Chapter 14
How the Science of HIV Treatment-as-Prevention Restructured PEPFAR's Strategy: The Case for Scaling up ART in 'Epidemic Control' Countries

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14.1 Introduction

Over the past decade, the clinical logics of HIV treatment as prevention (TasP) have transformed the global response to the epidemic. While clinical knowledge about the efficacy of TasP dates back to the turn of the twenty-first century when investigators first demonstrated that antiretroviral therapy (ART) could greatly reduce the chances of onward viral transmission (Cohen 2000; Quinn et al. 2000), in more recent years epidemiological modelling studies provided evidence that TasP could have population-level effects on HIV incidence and HIV-related mortality (Granich et al. 2009; Cambiano et al. 2010; Cohen 2010). On the heels of these findings, health organisations have launched ambitious strategies to change the course of the HIV epidemic. Strategies for creating an 'AIDS-free generation' began to be announced in 2010 (UNAIDS 2010) and have continued for several years.[1] For example, in 2010, the Joint United Nations Programme on HIV/AIDS (UNAIDS) outlined a vision for 'getting to zero' including zero new HIV infections, zero AIDS-related deaths and zero discrimination (UNAIDS 2010). In 2011, the US President's Emergency Plan for AIDS Relief (PEPFAR) also began to devise a new strategy to 'control' the HIV epidemic (PEPFAR 2012).

One of the earliest signs PEPFAR was crafting this strategy appeared in the organisation's annual report to US Congress, when PEPFAR leadership declared a commitment to 'saving lives by moving science into programs through smart investments' (PEPFAR 2012, p. 1). Guided by recent 'breakthroughs' in HIV

[1]For a detailed account of the rise of 'end of AIDS' rhetoric and strategies, see Kenworthy et al. 2018.

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science, PEPFAR would harness 'the power of evidence-based interventions to dramatically drive down the rate of new infections and save more lives' (PEPFAR 2012, p. 1). Later that same year, PEPFAR published a 'blueprint' for 'Creating an AIDS-Free Generation.' And by 2013 PEPFAR had officially launched its new strategic initiative to achieve 'epidemic control' in all recipient countries and regions (PEPFAR 2014b).

In 2014, UNAIDS updated its vision to 'end AIDS'. To achieve this ambitious goal, UNAIDS recommended a massive scale-up of HIV testing and expansion of access to ART, and set specific targets for achievement, including to ensure: 90% of people living with HIV know their status; 90% of them are on effective treatment; and 90% of people on effective treatment have an undetectable viral load. If '90-90-90' could be achieved by 2020, UNAIDS contended, we would see the 'end of AIDS' by 2030 (UNAIDS 2014).

Evidence that TasP could have population-level effects justified the new global agenda and the use of a new set of health metrics for monitoring performance. Whereas PEPFAR had previously measured programme reach by the number of people receiving clinical services, including HIV testing, counselling, condoms and ART, after the clinical logics of TasP were adopted, these organisations adjusted their metrics for impact to focus on reductions in HIV viral load among people living with HIV (PLWH), the number of new HIV cases averted, and HIV-related mortality. Drawing on the clinical science associated with TasP, PEPFAR's new strategy aimed to lower the number of people who acquire HIV below the number of people with HIV who die annually. By realising these two related aims, disease surveillance experts within the organisation suggested PEPFAR could effectively achieve 'epidemic control'.

To support the goals of the strategy, PEPFAR also began to update methods for monitoring the impact on the epidemic through a new set of health metrics, which track mortality among people living with HIV and population-wide HIV incidence. In the following years, PEPFAR analysed data in recipient countries to monitor the impact of this new strategy, and represented the outcomes in its annual report to Congress. By 2017, the organisation had identified a subset of 13 recipient countries that demonstrated potential to meet the identified targets. While maintaining its broad approach to control the epidemic in all recipient countries and regions, the organisation announced a new initiative to 'accelerate' epidemic control in this select group of 13 countries, which showed promise to achieve the goals of the strategy (2017b).

