

KNOW YOUR RIGHTS:

TUBERCULOSIS PREVENTION, DIAGNOSIS, AND TREATMENT

BY GISA DANG

Edited by Tsira Chakhaia, Brian Citro, Vivian Cox, Mike Frick, Jennifer Furin,
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KNOW YOUR RIGHTS: TUBERCULOSIS PREVENTION, DIAGNOSIS, AND TREATMENT

YOUR HUMAN RIGHTS AND TB

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Why this guide?

This guide is for people with tuberculosis (TB), people at risk for TB, and the people who take care of them. It aims to explain what the global standards for TB care are, including what services you have the right to receive. This guide aims to clarify what your rights are related to TB prevention, testing, treatment, and care. Our goal is for people affected by TB to be able to recognize when they should be receiving a higher level of care, so they can ask for globally recommended standards.

What are globally recommended standards?

The World Health Organization (WHO) is the organization of the United Nations (UN) that specializes in health. Part of the WHO's work is to guide a process that sets standards and guidelines for prevention, diagnosis, and treatment of TB. These standards support policymakers and health authorities to plan and equip their country's health programs to respect, protect, and fulfill everyone's right to health and other related human rights.

What are human rights, and why are they important for people affected by TB?

People with TB and those at risk for TB have human rights. Governments have legal obligations under international, regional, and domestic law to respect, protect, and fulfill these human rights. Human rights are universal: everyone has them. Human rights are also indivisible, interdependent, and interrelated. That means all human rights are equally important, depend on each other, and are closely related to each other. Taking away one right affects your other human rights.

Many human rights are important for people affected by TB. These rights exist in international and regional treaties, as well as the constitutions of countries around the world. They include the Right to Life; Right to Health; Right to Non-discrimination; Right to Liberty; Right to Science; Right to Informed Consent; Right to Information; Right to Privacy; Right to Participation; Freedom from Torture and Cruel, Inhuman, or Degrading Treatment; Freedom of Movement; Freedom from Arbitrary Detention; Freedom of Association; and Freedom of Assembly.

What does Right to Life mean for people affected by TB?

The Right to Life means that the state, that is, your country's government, may not deprive you of your life. The state also has the duty to take steps to protect your life. This means your government should take steps to end diseases and to ensure access to care, for example by taking a human-rights-based approach to eliminating TB.

What does the Right to Health mean for people affected by TB?

The Right to Health includes two important parts. The first part is a country's health care services and health care system. The Right to Health states that health care has to be available. For TB, this means a health care system with functioning facilities for TB prevention, diagnosis, and care; with goods including TB medication and testing equipment and supplies; and with services and programs including adequate budget for health care staff and TB programs. Health care must be accessible: everyone should have access to it and cannot be denied services (which is called non-discrimination). You also should be able to reach and enter facilities that are equipped to handle TB, including, for example, local health care stations, or, if necessary, services may have to come to you. You should be able to afford health care, including your medication. And you must be able to access information about available health care options for TB and knowledge on TB. Health care has to be acceptable; this means that health care has to be appropriate to the local culture, respect ethics, and be sensitive to gender and age of a person with TB. Health care must be of good quality: health interventions for TB should be based on science and should be medically appropriate, and medicines should be of good quality.

This "availability, accessibility, acceptability, and quality" part of the right to health is often called AAAQ. The second part of the Right to Health includes the "underlying determinants" of health. These include several human rights that relate to your health. For example, the rights to food; safe drinking water and adequate sanitation; adequate housing; healthy working conditions; and access to health education. These rights are important for prevention and treatment of TB. For you, that may mean that you should receive nutritional support in addition to medication during your TB treatment, if that would aid your healing. Or that you may need other additional support during or after you have completed your treatment, if TB has significantly changed your ability to live your life and protect your health.

Your government also must provide essential medicines. This is a "core obligation" under the Right to Health. This means that providing essential medicines is one of the most important things a government can and must do to respect, protect, and fulfill the Right to Health. The WHO has a Model List of Essential Medicines, that lists all important TB drugs in section 6.2.4 of the 19th version.

What does the Right to Non-Discrimination mean for people affected by TB?

Your health status should never be used as a reason to treat you, your family, or the person who takes care of you any differently from others. This means that you cannot be fired from your job, refused entry into school, denied housing, or treated in a disrespectful way in a health clinic because you have TB. If you are a member of a vulnerable group, for example a person with HIV, a person who uses illicit drugs, a migrant, or a prisoner, you may not be discriminated against when you try to access TB services.

What does Right to Liberty, Freedom of Movement, and Freedom from Arbitrary Detention mean for people affected by TB?

These rights guarantee that you cannot be imprisoned, detained, or stopped from moving around without legal proceedings. Any detention or arrest has to happen according to the law. This is important for TB when we think about whether treatment should happen in isolation. Isolation for TB treatment can be considered if it is medically necessary to protect others from TB. However, you should always be able to choose the least restrictive form of isolation possible. Basic respiratory isolation, for example, could mean wearing a specific mask until your treatment takes effect and your TB is no longer infectious. You should not be asked to stay in the hospital if wearing a mask is sufficient.

