Health workers in Thailand working with point-of-care G6PD tests
Photo by the Division of Vector Borne Diseases (DVBD)

APMEN Case Study

Thailand's Experience with Tafenoquine:
A Roadmap for Integrating Radical Cure into Routine Hospital Systems

Medicines for Malaria Venture
APMEN Asia Pacific Malaria Elimination Network

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The DVBD is under the Department of Disease Control (DDC), Ministry of Public Health, Kingdom of Thailand. The DDC's mission is to research, develop, standardize, apply and transfer knowledge and technologies to prevent and control diseases effectively. We also acknowledge the contribution of other partners in the tafenoquine rollout in Thailand, particularly the WHO country office and different civil society organizations.

ABOUT APLMA–APMEN

Uniting the Heads of Government across Asia Pacific to achieve malaria elimination by 2030, the Asia Pacific Leaders Malaria Alliance (APLMA) was formed at the behest of the Prime Ministers of Australia and Viet Nam at the 8th East Asia Summit in 2013. APLMA serves as a regional mechanism for technical advocacy, health diplomacy, and high-level convenings that build and sustain momentum towards the elimination goal.

Since 2017, APLMA has proudly hosted the Asia Pacific Malaria Elimination Network, or APMEN. This robust and inclusive framework supports national malaria programmes across the region by mobilizing resources, sharing technical expertise, and promoting peer-to-peer learning and evidence generation. All of this strengthens APLMA's push for high-level political action. By uniting regional partners, this collaborative structure accelerates progress towards the goal of malaria elimination in the Asia Pacific by 2030.

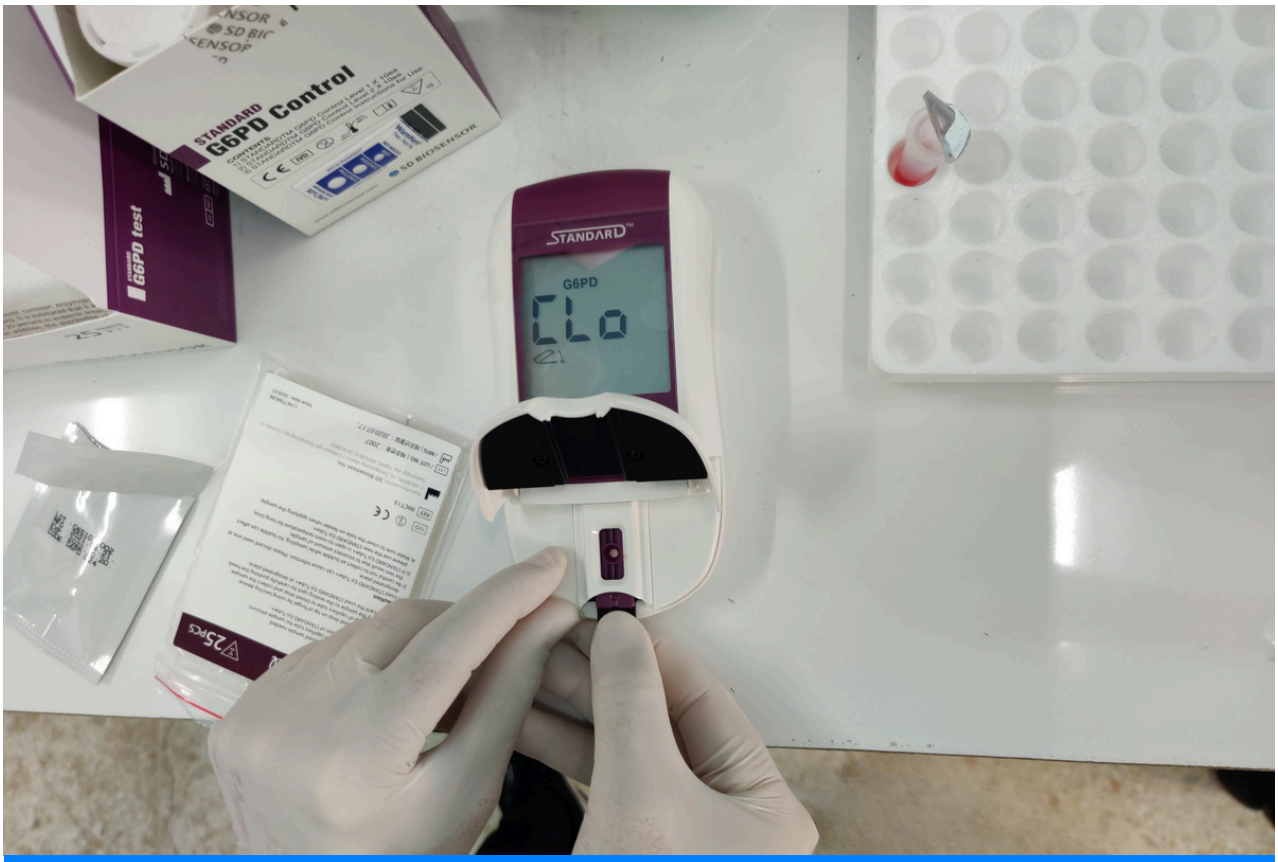
About Asia Pacific Malaria Elimination Network (APMEN):
Coordinated by the APLMA secretariat, APMEN works through partnerships with governments, national malaria programs, academic & research institutes, private sectors, UN agencies, and civil society to generate local evidence and build capacity. Through working groups on Surveillance & Response, Vector Control, and Vivax, and interest groups on climate & environmental change, border malaria, and outdoor transmission, APMEN facilitates technical exchange across stakeholders, delivers technical malaria expertise and research, and shares evidence-based practices for malaria elimination in the region.

