Frequently Asked Questions about Pyridoxine (Vitamin B-6)

These are answers to frequently asked questions (FAQ's) regarding the utilization of pyridoxine for persons who are on isoniazid (INH). This information is based upon recommendations from nationally recognized publications and tuberculosis resources that are endorsed by the Centers for Disease Control and Prevention (CDC). Because no guideline can address all possible circumstances, it is important to implement this information based upon the comprehensive assessment of the person and their clinical condition. Physician consultation should be ensured when medically indicated. If you need additional information, assistance in evaluating the person's clinical condition, or this does not answer your questions, please contact the Wisconsin Tuberculosis Program at 608-266-9692.

1. Who should be taking pyridoxine?

For certain patients who are known to have higher potential for neuropathy, pyridoxine therapy should definitely be taken, unless there is an unusual medical contraindication.

The best reference for this is the MMWR of June 9, 2000, "Targeted TB Testing and Treatment of Latent Tuberculosis Infection", specifically, page 26. "Peripheral neuropathy, caused by interference with metabolism of pyridoxine, is associated with isoniazid administration but is uncommon at a dose of 5mg/kg. In persons with conditions in which neuropathy is common (e.g., diabetes, uremia, alcoholism, malnutrition and HIV infection), pyridoxine should be given with isoniazid. Pregnant women and persons with seizure disorders should also take both pyridoxine and isoniazid." [(5.)] Also note answers below related to drug interactions with seizure medications and Antabuse.

2. What if the physician has prescribed pyridoxine for someone and they do not have any of these predisposing conditions?

Pyridoxine can be ordered to *prevent* neuropathy even if the person on INH does not have obvious risk factors, so long as there are no unusual medical conditions or it is not contra-indicated. The nurse's role is then to assess for the effects of both the medication and the pyridoxine when evaluating the person's clinical condition.

3. What should I do if there is no order for pyridoxine, the person does not have risk factors and they are going to proceed with INH alone?

Persons who are started on INH ***without*** pyridoxine should be closely assessed for, and effectively taught to report ***early*** signs of neuropathy to the public health nurse. ***Neuropathy can occur in persons without pre-existing risks.*** Malnutrition, although often unrecognized, may be common in persons for whom INH is ordered. The list of conditions that lead to neuropathy is also far from complete; these are just the most common. Unless medically contraindicated, persons with signs and symptoms of neuropathy should begin pyridoxine therapy promptly.

4. Are there certain persons for whom I should have more vigilance?

Yes. The rate by which a person can develop neuropathy varies among individuals and vigilance for drug interactions is also critical. The rate of metabolism and excretion of medications is genetically determined, but this variance in rates does not significantly alter the effectiveness of INH. It is estimated that about 50% of African Americans and Caucasians are "slow inactivators"[(3.)] (meaning they are slower in metabolizing and excreting the drug.) Therefore, toxic side effects may occur related to the potential for higher blood level accumulation of the drug. The majority of Eskimos and Asians are "rapid inactivators."[(3.)] Therefore, side effects may appear more quickly because these persons will rapidly metabolize and excrete the drug. When signs and symptoms are reported to the physician, the nurse must take precautions in how this is communicated

so that the INH is ***not*** discontinued unless necessary. **If it does become necessary to discontinue INH, another treatment regimen should be implemented so that the person who is started on treatment completes an approved treatment regimen.** The physician who prescribes in a low incidence state, such as Wisconsin, may not be familiar with managing persons on these medications. The nurse will need to promptly make effective recommendations for how these symptoms are likely to be reversed *before* it becomes necessary to stop the treatment.

Drug interactions must be carefully considered. For instance, "...The interaction of INH and phenytoin increases the serum concentration of both drugs. When these drugs are given concomitantly, the serum level of phenytoin should be monitored. No known interactions exist between INH and the antiretroviral medications used for the treatment of HIV infection."[5.] The nurse must comprehensively assess the person's drug regimen, including any herbal preparations they may use and any new drugs they begin taking during their treatment. Many physicians and providers treat a high number of persons in short amounts of time and they may often be unable to give sufficient attention to other conditions the person has, or to all the other drugs they are taking.

5. What if the physician has ordered pyridoxine because the person regularly consumes alcohol but the person has made a strong commitment not to drink or is incarcerated and will not be able to drink during their entire treatment? Do they still need B-6?

Yes. This person should be on pyridoxine for the duration of therapy and treatment for malnutrition may need to go on after TB treatment. The person who regularly consumes alcohol may already have, or is certainly *at risk for*, neuropathy or hepatic damage. **The condition goes on even if the person stops alcohol consumption temporarily.** If the person is on Antabuse, INH increases the disulfiram level. These side effects would need to be evaluated/assessed along with the INH and B6, and the treatment of this person should probably be medically re-evaluated. It is important for the public health nurse to ensure that this re-evaluation occurs, since it is possible that two different physicians may have prescribed these drugs.

6. Do I need a physician's order for vitamin B-6 ?

First determine if B-6 is clinically indicated for the person. The public health nurse may be more familiar with the person's clinical condition and the standard clinical indicators for B-6 than the physician. **Follow your local health department policy, procedure or standard of practice related to how nurses are to handle recommending and/or delivering over-the-counter medications.** Health departments will typically have a procedure/protocol signed by their medical director or a "standing medical order" for guidance related to over-the-counter preparations.

7. What should I do if the client's physician has ordered the INH discontinued after only two weeks of LTBI treatment due to a symptom such as tingling in the hands and feet?