In some rare situations, your government can require you to stay in isolation even if you do not agree (involuntary isolation). This can happen only if your TB is actively infectious, if you refuse to take TB drugs or to follow infection control measures, and if there is a real risk of spreading TB to others. Involuntary isolations should never be a routine requirement and should only be used if all other measures, including extensive counseling, have been tried and failed. Involuntary isolation needs to be based on an existing law or policy, and should hold up to external review. You as the person affected also have a right to appeal the decision to be isolated. You should never be isolated in a nonmedical setting, such as a prison cell. Also, you must be provided TB treatment and basic necessities, including food, water, and the opportunity to communicate with family. Isolation should be as brief as possible, which means only as long as you TB is infectious and presents a real risk to others. Isolation should never be a requirement of receiving access to new TB drugs.

What does Right to Privacy mean for people affected by TB?

Right to Privacy means that your health status, including whether you have TB, and your personal information should not be shared with anyone, unless you allow it or it is necessary to protect the health of others. In most places, TB is a “notifiable condition.” This means that health authorities have to report cases of TB to the national department of health. However, your personal information (like your name) should not be shared. If you have different health care providers, they may need to share information about your health with each other in order to provide you good quality care. If your TB is infectious and people you interact with are at a real risk of contracting TB, you should inform them, encourage them to get tested, and take steps to protect against the spread of TB. For example, you may choose to wear an appropriate mask in a closed family setting. Your health care provider may let people who are in close contact with you know that they need testing, without identifying who the close contact is. If you refuse or are unable to do this, your health care provider may notify these people that your TB is infectious so they can take steps to protect themselves. When there is no risk for others to contract TB, there should be absolute protection of your Right to Privacy.

What does Right to Science mean for people affected by TB?

Right to Science means that every person should be able to benefit from new scientific findings, including new and improved prevention, diagnosis, and treatment methods. Your government should take steps to make new medication, new ways to prevent TB, and new ways of testing for TB available in your country.

Governments also have an obligation to support and advance science. That means, for example, that your government should provide funding for scientific research and support public research institutions. When your government provides funding or other incentives for research to a private company, it should also make sure that the results of that research benefit people with TB in your country and are affordable. The Right to Science is also linked to the right to participation. Communities affected by TB should be included into research processes in a respectful and meaningful manner.

What does Right to Information mean for people affected by TB?

Right to Information means, among other things, that you—and, if you wish, the person involved in your care, like a relative or friend—need to be told about your options for medical treatment. It also means you and your community should be provided accurate information about how TB spreads, how to prevent its spread, and for how long people with TB are infectious. You should also receive counseling and all explanations that you need to consent (agree) to any medical interventions. It also means that you have the right to know the names and dosages of any medication or intervention that your doctor wants you to take; to know how long the treatment will take; and to understand all potential side effects and other ways in which a medication or intervention may affect your health or life. This is called treatment literacy. The Right to Information also means that you should receive a copy of your medical records if you want one.

What does Right to Informed Consent mean for people affected by TB?

The Right to Informed Consent is closely linked to the Right to Information and the Right to Participation. Informed consent means that you must agree to any medical intervention before it happens, and that you must first receive complete information about the risks and benefits of the intervention. Information is the basis for your decision on whether to allow the medical intervention (for example, a specific drug regimen for TB, or whether or not you want to take preventive therapy). This means that you should always have counseling before you make a decision, and that you must be given time to think of questions and receive answers to your questions. Forced treatment for TB is never allowed.

What does Right to Participation mean for people affected by TB?

The Right to Participation means that you as the person with TB should take part in the decisions that affect you. That, of course, includes your medical treatment. However, it also has a broader application. People affected by TB have the right to participate in deciding health policies, from the national level down to the community level. For example, this may mean that health authorities seek input from organizations that represent people with TB when evaluating a TB program, or involve the community in developing a local approach for person-centered care.



Photo Credit: David Harrison for Treatment Action Campaign

What do Freedom of Association and Freedom of Assembly mean for people affected by TB?

The Right to Participation is one reason why Freedom of Association and Assembly also play a role in TB. Freedom of Assembly allows groups of people to come together, for example to discuss input to a community health issue. Freedom of Association allows you and other people affected by TB to form and register organizations (for example, community groups that provide support to people affected by TB) or to advocate for the rights of people with TB.

What is person-centered care?

Person-centered care means that everything to do with TB prevention, diagnosis, and treatment should consider the whole person. This includes respecting each person's human rights and thinking about social and economic factors, not only about the medical information. Your treatment plan should be made to address your specific situation. It should protect your rights, not violate them. TB affects more than one person. That is why we think about family- and community-centered care as well. The people helping to take care of family or community members living with TB need to be informed about prevention, diagnosis, and treatment just like the person with TB does.

What does this mean for families and communities?

Families and communities play important roles in TB prevention, diagnosis, and treatment. That's why community-based organizations (CBOs) and support groups are important. You have the right to Freedom of Association and Freedom of Assembly. This means that you, other patients, and your community have the right to meet to share information. You have the right to form organizations that support people with TB, their caregivers, and their community.

What can I do if my rights are violated?

You have the right to make a complaint. Health authorities should have a channel for you to make a complaint. You also have the right to receive a response. If you do not receive a response, or if you receive a response that does not address your concerns or needs, you may have the right to take them to court. This depends on your country's laws, and you should contact a legal professional or legal aid organizations. There are organizations that specialize in rights violations around the right to health. That includes your rights in access to treatment, for example, and the other rights laid out in Section I, "Your Human Rights and TB."

