HARVARD MEDICAL SCHOOL
BRIGHAM AND WOMEN'S HOSPITAL

CASES IN GLOBAL HEALTH DELIVERY

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FOCUSED CASE STUDY

Roll-Out of Rapid Diagnostic Tests for Malaria in Swaziland

In April 2011 a malaria outbreak put Swaziland's new malaria diagnosis and surveillance systems to the test. The Bhalekane Nazarene Clinic diagnosed a feverish patient with malaria using a rapid diagnostic test (RDT). The malaria transmission was traced to the northern part of the Hhohho region (see **Exhibit 1** for a map of malaria endemicity in Swaziland and **Exhibit 2** for more on the socioeconomic and demographic indicators of Swaziland's population). Using the country's immediate disease notification system, the "977 Hotline," the health care workers at the clinic notified the country's National Malaria Control Program (NMCP). The program manager, Simon Kunene, and his team responded quickly to the outbreak.

By June 2011 Simon Kunene had been the manager of Swaziland's NMCP for 24 years, through many ups and downs. In the mid-1990s above-average rainfall, parasite resistance to chloroquine treatment, instability in neighboring Mozambique, and the emergence of HIV/AIDS and its destabilizing effect on the health system contributed to malaria incidence levels as high as those seen in the mid-1940s. Kunene had overseen a 99% reduction in confirmed cases of malaria—from 9,700 in 1996 to only 73 by 2009 (see **Exhibit 3** for the history of confirmed malaria cases in Swaziland).[1] In 2008 Swaziland received the first-ever grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria ("Global Fund") explicitly awarded for malaria elimination, and Kunene led the reorientation of the NMCP to try to reduce locally acquired malaria cases to zero by 2015. If Swaziland could maintain this level and prevent the reintroduction of malaria for three consecutive years, it would be certified malaria free by the World Health Organization (WHO; see **Exhibit 4** for milestones toward malaria elimination).[2]

Because clinic-level laboratory capacity in Swaziland was limited, Kunene initiated a nationwide roll-out of RDTs in both public and private health facilities in 2010. Expanding diagnostic capacity was paramount to the objective of eliminating malaria, and Kunene was keen to ensure that RDTs achieved their full potential to optimize malaria case management, improve turnaround time for malaria diagnosis, and enhance surveillance capacity.

Kileken ole-MoiYoi, Julie Rosenberg, and Rebecca Weintraub prepared this case for the purposes of classroom discussion rather than to illustrate either effective or ineffective health care delivery practice.

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Malaria in Swaziland

Historically, malaria prevalence rates fluctuated in Swaziland, and transmission occurred primarily during the rainy season from November to May. In the late 1940s as many as 75% of children between the ages of one and five years old were infected with malaria parasites.[3] In 2010 over 99% of malaria was caused by *P. falciparum* in Swaziland, and 30% of the population, or roughly 366,900 people, lived in malaria-endemic areas.[4]

According to the 2010 World Malaria Report, between 2001 and 2009 total malaria admissions declined by 87% from 1,737 to 230 and malaria deaths declined by 79% from 62 to 13.[5] As a result of this progress, Swaziland had already achieved both the malaria Millennium Development Goals and the Roll Back Malaria (RBM) Abuja Targets (see **Exhibit 5** for the RBM Abuja Targets).

Establishing Swaziland's Strategy for Malaria Elimination

After several countries in Southern Africa had demonstrated progress in controlling malaria, the African Union and the Southern African Development Community (SADC) selected Botswana, Namibia, South Africa, and Swaziland as candidates for eliminating malaria by 2015 (see **Exhibit 6** for key definitions in malaria agendas).[6] In the 2008 Global Malaria Action Plan, the RBM Partnership, and the WHO defined a set of key components for reorienting health systems toward malaria elimination that included improving surveillance systems, organizing national steering committees, clarifying and regulating public- and private-sector roles, developing advocacy objectives, and collaborating on cross-border initiatives to reduce the risk of reintroduction.[2] Prepared to address the RBM recommendations and cognizant of the WHO elimination requirements, Swaziland's 2008-2015 Malaria Elimination Strategy objectives were to:

1. Reduce and sustain the locally acquired malaria cases to zero by 2015
2. Reduce and sustain malaria deaths seen at health facilities to zero by 2015
3. Maintain zero locally acquired malaria cases by prevention of reintroduction for all years following 2015[7]

To achieve these objectives, the NMCP emphasized that all suspected malaria cases should be diagnosed by microscopy or RDTs; all confirmed uncomplicated malaria cases should be treated with an artemisinin-based combination therapy (ACT; excluding pregnant women in their first trimester who received oral quinine); all households in areas of malaria transmission should receive long lasting insecticidal nets and indoor-residual spraying with insecticides; potential epidemics had to be rapidly identified and addressed within two weeks of detection; and improved malaria information, education, and communication materials should reach the entire population.[7]

In 2009 the Global Fund and the government were the primary funding sources for malaria activities in Swaziland. The Global Fund provided funds for malaria control from 2003 to 2008 and awarded Swaziland a second five-year grant of USD 13.9 million during Round 8 to prepare the country for malaria elimination.[8] For the 2009 to 2010 malaria season, the government spent USD 1.14 million on malaria-related activities. Over the same time, the Global Fund Round 8 grant disbursement was USD 3.14 million for malaria elimination activities.[4] The Round 8 proposal identified strengthening the country's malaria diagnosis and surveillance capacity as top priorities for achieving malaria elimination. This included improving microscopy skills in Swaziland's 16 hospitals and health centers[9] and expanding parasitological diagnosis with RDTs to all health facilities, including more than 190 clinics,[10] and over 100 private-sector health facilities offering various levels of care.[11]

The NMCP would use Global Fund resources to procure RDTs for surveillance, training, and maintaining a buffer stock, while the government, via the National Laboratory Services (NLS), was expected to procure and distribute RDTs for clinical diagnosis in all public and private health facilities in the country.[4] The NMCP's other priorities for the Global Fund grant included improved health care worker training, diagnosis quality control, strengthening human resource capacity, and data management and analysis.[9]

