Package of care for adults with HIV who are hospitalised with possible Tuberculosis

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Foreword

Tuberculosis (TB) remains a serious public health threat in South Africa and is the leading cause of death in people living with HIV (PWH). Pre-hospital and early in-hospital mortality is of particular concern in PWH. Significant progress has been made to date, but a monumental effort is required to reach the END TB target of zero deaths due to TB by 2035. One of the measures would be to curb early in-hospital mortality due to TB. This goal provided impetus for the development of this package of care.

This package of care was developed to address the diagnostic work-up and management strategies for PWH who require hospital admission with a possible new diagnosis of TB. It is intended to enable doctors and clinicians staffing emergency rooms to appropriately, confidently, and timeously diagnose TB. The content of this package aligns with diagnostic and management guidelines of the South African Department of Health, the World Health Organization, and the Southern African HIV Clinicians Society. The package offers guidance on when and how to start empiric TB treatment and up-to-date information on the performance of different TB diagnostics for pulmonary and extra-pulmonary TB, together with considerations for commonly occurring drug-drug interactions. Of note is additional guidance on the use of TB nucleic acid amplification tests like GeneXpert Ultra on urine specimens at hospitalisation, based on evidence largely generated in South Africa in the last 10 years. The guidance also includes detail on patient monitoring post TB treatment initiation, as well as how to best pursue alternative diagnoses, should TB be excluded.

This document is not intended to cover the numerous reasons for pre-hospital mortality. Rather, it offers pragmatic, evidence-based guidance which will serve as a valuable tool, especially for junior staff in under-resourced settings.

Dr SSS Buthelezi
Director General: Health

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Dr Ribka Berhanu
Dr Denise Evans
Dr Panganai Dhliwayo
Dr Edwin Moalosi
Prof Yunus Moosa
Dr Lyle Murray
Prof Mpiko Ntseke

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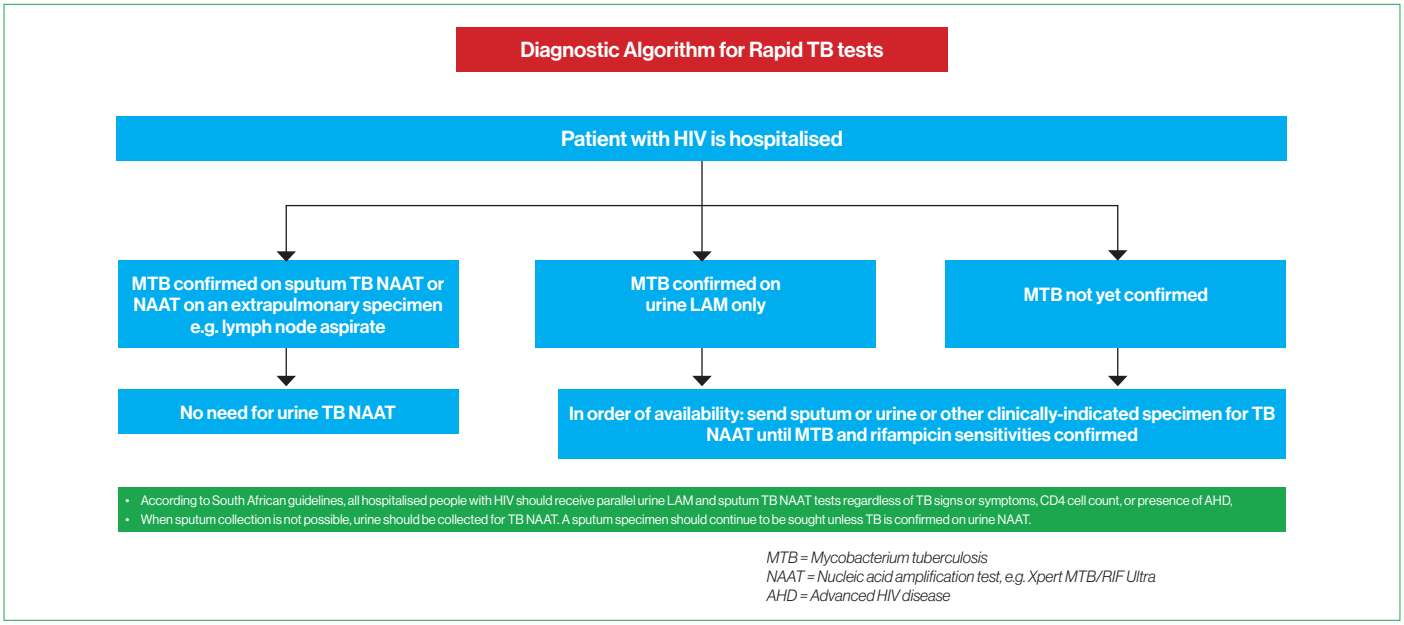
Prof Norbert Ndjeka
Chief Director: TB Control and Management Programme

