Price, Quality, and Market Dynamics of Malaria Rapid Diagnostic Tests: Analysis of Global Fund 2009–2018 Data

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Abstract

Background: Rapid diagnostic tests (RDTs) for malaria are a vital part of global malaria control. Over the past decade, RDT prices have declined, and quality has increased. However, the relationship between price and product quality and their larger implications on the market have yet to be characterized. We sought to use purchase data from the Global Fund together with product quality data from the World Health Organization and Foundation for Innovative New Diagnostics (WHO-FIND) Malaria RDT Product Testing Programme to understand three unanswered questions: 1) Has the market share by quality of RDTs in the Global Fund's procurement orders changed over time? 2) What is the relationship between unit price and RDT quality? 3) Has the Global Fund procurement market become more concentrated over time?

Methods: We merged data from 10,075 procurement transactions in the Global Fund's database, which includes year, product, volume, and price, with product quality data from all eight rounds of the WHO-FIND program, which evaluated 227 unique RDT products. To describe trends in market share by quality level of RDT, we used descriptive statistics to analyze trends in market share from 2009–2018. We then applied a generalized linear regression model to characterize the relationship between price and panel detection score (PDS), adjusting for order volume, year purchased, product type, and manufacturer. Third, we calculated a Herfindahl-Hirschman Index (HHI) score to characterize the degree of market concentration.

Results: Lower-quality RDTs have lost market share between 2009-2018, as have higher-quality RDTs. We find no statistically significant relationship between price per test and PDS when adjusting for order volume, product type, and year of purchase. The HHI was 3,570, indicating a highly concentrated market.

Conclusions: Advancements in RDT affordability, quality, and access over the past decade risk stagnation if health of the RDT market as a whole is neglected. Our results suggest that this market is highly concentrated and that quality is not a distinguishing feature between RDTs. This information adds to previous reports noting concerns about the long-term sustainability of this market. Further research is needed to understand the causes and implications of these trends.

Background

Globally, in 2019 there were an estimated 229 million cases of malaria, including 384,000 deaths [1]. While substantial gains have been made against malaria, especially in the past 20 years, more progress will be required to reach global elimination goals. A critical element to successful malaria case management is prompt, accurate diagnosis of malaria. Historically, this has been conducted through diagnosis by expert microscopists. However, there are limitations to this strategy related to costs, training, and proximity to patients. In the early 2000s, rapid point-of-care tests began to change the landscape, enabling fast test results with minimal training. Availability of rapid tests prompted the World Health Organization (WHO) to change its policy recommendations in 2010, from presumptive treatment to a “test and treat” policy, where patients are only given antimalarial drugs following a positive parasitological diagnosis [2, 3]. The widespread use of rapid diagnostic tests (RDTs) is vital to this policy, and the magnitude of their use has increased rapidly in the past decade [4]. In 2018, WHO estimated 412 million RDTs were sold globally, 259 million of which were distributed by national malaria control programs [5]. However, prior to the

disruptions to the market caused by COVID-19, estimates from Unitaid projected demand for RDTs would increase 26.3% between 2018 and 2021 based on continued expansion of their use in both the private and public sectors [6].

Despite this expansion of RDT purchasing, large gaps in malaria diagnostics use at the point of care persist. Between 2015–2018 in sub-Saharan Africa, the median percentage of febrile children who received a malaria diagnostic test (whether RDT or microscopy) was 66% in the public sector and 40% in the private sector [5], meaning a substantial proportion of febrile children were still not being tested adequately for malaria. Prompt diagnosis and treatment is not only vital to patient health, it can also reduce costs on the health care system [7], including major reduction in the presumptive use of artemisinin combination therapies [8]. Improving the ability to diagnose malaria quickly and accurately remains a crucial component of the global effort to reduce the burden of malaria on patients and health systems. Rapid diagnostic tests have many advantages over microscopy to achieve this, including no need for instrumentation, no need for reliable electricity, and the reduced amount of training needed for RDT use compared to microscopy [9].

Malaria RDT market characteristics

Donor-funded procurement represents half the RDT market by volume, with the Global Fund to Fight AIDS, Tuberculosis, and Malaria's (Global Fund's) Pooled Procurement Mechanism and the US President's Malaria Initiative being the largest institutional buyers [10]. An additional 20% of the market is RDT purchases made by designated country procurement agents using Global Fund grant dollars [10]. In 2019, according to the 2020 *World Malaria Report*, US\$3.0 billion was invested in malaria control globally, US\$1.2 billion (39%) of which was disbursed through the Global Fund [1]. Nearly half of the Global Fund's 2017 disbursements were spent on health product procurement, including RDTs [11]. The Global Fund plays a significant and deliberate role in shaping markets for global health commodities to maximize access to health products [11]. One of the mechanisms supporting transparency about affordability of health products such as RDTs is the Global Fund's Price and Quality Reporting (PQR) platform. One of the stipulations of a country receiving grants from the Global Fund is that all grant-funded purchases of key pharmaceutical and health products, including malaria RDTs, must be reported to the PQR database [12]. This extensive publicly available database thus provides an "an indicative picture of the range of prices paid by reporting grant recipients" [12]. In addition to this price transparency, the Global Fund also works to enhance product quality of RDTs it procures by requiring that products purchased with its funds meet the minimum quality standards defined by WHO.

