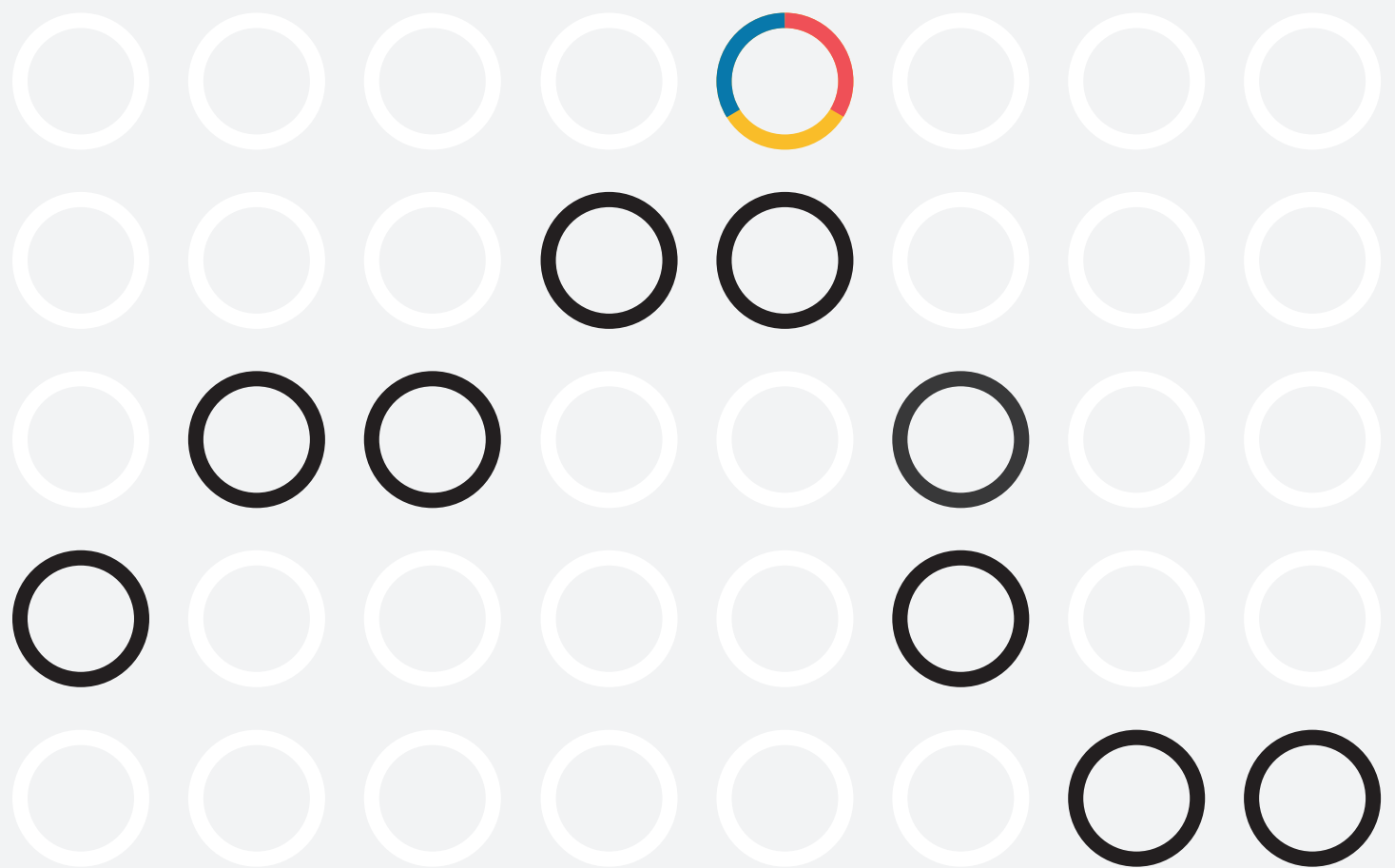


AT THE TIPPING POINT



**U.S. Leadership
to End **AIDS**,
Tuberculosis
and **Malaria****



FRIENDS
OF THE GLOBAL FIGHT
AGAINST AIDS, TUBERCULOSIS AND MALARIA

We need U.S. leadership to end the biggest epidemics

American leadership against the deadliest infectious diseases of our time has saved millions of lives, dramatically reducing the devastation of HIV/AIDS, tuberculosis (TB) and malaria.

Now the strategic imperative – serving U.S. economic, security, humanitarian and diplomatic goals – is to capitalize on our investments and concentrate directly on what it will take to end these epidemics for good.

The AIDS, TB and malaria epidemics are at a tipping point. Thanks to global efforts over the past 15 years, incidence and mortality have fallen dramatically. Nonetheless, drug resistance is a deadly and growing concern for each of these diseases, and new data remind us the threat of epidemic resurgence is real.

This brings American policy to a tipping point, too. We have a choice: to mobilize partners to accelerate the end of epidemics, or stall and permit resurgence and drug resistance to overpower success to date. For all of our progress, governments, global partnerships, and businesses are currently underinvesting to address epidemics. Until we intensify the global response, these diseases will continue to claim millions of lives, drain billions of dollars from economies, and put our security at risk.