Many countries have human rights ombudsmen or national human rights institutions. These are independent groups that exist to monitor, protect, and restore human rights and can receive complaints from individuals about human rights violations. You can look up whether your country has a national human rights institution by checking the directory here: <https://nhri.ohchr.org/EN/Pages/default.aspx>. In some situations, it may be faster to reach out to a local patient advocacy organization if you think that your rights have been violated and want to receive information on your options.



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YOUR RIGHTS AND TB PREVENTION

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What is preventive therapy for TB?

You can develop TB infection if you breathe in air from someone who is sick with TB and coughing. Your TB infection may be referred to as latent TB infection or LTBI. TB infection means you have the TB bacteria inside your body, but they are not making you sick. This means you cannot pass the TB germs to others. In many cases, your body is able to keep this TB infection under control and you do not have any symptoms. But in some cases—especially if the immune system is not working properly—TB germs in the body can multiply and make you sick sometime in the future, referred to as active TB disease.

How do I know if I have TB infection?

There are two kinds of tests for TB infection. One is called a tuberculin skin test, or TST. It involves injecting a small amount of harmless protein into your skin (usually in your arm) and asking you to come back a day or two later to see if your skin has reacted, which would mean you have TB infection. The other kind of test is called interferon gamma release assay, or IGRA. An IGRA test looks at a small amount of your blood for signs of TB infection. Having one of these tests may not be necessary for starting preventive therapy if you are at high risk of getting active TB disease. This is because these tests are not perfect. The TST can have a positive result in people who are not infected with TB but have had the BCG vaccine. In some people—especially those who are very young or those whose immune systems are not working well—either the TST or IGRA may have a negative result, even if there is TB infection. Persons who have been exposed to TB in their homes or other places may still benefit from preventive therapy and have the right to discuss this with their health care providers.

What is TB preventive therapy?

Preventive therapy means taking medicines for TB to prevent you from falling sick. Your doctor or nurse may recommend that you take preventive therapy after testing to see if you have TB infection, or after asking about your risk factors. Because the TB infection tests are not very good at telling who will go on to get active TB disease, your doctor or nurse may offer you treatment based only on the risk factors. One risk factor is being in close contact with someone with active TB—all contacts of someone with TB should be screened for TB and, if they have or are likely to have TB infection, should be offered preventive therapy. Another risk factor is having HIV. In fact, the WHO recommends anyone with HIV or children under five years of age who live with someone with TB should be offered preventive therapy (as long as they do not have active disease), even without a TB infection test.

There are several different preventive therapies that work and are safe:

- Six months, nine months, 36 months or lifetime treatment with an anti-TB medicine called isoniazid, taken daily. For people with HIV, this can also be given with cotrimoxazole to prevent other HIV-related conditions;
- Three months of isoniazid plus rifapentine, taken once a week. This is one of the newest options, and many people think it is the easier than other regimens because its duration is shorter and it only has to be taken once a week;
- One month of isoniazid plus rifapentine taken daily. This preventive therapy has only been studied in people with HIV. This is one of the newest options, and many people think it is the easier than other regimens because its duration is short, and people with HIV take daily medicine anyway;
- Three to four months of daily isoniazid plus rifampicin, another anti-TB medicine;
- Four months of daily rifampicin alone.

Please note: if you are taking preventive therapy that includes isoniazid, you should also be given vitamin B6 (also called pyridoxine) to prevent damage to your nerves. If you are taking antiretroviral therapy (ART), your doctor should prescribe with caution preventive therapy that contains rifampicin or rifapentine, since these can interact with common HIV medicines. Rifampicin and rifapentine should not be given to people taking protease inhibitors; they may be safely given to people on efavirenz-, raltegravir-, and dolutegravir-based ART. For more information on TB and HIV drug-drug interactions, please visit: <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/367/overview>.

Can preventive therapy work for multidrug-resistant TB (MDR-TB)?

MDR-TB means that the strain of TB is resistant to isoniazid and rifampicin, so the preventive therapy options mentioned above may not work. The WHO recently released updated guidance recommending that preventive therapy may be considered for persons living with someone with MDR-TB. There are several ongoing studies to assess the best treatment for MDR-TB infection. You should ask if any of these studies are being done in your area. In some situations, treatment of MDR-TB infection with medicines such as levofloxacin or moxifloxacin may be offered to individuals at high risk. Preventive therapy options for persons exposed to fluoroquinolone-resistant MDR-TB are currently being explored in observational studies and clinical trials. Given the excellent safety profile of delamanid, it appears to be the most suitable drug and could be considered in persons in high-risk exposure situations on a person-by-person basis. You should discuss the risks and benefits of receiving this medication with your health care providers.

Who should be able to access TB preventive therapy?

The WHO recommends that all people with HIV, and all children under five years of age who live with or are close to someone with TB, take preventive therapy when they do not have active TB disease. This is because children and people with HIV are at very high risk of developing TB if they are exposed to the bacteria. WHO also recommends that preventive therapy may be offered to people five years and over

who live with someone with TB, if they live in countries with high burdens of TB and do not have active TB. Because TB is transmitted through the air, everyone in close contact with a person with TB, or at other high risk for TB (such as working in a mine where you are exposed to silica dust that causes silicosis or living in a prison without proper ventilation) should have access to TB screening.

