

Test to Treat:

The link between primary health care, global health security, and emergency preparedness

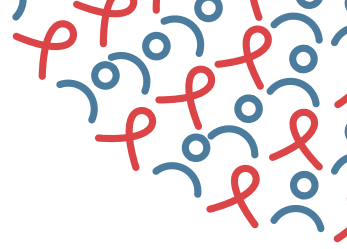
July 2024

Overview

From August 2022 to March 2024, EpiC conducted a five-country pilot of a Test to Treat (T2T) strategy for COVID-19 in Botswana, Côte d'Ivoire, El Salvador, Malawi, and Senegal. T2T, an established intervention for other infectious diseases such as HIV, tuberculosis, and malaria, offers an important strategy that connects high-level global health security efforts to pandemic prevention, detection, and response at the facility level.

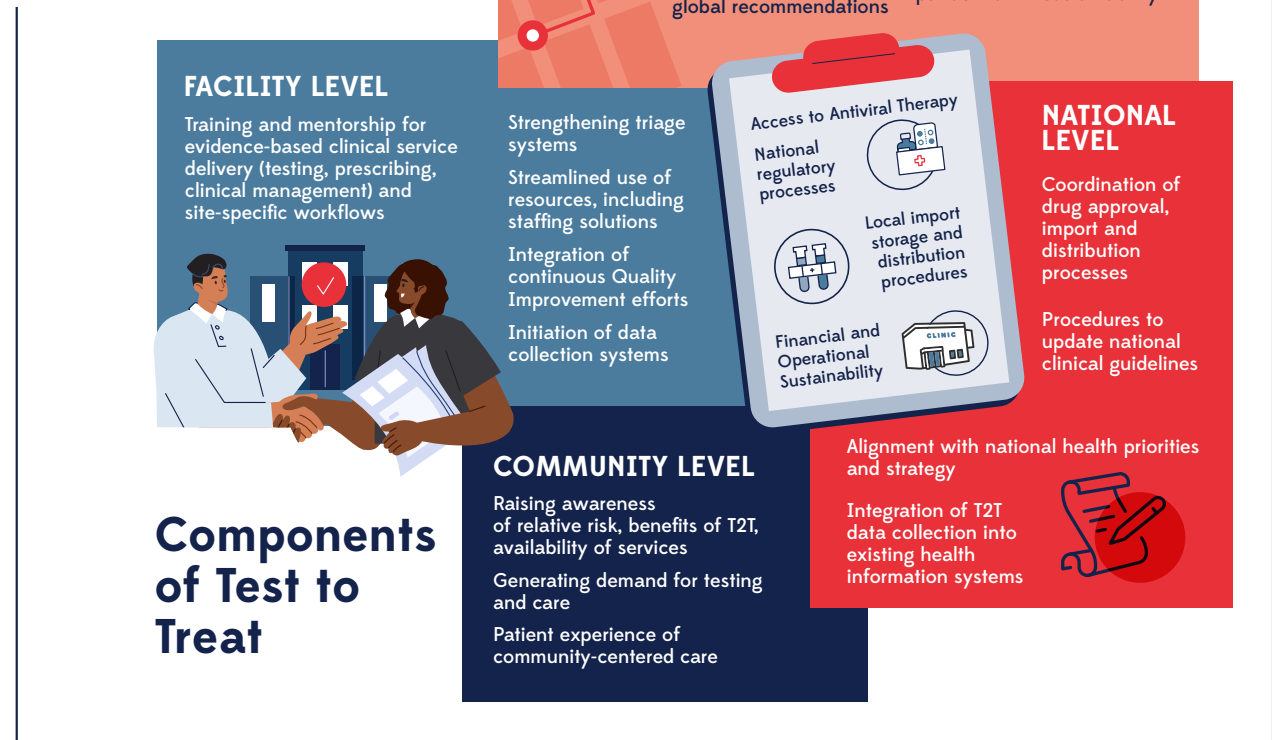
In its application to COVID-19, the goal of a T2T strategy is the early identification of COVID-19 cases followed by quick initiation of treatment with oral antivirals for patients meeting clinical criteria. EpiC collaborated with regulatory authorities, ministries of health (MOHs), subnational officials, facilities, and community-based organizations (CBOs) to implement the pilot across the continuum of care.

