

### **ASLM WEBINAR**

### Accelerating Malaria Elimination in Low Transmission Zones

16 February | 2023

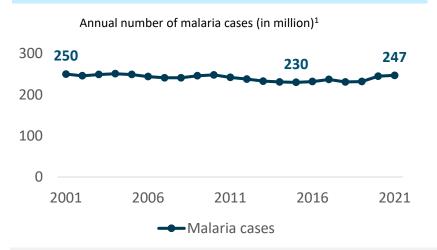
- 1. The Malaria Burden
- 2. Acceleration needed for Malaria elimination:
  - 2.1 Active/reactive case detection
  - 2.2 pregnant women screening
  - 2.3 asymptomatic and pregnant women rapid testing
  - 2.4 surveillance
- 3. Accelerating Malaria Elimination in low transmission zones
- 4. 1-3-7 Strategy for Elimination
- 5. Conclusion

### 1. The Malaria Burden

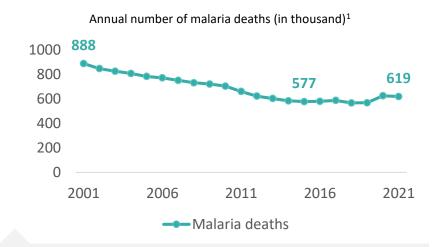
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### Malaria remains one of the most infectious and deadliest diseases with 247 million cases and 619,000 deaths globally each year

**247** million estimated malaria cases across 85 endemic countries were reported in 2021<sup>1</sup>



**619,000 estimated malaria deaths** occurred in 2021, representing a case fatality rate of 0.3%<sup>1</sup>

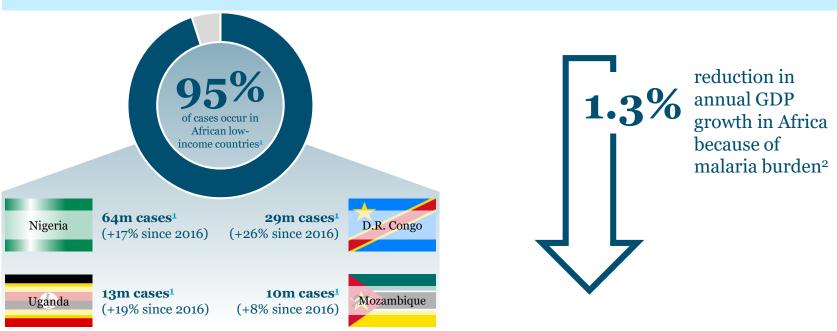


The steady decrease of malaria related deaths since the 2000's has stopped and, in some settings, even reversed

1 WHO. (2022). WHO malaria report 2022. https://www.who.int/publications/i/item/9789240064898.

### 95% of Malaria cases occur in low-and-middle income African countries and cause the continent an estimated annual loss of \$12 billion in GDP

### Malaria presents a major clinical and economic burden for some of the world's lowest income countries



 $<sup>1\</sup> WHO.\ (2022).\ WHO\ malaria\ report\ 2022.\ https://www.who.int/publications/i/item/9789240064898.$ 

<sup>2</sup> PMI. (2022). Malaria Burden. https://pmivectorlink.org/about/malaria-burden. Accessed October 20, 2022.

### A major ramp-up of global efforts is required to achieve the 2030 malaria milestones defined by the WHO in 2016

#### Current achievements toward malaria elimination remain significantly behind the targets set by WHO Baseline *Previous Target* Today Future WHO targets 2016 2020 2021 2025 2030 **Reduction of** 3% 40% malaria case **75%** 90% incidence<sup>1, a</sup> **Reduction of** 21% malaria 40% **75%** 90% mortality<sup>1, a</sup>

