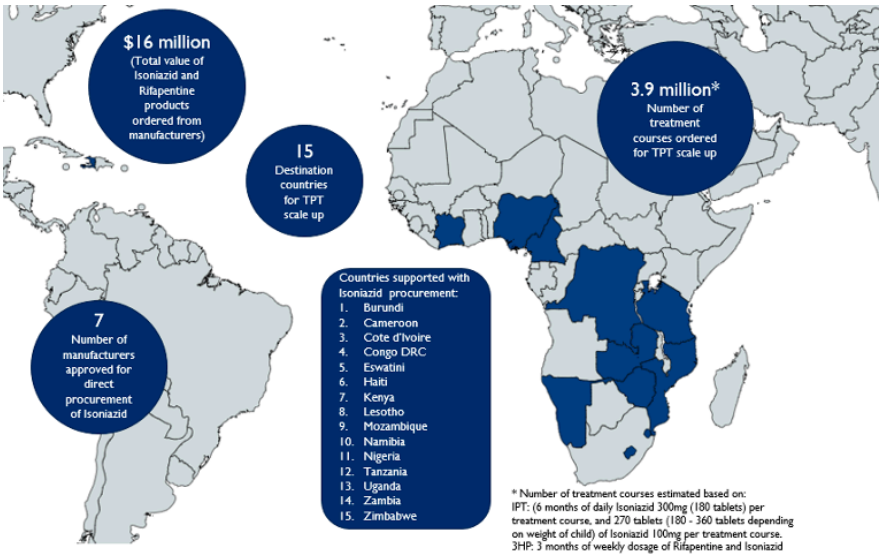
USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

SUPPORTING THE SCALE UP OF TUBERCULOSIS PREVENTIVE TREATMENT (TPT) IN PEPFAR-SUPPORTED COUNTRIES

New treatment regimens to reduce the pill burden on TB/HIV patients

Globally, tuberculosis (TB) is the leading cause of death among people living with HIV (PLHIV). According to the World Health Organization's 2020 Global Tuberculosis Report, 815,000 PLHIV developed active TB, and 208,000 PLHIV died from TB in 2019. As the world fights the COVID-19 pandemic through social distancing and lock downs, reports from STOP TB Partnership (STOP TB) indicate a significant reduction of TB case notification that can potentially reverse progress towards TB treatment and prevention. STOP TB estimates that three months lock down and extended 10-month return to normality may cause an extra 6.3 million cases and an additional 1.4 million TB deaths between 2020 and 2025.



Key data regarding GHSC-PSM's support of TPT. *Source: GHSC-PSM*

Isoniazid preventive therapy (IPT). A medicine called isoniazid is taken daily for 6 months (6H), 9 months (9H) or up to 36 months, or as a fixed-dose combination with cotrimoxazole (antibiotic). Vitamin B6 is also given as a supplement to avoid deficiency related to treatment.

To reduce the risk from latent to active TB, WHO recommends Tuberculosis Preventive Treatment (TPT) for people diagnosed with HIV/AIDS, with the most widespread regimen for latent TB infection currently being isoniazid preventive therapy (IPT), as well as a new shorter regimen being called 3HP (a weekly dose of rifapentine and isoniazid for 3 months), which significantly reduces the duration of treatment as well as the pill burden for patients over the course of therapy. The CDC Division of Global HIV and TB estimates that TPT can reduce deaths linked to TB among HIV-positive people by up to 80 percent, when taken with antiretroviral (ARV) treatment.

TPT SCALE UP ACROSS PEPFAR COUNTRIES

Considering the life sparing benefits of TPT in PLHIV, the President's Emergency Plan for AIDS Relief (PEPFAR) made a commitment to significantly scale up TPT in 2019 for all PLHIV – including pregnant women and children – making TPT an integral and routine part of the HIV/AIDS clinical care package.