PEPFAR's new strategy has been influenced by larger transformations in global public health, including the rise of 'evidence-based medicine' (EBM). Since the turn of the twenty-first century, evidence-based medicine has increasingly influenced global public health and the imperative to generate evidence has transformed the world of health provision and care into a space of calculation and accountability (Adams 2016). Models for health forecasting have obscured the political and economic factors influencing health through several layers of statistical abstraction (Erikson 2016). Programmes to improve basic health care, which have historically defined the contributions of international development agencies have been

overshadowed by biomedical interventions (Lock and Nguyen 2018), which can be more easily measured, even though these measures tend to be abstract, and in some cases, divorced from any meaningful evidence of impact (Wendland 2016). The consequences of this turn towards the biomedical approaches to care have manifested themselves in under-developed health systems (Pfeiffer 2013), where getting 'good numbers' has become a requirement for successful governance and increased aid (Oni-Orisan 2016). Just as EBM has transformed the logics and practices of this globalising field, TasP has reshaped the global agenda to 'end AIDS' and contributed to the ongoing biomedicalisation of the epidemic (Nguyen et al. 2011).

PEPFAR's strategic approach has also been influenced by political factors, including US Congressional oversight and a recent change in the budgetary approval process. The United States Congress first authorised the establishment of PEPFAR through the Leadership Act, and dedicated $15 billion to 'lead' the global response to the HIV/AIDS epidemic around the world (Hyde 2003). In 2008, Congress reauthorised PEPFAR (through the Lantos-Hyde Act) and increased its budget for bilateral aid to $48 billion (Biden 2008). However, in more recent years, Congress has not reauthorised a predetermined budget amount. While continuing to support PEPFAR's ongoing operations, Congress has required PEPFAR to implement a flexible budget structure, which would be reviewed annually. This change in budgetary oversight coincided with PEPFAR's new strategic approach to the global epidemic, and may have intensified reporting on programme performance. Therefore, the push for evidence-based interventions must also be examined within the context of an ongoing era of increasing austerity, and greater demands for accountability (Basu et al. 2017; Whitacre 2020).

Against this background, this chapter examines how the clinical logics of TasP structured PEPFAR's latest strategic initiative to achieve 'epidemic control' including the organisation's decisions for allocating funds to specific programmes and a subset of recipient countries, based on a set of metrics for evaluating performance. The findings draw from analysis of publicly available documents and data sets produced by PEPFAR, including the organisation's annual reports to the US Congress (PEPFAR 2005–2019), strategic updates (PEPFAR 2005, 2009a, 2013a, 2017b), and data sets on planned spending (PEPFAR 2020b). At the time of writing, strategic updates and annual reports were available online (US Department of State 2020) for all years of operations (PEPFAR 2004–2019) and planned spending data was available for all but the two most recent years (PEPFAR 2004–2017). In my analysis of this data set I traced broad trends in PEPFAR's planned spending, including by programme area and recipient countries, and changes in the use of health metrics after the strategy for achieving epidemic control was initiated.[2] To understand longitudinal trends in epidemic control countries, I also reviewed the

[2]The author has published the full analysed data set of PEPFAR's planned spending in 'epidemic control' countries for years 2004–2017. DOI: https://doi.org/10.5281/zenodo.4323072

epidemiological data provided by PEPFAR in supplementary tables included in annual reports, and plotted health outcomes by country over time.

Based on this research it is possible to observe how the clinical logics of TasP structured PEPFAR's latest strategic initiative to achieve 'epidemic control' including the organisation's metrics for evaluating performance, and decisions for allocating funds to specific programmes and countries. Supported by evidence from modelling studies that TasP could have population-level effects, 'epidemic control' was conceptualised as an 'evidence-based' solution that could be consistently measured and reported on. However, after several years of working toward the goals of this new biomedical approach to the epidemic, PEPFAR has not demonstrated its benefits over previous strategies. The organisation has not even demonstrated the ability to measure impact. The only clear effects of the new strategy are evident in the organisation's budget, including increased spending on treatment and decreased spending on other program areas, including care, govenrnance and systems, and management and operations, as well as decreased spending on countries not designated as priorities under the new strategy. The budget clearly shows programmes and countries that could not produce the right kinds of evidence to meet the goals of epidemic control have been systematically under-funded since the initiative began.

By highlighting this shift in PEPFAR's strategic approach, I do not intend to undermine the historical or contemporary importance of the organisation. PEPFAR has made undeniable contributions to the global response to the HIV epidemic. However, I do aim to tease out the strangeness of the particular set of metrics used to measure programme success, probe the reasons for using these metrics for bilateral assistance, or any such health programme, and call attention to the way this set of metrics has emerged in concert with evidence-based medicine, and the biomedical prevention of HIV.

