Quality Assurance for Fever Case Management in the Private Sector

A Manual for Practitioners
UNITAID QA PLAN

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

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

1| Plan
Policy and Strategy Tools:
- National guidelines on FCM in the private sector
- FCM quality standards

2| Do
Provider Competency Tools:
- Provider training manual
- SOPs for RDTs
- FCM algorithm
- Provider job-aid

3| Check
Quality Monitoring Tools:
- Client register
- Assessment checklist
- SOPs for assessment
- Supervisor job-aid
- Quality of care reports

Medical audit tools:
- SOPs for audit
- Audit checklist

4| Act
On-going Support:
- Trainings
- Marketing plan
- PBCC plan
- Advocacy, etc.
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: 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.

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

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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.

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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.
**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.
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

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/QA ACTs 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

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<th>Means of Verification</th>
<th>Metric</th>
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<tr>
<td><strong>1) Productivity</strong></td>
<td><strong># of patients with fever attended at facility/outlet level</strong></td>
<td>DHIS2</td>
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</table>
| **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

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.
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 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
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

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<td>Children under five</td>
</tr>
<tr>
<td>FCM</td>
<td>Fever Case Management</td>
</tr>
<tr>
<td>ICM</td>
<td>Integrated Case Management</td>
</tr>
<tr>
<td>IPT</td>
<td>Intermittent Preventive Treatment</td>
</tr>
<tr>
<td>IRS</td>
<td>Indoor Residual Spraying</td>
</tr>
<tr>
<td>LLINs</td>
<td>Long-Lasting Insecticide-treated Nets</td>
</tr>
<tr>
<td>NMCP</td>
<td>National Malaria Control Program</td>
</tr>
<tr>
<td>PfPR</td>
<td><em>Plasmodium falciparum</em> Prevalence Rate</td>
</tr>
<tr>
<td>RDTs</td>
<td>Rapid Diagnostic Tests</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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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\(^3\):

---

Kenya has four malaria epidemiological zones:

<table>
<thead>
<tr>
<th>Districts</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lake Victoria and coast region</td>
<td>Endemic: &gt; 20%</td>
</tr>
<tr>
<td>Western highlands</td>
<td>Epidemic-prone: 5 to ≤ 20%</td>
</tr>
<tr>
<td>Arid and semi-arid districts</td>
<td>Seasonal transmission: 0.1 to ≤ 5%</td>
</tr>
<tr>
<td>Central highlands including Nairobi</td>
<td>Low risk: &lt; 0.1%</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Epidemiology</th>
<th>Case Management</th>
<th>LLIN</th>
<th>IRS</th>
<th>Health Education/BCC</th>
<th>IPTp</th>
<th>EPR</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lake stable endemic &amp; Coast seasonal stable Endemic</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Highland epidemic prone</td>
<td>X</td>
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<td>Seasonal low transmission including arid and Semi arid</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Low risk</td>
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</table>
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,

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

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 outbreaks,
- Research and surveys,
- Improve malaria disease surveillance by reporting confirmed (true) cases.

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.

RDT Quality

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,
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:
  o Wear a laboratory coat,
  o Wear a new pair of gloves,
  o Wash hands,
  o Disinfect working bench: the recommended disinfectant could be 10% hypochlorite.
• Segregate waste material as follows:
  o Sharps: collect in puncture-proof container or sharps container,
  o Bio-hazardous waste: collect in hazardous waste bags (red bag),
  o 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.