In 2009 the NMCP trained 441 private and public sector health care workers in the new diagnostic and treatment guidelines emphasizing parasitological diagnosis of all malaria cases and prompt effective treatment. The NMCP continued to train health care workers annually due to staff turnover at the health facility level, and in April 2010 it made ACTs available free of charge at all health facilities as first-line treatment. In May 2010 the Swaziland Malaria Elimination Advisory Group was established to provide technical expertise and guidance for elimination.[4] By March 2011 the NMCP had extended indoor-residual spraying with insecticides and the distribution of long-lasting insecticidal nets to all communities in the malaria at-risk region.[1]

Rapid Diagnostic Test Roll-Out

Prior to the introduction of RDTs in Swaziland, Kunene believed the incidence of malaria was overestimated, especially at the clinic level where microscopy services were not immediately available. When the clinic suspected a case, it prepared a patient's blood slide for collection. Then, as Zandie Dlamini, an NMCP malaria program officer, explained "it [took] a long time–-more than a week from when we pick[ed] up the slides from the clinics and sen[t] back the results. It [was] for this reason all patients [were] treated for malaria at the first sign of symptoms, even before there [was] confirmation of the disease."[12]

In accordance with the WHO malaria elimination guidelines and Swaziland's strategic plan, the NMCP revised the national diagnosis and treatment guidelines in 2009, mandating that prior to treatment, all suspected cases of malaria be confirmed through parasitological diagnosis with microscopy or RDTs.[7] Kunene explained, "because we are now pursuing a malaria elimination agenda, there is no way that we can continue to base diagnosis and treatment on clinical presentation, hence the rationale to expand diagnostic capacity to lower levels in the health system by introducing rapid diagnostic tests."

The NMCP selected rapid diagnostics tests according to WHO protocols, paying attention to time required to perform each test and receive a result, stability of the tests including temperature variations and sensitivity to environment, type of malaria, and the overall cost of the RDTs. Following successful product testing by the Foundation for Innovative New Diagnostics (FIND) and lot testing for quality control with assistance from The Laboratory of Molecular Epidemiology of the Pasteur Institute of Cambodia, Swaziland selected and procured the First Response Malaria Ag HRP2 RDT (Premier Medical Corporation Limited; see **Exhibit 7** for a Technical Overview of RDTs). Each box of 25 RDTs cost roughly USD 41 and came with one bottle of diluent, 25 swabs, 35 auto-safety lancets, 75 result stickers, and instructions for use.

In February 2010 all private and public health facilities throughout Swaziland began offering free RDTs (see **Exhibit 8** for an overview of the Malaria Diagnosis Policy), primarily when microscopy was not available. Microscopy remained the "gold standard" for diagnosis but at the clinic level, there were no laboratories and sometimes the laboratory at hospitals and health centers was not functional, including on holidays or after hours, for example. The NMCP carried out trainings and health promotion activities with health practitioners and the general public, highlighting the accuracy of RDTs and their role in improving patient care.

In addition to demonstrating progress in malaria elimination in Swaziland, the expansion of diagnostic tools was intended to minimize presumptive treatment. There were several other conditions that caused fever in patients, and presumptive treatment of fever with antimalarials could result in misdiagnosis and mismanagement of limited resources (see **Exhibit 9** for health system and epidemiologic indicators). Kunene explained that coupling the ability of clinics to provide both diagnostics and treatment would reduce the number of clinic visits, improve the correct utilization of ACTs, decrease the burden on health care workers and ultimately lead to better health outcomes.

Quality Assurance Program

Although other countries in Southern Africa had introduced RDTs for malaria, Swaziland was the first country in the region to develop a comprehensive two-tier program—at the national level and in the highest at-risk region—for quality diagnosis assurance for both RDTs and microscopy. The NMCP and the National Laboratory Services designed the quality assurance program to improve the timely, accurate, and correct interpretation of diagnostic results and to create a high level of clinician and patient confidence in results. It aimed to improve the appropriate use of antimalarials and the overall health of patients (see **Exhibit 10** for stages of quality assurance). The quality assurance program included protocols for: RDT and microscopy product and reagent selection, standard operating procedures for different tiers of health care workers, inventory management, training, competency assessments, and workload and facility evaluations. It also delineated specific responsibilities for malaria diagnosis across the health facilities. The quality assurance manual was available in all health facilities in the malaria at-risk region; the NMCP and the National Laboratory met regularly to evaluate the quality assurance program (see **Exhibit 11** for malaria quality assurance roles and responsibilities).[13]

In the highest at-risk region in the country, all positive RDT or microscopy diagnostic results and 10% of negative results continually were collected and blind cross-checked with off-site microscopy or polymerase chain reaction analysis. The data from the quality assurance program allowed the NMCP to analyze diagnostic tools and health care worker performance. Kunene believed that the quality assurance program was integral to demonstrating progress toward elimination. "As you move toward elimination and WHO certification, you need to demonstrate that you took into consideration all of the quality and regulatory issues to ensure that there are no doubts about what you are reporting."

Immediate Disease Notification System

To monitor potential disease outbreaks and improve information exchange within the health system, the Ministry of Health created an immediate disease notification system, the "977 Hotline," for health care workers to report notifiable diseases such as malaria. The NMCP defined five or more locally transmitted cases of malaria as a malaria outbreak, which required immediate intervention. Kunene explained that "if there is a confirmed malaria case…the chief surveillance officer and myself receive an SMS to our mobile phones stating the confirmed case and identifying the facility." Within seven days of the 977 Hotline notification, NMCP staff were supposed to investigate confirmed cases using geographic information systems to track down and record the source of infection and collect patient and community data on bednet utilization, household indoor-residual spraying with insecticides, and any recent travel by household members or neighbors. As part of its active surveillance, the NMCP staff performed RDTs on community members living within a one kilometer radius around the patient's home to rapidly diagnose and treat all malaria cases and reduce onward transmission.

