THE REPUBLIC OF UGANDA

Ministry of Health

National

Guidelines for Implementation of Parasite Based Diagnosis of Malaria in Uganda

2013

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Ministry of Health
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Preface

The Health system in Uganda like other facets of socio-economic development such as general infrastructure, education system and security of person and property suffered the consequences of the general decline in socio-economic indices and lawlessness of the 1970's and early 1980s. There was widespread lack of funding and proper management of the health system leading to severe shortages of the key ingredients for a functional health system such as human resources, essential medicines and supplies and funding to efficiently provide health services. Many health facilities lay in a state of disrepair and often lacked sufficient cadre of health workers to provide quality health care to the population. This breakdown of health services was characterized by widespread:

- Lack of trained and skilled manpower (doctors, nurses, laboratory staff);
- Lack of medical equipment including microscopes and other essential equipment and supplies;
- Lack of Laboratory support services including reagents and other supplies; and limited and dilapidated infra-structure such as electricity and water, to mention but a few.

This poor state of affairs had devastating effects on the ability of the health system to deliver quality health services to the population. Indeed even where the recommendation was for proper diagnosis using "gold standard" laboratory tests to be done before treatment, the health system was besieged by the above mentioned problems that it became the norm to use "syndromic" approach to management of diseases. In the case of malaria which could easily be diagnosed using microscopy in the laboratory, it was decided that in the absence of microscopic diagnostic confirmation of malarial parasites in a patient's blood sample, a fever would be presumed to be of malarial origin until proven otherwise.

However, following recovery in socio-economic development in the recent past, the health system has witnessed rapid improvements - nearly 80% of people are living within 5 km radius from a health facility, staffing at these health facilities has greatly improved with 56% of vacancies filled, improved availability of drugs and supplies and generally better stewardship through a well-organized structure of health delivery system from Ministry of Health at the national level to the village health team at the community level. Additionally, new technologies for patient diagnosis and care have been introduced and are currently being rolled out such as use of rapid diagnostic tests (RDTs) for confirmation of malaria and other diseases.

For many decades, the prevalence of malaria in Uganda was extremely high that it made sense to assume that any fever was malaria until proven otherwise, especially that there was no infrastructure to be able to test all fever cases. It was therefore the teaching in all health institutions and indeed the practice by all clinicians to treat all fevers as malaria. This was the case in most Sub-Saharan countries.

In the last 10 years however, Uganda like other countries in the region has scaled up various malaria prevention and control efforts. Such efforts have included use of long-lasting

insecticide treated nets (LLINs), indoor residual spraying with insecticide (IRS) in selected districts, small-scale programs of larviciding, wide spread health education programs on malaria and increased availability of highly efficacious artemisinin-combination therapies (ACTs). While the impact of these interventions has not yet been measured however variations in malaria prevalence across the country is observed. Indeed, the 2009 Uganda Malaria Indicator Survey (UMIS) found variation in malaria prevalence across Uganda, from a parasite prevalence of 5% in Kampala to 63% in Northern Uganda among children under 5 years in the community.

Access to health facilities has also greatly improved. In the last 5 years strides have been made so that more than 80% of people reside within 5 kilometer radius of a health facility. In addition, new programs have been rolled out such as integrated community case management (ICCM) of childhood illnesses. Under ICCM, community health workers have been trained to identify and treat common illness such as malaria, pneumonia and diarrhea at community level, and where necessary, refer them to higher level facilities.

In light of the scaled up implementation of these interventions and programmes, and in consonance with guidance from the World Health Organization, Uganda has changed its malaria case management policy to move away from treating all suspected malaria cases to parasite based diagnosis and treatment of malaria.

These guidelines have therefore been developed to provide guidance to all health care providers and stakeholders in malaria control to ensure that there is universal access to malaria diagnosis to all people in Uganda. It is my sincere hope that these guidelines will facilitate smooth and rapid roll-out of parasite based diagnosis of malaria in Uganda.

Dr. D.K.W. Lwamafa
Commissioner Health Services – National Disease Control

Foreword

As part of its mandate to provide policy oversight, strategic direction and management, the Ministry of Health through the National Malaria Control Programme (NMCP) has developed guidelines on implementation of parasite based diagnosis of malaria in Uganda. The overall objective of these guidelines is to ensure harmonized, standardized and well coordinated roll out of malaria diagnostics at all levels of health services delivery in both private and public sectors including the community level. These guidelines will streamline the overall implementation of parasite based diagnosis of malaria by all stakeholders and ensure that all suspected malaria cases are subjected to laboratory testing before treatment with antimalarial drugs.

Not all fevers are due to malaria. Therefore, parasitological diagnosis of malaria is critical for effective fever case management. Universal access to malaria diagnostic testing for all fevers will ensure that some of the challenges of relying on clinical diagnosis alone such as misdiagnosis of malaria with resultant mismanagement of non-malaria febrile illness, wastage of antimalarial medicines and potential risk of contributing to the development of drug resistance.

The availability of these guidelines will complement other malaria prevention and control interventions; and will lead to provision of quality malaria services at all levels of service delivery in both private and public health facilities including the community level. This will be achieved through social mobilization, provision of adequate logistics and supplies for malaria diagnosis and improvement of service provider skills. It is intended that these guidelines will support strengthened collaboration among all stakeholders especially at district level and that all sectors will play their respective roles in mobilizing communities for positive behavior change about malaria diagnosis for effective and prompt treatment of fever cases.

I wish to express my appreciation to all those who contributed in one way or another in the development of these guidelines for implementation of parasite based diagnosis in Uganda. I wish to thank our development partners for their continued support without which these guidelines would not have been developed. I call upon all stakeholders in Uganda's malaria control efforts to follow the guidelines so as to achieve the intended mission of the National Malaria Control Programme.

I strongly recommend the use of these guidelines by all the health care providers in Uganda.

Dr. Aceng Jane Ruth
Director General Health Services

Acknowledgement

The development and finalization of these guidelines involved a series of consultations, meetings, and a workshop with the staff of Ministry of Health, malaria stakeholders and development partners. I thank you all for your hard work and dedication which has seen these guidelines developed.

The Ministry of Health acknowledges the leadership provided by Dr. Albert Peter Okui (the Acting Programme Manager, National Malaria Control Programme) and Mr. Bosco Bekiita Agaba, the program officer and focal person for diagnostics services at the NMCP in steering the process of developing these guidelines. I extend special thanks to Malaria Consortium and the President's Malaria Initiative (PMI) for the financial and technical support provided towards the development of this document.

The process of developing this document was highly consultative and various institutions participated at the various stages of its development and review. These included the WHO Country Office, CPHL, NTLP, NDA, NMS, JMS, IDI, MSF/EPICENTRE, UMSP/IDRC, UMRC, UMLTA, Makerere and Mbarara University Medical schools, Mulago, Itojo and Mubende Hospitals, Kabale, Ntungamo, Mubende and Masindi District Local Governments, USAID/CDC - PMI, Malaria Consortium and Stop Malaria Project. Individuals that were involved in this process are listed below.

This work would not have been completed without the technical assistance provided by Dr. Patrick Okello who was the consultant for this assignment.

Lastly, the Ministry of Health is grateful to all those institutions and individuals who have not been specifically mentioned above, but who directly or indirectly contributed to the successful development and finalization of this guideline.

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Acronyms and abbreviations

ACT	Artemisinin Combination Therapy
AMFm	Affordable Medicines Facility for Malaria
DHO	District Health Officer
GF	Global Fund
HF	Health Facility
HMIS	Health Management Information System
HSD	Health Sub-District
HW	Health Worker
ICCM	Integrated Community Case Management
IPT	Intermittent Preventive Treatment of Malaria during Pregnancy
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Net
IVM	Integrated Vector Management
LLIN	Long Lasting Insecticide Treated Net
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NHP	Nation Health Policy
NHSSIP	National Health Sector Strategic and Investment Plan
NMCP	National Malaria Control Program
OPD	Outpatient Department
PHP	Private Health Practitioners
PMI	U.S. President's Malaria Initiative
PNFP	Private Not for Profit
PSM	Procurement and Supply Chain Management
RBM	Roll Back Malaria
RC	Resource Centre
RDT	Rapid Diagnostic Test
SBCC	Social Behaviour Change Communication
SMC	Senior Management Committee
SMP	Stop Malaria Project
TWG	Technical Working Group
UDHS	Uganda Demographic Health Survey
UMLTA	Uganda Medical Laboratory Technology Association
UMRC	Uganda Malaria Research Centre
UMSP	Uganda Malaria Surveillance Project
VHT	Village Health Team

Operational definitions (*adapted from WHO[1])*

Accreditation: Procedure by which an authoritative body formally recognizes that a body or person is competent to carry out specific tasks.

Certification: Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements.

Competence: Knowledge, skills, abilities and attitudes at a level of expertise sufficient to perform in an appropriate work setting; this should be a measurable standard.

Combination rapid diagnostic test: Malaria rapid diagnostic test with more than one test line, detecting *P. falciparum* as well as other malaria species (in different combinations).

Diagnosis: The process of establishing the cause of an illness (for example, a febrile episode), including clinical assessment and diagnostic tests.

Diagnostic test: Diagnostic tool (technique) used to confirm or exclude the presence of a disease

Diagnostic test performance: Capacity of a test to confirm or exclude a disease; a combination of the sensitivity and the specificity of a test that by definition does not depend on the prevalence of the disease in the population tested.

External quality assessment: Set of activities organized outside a laboratory or health facility (by external supervisors or an external quality provider) to effectively and systematically monitor work carried out, including not only proficiency testing but also validation of the results of routine blood slide and on-site supervision.

Internal audits: Set of activities organized by a laboratory or health facility staff to effectively and systematically monitor work carried out internally.

Laboratory: Infrastructure with trained personnel specifically for the performance of analyses on clinical specimens, does not including health workers in a health facility or community health workers performing rapid diagnostic tests only.

Lot (of rapid diagnostic tests): A lot (or batch) is defined as a production run in which particular batches of monoclonal antibodies and nitrocellulose were used. Each lot is usually identified by a number by the manufacturer and usually consists of 40,000 - 80,000 tests.

Lot testing: Quality control testing of a product lot (batch) after release from the manufacturing site.

Malaria: Disease caused by infection of red blood cells with *Plasmodium* parasites, with fever as the commonest presenting sign.

Malaria infection: Presence of *Plasmodium* parasites in blood or tissues, confirmed by the presence of parasites in peripheral blood by microscopy, malaria antigenaemia by rapid diagnostic testing or parasite DNA or RNA by polymerase chain reaction (PCR).