WHO supports RDT procurement and availability in multiple ways. WHO, in collaboration with the Foundation for Innovative New Diagnostics (FIND) and the US Centers for Disease Control and Prevention, has historically provided thorough product quality testing of RDTs through its Malaria RDT Product Testing Programme. Since its inception in 2008, the program evaluated 332 products across the eight rounds of testing, from which all data are published and available publicly [4, 13–19]. The program was recently discontinued in 2019, and future replacement evaluation efforts remain uncertain [20]. The results of these evaluations principally provide data on each RDT product's panel detection scores as a measure of quality (see definition in Methods section) for both *P. falciparum* and *P. vivax* detection, as well as false positive

rates, thermal stability, and ease of use, among other RDT characteristics. Compliance of RDT procurement with WHO minimum quality standards has been improving since the publication of the first round of product evaluation results, with 26.8% of products meeting all WHO minimum quality standards in 2011 to 79.4% of products by the final evaluation round in 2018 [21]. This shift can be partially attributed to increased awareness of the product testing program from both the purchaser and the manufacturer side [22]. In addition to the product testing program results, WHO publishes guidance documents for procurement of malaria RDTs such as the *Recommended selection criteria for procurement of malaria rapid diagnostic tests* [23], which emphasizes the importance of the panel detection score, false-positive rate, and invalid rate, and then notes that once the minimum standards for those criteria are met, then heat stability, ease of use, and training requirements should be considered. After those criteria, the WHO procurement guidance states: “Price: After consideration of all the above factors, good procurement practice requires that the price be taken into account.”

Malaria RDT market dynamics

Three linked economic concepts are particularly useful in examining the market for Global Fund–procured RDTs and implications on market structure given the information made available to purchasers by the WHO-FIND product testing program. These concepts center on product quality, how firms compete, and market concentration.

The first concept is known as “the market for lemons,” where sellers have better information on the quality of the products they are selling than purchasers—that is, there is information asymmetry between the sellers and buyers. In this case, if purchasers are unable to accurately judge the quality of products they are buying, then purchasers’ lower expectations on average product quality cause their willingness to pay to fall. This eventually causes lower-quality goods to drive higher-quality goods, and potentially their sellers, out of the market [24]. The WHO-FIND product testing program should theoretically help purchasers judge the quality of the RDTs they are buying prior to purchase and avoid the market failure predicted by “the market for lemons.” Our analysis seeks to test that this is indeed the case and that the WHO-FIND program is helpful in avoiding this particular market failure.

The second concept is “vertical product differentiation,” which describes markets where manufacturers compete by having different levels of product quality compared to other firms [25]. In markets where products are primarily differentiated by a single characteristic of quality, purchasers with a higher willingness to pay will choose higher-quality products as they are willing to pay for quality improvements. If the costs of product improvements by firms result in products that are sufficiently differentiated, (i.e., there is a large marginal increase in quality for a given increase in cost), then there will be space in the market for many firms producing products of differing quality and prices that are attractive to consumers of differing willingness to pay. However, if an increase in costs, and associated prices, leads to only small marginal increase in quality, then there will be less space for firms to differentiate their products on quality. Thus, price competition will drive prices down and economies of scale will benefit large firms or those best positioned to invest in research and development that results in quality improvements. In this case, when there is little difference in price between the highest- and lowest-quality products, purchasers at any

willingness-to-pay level can purchase high-quality products and consequently the lowest-quality manufacturers will be pushed out of the market, resulting in increased market concentration. Theoretical predictions of vertically differentiated markets resulting in higher levels of market concentration have been shown empirically in the pharmaceutical industry and a collection of European industries [26–28]. Panel detection scores provide an important measure of quality that differentiate RDTs from one another.

The third concept is market concentration, which we measure with the Herfindahl-Hirschman Index (HHI). More concentrated markets have a greater percentage of the market share produced by relatively few firms, and less concentrated markets spread the market share among a relatively larger number of firms. The HHI is commonly used by market regulatory agencies to ensure there is sufficient competition in a market. For example, the United States Department of Justice (DOJ) uses it to scrutinize potential mergers to ensure they do not lead to an over-concentrated and under-competitive market. The DOJ considers an HHI score below 1,500 as an unconcentrated market, between 1,500 and 2,500 as a moderately concentrated market, and above 2,500 as a highly concentrated market [29]. Manufacturer data and purchase volume are collected in the Global Fund's PQR data, which allow the calculation of an HHI score over time.

Analysis objective

Past analyses have demonstrated that the average quality of available RDTs has increased significantly since 2008 [21, 22] and that average unit prices for malaria RDTs have declined in the past decade [10, 30]. However, price and quality have not been examined together across different RDT products, meaning a comparison of purchase prices at the RDT product-specific level (e.g., for products detecting the same species) remains a gap in our understanding of the malaria RDT market. The market concentration of RDT manufacturers in the Global Fund's procurement orders has also not been measured with the HHI.

In this paper, we use data from both Global Fund procurement orders at the transaction level and the WHO-FIND product testing program at the product level to understand the relationship between price and quality of malaria RDTs. Specifically, we aim to investigate three unanswered questions:

- 1) Has the market share by quality of RDTs changed over time?
- 2) Is there substantial differentiation in quality given a change in price? That is, what is the relationship between unit price and RDT quality?
- 3) Has the Global Fund procurement market become more or less concentrated over time?

By examining these relationships using real-world procurement data and independent product quality evaluations, we hope to gain insight into the importance of price and quality to those making RDT procurement decisions at the national malaria control program level. The relationship between price and quality in the global RDT market may also be of interest to RDT manufacturers as they consider designing and pricing products for large-scale purchase by the public sector. The level of concentration in the Global Fund's procurement orders may also be of interest to large purchasers and funders who want to ensure sufficiently diversified supply in order to avoid risks that could destabilize the market, such as a large manufacturer exiting the market. Several publications in the past decade have highlighted concerns about

sustainability in the malaria RDT market, for reasons related to price, quality, market concentration, and trends over time [6, 10, 31]. The onset of the COVID-19 pandemic in 2020 also proved a major stressor on the manufacture of malaria RDTs, sparking continued conversation about long-term market sustainability for diagnostics of global health importance [32, 33].