To meet the increased demand for IPT, in early 2019 the USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project began working closely with USAID and the USAID Global Health Supply Chain-Quality Assurance Program (GHSC-QA) to identify quality assured isoniazid and Q-TIB manufacturers. By June 2019, six manufacturers for TPT commodities were identified and approved for procurement by USAID to ensure adequate product availability during scale up.

As a result of the early groundwork collaboratively achieved by GHSC-PSM and USAID, including the implementation of bulk ordering strategy by consolidating demand from different USAID country programs, GHSC-PSM has reduced the average lead time (from when the order is placed to when it is available from the supplier) from 29.5 to 17 weeks. This reduction in lead time and proactive management of individual orders has greatly improved the project's ability to meet each country's requested delivery date.

A SHORTER TPT REGIMEN: 3HP

A key challenge with standard IPT is the burden on patients having to take daily pills for 6 or more months of isoniazid and vitamin B6 in addition to the other medicines they take to treat HIV/AIDS and other conditions. Consequently, some patients do not complete their TPT.

3HP. A weekly dose of rifapentine and isoniazid for 3 months. Vitamin B6 is also given as a supplement to avoid deficiency related to treatment.

In 2018, WHO added 3HP as a recommended regimen for TPT. This new shorter regimen significantly reduces the duration and pill burden over the course of treatment, therefore increasing the likelihood that patients will take and complete the full treatment cycle. However, the price of $45 per treatment quoted by suppliers at the time was significantly more than the $15 benchmark that most large donors and procurers were willing to accept to transition to the new regimen. With global price negotiations ongoing through 2019, IPT remained the main regimen of choice for PEPFAR-funded countries.

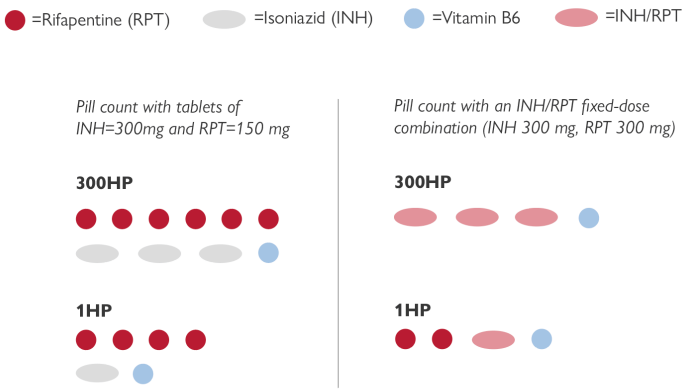
Between November 2019 and January 2020, Unitaid and partners successfully negotiated a lower cost of approximately $15 for a three-month course of 3HP with 2 suppliers – a more than 60 percent discount – for public health program in 136 eligible countries.

Following results of a Unitaid-funded study which demonstrated safety of 3HP when co-administered with DTG, in January 2020, PEPFAR included new guidance in their Country Operational Plan 2020 guidance stating that, "If and when there is sufficient production, 3HP will be the preferred PEPFAR regimen for TPT for adults and adolescents." To further support PEPFAR's guidance and secure supply, GHSC-PSM is working with USAID country programs to support supply planning efforts to include 3HP commodities when included in the national guidelines and aggregating quarterly supply plans from 11 PEPFAR-supported countries, to provide manufacturers reliable data on demand for 3HP and other TPT commodities. In the meantime, due to constrained supply of rifapentine and rifapentine/isoniazid, GHSC-PSM is working with USAID and the ARV Procurement Working Group (APWG) – of which PEPFAR is a part of – and manufacturers to validate monthly forecasts and prioritize orders and deliveries. For the longer term, a one-month regimen known as 1HP will likely become the preferred TPT, further reducing the pill burden on patients.

ILLUSTRATION:

Per-Dose Pill Count of 3HP and 1HP by Different Formulations of Rifapentine and Isoniazid

3HP = 900 mg isoniazid (INH) with 900 mg rifapentine (RPT), plus vitamin B6
1HP= 300 mg of INH with 600 mg of RPT, plus vitamin B6



Pill burden comparison. *Source: Treatment Action Group*