14.2 Measuring Impact: From Providing Clinical Services to Projecting Health Outcomes

The clinical logics of TasP have reshaped PEPFAR's methods for tracking programme performance and measuring impact. Since its establishment, PEPFAR has utilised many key indicators to measure its own impact.[3] In the earliest years of PEPFAR's operations (2004–2008), the majority of indicators counted the number of clients receiving HIV care services from sponsored programmes (PEPFAR 2007b). These indicators monitored the number of HIV testing and counselling services, mothers and newborns who know their HIV status, prevention services for orphans and vulnerable children, and patients receiving ART, newly per year and

[3]Information about indicators is available for download in the 'Additional Data' section of PEPFAR's website, listed under the 'Historical Data' tab: https://data.pepfar.gov/additionalData

ongoing. When the organisation updated its strategy in 2009, PEPFAR started to measure the number of patients who were retained in HIV care for at least 12 months, and the number who agreed to voluntary male medical circumcision (VMMC) (PEPFAR 2009b, pp. 61–64). In 2011, PEFAR added more indicators to its annual report to measure the scale of services provided and number of patients receiving HIV care, including those who received treatment for tuberculosis (TB) in addition to HIV (PEPFAR 2013b, pp. 75–77, 184). In 2013 and again in 2015, the organisation added yet more indicators: one counted the number of people living with HIV who were pregnant and on ART (PEPFAR 2013b, pp. 44–47); and a second measured the number of clients who maintained a suppressed HIV viral load for at least 12 months (PEPFAR 2015b).

Over this history PEPFAR expanded the scope and number of indicators it used to measure its own impact, including by tracking services offered for the biomedical prevention of HIV. By documenting the number of services provided as a result of US bilateral aid, PEPFAR could demonstrate how the USA was 'leading' the global response to the epidemic in low- and middle-income countries (LMICs). As PEPFAR added new indicators to its audit structure, the organisation could make further claims to its own impact while generating evidence about performance. But ultimately, these many indicators could only demonstrate the ways in which bilateral aid had facilitated the provision of HIV care services, as opposed to health outcomes.

After PEPFAR introduced the strategy to achieve epidemic control in 2013 the organisation started reporting health outcomes associated with TasP and related biomedical methods of HIV prevention in its annual report to Congress, including the number of new HIV cases averted and lives saved (PEPFAR 2014a). PEPFAR's leadership also began to make clear statements about the importance of this new method of measurement. For example, in the executive summary of the annual report leadership proclaimed, 'saving lives is the ultimate metric of success' (PEPFAR 2012, p. 1). However, PEPFAR had not collected data to support the use of these new metrics. To make claims about progress toward achieving the stated goals, PEPFAR leveraged data sets from UNAIDS, which were generated through a wide range of sampling methods, and used to estimate incidence of HIV and HIV-related mortality across entire populations (UNAIDS 2019).

PEPFAR's claims about progress toward achieving or accelerating 'epidemic control' present troubling issues, given this significant difference between the data PEPFAR collected from aid recipients and the metrics the organisation reported to Congress. UNAIDS data were based on country-level estimates, and therefore, not specific to hospitals or clinics that received funding from PEPFAR. The measures were also not proportional to the presence of US bilateral aid in the country. Since the majority of funding for HIV care and services originated from domestic sources (UNAIDS 2018), the impact of any of PEPFAR's programmes could have only been abstractly correlated to the country-level health outcomes reported by UNAIDS. Furthermore, to represent progress toward epidemic control, PEPFAR reported estimates of health outcomes from a single year—either one or 2 years previous—and thus did not represent impact over time. Nevertheless, PEPFAR published single-year, country-level estimates in its annual report to Congress to suggest its