Methods

Data sources and measures

To investigate these three research aims, we merged and analyzed malaria RDT data from two sources: 1) the Global Fund Price and Quality Reporting (PQR) public database, and 2) data from the WHO-FIND Product Testing Evaluations. The Global Fund PQR data contain country-reported transactions from Global Fund–supported programs, including manufacturer, country, date of purchase, order volume, and price of the order. All prices were reported in US dollars (USD) at the time of order, and our analysis adjusts all dollars to 2018 dollars by using World Bank gross domestic product (GDP) deflator data for the United States as recommended by the *WHO Guide to Standardization of Economic Evaluations of Immunization Programmes* [34]. The WHO-FIND product evaluations were conducted in eight rounds between 2008 and 2018, and they include data on panel detection score, false positive rates, heat stability, and usability of the product.

In this investigation, our primary measures of interest were 1) panel detection score (PDS) at 200 parasites/ μ l for *P. falciparum* and/or *P. vivax* depending on the RDT test line and 2) unit purchase price per RDT. Panel detection score is a surrogate for sensitivity and the main measure of performance used in the WHO-FIND product testing program evaluation. Panel detection score provides a good indication of adequate analytical sensitivity based on the recommendations made by the product testing program documentation that “this level is well below the mean parasite density found in many populations in areas with endemic malaria and is considered close to the threshold that must be detected in order to reliably identify clinical malaria in many settings” [4]. Additionally, it is a combined measure of positivity rate and inter-test and inter-lot consistency, rather than a measure of clinical sensitivity, which can vary depending on parasite prevalence in the population of use [4]. We did not adjust for heat stability or false positive rate because “generally, products with high performance in detecting parasites have low false-positive rates [and] good thermal stability” [4]. For these reasons, we chose PDS as our measure for RDT quality. For RDT products that include more than one test line (to detect *P. vivax* or other malarias), we used data from the results of both test lines.

Unit price per RDT is drawn from the PQR data, measured in 2018 USD, and is calculated as inflation-adjusted order price divided by the volume of RDTs procured. We adjusted price per test for inflation using World Bank GDP deflator data in USD based on year of purchase [35]. In order to understand price changes in relation to quality of the product at the time, we examined each product based on the quality (PDS) data that was available at the time of its purchase. In several instances, the WHO-FIND Product Testing Evaluations reviewed the same product in different years of testing, and in these instances, we used the panel detection score that was most recently available at the time of the RDT purchase.

The Global Fund PQR data and the WHO-FIND Product Testing Evaluations data were matched on product name and catalog number (Appendix A) after manual review based on the reported product name, catalog numbers (expired and current), manufacturer, and test characteristics. If a product name and information were too ambiguous to determine a match, the product was excluded from the analysis.

After joining the PQR and WHO-FIND data, we saw outliers in both price per test and PDS in the resulting dataset. We removed outliers with price per test greater than ten times the mean price ($n = 2$) and outliers with a PDS score $< 50\%$ for a non-endemic species ($n = 55$). We also excluded procurement orders that were missing values in the data fields required to calculate price per test ($n = 75$). Additional detail on outlier identification as well as the complete cleaned dataset are available in Appendix B and D, respectively. This data collection and cleaning process is summarized in Fig. 1 below.

Sample characteristics

After using the defined exclusion criteria, the dataset for analysis included 925 orders of 39 unique RDT-PDS pairs between 2009 and 2018, totaling 776,960,035 individual tests ordered across all six WHO regions. This set of RDTs comprises approximately 37% of the estimated 2.1 billion RDTs procured by the public sector between 2009 and 2018 [10], meaning most of the RDT market is procured outside of this mechanism. However, data on these other segments are largely not publicly available. Our sample included four types of malaria RDT products: 60.1% of the RDTs purchased were for P.f.-only RDTs, 31.3% were for P.f./Pan RDTs, 8.5% were P.f./P.v. RDTs, $< 0.01\%$ were Pan-only RDTs, and none of the tests were P.v.-only. The majority of RDTs purchased (89.5%) were in the WHO Regional Office for Africa (AFRO) region. The median unit price of an RDT in the total sample was US\$0.47, and P.f.-only tests were the least expensive product type with a median price per test of US\$0.35. The median panel detection score for RDTs detecting *P. falciparum* was 95.0%, and the median PDS for RDTs detecting *P. vivax* was 91.4%. See Table 1 and Table 2 for additional sample characteristics.

Table 1
Characteristics of the sample by product type and WHO region

Characteristics of the sample by product type and WHO region				
	Number of purchase orders (%)	Total RDT volume (%)	Unique RDT product evaluations ^{1, 2} (%)	Unique manufacturers ³ (%)
Total	925 (100%)	776,960,035 (100%)	39 (100%)	11 (100%)
Product type				
P.f.	403 (43.6%)	466,737,077 (60.1%)	19 (48.7%)	9 (81.8%)
P.f./Pan	372 (40.2%)	243,217,199 (31.3%)	10 (25.6%)	4 (36.4%)
P.f./P.v.	147 (15.9%)	66,414,819 (8.5%)	9 (23.1%)	4 (36.4%)
Pan	3 (< 0.01%)	590,940 (< 0.01%)	1 (2.6%)	1 (9.1%)
WHO region ⁴				
AFRO	579 (62.6%)	695,556,122 (89.5%)	29 (74.6%)	7 (63.6%)
SEARO	115 (12.4%)	28,818,510 (3.7%)	18 (46.2%)	6 (54.5%)
EMRO	82 (08.9%)	29,664,394 (3.8%)	15 (38.5%)	3 (27.3%)
WPRO	75 (08.1%)	18,154,870 (2.3%)	9 (23.1%)	3 (27.3%)
AMRO	71 (07.7%)	4,411,119 (< 0.01%)	19 (48.7%)	8 (72.7%)
EURO	3 (< 0.01%)	355,020 (< 0.01%)	3 (7.7%)	1 (9.1%)

¹ Certain RDTs were evaluated more than once by the WHO product testing program and PDS scores were updated in the dataset after each round of testing.