This document addresses the diagnostic work-up and management strategies for people with HIV (PWH) who require hospital admission with a possible new diagnosis of tuberculosis (TB). TB is the leading cause of hospitalisation and in-hospital mortality in PWH (1). Mortality in this group of patients is unacceptably high and delays in the diagnosis of TB are a major contributor (2-4). PWH admitted to hospital with TB frequently have disseminated disease, often present with non-specific signs and symptoms and have high early mortality. A further delay to TB treatment of a few days once patients are hospitalised may be associated with higher mortality. This needs to be considered in the initial diagnostic work-up and management.

All PWH who require admission to a medical ward should be investigated for TB with a urine lipoarabinomannan (LAM) and TB nucleic acid amplification test (NAAT), such as GeneXpert Ultra on sputum, performed in parallel, regardless of TB symptoms, CD4 cell count, or presence of advanced HIV disease. Urine should be collected for initial TB NAAT testing when a sputum specimen is not possible.

Suggested initial management approach on presentation to hospital when TB has not yet been confirmed:

1. TB symptom screen: Does the patient have any of the following: cough, fever, night sweats or weight loss?
2. Important points from medical history: ART status, current treatment, and prophylaxis.
3. Clinical examination: Evaluate for clinical features suggestive of TB: pallor, lymphadenopathy ≥3cm in diameter, hepatomegaly, splenomegaly, meningism, pleural effusion, pericardial effusion, or ascites.
4. Assess if any danger signs are present: respiratory rate > 30 breaths/min, heart rate >120 beats/min, inability to walk unaided, temperature >39 °C, confusion or decreased level of consciousness.
5. If the patient's HIV status is unknown, an urgent rapid HIV test must be done with appropriate counselling and consent.
6. Urine LAM TB test should be done in all PWH admitted to a hospital medical ward (irrespective of CD4 count or reason for admission to a medical ward) (5).
7. Sputum sample: All PWH admitted to a hospital medical ward should have sputum collected for TB NAAT such as GeneXpert Ultra if a sample can be obtained (6).
8. A urine specimen of 10mL or more should be sent for a TB NAAT if a sputum specimen cannot be collected (7,8).* Efforts to collect sputum for TB NAAT should continue unless TB is confirmed with a urine NAAT, as sputum is the most reliable specimen. *(See figure below)*



** If the urine specimen is not able to be processed within 6 hours, it should be kept on ice or in a fridge. Before running the test, laboratory staff should centrifuge the urine at 3000g for 15 minutes and resuspend the pellet in 0.75ml PBS and 1.5ml Xpert reagent buffer.*

9. Chest X-Ray should be done (6). Evaluate for infiltrates, lymphadenopathy, pleural or pericardial effusion. Even if the chest X-ray is normal, continue with the tests and suggested management below.

10. Provide supportive care such as antipyretics and hydration. If a bacterial pneumonia is clinically diagnosed, a broad-spectrum beta-lactam such as ceftriaxone is the preferred antibiotic.

11. Start on cotrimoxazole prophylaxis if indicated. All persons co-infected with HIV and TB should be started on co-trimoxazole prophylaxis for the prevention of Pneumocystis Jirovecii pneumonia (PJP) – 2 tablets daily. Contraindications to co-trimoxazole are hypersensitivity to co-trimoxazole, trimethoprim or sulphonamides, G6PD deficiency and porphyria. It should be used with caution in persons with folic acid deficiency, severe renal or hepatic impairment, serious haematological disorders and geriatric patients (9).