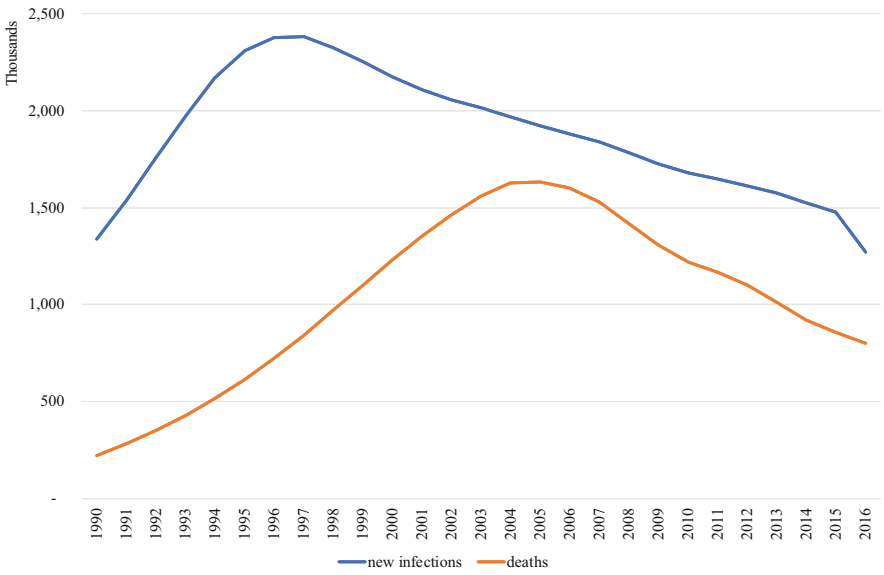

Fig. 14.1 Progress toward epidemic control in all PEPFAR countries (1990–2016)

programmes had discrete impact in specific countries that received bilateral aid from the USA.

Even if one were to bracket the limitations of this data and its uses, PEPFAR's claims about progress toward 'epidemic control' would be limited. For all countries receiving PEPFAR support, the ratio between new HIV cases and HIV-related deaths has not improved over the history of PEPFAR's existence. In fact, according to the UNAIDS data PEPFAR relied on to make claims about these metrics, the divide between new infections and deaths has widened over the organisation's history (Fig. 14.1). There were roughly 340,000 more new HIV infections than HIV-related deaths in 2004 (1.97 million new infections and 1.63 HIV-related deaths), and 470,000 more new infections than HIV-related deaths in 2016 (1.27 million infections vs. 0.8 million deaths).

The remaining distance between new infections and deaths complicates the picture of PEPFAR's progress toward epidemic control. On the one hand, it shows a glaring shortcoming of the strategy, which was not acknowledged in the annual report to Congress, but instead is tucked away in supplemental tables and buried within audit documents that number near 1000 pages. On the other hand, the gap between new infections and deaths could have been understood as the central ambition of the strategy. While the data demonstrate there has been no progress toward achieving the stated goals of 'epidemic control' across the entire group of PEPFAR's recipient countries, HIV incidence and HIV-related mortality have both decreased substantially over this same timeline, and the push to decrease incidence below mortality would be the ultimate mark of success. In any case, PEPFAR has not represented progress toward the metrics of epidemic control in aggregate (as shown

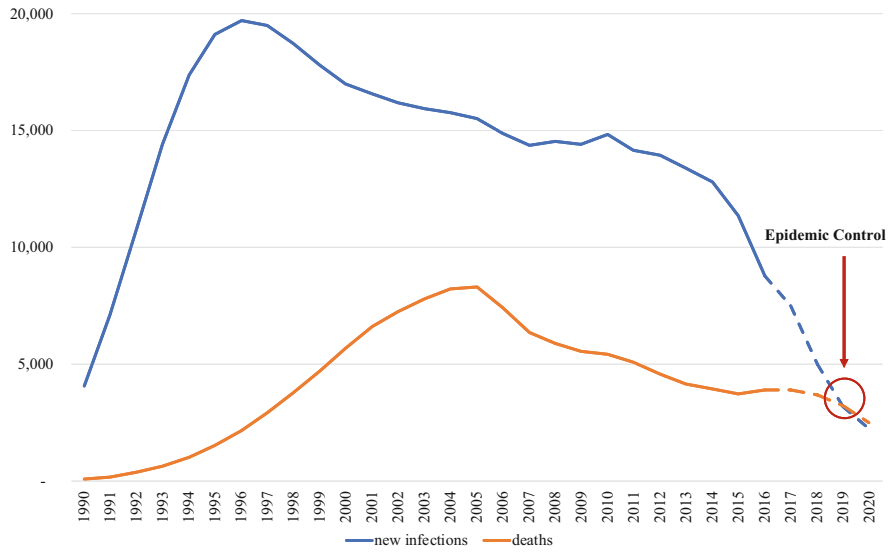

Fig. 14.2 Swaziland—Pathway to reaching epidemic control

in Fig. 14.1). Instead, the organisation has published individual charts for countries that have demonstrated progress toward realising the goals of epidemic control.