² Unique RDT product evaluations by region do not total 100% because some RDTs were purchased in multiple regions.

³ Unique manufacturers by product type and region do not total 100% because some manufacturers produce multiple product types and were purchased in multiple WHO regions.

⁴ WHO regions are defined as the Regional Office for Africa (AFRO), the Americas (AMRO), Europe (EURO), the Eastern Mediterranean (EMRO), Southeast Asia (SEARO), and the Western Pacific (WPRO).

Table 2
Median unit price and median panel detection score (PDS) by product type

Median unit price and median panel detection score (PDS) by product type			
	Median unit price of RDT \$USD (IQR ¹)	Median P.f. PDS (IQR)	Median P.v. PDS (IQR)
Product type			
P.f. (n = 403)	\$0.350 (\$0.233–\$0.591)	96.0 (95.0–98.7)	NA
P.f./Pan (n = 372)	\$0.572 (\$0.383–\$0.836)	92.9 (84.0–96.2)	90.0 (75.0–94.3)
P.f./P.v. (n = 147)	\$0.509 (\$0.427–\$0.683)	96.0 (92.0–96.0)	95.0 (94.3–95.0)
Pan (n = 3)	\$0.588 (\$0.588–\$0.591)	84.0 (84.0–84.0)	88.6 (88.6–88.6)
All (n = 925)	\$0.473 (\$0.323–\$0.718)	95.0 (91.0–97.5)	91.4 (75.0–95.0)
¹ Interquartile range.			

Analysis methods

Aim one: Trends in RDT PDS over time

To investigate our first aim, we plotted the distribution of PDS for each P.f. and P.v. panels for each year between 2008 and 2018. To understand trends in quality, we grouped the RDTs by their panel detection scores into ranges of PDS < 75%, 75–79.9%, 80–84.9%, 85–89.9%, 90–95%, and > 95%. We used descriptive statistics to analyze if market share of RDTs with similar-quality panel detection scores are increasing or losing market share over time.

Aim two: Relationship between RDT unit price and PDS

To investigate our second aim, we fit two different linear regression models, as have been used in similar analyses of the malaria RDT market [10, 36]. First (aim 2a), we fit one linear regression model for each of the *P. falciparum* and *P. vivax* panels, in which we evaluated changes in price for a given PDS, adjusted for order volume, year of purchase, and product type. In this first model, we did not adjust for manufacturer because our goal was to understand the relationship between price and PDS in the market as a whole,

agnostic of manufacturer. If the purchaser were to base a price purely considering quality and cost, variations in manufacturer-specific product lines would not be relevant.

Secondly (aim 2b), we included manufacturer fixed effects as a covariate in the models to understand relationships between price and quality when controlling for manufacturer. Because of economies of scale, larger manufacturers can charge lower prices than smaller competitors while maintaining profitability, which may cause average prices in the market to be lower and mask relationships between price and quality within each individual manufacturer's product lines.

In all model interpretations, statistical significance was calculated at the alpha = 0.05 level and robust standard errors were used to correct for heteroscedasticity and non-normality in our data [37].

Aim three: Market concentration over time

Lastly, we calculated the Herfindahl-Hirschman Index (HHI), which is expressed in a range from 0 to 1, or with points from 0 to 10,000. It is calculated by summing the squared market share of each firm, and the higher the HHI, the higher the market concentration, as shown in Eq. 1. We defined market share in Global Fund procurements as percent of the total RDTs procured that were made by a specific manufacturer, divided by the total number of RDTs procured. We performed this calculation for the total set of data as well as for each year of procurement transactions.

Equation 1 The Herfindahl-Hirschman Index (HHI)

$$HHI = \sum_{i=1}^N s_i^2$$

Matching of product names to the PQR database and the WHO-FIND program results was performed in Microsoft Excel. All other analyses were performed in RStudio version 4.0.2.

Results

Aim one: Trends in RDT PDS over time

For the *P. falciparum* panel, in 2009 1% of purchased RDTs were below the current WHO minimum quality standard of 75%, while 94% of all purchased RDTs had a PDS > 95% (the standard was 50% until 2012). In 2013, 0% were below standard, 35% were between 75–94.9%, and 65% of RDTs had a PDS of 95% or greater. By 2018, still 0% of purchased RDTs had a PDS below 75%; the majority (66%) had a PDS between 90–94.9%, and 34% had a PDS of > 95%. We saw a similar trend in the distribution of *P. vivax* PDS scores among purchased RDTs. Among the *P. vivax*-detecting RDTs, in 2009 46% of RDTs were below the WHO standard of PDS 75% while 50% had scores of 90–94.9% and 4% were 95% or greater. By 2013, 0% of purchased RDTs were below the WHO minimum, 42% were 75–94.9%, and 58% were 95% or greater. By 2018, 100% of purchased RDTs had PDSs of 90–94.9%.

For both P.f. and P.v. parasite panels, we see that RDTs with panel detection scores below the WHO minimum acceptable threshold of 75% and those barely above (75–79.9%) have seen their market share in Global Fund procurement orders decrease over time. In addition to the low-quality tests, tests with the highest PDS scores of > 95% also appear to be losing Global Fund procurement market share over time.

