**

↓

If Yes:
Repeat treatment

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PAGE 141

Bubo

Patient complains of hot tender inguinal swelling with surrounding erythema and/or oedema.

↓

Take history and examine. Emphasise HIV testing.
Exclude hernia or femoural aneurysm.

↓

Bubo Symptoms Are Confirmed
Treat with:
Doxycycline, oral, 100 mg 12 hourly for 14 days
AND **Ciprofloxacin, oral, 500 mg 12 hourly for 3 days**
In pregnancy during/breast feeding, replace the above with:
Erythromycin, oral, 500 mg 6 hourly for 14 days

↓

If Bubo is fluctuant:
Aspirate pus in a sterile manner. (Check policy)
Repeat every 72 hours as necessary

↓

If ulcer is also present:
Add Acyclovir, oral, 400 mg 8 hourly for 7 days
AND **Benzathine Penicillin, IM, 2.4 MU immediately as a single dose**

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PAGE 142

Perform RPR/VDRL if indicated:
–Sexual assault case
–Suspected secondary syphillis
–Suspected tertiary syphillis
–3 month follow-up of recently treated early syphillis case

RPR/VDRL Positive

RPR/VDRL Negative

–Rules out secondary/tertiary syphillis
–Repeat RPR/VDRL in 3 months only in sexual assault cases
–Indicates cure in previously treated syphillis case

Is previous RPR/VDRL result available?

If No, were there symptoms/signs of genital ulcer or secondary syphillis present?

If Yes, what was the last positive RPR/ VDRL?

If Yes: Treat with Benzathine benzylpenicillin, IM, 2.4 MU immediately as a single dose

If No: Treat with Benzathine benzylpenicillin, IM, 2.4 MU once weekly for 3 weeks

Continued on Next Page

Continued

Syphilis

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Continued on Next Page

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PAGE 143

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PAGE 143

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Continued on Next Page

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PAGE 143

Continued

If Yes, what was the last positive RPR/VDRL?

Current RPR/VDRL is 4 fold lower, or in a known serofast patient, is the same, lower or no more than 2 fold higher than the previous RPR/VDRL, e.g. was 1:4 now no more than 1:8.

→ **Discharge**

Current RPR/VDRL is 4 fold or higher than the previous RPR/VDRL, e.g. was 1:8 now 1:32 or higher.

→ Is last RPR/VDRL less than 2 years ago?

If Yes:
Treat with **Benzathine penicillin 2.4 MU IM immediately as a single dose.**

If No:
Treat with **Benzathine penicillin 2.4 MU IM once weekly for 3 weeks.**

Syphilis

Continued

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PAGE 144

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PAGE 144

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PAGE 144

Syphilis Screening of Pregnant Women

All pregnant women at first antenatal visit

↓

Take history and examine, explain need for syphilis screening, do pre-test counselling for HIV

↓

Take blood for RPR test (always), for HIV test (if consent), and for other ANC routines

↓

Any STI syndrome or illness?

→ **If Yes,** Use appropriate flowchart, manage appropriately

Syphilis test positive?

→ **Treat pregnant woman with:**
- Benzathine Penicillin 2.4 MU imi once weekly for 3 weeks

Or in case of penicillin allergy:
- Erythromycin 500 mg 4X daily for 4 weeks (28 days)

\+

Treat all symptomatic newborns of mothers with positive RPR test during pregnancy with:
- Benzathine Penicillin 50 000 IU / kg imi stat

Symptomatic newborns (congenital syphilis):
- Notify (Notification of Medical conditions form GW17/5)
- Refer to doctor

HIV test positive?

→ **If yes,** Post test counselling, PMTC

→ **If no,** Repeat HIV test after 3 months

Continued

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Continued

PAGE 145

Syphilis Screening of Pregnant Women

Continued

All pregnant woman:
- Educate, ensure compliance and counsel; promote couple-counselling if applicable
- Explain the risk of vertical transmission
- Promote consistent condom use particularly during pregnancy, demonstrate condom use, provide condoms
- Stress the importance of partner treatment, issue one notification slip for each sexual partner
- Promote HIV counselling and testing of partner

Syphilis Screening of Pregnant Women

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PAGE 146

Drug Treatment of More than One STI Syndrome

STI Syndromes	Drug Treatment (New Episode)
MUS + SSW	Treat according to SSW flow chart
MUS + BAL	Treat according to MUS flow chart *plus* **Cotrimoxazole** cream 2x daily for 7 days
MUS + GUS	**Cefixime,** 400 mg p.o. stat *plus* **Benzathine Penicillin,*** 2.4 MU imi stat *plus* **Erythromycin**, oral, 500 mg 6 hourly for 7 days *plus* **Acyclovir,** oral, 400 mg 8 hourly for 7 days
VDS + LAP	Treat according to LAP flow chart *plus* treat for candidiasis, if required

**Continued*

**Penicillin-allergic men and non pregnant women, replace benzathine penicillin with: Doxycycline, oral, 100 mg 12 hourly for 14 days; Penicillin-allergic pregnant or breastfeeding women, replace benzathine penicillin and amoxicillin with: Erythromycin, oral, 500 mg 6 hourly for 14 days*

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MUS + BAL	Treat according to MUS flow chart *plus* **Cotrimoxazole** cream 2x daily for 7 days
MUS + GUS	**Cefixime,** 400 mg p.o. stat *plus* **Benzathine Penicillin,*** 2.4 MU imi stat *plus* **Erythromycin**, oral, 500 mg 6 hourly for 7 days *plus* **Acyclovir,** oral, 400 mg 8 hourly for 7 days
VDS + LAP	Treat according to LAP flow chart *plus* treat for candidiasis, if required

**Penicillin-allergic men and non pregnant women, replace benzathine penicillin with: Doxycycline, oral, 100 mg 12 hourly for 14 days; Penicillin-allergic pregnant or breastfeeding women, replace benzathine penicillin and amoxicillin with: Erythromycin, oral, 500 mg 6 hourly for 14 days*

Continued

PAGE 147

Drug Treatment of More than One STI Syndrome

STI Syndromes	Drug Treatment (New Episode)
VDS + GUS (non-pregnant and pregnant, breastfeeding)	**Cefixime,** 400 mg p.o. stat *plus* **Metronidazole,** 2 g p.o. stat *plus* **Benzathine Penicillin,*** 2.4 mu imi stat *plus* **Erythromycin**, oral, 500 mg 6 hourly for 7 days *plus* **Acyclovir,** oral, 400 mg 8 hourly for 7 days *plus* treat for candidiasis, if required
SSW/LAP + GUS	**Ceftriaxone,** 250 mg imi stat *plus* **Metronidazole,** 400 mg 12 hourly for 14 days *plus* **Erythromycin**, oral, 500 mg 6 hourly for 14 days *plus* **Acyclovir,** oral, 400 mg 8 hourly for 7 days *plus* treat for candidiasis, if required

**Penicillin-allergic men and non pregnant women, replace benzathine penicillin with: Doxycycline, oral, 100 mg 12 hourly for 14 days; Penicillin-allergic pregnant or breastfeeding women, replace benzathine penicillin and amoxicillin with: Erythromycin, oral, 500 mg 6 hourly for 14 days*

NB: Erythromycin covers Chancroid/LGV, Chalmydial Urethritis and Cervicitis

Drug Treatment of More than One STI Syndrome

STI Syndromes	Drug Treatment (New Episode)
VDS + GUS (non-pregnant and pregnant, breastfeeding)	**Cefixime,** 400 mg p.o. stat *plus* **Metronidazole,** 2 g p.o. stat *plus* **Benzathine Penicillin,*** 2.4 mu imi stat *plus* **Erythromycin**, oral, 500 mg 6 hourly for 7 days *plus* **Acyclovir,** oral, 400 mg 8 hourly for 7 days *plus* treat for candidiasis, if required
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PAGE 148

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PAGE 148

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PAGE 148

Neonatal Conjunctivitis

Neonate with eye discharge

Take history and examine. → Are eyelids swollen with purulent discharge?

