

CHANGE OF GUARD AT THE EDITORIAL DESK OF THE NIGERIAN JOURNAL OF GENERAL PRACTICE

Francis took the NJGP to an enviable height. I have determined to take it to even a more enviable height. I have brought more hands into the editorial board to assist. We have been doing manual manuscript handling and publishing. This is laborious and does not give our journal the projection it needs and deserves. International journals of repute are published online, open access. That is where I am heading to. That will

This edition of the NJGP is my maiden edition. By some uncanny coincidence UNITAD in collaboration with Malaria Consortium wants us to go back to “medieval” practice of “training” patent and propriety medicine vendors (PPMVs) to diagnose and treat Malaria in Nigeria in this 21st century. We are trying to move our journal from analogue to digital and they are trying to drag Malaria management from “digital” to “analogue”. Read the comment of the editorial board. Ebola Virus Disease is the current public health issue all over the world, especially in West Africa. Read our perspective. There are many original research articles that the researcher’s eyes cannot miss. Read on.

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Editor-in-Chief

UNITAID is an organization cooperating with WHO (and others) on the WHO millennium development goals. It is not an acronym. DEFeAT is an acronym for Project "Diagnose Early for Effective Accurate Treatment" of malaria. Unitaid is sponsoring the project in Nigeria and some other African countries. Malaria Consortium is implementing the project in Nigeria. The aim is to create a private sector market for quality-assured malaria rapid diagnostic tests QAmRDTs. The goal is to increase appropriate use of QAmRDTs in private sector market through targeted activities. Targeted providers are retail pharmacies, private laboratories, private clinics

National Malaria Control Programme organized a national stakeholders' consultative meeting on malaria rapid diagnostic tests (mRDTs) in the private sector in Abuja on 20th February 2014. The

aim of the meeting was to “engender open, accountable and participatory national consultation on the deployment of QAmRDTs in the private sector and its health related establishments in Nigeria”. The private sector includes those already stated above. In this meeting, it was decided that non-medical doctors including PPMVs will be trained on use of RDT to diagnose malaria and treat with ACT. This is because a good percentage of people, especially in the rural areas, seek care from this sector when they have malaria. This is because PPMVs are available in the remote areas where medical doctors are not. It is also because it is cheaper than accessing care from clinics. The communicate is yet to be published.

This procedure involves the invasive process of puncturing the finger tip, collecting blood, running the test, making the diagnosis based on the result of the test, prescribing and dispensing ACT. The consequent task of disposal of healthcare waste naturally follows. Decision was also reached to amend the current anti-malaria treatment policy and guidelines in Nigeria to allow PPMVs the latitude to engage in the invasive procedure of diagnosing malaria with RDT.

The argument may be sound

Malaria burden is high in Nigeria. About 60% of outpatient visits is due to malaria. An estimated 300,000 deaths occur annually attributable to malaria¹. Children under 5 years and pregnant women are more affected due to their low level of immunity. Malaria and poverty are co-related. Malaria thrives in poverty and keeps households poor².

Malaria case management involves early diagnosis and prompt treatment. Malaria diagnosis can be based on clinical symptoms and signs, microscopic, molecular or serological tests. Syndromic management is cheap. It only requires the clinical acumen of the clinician but it is unreliable because malaria symptoms are not specific. This can lead to over diagnosis and unnecessary use of antimalarials. Microscopic tests are laborious, capital intensive, need trained microscopist and reliable equipment. All these may not be available in resource poor settings. Yet it is the gold standard. Molecular diagnosis requires specialized

laboratories and is very expensive. Serological diagnosis only detects past infections and may not be used to diagnose current infection. All these drawbacks and need to diagnose malaria before treatment created the room for the introduction of RDTs. RDTs are based on immuno chromatographic techniques. It detects plasmodium antigen in finger prick blood samples within as short as 15 minutes and the procedure needs minimal training. It is cheap and cost effective.

Due to resistance to chloroquine and sulfadoxine-pyremethamine, ACT is now the recommended first line treatment for malaria in Nigeria. It is effective but expensive. The cost necessitated the need to be sure of the diagnosis before treatment. Rational use also reduces the chances of parasite developing resistance.

The big questions now pop up: How does one diagnose malaria? Who makes the diagnosis?

Infected female Anopheles mosquito while taking blood meal from human injects the parasites in the form of sporozoites into the human blood stream. The sporozoites travel to the liver and invade the liver cells. In 5 – 16 days the sporozoites grow, divide and become merozoites. The merozoites leave the liver cells and invade the red blood cells. Here asexual replication produces thousands of new merozoites that burst the red blood cells and release themselves into the blood stream. This occurs in 1 – 3 days depending on the species. As the new merozoites are released, cytokines are also released into the blood stream. These mediate the paroxysms of chills and fever that characterize malaria disease. The new merozoites re-enter new red blood cells and continue with the asexual replication, bursting of the red blood cells, release of more new merozoites and cytokines and re-entry into new red blood cells. This cycle causes the anaemia that also is characteristic of malaria. The sporozoites can also sequester in the lymphoid tissues especially the liver and cause hepatomegaly without the characteristic fever and rigors. In adults with some degree of immunity the clinical symptoms may not be obvious, yet red cells destruction continues manifesting in anaemia and lethargy without fever and rigors. In pregnant women, the sequestration can occur in the placenta leading to poor placenta perfusion, intrauterine fetal growth retardation and possible intrauterine fetal death and poor maternal outcome.