Kunene explained the 977 Hotline had not only improved active surveillance, but also the effectiveness of the NMCP as a whole by strengthening reporting and confidence: "People are motivated to report if they

see that you use the data. If you are a clinician, it makes a difference if you report today and tomorrow you see a member of the NMCP surveillance team at your facility to follow-up." In addition to notifying the NMCP, confirmed malaria cases were also recorded in the national health management information system (HMIS) from which the NMCP drew monthly reports.

Leading the NMCP

As a manager, Kunene's daily focus was on equipping and guiding the NMCP team to pursue its goal of eliminating malaria from Swaziland, of becoming the first sub-Saharan African country to achieve malaria elimination. Kunene explained, "As a leader, I must be sure to create an enabling environment for my team to deliver their targets and the NMCP targets. Seeing a program achieving most targets makes you happy as a leader. People may give me the credit, but I always say, 'Don't give me the credit, but give it to my young team. Those guys work very hard.'" Swaziland's NMCP benefited from relatively low turnover, with many staff having been there for at least 10 years. Kunene ensured that all NMCP team members had sufficient direction and the necessary resources to accomplish their objectives, but that they also had a degree of flexibility in their daily work.

Kunene valued exchanging ideas and expertise with other countries. "Sharing experiences and learning from other countries has helped me to be the manager that I am today." Kunene, with his 24 years of experience, had implemented new practices within Swaziland's surveillance and bed net programs using information learned from South Africa, Namibia, and Botswana. The prospect of eliminating malaria was a new concept in sub-Saharan Africa, and documenting lessons and progress in countries aiming for elimination was essential to advance the field and support countries to achieve their goals.

Key Challenges

Funding the Malaria Response

The increased global advocacy initiated by the RBM Partnership in 1998 and the creation of the Global Fund in 2002 significantly altered the landscape of malaria control and enabled many countries with sound malaria proposals to benefit from significant budget increases. As a result of the significant progress since 1996, Kunene feared that countries may be victims of their own success, that "policy makers might lose interest….[which] would be fatal because malaria can come back stronger than before…."[14].

Kunene explained that a clear and well structured strategic plan must guide the NMCP so that it could both receive further budgetary support from the government and donors and effectively coordinate resource allocation to work as efficiently as possible. He especially emphasized the significance of government support: "To be successful, the government must provide some resources…if the money comes from my government, then I decide what to do with the money as long as it fits within the strategic plan." Identifying specific gaps in the strategic plan enabled the NMCP to better request, align, and monitor additional assistance.

RDT Procurement and Distribution

Although the NMCP initially delivered RDTs to health facilities during the roll-out, the National Laboratory Services assumed the responsibility for the procurement and distribution of RDTs to all health facilities.[4] The transition to the NLS procurement and distribution system was not as smooth as Kunene desired. The NLS had the capacity to procure and deliver RDTs for health facilities that already had

laboratory capacity, but the expansion of diagnostics to the clinic level exceeded the NLS's capacity. Due to the NLS's delayed procurement, and to avoid stockouts, the NMCP used some of the Global Fund-supported RDTs intended for surveillance, training, and the buffer stock to supply both public- and private-sector health facilities with RDTs for clinical diagnosis.[4] While the NLS's procurement and distribution capacity was improved, Medical Stores Limited, the national supplier of essential medicines, assumed responsibility for the distribution of RDTs to the clinic level while the NLS retained responsibility for RDT procurement and distribution for health facilities with laboratory capacity. Because the Central Medical Stores also lacked the capacity to immediately deliver RDTs to facilities with low stocks and as a result, the NMCP continued to provide RDTs when there was an urgent need.

In addition to the procurement and distribution challenges, the NMCP had to track and quantify RDT consumption to both ensure proper usage and accurately forecast supplies to meet demand. Collecting the necessary level of data at the health facility level often added to the workload of already overburdened health care workers and was a challenge for the NMCP. By June 2011 the NMCP had sought input from international organizations and other countries to develop a data management system to strengthen RDT tracking and accountability.

Communications

In 2010, following the introduction of RDTs, data from the HMIS indicated that the number of reported malaria cases decreased by 76% from 2009 to 2010 (from 6,247 to 1,512 cases).[15] Between February and June 2010, 148 microscopy or RDT-confirmed cases were reported to the NMCP (see **Exhibit 12a** for changes in confirmed cases from 2001 to 2010 and **Exhibit 12b** for changes in reported cases after the introduction of RDTs).[4] The discrepancy between the number of HMIS-reported malaria cases and NMCP-reported confirmed cases concerned Kunene. In August 2010 the NMCP launched the 977 Hotline to improve the reporting of RDT- or microscopy-confirmed cases and to improve case management by further encouraging the use of diagnostics for confirmation prior to treatment. Because the discrepancy between the reported and confirmed cases of malaria was also potentially the result of clinical diagnosis and data entry errors, Kunene also emphasized the need for continued training.

Effectively integrating the private-sector clinicians into the data collection and malaria elimination trainings was also a challenge. The NMCP held training workshops for laboratory technologists, microscopists, doctors, nurses, phlebotomists, and malaria surveillance officers throughout the year following a well structured and regularly updated training manual (see **Exhibit 13** for the malaria training schedule). In addition to the training, NMCP officials carried out monthly mentoring visits with health care workers to personally meet and discuss challenges or concerns. However, NMCP officers were concerned by private-sector practitioners' frequent unavailability for the NMCP-led trainings and were working on ways to better engage private-sector health care workers.

The 977 Hotline enabled the NMCP to analyze data and compare it with the monthly HMIS-reported malaria cases to identify potential gaps in parasitological diagnosis and track down health facilities for additional targeted one-on-one training and mentorship. It was crucial for the NMCP to interact with health care workers in person to not only ensure that discrepancies were rectified, but also to demonstrate its commitment and instill a level of collegiality between the NMCP and health practitioners.