U.S. leadership has long served as the linchpin of global efforts to combat AIDS, TB and malaria. These investments have earned sustained bipartisan support because U.S.-funded programs produce tangible results. Bilateral efforts against AIDS, malaria and TB include the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and the U.S. Agency for International Development (USAID) TB program. Amplifying these bilateral efforts, the U.S. also supports the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), a model of aid efficiency that leverages U.S. contributions to increase investment from other donors, the private sector, and implementing countries themselves.

Building on extraordinary progress, it is time to focus our investments in a determined effort to end the epidemics, not simply reduce their carnage. Other countries can and should do more, but American leadership is essential. The United States provides unmatched expertise, sizeable resources and – crucially – strategic resolve in tackling the challenge.

This report reviews the status of U.S. efforts against AIDS, TB and malaria, identifying major advances, risks and challenges, along with opportunities to accelerate progress. It argues for a whole-of-government approach in the U.S. against these diseases, and a renewed effort to marshal the energies of public sector, private sector and civil society actors internationally. It calls for new strategic investments by other donors – along with modest but consequential increases from the U.S. itself – to scale up effective interventions now and pursue research to find powerful new tools for the future.

We must not fool ourselves that ending the AIDS, TB and malaria epidemics will be easy, but it is possible. And if we do not seize this historic opportunity, achievements

U.S. leadership has supported significant global progress:



AIDS-related deaths have **fallen by 48%** since the peak in 2005.¹



53 million lives saved with TB interventions from 2000 to 2016.²



The number of deaths due to malaria **declined by 42%** since 2000.³

from U.S. investments to date could be squandered. "All infectious diseases will revert and come back," warns Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases. "We have seen through multiple experiences over the years; we cannot stop until it's over."⁴

Achieving groundbreaking progress in reducing AIDS, TB and malaria transmission and mortality is America's pride; ending these epidemics as public health threats can be our legacy to future generations.

HIV/AIDS



Global status and the U.S. response

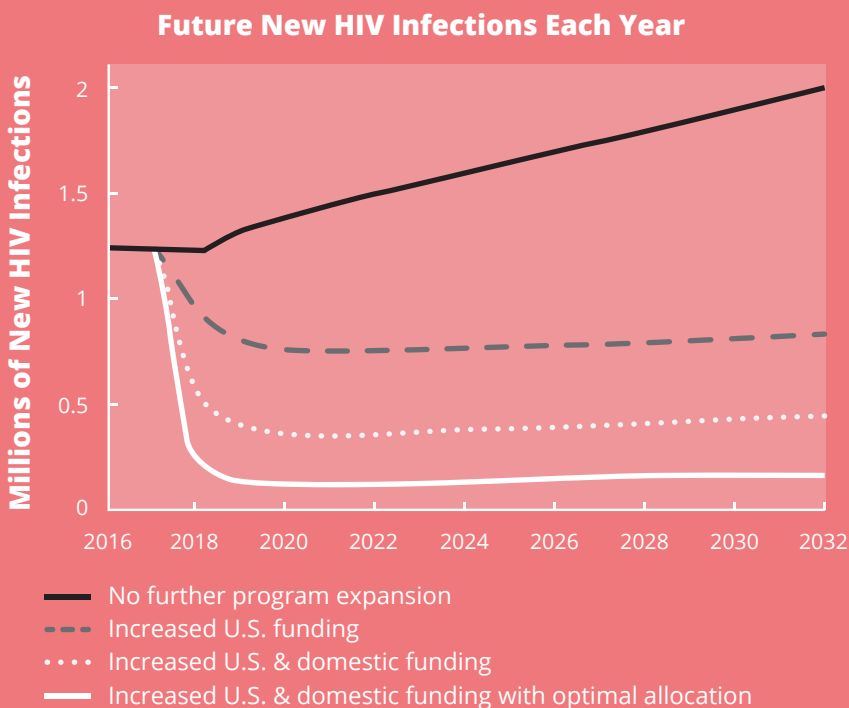
Over the last two decades, historic progress has been made in combatting HIV/AIDS. Globally, new HIV infections fell by 56 percent from 1997 to 2016. AIDS-related deaths dropped from 1.9 million in 2005 to 1 million in 2016.⁵ Nonetheless, AIDS remains the “epidemic of our times,” with 36.7 million people living with HIV worldwide.⁶ AIDS-related illnesses remain the leading cause of death globally among women ages 15 to 49.⁷

The U.S. has led the world in the fight against AIDS through investments in PEPFAR and the Global Fund, aligned with UNAIDS’ global HIV treatment targets for 2020. PEPFAR is also leading efforts with partners on the Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe (DREAMS) initiative, which in 2017 produced impressive reductions in new HIV infections among adolescent girls and young women.⁸ The Global Fund’s new HIV Epidemic Response (HER) Initiative also focuses on additional strategic support for this population.

