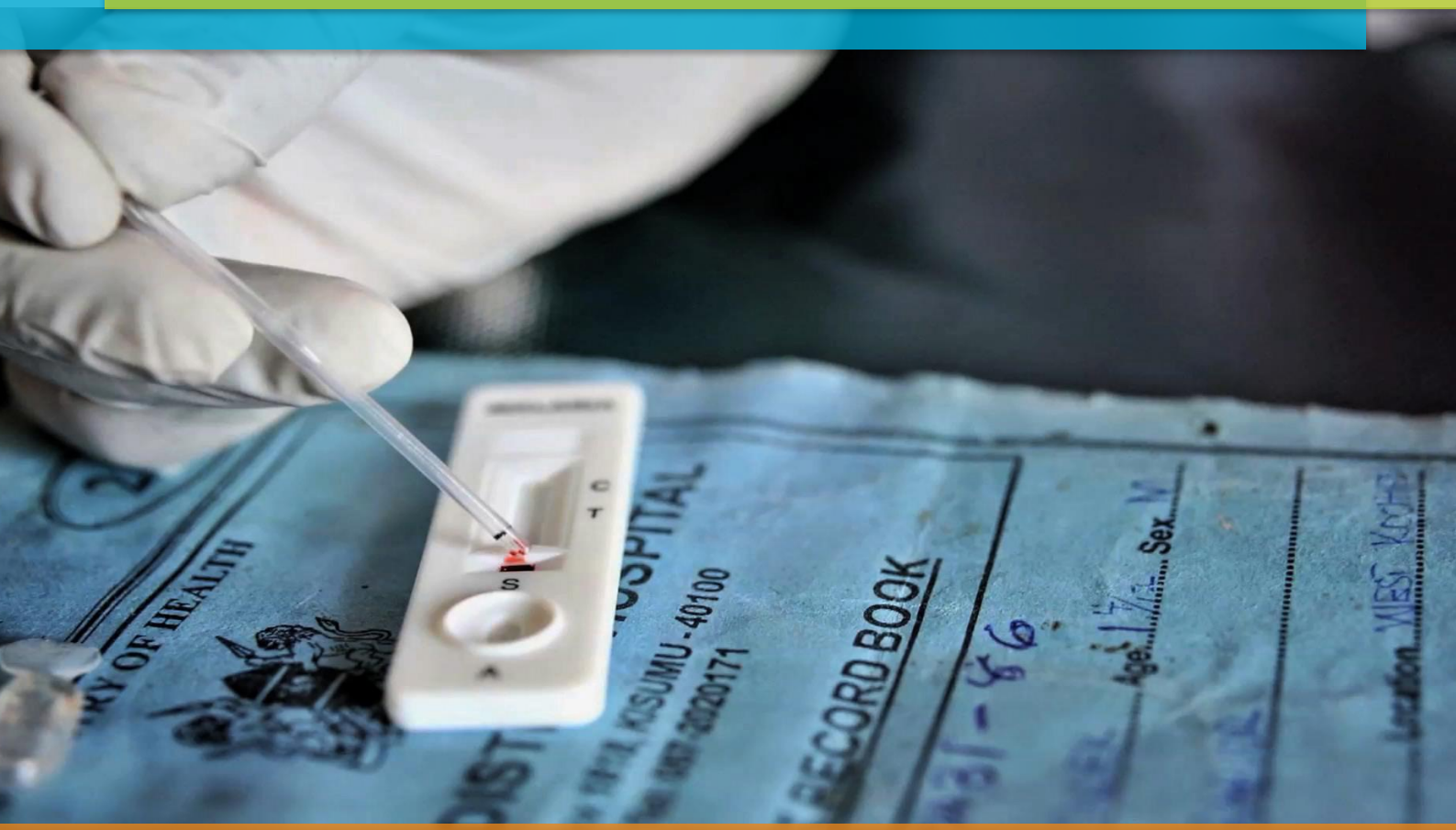


Quality Assurance for Fever Case Management in the Private Sector

A Manual for Practitioners

UNITAID

psi

This manual was produced by Population Services International (PSI) as part of the UNITAID funded Private Sector RDT project. The project was led by PSI, together with collaborating implementers, Foundation for Innovative New Diagnostics (FIND), Malaria Consortium (MC), Johns Hopkins School of Public Health (JHSPH) and the World Health Organization (WHO) and implemented in five countries. This manual and the tools included were originally designed for the three countries in which PSI was the implementer, Kenya, Madagascar, and Tanzania, yet were developed to be repurposed for other country contexts.

For additional copies, please email acutherell@psi.org or download the Manual and all tools via the "Resources" section of the PSI website (http://www.psi.org/research/library/).

Cover Photo: Courtesy of Population Services Kenya (PSK)

Acronyms

BCC	Behavior Change Communication
DHIS2	District Health Information System 2
FCM	Fever Case Management
FIND	Foundation for Innovative New Diagnostics
ICM	Integrated Case Management
IEC	Information Education Communication
JHSPH	Johns Hopkins School of Public Health
MC	Malaria Consortium
M&E	Monitoring and Evaluation
mHealth	Mobile Health
MOH	Ministry of Health
NMCP	National Malaria Control Program
PBCC	Provider Behavior Change Communication
PSI	Population Services International
QA	Quality Assurance
QAACTs	Quality-Assured Artemisinin-Based Combination Therapies
QAO	Quality Assurance Officer
RDTs	Rapid Diagnostic Tests
SOPs	Standard Operational Procedures
WHO	World Health Organization

Contents

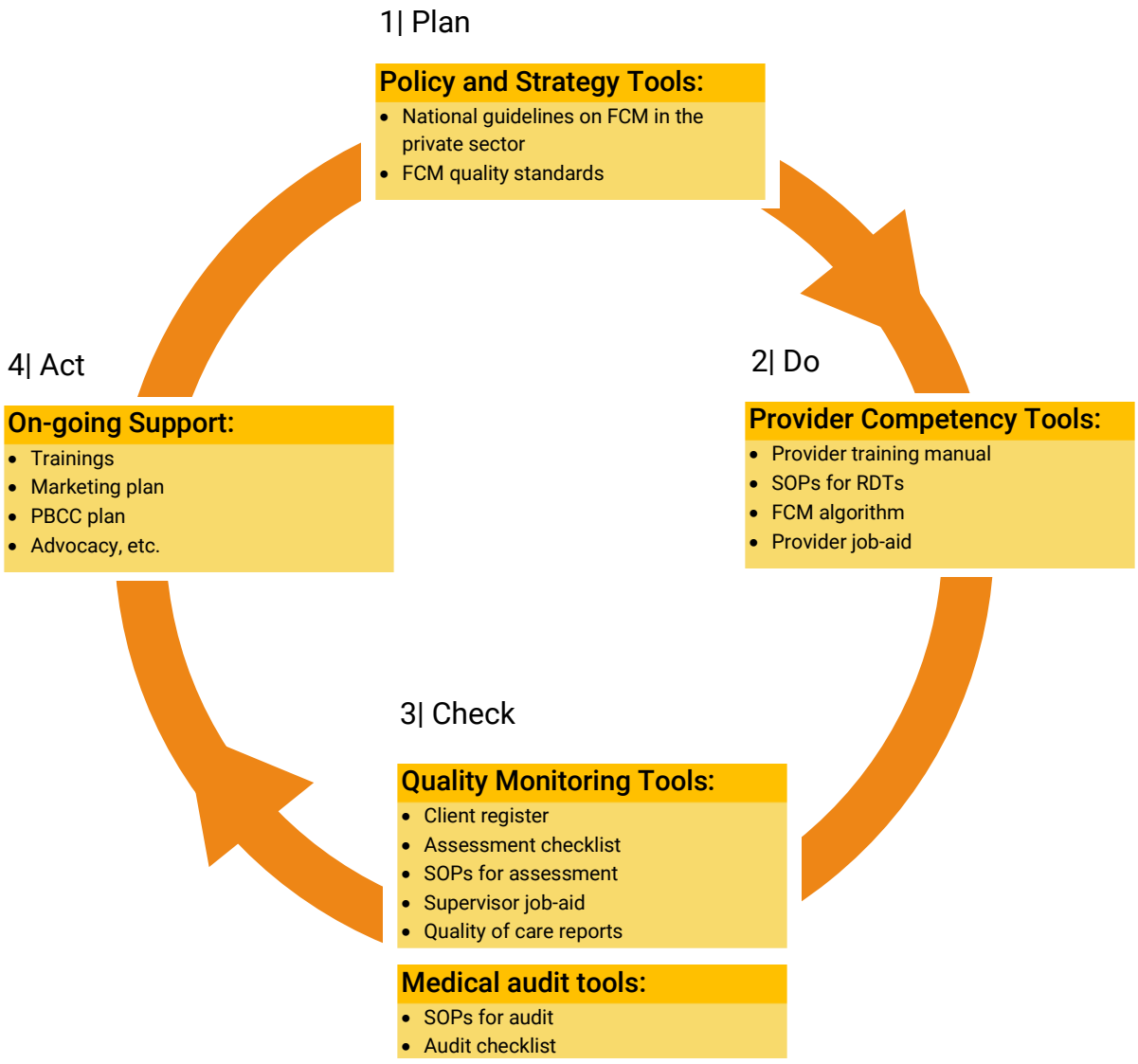
Acronyms 2
Contents 3
Summary 5
Background 6
Overview 7
Aim 7
Specific objectives 7
Structure 7
1| Plan 8
Policy and Strategy Tools 8
National Guidelines on FCM in the Private Sector 8
Fever Case Management Quality Standards 8
2| Do 10
Provider Competency Tools 10
Provider Training Manual 10
SOPs for RDTs 10
FCM Algorithm 11
Provider Job-aid 11
3| Check 12
Quality Monitoring Tools 12
Client Register 12
Assessment Checklist 12
SOPs for Assessment 13
Supervisor Job-aid 14
Quality of Care Reports 15
Medical Audit Tools 17
SOPs for Audit 17
4| Act 18
On-going support 18
Annexes 19
Annex 1: Fever Case Management Provider Training Manual (Kenya) 20
Annex 2: Standard Operating Procedures (SOPs) for RDTs 50
Annex 3: FCM Algorithm 53
Pharmacists and Drug Sellers (Madagascar) 53
Physicians (Madagascar) 54
Annex 4: Provider Job Aid 55
Kenya 55
Tanzania 56
Madagascar 57
Annex 5: Client Register 58
Annex 6: Assesment Checklist 60
Tanzania 60
Madagascar 62

Annex 7: HNQIS Overview 64
Annex 8: Supervisor Job-Aid 65
Annex 9: SOPs for Audit 70
Audit Scorecard 73

Summary

Quality Assurance (QA) best practices for Fever Case Management (FCM) fit into the plan-do-check-act cycle: the first three steps are constituted by groups of tools that offer a path to *plan*, *do* and *check* quality of FCM service provision. What is obtained throughout these three steps drive country teams through the *act* component of the cycle by tailoring the activities to undertake in order to best maintain/improve quality.

Quality Assurance best practices for Fever Case Management



Background

This manual was originally developed for the UNITAID funded Private Sector RDT project. The three year (April 2013 – April 2016) project worked to improve the appropriate management of fever with use of rapid diagnostic tests (RDTs) in the private sector across multiple countries, by

- ✓ increasing both access to and demand for affordable, quality assured RDTs,
- ✓ improving private providers' fever case management skills,
- ✓ developing and implementing a global roadmap for private sector engagement to guide policy and regulation.

This manual and the accompanying tools were developed as a part of the component focused on improving private providers' fever case management skills. While this manual and the tools included were originally focused on the three key countries where PSI was the implementer (Kenya, Madagascar, and Tanzania), they were developed to be repurposed for other country contexts.

UNITAID Private Sector RDT Project Goal, Purpose and Outputs

Goal (Impact)	Increase the use of quality-assured RDT results to improve treatment decisions of people with fevers in private sector facilities of beneficiary malaria endemic countries (Kenya, Madagascar, Nigeria, Tanzania, Uganda)
Purpose (Outcome)	Increased uptake of quality-assured RDTs in private sector markets
Outputs	Increased availability of affordable, quality-controlled RDTs in the private sector markets
	Increased provider and consumer informed demand for RDTs in private sector markets
	Improved quality of malaria case management among private providers
	Development and dissemination of a "road map" for public-private engagement in malaria case management
	Coordinated project learning on the introduction of RDTs in the private sector
	Affordable, quality-assured RDTs continue to be made available in the private sector by leveraging the systems, learning and evidence-base generated through this project.

Overview

QA is key to successful fever case management in the private sector. Why? Because without strong assessments and feedback, we won't know if providers are giving the best quality of care and adhering to clinical standards and we won't be able to provide ongoing support for improvement. Furthermore, without tracking quality of care we won't know *which* private sector providers can safely manage fever cases at their outlets and correctly administer RDTs.

Aim

This QA Manual aims to improve quality of care by within the private sector by ensuring that FCM service provision is both developed and managed according to international standards of care that confirm technical competence, client safety, privacy and confidentiality, and continuity of care.

Specific objectives

This QA Manual is designed to:

- ✓ ensure that providers conduct FCM in the private sector according to quality standards,
- ✓ identify existing gaps in FCM service provision at provider level with RDTs, and
- ✓ ensure that feedback is correctly provided to reach quality standards in FCM through provider behavior change communication (PBCC).

Structure

The QA Manual is built around QA best practices in FCM. These fit into the plan-do-check-act project cycle[1]: the first three steps of the cycle offer countries a path to *plan*, *do* and *check* the quality of FCM service provision. The results of these three steps drive countries through the *act* component of the cycle by offering a way to tailor the planned activities according to what is identified in the first three steps of the cycle. Included within the first three steps of the manual are numerous tools developed to guide providers, supervisors and project managers along the path to deliver quality care; the fourth step specifies the activities to be taken to ensure quality standards:

1| **Plan**: policy and strategy tools to define how the project fits into the larger international and national frame,
2| **Do**: provider competency tools to provide the fundamental blocks,
3| **Check**: quality monitoring tools and medical audit tools to track providers' performance,
4| **Act**: on-going support (training, marketing plans, provider behavior change communication, etc.) to maintain and/or improve quality.

[1] http://asq.org/learn-about-quality/project-planning-tools/overview/pdca-cycle.html

1| Plan

Policy and Strategy Tools

Policy and Strategy tools are developed to outline how national governments should monitor fever case management in the private sector, in terms of the qualifications of the provider to perform RDTs and of the necessary quality standards to manage fever cases.

The Policy and Strategy Tools consist of:

- ✓ National guidelines on FCM in the private sector,
- ✓ FCM quality standards.

National Guidelines on FCM in the Private Sector

It is fundamental that countries act in a regulated environment which facilitates and supports the uptake of RDTs in the private sector. Thus, regulatory institutions should work on national guidelines for FCM in the private sector to allow private providers like pharmacists, drug sellers, physicians, etc., to administer RDTs. Advocacy work should take place with local institutions such as the Ministry of Health (MOH), national malaria control programs (NCMPs) and professional associations to create a conducive policy environment for RDTs in the private sector, in line with the latest WHO guidelines[2] and existing national guidelines on malaria treatment and diagnosis.

The national guidelines on FCM in the private sector should define:

- ✓ RDTs quality criteria,
- ✓ Provider's minimum qualification to be enrolled for training on FCM in the private sector,
- ✓ Training content and minimum qualification requirement to be allowed to perform RDTs in the private sector,
- ✓ Integration of data coming from the private sector into the malaria surveillance system.

Once the national guidelines have been drafted, interventions should be planned accordingly, by enrolling the private sector channels allowed to store and sell RDTs, procuring RDTs in line with national quality criteria, and conducting assessments and supervisions with the health professionals who are qualified to offer FCM service provision in the private sector as trained and certified by local institutions.

Fever Case Management Quality Standards

If standards for the private and public sectors are not already established at the national level, they should be developed according to the following FCM quality standards:

> **Technical competence:** Providers are technically competent to perform the tasks required as described in the standard operational procedures (SOPs). Technical competence is achieved through selection of appropriately qualified providers that possess the basic supporting skills needed to deliver RDT services and through on-going training and skills development. SOPs and algorithms provide step-by-step procedures for delivering technically competent services in FCM. Training programs are tailored to impart the knowledge and skills necessary to follow these protocols.

[2] World Health Organization. T3. Test. Treat. Track. Scaling up diagnostic testing, treatment and surveillance for malaria. Geneva: World Health Organization, 2012.

Client safety: Appropriately screening potential clients to ensure they are eligible to get tested with RDTs, as well as maintaining the premises and any equipment that will be used to conduct malaria diagnosis are all part of making sure no harm is done in the delivery of malaria diagnosis in the private sector. Providers are knowledgeable and skilled at delivering RDT service in a safe manner and procedures to ensure client safety are integrated throughout the SOPs and algorithms, i.e. checking for danger signs and asking for medical history.

Privacy and confidentiality: Clients' rights to privacy and confidentiality are protected. Providers recognize and respect the need for client's privacy and perform RDTs in a space that protects the client from being seen by others: if required by clients, the setting where RDTs will be performed should be screened in a way that ensures visual privacy. Providers keep any information learned about their clients confidential; this includes storing client records in a safe and confidential manner.

Continuity of care: Clients receiving services have access to follow-up care. Where channels involved in delivering the initial service of RDTs are not available for follow-up care, a referral network of skilled providers from whom clients can be referred in the case of a negative RDT or can seek out follow-up care is established.

2| Do

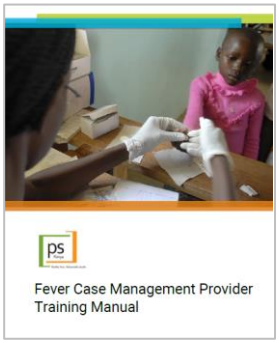
Provider Competency Tools

Provider competency tools are developed to standardize providers' training towards best practices for FCM. These tools help define what providers are expected to deliver in the private sector as well as help determine what providers need to be trained on.

The Provider competency tools consist of:

- ✓ Provider training manual,
- ✓ SOPs for RDTs,
- ✓ FCM algorithm,
- ✓ Provider job-aid.

Provider Training Manual



Providers must be trained on RDT administration and FCM. More specifically, private sector providers should be taught how to recognize danger signs, how to diagnose malaria using RDTs, how to treat uncomplicated malaria by administering quality assured artemisinin-based combination therapies (QAACTs) and which cases to refer. Training manuals should be tailored to each type of provider (drug sellers, health workers, pharmacists, social franchise providers, etc.) and to each country context. Training manuals must meet national approval and should build on existing national guidelines. Training manuals represent a comprehensive basis to conduct training but depending on the specific type of providers trained, some sessions may be more in-depth, while others may be shortened.