If Yes:
Treat Baby with:
Ceftriaxone 50 mg/kg imi stat (maximum 125 mg)
Erythromycin syrup 50 mg/kg/day in four divided doses for 14 days
Treat Mother with:
Cefixime, oral, 400 mg stat
AND **Erythromycin, oral, 500 mg 4 x daily for 7 days**
Treat Father with:
Cefixime, oral, 400 mg stat
AND **Doxycycline, oral, 100 mg 2 x daily for 7 days**

If No:
Reassure mother
Advise to return if necessary

Review in 2 days (or earlier if necessary)

If Improved:
Finalise treatment
Reassure mother

If NOT Improved:
Complicated case – Refer to doctor!
Reassure mother

Continued

Neonatal Conjunctivitis
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Take history and examine. → Are eyelids swollen with purulent discharge?
If Yes: Treat Baby with: Ceftriaxone 50 mg/kg imi stat (maximum 125 mg) Erythromycin syrup 50 mg/kg/day in four divided doses for 14 days Treat Mother with: Cefixime, oral, 400 mg stat AND Erythromycin, oral, 500 mg 4 x daily for 7 days Treat Father with: Cefixime, oral, 400 mg stat AND Doxycycline, oral, 100 mg 2 x daily for 7 days
If No: Reassure mother Advise to return if necessary
Review in 2 days (or earlier if necessary)
If Improved: Finalise treatment Reassure mother
If NOT Improved: Complicated case – Refer to doctor! Reassure mother
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If No: Reassure mother Advise to return if necessary
Review in 2 days (or earlier if necessary)
If Improved: Finalise treatment Reassure mother
If NOT Improved: Complicated case – Refer to doctor! Reassure mother
Continued
PAGE 149

Neonatal Conjunctivitis

Parents of baby with confirmed neonatal conjunctivitis

- Educate, ensure compliance, and counsel; promote couple-counselling if applicable.
- Promote abstinence from penetrative sex during the course of treatment.
- Promote and demonstrate condom use, provide condoms.
- Stress the importance of partner treatment and issue one notification slip for each sexual partner. Follow up partner treatment during review visit.
- Promote HIV counselling and testing. For negative results repeat test after 3 months.

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PAGE 150

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PAGE 150

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PAGE 150

Treatment Protocol of Asymptomatic Sexual Partner

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
VDS	MUS *plus* **Metronidazole,** 2 g stat	MUS	VDS
LAP	MUS *plus* **Metronidazole,** 2 g stat	SSW	VDS
GUS	GUS	BAL	**Contrimazole,** vaginal pessary, 500 mg inserted stat
GW	GW if signs	GUS	GUS
PL	PL	GW	GW if signs
MC	MC if signs	PL	PL

Continued

Treatment Protocol of Asymptomatic Sexual Partner

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
VDS	MUS *plus* **Metronidazole,** 2 g stat	MUS	VDS
LAP	MUS *plus* **Metronidazole,** 2 g stat	SSW	VDS
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GW	GW if signs	GUS	GUS
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PAGE 151

Continued

Treatment Protocol of Asymptomatic Sexual Partner

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
VDS	MUS *plus* **Metronidazole,** 2 g stat	MUS	VDS
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GUS	GUS	BAL	**Contrimazole,** vaginal pessary, 500 mg inserted stat
GW	GW if signs	GUS	GUS
PL	PL	GW	GW if signs
MC	MC if signs	PL	PL

PAGE 151

Continued

Treatment Protocol of Asymptomatic Sexual Partner

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
VDS	MUS *plus* **Metronidazole,** 2 g stat	MUS	VDS
LAP	MUS *plus* **Metronidazole,** 2 g stat	SSW	VDS
GUS	GUS	BAL	**Contrimazole,** vaginal pessary, 500 mg inserted stat
GW	GW if signs	GUS	GUS
PL	PL	GW	GW if signs
MC	MC if signs	PL	PL

PAGE 151

Continued

Treatment Protocol of Asymptomatic Sexual Partner

Continued

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test	MC	MC if signs
	In addition: treat any symptomatic STI		In addition: treat any symptomatic STI
		RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test

Treatment Protocol of Asymptomatic Sexual Partner

Continued

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test	MC	MC if signs
	In addition: treat any symptomatic STI		In addition: treat any symptomatic STI
		RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test

PAGE 152

Treatment Protocol of Asymptomatic Sexual Partner

Continued

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test	MC	MC if signs
	In addition: treat any symptomatic STI		In addition: treat any symptomatic STI
		RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test

PAGE 152

Treatment Protocol of Asymptomatic Sexual Partner

Continued

Female Patient Diagnosis	Male Partner Treatment	Male Patient Diagnosis	Female Partner Treatment
RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test	MC	MC if signs
	In addition: treat any symptomatic STI		In addition: treat any symptomatic STI
		RPR+	**Benzathine Penicillin,** imi 2.4 MU stat. In addition do RPR test

PAGE 152

DRUG SIDE EFFECT MONITORING

Reference: South Africa. National Department of Health. ANTIRETROVIRAL THERAPY in SOUTH AFRICA: A Pocket Guide on Prevention and Management of Side Effects and Drug Interactions (2009)

DRUG SIDE EFFECT MONITORING

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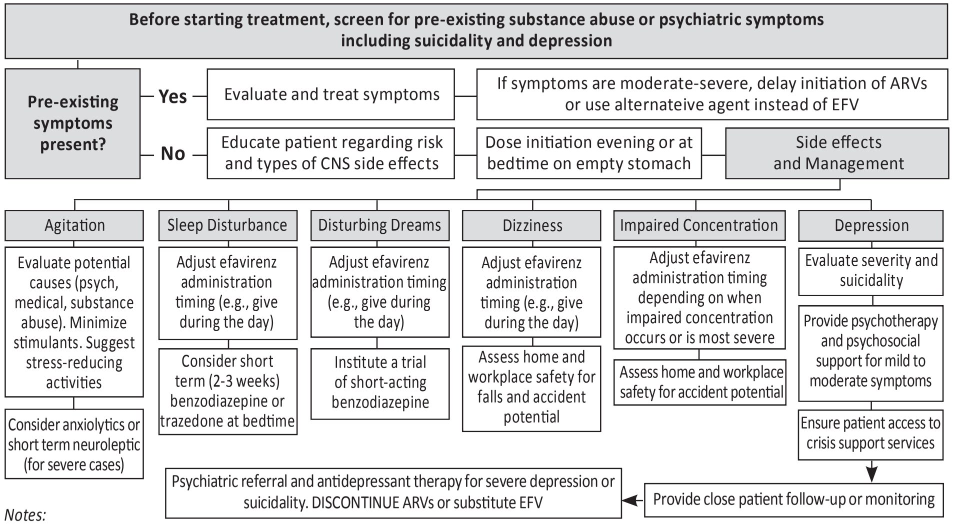
Management of Efavirnez-related Central Nervous System Side Effects



Notes:
1. If a switch from efavirenz to nevirapine is made, the lead-in dose is not required and nevirapine should be started at a dose of 200mg bd

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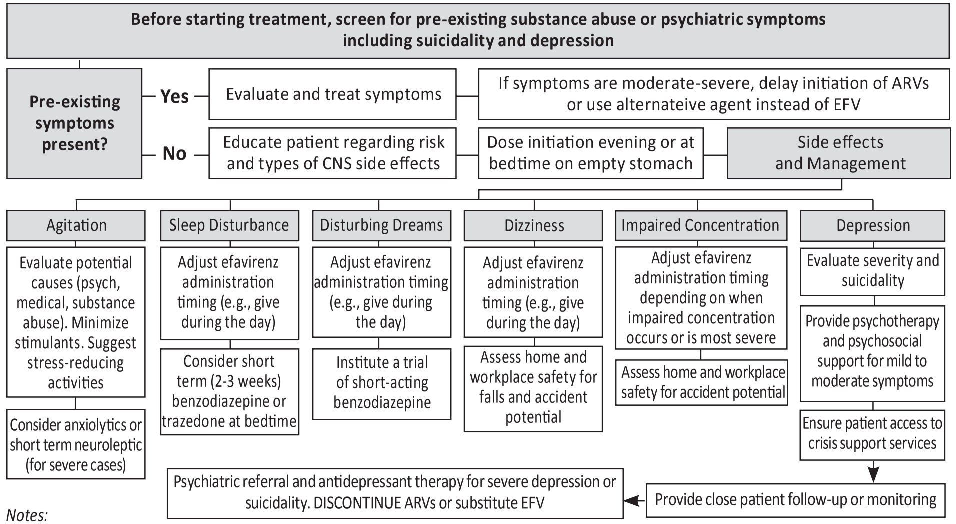