The Global Fund is the largest financier of global HIV programming after PEPFAR, and the two agencies are closely interconnected through in-country planning and programming. Stigma and discrimination are major factors in HIV, and ending the epidemic will require expanded work to address the social and legal factors that help drive the disease. Civil society, including U.S.-based advocacy and community groups, have advanced major improvements in the AIDS response since the 1980s, and play a critical role in global HIV services.

The Possibility:

*Potential for HIV incidence, with and without strategic increased investment.**



The Risk of Inaction:

From 2017-2050, nearly 60% of global population growth is projected to occur in Africa. This growing youth population brings great opportunity, but also greater risk of HIV infection. Also concerning is HIV's disproportionate effect on young women in Africa; despite representing just 4% of the world's population, 13 countries in Africa account for more than half of new HIV infections among young women and girls.⁹



* Source: McGillen, K, et al, Consequences of a changing U.S. strategy in the global HIV investment landscape, AIDS 2017, 31:F19-F23

Challenges to ending AIDS

Although global investments have galvanized substantial gains, major challenges remain:

Millions still need lifesaving

treatment: There are 15.8 million people living with HIV who do not yet have access to treatment.¹⁰ In addition to saving lives, treatment greatly reduces the risk of transmitting HIV, which means the treatment shortfall also undermines HIV prevention.¹¹ Drug resistance is also a growing concern. It is primarily caused by treatment interruption, inadequate adherence to treatment regimens, and use of sub-optimal regimens. But even people who have never been on treatment can acquire drug-resistant HIV. Of the 11 countries that have reported data on pre-treatment HIV drug resistance, six countries reported resistance levels at or above 10 percent to the two most affordable and widely used drugs.¹²

Access to HIV prevention is

inadequate: Evidence-based prevention interventions remain essential but are not available to millions at risk – even as the world's largest-ever generation of young people is entering adolescence and young adulthood, when HIV risks are greatest.¹³

Populations left behind: Some East and Southern African countries appear on track to achieve epidemic control with sustained investments in treatment and prevention, yet other African countries, and countries in Eastern Europe, Central Asia and the Middle East, are actually seeing an

increased number of new infections. Outside of sub-Saharan Africa, key populations – people who are often socially and politically marginalized – account for 80 percent of new HIV infections, yet are the least likely to obtain HIV services.¹⁴ Unless these gaps are closed, HIV/AIDS may be controlled as a public health emergency in some parts of the world, but will remain at epidemic levels in others.

Opportunities to accelerate progress toward ending AIDS

Due to flat funding over the last decade, the U.S. has been forced to make difficult choices in its AIDS response, leaving effective interventions out of reach of millions. With additional resources from partners and the U.S., the world can get on track to end AIDS as an epidemic.

Expand treatment and prevention:

The U.S. has played a decisive role in expediting gains towards global treatment targets. With more resources, PEPFAR could reach millions more with scaled up treatment and prevention services. These services include pre-exposure prophylaxis (PrEP) and voluntary medical male circumcision.¹⁵ In fact, a modest increase in U.S. investment to fight HIV in sub-Saharan Africa through PEPFAR and the Global Fund could prevent 22 million new infections by 2032.¹⁶

Expand geographical and

population focus: In its 2017-2020 strategy, PEPFAR committed to a focused effort to achieve epidemic

control in 13 of the 63 countries in which it is active.^{17, 18} With expanded financing, PEPFAR could intensify efforts where new infections are rising and key populations are heavily affected, and in high-burden countries such as Nigeria, South Africa and Mozambique, which in 2016 collectively accounted for 573,000 new HIV infections.¹⁹ The Global Fund, which has supported HIV programming in more than 100 countries, is crucial to achieving broader epidemic impact.²⁰

Scale up superior medicines:

Dolutegravir (DTG), an antiretroviral from the class of drugs known as integrase inhibitors, is a best-in-class drug that slows drug resistance and minimizes side effects.²¹ Thanks to a new agreement, a generic regimen will soon be available for 92 low- and middle-income countries.²² Accelerating scale up of this and other regimens will save money, reduce drug resistance, and lower demand for more costly second- and third-line regimens.

Sustain robust research: Sustained and expanded research is needed for next-generation treatment and prevention options, including injectable drugs, a vaccine and a cure.

TUBERCULOSIS



Global status and the U.S. response

TB is curable, yet it has become the world's leading infectious disease killer.²³ The epidemic is a global health security threat that must be brought out of the shadows. A recent report estimates that failing to tackle TB will cost the world economy \$1 trillion by 2030.²⁴