<table>
<thead>
<tr>
<th>Level of Use</th>
<th>Inventory Record</th>
<th>Information</th>
</tr>
</thead>
</table>
| 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/dispens 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**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Source</th>
<th>Frequency</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  % of clients under 5 years seeking fever treatment through registered private sector outlets</td>
<td>Client register</td>
<td>Monthly</td>
<td>Monitor fever cases footprint into the private sector</td>
</tr>
<tr>
<td>2  % of clients under 5 years seeking fever treatment through registered private sector outlets that received an RDT test</td>
<td>Client register / lab register</td>
<td>Monthly</td>
<td>Encourage testing for all malaria suspected cases.</td>
</tr>
<tr>
<td>3  % of clients 5 years and above seeking fever treatment through registered private sector outlets that received an RDT test</td>
<td>Client register / lab register</td>
<td>Monthly</td>
<td>Encourage testing for all malaria suspected cases.</td>
</tr>
<tr>
<td>4  % of clients under 5 years seeking fever treatment through registered private sector testing positive for Malaria treated with an effective antimalarial.</td>
<td>Lab register AL Register</td>
<td>Monthly</td>
<td>Comparison of confirmed cases against medicine consumption</td>
</tr>
<tr>
<td>5  % of clients 5 years and above seeking fever treatment through registered private sector testing positive for Malaria treated with an effective antimalarial</td>
<td>Lab register AL Register</td>
<td>Monthly</td>
<td>Comparison of confirmed cases against medicine consumption</td>
</tr>
<tr>
<td>6  Number of tested cases that are negative.</td>
<td>Client register</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7  Percentage of tested cases that are negative managed appropriately</td>
<td>Client register</td>
<td>Monthly</td>
<td>ICM</td>
</tr>
</tbody>
</table>
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 worsens 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?
Intergrated Case Management
(Primary Health Care Facilities)

Investigate OTHER cause of Disease in ALL cases
Fever of ≥ 37.5 °C and tested positive or negative with mRDTs

Ask for Presence of COUGH
IF YES
Assess for:
- Fast breathing,
- Chest in-drawing.
IF NO

Give one dose of paracetamol (if temperature 38.5°C or above),
- Follow up in 3 days if fever persist,
- If fever is present every day for more than 7 days, REFER.

Ask for Presence of DIARRHEA
IF YES
Ask if:
- More than 15 days,
- Blood in the Stool.
IF NO

Pneumonia
TREAT with Amoxicillin
IF YES
Common Cold
TREAT with Paracetamol
IF NO
REFER
Diarrhea
TREAT with ORS & Zinc
IF YES

Normal body temperature is between 36.5°C and 37°C.
Fever is ≥ 37.5°C.
Refer always to a pre-established facility.
Treatment of Pneumonia

Recommended Medicine

Amoxicillin dispersible tablets (250mg)

Dosing Schedule

- Weigh the patient,
- Select appropriate dosage.

<table>
<thead>
<tr>
<th>Day</th>
<th>2 months up to 12 months (weight: 4 to ≤ 10 Kg)</th>
<th>12 months up to 5 years (weight: 10 to ≤ 19 Kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 HRS</td>
<td>12 HRS</td>
</tr>
<tr>
<td>ONE</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>TWO</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>THREE</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>FOUR</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>FIVE</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Weight: 5 to ≤ 15 Kg</th>
<th>Weight: 15 to ≤ 25 Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DAY</strong></td>
<td><strong>Hours</strong></td>
</tr>
<tr>
<td>ONE</td>
<td>1</td>
</tr>
<tr>
<td>TWO</td>
<td>1</td>
</tr>
<tr>
<td>THREE</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight: 25 to ≤ 35 Kg</th>
<th>Weight: &gt; 35 Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DAY</strong></td>
<td><strong>Hours</strong></td>
</tr>
<tr>
<td>ONE</td>
<td>3</td>
</tr>
<tr>
<td>TWO</td>
<td>3</td>
</tr>
<tr>
<td>THREE</td>
<td>3</td>
</tr>
</tbody>
</table>

**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)
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)

**Prise en charge des cas de fièvres**

- FIEVRE ou signes évocateurs du paludisme
  - Febrile ou antécédents de fièvre, température axillaire ≥ 37,5°C non corrigée
  - Enfant de moins de 2 mois et femme enceinte au cours du 3er trimestre
  - Référer

- Rechercher des signes de gravité/cânter
  - OUI
    - Réféler le plus tôt possible vers un centre de santé
  - NON
    - Effectuer un RDT

- RÉSULTAT
  - NÉGATIF = PAS DE PALUDISME
    - Donner antipyrétique
    - Référer
  - POSITIF = PALUDISME
    - Conseiller ACT
    - Suivi après 4h
    - Référer si aucune amélioration
Prise en charge des cas de fièvres dans les centres de santé