Malaria test: For the purposes of this manual, a rapid diagnostic test (RDT) for malaria or microscopic examination of a blood slide (thick or thin smear) for malaria parasites; PCR is not included, as this manual focuses on tests used for the management of patients.

Panel detection score: Main measure (score between 0 and 100) of performance used in WHO product testing of malaria RDTs, corresponding to the percentage of times a malaria RDT gives

[1] *WHO universal access to malaria diagnostic testing: an operational manual, 2011*

a positive result on all tests from both lots tested against samples of parasite panels at a specific parasite density (i.e. four tests at 200 parasites per microlitre, two at 2000 parasites per microlitre). It is not a direct measure of RDT sensitivity or specificity.

Parasite density: Number of asexual parasites per microlitre of blood, detected by microscopic examination of peripheral blood films. Any level of parasite density can lead to clinical illness.

Plasmodium antigens: Antigens produced by malaria parasites and detected with RDTs; the antigen concentration depends on the parasite density in peripheral blood and the total parasite load (including sequestered parasites); may also vary with parasite species, stage of parasite life cycle, duration of infection, host immunity and other factors.

Proficiency testing: Inter-laboratory comparisons organized regularly to assess the performance of analytical laboratories and the competence of the personnel. In such programmes, multiple samples are periodically sent to laboratories for analysis or identification, and each laboratory's results are compared with those of other laboratories, with an assigned value and reported to the participating laboratories and others.

Quality assurance: All processes involved in ensuring that results obtained with a tool are as accurate as the tool is designed to be (all diagnostic tools have limitations). Addresses all factors that affect diagnostic performance, including test performance by health staff, internal audits, external quality assessment, microscopy equipment and reagent quality, quality of RDT devices, storage and transport of RDTs, use of test results by clinicians, workload, workplace conditions, training and staff support and community perception.

Quality management system: System to direct and control an organization with regard to quality.

Quality monitoring: All activities involved in ensuring that the diagnostic tests continue to conform with established specifications during storage, distribution and use; part of quality assurance.

Quantification: Estimation of the quantities and frequencies of supplies necessary to meet demand in a specific area, avoiding stock-outs and over-stocking.

Sensitivity: For diagnostic tests, proportion of patients with the disease who have a positive result in the test being evaluated, determined from the results of the reference or 'gold standard' test; ranges from 0% (bad performance) to 100% (optimal performance).

Specificity: For diagnostic tests, proportion of patients without the disease who have a negative result in the test being evaluated, determined from the results of the reference or 'gold standard' test; ranges from 0% (bad performance) to 100% (optimal performance).

Testing site: Any place in which malaria tests (RDTs or microscopy) are performed in the context of the clinical management of patients.

Test performer: Health worker or laboratory technician performing and interpreting an RDT or preparing, staining and examining a blood slide by microscopy.

Universal access: For malaria diagnostic tests, all sick people who fulfil the definition of a suspected malaria case have access to a reliable malaria test, administered by a trained health worker at a health facility or community health centre. Does not include asymptomatic people in the context of strategies for eliminating malaria.

1.0 Background to the Guidelines

1.1 Introduction

The purpose of this document is to guide implementers at all levels of health services delivery on practices and activities related to parasitological diagnosis of malaria in Uganda. It aims at harmonizing and standardizing implementation modalities for parasite based diagnosis of malaria at both health facility and community levels of care in both public and private sectors. It is intended to be used by both decision-makers and service providers at all levels of health service delivery.

By following the guidance provided in this document, health planners, managers and practitioners at all levels will be able to contribute to a harmonized and well-functioning roll-out and national scale-up of accurate and reliable parasite based diagnosis of malaria and this will lead to effective treatment and management of fever in Uganda. This guideline will therefore support and enhance the already existing efforts to control malaria in Uganda.

This document contains what you need to know, where to find it and how to do it. It provides an overview of malaria situation in Uganda and the national plan for deployment of diagnostic testing capability at all levels of health service delivery in Uganda. It draws heavily on existing national guidelines and is not intended to replace any of those guidelines but rather to augment their use. Appropriate reference to existing policies and guidelines is made and the users are encouraged to ensure they have either a hard copy of the same or can access soft copies typically on the Ministry of Health website library found on www.health.go.ug or in the World Health Organization website www.who.int.

This guideline therefore provides specific guidance on the specific parameters which are envisaged to affect smooth implementation and national scale-up of parasite based diagnosis of malaria. Specifically addressed are issues such as: procurement and supply chain management for malaria diagnostics, safety and waste management, training and supervision of health workers, quality management systems for diagnosis including quality assurance and control, social and behavior change communication and advocacy for parasite based diagnosis of malaria, monitoring and evaluation and research and the institutional arrangements to implement this guideline.

The process of developing this guideline followed the generally recommended steps for development of national guidelines as prescribed by the Ministry of Health. Wide consultations including meetings, document review and stakeholders workshop were carried out. This document is therefore a product of wide stakeholder consultation, participation, review and approval through Ministry of Health (MOH) structures, namely; the malaria case management working group, the communicable disease control (CDC) technical working group (TWG) and the senior management committee (SMC) of the Ministry of Health. All these structures reviewed and provided input into the final document.

1.2 Overview of malaria situation in Uganda and control efforts

Malaria remains the leading cause of morbidity and mortality in Uganda. It accounts for 25 - 40% of outpatient visits at health facilities, 15 - 20% of all hospital admissions, and 9 - 14% of all hospital deaths. A significant percentage of deaths however occur at home and are not reported by the facility-based Health Management Information System (HMIS)[1].

The Uganda Malaria Indicator Survey (UMIS), conducted in late 2009, showed that Plasmodium *falciparum* is responsible for 99% of malaria cases. P. *malariae*, accounts for 0.2% of cases as mono-infection but is more commonly found as a mixed infection with P. *falciparum* (up to 2.7% of childhood infections in highly endemic areas). Both P. *vivax* and P. *ovale* are rare and do not exceed 2% of malaria cases in Uganda.

The 2009 UMIS found that malaria prevalence among children aged 0-59 months by microscopy was 42% tested positive for malaria. Prevalence was higher in rural areas than in urban areas (47% versus 15% using microscopy) and ranged from 5% in Kampala to 63% in the mid-northern region[2].

Since 2007, Uganda has rapidly scaled up malaria control efforts with increased funding resources from both governmental and non-governmental actors. For instance, Uganda has been a beneficiary of four Global Fund rounds (Rounds 2, 4, 7, and 10) that targeted increasing access to ACTs, universal coverage with LLINs and training of health workers and more recently the Affordable Medicines Facility for malaria (AMFm) programme of Global Fund which has led to increased availability of ACTs and RDTs in both the public and private sectors.

The interventions supported by these various sources of funding have been integrated and include:

- Provision of prompt and effective treatment using artemisinin combination therapies (ACTs) for malaria case management
- Vector control using long lasting insecticide treated nets (LLINs), indoor residual spraying (IRS) and other vector management strategies such as larviciding
- Prevention and treatment of malaria in pregnancy (MIP) and
- Epidemic preparedness and response

Other supporting interventions which have been scaled-up include social behavioral change communication, M & E, Research and surveillance.

In 2012, Uganda adopted a revised Malaria Control Policy and Strategic Plan for the period 2011 – 2015. The revised policy incorporates the World Health Organization

[1] Uganda Ministry of Health. Uganda National Malaria Control Policy, 2012. Kampala
[2] UBOS and ICF International. Uganda Malaria Indicator Survey, 2009. Calverton, MD, USA.

policy recommendations for management of malaria published in 2010[1] and the recent 2011 resolutions on malaria from the UN General Assembly and the World Health Assembly that highlighted the importance of malaria diagnostic testing in reaching 2015 goals. These resolutions noted that the scaling up of diagnostic testing is critical to ensuring good management of malaria and non-malarial febrile illnesses, targeting antimalarial medicines (ACTs) to those who actually need them, curbing the threat of artemisinin resistance, and providing data for accurate malaria surveillance.

The key Case Management policy of objectives of the revised Uganda Malaria Control Policy are: (i) to ensure early diagnosis and prompt and effective treatment of malaria, and (ii) to ensure that all suspected malaria cases are subjected to parasitological diagnosis before treatment[2].

The Uganda Malaria Control Policy 2012 specifically recommends that parasite-based diagnosis with Microscopy or Rapid Diagnostic Tests (RDTs) shall be part of malaria case management in all health facilities and at the community level. It states that:

i. Suspected malaria cases will be subjected to parasite-based diagnosis.
ii. Microscopy remains the "reference or gold standard" for malaria diagnosis in case management and shall be the diagnostic method at all Health Facilities from level III and above.
iii. RDTs will be used at HC II and community levels and to fill the gaps at higher level health facilities whenever microscopy is not possible.
iv. The type of RDTs to be deployed in the country will be guided by evidence on sensitivity, specificity, ease of use and stability in the field, as determined by the performance evaluation and pre-qualification schemes of the WHO coupled with in-country testing.

In line with guidelines from the WHO, the Uganda treatment policy states that treatment solely on the basis of clinical suspicion should only be considered when a parasitological diagnosis is not accessible, such as during periods of lack of qualified staff to conduct testing and stock-outs of testing supplies.

The National Malaria Control Programme (NMCP), as directed by the National Malaria Control Policy 2012, adopted in its Strategic Plan a benchmark of increasing from 25% to 90% by 2015 the proportion of malaria cases parasitologically confirmed and treated with effective antimalarial drugs.

This guideline is therefore developed so as to operationalize both the policy objective and to guide an orderly process of national roll-out of parasite based diagnosis of malaria in Uganda. It provides an easy-to-use reference tool targeting health policy decision-makers, planners, managers and health care providers. It addresses issues pertinent to

[1] WHO. Guidelines for treatment of malaria, second edition, 2010. Geneva.
[2] Uganda Ministry of Health. Uganda Malaria Control Policy 2011 – 2015. Kampala.

implementation of diagnosis at all levels of service delivery including both the public and private sectors.

The policy for treatment of malaria recommends ACTs for treatment of uncomplicated malaria and intravenous Artesunate and Quinine for treatment of severe malaria. Artemether/Lumefantrine (AL) is the first line treatment for uncomplicated malaria, while Artesunate/Amodiaquine is the alternative first line treatment. Artesunate (given intravenously) is the recommended medicine for the treatment of severe malaria while intravenous Quinine or Intramuscular Artemether is the alternatives to be used when Artesunate is not available.