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PAGE 154
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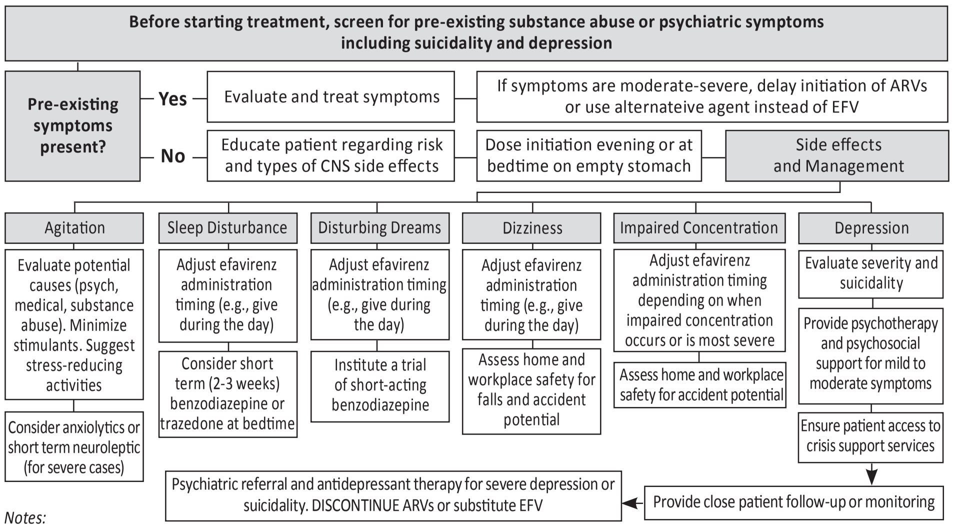

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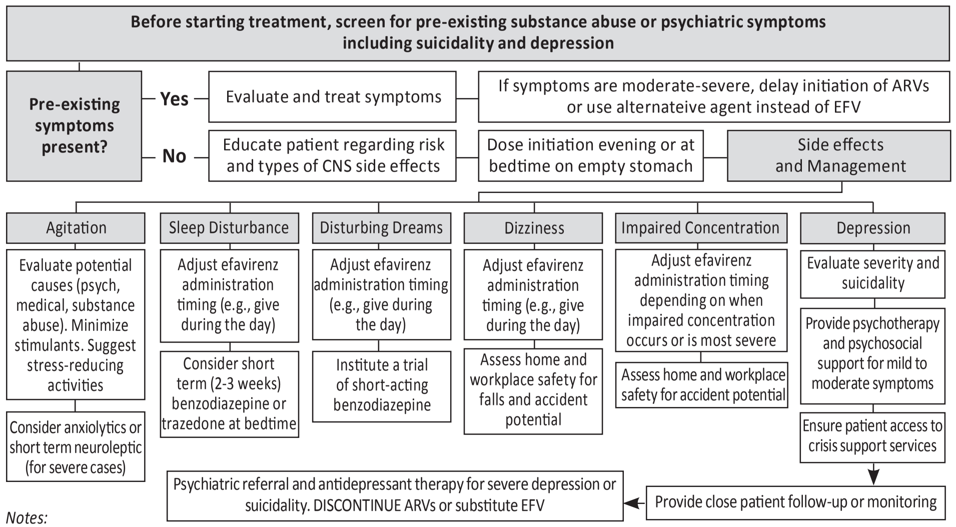

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PAGE 154

AZT-Related Hematologic Toxicity

AZT can cause anemia and neutropenia, but rarely thrombocytopenia

- Anemia (usually macrocytic)
  - Correct other causes (e.g. iron deficiency, folate deficiency)
    - Hgb 7.0 - 9.4
      - Reduce AZT dose to 200 mg 12 hourly
      - Repeat Hgb in 1 - 2 weeks
      - Replace AZT with Tenofovir if no improvement
    - Hgb < 7.0
      - • Replace AZT with Tenofovir • Blood transfusion may be required
      - Repeat Hgb in 1 week
- Neutropenia
  - Calculate absolute neutrophil count (ANC) = WBC x % (segs+bands)
    - ANC 0.75 - 0.95
      - Reduce AZT dose to 200 mg 12 hourly
      - Repeat ANC in 1 - 2 weeks
      - Replace AZT with Tenofovir if no improvement
    - • ANC < 0.75 • No fever
      - Replace AZT with Tenofovir
      - Repeat ANC in 1 week
    - • ANC < 0.75 • Fever
      - • Obtain blood cultures • Administer Ciprofloxacin 750 mg + Gentamicin at once • Replace AZT with Tenofovir
      - Refer immediately to hospital

Notes:

1. *Systematic evaluation of anaemia is based on MCV (microcytic, normocytic, macrocytic), whether bone marrow response is appropriate (high reticulocyte count), whether all cell lines are involved (pancytopenia) or not.*
2. *AZT causes a hypoproliferative macrocytic anaemia. Another cause of severe hypoprolifertive anaemia in HIV patients is Parvovirus induced pure red cell aplasia.*
3. *If anaemia and thrombocytopenia are present, consider the possibility of thrombotic thrombocytopenic purpura (TTP) and examine blood smear for schistocytes.*
4. *Reference: South Africa. National Department of Health. CLINICAL GUIDELINES FOR THE MANAGEMENT OF HIV & AIDS IN HEALTH FACILITIES (2008). Section 3.8*

Reference: South Africa. National Department of Health. ANTIRETROVIRAL THERAPY in SOUTH AFRICA: A Pocket Guide on Prevention and Management of Side Effects and Drug Interactions (2009)

AZT-Related Hematologic Toxicity
AZT can cause anemia and neutropenia, but rarely thrombocytopenia
Anemia (usually macrocytic) / Neutropenia (flowchart repeated)
Notes: 1.–4. (repeated)
Reference: South Africa. National Department of Health. ANTIRETROVIRAL THERAPY in SOUTH AFRICA: A Pocket Guide on Prevention and Management of Side Effects and Drug Interactions (2009)
PAGE 155

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PAGE 155

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PAGE 155

Dyslipidemia Management

Obtain fasting glucose and lipid profile prior to starting antiretrovirals (protease inhibitors or efavirenz contain) & within 3-6 months of starting new regimen

Count number of CHD risk factors. If > = 2 risk factors, perform 10-year risk calculation

Intervene for modifiable non-lipid risk factors, including diet and smoking

If above the lipid threshhold based on risk group despite vigorous llifestyle interventions, consider:
- Altering antiretrovirol therapy after consultation with expert OR
- Using lipid lowering drugs

If lipid lowering drugs are necessary

Serum LDL cholesterol above threshhold OR triglycerides 2.26-5.65 mm/L (200-500 mg/dl) with elevated non-HDL cholesterol	Serum triglycerides greater than 5.65 mm/L (500 mg/dl)
Statin therapy	Fibrate therapy

Notes:
1. *Treat patients with hypertriglyceridaemia where the triglyceride level is > 10 mmol/L medical therapy with a fibrate (e.g. Bezafibrate 400 mg daily after food). "The main risk associated with hypertriglyceridaemia is pancreatitis (usually when level is > 15 mmol/L).*
2. *Major risk factors (exclusive of LDL cholesterol) that modify LDL goals are: cigarette smoking, hypertension (BP > = 140/90 or on antihypertensive medication), low HDL cholesterol (< 1 mmol/L or <40 mg/dl), family history of premature CHD (CHD in male first degree relative < 55 years; Diabetes CHD in female first degree relative < 65 years), age (men > = 45 years; woment > = 55 years). Diabetes is regarded as a CHD equivalent.*
3. *10-year cardiovascular risk assessment tools (Framingham) available at: http://cvrisk.mvm.ed.ac.uk/calculator/calc.asp (using mmol/L units) and http://hp2010.nhlbihin.net/atpiii/calculator.asp (using mg/dL units)*
4. *Treat patients with a statin if their Framingham risk for MI is calculated to be 20% over 10 years.*
5. *Simvastatin and most other statins are contra-indicated for use with PIs because of drug interactions. However, Pravastatin and low dose Atorvastatin are safe.*