What if I'm pregnant?

Women who are pregnant are at higher risk for becoming sick with TB than the general population. This is due to changes in the immune system that occur during pregnancy. For this reason, all pregnant women have a right to be assessed for TB during their pregnancy, including checking for symptoms, sending a sputum sample, and/or having a chest X-ray (with lead shielding of the abdomen to protect the fetus). If as a pregnant women you are found to be infected with TB and active disease has been ruled out, you have a right to be given TB preventive therapy. Some small studies have shown that the use of isoniazid during pregnancy could be associated with a risk of liver toxicity for the pregnant woman and both miscarriage or low birth weight. Others have shown that isoniazid is safe to use in pregnancy. Pregnant women should discuss the risks and benefits of isoniazid-based TB preventive therapy with their health care providers, consider possible alternatives (i.e. delaying therapy until after the birth of the child, initiating rifampicin- or rifapentine-based preventive therapy, or increased monitoring during pregnancy), and make a decision about preventive therapy that is consistent with their goals and values. Whatever decision is made, pregnant women have a right to receive high-quality care for themselves and their babies.



Photo Credit: Delek Hospital

Can I be forced to take preventive therapy?

Preventive therapy should never be mandatory. You should always have the choice of taking it (consent) or not. You may encourage an at-risk loved one to take preventive therapy, but it is their choice to take it or not. You have the right to be fully informed about the potential benefits, risks, and existing knowledge about TB preventive therapy. For children, their parent or legal guardian must provide consent to any procedure or medication, including preventive therapy. In some places, the law does not allow children to consent to treatment and medical decisions by themselves. Laws about consent and ages of consent vary. In many countries this is 18 years old, but in some countries it is younger or older.

What if I have side effects while on preventive therapy?

While reactions to TB preventive therapy are usually minor and rare, some are serious. If you are taking isoniazid, the main side effects of concern are liver damage and nerve damage (which vitamin B6 helps prevent). If you are taking rifampicin or rifapentine, the main concerns are skin and hypersensitivity reactions (a flu-like reaction), and liver damage. If you have a history of liver disease, drink more than seven alcoholic drinks per week, are HIV-positive, are pregnant, or delivered a baby within the past three months, you should ask for a liver function test at the start of therapy to make sure you are not at risk.

If you have stomach pain, nausea, vomiting, loss of appetite, fatigue or weakness, weight loss, pale stools, dark-colored urine, or yellowing of the eyes or skin, contact your health care provider immediately, as you could have liver damage. (Rifampicin and rifapentine can dye your body fluids red, brown, or orange; this is normal unless the urine is dark). If you feel any tingling, burning, or numbness in your hands or feet, contact your health care provider immediately; these can be signs of nerve damage. If your health care provider is not available, immediately stop taking preventive therapy while you wait to talk to them.

I am taking care of a family member with TB. What do I need to know?

TB is infectious, but remember, TB can only be passed through the air when someone sick with still-infectious TB (sometimes called smear-positive TB, though smear-negative TB can also be infectious) coughs, sneezes, sings, or shouts. TB is NOT spread through touch, blood, sperm, or vaginal fluids, or through sharing food, utensils, plates, or cups. TB is generally not infectious after two weeks of good treatment. Most transmission (spread) occurs before someone is on effective therapy. Soon after effective therapy starts, the risk of transmission drops dramatically.

We know the most important way to stop the spread of TB is to quickly diagnose all persons with disease, start them on effective therapy, and support them to successfully complete therapy. If you are in close contact with someone with still-infectious TB, try to stay in well-ventilated areas, preferably with sunlight or a UV light, when you are with the person. You should have access to regular TB screening and pay close attention to any signs of TB in yourself. If you do not have TB symptoms, but think you have been exposed to TB, you should have access to preventive therapy.

Different kinds of masks can help stop the spread of TB. Persons living with TB can wear a surgical paper or cloth mask, as these can stop the TB germs that they cough from being spread to the air. If you are caring for someone with TB but you are not sick, a special type of mask needs to be worn to prevent breathing in the TB germs. This is called an N-95 respirator, and it stops germs from getting in. If you do not have TB and are trying to protect yourself, do not wear a regular surgical mask; this is actually worse than wearing no mask.



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YOUR RIGHTS AND TB DIAGNOSIS

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How do I know if I need to be tested for TB?

If you are coughing for more than two weeks, losing weight, coughing up blood, or having night sweats, you should be tested for TB. If you have HIV, you should also be regularly tested for TB. Sometimes you may first be asked about these symptoms, or offered a chest X-ray. This can give information about whether you need a TB test. X-ray is not a TB test itself because many things that are not TB can look like TB on an X-ray, so more specific TB testing is needed if it seems likely that you have TB from the X-ray.

If you live with or have close contact with someone who finds out they have TB, you should go to the health center to see if you might have TB as well. The health center should ask you about any symptoms you may have and might offer you an X-ray or collect a sputum sample (phlegm or mucus that you cough up) from you to test for TB. Please see the "Your Rights and TB Prevention" section for information on how to protect yourself if you are caring for someone with TB.