The purpose of the pilot was to understand the feasibility and scalability of a T2T strategy in low-resource settings and to identify components of a successful scale-up and implementation approach. After an initial preliminary analysis of the implementation context, the five countries were selected due to their feasibility and readiness environment for implementation. EpiC supported regulatory approval for tests and antiviral treatments; increased risk perception and demand for testing among populations most vulnerable to adverse COVID-19 outcomes; increased diagnostic and clinical capacity among health care workers; and strengthened management of the supply chain of test kits and antivirals. The project supported MOHs to receive regulatory approval for antivirals, trained hundreds of clinical staff and CBOs, and established a platform for countries to expand T2T nationally.



HEALTH SYSTEM RESILIENCE

- Person-centered care
- Equity
- Science-backed approaches
- Early detection and access to care
- Integration into routine processes



TECHNICAL SUPPORT DOMAINS



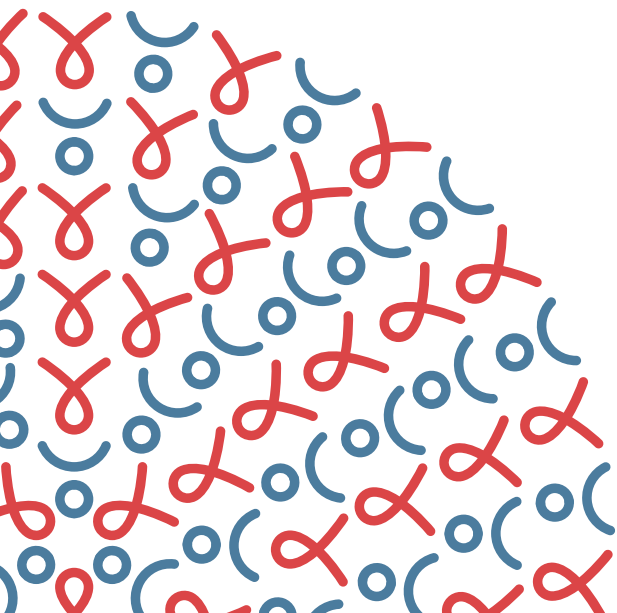
Regulatory and Policy Approvals

A key objective of the preliminary analysis was to assess readiness at the national regulatory level for the cross-system T2T intervention. The five countries reported strong government support and potential for success for the T2T strategy from a policy and regulatory perspective. This rapid analysis was conducted in June 2022, when COVID-19 remained a global health emergency and top priority.

In-country planning and preparation started in August 2022. [Clinical training materials](#) were developed by EpiC and adapted to local contexts in each of the five countries. Facility level assessments to identify assets, gaps, and opportunities were completed with efficiency to guide the next phase of implementation planning

Despite this strong start, several factors affected implementation across the countries. First, the need for immediate response to the COVID-19 emergency prompted the creation of stand-alone entities to handle emerging priorities in many countries. These entities built a system of parallel emergency response structures to address the multiple demands of the pandemic. EpiC leveraged these systems to springboard implementation of T2T, which proved challenging to navigate, particularly when the COVID-19 emergency period subsided.

Second, the timing of fluctuations in local prevalence and the shift from the emergency to the endemic phase of the pandemic had an effect on local regulatory and government buy-in. The World Health Organization (WHO) declared the COVID-19 emergency over in May 2023, reflecting a decrease in the number of COVID-19 cases and deaths reported by countries. As local health priorities shifted, the emergency response structures brought about by COVID-19 were actively dismantled. As a result, navigating regulatory drug policies proved to be a significant challenge. During the pandemic, regulatory authorities created a “waiver” program for new drugs, devices, and supplies. The declaration of the “end of the public health emergency” was more than just rhetoric; it had tangible impacts on perceptions, procedures, and priorities. Doors that would have remained open in the face of an emergency were now closed.





EL SALVADOR:

Aligning T2T with National Priorities

EpiC began supporting the COVID-19 response in El Salvador in 2021 and forged a close and supportive working partnership with the Government of El Salvador (GoES) and the Ministry of Health (MINSAL) to navigate the public health emergency. The project had been assisting with clinical case management capacity building, public health emergency preparedness planning, surveillance and reporting, and vaccination efforts, so the T2T initiative seamlessly fit into the arc of pandemic response. Furthermore, GoES had already approved and procured one antiviral (molnupiravir) and was distributing it from central telemedicine hubs for the general population. The government aimed to decentralize COVID-19 response activities, an initiative with which T2T was well aligned.