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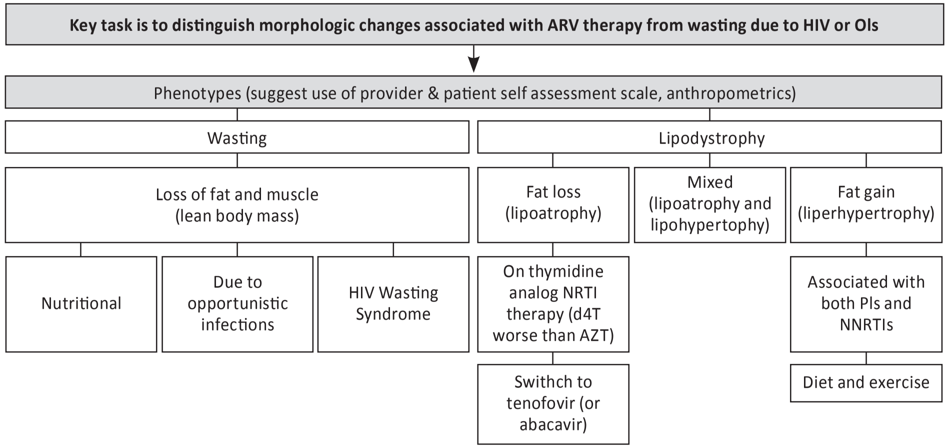
PAGE 156

Wasting and Lipodystrophy Management



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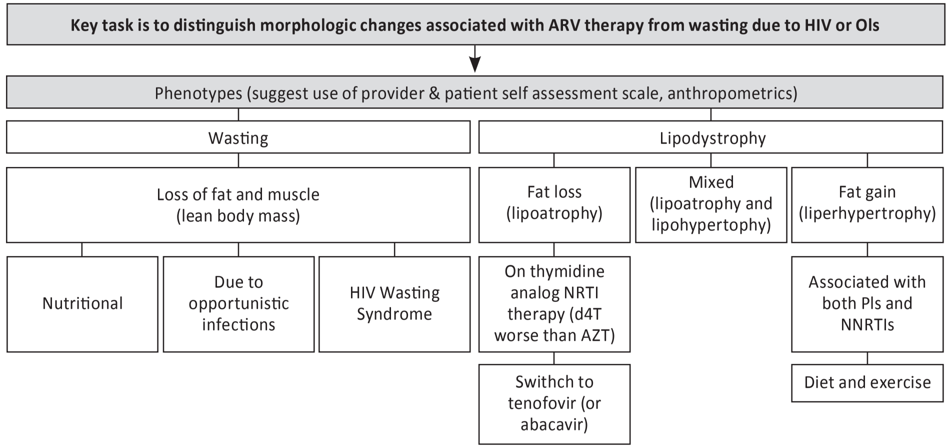
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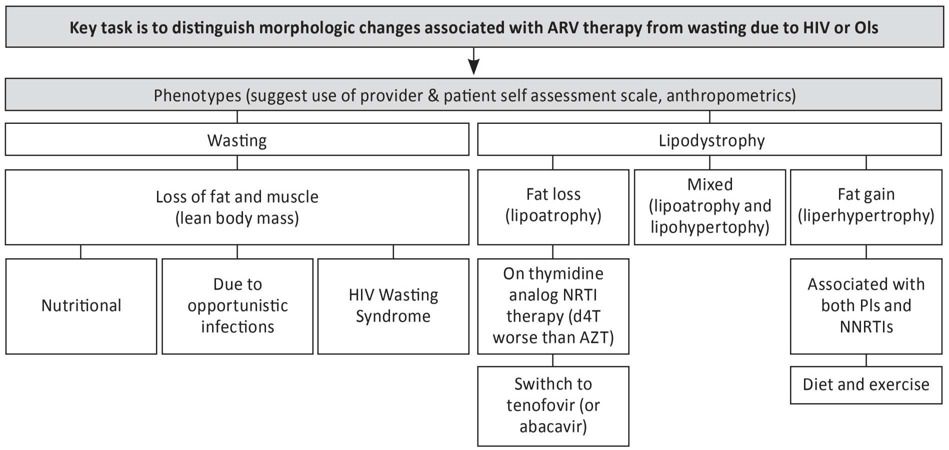
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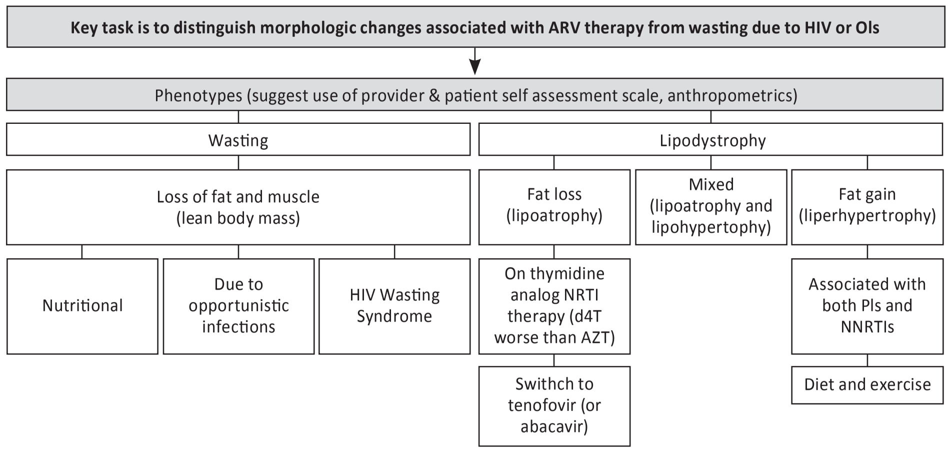
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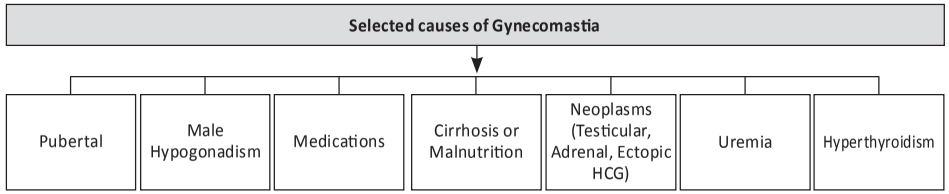
Gynecomastia



Notes:

1. *Efavirenz and ddl have been associated with developement of gynecomastia. In most cases it resolves spontaneously over 1-2 years. Switch drugs if its effects are severe (e.g. psychological distress). Nevirapine could be an option (monitor hepatotoxicity in regard to CD4 levels).*
2. *Many other drugs have been associated with development of gynecomastia. Commonly used ones include: spironolactone, isoniazid, cimetidine, ACE inhibitors, calcium channel blockers, anabolic steriods, estrogens, haloperidol, phenothiazines, tricyclic antidepressants, phenytoin, metoclopramide.*
3. *Evaluation of hormonal causes would include (when available) measurement of: testosterone, LH, HCG estradiol, and TSH. Generally refer to a specialist when hormonal causes are suspected.*

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Gynecomastia

Selected causes of Gynecomastia
Pubertal
Male Hypogonadism
Medications
Cirrhosis or Malnutrition
Neoplasms (Testicular, Adrenal, Ectopic HCG)
Uremia
Hyperthyroidism

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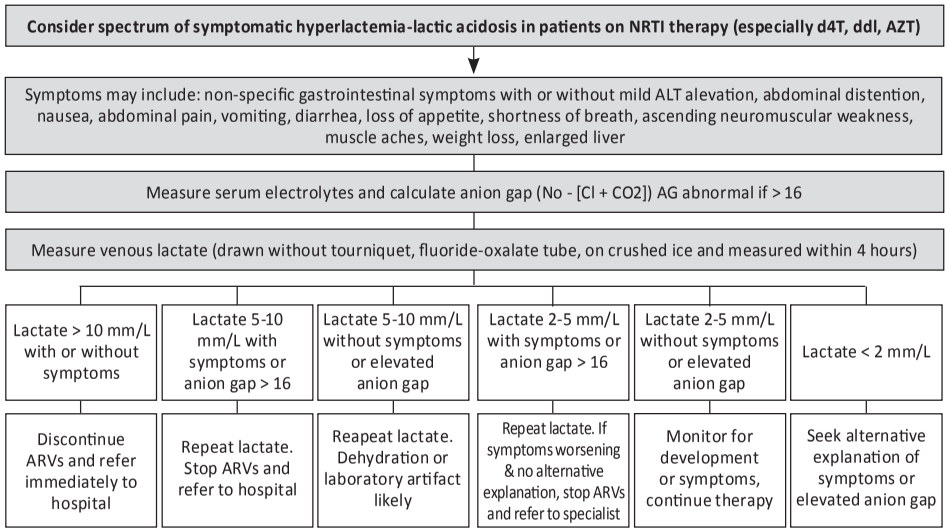
PAGE 158