1. Introduction: A New Chapter in Thailand's Malaria Elimination Journey

The global and regional goal of malaria elimination hinges on effectively tackling *Plasmodium vivax*, a persistent parasite that poses unique challenges to public health systems (1). This case study serves as a practical roadmap for national malaria programs, detailing Thailand's pioneering journey in integrating the single-dose radical cure, tafenoquine (TQ), into its routine health system. This document deconstructs Thailand's journey into distinct phases, from regulatory groundwork and evidence generation to systemic integration and adaptive management, providing a replicable framework for other countries considering tafenoquine for their radical cure policy.

The core challenge of *P. vivax* lies in its ability to remain dormant in the liver as hypnozoites, causing relapsing episodes of illness - weeks, months, or even years after the initial infection (2). These relapses not only prolong patient suffering and increase the burden on health systems but also sustain a silent reservoir of parasites that fuels ongoing transmission (3). The introduction of an effective, single-dose radical cure represents a monumental step forward in breaking this cycle.

This initiative was made possible in Thailand through a robust collaboration between Thailand's national health authorities and international partners. The effort was led by the Division of Vector-Borne Diseases (DVBD) of the Thai Ministry of Public Health, with additional financial support from the Global Fund, technical support from World Health Organization (WHO) and Medicines for Malaria Venture (MMV), pharmacovigilance support from Thai FDA, community engagement from civil society organizations, and technical advocacy from the APMEN Vivax Working Group (4). Together, these organizations navigated the scientific, regulatory, and operational hurdles required to bring this innovative tool to patients. To fully appreciate this achievement, it is essential to first understand the specific epidemiological context that drove the need for change in Thailand.



Using a G6PD test kit in a Thai Division of Vector Borne Diseases (DVBD) lab. Photo by DVBD.

1.1. The Shifting Malaria Landscape in Thailand

Understanding the specific epidemiological context is crucial to appreciating the strategic imperative for a new treatment tool in Thailand. As the country made significant strides in controlling Plasmodium falciparum malaria, the distinct challenge posed by *P. vivax* became increasingly prominent (5). Over time, *P. vivax* has emerged as the primary obstacle standing in the way of Thailand's national malaria elimination goal (6).

In recent years, *P. vivax* has become the dominant species, now accounting for more than 90% of all malaria cases in the country. This epidemiological shift prompted Dr. Cheewanan Lertpiriyasuwat, former Director of the DVBD, to describe the parasite as the "thorn in the side of Thailand's malaria elimination efforts." The persistence of *P. vivax* highlighted the limitations of the existing standard of care for preventing relapse.

The standard treatment regimen required patients to complete a 14-day course of primaquine. However, ensuring patient adherence to this two-week course proved to be a significant challenge, particularly for at-risk populations in remote areas where regular follow-up is difficult (7). Patients often stop taking the medication once their initial symptoms subside, leaving them vulnerable to relapse and allowing the transmission cycle to continue.

It was in this context that tafenoquine (TQ) was introduced as a critical new tool. Its primary advantage is that it provides a radical cure in a single dose, a characteristic that directly addresses the patient adherence issues associated with the 14-day primaquine regimen (8). This innovation offered the potential to dramatically improve treatment effectiveness in real-world settings.

Standard treatment (Primaquine)	New Tool (Tafenoquine)
14-day course of daily tablets required for radical cure.	Single 300 mg dose provides radical cure (Two 150mg tablets).
Patient adherence is a significant challenge, especially after initial symptoms improve.	Single-dose regimen facilitates patient adherence and allows for directly observed therapy.

The introduction of tafenoquine marked a paradigm shift in the approach to *P. vivax* treatment. However, making this new tool available to patients required navigating a complex landscape of policy, regulatory approval, and international partnership.

2. Laying the Groundwork: From Global Pipeline to National Approval

The successful introduction of any new health technology depends on strong partnerships and a clear, efficient regulatory pathway. Thailand's success in bringing tafenoquine from the global development pipeline to national use was built on a foundation of international collaboration, regional leadership, and decisive national action.

A pivotal regulatory milestone was achieved in March 2020, when Thailand became the first country in Asia to register tafenoquine for the radical cure of *P. vivax* in patients aged 16 years and older (9). This was the result of a forward-thinking partnership between the Australian Therapeutic Goods Administration (TGA) and the Thai Food and Drug Administration (FDA), who worked together through the Indo-Pacific Regulatory Strengthening Program to fast-track the review process. Tafenoquine itself was developed through a product development partnership between GSK and Medicines for Malaria Venture (MMV), demonstrating the power of public-private collaboration in addressing global health needs.

While national regulatory approval was a critical achievement, it was only the first step. To confidently move from policy to practice, the Thai Ministry of Public Health recognized the need for local, real-world evidence to guide the safe and effective implementation of tafenoquine within its unique health system. This led to the design of the ARCTIC study.