**FIEVRE ou signes évocateurs du paludisme**
Fièvre ou antécédents de fièvre, température axillaire ≥ 37.5°C non corrigée

- Rechercher de signes de gravité danger

  - **NON**
    - Effectuer un RDT
      - **POSITIF**
        - Trarther par ACT
        - Donner un antipyrétique
        - Prendre en charge les autres causes de fièvre
        - Hôpitaux associés et le s traiter
      - **NEGATIF**
        - Rechercher autres causes de fièvre : pneumonie, diarrhée ...
        - Prendre en charge les autres causes diagnostiquées
  
  - **OUI**
    - Instaurer un traitement d’urgence
      - Effectuer RDT
      - **POSITIF**
        - Donner un traitement précocement
        - Quinine injectable
        - Antibiothérapie à large spectre
        - Référer
      - **NEGATIF**
        - Référer

**FIEVRE ou signes évocateurs du paludisme**
Fièvre ou antécédents de fièvre, température axillaire ≥ 37.5°C non corrigée

- Rechercher de toux

  - **OUI**
    - FR ≥ 50 : 2 à 12 mois
    - FR ≥ 40 : 12 mois à 5 ans
  
  - **NON**

- Rechercher de diarrhées

  - **OUI**
    - Selles liquides, glaireuses ou sanguinolentes ou diarrhées >15J
  
  - **NON**

**PNEUMONIE**
Donner antibiotique

**Grippe simple**
Donner antipyrétique
Annex 4: Provider Job Aid

Kenya

HOW TO DO A RAPID TEST FOR MALARIA

REQUIREMENTS FOR TEST PERFORMANCE

New unopened test kit to include the following:
- Alcohol wipe
- Blood lancet
- Cassette
- Buffer solution
- Repellent/blood collecting device
- Timer

New pair of gloves

Sharps box

Sterile gauze/ cotton wool

PROCEDURE

1. Check expiry date before opening the test kit.
2. Open Alcohol wipe and clean the test cassette.
3. Open the alcohol wipe. Clean the 4th finger of the patient’s non-dominant hand with the alcohol wipe. Allow the finger to dry before picking. Open the lancet. Prick patient’s finger on the side to get a drop of blood.
4. 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.
5. Transfer the collected blood into the sample well marked “S”.
6. Incubate Single Pack, emery the buffer ampoule into the well marked “A”. In case of Hospital Pack, add 2 drops of buffer into the well marked “S”.
7. Write down the time when the test result has to be read on the cassette. Read test results after 20 minutes.

WASTE DISPOSAL

1. Discard the used lancet, pipette or blood collecting device in the sharps box immediately after use.
2. Dispose of gloves, alcohol wipes and collection device into the designated waste bin and the desiccant packet and packaging into a general waste bin immediately after use.

TEST RESULTS

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

NEGATIVE
4 lines near letter “C” and NO LINE near letter “T” means the patient does NOT have malaria.

INVALID
NO LINE near letter “C” and NO LINE near letter “T” means the test is INVALID.

RECORD

Record the test results in your register.

Note: A blank test can be used ONLY ONCE. Do not try to use the test more than once.

This job aid is based on the CareLabs Malaria HRP2 (pfs2HqA) and RDT tests and the following may have been used: the manufacturer’s number of buffer drops to use, type of blood collection device, number of minutes to wait before reading the results.

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Tanzania

Namna ya Kufanya Kipimo cha Haraka cha Kutambua Vimelea vya Malaria
Ilyopitisha kwa ajili ya mafunzo katika matumizi ya kipimo cha SPAN ParaHIT F kwa falciparum malaria

SOMA MAELEKEZO YAFUATAYO KWA MAKINI KABA HUAANZA

1. Angalia tamba ya kumalatika kwa muda au matumizi kwenye pakti ya kipimo.

2. Pungua pakti na uoto:

3. Andika utambulisho wa mgonjwa na tontoni.


5. Safla, ncho ya kikolo chako cha mgonjwa. Haki hilo inaweza kusaidia kwa kiwango cha kubadilika kabla ya kubadili kwa ncho ya mgonjwa.