Over the last 5 years, Uganda has implemented various programs to increase parasite based diagnosis at both health facilities and community using the village health team (VHT) as prescribed in the integrated community case management (ICCM) guidelines[1]. A body of knowledge has been accumulated in the course of implementing these various activities in microscopy and use of RDTs in health facilities and communities. Some of the challenges that have been observed as a result of these experiences include:

- Programmatic factors such as limited infrastructure, poor staffing levels and training are impeding effective use of diagnostic tools (microscopy at health facilities and RDTs at both health facilities and community level)
- Lack of confidence of health workers and patients in the test results which potentially leads to conflicts and wastage of resources
- Lack of quality assurance systems in place to guarantee reliable and accurate results and lack of Point- of- Care tools for quality control
- The distribution and use of non-standardized materials and procedures for microscopy and RDT use
- Uncoordinated expansion of malaria diagnostic services to include lower public health facilities, private facilities and communities impeding ability to achieve universal access to diagnosis for malaria
- Inadequate monitoring of results for planning at all levels
- Limited resources for provision of diagnostic tools leading to patchy implementation across the country
- Reliance on donor funding to support diagnosis at all levels,
- Commercialization of results especially in the private sector, making diagnosis inaccessible to the poor.

In developing this guideline, these experiences and challenges have been taken into consideration. It is hoped that those lessons will guide all the different actors to ensure that plans developed for scaling up parasite based diagnosis address these potential obstacles to smooth roll-out of malaria diagnostics in Uganda.

[1] Ministry of Health. Integrated community case management (ICCM) guidelines

2.0 Purpose and target population of the implementation guidelines

2.1 Purpose

This guideline is intended to provide operational, managerial and technical guidance on the planned national roll-out and implementation of parasite based diagnosis of malaria in Uganda. It draws heavily on existing national policies and guidelines on cross-cutting aspects of other programmes that in the end enhance planning and implementation of parasite based diagnosis of malaria. Following the guidance provided in this document will support the implementation of the WHO policy for the treatment of malaria based on parasitological diagnosis of malaria in Uganda.

This guideline is expected to specifically:

- Guide the procurement and supply chain management processes for malaria diagnostics in Uganda
- Provide guidance on quality management systems for malaria diagnostic testing
- Guide on safety and management of health care waste from malaria diagnosis
- Provide a framework for coordinated training and supervision of health care providers at all levels
- Guide on best practices for social behavior change communication and advocacy for malaria diagnostics
- Provide a framework for monitoring and evaluation and research, and to
- Delineate the roles and responsibilities of different actors at all levels; i.e. national, district, implementing partners and NGOs, and community levels.

2.2 Target Audience

This guideline is intended to be used by policy makers, health managers, planners, health care providers in both public and private sectors and by all stakeholders at all levels of the healthcare system including the community level.

This report is intended for specific audiences, namely:

- Projects and programmes with intention to deploy malaria microscopy and point of care diagnostics as part of the fever case management profile
- Health policy decision-makers, managers and all health workers at national and sub national levels of healthcare delivery
- Institutions of higher learning in public health
- Donors considering the quality of funding requests and plans for improved case management
- Public and private health sector organizations with an interest in supporting national scale implementation of the malaria parasite based diagnosis policy

3.0 Rationale for development of the guidelines

In 2012, Uganda changed its malaria case management policy to reflect WHO's policy guidance. The WHO guidelines for the treatment of malaria recommend confirmation of the diagnosis of malaria in all suspected cases before administration of treatment[1]. Confirmation requires the use of a test that demonstrates evidence of the malaria parasites in the blood of the patient (i.e. actual parasite or parasite protein), hence the term "parasite-based" or "parasitological" diagnosis. This recommendation emphasizes the importance of high-quality microscopy or, where not feasible or available, quality-assured rapid diagnostic tests (RDTs) for malaria. The recommendations in the WHO treatment guidelines are a response to several factors: the introduction of new, more costly antimalarial medicines, concerns regarding the rise of drug resistance, and the recognition that in most malaria-endemic areas (as a result of more effective antimalarial control measures), a majority of cases of febrile illness are actually not due to malaria.

Also, Uganda has witnessed a rapid increase in funding and programmes supporting parasite based diagnosis of malaria. There is therefore an urgent need for Uganda to develop guidelines that will standardize and harmonize all efforts geared at scaling up parasite based diagnosis of malaria. However despite this observed surge in programmes and funding to support national scale up of diagnosis for malaria, evidence from studies carried out in Uganda point to specific challenges that will impact on how well universal access to parasite based diagnosis of malaria in Uganda can be achieved. A study by Kyabayinze et al. in 2012[2] found that primary health care facilities (health centres IIIs to community level) had inadequate human and infrastructural capacity to effectively implement universal parasite-based malaria diagnosis. It identified priority capacity building needs that needed to be addressed as:

- recruitment and retention of qualified staff,
- comprehensive training of health workers in fever management,
- malaria diagnosis quality control systems, and
- strengthening supply chain, stock management and referral systems.

This guideline is therefore timely as it will be a reference tool to be used at all levels and by all actors involved in strengthening malaria diagnosis and case management in Uganda and to galvanize all efforts to address the challenges highlighted above that will impact on how well universal access to parasite based diagnosis of malaria will be achieved in Uganda.

[1] WHO. Guidelines for treatment of malaria, second edition, 2010. Geneva

[2] Kyabayinze et al. Parasite-based malaria diagnosis: Are Health Systems in Uganda equipped enough to implement the policy? BMC Public Health 2012, 12:695

4.0 Implementation guidelines for parasite based diagnosis of malaria in Uganda

This document identifies key processes and activities necessary to be implemented in an orderly fashion in order to ensure universal access to diagnosis for malaria in Uganda, in well-planned and coordinated way. The processes and activities identified and laid out below include: the deployment plan for diagnostics, procurement and supply chain management, safety and management of health care waste, quality management systems for diagnostics, training and supervision of health care providers, social and behavior change communication and advocacy for diagnostics, monitoring and evaluation framework and institutional arrangements that describe the roles and responsibilities of the different levels and actors. Detailed national guidelines exist for most of these parameters and reference is made to them. Only specific areas will therefore be highlighted in this document. In order to ensure that this guideline remains concise but comprehensive, the reader has been directed to those other national policies and guidelines that may contain additional detailed information pertinent to a specific area. The referenced documents are generally available either at the respective points of service or at the district health offices, Ministry of Health Head Quarters or online at the Ministry of Health website www.health.go.ug library for easy download.

The reader is therefore urged to read the following sections in conjunction with the referenced manuals, standard operating procedures (SOPs), job aids and guidelines already provided by the Ministry of Health elsewhere.

4.1 Planning and deployment of diagnostics

The Uganda National Malaria Control Policy 2011 – 2015 identifies the deployment plans for diagnostic tools for malaria and recommends that:

i. Microscopy shall be the diagnostic method at all Health Facilities from level III and above.
ii. RDTs will be used at HC II and community levels and to fill the gaps at higher level health facilities whenever microscopy is not possible.

For practical purposes, RDT deployment in Uganda will be done in a phased approach. Deployment in the various districts will be preceded by RDT training program using the recommended Uganda RDT training manuals until the entire country is covered. In line with this guidance, RDTs shall be provided to and used at community level. Village Health Team members will be trained using the ICCM guidelines that contain a module on RDT use. While the policy recommends RDT use at community level, actual deployment will begin at the health facilities to ensure facilities are adequately stocked and trained and have enough capacity built to supervise the community level. In addition, RDT job aids shall be distributed to the VHTs and closely supervised to ensure effective use of RDTs at community level.

Detailed guidance on how to manage cases of fever at the different levels is described fully in the Ministry of Health's treatment guidelines for Integrated Management of Malaria[1].

In summary:

a) **At the community**, VHT members will see all children (2 months to five years) with fever from their community and do the following:
   i. For suspected uncomplicated malaria – test with RDT, treat with ACT when positive, refer if negative
   ii. For severe malaria – test with RDT, give rectal Artesunate/quinine if positive and refer; if negative also, refer.

b) **At health centre II level** (both public and private facilities), RDTs will be provided to all public facilities and private facilities should stock RDTs. All health workers at this level should be trained on how to use RDTs. At this level, health workers will do the following:
   i. For suspected uncomplicated malaria – test with RDT, treat with ACT when positive; if negative, reassess and treat or refer if cannot manage
   ii. For suspected severe malaria – test with RDT, give rectal Artesunate/quinine if positive and refer; if negative refer.

c) **At health centre III levels and above**, microscopy is the recommended diagnostic tool for malaria diagnosis to exploit its potential to diagnose other diseases in addition to malaria. However RDTs should be used in the management of malaria cases at these levels in situations where:
   - There is no microscope
   - There is no skilled microscopist
   - There are no reagents for microscopy
   - There is no supply of electricity to support microscopy
   - During "after-work-hours", including weekends when there is no microscopist, and
   - To ease on the heavy work load in facilities with high patient load which cannot be appropriately be met by microscopy.

At these levels of care generally therefore:
   i. For suspected uncomplicated malaria – all suspected malaria cases should be tested, treat with ACT when positive; if negative reassess and treat, refer if cannot manage
   ii. For suspected cases with signs or symptoms of severe malaria – test, if positive treat with IV Artesunate; if negative reassess and treat, refer if cannot manage
   iii. For suspected malaria in pregnancy – test, if positive and uncomplicated malaria, treat with quinine (1st trimester), treat with ACT (2-3rd trimester – after quickening); if positive and has signs and symptoms of severe malaria, treat with IV artesunate; if negative reassess and treat, refer if cannot manage.

[1] Uganda Ministry of Health. Integrated Management of Malaria. 2012

4.2 Procurement and supply chain management

In the Public sector in Uganda, procurement of medicines and health supplies is the function of National Medical Stores[1]. In certain circumstances however Development Partners may decide to procure medicines and health supplies using their own mechanisms such as the Voluntary Pooled Procurement Mechanism of the Global Fund. In either case, it is recommended that procurement of Microscopes, RDTs and other diagnostic supplies shall be in line with the National Procurement Guidelines as envisaged in the Public Procurement and Disposal of Public Assets Act as amended 2011 (PPDA)[2] and the WHO recommendations[3]. In order to align procurement decisions for malaria diagnostics with the national malaria policies, malaria epidemiology and health workers training requirements, all technical specifications for malaria diagnostics and supplies will be provided by the Ministry of Health National Malaria Control Program (NMCP) in consultation with the stakeholders. Procurement should be planned in a manner that prevents shortages and wastages. The private sector players are encouraged to follow similar guidance as for the public sector.

