MALARIA

BLINDED RECHECKING

REPORT

2020

NATIONAL MALARIA REFERENCE LABORATORY

ROYAL CENTRE FOR DISEASE CONTROL

DEPARTMENT OF PUBLIC HEALTH

MINISTRY OF HEALTH

Contents

Abbreviations

MP	Malaria Parasite
NMRL	National Malaria Reference Laboratory
RCDC	Royal Centre for Disease Control
PL	Participating Laboratories
IQC	Internal Quality Control
EQA	External Quality Assessment
NEQAS	National External Quality Assessment Scheme
TP	True Positive
FP	False Positive
FN	False Negative
TN	True Negative
MPD	Malaria Parasite Detection
PC	Parasite Count
QI	Quality Improvement
M & S	Monitoring and Supervision
TAT	Turn-Around-Time
RDT	Rapid Diagnostic Test
Pf	Plasmodium falciparum
Pv	Plasmodium vivax

Introduction

National Malaria reference laboratory (NMRL) under the Royal Centre for Disease Control (RCDC) is mandated to oversee Quality Assurance (QA) on malaria diagnosis to improve the competency skills of participating laboratories on malaria microscopy.

The competency of microscopists is very crucial to detect and confirm the malaria infection before administration of antimalarial drugs. The reference laboratory conducts National External Quality Assessment Scheme (NEQAS) on malaria diagnosis. The NEQAS for malaria diagnosis includes malaria blinded rechecking, malaria panel testing and on-site monitoring and supervision of participating laboratories.

The blinded rechecking of MP slides receive from participating laboratories is conducted on month-wise whereby the participating laboratories sent their all positive and 10% negative slide to NMRL for concordance and quality assessment. The NMRL examine all the slides on blinded based and all the slides receives were evaluated for quality of blood film preparation and quality of stain (if Positive detected, the following parameters is evaluated such as results concordance, species, stages and parasite density concordance between the participating laboratory and the reference laboratory). The NMRL sends performance feedbacks to participating laboratories on monthly basis and provide technical assistance so to improve the internal quality Control (IQC) system.

The panel testing MP slides is conducted biannually whereby the reference laboratory prepared both positive and negatives slides and sends to participating laboratories to examine the panel slides. All the participants are mandatory to examine the slides and send their results within the stipulated time period (1 month from the date of dispatched) after examining. This panel slides help reference laboratory to check their proficiency testing on malaria microscopy performance.

On-site monitoring and supervision of participating laboratories is conducted annually to monitor and evaluate the laboratory IQC and QA performance on-site. With the help of checklist guided from QA manual, laboratory unit is evaluated and necessary feedback and recommendation were discussed with lab incharge, malaria technician and laboratory technician by conducting short meeting.

The QA Performance Report 2020 consists of comparative findings at the National level and Individual Health centres in absolute figures, averages, percentages, graphs, and tables.

Malaria QA Analysis Report:

1. Summary of health centres participated for malaria blinded rechecking and total blinded slide rechecked:

A total of 180 participating laboratories have shipped their malaria slides on monthly base to malaria reference laboratory for blinded rechecking. There was decreased in the total no of participating laboratories as compared to previous year with reduction rate of 16.66% (216 vs 180).