12. Commence all hospitalised patients on thromboprophylaxis unless it is contraindicated.

13. The following blood tests are suggested:
    - Baseline renal function, full blood count, a serum cryptococcal antigen test (CrAg) if indicated i.e. in PWH with a CD4 count <100 cells/µL. Liver function tests should be done only where an indication exists and not routinely (10).
    - If the patient is on ART, a CD4 count and a HIV viral load test should be done if there are no recent results. If not on ART, do a CD4 count only.

14. Based on clinical findings, send relevant clinical samples to further investigate TB. These are listed in the additional tests on page 6&7.

Ensure that all clinical samples get to the laboratory as soon as possible.

Consider the possibility of more than one diagnosis. It is not unusual for patients to present with multiple opportunistic infections at the same time. Initiate treatment for other diagnosed opportunistic infections which may be life threatening whilst diagnostic work up for TB is in progress, such as cryptococcal meningitis and Pneumocystis jiroveci pneumonia (PJP). PJP is an important initial consideration in patients with advanced HIV disease. Factors that suggest this diagnosis include a compatible Chest X-Ray (bilateral symmetrical "ground glass" infiltrates) and room air oxygen saturation <94%. Empiric PJP therapy should be considered for patients fitting this description. Serum beta-D-glucan and/or sputum PJP PCR can be sent in equivocal cases. A diagnosis of PJP does not exclude dual disease. TB workup should be continued.

Consider empiric TB treatment with standard drug susceptible TB treatment if:

- Compatible presenting symptoms AND radiological features compatible with TB OR
- Clinical features are in keeping with extra pulmonary TB such as large peripheral lymph nodes (≥3cm in diameter), a miliary picture on chest X-ray, an exudative lymphocyte-predominant pleural effusion, a pericardial effusion, or a lymphocyte-predominant picture on cerebrospinal fluid (provided cryptococcal meningitis has been excluded).

Whilst none of these features are specific, TB is the most likely diagnosis in most cases and empiric therapy should be strongly considered. However, it is critical to still pursue a microbiological diagnosis even if empiric TB treatment is initiated; and to follow-up to evaluate clinical response to TB treatment. Conditions such as lymphoma may mimic extrapulmonary TB and should be investigated if there is a poor response to empiric TB treatment.

In patients who present with danger signs the decision to initiate empiric TB treatment may be expedited, however many other conditions can cause a patient to present with danger signs. Therefore, if another diagnosis is more likely based on clinical presentation, for example PJP, it is acceptable to initiate therapy for PJP and review treatment response before initiating empiric TB treatment.

Review results within 12 hours and review TB treatment decision.

PWH admitted to hospital with possible TB

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Rapid initial work-up:
1. Urine LAM
2. Sputum and/or urine for TB NAAT
3. Chest X-ray
4. Bloods: baseline FBC, renal function, LFT if jaundiced. Serum CrAg, CD4 and HIV viral load if indicated
5. Other clinical samples to support TB or alternative diagnoses

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Consider empiric TB treatment with standard drug susceptible TB treatment if:
1. Compatible presenting symptoms AND
2. Radiological features compatible with TB OR
3. Features of extra pulmonary TB

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Review all results within 12 hours and review decision about empiric TB treatment.

PWH: People with HIV; LAM: lipoarabinomannan; NAAT: nucleic acid amplification test; FBC: full blood count; LFT: liver function test; CrAg: cryptococcus antigen test

If the initial TB workup is negative, consider the following additional tests if TB is considered possible, directed by clinical presentation and available resources:

1. If TB NAAT is negative and there is clinical suspicion for TB, send sputum for TB culture and drug susceptibility testing (DST). A positive TB NAAT on a urine specimen should be interpreted as bacteriological confirmation of TB regardless of other negative or absent TB test results (e.g. urine LAM, TB NAAT on sputum). The sensitivity of sputum TB NAAT is lower in people with advanced HIV. Many hospitalised patients with HIV are unable to produce a sputum sample. If available, sputum induction can assist the patient in producing a sputum specimen.