One chart representing progress toward epidemic control appeared in the 2017 strategic update (PEPFAR 2017b). It highlighted PEPFAR's impact on the epidemic in a single country: Swaziland (Fig. 14.2). According to data from 2016, the last available year data were available from UNAIDS, there had been no significant progress toward meeting the goals of the new strategy in Swaziland. In this sense, it mirrored the figure for all of PEPFAR's recipient countries. However, in this chart PEPFAR also projected possible future health outcomes to demonstrate what achieving 'epidemic control' would look like. By leveraging these broad epidemiological estimates, PEPFAR constructed a hypothetical future in which success would be realised. Of course, without current data this hypothetical 'future' could not be validated.

The clinical logics of TasP have guided PEPFAR's use of a new set of health metrics, and allowed the organisation to make claims about its potential impact on the epidemic through estimates of population-wide health outcomes. These metrics were divorced from any data PEPFAR collects from recipient countries, and only very loosely connected to the organisation's impact by a string of abstract correlations based on the very presence of US bilateral aid for HIV. Yet, PEPFAR has used these data to represent the impact of its programmes on the epidemic.

14.3 Planned Spending: Scaling up ART in 'Epidemic Control' Countries

Just as the clinical logics of TasP have influenced the use of a new set of metrics for measuring impact, they have also justified PEPFAR's decisions for allocating resources to select programme areas in a subset of recipient countries. Over its history, the organisation had channelled aid to a large number of recipient countries to support the ongoing response to the HIV epidemic. In fact, since its establishment, the organisation has expanded its reach to provide resources to 42 countries and regions for work in five programme areas, which have been broadly characterised as: care, governance and systems, management and operations, prevention, and treatment (amfAR 2020). However, when PEPFAR adopted the strategy of 'epidemic control' the organisation reprioritised programme areas and countries that could produce the right kinds of evidence to meet the specified metrics (PEPFAR 2013a).

In the initial years of PEPFAR's operations planned spending on the different programme areas was relatively consistent (Fig. 14.3). The budget for antiretroviral treatment and governance and systems, for example, both paralleled the general trend of rising spending. Shortly after the financial crisis of 2008, however, the budget for all programme areas plateaued, and planned spending for treatment dropped to levels approximately equivalent to prevention. However, since the implementation of PEPFAR's most recent strategic initiative, spending on treatment has greatly outpaced spending on other programme areas. In fact, since 2013, spending on treatment has increased by nearly 150% meanwhile planned spending