Refer to Annex 1 for an example of a provider training manual.

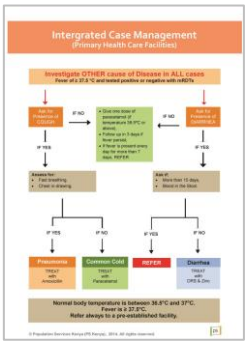
SOPs for RDTs

Malaria diagnosis with RDTs is a clinical service and as such SOPs are required to guide health care workers on how to perform and read RDTs. SOPs represent the core of the training manual and every private provider administering RDTs must be trained on how to follow SOPs step-by-step. Similar to the training manual, SOPs represent an agreement between what providers have been trained on and what is expected from them at their service provision outlets.

SOPs may be seen as a technical 'memorandum of understanding' on how to perform RDTs. Once set, supervisors should refer to them as the 'gold standard' private providers should aim to reach when administering and reading an RDT.

Refer to Annex 2 for example SOPs for RDTs.

FCM Algorithm



Treatment algorithms are simple decision trees that consist of a series of questions that can be easily answered by a "yes" or "no". They provide step-by-step guidance for diagnosis, treatment or referral of customers presenting with febrile illness. Algorithms are needed to ensure that all the providers enrolled in the project manage fever cases correctly. Algorithms also help providers identify patients who should be referred without getting tested (patients with danger signs, pregnant women in the first trimester of pregnancy, or children under two months) and determine what to do in the case of a positive or negative RDT result.

Given that the level of education and medical expertise of private providers will likely vary, it may be necessary to develop two types of FCM algorithms:

1. Addressed to physicians or other health professionals qualified to conduct differential diagnosis. In case of negative RDT results, the algorithm expands on how to investigate other causes of fever (i.e. pneumonia and diarrhea) and it is mainly built on the integrated case management (ICM) algorithm;
2. Addressed to health workers who don't have the level of education required to conduct differential diagnosis of malaria. It focuses on how to test fever cases for malaria and in case of negative RDT results, providers are advised to refer patients to a referral unit to investigate other causes of fever.

Refer to Annex 3 for example FCM algorithms for different providers.

Provider Job-aid

The aim of the provider job-aid is to visually support providers during their day-to-day activities and guide them through the steps they have to undertake to perform, read and dispose of RDTs. Provider job-aids are a one-page document meant to be the visual translation of SOPs for RDTs and must be consistent with national guidelines. Provider job-aids should always be present at outlets since they offer an easy way to assist providers go through all the steps needed to perform and read RDTs, while providing at the same time a means of verification to clients to check if providers perform and read RDTs correctly.

Refer to Annex 4 for example provider job-aids.

3| Check

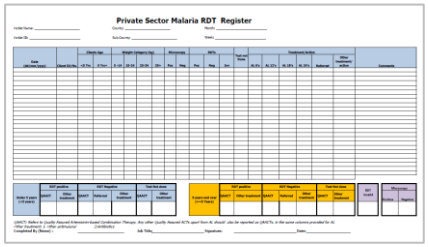
Quality Monitoring Tools

Quality monitoring tools are developed to help assess the quality of care being given by private sector providers.

The Quality Monitoring Tools consist of:

- ✓ Client register,
- ✓ SOPs for assessment,
- ✓ Assessment checklist,
- ✓ Supervisor job-aid,
- ✓ Quality of care reports.

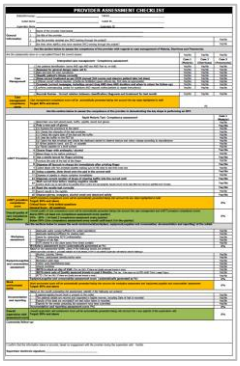
Client Register


Private Sector Malaria RDT Register

To be used by providers, client registers aim to capture the universe of FCM from a qualitative and quantitative point of view. Client registers capture data on the different types of cases providers see at their outlet every week/month (i.e. number of cases of fever tested positive with an RDT and treated with a QAACT, number of cases of fever tested positive with an RDT and treated with other treatments, etc.). Client registers are useful to track case-load by outlet and get a better sense of how many fever cases are seen at each outlet by week/month as well as to ensure that cases are managed correctly in terms of treatment and referrals. Analysis of client register data can help supervisors determine how to better allocate resources and plan assessments. It is important to note that client registers should be based on tally sheets already developed for existing registers required by the government.

Refer to Annex 5 for an example of a client register.

Assessment Checklist



The assessment checklist is a valuable tool that offers a picture of quality of care at the point of service provision. It is composed of six sections:

1. General information,
2. Case management,
3. mRDT procedure,
4. Workplace assessment,
5. Equipment, supplies and consumables assessment,
6. Documentation and reporting.

During assessments, supervisors should go through the assessment checklist and record data. Use of the Demographic Health Information System (DHIS2) platform is recommended for data storage. Data can be automatically stored into the DHIS2 platform and at the end of each assessment supervisors will have the opportunity to highlight topics that require improvement and provide on-the-spot feedback to providers. Based on the assessment score, supervisors can also plan the frequency of upcoming assessments.

The assessment checklist is fundamental to measure and track quality of care performance. On a regular basis, assessment findings should be used to:

1. Track, measure and compare providers' quality of care,
2. Design provider-specific interventions that address any identified performance gaps and reward providers for outstanding quality, including:
    - improving infrastructure, equipment or supplies needed to perform services;
    - training or re-training providers to ensure service provision is in line with SOPs,
    - developing performance rewards and incentives.
3. Make decisions about the long-term viability of the affiliation based on performance.

Refer to Annex 6 for example assessment checklists.

SOPs for Assessment

To monitor and document on-going compliance with FCM quality standards, supervisors must conduct comprehensive assessments of the quality of service delivery periodically. Because a provider's skills and elements related to the outlet out of which (s)he operates factor in to the overall quality equation, a provider performance assessment involves thoroughly auditing the outlet conditions and carefully observing the provider's clinical skills. Not all the providers need to be assessed with the same frequency; rather the frequency should be determined by a combination of elements (score of the assessment checklist, productivity and where the provider stands in the adoption stairway).

SOPs for assessment are required to standardize the process and guide supervisors through the assessments. The content of SOPs for assessment should be as follows, with adaptations as required by the types of private providers enrolled in country:

1. **Conduct assessment of outlet in terms of infrastructure, equipment, and/or supplies needed to meet quality standards**

   To deliver quality services, providers must operate out of an outlet that has appropriate infrastructure, equipment, and supplies. The assessment checklist ensures the presence of all items needed to store, perform and dispose RDTs ("Workplace assessment" section of the checklist).

2. **Conduct assessment of provider's ability to perform FCM**

   Provider's ability is determined by knowledge and skills:

   Knowledge: All the providers should have a basic level of knowledge about FCM, acquired in trainings and through ongoing supervision. Provider's level of knowledge is captured by combining information collected into two different sections of the assessment checklist ("Case management" and "mRDT procedure").

   Skills: Supervisors evaluate providers' skills by observing how providers manage fever cases (real or simulated). The assessment checklist allows for up to three cases to observe ("Case management" section) and the "mRDT procedure" section captures all the steps that are required to correctly perform RDTs.

3. **Determine score**
   The assessment checklist should be built in a manner that automatically generates the overall score of the assessment by outlet. The overall score should be calculated based on the score of some sections of the checklist and not all sections should contribute equally to the final score. Furthermore, the provider's performance score factors into the overall score and has been designed to emphasize and reflect the importance of some indicators over others (e.g. dispensing the correct number of drops of buffer is considered with less importance than reading RDT results correctly). The overall score by outlet obtained from the assessment checklist makes it simpler to track overall performance scores over time and identify high and low performing outlets so that special attention can be given to reward or penalize outlets by allocating resources accordingly.

4. **Provide feedback**
   Apart from providing the overall score of assessments, the assessment checklist also identifies 'flags' that might require supervisors' attention. Measuring quality of care without providing valuable feedback on-the-spot meets only half of the goal of providing quality services. Supervisors must provide feedback to providers: this PBCC activity conducted at the end of assessments reinforces relationships between providers and supervisors and ultimately improves quality of care because supervisors address gaps in knowledge as identified during the assessments.

A PSI designed electronic tablet-based system, called the Health Network Quality Improvement System (HNQIS), is recommended to support quality improvement delivered by providers.

Refer to Annex 7 for more information about HNQIS.

Supervisor Job-aid

Supervisor job-aids ensure that quality of FCM is preserved even many months after trainings. Indeed supervisor job-aids are directed to providers to reinforce the knowledge acquired in trainings and to supervisors as a support manual to explain correct management of fever cases. A fundamental tool to be used in assessments, supervisor job-aids are a simplified version of the provider training manual and are meant to support supervisors in giving feedback to providers at the end of their assessments.

Supervisor job-aids support supervisors in conducting PBCC: first the assessment checklist helps supervisors in identifying providers' incorrect behaviors and then supervisor job-aids support them in providing inputs to providers on how to modify the incorrect behaviors as identified through the checklist and how to explain correct behaviors in FCM. Ultimately, this system offers opportunity to change providers' behavior in FCM and improve quality of care over time.

Refer to Annex 8 for an example of a supervisor job-aid.

Quality of Care Reports

The basics of quality of care ensure that providers offer clients adequate, competent and safe services. Quality of care in FCM means that providers offer a RDT service when it is needed (*adequate*), RDTs are performed according to quality standards (*competent*) and the care provided does not harm (*safe*). The FCM quality standards as defined in the Policy and Strategy tools represent the wider frame into which quality of care fits. Measuring quality is essential to identify behaviors or factors that may jeopardize the quality of services delivered by the providers.
The following quality of care indicators aim to capture the most critical components of FCM in the private sector. These indicators are indicative only, and should be aligned to host-country indicators for Quality of Care.

1. **Productivity:** # of patients with fever attended at facility/outlet level
2. **Testing rate:** % of fever cases tested with RDTs
3. **Correct RDT procedure:** % of providers who correctly execute an RDT
4. **Correct FCM practice:** % of providers who correctly manage fever cases
5. **Availability of TX and DX:** % of outlets with RDTs/QAACTs in stock on the day of visit
6. **Counseling quality:** % of providers who provide proper counseling during visits
7. **Equity:** % of patients attended from the 2nd and 3rd wealth quintiles
8. **Client satisfaction:** % of patients satisfied with the service received
9. **Cost effectiveness:** Cost in USD of each assessment visit per provider

DHIS2 can greatly help inform the above mentioned indicators on quality of care. Data analysis should be conducted on a semi-annual basis to evaluate quality of care of private providers and to identify areas that might require intervention on provider behavioral change that will ultimately deliver better quality services.

Quality of Care Indicators, Definitions, Means of Verification and Metrics

DEFINITION	MEANS OF VERIFICATION	METRIC
1| PRODUCTIVITY		
# of patients with fever attended at facility/outlet level	DHIS2	# of fever cases attended at facilities/outlets
2| TESTING RATE		
% of fever cases tested with RDTs	DHIS2	**Numerator:** # of cases tested with an RDT **Denominator:** # of fever cases attended
3| CORRECT RDT PROCEDURE		
% of providers who correctly execute an RDT	DHIS2	**Numerator**: # of providers who score more than 80% in the mRDT procedure **Denominator**: # of providers assessed
4| CORRECT FCM PRACTICE		
% of providers who correctly manage fever cases	DHIS2	**Numerator**: # of providers who score more than 80% in QoC **Denominator**: # of providers assessed
5| AVAILABILITY OF TX AND DX		
% of outlets with RDTs/QAACTs in stock on the day of visit	DHIS2	**Numerator:** # of outlets with RDTs/QAACTs in stock **Denominator:** # of outlets enrolled
6| COUNSELING QUALITY		
% of providers who provide proper counseling during visits	DHIS2	**Numerator:** # of providers who provide proper counseling to customers **Denominator:** # of providers assessed
7| EQUITY		
% of patients attended from the 2nd and 3rd wealth quintiles	EIs	**Numerator**: # of patients in wealth quintiles 2 and 3 **Denominator**: # of patients in wealth quintiles # 1-5
8| CLIENT SATISFACTION		
% of patients satisfied with the service received	EIs	**Numerator**: # of patients *very* satisfied with the service received at facilities/outlets enrolled **Denominator**: # of patients interviewed (EIs)
9| COST EFFECTIVENESS		
Cost in USD of each assessment visit per provider	Country budget	**Numerator**: # of providers assessed **Denominator**: total expenditure for assessment visits

Medical Audit Tools

Medical audit tools are developed to deliver high quality services in FCM (malaria diagnosis, treatment and referral) and to have robust systems that monitor and maintain high-quality services.

The Medical Audit Tools consist of:

- ✓ SOPs for audit,
- ✓ Audit checklist.

SOPs for Audit


STANDARD OPERATING PROCEDURES (SOPs)
FOR MEDICAL QUALITY ASSURANCE (QA) AUDITS

Unlike quality of care reports, QA audits are targeted to the wider frame of FCM quality standards and evaluate if activities are in fulfillment with international standards on clinical service delivery. SOPs for audit are required to standardize the process that evaluates FCM quality standards and to raise the bar for best practices of FCM.

SOPs for audit should follow the six main components of audits:

1. **Auditor orientation** between the auditor, country medical coordinator, supervisors and country teams,
2. **In-country management review/orientation meeting** between supervisors, country medical coordinator and country teams to review the country program approach focusing on service delivery models, type of outlets employed and supervisory systems,
3. **Document and service statistics review,**
4. **Site visits** conducted by the auditor and the country medical coordinator on project sites, supported by country teams as appropriate,
5. **Debrief** at which observations and conclusions from the visits will be discussed and at which country teams and QAOs will address any concerns with development of an action plan,
6. **Audit report** which will be reviewed by the medical coordinator. Country teams will be required to respond and develop an action plan for key findings and follow-up activities.

Refer to Annex 9 for an example of a SOP for QA and an Audit Scorecard.

4| Act

On-going support

In order to improve quality of care over time, a system should be in place to continually stimulate quality in FCM service provision. The specific type of activities and support depends on the findings obtained in assessments and audits, and also depends on the type of outlets enrolled, the number and type of clinical services provided, the delivery channels being used, and so on.

The following are examples of on-going support to providers that may be needed:

- ✓ On-going training and skills development opportunities (continuous medical education activities, on-the-job training, etc.),
- ✓ Literature and technical updates,
- ✓ On-going supply of information, education and communication (IEC) or behavior change communication (BCC) materials,
- ✓ On-going supply of referral cards, record keeping forms, etc.,
- ✓ updates on referral sites,
- ✓ On-going supply of consumables (i.e. timers, lab-coats, products, gloves, bleaches, etc.),
- ✓ Procurement of new equipment as needed,
- ✓ Access to medical staff for advice when needed (i.e. via tel. hotline).

Annexes

Annex 1: Fever Case Management Provider Training Manual
Annex 2: Standard Operating Procedures (SOPs) for RDTs
Annex 3: Fever Case Management (FCM) Algorithm
Annex 4: Provider Job-Aid
Annex 5: Client Register
Annex 6: Assessment Checklist
Annex 7: HNQIS Overview
Annex 8: Supervisor Job-aid
Annex 9: Standard Operating Procedures (SOPs) for Audit

ps Kenya

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Fever Case Management Provider Training Manual

Overview of the provider training manual

Aim: This is a learner's manual for malaria diagnosis and treatment addressed to health care workers who work in private outlets enrolled in the UNITAID Private Sector RDT project. This manual is intended to be used during training on national guidelines for malaria diagnosis and treatment. The manual includes different activities which focus on increasing providers' knowledge, skills and change of attitude towards effective management of malaria. Detailed information can be found in the National Guideline for Malaria Diagnosis and Treatment, 2010.

Audience: Private providers as physicians, pharmacists and drug sellers whose outlets are enrolled in the UNITAID Private Sector RDT project.

Contents:
- Diagnosis and treatment of uncomplicated malaria,
- Parasitological diagnosis,
- Basic techniques in managing malaria commodities
- Monitoring & Evaluation

Acronyms

ACTs	Artemisinin-based Combination Therapies
AL	Arthemeter -Lumefantrine
CU5	Children under five
FCM	Fever Case Management
ICM	Integrated Case Management
IPT	Intermittent Preventive Treatment
IRS	Indoor Residual Spraying
LLINs	Long-Lasting Insecticide-treated Nets
NMCP	National Malaria Control Program
PfPR	*Plasmodium falciparum* Prevalence Rate
RDTs	Rapid Diagnostic Tests
WHO	World Health Organization

Contents

Overview of the provider training manual 1
Acronyms 2
Contents 3
Learning Unit 1: Diagnosis and treatment of uncomplicated malaria 5
Epidemiology of Malaria in Kenya 5
Malaria disease burden 5
What is the current distribution of malaria in Kenya? 6
Malaria control interventions 7
Prevention 7
Case management 7
Others 7
Kenya National Malaria Policy 8
Algorithm for diagnosis of malaria 8
Uncomplicated Malaria 8
What are the signs and symptoms of uncomplicated malaria? 8
Recommended medicines and dosages 9
Rationale for malaria treatment 9
Supportive treatment 10
Dosing schedule for AL 10
Dispensing and Counseling 10
Follow-up care 10
Suspected Treatment Failure: 10
Management of Suspected Treatment Failure: 10
Complicated/Severe Malaria 10
Learning Unit 2: Parasitological Diagnosis 12
The life cycle of malaria parasite 12
Rationale for malaria parasitological diagnosis 12
Methods of malaria parasitological diagnosis 13
Microscopy 13
Malaria Rapid Diagnostic Tests (mRDTs) 13
Preparing to perform the test 15
RDTs procedure 16
Quality Assurance and Sources of Common Errors 17

Biohazard, Safety and Waste Management 18
Learning Unit 3: Basic Techniques in Managing Malaria Commodities 19
Definition of Commodity Management 19
Commodity Management Cycle 19
How to receive: 20
Storage 20
Good arrangement 20
Good stock rotation: 20
Stocking Conditions: 20
Assured Security, Restricted Access: 21
Use 21
Good record keeping 21
Learning Unit 4: Monitoring & Evaluation 23
Definitions 23
Importance of M&E in Malaria Case Management 23
Indicators, Source and Frequency of collection and use in Malaria 23
Sources of data to measure the indicators: 24
Reporting tools for malaria case management: 24
Data Quality 24
Supportive Supervision 24
Definition 25
Who should be supervised? 25
Supervision process 25
Annexes 26

Learning Unit 1: Diagnosis and treatment of uncomplicated malaria

By the end of this session participants should be able to:

- ✓ Describe current epidemiology of malaria in Kenya,
- ✓ Describe malaria control interventions in line with current epidemiological map,
- ✓ Describe diagnosis and treatment of malaria.

