Operational Guidance: Procurement of Malaria Rapid Diagnostic Tests through Global Fund Grants

Effective as of 1 November 2019

Background

Ensuring universal access to malaria prevention, diagnosis and treatment is an essential pillar of the Global Technical Strategy-2016-2030. As a cornerstone of effective case management, WHO recommends that all suspected cases of malaria be confirmed with a parasitological diagnostic test prior to treatment with a quality assured anti-malarial medicine.

Malaria rapid diagnostic tests (RDTs) are crucial to improve the diagnosis and management of malaria, especially where quality microscopy diagnosis cannot be provided. Continued supervision and training on the use of RDTs is required as part of ensuring quality of diagnosis.

Countries have demonstrated effective use of multiple types of RDTs (targeting the same species) at the same time and thus training and supervision should be independent of product brand to ensure health workers are able to use the product(s) available at any given time.

A variety of RDTs for the detection of the different malaria antigens are available on the market; quality and performance might vary substantially among the different products. Ensuring the quality of RDTs is essential to ensure accurate diagnosis. Eligibility of malaria RDTs is guided by the listing by WHO Prequalification of Diagnostics[1] and List of Rapid Diagnostic Test (RDT) kits for malaria classified according to the Global Fund Quality Assurance Policy[2].

Selection and Procurement of RDTs

Recipients are reminded of their obligations under their grant agreement, the Global Fund's Quality Assurance Policy for Diagnostics Products, the Guide to Global Fund Policies on Procurement and Supply Management of Health Products[3], and of the following requirements:

1) Subject to a few exceptions, Recipients shall undertake a competitive process for the award of contracts for diagnostic products. Therefore, as all malaria HRP2-based RDTs targeting the same species (i.e. all RDTs targeting P. falciparum only or RDTs targeting

[1] WHO List of prequalified products http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/index.html
[2] The Global Fund, List of Rapid Diagnostic Test Kits for Malaria classified according to the Global Fund Quality Assurance Policy https://www.theglobalfund.org/media/5891/psm_qadiagnosticsmalaria_list_en.pdf?u=637030120050000000
[3] Guide to Global Fund Policies on Procurement and Supply Management of Health Products https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf

P. falciparum/P. vivax) are interchangeable, products cannot be selected based on individual product trainings. Historical use of a specific brand and/or brand preference is not a criterion for selection. HRP2 deletions: It is noted that should a country require alternative RDTs to address HRP2 deletions, the Global Fund does support procurement of non-HRP2-based RDTs.

2) Grant funds may only be used to procure diagnostic products that are consistent with WHO guidance. Technical considerations for the selections must be based primarily on the epidemiologic context of malaria in the country and in alignment with national treatment guidelines and WHO policy. Multi-species RDTs (e.g. Pf/Pv of Pf/PAN) should only be procured in countries in relation to their prevalence of malaria species in accordance with WHO recommendations.

Recipients must comply with the WHO GMP Good practices for selecting and procuring rapid diagnostic tests for malaria[4]. Recipients should also consider the WHO Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests[5].

3) Procurement of all RDTs must follow procurement principles set out in the Grant Regulations and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products.

[4] WHO Good practices for selecting and procuring rapid diagnostic tests for malaria
http://apps.who.int/iris/bitstream/handle/10665/44530/9789241501125_eng.pdf?sequence=1#page=37
[5] Information Note: Recommended selection criteria for procurement of malaria rapid diagnostic tests, January 2018
https://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/