As the incidence of malaria decreased, Kunene emphasized the need for health promotion campaigns. The public needed to be reminded of the importance of continuing to sleep under insecticide-treated bednets and seeking treatment from the nearest health facility quickly if they became sick as well as the availability of free diagnosis and treatment.

Moving Forward

Reflecting on the progress made so far in Swaziland's RDT roll-out, Kunene believed that the Ministry of Health and the National Laboratory Services' support was crucial to the program's success. Kunene was in constant communication with senior Ministry of Health officials to ensure they were aware of progress and challenges and that they too were fully committed to eliminating malaria from Swaziland.

Kunene underscored the need to remain vigilant as the population's acquired immunity decreased due to reduced exposure to malaria, making all populations at heightened risk of developing severe malaria.[16] The increased vulnerability would mean that improvements in malaria prevention, diagnosis, treatment, and surveillance would need to be sustained well beyond 2015 as would the financing to support such improvements. Expanding malaria diagnosis capacity to border posts would also become relevant; roughly one million people crossed the borders between Swaziland, Mozambique, and South Africa yearly.

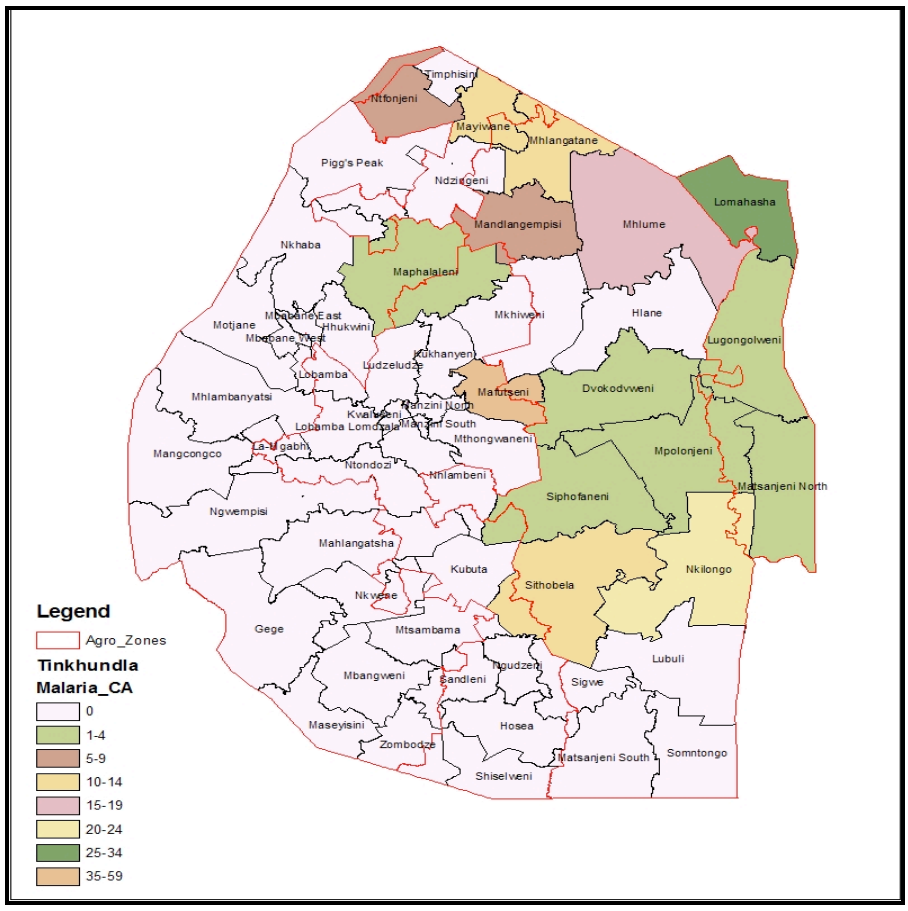
Following the recent malaria outbreak in Northern Swaziland, the NMCP's surveillance program, which included testing of community members with RDTs, found an additional 51 cases of malaria that were linked to the initial case. Kunene suspected that the malaria originated in a neighboring country and was transmitted by mosquitoes. The NMCP responded by treating the infected individuals with ACTs, carrying out indoor-residual spraying of the relevant households, and distributing bed-nets and malaria education materials in the affected communities. Kunene remarked that "the NMCP will do everything in its power to prevent malaria outbreaks in the country and eventually eliminate the disease entirely. It is the responsibility of the community to do everything they can to protect themselves against malaria."[17]

The NMCP believed the rollout of RDTs, the quality assurance program, and the 977 Hotline were crucial to its progress. The 2010/2011 malaria outbreaks and the lingering discrepancies between the reported and confirmed malaria cases concerned Kunene, however. As Swaziland approached the end of the malaria transmission season, Kunene conducted a review of all services and products within the Malaria program to assess if Swaziland was on course to achieve its elimination targets.

Appendix *List of Abbreviations*

ACT	artemisinin-based combination therapy
HMIS	Health Management Information System
NLS	National Laboratory Services
NMCP	National Malaria Control Program
RBM	Roll Back Malaria Partnership
RDT	rapid diagnostic test
USD	United States' dollars
WHO	World Health Organization