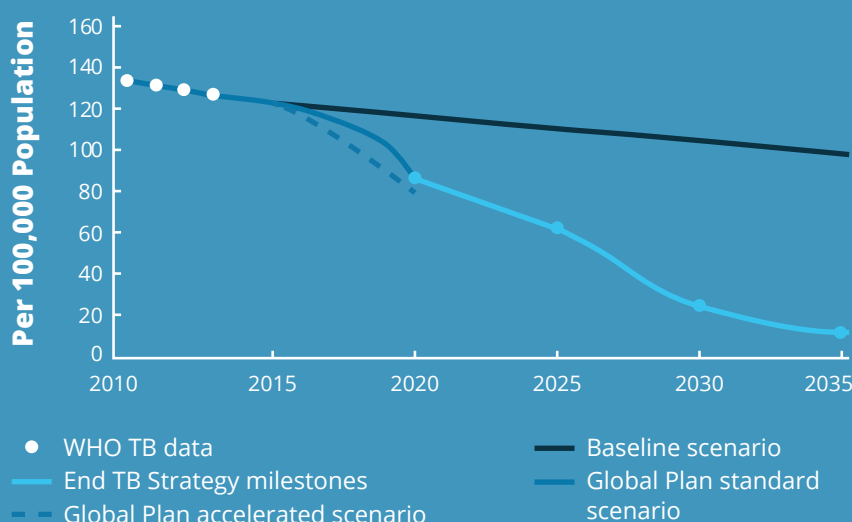
TB statistics are sobering. In 2016 alone, the World Health Organization (WHO) estimates there were 10.4 million new TB cases and 1.7 million TB deaths, including 374,000 deaths among people who were also HIV-positive. Nonetheless, significant progress has been achieved, with diagnosis and treatment saving 53 million lives from 2000 to 2016.²⁵

Fortunately, there is now a major opportunity for political will to turn the tide on the epidemic. TB is an excellent example of shared global responsibility for health programs – 84 percent of prevention and care is provided from domestic resources. Investments in TB are also highly cost effective, with \$43 returned for every dollar spent.²⁶

U.S. leadership is a chief driver of TB progress. In 2017, donors contributed \$1.1 billion to TB efforts worldwide, more than 65 percent of which was allocated through the Global Fund.²⁷ In addition, as the world's largest bilateral TB effort, the USAID TB program leverages U.S. investment in the Global Fund by providing technical assistance to support the implementation of Global Fund TB grants in 54 countries.²⁸

The Possibility:

*Potential for falling TB incidence with stepped up programming.**

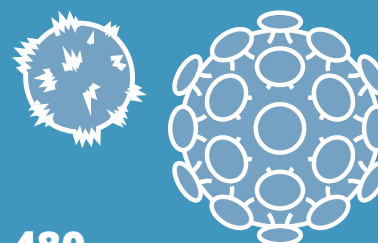


The Risk of Inaction:

Major risk from growing drug resistance to TB drugs.

Antimicrobial resistance (AMR) occurs when microorganisms, such as the bacteria that cause TB, are no longer susceptible to the drugs designed to destroy them.

Drug-resistant TB is responsible for about 29% of all AMR deaths today.²⁹



480

Pills required to treat drug-susceptible TB, as part of a broader regimen.^{30, 31}

14,000

Pills required to treat drug-resistant TB, as part of a longer, more complicated, less successful, and drastically more expensive treatment regimen.³²

* Source: The Paradigm Shift 2016-2020: Global Plan to End TB, Stop TB Partnership and UNOPS, 2015

Challenges to ending TB

The U.S. and partners face major challenges in preventing millions of deaths from TB, and ultimately ending TB as an epidemic. Chronic underfunding of TB research and development has resulted in a limited number of prevention and treatment options. Challenges include:

Reaching people who need

treatment: Every year, roughly 40 percent of new TB cases are not reported to national TB programs.³³ These “missing” cases result from a variety of factors, including: under-diagnosis; under-reporting; inadequate access to health services; gaps and weaknesses in health systems and surveillance; and inadequate linkages between the private and public health sectors. Vulnerable populations, such as people living with HIV, are also not being screened, diagnosed or treated sufficiently. These missing 4.1 million people are at the root of why TB transmission continues to be a serious health challenge.³⁴

Obstacles to prevention and

treatment: Tools currently accessible to prevent TB are inadequate, especially for people living with HIV, though recent research has indicated there is potential for a shorter course of preventative treatment.³⁵ TB treatment has improved, now consisting of a six-month course with drugs costing approximately \$40 per person, and with a success

rate of at least 83 percent.³⁶ Yet the drug regimen remains difficult to administer. Treatment for drug-resistant and multidrug-resistant TB (MDR-TB) demands drastically greater resources and time, and can lead to major side effects such as hearing loss. Treatment for MDR-TB has a success rate of only 54 percent due to low rates of follow-up and efficacy.³⁷

Drug resistance is among the largest challenges to ending TB, with the disease accounting for more than 1 in 4 AMR fatalities each year.³⁸

It is estimated that 4.1 percent of new cases and 19 percent of recurrent cases develop resistance to one or more drug regimens.³⁹ For U.S. health security, this factor is especially concerning.

Funding gaps: Funding for TB in low- and middle-income countries doubled from 2006 to 2017, reaching \$6.9 billion in 2017. However, the TB response remains seriously underfinanced. WHO estimates that \$52 billion is required to implement interventions over five years. For 2017, this translated to a need of \$9.2 billion – \$2.3 billion more than current funding levels for TB per year.⁴⁰

Opportunities to accelerate progress toward ending TB

Access to diagnosis and

treatment: The U.S. can work with global partners to integrate TB

screening into primary care check-ups to help find millions of missing cases. The U.S. and partners must continue to integrate TB and HIV services, and increasingly provide preventative TB treatment for people living with HIV.