Hyperlactatemia and Lactic Acidosis due to NRTI Therapy



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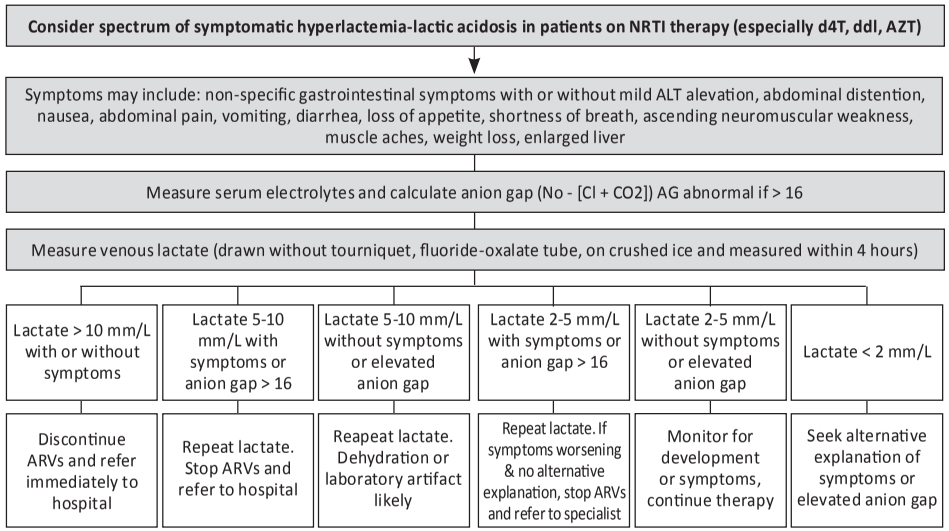

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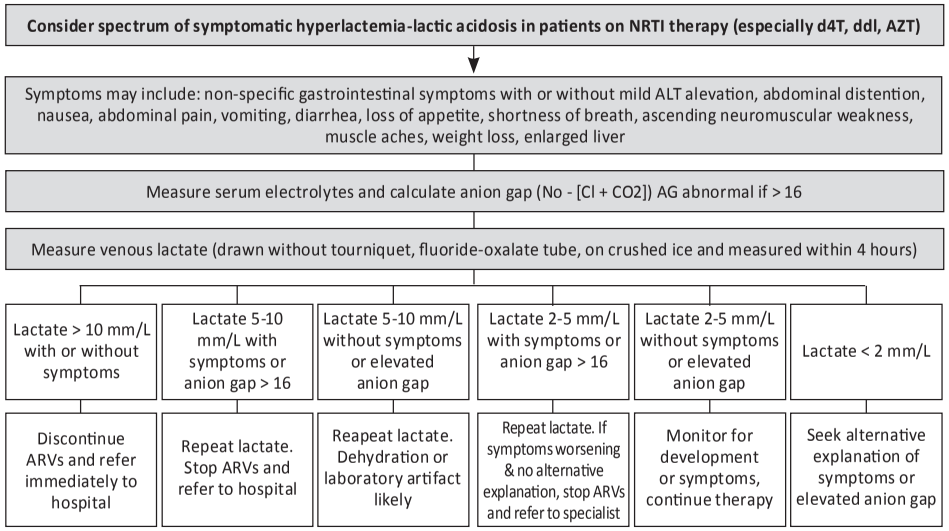

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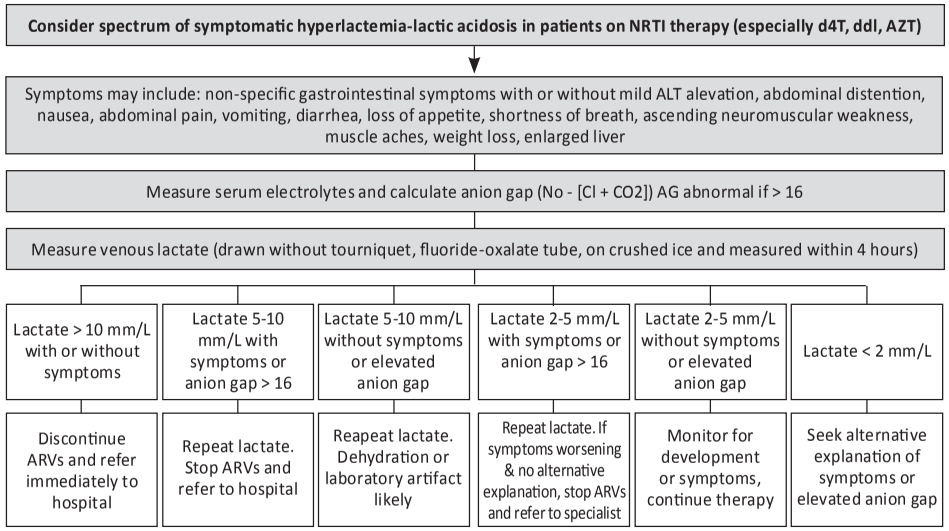

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PAGE 159

Hyperlactatemia and Lactic Acidosis due to NRTI Therapy

Notes:

1. *In patients with mild hyperlactataemia and minimal symptoms (lactate 2.5-5 and no metabolic acidosis - standard bicarbonate > 20):*
   - *The d4T should be switched to AZT*
   - *The lactate rechecked within 3 days and then weekly until normalized*
   - *Stop ART if the lactate cannot be nonitored in the way described*
   - *Stop ART and follow the guidelines below if symptoms are severe or the lactate continues to rise or symptoms get worse despite the switch*
2. *Patients with moderately sever hyperlactataemia/moderate metabloic acidosis (lactate 5-10 and/or standard bicarbonate 15-20):*
   - *Stop ART and observe as inpatient for 1-2 days*
   - *Give oral vitamins (vitamin BCo 2 tablets bd and thiamine 100 mg bd)*
   - *Hydrate well (orally or IVI)*
   - *Exclude sepsis*
   - *Exclude OIs*
   - *Recheck lactate and discharge for outpatient follow-up if clinically stable*
   - *Recommence ART regimen 1d (Tenofovir, 3TC, EFV) only when lactate and bicarbonate has normalized (this may take months)*
3. *Patients with severe hyperlactataemia (lactate > 10 without metabolic acidosis) or significant lactic acidosis (raised lactate regardless of level and significant metabolic acidosis - standard bicarbonate < 15). The mortality is high in this scenariao (up to 60%). These patients should preferably be managed in a hight care facility as such:*
   - *Stop ART*
   - *IVI Thiamine 100 mg 12 hourly and BCo 1 amp 12 hrly*

Continued

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Continued

PAGE 160

Hyperlactatemia and Lactic Acidosis due to NRTI Therapy

Notes Continued:

- *IVI fluids*
- *Blood culture / urine culture / septic search AND*
- *Broad-spectrum antibiotic (e.g. third-generation cephalosporin or co-amoxyclav). This is important because sepsis may mimic or precipitate NRTI-associated lactic acidosis.*
- *IVI NaHCO3 if profound acidosis*
- *Ventilation if respiratory fatigue occurs*
- *Dialysis*
- *Inotropes AND*
- *Other supportive measures as necessary*
- *Monitor:*
  - *Lactate*
  - *Blood gas*
  - *Lipase*
  - *ALT and*
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- *Recommence ART Regimen 1d (Tenofovir, 3TC, EFV) Lopinavir/Ritonavir (Kaletra) when lactate has significantly decreased and they are clinically improved (this may take weeks to months)*