2. If lymphadenopathy > = 3cm in diameter is present, a fine needle aspirate (FNA) should be done, and two specimens taken for: 1) TB NAAT; and 2) TB culture and sensitivity. The two aspirates can be sent in a TB transport medium if available. If a TB transport medium is not available, a sterile tube may be used with a small amount of saline. This will ensure that the specimen remains viable.

3. An abdominal ultrasound should be done to determine if there is abdominal lymphadenopathy, ascites, or micro or macro abscesses in the liver or spleen which support a diagnosis of TB. However, other conditions, like lymphoma, can also cause these features.

4. Blood for TB culture and sensitivity should be collected in a Myco/F lytic blood culture bottle.

5. If a pleural effusion or ascites is present, and fluid can be safely obtained, it should be sent for TB NAAT, as well as TB culture and sensitivity. Although the diagnostic sensitivity of TB NAAT and culture in serous effusions is low, specificity is high, so TB NAAT should still be done. In the case of an exudative pleural effusion, if the suspicion of TB is high and the pleural fluid TB NAAT is negative, consider a pleural biopsy and start empiric TB treatment. In the case of pleural or pericardial fluid, an adenosine deaminase (ADA) of >30 U/L with a lymphocyte preponderance is suggestive of TB or malignancy; while ADA of >30 U/L with a neutrophil preponderance is suggestive of a bacterial infection. Large pleural effusions, for example half of lung volume, are highly likely to be due to TB, but TB can cause effusions of any size. In the case of ascitic fluid, an ADA of >30 U/L is suggestive of TB (NHLS reference ranges indicated).

6. If a patient presents with symptoms and clinical signs of a moderate/large compressive pericardial effusion, (such as raised venous pressure, muffled heart sounds, ECG changes, large cardiac shadow on chest X-ray, etc) in addition to symptoms compatible with TB, once the effusion is confirmed by ultrasound, the patient should have a safe diagnostic and/or therapeutic ultrasound guided pericardiocentesis followed by commencement of TB therapy. This is to: a) confirm the TB diagnosis and drug sensitivities; b) rule out alternative treatable conditions; c) relieve cardiac compression and tamponade; and d) reduce future constrictive pericarditis. If safe ultrasound guided pericardiocentesis cannot be performed, the patient should preferably be transferred to a facility where this can be done, as complications of blind pericardiocentesis are high. Empiric TB treatment initiation should be considered only when clinical suspicion is extremely high, alternatives are considered very unlikely and safe pericardiocentesis cannot be performed because of the location of the effusion (e.g., posterior to the heart). "Bystander" pericardial effusions (i.e., small asymptomatic) that are found incidentally on ultrasound in patients without constitutional symptoms and no evidence of TB elsewhere, should NOT be used as confirmation of a TB diagnosis. Pericardiocentesis of such effusions are associated with high complication rates and carry a very low diagnostic yield for TB diagnosis and are discouraged.

7. In patients with focal back pain (and particularly with lower limb neurological deficits) conduct spinal imaging (plain films ± CT scan or MRI) to evaluate for vertebral osteomyelitis. Symptoms may be insidious and clinical signs are often subtle initially.

8. If symptoms/signs including a dry cough, fever, progressive shortness of breath, respiratory rate >30/min, desaturation and a chest X-ray showing interstitial "ground glass" infiltrates are present, consider PJP. PJP is common in this patient population and an important differential diagnosis to exclude.

9. Viral pneumonia (COVID-19, influenza, VZV) should be a consideration in patients with a dry cough, fever, dyspnoea and desaturation.

10. If the TB workup is negative and the patient continues to deteriorate, especially in instances where empirical TB treatment was started, the following differential diagnoses should be considered:
    - Lymphoma, Kaposi sarcoma, endemic fungal infections (histoplasmosis, emergomyces), or a non-tuberculous mycobacterial infection (NTM). Trucut or excision biopsy should be considered to exclude lymphoma.
    - If thrombocytopenia and/or anaemia is present, consider malaria, lymphoma, immune thrombocytopenia (ITP), thrombotic thrombocytopenic purpura (TTP), haemolytic uremic syndrome (HUS), or endemic mycoses.
    - If there are neurological signs and symptoms which suggest a central nervous system (CNS) lesion, consider TB meningitis, tuberculomas, toxoplasma encephalitis, cryptococcal meningitis or cryptococcomas.
    - To exclude drug-resistant TB in this situation, culture and drug-susceptibility testing should be performed on a sputum or urine specimen (in order of preference) if initial TB NAAT is negative.
    - If gastro-enteritis is present, consider NTM, isospora, giardia, cryptosporidium, helminths, salmonella, shigella or Cytomegalovirus (CMV). Additional microbiological testing on stool and endoscopy may be required.