Investment in scale up: The USAID TB program is woefully underfinanced, and increased support would bolster the global response, enabling the program to intensify efforts and expand the number of countries in which it operates.

Advancing political will for TB:

Advances in diagnostics and treatment, and the 2017 Moscow Declaration to End TB, have generated global momentum against TB. With the 2018 United Nations High Level Meeting (HLM) focused specifically on TB, the U.S. can play a key role in accelerating political will and turning Stop TB's Global Plan to end the TB epidemic into reality. The HLM should include commitments for new resources from high-burden countries as well as increases from current donors to the Global Fund.

More research: Expanded research is needed for point-of-care diagnostics, shorter and less difficult treatment regimens, and a highly effective vaccine.

MALARIA



Global status and the U.S. response

In recent years, the world has seen remarkable progress in the global fight against malaria. In 2016, there were 21 million fewer cases of malaria worldwide than in 2010.⁴¹ Yet in 2016 there were still 445,000 deaths from malaria, 70 percent of which were in children under age 5. Of concern, the 2017 WHO malaria report found growth in the number of cases from the previous year.⁴² Countries are increasingly falling into one of two categories: those progressing toward elimination, and those with a high burden of malaria that are experiencing setbacks.⁴³ According to WHO, funding shortfalls are the primary reason for stalled progress.⁴⁴

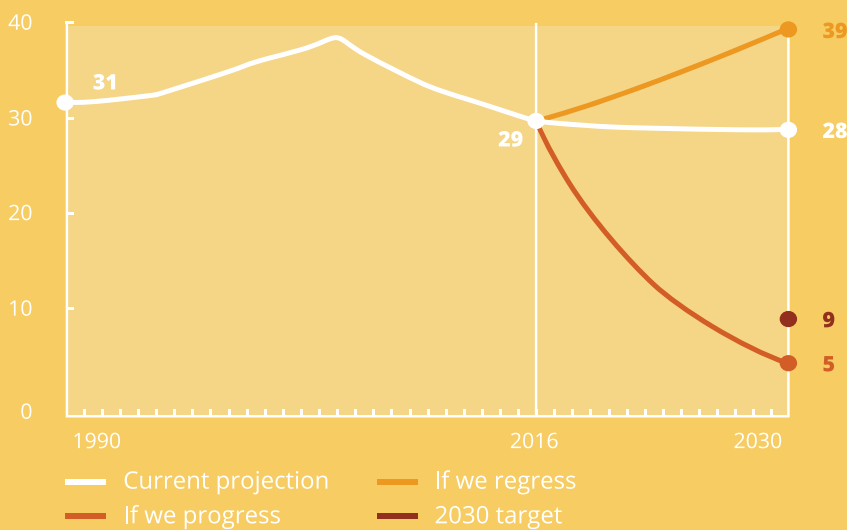
PMI has sought to complement the Global Fund from the start; all 27 PMI focus countries (including five additions in 2017) are Global Fund grantees, allowing PMI to strategically assess available resources and fulfill unmet needs.⁴⁵ Together, the U.S. government and the Global Fund provide more than half of all funding for global malaria programs and policies.⁴⁶

U.S. efforts to end malaria align with the RBM Partnership to End Malaria and WHO malaria strategies, all of which call for an increase in global funding. These strategies also call for an acceleration of elimination efforts through scale up of effective interventions such as insecticide-treated nets (ITNs), indoor residual spraying (IRS), and treatment. An estimated \$4 trillion in additional economic output would be generated if global targets for 2030 are achieved.⁴⁷

The Possibility:

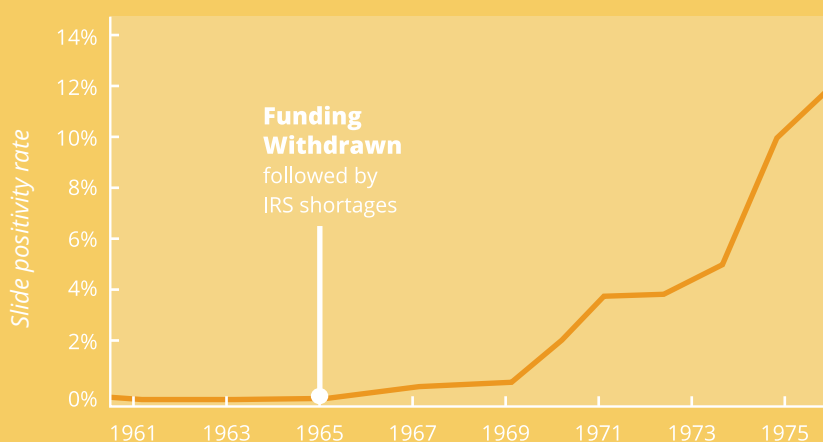
*Potential paths to malaria elimination**

New Cases of Malaria Per 1,000 People



The Risk of Inaction:

*There is serious threat of resurgence without sufficient resources to fight malaria, as demonstrated by this historic case study from India***