Epidemiology of Malaria in Kenya

Malaria is a disease caused by the parasite plasmodium and it is transmitted by the bite of an infected female anopheles mosquito. Clinical features vary from mild to severe depending on:

- Infecting species of the parasite,
- Patient state of immunity e.g. HIV,
- Acquired malaria Immunity,
- Intensity of the infection,
- Presence of other co-morbidities, e.g. malnutrition, anaemia, etc.

Common species of malaria parasite:

Malaria is caused by four plasmodium species, which are *Plasmodium falciparum*, *P. vivax, P. malariae* and *P. ovale*. P. falciparum which causes the severest form of the disease, accounts for 98% of all malaria infections.

Factors contributing to transmission of malaria:

The transmission of the diseases is influenced by a number of factors:

- Distribution of the mosquito vector species (vector density)
- Vectorial capacity of the mosquito vector species,
- Man-Biting Habit of the vector,
- Temperature and humidity,
- Rainfall and Altitude,
- Hydrology and water supply systems,
- Human immunity against malaria parasites.

Malaria Disease Burden

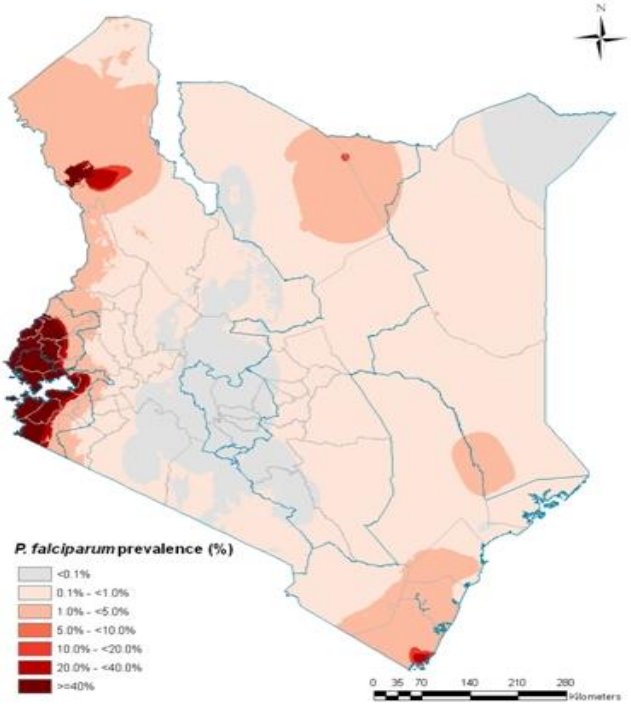
- Children under 5 years and pregnant women are at greater risk of malaria,
- 15-19% of hospital admission in Kenya are due to malaria with 3-5% in patient deaths (HIS 2007),
- Malaria accounts for > 20% outpatient attendance in Kenya. Each family spends Ksh 1,400 or more annually for treating malaria,
- 170 million working days are lost each year.

Kenya has four malaria epidemiological zones with diversity in malaria risk determined by altitude, rainfall patterns and temperature:

- **Endemic zones:** Areas of stable malaria transmission around Lake Victoria in Western Kenya and along the coast. Transmission is intense throughout the year, with annual percentages of entomological inoculation rates ranging from <10% to 100%. The parasite prevalence rate is estimated at 4.8 PfPR and 38% PfPR for the Coastal and Lake endemic regions respectively.
- **Seasonal malaria zones:** Semi- arid areas in northern, eastern and south eastern parts of the country that experience short periods of intense malaria transmission during the rainfall seasons which may result in epidemics. The parasite prevalence rate is normally less than 1% PfPR in this zone.
- **Highland epidemic zones:** Areas of seasonal malaria transmission in the western highlands of the Rift Valley. Malaria epidemics, which occur when climatic conditions favor vector breeding, were common during the early years of the malaria control program in Kenya. The normal parasite prevalence rate now, however, is less than 1% PfPR.
- **Low risk zones:** Central highlands of Kenya, which includes Nairobi where traditionally low seasonal temperatures inhibit sporogony; however, the increasing temperatures and changes in the hydrological cycle associated with climate change are likely to increase the areas suitable for malaria vector breeding, with the introduction of malaria transmission in areas where it had not existed before. Again, the prevalence rate in this zone is generally less than 1% PfPR.

Current Distribution of Malaria in Kenya

Malaria endemicity map[3]:



[3] Noor AM, *et al.* The risks of malaria infection in Kenya in 2009. *BMC Infectious Diseases* 2009 **9**:180.

Kenya has four malaria epidemiological zones:

Districts	Risk
Lake Victoria and coast region	Endemic: > 20%
Western highlands	Epidemic-prone: 5 to ≤ 20%
Arid and semiarid districts	Seasonal transmission: 0.1 to ≤ 5%
Central highlands including Nairobi	Low risk: < 0.1%

Malaria Control Interventions

Prevention

- Long lasting insecticide treated nets (LLINs): a household owns one insecticide treated net for every two people living there.
- Indoor residual spraying (IRS): the interior walls of every house are routinely sprayed at appropriate intervals with an effective insecticide.
- Intermittent Preventive Treatment (IPTp): a pregnant woman living in a high transmission setting receives at least 2 doses of an appropriate anti- malaria drug during her pregnancy.

Case management

- Diagnosis: a patient receives prompt parasitological confirmation by microscopy or rapid diagnostic tests (RDTs) for malaria diagnosis.
- Treatment: an infected person receives appropriate anti-malarial drugs for uncomplicated or severe malaria within one day of onset of illness.

Others

- Epidemic Preparedness and Response: establishment of early warning systems and responding appropriately.
- Surveillance: data use to provide progress on malaria control measure.
- Health Education and Behavior Change and Communication: arm the public with the malaria preventive and treatment knowledge.

Epidemiology	Case Management	LLIN	IRS	Health Education/BCC	IPTp	EPR	Surveillance
Lake stable endemic & Coast seasonal stable Endemic	X	X	X	X	X		X
Highland epidemic prone	X	X	X	X		X	X
Seasonal low transmission including arid and Semi arid	X			X		X	X
Low risk	X			X			X

Kenya National Malaria Policy

Not all fevers are caused by malaria, therefore all fever cases should be tested to confirm malaria. The low prevalence of malaria in most parts of the country (as demonstrated by the declining malaria prevalence) has led to changes in policy to advocate for the testing of all suspected malaria cases.

The Kenya national malaria policy recommends accurate parasitological diagnosis of malaria using microscopy or rapid diagnostic tests in all persons with fever and/or other symptoms of malaria and treatment of only parasitological confirmed cases (malaria positive cases).

All age groups:

- All patients with fever or history of fever should be tested for malaria:
    - If the test is positive: treat for malaria,
    - If the test is negative: DO NOT treat for malaria, look for other causes of fever and treat accordingly.
- If parasitological confirmation is not available, patients with fever or history of fever should be assessed further for other causes of fever, managed accordingly or referred.

Consequences of Presumptive Treatment

Not all fevers are malaria hence presumptive treatment of malaria causes:

- Poor prognosis in patients given wrong diagnosis and inappropriate treatment
- Wastage of scarce and expensive ACTs
- Increased risk of ACT resistant parasites
- Increased risk of unnecessary drug reactions
- Erosion of confidence and trust in health services

Algorithm for Diagnosis of Malaria

Refer to Annex 1 and 2:

- Annex 1: Fever Case Management for private pharmacists and drug sellers,
- Annex 2: Integrated Case Management for private physicians.

Uncomplicated Malaria

Uncomplicated malaria: Malaria without signs of severity or evidence of vital organ dysfunction.

Signs and symptoms of uncomplicated malaria

- Fever
- Chills
- Profuse sweating
- Muscle pains
- Joint pains
- Abdominal pain
- Diarrhea
- Nausea
- Vomiting
- Irritability
- Refusal to feed

Recommended Medicines and Dosages

Rationale for malaria treatment:

- To provide rapid and long lasting clinical and parasitological cure,
- To reduce malaria related morbidity e.g. anemia,
- To halt the progression of simple disease into severe and potentially fatal disease.

Artemisinin-based Combination Therapies (ACTs) are recommended by WHO to be used for the treatment of uncomplicated malaria. ACTs are combinations in which one of the components is artemisinin or its derivatives (artesunate, artemether or dihydroartemisinin) and the other component is an antimalarial with a known good efficacy profile (e.g. lumefantrine, piperaquine, mefloquine, amodiaquine). The artemisinin compounds are active against all four species of malaria parasites that infect humans and are generally well tolerated.

For the ACTs to eliminate at least 90% of the parasitaemia, a 3-day course of treatment is required. This ensures that only about 10% of the parasitaemia is present for clearance by the partner medicine.

Fixed-dose combinations (the components are mixed in the same tablet) are highly preferable to the loose individual medicines co-blistered or co-dispensed (the components of the combination therapy are in separate tablets). It promotes adherence to treatment and reduces the potential for selective use of the medicines as monotherapy.

First Line Treatment:

- Artemether-Lumefantrine (AL): 6 doses given over 3 days,

Second Line Treatment:

- Dihydroartemisinin-Piperaquine: 3 doses given over 3 days.
- In absence of Dihydroartemisinin-Piperaquine oral quinine should be used.

All other previously used monotherapies including oral artemisinins should not be used for treatment of malaria and are no longer licensed for this purpose anymore. This includes chloroquine, amodiaquine and sulphadoxine-pyrimethamine (SP).

Contraindications:

- Hypersensitivity to either artemether or lumefantrine.
- Not recommended in the first trimester of pregnancy. The recommended treatment for uncomplicated malaria in the first trimester is a 7 day therapy of oral quinine.

Adverse Effects of Artemether-Lumefantrine

While the overall incidence of side effects to AL is low, the common adverse effects reported include sleep disorders, headache, dizziness, nausea, anorexia, abdominal pain, pruritus, rash, cough, palpitation, arthralgia and myalgia. Lumefantrine does not cause prolongation of QT intervals and therefore it is safe in patients with cardiac illness.

Supportive treatment

- Fever Management:
  - Children and Adults: paracetemol,
  - Tepid sponging, exposure, fanning, etc.
- Fluids and Nutrition:
  - Encourage giving extra fluids; continue breastfeeding where applicable.

Dosing schedule for AL

Refer to Annex 3: Treatment of uncomplicated malaria.

Dispensing and Counseling

- Weigh the patient,
- Select appropriate dosage,
- Tell the patient why they are getting the drug,
- Explain dosing schedule:
  - Emphasize the need to complete all doses even if the patient is feeling better,
  - Demonstrate and give instructions for dispersible formulations of AL,
- Give first dose under observation (DOT),
- Observe patient for 30 minutes for vomiting,
- If patient vomits, repeat the dose after 10 minutes.,
- Advise to return IMMEDIATELY if condition worsens,
- Advise to return after 3 days if fever persists,
- Check that the patient or caregiver has understood the instructions before leaving the clinic.

Note: 2nd dose on the 1st day should be given 8 hours after the 1st dose, doses on the 2nd and the 3rd days are twice a day (12 hours apart)

Follow-up care

Suspected Treatment Failure:

- Failure to achieve desired therapeutic response after initiation of therapy,
- May result from non-adherence, vomiting, wrong diagnosis, unusual drug pharmacokinetics, drug resistance, poor quality medicines,
- Should be suspected if there is no improvement 3-14 days after initiation of treatment,
- If symptoms reappear after 14 days treat as a new infection.

Management of Suspected Treatment Failure:

- In cases of non-adherence or non-completion repeat full course of AL after addressing the cause (of non adherence),
- Malaria microscopy should be used to confirm (RDTs not recommended because it remains positive 14-21 days after successful treatment of malaria),
- In facilities with no microscopy patients with suspected treatment failure should be referred,
- Treat confirmed treatment failure cases with Dihydroartemisinin-Piperaquine.

Complicated/Severe Malaria

Severe malaria occurs when infections are complicated by serious organ failures or abnormalities in the patient's blood or metabolism. Nearly all deaths from severe malaria result from infections with *P. falciparum*. It's important to recognize the danger signs and refer immediately.

Danger Signs in Children:

- Convulsions
- Unconsciousness or altered mental state or lethargic
- Respiratory distress
- Vomiting everything
- Failure to eat or drink
- Extreme weakness or prostration
- Stiff neck/severe headache
- Severe dehydration
- Severe pallor

Danger Signs in Adults:

- Convulsions
- Difficulty in breathing
- Vomiting everything
- Extreme weakness
- Stiff neck or severe headache.

The manifestations of severe malaria include:

- Cerebral malaria, with abnormal behavior, impairment of consciousness, seizures, coma, or other neurologic abnormalities,
- Severe anemia due to hemolysis (destruction of the red blood cells),
- Hemoglobinuria (hemoglobin in the urine) due to hemolysis,
- Acute respiratory distress syndrome (ARDS), an inflammatory reaction in the lungs that inhibits oxygen exchange, which may occur even after the parasite counts have decreased in response to treatment,
- Abnormalities in blood coagulation,
- Low blood pressure caused by cardiovascular collapse,
- Acute kidney failure,
- Hyperparasitemia, where more than 5% of the red blood cells are infected by malaria parasites,
- Metabolic acidosis (excessive acidity in the blood and tissue fluids), often in association with hypoglycemia,
- Hypoglycemia (low blood glucose). Hypoglycemia may also occur in pregnant women with uncomplicated malaria, or after treatment with quinine.

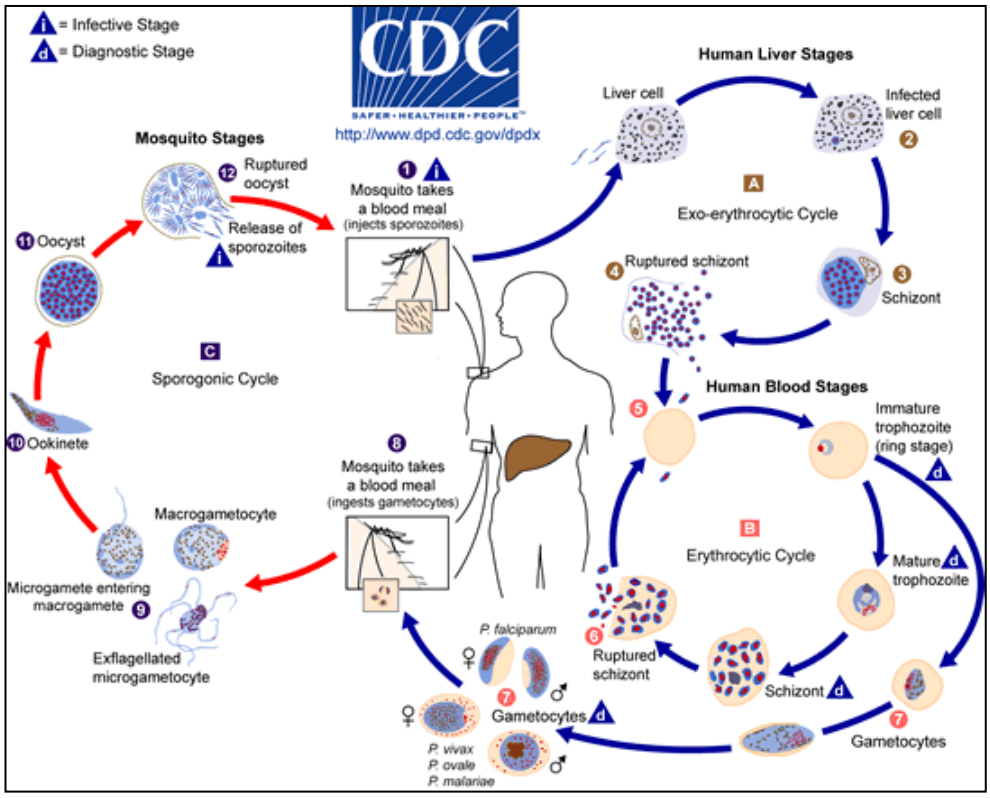
Severe malaria is a medical emergency and should be treated urgently and aggressively.

Learning Unit 2: Parasitological Diagnosis

By the end of this session participants should be able to:

- ✓ Explain the rationale of parasitological diagnosis of malaria,
- ✓ Describe malaria rapid diagnostic tests (RDTs),
- ✓ Perform an RDT, read and interpret results,
- ✓ Describe quality assurance system for relating to malaria RDTs,
  Describe safety and waste disposal of contaminated materials.

The life cycle of malaria parasite[4]



Rationale for malaria parasitological diagnosis

- To differentiate malaria cases from other diseases with similar presentations and improve the quality of patient care by confirming parasite-positive patients
- To minimize irrational use of antimalarials and target other fever causing illnesses. This prevents unnecessary use of antimalarials, reducing frequency of adverse effects, especially in those who do not need the medicines, and medicine pressure selection for resistant parasites.
- To monitor response to malaria treatment,
- To confirm/ or predict out breaks,
- Research and surveys,
- Improve malaria disease surveillance by reporting confirmed (true) cases.

[4] http://www.cdc.gov/malaria/about/biology/

Methods of malaria parasitological diagnosis

The two common methods for parasitological confirmation of malaria are microscopy and RDTs. The Kenya national malaria policy recommends parasitological confirmation of all suspected malaria cases with either microscopy or RDT.

Microscopy

While microscopy is the gold standard, it requires skilled manpower, quality assured reagents and equipments. A reliable and well maintained binocular microscope is essential for accurate malaria microscopy. Malaria microscopy is a skilled exercise requiring great care at each step of the standard operating procedures and, precise visual and differential skills.

Advantages of microscopy:

- It is cost effective,
- Can be used to quantify malaria parasites,
- Can be used for all malaria parasites,
- Can be used to monitor treatment of malaria,
- Can give information on other blood parasites and blood picture.

Disadvantages of microscopy:

- Requires more time,
- Can only be performed by qualified laboratory personnel,
- Is a complex procedure requiring high degree of competency and quality management system,
- Requires reliable electrical supply.

Malaria Rapid Diagnostic Tests (mRDTs)

Malaria RDTs are qualitative techniques which specifically detect antigens (proteins) produced by malaria parasite. The tests can be done by minimally trained personnel, and are rapid as results can be obtained within 20 minutes.

- Malaria RDT is an immunochromatographic test based on an antigen antibody reaction,
- May be in form of cassette, dipstick or even a card,
- The test contains a strip with antibodies against malaria parasites/antigens,
- The tests are specific to HRP2, pLDH and aldolase parasite antigens,
- If malaria parasite antigens are present two bands are formed: a control band and a positive band. In the absence of malaria parasite antigens, only the control band is formed.
- There are two main groups of commercially available RDTs:
    - Specific antigen: RDTs detect one species of human malaria parasites.
    - Pan specific antigen: RDTs detect all human species of malaria parasites.