Aim two: Relationship between RDT unit price and PDS

Our adjusted linear regression models showed no significant association between price per test and P.f. PDS (estimate: -0.002 , $p = 0.188$) and between price per test and P.v. PDS (estimate: 0.001 , $p = 0.564$). The results are summarized in Fig. 3 below.

Results from the adjusted linear regression models for our aim 2b, including manufacturer as a covariate, found varying relationships as summarized in Fig. 4 below. For RDTs with a P.f.-detecting test line, we found a statistically significant relationship between price per test and P.f. PDS (estimate: 0.01 , $p < 0.001$) among RDTs made by the same manufacturer, purchased in the same year and with the same order volume. This estimate corresponds to the trend that for every 1 percentage point increase in PDS, the mean RDT price is 1 cent higher. For RDTs with a P.v.-detecting test line, there was no significant relationship between price per test and PDS ($p = 0.394$).

A post-hoc sensitivity analysis for this aim removing manufacturers with less than 3 percent of market share in any year found that there was still a significant relationship between price per test and PDS for P.f.-detecting tests (estimate 0.011 , $p < 0.001$) and still no significant relationship between price per test and PDS for P.v.-detecting tests ($p = 0.38$).

Aim three: Market concentration over time

Calculating for the total dataset, the HHI is 3,570. The HHI score by year is presented in Fig. 5 below, noting the market share of the top three companies each year. Underlying data including names of manufacturers and their percent market share for each year can be found in Appendix C.

Of note, in each year, the same three companies are the top three manufacturers by market share of procured RDTs. In the last three years of analysis, they are the only three manufacturers from whom RDTs were procured.

To understand which products remained in the market, we explored the RDT purchase orders placed in 2017 and 2018 post hoc. All were for products from only three manufacturers: Standard Diagnostics (45% of orders), Premier Medical Corporation (37%), and Access Bio (18%). Looking at total RDT volume purchased, however, nearly all (94%) are manufactured by either Access Bio or Standard Diagnostics, as there were a higher number of smaller-volume orders for Premier. This information is summarized in Table 3.

Table 3
Characteristics of RDTs purchased in 2017 and 2018

Product Name	Manufacturer	Total Orders	Total RDT Volume	Median Price	Median PDS (Pf. / Pv.)	
First Response® Malaria Ag P. falciparum (HRP2) Card Test	Premier Medical Corporation	32	4,697,300	\$0.510	95.0	NA
SD Bioline Malaria Ag P.f/P.v	Standard Diagnostics	18	13,370,905	\$0.539	92.0	94.3
SD BIOLINE Malaria Ag P.f	Standard Diagnostics	12	17,177,075	\$0.225	95.0	NA
SD BIOLINE Malaria Ag P.f/Pan	Standard Diagnostics	9	1,225,525	\$0.668	94.0	91.4
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	Access Bio	4	1,337,805	\$0.240	90.8	94.1
CareStart™ Malaria Pf (HRP2) Ag RDT	Access Bio	3	2,715,250	\$0.235	91.0	NA
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	Access Bio	3	270,250	\$0.486	90.0	94.3
CareStart™ Malaria Pf (HRP2) Ag RDT	Access Bio	2	1,366,550	\$0.199	96.0	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	Access Bio	2	41,315,625	\$0.235	91.0	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	Access Bio	1	532,125	\$0.469	91.0	97.1
CareStart™ Malaria Screen RDT	Access Bio	1	525,050	\$0.459	93.0	94.3

Discussion

Low-quality (< 85% PDS) RDTs have seen decreased market share over this same time period, as have high-quality (> 95% PDS) RDTs. Among all four of our linear regression models examining price and quality, there is either no significant relationship ($p > 0.05$) or a very minimal one (estimate .01, $p < 0.001$) between price per test and panel detection score among RDT purchases in the Global Fund Price and Quality Reporting database from 2009–2018, for either *P. falciparum*-detecting RDTs or *P. vivax*-detecting RDTs. This indicates that there is little space for manufacturers to differentiate products on quality, and as such, purchasers at any willingness to pay can afford high-quality RDTs. The HHI score for the market overall was 3,570 and

was above 2,500 every year of analysis. This would categorize the market as well above the threshold for a “highly concentrated” market by US Department of Justice standards. Economists and regulators would generally prefer to avoid such high degrees of market concentration because they can result in decreased innovation and higher prices due to the lack of competition. Procurement agencies and malaria programs also may not prefer such concentrated markets that result in fewer choices and increased supply chain risks posed by the small number of manufacturers. However, high levels of market concentration do not necessarily decrease consumer welfare; for example, it is recognized that economies of scale can lead to lower prices in some markets [38, 39]. In order to encourage a healthy pipeline of products and create space for new high-quality products, the reasons for this high degree of concentration in the malaria RDT manufacturer space need to be understood.

Previous studies have identified related trends that are supported by these results. Similarly to Cunningham et al. our findings demonstrate that quality of RDTs, as defined by PDS, has improved over the course of the WHO-FIND product testing program [21]. However, RDTs with the highest PDS have become less prevalent over time. So, while the WHO-FIND product testing program has encouraged an overall improvement of test quality in the market [21], there has also been a consolidation toward very good but not the best RDTs, with some of the highest-quality products leaving the market.

One possible cause of this is that purchasers may not prioritize higher-quality RDTs once the product is simply “effective enough” or above the minimum WHO standard, even if higher-scoring tests can be purchased for the same price. Our results suggest it is possible that, from either the manufacturer or the purchaser perspective, as long as RDTs meet the WHO minimum standard, there is no need to place importance on quality, and rather competing on price, customer service, or other factors may be more central. This may have implications for producers of RDTs as they consider future product development and pricing of RDTs with higher panel detection scores—an issue that merits further study.