NOTE: Slide positivity rate is the number of laboratory-confirmed malaria cases per 100 suspected cases examined

Sources:

* Gates Foundation's Goalkeepers Report, 2017

** Investing for a Malaria-free World, RBM Partnership to End Malaria, 2016

Challenges to ending malaria

Even with impressive progress, we are in serious danger of backsliding in the battle against malaria:

Drug resistance: The growth of resistance to anti-malarial drugs, especially artemisinin, undermines treatment efforts. Resistance can arise from poor treatment practices, non-adherence to treatment regimens, and the presence of sub-standard and counterfeit drugs on the market.⁴⁸ As of March 2018, artemisinin resistance was confirmed in five countries of the Greater Mekong region.⁴⁹ If drug resistance were to continue spreading across borders or arise independently in new geographic areas, the basic foundations of global malaria control could be jeopardized.

Insecticide resistance: ITNs and IRS have been two of the primary drivers of success in the fight against malaria, and remain essential to future advances. However, of the 91 countries where malaria is endemic, 61 have reported cases of insecticide resistance since 2010.⁵⁰ Resistance is most commonly reported for the pyrethroid class of insecticides; until recently, this was the only class of insecticides used in all ITNs.⁵¹

Inadequate resources and availability of services: According to WHO, progress against malaria is slowed by insufficient global and domestic financing, and inadequate political commitment.⁵² Neglected populations, such as migrants, people in humanitarian crises, and indigenous and rural populations, face disproportionate risk. The challenge is further compounded by the fact that, even as incidence declines and elimination is achieved, the threat of malaria resurgence demands ongoing, steady investment in core surveillance and diagnostic tools to avoid rebound.

Opportunities to accelerate progress toward ending malaria

Regional control efforts: Initiatives such as those uniting countries within Southeast Asia's Greater Mekong region and Mesoamerica, respectively, can help to encourage stronger political and financial commitments from each country involved. In addition to promoting collaboration and data sharing across borders, these efforts can help countries to reach transient populations more efficiently, which in turn can improve long-term malaria control.

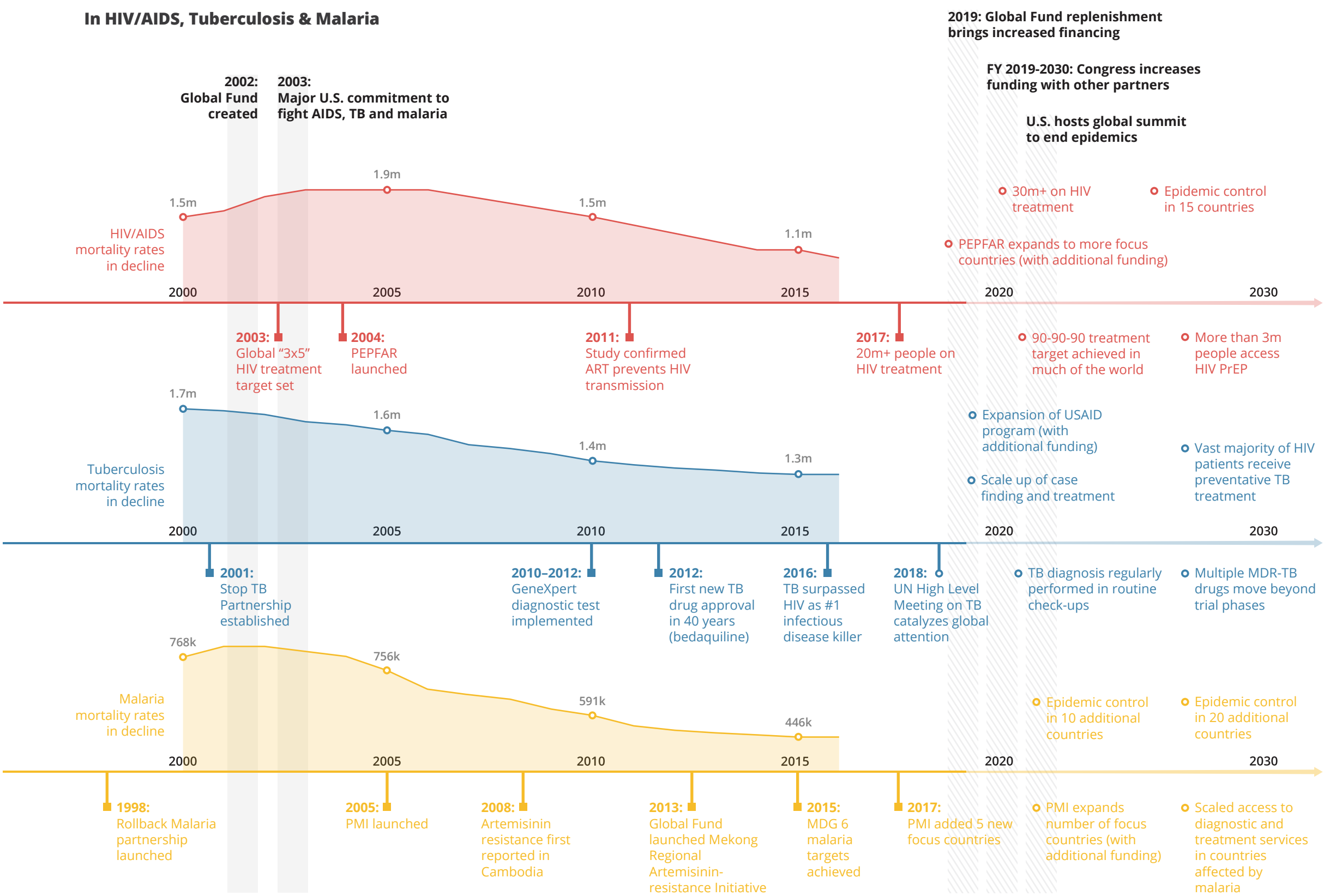
New technologies to stop malaria's spread: In early studies, a new ITN that uses both pyrethroid and the synergist piperonyl butoxide (PBO) has demonstrated effectiveness against pyrethroid resistance.⁵³ This new ITN may help to slow the spread of resistance and ensure that ITNs, as well as next-generation nets that use other classes of insecticides, remain effective in malaria control efforts.