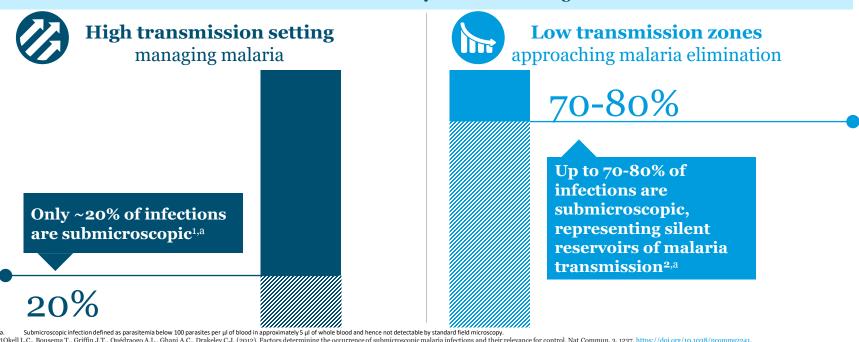
a. Reduction vs. baseline case incidence/mortality reported in 2016

<sup>1</sup> WHO. (2021). Global technical strategy for malaria 2016–2030, 2021 Update. https://www.who.int/publications/i/item/9789240031357...

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### Achieving complete malaria elimination presents a major challenge due to the risk of silent reservoirs of transmission

In areas approaching elimination with few to no symptomatic patients, submicroscopic infections carrying the disease can remain undetected by conventional diagnostic method



<sup>10</sup>kell L.C., Bousema T., Griffin J.T., Onedrango A.L., Ghani A.C., Drakeley C.J. (2012). Factors determining the occurrence of submicroscopic malaria infections and their relevance for control. Nat Commun., 3, 1237. https://doi.org/10.1038/ncomms2241.
2 Villasis, E., Garcia Castillo, S. S., Guzman, M., Torres, J., Gomez, J., Garro, K., ... & Torres, K. (2022). Epidemiological characteristics of P. vivax asymptomatic infections in the Peruvian Amazon. Frontiers in cellular and infection microbiology, 1184. https://doi.org/10.3189/fcimb.2022.901423.



### Impact of asymptomatic *P falciparum* infections on transmission and on malaria in a longitudinal cohort in Kenya

Steve M Taylor MD MPH steve.taylor@duke.edu 1 November 2022







# Asx infection Transmission Transmission Transmission Transmission Asymptomatic infection contribution Symptomatic infection contribution Percent infections asymptomatic infection symptomatic infection symptomatic infection contribution Percent infections asymptomatic infection contribution Percent Per

#### Asx infection → transmission









95% of infected mosquitos resulted from asymptomatic human infections

Sumner... O'Meara, Taylor Nat Commun 2021

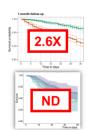
#### **Conclusions**



 What are the relative contributions of asymptomatic and symptomatic infections to mosquito infections?



- What is the risk of symptomatic malaria following:
  - an asymptomatic *P falciparum* infection?
  - a symptomatic RDT-negative (i.e. subpatent) P falciparum infection?



### The WHO acknowledges the effectiveness of active and reactive case detection for accelerating malaria elimination in low transmission zones

Active and reactive case detection become important tools to achieve malaria free status

### **Active case detection**



Involves mass parasitological testing of a population either in a specific geographic area or at higher risk of malaria infection, followed by treatment of positive cases (MTaT vs TTaT)<sup>2</sup>



In low transmission settings, prevention of new infections will be "guided by active case detection and case investigations as part of a malaria surveillance and response programme"

and response programme"

### Reactive case detection

Involves parasitological testing of every person near or exposed to a person who has a confirmed malaria case, followed by treatment of positive cases<sup>2</sup>





"RACDT becomes an **essential component of**surveillance when countries are nearing
interruption of transmission to monitor progress
towards elimination"3

MTaT = Mass Testing and Treatment; TTaT = Targeted Testing and Treatment; RACDT = Reactive Case Detection and Treatment

1WHO. (2021). Global technical strategy for malaria 2016-2030, 2021 Update. https://www.who.int/publications/i/item/9789240031357.

2WHO. (2022). WHO guidelines for malaria (Rev.3). Published on 25 November, 2022. https://www.who.int/publications/i/item/guidelines-for-malaria.

3WHO. (n.d.). WHO recommendations on malaria elimination. <a href="https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination/recommendations-on-malaria-elimination#">https://www.who.int/teams/global-malaria-programme/elimination#">https://www.who.int/teams/global-malaria-programme/elimination#</a>

### Reactive case detection can reduce onward malaria transmission and thereby contribute to malaria elimination in low transmission zones...