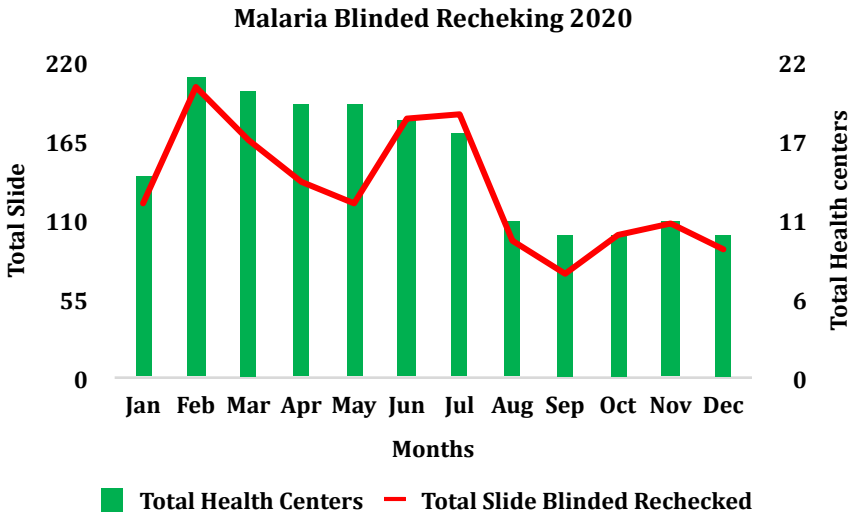


Figure 1: No of laboratories participated and total blinded slides rechecked

During the 2020, a total no of 1582 malaria slides were received with the reduction rate by 32% (2325 Vs 1582) as compared to 2019. The decreased number of participating laboratories could be due to Covid -19 pandemic where most of the health centers were not able to ship their slides or decreased incidence of malaria whereby less screening of malaria slides. **(Figure.1)**

2. Malaria slides examine during blinded rechecking:

From the total of 1582 slides examined, 28 malaria positives slides were detected (1.77%) and 1556 malaria slides were declared as No malaria parasite seen (Nmps) (**Figure 2).**

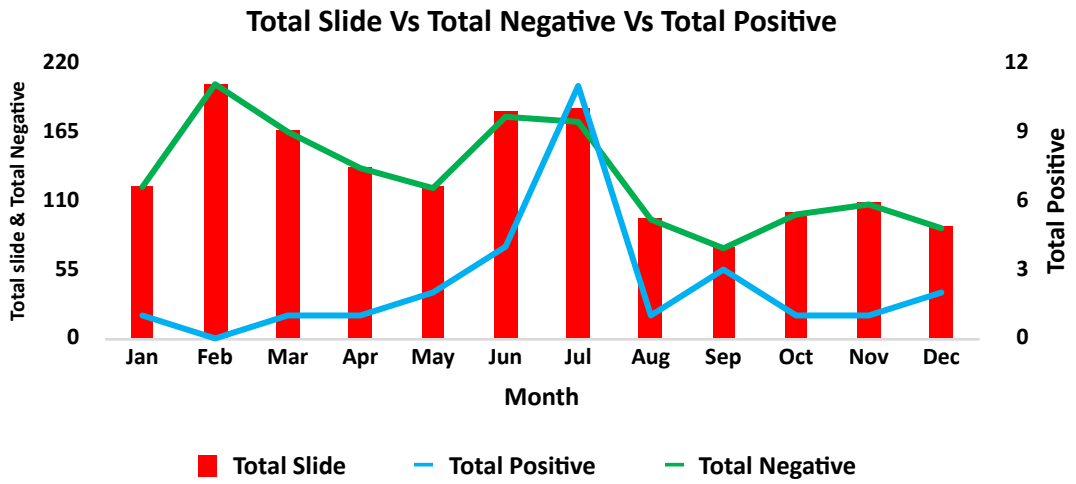


Figure 2: No of malaria positive and negative detected

3. Status on malaria detection:

Out of 28 positives detected, 24 were identified as Plasmodium vivax species (85.7%) and 4 were identified as Plasmodium falciparum species (14.3%) during the blinded rechecking. (**Figure 3& 4)**

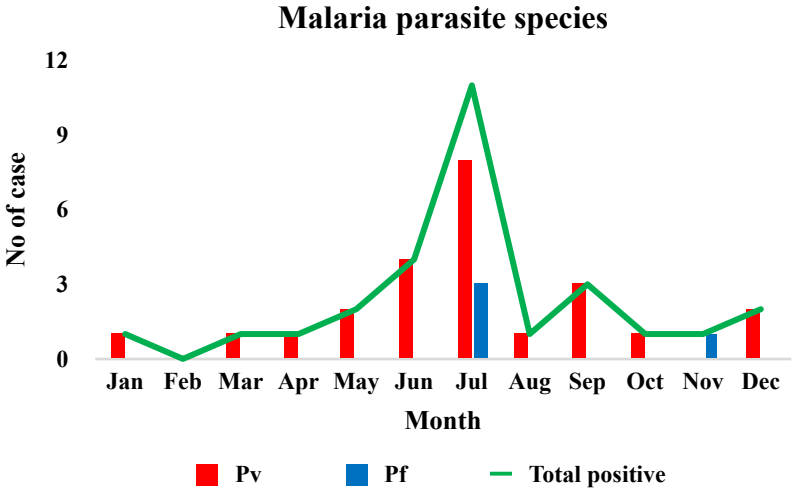


Figure 3: No of malaria parasite species detected.