<u>RDT Quality</u>

The RDTs procured for use in Kenya are of high quality with excellent performance characteristics. They are selected, procured, shipped to Kenya and distributed for use in Kenya after fulfilling the following conditions:

- In country requirements for registration of RDTs,
- WHO RDT product testing,
- Pre-shipment Lot testing,

- Post shipment Lot testing,
- In country sensitivity and specificity testing.

Advantages of RDTs

- RDTs are diagnostic tools that can diagnose malaria using finger prick blood.
- RDT pick antigens rather than parasites hence can detect malaria in patients with low parasitaemia.
- They are accurate and easy to use.
- They do not need specialized buildings, electricity or equipment (microscopy laboratory).
- They give results within a short time, usually around 20 minutes.

Limitations of RDTs

- Not quantitative i.e. cannot be used to calculate parasite density.
- Remain positive for 14 to 21 days after successful treatment - HRP2 clears slowly and the test may be positive because of a previous infection and not a current infection (within 14 days).
- Some RDTs are only specific to a certain species of malaria.

When to use RDTs

- Health workers with limited training in laboratory skills or settings with limited resources for supervision.
- Health care workers in the community and health posts with no laboratories.
- Settings with high work load per health worker e.g. outpatient departments of hospitals or health centers in areas of high endemicity.
- Areas with no electricity or high degree of interruption of power supply.
- Areas with poor microscopy training programs and with no quality management system functioning.

Materials required to perform RDTs

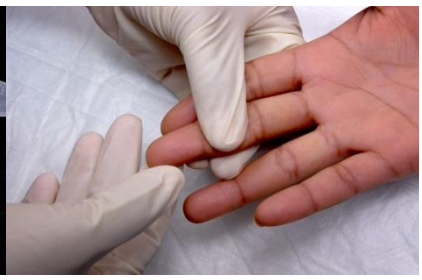
- RDT kit (test cassette, buffer, blood collecting device),
- Sterile lancet,
- Alcohol swab,
- Pencil or pen for labeling,
- Gloves,
- Sharps container,
- Waste disposal container,
- Timer or clock,
- Instruction manual for the specific RDT,
- Dry cotton wool.

Preparing to perform the test

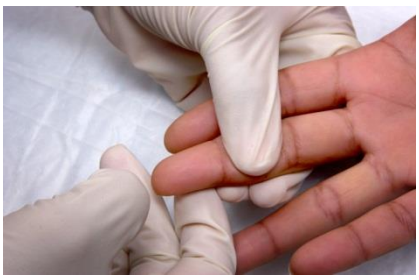
1. Gather the necessary materials in the testing area,
2. Check the expiry date at the back of the test package. If the test kit has expired use another test,
3. Ensure the RDT packaging is not damaged by squeezing gently and feel/listen for air leakage. Note: if the foil packaging is damaged, use another test kit,
4. Explain to the patient what the test is for and procedure,
5. Open the package tearing along the nick and look for the following
    a) colour of desiccant (to be consistent with what indicated by the manufacturer),
    b) cassette,
    c) dropper,
6. Remove the cassette from the foil packaging and label it with patient particulars and reading time,
7. Wear a new pair of gloves,
8. Disinfect the puncture site (4th finger of the non-dominant hand) with an alcohol swab or appropriate disinfectant. The 4th finger is preferred because it's the less used and will cause least inconvenience even if it becomes sore.

Best practices for finger prick:

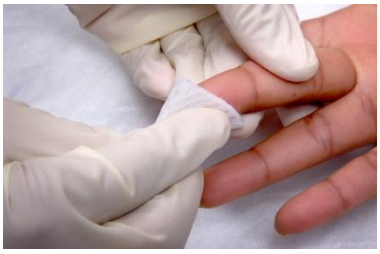
1. Collect supplies.



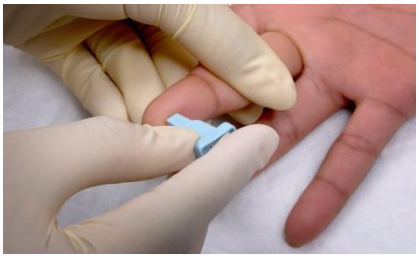
2. Position non-dominant hand palm-side up. Take the 4th finger.



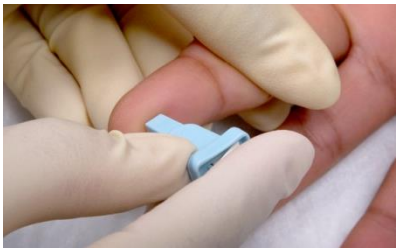
3. Apply intermittent pressure to the finger to help the blood to flow.



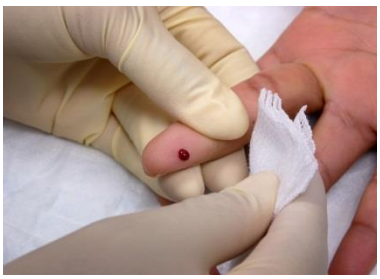
4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.



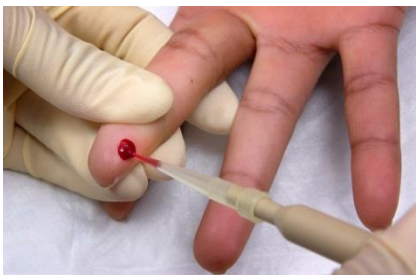
5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip.



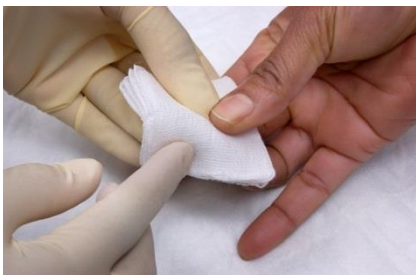
6. Firmly press the lancet to puncture the fingertip.



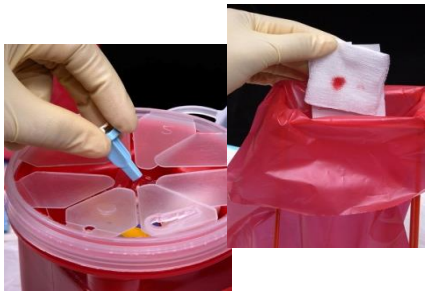
7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball.



8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.



9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops.



10. Dispose of waste

RDTs procedure

1. Make a gentle prick towards the pulp (ball) of the 4th finger with a sterile lancet at the disinfected site. Pricking at the tip or midline is more painful. Discard the used lancet in an appropriate sharps container immediately after use. By applying gentle pressure to the finger express the first drop of blood and wipe it away with a dry piece of cotton wool. Make sure no strands of cotton remain on the finger to contaminate blood. Apply gentle pressure to the finger until a new blood drop appears. Emphasize the need for the right skills to ensure correct test performance and accurate results. The reason for wiping out the first drop is because it contains too much tissue fluid which might dilute the antigens and it might be contaminated with the alcohol used for wiping the finger.
2. Using the blood collection device (pipette or capillary tube) provided in the RDT kit, gently immerse the open end in the blood drop. Collect the required volume of blood as per manufacturer's instructions. Good blood collection and adequate amount of blood are fundamental to ensure good results. After pricking and collecting blood, apply a dry cotton wool at the puncture site to stop the bleeding.
3. Transfer the collected blood to the sample well (as indicated on the RDT cassette by the manufacturer). It's important to put the sample in the right well as indicated by the manufacturer. Different manufacturers may have different labeling for the different wells.
4. Holding the buffer bottle vertically, add the recommended number of drops of buffer into the buffer well. Put the exact amount of buffer as indicated by the manufacturer at the correct well of the test device and don't use any other buffer apart from the one provided and specified. Some test kits will come with a bottle of buffer for many tests and others will have enough buffer packed for a single test.
5. Time the test as recommended by the manufacturer. View the result window of the cassette for colour band(s).
    - **Negative** – The presence of only a control band, at the C mark, indicates a negative result for *P. falciparum* malaria. If RDT result is negative, alternative causes of fever should be investigated and treated appropriately. Note: Do not read the results before or after the set time. Don't treat any fever as malaria despite a negative result.
    - **Positive** – The presence of both a control band at the C mark and a test band at the T mark indicates a positive result for *P. falciparum* malaria.
    - **Invalid** — If the test does not show the control band at the C mark, even if there is test band at the T mark, the test is invalid. Perform another RDT.

    Refer to the "RDT Provider job-aid" for pictures of negative, positive and invalid results.
6. Report the results as "RDT Negative" or "RDT Positive" or "RDT Invalid" (in which case the RDT should be repeated). If the RDT is performed in the clinic, outpatient department or in the wards, the result, even if it is negative, should be reported on the appropriate patient card/form. As well as in the OPD register, malaria commodity daily activity register and any other register. The malaria commodity daily activity register contains information for both ACT and RDT.

Quality Assurance and Sources of Common Errors

- Read the manufacturer's instructions prior to performing the test,
- Follow the test procedure, precautions and interpretation of results for this test,
- Check expiry date of the test kit before use,

- Use the correct amount of blood and buffer: incorrect amount of buffer and blood may lead to inaccurate results,
- Read the test at the recommended time,
- Perform and read the test under adequate lighting,
- Only open the foil packaging and remove the RDT immediately before performing the test. If preparation is delayed after opening the packaging, the RDT may be damaged by humidity and results may not be accurate,
- Use only the buffer supplied with the kit; don't use buffer from different lots of RDTs or from different rapid tests,
- Label correctly the patient details on the test cassette to avoid mix ups,
- Record the patient results appropriately,
- Proper storage conditions as per manufacturer's instructions.

Biohazard, Safety and Waste Management

- Protect yourself and others:
    - Wear a laboratory coat,
    - Wear a new pair of gloves,
    - Wash hands,
    - Disinfect working bench: the recommended disinfectant could be 10% hypochlorite.
- Segregate waste material as follows:
    - Sharps: collect in puncture-proof container or sharps container,
    - Bio-hazardous waste: collect in hazardous waste bags (red bag),
    - Non-pathological waste: pour in sink, latrine, or waste pit (black bag).
- All bio-hazardous waste should be incinerated. Outlets with no incinerators should send this waste to larger facilities for incineration.

Learning Unit 3: Basic Techniques in Managing Malaria Commodities

By the end of this session participants should be able to:

- ✓ Describe the basic concepts of malaria commodity management especially for RDTs and malarial medicines,
- ✓ Use commodity management tools to ensure accountability of all commodities in the facility,
- ✓ Adequately report on malaria commodities consumption.

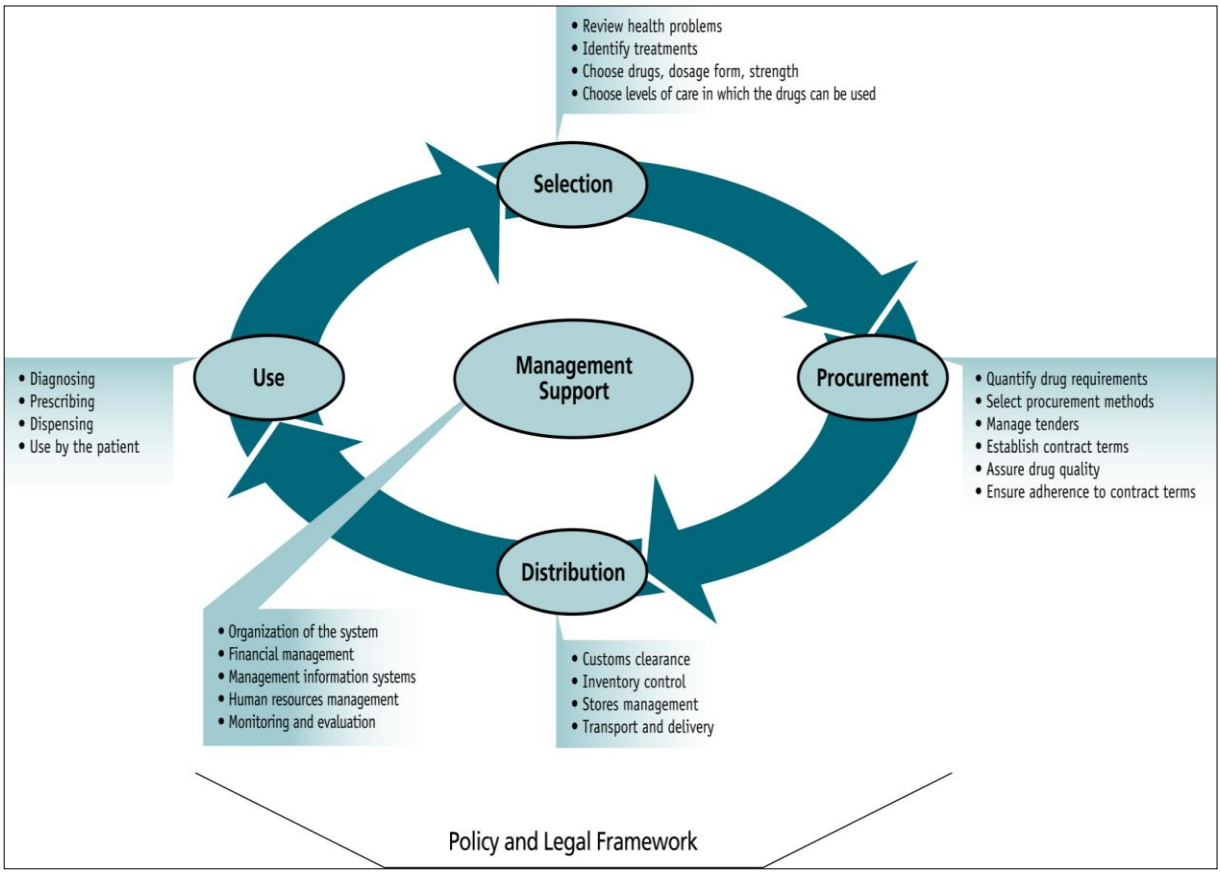
Definition of Commodity Management

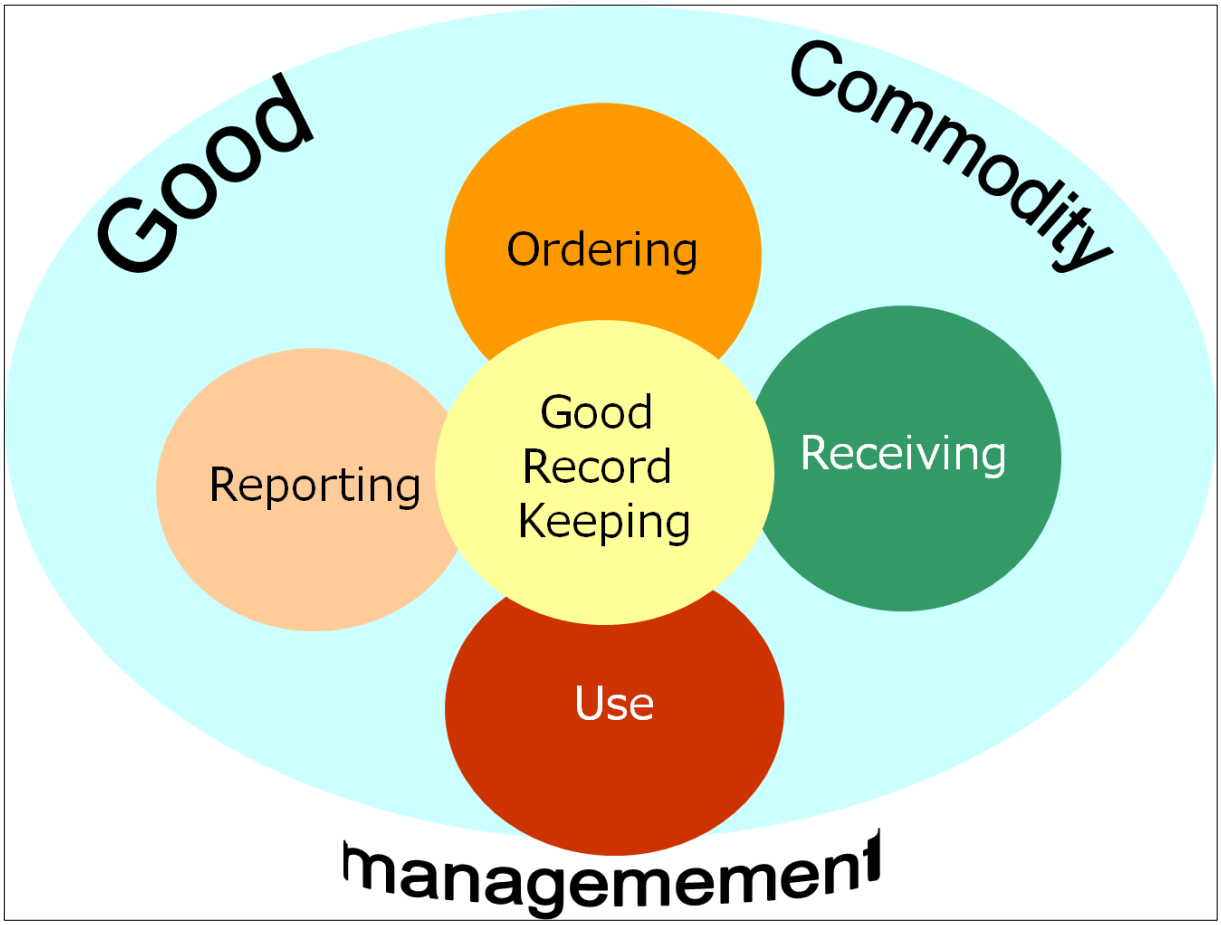
Commodity management is ensuring that the right product of the right quality in right quantities is delivered at right time at right place to the right customer.

Commodity management has to do with:

- Availability,
- Timeliness,
- Safety,
- Effectiveness,
- Quality,
- Rational use of medicines and commodities.

Commodity Management Cycle





How to receive:

- Record any discrepancy or other problem (e.g. wrong item, wrong quantity, damaged item, etc.) on the **EMMS Discrepancy Report Form** (file duplicate copy for health facility records and send original to KEMSA),
- Essentially you are not supposed to accept damaged, deteriorated, expired, excess or otherwise unwanted/unordered items,
- Always enter the received commodities in the BIN Card.

Storage

Good arrangement:

- Keep commodities off the floor, in cartons facing up. This allows easy cleaning and minimizes damage by water.