Our data also indicate that there is either no significant relationship between RDT price and quality or only a very minimal one. If most products are of similar quality, as shown by the RDT market share by quality (Fig. 2), and there is minimal variation in quality for a corresponding increase in price, then this would create very little market space for companies to differentiate their products on quality. This situation would cause companies to compete on price and benefit the lowest-cost producers, likely the largest with economies of scale.

Several reports by PATH, Unitaids, and the Clinton Health Access Initiative, as well as peer-reviewed publications, have noted the concern around lack of sustainability in the malaria RDT market, for the reasons listed above and others [6, 10, 31]. For example, the purchase price is approaching the cost of manufacturing the RDTs, which creates a market that is not attractive for additional investment and has a high barrier to entry for new manufacturers. If national malaria control programs are to rely on large private-sector manufacturers to produce good-enough products at a near-zero profit margin in the long run, these market conditions put RDT quality and innovation at risk [31]. This was demonstrated in January 2020 when quality control issues with one of the most prominent manufacturers, Access Bio, caused WHO to issue a Notice of Concern warning users about non-conformance with WHO standards and to not place any

new orders for products from this company until issues are resolved [40]. Additionally, in 2020 the COVID-19 pandemic disrupted the diagnostics market broadly as the companies with RDT capabilities pivoted resources, which has caused concern about future supply crises for malaria RDTs and disruption of malaria health services in both the near term and long term [32, 33].

A useful comparison to highlight unique forces in the malaria RDT market is to compare malaria RDTs to other RDTs procured at high volumes through the Global Fund. A similar analysis of HIV rapid diagnostic tests reported in the Global Fund's PQR database found that inflation-adjusted price per test remained constant between 2005–2012 [41], as opposed to decreasing over time as previous literature has shown for malaria RDTs [10, 36]. The number of malaria RDTs and HIV RDTs procured each year are roughly similar: about 417–435 million HIV RDTs were procured in 2018, versus 412 million malaria RDTs in that same year [42]. Further research into the different characteristics of these two RDT markets could provide additional insight to address risks associated with the Global Fund's malaria RDT market structure.

Strengths and limitations

There are several important limitations to this analysis. Our data only include purchase price data from country procurement officers using Global Fund resources and reported in the PQR database. This excludes some important purchasing channels such as large single-source contracts, the Global Fund's voluntary pooled procurement mechanism (VPP), and private-sector purchasing. Our results may not be generalizable to these other purchasing mechanisms and contexts. The study by Incardona et al. [22] found that two-thirds of the responding country representatives described more than one organization being involved with RDT procurement. Thus, our data are incomplete in that they do not describe all RDT purchase orders by national malaria control programs. However, these data are consistent with reports that summarize other procurement mechanisms such as the VPP and manufacturer-provided estimates [10, 31]. They also represent the largest proportion of transaction information that is publicly available and span nearly a decade of procurement transactions across countries in every WHO region.

There are limitations in the PQR dataset we used as well. There are often reporting delays in entering of purchase data to the system, and much of the 2018 data may not be included in our analysis. Some data may not be complete or may be entered incorrectly. The guidance documents for the PQR database note that in some instances, the reported purchase price of an RDT order includes some supply chain fees, which may inflate our mean price per test. However, since our data examine high-level trends comparing change in average purchase price over time, we do not believe these data limitations substantially alter our conclusions.

Despite these limitations, this study still fills important gaps in the literature. Our analysis is the first to combine the two largest publicly available datasets of purchase price and product quality data for malaria RDTs. Our results describe important trends and relationships within the global market of malaria RDTs that have not yet been characterized and which prompt areas for future study.

Conclusion

High-quality rapid diagnostic tests are an essential element of any malaria control strategy. Important advancements have been made over the past decade in reducing price, increasing quality, and expanding access to RDTs globally; however, this progress risks stagnation if the health of the RDT market as a whole is neglected. The results of this study provide evidence suggesting that 1) while low-quality malaria RDTs have exited the market, so too have the highest-quality RDTs, 2) there is no relationship between product price and product quality, and 3) the market of malaria RDT manufacturers is highly concentrated around only a few primary suppliers.

Additional research is needed to understand the degree to which price and quality are weighed in decision-making by procurement officers, implications for manufacturers regarding development and pricing of ultra-sensitive RDTs, and if this relationship applies in other malaria RDT procurement channels. This additional research could also lead to identification of similar trends in other vital global health commodities.

List Of Abbreviations

Abbreviation	Meaning
FIND	Foundation for Innovative New Diagnostics
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HHI	Herfindahl-Hirschman Index
HIV	Human immunodeficiency virus
PDS	Panel detection score
P.f.	<i>Plasmodium falciparum</i>
PQR	Global Fund’s Price and Quality Reporting
P.v.	<i>Plasmodium vivax</i>
RDT	Rapid diagnostic test
USD	United States dollars
WHO	World Health Organization

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analyses during this study are included in this published article as supplementary information files.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

RW and SN conceived of the analysis. SN sourced the data for analysis. RW performed the analysis and wrote the initial manuscript draft. SN and NL provided substantial reviews of the results interpretation and written report. All authors read and approved the final manuscript.

