

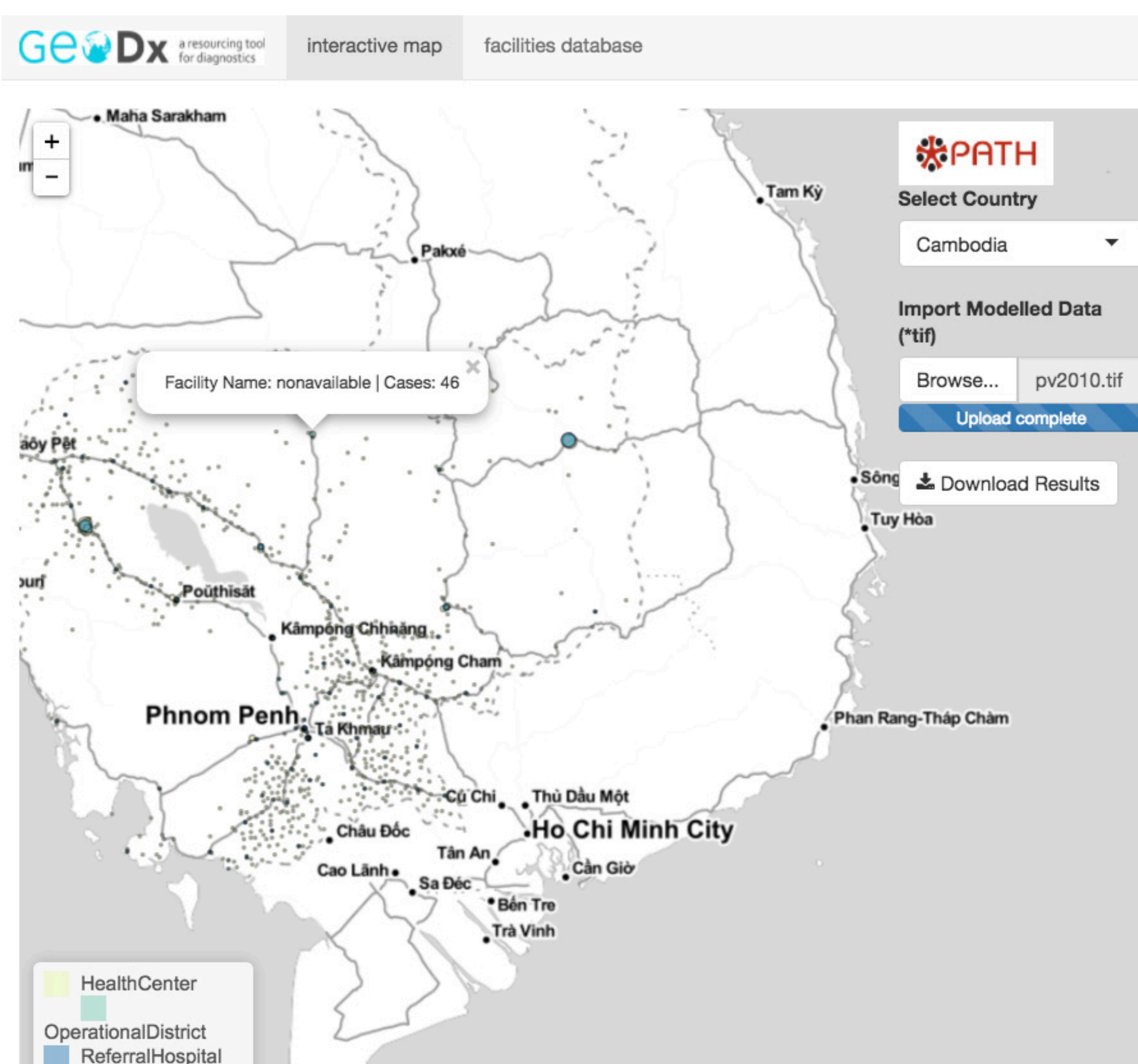
USING MODELED *PLASMODIUM VIVAX* PREVALENCE DATA TO ESTIMATE THE MARKET SIZE FOR GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) DEFICIENCY TESTS IN ORDER TO SUPPORT DECISION-MAKING ON SERVICE DELIVERY MODELS

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BACKGROUND

Plasmodium vivax (*P. vivax*) is estimated to be responsible for over 100 million clinical infections annually. The 8-aminoquinoline family of drugs, such as primaquine, can completely clear *P. vivax* parasites by killing malaria gametocytes and consequently blocking vector-borne transmission. However, the 8-aminoquinoline family of drugs can cause severe hemolysis in patients with reduced activity of the glucose-6-phosphate dehydrogenase (G6PD) enzyme; therefore, the World Health Organization recommends identifying the G6PD status of patients infected with *P. vivax* malaria prior to administering these drugs. Point-of-care (POC) tests that can rapidly and affordably identify G6PD status are needed to support safer and wider use of the 8-aminoquinoline family of drugs. During the time that PATH has been supporting the development and market entry of POC G6PD quantitative and qualitative tests, we have also developed a computer program called GeoDX to estimate the *P. vivax* burden per health facility (i.e., the number of patients testing positive for *P. vivax* that visit each health facility), the total quantity of G6PD tests per country, and the associated costs.