There was a clear vision for the national strategy to transition from COVID-19 emergency response to a broader and more sustainable version of national public health emergency preparedness and global health security work. T2T served as an ideal mechanism to pilot this transition to decentralization and establish a community-based sentinel surveillance system for acute respiratory syndromes. This alignment of the T2T project with national priorities, informed and supported by EpiC, created an optimal environment for implementation. In El Salvador, the focus of the T2T pilot was never centered on prescription of the antiviral—a system for access to molnupiravir was in place before T2T and cases dropped significantly throughout the course of the pilot. Nevertheless, T2T provided an ideal platform to execute other national priorities as part of a larger vision for transitioning pandemic response to decentralized care at the district and community level, and public health emergency preparedness at the national level. At the time of this writing in July 2024, EpiC El Salvador continues to engage in global health security activities, building on the foundation of success in COVID-19 response and T2T.

Strengthening Supply Chain for T2T

T2T faced significant challenges regarding the supply chain for tests and antiviral drugs, at both global and national levels in all country settings. At the global level, formal procurement requests were made by ministries of health to global manufacturers. However, this process was fraught with delays due to a series of shocks, such as the conflict in Ukraine, and pandemic-related macro trends in the economy.

At the country level, manufacturer restrictions on minimum ordering quantities created a barrier, making it difficult for implementing countries to order smaller, more reasonable amounts of drugs for pilot programs or to support smaller populations (especially in the context of reduced COVID-19 cases). To support accurate estimations, implementing countries used a quantification tool, developed by the United States Agency for International Development (USAID), to recommend drug quantities based on local prevalence. While useful, this put countries in a difficult position, risking the waste of drugs if under prescribing due to fluctuations in local prevalence. As such, the ability to order drugs in smaller amounts would have allowed for better anticipation of needs and changes in demand.

Finally, at the country level, lags in drug delivery to sites, drug expiration dates, and central storage of drugs (in adherence to MOH regulations) further complicated the process and delayed patient access to antivirals.



SENEGAL:

Quantifying Projected Need for Tests and Treatment

Amid the fluctuating prevalence of COVID-19 in August 2022, EpiC Senegal used the USAID quantitative tool to estimate local need for drugs and tests. The tool was crucial for understanding projected need for rapid detection tests (RDTs) and antivirals, enabling EpiC to order appropriate quantities. It also fostered MOH buy-in, by allowing insight into how product quantities were calculated. As a result, EpiC Senegal found there was no need for procurement of RDTs. Procurement of antivirals was supported by The Global Fund and USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM). EpiC expected future use of this tool to be further informed by patient preference, for example, knowing they preferred Paxlovid (nirmatrelvir co-packaged with ritonavir) to molnupiravir.

Implementation Planning at Selected Sites

A key goal of the T2T strategy was to implement across multiple levels of a country's health system to understand patient pathways and interactions from community to district health centers. These facilities, representing a "slice of the system," were evaluated by country teams and MOHs using the Exploration, Preparation, Implementation, Sustainment (EPIS) pre-implementation framework to determine appropriateness of context for implementation. This slice included a district or regional hospital, several satellite health facilities, and communities living in the catchment areas. Site readiness (enablers), including staffing and current COVID-19 work, as well potential barriers to implementation were evaluated.

Once sites were selected and approved by MOHs, EpiC worked closely with implementation sites to engage with staff and conduct trainings, including support for task shifting (as needed), navigating staff buy-in to the project, and ensuring constant communication and support to the sites across clinical, regulatory, supply chain, monitoring and evaluation (M&E), and demand generation activities.



MALAWI:

Adapting to Emerging Contextual Challenges

When Tropical Cyclone Freddy struck Malawi in March 2023, causing widespread destruction across the country, the T2T Malawi team was forced to go back to the drawing board to reconsider the sites of implementation. Considering the new contextual challenges and local needs brought on by the cyclone, the team pivoted strategy to integrate screening for cholera, which emerged as a public health threat, into T2T implementation, and worked closely with newly selected sites to meet public needs. This step ensured the T2T project aligned with current government priorities, addressed barriers caused by the cyclone, and built on current system strengths.