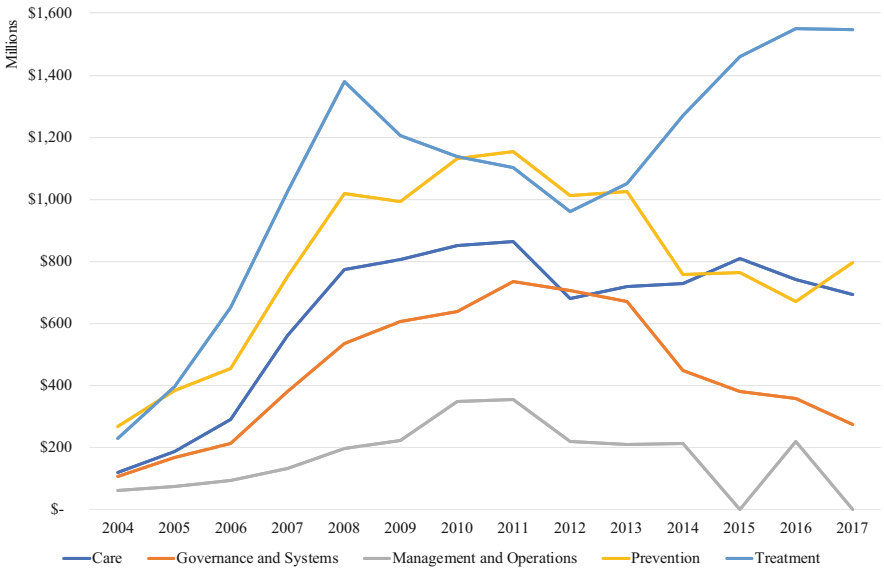

Fig. 14.3 PEPFAR's planned spending by programme area, 2004–2017

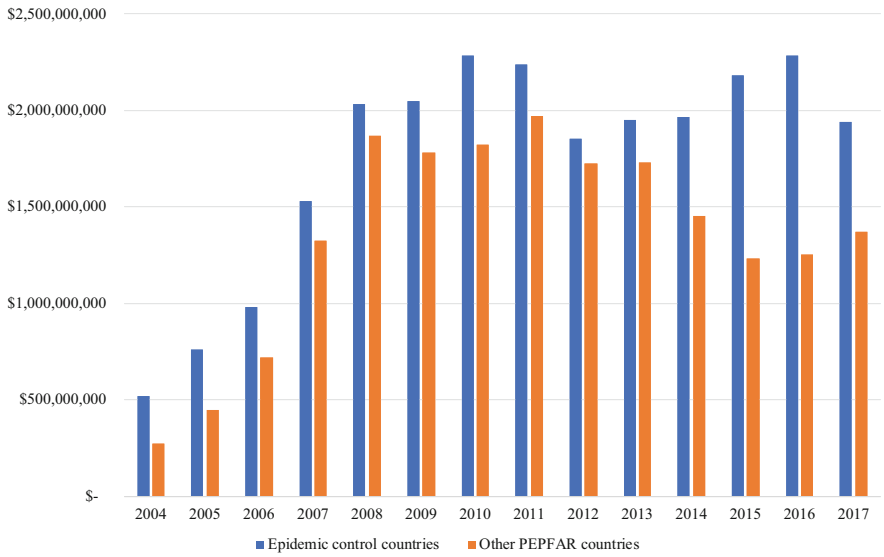

Fig. 14.4 PEPFAR's planned spending in 'epidemic control' countries vs. other recipient countries, 2004–2017

for governance and systems has been significantly reduced, and the budget for management and operations has been gutted.

There has been a similar trend in PEPFAR's planned spending in specific countries. Under the most recent initiative to 'accelerate epidemic control' PEPFAR announced it would prioritise countries that had the greatest potential to achieve epidemic control by 2020. With this announcement, the organisation suggested it would shift resource commitments from 42 countries and regions across the globe to 12 countries in sub-Saharan Africa in addition to Haiti.[4] While the prioritisation of these countries suggested a significant transition in resource allocation, upon review of the organisation's budget, it is clear that PEPFAR has historically given more aid to this subset of 13 countries over the history of its existence (Fig. 14.4). In fact, the planned spending differential between these 13 countries and all others began in 2004, the very first year of reported spending when this subset of countries collectively received just over $500 million, whereas the rest of the countries and regions given PEPFAR funds collectively received approximately half of that amount—$270 million. This spending differential has been maintained year-over-year for every year of PEPFAR's history, reaching a peak in 2010 when PEPFAR earmarked $2.3 billion for these 13 countries, and set aside approximately $500 million less ($1.8 billion) for all others.

[4]The list of countries chosen to 'accelerate epidemic control' includes: Botswana, Côte d'Ivoire, Haiti, Kenya, Lesotho, Malawi, Namibia, Rwanda, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

Following the launch of the 2013 strategy, the 13 epidemic control countries continued receiving disproportionately more funding than other recipients, but not because the budget for these countries grew to unprecedented levels. Instead the budget for epidemic control countries merely returned to the levels of previous years (2010, 2011). Meanwhile the budget for all other countries and regions decreased, thus widening the gap between countries that were prioritised under the new initiative, and those that were not. This steep decrease in funding for non-priority countries was first evident in 2014, however it widened in 2015, and grew even larger in 2016, when PEPFAR increased spending in epidemic control countries, and set aside $1 billion less for the others.

The strategy of epidemic control stitched together the science of biomedical HIV prevention with the geopolitical interests of the USA in a way that obscured the nation's declining investments in HIV abroad. While it is true that PEPFAR started to devote more resources to countries that were demonstrating potential to meet the goals of the new strategy, trends in the history of planned spending reveal these 13 countries had received more resources historically. In addition, by dedicating more funds to treatment programmes in these countries, PEPFAR privileged a budget line that could, in theory, produce the right kinds of health outcomes. Meanwhile, the organisation has left other programmes and countries sorely underfunded.