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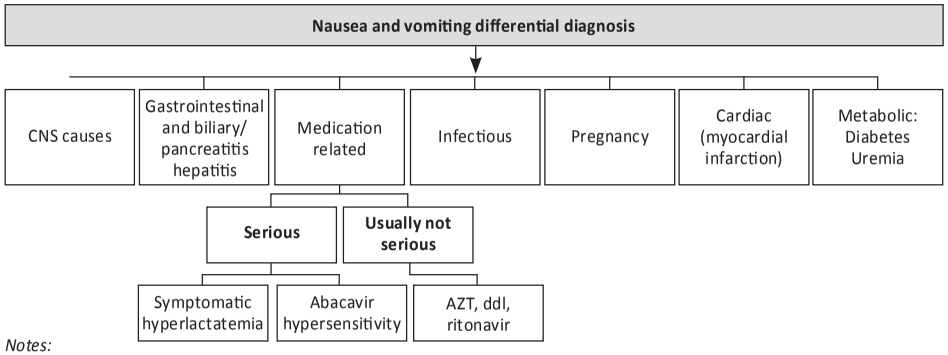
PAGE 161

Nausea and Vomiting



Notes:

1. *Symptomatic hyperlactatemia due to d4T and other NRTIs can present with loss of appetite, nausea and vomiting. See Lactic Acidosis algorithm.*
2. *Abacavir hypersensitivity (HSR) can present with gastrointestinal symptoms. See Abacavir HSR algorithm.*
3. *D4T and ddI can casue pancreatitis, presenting with nausea, vomiting and epigastric pain. See abdominal pain algorithm.*
4. *Actively manage nausea due to antiretroviral medication, or adherence will suffer. The common causative agents are AZT and ddI.*
5. *Administering anti-emetics half an hour before the antiretroviral dose up to 3 times daily may be helpful. If the nausea does not settle, refer to a doctor trained on ART.*
6. *Check for jaundice and take blood for ALT as nausea and vomiting may be the first symptoms of drug-induced hepatitis.*

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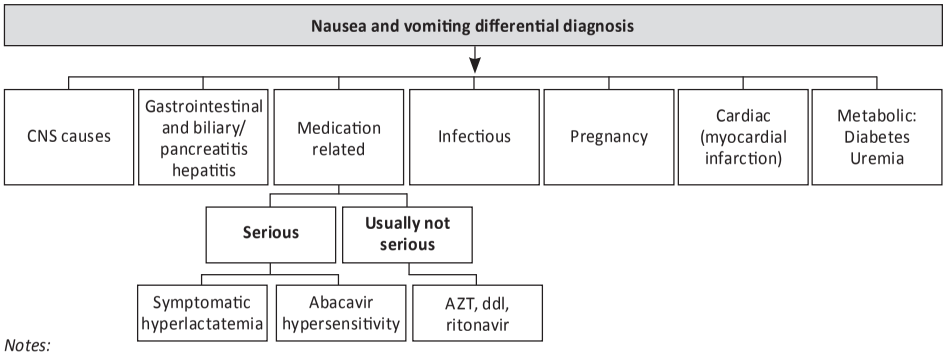
Nausea and Vomiting



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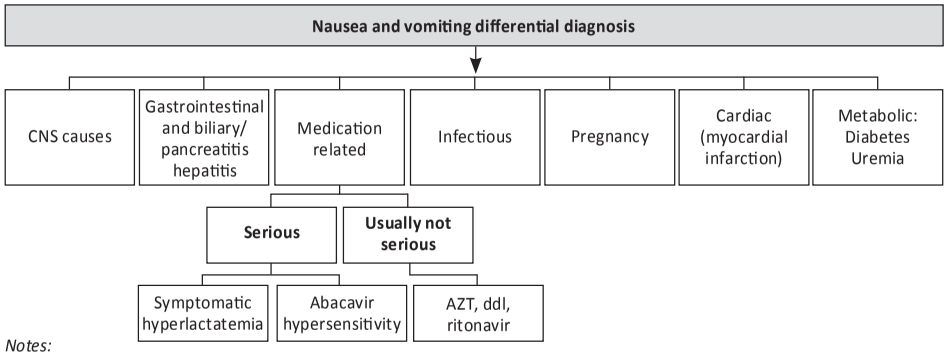

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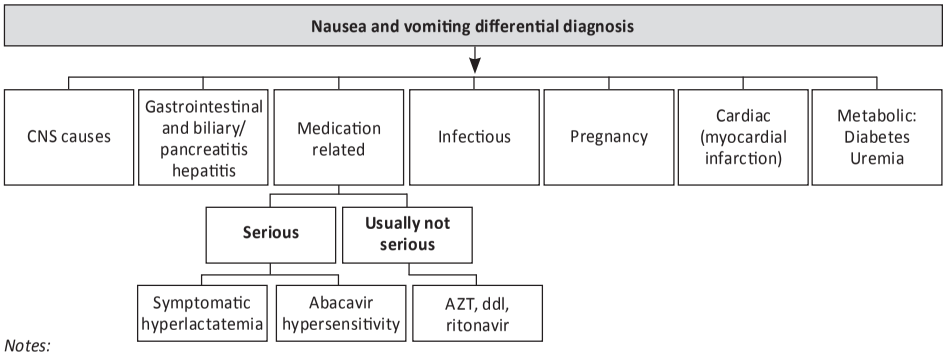

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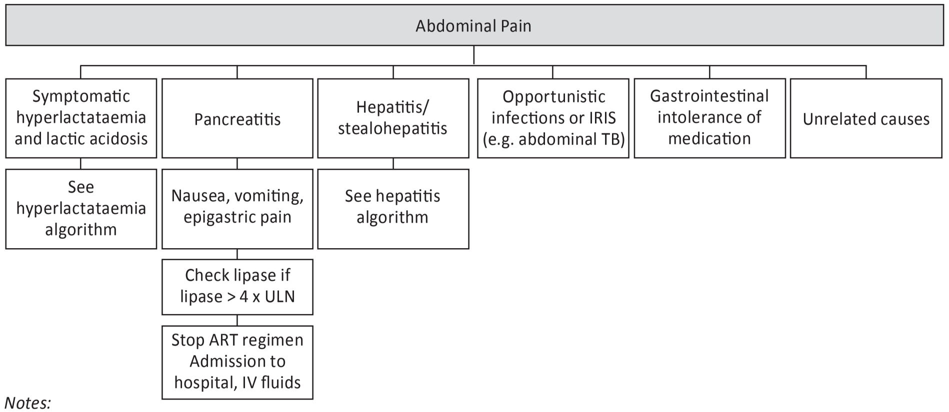
PAGE 162

Abdominal Pain



Notes:

1. *Causes of pancreatitis include drug induced (d4T, ddl, 3TC (in children), Kaletra), infections (e.g. CMV) alcoholic pancreatitis, hypertriglyceridemia and biliary pathology (e.g. gallstones).*
2. *NRTI induced pancreatitis may be associated with mitochondrial toxicity. Check lactate after hemodynmically stabilized.*
3. *Unrelated causes include: pregnancy, diabetic ketoacidosis, appendicitis, peptic ulcer disease, pelvic inflammatory disease, and urinary tract infections.*

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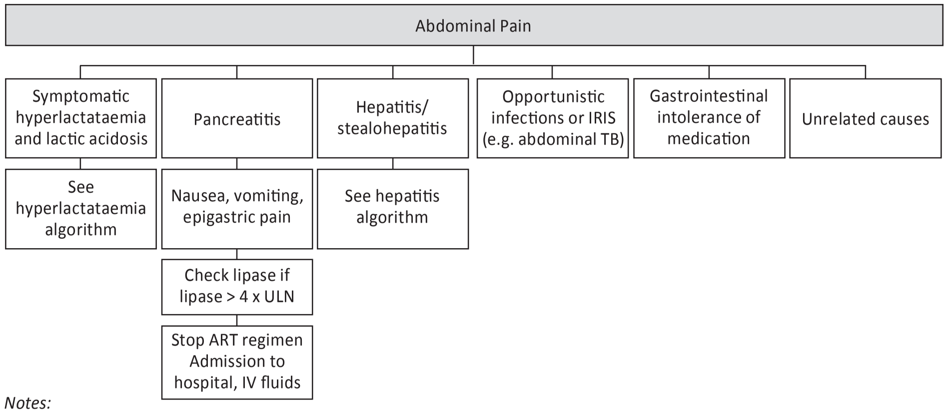