7. Tumbukiza kikolo cha mgonjwa na kudhibitiwa kuwa unuhusiana kwa kuchachua mgonjwa. Tumia mgonjwa na kufikia kiamania.

8. Tumia kikolo cha mgonjwa na kufikia kiamania.


10. Tumbukiza kikolo cha mgonjwa na kudhibitiwa kuwa unuhusiana kwa kuchachua mgonjwa. Tumia mgonjwa na kufikia kiamania.

11. Waka tana la damu kwenye tunato "B" kwenye kipimo.

12. Andika muda na kwano basi na kufikia buffer na muda utumiaji mgonjwa au kipimo.


15. Namna ya kusoma maji:

CHANYA (POSITIVE)
Kama mstoni kivunye herufi "C" na mstoni kivunye herufi "F" namna 15 ilikuwa kwa kipimo ni changa kwa malaria.

Kufikia kipimo ni changa kwa kama mstoni kivunye herufi "T" ni hatu.

HASI (NEGATIVE)
Kama mstoni kivunye herufi "C" lakini hakuna matumizi kivunye herufi "T".
Majibu yake hakuna vinirea ywa mstoni kivunye damu ya mgonjwa.

MAJIBU BATILI (INVALID RESULTS)
Hakuna mstoni kivunye herufi "C", au, hakuna mstoni kivunye herufi "T" na herufi "F", au, kama mstoni kivunye herufi "F" pelezi.

Ruda kipimo utumiaji mRDT mpaka kama hakuna mstoni uliokubali kivunye herufi "C".

KAMBAKA: Kila kipimo kinaweza tumika MARA MOJA TU. Ujijiari kutumia kipimo kwa zaidi ya mara moja.

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Annex 4. Provider Job-aid
**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.
+ QA ACT: Refers to Quality Assured Artemisinin-based Combination Therapy. Any other Quality Assured ACTs apart from AL should also be reported as QA ACTs, 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**

<table>
<thead>
<tr>
<th>Date</th>
<th>Client ID/No.</th>
<th>Clients Age</th>
<th>Weight Category (kg)</th>
<th>Microscopy</th>
<th>RDTs</th>
<th>Test Not Done</th>
<th>Treatment/Action</th>
<th>Other treatment/ action</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/02/2015</td>
<td>001</td>
<td>✓</td>
<td>&lt;5 yrs</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>04/02/2015</td>
<td>004</td>
<td>✓</td>
<td>5-14</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>02/02/2015</td>
<td>003</td>
<td>✓</td>
<td>15-24</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>02/02/2015</td>
<td>002</td>
<td>✓</td>
<td>25-34</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>07/02/2015</td>
<td>005</td>
<td>✓</td>
<td>35+</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**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):**

<table>
<thead>
<tr>
<th>RDT positive</th>
<th>RDT negative</th>
<th>Test Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA ACT</td>
<td>Other treatment</td>
<td>QA ACT</td>
</tr>
<tr>
<td>Other treatment</td>
<td>QA ACT</td>
<td>Other treatment</td>
</tr>
</tbody>
</table>

| 5 years and over (≥ 5 years): |

<table>
<thead>
<tr>
<th>RDT positive</th>
<th>RDT negative</th>
<th>Test Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA ACT</td>
<td>Other treatment</td>
<td>QA ACT</td>
</tr>
<tr>
<td>Other treatment</td>
<td>QA ACT</td>
<td>Other treatment</td>
</tr>
</tbody>
</table>
# Private Sector Malaria RDT Register

**Outlet Name:** __________  
**County:** __________  
**Month:** __________  
**Sub-County:** __________  
**Week:** __________

<table>
<thead>
<tr>
<th>Date (dd/mm/yyyy)</th>
<th>Client ID/No.</th>
<th>Clients Age</th>
<th>Weight Category (kg)</th>
<th>Microscopy</th>
<th>RDTs</th>
<th>Test not done</th>
<th>Treatment/Action</th>
<th>Other treatment/action</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;5 yrs</td>
<td>5-14</td>
<td>15-24</td>
<td>25-34</td>
<td>35+</td>
<td>AL 6’s</td>
<td>AL 12’s</td>
<td>AL 18’s</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AL 24’s</td>
<td></td>
<td>Referred</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