4.2.1 Selection of products for malaria diagnosis

Selection of malaria diagnostics commodities to be deployed in Uganda shall be done by the NMCP under the overall guidance of the Ministry of Health Communicable Diseases Control Technical Working Group (TWG) in consultation with key stakeholders. The CDC TWG together with the NMCP will select and keep an inventory list of recommended RDTs for use in Uganda.

4.2.1.1 Malaria Rapid Diagnostic Tests (RDTs)

For malaria RDTs to be procured for use in Uganda, the NMCP in partnership with NDA and respective oversight committees such as the CDC TWG, will develop a set of clear criteria for RDT selection and will create an approved RDT product list, to be shared with partners. Such selection criteria may be revised based on evidence on changing malaria epidemiology and other study findings that may inform such decision.

- This list will be updated annually.
- This list shall be enforced by NDA, so that only these products are allowed into the country.

Specifically;

- RDTs must have passed the WHO Product testing for the current list[4] and /or FDA approval. This is the first basic step for any RDT product to quality for use in malaria

[1] Republic of Uganda. National Medical Stores Act 1993
[2] Republic of Uganda. The Procurement and Disposal of Public Assets Act as amended 2011.
[3] Good practices for selecting and procuring rapid diagnostic tests for malaria. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf
[4] Good practices for selecting and procuring rapid diagnostic tests for malaria. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf

testing in Uganda[1].

- RDTs should be HRP-2 based with a minimum of 85% Panel Detection Score (PDS) at 200 parasites per microlitre (µl) of blood; less than 10% false positive rate. However, the Ministry of Health National Malaria Control Program may introduce other non-HRP-2 based RDTs that detect other parasite species other than P.*falciparum* if the prevalence of P.*falciparum* is found to be less than 90%.
- RDTs should be Cassette format (in protective enclosures from temperature and humidity i.e. moisture-proof envelopes).
- RDTs should be packaged with other essential accessories necessary for testing such as: blood transfer device - this can be a pipette, a loop or inverted cup, buffer, lancets and alcohol swabs.
- RDTs should have a shelf-life of at least 18 months as at the time of supply.
- RDTs should maintain stability at temperature of up to 45 degrees Celsius (45ºC). The RDT should be stable for the shelf life of the product in all sections of the country especially the areas where temperature could be increasingly high.
- RDTs for Public sector health facilities should be labeled "GOVERNMENT OF UGANDA, NOT FOR SALE" on the outer packaging of the 20 – 30 test packs.

- RDTs should demonstrate a clinical sensitivity and specificity of ≥ 95%. However, as the RDTs are used in the health facilities, there will be continuous performance monitoring through operational research and quality assurance systems to ensure reliable tests results.

4.2.1.2 Microscopes

The type of microscopes to be procured for malaria diagnosis in Uganda should conform to the following minimum standards:

- For new purchases, microscopes for all health facilities should be binocular. A binocular microscope with paired x10 eyepieces and x10, x40 and x100 objectives (the latter as 'oil immersion') and a built-in electrical light source is the 'gold standard'. Every new microscope purchased should also have an alternative for using a natural light source, that is, be provided with good mirrors to harness the abundant and most reliable source of light in Uganda.
- The detailed specifications for microscopes will be regularly reviewed in consultation with the National Laboratory Committee (Sub-committee on equipment and infrastructure) and published in the MOH website.
- Manufacturers of microscopes should meet national and internationally recognized general manufacturing quality standards (ISO 9000).

[1] Malaria RDT product testing: Interactive Guide. FIND. Available at: http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf

4.2.1.3 Microscopy stains, buffer solutions, slides and immersion oil

- The Romanowsky stains (staining nuclei red and cytoplasm blue), of which Giemsa is one, have proved to be the most reliable stains and is recommended for routine malaria microscopy by WHO. In line with WHO recommendation, in Uganda Giemsa (analytical grade) will be the stain used at all levels of service delivery and should be bought from reputable suppliers to be regularly approved through approved structures of the Ministry of Health. The CPHL working with NMS and the NMCP will ensure the change from the current use of Fields stain to Giemsa in all Laboratories. CPHL will provide with the necessary technical and supervisory support to effect this change.
- All laboratory accessories required for the use of Giemsa stain should be provided including but not limited to analytical grade phosphate buffer tablets or phosphate buffer solutions to monitor the quality of the working solution, Immersion oil with the same refractive index as glass slides, Simple hand-held pH meters and high quality microscope slides

4.2.2 Quantification and forecasting of requirements for malaria testing

At the national level, quantification and forecasting for malaria diagnostics is to be done by the pharmacy division of the MOH in consultation with NMCP and CPHL. At district level, all health facilities using the "pull system" of ordering malaria diagnostics should quantify their needs based on their consumption taking into consideration:

- the total number of suspected malaria cases;
- the number of malaria cases confirmed by microscopy;
- the total number of slides examined for malaria by microscopy;
- the number of malaria cases confirmed by RDTs; and
- the total number of malaria RDTs performed.

For all Health centres IIIs, IIs and community level where the "push system" is used currently as an interim measure by the National Medical Stores to provide malaria diagnostics, their needs should be quantified taking into consideration the implementation capacity and programme aspects in the given points of care, such as the number of people performing the tests, the number of tests expected to be performed per day and the number of working days during which the test will be performed. To this estimate, 20% buffer stock should be added for safety stock. The following factors need to be taken into account:

- differences in the number of health facilities and their level of functioning, which affect patient flow at different levels of the health-care system;
- expected variations in patient treatment-seeking behaviour after introduction of a new malaria treatment policy or differences in pricing of medicines and diagnostic testing in the private sector;
- and, the different scale of deployment of malaria diagnostic services to health centres IIs and community levels.

It is recommended that the Quantification Planning and Procurement Unit (QPPU) of the Pharmacy Division periodically reviews the quantities of diagnostic supplies provided in the standard kits used in the "push system" to reflect changing quantities of supplies required at these levels. mTrac data should be used to better inform the 'push' of RDTs to HC IIs and HC IIIs via the Essential Medicines Kit.

However, where the health facilities use a "PULL SYSTEM", the following formula may be used to estimate or quantify RDT needs:

The number of RDTs required will be equal to (Suspected malaria cases less the number of blood examinations for malaria by microscopy) divided by health facility reporting completeness for malaria. Note: if the report completeness is 80% the denominator should be 0.8, 100% it should be 1.

Facilities using Pull System should ensure that their RDT orders are properly planned in terms of timing and quantity. RDT re-orders should take note of:

Time: WHEN: once the stock has reached a minimal (re-order) level

Quantity: When the amount of RDTs to order is based on a "pull system",

A simple formula is provided below for making facility orders for RDTs.

RDTs to order can be computed as follows: Average monthly consumption multiplied by the sum of lead time and procurement period plus the safety stock levels after removing from the latter the stock on order and the stock in inventory. This is expressed as:

$Qo = Ca \times (LT + PP) + SS - (Si + So)$ where:

Qo = Quantity of RDTs to re-order in the next procurement period

Ca = average monthly consumption, adjusted for reporting

LT = lead time (time from placing the order to delivery)

PP = procurement period (time taken for preparing the order, signatures and approvals by the order is actually placed)

SS = Safety stock

Si = Stock in inventory (on hand)

So = Stock on order, but not yet received (if you have a pending previous order)

Average Monthly Consumption: This can be got from the RDT stock card. The stock record form allows calculating the consumption over a period of at least three months which is the recommended minimum period for computing average consumption data for RDTs:

Consumption = opening stock + RDTs received - closing stock

Safety stocks: Since it is impossible to estimate the requirements with complete accuracy and to be certain about performance and efficiency of the supply chain system, a certain amount of RDTs in stock (inventory) is needed to absorb fluctuations in supply and demand and to reduce the risks of stock-outs. Since high stock levels increases inventory costs (personnel, storage, as well as risk of spoilage, expiry and theft), there is need to calculate the minimum "safety stock" to protect against stock-outs.

The safety stock is calculated by multiplying the adjusted average monthly consumption by the expected lead time, according to the formula:

Safety Stock (SS) = Ca x LT where:
Ca = average consumption, LT = lead time (from order to delivery) same unit of measure, often in months

4.2.3 Product procurement and Supply

In the public sector in Uganda, all procurement for medical and laboratory supplies are the responsibility of the NMS. Alternative procurement mechanisms can however be used depending on donor conditions and preferences. However the NMCP in consultation with partners will provide the right technical specifications that are appropriate for diagnostic tools which are in line with the local malaria epidemiology and health workers' training needs and previous in-country experience and trainings conducted. In particular;

4.2.3.1 RDTs

- A uniform RDT type shall be procured and distributed across the national health system rather than multiple RDT types to ensure standardization in the public sector. For the private sector product choice may change to ensure competitive tendering although it is encouraged that the format of RDTs procured in the private sector be similar to those available in the public sector. This standardization eliminates the need for repetitive training of health workers whenever different formats of RDTs are introduced to the health system.
- The Ministry of Health National Malaria Control Program may change and replace a given RDT when it is discovered to give inferior quality performance results as indicated from operational research and supervision reports by the Malaria Program.
- RDT consignments should be monitored with temperature monitors from manufacturer to the user facilities. NMS will be required to notify the shipper of the temperature storage requirements by the manufacturer in writing and by clear markings on cartons and related documents.

4.2.4 Special conditions for RDTs

a) Lot testing of all RDTs imported into Uganda will be required. Specifically:
   - It is the full responsibility of the Manufacturers to send their RDT samples for lot-testing to a WHO approved laboratory before shipment. The lot-testing results should be availed at port of entry. RDTs that fail this testing will be rejected. A copy of the lot test certificate should be provided to NMS, NDA and the Ministry of Health NMCP as well.
   - After distribution to points of care (health facility and community levels) post-distribution testing may be conducted to investigate field reports of suspected deteriorated performance and false results at the health facilities and community level.

b) RDTs shipped under inappropriate temperature conditions shall be rejected. The procurement shall be considered fully executed when the tender requirements, specification, packaging, supply specifications stated above have all been complied with.

4.2.5 Regulatory Requirement

All regulatory aspects of diagnostics commodities imported in Uganda are the responsibility of the National Drug Authority (NDA) or other organization that is mandated by law or delegated by the Ministry of Health to carry such a function. The regulatory body should be contacted for details pertaining to guidelines and regulations related to product quality for registration purposes of diagnostic equipment and supplies.

4.2.6 Distribution, transport and storage of RDTs

Transportation of RDTs from the manufacturer and road transport within the country is very important in ensuring the preservation of the integrity of the RDTs for better performance. Prolonged exposure to high temperature and humidity will rapidly degrade RDTs, and may occur when exposed to intense heat (above $35\ ^{0}$ C). Therefore transportation by road should ensure that the RDTs are not exposed to adverse weather conditions which affect their potency. All handlers of RDTs should ensure that they are covered and stored in a dry-cool place with temperatures not exceeding 35 degrees Celsius. Distribution should align with the malaria transmission seasons and local malaria epidemiological patterns to ensure adequate stocks.