Reactive case detection has the potential to find malaria cases in proximity to the index case early, reducing further transmission of malaria



higher likelihood of infection in individuals with proximity to an index case<sup>1</sup>



of households with RDT positive residents are likely **not identified through passive case detection<sup>2,a</sup>** 

of RDT positive individuals missed through passive case detection can be **identified** with RACD<sup>2,a</sup>

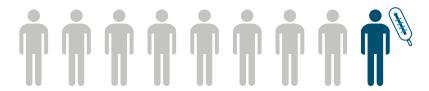
RACD = Reactive Case Detection. b. Simulation using survey results in low transmission setting - RACD involved testing all individuals residing within 500 meters of an index household

<sup>1</sup> Perera, R., Caldera, A. & Wickremasinghe, A.R. (2020). Reactive Case Detection (RACD) and foci investigation strategies in malaria control and elimination: a review. Malar J, 19, 401. https://doi.org/10.1186/s12936-020-03478-0.

<sup>2</sup> Searle, K., Shields, T., Hamapumbu, H., et al. (2013). Efficiency of household reactive case detection for malaria in rural Southern Zambia: Simulations based on cross-sectional surveys from two epidemiological settings. PLOS One, 6(8), e70972. https://doi.org/10.1371/journal.pone.0070972.

....but currently used RDTs cannot accurately detect asymptomatic patients in low transmission areas, limiting their value in such settings

Asymptomatic individuals represent almost all cases and drive disease transmission in low-transmission areas but conventional RDTs miss most of them

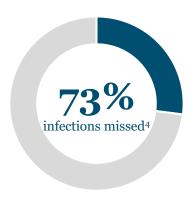


~90% of infections in low-transmission areas **remain asymptomatic** ...<sup>1,2</sup>





### Performance of conventional RDTs based on pool sensitivity



#### among asymptomatic individuals

<sup>1</sup> Zainabadi K. (2021). Ultrasensitive diagnostics for low-density asymptomatic Plasmodium falciparum infections in low transmission settings. J Clin Microbiol, 59(4), e01508-20. https://doi.org/10.1128/JCM.01508-20.

<sup>2</sup> Ferreira, M. U., Corder, R. M., Johansen, I. C., Kattenberg, J. H., Moreno, M., Rosas-Aguirre, A., ... & Vinetz, J. M. (2022). Relative contribution of low-density and asymptomatic infections to Plasmodium vivax transmission in the Amazon: pooled analysis of individual participant data from population-based cross-sectional surveys. The Lancet Regional Health-Americas, 9, 100169. https://doi.org/10.1016/j.lana.2021.100169.

<sup>3</sup> Slater, H., Ross, A., Quédraogo, A. et al. (2015). Assessing the impact of next-generation rapid diagnostic tests on Plasmodium falciparum malaria elimination strategies. Nature, 528, S94–S101. https://pubmed.ncbi.nlm.nih.gov/26633771/.

<sup>4</sup> Yimam Y., Mohebali M., Abbaszadeh Afshar M.J. (2022). Comparison of diagnostic performance between conventional and ultrasensitive rapid diagnostic tests for diagnosis of malaria: A systematic review and meta-analysis. PLOS One, 17(2), e0263770. https://doi.org/10.1371/journal.pone.0263770.

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### Malaria in pregnancy accounts for 575 maternal and infant deaths per day, the majority of which are preventable<sup>1</sup>

Malaria infections disproportionally affect pregnant women, posing substantial risks not only to the mother, but also to the fetus and newborn

**Pregnant women** 

125 million

**pregnant women** at risk of malaria infection<sup>2</sup>

3X more likely to suffer from severe malaria<sup>1</sup>

#### **Maternal outcomes**

3.8x

higher likelihood for pregnant women to be anemic due to malaria infection<sup>3</sup>

mortality rate in pregnant women due to severe disease from malaria infection<sup>1</sup>

#### **Fetal outcomes**

1.8x

higher likelihood of **stillbirth** due to malaria infection in pregnant women<sup>2</sup>

#### **Infant outcomes**

2**X** 

higher likelihood of **low**birthweight among
infants due to placental
malaria infection<sup>1</sup>

risk of mother-to-child HIV transmission with underlying malaria

infection4

18chantz-Dunn, J., Nour, N.M. (2009). Malaria and pregnancy: a global health perspective. Rev Obstet Gynecol, 2(3), 186-192. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2760896/.
2Bauserman M, Conroy AL, North K, Patterson J, Bose C, Meshnick S. (2019). An overview of malaria in pregnancy. Semin Perinatol, 43(5), 282-290. https://doi.org/10.1053/i.semperi.2019.03.018.

