Documentation related to Session 4 of the meeting
Click on the links below to see the pre reads and presentations

Malaria Policy Advisory Group (MPAG) Meeting

13 – 15 April 2021 *(CEST time zone)*
Virtual meeting

PROVISIONAL PROGRAMME*

Tuesday, 13 April 2021			
	Session 1	**Open**	
12:00 – 12:05	Welcome by the ADG, UCN	Dr Ren Minghui	
12:05 – 12:15	Welcome by the Chair, MPAG	Dr Dyann Wirth	
12:15 – 13:00	Report from the Director, GMP	Dr Pedro Alonso	
13:00 – 13:30	Partner Perspective, US President's Malaria Initiative	Dr Raj Panjabi	
13:30 – 14:00	Rethinking malaria	Dr Rose Leke & Dr Alastair Robb	**For guidance**
14:00 – 14:15	*Coffee break*		
	Session 2	**Open**	
14:15 – 15:00	Clinical malaria – parasite density thresholds in different transmission settings and implications for use of RDTs	Dr Jane Cunningham	**For guidance**
15:00 – 15:30	Update on the situation of antimalarial drug efficacy and resistance in Africa	Dr Pascal Ringwald	
15:30 – 16:00	Proposed technical consultation to stage *P. knowlesi* along the continuum between zoonosis and human pathogen	Dr Kim Lindblade	
16:00	*End of day*		

Wednesday, 14 April 2021			
	Session 3	**Open**	
12:00 – 12:45	HRP2 gene deletions – a focus on horn of Africa region	Dr Jane Cunningham	**For decision**
12:45 – 13:30	Proposed technical consultation on urban malaria	Dr Abdisalan Noor	**For guidance**
13:30 – 13:45	*Coffee break*		
	Session 4	**Open**	
13:45 – 14:15	Update on guidance for severe malaria	Dr Peter Olumese	**For decision**

14:15 – 14:45	Update on the classification of insecticide-treated net products – annual update as requested by MPAG Background / Presentation	Dr Jan Kolaczinski & Dr Marion Law	**For guidance**
14:45 – 15:15	Update on digital solutions for malaria elimination surveillance Background / Presentation	Dr Abdisalan Noor & Ms Mwalenga Nghipumbwa	
15:15	*End of day*		

Thursday, 15 April 2021			
	Session 5	**Closed**	
12:00 – 15:00	Finalization of wording of recommendations	Dr Dyann Wirth	**For guidance**

** Provisional programme and may be subject to change*

Management of severe malaria

WHO GMP MPAG Meeting – April 14, 2021

Dr. Peter Olumese

Diagnostics, Medicines & Resistance Unit

Global **Malaria** Programme

World Health Organization

Outline of the presentation

- Introduction
- Clinical and epidemiological definitions of severe malaria,
- Management of severe malaria
- WHO Norms and standards documents
- Implementation challenges
- Way forward

Introduction

- Severe malaria is defined by clinical and laboratory evidence of vital organ dysfunction
- It is most caused by P. falciparum, however, P. vivax and P. knowlesi can also cause severe disease
- Risk populations
  - High transmission areas – young children and visitors (any age) from nonendemic areas
  - Other transmissions areas – all age groups
- Therapeutic objectives
  - Main objective is to prevent the patient from dying
  - Secondary objectives are to prevent disabilities and prevention of recrudescent infection
- Medical emergency, rapid diagnosis and start of effective treatment at the highest possible level of care.

Clinical signs of severe malaria

- One of more of the following features in a patient with confirmed falciparum malaria:

Clinical features of severe malaria

- impaired consciousness (including unrousable coma);
- prostration, i.e. generalized weakness so that the patient is unable to sit, stand or walk without assistance;
- multiple convulsions: more than two episodes within 24h;
- deep breathing and respiratory distress (acidotic breathing);
- acute pulmonary oedema and acute respiratory distress syndrome;
- circulatory collapse or shock, systolic blood pressure < 80mm Hg in adults and < 50mm Hg in children;
- acute kidney injury;
- clinical jaundice plus evidence of other vital organ dysfunction; and
- abnormal bleeding.

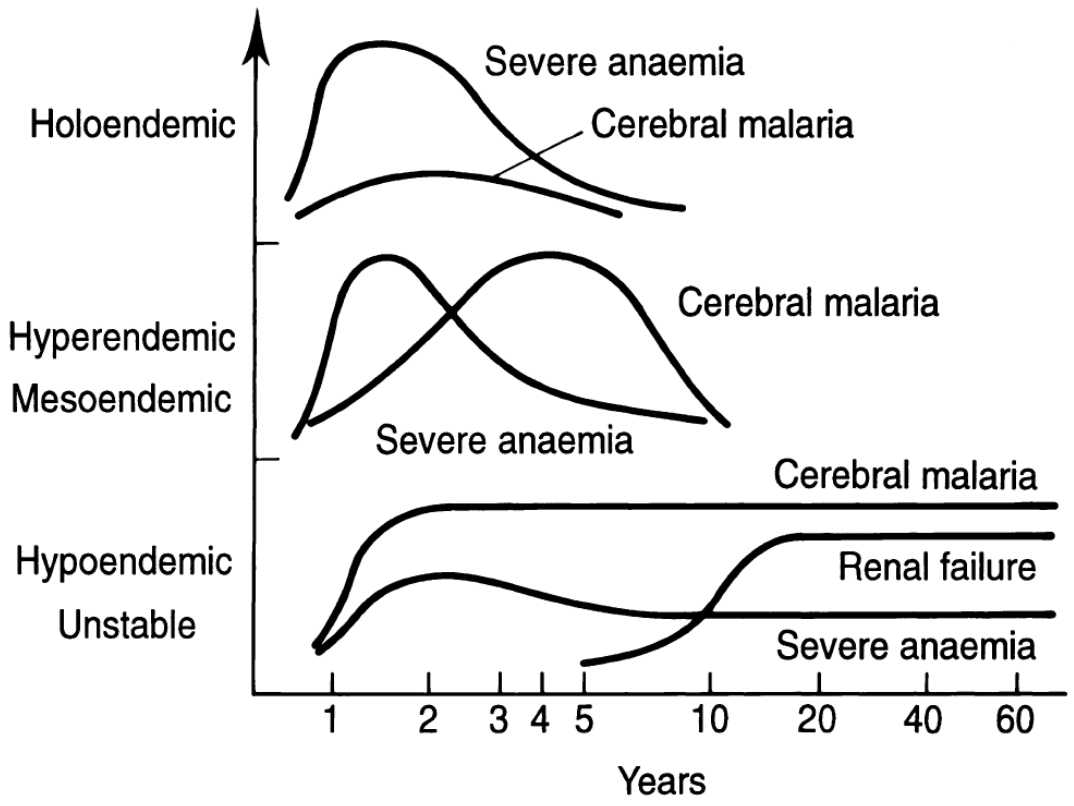
Laboratory findings of severe malaria

- One of more of the following laboratory findings in a patient with confirmed falciparum malaria

Laboratory and other findings

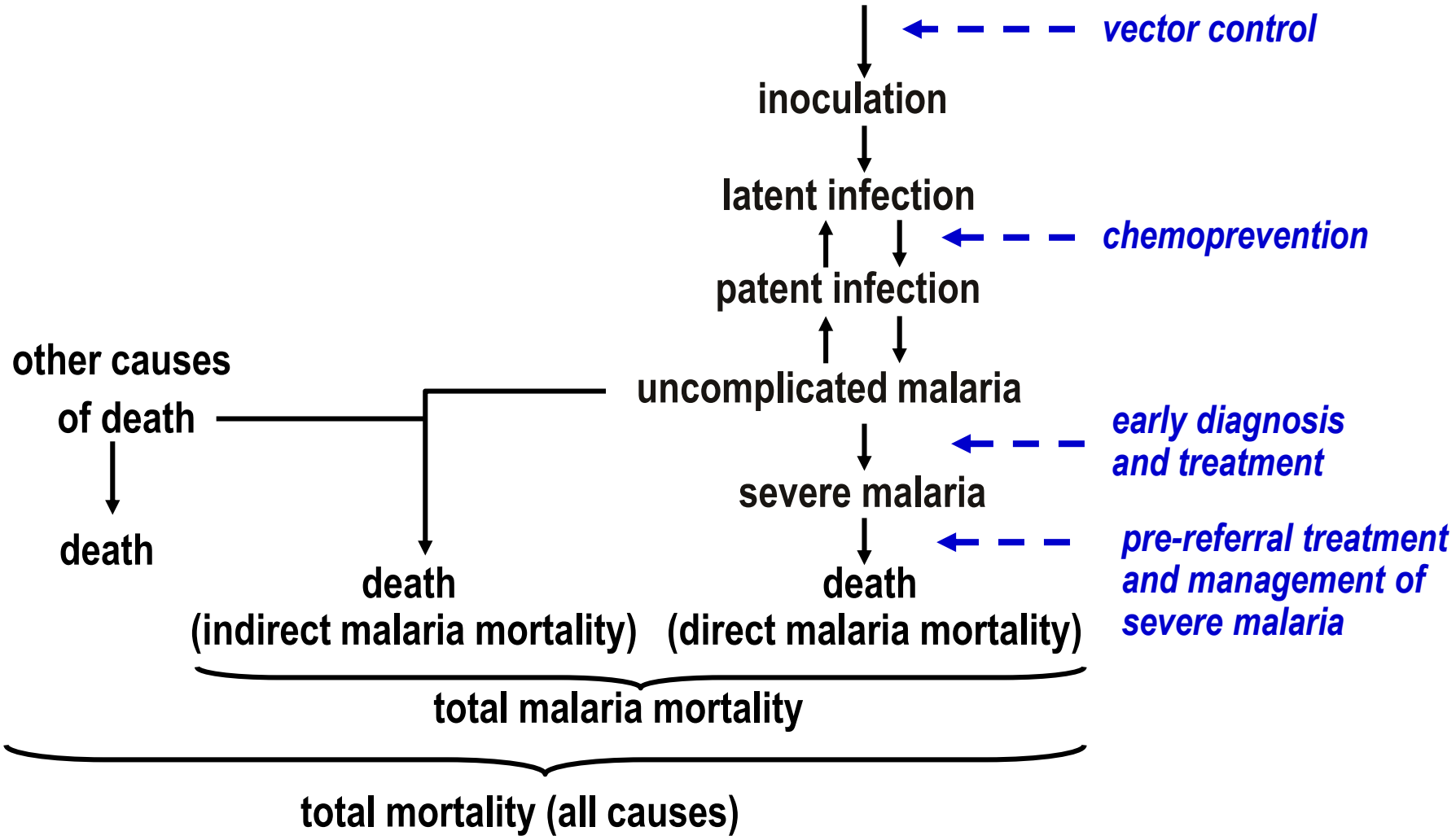
- hypoglycaemia (< 2.2mmol/l or < 40mg/dl);
- metabolic acidosis (plasma bicarbonate < 15mmol/l);
- severe normocytic anaemia (haemoglobin < 5g/dl, packed cell volume < 15% in children; <7g/dl, packed cell volume < 20% in adults);
- haemoglobinuria;
- hyperlactataemia (lactate > 5mmol/l);
- renal impairment (serum creatinine > 265µmol/l); and
- pulmonary oedema (radiological).

Age distribution



Age-distribution of severe anaemia, cerebral malaria and renal failure due to falciparum malaria at different levels of malaria transmission

Preventing malaria progression and death



Management of severe malaria

- **Medical emergency**
- Therapeutic objectives
- The primary objective of antimalarial treatment in severe malaria is to prevent death (untreated mortality approaches 100%, but falls to 15-20% with antimalarial treatment).
- In treating cerebral malaria, prevention of neurological deficit is also an important objective.
- In the treatment of severe malaria in pregnancy, saving the life of the mother is the primary objective.
- In all cases of severe malaria, prevention of recrudescence and avoidance of minor adverse effects are secondary.

- Management of severe malaria comprises four main areas
  - Clinical assessment of patient,
  - Specific antimalarial treatment,
  - Additional treatments (managements of other complications),
  - Supportive care

Diagnosis of severe malaria

- All cases of suspected severe malaria should have a parasitological test (microscopy preferred over RDT) to confirm the diagnosis.
  - *In the absence or delay, patients with suspected severe malaria, and other high risk groups, should be treated on clinical grounds.*
- Diagnosis include confirming the presence and extent of organ dysfunction
- Results of initial diagnostic evaluation can guide the management of the patient as well as serve as prognostics indicators of the disease.

Treatment of severe malaria

- Treat children and adults with severe malaria (including infants, pregnant women in all trimester, and lactating women) with intravenous or intramuscular artesunate for at least 24 hours and until able to tolerate oral medication.
- Once the patient has received at least 24h of parenteral therapy, and can tolerate oral therapy, complete treatment with 3 days of ACT
- Children weighing <20 kg should receive a higher dose of artesunate (3 mg/kg/dose) than larger children and adults (2.4 mg/kg/dose) to ensure an equivalent drug exposure.
- If parenteral artesunate is not available, use artemether i.m. 3.2mg/kg stat following by 1.6mg/kg daily in preference to quinine for treating children and adults with severe malaria

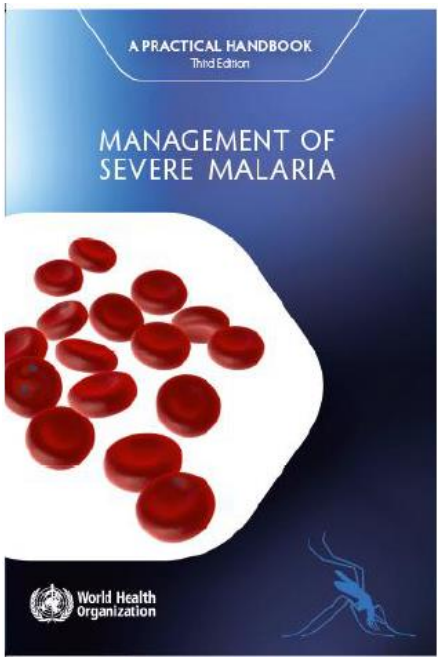
Pre-referral treatment of severe malaria

- Where complete treatment of severe malaria is not possible, but injections are available, give children and adults a single dose of intramuscular artesunate and refer to an appropriate facility for further care.
- Where intramuscular artesunate is not available use intramuscular artemether or, if that is not available, use intramuscular quinine
  - **Where intramuscular injections are unavailable, treat children <6 years with a single rectal dose (10mg/kg) of artesunate, and refer immediately to an appropriate facility for further care.**
  - **Do not use rectal artesunate in older children and adults.**

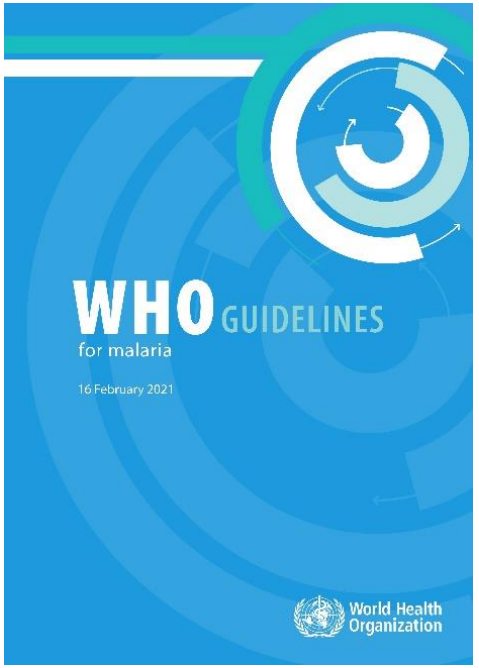
- Severe anaemia
- Hypoglycemia
- Respiratory oedema
- Renal failure
- etc…

WHO Publications, Guidelines and Manuals on severe malaria

Severe Malaria: Supplement to European Journal TM&IH 2014

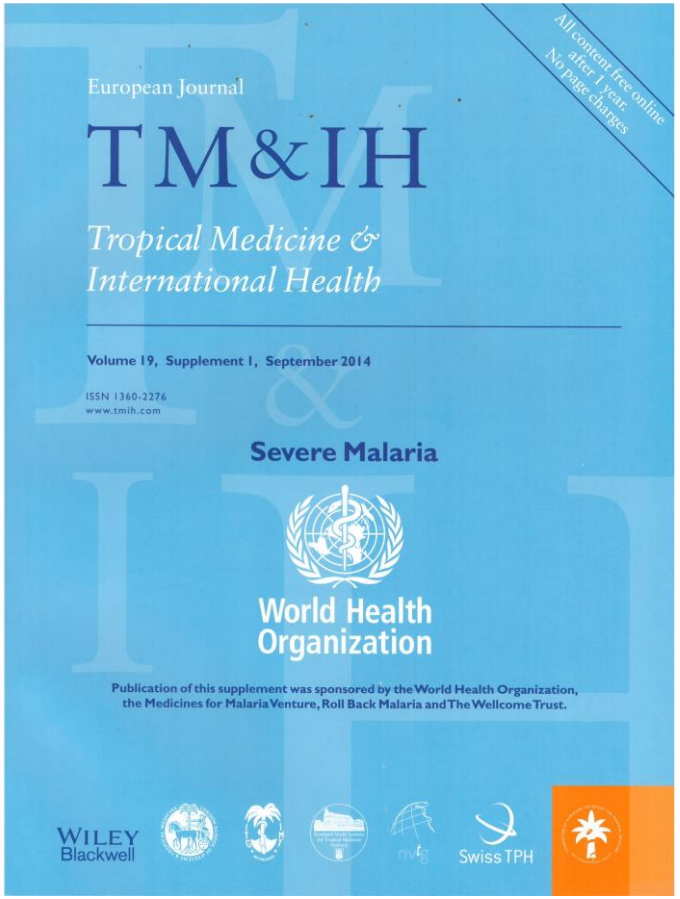


Management of severe malaria: A Practical Handbook (3rd ed) 2012

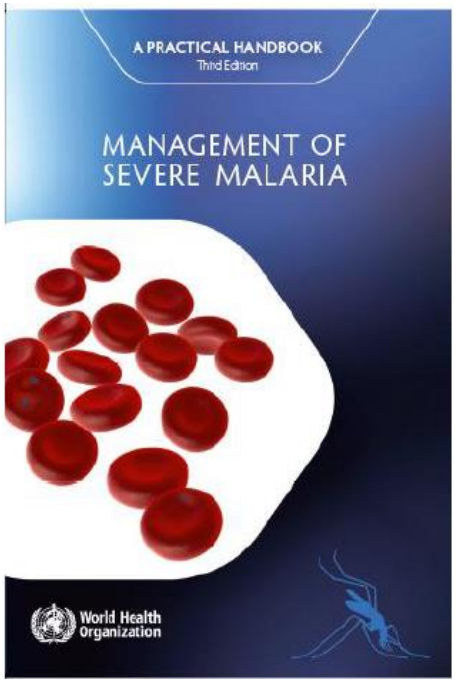


WHO Guidelines for malaria 2021; treatment recommendations last updated in 2015

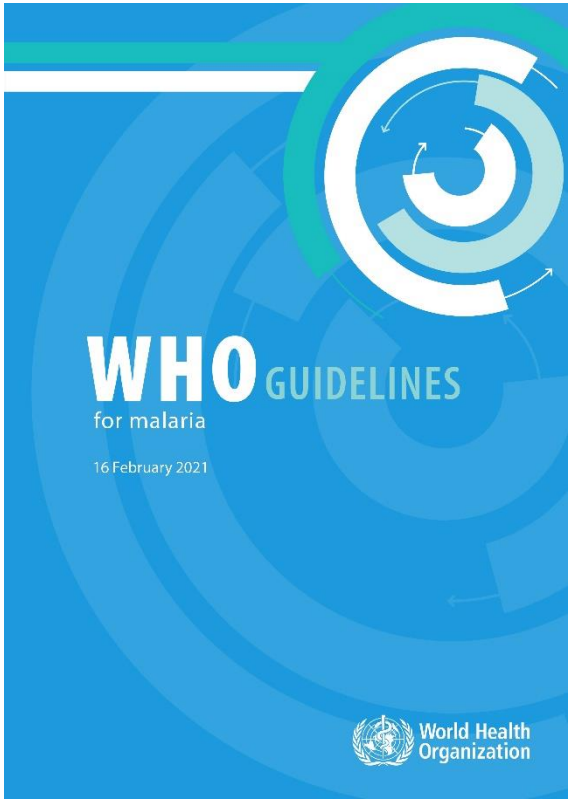
- Published in 2014 following a WHO Technical consultation in 2011
- The 4th ed of the supplement. First published in 1986, with subsequent editions in 1990 and 2000
- Provides a series of literature reviews and consensus opinions covering many aspects of severe malaria. Areas covered included
  - Epidemiology; definitions; clinical disease in different categories (children, adults, special groups); pathophysiology; pathology; management and pharmacology of antimalarial medicines..



- Published in 2012 following a WHO Technical consultation in 2011
- The 3rd ed of the Practical Handbook for the management of severe malaria. First published in 1986, with subsequent ed in 2000
- This implementation manual focuses on the practical management of severe malaria based on recommendations in the Guidelines for the Treatment of Malaria (2nd ed; 2010).
- The handbook is intended primarily for health professionals working in hospitals or health centres with inpatient facilities, who are responsible for management of patients with severe malaria.
- It covers all aspects of management, from triaging, to diagnosis and treatment; nursing care, follow up and post treatment rehabilitation.



- The *WHO Guidelines for malaria* include the recommendations published in the 3rd edition of the Guidelines for the Treatment of Malaria (2015). First published in 2005, with subsequent ed in 2010
- Has a section on the recommendations for the management of severe malaria.
- The target audience of the Guidelines is primarily policy makers to guide the development of National treatment policies and guidelines. It is not intended to be used as a manual or treatment handbook for health professionals.



Implementation challenges at country level

- Uptake of WHO guidelines
- Robustness of the health system
  - Availability of the medications at required levels of the health service
  - Referral systems
- Capacity of the health work force
  - Training and continuing update (in-service and post- service)
  - Community health delivery systems
- Quality of care
- The use of monotherapy

Going forward: Normative guidance

- Guidelines and implementation manuals
  - Recommendations on the management of severe malaria in the Guidelines are current. There is presently no indications or evidence to make any changes or modifications.
  - The Practical Handbook for the Management of Severe Malaria (3rd ed) requires an update to reflect specific details that became available with the update of the Guidelines in 2015, after the publication of this edition. The specific areas are
    - Preference in the order of antimalarial choices for treatment of severe malaria
    - Recommendation on dosage adjustment in children.
    - Review fluid management and other supportive treatment
  - The development of an implementation guide for effective deployment of rectal artesunate by community health workers following the completion of the ongoing UNITAID-funded Community access to rectal artesunate for malaria (CARAMAL) project.

Going forward: Implementation support

- Implementation and country support
  - Countries supported to update their national policies and build the required systems and capacity to effectively manage severe febrile illness including severe malaria.
    - Revamp the national training curriculum on management of malaria for all categories of health workers
    - Innovative mechanism for training support
    - Using lessons from the CARAMAL studies as an advocacy tool to support strengthening of the health system, including the referral systems.
    - Keeping the unacceptable high mortality from malaria high on the political / health agenda, and making a link between effective case management including treatment of severe malaria and reduction in malaria deaths.

MPAG discussion and Guidance

- Policy and Guidelines
  - Are there potential policy or guidelines updates needed to further improve the outcome of severe malaria patients?
- Implementation support
  - How to improve guidelines uptake and implementation at country level
  - Strengthening the health system including referral systems
  - Dealing with use of monotherapy (artemisinins) especially for uncomplicated malaria

Malaria Policy Advisory Group Meeting

13—15 April 2021, Geneva, Switzerland
Background document for Session 4

Updates related to the classification of ITN products – supplementary reading

Dr Jan Kolaczinski, Head, Vector Control & Insecticide Resistance Unit, Global Malaria Programme &
Ms Marion Law, Team Lead, Prequalification Team, Vector Control Products, Geneva, Switzerland

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Norms, standards and processes underpinning WHO vector control policy recommendations. Geneva: World Health Organization; 2020.

Norms, standards and processes underpinning WHO vector control policy development

World Health Organization

Norms, standards and processes underpinning WHO vector control policy development

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Norms, standards and processes underpinning WHO vector control policy recommendations

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CONTENTS

INTRODUCTION

In 2018, the World Health Organization (WHO) reviewed its processes for developing and disseminating policy guidance, spearheaded by a detailed analysis conducted within the Global Malaria Programme (GMP). The review identified areas for improvement, one of which is the better communication of the norms, standards and processes underpinning policy recommendations. Better communication will ensure that product developers and researchers are fully aware of the WHO's requirements for assessing and ultimately recommending interventions for vector control. In this context, a vector control intervention is defined as a tool, technology or approach/strategy, and thus is not limited to products (see Annex 1 for glossaries of terms).

The current evaluation process for vector control was first communicated in 2017, following the transition from the WHO Pesticide Evaluation Scheme (WHOPES) to a process co-managed by the WHO Prequalification Team for Vector Control Products (PQT-VCP) and the two technical departments involved in vector control: GMP and the Department of Control of Neglected Tropical Diseases (NTD). While PQT-VCP assesses the safety, quality and efficacy of all vector control products and interventions, the three departments together support the Vector Control Advisory Group (VCAG), which is tasked with evaluating the public health value of novel interventions for which no policy recommendation exists.

Since this first communication, the evaluation process and associated communication have been refined and continue to evolve. The implementation of the new WHO policy-making process provides an opportunity to communicate these developments within the overarching framework of the WHO revised process, while highlighting the elements specific to vector control.

This document is mainly aimed at manufacturers and procurers of vector control products, and at researchers generating data, technologies and approaches/strategies. However, it is also envisaged that this document will provide reassurance to WHO Member States regarding the rigour applied by WHO in formulating policy recommendations, considering that such policy recommendations are used by Member States to inform the development and implementation of national strategies.

The document provides a detailed overview of the norms, standards and processes underpinning the development of WHO policy recommendations for vector control interventions.[1] It also includes high-level information on the prequalification process, which is complementary to and coordinated with policy development. Detailed information on prequalification requirements and processes are available on the PQT-VCP website (https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list).

In addition, this document provides an overview of the roles and responsibilities of the two technical departments involved in the development of vector control policy, namely GMP and NTD, and how they interact with PQT-VCP, which oversees the prequalification process in this area (see Annex 2). A RACI matrix is used to describe the various roles in completing the required tasks or deliverables for the vector control evaluation process, and the associated norms, standards and policy-making process. RACI is an acronym derived from the four key responsibilities most typically used: Responsible, Accountable, Consulted and Informed.

1 This document replaces: The evaluation process for vector control products. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255644) and Malaria vector control policy recommendations and their applicability to product evaluation. Geneva: World Health Organization; 2017.

THE POLICY-MAKING PROCESS

A revised policy-making process is being rolled out across WHO departments beyond GMP, structured around three high-level steps:

- **Better anticipate:** This step involves activities that build up to and trigger the policy development process, including horizon scanning and developing or endorsing preferred product characteristics (PPCs)/target product profiles (TPPs), in order to stimulate innovation, guide product development and provide predictability to manufacturers with respect to the evaluation process anticipated for these new tools.
- **Develop policy:** In this step, activities are undertaken to develop WHO policy, including recommendations based on the generation of evidence by manufacturers and/or research groups to demonstrate that an intervention has public health value; the assessment of these data by the relevant WHO advisory groups; and the formulation of policy recommendations by WHO.
- **Optimize uptake:** Policy guidance is disseminated and its use monitored.[2]

As outlined in Fig. 1, these process enhancements enable WHO to identify and communicate unmet public health needs; develop policy through an open and transparent process with shortened timelines; and optimize uptake through the use of tools such as digital technology.

This document outlines the links between the evolution of the policy-making process and the evolution of the evaluation process for vector control interventions. It also describes how the outputs from this evaluation process inform the development of new WHO policy recommendations. Topics covered include the determination of the evaluation pathways (Prequalification Pathway or New Intervention Pathway), detailed steps to be followed by applicants, and key epidemiological evaluation standards for vector control interventions, including study design and WHO requirements for trials.

OVERVIEW OF THE EVALUATION PROCESS FOR VECTOR CONTROL INTERVENTIONS

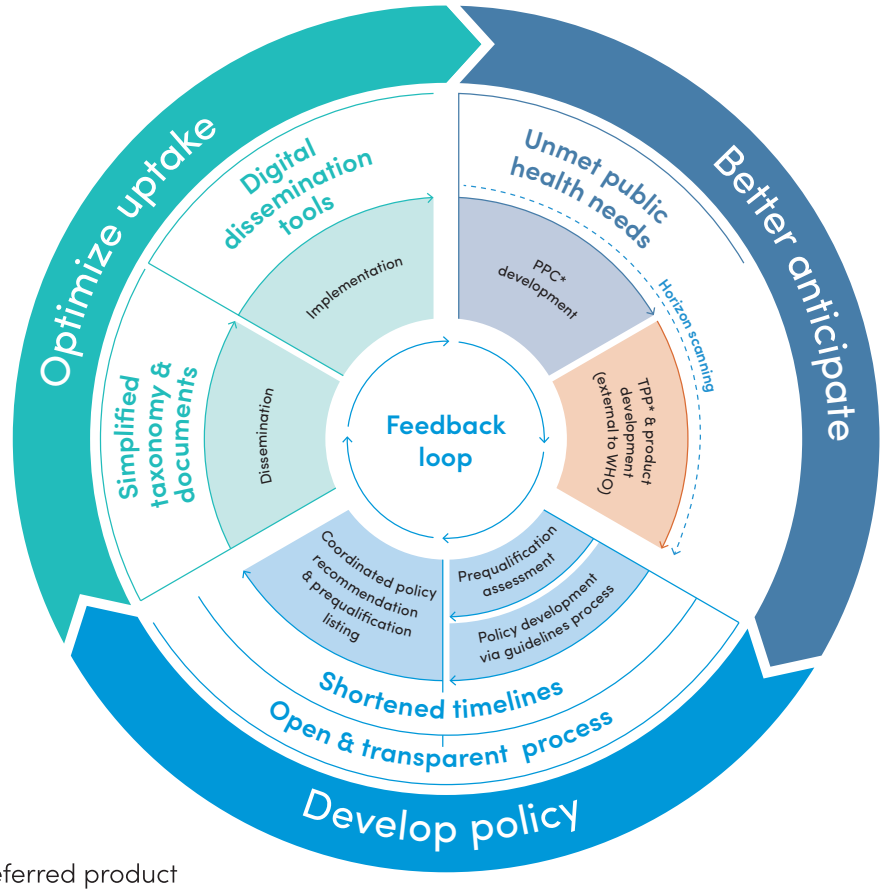
The WHO process for evaluating vector control interventions consists of two separate yet complementary pathways (Fig. 2). To decide which pathway an intervention will follow, the WHO Pre-submission Coordination Committee (PCC)[3] determines whether or not a new submission falls into an existing intervention class, based on the categorization of interventions in Annex 3 (and see "Identification of class and determination of pathway" below). In vector control, an intervention class is a group of interventions that share a common entomological effect, mechanism and use pattern through which they reduce pathogen transmission, and thus reduce infection and/or disease in humans.