**Under 5 years (<5 years)**

<table>
<thead>
<tr>
<th>RDT positive</th>
<th>RDT Negative</th>
<th>Test Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA ACT</td>
<td>QA ACT</td>
<td>QA ACT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other treatment</th>
<th>QA ACT</th>
<th>Referred</th>
<th>Other treatment</th>
<th>QA ACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other treatment</td>
<td>QA ACT</td>
<td>Other treatment</td>
<td>QA ACT</td>
<td></td>
</tr>
</tbody>
</table>

**5 years and over (≥5 Years)**

<table>
<thead>
<tr>
<th>RDT positive</th>
<th>RDT Negative</th>
<th>Test Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA ACT</td>
<td>QA ACT</td>
<td>QA ACT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other treatment</th>
<th>QA ACT</th>
<th>QA ACT</th>
<th>Referred</th>
<th>Other treatment</th>
<th>QA ACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other treatment</td>
<td>QA ACT</td>
<td>QA ACT</td>
<td>Other treatment</td>
<td>QA ACT</td>
<td></td>
</tr>
</tbody>
</table>

**RDT Invalid**

<table>
<thead>
<tr>
<th>Microscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
</tr>
</tbody>
</table>

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

Other treatment: 1. Other antimalarial  2. Antibiotics

Completed By (Name): __________________  
Job Title: __________________  
Signature: __________________  
Date: __________________
Annex 6: Assessment Checklist

Tanzania

**PROVIDER ASSESSMENT CHECKLIST**

<table>
<thead>
<tr>
<th>Date (mm/dd/yyyy)</th>
<th>District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outlet Name</td>
<td>Outlet ID</td>
</tr>
<tr>
<td>Supervisor Name</td>
<td>Supervisor ID</td>
</tr>
</tbody>
</table>

### 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, Diarrhoea and Pneumonia.

Are the assessments done on a real patient? Enter the correct answer: Yes/No

#### Integrated case management - Competency assessment

**Case 1 (Malaria)**

| 1. Assess patients identification (name AND age AND sex) and first vs. re visita | Yes/No |
| 2. Assess for general danger signs (all 5) | Yes/No |
| 3. Assess and look for main symptoms | Yes/No |
| 4. Classify patient’s illness correctly | Yes/No |
| 5. Gives correct treatment as per ICMM manual (full course and observe patient take 1st dose) | Yes/No |
| 6. Updates correct referral destination (if referral facilitated, gives referral slip; first dose as appropriate) | Yes/No |
| 7. Tells mother/caregiver correct messages, including correct drug and dose AND duration and when to return for follow-up | Yes/No |
| 8. Confirms understanding (ask for questions AND request mother/patient to repeat instructions) | Yes/No |

**Case 2 (Diarrhoea)**

| 1. Records Review - Correct relation between classification/diagnosis and treatment for last month | Yes/No |

**Case 3 (Pneumonia)**

| Case management competence score | Yes/No |

Case management competence score will be automatically generated taking into account the key steps highlighted in bold.

Target: 80% and above

Use the section below to assess the competence of the provider in demonstrating the key steps in performing an RDT.