Feleke, D.G., Adamu, A., Gebreweld, A. et al. (2020). Asymptomatic malaria infection among pregnant women attending antenatal care in malaria endemic areas of North-Shoa, Ethiopia: a cross-sectional study. Malar J, 19, 67. https://doi.org/10.1186/s12936-020-3152-9. 4Mbachu, I.I., Ejikunle, S.D., Anolue, F. et al. (2020). Relationship between placenta malaria and mother to child transmission of HIV infection in pregnant women in South East Nigeria. Malar J, 19, 07, https://doi.org/10.1186/s12936-020-03171-2.

To tackle malaria in pregnancy, the WHO advises a packaged approach of prevention and prompt, effective case management, but systematic asymptomatic screening is not yet recommended



WHO guidance for prevention and treatment of malaria in pregnancy:

- Insecticide-treated nets (ITNs)
- Intermittent preventative treatment (IPTp)<sup>a</sup>
- Quality diagnosis and treatment

### **Diagnosis**

 "Prompt parasitological confirmation by microscopy or alternatively by RDTs is recommended in all patients suspected of malaria before treatment is started."

#### **Treatment**

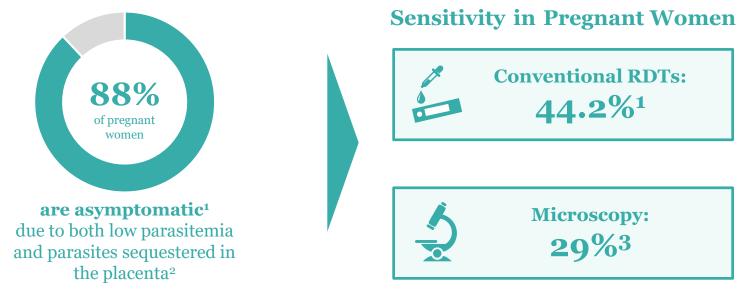
 "Pregnant women in the first trimester with uncomplicated falciparum malaria should be treated with quinine plus clindamycin for seven days."

A systematic malaria screening of pregnant women without symptoms is not yet recommended, despite the high number of asymptomatic patients and the substantial risks arising from malaria during pregnancy<sup>2</sup>

aIn high-transmission settings only.

### Conventional RDTs and microscopy used in decentralized settings have poor accuracy in detecting malaria in pregnant women

The diagnosis of malaria in pregnancy is challenging as the vast majority remains asymptomatic with parasitemia below the limit of detection of conventional test methods



<sup>1</sup> Briand, V., Cottrell, G., Tuike Ndam, N., Martiáñez-Vendrell, X., Vianou, B., Mama, A., et al. (2020). Prevalence and clinical impact of malaria infections detected with a highly sensitive HRP2 rapid diagnostic test in Beninese pregnant women. Malar J, 19(1), 188. https://doi.org/10.1186/s12936-020-03261-1.

 $<sup>2 \\</sup> Takem, E.N., \\ D'Alessandro, \\ U. (2013). \\ Malaria in pregnancy. \\ Mediterr \\ J \\ Hematol \\ Infect Dis, \\ 5(1), \\ e2013010. \\ \\ \underline{https://www.ncbi.nlm.nih.gov/pmc/articles/PMC/895297/.}$ 

<sup>2</sup> Mayor, A., Moro, L., Aguilar, R., Bardají, A., Cisteró, P., Serra-Casas, E., Sigaúque, B., Alonso, P.L., Ordi, J., Menéndez, C. (2012). How hidden can malaria be in pregnant women? Diagnosis by microscopy, placental histology, polymerase chain reaction and detection of histidine-rich protein 2 in plasma. Clinical Infectious Diseases, 54(11), 1561–1568. https://doi.org/10.1003/cid/cis236.