4.2.7 Storage of microscopes and stains

- Microscopes should always be stored in a dry environment, preferably in their storage boxes, to avoid dust and exposure to humidity, which promotes growth of fungus on lens surfaces. They should be kept on a firm surface. Dry conditions can be obtained by placing a lighted 25-watt bulb inside a small cupboard, in which the microscope is stored at night.
- Giemsa stock staining solutions should be kept away from direct sunlight, in a cool place, in dark bottles with tightly fitting lids, as moisture can affect the quality of the stain. For this reason, it is suggested that the working solution be kept in a small volume

in a different container from the main solution, and that only dry glassware be used for preparing staining solution daily.

4.2.8 Stock management

Uganda has always recommended the use of logistics management information system for coordinating the supply distribution network for medicines and other supplies right from community level up to the highest levels. A similar information system is recommended for use with diagnostic devices such as RDTs or supplies for microscopy. All the points of care: hospitals, health centres and communities are required to use the stock cards for stock monitoring for malaria diagnostics. The use of stock cards allows the tracking of stocks coming in and going out of the facility store. This makes it possible to utilize the "FI – FO" (first in, first out) and "FE – FO" (first expiry, first out) system thus avoiding expiry, over-, under- and out-of-stock situations. For RDTs in particular, the stock record form should state the smallest unit of dispatch, i.e. the number of boxes, rather than the number of individual tests (cassettes).

Also, the national policy allows for redistribution of medicines and supplies. Within a district, it is allowed for the DHT to redistribute supplies from areas/ facilities where there is over-stock to those with no or limited stock. Therefore, at point-of-care level, when the consumption is lower than expected (e.g. of ACT due to fewer malaria cases than expected), health facilities are allowed to move excess stocks to other facilities that have higher consumption. It is recommended that each unit must make regular, periodic counts of the actual stock on hand to ensure that the balance recorded in the stock record form is correct and that the minimal safety stocks are available.

Note: RDTs to the community should be supplied from the nearest health facility. In situations of general inadequate stock of RDTs in the country or within a district, health managers at those levels should ensure that RDT supplies to the formal health centers take precedence over supply to the community level.

4.3 Management of Health Care Waste

Introduction

Health care waste includes all the wastes (hazardous or not) generated during health care delivery and includes sharps, non-sharps, blood, body parts, chemicals, pharmaceuticals, medical devices and radioactive materials[1].

In Uganda, 75-90% of the health care waste produced is non-hazardous, comparable to domestic waste, while 10-25% of waste is hazardous therefore requiring special care from the point of generation until final disposal[2].

The objectives of health care **waste management in malaria diagnosis** are**:**

- To guide appropriate containment of waste generated and prevent risks of infection during malaria diagnostic procedures
- To ensure that waste generated during malaria testing at all levels is not harmful to the community and the health care providers
- To ensure that all waste generated during malaria testing undergoes proper waste management procedures (segregation, packing, labeling, handling, storage, transportation and disposal) as per national guidelines.

4.3.1 Ministry of Health guiding principles for management of health care waste.

The Ministry of Health in its guidelines for management of health care waste prescribes a set of guidelines health facilities and health workers should adhere to[3]. These include:

- Every health facility shall have some one in-charge of health care waste management.
- Waste management guidelines shall be made available to health workers.
- All health workers will follow waste management guidelines as elaborated in the national infection prevention and control guidelines.
- Health care waste shall be segregated at the source into pre-color coded containers. Pre-coded (red-color) plastic garbage bags are the recommended containers for disposal of medical waste that has been contaminated by blood or body fluid. Non-hazardous waste should be put into a different color bag.
- Sharps shall be collected into secure sharps containers or safety boxes immediately after use.
- Sharps containers will be disposed of when 3/4 full.

[1] World Health Organization. Prevention of Hospital Acquired Infections – A practical Guide. Second edition. WHO/CDS/EPH/2002.12 Geneva, WHO, 2002

[2] Uganda Ministry of Health. National policy on injection safety and health care waste management, 2004

[3] Uganda Ministry of Health. National policy on injection safety and health care waste management, 2004

- The recommended final disposal method is incineration. Where incinerators are not available; the sharps' containers shall be burnt followed by burying.

The national policy on injection safety and health care waste management has recommended incinerators with high temperature as the preferred method of final waste disposal. The incinerators where available, should be regularly monitored for maintenance of appropriate temperatures[1].

4.3.2 Waste generated in malaria testing

In malaria diagnostic procedures, the following types of wastes are generated: general waste (generated from administrative and housekeeping functions of the laboratory), infectious waste (cultures and stocks of infectious agents from laboratory work), pathological waste (tissues, and materials or equipment that have been in contact with blood or other body fluids), sharps (needles; infusion sets; scalpels; knives; blades; broken glass), pharmaceutical waste (pharmaceuticals that are expired or no longer needed; items contaminated by or containing pharmaceuticals), and chemical waste (laboratory reagents; disinfectants that are expired or no longer needed and solvents).

The procedures to manage waste generated from malaria diagnosis are therefore as prescribed by the Ministry of Health. Specifically, the tenets of management of health care waste at any of the levels of service delivery should bear in mind the following principles:

- Minimizing health care waste requires that all purchases of material and supplies be made with waste reduction in mind
- Segregation of waste by deliberately separating waste according to type of waste at the source of generation. Different types of waste are separated in different color-coded containers. Waste should be separated by the person who generates it immediately. Health workers, particularly waste handlers, should never sort waste after it has been placed in the bin as this may cause injury and exposure to blood-borne pathogens;
- Disposal of waste through burying (waste is placed in a pit and covered with soil), burning (waste is placed in a pit and burned on a regular basis, at least once a week, according to the volume of waste and the size of the pit), and
- Incineration of waste (high temperature burning).

1. At the Community level

- Contaminated (infectious) sharps: these include lancets/ prickers and should be collected in puncture-proof sharps containers fitted with covers and treated as infectious and should be transported to the nearest health centre for final disposal.
- Infectious non-sharps waste such as contaminated cotton wool should be placed in strong leak resistant plastic bags, packaged and transported to the nearest health facility for disposal.
- Non-infectious non-sharps waste is considered as house hold waste. This should be collected in a plastic bag or other collection device colored green and disposed of

[1] Uganda Ministry of Health. Uganda National Infection Prevention and Control Guidelines, 2013

appropriately. All waste should be put into the sharps box except RDT packaging and gloves.

- Expired RDT kits should be transported back to health facility for further management.
- A well prepared laminated wall chart with clear safety pictorial guide will be provided to the VHTs
- VHTs should be provided with personal protective equipment (PPE) and taught how to use it before they are allowed to do RDT testing
- If VHT is exposed to blood and body fluids, say through finger prick, should report to higher health facility immediately where post-exposure prophylaxis (PEP) should be given as described below.

2. At Health Centre II level

- Contaminated (infectious) sharps and infectious non-sharps wastes: disposal is done at site in accordance with national guidelines for waste disposal.
- Non-infectious non-sharps wastes: considered as house hold waste, should be collected in a plastic bag or other collection device marked green and disposed of appropriately.
- Expired RDT kits should be transported back to NMS through the established channels for further management.

3. At Health Centre III level

In addition to infectious and non-infectious waste generated at this level, broken and used slides and chemical wastes may be generated as a result of microscopy.

- Infectious materials should be decontaminated and disposed according to national guidelines.
- Chemical effluents should be decontaminated prior to disposal
- Expired stains/chemicals should be transported to national level for appropriate handling. Where sinks are available, expired chemicals should be flushed with plenty of water down the drainage system at the health facility
- Autoclave microbiological waste

4. **At Health Centre IV level,** all the above functions are carried out in addition to autoclaving and incineration where the facility exists.

5. **Private facilities (PNFP & PHP)**
   All private health facilities (private not for profit and private for profit) with laboratory services should handle waste in accordance with the national guidelines for management of waste.

4.3.3 Health and medical surveillance

As health care workers and VHTs at community level working with blood, it is possible to acquire blood-borne pathogens such as hepatitis B, C and HIV. The following guidelines should be followed in the event of such exposure:

- Provision of active and passive immunization or prophylactic treatment where indicated

- Facilitation of the early detection of laboratory- acquired infections
- Provision of effective PPE and procedures

4.3.3.1 Guidance on Post Exposure Prophylaxis (PEP)

Post-Exposure Prophylaxis (PEP) is an emergency medical response consisting of short-term disease-specific treatment to reduce the likelihood of a particular infection after exposure to potentially infectious blood or body fluids either through occupational or non-occupational contact. Any healthcare worker accidentally exposed to blood or body fluids must take the following steps:

- Get the source and yourself tested for HIV and Hepatitis B according to national guidelines
- Refer to national guidelines for PEP

4.4 Quality Management system for malaria diagnostic tests

Introduction

The Ministry of Health has developed a national framework for quality improvement as elaborated in the MOH's Health Sector Quality Improvement Framework and Strategic Plan 2010/11 – 2014/15 published in 2011[1]. It targets all public and private health institutions, partners and stakeholders. It is the framework intended to coordinate, plan, mobilize resources, implement, monitor and evaluate quality improvement initiatives in Uganda in order to "ensure provision of high quality health services and contribute to the attainment of good quality of life and well-being at all levels of health care". A well-performing diagnosis programme requires a well-designed, fully implemented quality management system (QMS). This is critical because clinicians can only have faith in the results they receive if they are confident of the quality standards in malaria diagnosis. The QMS for malaria diagnostic tests will include all the processes necessary to ensure that the laboratory diagnostic results for microscopy and RDTs are reliable and timely for prompt patient management. The quality management system is designed to provide control mechanisms at the critical points of the test processes and covers both microscopy and RDTs.

Objective

- To provide a guide for ensuring accurate, reliable and timely laboratory malaria test results

[1] Uganda Ministry of Health. Health Sector Quality Improvement framework and strategic plan 2010/11 – 2014/15, published 2011.