Scaling effective programs: With sufficient U.S. resources, the highly effective PMI program could strategically scale up services in current and additional focus countries. Over the last two decades, many new partners have joined the malaria fight, including those in the private sector and implementing countries themselves. These partners help spur new forms of collaboration by sharing and adapting lessons learned, supporting faster expansion of effective programs and helping to achieve greater impact.

More research: Expanded research is needed for improved prevention and treatment interventions, longer-lasting insecticides, a vaccine and more efficient treatments.

MILESTONES PAST & FUTURE

In HIV/AIDS, Tuberculosis & Malaria



- Past Events and Achievements
- Future Opportunities

Potential Game-Changers

HIV/AIDS



Long-term game-changers:

- ★ Long-acting ARVs
- ★ Scalable cure for HIV
- ★ Vaccine

Short-term game-changers:

- ★ Dolutegravir (ARV) widely delivered
- ★ Injectable medicines for prevention and treatment

TUBERCULOSIS



Long-term game-changers:

- ★ Vaccine for adult TB
- ★ Simpler, safer drugs requiring shorter-term use
- ★ New drugs for drug-resistant TB deployed

Short-term game-changer:

- ★ Simplified diagnosis and treatment technologies

MALARIA



Long-term game-changers:

- ★ New insecticide for use in nets and residual spraying to combat pyrethroid resistance
- ★ Vaccine

Short-term game-changers:

- ★ ITNs using both pyrethroid and PBO
- ★ Single-dose treatments

This timeline was inspired by the Action Agenda to End AIDS timeline from AVAC and amfAR

What course for the future?

A careful review of U.S. global health programming leads to two irrefutable conclusions. First, we have made remarkable progress in freeing communities from the burdens of AIDS, TB and malaria, while strengthening global health security for the U.S. and the world in the process. Second, the risk of backtracking is real. The question is: what course do Americans want to set for our future investment in these diseases? Should the U.S. simply maintain efforts at the current level and risk growing drug resistance and

resurgence, or challenge the world to join us in a bold and intensified effort to bring these epidemics to an end?

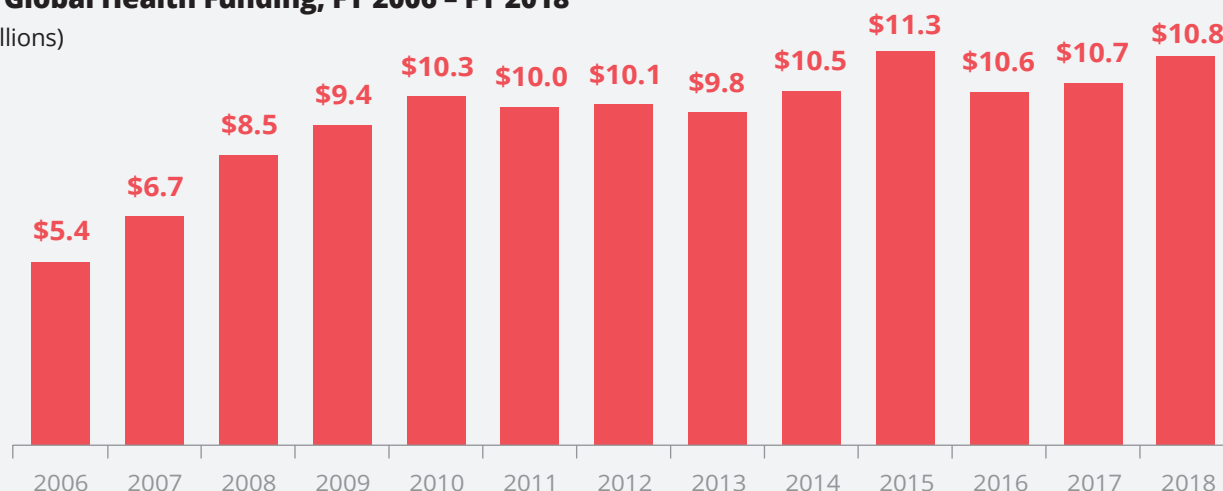
The following are ways we can make even greater progress against the three biggest infectious disease killers.

