Rapid, Point-Of-Care Test for Glucose-6 Phosphate Dehydrogenase Deficiency

Health need
Glucose-6 phosphate dehydrogenase (G6PD) deficiency is the most common enzyme deficiency in the world, occurring in 400 million people worldwide. The majority of these people live in malaria-endemic areas. The degree of deficiency varies greatly among different ethnic populations and within each population. Plasmodium vivax (P. vivax), the most persistent form of malaria, is a parasite species common in South and Southeast Asia, South America, and the Mediterranean that becomes dormant in the liver and can be killed only by a certain class of drug, 8-aminoquinoline drugs (such as primaquine). While malaria symptoms can be treated with widely used antimalarial drugs, only a drug such as primaquine which attacks the liver stage of the parasite, can totally cure a patient with P. vivax. A total or radical cure is accomplished by killing all malaria parasites in the body, specifically those in the liver, thus eliminating any chance of relapse and malaria transmission. However in patients with G6PD deficiency, 8-aminoquinoline drugs stress the red blood cells to the extent that they can trigger acute hemolytic anemia, which is potentially lethal. For the safe use of 8-aminoquinoline drugs, there is an essential unmet need for a reliable test for G6PD deficiency as a point-of-care diagnostic.

Technology solution
Since G6PD levels vary widely, current qualitative tests that may differentiate between severe and normal activity levels cannot accurately distinguish among the many intermediate deficiencies—a test characteristic that is essential for determining whether a radical cure treatment may be used safely. The ideal point-of-care G6PD test would be fully quantitative, low cost, and easy to use. A test with these characteristics would enable a provider to accurately assess a patient’s G6PD status before prescribing 8-aminoquinoline drugs for malaria treatment. To address this, PATH is working with diagnostic developers and stakeholders from around the world to develop a rapid point-of-care diagnostic test for G6PD.

Current status and results
PATH is working with a partner to conduct field studies of existing commercial G6PD tests in three countries in Asia. PATH is also collecting relevant market research data in order to ensure a successful launch of a point-of-care G6PD diagnostic. Next steps include finalizing standards by which the suitability of adopting current tests to support malaria treatment use-case scenarios will be established. These standards will be validated in field evaluations. PATH will also engage and select diagnostic developers to develop prototype G6PD point-of-care diagnostics and host workshops in target countries to assess market readiness and barriers to entry. In order to support these development efforts, PATH has established a specimen panel comprising samples from patients with normal, intermediate, and deficient G6PD levels. This panel will be made available to all G6PD diagnostic test developers.

Availability
For more information regarding this project, contact Gonzalo Domingo at gdomingo@path.org or visit http://sites.path.org/dx

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