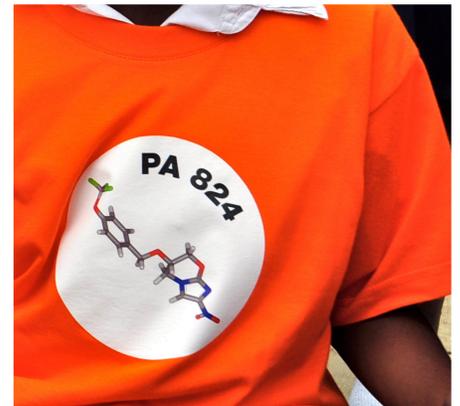




TRANSFORMING TB TREATMENT

New Weapons to Impact the Pandemic



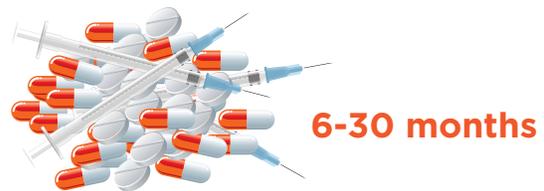
Today's TB drugs are far too lengthy, complex, and burdensome—simply put, inadequate—to be effective in the fight against the pandemic. Drug-sensitive TB requires a minimum of 6 months of treatment with multiple drugs, while treatment of drug-resistant TB can take 2 years or more and require 12,000 pills and almost 200 injections. Difficulties in adherence are augmented by the administrative challenge of dispensing such treatments, which only further exacerbates the pandemic.

The good news is that a decade-long effort to invest in improved TB treatments means that the global pipeline of TB drugs is more promising than ever and poised to deliver. What's more, efforts on the part of a product development partnership to coordinate research mean that transformational treatments—in the form of multi-drug regimens—are in late stages of testing.

The first new drugs to supplement current TB treatments are on the precipice of introduction. Two new drugs, bedaquiline (Janssen) and delamanid (Otsuka) have been or are projected to be approved to treat MDR-TB on top of the current background regimen. This is a first step in improving TB treatment.

However, the true transformation of TB treatment will come by delivering new regimens that are shorter, simpler, and safer, and because they are novel, can treat both drug-sensitive and drug-resistant TB. The TB drug combinations currently under development show promise to drastically reduce the length, cost, and complexity of treating various forms of TB, enabling the necessary scale-up of treatment to defeat the pandemic.

current treatment



6-30 months

treatment in development



2-4 months

ultimate goal



7-10 days

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A NUMBER OF LATE-STAGE CLINICAL TRIALS, IF SUCCESSFUL, ARE POISED TO DELIVER VALUABLE NEW TOOLS TO FIGHT TB AROUND THE WORLD.

MAJOR BREAKTHROUGHS ARE ON THE HORIZON

A number of late-stage clinical trials, if successful, are poised to deliver valuable new tools to fight TB around the world. The first steps in improving treatment have been taken with the approval of bedaquiline and development of delamanid. New innovations soon to come include:

MOXIFLOXACIN

A reformulated drug which, when substituted in the current TB regimen, may reduce treatment of TB by 33%, from 6 months to 4 months, saving countries and patients time and money. The clinical trial to test moxifloxacin is complete, and if successful, approval is estimated in 2015.

PaMZ

This TB regimen includes multiple new drugs. PaMZ (PA-824 + moxifloxacin + pyrazinamide) has the potential to cure both TB and some forms of MDR-TB, drastically improving treatment. This is particularly true for MDR-TB, where PaMZ shows promise to reduce treatment from 2 years to 3-4 months and cost just a fraction of the current MDR-TB treatment. Currently undergoing advanced Phase II clinical trials, PaMZ could enter registration trials in 2014.

ADDITIONAL NOVEL REGIMENS

Efforts are ongoing to continuously examine the new drug candidates in the global pipeline to identify the most promising combinations for clinical development. Through this preclinical identification program, novel regimens have already been identified with the potential to reduce TB treatment to less than 2 months.

APPROPRIATE TB DRUGS FOR CHILDREN

Today, there are no pediatric TB drugs in the proper doses, resulting in mistreatment and the growth of more difficult to treat drug-resistant TB in children. New efforts are emerging to reformulate the current TB treatment. These efforts will set the stage for accelerating pediatric development of new drug candidates currently undergoing development for adults.

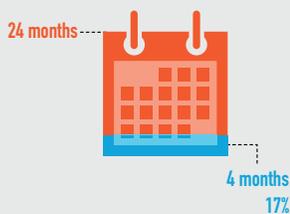
HOW MUCH DOES INNOVATION COST?

TB will cost the world \$3 billion over the next decade, so investments in reducing the global TB burden are unequivocally sound. However, developing new tools are not cheap. A registration Phase 3 clinical trial can cost \$70 million. Earlier-stage trials routinely cost \$2 - \$5 million. Often, organizations like TB Alliance leverage contributions from private partners to increase the impact of donor funds. It is important to remember the substantial global economic impact of TB, and with increasing rates of drug resistance, the cost of inaction rises daily.

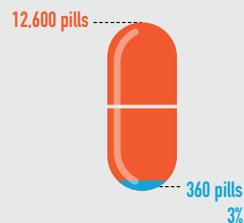


■ Current MDR-TB Regimen
■ Proposed PaMZ Regimen

LENGTH OF TREATMENT



NUMBER OF PILLS



NUMBER OF INJECTIONS



NUMBER OF SACHETS

(powdered medicine doses)