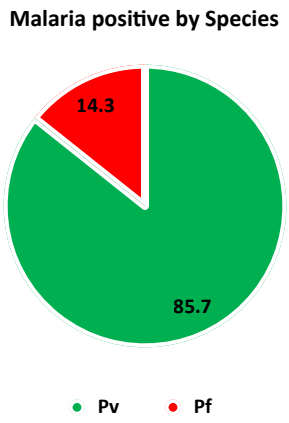


Figure 4: Percentage of malaria parasite species detected.

4. Status on malaria species detection

The overall concordance performance score 100%, indicates those participating laboratories reported malaria positive don't have problems in identification and differentiation of Plasmodium *falciparum and*

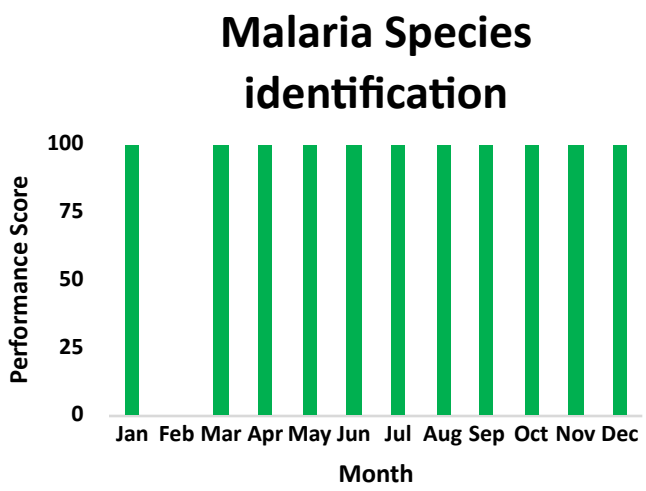


Figure 5: Performance score on Malaria species identification.

5. Status on malaria stages detected

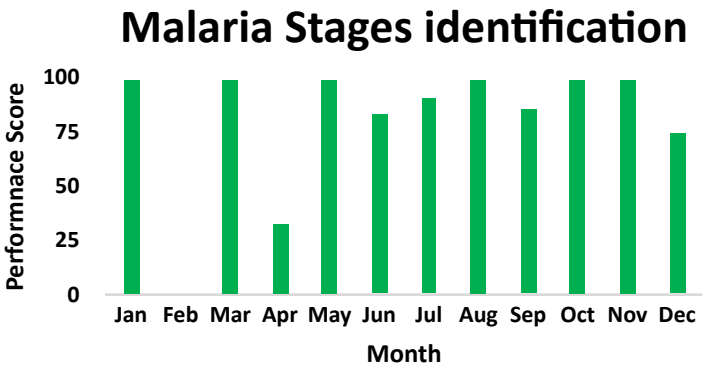


Figure 6: Performance score on Malaria stages identification

The overall average concordance score in stages identification parameter evaluated show 87.91%. Regarding stage identification, maximum of the reported participating laboratory face problems in identifying the parasite stages especially gametocytes and schizont.