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### Ultra sensitive Malaria Pf RDT sensitivity is 114% higher in asymptomatic individuals and 72% higher in overall low transmission zones

PLOS ONE	PUBLISH	ABOUT	BROWSE
⑥ OPEN ACCESS  ₱ PEER-REVIEWED RESEARCH ARTICLE			
Comparison of diagnostic perform conventional and ultrasensitive radiagnosis of malaria: A systematic	nance between diagnost review and	een stic tests meta-a	s for nalysis
Yonas Yimam 🖪, Mehdi Mohebali, Mohammad Javad Abbaszadeh Afsha	ır		
Published: February 10, 2022 • https://doi.org/10.1371/journal.pone.0263	3770		

#### Meta-analysis, 15 studies, 20k samples, molecular as comparator

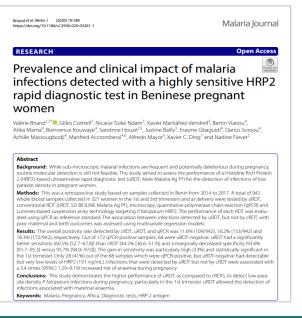
Vs. Molecular	Pooled Sens %	Pooled Spec%	Asympto Sens%	Asympto Spec %	Low Transmission Pooled Sens%	High Transmission pooled Sens%
Ultra-sensitive Malaria Pf RDT	61	99	58	98	62	75
Conventional RDT	42	99	27	100	36	62

#### "Conclusion

The us-RDT test showed better performance than co-RDT test, and this characteristic is more evident in asymptomatic individuals and low transmission areas......" Comparison of diagnostic performance between conventional and ultrasensitive rapid diagnostic tests for diagnosis of malaria: A systematic review and meta-analysis | PLOS ONE

### Ultra sensitive Malaria Pf RDT showed higher sensitivity in pregnant women vs conventional RDTs

A retrospective study was based on 942 blood samples collected in 327 women in 1st and 3rd trimesters



Publication showed significantly superior performance of ultra-sensitive Malaria Pf RDT vs conventional RDTs

Ultra-sensitive Malaria Pf RDT

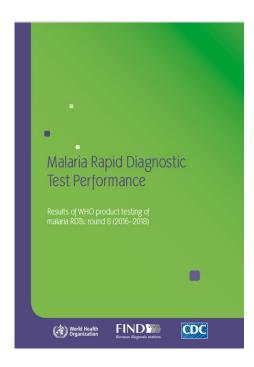
+37%

Increase in sensitivity in pregnant women versus

### **Conventional RDTs**

1 Briand, V., Cottrell, G., Tuike Ndam, N., Martiáñez-Vendrell, X., Vianou, B., Mama, A., et al. (2020). Prevalence and clinical impact of malaria infections detected with a highly sensitive HRP2 rapid diagnostic test in Beninese pregnant women. Malar J, 19(1), 188. https://doi.org/10.1186/s12936-020-03261-1.

### Abbott ultra sensitive Pf RDT o5FK140 is WHO pre-qualified



Abbott ultra sensitive Pf RDT 05FK140 is intended to aid in the diagnosis of malaria infection to a general population including pregnant women

PQDx 0349-012-00

WHO PQ Public Report

November 2020, version 2.0

PQDx 0349-012-00

WHO PQ Public Report

November 2020, version 2.0

### WHO Prequalification of In Vitro Diagnostics PUBLIC REPORT

Product: NxTek Eliminate Malaria Pf<sup>1</sup> WHO reference number: PQDx 0349-012-00

NXTek Eliminate Malaria Pf with product codes <u>05FK140</u>, 05FK141, 05FK142, and 05FK143, manufactured by Abbott Diagnostics Korea Inc<sup>2</sup>, CE-marked regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 12 April 2019.

#### Summary of WHO pregualification assessment NxTek Eliminate Pf

	Date	Outcome
Prequalification listing	12-Apr-2019	listed
Dossier assessment	12-Jan-2019	MR
Site inspection(s) of quality	26-Apr-2018	MR
management system		
Product performance	2016	MR
evaluation		

MR: Meets Requirements

#### Intended use

According to the claim of intended use from Abbott Diagnostics Korea Inc, "the NxTek Eliminate Malaria Pf is an ultra sensitive, qualitative in vitro test for the detection of histidine rich protein 2 (HRP2) antigen of Plasmodium falciparum malaria in human whole blood. The test is intended for professional use and the point-of-care testing to aid in the diagnosis of malaria infection to a general population including pregnant women."