1. **Challenge global leaders – public and private – to join together in an expanded effort to end the AIDS, TB and malaria epidemics.** U.S. leadership could build on its successes in catalyzing global investments by pledging increased U.S. funding if other donors, implementing countries and the private sector join us. The U.S. could convene a high-profile meeting of global leaders to commit to collaborative funding and programming efforts to accomplish the goal.
2. **Increase appropriations to U.S. bilateral global health programs.** U.S. investment in global health has been relatively
3. **Fully fund the Global Fund and increase the U.S. pledge in the 2019 Replenishment.** The Global Fund is the world's largest financier of global health programming and consistently receives high

flat for nearly a decade and represents only a quarter of 1 percent of the U.S. budget.⁵⁴ Americans support these investments. A 2018 Kaiser Family Foundation poll found that 59 percent of Americans believe the U.S. is spending the right amount or not enough on global health.⁵⁵ Americans' support for foreign assistance increases when they learn how small a fraction of the budget these investments represent.⁵⁶ As part of an effort to encourage other donors and implementing countries to increase investment, Congress can expand the highly effective PEPFAR, PMI and USAID TB programs along with global health investments overall.

U.S. Global Health Funding, FY 2006 – FY 2018*

(In Billions)



SOURCE: Kaiser Family Foundation

* NOTE: This represents the total known funding provided through the State Department, USAID, CDC, NIH and DOD. FY 2013 includes the effects of sequestration, and FY 2015 and FY 2016 include emergency Ebola and Zika funding specified for global health security activities. FY 2017 and FY 2018 are preliminary estimates, as some amounts are not yet known but are assumed to remain at prior year levels.

marks for results, efficiency and transparency. The Global Fund and bilateral programs are now highly coordinated and depend on each other for success. U.S. pledges to the Global Fund leverage other donors to contribute more. Congress should reject the Administration's proposal for a \$425 million (or 31 percent) cut to the Global Fund in FY 2019 and instead appropriate \$1.35 billion, consistent with the U.S. pledge. The U.S. should make an increased pledge at the launch of the next Replenishment cycle in 2019.

4. **Incentivize private investment.**

Congress and the Administration can adopt policy options to incentivize private investment and collaboration against the three diseases. This would include encouraging innovative financing approaches, such as those already pursued by USAID and the Global Fund. This is not a matter of corporate philanthropy: according to World Bank estimates, the annual global cost of “moderately severe” to “severe” pandemics is roughly \$570 billion.⁵⁷ The World Economic Forum notes most economic losses are not typically caused by disease directly. They are instead caused by consumer reactions, labor and equipment shortages, and by cascading failures in tourism, retail, financial and other sectors.⁵⁸ The private sector has a bottom line interest in ending epidemics.

5. **Incentivize domestic investment.**

Domestic investment by implementing countries that are heavily affected by the three epidemics has increased markedly, but there remains room to grow. U.S. agencies can ensure there are

incentives in place to encourage countries to invest more in the health of their own people. The Global Fund, which works intensely with implementing governments to increase domestic financing for health, offers 15 percent or more of a country's grant allocation as a co-financing incentive.⁵⁹ This funding becomes accessible when countries commit additional funds to their own health response.

6. **Promote civil society engagement.**

U.S. government agencies can strengthen policies that encourage engagement of civil society in the planning and delivery of health services. The U.S. government and private philanthropies can support civil society organizations in their crucial efforts to promote greater domestic investment in health, with an emphasis on reaching those most affected, including marginalized populations, with health services.

7. **Reach those most at risk.**

For each of the three epidemics, certain groups are particularly vulnerable to disease and often lack access to health services. Often these groups are socially or economically marginalized. Reaching marginalized groups is critical to accomplishing public health goals, and has been and should continue to be a hallmark of U.S. global health efforts.

8. **Expand investments in health research at NIH and elsewhere.**

The cures and vaccines that we need for all three diseases, along with improved diagnostics, prevention and treatment, rely on a robustly funded National Institutes of Health (NIH). U.S.

support for NIH drives discovery, supports private sector partners, and is essential to keep us safe from emerging health threats. Game-changing innovation depends on NIH.

9. **Ensure medications and diagnostics are accessible.**

Policymakers should ensure that drugs and diagnostics are available to all in need, and that access and broad delivery of these commodities is not inhibited by trade policies or drug pricing.

10. **Build political mobilization on TB.**

World leaders will meet in fall 2018 to discuss the path forward in the global TB epidemic. The U.S. can engage proactively in the meeting and encourage leaders in heavily affected middle-income countries to use the UN High Level Meeting as an opportunity to achieve new commitments on TB.

With U.S. leadership, the world has made impressive strides in combatting the most daunting infectious diseases. But we remain at a tipping point. We are not yet on track to end these epidemics, or realize the vast human, economic and security gains this accomplishment would bring.

Now is the time to rededicate ourselves and challenge the world to focus with us on ending epidemics for good.

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