Interventions that fall into a class already covered by a WHO policy recommendation will be assigned to the Prequalification Pathway to assess the intervention's safety, quality and entomological efficacy (see "Prequalification Pathway" below). No epidemiological trials are required, given that the intervention's impact on infection and/or disease – also termed public health value – has already been demonstrated by the first-in-class intervention that received a WHO policy recommendation. Once the safety, quality and entomological efficacy of the intervention have been demonstrated, it will be prequalified and added to the listing of

2 For more information on the policy-making process, see https://www.who.int/teams/global-malaria-programme/policy-making-process.

3 The Pre-submission Coordination Committee (PCC) is made up of staff members from the three WHO units responsible for managing VCAG: GMP, NTD and PQT-VCP.

Fig. 1. High-level diagram of GMP's policy pathway for new products. The work of VCAG falls under the orange sector of "Better anticipate": "TPP & product development".



***PPC:** Preferred product characteristic
***TPP:** Target product profile

prequalified products by PQT-VCP.[4] If the formulation of the product changes, PQT-VCP will need to be consulted to make sure the product maintains the same specifications.

The prequalification process includes a review of data supporting the quality, safety and efficacy of the intervention. The data are compiled into a dossier that conforms to a standard format. The process also involves inspection of the manufacturing/production site(s). This information, in conjunction with other procurement criteria, is used by the United Nations (UN) and other procurement agencies to make purchasing decisions. Due to the stringent assessment of the prequalification process, many governments also base their procurement on the prequalification listing of vector control interventions instead of conducting an independent evaluation. Unfortunately, WHO cannot utilize or deploy philanthropic donations of interventions if they are not yet prequalified and/or validated as having public health value.

Issuing a PQT-VCP listing is dependent on there being a WHO policy recommendation for a product class that covers the specific intervention to be prequalified. WHO policy recommendations in the area of vector control are developed by GMP and/or NTD, depending on the use pattern of the intervention. Such policy recommendations are communicated via guidelines documents, for example, the *Guidelines for malaria vector control*.[5] The publication of a policy recommendation jointly with a PQT-VCP listing provides a single WHO position on the Organization's recommendations for vector control, including specific tools and

4 Available from: https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list.
5 Guidelines for malaria vector control. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/310862).

technologies. This information is intended to support WHO Member States in the design and implementation of their vector control and disease elimination strategies.

Products and/or interventions belonging to a class not covered by a WHO policy recommendation will be assigned to the New Intervention Pathway, described in further detail below. This pathway is designed to validate whether the intervention has public health value. WHO's process for determining public health value is supported by VCAG. VCAG's review of any new intervention for its public health value is complemented by a PQT-VCP assessment of the intervention's quality, safety and entomological efficacy.

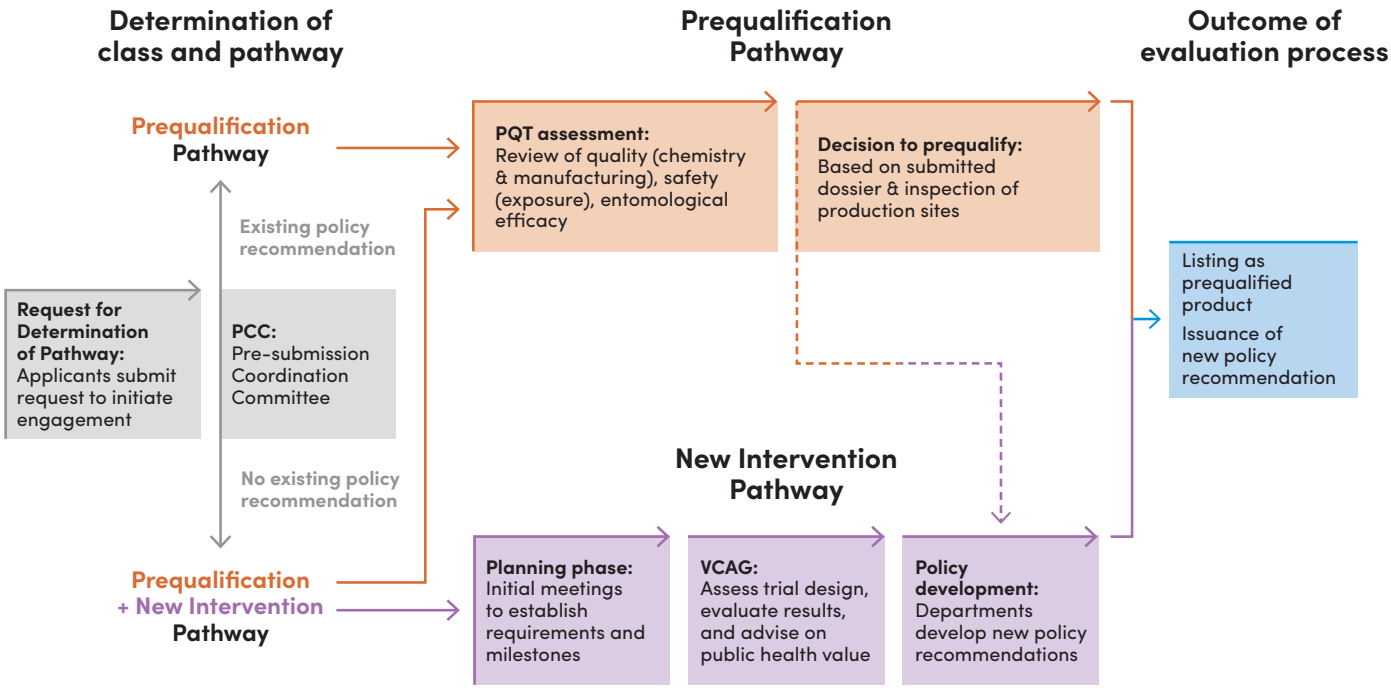
Once an intervention has demonstrated public health value, it is termed a first-in-class product, and WHO will convene a Guideline Development Group (GDG) to formulate a policy recommendation. As outlined by the WHO Guidelines Review Committee (GRC) in Annex 3, the body of evidence that informs the recommendations in WHO guidelines includes:

- all types of study designs that are appropriate to the question(s) underlying a recommendation, and according to other relevant considerations;
- primary data, research studies or systematic reviews;
- evidence from multiple sources;
- publicly available evidence.

Further to this, VCAG's recommendations and PQT-VCP's evaluation of the intervention's safety, quality and efficacy are also provided to the GDG to inform its deliberations on a specific policy recommendation. The GDG's outputs will be an evidence-to-decision table and GRADE assessment. These will be presented to the relevant policy advisory group(s) – the Strategic and Technical Advisory Group (STAG) for NTD and MPAC for GMP – for review and endorsement, before being formally submitted to the GRC in the form of a revised guideline document that includes the new policy recommendation. Once GRC approval is granted, the new policy recommendation and its supporting information will be made available online. From early 2021, all malaria policy recommendations will be accessible via MAGICapp (https://app.magicapp.org/#/guidelines).

Following validation of an intervention's safety, quality and entomological efficacy, it will be prequalified and listed. To the extent feasible, the two processes will work in parallel to ensure that a prequalification listing can be published alongside a new policy recommendation. The exact timing is dependent on the speed with which epidemiological studies are planned and implemented, as well as on PQT-VCP promptly receiving a dossier with a full data package (explained in more detail in the following section) to support its review. It is envisioned that the WHO evaluation process will evolve to a stage where the two pathways are fully synchronized so that policy and prequalification decisions can be communicated simultaneously. In this context, it should be noted that a policy recommendation is a prerequisite for a prequalification listing and can no longer be preceded by such listing.

Fig. 2. Evaluation pathway for vector control interventions



Determination of class and pathway

Request for Determination of Pathway

The evaluation of vector control interventions commences when a product developer, manufacturer or researcher, referred to henceforth as the "applicant", submits a "Request for Determination of Pathway (RDP)" via the single entry portal managed by PQT-VCP (**pqvectorcontrol@who.int**). The RDP is then processed for consideration by the PCC for vector control interventions.[6]

Pre-submission Coordination Committee

The PCC consists of staff from PQT-VCP, GMP and NTD. The PCC will consider the submitted RDP and compare the intervention description, including its entomological effect, mechanism of action, and anticipated use pattern (e.g., whether an insecticide is intended for use as a larvicide or for indoor residual spraying) against WHO's categorization of vector control intervention types and classes (Annex 3). The PCC will assess whether the intervention belongs to a class already covered by a WHO policy recommendation, and hence is assigned to the Prequalification Pathway, or whether complementary assessment in the New Intervention Pathway is required to determine public health value. If interventions have more than one anticipated use pattern, each use pattern will require separate assessments of the appropriate modules (see "Prequalification assessment" below) and VCAG evaluation.

The PCC will provide feedback to the applicant through PQT-VCP, describing the applicable pathway(s) and the rationale for the determination. A WHO focal point(s) will be assigned to the intervention to support the applicant through the process.

6 The task of the PCC is to determine whether or not the proposed intervention is supported by an existing WHO policy recommendation; and to provide a coordination mechanism between the departments on policy updates, implementation, prequalification assessments of products, and prequalification listings concerning vector control interventions.

Prequalification Pathway

Irrespective of whether an intervention is first-in-class or whether a policy recommendation supporting its use is already in place, all new products must undergo the prequalification evaluation if they are to be listed as a prequalified intervention. PQT-VCP ensures that vector control products are effective, safe, and meet stringent quality and manufacturing standards. The team assesses product dossiers, inspects manufacturing sites and supports quality-control testing of products as appropriate. The Prequalification Pathway for vector control products is managed by PQT-VCP, under the Regulation and Prequalification Department of the Medicines and Health Products Division.

Prequalification assessment

For all new interventions (including both products and technologies), the applicant is required to submit an application for prequalification to PQT-VCP. This includes the submission of a dossier compiled according to the PQT-VCP standard format. The dossier includes a full data package to support the assessment of the intervention's quality, safety and entomological efficacy, along with its proposed label information and/or product information. Six modules are included in the submission dossier: Module 1: Administrative Information and Labelling; Module 2: Discipline Summaries; Module 3: Quality (chemistry and manufacturing); Module 4: Safety (hazard, exposure, and risk); Module 5: Efficacy (efficacy to target vectors); and Module 6: Inspections (Site Master Files). More information about each module can be found at: https://extranet.who.int/pqweb/.

Once submitted, the application will be screened to ensure that all the required information and data are included in the dossier. When the PQT-VCP evaluation is completed and found to support a prequalification decision, PQT-VCP will review the label information and provide advice to the manufacturer based on the assessment. Part of the prequalification assessment also involves inspections of the manufacturing/production site.

Decision to prequalify

PQT-VCP's decision on whether to prequalify a product will be made based on the data and information to support the use of the product and inspection of the manufacturing facilities. Once the product is prequalified, the applicant will be informed and the product will be listed on the WHO PQT-VCP website (https://extranet.who.int/pqweb/vector-control-products). The listing will be linked to current, updated or new policy recommendation(s).

PQT-VCP is responsible for monitoring the intervention throughout its life cycle. This includes any changes made to the product (formulation, use, claims, etc.), monitoring and surveillance, complaints and product testing in collaboration with partners, and periodic monitoring of manufacturing sites.

New Intervention Pathway

Interventions without a WHO policy recommendation will follow the New Intervention Pathway, which complements the Prequalification Pathway. The New Intervention Pathway is designed to help substantiate an intervention's public health value and, in doing so, to support the development of an evidence base to inform deliberations on a policy recommendation by a GDG. This evaluation pathway is jointly managed by all three departments (GMP, NTD and PQT-VCP) and is supported by VCAG. VCAG is a WHO advisory group that assesses the public health value of new vector control interventions submitted to WHO. As described in the VCAG Standard Operating Procedures[7], the advisory group consists of up to 15 members (who may be joined by temporary advisors on an ad hoc basis). These experts provide guidance to applicants on the

7 Standard operating procedures for Vector Control Advisory Group (VCAG) applicants. Updated November 2020. (https://apps.who.int/iris/bitstream/handle/10665/274450)

generation of epidemiological data and study designs, and assess the public health value of new vector control interventions.[8]

As VCAG guides the generation of epidemiological evidence to support the assessment of public health value, it is expected that preliminary entomological data from field and/or semi-field studies will have been collected prior to any VCAG submission.[9]

Planning phase

After assignment to the New Intervention Pathway, an initial meeting is held with the applicant, GMP/NTD and PQT-VCP to outline WHO requirements and define the way forward.

To initiate interaction with VCAG, the applicant must complete the VCAG Application Form.[10] An initial meeting between the applicant and the WHO VCAG Secretariat will be held to discuss plans for epidemiological studies and other associated research.

As guiding principles, it would generally be expected that, prior to interacting with VCAG, applicants consider in their planning factors that may potentially influence their study outcomes. Such considerations may include (but are not limited to):

- spatial, temporal and historical heterogeneity in disease prevalence in the study location;
- spatial and temporal heterogeneity in vector prevalence;
- ecological diversity, with specific attention to variation in vector ecology within and between the selected study sites;
- variation in vector behaviour (that may be influenced by the intervention itself throughout the duration of the study).

As the strength of a policy recommendation is influenced by the weight and strength of the available evidence, applicants are encouraged to consider testing their intervention across different geographic settings. The term 'geography' in this sense is not restricted to physical geography, but encapsulates other epidemiologically relevant factors, including local ecologies of co-circulating (and potentially interacting) pathogens, differences in vector ecology, and climatic factors.

Interaction with VCAG

All communication between VCAG and the applicant will be through the WHO VCAG Secretariat. Through WHO, VCAG will support applicants with the development of epidemiological study design, and related data generation and assessment, including review of draft protocols and associated documents.[11] VCAG will review and assess trial results submitted by applicants for new vector control interventions and may additionally draw on entomological data to support the assessment of the epidemiological results.

Formal written feedback on study protocols and data from trials will be through VCAG meeting reports. If changes related to the evaluation of a specific intervention are made, such as to the protocol or statistical analysis plan, these changes should be communicated to the WHO VCAG Secretariat.

8 WHO VCAG website (https://www.who.int/groups/vector-control-advisory-group) and Terms of Reference (https://apps.who.int/iris/handle/10665/276401)

9 It is, however, acknowledged that for some novel interventions that raise ethical concerns (e.g., genetically modified organisms), semi-field and field studies may not be possible in all situations and only data derived from laboratory studies will be available.

10 The application form will be emailed to applicants directly by the VCAG Project Manager.

11 Associated documents include but are not limited to statistical analysis plans, SOPs and study designs.

When trial results are available, they should be submitted to WHO for VCAG's assessment and verification of the intervention's public health value against the targeted disease(s). The vector control evaluation process of WHO requires that at least two trials with epidemiological endpoints are conducted in order to provide some reassurance that the study results are reproducible.[12] While data analysis of the trial results is to be conducted by the investigator(s) of the studies, WHO may commission an independent analysis of raw data if VCAG identifies potential concerns that are not adequately addressed by applicants. Once epidemiological data and, where applicable, supporting entomological data for a new intervention have been reviewed, VCAG will provide WHO with an assessment of the data, including the extent to which the data demonstrate public health value. This assessment provides the foundation for the development of a new policy recommendation by a WHO GDG. Once new guidelines have been developed, other interventions subsequently submitted to WHO that share the characteristics of the given intervention class (Annex 3) will not be required to conduct epidemiological trials.[13]

Policy development

Once VCAG provides WHO with its assessment of an intervention's public health value, a GDG will be convened by the relevant department. The GDG will review the assessment, as well as other evidence that may have been generated outside of the WHO evaluation process, and deliberate on a policy recommendation. The available evidence will be assessed using the GRADE methodology, which provides a tool to systematically judge the quality of a body of evidence and the strength of recommendations derived from that evidence. Detailed criteria that will be considered when moving from evidence to decision, include (but are not limited to) the quality of the evidence, the balance of benefits and harms, resource implications, the priority of the problem, equity and human rights, acceptability and feasibility.[14] An evidence-to-decision table outlines how these factors informed the process of developing a specific policy recommendation and determined its direction and strength. Such tables enhance the transparency of the process, focus the discussions of the GDG, and permit recording of the judgements made about each factor and how each one contributed to the recommendation.

The GDG's recommendations on an intervention, including its appropriate application and scope, will be presented to the relevant policy advisory group of each department. Any suggested modification will be returned for reconsideration by the GDG. A revised recommendation will be accepted by the relevant policy advisory group and Director, on behalf of the Director-General.

Finally, the WHO GRC will then review, provide feedback and subsequently approve the updated guidelines that include the new policy recommendation, and the accompanying evidence-to-decision table.

Outcomes of the evaluation process

While a WHO policy recommendation supporting the public health value of a new intervention is being developed, assessment of the data supporting a product's safety (for its intended use pattern), quality and entomological efficacy occurs in parallel. Once the policy recommendation is published in a revised guideline, the new intervention will be added to the list of prequalified interventions.

12 Two epidemiological trials is the minimum requirement for WHO to initiate the process of evidence review and policy formulation.

13 Evaluation of an intervention's safety, quality and efficacy will still be required, as assessed through the Prequalification Pathway.

14 WHO handbook for guidance development, 2nd ed. Geneva: World Health Organization; 2014 (https://apps.who.int/iris/handle/10665/145714).

EPIDEMIOLOGICAL EVALUATION STANDARDS FOR VECTOR CONTROL INTERVENTIONS

WHO's policy-making process for new vector control interventions relies on evidence from well-designed and well-conducted trials with epidemiological endpoints to demonstrate the public health value of the intervention.

Applicants are strongly advised to work closely with statisticians and epidemiologists to conduct epidemiological trials, and engage with VCAG early in the protocol development process in order to ensure that trial data meet WHO's standards for determining public health value. WHO requires studies to be conducted in compliance with international ethical standards and good clinical and laboratory practices. Guidance in this area is readily available.[15] For information on reporting randomized controlled trials (RCTs), the Consolidated Standards of Reporting Trials (CONSORT) website outlines the minimum set of recommendations for reporting randomized trials (http://www.consort-statement.org/). It also offers a standardized approach for presenting trial findings, which facilitates complete and transparent reports, and critical appraisal and interpretation.

The WHO norms and standards that guide VCAG's advice on the generation of epidemiological data and study designs for trials assessing the public health value of novel vector control interventions are outlined below.

Number of trials

Within WHO's vector control evaluation process, a minimum of two trials with epidemiological endpoints is required to initiate convening the GDG. This minimum number is based on the need to demonstrate that any observed public health value is replicable across settings.

If the initial two studies generate contradictory or inconsistent results or suffer from design limitations that preclude comprehensive assessment of an intervention's potential public health value, further trials with epidemiological endpoints may be required.

Types of trials

At present, RCTs are considered the gold standard of vector control trial design for generating data to inform WHO policy recommendations. However, the WHO guidelines development process will consider evidence generated from other trial designs also (Annex 3).

Work is ongoing to both investigate the rigour of trial designs other than RCTs and assess whether entomological endpoints can be identified that reliably correlate with epidemiological endpoints and can act as surrogates. Once results of these ongoing efforts are available, WHO will review these with a view to potentially modifying its guidance on the trial endpoints required for assessment of public health value.

Choice of trial sites

Given that interventions are generally deployed across different epidemiological settings, WHO recommends conducting the two trials in geographically separate settings, enabling independent replication of study outcomes.

15 Good clinical laboratory practice (GCLP). Geneva: World Health Organization; 2009 (https://apps.who.int/iris/handle/10665/44092).

Applicants are expected to consider the choice of study setting and its appropriateness for meeting trial objectives, and should be able to justify this decision in their interaction with VCAG. Several guiding principles are offered under "Planning phase".

Trial duration

Applicants should design their trials with durations that consider the characteristics of the intervention and its intended deployment, expected durability/residual efficacy and replacement intervals, and the epidemiology (e.g., pathogen transmission intensity) of the selected study site.

It should be noted that for insecticide-treated nets (ITNs), the minimum intervention period of the study should be two years, excluding the period of baseline data collection; a third intervention year is strongly encouraged to demonstrate continued impact over the anticipated life of the net. The VCAG assessment may be initiated once data from two 24-month intervention trials are available in order to determine whether these confirm public health value. Data from a third year of intervention, once available, will facilitate refinement of the associated evidence-to-decision table.

Although in the past VCAG has requested trial durations of either two transmission seasons or two calendar years, WHO does not stipulate trial durations of two years for any intervention other than ITNs. For other interventions, the trial duration may be shorter (or longer) depending on the characteristics of the intervention, the study design and the study setting. Applicants are free to propose the duration they consider appropriate, and VCAG will request justifications for the proposed trial durations. Applicants are encouraged to focus on trial durations that maximize the likelihood that the study objectives and targeted statistical power will be robustly achieved so as to strengthen the evidence used to inform deliberations on a policy recommendation.

In addition, where appropriate, applicants are advised to consider factors that might influence the long-term efficacy of an intervention (including behavioural or genetic adaptation to the existence of the intervention). If there are immediate concerns over the rapid loss of efficacy of a product, it is recommended that the trial duration be adjusted to generate data to assess this concern.

Primary epidemiological endpoints

To determine the epidemiological impact of a vector control intervention, the preferred endpoints are generally the incidence of disease and/or detection of new infections in humans. In situations where infection is chronic, or an infection frequently manifests sub-clinically, the prevalence of pathogen infection (or prior infection) is warranted. Prevalence may also be used as a secondary trial endpoint for those trials designed to collect incidence data.

Epidemiological outcomes

VCAG will consider whether an intervention has demonstrated a statistically significant epidemiological impact over the control arm (which should include the standard of care in the study setting).

Applicants will be expected to prepare and submit their statistical analysis plans in advance of the trial, with a clear indication of the a priori hypothesis, target effect sizes and levels of significance, justified by appropriate power calculations. As with any clinical trial, any and all deviations from the approved statistical plan and post-hoc analyses should be accompanied by adequate justification.

Neither WHO nor VCAG stipulates a specific target effect size for the primary endpoints of trial outcomes. Applicants are encouraged to consider a contextually relevant effect size that is likely to be appropriate for the intended deployment environment. The strength of policy recommendations developed for a given intervention will be guided by the magnitude of the observed effect in associated trials.

ANNEX 1. GLOSSARIES

Key terms

biochemical mode of action	A biochemical mode of action describes the manner in which pesticides interfere with the biochemistry of animals and plants.
biological agent	In the context of vector control interventions, this refers to the exploitation of an organism's parasitic behaviour, predation or other biological mechanisms (such as sterilization) to control target vectors, and/or their ability to transmit a pathogen. Examples may include bacteria, fungi or insect-specific viruses that infect vectors, or indeed the sterilized vectors themselves.
entomological effect	Entomological effect refers to a product's effect on a disease vector in terms of killing, deterring, and reducing fertility or susceptibility to infection. Products with different biochemical modes of action may have similar entomological effects on target insects; for example, indoor residual spraying (IRS) formulations with pyrethroids and carbamates differ in their biochemical modes of action, yet are considered to have a similar impact on the target insect in areas of insecticide susceptibility.
first-in-class	First-in-class refers to the first intervention with a novel entomological effect. The intervention classification table is used in the process of determining classes. The public health value of a first-in-class product is ascertained by VCAG based on the demonstration of epidemiological efficacy against human infections and/or disease. Once the public health value of a first-in-class product has been ascertained, a new product class is established.
GRADE	The "Grading of Recommendations Assessment, Development and Evaluation" method is a systematic and explicit approach to making judgements about the quality of a body of evidence and the strength of recommendations made from that evidence.
intervention	The term intervention in this context applies to any new vector control product/tool, technology or strategy/approach to control a vector population.
intervention class	The intervention class is defined as a group of interventions with a similar entomological effect and mechanism by which the effect is derived. For interventions that fall within the same intervention class, two trials with epidemiological endpoints must demonstrate a significant reduction in the primary epidemiological endpoint for that intervention to be confirmed as an established class, with a policy recommendation and associated prequalification listing. Note that for many interventions, different target diseases will mean that the interventions fall into different classes, because the epidemiological effect needs to be substantiated against each group of vector-borne diseases.
intervention type	Intervention type is a broad category referring to the entomological effect and use pattern of an intervention. Multiple intervention classes may fall under the umbrella of a single intervention type.
pesticide	Any substance, mixture of substances, microorganism (including viruses) or biological agent intended for repelling, destroying or controlling a pest. Targets include vectors of human or animal disease, nuisance pests, and unwanted species of plants or animals that are causing harm or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feed stuffs. Pesticides may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term also includes substances intended for use as insect or plant growth regulators; defoliants; desiccants; agents for setting, thinning or preventing the premature fall of fruit; and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. Pesticide synergists and safeners, where they are integral to the satisfactory performance of the pesticide, also come under this term.
prequalification	Prequalification for vector control interventions is WHO's standardized assessment procedure for evaluating the acceptability, in principle, of vector control products for purchase by United Nations agencies. Agencies using the information resulting from the prequalification procedure should perform additional assessment prior to purchasing, such as verifying the supplier's financial stability, standing and ability to supply the required quantities; ensuring the security of the supply chain; and evaluating pre-shipment quality control and other related aspects.

product amendment	A product amendment is a change in the specification of an active ingredient and/or a formulation (including source of materials), labelling, production process or manufacturing site of a prequalified product; any amendment must be submitted to WHO for review.
product claim	A product claim is information contained in the product's label and advertisement materials. For vector control products, this includes the product's chemical content (where appropriate); target arthropod vector; entomological effect in controlling target vectors or protecting against infection and/or disease; duration of effect; and role in mitigating insecticide resistance, etc.
product class	A product class in vector control is a group of products that share a common entomological effect by which it reduces pathogen transmission and thus reduces infection and/or disease in humans. For products in a class not currently recommended by WHO, efficacy trials with a first-in-class product must generate epidemiological evidence of protective efficacy against infection and/or disease. The evidence is then reviewed by VCAG to validate the public health value of the product class. This validation forms the basis of a WHO policy recommendation for the new product class.
product label	The written, printed or graphic matter on or attached to the vector control intervention or its immediate container, as well as the outside container or wrapper of its retail package.
product life cycle	This refers to the period of time that the product is on the market until it is withdrawn from the market. The management of the product life cycle includes the applicant's continual updating of product information (formulation, labelling, production sites and manufacturing processes) to WHO. A product that has been withdrawn or delisted has effectively ended its life cycle, and there will be no further maintenance of the product's prequalification.
public health value	A product has public health value if it has proven protective efficacy to reduce or prevent infection and/or disease in humans.
use patterns	A use pattern of a vector control intervention is the way in which an intervention is applied to control the vectors. This may not apply to all types of interventions because they can only be used in a single manner. Examples of different use patterns for the same intervention might be the application of an insecticide for space spraying to control adult mosquitoes and to water bodies to control immature mosquitoes.
vector control product	A vector control product is any tool designed to reduce infection and/or disease caused by a vector-borne pathogen through control of the disease vector.

Study designs

case–control study	This type of study compares the prevalence of an exposure (for example, the use of a protective intervention) between a group of people with the disease of interest (cases) and a group of people without the disease (controls). In a study of this type, the controls should be selected so that they are representative of the case population as much as possible.
cluster randomized controlled trial (CRCT)	A cluster randomized controlled trial is a study in which groups of individuals (for example, a household, village, geographical area, or administrative unit) are randomly allocated to receive either an intervention treatment or the control.
cohort study (observational)	This is a type of observational study in which groups of disease-free individuals are identified, who are either 'exposed' (they use the protective intervention) or 'unexposed' (they do not use the protective intervention). The groups are then followed over a period of time to evaluate the outcome of interest (usually disease or infection). In this study type, individuals are not allocated to the intervention of interest by the investigators.
cohort study (randomized)	This is a randomized controlled trial in which a cohort of recruited individuals is randomized to receive either the treatment intervention or control intervention. The cohorts are followed up for the outcome of interest for a specified period.
control group	This is the group of participants that receives no intervention, a placebo or the current standard of care (depending on the study design), and this group thereby serves as a comparison group when the intervention results are evaluated.

cross-sectional study	In an analytical cross-sectional study, information is collected at one point in time on the prevalence of the outcome of interest (for example, a disease or infection) and exposure (for example, the use of a protective intervention).
controlled before & after study	A study in which observations are made about an intervention both before and after the implementation of an intervention in both the treatment (intervention) group and a control group (that does not receive the intervention. This is also known as a pre–post study.
crossover study	A study in which individuals or clusters are allocated to the intervention or control group for a period of time before switching (or crossing over) to the other group. There is usually a washout period before the switch is made to avoid carry-over effects from the intervention.
effectiveness study	These studies estimate the effect of an intervention under pragmatic (or real-life) conditions (for example, interventions delivered under routine conditions) so that the relevance of the findings for policy and practice is maximized.
efficacy trial	These studies estimate the effect of an intervention under the ideal conditions that can usually be achieved only in a trial, for example, by ensuring maximal coverage of the target population and adherence to the intervention.
interrupted time series	This is a type of study in which the outcome (for example, disease incidence) is measured on a number of occasions, both before and following the introduction of an intervention. This allows an investigator to determine whether an intervention has had an impact greater than any underlying trend in the data. This design may include a parallel control group.
non-inferiority study	A non-inferiority trial aims to demonstrate that the tested product is not worse than the comparator by more than a small, pre-specified amount, which is known as the non-inferiority margin (delta; δ). The difference between the effect of the test product (T) and the effect of the comparator (C) must be less than δ – that is, the upper bound of the 95% confidence Interval of C – T must be less than δ. The choice of δ is a clinical (or entomological) judgement, not a statistical one. The smaller the δ, the less T is inferior to C, but the larger the required sample size.
observational study	This is a type of study in which the effect of the exposure on the participants is observed, but the investigator has no role in assigning participants to the exposure.
randomized controlled trial (RCT)	In this study design, individuals are randomly allocated to either the intervention or control group. The intervention and control groups are then followed up for the outcome of interest for a specified period.
stepped-wedge design	This is a type of study in which the intervention is rolled out to different clusters in a staged fashion. At the end of the study, all clusters will have received the intervention. The order in which clusters receive the intervention is usually determined at random.
test-negative case–control study	This is a type of case–control design wherein the use of an intervention is compared between cases who test positive and those who test negative (controls) who present to a health facility. The advantage of this design is that cases and controls are recruited in a single step and there is no need to spend time testing individuals to identify controls from the community.
time series study	In this type of study, the outcome (for example, the incidence of disease) is measured on a number of occasions following the introduction of an intervention. Typically, measurements are made at equally spaced time points, for example, monthly or yearly. In some cases, there may also be a control time series of people who have not received the intervention, in which the same measurements are made, although some time series studies do not have a control group.