Good stock rotation:

- Not all commodities have expiry dates. For those that do, the FEFO principle applies.
- For those where all commodities have same expiry dates or the commodities do not have expiry dates, the FIFO principle applies.

Stocking Conditions:

- Store Commodities at manufacturer's recommended conditions (e.g 4-30°C for RDTs),
- Have air conditioner if possible,
- Should have the max-min thermometers,

- Always follow the manufacturers instructions when storing commodities,
- Avoid extreme temperatures: they damage products (>40°C or for some products < 0°C),
- Monitor the temperature regularly at the hottest time of the day (keep thermometers in various zones).

Assured Security, Restricted Access:

- Access to storage areas should be restricted for security reasons,
- All staff who handle supplies should be accountable for their actions,
- One or two trustworthy people should be responsible for keeping the keys, and one should be available on the premises at all times,
- The person in charge of the health facility is ultimately held responsible,
- All storeroom windows should have burglar proofing, and doors must be fitted with security locks,
- Work areas such as the pharmacy or dispensary should have double locks on the doors.

Use

- During dispensing of ACTs and RDTs, all health workers must ensure they record the usage in the provided Daily activity Register for malaria commodities,
- All dispensing procedures should be followed including Direct Observed Therapy (DOT) for the first dose.

Good record keeping

Records to track stock levels and transactions:

- Inventory records,

Other records:

- Temperature record to monitor temperature.

Level of Use	Inventory Record	Information
Receiving and storing commodities	Delivery Notes Bin cards/stock ledger	Confirmation of delivery and receipt of commodities
Issuing	Bin cards S11/S12	Issues to dispensing area or other facilities
Dispensing	Daily activity registers AL register Tally sheets	Amount of commodities actually dispensed to patients
Reporting & Ordering	SORF Health facility monthly summaries	The consumption/dispensed to user data. Stock balances at end of each reporting period

Learning Unit 4: Monitoring & Evaluation

By the end of this session participants should be able to:

- ✓ Describe the importance of Monitoring and Evaluation in malaria case management,
- ✓ Demonstrate the use of various data collection tools in malaria case management,
- ✓ Describe the importance of quality data,
- ✓ Describe the key elements in supportive supervision.

Definitions

- **Monitoring:** the continuous review of the degree to which program activities (i.e. program inputs, output and processes) are completed and targets are met,
- **Evaluation**: periodic assessment of change in targeted results (i.e. outcome or impact) that can be attributed to an intervention.

Importance of M&E in Malaria Case Management

- Accurate quantification,
- Accountability,
- Research.

Indicators, Source and Frequency of Collection and Use in Malaria

	Indicator	Source	Frequency	Use
1	% of clients under 5 years seeking fever treatment through registered private sector outlets	Client register	Monthly	Monitor fever cases footprint into the private sector
2	% of clients under 5 years seeking fever treatment through registered private sector outlets that received an RDT test	Client register / lab register	Monthly	Encourage testing for all malaria suspected cases.
3	% of clients 5 years and above seeking fever treatment through registered private sector outlets that received an RDT test	Client register / lab register	Monthly	Encourage testing for all malaria suspected cases.
4	% of clients under 5 years seeking fever treatment through registered private sector testing positive for Malaria treated with an effective antimalarial.	Lab register AL Register	Monthly	Comparison of confirmed cases against medicine consumption
5	% of clients 5 years and above seeking fever treatment through registered private sector testing positive for Malaria treated with an effective antimalarial	Lab register AL Register	Monthly	Comparison of confirmed cases against medicine consumption
6	Number of tested cases that are negative.	Client register		
7	Percentage of tested cases that are negative managed appropriately	Client register	Monthly	ICM

Sources of data to measure the indicators:

Possible data sources include:

- Various facility registers
- Health facility monthly summary
- Laboratory registers
- Supervision reports
- Surveys
- Delivery notes for AL and RDTs
- AL/RDTs registers

Reporting tools for malaria case management:

Summary reports:

- Facility monthly summary for malaria medicines, with AL/RDT component
- District monthly summary report for malaria medicines, with AL/RDT component

RDT implementation key indicators:

- Percentage of facilities with malaria testing capacity
- Percentage of facilities that have received supervision on malaria (including RDTs) for the last three months
- Percentage of invalid RDTs
- Percentage of RDT negative patients treated with ACT

Data Quality

- The characteristics of good quality data are:
  - Accuracy: only factual information should be reported
  - Timeliness: reports should be submitted within defined deadlines (submit summary report to the district headquarters by the 5th of every month)
  - Completeness: all sections of the report should be filled

Emphasis that data should be analyzed and used at source:

- Reliability and consistency
- Timeliness of service and courtesy,
- Accuracy and convenience
- Completeness

Supportive Supervision

Definition

Supportive supervision is the process of assessing that personnel have the correct knowledge, attitude and skills required to carry out their responsibilities effectively and providing immediate on-the-job training as needed.

Supervision refers to the process of assessing the performance and impact of health providers in specific aspects in malaria case management by the technical expert.

Who should be supervised?

- All health facilities should be supervised with special focus on:
  - facilities with inaccurate or incomplete reports
  - Quality of care assessment
  - non reporting facilities
  - facilities which are under stocked or overstocked

Supervision process

- At district level, a desk review of health facility monthly summary reports
- Planning for field visits and informing the health facility in advance
- Standardized checklists provided in the supervision manual should be used
- Supervision report should be compiled and sent to the next level
- Supervision report should be shared with the health facility too and discussions on areas of improvement held
- Joint Supportive supervision: in this UNITAID project, quarterly joint supportive supervision on a sample of outlets should be conducted by involving the MoH County teams (County Malaria focal person and County Laboratory QAO's). This is to provide added objective supervision and encourage teamwork and collaboration with the MoH staff.

Annexes

Annex 1: Fever Case Management algorithm (private pharmacists and drug sellers)
Annex 2: Integrated Case Management algorithm (private physicians)
Annex 3: Treatment of uncomplicated malaria

ANNEX 1

Fever Case Management
(Pharmacies and Drug Outlets)

Fever

History of fever in the last 48 hours or axillary temperature ≥ 37.5°C

Assess patient for:

1. Signs of Severe Malaria or
2. Danger Signs* or
3. Infant less than 2 months or women in the 1st trimester of pregnancy

IF YES →

Refer urgently

Very Severe Febrile Disease

- Give first dose of artesunate or quinine for severe malaria,
- Give first dose of an appropriate antibiotic,
- Give one dose of paracetamol (38.5° C or above).

IF NO ↓

Perform Malaria RDT

IF TEST NEGATIVE →

Non-Malarial Febrile Illness

1. REFER to investigate other causes of fever.

IF TEST POSITIVE ↓

Uncomplicated Malaria

1. TREAT with ACTs,
2. Refer to investigate other causes of disease,
3. Instruct patient to come back immediately if condition worsen or in 2 days if no improvement.

*** Danger Signs in Children**

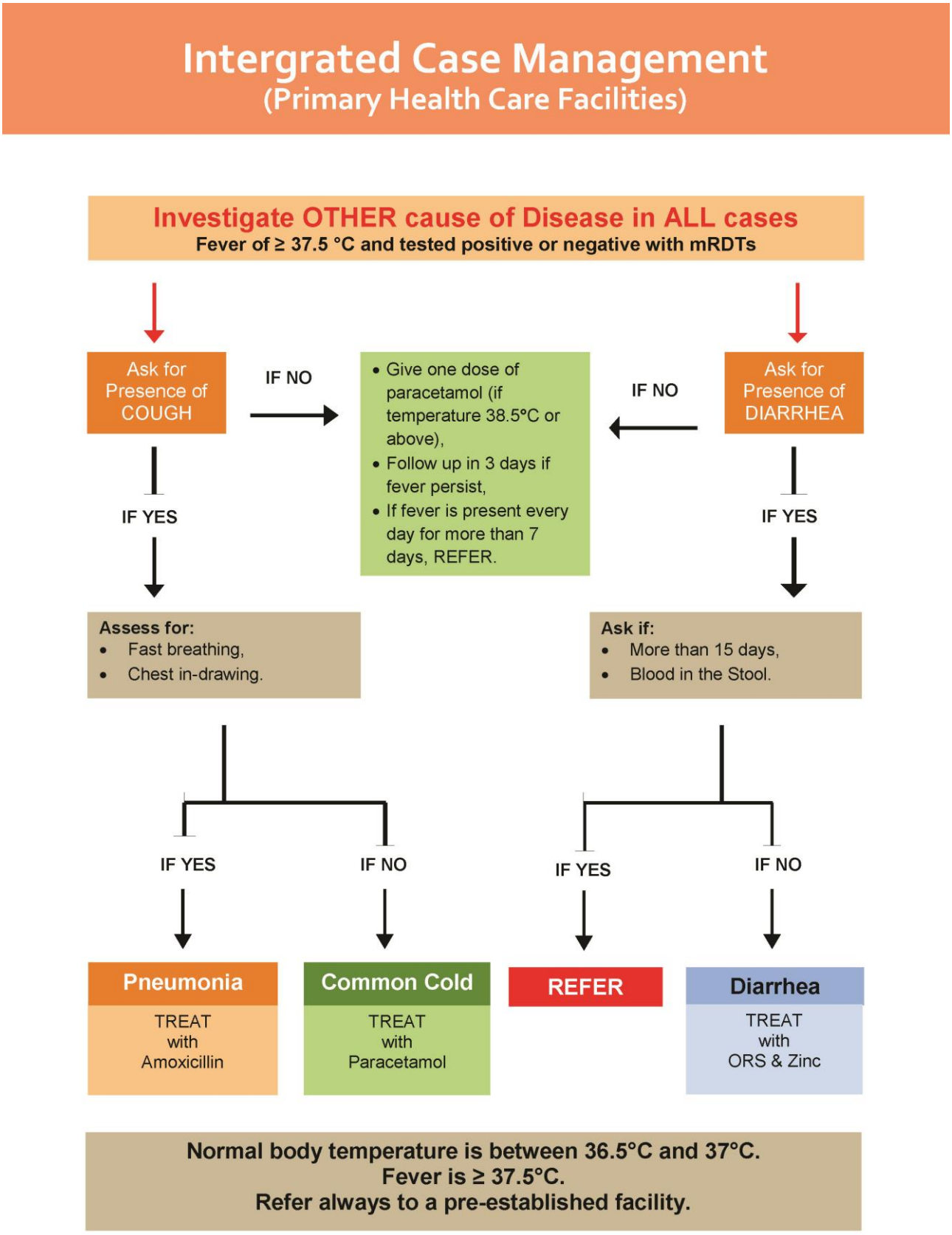
Ask:

- Is the child able to drink or breastfeed?
- Does the child vomit everything?
- Has the child had convulsions?

Look:

- See if the child is very sleepy /no able to awake.
- Is the child convulsing now?

ANNEX 2



Intergrated Case Management
(Primary Health Care Facilities)

Treatment of Pneumonia

Recommended Medicine

Amoxicillin dispersible tablets (250mg)

Dosing Schedule

- Weigh the patient,
- Select appropriate dosage.

2 months up to 12 months (weight: 4 to ≤ 10 Kg)

DAY	Hours	
	0 HRS	12 HRS
ONE	1	1
TWO	1	1
THREE	1	1
FOUR	1	1
FIVE	1	1

12 months up to 5 years (weight: 10 to ≤ 19 Kg)

DAY	Hours	
	0 HRS	12 HRS
ONE	2	2
TWO	2	2
THREE	2	2
FOUR	2	2
FIVE	2	2

Note: if only available amoxicillin tablets of 125mg then double the number of tablets.

Dispensing and Counseling:

- ✓ Tell the patient why (s)he is getting the drug,
- ✓ Explain dosing schedule,
- ✓ Emphasize need to complete all doses even if the patient is feeling better,
- ✓ Demonstrate and give instructions for dispersible formulations of amoxicillin,
- ✓ Give first dose under observation (Direct Observation Therapy),
- ✓ Advise to return IMMEDIATELY if condition worsens,
- ✓ Advise to return after 2 days if fever persists,
- ✓ Check whether the patient or caregiver has understood the instructions before leaving the clinic.

Fever Management:

- Children and Adults: paracetamol,
- Tepid sponging, exposure, fanning, etc.

Fluids and Nutrition:

- Encourage giving extra fluids,
- Continue breastfeeding where applicable.

ANNEX 3

Fever Case Management

Treatment of Uncomplicated Malaria

First Line Treatment

Artemether Lumefantrine (AL)
6 doses given over 3 days

Dosing Schedule

- Weigh the patient,
- Select appropriate dosage.

Weight: 5 to ≤ 15 Kg

DAY	Hours		
	0 HRS	8 HRS	12 HRS
ONE	1	1	
TWO	1		1
THREE	1		1

Weight: 15 to ≤ 25 Kg

DAY	Hours		
	0 HRS	8 HRS	12 HRS
ONE	2	2	
TWO	2		2
THREE	2		2

Weight: 25 to ≤ 35 Kg

DAY	Hours		
	0 HRS	8 HRS	12 HRS
ONE	3	3	
TWO	3		3
THREE	3		3

Weight: > 35 Kg

DAY	Hours		
	0 HRS	8 HRS	12 HRS
ONE	4	4	
TWO	4		4
THREE	4		4

Note:

- 2nd dose on the 1st day should be given 8 hours after the 1st dose,
- Doses on the 2nd and the 3rd days are twice a day (12 hours apart)

STANDARD OPERATING PROCEDURES (SOPs) FOR RDTs

Overview of the SOPs for RDTs

Aim: These Standard Operational Procedures (SOPs) for malaria Rapid Diagnostic Tests (RDTs) are meant to define a standardized procedure to perform RDTs as agreed by private providers, trainers and supervisors enrolled in the UNITAID Private Sector RDT project.

Audience: Private providers, trainers and supervisors who are enrolled in the UNITAID Private Sector RDT project.

Contents:

- Materials required to perform RDTs
- Preparing to perform the test
- RDT procedure.

Materials Required to Perform RDTs

- RDT kit (test cassette, buffer, blood collecting device),
- Sterile lancet,
- Alcohol swab,
- Pencil or pen for labeling,
- Gloves,
- Sharps container,
- Waste disposal container,
- Timer or clock,
- Instruction manual for the specific RDT,
- Dry cotton wool.

Preparing to Perform the Test

1. Gather the necessary materials in the testing area,
2. Check the expiry date at the back of the test package. If the test kit has expired use another test,
3. Ensure the RDT packaging is not damaged by squeezing gently and feel/listen for air leakage. Note: if the foil packaging is damaged, use another test kit,
4. Explain to the patient what the test is for and procedure,
5. Open the package tearing along the nick and look for the following
    a. colour of desiccant (to be consistent with what indicated by the manufacturer),
    b. cassette,
    c. dropper,
6. Remove the cassette from the foil packaging and label it with patient particulars and reading time,
7. Wear a new pair of gloves,
8. Gather the necessary materials in the testing area,
9. Check the expiry date at the back of the test package. If the test kit has expired use another test,
10. Ensure the RDT packaging is not damaged by squeezing gently and feel/listen for air leakage. Note: if the foil packaging is damaged, use another test kit,
11. Explain to the patient what the test is for and procedure,
12. Open the package tearing along the nick and look for the following
    a. colour of desiccant (to be consistent with what indicated by the manufacturer),
    b. cassette,
    c. dropper,
13. Remove the cassette from the foil packaging and label it with patient particulars and reading time,
14. Wear a new pair of gloves,
15. Disinfect the puncture site (4th finger of the non-dominant hand) with an alcohol swab or appropriate disinfectant. The 4th finger is preferred because it's the least used and will cause least inconvenience even if it becomes sore.

RDTs Procedure

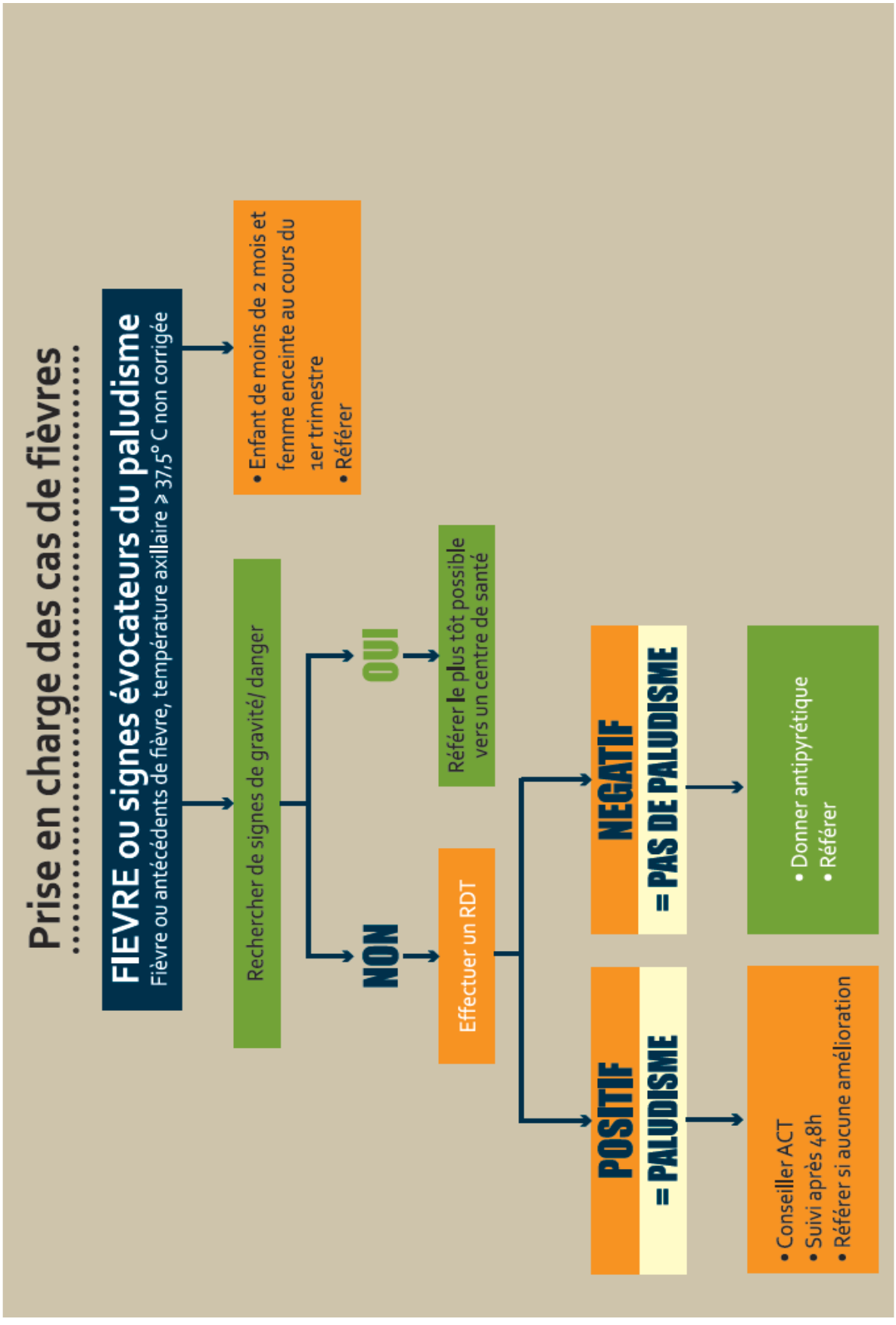
1. Make a gentle prick towards the pulp (ball) of the 4th finger with a sterile lancet at the disinfected site. Pricking at the tip or midline is more painful. Discard the used lancet in an appropriate sharps container immediately after use. By applying gentle pressure to the finger express the first drop of blood and wipe it away with a dry piece of cotton wool. Make sure no strands of cotton remain on the finger to contaminate blood. Apply gentle pressure to the finger until a new blood drop appears. Emphasize the need for the right skills to ensure correct test performance and accurate results. The reason for wiping out the first drop is because it contains too much tissue fluid which might dilute the antigens and it might be contaminated with the alcohol used for wiping the finger.
2. Using the blood collection device (pipette, inverted cup or capillary tube) provided in the RDT kit, gently immerse the open end in the blood drop. Collect the required volume of blood as per manufacturer's instructions. Good blood collection and adequate amount of blood are fundamental to ensure good results. After pricking and collecting blood, apply a dry cotton

wool at the puncture site to stop the bleeding. Discard the blood collection device in the box for infectious waste.