Figure 1. GUI for GeoDx displaying locations of health care facilities and health care facility type.



MATERIALS AND METHODS

Leveraging data modeled by the Malaria Atlas Project (i.e., *P. vivax* prevalence and population per geographical area,

MATERIALS AND METHODS (CONTINUED)

geospatial facility data, and certain assumptions about facility catchment area) GeoDX estimates the *P. vivax* burden per health facility. This estimate was further used to calculate the total quantity of G6PD tests required per country and the associated costs over a ten-year period. GeoDX is interactive, and users can adjust parameters such as diagnosis-to-treatment algorithms, malaria elimination scenarios, and characteristics of any G6PD test for which they choose to generate country-specific data. Characteristics that can be modulated are:

1) Pilot Study

- Number Pilot Locations
- Duration of Pilot Study

2) Malaria Burden Parameters

- Time till maximal coverage
- Years until complete *Pv* elimination

3) Distribution and screen algorithm

- Distribution of quantitative component to tier 3,4 or 5 facilities

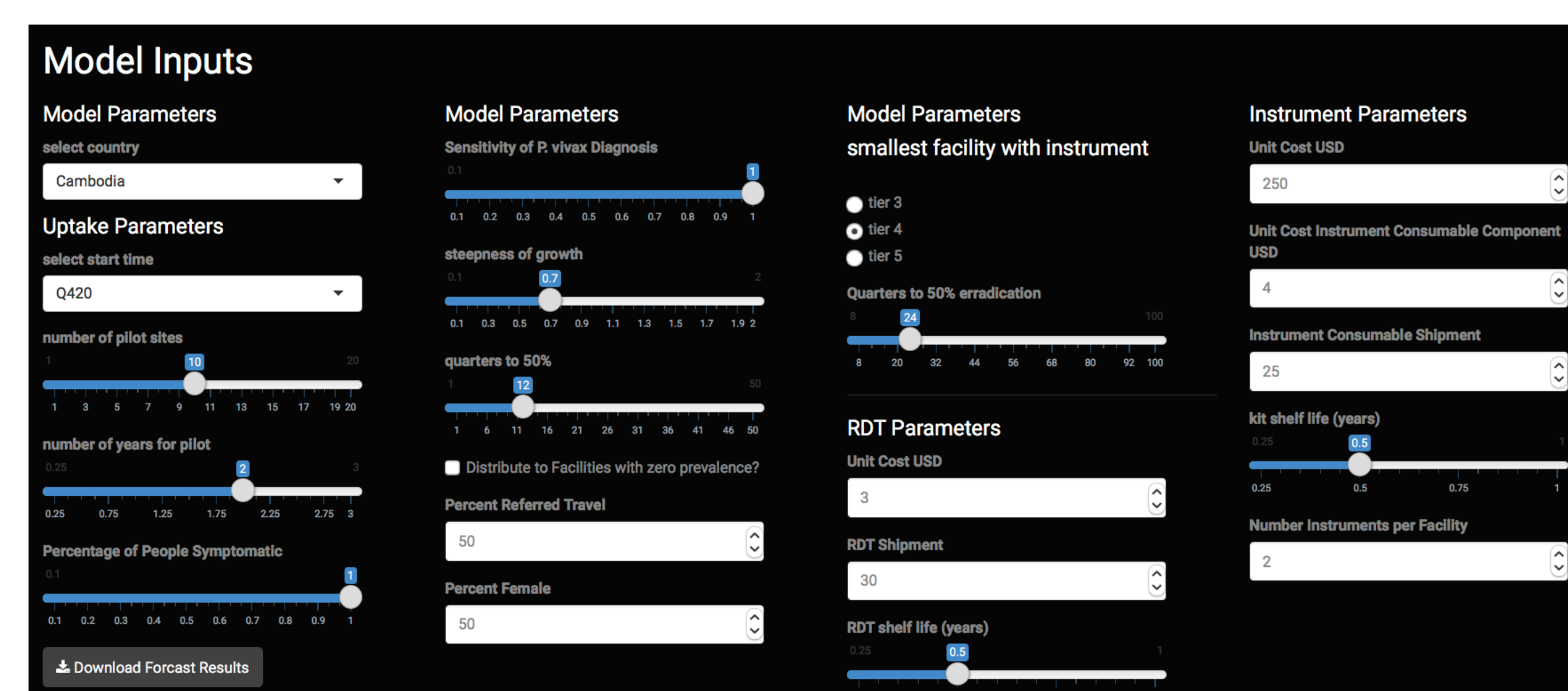
4) Population and Care Seeking

- Percent population female
- Percent population that travels when referred

5) Product specific parameters

- Unit shipment disposable component
 - Disposable component shelf life
 - Quantitative G6PD diagnostic device cost
 - Quantitative G6PD diagnostic device lifespan
-) *P. vivax* diagnostic sensitivity
- Can be modulated

Figure 2. Graphical user interface where user can modulate parameters to estimate market size of G6PD diagnostic commodities.