ANNEX 2. ROLES AND RESPONSIBILITIES

PATHWAY STEP	OUTCOME	TASK	INPUTS	OUTPUTS	APPLICABLE TO		APPLICANT	WHO			
					PRODUCT WITH WHO POLICIES	PRODUCT WITHOUT WHO POLICIES		PQT -VCP	GMP	NTD	VCAG
Determination of pathway	Evaluation pathway determined by WHO Pre-submission Coordination Committee (PCC)	Convene meeting with applicant to field process enquiries on the determination of pathway process	Pre-submission enquiry	Clarity on requests for determination of pathway	X	X	I	R,A	C	C	
		Submit pre-submission package to PQT-VCP (pqvectorcontrol@who.int)	Cover letter, completed request for determination of pathway, and draft product label	Addition to agenda for next PCC	X	X	R,A	I			
		Screen pre-submission package	Pre-submission package	Potential request for clarification	X	X	C	R,A			
		Convene PCC meeting to determine appropriate evaluation pathway	Pre-submission package; other information	PCC conclusion on appropriate pathway	X	X	I	R,A	C,A	C,A	
		Communicate PCC meeting conclusions to applicant	PCC conclusion on appropriate pathway	Correspondence sent to applicant	X	X	I	R,A	I	I	
Evaluation of vector control tool, technology or approach	Dossier submitted	Submit dossier to PQT-VCP	Product dossier	Logged application	X	X	R,A	I			
	Dossier screened	Screen dossier for completeness	Product dossier	Acceptance for assessment, request for information, or failure	X	X	I,C	R,A			
	Safety assessment	Conduct human health assessment	PQ dossier - Module 4	Data evaluation records (DERs), risk assessment, discipline summary	X	X		R,A	I	I	
	Environmental assessment	Conduct environmental assessment (depending on product type)	PQ dossier - Module 4	DERs, risk assessment, discipline summary	X	X		R,A	I	I	

R = Responsible, A = Accountable, C=Consulted, I= Informed

PATHWAY STEP	OUTCOME	TASK	INPUTS	OUTPUTS	APPLICABLE TO		APPLICANT	WHO			
					PRODUCT WITH WHO POLICIES	PRODUCT WITHOUT WHO POLICIES		PQT -VCP	GMP	NTD	VCAG
Evaluation of vector control tool, technology or approach (cont.)	Quality assessment	Carry out physical/ chemical and manufacturing assessment	PQ dossier - Module 3	DERs, draft specification, discipline summary	X	X		R,A	I	I	
		Develop specifications through JMPS process	Module 3, DERs, draft specification	Final specification	X	X	I	R,A	I	I	
	Entomological efficacy assessment	Provide advice on entomological data requirements and test procedures to manufacturers	**Tools without policy:** PQT-VCP works with applicants (or another group) to devise appropriate and reliable indicators of quality and efficacy	Guidance on entomological data requirements and test procedures provided to applicant		X	I	R,A	C,I	C,I	
			Tools covered by policy: Enquiry from manufacturer and submission of data package as part of dossier		X		I	R,A	C,I	C,I	
		Develop/update evaluation criteria/thresholds to assess entomological efficacy	Advice provided to manufacturers of new tools and/or new evidence on evaluation methods	New evaluation criteria/ thresholds established or existing ones modified	X	X		R,A	C	C	
	Entomological efficacy assessment (cont.)	Develop/update testing guidance	Advice provided to manufacturers of new tools and/or new evidence on evaluation methods	Efficacy test guidelines	X	X		R,A	C	C	
		Conduct entomological efficacy assessment	PQ dossier - Module 5	DERs, Discipline Summary to	X	X	I	R,A	I	I	

PATHWAY STEP	OUTCOME	TASK	INPUTS	OUTPUTS	APPLICABLE TO		APPLICANT	WHO			
					PRODUCT WITH WHO POLICIES	PRODUCT WITHOUT WHO POLICIES		PQT -VCP	GMP	NTD	VCAG
Evaluation of vector control tool, technology or approach (cont.)	Assessment of public health value (i.e. epidemiological efficacy)	Review preliminary entomological data from laboratory & small scale field studies to inform epidemiological trial designs	Preliminary entomological data as submitted by applicant	Feedback on preliminary entomological data provided to applicant via WHO		X	I	R,A	C	C	I
		Develop protocol for epidemiological studies	Guidance as provided in trial design manual and, tailored to specific interventions, in VCAG reports	Draft study protocol		X	R,A	I	I	I	I
		Review draft protocol for epidemiological studies	Draft protocol	Guidance on study design to applicant		X	I		R,A	R,A	R
		Finalize study protocol	Updated protocol	Final VCAG endorsed study protocol		X	R,A		I	I	I
		Initiate epidemiological efficacy studies	VCAG endorsed study protocol	Data package from epidemiological trials, incl. data analysis by applicant		X	R,A	I	I	I	I
		Carry out periodic review of study progress	Investigator update to VCAG	Technical advice to applicants		X	I		R,A	R,A	R
		Assess public health value based on the data generated	Data analysis as conducted by investigator. Independent analysis of raw data may be required.	VCAG recommendation to GMP and NTD (MPAC and STAG) regarding public health value		X	I	I	R,A	R,A	R
	Assessment of public health value (i.e. epidemiological efficacy) (cont.)	Assess public health value based on the data generated	Data analysis as conducted by investigator. Independent analysis of raw data may be required.	VCAG recommendation to GMP and NTD (MPAC and STAG) regarding public health value		X	I	I	R,A	R,A	R
	Label review	Review labelling based on outcomes of reviews of Modules 3,4,5	Declaration of Labelling (included in dossier submission)	Declaration of Labelling	X	X	C	R,A	I	I	

PATHWAY STEP	OUTCOME	TASK	INPUTS	OUTPUTS	APPLICABLE TO		APPLICANT	WHO			
					PRODUCT WITH WHO POLICIES	PRODUCT WITHOUT WHO POLICIES		PQT -VCP	GMP	NTD	VCAG
Evaluation of vector control tool, technology or approach (cont.)	Inspection	Inspect manufacturing/ production facilities to ensure compliance with WHO-recommended quality standards	PQ dossier - Module 6 (Site Master Files)	Inspection report(s)	X	X	C	R,A	I	I	
	Policy recommendation for programmatic use	GMP / NTD develops WHO policy recommendation with support of a WHO Guideline Development Group	VCAG recommendations regarding public health value communicated to WHO	WHO policy recommendation and establishment of new product class, as communicated by means of updated guidelines document		X	I	I	R,A	R,A	I
Product prequalified	Product listed on PQT website	PQT-VCP prequalifies product based on assessment of product efficacy, safety and quality and outcomes of site inspection	Decision document	Product and related information included on the WHO PQT-VCP website	X	X	I	R,A	I	I	
Communications	VCAG outcomes communicated	Establish and maintain clear communication with applicants	Submission of application to VCAG Secretariat	Meeting reports, direct communication with applicants.		X	I	C	R,A	C	
	Product prequalification communicated	Regularly update and publish list of prequalified products	Decision Document	Product listing	X	X	I	R,A	I	I	
	Policy recommendations and deployment guidance communicated	Conduct webinars; disseminate guidance through regional meetings and other communications opportunities	Updated WHO guideline document. For malaria, all guidelines will be available via MAGICapp from January 2021.	Updated guidelines shared with vector control community through various channels	X	X	I	I	R,A	R,A	

ANNEX 3. OVERVIEW OF INTERVENTION CLASSES FOR VECTOR CONTROL

INTERVENTION TYPE	DESCRIPTION OF INTERVENTION TYPE	INTERVENTION CLASS	DESCRIPTION OF INTERVENTION CLASS (ENTOMOLOGICAL EFFECTS)	DESCRIPTION OF PROTOTYPE / INTERVENTION	TARGET ORGANISM (GENUS AND/OR SPECIES)[19]	TARGET DISEASE/ PUBLIC HEALTH PROBLEM
Insecticide-treated nets (ITNs)[20]	ITNs that kill mosquitoes and may exert other entomological effects that alter mosquito population dynamics[21]	**ITNs designed to kill host-seeking insecticide-susceptible mosquito populations and whose entomological effects consist of killing and reducing the blood-feeding of insecticide-susceptible mosquito vectors**	Long-lasting insecticidal nets (LLINs) that kill pyrethroid-susceptible mosquitoes	Mosquito net treated with a pyrethroid	*Anopheles* mosquitoes	Malaria
		ITNs designed to kill host-seeking insecticide-resistant mosquitoes	ITNs designed to kill pyrethroid-resistant mosquitoes	Mosquito net treated with a pyrethroid and non-pyrethroid insecticide Mosquito net treated with a pyrethroid insecticide and a synergist, piperonyl butoxide (PBO)	*Anopheles* mosquitoes	Malaria
		ITNs designed to sterilize and/or reduce the fecundity of host-seeking insecticide-resistant mosquitoes	ITNs that, in addition to killing mosquitoes, induce sterility and/or reduce the fecundity of exposed mosquitoes	Mosquito net treated with an insecticide as well as an insect growth regulator	*Anopheles* mosquitoes	Malaria
Mosquito larvicides	Biological or chemical agents that kill larvae or reduce emergence of adults	**Mosquito larvicides**	Biological or chemical agents that kill mosquito larvae and/or pupae	Biological or chemical agent applied into open or closed bodies of water to kill mosquito larvae and/or pupae	*Anopheles, Aedes* and *Culex* mosquitoes	All mosquito-borne diseases
Chemosensory interference	Chemicals that interfere with vector sensory perception	**Spatial repellents[22]**	Devices that release a volatile chemical into the air and prevent human–vector contact within the treated space	Devices that passively emanate a chemical stimulus, acting as a mosquito repellent, and cause interference with host detection (attraction inhibition) and feeding response	*Anopheles* mosquitoes *Aedes* mosquitoes	Malaria *Aedes*-borne arboviral diseases
		Bait station	Devices designed to attract and kill mosquitoes	Devices designed to attract and kill sugar-seeking *Anopheles* mosquitoes	*Anopheles* mosquitoes	Malaria

INTERVENTION TYPE	DESCRIPTION OF INTERVENTION TYPE	INTERVENTION CLASS	DESCRIPTION OF INTERVENTION CLASS (ENTOMOLOGICAL EFFECTS)	DESCRIPTION OF PROTOTYPE / INTERVENTION	TARGET ORGANISM (GENUS AND/OR SPECIES)[19]	TARGET DISEASE/ PUBLIC HEALTH PROBLEM
Chemosensory interference (cont.)	Chemicals that interfere with vector sensory perception (cont.)	**Repel and lure strategy**	Devices placed around a house and/or its surroundings that repel or kill mosquitoes	Includes spatial repellent products placed on the eaves of houses, and solar-powered odour-baited mosquito traps placed outside houses	*Anopheles* mosquitoes	Malaria
		Topical repellents	Topical repellents applied to skin or clothing of individuals for personal protection	Topical creams or sprays that contain active ingredients to be applied to the skin of an individual	*Anopheles, Aedes* and *Culex* mosquitoes *Phlebotomus* sandflies	All mosquito-borne diseases Leishmaniasis
Vector traps	Devices that lure and kill vectors	**Combined adulticidal and larvicidal traps**	Traps that attract and kill gravid or ovipositing mosquito females, as well as kill any larvae/pupae that develop in the trap water	Traps that attract gravid females with olfactants and capture them when they attempt to oviposit; as well as kill any emerging larvae/pupae	*Ae. aegypti* and *Ae. albopictus*	*Aedes*-borne arboviral diseases
		Larvicidal traps	Traps that kill larvae	Larvicidal trap designed to attract Aedes mosquitoes to deposit their eggs into the provided artificial water bodies where they will be destroyed by physical means	*Ae. aegypti* and *Ae. albopictus*	*Aedes*-borne arboviral diseases
		Auto-dissemination devices	Devices that exploit female oviposition behaviour to both expose ovipositing vectors to a slow-killing adulticide, while promoting the vector's continued distribution of that insecticide to other oviposition sites	Devices that 1) kill larvae developing in traps, and 2) contain an insect growth regulator and apupacide for dissemination to other oviposition sites	*Ae. aegypti* and *Ae. albopictus*	*Aedes*-borne arboviral diseases
Genetic manipulation	Genetic construct(s) used to bias inheritance patterns of a desired trait	**Reduction of pathogen transmission induced by gene drive**	Genetic construct that drives itself into the population and alters capacity of the vector population to transmit a pathogen	Gene construct that renders vectors incapable of transmitting malaria parasites	*An. gambiae* and *An. stephensi* mosquitoes	Malaria
		Sex-ratio distortion	Genetic construct that drives itself into the population and distorts the sex ratio in preference of males with the aim of suppressing the population	Genetic construct that disrupts the fertility of female mosquitoes and/ or distorts the sex ratio (e.g., by decreasing the ratio of female:male mosquitoes)	*An. gambiae* mosquitoes	Malaria

INTERVENTION TYPE	DESCRIPTION OF INTERVENTION TYPE	INTERVENTION CLASS	DESCRIPTION OF INTERVENTION CLASS (ENTOMOLOGICAL EFFECTS)	DESCRIPTION OF PROTOTYPE / INTERVENTION	TARGET ORGANISM (GENUS AND/OR SPECIES)[19]	TARGET DISEASE/ PUBLIC HEALTH PROBLEM
Sterilization agents	Release of sterile insects into a wild population	**Sterilization of male mosquitoes**	Continued release of sterilized male mosquitoes to suppress the population	Irradiated (SIT) and/or *Wolbachia*-infected males (containing *w*AlbB or other strain)	*Ae. aegypti* and *Ae. albopictus*	*Aedes*-borne arboviral diseases
Reduced pathogen transmission by a microorganism	Use of a microorganism to reduce the capacity of vectors to transmit pathogens	**Reduced pathogen transmission induced by *Wolbachia***	Introgression of *Wolbachia* into vector population to alter capacity for population to transmit pathogen	*w*Mel Wolbachia introduced to mosquito population, which inhibits virus transmission by mosquito vector	*Ae. aegypti*	*Aedes*-borne arboviral diseases
Systemic insecticides and endectocides	Drug treatment of humans and/or livestock	**Systemic treatment of livestock with an insecticide or a drug[23]**	Treatment of livestock with a drug that kills or reduces blood feeding in the insects that feed on them	Drug bolus administered to livestock with residual insecticidal activity	*Phlebotomus* sandflies	Leishmaniasis
		Treatment of humans and/or livestock with an endectocide	Treatment of humans and/or livestock with a drug that kills the insects that feed on them	Seasonal mass drug administration (MDA) with short-term duration (three months) to reduce vector density and subsequent disease transmission	*Anopheles* mosquitoes	Malaria[24]
Housing modifications	Modifications made to a house/building to create a lethal house lure	**Lethal house lures**	Screening of main entrances to dwellings, with remaining access installed with an insecticide-treated material	Screened houses with eave tubes installed, with electrostatically charged coating for delivery of powder formulation of an insecticide	*Anopheles* mosquitoes	Malaria
		Insecticide-treated door and window curtains	Insecticide-treated curtains or baffles installed in doors and windows of dwellings	N/A	*Anopheles* mosquitoes	Malaria
Residual insecticide surface treatment	Treatment of surfaces with residual insecticide	**Full indoor surface *fast-acting* formulations**	Surface insecticides with fast killing action on vectors	Treatment of indoor surfaces with fast-acting insecticides to kill indoor-resting vector species	*Anopheles* mosquitoes *Phlebotomus* sandflies Triatomine bugs	Malaria Leishmaniasis Chagas disease

INTERVENTION TYPE	DESCRIPTION OF INTERVENTION TYPE	INTERVENTION CLASS	DESCRIPTION OF INTERVENTION CLASS (ENTOMOLOGICAL EFFECTS)	DESCRIPTION OF PROTOTYPE / INTERVENTION	TARGET ORGANISM (GENUS AND/OR SPECIES)[19]	TARGET DISEASE/ PUBLIC HEALTH PROBLEM
Residual insecticide surface treatment (cont.)	Treatment of surfaces with residual insecticide (cont.)	**Full indoor wall *slow-acting* formulations**	Insecticides with delayed killing action and reduced vector fecundity	Treatment of indoor surfaces with slow-acting insecticides to kill indoor-resting vector species	*Anopheles* mosquitoes *Phlebotomus* sandflies Triatomine bugs	Malaria Leishmaniasis Chagas disease
		Selective indoor wall application	Spray or paint application of insecticides with fast killing action to a limited surface area within the dwelling	Treatment of selected indoor surfaces (e.g., ceilings, sections of walls) to kill indoor-resting vector species	*Anopheles* mosquitoes	Malaria
		Targeted indoor surface fast-acting formulations	Spray or paint application of insecticides with fast killing action to some surfaces within the dwelling	Treatment of indoor surfaces, targeting specific areas where *Aedes* vectors frequently rest indoors	*Aedes* mosquitoes	*Aedes*-borne arboviral diseases
		Insecticide-treated material	Insecticide-treated clothing, topsheet, blanket, ground or wall cover, door or window curtain	Apparel and equipment impregnated with insecticides (e.g., permethrin and PBO)	*Anopheles, Aedes* and *Culex* mosquitoes, sandflies	Malaria *Aedes*-borne arboviral diseases Leishmaniasis
Space spraying	Space treatments indoors and outdoors	**Indoor space spraying**	Application of fast knockdown/ killing insecticides in aerosols in closed spaces for control of flying mosquitoes		*Aedes* mosquitoes *Anopheles* mosquitoes	*Aedes*-borne arboviral diseases Malaria
		Outdoor space spraying	Application of fast knockdown/ killing insecticides in aerosols outdoors for control of flying mosquitoes		*Aedes* mosquitoes	*Aedes*-borne arboviral diseases

INTERVENTION TYPE	DESCRIPTION OF INTERVENTION TYPE	INTERVENTION CLASS	DESCRIPTION OF INTERVENTION CLASS (ENTOMOLOGICAL EFFECTS)	DESCRIPTION OF PROTOTYPE / INTERVENTION	TARGET ORGANISM (GENUS AND/OR SPECIES)[19]	TARGET DISEASE/ PUBLIC HEALTH PROBLEM
Aircraft disinsection	Aerosol spray application	**Aircraft disinsection by aerosol treatment of cabin and/or cargo hold**	Products applied in aircraft using an aerosol can, and provide a rapid knock-down of insects, and may have a short-term residual effect	Insecticides formulated for treatment of aircraft cabin or cargo hold to assist with International Health Regulation (IHR) compliance and to stop introduction of vectors to other regions[25]	Any mosquitoes transported via aircraft to new destinations	Vector transport and establishment in new locations
		Aircraft disinsection by residual treatment of cabin and cargo hold	Products applied in aircraft by residual treatment method	Residual treatments applied in aircraft to assist with IHR compliance and stop introduction of vectors to other regions[26]	Mosquitoes	Vector transport and establishment in new locations
Molluscicides	Chemicals targeting snail vectors (molluscs)	**Molluscicides applied to open bodies of water**	Chemical applied in open bodies of water to kill snail vectors	Fast-acting compound (drug) administered to waters inhabited by snail vectors	Snail vector species	Schistosomiasis
Rodenticides	Chemical agents targeting rodents and the vectors that feed on them	**Systemic treatment of rodents with chemicals that have insecticidal properties**	Anticoagulants and fast-acting lethal products applied with or just after insecticides (for flea control) in outbreaks	A highly lethal vitamin K antagonist anticoagulant poison	Rodents as carriers of fleas that transmit pathogens	Rodent-borne human infections

19 Depending on the specificity of the tool or product claim
20 WHO malaria terminology. Geneva: World Health Organization; 2016, updated 2019 (http://apps.who.int/iris/handle/10665/208815).
21 Malaria Policy Advisory Committee meeting report (May 2020). Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240007024).
22 The term 'spatial repellency' is used here to refer to a range of insect behaviours induced by airborne chemicals that result in a reduction in human–vector contact and therefore provide personal protection. The behaviours can include movement away from a chemical stimulus, or interference with host detection (attraction inhibition) and feeding response.
23 Systemic insecticides also reduce the livestock ectoparasite burden.
24 Plus a direct benefit in the treatment of human scabies, lice and some soil-transmitted helminths
25 Types of aerosol disinsection in aircraft include pre-embarkation cabin treatment, pre-departure cabin treatment, pre-departure cargo hold disinsection, and on-arrival cabin and cargo hold disinsection.
26 These treatments are performed every eight weeks during routine aircraft maintenance, using different equipment than standard sprayers and with a lower discharge rate of the insecticide liquid than the usual IRS in households.

ANNEX 4. CRITERIA FOR USE OF EVIDENCE TO INFORM RECOMMENDATIONS IN WHO GUIDELINES

Guidelines Review Committee guidance (16 March 2019)

Background

World Health Organization (WHO) guidelines contain one or more recommendations which are informed by a comprehensive, systematic review of the relevant evidence on benefits and harms of an intervention or effects of exposure on priority outcomes. In addition, recommendations are informed by evidence on other important considerations that may modify the successful implementation and impact of the recommendations in various contexts.

Decisions on the inclusion of types of evidence for specific recommendations are based on the underlying principles of evidence-informed decision-making, which are, in turn, based on the principles of scientific rationale.1

Principles

These principles underpin all decisions to include or exclude particular study designs, individual studies, or data from specific sources from the body of evidence that informs a recommendation.

1. All WHO guidelines must be developed based on sound scientific and ethics principles and practices and must meet the highest international standards.
2. The evidence that is used to inform a WHO recommendation should be:
    a. relevant (applicable to the key question(s) at hand),
    b. obtained ethically and in accordance with human rights standards and ethics;[2]
    c. of the highest quality ("best") available (based on an assessment of the risk of bias); and
    d. publicly-available at the time of publication of the recommendation or guideline.
3. The choice of specific study designs will vary depending on the question, the amount of evidence available, and factors related to the risk of bias and applicability of the study design to the question at hand.
4. The type of guideline will impact on the comprehensiveness of the retrieval, the assessment of the evidence, and the choice of restrictions on date and language of publication (e.g. guidelines produced in response to a public health emergency may require modified approaches but in no case shall exceptions to 2(b) be permitted).
5. WHO guidelines must be transparent with respect to the sources for evidence; methods for searching, retrieving, summarizing and assessing the evidence used to inform recommendations; and the rationale for decisions on selected approaches and methods, and for each recommendation must be clear.
6. All conflicts of interest among any contributor to primary data and studies, to evidence synthesis and appraisal, or to guideline development must be disclosed and significant conflicts of interest managed.
7. WHO and its staff have a responsibility to promote and support the highest quality of data generation, research, evidence synthesis and guideline production. To that end, WHO has a critical role in promoting and facilitating research study registration; publication of research and systematic review protocols; data sharing and transparency; optimal reporting of

1 Scientific rationale entails three domains: the "episteme" (knowledge), the "phronesis" (practical wisdom), and the "techne" (technique or know-how to do). De-Regil LM 2008 (Scientific rationality, causality and metaanalyses of clinical trials. Salud Publica Mex 2008;50:523-529).

2 Universal Declaration of Human Rights and Bioethics Art 6(2) (3), WHO Guidance on ethics of research in emergencies (2015).

datasets, research studies and guidelines; publication of all research studies and all results; and identification of gaps in knowledge and guidance to inform future research and guidelines including attention to redressing gender and other biases in research and reporting.

Policy for WHO staff who develop guidelines

This policy outlines the general approaches for establishing criteria for inclusion of various types of evidence and their sources to inform recommendations in WHO guidelines. It does not provide detailed guidance on the methods for identifying, appraising and presenting evidence.

The body of evidence informing questions or recommendations in a WHO guideline includes:

1. All types of study designs as appropriate to the question(s) underlying a recommendation and according to other relevant considerations.
    a. For questions on the benefits and harms of interventions, high-quality randomized controlled trials (RCTs) addressing the question provide the highest quality evidence with regards to causality and potential confounding. However, RCTs may not be available, may be unethical or infeasible, or may have significant limitations, including for example, inclusion of highly selected populations which may not be representative of the populations to which the recommendation is intended to be applied.
        i. Thus, non-randomized study designs including experimental designs (e.g. quasi- randomized trials and investigator-assigned cohort studies) as well as observational studies (e.g. before-after or parallel-group cohort studies or surveillance data) may be included in the body of evidence to inform benefits and harms. Case studies or case series may be included in selected situations.
    b. For questions related to considerations other than benefits and harms of an intervention (e.g. feasibility, equity, acceptability, resource use), the best available evidence should be used and the choice of specific study designs will vary depending on the question and other factors.
    c. Regardless of study design, risk of bias needs to be assessed using a tool appropriate for a given study design. Sufficient information must be available to permit this assessment and assessments must be performed by persons who are independent of the data or studies (i.e. have no significant conflicts of interest).
    d. Studies at significant risk of bias, either considered as a group according to study design, or according to assessments of individual studies, can be explicitly excluded using pre-defined, explicit and evidence-based criteria. However, excluding individual studies based on assessments of risk of bias must be done carefully as such assessments are a judgement and the criteria can be debated. A common approach is to perform a sensitivity analyses around various criteria, rather than using them as exclusion criteria.
2. Primary data, research studies or systematic reviews
    a. All relevant evidence should be included, whether primary data (raw data, individual-patient data), data from research studies, results from mathematical modelling studies, or existing or newly commissioned systematic reviews. Data and studies can be quantitative, qualitative or encompass mixed-methods approaches.
    b. The criteria for including data and studies in the evidence base used to inform each specific recommendation within a guideline are developed according to the relevant considerations for that question or recommendation. These criteria include but are not restricted to: study design considerations, potential confounders and

other potential sources of bias, the nature of the review question (e.g. prognosis, risk assessment, intervention effect, impact on health equity), the amount of evidence available, the date of the data collection in a study or the date of searching for a systematic review, and feasibility and timelines for guideline production.

3. Evidence from multiple sources

   a. Searches for data and study results should be tailored to the research question and should not generally be restricted to those indexed in bibliographic databases.

   b. Data and studies accessible in all languages should be considered for inclusion.

   c. Searches should encompass clinical trial registries such as the WHO International Clinical Trials Registry platform (ICTRP, http://apps.who.int/trialsearch/) when the evidence base may include RCTs. Other sources should be examined as appropriate, for example local programmatic data and evaluations, and pre-publication data shared by investigators with the expectation that at least a summary of the methods and results will be made publicly available no later than the time of publication of the recommendation or guideline.

   d. Databases, publication sites, predatory journals, or other sources that are not deemed credible or trustworthy should not be used as sources for evidence.

   e. All included evidence regardless of source must be evaluated for risk of bias and the highest quality evidence should be used to inform recommendations.

   f. Study results that may be preliminary such as those presented at conferences or in meeting abstracts can be included on a case-by-case basis after careful assessment of their nature, likelihood that they might change, and risk of bias. The use of any data, whether summary results or primary data, that may be deemed preliminary must be done with extreme caution, after discussions with the principle investigator(s) and with careful consideration of the benefits versus potential down-sides of their use.

4. Publicly available evidence

   a. The methods and results of research used to inform a recommendation in a WHO guideline must be publicly available to the reader/end-user at the time of publication of the guideline. Throughout the guideline development process, WHO staff should make this requirement explicit to all relevant parties.

   b. Both published and unpublished data and studies should be considered equally as part of the evidence base used to inform a WHO recommendation.

      i. The terms "published" and "unpublished" data and studies (or evaluations) are inexact and variably defined, and publication status does not correlate with quality or trustworthiness of data or studies. Herein we define published data or studies to be those where the information is reproduced in an indexed journal or in a monograph from an established publisher. Publicly-available means that the data or studies are available in print or online to the public, whether free or for a fee, irrespective of whether they are indexed in a bibliographic database.

      ii. An important resource providing access to unpublished data is the summary results section of clinical trials registries. Results disclosure in such registries is legally required in many jurisdictions including United States and the European Union and is WHO's official position.3

   c. If for some reason the data or studies cannot be made accessible at the time of publication of a WHO guideline, the WHO Steering Group for the guideline, in collaboration with the (external) Guideline Development Group and WHO senior management in the technical unit producing the guideline need to carefully weigh

3 WHO Statement on Public Disclosure of Clinical Trial Results, available at https://www.who.int/ictrp/results/reporting/en/ (accessed 11 February 2019) .

the risk to the Organization and to global public health of using these data versus not using them. Note the following options and considerations:

i. A summary of the data or study can be made available on a WHO or other web-site which is freely accessible to the public in the situation where full access to the data or to detailed summary study results is not possible.

ii. If the data owner will not agree to make the study results or a summary thereof publicly available at the time of publication of the WHO guideline, at a minimum WHO must provide a list of the studies and/or datasets that were included in the assessment on a publicly available web-site, and highlight those that were not released into the public domain by the interested party. WHO should indicate that all efforts were made to seek permission to make the results publicly available and for which studies this permission was denied and by whom. This is not an optimal approach as it limits accessibility and transparency, however it does provide some level of transparency on what information was used by the Guideline Development Group to make its decisions, and it allows other interested parties to seek access to these data to verify the findings.

iii. The original (raw) dataset does not have to be made publicly available; a synthesis of the results will suffice.

iv. If the data owner shares study results with a WHO Guideline Development Group for the purposes of informing a recommendation, but will not make the study results available publicly in any way (including in summary form or as part of a systematic review) by the date that WHO releases the guideline, the WHO guideline will name the principal investigator and data owner and indicate that they refused to permit public disclosure of the study results at the time of publication of the WHO guideline. A citation as a personal communication should be included. The guideline may present sensitivity analyses including and excluding these data as indicated.

v. If the principal investigator or data owner refuses to share study results with WHO for the purpose of informing a recommendation in a guideline, the WHO guideline will name the principal investigator and data owner and indicate that they did not share the study results with WHO to inform a specific recommendation or guideline.

World Health Organization

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9789240017382

Updates related to the classification of ITN products

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&

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Team Lead, Prequalification Team, Vector Control Products

Malaria Policy Advisory Group (MPAG)
virtual meeting, 13-15 April 2021

World Health Organization

Background

In May 2020, the classification of ITNs was revised into three classes :

1. ITNs designed to kill host-seeking insecticide-susceptible mosquito populations that have demonstrated public health value compared to untreated nets and whose entomological effects consist of killing and reducing the blood-feeding of insecticide-susceptible mosquito vectors.

2. ITNs designed to kill host-seeking insecticide-resistant mosquitoes for which a first-in-class product has demonstrated public health value compared to the epidemiological impact of pyrethroid-only nets.

3. ITNs designed to sterilize and/or reduce the fecundity of host-seeking insecticide-resistant mosquitoes for which a first-in-class product has demonstrated public health value compared to the epidemiological impact of pyrethroid-only nets.