Monitoring patients after initiating TB treatment

1. Baseline liver function tests (ALT, ALP, total bilirubin) are often done if the patient has risk factors for anti-tuberculous drug induced liver injury, but are not required in all patients. Abnormal LFTs are not a contraindication for initiation of standard anti-TB treatment (10).

2. In patients with a raised baseline ALT or total billirubin who are initiated on TB treatment, repeat ALT and/or bilirubin at least weekly until the ALT and bilirubin have stabilised or improved. Laboratory monitoring is not required in persons with isolated increases in AST, or increased ALP and GGT alone.

3. Review medication list and monitor possible drug interactions with rifampicin. Rifampicin is a potent inducer of the cytochrome P450 enzyme system (notably CYP3A4), which can lead to increased clearance and lower concentrations of many drugs. These are common drug-interactions clinicians need to be aware of:
    - ART: dolutegravir requires 12 hourly dosing
    - Corticosteroid dosing should be increased as rifampicin induces metabolism of corticosteroids (1.5 x planned dose)
    - Warfarin dosing usually needs to be increased, as coadministration with rifampicin will result in a reduction in warfarin exposure and the international normalised ratio (INR). Close monitoring of the INR is needed.
    - Anti-convulsants and many other drugs need dose adjustments (11) and expert consultation is recommended.
    - Rivaroxaban is a novel anti-coagulant. Rivaroxaban is affected by potent CYP3A inhibitors like rifampicin. Co-administration of rivaroxaban and rifampicin will significantly decrease the plasma concentration of rivaroxaban – avoid co-administration.

4. Pyridoxine 25mg per os daily should be given to all adult patients on anti-tuberculosis therapy to prevent peripheral neuropathy. The dose can be increased to 50 – 75mg daily in patients with neuropathy symptoms up to a maximum of 200mg until symptom resolution. Once symptoms have subsided, it can be reduced to 25mg per os daily (11).

This is not an exhaustive list. Clinicians are advised to consult websites such as the mic.uct.ac.za or telephonically at 0800 212 506 or to download the National HIV and TB Health Care Worker Hotline App

Table summarising TB diagnostic tests (12):