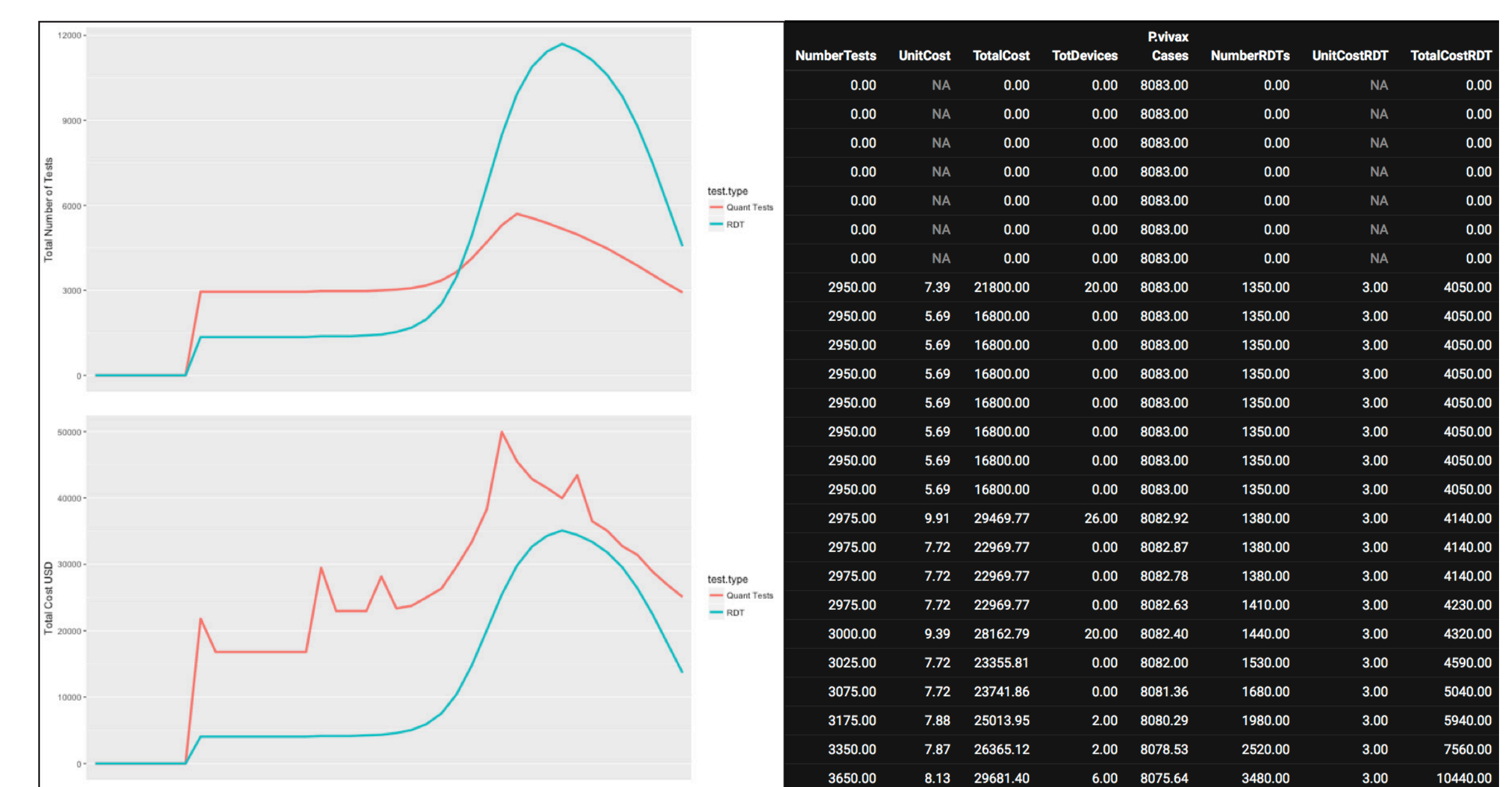


MATERIALS AND METHODS (CONTINUED)

Figure 3. Validation of our methodology for estimating *P. vivax* + cases by comparing GeoDx 2015 outputs to number of confirmed *P. vivax* + cases in 2015 reported by WHO.

	Reported Cases of <i>P. vivax</i>	GeoDx Total <i>P. vivax</i> infections	GeoDx Cases <i>P. vivax</i> 50% symptomatic	% Difference
Brazil	126,211	280,469	140,234	11%
Cambodia	13,146	33,820	16,910	28%
Ethiopia	678,432	869,785	434,892	35%

Figure 4. A detailed display of market size forecast and cost values for a qualitative G6PD diagnostic device and a G6PD RDT output by GeoDx.



RESULTS AND CONCLUSIONS

National malaria control programs and other program implementers can use the outputs of GeoDX to evaluate which use cases would most likely attain the desired target coverage in the most effective manner. They can also use the outputs to determine what the cost impact of the selected G6PD diagnostic test(s) would be on their budget. Test manufacturers can use this same information to identify the production quantity required, which will enable them to evaluate their production costs and pricing structure over time. Thus we believe GeoDx can serve as an important resource for malaria control programs and diagnostic manufacturers.