It is obvious that malaria typically manifests with fever and rigors but this is not invariable. Malaria can progress to severe malaria without the typical symptoms. When the parasites are sequestered, there will be low parasitemia that may not be picked by RDT or even microscopy. This leads to false negative results. One can only imagine the consequences of a false negative not being given antimalarial when in fact he/she has malaria. Still some people can harbour the parasites and still not be sick. This occurs in adults who live in high transmission areas and have developed immunity. Diagnosis of malaria depends on the knowledge of this pathophysiology, the symptoms that are associated with the stages of the parasite's life cycle and ability to demonstrate the parasites in the human blood sample. With RDT what is needed is demonstration of the parasite antigen in the blood sample.

History taking is crucial to eliminating co-morbidities. Painsstaking detailed history which only a trained clinician can perform well exposes the likely systems that need thorough examination. It is the tool that the clinician uses to draw up differentials. Physical examination helps trim the differentials to a few. One can rule out or implicate co-morbidities from history and physical examinations alone. In malaria disease, laboratory tests only add to the reasons the clinician will base his diagnosis on. Negative result does not rule out malaria disease nor does positive result confirm it.

Malaria infection/disease

Malaria infection, like in most other etiologies; fungal, bacterial, viral, does not mean disease. Presence of "hypnozoites" in the liver in cases of *P. vivax* or *P. malariae* is infection but not disease. A high proportion of adults, apparently healthy, are carriers of malaria parasites in their blood. Should malaria disease be regarded as fever with positive RDT (or microscopy)?

Malaria disease as fever plus parasitemia

From the previous discussion, it is obvious that one may have malaria infection without fever. In endemic areas depending on the transmission intensity and season, more than 50% of people are carriers of malaria parasites but are apparently healthy; no fever³. If a carrier develops pneumonia or typhoid or meningitis or hepatitis or Ebola virus disease, the malaria parasite will obviously still be

there. This patient will have fever plus malaria parasites. If subjected to malaria laboratory tests, the result will be positive. Indeed it will be a true positive! Yet he does not have malaria disease. The unwary healthcare provider, following the protocol of fever (or history of fever) plus positive RDT will go ahead, and rightly too, to treat with ACT. This will obviously be a grave mistake, made innocently!

Malaria may be diagnosed by fever and high parasite density. Parasite density is estimated as percentage of infected red blood cells in a thick blood film when one has counted 200 white blood cells⁴. When in severe malaria disease, the schizonts are sequestered in the brain or liver or spleen and in the lymphoid tissues, the high parasites burden may not be evidenced by the density in peripheral blood. Will the fever and low parasitemia exclude malaria, indeed severe malaria?

It is obvious that from the above discussion, malaria diagnosis cannot be based on fever and positive laboratory tests alone. Thorough knowledge of malaria pathophysiology with high index of suspicion is indispensable. It is only a trained clinician that can rule out, clinically, other possible causes of fever. Positive parasitemia test can help him confirm the diagnosis. In patients without fever, clinical suspicion can still lead the clinician to suspect malaria. Laboratory tests can then help confirm this suspicion. PPMVs and poorly trained healthcare providers cannot obviously diagnose malaria disease.

Wider perspective

Nigeria has moved from malaria control to malaria elimination. The best hands must be on deck. Let us borrow a leaf from Maternal and Child Health. In 1980s Professor Olikoye Ramsom Kuti, the then minister for health, introduced traditional birth attendants (TBA) to provide maternal health services in the rural areas. Reason then was due to unacceptably high maternal mortality ratio (MMR) and lack of trained personnel in the remote areas. It was a mistake. Clearly, this strategy failed to reduce maternal mortality because the TBAs cannot manage the obstetric and medical causes of maternal death⁵.

A midwife or an obstetrician knows the physiology and pathophysiology of pregnancy and delivery. Only he/she appreciates the causes of maternal

mortality which include hemorrhage, sepsis, pregnancy induced hypertension, abortion complications, prolonged obstructed labour. He/she understands the principles of their management and knows when to refer. The TBAs obviously do not know all these. It is wrong to assemble illiterate women in the villages, give them a few days 'training' on obstetrics and unleash them on the hapless women in the villages with government authority as legal midwives. Of course, the MMR did not improve. The Nigerian Federal Government has realized this. It has mopped up all retired staff nurses and midwives in addition to currently engaged ones plus trained community health extension workers and sent them to the villages to provide adequate obstetric services to the people. This is the correct thing to do. TBAs were not trained to perform the duty assigned to them.

