
"Partnering to promote, protect and preserve health in our community."

HEALTH ALERT NETWORK HEALTH DISTRICT 4

INH SHORTAGE ADVISORY FOR HEALTH CARE PROVIDERS

January 28, 2013

Idaho Recommendations for Prevention and Treatment of Tuberculosis During Isoniazid Shortage

U.S. isoniazid (INH) production has been interrupted, and stocks are dwindling. The Idaho Division of Public Health's tuberculosis program is not able to order additional INH at this time. In addition to a critical shortage of 300 mg tablets, the stocks of 100 mg tablets in some localities are reportedly being depleted. An initial forecast date for restoring INH production has been extended from late January 2013 to as late as March 2013; however, the forecasts are unstable and vary by company. One of three pharmaceutical companies supplying INH, VersaPharm Incorporated, Marietta, Georgia, has notified public health officials that it is cancelling all INH backorders and not accepting new orders.

Clinical and Public Health Recommendations

While INH is in shortage, clinicians should coordinate TB and LTBI treatment plans with their local district public health tuberculosis program staff, who have set priorities for allocating INH stock locally. These priorities are set according to the immediate medical needs of individual patients and for general TB control:

- 1) treating patients who have TB disease,
- 2) treating LTBI patients who are diagnosed during contact tracing of contagious TB (i.e., contact investigations), and
- 3) treating LTBI patients who face the greatest likelihood of TB disease or the hazard of severe illness.

Initiation of treatment for LTBI can be postponed when the likelihood or hazard of TB disease is low, but a process should be developed for recalling patients when INH becomes available.

The abrupt onset of the INH shortage means that treatment for some TB patients could be disrupted in mid-course. Decisions for continuing treatment in these situations should be made on a case-by-case basis in consultation with a TB expert, and coordinated with your local public health district tuberculosis program staff.

Regimens without INH for treating TB disease are less well studied than those with INH. CDC, the American Thoracic Society, and the Infectious Diseases Society of America have recommended a regimen of rifampin, pyrazinamide, and ethambutol for 6 months, with consideration of a fluoroquinolone, such as moxifloxacin or levofloxacin, for more extensive disease, when the infecting *M. tuberculosis* isolate is INH-resistant or the patient is intolerant of INH. Directly observed therapy should be used for reducing the potential for acquired rifampin resistance.

An alternative treatment regimen for LTBI, when the infecting *M. tuberculosis* is believed to be INH resistant, or when the patient cannot tolerate INH, is rifampin administered for 4 months, either self-administered or directly observed. This regimen has been adopted for routine use by some U.S. TB program directors. Rifampin treatment for LTBI is much more expensive than INH, and all rifampin orders to the Division of Public Health's tuberculosis program for treatment of LTBI must be pre-approved until further notice.

CDC is working with the Food and Drug Administration (FDA), the National Tuberculosis Controllers Association, and the two pharmaceutical companies currently planning to supply INH (Teva Pharmaceuticals USA, Sellersville, Pennsylvania; and Sandoz Inc., Princeton, New Jersey) to determine current INH stocks, jurisdictions with urgent needs, and options for restoring supplies as soon as can be safely done. CDC will monitor notifications from public health officials of INH shortages and stocks, and will provide updates as they are available on the website for the Division of Tuberculosis Elimination at <http://www.cdc.gov/tb/>.

If you have specific questions about patient management or ordering of rifampin, you may contact Dr. Christine Hahn or Ms. Ellen Zager Hill in the Division of Public Health's tuberculosis program, at (208) 334-5939.

#####

INH SHORTAGE J