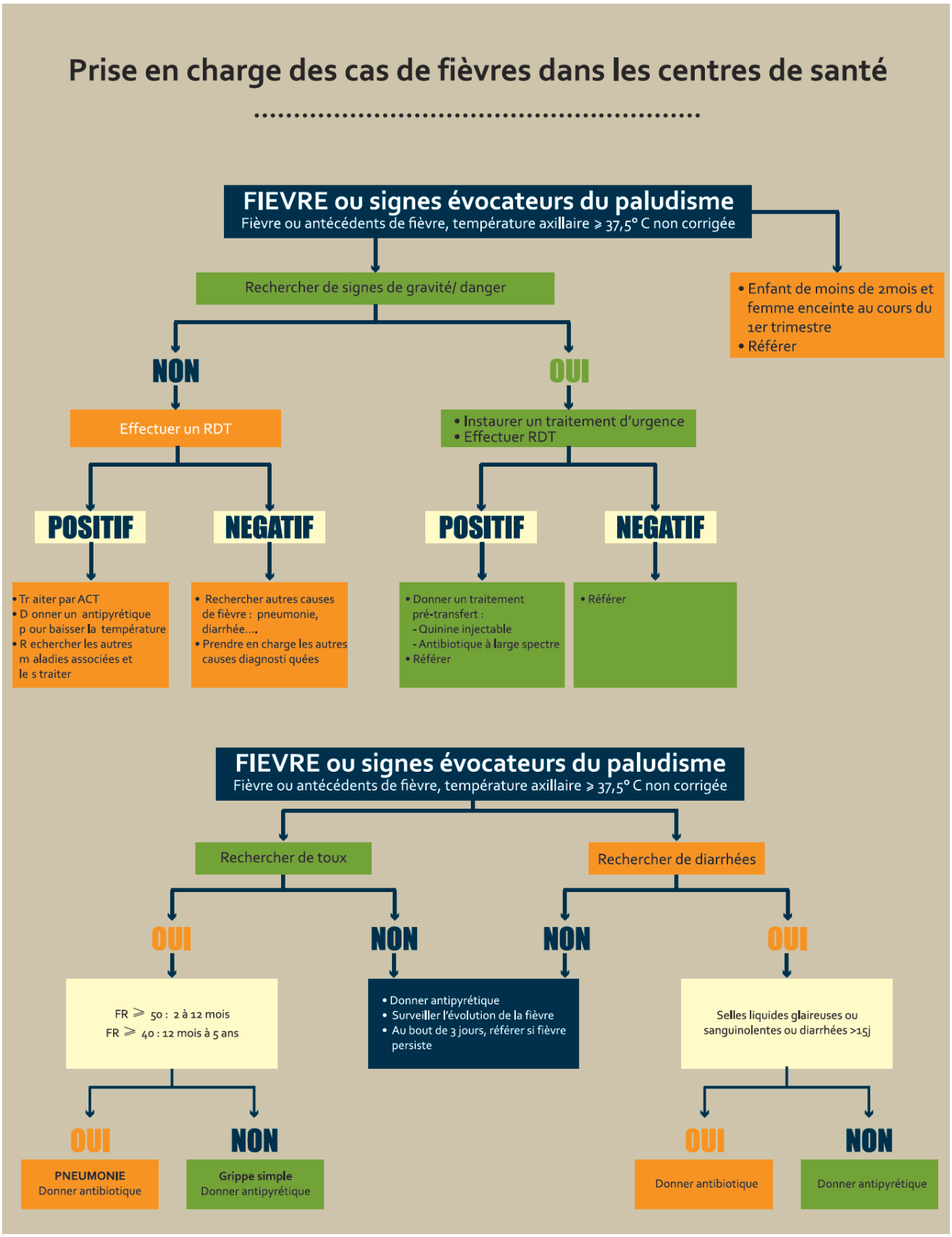
3. Transfer the collected blood to the sample well (as indicated on the RDT cassette by the manufacturer). It's important to put the sample in the right well as indicated by the manufacturer. Different manufacturers may have different labeling for the different wells. Discard the blood collection device in the box for infectious waste.
4. Holding the buffer bottle vertically, add the recommended number of drops of buffer into the buffer well. Put the exact amount of buffer as indicated by the manufacturer at the correct well of the test device and don't use any other buffer apart from the one provided and specified. Some test kits will come with a bottle of buffer for many tests and others will have enough buffer packed for a single test.
5. Time the test as recommended by the manufacturer. View the result window of the cassette for colour band(s).
    a. **Negative** – The presence of only a control band, indicates a negative result for *P. falciparum* malaria. If RDT result is negative, alternative causes of fever should be investigated and treated appropriately. Note: Do not read the results before or after the set time. Don't treat any fever as malaria despite a negative result.
    b. **Positive** – The presence of both a control band and a test band indicates a positive result. Refer to manufacturer's instructions to read positive results.
    c. **Invalid** — If the test does not show the control band, even if there is test band, the test is invalid. Perform another RDT.
    d. Refer to the "RDT Provider job-aid" for pictures of negative, positive and invalid results.
6. Report the results as "RDT Negative" or "RDT Positive" or "RDT Invalid" (in last case the RDT should be repeated. Record patient's information and RDT result in the appropriate register.'
7. Discard the cotton wool, RDT cassette and gloves into the box for infectious waste. Discard empty bottles/ampulla of buffer, instructions and RDT packaging into the box for non-infectious waste.

Annex 3: FCM Algorithm

Pharmacists and Drug Sellers (Madagascar)



Physicians (Madagascar)



Annex 3: FCM Algorithm

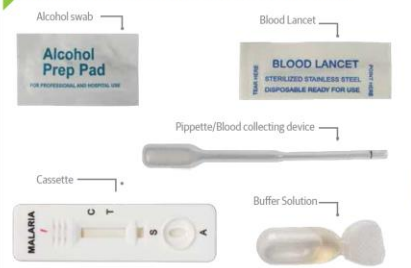
Annex 4: Provider Job Aid

Kenya

HOW TO DO A RAPID TEST FOR MALARIA

REQUIREMENTS FOR TEST PERFORMANCE

a New unopened test kit to include the following:



b New pair of gloves

c Timer

d Sharps box

e Sterile gauze/ cotton wool

PROCEDURE

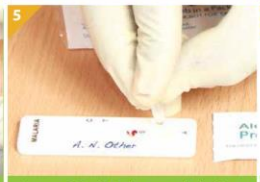
Patient's name

Check expiry date before opening the test kit.
Open & label the test cassette.

Open the alcohol swab. Clean the 4th finger of the patient's non-dominant hand with the alcohol swab. Allow the finger to dry before pricking.
Open the lancet. Prick patient's finger on the side to get a drop of blood.

Wipe the first drop with the sterile gauze/cotton wool. Use the pipette/ collecting device to collect the drop of blood up to the black line.

Transfer the collected blood into the sample well marked "S".



In case of Single Pack, empty the buffer ampoule into the well marked "A". In case of Hospital Pack, add 2 drops of buffer into the well marked "A".

Write down the time when the test result has to be read on the cassette. Read test results after 20 minutes.
NOTE: Do not read the test sooner/later than the recommended time after adding the buffer. You may get FALSE results.

WASTE DISPOSAL

Discard the used lancet, pipette or blood collecting device in the sharp box immediately after use.

Dispose the gloves, alcohol swabs and cassette into the biohazard waste bin and the desiccant sachet and packaging into a general waste bin immediately after use.

This job-aid refers to the CareStart Malaria HRP2 (pf)-GO141 and if other tests are used, the following may change as indicated by the manufacturer: number of buffer drops to use, type of blood collection device, number of minutes to wait before reading the results.

TEST RESULTS

POSITIVE
A line near letter "C" and a line near letter "T" means the patient is POSITIVE for malaria in single species detecting tests.

The test is positive even if the line near "T" is faint.

NEGATIVE
A line near letter "C" and NO LINE near letter "T" means the patient DOES NOT have malaria.

INVALID
NO LINE near letter "C" and one or no line near letter "T" means the test is INVALID.

Perform another RDT using a new RDT kit.

RECORD

Record the test results in your register.

NOTE: Each test can be used ONLY ONE TIME. Do not try to use the test more than once.

Ministry of Health · Roll Back Malaria · CDC · USAID · President's Malaria Initiative · World Health Organization · Johns Hopkins Bloomberg School of Public Health · FIND · Because diagnosis matters · UNITAID · ps Kenya

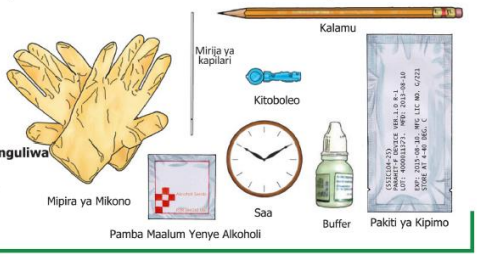
Tanzania

Namna ya Kufanya Kipimo cha Haraka cha Kutambua Vimelea vya Malaria

*Iliyopitishwa kwa ajili ya mafunzo katika matumizi ya kipimo cha **SPAN ParaHIT F** kwa falciparum malaria*

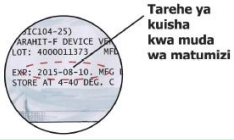
Andaa:

a. Kipimo ambacho **hakijafunguliwa**
b. Saa
c. Kitoboleo **kipya kisichofunguliwa**
d. **Jozi mpya** ya mipira ya mikono
e. Buffer
f. Pamba maalum yenye alkoholi **isiyofunguliwa**
g. Vitupia taka vitatu; cha taka **zenye ncha kali,** taka **zenye uambukizo** na taka **zisizo na uambukizo**
h. Kalamu
i. Kifaa cha **kuhamishia damu**

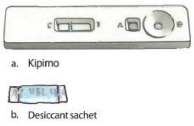


SOMA MAELEKEZO YAFUATAYO KWA MAKINI KABLA HUJAANZA

1. Angalia tarehe ya kumalizika kwa muda wa matumizi kwenye pakiti ya kipimo.



2. Fungua pakiti na utoe:



3. Andika utambulisho wa mgonjwa na tarehe.

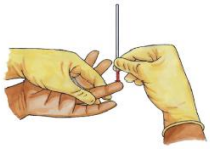
4. Vaa mipira ya mikono (glavu). Tumia mipira ya mikono mipya kwa kila mgonjwa.

5. Safisha ncha ya kidole cha pete cha mkono wa kushoto na pamba maalum yenye alkoholi na subiri kidole kikauke kabla ya kukitoboa.

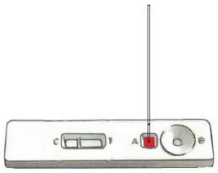
6. Toboa ncha ya kidole cha mgonjwa. Hakikisha kuwa ncha ya kitoboleo haigusi kitu chochote kabla ya kutoboa ncha ya kidole cha mgonjwa.

7. Tumbukiza kitoboleo katika sanduku la kutupia vitu vyenye ncha kali haraka mara baada ya kutoboa kidole. **Usiweke kitoboleo chini kabla ya kukitupa.**

8. Tumia kifaa cha kuhamishia damu kuchukua damu kutoka kwenye ncha ya kidole cha mgonjwa



9. Weka tone la damu kwenye tundu "A" kwenye kipimo



10. Tumbukiza kifaa cha kuhamishia damu kwenye **sanduku la taka zenye ncha kali.**

11. Weka buffer kwenye shimo mduara kwenye alama **"B".**

12. Andika muda wa kuanza baada ya kuweka buffer na muda utakaosoma majibu juu ya kipimo

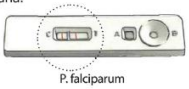
13. Subiri **dakika 25** baada ya kuweka buffer.

14. Soma majibu zitimiapo **dakika 25** na si **zaidi ya dakika 30** baada ya kuongeza buffer

15. Namna ya kusoma majibu:

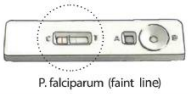
CHANYA (POSITIVE)

Kuna mstari kwenye herufi **"C"** na mstari kwenye herufi **"T"** inamaanisha kuwa kipimo ni chanya kwa malaria.



P. falciparum

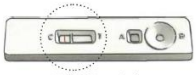
kipimo ni chanya hata kama mstari kwenye herufi **"T"** ni hafifu.



P. falciparum (faint line)

HASI (NEGATIVE)

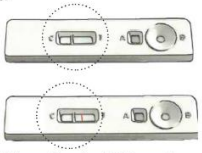
Kuna mstari kwenye herufi **"C"** lakini hakuna msitari kwenye herufi **"T"**. Maana yake hakuna vimelea vya malaria kwenye damu ya mgonjwa



Hasi (Negative)

MAJIBU BATILI (INVALID RESULTS)

Hakuna mstari kwenye herufi **"C"**, au, hakuna mstari kwenye herufi **"C"** na herufi **"T"**, au, kuna mstari kwenye herufi **"T"** pekee.



Rudia kipimo ukitumia mRDT mpya kama hakuna mstari uliojitokeza kwenye herufi **"C"**.

Kama hakuna mstari uliojitokeza karibu na herufi "C", rudia kipimo ukitumia pakiti ya kipimo **KIPYA** na kitoboleo **KIPYA**.

16. **MUHIMU**

i. Tumbukiza kitoboleo na kifaa cha kuhamisha damu kwenye sanduku la taka zenye ncha kali.
ii. Tumbukiza mipira ya mikononi, pamba maalum yenye alkoholi na kipimo kwenye kasha la taka zenye uambukizo.
iii. Tupa bahasha (kifungashio) ya kipimo, "Desiccant" na bahasha ya pamba maalum yenye alkoholi kwenye kasha la taka zisizo na uambukizo

17. Rekodi majibu ya kipimo kwenye rejesta ya mRDT na rejesta wagonjwa"

KUMBUKA: Kila kipimo kinaweza tumika **MARA MOJA TU**. Usijaribu kutumia kipimo kwa zaidi ya mara moja.

mRDT

Tanzania

NATIONAL MALARIA CONTROL TANZANIA

WORLD HEALTH ORGANIZATION

Madagascar

KENYA: Private sector Malaria RDT register Instructions

How to complete: Every week ensure you start a new register sheet unless the number of clients exceeds the rows provided, then turn to another sheet but indicate its same week as previous

Use a tick [√] to mark the service provided to the client in the client register.