14.4 An Exit Strategy

Amid the reprioritisation of programme areas and countries to 'control' the epidemic, PEPFAR has also begun to devise a 'sustainability plan' for recipient countries and an 'exit strategy' for US bilateral support for HIV. The basic idea of the exit strategy was to allow individual countries to transition from dependence on US bilateral aid to greater utilisation of domestic resources. This was considered a 'sustainable' solution for the ongoing management of the HIV epidemic in any given country. The strategy has been strengthened by the United Nation's action plan to attain universal health coverage (UHC), which catalysed the formation of new mechanisms of accountability for greater domestic resource mobilisation. However, the exit strategy has raised significant questions about the transition to country ownership and how success could be ensured (Collins and Beyrer 2013; Esser 2014).

The clinical logics of TasP helped PEPFAR map its exit strategy and define the terms of success. If the epidemic control countries could achieve the goal of lowering new infections below HIV-related deaths, PEPFAR would begin to transfer responsibility for managing the epidemic to the countries. Thus, the estimates of infections and deaths that were inspired by epidemiological models about the population-level effects of TasP, and which PEPFAR sourced from UNAIDS, are key to articulating success. Meeting the metrics would also be the key trigger for handing over responsibility for managing the epidemic to national governments.

However since the clinical logics of TasP had influenced the organisation to devote a disproportionate amount of resources to a select group of countries, and to treatment programmes, over and above all other programme areas, the exit strategy was troubled by a central irony: namely, the programmes and countries that have been systematically under-funded would need to be funded at significant higher levels before the organisation could exit. That is, before transferring responsibility to countries, PEPFAR would need to ensure local partners had sufficient health infrastructures in place, and to do that, the organisation would need to increase the budget for governance and systems as well as management and operations. Indeed, the exit plan hinged on revitalising programme areas that have been in decline for nearly a decade.

The exit strategy also raised concerns about who would be left behind, which epidemiological models based on TasP could not adequately address. Along with the vision to 'end AIDS', PEPFAR had adopted the UNAIDS ethic to 'leave no one behind' which was applied universally across all populations for whom HIV care services could be beneficial. However, as advocates and scholars have contended, in the transition to 'country ownership' some would clearly be left behind, including sex workers, transgender people, and gay and other men who have sex with men in countries that criminalise these populations or otherwise allow lawful discrimination against them (Davis et al. 2017). In the transition toward country ownership, who would care for these key populations? This question challenged any claims to a 'sustainable' solution (Committee on the Outcome and Impact Evaluation of Global HIV/AIDS Programs 2013). This was not an issue that could be resolved by increasing funding for treatment, or other programme areas, but was exacerbated by plans for PEPFAR to pull aid.

Extending trends in planned spending associated with the strategy of epidemic control, the exit plan also stitched together the science of biomedical HIV prevention with the geopolitical interests of the USA in ways that obscured the nation's declining investments in HIV abroad. However, in this case, the over-reliance on a biomedical approach to the epidemic also presented obstacles for a successful exit.

14.5 Conclusion

The clinical logics of TasP structured PEPFAR's latest strategic initiative to achieve 'epidemic control' including the organisation's use of metrics for evaluating performance, and decisions for allocating funds to specific programs and countries. While TasP was initially conceptualised as an 'evidence-based' solution for effectively treating *and* preventing HIV, which could be consistently measured and reported on, its ability to produce the right kinds of evidence remained abstract and hypothetical. Nevertheless, PEPFAR relied on these metrics to make big claims about its own impact on the epidemic.

The effects of TasP have also been evident in the budget since PEPFAR launched the strategy to achieve 'epidemic control'. Whereas under previous initiatives to

'lead to the global response' to the epidemic, PEPFAR supported a wider variety of program areas, including by strengthening health systems, under the strategy of epidemic control PEPFAR has prioritised treatment programs over and above all others. TasP also justified disproportionate spending on a subset of countries. While this subset of 13 countries has received significantly more support since the initiative began, long-term trends in the budget also reveal that PEPFAR has prioritised these countries since its establishment as an organisation.

By adopting the clinical logics of TasP, PEPFAR justified spending on a limited number of programmes in a small set of countries that could produce what it defined as the right kinds of outcomes, and laid the groundwork for the retreat of US foreign aid. However, PEPFAR must now reckon with the blind spot of an overly biomedical approach, and answer difficult questions about who, and what, has and will be left behind.

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