For further details on the classification please consult the MPAG meeting report for May 2020, available from: https://www.who.int/publications/i/item/9789240007024

Background

Adoption of the revised classification was made conditional on a number of areas being addressed by WHO:*

- Update WHO documentation on the evaluation process to reflect changes made to ITN classification and evaluation
- Identification and closure of existing data gaps on new types of nets currently prequalified (incl. pyrethroid+PBO nets)
- Establishment of a process within WHO to define similarities for existing and future ITN products
- Revision of ITN testing guidelines to allow comprehensive evaluation of nets other than pyrethroid-PBO products
- Review of the ITN classification within a period of 3 years to establish whether the revised classification continues to capture the available products and those under development, and whether there may be opportunities to further simplify classification
- MPAG requested at least annual updates on the data available to update this classification

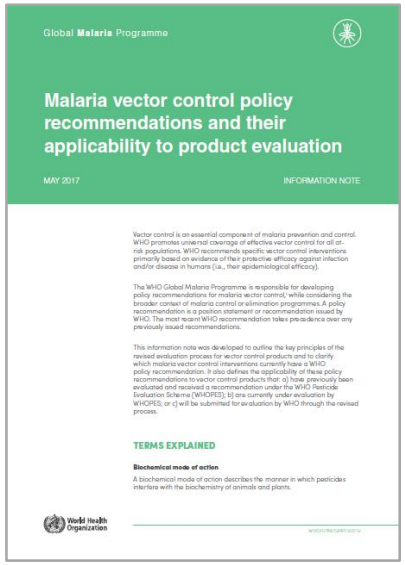
* Note that the order of these areas has been modified from the 2020 MPAC report to provide improved flow of this presentation

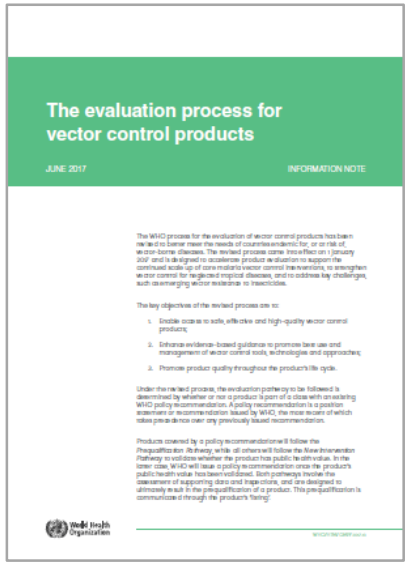
Updates – Global Malaria Programme

Task: Update WHO documentation on the evaluation process to reflect changes made to ITN classification and evaluation

Progress:

- Evaluation process guidance updated and expanded (jointly with PQT and NTD)





https://www.who.int/publications/i/item/9789240017382

- Revision ongoing to reflect latest WHO terminology

World Health Organization

Updates – Global Malaria Programme

Task: Identification and closure of existing data gaps

Progress:

- Epidemiological data to inform update/development of WHO recommendations:

  i. PBO nets: Second trial in Uganda completed by research consortium → Submitted for VCAG review at April 2021 meeting → Update of Cochrane systematic review ongoing → Guideline Development Group (GDG) meeting schedule for June 2021; revisit of the current conditional PBO recommendation on the agenda

  ii. Pyrethroid + chlorfenapyr nets and pyrethroid + pyriproxyfen nets: Trials ongoing → Results to be reviewed by VCAG once data from two trials are available (Q3 2022) → GDG

Updates – Global Malaria Programme

Task: Establishment of a process within WHO to define similarities for existing and future ITN products

Progress:

- WHO Pre-submission Coordination Committee (PQT, GMP & NTD) serves as WHO body to review product characteristics against established intervention classes / recommendations
- No specific further process to define similarities between current and future products developed yet, as no immediate need/examples identified
- Non-inferiority method is being evaluated as a potential way to assess comparative effectiveness of products that fall within the same intervention class. Experimental hut trials on pyrethroid-PBO nets ongoing → Data submission to WHO anticipated for June 2021 → Technical consultation scheduled for September 2021 → Feedback to MPAG planned for Q4 2021

World Health Organization

Update: PQT/VCP

Task: Review, revision and strengthening of data requirements to support the safety, quality and entomological efficacy of all classes of ITNs.

Progress:

- requirements for classification of ITNs for purposes of determination of public health value
  - Principles to guide development of appropriate requirements are in place
  - Data requirements developed
- Requirements for chemistry and manufacturing data to support the quality of the product, i.e., the ITN
  - Physical and chemical properties of the active ingredient, formulation and net material - review completed
  - Data to establish meaningful and reproducible manufacturing product specifications and for quality assurance purposes - actively under review and role of JMPS assessed
  - Data to indicate the product will be effective throughout its lifecycle (3 years) - under review
    - chemical durability
    - new data requirements for physical durability

Update: PQT/VCP

Task: Review, revision and strengthening of data requirements to support the safety, quality and entomological efficacy of all classes of ITNs.

Progress:

- Requirements for safety determined through an assessment of exposure data - ongoing
  - PQ/VCP development of Generic Risk Assessments for specific insecticides and significant other formulants/ additives, e.g., PBO, - completed and available for manufacturers
  - Risk Assessment for the end use product (ITN) incorporated as part of the PQ/VCP safety assessment

Update: PQT/VCP

Task: Data requirements to support the impact of the product on the vector (entomological efficacy)

Progress:

- Review of current data requirements completed, and areas for strengthening the requirements identified
- Discussions with PQT/VCP Assessor Group on developing new and additional requirements initiated in March 2020 and first report completed
- Knowledge drawn from assessors' expertise, current research and publications on this topic, as well as, 3 years experience in reviewing data submitted through the prequalification process
- Scope of new data requirements focusses on strengthening and expanding laboratory studies and semi-field studies
- Scope will also focus on aligning data which supports chemistry and manufacturing requirements and efficacy requirements in order to better understand the performance of the product and allow for a more robust analysis of this data.

Update: PQT/VCP

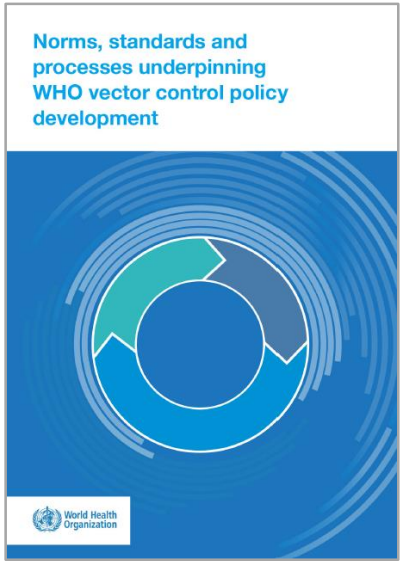
Task: Revision of 2012 *Guidelines for laboratory and field-testing of long-lasting insecticidal nets*

Progress

- Background documents and documents related to ITN Guidance and required by PQT, drafted, approved and awaiting publication, e.g., PQ/VCP Oversight Document, Operations Manual
- Process established to build and expand the revised guidance developed in 2017 (not published)
- Format, scope of document and table of contents agreed and development of content for each section initiated.

Summary Updates – Global Malaria Programme

- Evaluation process guidance updated and expanded
- Pyrethroid-PBO nets: New epidemiological impact data to be reviewed by VCAG in April 2021. Update of Cochrane systematic review ongoing. Guideline Development Group to revisit current conditional recommendation in June 2021.
- Pyrethroid + chlorfenapyr nets and pyrethroid + pyriproxyfen nets: Trials ongoing. Data from first trial to be reviewed by VCAG in late 2021. VCAG review of second data set anticipated for Q3 2022. WHO recommendation to be formulated thereafter.



- No immediate need to further evolve process to define similarities between current and future products identified
- Potential use of non-inferiority method to differentiate between products within same class to be further discussed in September 2021 drawing on data from experimental huts studies on pyrethroid-PBO nets

Summary of Updates – Prequalification Team, Vector Control Products

- **Review, revise and strengthen data requirements to support the safety, quality and entomological efficacy of all classes of ITNs**
- **Product Safety**
  - updated Generic Risk Assessments for insecticide active ingredients developed and end product risk assessments incorporated into PQ/VCP assessment
- **Quality (Product Chemistry and Manufacturing)**
  - review of data required to establish meaningful and reproducible manufacturing product specifications and to demonstrate product quality throughout its lifecycle and for quality assurance purposes completed
  - Consideration of including additional attributes to assess physical durability of ITNs ready for consultation
- **Entomological efficacy**
  - requirements for classification of ITNs for purposes of determination of public health value are developed
  - review of current data requirements completed, areas for strengthening the requirements are identified
  - scope of new data requirements focusses on strengthening and expanding laboratory studies and semi-field studies
  - scope will also focus on aligning data which supports chemistry and manufacturing requirements and efficacy requirements in order to better understand the performance of the product and allow for a more robust analysis and understanding of this data.

Revision of 2012 *Guidelines for laboratory and field-testing of long-lasting insecticidal nets:* development progressing

Malaria Policy Advisory Group Meeting

13—15 April 2021, Geneva, Switzerland
Background document for Session 4

World Health Organization

Digital Solutions for Malaria Elimination

Strategic Information for Response Unit,
WHO Global Malaria Programme. Geneva, Switzerland

Contents

WHO/UCN/GMP/MPAG/2021.04

Glossary

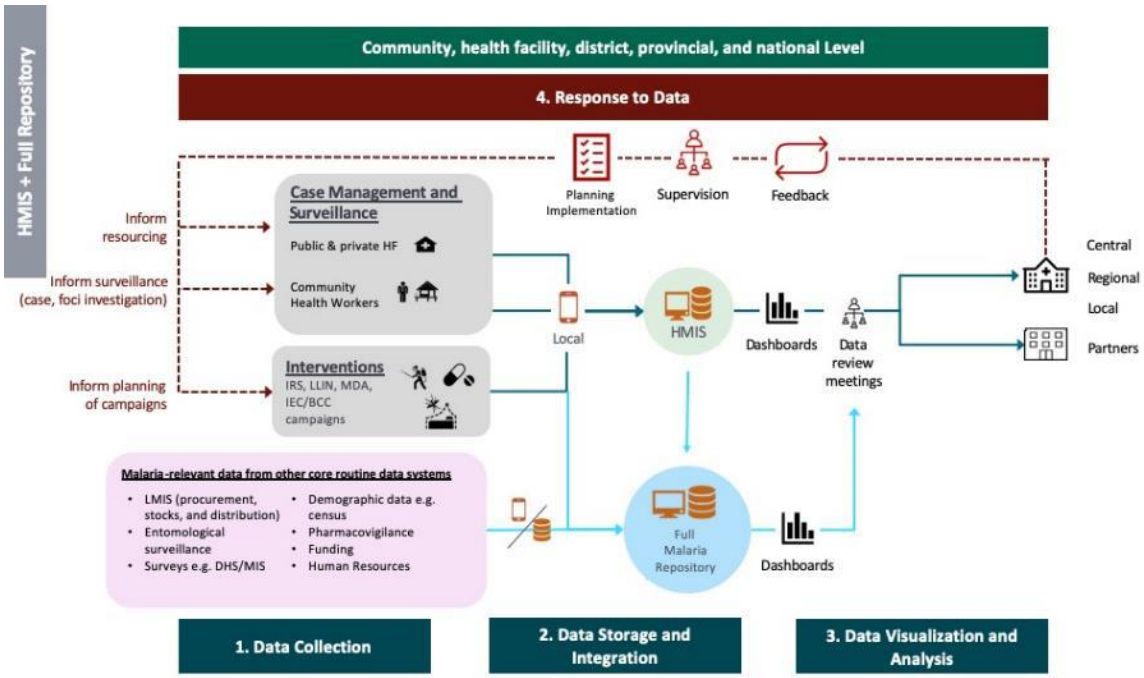
CHAI	Clinton Health Access Initiative
CMPE	Center for Malariology, Parasitology and Entomology
CNM	National Center for Parasitology, Entomology, and Malaria Control
DELR	Direction d'Epidémiologie, de Laboratoire et de Recherches
DHIS2	District Health Information Software
DSME	Digital Solutions for Malaria Elimination
DVBD	Division of Vector Borne Diseases
eCDS	electronic communicable disease system
EHP	enviromental health practitioner
GMP	Global Malaria Programme
GPS	Global Positioning System
HISP	Health Information Systems Program
HMIS	Health Management Information System
iMISS	integrated malaria information storage system
IO	information officer
IRS	indoor residual spraying
IT	information technology
M&E	monitoring and evaluation
MIS	malaria information system
MoH	ministry of health
NDoH	National Department of Health
NIMPE	National Institute of Malariology, Parasitology, and Entomology
NMCP	national malaria control programme
NVDCP	National Vector-borne Diseases Control Programme
OpenSRP	Open-Source Smart Register Platform
SLA	service-level agreement
SOP	Standard Operating Procedure
SUS	System Usability Scale
UGI	Information Management Unit
UVS	Health Surveillance Unit
UI	user interface
WHO	World Health Organization

1. Background

1.1 Problem statement

Transforming the surveillance system into a core intervention is the third pillar of the *Global technical strategy for malaria 2016–2030.*[1] As countries progress towards malaria elimination, the aim of surveillance is to detect all malaria infections; investigate every malaria case; identify the likely location of an infection in order to direct actions towards interrupting transmission; and ensure that each detected case is promptly treated and monitored to prevent secondary infection. An ideal surveillance information system for malaria elimination[2] includes rapid and complete case reporting, central data storage and management, automated data analysis, and customized outputs and feedback that lead to timely and targeted responses. The following diagram illustrates an optimal, fully integrated malaria information system (MIS) – from the collection of complete and timely data to reporting, data analysis, active follow-up, and selection of interventions to adequately address malaria transmission (Fig. 1):

FIG. 1.
Example of an ideal malaria elimination information system



In 2015–2016, a landscape assessment[3] was conducted by the Clinton Health Access Initiative (CHAI) in collaboration with governmental malaria programmes in 16 countries (Botswana, Cambodia, Costa Rica, Dominican Republic, Eswatini, Guatemala, Haiti, Honduras, Lao People's Democratic Republic [PDR], Mozambique, Myanmar, Namibia, Panama, South Africa, Viet Nam and Zimbabwe) to assess the status of national surveillance systems, based on the minimum standards recommended by the

[1] Global technical strategy for malaria 2016–2030. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/bitstream/handle/10665/176712/9789241564991_eng.pdf).
[2] Malaria surveillance, monitoring and evaluation: a reference manual. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/bitstream/handle/10665/272284/9789241565578-eng.pdf).
[3] Lourenco C, Tatem AJ, Atkinson PM, Cohen JM, Pindolia D, Bhavnani D, et al. Strengthening surveillance systems for malaria elimination: a global landscaping of system performance, 2015–2017. Malar J. 2019;18:315. doi:10.1186/s12936-019-2960-2).

World Health Organization (WHO). This assessment showed several shortcomings of existing information systems. Data collection relied largely on paper forms that were prone to data entry errors, had longer timelines for reporting, and limited the collection of geospatial data at the community or health facility level. While some countries had begun to roll out digital surveillance systems, no single information system, including DHIS2 – the most commonly used health information system in the priority countries – could functionally support the data collection and analysis of individual cases, case investigations, focus investigations, and interventions. Additionally, the assessment revealed gaps in data analytics, visualization, and the integration and linking of different types of malaria data. Furthermore, the mobile surveillance tools that were in use often did not correspond to the operational workflows of malaria health workers, were not built appropriately for low infrastructure and low literacy settings and were difficult to configure and customize for different countries.

An analysis of existing mobile platforms to support malaria elimination[4] further identified several gaps in the electronic data collection and data analysis using mobile platforms. Existing platforms were not easy or straightforward to configure or customize, were unable to collect data in a non-sequential way that would better match the realities of data collection in the field, and did not support complex or non-hierarchical relationships among cases, foci, or other geospatial entities.

1.2 Project background

To solve these problems, the Digital Solutions for Malaria Elimination (DSME) project was initiated in 2017, as a collaboration between WHO, CHAI and other partners, to develop and deploy effective digital surveillance tools in malaria-endemic countries. Under the DSME umbrella, governments were supported to deploy configurable systems to streamline, integrate and improve the timeliness of data collection, and coordinate actions among different cadres of health workers in malaria elimination settings. Additionally, a suite of tools was developed to satisfy the requirements of such systems, which were identified through:

- a desk review of global and country-specific malaria programme and health information system documentation;
- discovery visits in four countries (Haiti, Honduras, Lao PDR and Zimbabwe) with a range of experience with digital solutions for malaria surveillance; discovery visits included key informant interviews and shadowing of malaria programmes, subnational offices, health facility staff, and field-based surveillance officers to identify challenges with current tools;
- phone interviews and feedback on early drafts of the requirements document from WHO and a DSME Community of Practice consisting of implementing and technology organizations;
- a WHO-hosted workshop in Geneva attended by WHO Global Malaria Programme (GMP) members and subject matter experts, which enabled review of the draft requirements document to ensure its contents were representative of WHO's surveillance reference manual.[5]

[4] Mobile solutions for malaria elimination surveillance systems: a roadmap. Palo Alto: Vital Wave; 2017 (https://vitalwave.com/case-study/mobile-solutions-for-malaria-elimination-surveillance-systems/).
[5] Malaria surveillance, monitoring and evaluation: a reference manual. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/bitstream/handle/10665/272284/9789241565578-eng.pdf).

2. Digital Solutions for Malaria Elimination: tool descriptions

A suite of digital tools was developed or enhanced to support the following use cases (Fig. 2):

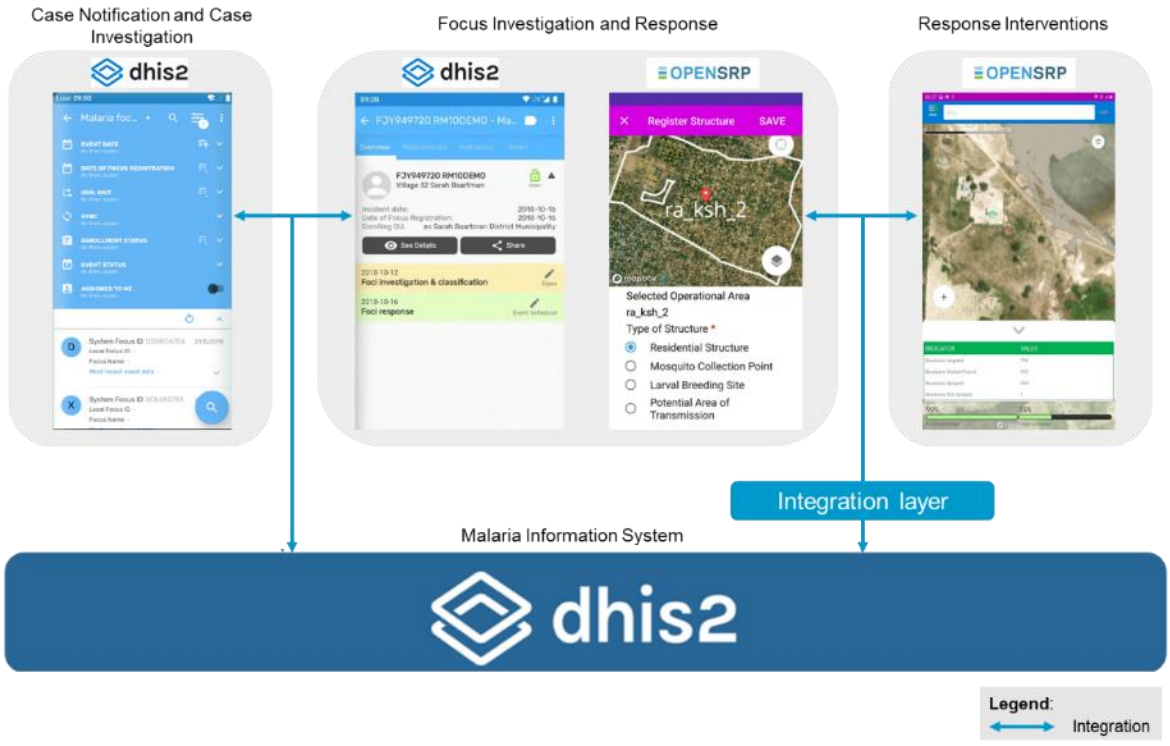
- MIS, using the DHIS2 web platform
- case notification and case investigation, using the application DHIS2 Android Capture app
- focus investigation and response, using two platform options: OpenSRP and DHIS2 Android Capture app
- response interventions, using OpenSRP.

Interoperability between mobile tools and the MIS enables a seamless flow of information between field-based users and surveillance officers. While the case notification and investigation app, DHIS2-based focus investigation and response app, and DHIS2-based MIS were already integrated within the DHIS2 ecosystem, mechanisms were explored to ensure that data from the OpenSRP-based response interventions app were available in the DHIS2 Web platform.

A proof-of-concept integration between the response interventions application and DHIS2 Web was completed in Namibia. Once metadata in the response interventions application and DHIS2 are mapped, automated scripts export the data into DHIS2 based on the mapping. This enables data collected in the response interventions application to be visualized in DHIS2 Web alongside other malaria indicators.

Furthermore, the OpenSRP focus investigation and response application was integrated with Thailand's custom MIS, enabling the case data from the MIS to flow into the OpenSRP focus investigation and response application to trigger focus investigation activities.

FIG. 2.
Suite of digital tools developed that can be used together or independently based on country need



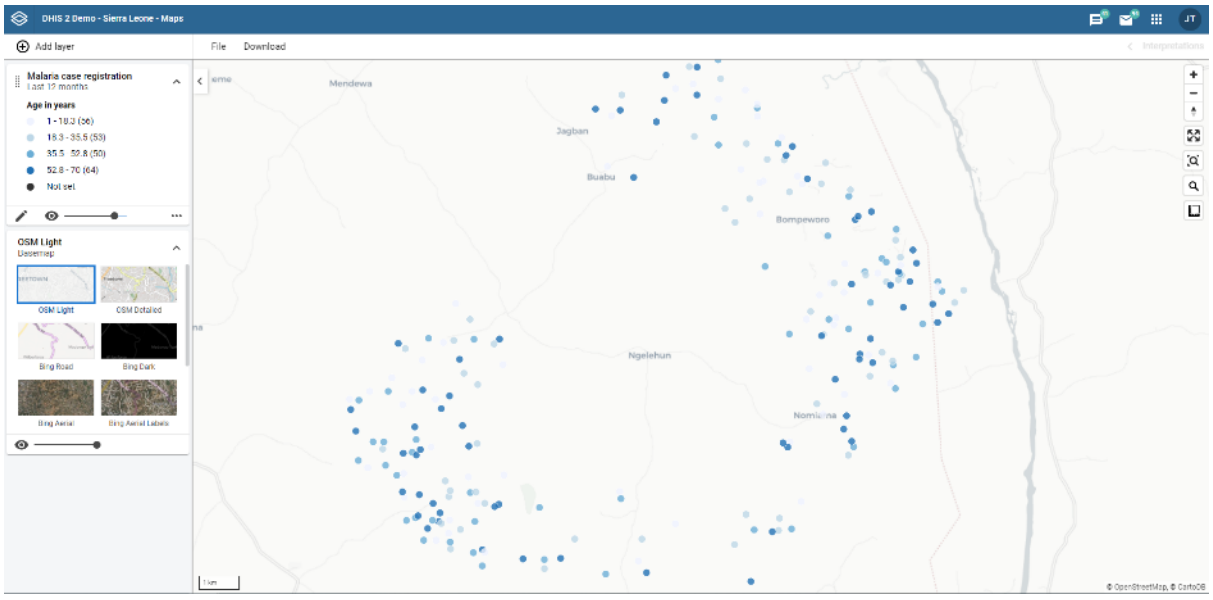
2.1 Malaria information system (MIS)

DHIS2 Web is one of the leading Health Management Information Systems (HMISs) to enable data collection, analysis, visualization and sharing of data. National malaria control programmes (NMCPs) have noted common challenges with DHIS2 Web for malaria information management, including the inability to perform complex analytics and the inability to link data across malaria surveillance activities.

To respond to these challenges, enhancements to the platform to make it fit for purpose as an MIS included:

- introducing the concept of relationships in malaria data, whereby users are able to link and visualize relationships (e.g., two malaria cases within the same household);
- enhancing analytics capabilities through the consolidation of various analytics apps and development of combination charts to compare indicators across years;
- improving data entry flows through the creation of filters to enable data entry officers to filter outstanding tasks by due date;
- updating the visualization of malaria data using maps and enabling users to filter data on maps by status of tasks or demographic information (Fig. 3);
- enabling analysis at patient level through line-listing, whereby users can track patients through the malaria diagnosis, notification and treatment cycle.

FIG. 3.
Visualization of malaria case burden by age in a region on DHIS2 Web



2.2 Case notification and investigation application

A case notification and investigation application was developed using the DHIS2 Android Capture app, a mobile-based data collection tool. This application was developed to address challenges that NMCPs identified in previous data collection systems, including complex data collection flows resulting in data entry errors, difficulty in searching patient records in the mobile tool leading to fragmented or duplicate records, and issues syncing with the MIS. Consultations with WHO also indicated a lack of standardized terminology in forms for malaria surveillance programmes, making it difficult to measure and compare indicators across countries.

To respond to these challenges, the new case notification and investigation application was built to:

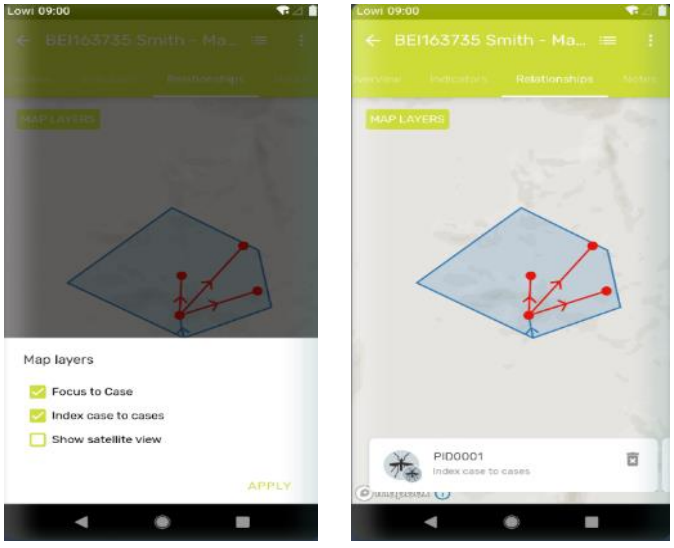
- improve syncing so that data entered in the case notification and investigation application are sent directly to a web-based MIS, if using DHIS2, at a frequency determined by programme teams (e.g., daily, hourly);
- improve data collection with offline functionality;
- simplify the user interface (UI) through use of icons and validation logic;
- introduce the ability to search, filter and sort through malaria case records to enable users to quickly identify patients through long lists of records;
- standardize the terminology used for the case notification and case investigation form templates based on WHO recommendations.

2.3 Focus investigation and response applications

Two focus investigation and response apps were developed: one built on the DHIS2 Android Capture app and the other on OpenSRP. These two different options enable countries to select the tool that is best fit for purpose for the country-specific focus investigation approaches.

The DHIS2 Android Capture app version can be used for data collection on foci that may be embedded in case notification and investigation activi-ties, particularly in a digital ecosystem where DHIS2 is already being used for data collection for other malaria surveillance activities. The OpenSRP version can be used to support dedicated focus investigation operations and response activities (e.g., indoor residual spraying [IRS], entomological surveillance, bed net distribution), providing more granular household-level data to conduct and monitor such activities. This version also offers an option that can be easily deployed independent of DHIS2 in countries where DHIS2 is not widely used.

Fig. 4.
Viewing relationships between cases and case to focus in the DHIS2 Android Capture app -based focus investigation and response app



During discovery, NMCPs identified challenges with existing focus investigation tools, including the inability to track interventions at household level (e.g., bed net distributions), difficulty searching for households, inability to link malaria cases to focus areas, and inability to create tailored focus

investigations district by district. To solve these problems, the following features were included in the DSME tools:

- DHIS2 Android Capture app: the ability to create and visualize relationships between records and focus areas (Fig. 4);
- OpenSRP: the ability to create and visualize relationships between records and focus areas;
- OpenSRP: creation of flexible focus investigation plans, whereby users can customize the tasks for a particular focus investigation;
- OpenSRP: historical index cases can be viewed to inform focus operations (Fig. 5).

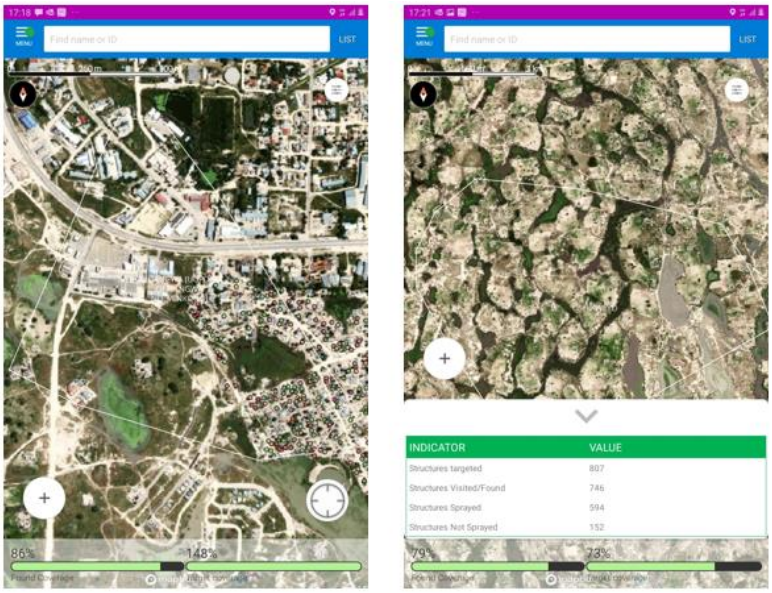
FIG. 5.
Viewing case index information for a particular focus, while collecting or monitoring data on OpenSRP

2.4 Response interventions application

The response interventions application, built on the OpenSRP platform, uses geospatial information to support the operationalization of field-based routines and reactive interventions offline. Data entered in the mobile app are synced with the web platform, where supervisors can monitor data. The web platform can also be integrated with an existing MIS – whether it be a DHIS2-based system or custom system (see Thailand profile).

Key challenges with prior tools for response interventions (e.g., IRS) included the inability to track interventions (e.g., difficulty in monitoring spray coverage of an IRS campaign in real-time), inability to track or view data at household level (e.g., status of spraying at a household), difficulty in searching/identifying households, and the need to re-register families each year for annual interventions.

FIG. 6.
Interactive map to navigate through tasks and in-app indicators to monitor spray coverage in real-time



To address these challenges, functionality was built into the response interventions app, including:

- creation of household-level tracking with which a user can add a household, register a family and then perform an intervention;
- introduction of in-app indicators with which users can track the progress of an IRS campaign against the target coverage in real-time (Fig. 6);
- introduction of an intuitive map-based UI wherein the colour of a structure provides information on the status of tasks for that household (e.g., green = all tasks completed), and search and filter capabilities for users to search through lists of households quickly;
- use of GPS to ensure data capture at household level, which prevents users from entering data for a household unless they are in the vicinity of the household;
- creation of web dashboards to enable users to monitor the progress of an intervention at household level.

3. Monitoring and evaluation (M&E) framework

WHO-GMP and CHAI have developed an M&E framework to evaluate the performance of the DSME suite of tools in pilot settings. The objectives of the framework are to:

- understand how digital tools are used for surveillance;
- quantify the impact of digital solutions, particularly on reporting rates;
- understand the overall value and usability of digital solutions in disease surveillance and intervention activities.

In order to measure progress, indicators were proposed to assess surveillance impact, data quality and reporting, system performance, user profile and usage, user engagement, sustainability and scalability, governance impact, and hardware performance – along with guidance on data sources, analysis methods, and sample questionnaires for focus groups and key informant interviews. This framework was adapted, and indicators selected by country programmes for data collection and analysis in Honduras, Namibia, South Africa and Thailand (Table 1).