Exhibit 1 *Confirmed Malaria Cases in Swaziland 2007–2009*



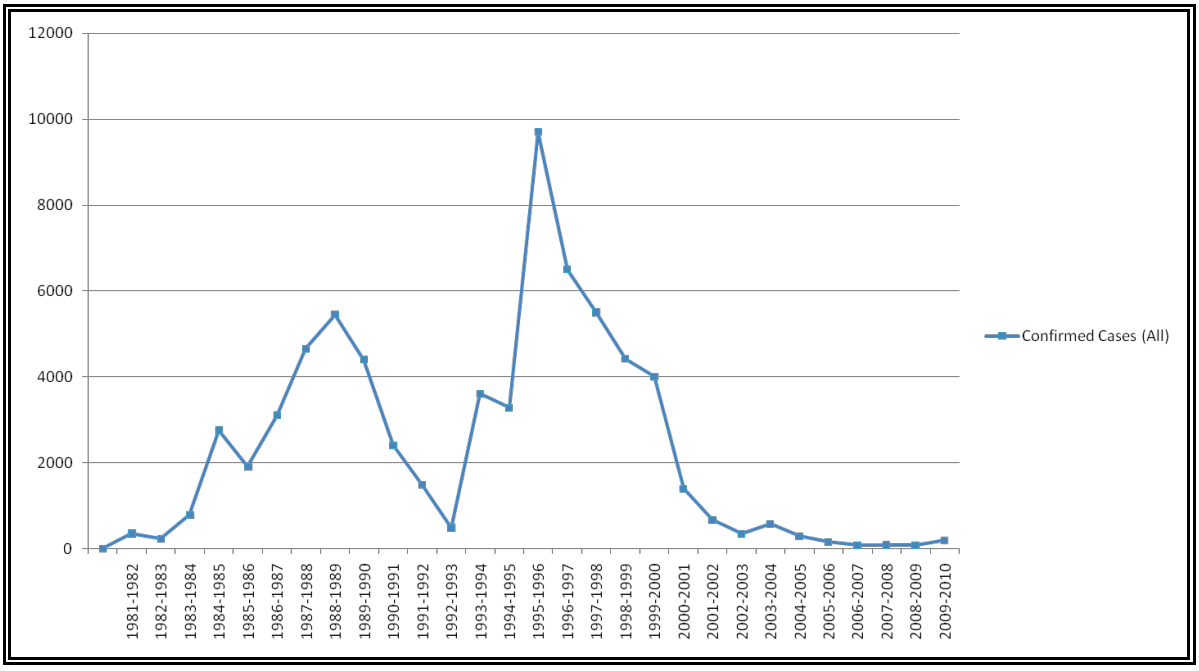
Source*:* Swaziland National Malaria Control Program. Swaziland Malaria Indicator Survey Presentation. Presented at Swaziland Malaria Elimination Advisory Group Meeting. February 3, 2011.

Exhibit 2 *Basic Socioeconomic and Demographic Indicators for Swaziland*

INDICATOR		YEAR
UN Human Development Index ranking	121 out of 177	2010
Population (thousands)	1,185	2009
Fertility rate (total births per woman)	3.5	2009
Urban population (%)	25	2009
Drinking water coverage (%)	69	2008
Poverty rate (% living under USD 1.25 per day)	63	2001
Gini index	50.7	2001
GDP per capita in PPP (constant 2005 international dollars)	4,539	2009
GDP per capita (constant 2000 USD)	1,553	2009
Adult literacy (%)	86.9	2009

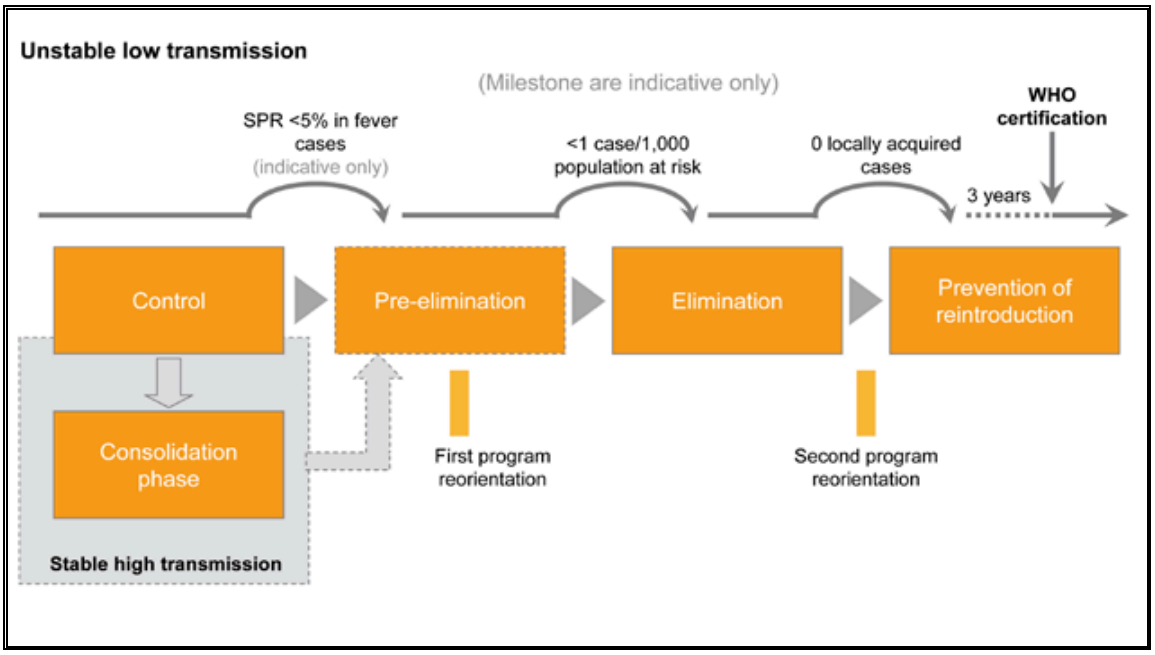
Sources*:* United Nations Agencies and the World Bank.

Exhibit 3 *Lab-Confirmed Malaria Cases in Swaziland, 1981–2010*



Source: Swaziland National Malaria Control Program. Swaziland Ministry of Health. 2010.

Exhibit 4 *Milestones toward Malaria Elimination*



Source: The Global Malaria Action Plan: For a malaria-free world. Roll Back Malaria Partnership, 2008.