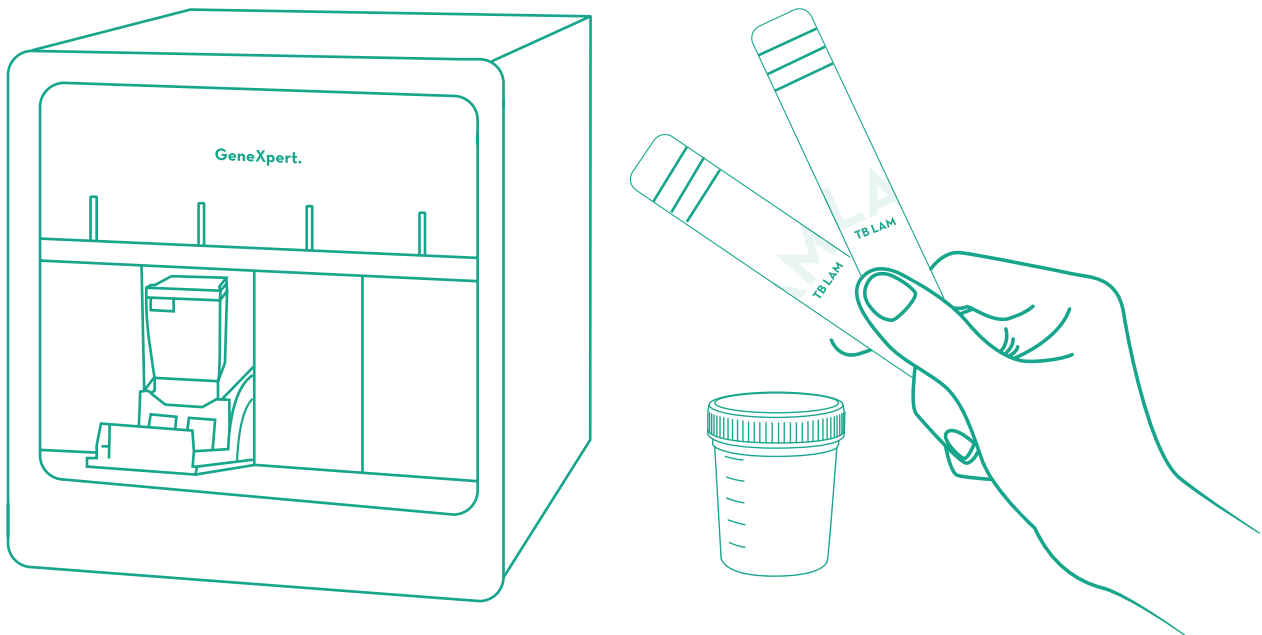
How should TB be diagnosed?

Everybody being tested for TB should have access to GeneXpert MTB/RIF or the new GeneXpert MTB/RIF Ultra as the first test (also sometimes called a CBNAAT test). GeneXpert is faster and more accurate than the common sputum smear microscopy test. This is true for adults and children, and for people with HIV. If GeneXpert does not find TB, but you or your health care provider is worried you have TB, you have the right to additional diagnostic tests, such as a TB culture. The only time GeneXpert should not be the very first TB test is when people are very sick and may have AIDS. Then both the faster urine LAM test and GeneXpert should be used; see below.

Even though GeneXpert should be the first test, many places still use smear microscopy as the first test. If this is the case where you live, you may want to encourage your government to update its policies for diagnosing TB, in accordance with the Right to Science and the Right to Health.

How should children be tested for TB?

Diagnosis can be more challenging in children because they usually have fewer bacteria than adults and can have trouble coughing up sputum. Children should be offered chest X-ray routinely and may require more invasive methods for getting a sample that can be tested on GeneXpert (called gastric aspirate).



What about diagnosing drug-resistant TB?

For TB treatment to work, your TB should be susceptible to the drugs you are being treated with. It is important to find out early if your TB is resistant (not susceptible) to any drugs in your treatment regimen. Diagnosing drug-resistant TB is also called drug susceptibility testing, or DST. GeneXpert can detect resistance to the medicine rifampicin. Another test called a line probe assay can say in a few days if your TB is resistant to other important medicines including isoniazid, the second-line injectables (amikacin, and the no-longer recommended capreomycin and kanamycin — see “Your Rights and TB Treatment”) and fluoroquinolones (levofloxacin, moxifloxacin). Line probe assays should be available. If they are not, liquid culture (which takes a few weeks) can also be used.

What if I am living with HIV?

Diagnosing TB in people with HIV can be more difficult, because people with HIV may have varying levels of TB in their lungs and often have TB outside the lungs (extrapulmonary TB). GeneXpert, especially the new MTB/RIF Ultra cartridge, is much better at detecting TB—including extrapulmonary TB—in people with HIV than smear microscopy.

TB LAM is a newer test that can find TB in urine. The WHO recommends TB LAM for people with advanced HIV (people who are very ill from HIV or have CD4 cell counts of ≤ 100 cells/mm³, if CD4

testing is available). Research also shows the test works well when given to any person with HIV entering a hospital. If the TB LAM test is positive, you should start treatment immediately without waiting for other tests. TB LAM testing can miss cases of TB, so if the TB LAM test is negative for TB, you may still have TB, and it is important to follow with GeneXpert.