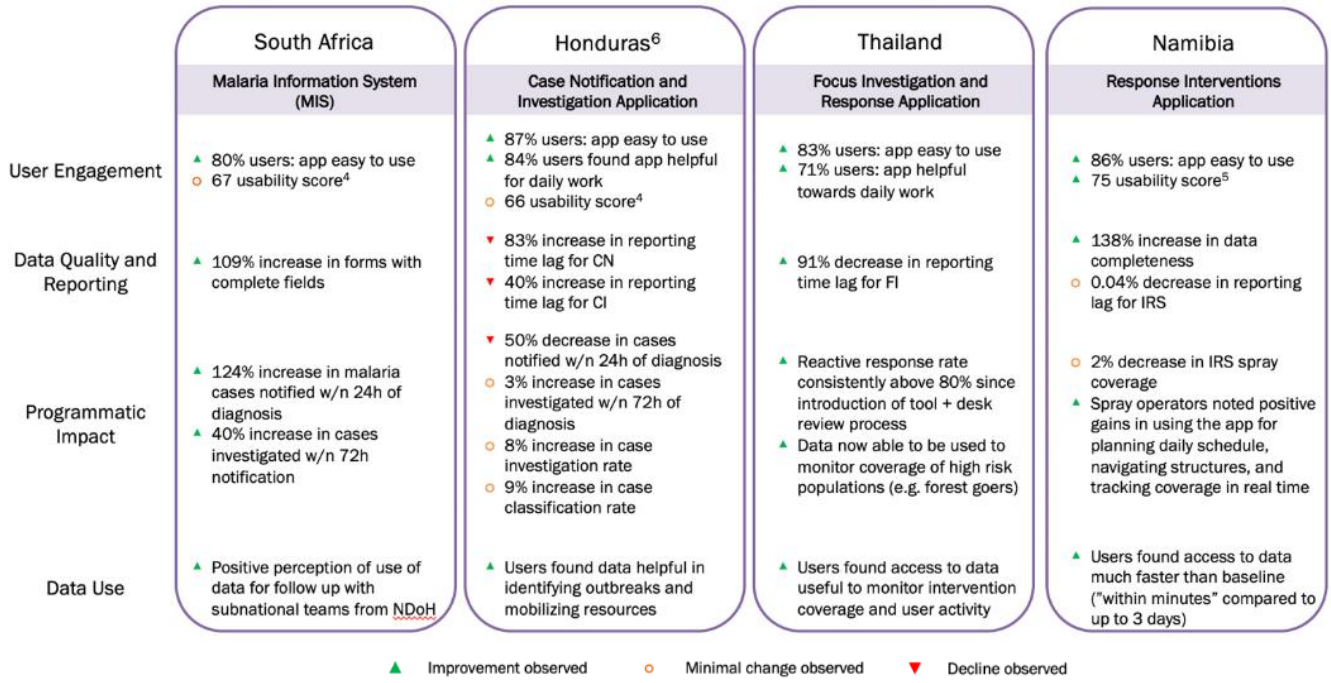
TABLE 1.
Overview of DSME pilots and M&E activities

Country	South Africa	Honduras	Thailand	Namibia
Tools assessed	**Malaria Information System (MIS)**	**Case Notification and Investigation Application**	**Focus Investigation and Response Application**	**Response Interventions Application**
Platform	DHIS2 Web	DHIS2 Android Capture	OpenSRP	OpenSRP
Baseline data source	Microsoft Access	Paper data & country MIS	Country MIS	Baseline IRS application
Baseline date	Q1 2018	Q2 2019	Q4 2018	Q4 2018
Midline/endline data source	DHIS2 database, key informant interviews	DHIS2 database, key informant interviews	OpenSRP database, key informant interviews	OpenSRP database, key informant interviews
Midline date	Q1 2020	Q1 2020	Q1 2020	Q4 2019
Endline date	Q1 2021	Q4 2020	Q1 2021	Q4 2020
User profile	30 users: - info officers, - data capturers	60+ users: - vector control teams, - data entry staff, - epidemiologists, - microbiologists	30 users: - field investigators, - health workers	30 users: - field supervisors, - spray team leaders
Provinces	Limpopo, Mpumalanga, Kwazulu-Natal	Gracias a Dios, Colon, Yoro, El Paraiso, Isla de la Bahia	Trat, Tak, Ubon Ratchathani	Oshana

4. Pilot country results

Across pilot countries, positive indications were observed for user engagement and data use; all respondents noted that increased access to and granularity of data were useful for surveillance activities. Data quality and reporting varied, with challenges with reporting lag observed in areas with low connectivity. Programmatic impact also varied across pilot countries, with some countries observing minimal change in surveillance indicators and others seeing improvement or decline. However, even in the countries that had yet to observe net improvements, respondents noted that the tools had added value in supporting day-to-day operations and coverage monitoring. See Fig. 7 for a snapshot of the pilot country results and sections 4.1–4.4 for further pilot country details.

FIG. 7.
Summary of select DSME pilot country results



Each pilot country also provided insights into the prerequisites for long-term sustainability, particularly focusing on institutionalization, technical capacity, financial planning, training, and system integration. Key insights included the need for a mix of (i) government-led technical capacity to provide direct support to users (training, troubleshooting), and (ii) some degree of external technical support from the DHIS2 community or OpenSRP community for initial set-up, customization and upgrades. All countries noted a need to include digital tool support in annual budgets (e.g., for technical support, training, supervision, platform maintenance and routine upgrades). Some respondents suggested that funding opportunities to support these tools could be made available with the implementation of a digital health policy, incorporation of the apps into existing guidelines, and/or integrations with existing technical systems outside of the malaria programme.

[6] The usability score was measured using the System Usability Scale (SUS), an industry standard survey to measure usability of digital tools. A score of 80 or over is excellent; a score between 68 and 80 is good; a score of 67 is average; a score between 51 and 66 is below average; and a score below 51 is poor.
[7] In Honduras, while assessment was done across five regions, 99% of the malaria cases came from Gracias a Dios – a region with extremely limited connectivity. Many challenges with data reporting and timeliness were found to be associated with data syncing issues (see section 4.2).

4.1 South Africa – MIS

Until 2018, South Africa used three different case notification and investigation forms for the three different endemic provinces (Limpopo, Mpumalanga, KwaZulu-Natal), and data were saved across isolated Microsoft Access or Excel-based databases. At the central level, the malaria programme within the National Department of Health (NDoH) had to reconcile and merge the different data sources, leading to delays in data analysis and impacting the ability to make timely decisions on intervention delivery. To address these challenges, the NDoH decided to transition to a DHIS2-based MIS with standardized forms and integrated databases across three provinces.

With support from the DSME project, a DHIS2-based MIS was built to include modules on case surveillance, IRS, entomology and focus investigation activities, with an integrated dashboard to analyse data accessible across all levels. Over 100 users were trained on how to input data from paper-based forms into the MIS and/or analyse data in the MIS. The MIS was upgraded to v2.33 in July 2020 to benefit from new DSME features on relationships, analytics and mapping.

The M&E for the new MIS was conducted over the course of a few years. Baseline data were collected from the old Microsoft Access databases, using a sample of cases from 2015–2017, and surveys conducted with two information officers in 2018. At midline (Q1 2020), data from April 2018 to March 2020 were reviewed in the DHIS2-based MIS, and surveys were conducted with 15 users. At endline (Q1 2021), analysis was conducted with MIS data from April 2020 to January 2021, and one interview was conducted with a central-level user. As a result of COVID-19, the scheduled endline (Q1 2021) surveys on data use for information officers and data capturers are delayed until late 2021.

4.1.1 M&E results

User engagement

The results below are from the midline (Q1 2020) analysis unless otherwise specified:

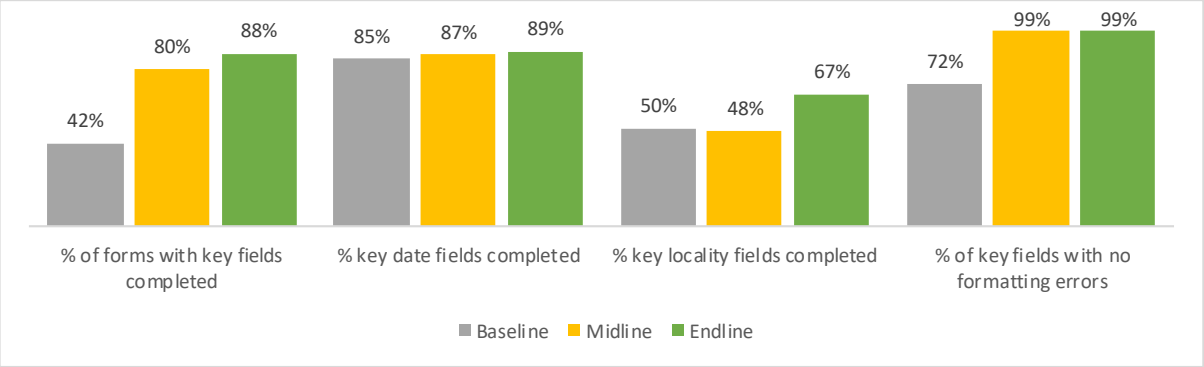
- 80% of users surveyed found the DHIS2-based MIS easy to use. However, 50% of users indicated that the MIS was crashing, freezing or taking a while to save records. This feedback was addressed in later versions of the MIS.
- The usability score for the DHIS2-based MIS was 67, which is an average score among digital health tools.[8]

Data quality and reporting

Form and field completeness have improved since the introduction of the DHIS2-based MIS. National M&E leads made the decision to configure fields as mandatory and introduce validation checks in forms, preventing users from submitting forms to the MIS without completing the mandatory fields or inputting data in the expected format (Fig. 8). This has equipped information officers (IOs) with more complete data for in-depth analysis of specific cases or across cases.

[8] 15 respondents surveyed at midline

FIG. 8.
Field completeness and formatting errors (# of forms with correct fields)/(total # of forms)



While field and form completeness has increased, data entry time has increased by an average of 2.5 minutes compared to the previous MIS for which data entry took just under 4 minutes. This increase is to be expected with the introduction of mandatory fields and more fields for users to complete. As data entry officers become more familiar with the MIS, it is anticipated that the time taken for data entry will reduce over time.

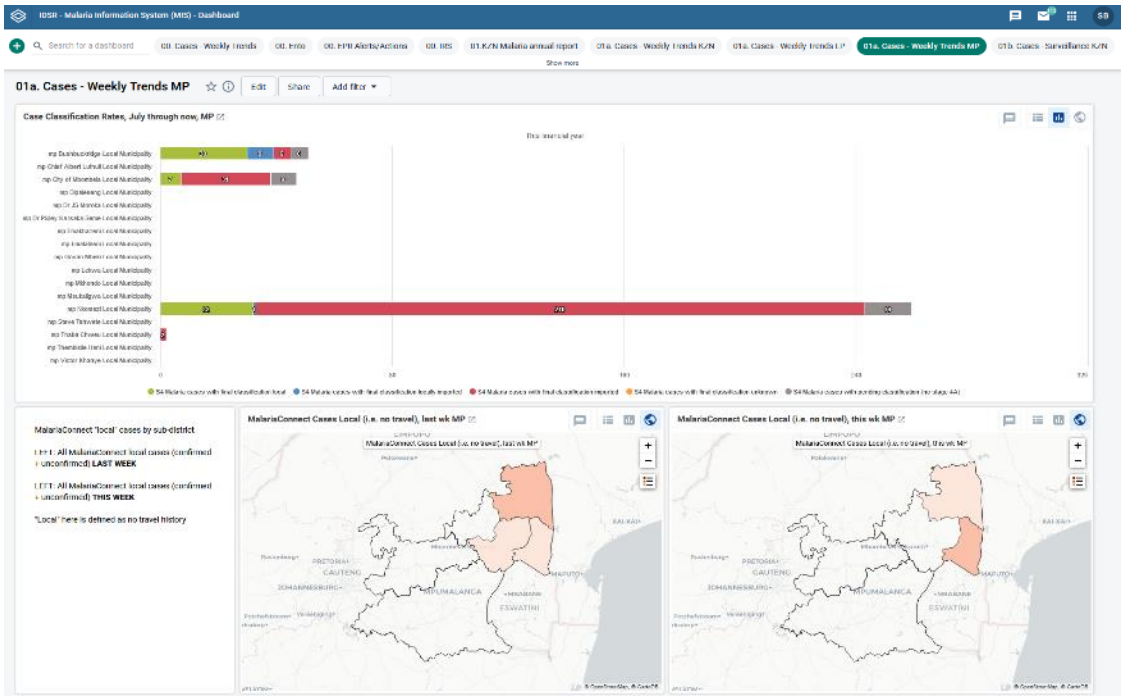
Data use impact

Data use has increased since the introduction of the DHIS2-based MIS (Fig. 9). Users indicated that the timeliness and accessibility of data has enabled them to follow up with health facilities/environmental health practitioners (EHPs), check data quality, and make reports to supervisors. A central-level malaria programme user commented on data use: "*With the new MIS and data at our fingertips, I am able to use data to follow-up with provinces to make timely decisions and check any data discrepancies. For example, if there is any malaria outbreak we are able to use the data to make decisions in real-time, previously I had to wait for the data captured to enter the system (which could take weeks) and by then, an outbreak might have been over.*"

Additionally, the introduction of the MIS has been complemented by the initiation of monthly data review at the provincial/district level. Provincial/district-level staff's increased access to data and dashboards (Fig. 10) has made decision-making more decentralized. The total number of dashboard views increased from 575 to 1,827 between midline (Q1 2020) and endline (Q1 2021) assessments across levels, further indicating an increase in MIS engagement and routine data review.

FIG. 9.
Data use for various routine activities (# of respondents surveyed at midline)

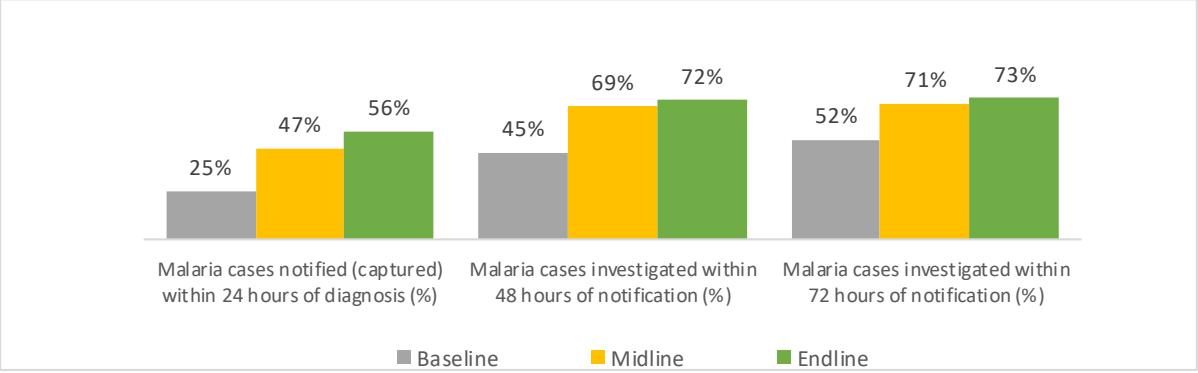
FIG. 10.
Weekly trend of malaria cases dashboard from the MIS



Programmatic impact

Case notification and case investigation rates improved in the time period after the DHIS2-based MIS was introduced (Fig. 11). Users noted that this is likely due to a combination of programmatic improvements, targeted resource mobilization, and the DHIS2-based MIS. The 60% increase in malaria cases investigated within 48 hours of case notification from baseline (45 cases investigated) to endline (72 cases investigated) is in line with the positive feedback from the NDoH that the MIS has contributed to increasing access to data in a timely manner to plan for case investigations.

FIG. 11.
Surveillance protocol adherence



Tool sustainability in-country

Users noted that the MIS is consistently used and embedded in day-to-day processes across the central, provincial and locality levels, reflecting strong institutionalization and capacity to manage and maintain the system. Areas of improvements to further ensure long-term sustainability of the tool include continuing to increase uptake by central-level managers, conducting long-term financial planning for maintenance of the system, and integrating with systems beyond malaria. Additional insights into sustainability from the endline interviews are noted in Table 2.

TABLE 2.
Insights into tool sustainability from the NDoH

Category	Current strengths	Areas of improvements
Institutionalization	• Use of the MIS is embedded and consistent across users at provincial and district levels. • Existing guidelines on the use of digital tools is being revised based on the new National Strategic Plan.	• Support the uptake and use of the MIS by some central-level managers. • Formalize the process to record and address user feedback on the MIS.
Programme technical capacity	• A responsive WhatsApp group is in place to provide timely assistance in troubleshooting issues from provincial IOs.	• Engage with the wider NDoH to develop a plan for maintenance as part of the wider HMIS.
Financial planning	• There are existing service-level agreements (SLAs) for maintenance support with external developers (Health Information Systems Program, HISP South Africa) with the wider HMIS but not currently with the MIS.	• Advocate for the inclusion of the MIS in the broader technical tool maintenance. • Determine funding allocation for training and data bundles with provincial offices.
Training	• Quarterly reviews on the MIS are conducted between central and subnational staff to help trigger follow-up trainings. • The central-level NDoH led online trainings.	• Conduct periodic refresher trainings for central-level managers on how to navigate and use dashboards in order to promote uptake and usage of the tool.
System integration	• All malaria programme data in the endemic provinces are integrated in the MIS.	• Transition away from duplicate case notification systems at the health facility level by moving to a streamlined notifiable diseases app. • Integrate the MIS into the HMIS.

4.1.2 Lessons learned and next steps

As part of implementing a new MIS, strong in-country technical support and engagement across subnational levels has been key. HISP South Africa (the in-country DHIS2 technical team) has been essential in configuring the system and troubleshooting any issues faced by users. With the NDoH and HISP teams managing the implementation of the MIS, IOs have had better access to national and technical teams to provide feedback. This in turn has led to improvements in the system and thus better uptake and data use by IOs.

Moving forward, the NDoH will introduce bulletins to present data from the MIS to national and regional management teams of the data that are available. Additionally, the NDoH is currently completing the roll-out of the case notification and investigation mobile application for focus investigations to increase the timeliness of the data received in the MIS. The NDoH plans to expand the MIS to include data from other malaria activities in non-endemic regions (from the HMIS), with the goal of storing all malaria data in a single system. Integration between the MIS and HMIS will enable the MIS to benefit from existing funding and resources and to further institutionalize the MIS in country.

4.2 Honduras – Case notification and investigation

Honduras historically had two national-level surveillance systems: an aggregate locality-level reporting system and a case-based reporting system. For both systems, data collected on paper were sent to the national level for entry, which resulted in incomplete data, no integration of case investigations or other sources of data, severe reporting lag from the community level into the system, and data inconsistencies between the aggregate and case-based systems. To solve these problems, the Information Management Unit (UGI) consolidated the systems into a DHIS2-based system – including the introduction of a case notification and investigation app to be used at health facilities in 2019. The app was introduced to 60 users across five regions (Gracias a Dios, Colon, Yoro, El Paraiso, Isla de la Bahia) in 2019 to track case-based data.

The M&E for the new case notification and investigation app was conducted over the course of a few years. Baseline data from October 2018 to April 2019 were collected from the paper-based system and DHIS2 Web; midline (Q4 2020) data review looked at data on the case notification and investigation app from October 2019 to April 2020; and the endline (Q1 2021) data review looked at data on the case notification and investigation app from October to December 2020. Furthermore, endline (Q1 2021) assessment included interviews with 38 end users, seven central-level users (three from the Health Surveillance Unit [UVS], two from UGI and two from the National Laboratory) and seven regional-level users (epidemiologists).

4.2.1 M&E results

User engagement

The results below are from the endline (Q1 2021) analysis unless otherwise specified:

- 87% of users found data entry easy using the case notification and investigation app.
- The usability score for the app was 66, an average score among digital health tools.
- 84% of users found the app useful for their daily work.
- 52% of users commented that the same data had to be inputted across multiple forms. Users recommended form consolidation.
- Users noted that poor Internet connectivity led to delays in loading and syncing data.

Programmatic impact

Since the introduction of the case notification and investigation app, time lag from case diagnosis to case notification and case investigation has increased[9] (Fig. 12). Furthermore, the proportion of cases

[9] In Honduras, the time lag for case notification is calculated by UGI as the time between the date of diagnosis and date of notification, with the latter requiring paper data entry before submission to a regional team for entry into the system via the app. The time lag for case investigation is calculated as the time between the

notified within 24 hours of diagnosis has decreased, while the proportion of case investigations within 72 hours of diagnosis has had minimal change (Fig. 13).

FIG. 12. Time lag

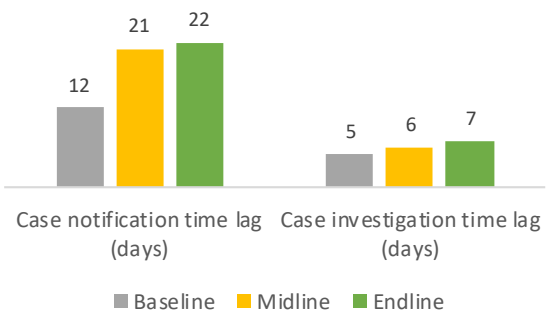
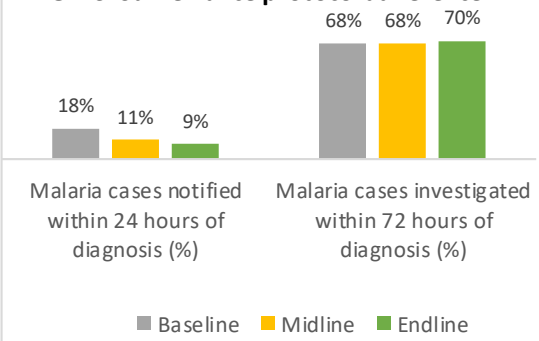


FIG. 13. Surveillance protocol adherence

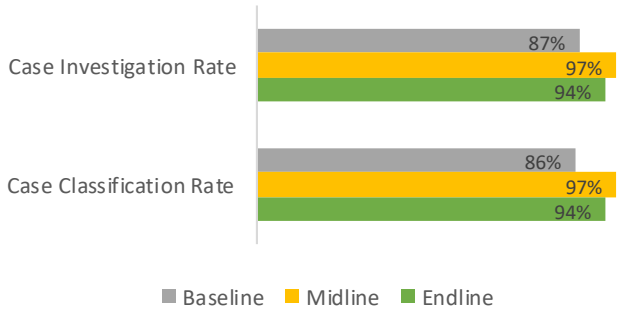


These observations are largely attributable to Gracias a Dios, which contributed 57% of the country's malaria cases at baseline (Q2 2019) and 99% of cases by endline (Q4 2020). Gracias a Dios is an extremely remote region where Internet connectivity is limited, thus affecting data syncing times. Furthermore, between baseline (Q2 2019) and midline (Q2 2020), syncing issues between the app and DHIS2 Web not linked to connectivity led to form changes being only partially reflected on the app. This was confusing to users and contributed to delays in data entry.

Improvements were seen in both case classification rate (number of cases classified against the number of cases investigated) and case investigation rate (number of cases investigated against total number of cases) (Fig. 14).

Improvements in case investigation and classification rates may also be attributed to the programmes efforts to strengthen the surveillance system through field trainings, supervision visits and validation rules.

FIG. 14: Case classification and case investigation rate



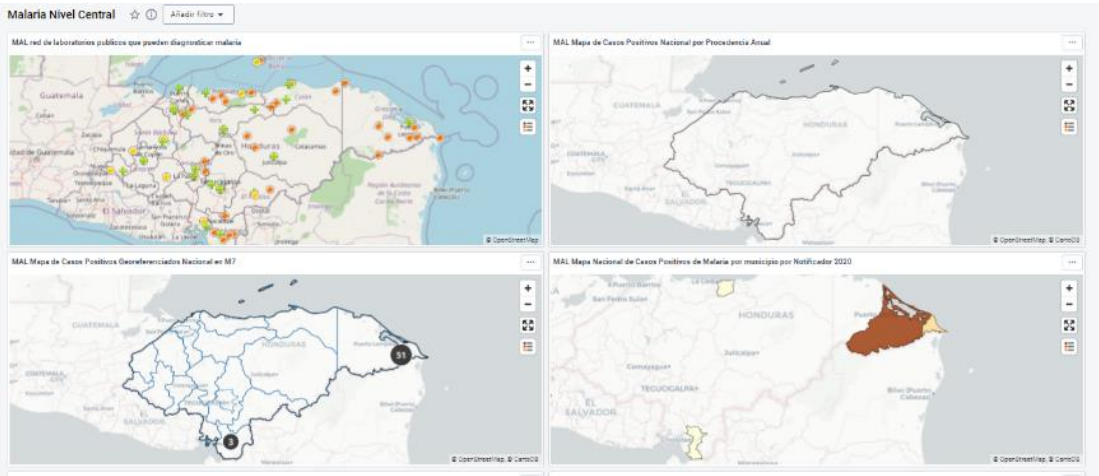
Data use impact

There are currently 12–15 data review meetings per year at the central level and four data review meetings at the regional level. Since the introduction of the app, all users have been positive on the influence of the app on surveillance actions. Once data from the app were synced with the MIS, users found that access to data in one place helped with decision-making, such as identifying outbreaks, mobilizing resources based on needs or revising programme plans if activities are delayed in certain regions (Fig. 15). UVS has introduced epidemiology bulletins and malaria breakfasts in which data from the case notification and investigation app are frequently discussed. A few central users have refrained from using the dashboards in the MIS, as the data presented have yet to undergo quality checks. A few regional users commented that dashboard loading is slow in areas with poor Internet connectivity,

date of diagnosis and date of investigation, which can happen prior to when notification data is entered into the system. For this reason, the time lag for case investigation may be shorter than the lag for notification.

and the dashboards sometimes do not present information in an intuitive manner (e.g., no breakdown by focus).

FIG. 15.
Screenshot from the MIS dashboard to track malaria cases in Honduras



Tool sustainability in-country

Central-level interviewees indicated that the app was an improvement over previous systems and is well supported by in-country government technical staff for troubleshooting and upgrades. In order to further ensure the sustainability of the system, respondents expressed the need to decentralize technical management at the regional level and both strengthen and finance maintenance protocols. Additional sustainability insights from endline (Q2 2019) interviews are noted in Table 3.

Table 3.
Insights into tool sustainability from Honduras central-level users

Category	Current strengths	Areas of improvement
Institutionalization	• All users found the app to be an improvement over the previous system.	• Draft Standard Operating Procedures (SOPs) for the use of digital tools for malaria surveillance activities.
Programme technical capacity	• WhatsApp is used for troubleshooting and to resolve any issues. • Regular app upgrades are driven by UGI.	• Train regional offices to manage technical problems, as one UGI programme manager is currently resolving issues across all regions. • Define the process for system maintenance, as current maintenance support is ad hoc.
Financial planning	• UGI has budget to cover training for central-level users through partners.	• Assess and define the budget for maintenance, training and hardware costs.
Training	• Successful deployment of e-training during the COVID-19 pandemic.	• Define training frequency and a training plan.

Category	Current strengths	Areas of improvement
		• Track individual training status and needs.
System integration	• App is integrated with the wider MIS.	• Integrate different data collected into the MIS. Data on medicines are collected and stored in a different system, and data collection is still paper based in health facilities (then transferred to the case notification and investigation app).

4.2.2 Lessons learned and next steps

Users identified the introduction of the case notification and investigation app as an improvement over the previous data entry system, enabling programme managers to easily access the data. Furthermore, improved case notification and investigation rates have been observed. However, the timeliness of surveillance activities decreased in areas with poor Internet connectivity. UGI is exploring solutions to address the network connectivity challenge. As part of institutionalizing the app, UGI plans to update SOPs on the use of digital tools for malaria surveillance, develop a longer-term sustainability plan for the app and MIS, and identify programmatic funding needs for national and subnational levels to maintain the app.

4.3 Thailand – Focus investigation and response

Until 2019, the Division of Vector Borne Diseases (DVBD) planned focus investigation and response activities using paper-based forms that were subsequently entered into a custom MIS. While the information collected on paper was very granular, the DVBD could only routinely access the aggregated focus information available in the MIS. This created difficulties in monitoring the quality and coverage of activities at the focus level and prevented the identification of gaps in surveillance.

The DVBD aimed to improve the monitoring of focus response through better tracking of access and coverage of focus interventions at the household and individual levels. Therefore, it adopted the OpenSRP focus investigation and response application in 2019. The app enabled the DVBD to draw boundaries and conduct a full enumeration of each focus so as to better capture population characteristics and behaviour data relevant to malaria response activities (e.g., gender, age, forest-related activities). It also enabled data collection at both household and individual level for mass blood screening, bed net distribution, and reactive case detection for both routine and reactive focus activities. Finally, the tool was integrated with the custom MIS so that case notification data in the MIS automatically trigger a focus response plan with a set of predefined focus interventions needed according to the national guidelines.[10] Plans can be customized in the app based on a review of historical data on the focus profile. The app was initially piloted in three provinces (Trat, Tak and Ubon Ratchathani) in late 2019 before being scaled up nationally (across 41 provinces) in late 2020.

The M&E for the focus investigation and response app was conducted over the course of a few years. Baseline data from October to December 2018 were collected from the custom MIS; midline analysis was conducted on data from October 2019 to May 2020; endline (Q1 2021) analysis was conducted

[10] Focus response activities for reactive focus include (i) family registration of all households and family members, (ii) identification and confirmation of index case household, (iii) reactive case detection, (iv) bed net distribution survey and top-up, (v) larvae dipping and mosquito collection, and (vi) health education.

on data from October 2020 to January 2021. The endline (Q1 2021) assessment also included interviews with 49 users, one DVBD Public Health Technical Officer, and three IT officers.

4.3.1 M&E results

M&E results below focus on data collected from the three pilot provinces (Trat, Tak and Ubon Ratchathani).

User engagement[11]

The results below are from the endline (Q1 2021) analysis unless specified otherwise:

- 93% of users found it easy to navigate through the focus investigation and response app.
- 71% of users found the focus investigation and response app helpful in their daily work.
- 57% of users commented that some tasks within the app were unclear and difficult to complete due to the layout of the forms.

Data quality and reporting

Data concordance between the MIS (which still stores paper-based data) and the focus investigation and response app was analysed by reviewing data on the total number of blood screening tests in the two systems. An average of 98% concordance was found with the data in the two systems (Fig. 16). The reporting lag between a focus investigation being conducted and data being available for analysis at all levels decreased from 3.7 days to 0.3 days (Fig. 17).

FIG. 16. Concordance across data entered in the app and custom MIS at midline

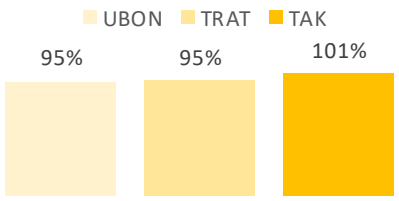
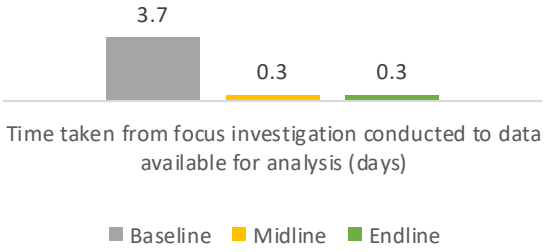


FIG. 17. Reporting lag

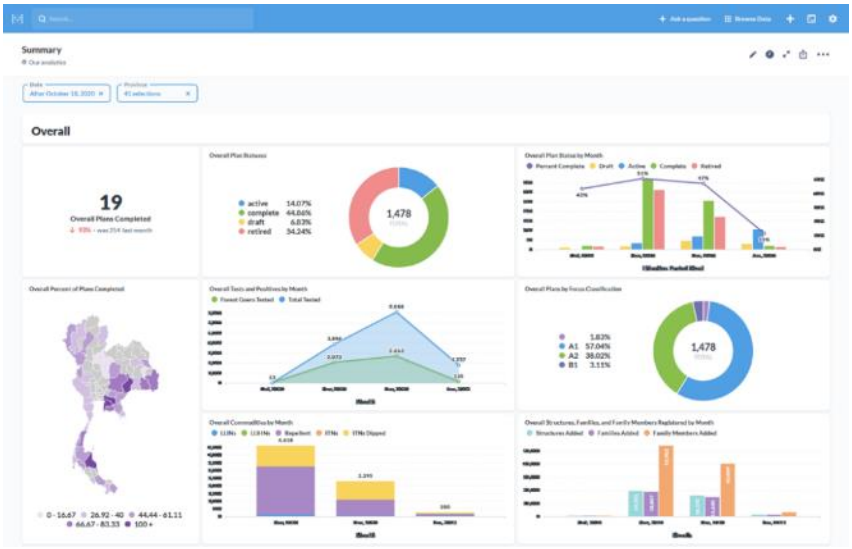


Data use impact

While some dashboards were available within the tool to track intervention coverage, the DVBD worked with partners to develop custom dashboards in Metabase for supervisors to monitor user activity, population targeted, focus intervention coverage and quality, user group, focus plan, and/or time (Fig. 18). In addition, regional DVBD teams review operational coverage via a web interface on the focus investigation and response app to follow up with field teams or mobilize additional resources in order to ensure that coverage targets for response activities are met.