2.1. *The ARCTIC Study: Building Confidence with Real-World Evidence*

Operational research is a critical step in de-risking the rollout of a new medical intervention. Before tafenoquine could be deployed at scale, it was essential to confirm its safety and feasibility within the routine operations of Thailand's public health system. The Assessing Radical Cure Treatment in Routine Care (ARCTIC) study was the crucial link between policy approval and national practice, providing the real-world evidence needed to build confidence among policymakers, clinicians, and patients (10).

The primary objective of the ARCTIC study was to assess the operational feasibility and safety of administering tafenoquine or primaquine after quantitative glucose-6-phosphate dehydrogenase (G6PD) point-of-care testing within the Thai public health system (10). Both tafenoquine and primaquine can cause severe hemolysis in individuals with G6PD deficiency, making accurate G6PD testing an essential prerequisite for treatment.

The study's methodology was designed to reflect real-world conditions:

- **Study Design:** A prospective, observational, multi-centre study conducted between May 2022 and September 2023.
- **Locations:** Seven sites across two high-burden provinces, Yala and Mae Hong Son, including community hospitals and specialized malaria clinics.
- **Participants:** 187 patients aged ≥16 years with confirmed, uncomplicated P. vivax malaria were enrolled.
- **Core Intervention:** A point-of-care quantitative G6PD test was used to guide the appropriate radical cure regimen: single-dose tafenoquine for patients with normal G6PD activity, or a 14-day or 8-week primaquine regimen for those with intermediate or deficient G6PD activity, respectively.

The study yielded overwhelmingly positive results (10), confirming that the new treatment algorithm could be safely implemented:

- **Operational Feasibility:** The study demonstrated that quantitative G6PD testing was operationally feasible in routine settings. A total of 100% of enrolled patients successfully completed the point-of-care test, proving the tool could be effectively integrated at both community hospitals and malaria clinics.

- **Treatment Appropriateness:** Adherence to the treatment algorithm was exceptional. The appropriate use or non-use of tafenoquine according to the patient's G6PD status was 100% (95% CI 97.2, 100). This confirmed that healthcare workers could correctly interpret test results and prescribe the proper medication.

- **Safety Profile:** The study found no confirmed cases of drug-induced acute hemolytic anaemia (AHA). While some patients reported adverse events possibly related to hemolysis, such as fatigue (which is also a common symptom of malaria itself), there were no concerning safety signals. The four serious adverse events reported during the study were assessed by physicians and not considered to be related to the treatment.

The study's conclusion provided a clear and confident endorsement for moving forward (10):
"The use of quantitative G6PD testing prior to tafenoquine or primaquine was operationally feasible and had acceptable safety when deployed in community hospitals and malaria clinics in Thailand. Consequently, the Thailand Ministry of Public Health has taken the decision to fully implement this radical cure treatment algorithm across the six provinces along the Thailand–Myanmar border."

These robust findings provided the green light for the Ministry of Public Health to proceed with a carefully planned national rollout, underpinned by a structured training program and a proactive pharmacovigilance system to ensure patient safety at scale.

Training for glucose-6-phosphate dehydrogenase (G6PD) point-of-care testing. Photo by DVBD.

2.2. Navigating an interconnected Health System

Thailand's health services operate through two interconnected structures: the malaria program, led by DVBD under the Department of Disease Control, and the general health service system under the Office of the Permanent Secretary (11). Tafenoquine's rollout required close coordination across both systems.

This dual structure, common in many countries of the region, makes Thailand's experience especially relevant as a model for how malaria programs and general health services can work together to deliver innovative treatments safely.

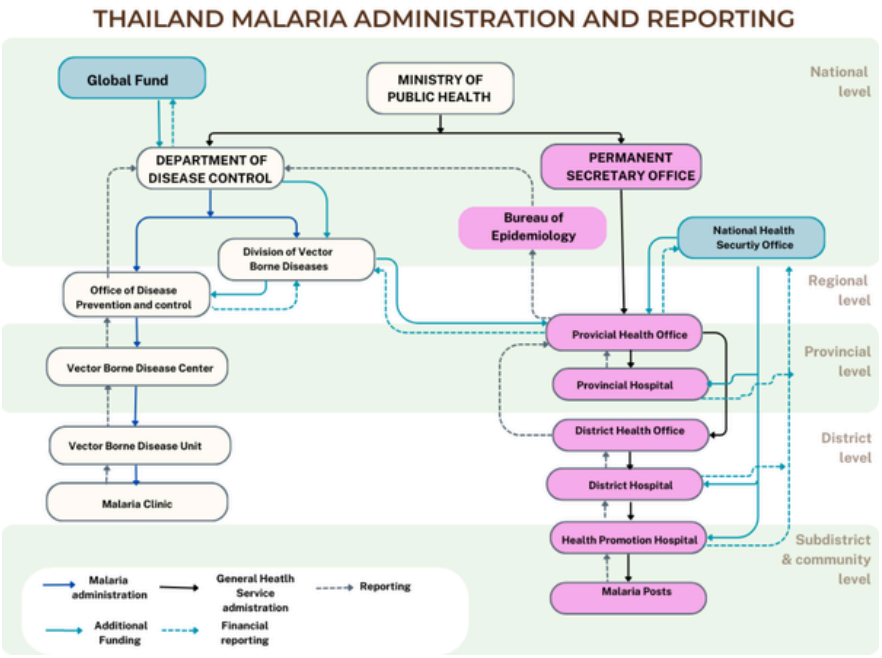


Figure 1. Anti-malarial public health administration and reporting in Thailand

2.3. Policy and Guideline Integration

Tafenoquine was officially included in the 2025 National Malaria Treatment Guidelines (12) (Figure 2). To support this, the DVBD developed a standardized package for healthcare workers containing information leaflets, training materials, reporting forms, and job aids, ensuring a consistent and high-quality standard of care across all participating facilities (13, 14).

