Solano County
T-SPOT.TB Experience

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Where is Solano County?
Why implement an IGRA?

- Mistrust of TST results in some populations
- Only one visit required
- TST readings very subjective
- Poor function of TST in the high risk groups including immunosuppressed (Sensitivity)
- BCG vaccination affects TST results, particularly in children (Specificity)
T-SPOT.TB in Solano County

Why I chose to implement T-SPOT

- Many foreign born residents with BCG vaccination
- Two PH clinics that serve patients at higher risk of TB
- Two PH HIV clinics
- Two state prisons
Subjects in ATS/CDC Risk Groups

N= 1403: Largest group in clinical trial.

- Number of positive T-SPOT.\textit{TB} test results relative to TST results in populations with ATS/CDC risk factors including:
  - HIV-infected (328)
  - Children (93)
  - DM (108)
  - Congregate settings (613)

Findings:
- There was no association between T-SPOT.\textit{TB} test results and immunocompromised status.
  - A negative TST was associated with being immunocompromised

- T-SPOT.\textit{TB} test was not impacted by age.
  - Although FDA recommended more studies in children
Sensitivity

Several studies have demonstrated that T-Spot is a very sensitive test (>90%)

WHY?

- PBMCs separated from the whole blood are washed and counted to ensure that a standardized number of cells are added to the assay
T-Spot in HIV infected

T-Spot results do not seem to be affected by CD4 levels

Leidl ERJ July, 2009
Solano Experience

- Implementation of test into HIV clinics
  - Recent: Still collecting data
  - More positives
  - More than one tube of blood is sometimes necessary

- In the future: DM screening, Rheumatologic screening.
Sensitivity vs. Specificity

- Has high sensitivity of the test come at the cost of low specificity.

- I don’t think so...

- Specificity is determined using low risk groups
Specificity

- In a recent large study in a truly low risk population (Recent Navy boot camp graduates) n=326

- Specificity = 98.9% (95%CI 96.9-99.8)
69 percent of children with BCG vaccination and pos TST (n=104) had neg T-Spot

Percentage of negative T-Spot decreased with increasing age
Is it cost effective?

- **Savings:**
  - Decreased LTBI treatment
  - Decreased progression of LTBI to Active TB with improved adherence to treatment
  - One visit for testing

- **Costs:**
  - More expensive per test than TST
  - Lab implementation
    - Alternatively specimens can be sent to Oxford Diagnostics Lab
Conclusion

- T-SPOT.TB has been an excellent test for Solano County
- Benefits in high risk patient groups
  - Longitudinal studies needed to determine predictive value of IGRAs
- Significant reductions in LTBI diagnoses and treatment for individual with BCG vaccination
- Cost savings
  - Still need be better quantified with Cost Effectiveness Analyses
Questions