[11] A total of 49 users from the pilot provinces were interviewed.

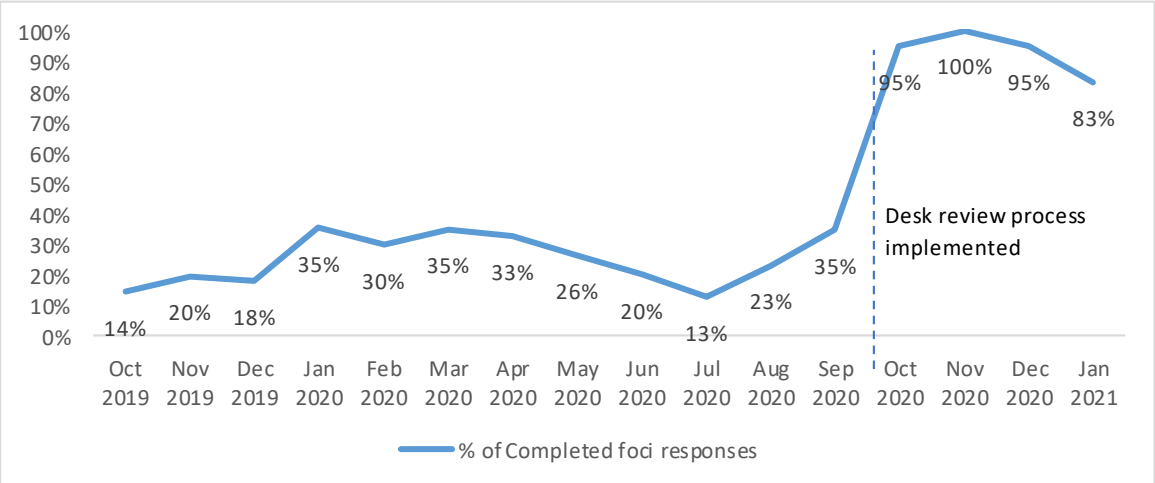
FIG. 18.
Metabase dashboard that the DVBD uses to review focus investigation rate and user statistics, and monitor epidemiology indicators



Programmatic impact

Since the introduction of the app, the DVBD has noted positive gains in being able to track the completeness and quality of the focus response activities. The number of focus interventions conducted compared to the number of interventions expected has increased over time (Fig. 19).[15] During the pilot (Oct 2019–Sep 2020), it was found that provinces with high case load had low reactive focus response rates due to resource constraints, which made them unable to investigate every malaria case. Since the introduction of a desk review process using the focus investigation and response app, users can prioritize where a focus investigation is required based on historical case data. As a result, reactive focus response rate has been consistently over 80%.

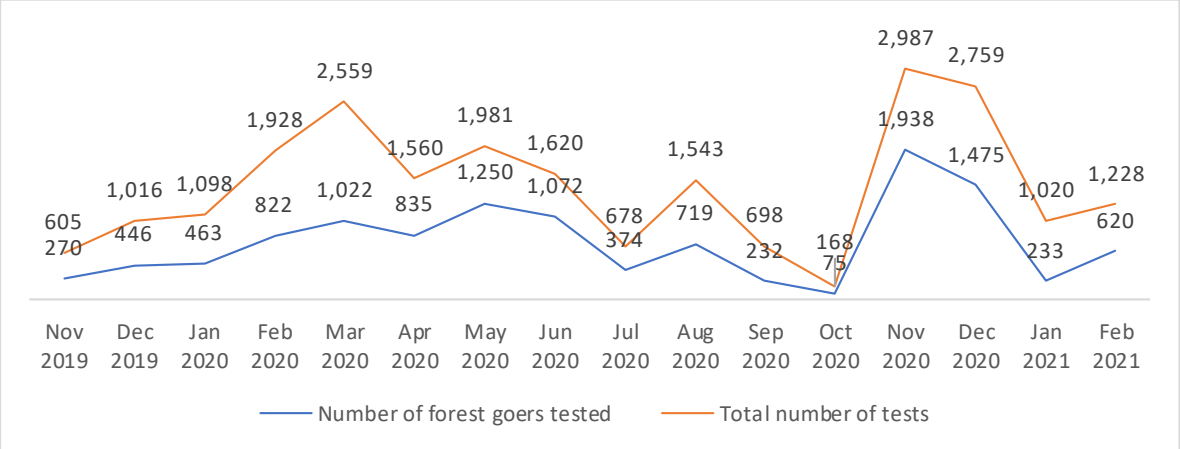
FIG. 19.
Reactive focus response rate (pre- and post- desk review implementation)



The DVBD has also recognized that the availability of highly granular data from the focus investigation and response app is useful for monitoring whether interventions are reaching the target population.

For example, the combination of demographic data, surveillance and response intervention data found in the app has enabled the malaria programme to monitor whether the populations reached during response activities are those at highest risk (Fig. 20).[12] These data can then be used to trigger adjustments in programmatic activities in order to ensure full coverage of the at-risk population.

FIG. 20.
Number of tests done during focus response for forest-goers compared to total tests



Tool sustainability in-country

The DVBD recognized the need to have a strong enabling environment that supports long-term tool sustainability. Not only are guidelines in place to include use of the digital tool, but there is also a strong technical team that has taken ownership of training, troubleshooting, enumeration and M&E. Furthermore, the app servers are hosted in country, the system is integrated with the established MIS, and costs have already been absorbed into the national budget. Areas of improvement noted by the DVBD include expansion of tool configurability to further increase the local technical team's ownership of the tool beyond current troubleshooting. Additional insights into tool sustainability from endline (Q1 2021) interviews are found in Table 4.

TABLE 4.
Insights into tool sustainability from the Thailand DVBD

Category	Current Strengths	Areas of Improvement
Institutionalization	• Users have recognized positive results in data availability and data use, and improvement in the quantity and quality of the focus response activities. The DVBD has also recognized that the tool has the potential for expansion to other community-based interventions. • National guidelines on the use of digital tools for malaria elimination activities are in place, and SOPs on the use of the application have been implemented and are widely monitored.	• Include the focus investigation and response app in the national digital health policy. • Improve the ability of programme teams to configure all features without technical support (e.g., creating users, modifying area boundaries).

[12] Adult with forest-going behaviour

Category	Current Strengths	Areas of Improvement
Programme technical capacity	• The DVBD has a technical team (M&E officers, IT officers) that has taken ownership of training, troubleshooting, enumeration and M&E. • The DVBD has set up a troubleshooting mechanism with field-level users using different communication tools (Line, Team Viewer and phone calls) to provide feedback and troubleshoot.	N/A
Financial planning	• The app servers are hosted in country on the existing infrastructure. • Hosting and maintenance costs have been included in the national health annual budget up to 2024.	• Secure long-term financing for tool hosting and maintenance costs for post-2024.
Training	• Annual training on the focus investigation and response app has been planned for supervisors and users. • Qualified master trainers and users can independently lead trainings.	N/A
System integration	• The focus investigation and response app is integrated with the wider MIS system, and focus response plans can be triggered from positive malaria case detection in the MIS system.	• Suspend parallel paper-based data collection. • Integrate the focus response app dashboards, Metabase dashboards, and MIS dashboards.

4.3.2 Lessons learned and next steps

The DVBD has indicated that the introduction of the focus intervention and response app has been a positive improvement, enabling granular data access and informing decisions on programmatic priorities. The DVBD has decided to scale up the tool nationally and plans to conduct a complete epidemiological analysis of data from the focus response app in late 2021 in order to understand the effectiveness of focus investigations conducted through electronic means. This analysis will also be used to inform updates to the national guidelines and SOPs. Technical development for the app will focus on increasing configurability so that the DVBD can take full ownership and customize it for other malaria activities.

4.4 Namibia – Response interventions

In 2017 and 2018, the National Vector-Borne Diseases Control Programme (NVDCP) piloted an IRS application (used as the baseline tool) for their annual IRS season in all endemic regions. The baseline IRS application was used for field-based household-level data collection. The pilots intended to improve data quality and spatial granularity at household level. However, several technical challenges emerged with the baseline IRS application, including app crashes, difficulty in syncing data, and battery draining while in the field. In addition, inconsistencies between the baseline IRS application and the paper-based system rendered data collected from the baseline IRS application unreliable. As part of the DSME project, the baseline IRS application was replaced with the DSME response interventions

application for IRS in the Oshana region. For both the 2019 and 2020 IRS seasons, 30 users were trained and used the response interventions application to record and monitor spray coverage.

The M&E for the response interventions app was conducted over the course of a few years. Baseline data were collected from the baseline IRS application in 2018; midline (Q4 2019) analysis reviewed data from the response interventions app from September to November 2019, including interviews with nine users; and endline (Q4 2020) analysis reviewed data from the response interventions app from October to December 2020, including interviews with five users.

4.4.1 M&E results

User experience

The results below are from the midline (Q4 2019) analysis unless specified otherwise:

- 86% of all users found the response interventions application easy to use.
- The usability score was 75 for the response interventions application (2020)[1] – a good score among users and an improvement from 51.3 for the baseline IRS application (Q4 2019).

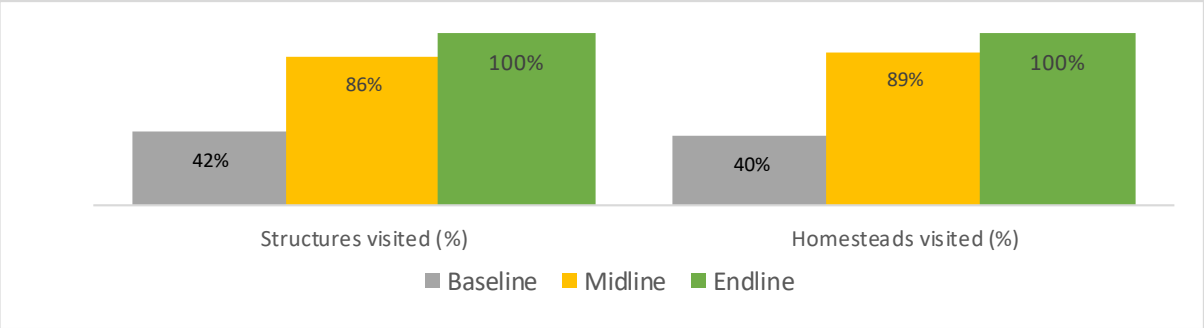
All users found that the response interventions application added value to the IRS campaign, particularly the use of map visualizations to navigate to specific households, ability to track spray progress, and availability of modules to plan resources accordingly. The average data entry time reduced by 8% from 03:38 minutes at midline to 03:20 minutes at endline (Q4 2020), indicating that users became more familiar with the tool and it saved time in the field. User feedback on data entry time for the paper-based system indicated that it was comparable to that of the response interventions application (<5 minutes).

Some users noted issues of maps not loading when in areas of poor connectivity and being periodically logged out of the mobile app while in the field, and challenges with the accuracy of the village boundaries that were loaded into the tool following the enumeration process.

Data quality and reporting[13]

Data completeness was measured based on the number of entries in which structures had an associated village name against the total number of structures. At baseline (2018), data completeness was low, making it difficult to measure spray coverage by region. In the response interventions app, the village name field was made mandatory using validation logic. As a result, at midline (Q4 2019) and endline (Q4 2020), the proportions of structures with an associated village had increased (Fig. 21).

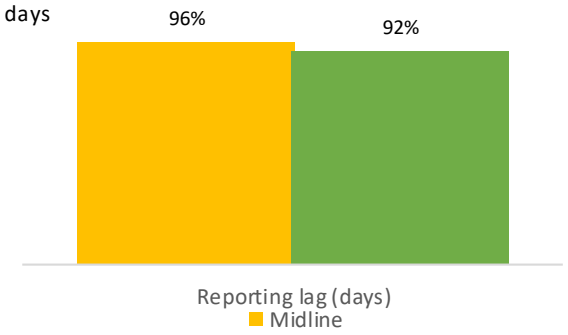
FIG. 21.
Data completeness ((# structures corresponding to a village name) / (total # structures)



[13] As a result of COVID-19, physical copies of paper records could not be accessed to compare them to OpenSRP performance on data quality indicators.

Reporting lag was measured as the time taken for entries in the response interventions app to sync with the server. Over 90% of spray entries collected in the response interventions app were synced to the server within five days, with an average reporting lag of 1.6 days at endline (Q4 2020) (Fig. 22). Users noted that by using the response interventions app, the time taken from data being collected in the field to those data being available for analysis at all levels has reduced to minutes, compared to up to three days with the baseline IRS application or one to two weeks with the pre-2017 paper-based systems.

FIG. 22. Reporting lag

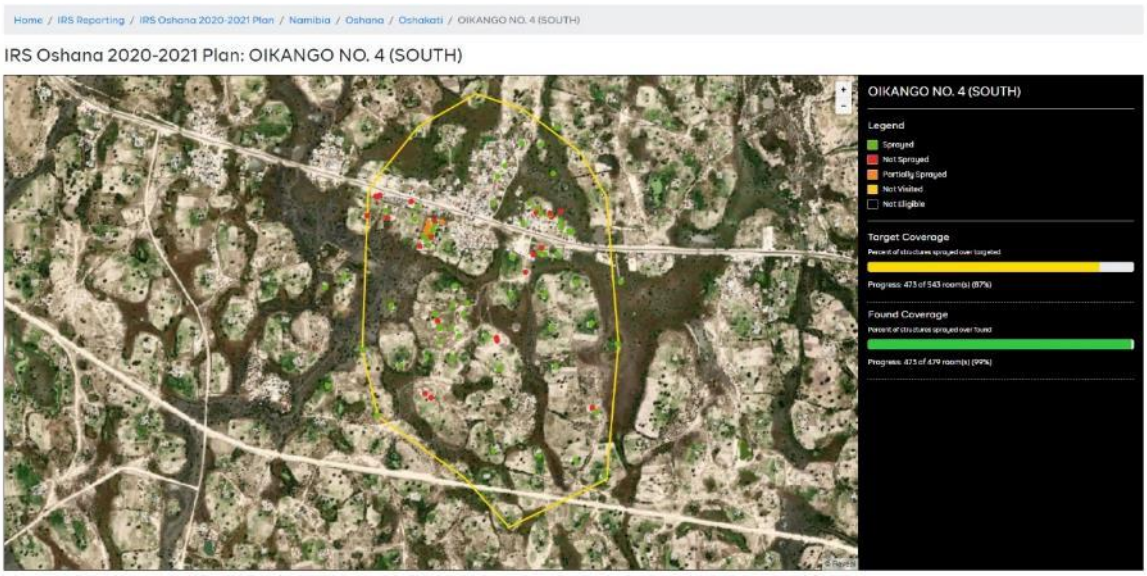


Data use impact

Dashboards were used by supervisors to monitor and guide teams on their operations once a technical issue with data loading on the dashboard was fixed. One supervisor commented that the dashboard enabled teams to visualize spray progress within minutes, while the old system took up to three days (Fig. 23). In addition, as the dashboard contained geo-located and colour-coded household-level data, surveillance officers and supervisors could review the dashboard and use it to resolve challenges with household refusals, scheduling or limited resources while the team was still within village boundaries.

Data review meetings currently take place quarterly, while, during an IRS campaign, supervisors review data at least weekly. Piloting the response interventions app in one region led to strong engagement among supervisors and surveillance officers at the regional level, but with limited engagement at the national level due to their supervisory role across all regions.

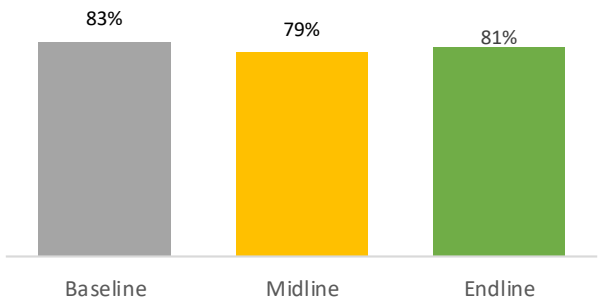
FIG. 23.
Screenshot of the web dashboard displaying a map interface with dots for registered households, colour-coded by intervention delivery success



Programmatic impact

IRS operational spray coverage has shown minimal change since the introduction of the response interventions app (Fig. 24). This could be due to operational factors, such as insecticide shortages preventing IRS mop-ups from being performed and challenges related to COVID-19 at endline (Q4 2020).

FIG. 24. IRS spray coverage
(# structures sprayed / # structures visited)



However, spray operators provided positive feedback on the new tool, indicating that it was useful for planning their daily schedule. In particular, users found that the map visualizations helped them to navigate the different structures within a village, in-app indicators provided a way for users to track their spray coverage in real-time, and the colour-coded system used to denote the spray status of a household helped teams to determine which household to visit next.

Tool sustainability in-country

The NVDCP indicated that institutionalization of the app is in progress through the incorporation of regional SOPs that include use of the tool. Furthermore, regular trainings and meetings are in place to encourage continued tool uptake. To further improve long-term sustainability for the tool, respondents suggested developing national guidelines, engaging further with the Ministry of Health's (MoH) IT team in this work – particularly for integrations – and ensuring there is long-term in-country budget allocated to support the application. Additional insights into sustainability are shared in Table 5.

TABLE 5.
Insights into tool sustainability from Namibia NVDCP at all levels

Category	Current Strengths	Areas of Improvement
Institutionalization	• All national-level and district-level staff want to continue using the response interventions app in Oshana and potentially pilot it in other regions. • Regional SOPs on the app were developed as part of training.	• Ensure better communication with local authorities to increase support from town councils with app. • Develop national surveillance guidelines to include use of digital tools.
Programme technical capacity	• A WhatsApp group is currently in place to troubleshoot and raise issues from spray teams to tech providers.	• Engage with the MoH's IT team to benefit from local technical support.
Financial planning	• The programme budget planning process includes digital tools.	• While digital tools are included in budget planning processes, allocation for specific apps remains a challenge.

Category	Current Strengths	Areas of Improvement
		• There is concern over the sustainability of the response interventions app without partner funding.
Training	• Annual IRS trainings take place at the start of each spray campaign. • The quarterly meetings at regional level can be used for refresher trainings.	• Train central-level users on how to update and maintain the response interventions app.
System integration	• Proof of concept demonstrates that the app can be integrated with MIS	• Integrate response interventions app data with the wider DHIS2 MIS, which requires support from the MoH IT team.

4.4.2 Lessons learned and next steps

When monitoring IRS campaigns, digital tools that can collect spatial data at household level provide valuable data to inform mid-campaign adjustments to ensure that targets are met, rather than facilitating changes only for future mop-ups or campaigns. However, technical constraints such as network connectivity led to maps failing to load. The NVDCP will need to consider how to address the network connectivity challenges faced at district offices while the technology provider considers improvements to offline functionality within the response interventions app.

For future enumeration processes, the NVDCP may also want to involve town councils and local communities to improve the accuracy of village boundaries loaded into the response interventions app and to increase support from communities. The NVDCP will also need to consider updating national surveillance guidelines to include the use of digital tools and the financial budgeting for the response interventions app.

5. Additional countries: considerations for piloting

Of the DSME focus countries, Honduras, Namibia, South Africa and Thailand decided to begin tool adoption in 2019 and conducted M&E studies. Conditions for pilot readiness and conducting comprehensive M&E included strong stakeholder alignment, operational alignment with existing malaria surveillance processes (e.g., existing focus investigation protocols), and available technical infrastructure and capacity.

Of the remaining countries, Lao PDR and Mozambique adopted DHIS2 Web updates to their HMIS and MIS, respectively, in 2019 and 2020, and Zimbabwe initiated a pilot of the case notification and investigation application and DHIS2 Web in 2019. These countries have not conducted extensive M&E on these tool adoptions and hence have not been included as detailed case studies in this report.

In the remaining countries, barriers to early adoption ranged from country buy-in (Botswana, Cambodia, Viet Nam) to technical capacity gaps (Haiti). Furthermore, limitations in available infrastructure also stalled existing pilots (Zimbabwe). Although some countries were able to resolve these barriers in 2019, there were limited opportunities to pilot in 2020 due to the shift in country priorities to focus on COVID-19 control. Four of the countries – Haiti, Lao PDR, Mozambique and Zimbabwe – are now planning additional tool roll-outs in 2021.

Countries planning to expand use of the digital solutions in 2021

- **Haiti:** In 2018, the Direction d'Epidémiologie, de Laboratoire et de Recherches (DELR) developed a digital solutions implementation plan focused on upgrading the core DHIS2-based MIS platform and moving to the case notification and investigation app. However, it was identified that technical capacity-building would need to be prioritized before the roll-out of new tools. Therefore, in 2019, the DELR focused on attending DHIS2 academies to prepare for the adoption of upgraded versions. A pilot of a DHIS2 upgrade and the case notification and investigation app was scheduled to commence in the last quarter of 2020. However, due to the COVID-19 pandemic, the start of the pilot has been postponed to 2021.

- **Lao PDR:** In early 2018, core DSME partners conducted a discovery visit to Lao PDR to document the requirements across malaria surveillance use cases and systems. This information has guided enhancements to the DHIS2 Web and DHIS2 Android Capture application as part of the DSME project. The Center for Malariology, Parasitology and Entomology (CMPE), in collaboration with WHO, disseminated findings to the surveillance technical working group. These DSME features were progressively adopted in upgrades to the country's DHIS2-based HMIS in 2018 and 2019. The system was upgraded again in late 2020 when the new DSME functionality in DHIS2 was significant enough to augment the case investigation pilot, among other activities such as stock management and supervision of surveillance activities.

- **Mozambique:** The NMCP in Mozambique prioritized the development and roll-out of an integrated malaria information storage system (iMISS) in which all malaria data from any new tools could be maintained. Requirement gathering began in 2019, which led to the development and roll-out of the centralized DHIS2-based malaria repository in late 2020. This system leveraged improvements in DHIS2 Web (v2.32) and the DHIS2 Android Capture app (v2.2) from DSME, and key surveillance-specific features and mobile enhancements will be further explored once iMISS use has matured.

- **Zimbabwe:** In 2018, the Zimbabwe NMCP developed a roadmap that included a pilot of the new case notification and investigation app and DHIS2-based focus investigation and response app. Although a pilot began in February 2019 for the case notification and investigation app with 20 EHPs across all elimination districts, it was paused in early 2019 due to application stability issues.

Feedback provided to the technical developers led to the release of a more stable version of the application in mid-2019. Subsequently, a review of existing tablets was conducted to ensure compatibility with the new version of the app. This revealed that over 600 devices in the field were incompatible with the new application's minimum specifications. The NMCP has engaged the Global Fund to secure adequate compatible tablets to facilitate the adoption of tools in 2021. Furthermore, the NMCP has also developed a roadmap with other departments to ensure that upgrading of the tools can be done seamlessly without disruption to other services.

Countries that preferred existing or customized solutions

- **Cambodia:** The National Center for Parasitology, Entomology, and Malaria Control (CNM) piloted the first version of the case notification and investigation app in one province in 2018. Over the course of the pilot from May to November 2018, 360 cases were reported. Of these, 86% were reported using the app, and the reporting rate increased over time as supervision activities continued and the app was upgraded. High rates of timeliness (95%) and case investigation (100%) were also achieved during this time, suggesting that it is feasible to operationalize surveillance for elimination using digital tools in Cambodia. As the first country to use the case notification and investigation app, Cambodia played a key role in its development and testing. However, the CNM decided not to move forward with the DHIS2 system in favour of an in-house custom MIS for malaria surveillance.

- **Botswana:** In 2018, the National Malaria Programme (NMP) worked with implementing partners to develop a roadmap for improving user experience with the existing MIS and paper-based IRS M&E tools by using the new response interventions application and upgrading their DHIS2-based MIS. In 2019, however, the MoH decided it was best to shift focus towards integrating all IT and health information tools across diseases and maximizing the use of existing tools before exploring any new tools; therefore, the implementation plan did not move forward. Any further exploration of the tools in 2020 was paused due to a shift in government priorities to focus on COVID-19 control.

- **Viet Nam**: In 2018, the National Institute of Malariology, Parasitology, and Entomology (NIMPE) decided to build a malaria module within the existing electronic communicable disease system (eCDS) that had been in place since 2016. Building the malaria module within the eCDS facilitated a reduction in parallel reporting and broader support from other areas of the MoH. The NIMPE has been exploring opportunities to roll out updated mobile DSME tools that could interact with the eCDS. However, since the roll-out of the full module was only completed in 2020, current priorities are focused on tool maturity before exploring new mobile enhancements.

6. Summary

The digital tools developed as part of the DSME project are aligned with WHO standards, are adaptable to meet country needs, and are either built using DHIS2 or are interoperable with DHIS2 if needed. These tools show enormous potential for improving malaria elimination activities. Initial M&E results from country pilots have demonstrated gains in user engagement and use of data. Some pilots also observed surveillance activity improvement after extended use of the tools and operational improvements. However, impact was also closely linked to operational prerequisites that could not all be addressed during the pilot (e.g., availability of commodities such as insecticides or other planned programmatic activities). Additionally, there were limitations to digital tool impact in areas with lower network connectivity that affected data syncing. It was not uncommon for the initial roll-out of these tools to face challenges in uptake and unexpected app issues. However, in-country technical support helped to facilitate troubleshooting, improve the tools, and facilitate engagement over time. Lessons learned on strengths and challenges from pilot countries have indicated a need to:

- **Strengthen in-country technical capacity**: Strong in-country technical support with insights into user challenges can lead to the rapid resolution of issues and improve user experience with tools over time. This should include both staff at national and subnational level, messaging mechanisms to facilitate communications with end users (e.g., platforms such as WhatsApp), and processes to document and track user feedback. As with any digital tools, some issues may not be resolved without external developer support (e.g., from the DHIS2 community / HISPs or the OpenSRP community). However, the presence of in-country technical support can help to triage and troubleshoot issues, facilitate technical partner relationships when needed, and reduce external reliance.

- **Budget for maintenance in annual budgets:** Government programmes should include maintenance costs for digital tools in annual budgets. These costs should cover (i) in-country technical capacity, (ii) service packages with external developers as needed (e.g., upgrades to maintain compatibility with new operating systems, hardware, etc), (iii) operational support (e.g., refresher trainings), (iv) hardware upgrades as needed to ensure compatibility with tools, and (v) data bundles. Linkages to other technical systems can also open up opportunities to leverage maintenance budgets and developer service packages that may already be in place for other entities (e.g., MoH HMIS or IT teams).

- **Institutionalize digital tools within health programme operations and policies**: For tools to be embedded in routine health operational processes, surveillance guidelines and SOPs should be updated to include the use of digital tools. Pilot countries have also recommended roll-out of dedicated digital health policies that may encourage MoH-wide institutionalization and open opportunities for funding. Furthermore, dedicated data review with different levels of government stakeholders will be critical to improve the perceived value of the tools and the data outputs. Periodic refresher trainings on tools and data outputs can also facilitate greater perceived value and longer-term uptake.

- **Strengthen in-country interdepartmental and partner collaboration:** All collaborating technical partners and internal MoH divisions involved in surveillance activities should form a core team when introducing new tools. This will enable better coordination of tool roll-out in countries. External financial resources and technical advisory may be helpful for initial start-up, pilot and scale-up costs. However, countries that are interested in adopting digital tools should build capacity to ensure longer term sustainability and ownership by government stakeholders.

Based on these results, WHO would like to:

1. **Make the DSME digital tools available to countries for adoption to augment surveillance processes in malaria elimination settings**. The tools presented in this report are open-source and available for implementation, although they may need customization to ensure they are fit-for-purpose for each country.

2. **Disseminate these tools through clear communication across stakeholders:** Dissemination of the tools will inform all levels of WHO, national programmes, and partners on methods to augment surveillance efforts. WHO will advocate for the scale-up of digital tools as part of broader national surveillance efforts, while acknowledging that, in certain settings, countries may implement elimination surveillance processes vertically.

3. **Work with partners and donors to help countries to adopt, use and maintain these tools:** Initial adoption relied on country buy-in, operational readiness, technical capacity, and available technical infrastructure (e.g., hardware and connectivity). A strong enabling environment was particularly critical once pilots began to help stabilize tools during initial roll-out, encourage tool uptake over time, and support long-term sustainability. WHO will work with partners to facilitate support for interested countries in the installation of digital tools, training capacity and maintenance of digital tools.

4. **Continuously monitor uptake of tools and implement any necessary improvements:** New digital tools should be continuously monitored for usability, data quality, and impact on existing processes. Regular M&E of tools should be embedded in existing programme M&E processes in order to ensure continued added value over time. Periodically, these digital tools will require updates and WHO will work with relevant departments and partners to ensure regular updates of tools in country.