#### Rapid Malaria Test - Competency assessment

<table>
<thead>
<tr>
<th>Case 1 (Malaria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assemble test cards (check expiry, buffer, pipette, lancet and gloves)</td>
</tr>
<tr>
<td>2. Put a new pair of gloves</td>
</tr>
<tr>
<td>3. (a) Explains the procedure to the client</td>
</tr>
<tr>
<td>4. (b) Checks the integrity of the test envelope</td>
</tr>
<tr>
<td>5. (c) Checks the expiry date of the test and the buffer</td>
</tr>
<tr>
<td>6. (d) Uses the buffer on the slip</td>
</tr>
<tr>
<td>7. (e) Opens the test envelope and checks the desiccant packet to observe texture and colour change according to manufacturer</td>
</tr>
<tr>
<td>8. (f) Wipes patient’s name and ID on cassette</td>
</tr>
<tr>
<td>9. (g) Places cassette on a level surface</td>
</tr>
<tr>
<td>10. (h) Cleans finger with antiseptic/ alcohol</td>
</tr>
<tr>
<td>11. (i) Allows finger to dry before pricking</td>
</tr>
<tr>
<td>12. (j) Use a sterile lancet for finger pricking</td>
</tr>
<tr>
<td>13. (k) Prick the side of the ball of the finger</td>
</tr>
<tr>
<td>14. (l) Dispose off lancet in sharps bin immediately after pricking finger</td>
</tr>
<tr>
<td>15. (m) Collect blood with the enclosed pipette making sure to fill close to the first cross line</td>
</tr>
<tr>
<td>16. (n) Using a pipette, blow blood onto the pad in the correct well</td>
</tr>
<tr>
<td>17. (o) Dispose of pipette in sharps container immediately</td>
</tr>
<tr>
<td>18. (p) Dispose correct number of drops of clearing buffer into the correct well</td>
</tr>
<tr>
<td>19. (q) Wait correct time before reading negative results</td>
</tr>
<tr>
<td>20. (r) Place test card on a test receptacle and label with date of control line key appearance. Result should not be read after the maximum specified time minutes</td>
</tr>
<tr>
<td>21. (s) Read the results test correctly</td>
</tr>
<tr>
<td>22. (t) Record results in the register</td>
</tr>
</tbody>
</table>

#### mRDT procedure competence score

<table>
<thead>
<tr>
<th>Case 1 (Malaria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRDT procedure competence score</td>
</tr>
</tbody>
</table>

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

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 competence score.

Above 80% (at least one competence assessment every quarter)

50% - 80% (At least 2 competence assessment every quarter)

Below 50% (One competence assessment every month until reach 3 in the quarter)

Use the sections below to assess the work environment (workplace, equipment, supplies and consumables, documentation and reporting) at the outlet.

#### Workplace assessment

<table>
<thead>
<tr>
<th>Case 1 (Malaria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workplace assessment score (automatically generated as %)</td>
</tr>
</tbody>
</table>

**Noted on the assessment WMA, check if any positioning stocks are present:**
- (a) Water sufficient for outlet operations
- (b) Adequate lighting sufficient for reading tests
- (c) Space for conducting ACTs (Confidential)
- (d) Presence of job AIDs
- (e) RDTs stored in a dry place away from direct sunlight

#### Equipment, supplies and consumables assessment

<table>
<thead>
<tr>
<th>Case 1 (Malaria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment, supplies and consumables assessment score (automatically generated as %)</td>
</tr>
</tbody>
</table>

**Amounts by the assessment WMA, check if any positioning stocks are present:**
- (a) Antimus, Needles, Gloves
- (b) Timers, Long/medium, medium/short pens markers pens
- (c) RDTs in stock on day of visit
- (d) ACTs (not on stock, 10% if there are quality assured brands in stock)
- (e) RDTs in stock on day of visit
- (f) ACTs (not on stock, 10% if there are quality assured brands in stock)
- (g) ACTs (not on stock, 10% if there are quality assured brands in stock)
- (h) ACTs (not on stock, 10% if there are quality assured brands in stock)
## Assessment Checklist Tanzania Cont.

### Work environment score

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
<th>Target: 80% and above</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall supervision visit assessment score will be automatically generated taking into account the 4 key aspects of the supervision visit.

### Documentation and reporting

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Logbook/record book is present at the outlet</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>The patients details are recorded and organized in legible manner, including Date of test is recorded</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Results of the tests are recorded if not test action taken is recorded</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Reports for the weeks preceding the assessment have been submitted</td>
<td></td>
</tr>
</tbody>
</table>

Documentation and reporting assessment score (%) 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

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# Madagascar

## CHECKLIST de SUPERVISION

<table>
<thead>
<tr>
<th>Information</th>
<th>District</th>
<th>Name du centre ou Point de distribution</th>
<th>Nom du superviseur intervenant</th>
<th>Nom de l'expéditeur</th>
</tr>
</thead>
</table>