Exhibit 5 *Abuja Declaration at the African Summit on Roll Back Malaria*

Abuja Declaration is a commitment to halve the malaria mortality for Africa's people by 2010, through implementing strategies and actions for Roll Back Malaria, as agreed at the Summit. In addition, they agreed:

1) to catalyze actions at regional level to ensure implementation, monitoring and management of Roll Back Malaria;
2) to initiate actions at country level to provide resources to facilitate realization of RBM objectives;
3) to work with partners towards stated targets, ensuring the allocation of necessary resources from private and public sectors and from non-governmental organizations; and
4) to create an enabling environment in their countries which will permit increased participation of international partners in malaria control actions. The Leaders resolved to initiate appropriate and sustainable action to strengthen the health systems to ensure that by the year 2005:
   - at least 60% of those suffering from malaria have prompt access to, and are able to correctly use, affordable and appropriate treatment within 24 hours of the onset of symptoms,
   - at least 60% of those at risk of malaria, particularly children under five years of age and pregnant women, benefit from the most suitable combination of personal and community protective measures such as insecticide treated mosquito nets and other interventions which are accessible and affordable to prevent infection and suffering, and
   - at least 60% of all pregnant women who are at risk of malaria, especially those in their first pregnancies, have access to chemoprophylaxis or presumptive intermittent

Source: Roll Back Malaria: An Extract from The African Summit on Roll Back Malaria, Abuja, 25 April 2000. (WHO/CDS/RBM/2000.17).http://www.rollbackmalaria.org/docs/abuja_declaration_final.htm).

Exhibit 6 *Key Definitions in Malaria Agendas*

I. *Malaria control*: reducing the disease burden to a level at which it is no longer a public health problem.

II. *Malaria elimination*: interrupting local mosquito-borne malaria transmission in a defined geographical area, i.e., zero incidence of locally contracted cases, although imported cases will continue to occur. Continued intervention measures are required.

III. *Malaria eradication*: permanent reduction to zero of the worldwide incidence of malaria infection.

Source: World Health Organization. Global Malaria Control and Elimination: report of a technical review. January 17–18, 2008.

Exhibit 7 *Technical Overview of Rapid Diagnostic Tests*

RDTs detect malaria parasite antigens using lateral flow immuno-chromatography. Blood is deposited on nitrocellulose paper and flows past a strip of antibodies designed to detect specific parasite antigens such as HRP2, pLDH, or pan-specific aldolase.* Depending on the choice of antigens, the test is able to detect *P. falciparum* alone, *P. vivax* alone, *P. falciparum* and non-*P. falciparum* without differentiation, and *P. falciparum* and non-*P. falciparum* with differentiation.†

There are over 70 malaria RDTs available for purchase worldwide. The test performance, including sensitivity, specificity, and heat stability, varies widely between manufacturers and is influenced by test design, materials, and packaging.‡ Beyond technical details, the test performance is also influenced by logistical components such as shelf life, supply chain, storage conditions, and training. RDTs exposed to high temperatures (above 30 degrees Celsius) or RDTs with results read beyond the manufacturer's recommended time can greatly reduce the sensitivity and specificity, respectively.§ Attention to cool chains, storage facilities, quality control, and training can improve the accuracy of an RDT. Thus, the quality of a test depends not only on technical components, but also on health systems components.

Considerations When Assessing New Technologies.

Technical	Logistical	Health Systems
Sensitivity	Storage conditions	Human resources
Specificity	Shelf life	Training
Heat stability	Infrastructure requirements	Impact on existing lab networks
Time to result	Treatment availability	Treatment availability
Technology platform	Delivery	Acceptability
Ease of use	Supply chain	Impact on health outcomes
Quality control	Cost	Potential for local production/technology transfer

Source: Compiled by Ailis Tweed-Kent.

* Frost L, Reich M. *Access: How do good health technologies get to poor people in poor countries?* Cambridge, MA: Harvard University Press; 2008.

† World Health Organization. Malaria Rapid Diagnostic Test Performance. Results of World Health Organization product testing of malaria RDTs: Round 2 (2009).

‡ Murray CK et al. Update on rapid diagnostic testing for malaria. *Clinical Microbiology Review.* January 2008; 21(1):97–110

§ Jorgensen P. et al. Malaria rapid diagnostic tests in tropical climates: the need for a cool chain. *American Journal of Tropical Medicine and Hygiene* May 2006; 74 (5):750–754.

Exhibit 8 *Overview of the Malaria Diagnosis Policy*

Facility	Clinical Capacity	Laboratory Capacity
Clinics	• Staffed by nurses • No inpatient facilities • Refers all severe and complicated malaria cases to hospitals and health centres	• Diagnosis of *P. falciparum* malaria by rapid diagnostic tests (RDTs) • When diagnosis is uncertain (e.g., suspected non-*P. falciparum* malaria and treatment failures), referral of patients to hospital or health centres for microscopy • Preparation of blood smears and dried blood spots for quality assurance purposes
Health centers	• Staffed by doctors and nurses • Inpatient and outpatient facilities available	• Diagnosis of malaria by RDTs and microscopy • Preparation of blood smears and dried blood spots for quality assurance purposes
Hospitals	• Staffed by doctors and nurses • Inpatient and outpatient facilities available • Intensive care unit at Mbabane Government Hospital	• Diagnosis of malaria by RDTs and microscopy • Preparation of blood smears and dried blood spots for quality assurance purposes

Source: Swaziland Malaria Diagnosis Quality Assurance Programme—2009.