4.4.1 Requirements for national quality management system

National level

At the national level, the malaria microscopy and RDT quality management activities will be performed by the National Malaria Control Program as the technical lead supported by the CPHL. Existing structures at this level will:

- develop and coordinate quality management plan for malaria diagnostic tests
- set and regulate quality standards for all the testing sites and test performance
- provide oversight for malaria diagnostics at all levels as specified by the national malaria microscopy and RDT guidelines
- establish and manage national malaria microscopy slide bank, national external quality assessment schemes programs (proficiency testing, blinded re-checking and site evaluation) as may be deemed necessary
- coordinate the in- country validation of RDT performance through use of known positive and negative control samples and positive control well lot testing
- coordinate the development of standard operating procedures, job aids and operation plans for malaria microscopy and RDTs
- identify poor quality performance through EQA program and supportive supervision and guide relevant corrective action towards continuous quality improvement
- coordinate a national program for malaria diagnostic and device servicing and maintenance management
- build the capacity for malaria microscopists and their laboratories for accreditation with recognized bodies

Regional level

At the regional level, the malaria microscopy and RDT quality management activities will be led by the regional laboratory quality coordinator. Activities at this level will be to:

- develop and coordinate the district quality management plan for malaria diagnostic tests
- work with the implementing partners operating within the region to supervise the malaria microscopy and RDTs quality management activities
- provide technical support to the districts and health facilities in the implementation of national malaria external quality assessment
- support the implementation of the recommended corrective actions towards continuous quality improvement

District level

At the district level, the malaria microscopy and RDT quality management activities will be led by the district laboratory focal person. Specific activities will consist of the following:

- develop and coordinate the district quality management plan for malaria diagnostic tests at facility level
- work with the implementing partners operating within the district to supervise the malaria microscopy and RDTs quality management activities
- supervise EQA programs for slide proficiency testing, lot testing for RDTs and validation of routine blood slide results (cross-checking)
- distribute the malaria microscopy and RDTs standard operating procedures and job aids to the health facilities
- identify gaps in laboratory personnel competency through supervision and participate in training of the laboratory personnel in the district
- provide support to the health facilities to implement recommended corrective actions towards continuous quality improvement
- monitor quality control of reagents, kits and equipment

Health facility level

At the health facility level, the malaria microscopy and RDT quality management activities will be led by the laboratory quality manager supported by the facility in-charge. The activities will consist of the following:

- develop and implement quality management plan for malaria diagnostic tests in the laboratory
- provide oversight for quality management of malaria microscopy and RDTs where applicable
- participate in nationally recommended malaria EQA scheme
- perform malaria diagnosis according to the approved standard operating procedures and/or job aids for malaria microscopy and RDT techniques
- implement recommended corrective action geared towards continuous quality improvement
- routinely perform internal quality control for reagents, kits and monitor equipment performance and reporting quality system failure to the health facility management
- participate in regular competency appraisal in the malaria microscopy and RDT diagnostic techniques
- develop and implement an updated laboratory document control system
- perform regular laboratory process quality audits and taking actions to rectify the root causes of poor performance
- store the malaria diagnostic reagents appropriately
- regularly perform and interpret internal quality control testing
- provide EQA support to VHTs by routinely testing the quality of RDTs kept at the community level.

Community level

At the community level, although RDT will be used and the quality management activities performed by the village health team, health workers from the supervising health facility will be expected to provide close supervision of VHT activities. VHTs will be expected to:

- strictly adhere to the job aid for RDTs testing and reporting
- correctly store RDTs at the recommended storage conditions
- be regularly supervised by health workers and their RDT testing competency appraised by nearest health center

Implementing partners

The NMCP will provide the overall strategic and policy oversight in the implementation of the QMS while the CPHL will provide technical oversight. Implementing partners operating at the different levels of the laboratory services delivery i.e. national, regional, district, health facility and the community levels will implement QMS activities for malaria diagnosis within the national malaria control policies and laboratory framework at the different levels of service delivery as described above.

Private sector

The private sector will work with the MoH as provided for in the Public - Private – Partnership in Health (PPPH) guidelines in order to bring its quality management system to the same standards as of the public sector.

National Drug Authority

The National Drug Authority (NDA) or other body mandated by law or delegated by the Ministry of Health will ensure that only high quality malaria diagnostic commodities are imported into the country[1]. Pre-market and post-market evaluation will be conducted on all malaria diagnostics commodities. This process includes:

- ensuring that all diagnostic products in-country conform to recommended WHO and national standards
- inspection of samples at ports of entry by the NDA
- monitoring the quality performance of diagnostic product in the market
- strengthening control against illegal entry of diagnostic products at all border points by NDA
- make recommendations and disseminate to relevant stakeholders
- post-market surveillance

[1] Uganda National Drug Authority. (1) guideline for registration of medical devices, and (2) guideline for registration of malaria RDTs. 2009

4.4.2 Key responsibilities of selected institutions with regard to supporting the Quality Management system for malaria diagnostics

National Malaria Control Program (NMCP)

The National Malaria Control Program (NMCP) will support the quality management system for malaria diagnostics through:

- Providing oversight in policy formulation and review, guidance and strategic planning and management of the quality management system for malaria diagnostics
- Mobilizing resources for implementation of the quality management system
- Establishing standards for:
  - Pre- and in-service training programs for laboratory staff and development of training materials and curriculum
  - Competency assessment and performance of microscopists according to international standards
  - Accreditation of microscopists in liaison with the WHO
  - Establish a national reference group of expert microscopists who will support microscopy district capacity
- Participating in pre- and in-service training programs for laboratory staff
  - Set up a national blood slide bank and prepare reference slide sets for training
- Defining specifications for malaria diagnostics commodities and supplies
- Ensuring that equipment is maintained in good working order at all times and that there are no breakdowns in the supply-chain for laboratory equipment and supplies including RDTs.

Central Public Health Laboratories

In line with the Uganda National Health Laboratory services policy, 2009[1], the Central Public Health Laboratories (CPHL) will provide technical support to the implementation of the Malaria Quality Assurance program. The technical support will include the following areas:

- In collaboration with partners conduct needs assessment and sensitization for the malaria microscopy and RDT quality assurance program
- Coordinates international external quality assessment programme for reference laboratories
- Develops and guides implementation of national malaria quality assessment scheme
- Provides feedback reports to health facilities and stakeholders on adherence of testing sites and test performers to set quality standards
- In collaboration with partners develop training materials for national laboratory training institutions
- In collaboration with partners develop malaria refresher training curriculum for health facility staff in the laboratory diagnosis of malaria
- In collaboration with partners support supervise the health facilities
- In collaboration with partners supervise slide re-reading at the secondary level
- In collaboration with partners participate in the evaluation of health facilities, providing feedback on facility performance and national dissemination of activity report

[1] Uganda Ministry of Health. Uganda National Health Laboratory services policy, 2009

- In collaboration with partners participates in the management of Malaria External Re-checking Quality Database
- Advise on the procurement of laboratory reagents, supplies and equipment
- In collaboration with partners initiate the formulation of policies on laboratory malaria diagnosis
- Conduct equipment audits and regular maintenance /servicing

Regional referral laboratories

The regional reference laboratories shall be responsible for the following:

- Perform needs assessment of the health facilities under their supervision
- Plan and implement training and training activities
- Maintain equipment and repair
- Supervise the district laboratory focal persons
- Ensure SOPs for both microscopy and RDTs are available and are up-to-date in all health facilities
- Provide advice on supply chain of equipment and supplies at health centers thus eliminating stock-outs.

Districts

The district laboratory/ malaria focal person shall be responsible for the supervision and monitoring of activities to maintain the quality of malaria microscopy and RDT at the district peripheral laboratories and at the community level. Their roles include the following:

- Conduct quarterly (or at least semi-annual) visits to laboratories. Joint visits by clinicians and laboratory staff is recommended
- Supported by CPHL, carry out the external cross-checking of slides and RDT panel testing taken at district/health centre (peripheral level) in accordance with the SOPs provided by the CPHL.
- Provide feedback of results to health facility, VHTs and stakeholders on adherence of testing sites and test performers to set quality standards
- Plan and implement training and refresher training activities
- Ensure that equipment is maintained in good working order
- Provide advice on supply chain of equipment and supplies at health centers thus eliminating stock-outs.
- Monitor temperature of RDT storage areas in health facilities

Health facility level

The diagnostic performance of malaria microscopy depends strongly on the competence of the microscopist in preparing, staining, examining and interpreting malaria blood slides. A microscopist at the lowest level of the laboratory network should be able to detect the presence or absence of malaria parasites (in a slide set of 10 negative and 10 positive slides) with more than 90% accuracy.

To ensure satisfactory quality at the testing site level, the minimum competencies expected of a microscopist for basic malaria microscopy against which QA shall be performed include the following:

- Correctly prepare blood film
- Properly stain blood films
- Correctly use and maintain microscopes
- Correctly identify and quantify malaria and other heamo-parasites
- Correctly report and record data
- In depth understanding of IQC, EQA and other performance evaluation standards
- Knowledge of the HMIS 033B reporting format for malaria diagnostic and treatment data
- Microscopy reagent stock management and reporting

The following are the minimum competencies for performance of RDTs

- Undergoing MoH recommended RDT training for testing
- Ability to perform and interpret the result correctly
- Proper kit management including proper storage and temperature monitoring of RDT storage
- All testing facilities without provision for laboratory services should have a designated place with a water-proof (may be polyethylene) testing surface.
- Knowledge of the HMIS 033B reporting format for malaria diagnostic and treatment data
- RDT stock management

Other general competencies are:

- Conduct internal audits, where possible, to check their own performance and to ensure the reproducibility and sensitivity of laboratory diagnoses
- Undertake training in basic quality control
- Undertake training in blood safety
- Bio safety/waste management
- Basic inventory control and stock management
- Conduct supervisory visits to the community to ensure the quality of RDTs, the competence of VHTs to perform RDT and to interpret and correctly use the results of RDT testing

At community level

The VHT trained to use RDTs should be able to:

- correctly perform an RDT
- correctly interpret the result
- correctly use the results of the RDT test in treating patients

- correctly store RDTs using locally adapted cooling boxes for storage of RDTs
- ensure RDTs are not exposed to direct sunlight or high temperatures.

4.4.3 Standard operating procedures and job aids

Uganda has developed a series of standard operating procedures (SOPs) and job aids for both microscopy and RDT use. These SOPs and job aids well documented in the Ministry of Health's Central Public Health Laboratory: Standard Operating Procedures (SOPs) for Health Laboratory Services. Third Edition. 2011 document.

Monitoring of the quality management system

All the actors at the various levels of the health system are required to continuously monitor the quality management system for malaria diagnosis. The key components to be monitored include:

- Capacity (documentation, infrastructure, staff and workload)
- Performance (procedures, quality control, patient care, competency and ability to read slides or interpret RDTs correctly)
- Safety (blood collection and laboratory)
- Diagnostics stocks
- Coverage of Diagnostics programs (training, Test Rates, Slide Positivity)

4.5 Training and supervision

Capacity development through training, mentoring, coaching and supervision are key elements of proper malaria diagnosis. The Ministry of Health National Malaria Control Program will provide the overall oversight and coordination of all malaria diagnostics training programs in the Country. Everybody conducting trainings shall use the nationally approved curriculum and training manuals and nationally accredited and certified National Trainers.