Figure 2. Timeline of tafenoquine registration to integration in national treatment guidelines

The following patient algorithm is recommended by the 2025 National Treatment Guidelines (12):

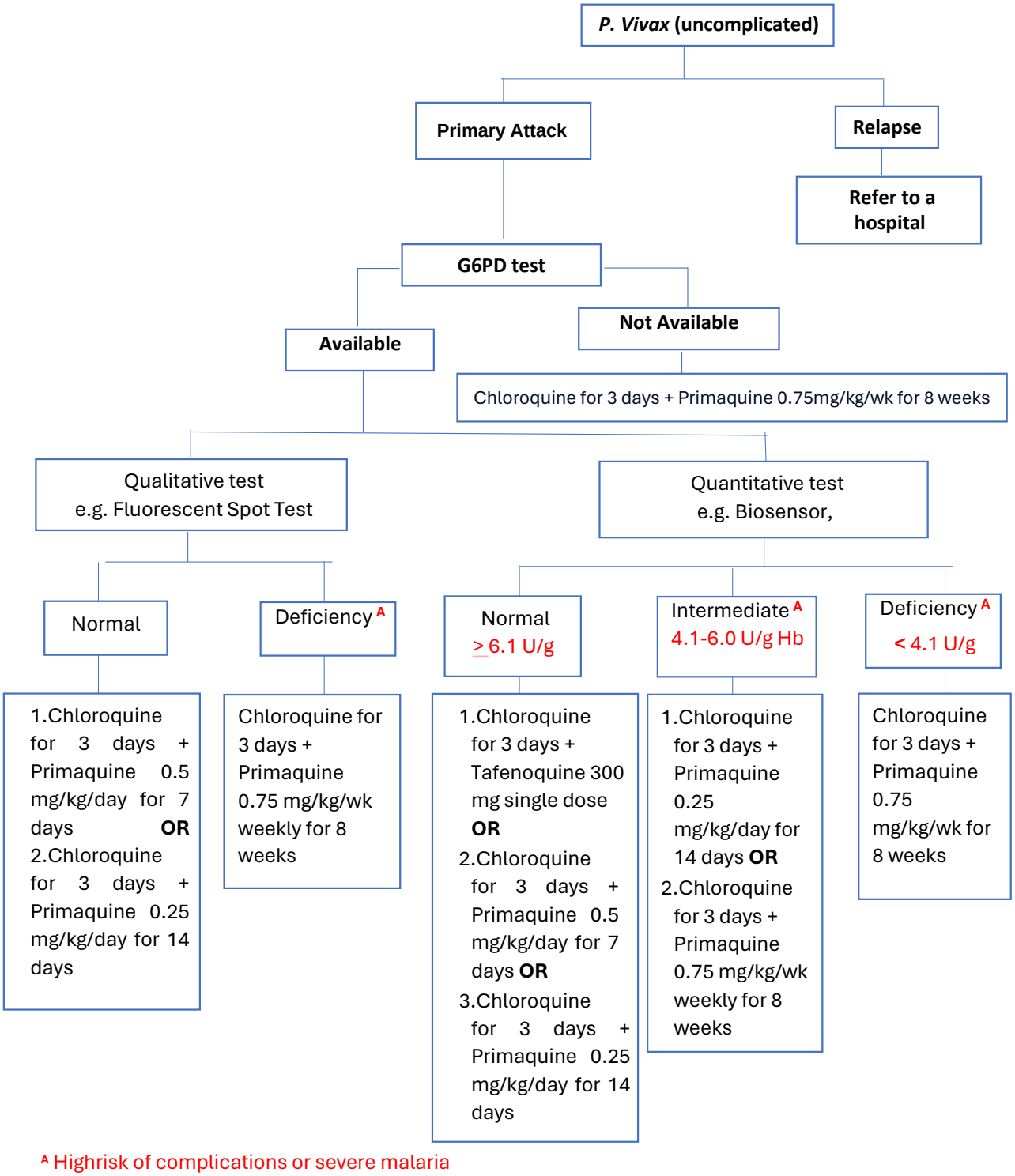


Figure 3: Treatment of uncomplicated vivax malaria in Thailand

2.4. *Building a Resilient System for Safe National Rollout*

Moving from a successful pilot study to a scaled national program required the development of a robust operational framework. The success of the tafenoquine rollout depended not just on the drug itself, but on a resilient system of training, data management, and proactive safety monitoring. This systematic approach was essential for building the capacity and confidence of frontline healthcare workers.