Summary performance	Panel detection score	False positive rate	(%)	Invalid rate (%)
characteristics	200 parasites/μl	200 parasites/μl	Clean	
			negatives	
	Pf	Pv		
NxTek Eliminate Malaria Pf	98%	0%	0.9%	0.1%

## n." avalid ate (%)

#### Warning/limitation

WHO PQ independent evaluation verifies performance to detect clinically significant (symptomatic) malaria infection (parasitemias >200 p/ul). WHO does not recommend screening of asymptomatic pregnant women for malaria or screening for asymptomatic infections except for reactive case detection in elimination settings. Therefore, claims of performance in asymptomatic populations have not been verified.

Abbott
NxTek™

Eliminate Malaria Pf

### Abbott ultra sensitive Pf RDT is listed at Global Fund. GF to Support use for targeting low density parasite infections provided that additional evidence and WHO guidance are developed



(with Assay diluent, disposable inverted cup, Alcohol Swab, sterile lancet)

Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea



#### 3.1. Diagnosis

The Global Fund supports early diagnosis of malaria through testing of suspected cases with microscopy or Rapid Diagnostic Tests (RDTs). Achieving universal coverage of testing and confirmation of parasitological diagnosis of malaria before treatment requires availability of testing capacity, reinforced by training, supervision, agile supply chain and quality assurance at all levels of the health system. In the case of microscopy, consider efficiencies across disease programs when funding external quality assurance (EQA), procurement and lab technicians' capacity.

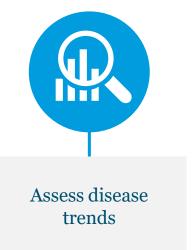
Current evidence is still limited on the individual and public health cost-benefits of detecting and treating low density malaria infections contribution to malaria transmission reduction. As a result, for routine case management, the Global Fund does not support more sensitive diagnostic tools targeting low density parasite infections such as polymerase chain reaction, highly sensitive RDTs, and loop-mediated isothermal application (LAMP). If additional evidence and related WHO policy guidance are developed, the Global Fund will reassess support for these tools.

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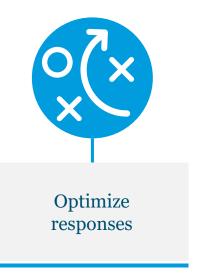
### The lack of broad and effective usage of surveillance solutions prevent optimized, data-driven decisions in malaria management

Many countries with a high disease burden are not in a position to capture essential malaria data

The lack of effective disease surveillance makes it difficult for national malaria programs to<sup>1</sup>:







1 WHO. (2021). Global technical strategy for malaria 2016-2030, 2021 Update. https://www.who.int/publications/i/item/9789240031357.

### The WHO recognizes digital surveillance tools as a key success factor for effective malaria management and elimination

Effective malaria case surveillance represents one of the three strategic pillars defined by the WHO with a number of potential use cases highlighted<sup>1</sup>

Tracking the progress of male	aria control	Investigating case clusters to better understand risk factors and eliminate foci of transmission
Advocating for investment from international sources	rom domestic/	Identifying and responding to threats
Identifying populations expedisadvantage and allocating reso		<b>Certify malaria elimination</b> and preventing reestablishment



"Irrespective of where countries are on the path to elimination, **surveillance of malaria** should be considered a **central intervention** in national and subnational malaria strategies" <sup>1</sup>

1 WHO. (2021). Global technical strategy for malaria 2016-2030, 2021 Update. https://www.who.int/publications/i/item/9789240031357.

