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Use of the *CareStart*™ G6PD Biosensor to measure total activity of G6PD in Haiti

Abstract

There has been renewed interest in developing an efficient method to identifying individuals who are G6PD deficient in countries with endemic malaria. Since primaquine is an effective drug for radical cure for *Plasmodium vivax* infection and has gametocytocidal effects against *Plasmodium falciparum*, it has a central role in malarial elimination efforts. However the concern over G6PD deficiency and hemolytic anemia has been the main cause for underutilization of primaquine. We evaluated a new point-of-care quantitative test for G6PD status and compared it to spectrophotometric method. We screened 346 school-age children from three schools outside of Gressier, Haiti. G6PD levels were measured in the field using quantitative Biosensor test and repeated in controlled laboratory setting with the Trinity Biotech spectrophotometer test. The Biosensor estimated the population prevalence of severe to moderate G6PD deficiency at 0.9 and 14.9%, compared to the gold standard estimates of 9.9 and 19.5%. Though the test lacked the ability to determine the moderate or severe cases, it had high specificity (94.5%) and was able to determine negative population members. To determine those at risk of drug induced hemolysis (<30% residual activity), the specificity was found to be 99.6% and the negative predictive value was 90.6%. While the test lacked sensitivity, given that the goal is to treat population members with normal G6PD activity, this diagnostic test holds value for the application for mass drug administration of potentially hemolytic chemotherapy agents.