Building Clinical Case Management Capacity

A comprehensive package, including training resources, drug reference guides, and an interactive self-paced virtual training offering, was swiftly developed to build the capacity of clinicians at T2T implementing sites. However, three key challenges emerged.

First, staff shortages and turnover made it difficult to retain technical knowledge of the processes at site level. These shortages prompted already overworked staff to resist training on and incorporating new processes into their workstreams. While the T2T team attempted to address this turnover and loss of technical knowledge via the development of a virtual, self-paced hybrid T2T training curriculum, uptake of this virtual curriculum at the facility level was minimal.

Second, clinical guidelines were continually changing as the understanding of risks, symptom presentation, and relative efficacy of antiviral medication shifted. Unfortunately, there was no budgeted mechanism to continuously update the training materials as new guidelines were announced by WHO. Moreover, constant changes in staff structures and information made it difficult for staff to keep up, and globally developed clinical tools were often unavailable in country. For example, the Liverpool Drug Interaction Tracker, while available as a website, was not available as a downloadable app in most countries, and therefore could not be used offline by clinicians at facilities during their interactions with patients.

Finally, the promotion of self-testing was met with hesitancy from many governments, despite the potential to decentralize COVID-19 care. This hesitancy meant demands on health care workers at the site level were maintained, forgoing opportunities to decrease workloads. As such, site-specific support for new workflows was crucial, requiring interdisciplinary team process mapping, dedicated quality improvement support, and occasional minor infrastructure upgrades. It is worth noting that not all governments felt this way, with Malawi MOH planning to distribute assisted self-tests following project closeout in May 2024.



EL SALVADOR:

Leveraging a Quality Improvement Approach to Clinical Training

EpiC El Salvador considered several approaches for training and preparing clinical teams to implement T2T at the site of direct patient care, beyond sharing basic clinical and pharmaceutical information about RDTs and drugs. When basic training sessions were offered to clinical staff at the pilot sites, it quickly became clear that the teams also needed support with how the T2T strategy changed patient flow and processes at the facility level. For instance, in the first few weeks of implementation, there were complaints of excessive wait times for patients, or patients leaving before they could be seen to get a prescription. Staff turnover and reassignment were pervasive in many health facilities – which meant information shared with staff often left the teams when the staff member departed.

EpiC El Salvador navigated these challenges by adopting a mentorship-based quality improvement (QI) approach focused primarily on small changes to site-specific workflows that streamlined clinical activities, reduced wait times, improved patient and provider experience, and improved clinical service delivery of T2T as an integrated part of routine sick care at primary health care facilities. The team also engaged in longer-term mentorship to support local champions as a buffer against staff turnover to ensure that the essential information for T2T was not lost if key staff members departed or were reassigned out of the pilot site.

Generating Demand for Testing and Treatment

To generate demand for T2T, EpiC used a systematic approach to rapidly develop, implement, and monitor social and behavior change (SBC) strategies and activities tailored to the local context. In the design process, the team explored (1) what behaviors need to be targeted to increase public engagement with testing and treatment for COVID-19 and what are the barriers and facilitators to the adoption of these behaviors; and (2) within the context of the T2T pilot implementation, how to strike a balance between generating demand for services and the in-country realities of availability of COVID-19 tests and antiviral drugs. While the SBC strategies for demand generation drew on global best practices, including the use of larger scale mass media channels and platforms, they also leveraged and adapted locally tailored solutions and channels at the site level to address local challenges and increase reach, relevance, and effectiveness. For example, within T2T there was a need to reach older adults and people with complex chronic diseases, populations not often targeted through traditional health promotion programs. These populations are often harder to reach with standard SBC approaches and media channels, and therefore required tailored strategies.

COVID-19 fatigue, defined as the general trend of waning interest in, or concern for, COVID-19, resulted in a direct proportional decrease in COVID-19 risk perception. This phenomenon presented another clear challenge. Not only was the public tired of hearing about COVID-19, but by August 2022, the public risk perception for COVID-19 was low. This not only affected health-seeking behaviors for COVID-19 (i.e., consultation, testing, and treatment), but also the perceptions of health care workers tasked with establishing new triage and testing workflows for T2T. In hindsight, more emphasis on targeting health care worker perceptions and behavior may have further supported demand generation strategies, in addition to targeting public perceptions.