### Seamless integration of RDTs with Abbott's Cloud platform enables effective malaria surveillance

Empowers decision-makers to gain deep insights supporting the identification of hotspots in near real time

Capturing test data and health related information even in area with little or no connectivity with mobile technology

SUBMIT RESULT

SUBMIT RESULT

SUBMIT RESULT

SUBMIT RESULT

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Interactive maps with hotspots, trends and reporting<sup>55</sup> for assessing disease trends and tracking the progress of malaria control



#### Key benefits

- Capturing and transfer of data in near real time from decentralized sites enables monitoring from anywhere building transparency and fostering accountability
- Effective disease monitoring leveraging advanced analytical and data visualization capabilities as a critical component for evaluating performance of test programs
- Supports offline data capture in locations with limited to no connectivity to broaden the reach to decentralized services

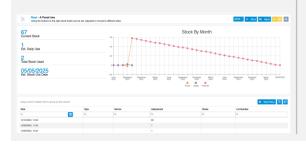
### Opportunity to optimize the management of RDT stock, supporting the avoidance of stock outs

### Empowering stakeholders at different levels to accurately monitor and manage RDT consumption to optimize stock management and logistics



#### Monitoring and reporting of stock levels

- Enables adding/removing/reconciling stocks at sites
- Tracks stock levels at all testing sites in terms of stock utilization





### 2D barcode and accuracy with a mobile solution

- 2D barcode enables quickly scan of product information
- Avoid common errors associated with paper-based records







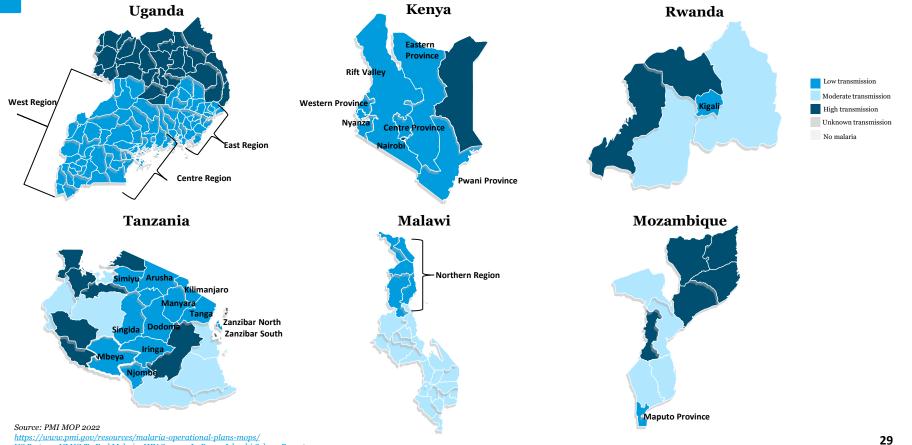
#### Data security and encryption

Industry-grade encryption security (e.g. ISO 9001 and ISO 27001 data security requirements)

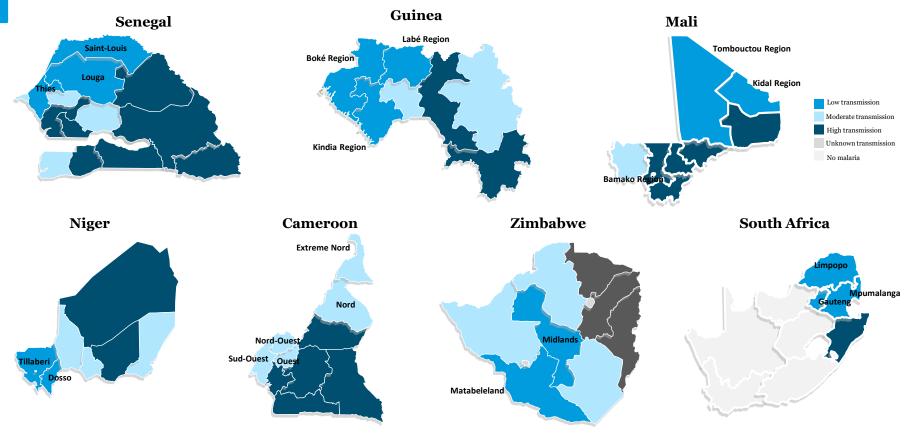
Encryption
in transit
and at rest
dedicated
customerspecific
database

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### There are low malaria transmission zones even within high burden countries