The training processes will include:

- Conducting a training needs assessment
- Mobilization for training
- Plan for pre-service training
- Plan for in-service training at all levels
- Support supervision and mentoring at all levels

All training activities will be based on the existing national training materials/Manuals (e.g. RDT users manual, SOPs, manufacturer job aids, microscopy training curricula). All trainings in malaria diagnostics will be conducted in close consultation with the National Malaria Control Program to ensure coordination, avoid duplication and wastage of resources. National trainers on RDTs and Microscopy will be senior members of the health profession with demonstrated

experience, proficiency and expertise in malaria and malaria diagnostics. All national trainers will under-go national TOT programs before they are allowed to participate in the roll-out of training malaria training programs.

Objectives

The objectives of training are to:

- Provide information on malaria diagnostic methods using microscopy and RDT
- Facilitate continuous improvement of health workers' malaria diagnostic skills
- Harmonize malaria diagnostic practices among all stakeholders
- Strengthen safety and waste management practices
- Educate users on medical device regulation and registration
- Strengthen the knowledge base on weekly and monthly reporting of health data through the HMIS
- Develop support supervision and mentorship capabilities

4.5.1 Training needs assessment

Identification of training gaps will be done by the Ministry of Health National Malaria Control Program, District Health Team, CPHL and development partners. Strategies for this assessment will be through;

- Administration of questionnaires
- Interviews
- Support supervision findings, and
- Self assessments

The gaps identified in the needs assessments will guide the review of the existing curricula.

4.5.2 Mobilization for training

In order to gain stakeholders' support for a successful training process, the following should be mobilized;

- National (MOH/NMCP) and district health managers,
- Persons in charge of laboratories and health facilities providing malaria diagnostic services;
- Clinicians, laboratory staff and paramedics (nurses, pharmacists, community health workers and supervisors) involved in malaria diagnosis and treatment in the public sector;
- Health workers in the private sector involved in malaria diagnosis and treatment; and
- Representatives of the community.

The mobilization will be done through sensitization meetings. The discussions at these meetings focus on:

- The importance of parasitological confirmation of malaria diagnosis,
- The equivalence of microscopy and RDTs to detect malaria in symptomatic individuals, including a demonstration of the performance of malaria RDT.
- Discussions on issues such as the tasks and capacity of the focal person for malaria diagnosis at health facilities with no laboratory; where and by whom RDTs should be performed in health facilities; the role of clinical and laboratory supervisors in sites with laboratories; blood safety; waste management; beliefs and concerns of community members in relation to blood examination and finger-pricking.
- Safety of treating patients on the basis of the malaria test result.
- Sustainability of the training programme

4.5.3 In-service training at all levels

In-service training will be carried out using the cascade mode of training. A pool of master trainers at the national level will be selected from Ministry of Health, Referral hospitals, Training institutions and implementing partners and other NGOs. The master trainers will conduct training of trainers (TOT) courses up to district level. The trainees to attend the TOT will be drawn from DHTs, In-charges of health units/wards and Senior Health workers.

Trainers trained by master trainers will thereafter cascade the training up to all the other health workers and the community (VHTs). The criteria for selection of trainees at the community level as VHTs will be as provided for in the guidelines for selection of VHTs[1]. Training will be continuous including refresher trainings and training of new staff. The details (content, methodology, time frame, materials etc) of the training for the different levels of trainees will be obtained in the training manuals and curricula. The training content will be developed and regularly updated by the diagnostics steering committee of the NMCP.

4.5.4 Pre-service training

The new diagnostic technologies for malaria should be introduced in the curriculum for pre-service training so that fresh graduates from training institutions have the requisite knowledge, attitude and skills for parasite based diagnosis of malaria. Health training schools and institutions should all update their curricula to cover at the minimum training in integrated management of fever guideline[2] adopted by the Ministry of Health.

4.5.5 On-going support supervision and mentoring

The Ministry of Health already has guidelines for support supervision[3]. These guidelines prescribe the process and steps for conducting supervision at different levels of health service delivery. The supervision is conducted to assess the quality and performance of diagnostic

[1] Uganda Ministry of Health. VHT handbook
[2] Uganda Ministry of Health. Integrated Management of Malaria (IMM) training manual, 2012
[3] Uganda Ministry of Health. Support supervision guidelines: support each other

testing on site by qualitative and/or quantitative surveys at all levels of service delivery. The support supervision should include:

- Capacity strengthening for national and district support supervisors (technical, managerial and supervisory skills) to evaluate health facilities across public and private health sectors
- Developing a supervisory team within districts and health facilities for a feasible performance evaluation system that can provide a day-to-day support and supervision
- Ensuring availability of job aids, algorithms, stock monitoring tools and other appropriate tools
- Observation of procedures
- Verification of recorded and collected data
- Identification of constraints and causes of deficiencies
- Identification of corrective measures
- Provision of on-site re-orientation, training and mentoring
- Formulation of recommendations for improvement

It is recommended that supervision of malaria diagnosis should be integrated with that of the clinical management of malaria and of febrile patients in general.

Supervision should also include components of quality management for malaria diagnostics, such as:

- the availability and regular use of standard operating procedures and job aids
- competence in performing RDTs and microscopy, by direct observation of health workers performing an RDT and interpreting the result
- quality of microscopy for malaria
- RDT storage
- Stock management
- Waste management
- Internal audits
- Equipment and maintenance.

Supervision and mentorship should also include observation of clinicians attending patients to ensure their adherence to malaria test results, their ability to manage malaria-negative patients and their ability to advise patients on when to return. The observations and corrective actions taken during supervisory visits should be documented on checklists, to give prompt feedback and to monitor changes over time.

4.6 Social and Behaviour Change Communication (SBCC) and Advocacy

Introduction

Not all fevers are due to malaria. Parasitological diagnosis of malaria is therefore critical for effective fever case management. Universal access to malaria diagnostic testing requires a major shift, from presumptive treatment of febrile episodes to treatment based on test results. This change in behaviour requires a change in health workers' and patients' attitudes and habits with regard to fever. This is the focus of all social and behavior change communication activities to be implemented in support of parasite based diagnosis of malaria in Uganda.

The main objective is:

- To increase consumer engagement in decision making regarding their health, as well as adherence of health service providers to parasite based diagnosis and test based treatment of malaria.

Within the department of Community Health in the Ministry of Health is the division of Health Promotion and Health Education. The Health Education division supports all information, education and communications activities of the MOH. The NMCP has a Team Leader for IEC/BCC. The NMCP strategic plan has a section on social and behavior change communication (SBCC) and supporting communication and advocacy activities for malaria diagnosis is one of its functions. The main outcomes expected of these SBCC activities are:

- rational use of medicines by patients by actively demanding for proper diagnoses; not demanding for antimalarial medicines when a malaria test is negative or for antibiotics in the case of upper respiratory tract infections; and not demanding for injections for uncomplicated illnesses; and
- correct diagnostic and medicine-dispensing practices by health-care providers, confirmation of a malaria diagnosis by microscopy or RDT, reliability of test results, compliance with positive and negative test results, and prescription of antibiotics when, and only when, indicated.

4.6.1 Roles and responsibilities at different levels:

In order to realise these objectives, all the stakeholders at all levels - policy-makers, government, multilateral and bilateral agencies, professional medical and pharmacy associations, non-governmental organizations, community-based organizations, hospitals and community and private sector representatives - should be brought together, since each of these have specific roles and responsibilities to play.

- National level: Prepare and finance a plan for advocacy, communication and social mobilization.
- District level: Disseminate the messages as widely as possible.

- Health facility and community levels: adopt the messages and transmit them through the agreed delivery channels, e.g. during routine interactions with patients and community members, particularly those with influence, such as teachers and village leaders.

Communication and education activities should be synchronized with training and distribution of diagnostic test. For each category of audience to be reached, an appropriate delivery channel must be identified which may be television, print, radio or interpersonal communication approaches.

4.7 Monitoring and evaluation and research

Introduction

Monitoring, Evaluation and Research are key components of this implementation guideline. A sound M&E and Research plan for malaria diagnostics at the country level is critical to track the scale up of diagnostics and implementation of the guidelines. This plan allows tracking coverage and measuring the impact of the scale up of malaria diagnostics and making effective use of information for continued planning and advocacy.

Objectives

1. To provide a quality assured body of evidence for the roll out of malaria diagnostics in Uganda in a timely manner
2. To track progress or lack thereof of the implementation of the malaria diagnostics guideline
3. To update the existing data collection tools in line with the national quarterly HMIS review and/or new recommendations by WHO and national regulatory bodies.
4. To set malaria research priorities that are relevant to malaria diagnostics scale up in Uganda
5. To review the new body of evidence base to inform a change or replacement of existing diagnostic tools and introduce new ones
6. To mobilize resources for malaria research in a coordinated manner, throughout the country

4.7.1 Monitoring

The Ministry of Health already has a framework for measuring the performance of the Malaria Control Programme and its component parts are articulated in the MOH's Monitoring & Evaluation Plan for National Malaria Control Strategic Plan 2010/11 – 2014/15 published in 2012[1]. This Plan includes information about the programme such as inputs, activities, outputs and outcomes. The monitoring of this national roll-out of parasite based diagnosis of malaria will be implemented within the same framework. Monitoring will be based on assessments of monthly data collected through the routine Health Management Information System (HMIS) of the MOH and through project and programme reports of implementing partners and reports from the private sector.

Key indicators

Some of the indicators to be monitored will include:

- Number of suspected malaria cases
- Number of patients tested by RDT

[1] Uganda Ministry of Health. Monitoring and Evaluation Plan for National Malaria Control Strategic Plan 2010/11 – 2014/15

- Number of patients tested by microscopy
- Proportion of fever cases subjected to a parasitological test.
- Number of confirmed malaria cases receiving first- line antimalarial treatment (ACT)
- Number of health workers trained to perform RDTs for malaria per health facility
- Number of technicians accredited for malaria microscopy per targeted laboratory

The main outcome of strengthening diagnostic services will be the ***'percentage of suspected malaria cases tested for malaria'***. Universal access to malaria diagnostics will be reached when this indicator is close to 100%. If it is < 100%, there is under-testing of patients, and more effort should be made to achieve universal access; if it is > 100%, there is over-testing of patients and thus wastage of malaria tests.

