Pharmacist Led Case Management for Tuberculosis Infection Treatment: An Alternative Model for the Provision of Directly Observed Therapy for 3HP

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The Problem
- A barrier to implementation of treatment for latent tuberculosis infection (LTBI) in non public health setting is providing case management for adherence and monitoring of toxicity that is standard of care in public health TB programs.
- Non-adherence to therapy for LTBI is common due to the asymptomatic nature of the infection, length of therapy, psychosocial and medical comorbidities of populations at high risk for LTBI infection, and the side effects of the medications.

Project Goal(s)
- Implement and track case management for patients initiating therapy for LTBI who are at high risk for TB activation or at high risk for poor adherence to LTBI therapy provided by a clinical pharmacist in a primary HIV/ID specialty care clinic.
- Quantify the completion rate of LTBI therapy in patients managed by a pharmacist from 5/2013 to 12/2014.
- Compare the treatment completion outcomes for patients that were provided case management by the clinical pharmacist to those managed by public health.

Project Plan
- From 5/2013 to 12/2014, patients were referred to a weekly Veterans Affairs Medical Center (VAMC)-based pharmacist-managed TB clinic once they were initiated on LTBI therapy.
- The regimens prescribed to the patients include the following:
  - Isoniazid (INH) for 6 -9 months of daily therapy or Rifampin (RIF) for 4 months of daily therapy by self-administered therapy (SAT), or
  - Isoniazid/Rifapentine (3HP) weekly for 12 weeks by directly observed therapy (DOT)
- Patients were selected for case management based on their comorbidity, higher risk for non-adherence or toxicity, and increased risk for TB reactivation.
- The clinical pharmacist educated patients about their LTBI medication(s), provided DOT for patients on 3HP, and performed at least a monthly assessment of treatment related adverse effects and adherence.
- The clinical pharmacist also ordered laboratory testing to monitor medication toxicity, facilitated medication refills, and could prescribe and change doses of medication under the supervision of an infectious disease physician.
- The clinical pharmacist referred patients to an infectious diseases attending for evaluation of medication toxicity or need for change in drug regimen.
- Treatment completion rates were calculated for each treatment group at the end of the study.

Results / Progress to Date
- Case management by the pharmacist resulted in high completion rates in all three different LTBI treatment regimens.
- 22 out of 27 patients who completed LTBI treatment had a high-risk comorbidity.
- The most common high-risk comorbidity was substance abuse.
- 5 out of 7 patients with substance abuse received and completed 3HP.

Lessons Learned & Next Steps

Conclusions:
- Clinical pharmacist led case management for complicated LTBI treatment is an effective strategy to achieve excellent treatment outcomes that are comparable to those achieved in public health settings.
- 3HP by directly observed therapy is feasible and a good option for many high-risk patients.

Next steps:
- Program rollout to the San Francisco VA Downtown Clinic, a comprehensive homeless center, with an emphasis on making 3HP available as a treatment option.
- Provide case management and consultation services to primary care providers in rural communities via the Specialty Care Access Network Extension for Community Healthcare Outcomes (SCAN-ECHO).