ADVISORY NOTICE Re Current Shortage of Tuberculin PPD RT 23 SSI (2TU)

For the attention of:
Public Health Physicians, Respiratory Physicians, ID Physicians, Consultant Microbiologists, Occupational Health Physicians, Infection Prevention & Control nurses and Hospital Pharmacy Staff

Current shortage of Tuberculin Skin Tests Antigens: Recommendations for Patient Care and Public Health Practice

Tuberculin PPD RT 23 SSI (2TU), a ready-to-use solution for performing the Tuberculin skin test (Mantoux test), is in short supply nationwide until at least the end of March 2015. It is the only licensed purified-protein derivative (PPD) tuberculin product for use in Ireland and the Staten Serum Institute (SSI) in Denmark is the only licensed manufacturer of 2TU (and BCG vaccine) in the European Union. Guidance on the preparation and administration of Tuberculin PPD is available at http://www.hse.ie/eng/health/immunisation/hcpinfo/Other%20Vaccines/bcgTB/guidebcg.pdf

Two types of immunological methods are used for the detection of Latent TB infection (LTBI): (i) tuberculin skin tests (TSTs) and (ii) interferon-γ release assay (IGRA) blood tests. The indications for using these tests are the same for the two methods, although one or other is preferred for certain populations (e.g. TST is preferred for children aged < 5 years). This will influence setting priorities when one of the methods is unavailable. Both tests are the only means of detecting LTBI and they contribute to diagnosing active TB disease. Most cases of TB disease in Ireland are diagnosed with a set of findings e.g. chest X-ray/CT of thorax, mycobacterial cultures and also results from either a TST and/or an IGRA test. When TB disease is strongly suspected, specific treatment should be started regardless of results from a TST or an IGRA blood test.

Recommendations

It is recommended that TST (Mantoux test) using Tuberculin PPD RT 23 SSI (2TU) is prioritised for use in the following situations/groups, following clinical risk assessment:

1. TB contact investigations as deemed necessary by Public Health physicians
2. Children aged < 5 years
3. Children aged < 16 years who will be commencing treatment with Biologics
4. Persons with HIV whose CD4 counts are less than 200 cells /mm³ should always have a TST performed concordantly with an IGRA test. If either test is positive, further clinical assessment is needed to exclude active TB and consideration of prophylaxis for latent TB infection if appropriate.
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Ensuring Efficient PPD Use

It is recommended that hospitals coordinate clinics for undertaking TSTs in order to ensure efficient use of Tuberculin PPD i.e. one to two clinics a week where in-patients can have TSTs performed to ensure efficient use of currently limited stocks. It is recommended that hospitals assign this coordination duty to a designated person e.g. hospital pharmacist who will be more familiar with stock demands and requirements. Public Health clinics should similarly ensure efficient Tuberculin PPD use.

IGRA alone may be used for the following groups:

1. Persons commencing immunomodulator medications for chronic disease e.g. rheumatoid arthritis, ulcerative colitis etc.
2. New healthcare workers who are commencing employment if they have recently arrived from a country with a high incidence of TB (≥40 cases TB/100,000 per annum)
3. Persons with HIV whose CD4 counts are between 200-500 cells /mm$^3$ may have an IGRA alone or an IGRA with concurrent TST performed. If either test is positive, further clinical assessment is needed to exclude active TB disease and consideration of prophylaxis for latent TB infection if appropriate.
4. All other immunosuppressed persons, including those on:
   a. prolonged steroid treatment,
   b. TNF alpha antagonist treatment and
   c. drugs used to prevent rejection of transplanted organs

   can be offered IGRA alone or IGRA with concurrent TST.

NOTE: It is strongly recommended that IGRA results be reported with both quantitative and qualitative parameters in order to fully augment the clinical risk assessment. Laboratories should avoid reporting only ‘positive, indeterminate or negative’ results but should include IGRA levels. IGRA levels that are close to cut off values may better inform an individual clinical risk assessment.