Exhibit 9 *Health System and Epidemiologic Indicators*

INDICATOR		YEAR
Average life expectancy at birth (total/female/male)	46/46/47	2009
Maternal mortality ratio (per 100,000 live births)	420	2008
Under-five mortality rate (per 1,000 live births)	79	2009
Infant mortality rate (per 1,000 live births)	52	2009
Vaccination rates (% of DTP3 coverage)	95	2009
Undernourished (%)	18	2007
HIV prevalence (% of population ages 15–49)	25.9	2009
HIV antiretroviral therapy coverage (%)	85	2009
Tuberculosis incidence (per 100,000)	1,257	2009
Tuberculosis treatment success rate (% of registered cases)	68	2008
Malaria cases (per 1,000)	0.1	2009
Government expenditure on health (% of total government expenditure)	9.3	2009
Government expenditure on health per capita (international dollars, USD)	198	2009
Total health expenditure per capita (constant 2005 international dollars, USD)	312	2009
Out-of-pocket health expenditure (% of private expenditure on health)	42	2009
External resources for health (% of total expenditure on health)	12	2009
Physician density (per 10,000)	0.2	2004
Number of hospital beds (per 10,000)	2.1	2006

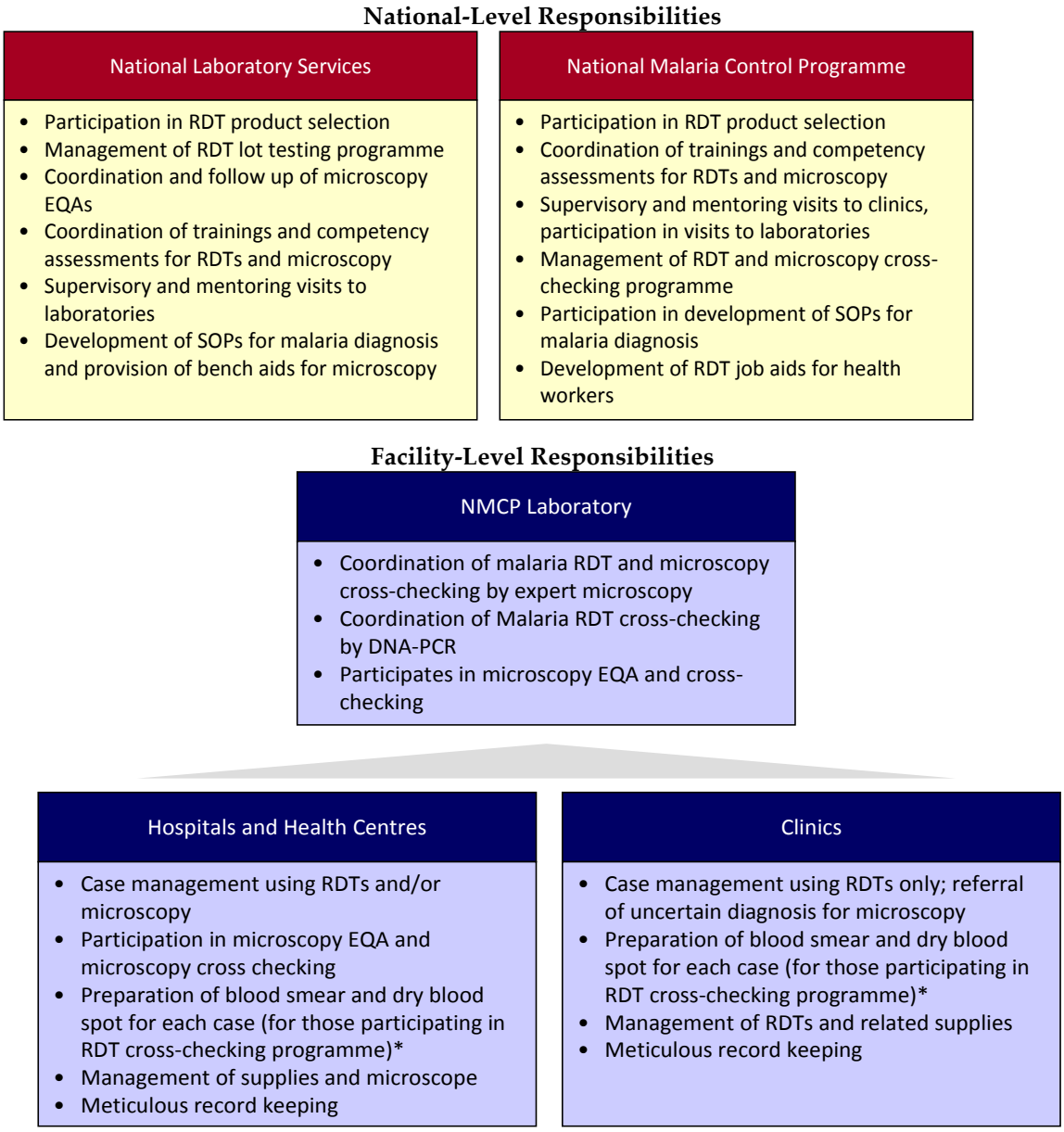
Source: World Bank Data and National Health Strategic Plan 2006–2010.

Exhibit 10 *Stages of Quality Assurance Program*

Pre-Analytic	Analytic	Post-Analytic
• Specimen collection • Specimen transport • Specimen quality	• Result accuracy • Clerical errors • Analytical errors • Assay repeat rates	• Result reporting • Record keeping for patient and QC results

Source: Swaziland Malaria Diagnosis Quality Assurance Programme—2009.