BOTSWANA:

Using a Person-Centered Approach to Engage Hard-to-Reach Groups with T2T

In many countries around the world, young adults, mainly women, seek most primary care visits. The target population for the T2T initiative—those most at risk for developing severe complications of COVID-19 and therefore eligible for treatment with oral antiviral therapy—was older adults and adults with chronic diseases. Members of this population experience many barriers to care, including high rates of being homebound or reliance on others for transportation to facilities. When the EpiC Botswana team observed a low rate of clinical encounters with this group in the first few weeks of implementation despite a broad-reaching, community-based demand generation strategy, they shifted gears to a more targeted, person-centered approach. Key examples included placing materials and staging outreach activities at local post offices on the days that older people would pick up their pension checks, at local ear and eye clinics where they went for glasses or hearing devices, or at health facilities with chronic care programs.

The EpiC team also identified a low rate of engagement with T2T services among men of all ages; therefore, they sponsored soccer tournaments in several districts with on-site educational material on the importance of early testing for both men and their family members.

Monitoring, Evaluation, and Learning (MEL) and Health Information Systems

Prior to implementation of T2T, the countries had a wide variety of data collection tools and systems, including a combination of paper-based and electronic. Four of the five were using electronic systems, at least in part, to collect COVID-19 data, and one country was using a paper-based system. EpiC took this opportunity to assist with data collection enhancement and learning. Throughout the project, some countries made system and/or data collection tool improvements; in others, DHIS2 e-tracker modules were created. However, progress was slow due.

Key challenges included navigation of staff capacity and turnover, availability of site resources, varying quality of data entry, and staff buy-in. The teams worked closely with facility staff to provide training and leveraged existing or developed new tools or systems that would be least burdensome to staff and avoid the creation of parallel systems that would require duplicate effort from staff. Teams also ensured that every site had sufficient data collection forms (paper-based), computers (for electronic), and stable internet connectivity to support reporting.



SENEGAL:

Integrating National Information Systems to Align with COVID-19 Response

At the start of the T2T project in Senegal, DHIS2 was being used by the MOH to collect COVID-19 data. However, EpiC Senegal quickly recognized the need for a streamlined health information system not only to ensure local COVID-19 prevalence estimates aligned with government estimates (to avoid the reporting of different figures), but also to ensure information publicized by EpiC to stakeholders was validated as true by the government. EpiC Senegal worked closely with MOH to develop a DHIS2 e-tracker to facilitate T2T data collection across 45 sites. The team trained 87 staff on T2T data collection and ensuring points of contact were identified for data verification and validation. The team also managed the data entry system despite reporting challenges associated with national labor movements. EpiC Senegal's close relationship with MOH, which positioned T2T as a government priority from the beginning, allowed the team to build a nationally integrated health information system.

Reflections and Recommendations

As the world moves forward from the COVID-19 pandemic, many lessons that emerged during this time are crucial for responding to future emergencies and have shaped current global health security approaches.

COVID-19 should be considered one possible differential diagnosis for any acute respiratory illness and incorporated into routine primary healthcare/acute respiratory infection guidelines. As countries prepare for future public health emergencies, strategies for clinical case management during public health emergencies should be designed to be less disease specific, and more focused on rapid response. This includes principles of infection prevention and control, general use of rapid tests, clinical triage and management of patients, reporting structures, and risk communication and community engagement. Doing so would prepare a wider range of public health workers to flexibly respond to a potential outbreak.

Though the T2T project started about two years after COVID-19 emerged, the systems that were rapidly set up to respond to the pandemic impacted the ability of the project to move forward. Parallel systems and regulatory authorities, often requiring different documentation, proved difficult to navigate and often required longer waiting times while the multiple groups communicated with each other. Furthermore, emergency use authorization for drugs is not sufficient for the dynamics of an evolving public health emergency. As experienced through the T2T project, once a public health emergency has been declared as having ended, novel drugs should continue to have another fast-tracked option for authorization. While both these processes are intended for use during a national emergency, these systems need to be considered outside of an emergency context to ensure they are aligned and ready for response.