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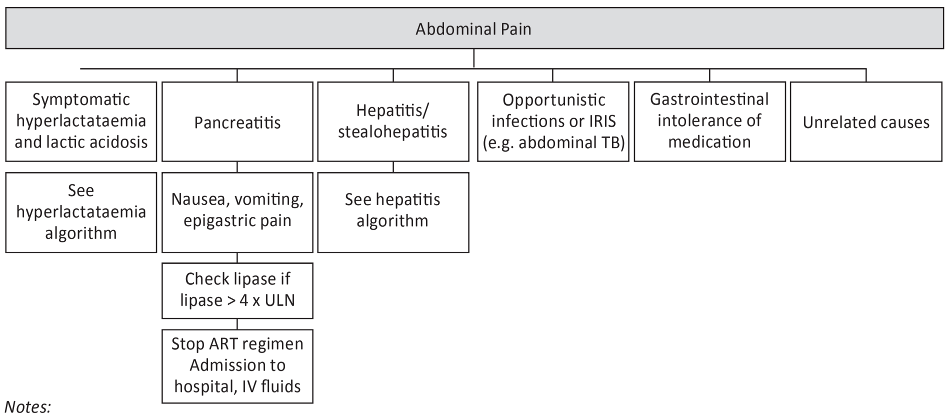

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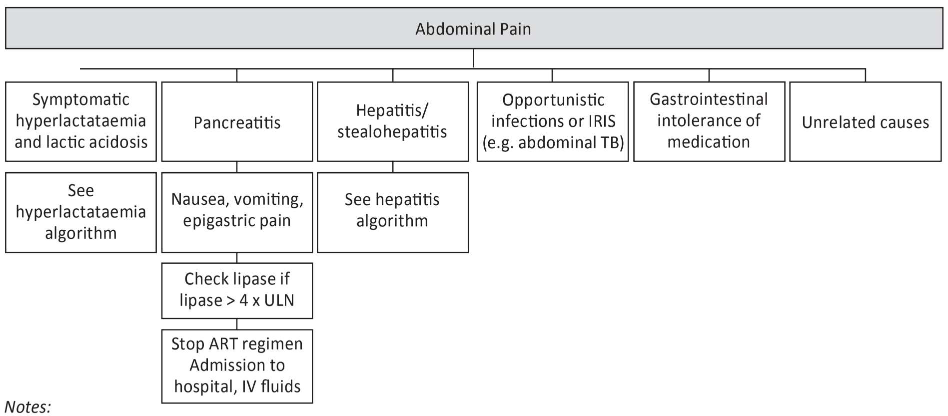

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PAGE 163

ARV-Associated Diarrhea Management

Diarrhea may be associated with ddl & protease inhibitors.
Must distinguish ARV-induced diarrhea from other causes.
Is diarrhea associated with fever or mucous/blood in the stool?

- **Yes** → Not due to ARVs. Evaluate and treat for infectious diarrhea
- **No** → Probably due to ARVs
  - Did diarrhea start within days/weeks of starting ARVs?
    - **Yes** → Administer antimotility agent (if no fever, blood or mucous in stool)
      - If no improvement, evaluate for other causes of diarrhea
    - **No** → Evaluate for other causes of diarrhea by stool examination for WBCs culture, and parasite examination)
      - Treat based on test results or syndromically for infectious diarrhea

Notes:
1. *For symptomatic treatment of non-inflammatory diarrhea, use Loperamide, oral, 4 mg immediately, followed by 2 mg after each loose stool, up to 16 mg/day for severe diarrhea, OR Codiene syrup/tablets 15-30 mg po 3-5 times a day (as required).*
2. *Ensure hydration with home-made sugar and salt solution: 1/2 level teaspoon of salt and 8 level teaspoons of sugar dissolved in 1 litre of boiled then cooled water.*

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PAGE 164

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PAGE 164

ARV Rash Management Flow Chart

Patient is on nevirapine or efavirenz containing regimen for less than 1 month

↓

Does patient have any of the following findings? Fever, eye discomfort or blurred vision, mouth or genital sores, blisters on skin, rash that is hemorrhagic (doesn't blanch)

Yes ↓

- STOP ALL ARVs and any other medications started within last month
- Refer immediately to hospital

No ↓

- Stop any unnecessary medications or traditional remedies started within last month
- Teach patient warning signs of severe rash
- Administer Benadryl 25-50 mg by mouth every 6-8 hours
- Arrange daily follow-up until rash either resolves or becomes severe

Notes:

1. *Drug rashes are typically associated with nevirapine (and the abacavir hypersensitivity syndrome which is covered separately). Less commonly they are associated with efavirenz and rarely with other antiretrovirals. A number of other drugs used in patients with HIVs (e.g. co-trimoxazole and TB medications) may also result in drug rashes.*
2. *About 15% of patients started on nevirapine will develop a drug rash. This typically occurs in the first 3 months. It typically presents with a morbiliform or maculo-papular eruption but may progress to blistering, desquamation and a Stevens-Johnson syndrome.*
3. *Most nevirapine skin rashes are mild and will settle despite continuing the drug. However, about 7-33% of patients require that nevirapine be stopped.*
4. *Check the following in patients presenting with a nevirapine skin rash: ALT, temperature, ask about systemic symptoms.*
5. *Avoid systemic steroids in HIV patients with Stevens Johnson Syndrome unless there is evidence of adrenal insufficiency.*

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PAGE 165

Abacavir Hypersensitivity Reaction (HSR)

Abacavir (ABC) HSR

1. Incidence: 5%
2. 90% within 6 weeks of initiation
3. Symptoms complexes:
   - **Fever 80%**
   - Rash (mild) 70%
   - GI (nausea, vomiting, diarrhea, abd pain)
   - Fatigue, Myalgias, Arthralgias
   - Cough, SOB, sore throat

>=2 symptoms from 2 complexes	0-1 symptoms
• Stop ABC • Do NOT re-challenge	Continue ABC with close monitoring

Notes:

1. *Use caution when initiating ABC if Immune Reconstitution Syndrome (IRIS) likely (e.g. recent TB diagnosis) to avoid confusion when fever occurs.*
2. *ABC HSR symptoms usually worsen daily if ABC continued.*
3. *ABC HSR can progress to multi-organ failure and death, especially with re-challenge.*
4. *Rash alone not indicative of ABC HSR.*
5. *If HLA-B*5701 testing available, do not use ABC if positive.*

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PAGE 166

Peripheral Neuropathy

- **Don't start ddl of d4T containing regimen if patient has symptoms of pre-existing neuropathy**
- **If pre-existing neuropathic symptoms, determine causes and treat (nutritional, drug induced e.g. INH diabetes, alcohol)**
- **Neuropathic symptoms due to HIV itself: diagnosis of exclusion**

Symptoms

Peripheral Neuropathy symptoms: Burning, tingling pain of feet, often worse at night. Occasionally manifest by leg cramps

Grade the severity of symptoms and relationship to start d4T and ddl (e.g. visual analog scale 0-10; Brief Neuropathy Screening Tool (BNST))

Pain Mild

- Symptomatic therapy with simple analgesia Amitriptyline 25-75 mg daily
- Vitamin supplementation (B6 and BCo)
- Selected self care modalities

No relief or worsens

- Switch to AZT if not contraindicated
- If AZT contraindicated, switch to Tenofovir

Pain Moderate or Severe (not controlled with NSAIDs, adjuvants, and vitamin supplementation)

- Switch to AZT if not contraindicated
- If AZT contraindicated, switch to Tenofovir
- Palliate pain with more effective adjuvants and opiates

Notes:

1. *Additional adjuvants with same demonstrated efficacy for HIV distal symmetric polyneuropathy include gabapentin and lamotrigine.*
2. *Antiepileptic drugs including phenytoin and carbamazepine are both inducers of the cytochrome P-450 enzyme system and can lower levels of antiretrovirals metabolized by that system (NNRTIs and protease inhibitors) and compromise antiretroviral therapy effectiveness.*
3. *Self-help strategies such as warm baths have been reported in observational studies to palliate HIV-related neuropathic pain.*
4. *Depending on clinical picture, d4T can be switched with Tenofovir. Tenofovir can also be used in place d4T when initiating therapy.*

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PAGE 167

Glucose Intolerance, Dibetes, and Metabolic Syndrome

Definitions of Abnormal Glucose Metabolism			
	Fasting mmol/L (mg/dL)	**After OGTT mmol/L (mg/dL)**	Comments
Normal	< 5.5 (<100)	< 7.7 (<140)	Symptoms (poyuria, polydypsia, weightloss + random glucose ≥ 11 mmol/L)
Pre-Diabetes	IFG: 5.5-6.89 (100-125)	7.7-10.99 (140-199)	
Diabetes	≥ 6.9 (≥ 126)	≥ 11 (≥ 200)	
OGTT: Oral Glucose Tolerance Test (75 gm glucose load) IFG: Impaired Fasting Glucose			