The rollout strategy was built on several key components:

1. **Training and Capacity Building:** Multidisciplinary teams from participating hospitals: including doctors, nurses, pharmacists, and lab technicians, received structured training. This covered patient screening, G6PD testing, correct dosing, follow-up schedules, and adverse event (AE) monitoring. The training combined central workshops with on-site mentorship to ensure practical skills were developed (15).

2. **Digital Integration and Support:** To streamline care, G6PD test results and tafenoquine prescriptions were integrated into hospital electronic medical records (EMRs). A dedicated LINE group was established, creating a real-time communication channel where hospital staff could consult with clinical experts and DVBD focal points on any clinical or safety questions, fostering a supportive and responsive environment.

3. **Supervision and Peer Learning:** Continuous quality improvement was driven by quarterly on-site supervision and monthly virtual meetings. Furthermore, peer-learning networks coordinated by DVBD allowed hospitals to share experiences and best practices, which helped build confidence and accelerate the adoption of the new protocols.

4. **A Proactive Pharmacovigilance Framework:** A cornerstone of the national rollout was a proactive and well-defined pharmacovigilance system to ensure patient safety. The system's foundation was established through Thailand's Health Product Vigilance Center (HPVC), which was assigned to initiate active surveillance of tafenoquine as part of the WHO's Smart Safety Surveillance (3S) project (16). This provided an internationally recognized framework for monitoring the safety of a new medicine.

3. National Rollout of Tafenoquine

Tafenoquine was introduced as part of the radical cure strategy through a phased national rollout coordinated by DVBD, beginning with facility selection and readiness assessments, followed by nationwide deployment of quantitative G6PD testing and supervised implementation across endemic provinces.

3.1. Health-facility readiness and selection

Hospitals were selected based on epidemiological need, provincial confirmation, formal expression of interest, staff training completion, logistical preparedness, and checklist-based readiness verification. Facilities were required to demonstrate capacity in personnel, supplies, reporting systems, and AE/SAE pharmacovigilance. All participating hospitals also provided quantitative G6PD testing using SD Biosensor, with results regularly submitted to DVBD for quality assurance.

3.2. G6PD testing and data management

After national training, hospitals received SD Biosensors and test strips, and began parallel pilot use and routine diagnostics. No operational issues were reported. Provincial and central teams accessed testing results through a shared database, enabling real-time monitoring and troubleshooting. Monthly quality control checks were recommended, along with those for new supply batches. A comparative evaluation of Fluorescent Spot Test (FST) and quantitative SD Biosensor data showed closely aligned proportions of G6PD-deficient results.

3.3. Implementation timeline and coverage

The rollout began with training in late 2023, G6PD data collection from February 2024, and the first administration of TQ on 12 June 2024. The program expanded from 6 to 11 provinces, including Mae Hong Son, Tak, Kanchanaburi, Phetchaburi, Ratchaburi, Prachuap Khiri Khan, Chumphon, Ranong, Uthai Thani, Rayong, and Bangkok. During the first year of implementation, supervision visits, continuous reporting, and regular data review ensured standardized practice across hospitals.

By November 2025, the national program had achieved significant reach:

- **Scale:** A total of 782 patients were treated with tafenoquine across 28 hospitals that had initiated treatment out of 33 that had achieved operational readiness in 11 provinces.
- **Patient Profile:** The cohort included 584 males and 234 females, with a mean age of 35.68 years. Approximately 64% of patients were Thai nationals, while 31% were migrants, reflecting the diverse populations affected by malaria along Thailand's borders.
- **Safety:** The robust pharmacovigilance system reported zero serious adverse events or adverse drug reactions linked to tafenoquine, reinforcing the drug's strong safety profile when used with G6PD testing.

3.4. *Follow-up and adherence outcomes*

Patient follow-up was conducted on Days 7, 14, 28, 60, and 90 to monitor safety and treatment outcomes. While Day 7 follow-up data were not collected through the online Malaria information system (MIS), these data were available from hospital records. Return rates for scheduled follow-up visits after tafenoquine (TQ) ranged from 37% to 54%, while only 17% of patients completed all scheduled visits. Within the Integrated Drug Efficacy Surveillance (iDES) system, Day 14 follow-up rates declined from 53.5% in 2024 to 42.6% in 2025 and 39.7% in 2026. Although overall follow-up completion remained low, Day 14 follow-up may serve as a pragmatic proxy indicator for routine programmatic monitoring. Loss to follow-up was particularly high among migrant populations.

Follow-up data was collected and analyzed using the following methods:

- **Reporting Forms:** Data was derived from hospital drug-use reporting forms ("Tafenoquine usage report form") submitted by hospitals via email.
- **MIS and iDES Integration:** Reports were integrated with patient data from the Malaria Information System (MIS) and iDES to track outcomes for all patients, including those tracked by local Vector-Borne Disease Units (VBDU).

Adherence issues were assessed through patient and staff feedback, comparing the TQ regimen to the older multi-day regimen:

- **Patient Preference:** Patients reported that they felt good about taking only one pill (single-dose TQ).
- **Primaquine Challenges:** Patients acknowledged that they often fail to complete the 14-day Primaquine regimen once their symptoms improved (usually after 3 – 4 days), indicating adherence difficulties with multi-day regimens. The TQ regimen was intended to help address this specific problem of incomplete adherence.