What if I am pregnant?

Pregnancy is an opportunity to obtain health care. In some cases, pregnancy may increase your risk of developing TB. If you live in a setting with high rates of TB, you should ask your doctor for a TB test. Because symptom screens do not work as well in pregnant women, you should ask for a GeneXpert or rapid culture test—especially if you have HIV. According to the WHO, chest X-ray does not pose any special risk for your developing baby, as long your clinician follows good practices, like giving you a leaded apron to wear over your abdomen (belly).

Can I be forced to take a test?

TB testing should be done only with your permission (consent). Some professions or immigration procedures require TB tests. However, a positive test should not prevent you from working in your job or living in another country. If your test shows you have TB infection or TB disease, you should get access to treatment.



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Where should I get TB treatment?

Treatment should be given where it's convenient for you, for example, at a primary care doctor or community health center close to where you live or work, or by having a health care worker come to your house if you are comfortable with that, or by taking it at home with regular check-ins with your health care provider. If TB treatment is not convenient where you live, you may want to encourage your government to update its policies for community-based TB care, in accordance with the Right to Science and the Right to Health.

Why is it not generally necessary to stay in a hospital for TB treatment?

You should not have to stay in the hospital for TB or even drug-resistant TB treatment, unless it is absolutely medically necessary. Hospitalization is not required or even preferred for the majority of cases. Hospitals with poor ventilation can, in fact, spread TB. Hospitalization is more expensive. Sometimes hospitals don't have enough space, meaning patients have to wait to start treatment.

When do I need to stay in the hospital?

You should never have to automatically stay in the hospital for the duration of your treatment. If you are very ill, or if you have side effects that need to be very closely monitored, your doctor may recommend hospitalization. Some hospitals are quite good at caring for people with TB and preventing the spread of TB and can provide a supportive environment for cure, especially for people with complicated TB, so there are times when hospitalization will be the best option. You should not have to stay in a hospital as a condition to get access to newer treatment regimens.

What treatment/drugs should I be able to access?

You should have access to the drug regimen that is effective for your form of TB. Regular drug-susceptible TB requires six months of daily treatment. The WHO recommends daily, fixed dose combinations, which combine different drugs (isoniazid, rifampicin, ethambutol, and pyrazinamide for the first two months, followed by isoniazid and rifampicin for four months) into one tablet and make it easier for you to stick with your treatment. TB meningitis (which is TB of the nervous system, like the brain) and TB of the bones and joints require 12 months of treatment.

If your TB is resistant to isoniazid (but susceptible to rifampicin and fluoroquinolones), you should receive six months of daily treatment with rifampicin, ethambutol, pyrazinamide, and levofloxacin. Because these medicines are not available in a combined tablet, your clinician may give you the standard isoniazid, rifampicin, ethambutol, and pyrazinamide combined tablet, plus levofloxacin. You should have a choice as to whether to take the combined tablet (which is easier to swallow but contains isoniazid, a medicine that likely will not work against your TB and has side effects), or loose individual tablets (which require swallowing more tablets, but you will be avoiding an unnecessary medicine).

If your TB is resistant to rifampicin, you should receive treatment with a combination of four to five medications. The medications should be chosen based on their effectiveness, the side effects they cause, and the type of drug resistance your strain of TB shows. You have a right to have TB treatment based on a drug susceptibility test. Although regimens may vary, the WHO strongly recommends three medications: bedaquiline, linezolid and either levofloxacin or moxifloxacin, because they have been associated with better treatment outcomes and a lower rate of death. You should be given these three medications unless your TB has resistance to them, or you have a medical reason why they cannot be used. The WHO also recommends cycloserine (or a similar drug, terizidone) and clofazimine as these drugs have been associated with better treatment outcomes. The WHO no longer recommends the use of two injectable agents, kanamycin and capreomycin. Though the WHO still recommends injectable agent, amikacin (if there are no other treatment options, if there is documented susceptibility to the drug, and if formal hearing assessments can be done at baseline and monthly while on the medication), the latest guidelines emphasize that all-oral regimens are the preferred standard of care.

The duration of therapy recommended is for 18-20 months. Some countries may offer people with rifampicin-resistant TB shorter treatment regimens (9-12 months) containing all-oral medications under carefully monitored conditions. There are some ongoing studies (clinical trials) to evaluate all-oral shorter treatment regimens using combinations of new and repurposed TB medicines, including bedaquiline, delamanid, linezolid, clofazimine, and pretomanid. You should ask if any of these are being conducted in your area.

There is a standardized shorter treatment regimen that is 9–12 months that does not contain all of these recommended drugs and instead contains older drugs including the painful and toxic injectable amikacin. Though they have not been compared in a study head-to-head, evidence indicates the standardized, shorter, injectable-containing regimen does not work as well as longer regimens that contain the medications bedaquiline, linezolid, and the fluoroquinolones.