If malaria will be controlled or eliminated in Nigeria, it certainly cannot be by assembling poorly educated PPMVs and their likes, 'train' them for a few days on how to puncture the finger, draw blood and use RDT to diagnose malaria and go ahead to treat! PPMVs are traders. They buy and sell patented medicines for profit⁶. They lack the knowledge and most importantly, lack the capability to acquire the knowledge. They do not have basic medical scientific knowledge and just cannot learn applied medicine which requires the basic knowledge as a building block.

There are 774 local government areas (LGA) in Nigeria. Each LGA has comprehensive health centers, primary health centers and health posts. These health facilities are manned by trained nurses, midwives and community health extension workers. They have some basic medical knowledge. They can be trained. Train them on how to refine their clinical suspicion of malaria with RDT. There is a medical officer of health that oversees their activities. Government should employ more medical doctors to work as medical officers of health in the local government areas. One medical officer of health in a local government area is grossly inadequate.

Private hospitals and clinics are springing up all over the place. With the Federal Government opening up villages by constructing roads more clinics are relocating to the rural areas that are now quickly becoming urban. There can also be a public

private partnership (PPP) between the government and the private doctors operating clinics located in the villages to compliment the work of the medical officers of health. This can easily be worked out. Medical doctors in private practice are willing to partner with the government in this regard.

Community Pharmacists in areas where there are no trained health officers can be trained. They can work as a stop gap until proper clinicians and trained healthcare workers are in place. They can then go back to their role as community pharmacists. PPMVs and their likes who are merely traders on patented drugs and over the counter medicines cannot be allowed to diagnose and treat malaria. It is beyond their competence.

From professional point of view

The aim of Malaria Consortium with the support of Ministry of health to increase uptake of RDTs and in the process diagnose malaria before treatment is laudable but there are serious flaws in the model. The flaws include.

- **Encouragement of quackery:** This model will train non-medical doctors to make diagnosis of malaria. You will inadvertently make diagnosticians of Pharmacists, Laboratory Technicians, and PPMVs. This will lead to mass production of "doctors" who will invariably **diagnose** all RDT positive febrile illnesses as malaria and **treat** as such. Diagnosis cannot be made without a detailed history which only the medical doctor is trained to take. Laboratory tests come in only to refine, confirm or rule out clinical diagnosis or differentials. Non doctors do not have the training to and cannot make diagnosis. Training them to make diagnosis of malaria by using RDT **ONLY** is encouraging quackery.
- **Medical Ethics:** Diagnosis of malaria by RDT is an invasive procedure. The patient's finger or toe must be pierced to collect blood. There is no guarantee that the personnel have been trained on hygiene, infection control and prevention, healthcare waste disposal, prevention of HIV, etc. It is highly unethical and dangerous to allow untrained people to collect blood from patients. It is more so at this period of Ebola Virus Disease.

- **Marketing Ethics:** The PPMVs are marketers. They have financial interest and it is likely to tilt their diagnosis to favour their trade. Researchers are required to disclose interests, especially financial, they have with their work that will bring about conflict of interest. If a researcher is in a position to control the process or result of his work and has financial interest in it, the outcome of such a research will be taken with a pinch of salt. Traders that sell drugs cannot be allowed to diagnose ailments for which their business is to sell drugs used in treating them. Is it likely that they will refer patients that test negative? What will be their provisional diagnosis? What happens to the drugs they stocked on their shelves and counters? His gain is in selling the drugs when he makes the diagnosis. RDT marketed this way is illegal and unethical. It is just a marketing stunt that will not help anyone.
- **Delay proper diagnosis:** A positive RDT test does not necessarily mean malaria disease or malaria as the only diagnosis. Patients with febrile illness can have positive RDT test but be suffering from URTI, Pneumonia, UTI, HIV/AIDS, Ebola, etc. The non-doctor cannot "read between lines" and making the right diagnosis will be delayed as the person "trained" as malaria diagnostician will be busy treating the RDT positive febrile illness with ACT.
- **Inappropriate drug use:** All RDT positive patients will be given ACT whether they have malaria or not and irrespective of whether the patient had already bought ACT over the counter and taken before going to see the "diagnostician". This inappropriate use of ACT will certainly promote drug abuse and resistance.
- **Public Health Issue:** In this era of Ebola and Hepatitis viral diseases, these ignorant home care givers and PPMVs will invariably form a potential source of community infection. There is no guarantee that they practice universal precaution. They may not even know what it is. Ebola requires something more than universal precaution in handling. The symptoms of Ebola are like the symptoms of Malaria! These PPMVs and home care givers will be exposed to infected patients' blood and body fluids and get themselves infected. They now go ahead to infect other

people in their locality. This will lead to public health disaster.

- **Consequence:** The overall consequence of this model is a deterioration in the health of our people by compounding the morbidity that will eventually lead to increase in mortality.

Conclusion

It is only the trained clinician that can diagnose Malaria disease. He/she will use his/her clinical acumen, based on history, physical examination, high index of suspicion and laboratory tests where available. The other healthcare providers working in a clinic setting and under the supervision of a medical doctor can be trained to assist. PPMVs and other business people working outside the clinic setting cannot, and should not be allowed to, diagnose malaria using RDT or any other invasive procedure for that matter.

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