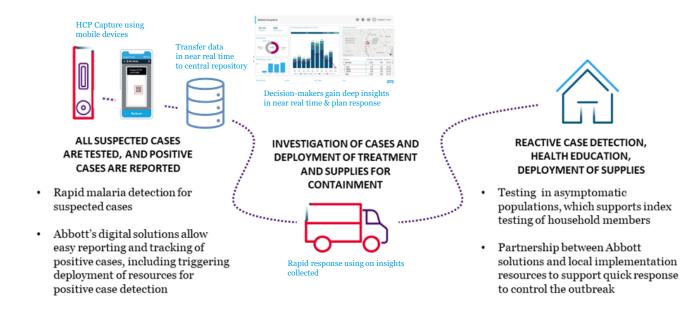
### There are low malaria transmission zones even within high burden countries



Source: PMI MOP 2022

### Summarizing the power of screening and surveillance in decentralized settings to enable a swift response from malaria case identification and control

Ultra-sensitive rapid testing and digital connectivity can help support 1-3-7 strategy to bend the curve to elimination in low transmission zones





- Prevents malaria outbreaks from gaining momentum
- Reactive case detection and index testing of household members prevents additional potential infections from spreading
- Screening, surveillance and response is essential for controlling the outbreak

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### China's "1-3-7" strategy is at the core of its successful malaria elimination effort



political commitment and an effectively integrated approach across 13 ministries and

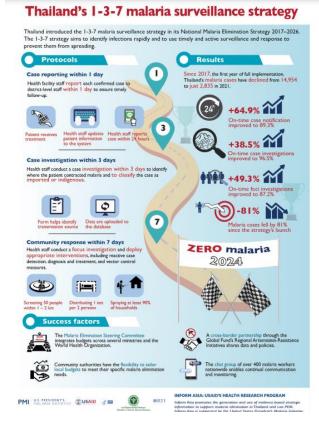
between central and local levels.

"China's "1-3-7" strategy is at the core of its **successful malaria elimination effort.** The strategy refers to the diagnosis, investigation and follow-up of cases that must occur within 1, 3 and 7 days. On Day 1, any malaria case, confirmed by a rapid diagnostic test or microscopy and treated, must be reported to the local CDC. By the end of **Day 3**, the county CDC must confirm and investigate the case and determine if there is a risk of spread. By the end of **Day 7**, the county CDC manages any malaria risks in the areas where the person with malaria has spent time. including testing and treating community members; identifying the malaria type; raising awareness in the community; investigating the species of mosquitoes and reducing their numbers, including through indoor spraying of insecticides."

https://www.who.int/china/news/commentaries/detail/china-certified-as-malaria-free-by-who

1-3-7 suveillance strategy helped reduce 81% of the Malaria cases in

Thailand



https://www.rti.org/sites/default/files/related-content-files/1-3-7\_infographic\_final35.pdf

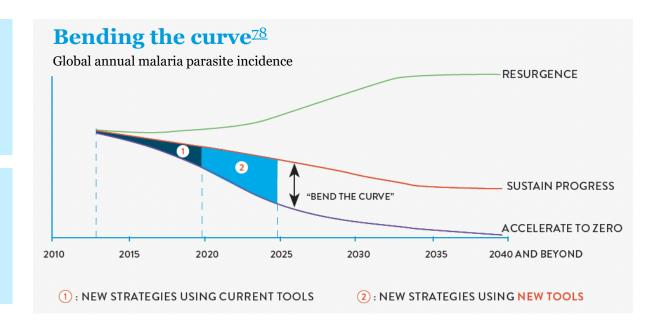
- 1. The Malaria Burden
- 2. Acceleration needed for Malaria elimination:
  - 2.1 Active/reactive case detection
  - 2.2 pregnant women screening
  - 2.3 asymptomatic and pregnant women rapid testing
  - 2.4 surveillance
- 3. Accelerating Malaria Elimination in low transmission zones
- 4. 1-3-7 Strategy for Elimination
- 5. Conclusion

### Abbott is committed to helping bend the malaria curve to reduce incidence and mortality rates by at least 90% by 2030

Abbott has invested to provide the Global Malaria Community with the tools to help win the fight against malaria

Years of innovation, experience and greater understanding of malaria prevention and treatment enable us to **support** a new paradigm to reset malaria elimination

Scaling up diagnostics are critical to bend the curve and accelerate progress of malaria elimination, as progress has slowed down recently and even reversed in some places



### Thank you!

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