6. Status on malaria stages detected

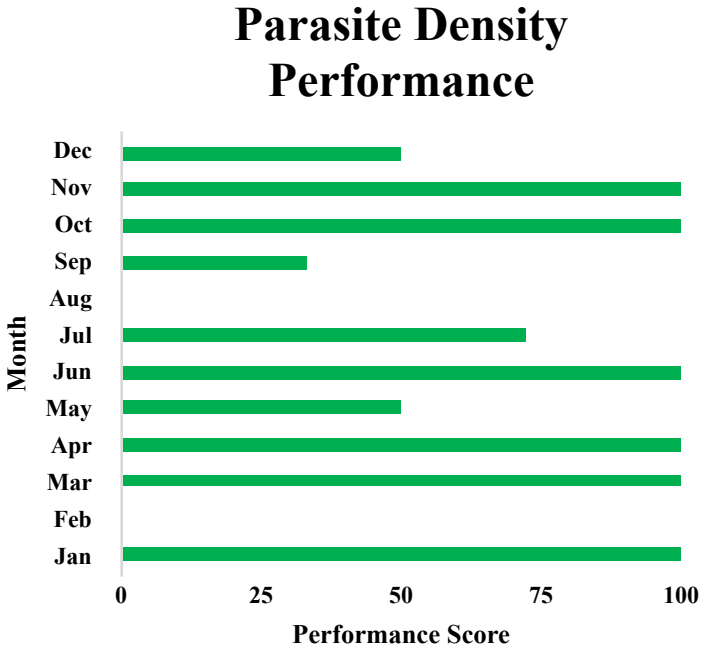
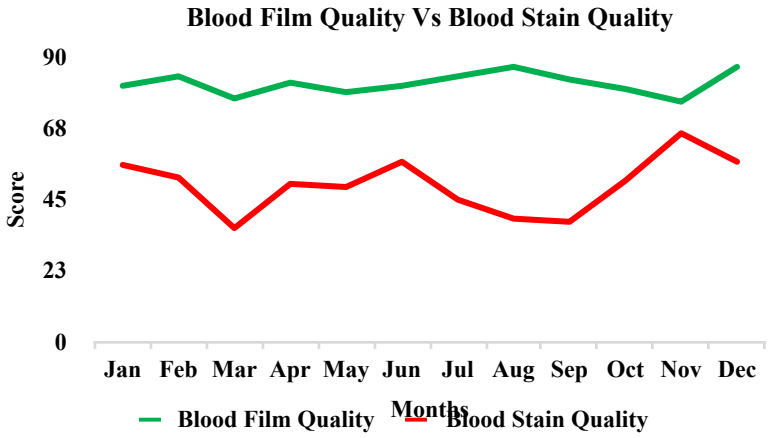


Figure 7: Performance score on parasite density determination

The average performance in the parasite density evaluated in 2019 and 2020 was 73.18 %.

Parasite density concordance in the month of January, March, April, June, October and November, participating laboratories obtained excellent results (≥ 100 % concordance), July month with acceptable results (≥ 72% concordance), May and December with poor results (≥ 50% concordance) and in August month with very poor results (0 % concordance) – **See figure 7**

7. Blood film quality and stain quality:



The average performance in the blood film quality evaluated was 81.8 % **(Figure 8)**

The average performance in the stain quality evaluated was 49.7%. **(Figure 8)**

Figure 8: Performance score on blood film quality and staining quality

Findings:

1. No regular participation in blinded rechecking

Out of 58 participating laboratories, only a few health centres regularly sent their slides for blinded rechecking. Some health centers perform malaria test using malaria RDT and they miss out sending slides for blinded rechecking.

2. Some positive slides were not sent for blinded rechecking:

Out of 47 totals positive detected during 2020, only 28 positive slides were received for blinded rechecking. From out of 28 slides, 3 false positive reported by participating laboratories.

3. False positive reporting:

This type of error considered as a minor error reported whereby the slides is miss read as positive slide. This will result in unnecessary admission and treating the patient thereby the risk of anti-malaria resistance and treatment failure.

The slides which were reported positive by participating laboratories is entirely washout and this could be due to carelessness while removing the oil immersion. It hardly find any cell and parasite while examined by controller.

4. Stages concordance:

Some of the participating laboratories still face problem in identifying and to differentiate malaria parasite stages (i.e., Trophozoite, Schizont and Gametocyte). In most of the positive slides reported by participating laboratories, microscopist have missed examining schizont and gametocyte stage.