Digital Solutions for Malaria Elimination

Mwalenga Nghipumbwa

&

Dr Abdisalan Noor

Global **Malaria** Programme

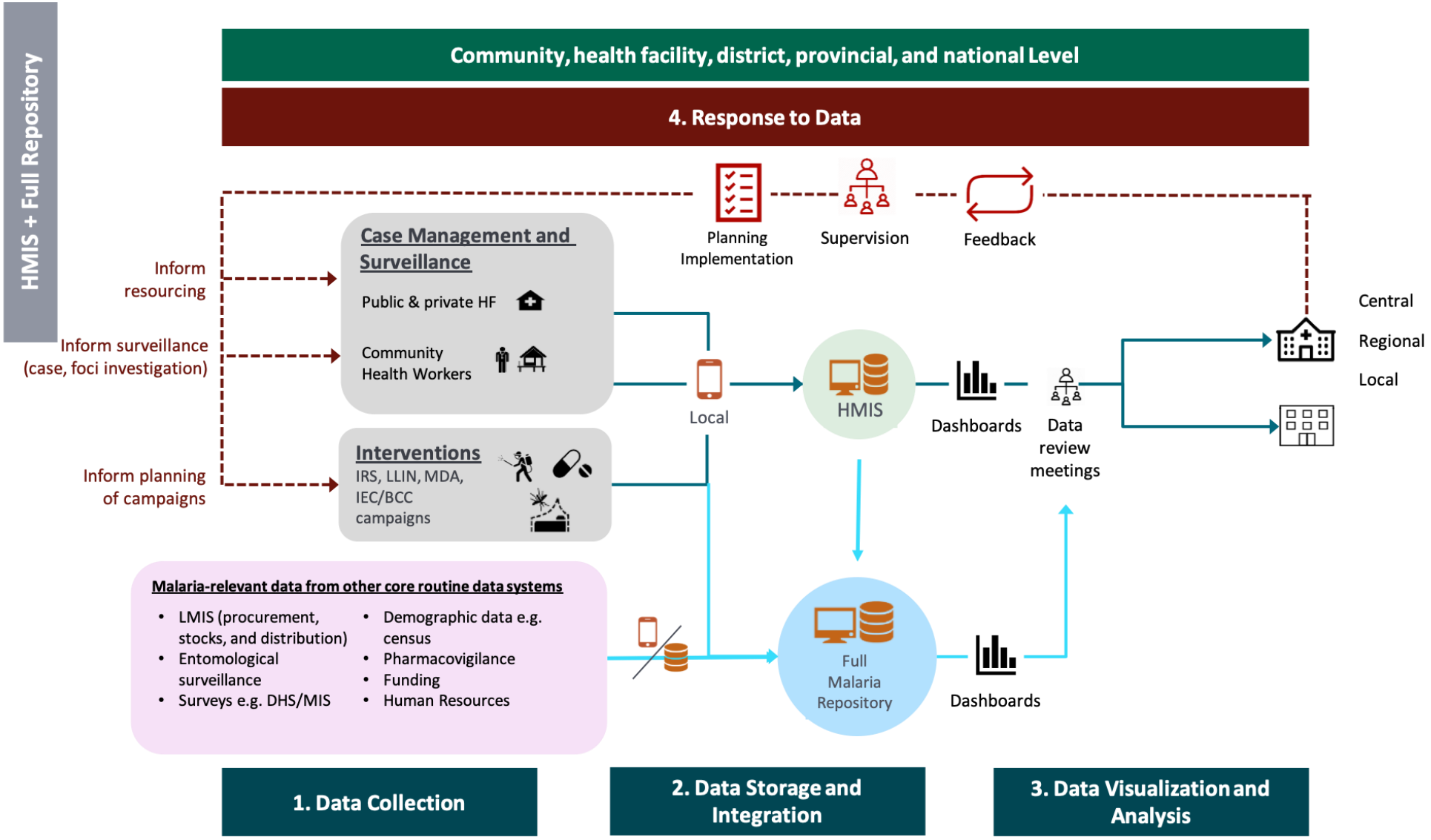
World Health Organization

Agenda

1. To discuss gaps in surveillance that can be addressed by digital tools
2. To provide an overview of the piloted digital tools for malaria elimination
3. To present select M&E results from four country pilots
4. To summarize learnings for sustainability
5. Next steps

Gaps in surveillance to be addressed by digital tools

Ideal Surveillance System



Why digital tools for surveillance?

- A landscape assessment of surveillance systems conducted in 16 countries from 2015-16 found that: most health information systems for surveillance had several shortcomings and provided inadequate support for malaria elimination.

- No single information system could facilitate the data collection and analysis of case investigations, focus investigations, response interventions, and support task management. Gaps existed in:
  - Data analytics and visualization, particularly on dashboards and geospatial visualization
  - integrating and linking different types of malaria data
- Mobile surveillance tools
  - did not correspond to the operational workflows of malaria health workers and health facilities,
  - were not built appropriately for low infrastructure settings,
  - and were difficult to configure and customize to different countries

Enhancement and development of existing and new digital solutions

to address these gaps in information systems and mobile tools

Digital Solutions for Malaria Elimination

Global **Malaria** Programme

World Health Organization

Suite of digital solutions to support malaria elimination

The digital solutions for malaria elimination (DSME) project was initiated to develop effective digital tools in malaria endemic countries for comprehensive and sustainable malaria surveillance systems to make complete, timely, and accurate data reporting easier and to improve decision-making processes.

Objective: Strengthen and roll out integrated surveillance information systems with upgraded core DHIS2 functionality and effective mobile tool applications (app) in a sustainable policy and tech environment across malaria elimination geographies

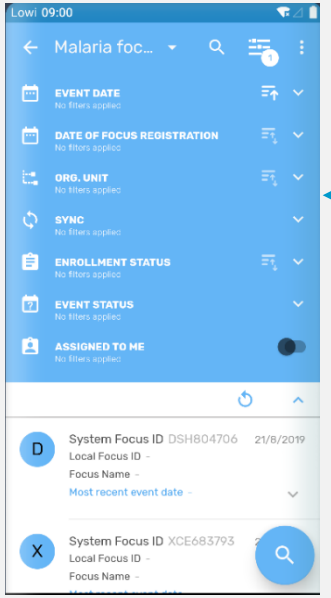
Tool Outputs:

Case Notification and Investigation mobile app	• Mobile app built on DHIS2 Android Capture App to support field-based workers in case notification and investigation
Focus investigation and response mobile apps	• Mobile app built on DHIS2 Android Capture App to support focus investigation data collection • Mobile app built on OpenSRP to support field-based focus investigation and response activities
Response interventions mobile app	• Mobile app built on OpenSRP to support IRS spray operators in operationalizing campaigns
DHIS2 web malaria module	• DHIS2 malaria module with standard malaria terminology • Enhancements to DHIS2 web including complex relationships between malaria concepts and improved analytics and map functionality

The suite of digital tools can be used together or independently based on the country digital ecosystem and operational readiness

Case Notification and Case Investigation

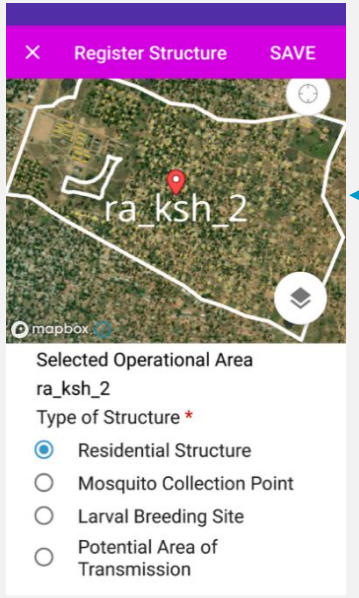
dhis2



Focus Investigation and Response

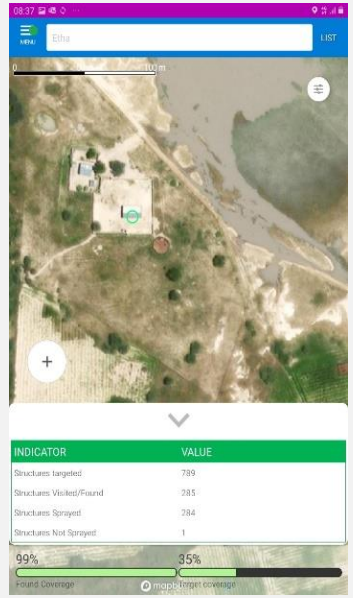
dhis2

OPENSRP



Response Interventions

OPENSRP



Integration layer

Malaria Information System

dhis2

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Legend: ⟷ Integration

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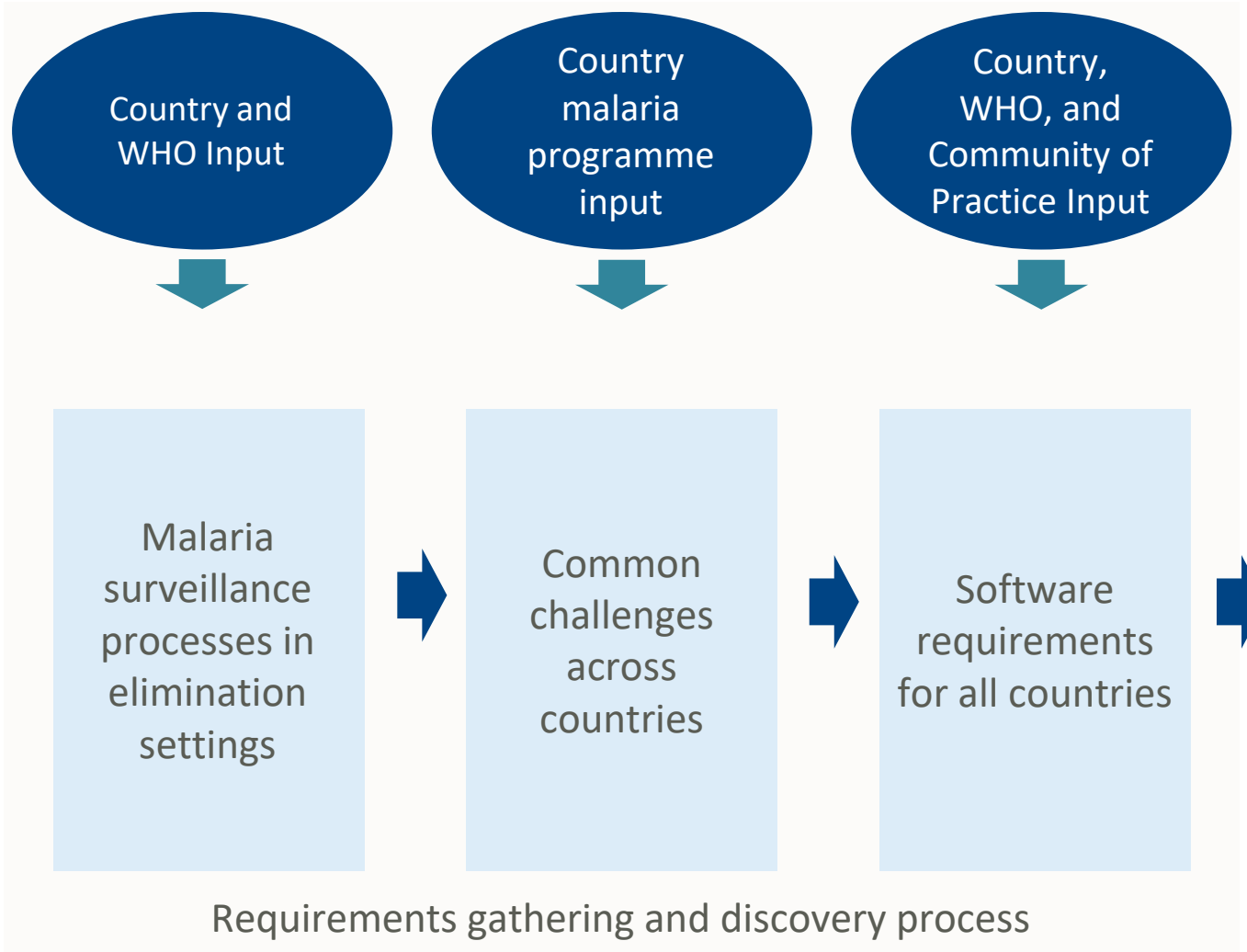
Tools were built to satisfy requirements gathered from WHO, subject matter experts, country programs, implementers

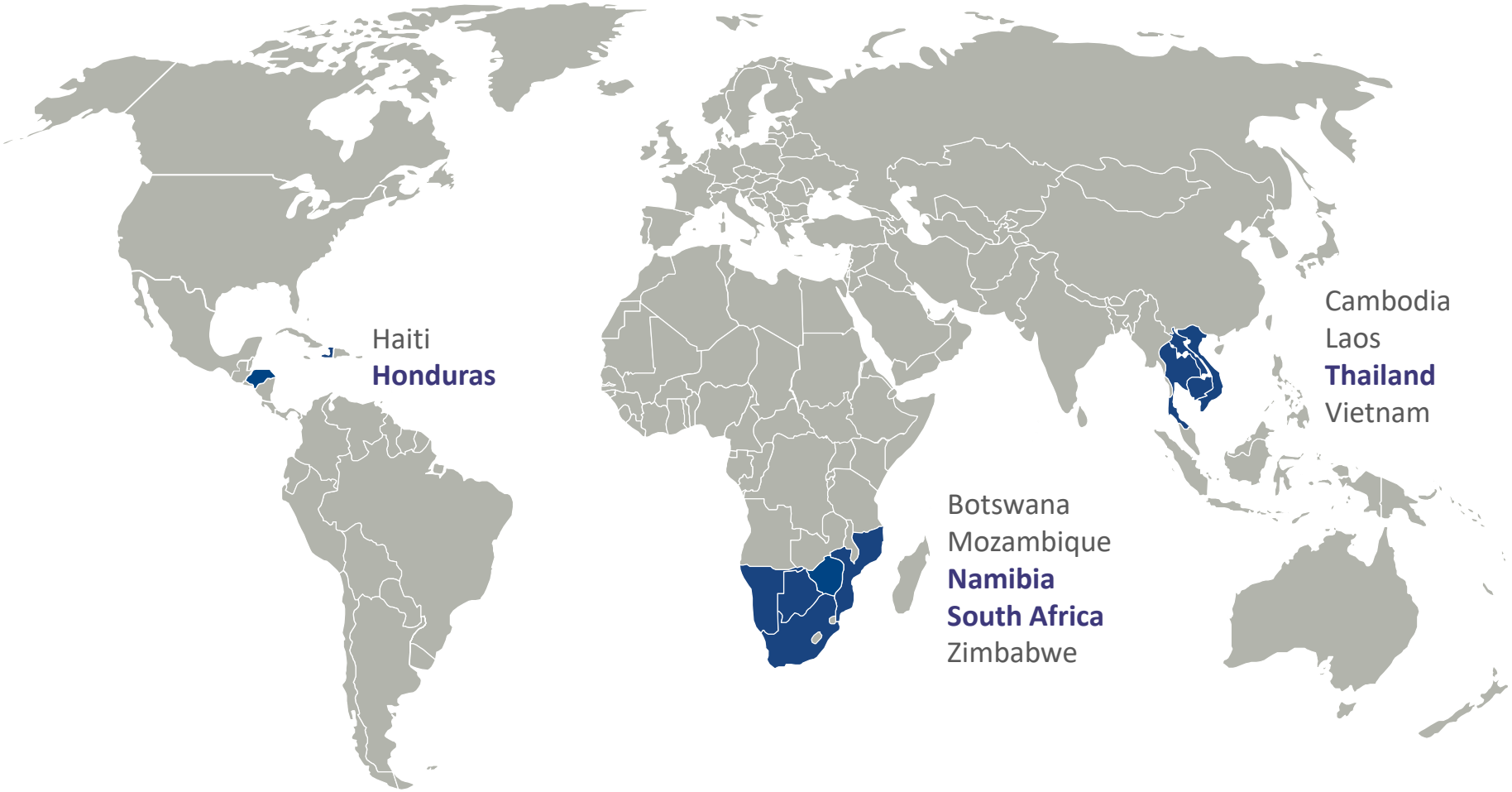


Common challenges found across countries included:

- Usability gaps
- Data inaccuracy
- Limited data use
- Data integration gaps
- Infrastructure gaps
- Notification delays
- Maintenance challenges

Pilot approach and M&E framework

11 countries were explored for piloting in 2018-2019



Countries were identified across regions based on interest from malaria programs, long term in-country presence by core partners, and existing adoption of surveillance processes and use of digital solutions

Four countries had the interest, capacity, and operational readiness to pilot and conduct M&E in 2018-2019.

- **Honduras:** case notification and investigation application
- **Namibia:** Response interventions application
- **South Africa**: DHIS2 web upgrade
- **Thailand:** Focus investigation and response application

Mozambique, Zimbabwe, and Laos introduced DHIS2 web upgrades for their MIS but did not conduct extensive M&E.

Zimbabwe, Laos, and Haiti plan to introduce new tools in 2021.

Indicators on performance, usage, data quality and system outputs were monitored to assess use and impact of introducing digital solutions

Pilot Overview

Country	South Africa	Honduras	Thailand	Namibia
Tool Assessed	Malaria Information System (MIS)	Case Notification and Investigation Application	Focus Investigation and Response Application	Response Interventions Application
Platform	DHIS2 Web	DHIS2 Android Capture	OpenSRP	OpenSRP
Baseline Data Source	Microsoft Access	Paper Data & Country MIS	Country MIS	Baseline IRS Application
Baseline Date	Q1 2018	Q2 2019	Q4 2018	Q4 2018
Midline / Endline Data Source	System Database, Key Informant Interviews	System Database Key Informant Interviews	System Database Key Informant Interviews	System Database Key Informant Interviews
Midline Date	Q1 2020	Q1 2020	Q1 2020	Q4 2019
Endline Date	Q1 2021	Q4 2020	Q1 2021	Q4 2020
End User Profile	30 Users; Info Officers, Data Capturers	60+ Users; VCTs, Data Entry, Epidemiologists, Microbiologists	30 Users; Field Investigators, Health Workers	30 Users; Field Supervisors, Spray Team Leaders
Provinces	Limpopo, Mpumalanga, KwaZulu-Natal	Gracias a Dios, Colon, Yoro, El Paraiso, Isla de la Bahia	Trat, Tak, Ubon Ratchathani	Oshana

Pilot Results: Select Indicators

INDICATORS	South Africa Malaria Information System (MIS)	Honduras Case Notification and Investigation Application	Thailand Focus Investigation and Response Application	Namibia Response Interventions Application
User Engagement	▲ 80% users: app easy to use ○ 67 usability score*	▲ 87% users: app easy to use ▲ 84% users found app helpful for daily work ○ 66 usability score*	▲ 83% users: app easy to use ▲ 71% users: app helpful towards daily work	▲ 86% users: app easy to use ▲ 75 usability score*
Data Quality and Reporting	▲ 109% increase in forms with complete fields	▼ 83% increase in reporting time lag for case notification ▼ 40% increase in reporting time lag for case investigation	▲ 91% decrease in reporting time lag for focus investigation	▲ 138% increase in data completeness ○ 0.04% decrease in reporting lag for IRS
Programmatic Impact	▲ 124% increase in malaria cases notified within 24h of diagnosis ▲ 40% increase in cases investigated within 72h notification	▼ 50% decrease in cases notified within 24h of diagnosis ○ 3% increase in cases investigated within 72h of diagnosis ○ 8% increase in case investigation rate ○ 9% increase in case classification rate	▲ Reactive response rate consistently above 80% since introduction of tool + desk review process ▲ Data now able to be used to monitor coverage of high risk populations (e.g. forest goers)	○ 2% decrease in IRS spray coverage ▲ Spray operators noted positive gains in using the app for planning daily schedule, navigating structures, and tracking coverage in real time
Data Use	▲ Positive perception of use of data for follow up with subnational teams from NMCPs	▲ Users found data helpful in identifying outbreaks and mobilizing resources	▲ Users found access to data useful to monitor intervention coverage and user activity	▲ Users found access to data much faster than baseline ("within minutes" compared to up to 3 days)

Global Malaria Programm

▲ Improvement observed ○ Minimal change observed ▼ Decline observed

*usability score calculated through the System Usability Scale: an industry standard survey to measure usability of a digital tool. A score of 67 is considered average.

World Health Organization

Takeaways

- **User engagement:** All tools were found to be easy to use and helpful towards daily work. Some tools had an average usability score, suggesting room for improvements.

- **Data quality and Reporting:** Some pilots saw significant increases in data completeness and decreases in reporting time lag with deployment of digital tools. However, areas that had very limited connectivity showed increases in reporting time lag.

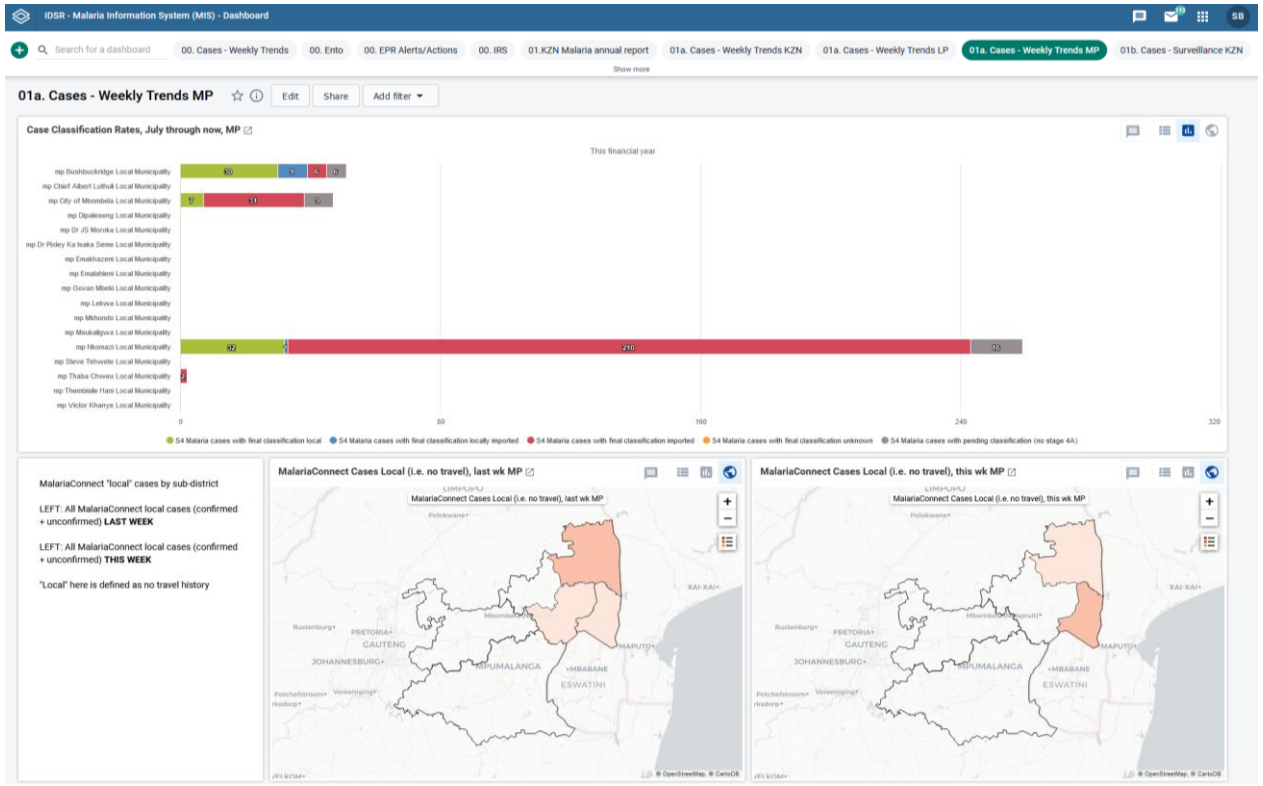
- **Programmatic Impact:** Some pilots saw improvements in malaria surveillance protocol adherence and the ability to use tools for granular tracking after rolling out digital tools. Some pilots did not see large improvements, which may also be linked to operational constraints.

- **Data Use:** All pilot users reported positive use of data outputs and timeliness of access compared to baseline.

Pilot results

Malaria Information System: South Africa

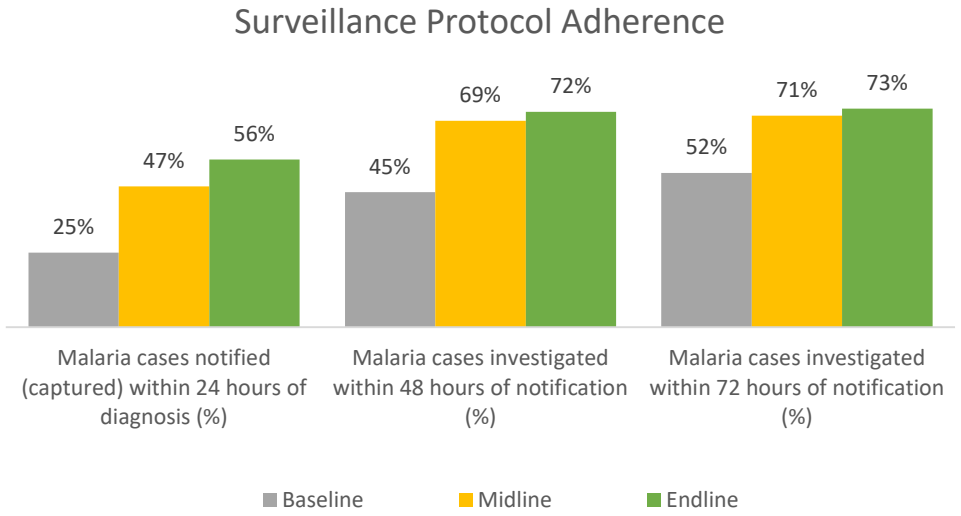
Until 2018, the NMCP in South Africa used a combination of Microsoft Access, Microsoft Excel, and MalariaConnect (SMS-based system) to capture malaria data, with different forms being used for different provinces. Case data was often completed on paper using non-standardized forms and then entered into provincial databases.

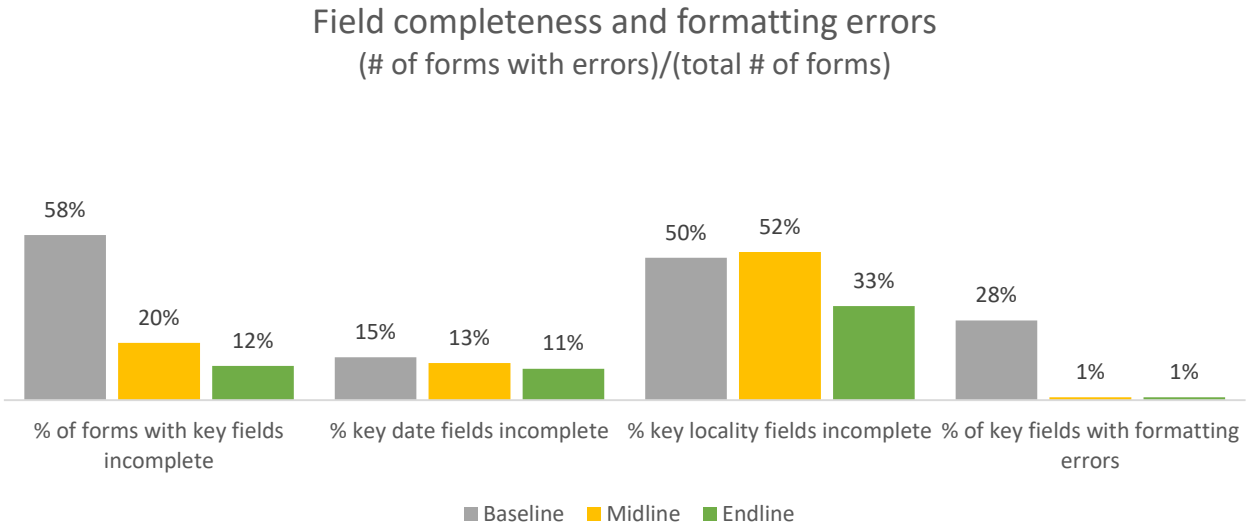


In 2018-2019, the NMCP transitioned to a DHIS2-based malaria information system that is used across provinces.

The MIS includes modules in case surveillance, indoor residual spraying, entomology and focus investigation with integrated dashboards.

Malaria Information System: Select M&E Results





- Surveillance protocol adherence increased steadily between baseline and endline. This may also be attributable to increased trainings and supervision.
- Data completeness improved as measured by field completeness across multiple field types.
- Routine data review meetings were introduced in 2020, which also led to increased use of data and dashboards at a decentralized level.

Time period for M&E: Baseline (Sample of cases 2015-2017), Midline (April 2019-March 2020), Endline (April 2020-January 2021)

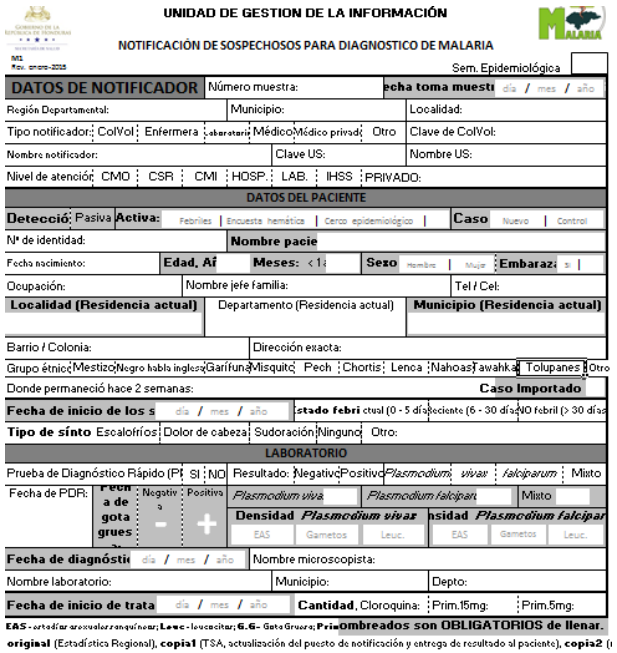
Malaria Information System: Sustainability

Category	Strengths	Areas for Improvement
Institutionalization	Use of MIS embedded and consistent across users at provincial and district levels. Guidelines are being updated to include the MIS.	Support uptake and use of MIS by central-level managers.
Technical capacity	Responsive messaging group in place to troubleshoot issues from provincial information officers	Develop a plan for maintenance as part of the wider HMIS
Financial planning	Existing Service Level Agreements for maintenance support with external developers exist for broader HMIS	Ensure MIS is included in broader technical tool maintenance and support
Training	Quarterly reviews between central-level NMCP, Environmental Health Practitioners, and Information Officers on MIS	Run periodic refresher trainings for central-level managers on use of dashboards
System integration	All malaria program data now integrated in the MIS	Remove duplicate case notification systems at health facility level and integrate the MIS with the wider HMIS

Case Notification and Investigation app: Honduras

Prior to 2019 surveillance challenges included:

- Limited case-based data
- High discordance of data across admin units
- Information officers only at regional level
- Low capacity to modify information system



UNIDAD DE GESTION DE LA INFORMACIÓN

NOTIFICACIÓN DE SOSPECHOSOS PARA DIAGNOSTICO DE MALARIA

Sem. Epidemiológica

DATOS DE NOTIFICADOR | Número muestra: | Fecha toma muestra: día / mes / año

Región Departamental: | Municipio: | Localidad:

Tipo notificador: ColVol | Enfermera | Laboratorio | Médico | Médico privado | Otro | Clave de ColVol:

Nombre notificador: | Clave US: | Nombre US:

Nivel de atención: CMO | CSR | CMI | HOSP. | LAB. | IHSS | PRIVADO:

DATOS DEL PACIENTE

Detección: Pasiva | Activa: Febriles | Encuesta hemática | Cerco epidemiológico | Caso: Nuevo | Control

Nº de identidad: | Nombre paciente

Fecha nacimiento: | Edad, Años | Meses: <1 | Sexo: Hombre | Mujer | Embarazada: si

Ocupación: | Nombre jefe familia: | Tel / Cel:

Localidad (Residencia actual) | Departamento (Residencia actual) | Municipio (Residencia actual)

Barrio / Colonia: | Dirección exacta:

Grupo étnico: Mestizo | Negro habla inglés | Garífuna | Misquito | Pech | Chortis | Lenca | Nahoas | Tawahka | Tolupanes | Otro

Donde permaneció hace 2 semanas: | Caso Importado

Fecha de inicio de los síntomas: día / mes / año | Estado febril actual (0 - 5 días) | reciente (6 - 30 días) | NO febril (> 30 días)

Tipo de síntomas: Escalofríos | Dolor de cabeza | Sudoración | Ninguno | Otro:

LABORATORIO

Prueba de Diagnóstico Rápido (PDR): SI | NO | Resultado: Negativo | Positivo | *Plasmodium vivax* | *falciparum* | Mixto

Fecha de PDR: | Fecha de gota gruesa | Negativo - | Positivo + | *Plasmodium vivax* | *Plasmodium falciparum* | Mixto

Densidad *Plasmodium vivax* | Densidad *Plasmodium falciparum*

EAS | Gametos | Leuc. | EAS | Gametos | Leuc.