As mentioned above, kanamycin and capreomycin are no longer recommended for TB treatment; if you are receiving one of these, tell your health care provider you want to receive bedaquiline instead immediately. If you are on a regimen containing any of the injectable medications (amikacin, streptomycin, or the no-longer recommended kanamycin or capreomycin), you should have your hearing tested prior to starting this medication and every month while you are taking it, and if there are any signs of hearing loss or you are having trouble tolerating the injections, you should ask to be switched to bedaquiline immediately.

You should always know the names of your specific medications, how often to take them, how many pills to take, and the most common side effects to watch out for.

What treatment is recommended for children?

Treatment specially made for children with drug-susceptible TB is now available. The new pills, called fixed dose combinations, are already at the right dose for children, so they do not need any crushing or splitting. They dissolve completely in water, and taste better than the adult tablets.

Most children with rifampicin-resistant TB should receive injectable-free regimens. Bedaquiline is recommended in children age 6 years and older and delamanid is recommended in children ages three years and above. There will be more evidence on younger children available soon. Bedaquiline and delamanid may need to be used in younger children with highly resistant forms of TB and you could ask your doctor to give bedaquiline or delamanid to a child "off-label," or your doctor can request bedaquiline under compassionate use (meaning access to a treatment not yet approved in a country or for a certain population) by writing to JanssenMAc@its.jnj.com. A pediatric formulation of delamanid is also available via compassionate use and information on how to access it can be found here: <http://sentinel-project.org/2019/04/10/delamanid-compassionate-use-patient-access-form/>. Linezolid is an excellent option for children of all ages, and some providers have had success using PAS in younger children.

The duration of therapy in children depends on the severity of their disease. Children can take an all-oral shorter (i.e. 9-12 month) regimen if the TB is not very extensive. For children with more severe TB, treatment can usually be completed in 15-18 months.

What if I am pregnant or nursing or might become pregnant?

If you have TB and are pregnant or become pregnant, you may have to make some difficult decisions regarding the best way to take care of yourself and your child(ren). There is not much information on safety of most TB drugs in pregnant or nursing (breastfeeding) women. Your health is important and in fact essential for the health of your child(ren). If you are pregnant or nursing, you should discuss with your clinician the risks and benefits of different options and decide what is best for you. You may not want to use certain drugs, or you may want to discontinue nursing or your pregnancy (abortion). If you are not pregnant, but are on TB treatment and may become pregnant, you should ask your provider about birth control options.

Two kinds of drugs used to treat MDR-TB, ethionamide (or a similar drug, prothionamide) and injectable drugs (amikacin, streptomycin, and no longer recommended capreomycin and kanamycin), are thought to be particularly dangerous to the developing baby (fetus). Amikacin and ethionamide/ prothionamide are part of the shorter regimen, but contraindicated for use during pregnancy. As such, pregnant women with MDR- TB are ineligible for the standardized (injectable-containing) shorter regimen. Instead, global standards recommend that pregnant women with MDR-TB be treated with a longer regimen (made for their particular strain of TB with four or more effective second-line medications). Some progressive national programs, including in South Africa, are using the newer drugs bedaquiline or delamanid in these longer individualized regimens for pregnant women. Based on information so far, both of these drugs are thought to be safe in pregnancy. Your doctor can request these drugs for pregnant women under compassionate use by writing to JanssenMAc@its.jnj.com for bedaquiline and medical@otsuka.de for delamanid.



Photo Credit: KUDUwave™ Portable Audiometers

What about side effects?

Your health care provider must inform you about the medicines you take, what the potential side effects are, and how they will be monitored (checked or tested). If they did not give you that information, you should ask for it. Some side effects are expected, like red urine or mild nausea. But some are severe, like liver damage, depression or psychosis, or loss of hearing or vision. These can be stopped if caught early. Your doctor should check that you are getting better, and that includes checking for side effects:

- Injectable drugs (amikacin and streptomycin, as well as no longer recommended capreomycin and kanamycin) can cause hearing loss. Your hearing should be tested (called audiometry) before you start the medicine and monthly afterward, so you know early on if there is damage. If your tests show hearing loss, or if you notice any signs of hearing loss, ask immediately to stop the injectable and switch to delamanid or bedaquiline. If hearing tests are not available, you have the right to ask for another drug such as bedaquiline or delamanid to replace the injectable;
- Cycloserine and other drugs can cause depression and psychosis. If you feel persistently depressed or like you do not want to live, tell your doctor immediately so you can safely switch medicines;