Specimen	TB NAAT	TB culture and sensitivity	Other tests	Notes	Performance of diagnostic test
Sputum	First line test for pulmonary TB	Follow-up test if sputum TB NAAT is negative and TB is suspected.		Sensitivity of sputum TB NAAT is lower in people with HIV. A negative test does not rule out pulmonary TB	Sputum MTB/RIF Xpert Ultra – Sensitivity 87.6%; Specificity 92.8%.
Urine by TB NAAT	Performed when sputum specimen is not possible. Efforts to collect sputum for TB NAAT should continue unless TB is confirmed with a urine NAAT.	Follow-up test if sputum specimen is not possible AND initial urine TB NAAT is negative AND TB is still suspected.		A negative test does not rule out TB disease. Can detect pulmonary or extra-pulmonary TB. Provides early rif-resistance detection amongst those in whom a sputum specimen is not possible. In patients with TB bacteraemia, who are at high risk of early death, urine TB NAAT is the single best performing rapid test.	Sensitivity ranges from 45-70% across studies, as good or better than urine LAM. Comparative studies in hospitalised PWH with pulmonary or extra-pulmonary TB show that Urine GeneXpert Ultra detected 52%, Sputum GeneXpert Ultra detected 56%, and Urine LAM detected 41% of people with TB. Using all three tests together enabled rapid TB diagnosis in 85% of patients. Specificity is >95% so a positive test is indicative of definite TB.
Urine			LAM	Performs best in hospital settings and in patients with low CD4 counts. False positive tests occur with disseminated non-tuberculous mycobacterial infections. No information on rifampicin susceptibility.	Sensitivity – 42%. Specificity – 91%
CSF	Should be done in all patients with suspected TB meningitis.	Should be done in all patients with suspected TB meningitis.	Protein, glucose, cell count, cryptococcal antigen, gram stain, bacterial culture (MCS)	CSF adenosine deaminase (ADA) not recommended. Clinicians should aim to collect a total of 2 full tubes of CSF to support TB NAAT and culture tests. As the sensitivity of TB NAAT in CSF is low, a negative test does not exclude TB meningitis. The diagnosis of TB meningitis remains a clinical diagnosis.	CSF MTB/RIF Xpert Ultra – Sensitivity 89.4%; Specificity 91.2%. (relative to CSF TB culture which is an imperfect gold standard)
Serous fluid (pleural, pericardial, ascitic)	TB NAAT should be done on all specimens where TB is suspected (low sensitivity, high specificity)	Should be done on all serous fluid specimens where TB is suspected.	Adenosine deaminase (ADA) > 30 U/l, likely due to TB. Exudate rich in lymphocytes, usually > 300 white cells/mm3 Bacterial MCS	Empiric TB treatment can be commenced if there is a convincing clinical picture. As the sensitivity of TB NAAT in serous fluid is low a pleural or peritoneal biopsy may be necessary.	Pleural Fluid MTB/RIF Xpert Ultra – Sensitivity 75.0%; Specificity 87.0%. (relative to effusion fluid TB culture which is an imperfect gold standard)
Mycobacterial (TB) blood culture	Not available	Should be done in patients with advanced HIV disease (CD4 < 100) with suspected TB.			Predicted probability of positive TB blood culture in inpatients with HIV-associated TB, WHO danger signs, and a CD4 = 76 was 45% in a metanalysis(13)
Lymph node aspirate	Aspirate and TB NAAT should be done on lymph nodes > or = 3cm in diameter.	Send off a sample at the same time for TB culture and sensitivity			MTB/RIF Xpert Ultra – Sensitivity 70.0%; Specificity 100.0%.

Further recommended resources:

World Health Organization Policy Brief: Providing care to people with advanced HIV disease who are seriously ill (14).
World Health Organization Policy Brief: Identifying common opportunistic infections among people with advanced HIV disease (15).

Authors and contributors

Davids Lee-Ann
Schutz Charlotte
Berhanu Ribka
Evans Denise
Dhliwayo P
Loveday Marian
Meintjes Graeme
Moalosi Edwin
Moosa Yunus
Mphothulo Ndiviwe
Murray Lyle
Nel Jeremy
Ntsekhe Mpiko

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15. Identifying common opportunistic infections among people with advanced HIV disease: Policy Brief. Geneva: World Health Organization; Licence: CC BY-NC-SA 3.0 IGO; 2023.

Abbreviations

ADA	Adenosine Deaminase
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
ART	Antiretroviral Therapy
AST	Aspartate Aminotransferase
CMV	Cytomegalovirus
CrAg	Cryptococcal Antigen Test
CSF	Cerebrospinal Fluid
CT	Computed Tomography
CNS	Central Nervous System
DST	Drug Susceptibility Testing
ECG	Electrocardiogram
FBC	Full Blood Count
FNA	Fine Needle Aspirate
G6PD	Glucose-6-Phosphate Dehydrogenase
GGT	Gamma-Glutamyl Transferase
HIV	Human Immunodeficiency Virus
HUS	Hemolytic Uremic Syndrome
INR	International Normalized Ratio
ITP	Immune Thrombocytopenia
LAM	Lipoarabinomannan
LFT	Liver Function Test
MCS	Microscopy, Culture, and Sensitivity
MRI	Magnetic Resonance Imaging
MTB/RIF	Mycobacterium Tuberculosis/Rifampicin
NAAT	Nucleic Acid Amplification Test
NHLS	National Health Laboratory Services
NTM	Non-Tuberculous Mycobacteria
PCR	Polymerase Chain Reaction
PJP	Pneumocystis Jirovecii Pneumonia
PWH	People with HIV
TB	Tuberculosis
TTP	Thrombotic Thrombocytopenic Purpura
VZV	Varicella-Zoster Virus
WHO	World Health Organization

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