Fecha de diagnóstico: día / mes / año | Nombre microscopista:

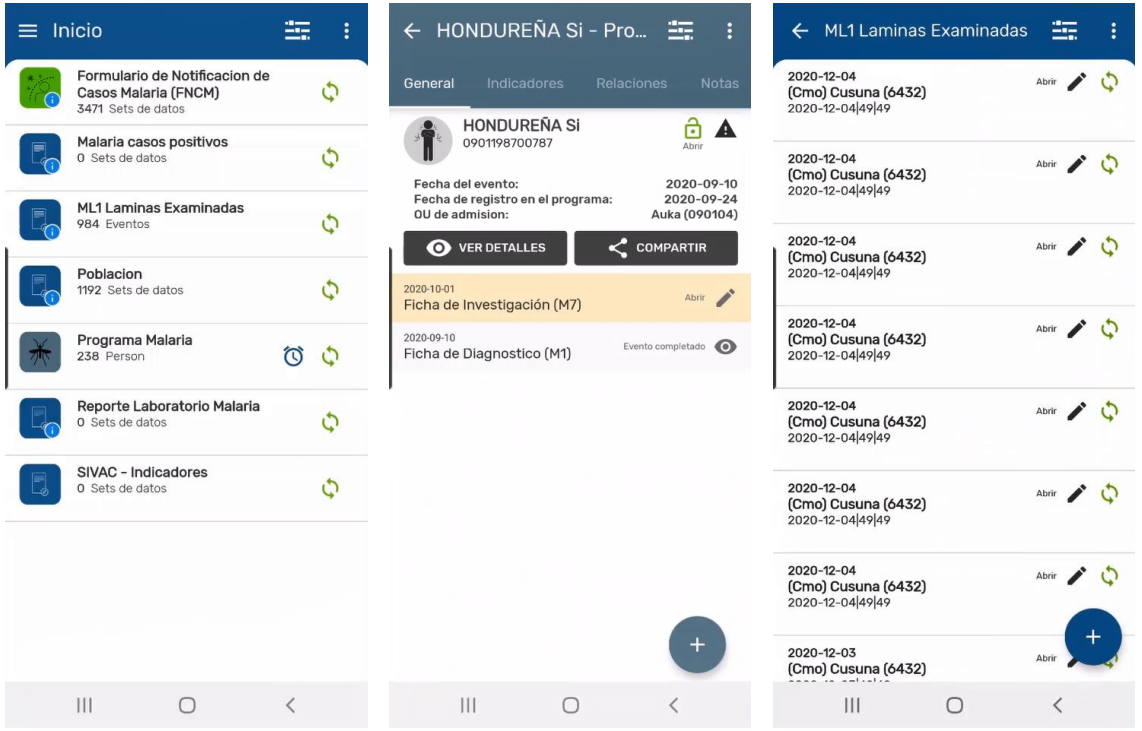
Nombre laboratorio: | Municipio: | Depto:

Fecha de inicio de tratamiento: día / mes / año | Cantidad, Cloroquina: | Prim.15mg: | Prim.5mg:

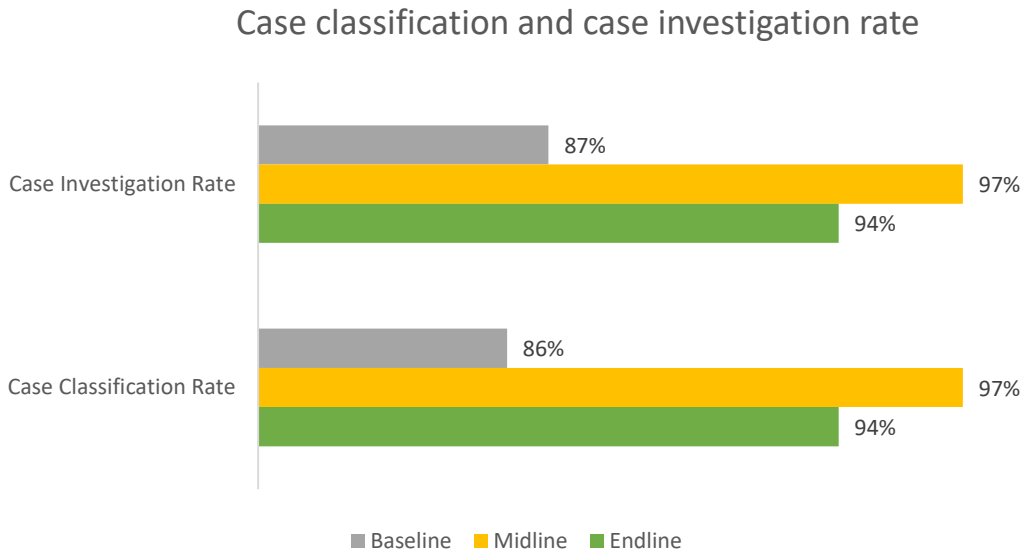
EAS - estadíos asexuales sanguíneos; Leuc - leucocitos; G.G - Gota Gruesa; Primombreados son OBLIGATORIOS de llenar.

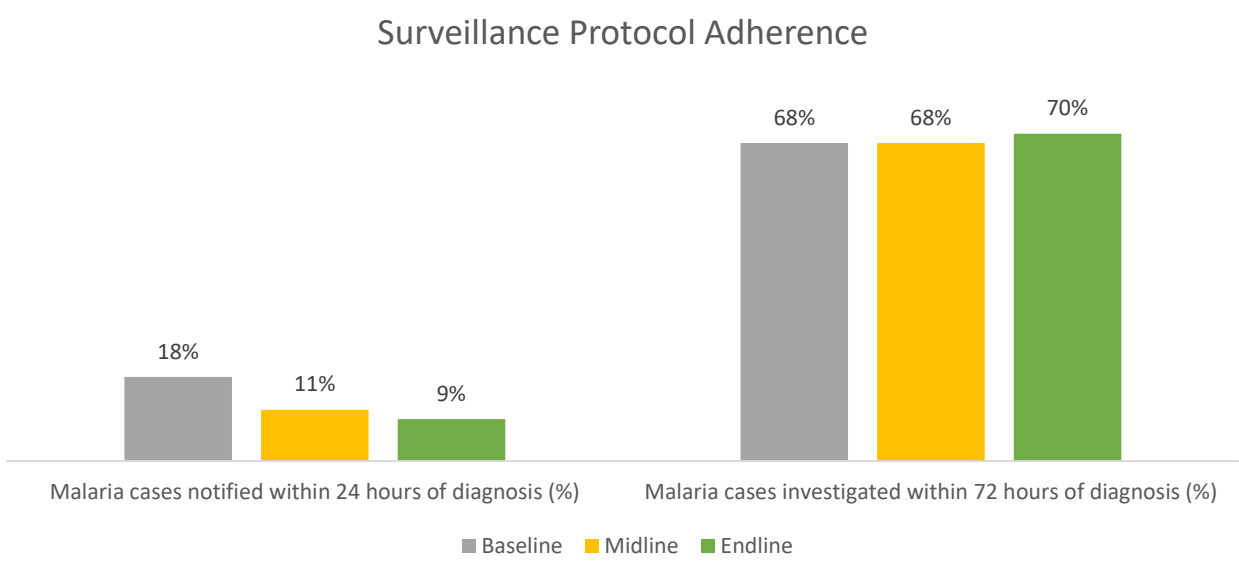
original (Estadística Regional), **copia1** (TSA, actualización del puesto de notificación y entrega de resultado al paciente), **copia2**

In late 2019, Case notification and investigation app deployed to 5 high-risk regions



Case Notification and Investigation app: Select M&E Results





- A greater percentage of cases were investigated and classified at midline and endline compared to baseline.
- The increase may be attributable to combined effect of new tools, in-field trainings, supervision visits, better investigations, and validation rules.

- Surveillance protocol adherence for case notification reduced and for case investigation slightly increased.
- Challenges were found in the areas of highest case burden, where there was very limited internet connectivity and thus data syncing challenges.

Time period for M&E: Baseline (Oct 2018-Apr 2019), Midline (Oct 2019 – Apr 2020), Endline (Oct-Dec 2020)

Case Notification and Investigation app: Sustainability

Category	Strengths	Areas for Improvement
Institutionalization	All users found the app to be an improvement from the previous system	Implement a digital health policy and SOPs for use of digital tools for surveillance activities.
Technical capacity	Strong central level technical support, with responsive messaging group to troubleshoot and resolve issues	Train regional offices to manage technical problems and define process for ongoing maintenance
Financial planning	Central level budget to support trainings for central level users	Assess and define budget for maintenance, training, and hardware costs
Training	Successful deployment of e-training during COVID-19 pandemic	Define training frequency and training plan, and track individual training status and needs
System integration	App is integrated with MIS	Integrate other data into MIS (e.g. stock data, paper-based data in some areas)

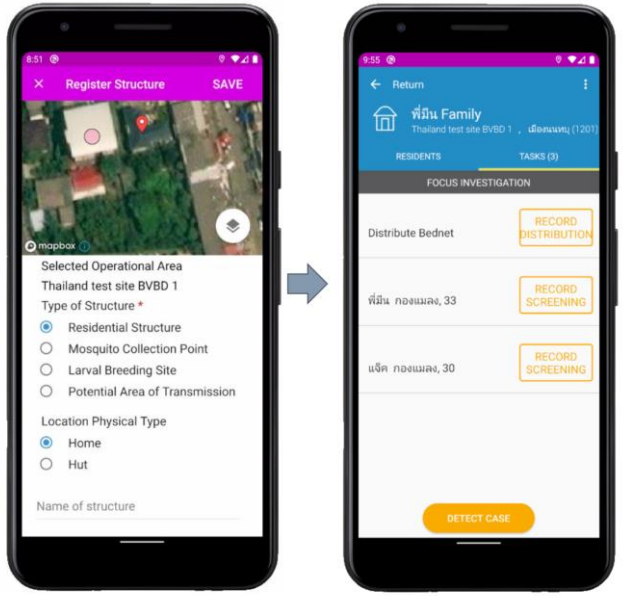
Focus investigation and response app: Thailand

Until 2019, Thailand conducted focus investigations and response (reactive case detection, net distribution, and entomological studies) on paper

- Adherence to focus investigation response protocol was >80% but unknown if interventions were targeting the right people
- Large amounts of data collected but not used to inform elimination strategy

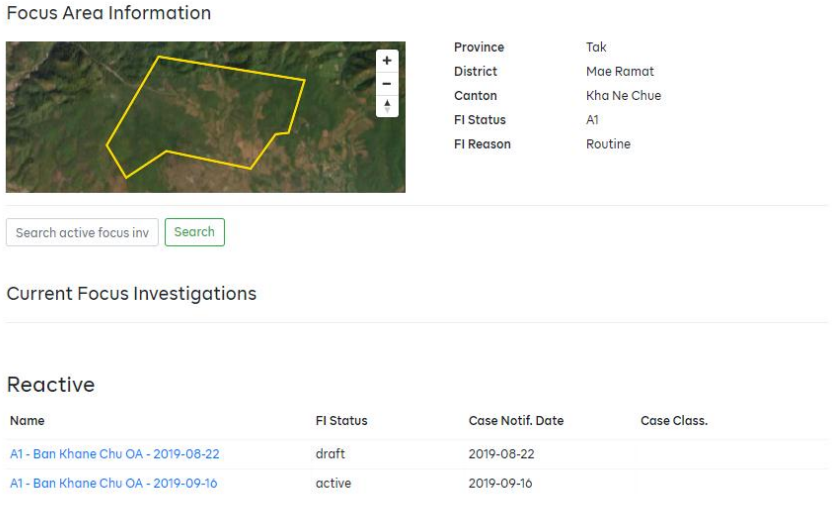
Focus investigation and response mobile app

- Collect data for the focus investigation and interventions at household- and individual-level



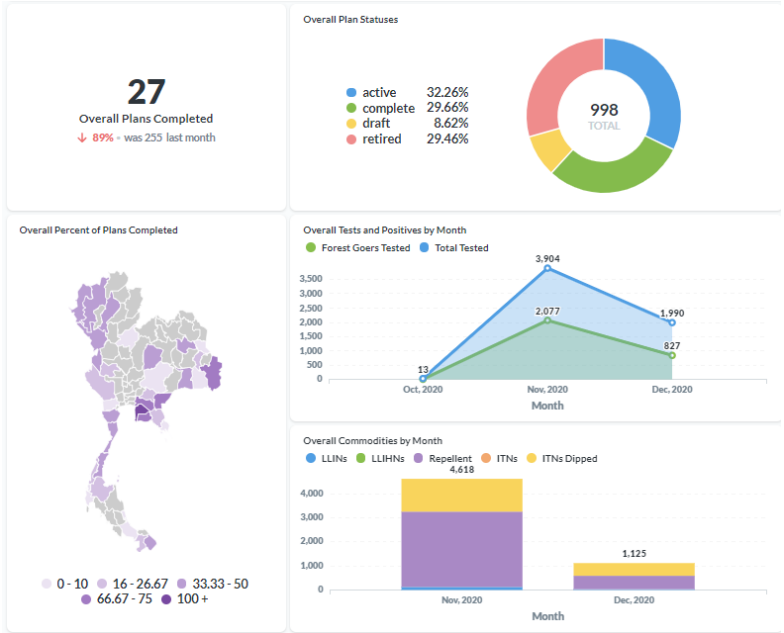
Focus investigation and response web platform

- Review historical focus data
- Plan routine and reactive focus investigation



Focus investigation and response dashboards

- Review data and adjust activities



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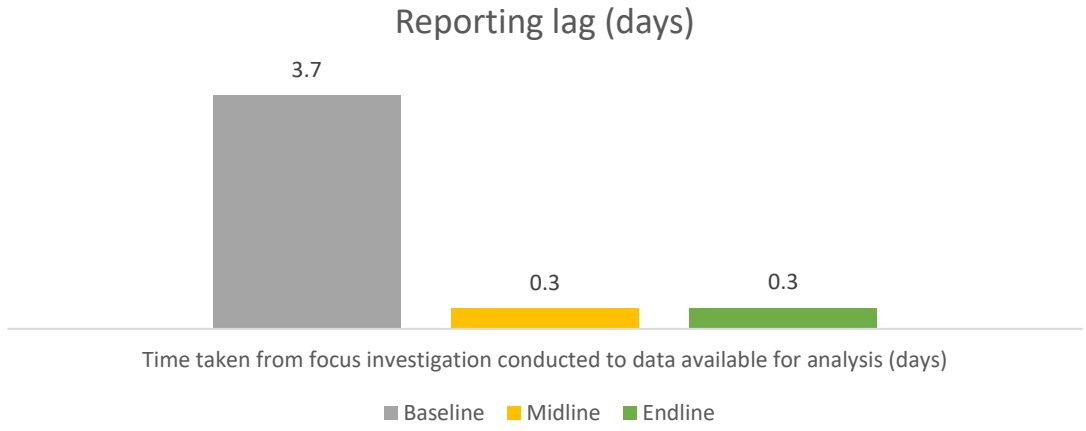
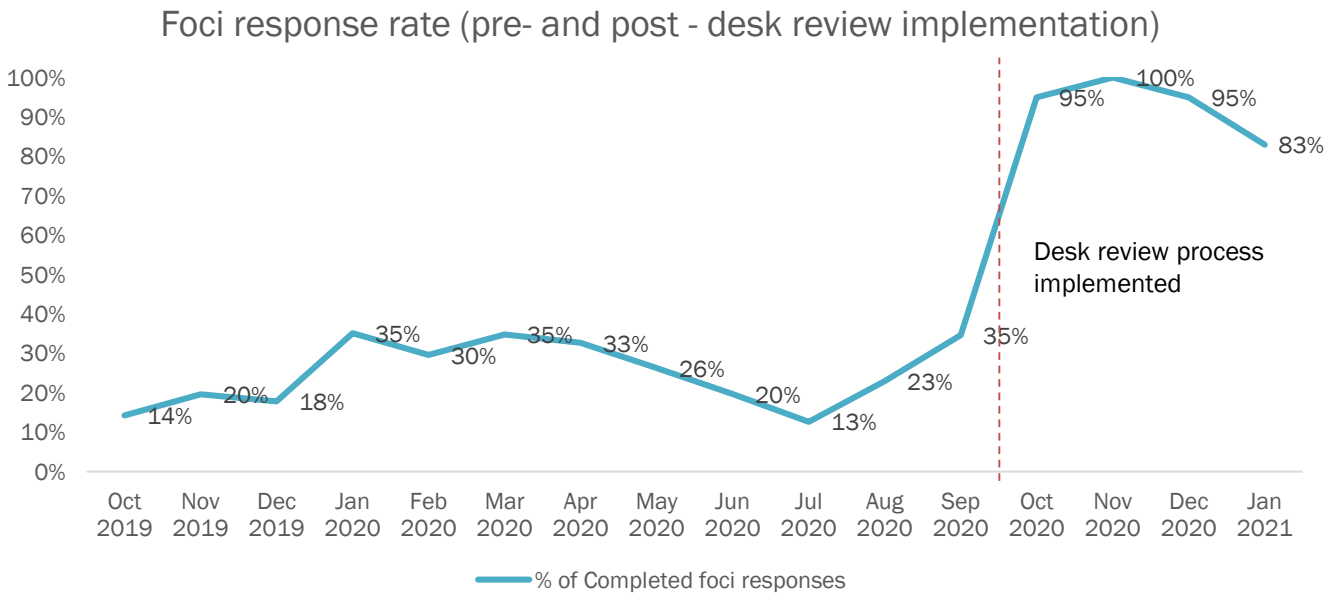
Focus investigation and response app: Select M&E Results





- Lag time between reporting date and date of entry/syncing to the malaria information system decreased from baseline to endline, enabling rapid review of data.
- Focus response rates were low at the outset due to technical challenges and operational limitations in high burden areas (limited # of focus investigations could be performed per month).
- Focus response rates increased over time with the introduction of the desk review process to the application which prioritizes areas to conduct investigations.

Time period for M&E: Baseline (2018), Midline (Oct 2019 – Mar 2020), Endline (Oct 2020 – Jan 2021)

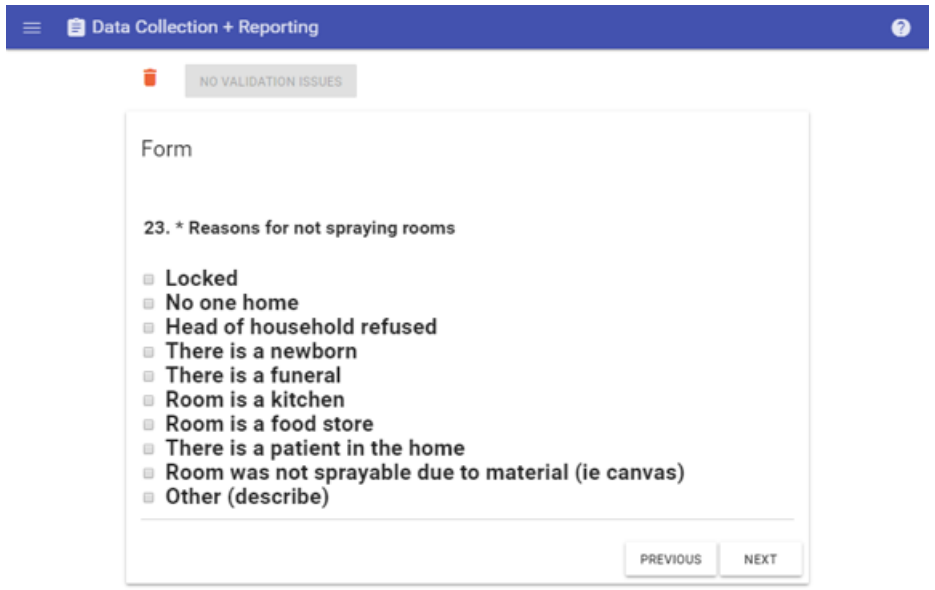
Focus Investigation and Response app: Sustainability

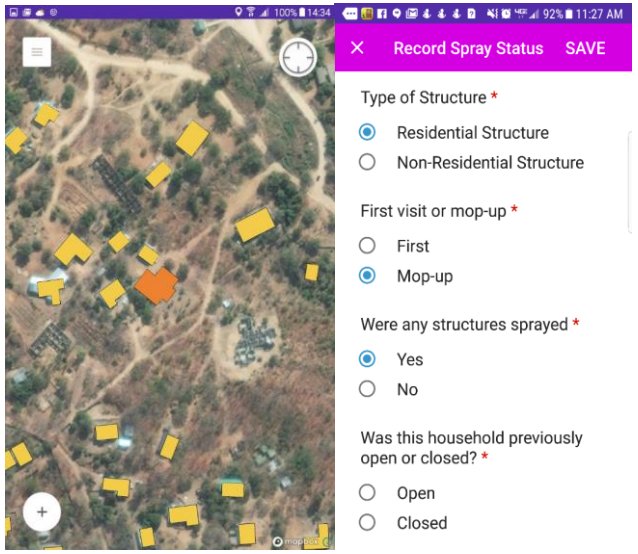
Category	Strengths	Areas for Improvement
Institutionalization	Users across all levels noted the tool has helped with focus investigations	Include the app in the national digital health policy
Technical capacity	Strong technical team that has taken ownership of training, troubleshooting, enumeration, M&E	Improve ability for program teams to configure the system without external technical developers
Financial planning	Hosting and maintenance costs have been included in the national health budget annually up to 2024	Secure financing for tool hosting and maintenance costs for post 2024
Training	Annual training on the app for supervisors and users have been planned, and qualified master trainers and users can independently lead trainings	N/A
System integration	App is integrated with the wider MIS and FI plans can be triggered in the app when a case appears in the MIS	Integrate different dashboards

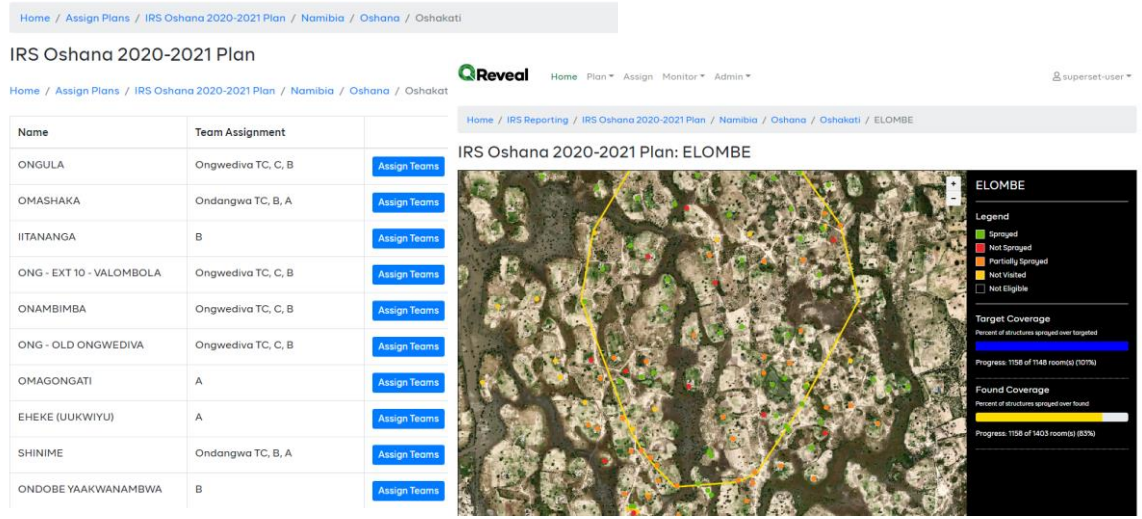
Response Interventions app: Namibia

In 2017 and 2018, Namibia piloted an IRS application to monitor IRS campaigns across all endemic regions and found:

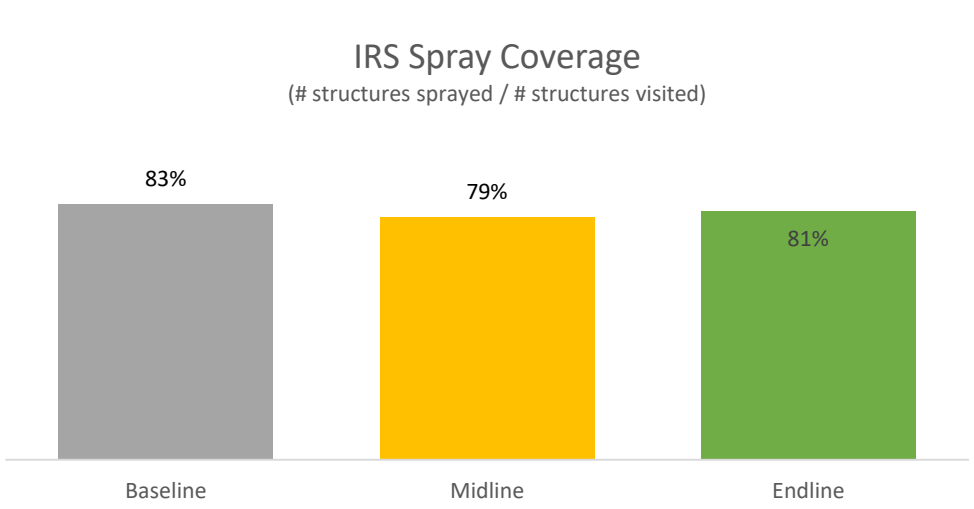
- Technical challenges with the IRS application where the app crashes or data sync difficulties
- Data inconsistencies between the IRS application and the paper-based system

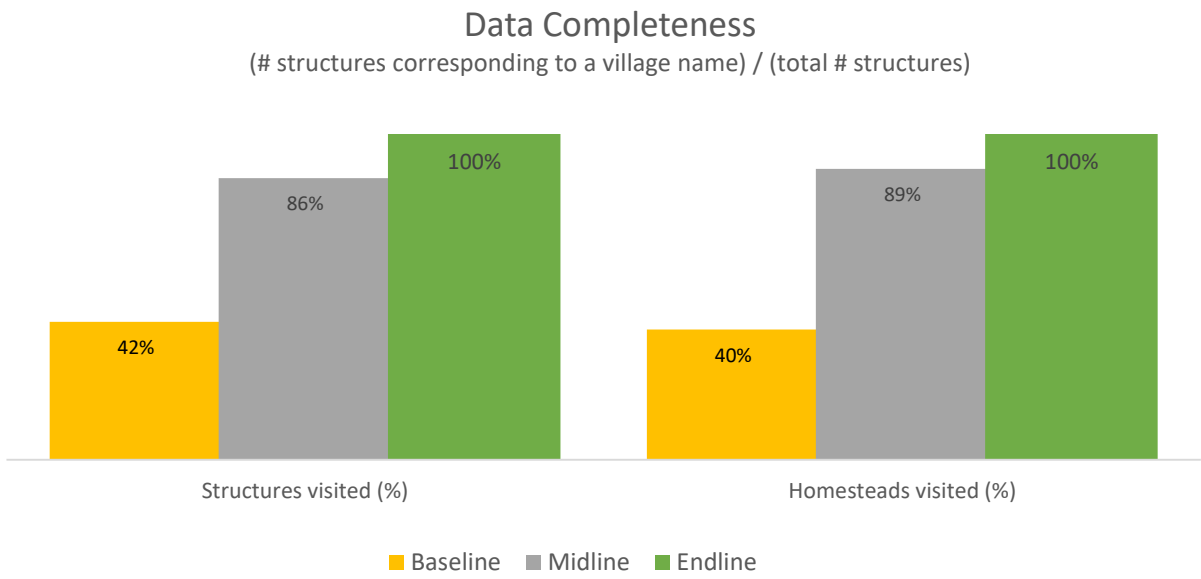






Response Interventions app: M&E Results





- Spray coverage remained approximately the same from baseline to endline.
- Data completeness increased from 40% to 100% from baseline to endline, as measured by # of structures that have a corresponding village attached.
- System Usability Survey score increased from 51.3 for the baseline application to 75 for the new response interventions application (by technology industry standards, considered a good acceptability score among users)

Time period for M&E: Baseline (2018), Midline (Sep – Nov 2019), Endline (Oct-Dec 2020)

Response Interventions app: Sustainability

Category	Strengths	Areas for Improvement
Institutionalization	All level of users have desired to continue the use of the app and expand to other regions. Regional SOPs for use of the tool have been developed and implemented.	Include use of digital tools in national surveillance guidelines.
Technical capacity	Messaging group currently in place for spray teams to raise issues	Engage MOH IT team to benefit from in country technical support
Financial planning	Program budget planning process includes digital tools	Specify response intervention app to be included in the budget planning process (as allocation to specific apps remains a challenge)
Training	Annual IRS trainings at the start of each spray campaign, and quarterly subnational meetings can be used for refresher trainings	Train central level users on how to update and maintain the app
System integration	Proof of concept demonstrates app can be integrated with the MIS	Integrate the response intervention app with the MIS, which will require engagement with the MOH IT team

Summary and Next steps

Summary Learnings for Long-term Sustainability

Strengths

1. INSTITUTIONALIZATION
   - Tools viewed as an improvement from baseline for usability, data quality, and surveillance activities
   - Positive feedback on usability and value of tools

2. TECHNICAL CAPACITY
   - Strong communication with end users to support troubleshooting
   - Some countries with strong in country technical capacity
   - Community-supported open-source software can increase capacity for general tool support

3. FINANCIAL PLANNING
   - Some countries have built digital tool support into annual budgets

4. TRAININGS
   - Effective user testing and feedback iterations in most settings

5. SYSTEM INTEGRATIONS
   - Integrations with MIS (whether DHIS2-based or custom) can improve governance and data uptake

Areas of improvement

1. INSTITUTIONALIZATION
   - Implement a digital health policy that includes specific tools
   - Continue to engage stakeholders at all levels on use of the tools

2. TECHNICAL CAPACITY
   - Routine maintenance plan needs to be developed
   - Continue strengthening in country technical capacity for troubleshooting (including at subnational level)

3. FINANCIAL PLANNING
   - Ensure financial support for technical support, training, supervision, platform maintenance, and routine hardware upgrades are in annual budgets

4. TRAININGS
   - Conduct periodic refresher trainings at central level on the tools
   - Train in country technical support teams on configuration and maintenance

5. SYSTEM INTEGRATIONS
   - Additional integrations can continue to strengthen access to malaria data

Building long term sustainability for digital tools

- **Strengthen technical capacity:** strong in country technical support with insights into user challenges can lead to rapid resolution of issues and improve user experience with tools over time. Some issues may not be resolved without external developer support from the DHIS2 or OpenSRP communities.

- **Budget for maintenance of tools in annual budgets:** programs should include maintenance costs for digital tools in annual budgets. These costs should cover (1) in country technical capacity, (2) service packages with developers to maintain the tool (e.g. upgrades to maintain compatibility with new operating systems, hardware, etc), (3) operational support (e.g. refresher trainings), (4) hardware upgrades as needed to ensure compatibility with tools, and (5) data bundles.

- **Institutionalize digital tools within health policies**: surveillance guidelines and standard operating procedures should be updated to include use of digital tools. Supporting roll out of dedicated digital health policies that may also lead to MOH-wide institutionalization and open opportunities for funding.

- **Strengthen in-country interdepartmental and partner collaboration**: all collaborating technical partners and internal MoH divisions involved in surveillance activities should form a core team when introducing new tools.

Next steps

- Make the DSME digital tools available to countries for adoption to augment surveillance processes in malaria elimination settings.
- Disseminate these tools through clear communication across stakeholders.
- Work with partners and donors to help countries in adopting, using and maintaining these tools.
- Continuously monitor uptake of tools and implement any necessary improvements .

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