### Utilisation des centaines pour évaluer les compétences des prestataires sur les prises en charge des maladies sexuellement transmissibles, diagnostiquées et confirmées

<table>
<thead>
<tr>
<th>Prise en charge (activité)</th>
<th>Évaluation de la compétence</th>
<th>Cas fréquents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
</tr>
<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
</tr>
<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
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<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
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<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
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<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
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<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
</tr>
<tr>
<td>Prise en charge intégrale</td>
<td>Évaluation de la compétence</td>
<td>Cas fréquents</td>
</tr>
</tbody>
</table>

### Compétences sur la prise en charge

<table>
<thead>
<tr>
<th>Compétence</th>
<th>Cas fréquents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compétence</td>
<td>Cas fréquents</td>
</tr>
<tr>
<td>Compétence</td>
<td>Cas fréquents</td>
</tr>
<tr>
<td>Compétence</td>
<td>Cas fréquents</td>
</tr>
<tr>
<td>Compétence</td>
<td>Cas fréquents</td>
</tr>
</tbody>
</table>

### Annex 5: Assessment Checklist

[Checklist details]

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Madagascar Assessment Checklist Cont.

<table>
<thead>
<tr>
<th>Work environment score</th>
<th>Work environment score will be automatically generated taking into account the workplace assessment and equipment/supplies and consumables assessment. Target: 80% and above</th>
<th>0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation and reporting</td>
<td>Based on the results of the assessment, identify if the following are present: 1. Logbook/registration book is present at the outlet 2. The patient's details are recorded and organized in legible manner, including date of test is recorded 3. Results of the tests are recorded if not test action taken is recorded 4. Reports for the weeks preceding the assessment have been submitted</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Overall supervision visit assessment score</td>
<td>Overall supervision visit assessment score will be automatically generated taking into account the 4 key aspects of the supervision visit. Target: 80% and above</td>
<td>0%</td>
</tr>
</tbody>
</table>

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 __________________________
Annex 7: HNQIS Overview

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. Information 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

Did You Know?

Not Every Fever is Malaria
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 5 years, 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.
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.
“\(\text{I have many patients everyday who come to me with fever but not all fever is Malaria. I use RDT to test them for correct diagnosis.}\)"

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 prevalence 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 mRD 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 20 kg, 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.
Fever Case Management

Investigate other cause of disease in all cases
Fever of ≥ 37.5 °C that tested positive or negative with mRDTs

- Ask for presence of cough
  - IF NO
    - Give one dose of paracetamol (38.5 °C or above)
    - Follow up in 3 days if fever persist
    - If fever is present every day for more than 7 days, refer for assessment
  - IF YES
    - Assess for:
      - Fast breathing
      - Chest in-drawing
    - IF YES
      - Pneumonia: Treat Amoxicillin
    - IF NO
      - Common Cold: Treat Paracetamol

- Ask for presence of diarrhea
  - IF NO
    - Ask if:
      - More than 15 days
      - Blood in the stool
  - IF YES
    - Diarrhea: Treat ORS & Zinc

Normal body temperature 36.5 °C – 37 °C
Fever 37.5 °C
Always refer to a pre-established facility

Refer for severe malaria
Annex 9: SOPs for Audit

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

## STANDARD 1: Technical Competency

<table>
<thead>
<tr>
<th>Benchmark</th>
<th>Means of verification</th>
<th>Fully met</th>
<th>Partially met</th>
<th>Not met</th>
<th>Action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1) RTIIs should be performed by licensed/registered providers who are authorized by the government to do so.</td>
<td>Copy of official license or registration authenticated by the government</td>
<td>Providers folder/file</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>1.2) All personnel providing RTI services in affiliation with the programs must have received training from PSIMC, MoH, or accredited organizations approved by PSIMC.</td>
<td>Copy of the training certificate approved by PSI</td>
<td>Providers folder/file</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>1.3) Providers must perform RTIIs according to the relevant protocol.</td>
<td>Current execution of critical stegic infection prevention control, correct blood collection, safe disposal, correct RTI performance, correct interpretation of results</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>1.4) PSIMC-affiliated providers will have a current letter of agreement with PSIMC that clearly stipulates the roles and responsibilities of both parties and consequences of non-compliance.</td>
<td>Copy of the initial agreement between the owner of the outlet and PSIMC</td>
<td>Providers folder/file</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>1.5) Agreements with PSIMC-affiliated providers must be renewed on annual basis, pending satisfactory evaluation of providers’ overall skills and procedural compliance.</td>
<td>Copy of the renewed agreement for the current year based on last year provider’s overall skills and procedural compliance</td>
<td>Providers folder/file</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
</tbody>
</table>