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Appendix

A. Matching RDT products between WHO-FIND and Global Fund catalogue numbers

Product Name (WHO-FIND Evaluations)	Catalogue Number (Global Fund)	Rounds Evaluated
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	3,6
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	1,5,8
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	7
CareStart™ Malaria Pf (HRP2) Ag RDT j	RMOM-02571	1,5,8
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT j	RMPM-02571	2,6,8
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	8
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT j	RMRM-02571	1,5,8
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT j	RMLM-02571	3,7,8
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	7
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT j	RMVM-02572	2,4,7,8
CareStart™ Malaria Screen RDT	RMAM-05071	3,7
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	6
FalciVax™ Rapid Test for Malaria Pv/Pf j	503010025	2,4,6,8
First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25	1,5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	1,2,5
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	6
ICT MALARIA DUAL TEST	ML03	3,5,7
ICT MALARIA P.F. CASSETTE TEST	ML01	1,3,7
One Step Malaria HRP2 (P.f) Test	W37-C	2,3,4,6,7
OnSite Malaria Pf Ag Rapid Test	R0114C	2,3,6
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	2,3,4,6
OptiMAL-IT	710024	1,3
Paracheck Pf Rapid test for P. falciparum Malaria (Dipstick)	30302025	1,3,4
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3) j	302030025	1,3,4,8
Parahit f® Ver 1.0 - Dipstick	55IC103-50	3,7

Product Name (WHO-FIND Evaluations)	Catalogue Number (Global Fund)	Rounds Evaluated
Parahit® f Ver 1.0 - Device	55IC104-50	3,7
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) j, k	05FK90	3,6,8
SD BIOLINE Malaria Ag P.f/P.f/P.v j, k	05FK120	6,8
SD Bioline Malaria Ag P.f/P.v	05FK80	2,6
SD BIOLINE Malaria Ag P.f/Pan	05FK60	1,3,5
SD BIOLINE Malaria Ag Pf	05FK50	1,5

B. Outlier identification process

After joining the PQR and WHO-FIND data, we saw outliers in both price per test and PDS in the resulting dataset. There were two small procurement orders (800 and 2,100 RDTs) with prices per test over nine times the size of interquartile range above the mean, which we considered to be outliers and removed from the analysis. We also identified and removed outliers in the PDS scores. At the beginning of the WHO-FIND product evaluation program, the WHO recommended minimum quality standard for PDS was > 50% (and in 2012 was raised to 75%) [21]. There were three products procured (across a total of 55 orders) with PDS lower than 50% (for either P.f. or P.v.): 1) a P.f./Pan test with P.v. PDS < 50%, 2) a P.f./Pan test with P.f. PDS < 50%, and 3) a P.f/P.v. test with a P.f. PDS < 50%. For each of these products, we excluded the data for the low-PDS test line if that parasite species was not endemic in the purchasing country. For example, Nigeria placed four orders for a two-line P.f./P.v. test of which the PDS *P. vivax* score was < 50%; however, *P. vivax* is not considered to be endemic in Nigeria, so for our analysis we assumed these tests were procured primarily for the purposes of diagnosing *P. falciparum* infection and excluded the *P. vivax* panel data. We also excluded procurement orders that were missing values in the data fields required to calculate price per test (n = 75).

C. Market concentration by manufacturer

The table below includes additional details on market share of the top three malaria RDT manufacturers included in this analysis.

Year	HHI Score ¹	Market Share of Top 3 Manufacturers
All years	3570	Standard Diagnostics (44.58%) Access Bio (34.38%) Premier Medical Corporation (20.00%) <i>Other manufacturers (n = 7, 1.04%)</i>
2009	3288	Standard Diagnostics (41.45%) Access Bio (28.27%) Premier Medical Corporation (27.69%) <i>Others (n = 2, 2.59%)</i>
2010	4752	Premier Medical Corporation (58.19%) Standard Diagnostics (36.61%) Access Bio (5.06%) <i>Others (n = 3, 0.14%)</i>
2011	3447	Access Bio (41.58%) Standard Diagnostics (32.05%) Premier Medical Corporation (26.28%) <i>Others (n = 1, 0.09%)</i>
2012	3182	Standard Diagnostics (33.31%) Access Bio (32.92%) Premier Medical Corporation (31.41%) <i>Others (n = 4, 2.36%)</i>
2013	3516	Standard Diagnostics (44.91%) Access Bio (32.90%) Premier Medical Corporation (20.34%) <i>Others (n = 3, 1.85%)</i>
2014	3600	Access Bio (41.91%) Standard Diagnostics (39.71%) Premier Medical Corporation (16.29%) <i>Others (n = 2, 2.09%)</i>

Year	HHI Score ¹	Market Share of Top 3 Manufacturers
2015	4222	Standard Diagnostics (52.56%) Access Bio (36.66%) Premier Medical Corporation (10.77%) <i>Others (n = 1, 0.01%)</i>
2016	7443	Standard Diagnostics (85.27%) Access Bio (13.01%) Premier Medical Corporation (1.72%) <i>Others (n = 0)</i>
2017	4716	Access Bio (57.12%) Standard Diagnostics (37.77%) Premier Medical Corporation (5.10%) <i>Others (n = 0)</i>
2018	3430	Access Bio (39.84%) Premier Medical Corporation (34.15%) Standard Diagnostics (26.00%) <i>Others (n = 0)</i>
¹ The US DOJ considers an HHI score below 1,500 as an unconcentrated market, between 1,500 and 2,500 as a moderately concentrated market, and above 2,500 as a highly concentrated market.		