The pandemic made clear that clinical and nonclinical staff are the backbone of any health intervention and must, therefore, be supported, invested in, and augmented when necessary to achieve public health initiatives. First, engaging those who are implementing the intervention is imperative. Leaders may do this by working to understand what contextual factors allow implementors to better navigate the intervention and by ensuring that systematic incentive structures are aligned with the facility context. Facility-level champions are also crucial to ensure bidirectional communication between the site and implementing partner, to act as a site-level resource for staff members, and to encourage engagement with the implementation activities. These champions should be adequately supported, incentivized, and included in the ongoing design and implementation as activities roll out. The CFIR model and other implementation science frameworks may be useful to identify and navigate contextual barriers from the beginning of an intervention.

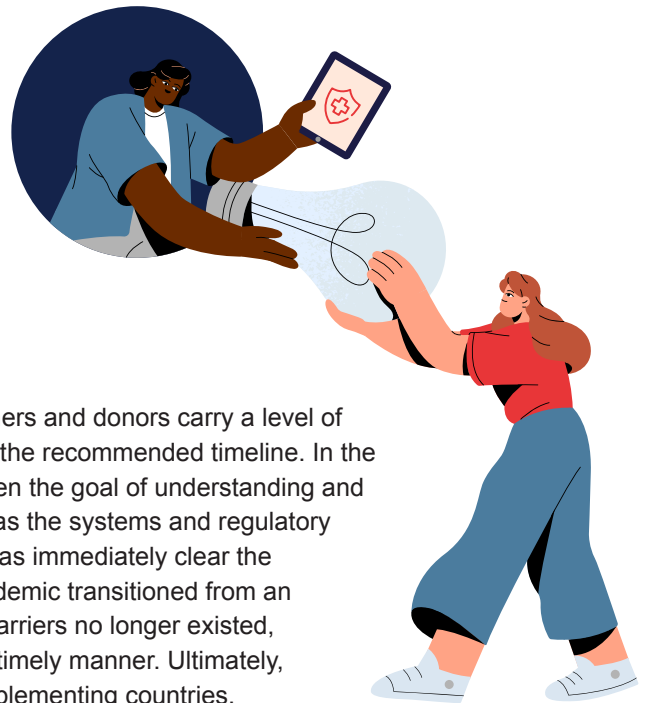


Second, human resources for health (HRH) shortages are pervasive around the world and create challenges to implementation at the facility level. Projects like T2T should acknowledge these shortages and design implementation within the existing constraints in advance, rather than discuss them as a limitation in hindsight. Furthermore, training (on topics such as clinical care, demand creation, MEL) should be recurrent and grounded in a continuous mentorship model to refresh current staff, mitigate the impact of staff turnover, and allow for bidirectional open communication about on-the-ground challenges, community concerns, and updates to clinical guidelines based on new evidence. Projects must plan and budget for the need to update and deliver training materials as evidence evolves, especially in the case of a novel health emergency.

Third, local organizations play a crucial role in informing, engaging, and supporting communities during outbreaks. They already carry a wealth of knowledge about the health system and the community. It is important to build the capacity of these CBOs where possible, partner where possible, and ensure they are engaged in the early planning and implementation of risk communication and community engagement interventions.

Finally, in bringing a project to a community, implementing partners and donors carry a level of responsibility to consider feasibility in the current context within the recommended timeline. In the case of T2T, the original six-month timeline was unrealistic. Given the goal of understanding and testing systems (both existing and possible new ones), as well as the systems and regulatory bodies with which the countries needed to interact to do so, it was immediately clear the timeline would be a challenge for this large task. When the pandemic transitioned from an emergency to an endemic situation, the urgency to overcome barriers no longer existed, which created additional barriers to completing this project in a timely manner. Ultimately, this project ended up being longer than six months in all five implementing countries. Last-minute timeline extensions caused challenges for staffing within EpiC teams and may have eroded some credibility among both government and community partners. As such, collaborating closely with local implementers and MOHs from the planning stages of the intervention is crucial for setting realistic expectations among partners and fostering positive relationships.

As the world moves toward a focus on global health security, the COVID-19 pandemic and implementation of the T2T project demonstrated the importance of investment in a strong primary health care system that is empowered to act as the first point of care (and first point of response) in the context of an emerging public health emergency.



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