To support follow-up and adherence, the program utilized a multi-channel follow-up system:

- **Methods:** Strategies included phone calls, monitoring by Village Health Volunteers (VHVs) or community health workers (CHWs), support from Civil Society Organizations (CSOs), local facility referrals, and blood tests during patient follow-up at the malaria clinics.
- **Patient Tools:** Patients were provided with TQ treatment cards (specifying the schedule and G6PD status) and received SMS/phone reminders to improve adherence.
- **Follow-Up Documentation:** The follow-up procedures were required to be documented using standardized reporting forms.

During the first year of implementation, supervision visits, continuous reporting, and regular data review ensured standardized practice across hospitals. Photo by DVBD.

3.5. *Safety monitoring and pharmacovigilance*

The reporting process was integrated directly into the implementation structure. Hospital pharmacists played a central role, assessing any potential adverse events and reporting them to the national database, Thai Vigibase. To ensure comprehensive oversight, the DVBD formally requests and reviews these reports monthly from the hospitals and from HPVC on a quarterly basis. This created a direct and regular line of communication between clinical sites and national regulatory bodies. This integrated safety system provided the necessary oversight to proceed with a confident national rollout.

The primary method for safety monitoring involved scheduled patient visits and counseling.

- **Scheduled Follow-up Visits:** Patients were required to undergo safety monitoring specifically on Day 7 after drug administration. This key visit was conducted to check for delayed adverse events (AEs), particularly Acute Hemolytic Anemia. Follow-up for treatment outcomes and general monitoring also occurred on Days 14, 28, 60, and 90.
- **Observation Period:** Some hospitals chose to hospitalize patients to ensure adherence and monitor for potential side effects, observing patients for a minimum of 1–3 hours after administration for any immediate reactions.
- **Patient Education and Self-Monitoring:** Prior to receiving the drug, patients were given verbal and written instructions on possible side effects, symptoms to report, and when to seek care. They were also provided with a patient card and leaflet summarizing key points and emergency contact channels. Patients were instructed to observe their own condition and report back to the hospital as soon as possible if they experienced symptoms of an adverse event.

Hospitals and central authorities used clear, expedited communication channels for timely response to safety issues:

- **Immediate Response for SAEs:** When a Serious Adverse Event (SAE) was detected, the hospital had a protocol to stabilize the patient first, and then report the SAE immediately via the dedicated LINE group and email. A formal report must be submitted to the DVBD within 24–72 hours.
- **Routine Internal Review:** Hospital Patient Care Teams were required to conduct internal monthly reviews of all TQ-related AEs to inform training and continuous quality improvement.
- **Standardized Reporting Forms:** Hospitals submitted monthly reports on patient treatment and adverse events (AEs) to the DVBD via email using standardized reporting forms.
- **Documentation and Review:** All safety follow-up procedures were conducted in accordance with the Operational Manual for Monitoring the Safety of Tafenoquine Use in Thailand, issued by the Thai FDA (17). The pharmacist formally documented and signed off on patient counseling sessions.

4. Challenges and Opportunities for Refinement

Thailand's rollout of tafenoquine progressed systematically, driven by rigorous facility selection, strong diagnostic capability, structured monitoring, and close coordination with national regulatory bodies. The program demonstrated safe use of TQ at scale, strengthened quantitative G6PD capacity nationwide, and provided operational evidence to guide sustained implementation of radical cure strategies for *P. vivax.*

Alongside these successes, the implementation process uncovered several key operational challenges that offer important lessons for other national programs:

1. **Inadequate Follow-Up:** A significant challenge was the high rate of patients Lost to Follow-Up (LTFU). Data revealed that only 17.0% of patients receiving TQ completed all five scheduled follow-up visits. This issue was particularly pronounced among migrant populations, who had a non-attendance rate of 52.3%. This high rate of LTFU critically undermines the primary advantage of a single-dose radical cure, as the absence of safety and efficacy follow-up data reintroduces programmatic uncertainty and mutes the epidemiological impact of preventing relapse. Automated reminders and integration with hospital SMS systems could enhance adherence tracking.

2. **Data Gaps and Accessibility:** Accessing comprehensive patient data from hospital systems was constrained by administrative barriers related to Thailand's Personal Data Protection Act (PDPA). This made it difficult to conduct thorough quality monitoring. Furthermore, gaps in voluntarily submitted data limited central monitoring; for instance, quantitative G6PD test results were not included in 60.63% of the submitted case forms, highlighting a need for improved data entry compliance.

3. **Sustainability and Financing:** Tafenoquine and the required quantitative G6PD tests are not yet included on Thailand's National List of Essential Medicines (NLEM). This creates a reliance on external funding sources for procurement and poses a significant risk to the long-term sustainability of the program as donor support declines. Fortunately, most of the current investment is under the national malaria program via government funds, and the next step is to drive them into NLEM under general health service. Moreover, planning early for local budgeting and digital stock-tracking systems can prevent stockouts during scale-up.