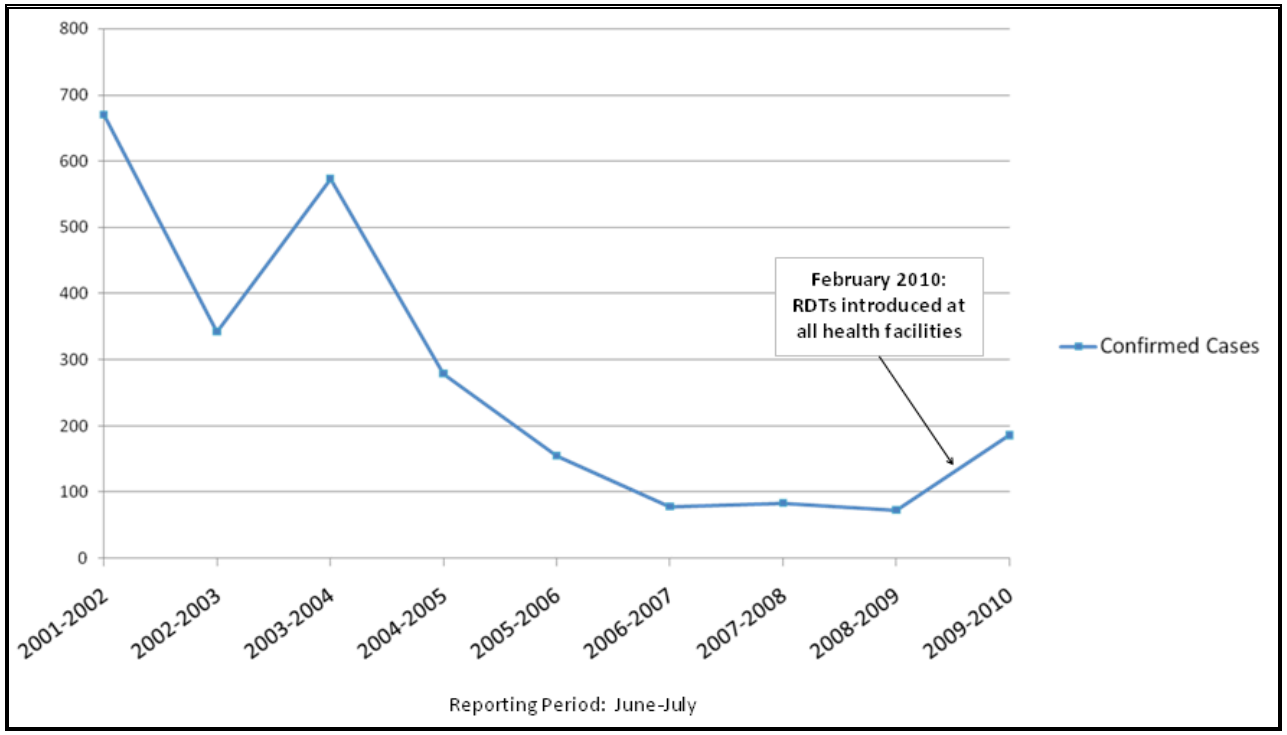
Exhibit 11 *Swaziland Malaria Quality Assurance: Roles and Responsibilities*



* Only sites participating in RDT cross-checking pilot are required to prepare of blood smear and dry blood spot for each case. In 2009-2010 malaria season, the pilot includes all health facilities in the Lubumbo region. In the future, RDT cross-checking procedures may be modified and the programme will be expanded to cover all sites.

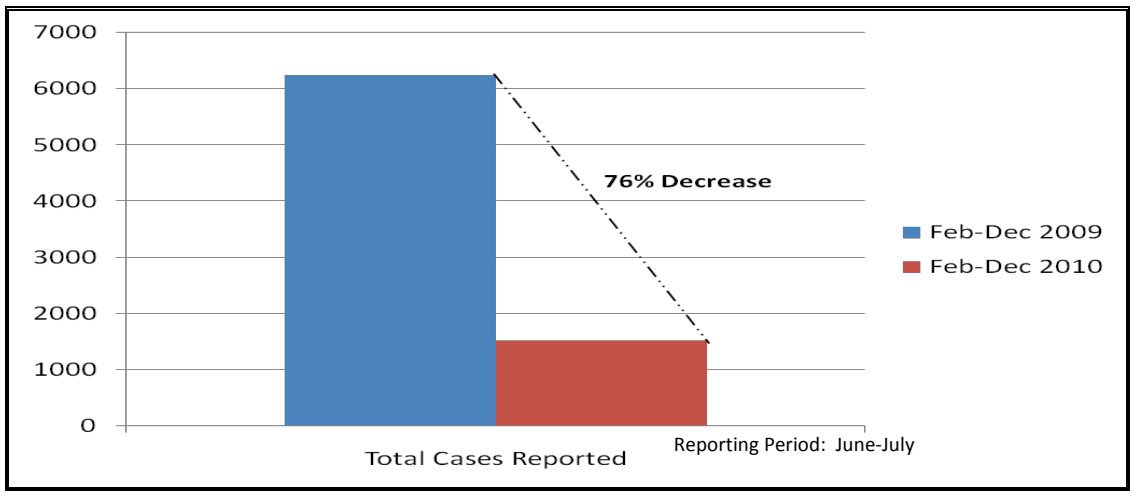
Source: Swaziland Malaria Diagnosis Quality Assurance Programme—2009.

Exhibit 12a *Change in Confirmed Malaria Cases in Swaziland, 2001-2010*



Source: Swaziland National Malaria Control Program, Swaziland Ministry of Health, 2010.

Exhibit 12b *Decrease in Reported Malaria Cases in Swaziland, 2009-2010*



Source: Strategic Information Department, Swaziland Ministry of Health. Health Management Information System Database; 2011.

Exhibit 13 *Malaria Training Schedule*

Cadre	Training
Microscopy Quality Officers	International malaria microscopy training every 3 years Will facilitate the in-country annual malaria diagnosis training covering microscopy, RDTs, and QA.
Laboratory Technologists and Malaria Microscopists	Annual malaria laboratory diagnosis training covering microscopy, RDTs and QA
Doctors	Annual malaria training occurs as part of the National Malaria Conference
Nurses	Annual malaria training on treatment and diagnosis
Phlebotomists*	Annual malaria training will include relevant aspects of malaria diagnosis (e.g., performing RDTs, preparing smears, and blood spots)
Malaria Surveillance Officers*	Annual malaria training will include relevant aspects of malaria diagnosis (e.g., performing RDTs, preparing smears, and blood spots).

* Training for these cadres might include attendance at relevant modules of the annual nurse and/or laboratory trainings.

Source: Swaziland Malaria Diagnosis Quality Assurance Programme—2009.

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