Data collection

Collection of data for these indicators will be through routine HMIS system which has a place for weekly reporting of malaria burden (through the weekly reporting form HMIS 033b) and the monthly health unit reporting form HMIS 105. Population-based indicators will be obtained through periodic surveys such as the Malaria Indicator Survey (currently on a 3-year schedule) and the Uganda Demographic Health Survey (on 5 year schedule). A self-assessment /feedback system will be embedded to ensure effective communication with end users.

Data collection tools

The MOH[1] has already a defined set of tools to be used for collecting these indicators. These include the patient register, the weekly, monthly and annual forms found in the HMIS manual. The HMIS manual defines the frequency of reporting and the channel of reporting by each level of health care.

Health workers will continuously be trained on how to use the various HMIS tools and how to analyze their own data. Also, the districts and national level are required to provide feedback to the lower facilities on their performance.

Indicators based on data provided by sources other than the HMIS will also be used, such as the quantities of RDTs and ACTs ordered by health facilities or issued by the National and Joint Medical Stores and reports from districts and health facilities on stock status of RDTs and ACTs.

Other mechanisms for data collection being rolled out include the use of **mTrac** for tracking of medicines and reports of ICCM implementation by the Village Health Teams. mTrac is an innovation using SMS to track the health facility stock of essential medicines like the anti-malarial drug ACT. Launched by the Ministry of Health with support from UNICEF and other partners, mTRAC allows health facility workers to send government reports by SMS, including real-time data to map facility stocks. The aim is to avoid unnecessary stock-outs and to ensure transparency and accountability for the drugs.

[1] Uganda Ministry of Health. HMIS Manual

The MoH has further emphasized the needs highlighted by this policy guideline, through SMS and PC based reporting of health data, including test data (mtrac and DHIS2). This enables real time access to the malaria diagnosis and treatment picture in a timely and complete manner, following validation at District level.

4.7.2 Evaluation

To further strengthen evaluation of the successful roll-out of parasite based diagnosis of malaria, diagnostics assessments will be included in the regular malaria program evaluations such as midterm and terminal reviews. Additionally, the Ministry of Health and development partners will be encouraged to design studies to evaluate cost of implementation of parasite based diagnosis of malaria in Uganda.

4.7.3 Operational Research

Some of the areas recommended for operational research include:

- Field testing of new RDTs (Quality Assurance for RDTs in the field) to inform policy
- Use of RDTs by VHTs and private drug shops (determine how to scale up RDTs in the private sector including adherence to test results)
- Adherence to RDT test results (assess factors influencing provider adherence to test results and pilot approaches to improve adherence)
- Accuracy of diagnostic algorithms, and the comparison between low and high prevalence areas
- Evaluating the sensitivities and cost-effectiveness of malaria RDTs verses microscopy especially in low transmission settings
- Assessing uptake, utilization and reporting on malaria diagnostics in formal private health sector
- Relative effectiveness of various communication and BCC strategies on a) uptake of RDTs and b) adherence to result
- Examine hybrid models for use of RDTs in higher level public facilities, in tandem with microscopy

4.7.4 Research Coordination mechanism

The Ministry of Health operates a Malaria Research Centre which will coordinate any operational research proposed. The Uganda Malaria Research Centre (UMRC) is charged with the responsibility of coordinating malaria researches in the whole country including the funding partners and disseminating findings from research. In collaboration with the various stakeholders such as the Uganda National Health Research Organization (UNHRO), Uganda Virus Research Institute (UVRI) and Uganda National Council of Science and Technology (UNCST), the UMRC leads efforts to translate current evidence for policy makers and planners through formal data discussion and dissemination platforms.

5.0 Institutional arrangements (Roles and responsibilities): NMCP, NMS, CPHL, NGOs, Development Partners, National, District, Health facilities, communities, regulatory and professional bodies

The National Health System (NHS) is made up of the public and the private sectors. The public sector includes all GoU health facilities under the MoH, health services of the Ministries of Defence, Education, Internal Affairs (Police and Prisons) and Ministry of Local Government (MoLG). The private health delivery system consists of Private Not-for-Profit (PNFP) providers, typically faith-based, Private Health Practitioners (PHP), and the Traditional and Complementary Medicine Practitioners (TCMP).

The formal health care system in Uganda is stratified into the National and Regional referral Hospitals (NRH & RRH), with a five-tier system at District level consisting of the health centre V (General District Hospitals), health centre IV (Health Sub-district), health centre III (Sub-county), health centre II (Parish) and the health centre I at village level is organized as the village health team (VHT). In each of the 112 districts, the District Health Officer (DHO) is responsible for overseeing all facilities (including pharmacies and drug shops) and health services in the district, including those operated by not-for-profit organizations, partners and the private sector. Some responsibilities are delegated to the Health Sub-Districts that form the lower level of health services management. Although not a physical structure, the Health Centre I is at community level organized in "village health teams". The traditional and complementary medicine practitioners are organized in several professional organizations and play an important role in malaria control in Uganda.

The roles and responsibilities at various levels for ensuring universal access to malaria diagnostics will be vested in the same levels of national health system described above.

5.1 At National level

The following stakeholders will be involved in the implementation of the guideline: NMCP, NDA, CPHL, NMS, Development Partners, Regulatory Councils, and Professional Associations.

Depending on their respective mandates and in close collaboration, the following shall be the roles at National level:-

- Provide policy oversight, strategic panning and management of malaria diagnostic programs
- Developing the annual national operational plan of activities
- Updating and harmonizing national health policies
- Selecting RDTs, microscopes, stains and related supplies; and conducting quantification for these equipment and supplies
- Transport equipment and supplies from national medical stores to district and hospital stores
- Carry out storage and stock management of diagnsostics and supplies at the National medical stores
- Implement Medical equipment management policy and maintenance tools

- Establish a quality management system: National reference laboratory, training in quality management, monitoring of sub-national reference laboratories, accreditation schemes for microscopists, proficiency testing and/or slide validation, request for lot-testing of RDTs
- Establish National standards, training curricula, training materials, planning, funding, coordination and facilitation of courses
- Develop advocacy and SBCC strategy development, produce materials and messages adapted to local context
- Standardize tools and reporting format, evaluation of supervisory system and overall performance
- Licensing and monitoring of private health facilities and private laboratories, quality control of private suppliers
- Integration of malaria diagnostics with other laboratory services
- Integration of malaria diagnostics into fever management and general healthcare delivery (e.g. IMCI, IMAI, ICCM)

Some of the roles above that include the following will be delegated to the zonal co-coordinators and districts depending on their capacity and resources:

- Support supervision
- M&E
- QA/QC
- Coordination of district activities
- Training

5.2 District Level

Key stake holders at district level include:

- DHT and DHMT members
- District political leaders
- Implementing partners at district level
- Opinion leaders

Roles and responsibilities at the district level

- Develop district plan of activities
- Compile requests for supplies based on local quantification and submit to NMS
- Transport equipment and supplies from district store to health facility when required
- Conduct Medical equipment maintenance
- Perform QMS at District reference laboratory, slide validation, visits to malaria testing sites, direct observation of microscopists and health workers performing RDTs
- Facilitate training courses

- Carry out planning and implementation of community sensitization activities at district level
- Conduct planning and implementation of on-site supervisory visits of health facility and community health workers and feed-back
- Conduct inspection, supervision and training of private health facilities and laboratories, and quality control of private suppliers
- Prepare reports and update district leadership on the progress of the roll out

5.3 Implementing Partners and NGOs

These include NGOs and projects implementing malaria control activities at all levels of service delivery. Examples include: MALARIA CONSORTIUM, AMREF, FIND, EPICENTRE, IDI, CHAI, MC, UNIVERSITIES, SMP, UMSP and others.

Implementing partners typically will have cross-cutting roles and responsibilities. These will include:

<u>At the National level</u>

- Participate in development of policy and guidelines
- Participate in Planning (National, Regional and Community) - development of work plans
- Advise on product selection and procurement
- Budgeting and resource mobilization

<u>At sub-national level and Community</u>

- Implement diagnostic programs (training, testing and quality assurance)
- Support the distribution of manuals & guidelines
- Participate in Advocacy, Communication & Social Mobilization
- Participate in supervision
- Partner with Private sector to provide the services
- Transport equipment and supplies to points of care
- Storage and stock management of laboratory diagnostics and supplies
- Advise and provide coordination for Quality management system
- Training (pre- and in-service) – Participate in funding & development of training tools (Training curricula, funding, facilitation of courses)
- Monitoring, Evaluation and Research – provide data on performance, tolerability, adherence and feasibility

5.4 At Health Facilities including hospitals, Health Centres IV, III and IIs.

- Supply chain management

- ✓ Documentation of consumption data of malaria supplies (reagents and consumables)
- ✓ Timely ordering of supplies from NMS and/or JMS
- ✓ Stock management through source documents

- Malaria testing
  - ✓ Prepare reagents
  - ✓ Do microscopy
  - ✓ Perform RDT testing
- Quality Assurance and QC
  - ✓ Write and/or use SOPs
  - ✓ Prepare and /or use positive and negative control slides
  - ✓ Store QC slides according to national guidelines
  - ✓ Maintain equipment
- Safety & infection control/waste management
  - ✓ Follow professional code of practice for ensuring safety and infection control
  - ✓ Adhere to safety procedures
  - ✓ Ensure that staff are given adequate health and medical surveillance (regular screening, immunization and PEP for staff)
  - ✓ Follow proper waste management procedures
- Training
  - ✓ Conduct performance needs assessment (knowledge and skills gap)
  - ✓ Conduct task based training
- Supervision & mentoring
  - ✓ Supervise and mentor lower health facilities
- Data management
  - ✓ maintain a good laboratory management information system
  - ✓ Timely analysis of data and submission of reports to relevant authorities.

- Plan for and conduct community health worker supervision
- Select health workers, community health workers and other staff for microscopy and/or RDT training
- Sensitize patients in health facility and dissemination of health education materials for use by community health workers

5.5 At the community (village health team - VHT)

In the implementation of this guideline, the community stakeholder will be the village health team (VHT) and will be responsible for:

- Ensuring timely ordering of supplies from health center 2 or nearest facility to maintain the stock levels
- Safe storage of the diagnostic supplies before use and guard against theft
- Adherence to the RDT standard operating procedures (job aids)
- Perform RDT tests at community level

- Ensure personal safety and adequate disposal of waste generated during laboratory testing
- Manage the testing records and submit to the higher level
- Adequately refer complicated cases to higher level of health facility for management
- Adequately mobilize and sensitize the community members on the malaria testing services offered