**Sub-score: Technical competency**

| Score | 0/10 |

## STANDARD 2: Client Safety

<table>
<thead>
<tr>
<th>Benchmark</th>
<th>Means of verification</th>
<th>Fully met</th>
<th>Partially met</th>
<th>Not met</th>
<th>Action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1) Providers must check for danger signs and obtain a medical history from the caregiver/patient.</td>
<td>Providers check for danger signs and obtain medical history from caregiver/patient</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>2.2) Providers must properly identify, test, and treat fever cases in accordance with the government approved treatment algorithm for the level of provider.</td>
<td>Providers properly follow government’s algorithm on FCT</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>2.3) All PSIMC-affiliated clinics where PSIMC’s program refer patients must comply with Service Delivery Standards and are approved by PSIMC medical representative.</td>
<td>Selected referral facilities comply with Service Delivery Standards</td>
<td>Direct observation of referral facilities</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>2.4) Facilities must have all required equipment (e.g., RTI, gloves, safety disposal unit) and appropriate drugs (e.g., ACTs and antivirals)</td>
<td>All required equipment and drugs are in place</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>2.5) Facilities must ensure all the conditions to prevent infections (hand-washing procedure, decontamination equipment, antiseptic ointments, etc.)</td>
<td>Facilities ensure infection prevention control measures</td>
<td>Direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>2.6) Facilities must ensure proper bio-hazard waste management: presence of appropriate waste disposal (sharp and infectious, non-sharp and infectious, non-infectious) and waste management system in place.</td>
<td>Facilities ensure bio-hazard waste management</td>
<td>Direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
</tbody>
</table>

**Sub-score: Client safety**

| Score | 0/12 |

## STANDARD 3: Privacy and Confidentiality

<table>
<thead>
<tr>
<th>Benchmark</th>
<th>Means of verification</th>
<th>Fully met</th>
<th>Partially met</th>
<th>Not met</th>
<th>Action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
<td>Privacy is secured at outlet level</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>3.2) Precautions must be taken to ensure that client records are stored safely and confidentially.</td>
<td>Confidentiality is secured at outlet level</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
</tbody>
</table>

**Sub-score: Privacy and Confidentiality**

| Score | 0/4 |

## STANDARD 4: Continuity of Care

<table>
<thead>
<tr>
<th>Benchmark</th>
<th>Means of verification</th>
<th>Fully met</th>
<th>Partially met</th>
<th>Not met</th>
<th>Action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Caregiver/patient receives appropriate counseling and instructions for follow-up care</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>4.2) Providers must give relevant documentation to the patient/caregiver and ensure that she understands the care management procedures and that she is firm and clear about the treatment or informal</td>
<td>Providers ensure patient/caregiver understanding of the instructions given for follow-up care and provide supportive documentation (takeway slips, etc.)</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>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.</td>
<td>Caregiver/patients are exposed to contacts of referral sites or referral providers</td>
<td>Past assessments or direct observation</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
<tr>
<td>4.4) PSIMC programs must have one of the recommended mechanisms to assess client satisfaction with services, including counseling, provider access, and follow-up care.</td>
<td>Follow-up action plan in place based on findings from EIS, HH survey or qualitative research activities</td>
<td>Follow-up action plan on client satisfaction with services</td>
<td>(2)</td>
<td>(1)</td>
<td>(0)</td>
</tr>
</tbody>
</table>

**Sub-score: Continuity of care**

| Score | 0/9 |

**TOTAL SCORE**

| Score | 0/34 |

**TOTAL SCORE (%)**

| Percent | 0% |