- Linezolid and other medicines can cause tingling, numbness, burning, or pain in the hands or feet. If you feel this, tell your clinician immediately as they may want to lower the dose or pause use of the drug before permanent nerve damage occurs. Your clinician should check for this at every visit. Linezolid can also affect the nerves in your eyes, so you should have your vision checked before starting treatment and each month while you're on treatment, and you should tell your doctor if you notice any changes in your vision while on this medication.
- Linezolid can also affect the way your body makes blood cells. Although TB itself can do this, people on linezolid may have low red blood cell counts ("anemia") or low levels of the blood cells that cause your blood to clot ("platelets") or that fight infection ("white blood cells"). Before starting and while on linezolid, your doctor should check your blood count each month.
- Many TB drugs can damage the liver. You should have a liver function test before you start treatment, and regularly thereafter, especially if you have any liver issues or have HIV. If you experience nausea, vomiting, itching, or changes in the color of your skin or eyes, you should request that your health care providers check your liver function. You should avoid drinking alcohol while on your TB medicine if you can. However, drinking alcohol should never be a reason for not allowing you to start treatment (the same is true if you use drugs or are on opioid substitution therapy [OST]);
- Bedaquiline, clofazimine, delamanid, and moxifloxacin (and many other non-TB drugs) can cause changes in the heart's electrical activity (called QT prolongation). This could lead to serious problems with the heart's rhythm. If you are taking one of these drugs, you should have a test called an ECG (electrocardiogram) before starting treatment, and at 2, 12, and 24 weeks after you start. If you are taking more than one of these drugs, you should have an ECG monthly;
- If you have vomiting or diarrhea, or are taking any of the following drugs—amikacin, capreomycin, kanamycin, streptomycin, bedaquiline, clofazimine, delamanid, or moxifloxacin—you should also have your levels of potassium checked. Potassium is a mineral in your body, like a salt. If your levels are too low or too high, it can cause problems with the muscles, with the way your heart beats, or with other systems in your body. You should ask your nurse or doctor to check your potassium levels regularly, which they can do by taking some of your blood. If your potassium levels are low, you should receive a supplement of potassium and of magnesium, another mineral (salt) important to help your body function properly. You do not need testing for magnesium; you should automatically receive a magnesium supplement. Ask your nurse or doctor if you are getting magnesium if you are not sure, and if you are not, tell them you want it.

Can I work or attend school during treatment?

Everyone whose TB is smear negative (not infectious) should be allowed to work or go to school. You should not have to wait until after you complete treatment to go back to work or school. You should not lose your job because you have TB. TB is not infectious after just a couple of weeks of good treatment (though you must still finish the full treatment course to make sure it does not come back). You do not have to tell your coworkers or classmates that you are taking TB medication. Your employer or school must keep your medical situation private. If your colleagues or classmates may also need to get tested for TB, this should be done in way that protects your right to privacy and confidentiality.

What is counseling, and why should I ask for it if I don't get it?

Counseling means that you receive support and a lot of information and explanation together with your treatment, to answer questions and help you finish your treatment (adherence). Treatment for TB can be difficult, with many pills and possible side effects. Good counseling will help you understand TB better, support you, and help you stick with your treatment.

What if I am living with HIV?

Many people have both HIV and TB, and getting treatment for both is important. If you are on antiretroviral therapy (ART), make sure your doctor knows which medicines you are taking. A small number of TB and HIV medicines do not work well together, but this can be solved by adjusting doses or by changing your drug regimen. If you are diagnosed with HIV and TB at the same time, your doctor should first start your TB treatment, and only start your ART after a few weeks. This is important to avoid a dangerous reaction called immune reconstitution syndrome. People with CD4 counts <50 cells/mm³ should start ART after 2 weeks; people with CD4 counts ≥ 50 cells/mm³ or people with TB meningitis should start ART after 8–12 weeks.

What is Category II treatment?

You should not be on Category II treatment. Category II is basically regular TB treatment plus an injectable medicine, streptomycin. The old recommendation for people who finished TB treatment but still had TB was to take Category II. In 2015, the WHO issued a "good practice statement" against the use of Category II treatment. The new recommendation is to do drug susceptibility testing to decide which drugs work best for your form of TB. If your doctor tries to give you Category II, you should instead ask for drug susceptibility testing and a treatment regimen based on your results.

If I don't want the treatment my doctor tells me, can I be forced to take it?

No, you cannot be forced. International standards are clear that forcing someone to take TB treatment against their will is ethically wrong. You have the right to accept or refuse all treatment, or a particular treatment. Because TB is infectious (can be passed from person to person), if you refuse treatment entirely, you must take steps to protect other people. This may include staying in respiratory isolation, which means keeping your breath from reaching other people. You can do this either through wearing a mask or through physical isolation in a properly ventilated hospital room or at home. On very rare occasions, your government can make you stay in respiratory isolation as a last resort. This is called involuntary isolation. However, you should never have to do so in a prison cell or similar facility.

Because children often need the approval of a parent or guardian to consent to treatment, it is up to the parent or guardian to accept or deny treatment on their behalf. When a parent or legal guardian refuses to give consent, but the medical treatment is considered necessary to prevent suffering or death, including from TB, government authorities may take steps to override the parents' decision. This can only happen through the appropriate legal mechanisms according to the laws of your country.

I am taking care of a family member with TB. What do I need to know?

You can take care of both yourself and your loved one with TB at the same time. To care for yourself, think about your physical and also mental/emotional health. You should have access to counseling and information on how to best protect yourself from TB (see Section II of this series, "Your Rights and TB Prevention").

If the person you are caring for is still coughing up sputum or hasn't gained weight after a few weeks of treatment, they should have access to a drug susceptibility test to make sure that their medications are right for their TB. You can help look out for any side effects and make sure they are having the right tests for side effects at the right times, as noted above. You can also help them keep their jobs or stay in school if they are being discriminated against. TB treatment can be difficult, so if you or the person you are caring for want to start or join a TB support group, you have the right to do so. Support groups can help fight stigma by educating others in your community about TB, helping them understand that TB is preventable and treatable. Remember that the person you are caring for has a right to privacy, and it should be their decision whether they want people to know they have TB.