4. **Physician Confidence:** Some physicians, particularly those new to the system, remained hesitant to prescribe tafenoquine. This was attributed to a lack of familiarity and the fact that the new treatment was not yet fully integrated into routine, automated hospital workflows. This suggests that while the 'what' of the training was covered, future programs should place greater emphasis on the 'why,' using real-world safety data from the ARCTIC study and the national rollout to build confidence and address specific clinical concerns proactively. Smaller, practical training sessions could deepen understanding, particularly for pharmacists and lab technicians.

These challenges did not detract from the overall success of the rollout but provided a clear, evidence-based agenda for refining the system and informing actionable recommendations for the future.

5. The Roadmap Forward: Key Recommendations for National Malaria Programs

Thailand's comprehensive and transparent approach to introducing tafenoquine provides a valuable operational roadmap for other countries preparing to integrate new radical cure tools into their health systems. The successes and challenges distilled from this experience offer a set of clear, actionable lessons that can help other national malaria programs accelerate their own progress while ensuring patient safety and program sustainability:

1. **Forge Joint Leadership Agreements from Inception:** Proactively engage both malaria program authorities and general hospital system leadership from the very beginning. Establishing a joint data roadmap with interdepartmental coordination and early alignment on policies, protocols, and reporting requirements is essential to prevent administrative bottleneck and ensure shared ownership.

2. **Embed Protocols into Existing Hospital Workflows:** Prioritize the integration of TQ protocols and data reporting into existing hospital systems, such as Electronic Medical Records and digital stock tracking. This approach is more sustainable than creating parallel, disease-specific structures that increase workload and lead to data fragmentation.

3. **Cultivate Clinical Confidence with Phased Mentorship and Real-Time Support:** Implement a "Master Trainer" model at the provincial or regional level to ensure continuous, decentralized training capacity. Complement formal workshops with real-time digital support channels, like the LINE group used in Thailand, to provide immediate expert guidance and build the competency of healthcare providers.

4. **Designate Clear Pharmacovigilance Roles and Reporting Lines Pre-Implementation:** Define clear roles and responsibilities for safety monitoring from the outset. Establish direct and efficient lines of communication between clinical sites, the national malaria program, and drug regulatory bodies to ensure adverse events can be reported, investigated, and addressed swiftly.

5. **Initiate Pathways for Domestic Financing and Reimbursement Early:** Begin the advocacy process early to include tafenoquine and quantitative G6PD tests in the National List of Essential Medicines (NLEM) and national health benefit packages. Securing domestic financing is critical for ensuring the long-term availability of these tools beyond the lifespan of external grants.

6. **Establish High-Level Data-Sharing Agreements Pre-Rollout:** Proactively negotiate data access protocols between the malaria program and hospital administrative bodies to circumvent predictable data protection barriers before implementation begins. Establishing clear protocols for data entry and ensuring access for quality monitoring are critical for program evaluation and improvement.

6. Looking Ahead

DVBD's focus now is on expanding tafenoquine access beyond hospitals to community-level facilities such as Health Promotion Hospitals and malaria clinics. A national TQ administration checklist developed from hospital experience, along with the monitoring visit checklist and SD Biosensor user proficiency assessment, guides new sites through readiness, monitoring, and quality assurance (see Annex). Peer-learning networks, refresher training, and integration with the national Malaria Online system are strengthening sustainability. Hospitals are encouraged to incorporate tafenoquine and G6PD test kits into their annual budgets to ensure long-term availability.

By strategically planning, building strong partnerships, and continuously learning from real-world implementation, Thailand has demonstrated that new and effective tools for radical cure can be moved safely from pilot to practice. This leadership provides an inspiring and practical model for the Asia-Pacific region, accelerating collective progress toward the shared goal of malaria elimination.

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8. Annex

TAFENOQUINE ADMINISTRATION CHECKLIST FOR HEALTH FACILITY

Hospital name:_____ **Province:**_____
Name:_____ **Position:**_____
Email:_____ **Telephone:**_____

1. DIAGNOSTICS		
1	G6PD Biosensor is available and in working order with new batteries	Yes/No
2	G6PD Biosensor test strips are available, stored in correct temperature as per instructions and within expiry date	
3	G6PD user instructions and interpretation chart are available and stored in an accessible area where the test is conducted and interpreted. These documents are the updated versions, in good condition and are easy to read.	
4	G6PD QA test control strips (Level 1 and 2), instructions and interpretation chart are available, stored in correct temperature and within expiry date	
5	In case SD Biosensor is not available, is Fluorescent Spot Test (FST) available in your laboratory?	
6	Focal person to record and report G6PD testing is identified and trained in reporting template/form/online form	
7	Health staff are trained to counsel the patient who are found to be G6PD deficient	

2. TREATMENT		
8	Tafenoquine (TQ) is available and stored in a controlled shelf/place in pharmacy	Yes/No
9	Focal person is identified for TQ receipt, recording lot number, quantity and consumption and trained on reporting form/online reporting	
10	Staff (s) in your hospital/facility have been trained in TQ administration	
11	TQ treatment guidelines are printed and available in OPD/IPD	
12	TQ patient card and urine containers are available for each patient receiving TQ	
13	Health staff are trained to counsel every patient who receives TQ	
14	Follow up days on Day 7 and 14 after TQ administration are recorded according to follow up form and recorded in patient card	
15	Pharmacist(s) trained to report AEs into the AE online reporting system to the Health Product Safety Monitoring Center (HPVC) and report initial ADR event within 1 day following HPVC guidelines	
16	Patients follow up days on Day 7 and 14 after TQ administration are recorded according to follow up form	

Monitoring visit checklist: The implementation of the malaria treatment program for Plasmodium vivax malaria in the hospital setting

Objectives:

1. Evaluate staff competency in tafenoquine / primaquine 7-day usage, G6PD biosensor testing, and case management protocols.
2. Check the usage of the biosensor and number of G6PD test strips, QC reagents, Tafenoquine, and data collection forms.
3. Review patient selection criteria and treatment administration procedures.
4. Assess patient follow-up procedures for monitoring side effects and treatment efficacy.

