On The Use of Rapid Diagnostic Test Kits for Malaria

By David J Witt, MD

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Since I wrote in *The Permanente Journal (TPJ)* (Fall 2005) about post-tsunami malaria in Indonesia, there have been several requests from *TPJ* readers regarding access to and anticipated availability of rapid diagnostic test kits (RDTs) for malaria. It is with regret that I relate that there is no intent to market these in the United States. There are several reasons for this, some valid, some not. Worldwide, the use of RDTs is a vital part of the World Health Organization's program for malaria control, to preserve the use of newer, more expensive regimens for actual malaria cases.

The Centers for Disease Control and Prevention (CDC) often opposes the use of these kits for diagnosis of malaria. In a conversation with the malaria officer on duty, my suggestion that they were of use was disparaged. Unfortunately, as is sometimes the case, an organization such as the CDC does not respond to the requirements of actually delivering care. When an organization has ready availability of world-class parasitologists, there is little need for RDTs. On the other hand, few of us practice in such an environment. Kain et al[1] described an average delay of three days between the time of ordering a malaria smear and confirmation of the diagnosis in nonspecialist Canadian medical centers.

In view of the rarity of malaria in this country, our best laboratory technicians are inexperienced in making this diagnosis and even experienced parasitologists can make errors in their reading of blood smears. Our average hospital laboratory is likely inferior in sensitivity to RDTs and probably in specificity as well, particularly if we consider only *P falciparum*, the only species that is rapidly fatal. One published small series[2] from Bethesda Naval Hospital reviewed the diagnostic accuracy of these two modalities among Marines with febrile illness evacuated from Liberia. Ten of 32 cases were accurately identified by RDTs and the same ten by thick smear. One of 32 patients had a positive RDT and a thin smear that was originally read as negative, but confirmed subsequently to have been positive.

In 2004, in the US there were only 1324 reported cases, 49% of these were *P falciparum*.[3] This seems to be a strong argument that our local labs will not be able to enhance their expertise in this disease. This would be even more significant for smaller hospitals in areas with less foreign travel among their patients.

Different RDTs have been studied in various studies in nonimmune returning travelers from malarious areas. The accuracy of various tests does vary, but later generation tests for *P falciparum* routinely demonstrate sensitivities greater than 90% (88-99%) and specificities that are 95-100%. The conclusion of the meta-analysis by Marx and colleagues[4] is that "rapid testing will lead to the detection of most clinically relevant *P falciparum* cases, with considerably better accuracy than that expected from routine microscopy in nonspecialist settings."

The arguments against the test are: the accuracy is not perfect; it is heat sensitive and it does not monitor the level of parasitemia, nor confirm efficacy of treatment. I believe these are false arguments. RDTs are certainly, at a minimum, grossly comparable to an experienced microscopist and confirmation by a reference laboratory can be readily arranged after a diagnosis is suspected. Identifying and starting treatment is the most vital part of diagnosis. The monitoring progress, while vital, can be arranged once a diagnosis has been confirmed. The argument of heat sensitivity seems disingenuous in North America where laboratory reagents are controlled for quality and stored in nontropical conditions. This is an argument of questionable validity even in tropical areas.

In summary, in the US we are stuck with less effective diagnostic capabilities for malaria, when compared to most Third World countries. This is not expected to change in the foreseeable future. ❖

References

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