5. Parasite Density Determination:

From the above findings, from the participating laboratories who reported positive report still have problem on

- How to input the formula in calculating parasite density
- Parasite density value not within +- 50% range determined by reference laboratory

6. Quality of Stain:

Most participating laboratories didn't perform well in stain quality indicating

- Poor internal quality control system
- Presence of stain particles- stain is not filter prior to staining
- RBCs too dark – distilled water used for dilution is too alkaline
- RBCs too pinkish – distilled water used for dilution is too acidic
- Fungal growth & vegetative spore – use of unclean slides
- Background of the slide is dark: use of unclean slides

7. Poor quality of blood film prepared:

Quality issue like

- Smear wash out – thin smear not fixed / vigorously washing- directly on the smear
- Thin smear not prepared as per standard –
    - Length of smear – too short / long.
    - Smear shape – Thin smear are raged form
- Spacing between the thin and thick smear & frosted part of the slide is not adequately standardized.
- Labelling of the blood slide is not adequate.

Recommendation:

1. No regular participation in blinded rechecking

All participating laboratories who perform malaria microscopy must sent 10% of their slides from the total slides examined on the monthly base for blinded rechecking.

In most of the health centers, the malaria test was performed using malaria RDT and which resulted less test performed through microscopy. Declining of competency skills in malaria microscopy due to utilization of RDT as the routine method including blood film preparation and staining

All participating laboratories must send their slides (including positive and 10 % negative slides) on monthly base to check their microscopy competency including their quality control in blood film prepared and stain used.

The used of malaria RDT can be used in situation such as

- emergencies time,
- mass screening and
- during busy routine schedule.
- No electricity
- No lab staff to carried out malaria microscopy

All the passive case to be detected by microscopy and if any doubtful finding, use RDT to resolve the finding.

2. **Some positive slides were not sent for blinded rechecking:**

   All participating laboratories must send their slides (including positive and 10 % negative slides) on monthly base.

3. **False positive reporting:**

   All the blood smears must be intact so that the controller who do blinded rechecking can examine the slides and provide true findings. From the washed blood smear, the controller hardly find any parasite and blood cells inside the field.

   Participating laboratories staff must take extra care during washing procedures, so blood smear is not washed out from the slide. Staff must remove the oil immersion after examining the slide by leaving the slides overnight face down on absorbent paper (tissue paper)- not clean slide immediately.

4. **Stages concordance:**

   The microscopist must examine the positive slide if available while examining routine slides to get familiar and update on malaria parasite morphology. To improve malaria microscopy competency, participating laboratories must participate in panel testing provided by reference laboratory where staff get a chance to examine positive slides both plasmodium falciparum and plasmodium vivax.

5. **Parasite Density Determination:**

   The microscopist must examine and practice performing parasite count if a positive slide is available. Practice improves skills on PC determination and more possibility to get his /her PC value fall within the stipulated PC range (+-50%).

   SOPs for parasite density determination clearly describe on how to calculate and perform the test.

6. **Quality of Stain:**

   The feedback report provided from NMRL will serves in solving the problem related to stain quality. The concerned staff must read the blinded rechecking feedback report and try to rectify the problem. All the issue and problem highlight should be record in the corrective action form for necessary quality improvement.

7. Quality of blood film:

The quality of blood film prepared can be improved by

- Rectify the issue /problem highlight in the feedback report
    - Angle of the spreader
    - Volume of blood to be dispense
    - Edge of spreader
    - Labelling of slide
    - Used of quality glass slide / clean before making blood film.
- Used of WHO template will help to prepared good thin and thick blood film

Conclusion:

Blinded rechecking remains as mainstay for monitoring quality of blood film prepared, staining and accuracy of results. Rechecking reflects the true performance of routine diagnostics services at health facility level.

A significant gap was observed which could significantly impact on malaria microscopy quality services including incompetent microscopist on malaria microscopy and quality assurance, poor blood film preparation, poor staining quality, poor parasite detection, identification and quantification of parasite density.

From the above findings, participating laboratories should follow the feedback report accordingly for the correction of poor-quality issue related to blood film and stain for continuous quality improvement.

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