D. Complete datasets and files

Additional files available

File Title	File Name	File Type	Description
Global Fund PQR Data	"globalfund_df.csv"	CSV	Data from the Global Fund including price, quality, volume, RDT product, and country
Adjusted PDS Data	"pds_adj_df.csv"	CSV	Data from eight rounds of WHO-FIND Product Testing Programme, organized by evaluation round
WHO-FIND Data	"find_df.csv"	CSV	Data from eight rounds of the WHO-FIND Product Testing Programme, organized by RDT product name, including PDS, heat stability, and false positive rate for each RDT type by evaluation round
WHO Regions	"who_region_df.csv"	CSV	List of countries and corresponding WHO regions
Analysis Script	"Malaria RDT Analysis Script.R"	R	R script containing code for data cleaning and analyses contained in this manuscript

Figures

Figure 1

Data included in this analysis are sourced from the Global Fund and the WHO-FIND Programme

Figure 2

Market share of RDT products by panel detection score (P.f. and P.v.) 2009–2018

Linear Regression Model Results: Cost per test vs. P.f. PDS					Linear Regression Model Results: Cost per test vs. P.v. PDS				
Predictors	Estimates	Cost Per Test		p	Predictors	Estimates	Cost Per Test		p
		CI					CI		
Intercept	124.646	108.023 – 141.268	<0.001		Intercept	153.050	124.480 – 181.620	<0.001	
Panel Detection Score (P.f.)	-0.002	-0.006 – 0.001	0.188		Panel Detection Score (P.v.)	0.001	-0.002 – 0.003	0.564	
Order Volume	-0.000	-0.000 – -0.000	<0.001		Order Volume	-0.000	-0.000 – -0.000	<0.001	
Purchase Year	-0.062	-0.070 – -0.053	<0.001		Purchase Year	-0.076	-0.090 – -0.062	<0.001	
Product Type: P.f./Pv (vs. P.f.-only)	0.072	0.020 – 0.123	0.007		Product Type: P.f./Pan (vs. P.f./P.v.)	-0.025	-0.089 – 0.039	0.440	
Product Type: P.f./Pan (vs. P.f.-only)	0.057	0.014 – 0.101	0.010		Product Type: Pan (vs. P.f./P.v.)	0.060	-0.279 – 0.399	0.728	
Product Type: Pan (vs. P.f.-only)	0.100	-0.206 – 0.407	0.520		Observations	484			
Observations	920				R ² / R ² adjusted	0.262 / 0.254			
R ² / R ² adjusted	0.306 / 0.302								

Figure 3

Results of aim 2a regression analyses on cost per test and panel detection score. Model 2a: We fit one linear regression model for each the P. falciparum and P. vivax panels, in which we evaluated changes in price for a given PDS, adjusted for order volume, year of purchase, and product type

Linear Regression Model Results: Cost per test vs. Pf. PDS			
Predictors	Cost Per Test		
	Estimates	CI	p
Intercept	107.410	91.065 – 123.754	<0.001
Panel Detection Score (P.f.)	0.008	0.004 – 0.013	<0.001
Order Volume	-0.000	-0.000 – -0.000	<0.001
Purchase Year	-0.053	-0.061 – -0.045	<0.001
Product Type: P.f./Pv (vs. P.f.-only)	0.154	0.097 – 0.211	<0.001
Product Type: P.f./Pan (vs. P.f.-only)	0.160	0.111 – 0.209	<0.001
Product Type: Pan (vs. P.f.-only)	0.383	0.090 – 0.676	0.011
Manufacturer: BIONOTE (vs. Access Bio)	-0.047	-0.400 – 0.307	0.796
Manufacturer: CTK Biotech (vs. Access Bio)	0.036	-0.181 – 0.253	0.742
Manufacturer: ICT Diagnostics (vs. Access Bio)	0.030	-0.181 – 0.242	0.780
Manufacturer: Orchid Biomedical (vs. Access Bio)	0.407	0.261 – 0.553	<0.001
Manufacturer: Premier (vs. Access Bio)	0.222	0.172 – 0.272	<0.001
Manufacturer: Span Diagnostics (vs. Access Bio)	0.980	0.758 – 1.202	<0.001
Manufacturer: Standard Diagnostics (vs. Access Bio)	0.117	0.074 – 0.160	<0.001
Manufacturer: Zephyr (vs. Access Bio)	0.175	-0.318 – 0.669	0.486
Observations	920		
R ² / R ² adjusted	0.398 / 0.388		

Linear Regression Model Results: Cost per test vs. Pv. PDS			
Predictors	Cost Per Test		
	Estimates	CI	p
Intercept	113.826	90.412 – 137.240	<0.001
Panel Detection Score (P.v.)	-0.001	-0.004 – 0.001	0.394
Order Volume	-0.000	-0.000 – -0.000	<0.001
Purchase Year	-0.056	-0.068 – -0.045	<0.001
Product Type: P.f./Pan (vs. P.f./P.v.)	-0.025	-0.082 – 0.032	0.399
Product Type: Pan (vs. P.f./P.v.)	0.117	-0.155 – 0.389	0.398
Manufacturer: CTK Biotech (vs. Access Bio)	-0.093	-0.307 – 0.120	0.391
Manufacturer: DiaMed/Bio-Rad (vs. Access Bio)	1.854	1.640 – 2.068	<0.001
Manufacturer: Premier (vs. Access Bio)	0.084	0.014 – 0.153	0.018
Manufacturer: Standard Diagnostics (vs. Access Bio)	0.097	0.041 – 0.154	0.001
Manufacturer: Zephyr (vs. Access Bio)	0.062	-0.414 – 0.539	0.797
Observations	484		
R ² / R ² adjusted	0.547 / 0.537		

Figure 4

Results of aim 2b regression analysis, with manufacturer included as a covariate. Model 2b: We fit one linear regression model for each the *P. falciparum* and *P. vivax* panels, in which we evaluated changes in price for a given PDS, adjusted for order volume, year of purchase, product type, and manufacturer.

Figure 5

HHI score and market concentration by year

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [MalariaRDTAnalysisScript.r](#)
- [finddf.csv](#)
- [globalfunddf.csv](#)
- [pdsadjdf.csv](#)
- [whoregiondf.csv](#)