Notes:

1. *A diagnosis of Metabolic Syndrome requires the presence of at least 3 of the following componets: impaired glucose tolerance, hypertension, elevated waist circumference or waist-hip ratio, and high triglyceride and/or low high-density lipoprotein cholesterol (HDL-C) levels. Metabolic Syndrome increases risk of diabetes and confers 3-fold increased risk of cardiovascular disease.*
2. *Effects of protease inhibitors (PIs) on glucose metabolism vary by agent. Among the PIs, atazanavir, darunavir, and saquinavir have least deleterious effects on glucose metabolism (not currently available in South African antiretroviral therapy program). Effects of Kaletra appear to be less than Indinavir, which has the greatest impact among the PIs.*
3. *Non-antiretroviral drugs including niacin, corticosteroids, and thiazide diuretics may impair glucose metabolism and therby worsen insulin resistance and diabetes.*
4. *Abacavir has been associated with increased risk of cardiovascular events in recent epidemiological studies.*

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Diabetes	≥ 6.9 (≥ 126)	≥ 11 (≥ 200)	
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PAGE 168

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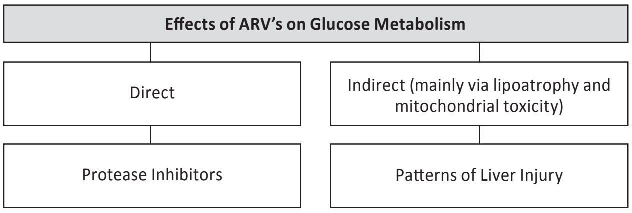
3. *Non-antiretroviral drugs including niacin, corticosteroids, and thiazide diuretics may impair glucose metabolism and therby worsen insulin resistance and diabetes.*
4. *Abacavir has been associated with increased risk of cardiovascular events in recent epidemiological studies.*

Reference: South Africa. National Department of Health. ANTIRETROVIRAL THERAPY in SOUTH AFRICA: A Pocket Guide on Prevention and Management of Side Effects and Drug Interactions (2009)

PAGE 168

Effects of ARV's on Glucose Metabolism



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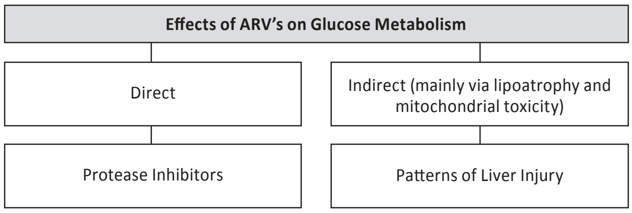

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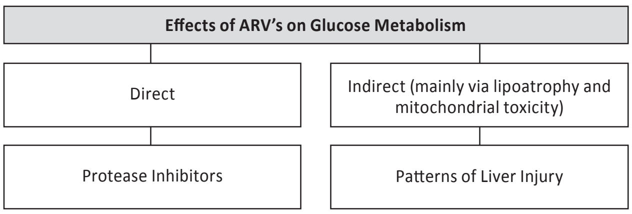

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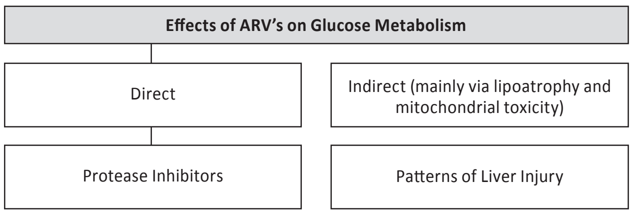

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Tenofovir-Related Nephrotoxicity

Reported Forms of Tenofovir Nephrotoxicity

- Acute renal failure
- Fanconi Syndrome (glyosuria, phosphaturia, aminoaciduria)
- Nephrogenic diabetes insipidus

Antiretroviral Drug, Dosing Category	
Tenofovir	**Dosage**
Usual dosage	300 mg po q.d.
	Dosage for patients with CKD or ESRD
Creatinine clearance ≥ 50 mL/min	No adjustment
Creatinine clearance 30-49 mL/min	300 mg po q48h
Creatinine clearance 10-29 mL/min	300 mg po q72h
Receiving hemodialysis	300 mg po every 7 days[c]
Receiving peritoneal dialysis	Unknown, use with caution

Cockcroft-Gault Equation (Creatinine clearance calculation equation)

$$CrCl = \frac{(140\text{-age}) \times (\text{IBW in kg}) \times (0.85 \text{ if female})}{\text{Serum Cr in mg/d/} \times 72}$$

Estimated Ideal Body Weight (IBW) in kg: IBW = 50kg (male) or 45kg (female) + 2.3kg for each inch > 5 ft.

In Sa: $IBW = 50\text{kg (male) or } 45\text{kg (female)} + 2.3\text{kg} \times \frac{(\text{Actual height in cm} - 152.4\text{cm})}{2.5\text{cm}}$

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PAGE 170

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PAGE 170

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PAGE 170

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Notes:

1. *Clinically significant nephrotoxicity in patients with normal underlying renal function is rare.*
2. *Patients receiving tenofovir who have a GFR > 90 mL/min per 1.73 m2, patients receiving other medications eliminated via renal secretion (e.g., adefovir, acyclovir, ganciclovir, or cidofovir), patients with other comorbid diseases (e.g., diabetes or hypertension), or patients receiving ritonavir boosted protease inhibitor regimens should be monitored at least biannually for measurements of renal function, serum phosphorus, and urine analysis for proteinuria and glycosuria.*
3. *Avoid concimittant use of nephrotoxic medications with tenofovir (e.g. aminoglycosides, amphotericin B, foscarnet).*
4. *Dosing of tenofofir should be based on estimated creatinine clearance (CrCl) using the Cockcroft-Gault formula above. The following website can be used to calculate CrCl: http://nephron.com/cgi-bin/CGSI.cgi*
5. *Fanconi Syndrome, a proximal tubular disorder, should be suspected when normoglycemic glycosuria, hypophosphatemia, and proteinuria are persistently present.*

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PAGE 171

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PAGE 171

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PAGE 171

Interpreting Blood Results: Alanine Transaminase (ALT)

ALT should be pulled for:
- Alternating nightshift/dayshift workers
- Patients with significant psychiatric/substance abuse/alcohol history

Gender	Normal Range	< 2x ULN	2 - 3x ULN	> 3 x ULN	5x ULN
Female	0-35	< 70	70-105	> 105	175
Male	0-40	< 80	80-120	> 120	200
Nevirapine Use	NVP safe	NVP safe	Avoid NVP	Avoid NVP	Avoid NVP
Referral	No		No	Consider (Phone)	Immediate
Additional Investigations	None		Hep B sAg Full LFT	→ Full Hepatitis Screen → Full LFT → Abdo Sonar → Look for TB → Other drugs?	Full work-up to be done at up-referral site

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PAGE 172

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PAGE 172

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PAGE 172

Interpreting Blood Results: Alanine Transaminase (ALT)

Continued

Gender	Normal Range	< 2x ULN	2 - 3x ULN	> 3 x ULN	5x ULN
Action Points	ALT only if develops rash/ signs of hepatitis		**If Hep B sAg positive and Full LFT abnormal** • Patient on permanent nightshift: give EFV in the mornings • Patient on day/nightshift – Aluvia or consider trial of EFV • Consider referral **If Hep B sAg negative and full LFT not abnormal:** • Repeat ALT after 1 month **If ALT abnormal:** • Full LFT **If LFT abnormal:** • Abdominal Sonar • Consider referral	Respond as per results If unsure: Refer e.g. if on hepatotoxic drug(s) consider interrupting treatment	Jaundiced → ADMIT
Children			REFER	REFER	REFER

Remember: If ALT ≤ 2x ULN and NVP initiated:
1. START with lead in dose of NVP 200mg
2. DAILY for TWO WEEKS
3. Repeat ALT only if clinically indicated: Rash/jaundice/ RUQ pain/ hepatomegaly

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PAGE 173

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PAGE 173