Aggregate the information, in the summary section provided below (for clients under 5 years on the left section (Blue) and that of 5 years and above on the right hand section (orange)

Note:

+ Test not done also includes clients that have been referred from other outlets having undertaken a test and/or client coming with a prescription
+ Where more than one treatment is provided to the client, only pick the main treatment provided based on the test results
+ QAACT; Refers to Quality Assured Artemisinin-based Combination Therapy. Any other Quality Assured ACTs apart from AL should also be reported as QAACTs, in the same columns provided for AL
+ Other treatment also includes other antimalarials that are not ACTs and antibiotics

For those tested with microscopy, aggregate only the positive and negative cases in the section provided (Purple)

When to complete: At the end of every week, aggregate the summary numbers from the client information recording into the respective box of the summary section

Who completes: This register should be completed by the provider who provides the service to the clients, while the summary section can be filled in by a designated staff who manages health records at the outlet

Example: HOW TO FILL THE SUMMARY SECTION

Date (dd/mm/yyyy)	Client ID/No.	Clients Age		Weight Category (kg)				Microscopy		RDTs			Test not Done	Treatment/Action					
		<5 Yrs	5 Yrs+	5 -14	15-24	25-34	35+	Pos	Neg	Pos	Neg	Inv		AL 6's	AL 12's	AL 18's	AL 24's	Referred	Other treatment/ action
01/02/2015	001	√		√						√				√					√
04/02/2015	004	√		√							√								√
02/02/2015	003	√		√									√						√
02/02/2015	002		√			√					√							√	√
07/02/2015	005		√				√			√							√		√

Step 1: Confirm clients' age → Step 2: Confirm type of test done → Step 3: Confirm test results → Step 4: Confirm treatment provided → Step 5: Add up the total → Step 5: Enter value in appropriate box

Under 5 years (<5 years)	RDT positive		RDT Negative			Test Not done		5 years and over (>=5 Years)	RDT positive		RDT Negative			Test Not done		RDT Invalid	Microscopy	
	QAACT	Other treatment	QAACT	Referred	Other treatment	QAACT	Other treatment		QAACT	Other treatment	QAACT	Referred	Other treatment	QAACT	Other treatment		Positive	Negative
	1				1		1		1			1						

Private Sector Malaria RDT Register

Outlet Name: _____ County: _____ Month: _____

Outlet ID: _____ Sub-County: _____ Week: _____

Date (dd/mm/yyyy)	Client ID/No.	Clients Age		Weight Category (kg)				Microscopy		RDTs			Test not Done	Treatment/Action						Comments
		<5 Yrs	5 Yrs+	5 -14	15-24	25-34	35+	Pos	Neg	Pos	Neg	Inv		AL 6's	AL 12's	AL 18's	AL 24's	Referred	Other treatment/ action	

Under 5 years (<5 years)	RDT positive		RDT Negative			Test Not done	
	QAACT	Other treatment	QAACT	Referred	Other treatment	QAACT	Other treatment

5 years and over (>=5 Years)	RDT positive		RDT Negative			Test Not done	
	QAACT	Other treatment	QAACT	Referred	Other treatment	QAACT	Other treatment

RDT Invalid

Microscopy	
Positive	Negative

QAACT; Refers to Quality Assured Artemisinin-based Combination Therapy. Any other Quality Assured ACTs apart from AL should also be reported as QAACTs, in the same columns provided for AL

Other treatment; 1. Other antimalarial 2:Antibiotics

Completed By (Name) : _____ **Job Title:** _____ **Signature:** _____ **Date:** _____

Annex 6: Assesment Checklist

Tanzania

PROVIDER ASSESSMENT CHECKLIST					
Date(ddmmyyyy) _____ District_____					
Outlet Name _____ Outlet ID_____					
Supervisor Name _____ Supervisor ID_____					
General Information	1	Name of the provider interviewed_____			
	2	Job title of the provider_____			
	3	Has the provider received any IMCI training through the project?			Yes/No
	4	Are their other staff(s) who have received IMCI training through the project?			Yes/No
Use the section below to assess the competence of the provider with regards to case management of Malaria, Diarrhoes and Pneumonia.					
Are the assessments done on a real patient?Insert the correct answer			Yes/No	Yes/No	Yes/No
		Intergrated case management - Competency assessment	**Case 1 (Malaria)**	**Case 2 (Diarrhoea)**	**Case 3 (Pneumonia)**
Case Management	1	Ask patients identification (name AND age AND sex AND first vs. re-visit)	Yes/No	Yes/No	Yes/No
	2	**Assesses for general danger signs (all 6)**	Yes/No	Yes/No	Yes/No
	3	Asks and look for main symptoms	Yes/No	Yes/No	Yes/No
	4	**Classify patient's illness correctly**	Yes/No	Yes/No	Yes/No
	5	**Gives correct treatment as per iCCM manual (full course and observe patient take 1st dose)**	Yes/No	Yes/No	Yes/No
	6	(i)Makes correct referral decision (ii)Referral facilitated (gives referral slip, first dose as appropriate)	Yes/No	Yes/No	Yes/No
	7	**Counsels (correct messages, including correct drug AND dose AND duration and when to return for follow-up)**	Yes/No	Yes/No	Yes/No
	8	Confirms understanding (probe for questions AND request mother/patient to repeat instructions)	Yes/No	Yes/No	Yes/No
		-			
	1	**Records Review - Correct relation between classification/diagnosis and treatment for last month**	Yes/No	Yes/No	Yes/No
Case management competence score		*Case management competence score will be automatically generated taking into account the key steps highlighted in bold* **Target: 80% and above**		0%	
Use the section below to assess the competence of the provider in demostrating the key steps in performing an RDT.					
		Rapid Malaria Test -Competency assessment			**Case 1 (Malaria)**
mRDT Procedure	1	Assembles new test packet,swab, buffer, pipette, lancet and gloves			Yes/No
	2	**Puts a new pair of gloves**			**Yes/No**
	3	(a) Explains the procedure to the client			Yes/No
		(b) Checks the intergrity of the test envelope.			Yes/No
		(c) Checks the expiry date of the test and the buffer			Yes/No
		(d) Uses the buffer on the RDT kit			Yes/No
		(e) Opens the test envelope and checks the desiccant sachet to observe texture and colour change according to manufacturer			Yes/No
		(f) Writes patient's name and ID on cassette			Yes/No
		(g) Places cassette on a level surface			Yes/No
	4	**Cleans finger with antiseptic/ alcohol**			**Yes/No**
	5	Allows finger to dry before pricking it			Yes/No
	6	**Use a sterile lancet for finger pricking**			**Yes/No**
	7	Puncture the side of the ball of the finger			Yes/No
	8	**Disposes off lancent in sharps bin immediately after pricking finger**			**Yes/No**
	9	Collect blood with the enclosed pipette making sure to fill close to the first cross line			Yes/No
	10	**Using a pipette, blots blood onto the pad in the correct well**			**Yes/No**
	11	Disposes of pipette in sharps container immediately			Yes/No
	12	**Dispense correct number of drops of clearing buffer into the correct well**			**Yes/No**
	13	**Wait correct time before reading negative results** (positive results may be read before the specified time if control line has appeared. Results should not be read after the maximum specified time minutes)			**Yes/No**
	14	**Read the results test correctly**			**Yes/No**
	15	Record results in the register			Yes/No
	16	**Dispose gloves, wrappers, alcohol swab and dessicant safely**			**Yes/No**
mRDT procedure competence score		*mRDT procedure competence score will be automatically generated taking into account the key steps highlighted in bold* **Target: 80% and above** **Critical Score - Only bolded questions** **General Score - All questions**			**0%**
Overall quality of care competence Classification		*Overall quality of care competence score will be automatically generated taking into account the case management and mRDT procedure competency scores* **Above 80% (at least one competence assessment every quarter)** **50% - 80% (At least 2 competence assesment every quarter)** **Below 50% (One competence assessment every month until reach 3 in the quarter)**			**0%**
Use the sections below to assess the work environment(workplace, equipment,supplies and consumables, documentation and reporting) at the outlet.					
Workplace assessment	1	Adequate water supply(Sufficient for outlet operations)			Yes/No
	2	Adequate lighting(Sufficient for reading test)			Yes/No
	3	Space for conducting RDT(Confidentiality)			Yes/No
	4	Presence of job Aids			Yes/No
	5	RDTs stored in a dry place away from direct sunlight			Yes/No
		Workplace assessment score (automatically generated as %)			**0%**
Equipent,supplies and consumables assessment		*Based on the assessment WEEK, check if the following stocks are present;* *(Where more than one item is provided indicate Yes if all present, if ANY is not present Supervisor will need to note for followup)*			
	1	Alcohol, Lancets, Gloves			Yes/No
	2	Timers, Lead/grease pencils,marker pens			Yes/No
	3	Biohazard wate bags			Yes/No
	4	Cotton wool,Disinfectants,Soap			Yes/No
	5	Sharps container			Yes/No
	6	**RDTS in stock on day of Visit** *(Tick Yes ONLY IF there are Quality assured brands in stock)*			Yes/No
	7	**RDTS stock outs of Quality asssured brands in past 3 Months** *(Tick Yes , if the stock out LASTED MORE THAN 1 week/7 days)*			Yes/No
	8	ACTS *(Tick Yes ONLY IF there are Quality assured brands in stock)*			Yes/No
		Equipent,supplies and consumables assessment score (automatically generated as %)			**0%**

Assessment Checklist Tanzania Cont.

Work environment score	*Work envirnment score will be automatically generated taking into account the workplace assessment and 'equipment,supplies and consumables' assessment* **Target: 80% and above**		**0%**
Documentation and reporting	*Based on the month preceeding the assessment, identify if the following are present;*		
	1	Logbook/register/record book is present at the outlet	Yes/No
	2	The patients details are recored and organised in legible manner, including Date of test is recorded	Yes/No
	3	Results of the tests are recorded/if not test action taken is recorded	Yes/No
	4	Reports for the weeks preceding the assement have been submitted	Yes/No
	Documentation and reporting assessment score (%)		**0%**
Overall supervision visit assessment score	*Overall supervision visit assessment score will be automatically generated taking into account the 4 key aspects of the supervision visit.* **Target: 80% and above**		**0%**
Comments/follow-up:			
I confirm that the information above is accurate, based on engagement with the provider during the supervision visit - Yes/No **Supervisor electronic signature**_____			

Madagascar

CHECKLIST de SUPERVISION			
Date(dd/mm/yyyy) _____		District _____	
Nom du centre ou Point de distr _____		ID du centre ou Point de distribution _____	
Nom du Superviseur _____		ID du Superviseur _____	
Information Générale	1	Nom du prestataire interviewé _____	
	2	Titre du prestatire _____	
	3	Est-ce que le prestatire a reçu une formation pour diagnostiquer les causes probables de fievre à travers ce projet? Oui / Non	Yes No
	4	Y a-t-il d'autres staff(s) qui ont reçu des formations pour diagnostiquer les causes probables de fievre à travers ce projet? Oui / Non	Yes No
Utiliser les sections sivantes pour évaluer les compétences des prestataires sur les prises en charge des maladies suivantes: paludisme, diarrhées et pneumonie. Pour chaque étape énumérée ci-dessous, Insérer 1 si l'observation est OUI sinon 0			
Est-ce que l'évaluation a été faite avec un vrai client?i Oui Non			Yes No
Prise en charge intégrée - Evaluation des compétences			**Cas (Paludisme)**
Prise en charge	1	Demander l'identité du client (nom ET age ET sexe ET adresse ET première visite VS. seconde visite ou plus)	Yes No
	2	**Evaluer les signes de graviter (cf liste en bas de page)**	Yes No
	3	Effectuer RDT	Yes No
	4	Si signe de gravite : i)Faire une décision correcte pour la référence ii)Facilitation de la référence (donner ordonnance/carnet de santé de référence, première dose appropriée)	Yes No
	5	Si pas de signe de gravite: Demander et chercher les principaux symptomes	Yes No
	6	**Classifier correctement la maladie (Selon l'algorithme de la PEC de la fievre)**	Yes No
	7	**Prescrire le traitement correct suivant la guideline; RDT>0 [prescrire ACT; Femme enceinte 1er Trimestre Quinine comprimee] RDT<0 [pas ACT]**	Yes No
	8	Premiere prise d'ACT supervisee	Yes No
	9	**Counseils (messages correctes, incluant médicament correcte, dose correcte, durée correcte ET quand est-ce qu'il faut revenir pour le suivi)**	Yes No
	10	Confirmer la compréhension (Sonder en posant des questions ET demander à la mère/accompagnant de répéter les instructions)	Yes No
	11	**Revu des données - Relation correcte entre classification/diagnostique et traitement pour le mois dernier**	Yes No
Compétence sur la prise en charge			
Incapacité de boire ou de téter ou de s'alimenter, Vomissements incoercibles, Convulsions multiples (Plus de deux épisodes par 24 heures), Prostration (Le malade est incapable de marcher ou de s'asseoir sans assistance), Somnolence/obnubilation, Troubles de conscience ou coma aréactif, Respiration profonde, détresse respiratoire, oedème pulmonaire, Collapsus cardio-vasculaire ou Etat de choc, TA Systolique < 70 mg Hg chez l'adulte et < 50 chez l'enfant, Ictère clinique , Urine coca cola, Saignements spontanés anormaux			
Utiliser les sections ci-dessous pour évaluer les compétences des prestataires démontrant les étapes clés pour effectuer un test utilisant un RDT.			
Test de diagnostic rapide pour le paludisme - Evaluation de compétence			**Cas 1 (Paludisme)**
Procedure mRDT	1	Préparer les fournitures pour le kit neuf: désinfectant, solution tampon, lancet, pipette et gant	
	2	**Mettre un nouveau pair de gant**	Yes No
	3	i)Vérifier la date d'expiration sur l'emballage ii)Vérifier si le sachet déssicant est bien sec (couleur) iii)Ecrire le nom ou ID du client sur la cassette iv)Mettre la cassette sur une surface plane et horizontale	Yes No
	4	**Nettoyer le doigt avec un antiséptique/alcool**	Yes No
	5	Laisser sécher le doigt avant de piquer	Yes No
	6	**Utiliser une lancet sterile pour piquer le doigt**	Yes No
	7	Piquer sur le côté lateral de l'extremité du doigt (annulaire)	Yes No
	8	**Jeter la lancet dans une boîte de sécurité immediatement après la piqûre**	Yes No
	9	Prélever le sang nécessaire avec la pipette en veillant de remplir près de la première ligne horizontale	Yes No
	10	**Aspirer le sang à l'aide d'une pipette et le verser avec precision dans la fenêtre**	Yes No
	11	Jeter immédiatement la pipette dans un sac pour déchets souillés non tranchant	Yes No
	12	**Verser le nombre suffisant de gouttes de solution tampon dans la fenêtre/puits approprié**	Yes No
	13	**Respecter le temps de lecture mentioné dans la notice avant de lire les résultats négatifs**	Yes No
	14	**Lire correctement les résultats suivant la notice**	Yes No
	15	Noter les résultats dans le registre	Yes No
	16	**Jeter les gants, enveloppe, tampon imbibé d'alcool et le dessicant dans un sac pour déchets non tranchant**	Yes No
Compétence sur la procédure mRDT	**La note pour la compétence sur la procédure mRDT sera automatiquement compilée prenant en compte les étapes clés mentionnées en gras Objectif: 80% ou plus**		
Classification de compétence sur la qualité globale de soin	*La note sur la classification de compétence sur la qualité globale de soin sera automatiquement compilée prenant en compte la prise en charge et la procédure d'exécution de mRDT* **plus de 80% (au moins une évaluation sur la compétence tout le trimestre) 50% - 80% (au moins deux évaluations sur la compétence tout le trimestre) en dessous de 50% (une évaluations sur la compétence par mois jusqu'à obtenir 3 visites pour le trimestre)**		
Utiliser les sections suivantes pour évaluer l'environnement de travail (lieu de travail, equipement, fournitures et consommables, documentation et reporting) au niveau du centre ou point de distribution.			
Evaluation du lieu de travail	1	Source d'eau adéquate(Suffisant pour le centre ou le point de distribution)	Yes No
	2	Lumière adéquate(Suffisant pour lire les résulttas du test)	Yes No
	3	Place adéquate pour effectuer le RDT(Confidentialité)	Yes No
	4	Job Aids est disponible	Yes No
	Note sur l'évaluation du lieu de travail (automatiquement généré en %)		
Evaluation: équipement, fournitures et consommables	*Basé sur l'évaluation hebdomadaire, vérifier si le stock est disponible pour les articles suivants: (S'il y a plus d'un article, indiquer YES ou si tout est présent; s'il y a aucun article le superviseur doit noter pour le suivi)*		
	1	Alcool, lancet et Gant	Yes No
	2	Timers, Crayon/stylo/marqueur	Yes No
	3	Sac pour objets souillés non tranchant	Yes No
	4	Cotton, désinfectant, savon	Yes No
	5	Boîte de sécurité (sharp container)	Yes No
	6	**RDT en stock le jour de la visite** (Mettre YES s'il y a de la qualité assurée en stock)	Yes No
	7	**Rupture de stock en RDT** plus d'une semaine/7 jours dans les **3 derniers mois**	Yes No
	8	ACT (Mettrez YES si seulement il y a une marque classée qualité assurée en stock)	Yes No
	Note sur l'évaluation: équipement, fourniture et consommables (automatiquement généré en %)		

Madagascar Assessment Checklist Cont.

Work environment score	*Work envirnment score will be automatically generated taking into account the workplace assessment and 'equipment,supplies and consumables' assessment* **Target: 80% and above**		**0%**
Documentation and reporting	*Based on the month preceeding the assessment, identify if the following are present;*		
	1	Logbook/register/record book is present at the outlet	Yes/No
	2	The patients details are recored and organised in legible manner, including Date of test is recorded	Yes/No
	3	Results of the tests are recorded/if not test action taken is recorded	Yes/No
	4	Reports for the weeks preceding the assement have been submitted	Yes/No
	Documentation and reporting assessment score (%)		**0%**
Overall supervision visit assessment score	*Overall supervision visit assessment score will be automatically generated taking into account the 4 key aspects of the supervision visit.* **Target: 80% and above**		**0%**
Comments/follow-up:			
I confirm that the information above is accurate, based on engagement with the provider during the supervision visit - Yes/No **Supervisor electronic signature**_____			

Using the Health Network Quality Improvement System (HNQIS) for Provider Assessment

In order to address challenges related to monitoring the quality of care given by providers, PSI established the **Health Network Quality Improvement System (HNQIS).** HNQIS is an electronic tablet-based system principally focused on enabling supervisors to:

- ✓ Effectively **plan** their support visits prioritizing where support is required, and where it will have most impact
- ✓ Undertake **assessments** with comparable scoring and benchmarking mechanisms
- ✓ Consistently and effectively provide **feedback** and coaching following assessments
- ✓ **Monitor** performance of providers over time in order to understand the return on their support efforts and conduct mid-course corrections (such as refresher trainings).

HNQIS is fully functional without Internet connectivity and operates off an Android application linked with the information management system Demographic Health Information Software 2 (DHIS2), an open source technology adopted by many ministries of health across the world. The system consists of four modules designed to support the focus areas above and is applicable to a range of health providers.

Plan module

This module automatically schedules future assessments based on where support is needed most (quality score), and where it will have most impact (client load). Furthermore, the planning module prioritizes planning of support visits by segmenting all outlets into (i) those that have never been assessed, (ii) those with overdue assessments, (iii) those scheduled to be assessed in the current month, (iv) those scheduled to be assessed in future months. Each health area has independent planning variables (quality score/client load), but the planning report is integrated across all areas the supervisor is responsible for supporting.

Assess module

This module enables supervisor to assess clinical procedures in each health area catered for by network providers through case observation or simulation. The assessment checklist is aligned with national supervision checklists. An assessment score is automatically generated on-site, and performance is subsequently benchmarked (e.g. Good/ Satisfactory/Poor). The module contains a consistent approach to scoring and benchmarking all health areas to allow comparability within and across network providers Informaiton collected from this module is used in the three other modules.

Improve module

This module ensures that provider feedback following a quality assessment is undertaken in a robust and consistent manner, rather than based on the subjectivity of the supervisor. The module (i) highlights the key areas of weakness identified during the assessment, (ii) displays tailored feedback scripts that take into account both how the procedure should be undertaken (as per protocols), as well as why it is important to do so. This places all the relevant information required to improve the performance of the provider in one place. The module facilitates a consistent approach to provision of feedback, eliminating subjectivity regarding the areas of focus or the actual feedback provided.

Monitor module

This module consists of a performance monitoring dashboard tailored to meet the needs of the supervisor. The dashboard contains a range of charts, graphs, maps and tables highlighting trends and overall performance of all the providers the supervisor is responsible for supporting. Dashboards can also be used to visualize data collected through other channels that is relevant to quality improvement, such as availability and sales of health commodities. The main purpose of this module is to facilitate the use of data in decision-making at the supervisor level. It offers the supervisor an opportunity to track the return on their support visit efforts over time, so as to give them insight on where they need to apply a different approach. The system also allows to develop tailored interfaces to meet the need in terms of data of different users of HNQIS (i.e. project managers, medical detailers, etc.), and therefore enable mid-course correction (e.g. conducting a refresher course in a particular, low performing health area).