Instruction: Complete the form by conducting interviews, checking medical supplies, observing working processes, and reviewing relevant documents. Attached name list of supervision team.

Staffing for malaria treatment project					
Please provide the names of the primary contacts or delegates responsible for the project. Clinician, Pharmacist, Medical technologist/Lab technician, Nurse, Public health officer etc.					
No.	Name	Position	Received training course organized by DBVD (Y/N)	Need additional training (Y/N)	Comment

Please use "User proficiency assessment" to evaluate performance in G6PD testing

Inventory						
Before beginning detailed item checks, inspect the overall physical environment and storage areas thoroughly						
No.	Item	Quantity on hand	Above Minimal stock level (Y/N)	Expiry Date	Ready for use (Y/N)	Comment
1	Analyzer		N/A	N/A		Check for the recent QC check, batteries and check strips
2	QC reagents		2 sets	dd/mm/yy		Store at 2-30 C
3	Test strips		10 sets	dd/mm/yy		Store at 2-30 C
4	Tafenoquine tablets		4 tablets	dd/mm/yy		Medicine stored in a secure, controlled area
	Other antimalarials					

Essential documents (guideline and hospital records)					
No.	Item	Availability (Y/N)	Complete (Y/N)	Update (Y/N)	Comment
1	Malaria treatment guideline-2024 (DBVD)				
2	Tafenoquine Safety Monitoring Manual (FDA)				
3	G6PD biosensor User manual				
4	TQ training materials-online set				
5	Visual Aid for hospital staff/ patients				
6	Patient appointment card/document				
7	Code for TQ and quantitative G6PD testing in the hospital data system				
8	Others develop by hospital				
	Hospital data collection form				

Case management and safety				
No.	Item	Yes	No	Comment
1	Are there clear criteria and procedures for selecting patients for TQ/PQ treatment?			
2	Are there records of TQ/PQ prescribing and proper patient selection based on G6PD status using biosensor?			
3	Are correct TQ/PQ dosages based on patient weight, age and contraindication documented?			
4	Are pharmacists/nurses following TQ/PQ dispensing procedures, and patient counselling?			
5	Are patients monitored for side effects and treatment efficacy?			
6	Are safety protocols in place for handling adverse events/ADR and treatment failures?			
7	Are patient follow-up visits and procedures in place for cases of lost follow-up recorded?			
8	Are standardized follow-up forms or checklists used consistently? (hospital standard form)			
9	Are malaria patient medical records complete and accurate?			
10	Is there a protocol for the secure and confidential handling of patient records?			

Any other issues and corrective actions:.....
.....
.....
.....
.....

Areas for improvement:.....
.....
.....
.....
.....

1. **Checker name**

2. **Checker name**

3. **Checker name**

SD Biosensor STANDARD G6PD test
User proficiency assessment - follow up at site

Instructions: The competency assessment of STANDARD G6PD test users should include:

1. Monitoring the performance of trainees at the health facility.
2. Documenting the integration of malaria treatment and G6PD testing into the hospital system.
3. Identifying any issues related to testing and supplies.

**This assessment can be conducted by the hospital's Medical Technologist as a self-assessment.*

The technical competency assessment should be conducted using STANDARD G6PD controls.

Site:_____ **Date:**_____

Monitoring the performance.

No.	Competencies	Does Not Meet Requirement	Meets Requirement	Suggestions
	Pretest procedure			
1	Demonstrates knowledge of key specimen handling/storage requirements			
2	Reads and understands the SD Biosensor instructions for use for G6PD-Hb			
	Testing procedure			
3	Observes universal precautions			
4	Checks expiration date of the test kit			
5	Demonstrates proficiency in preparing instrument for analysis including calibration with code chip			
6	Understands storage and labelling requirements for assay reagents and controls			
7	If using G6PD controls— properly reconstitutes G6PD controls and prepares them for analysis			
8	Demonstrates proper sample collection technique			
9	Demonstrates proper mixing and application to strip			
10	If using G6PD controls— successfully performs the assay with controls, by obtaining values that are "in range" with package insert			
11	Properly records both G6PD and hemoglobin values into the records			
12	Understands and interprets errors as per user instruction			
13	Demonstrates reproducibility, by obtaining similar values for the controls upon repeating the assay			

Results.

Result of Technical Competency Assessment	Completed	PASS (control data within range)	NOT PASS (control data NOT within range)
Watch demonstration of procedure from trainee			
Perform procedure under observation			
Capable of doing all the activities independently			

Comment:.....
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.....
.....

Analyst's name/date **Evaluator's name/date**

For further information, please contact:

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