First of all, assess whether or not the patient/client is taking pyridoxine. Working within the policy of your agency, and with the physician and patient, ensure the implementation of pyridoxine therapy and avoid the discontinuation of INH if at all possible. It is important that INH not be discontinued unless that action is absolutely necessary. While not ideal, a temporary interruption of INH while implementing pyridoxine is better than the physician or patient stopping the INH completely. **If it does become necessary to discontinue INH, another treatment regimen should be implemented.** Management of side effects that are not life threatening can often mean the difference between a person completing a full approved course of treatment or stopping the drugs prior to treatment completion, which may result in progression to active disease. Working diligently with the patient/client and the physician, through treatment completion, can be a challenge for the public health nurse. However, it is well worth the effort to enable the person to complete treatment when they are first diagnosed with infection or disease. It has been estimated that the cost of giving

directly observed therapy (DOT) to a person with LTBI is approximately $2000. If the public health department has to provide DOT for a person with active disease, it can cost $25,000 and if the person develops multi-drug resistant TB, the cost for DOT can be $200,000.

8. Are there any other concerns that I should have about people needing pyridoxine or physician evaluations when they are getting INH treatment?

If you are going to make a recommendation to a physician, or you are going to implement a standing order, be certain that the person has been comprehensively assessed. Nurses should always be certain to recognize that:

a.) **Appropriate dose of pyridoxine is 10 to 50 mg/day for adults**. Studies have shown that as little as 6 mg/day may provide protection against neuropathy; children are dosed with separate criteria from adults. (See question 10.)
b.) Pyridoxine does not have a high potential to cause harm in most persons, but there is some risk to certain individuals, such as those with hypersensitivity to pyridoxine, or those on Levodopa, Phenobarbital or Dilantin. Pyridoxine reduces the serum blood levels of these medications.
c.) Assessment of all medical conditions, as well as all potential drug interactions or side effects, is necessary to provide follow-up and patient education. This includes assessment for the effects or interactions of any herbal preparations the person uses.
d.) The nurse must ensure that patients clearly understand that taking B-6 with INH is for a specific protective effect for them, that it is not just an optional vitamin.
e.) When implementing pyridoxine by using standing medical orders, it is important to let the treating physician know that this approach is being used. This is to ensure that, if there are any contraindications for the patient of which the nurse is not aware, the physician has an opportunity to promptly alter this approach.

9. Are there some persons for whom more involved medical or clinical monitoring is indicated? How should these persons be managed in regards to pyridoxine?

The nurse should *always* secure physician involvement for a person with a sensitive medical condition for whom medical involvement is needed, such as the person with a neurological or seizure disorder, the person on Levodopa, Phenobarbital, Dilantin, etc., or for *anyone* who needs specific medical and/or chemical monitoring. The nurse's clinical evaluations will include assessment for any side effects of pyridoxine as well as INH if the patient is on both, along with appropriate reporting to the physician. It is also essential to sustain a commitment to work with the person and the physician to "weather" the non-life threatening side effects with appropriate nursing measures, such as the management of nausea by altering the time of administration, etc.

10. What about children? Should they be on Pyridoxine?

This varies according to several factors; there is no routine recommendation that a child receive pyridoxine. INH is metabolized in the liver and excreted primarily through the kidneys. Hepatotoxic effects, peripheral neuritis or seizures that are caused by lack of pyridoxine are rare in children, so most do not need B-6 supplements. ***However*, children and adolescents whose diet is deficient in meat and milk or in whom there are nutritional deficiencies, including all symptomatic HIV-infected children, should receive pyridoxine supplementation. Nutritional deficiencies may not be easily detected in some circumstances. Breast-fed infants and their mothers, pregnant adolescents and pregnant women on INH should receive pyridoxine.**[4.] Any child or adolescent with TB disease or infection needs evaluation on a case-by-case basis, especially in regards to medication interactions with tuberculosis drugs. Consult pharmacological and medical resources for dosage requirements when the person is not an adult because the dose varies according to age, sex

and clinical condition. The care of children or of pregnant or breast-feeding women and teens must be managed on a case-by-case basis by experts in these fields. A good pediatric reference is the most recently published Red Book, Report of the Committee on Infectious Diseases by the American Academy of Pediatrics. This is an annual report that should be consulted on a regular basis by those who are caring for infants, children or adolescents with tuberculosis.

11. Does it matter whether the person is on INH for active TB disease or for LTBI?

No. Regardless of the diagnosis, the INH will have the same impact upon the person.

12. What about the person who has no money? Can we purchase pyridoxine with the incentive/enabler funds we receive through the Wisconsin ALA (American Lung Association) program?

No. It is not permitted for these funds to be used to purchase medications. However, pyridoxine is an inexpensive drug and many local health departments have made a determination that they will fund the pyridoxine through their health department for persons who do not have insurance to cover the cost. If the person is eligible for the Medicaid Tuberculosis-Related Benefit, pyridoxine is covered. It is also covered by the regular Medicaid (T-19) benefit as long as the manufacturer has signed a rebate agreement. Pharmacies accustomed to billing the regular Medicaid program may be able to help with this issue. If there is a financial barrier for a person who should be on pyridoxine that cannot be overcome at the local level, the health department should call the WI TB Program to discuss the issue.

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Resources

1. Core Curriculum on Tuberculosis, What the Clinician Should Know, Fourth Edition, 2000, Centers for Disease Control and Prevention

2. Diagnostic Standards and Classification of Tuberculosis in Adults and Children. *Am. J. Respir. Crit. Care Med. 2000;161:1376-1395*

3. Physician's Desk Reference (PDR), Edition 56, 2002

4. Red Book 2000, 25th Edition, Report of the Committee on Infectious Diseases of the American Academy of Pediatrics

5. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection. Morbidity and Mortality Weekly Report (MMWR) June 9, 2000, Vol. 49, No. RR-6

6. Tuberculosis Nursing: A Comprehensive Guide to Patient Care. National Tuberculosis Controllers Association. 1997