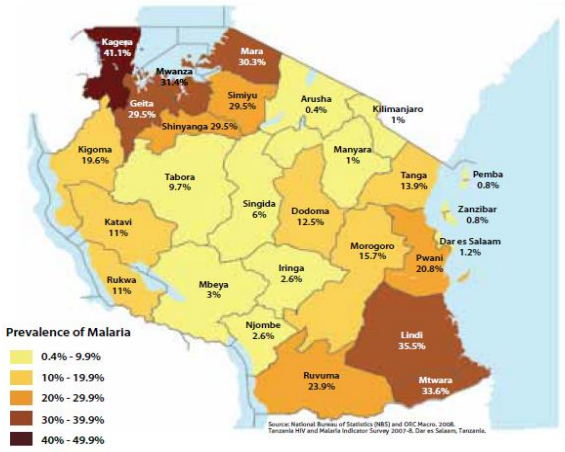
Annex 8: Supervisor Job-Aid

CURRENT MALARIA SITUATION IN TANZANIA

According to Tanzania HIV and Malaria indicator survey (THMIS) 2011, Malaria prevalence has declined in Tanzania from 18% in 2007 to 10% in 2011. In addition, Malaria has dropped by almost half within five years among children under 5years, it likely that the prevalence among adults is even lower.

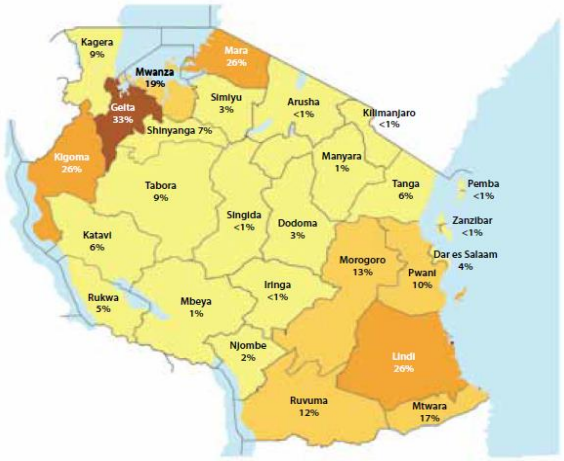
2007

Prevalence of Malaria in Children 6 – 59 months, 2007/8



2011

Prevalence of Malaria in Children 6 – 59 months, 2011/12



▸ ***Recommendation:***
Not all fever is Malaria. It is important to diagnose correctly and prescribe the right treatment

Annex 8: Supervisor Job-Aid

TEST BEFORE YOU TREAT USING mRDT

Why is it important to test for Malaria?

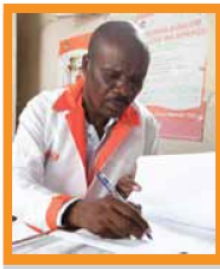
The old policy said clinical diagnosis was acceptable.

Now, because of declining prevalence, a high proportion of fever patients do not have malaria.

Clinical diagnosis will incorrectly diagnose many patients.

▸The new government policy says that:

ALL SUSPECTED MALARIA CASES SHOULD BE CONFIRMED WITH A BLOOD TEST BEFORE TREATING FOR MALARIA



▸ John – Provider in Muheza, Tanga.

"I have many patients everyday who come to me with fever but not all fever is Malaria. I use RDT to test them for correct diagnosis".

Mechanism Of Action

The mechanism of action is Antigen - Antibody reaction

Why mRDT?

- **It is recommended by WHO and MOHSW to be used in Tanzania where Malaria prevelance is declining.**
- **Quick and easy to use.**
  Results are obtained between 15 to 25 minutes (depending on the manufacturer).
  Can be performed by any trained health care provider
- **Reliable**
  High sensitivity (88 - 99%).
  High specificity (95 - 100%).
- **Helps to rapidly identify patients who might have other serious non-malarial illness**
- **Simple "yes or no" answer for malaria**
- **Low-cost**
  Doesn't require electricity or expensive equipment.
- **More profit**

MAMA FURAHA

FEVER CASE MANAGEMENT

FOR ALL CASES OF FEVER WITH SUSPECTED MALARIA, TEST WITH mRDT TREAT POSITIVE CASES WITH AN ACT, AND INVESTIGATE FOR OTHER DISEASES

▶ **Mama Furaha – Lives in a malaria endemic area**

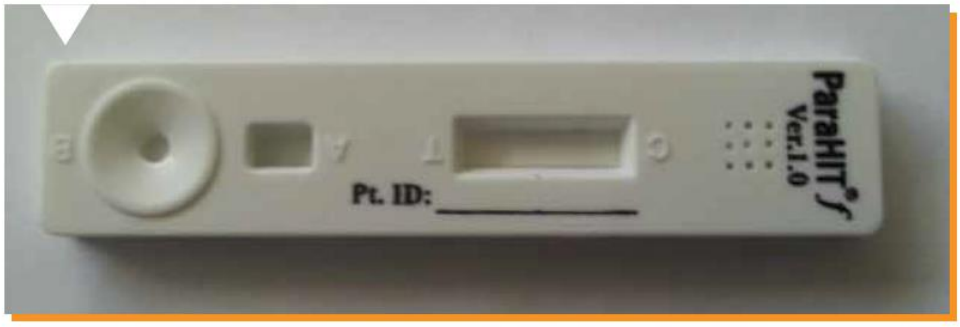
Brings in her 24-month old son who has a history of fever for two days. On examination you find that she is in fair general condition, weighs 20kg, with temperature 39.2°C. The rest of the physical examination is normal.

"What do you recommend I give her?"

▶ *Request for diagnostic testing to confirm or exclude malaria*

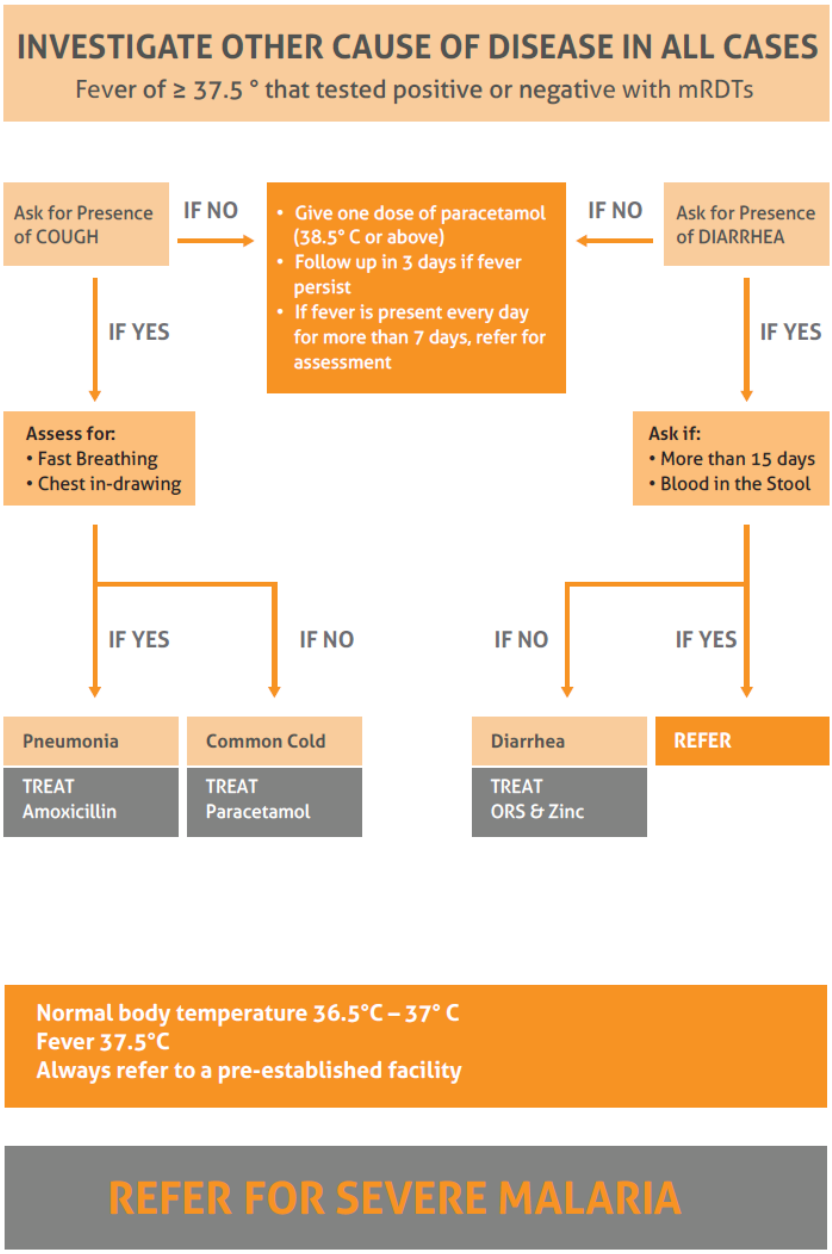
Why?

- Many illnesses cause fever and have symptoms common to malaria.
- When everyone with fever is treated for malaria, drug resistance increases and people with other illnesses do NOT get the right treatment.



Annex 8: Supervisor Job-Aid

FEVER CASE MANAGEMENT



STANDARD OPERATING PROCEDURES (SOPs) FOR MEDICAL QUALITY ASSURANCE (QA) AUDITS

Medical QA audits target to the wider frame of fever case management (FCM) quality standards and evaluate if activities implemented within the UNITAID project are in fulfillment with international standards on clinical service delivery. SOPs for audit are required to standardize the process that evaluates FCM quality standards in the 5 UNITAID countries. The main output of audits is a list of findings and follow-up actions to raise the bar of quality in FCM service provision.

SOPs for audit should follow the 6 main components of audits:

1. **Auditor orientation** between the auditor, country medical coordinator, supervisors and country teams,
2. **In-country management review/orientation meeting** between supervisors, country medical coordinator and country teams to review the country program approach focusing on service delivery models, type of outlets employed and supervisory systems,
3. **Document and service statistics review**,
4. **Site visits** conducted by the auditor and the country medical coordinator on project sites, supported by country teams as appropriate,
5. **Debrief** at which observations and conclusions from the visits will be discussed and at which country teams and supervisors will address any concerns with development of an action plan,
6. **Audit report** which will be reviewed by the medical coordinator. Country teams will be required to respond and develop an action plan for key findings and follow-up activities.

Composition of Audit Team

The QA audit team will be composed of the auditor (the QA Advisor or an external auditor), the country medical coordinator, plus relevant country staff and supervisors. The auditor will have inside knowledge of FCM, the country program, and the country context that will allow him/her to bring a complementary perspective to the audit. The role of the programmatic auditor will be to focus on factors such as:

- Assessing supervision system to ensure it operates in accordance with the UNITAID QA plan;
- Assessing the adequacy of supervision systems, including factors such as supervision frequency, quality of feedback and appropriateness of actions taken in response to feedback, etc;
- Assessing adherence to national guidelines, FCM quality standards, SOPs, algorithms and guidelines on record-keeping, counseling, and referrals.

Planning for an Audit

1. The auditor will participate in an **orientation** (in person or by phone) by the country medical coordinator, country team and supervisors. The objectives of this orientation will be to:
   a. Review the planned agenda/schedule for the visit,
   b. Orient the team to the evaluation philosophy, tools and instruments to be used,
   c. Brief the team on any problematic issues they are likely to face,
   d. Address any questions or concerns the team members might have.

   Responsibility: The county medical coordinator will conduct the auditor's orientation prior to the audit. Prior to the visit, the auditor will also be responsible for reviewing country QA plans and reports from previous audits.

2. In-country **management review** by country program staff. Objectives:
   a. The auditor will become oriented to:
      - the local "platforms" (type of providers, supply channels, outlets, etc.),
      - challenges noted by local program staff in meeting their objectives,
   b. Review the country-specific QA plan developed by local country team with focus on assessments and monitoring systems,
   c. Review service statistics accumulated during the evaluation period, including numbers of providers trained, clients served, outlets enrolled, etc.

   Responsibility: Country teams should prepare briefing documents and presentation, while the auditor will get most of this supportive material through the DHIS2.

3. **Document review**: to audit the presence and utility of documentation being used in-country as record outlet checks, training manuals, job-aids, etc. The auditor will:
   a. Conduct a review to ensure that key QA tools are in place and assess quality and comprehensiveness of documents, including protocols and policies,
   b. Also look for documentation related to assessment records, including:
      - Evidence of sign-off by supervisors before providers begin service delivery,
      - Records and findings of provider performance assessments,
      - Documentation of steps taken following assessments, etc.

   Responsibility: Prior to the document review, the county team should pull together documentation and have it easily accessible for the auditor to review. Again, the auditor will combine this information with the ones obtained through the DHIS2 and will review supervisory reports.

4. **Travel to field sites** to directly observe quality of FCM at provider level and review on-site documentation in a sampling of outlets countrywide. The auditor will:

a. Evaluate the components of quality being assessed (e.g. technical competence, client safety and counseling, outlet adequacy, etc.). To record the quality of FCM at provide level, the auditor will use the audit scorecard, based on service delivery standards for FCM. Refer to Annex 1 for further information.
b. Provide feedback to country teams and country medical coordinator concerning observations in the field,
c. Observe and evaluate assessments being conducted by supervisors,
d. Create summary of findings and recommendations.

Responsibility: the auditor should be accompanied by the country medical coordinator, supervisors where needed, and appropriate country team.

5. **De-briefing** with senior country staff. The auditor will:
   a. Present observations, conclusions and recommendations,
   b. Take the lead in providing service delivery "lessons learned" to project/MoH staff by other UNITAID countries,
   c. Facilitate creation of an action plan in collaboration with local country team,
   d. Give an update on specific topics (biological waste disposal, danger signs, treatment of uncomplicated vs complicated malaria, etc.) if desired/requested by either country team or project partners,
   e. Listen to and record feedback or questions and concerns from local staff about challenges they face in regards to ensuring QA best practices in FCM of the UNITAID project and also concerns related to the audit visit.

   Responsibility: The auditor will debrief the country medical coordinator, country teams and supervisors.

6. The country medical coordinator, supervisors and country team will write an **evaluation report** to be provided to the auditor within 2 weeks of leaving the field. The report will include observations, conclusions and recommendations. The auditor will determine priority findings and country teams will prepare an action plan based on auditor's feedback.

   Responsibility: The audit team in country will prepare the report and send it to the auditor, who will then share it with relevant UNITAID project staff.

Medical Quality Assurance (QA) Audit Scorecard

	Benchmark	Means of verification	Fully met (2)	Partially met (1)	Not met (0)	Action plan
STANDARD 1| Technical Competency						
1.1- RDTs should be performed by licensed/registered providers who are authorized by the government to do so.	Copy of official license or registration authenticated by the government	Provider's folder/file				
1.2- All personnel providing RDT services in affiliation with the programs must have received training from PSI/MC, MoH, or accredited organizations approved by PSI/MC.	Copy of the training certificate approved by PSI	Provider's folder/file				
1.3- Providers must perform RDTs according to the relevant protocol.	Correct execution of critical steps: infection prevention control, correct blood collection, safe lancet disposal, correct RDT performance, correct interpretation of results	Past assessments or direct observation				
1.4- PSI/MC-affiliated providers will have a current letter of agreement with PSI/MC that clearly stipulates the roles and responsibilities of both parties and consequences of non-compliance.	Copy of the initial agreement between the owner of the outlet and PSI/MC	Provider's folder/file				
1.5- Agreements with PSI/MC-affiliated providers must be renewed on annual basis, pending satisfactory evaluation of providers' overall skills and procedural compliance.	Copy of the renewed agreement for the current year based on last year provider's overall skills and procedural compliance	Provider's folder/file				
		Sub-score: Technical competency		0	/10	
STANDARD 2| Client Safety						
2.1- Providers must check for danger signs and obtain a medical history from the caregiver/patient.	Providers check for danger signs and obtain medical history from caregivers/patients	Past assessments or direct observation				
2.2- Providers must properly identify, test and treat/refer fever cases in accordance with the government approved treatment algorithm for the level of provider.	Providers properly follow government's algorithm on FCM	Past assessments or direct observation				
2.3- All PSI/MC-affiliated clinics where PSI/MC's program refer patients must comply with Service Delivery Standards and are approved by a PSI/MC medical representative.	Selected referral facilities comply with Service Delivery Standards	Direct observation of referral facilities*				
2.4- Facilities must have all required equipment (ie: RDTs, gloves, safe disposal units) and appropriate drugs (ie: ACTs and antipyretics).	All required equipment and drugs are in place	Past assessments or direct observation				
2.5- Facilities must assure all the conditions to prevent infections (hand-washing procedure, decontamination equipment, antiseptic detergents, etc).	Facilities ensure infection prevention control measures	Direct observation				
2.6- Facilities must ensure appropriate bio-hazard waste management: presence of appropriate waste disposals (sharp and infectious, non-sharp and infectious, non-infectious) and waste management system in place.	Facilities ensure bio-hazard waste management	Direct observation				
		Sub-score: Client safety		0	/12	
STANDARD 3| Privacy and Confidentiality						
3.1- Services must be performed in a setting that offers clients privacy in accordance with relevant government regulation (i.e. the setting is screened from view of others).	Privacy is secured at outlet level	Past assessments or direct observation				
3.2- Precautions must be taken to ensure that client records are stored safely and confidentially.	Confidentiality is secured at outlet level	Past assessments or direct observation				
		Sub-score: Privacy and confidentiality		0	/4	
STANDARD 4| Continuity of Care						
4.1- Providers must ensure that the patient/caregiver receives accurate information regarding on how to manage the case at home and identify signs of risk.	Caregiver/patient receives appropriate counselling and instructions for follow-up cares	Past assessments or direct observation				
4.2- Providers must give relevant documentation to the patient/caregiver and ensure that s/he understands the case management procedures and that s/he is firm and clear about the treatment or referral.	Providers ensure patients/caregivers' understanding of the instructions given for follow-up cares and provide supportive documentation (takeaways, etc.)	Past assessments or direct observation				
4.3- Providers or facilities must provide clients with information on who to call or where to go (approved referral sites) in case of emergency and complications.	Caregivers/patients are exposed to contacts of referral sites or referral providers	Past assessments or direct observation				
4.4- PSI/MC programs must have one of the recommended mechanisms to assess client satisfaction with services, including counseling, provider access, and follow-up care.	Follow-up action plan in place based on findings from EIs, HH surveys or qualitative research activities	Folllow-up action plan on client satisfaction with services				
		Sub-score: Continuity of care		0	/8	
		TOTAL SCORE		0	/34	
		TOTAL SCORE (%)		0%		

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