Rapid Diagnostic Tests – The Troubling Online Market for Unvalidated Tests

Dr. Melissa Chowdhury, BSc, MBBS, MRCP, UK

ABSTRACT

Statement of the Problem: Rapid Diagnostic Tests (RDTs) are useful tools to diagnose a variety of infections. RDTs generally use a dipstick or cassette format, and results are usually given in 10 minutes. They are particularly advantageous in resource limited settings where they can be implemented easily at the point of care and provide results quickly. However the appeal of RDTs has led to an explosion of products on the market. Most are neither WHO prequalified nor registered with a stringent authority such as the US Food and Drugs Administration meaning their quality and efficacy cannot be assured. In order to quantify this problem, a search was performed of available RDTs for purchase for two common infectious diseases. **Methodology:** A web based search on leading search engines, using the following search terms: Dengue Rapid Diagnostic Kit, Dengue Test Kit, HIV Rapid Diagnostic Test Kit and HIV Test Kit. Selecting the first page of the search, I then checked them against the WHO prequalified list. Variables of interest were: whether WHO prequalified or not, pharmaceutical supplier and country, validation data on website, validation data either on PubMed or googlescholar. Data was extracted in a standard format into a database. **Key Findings:** For Dengue, 76 test kits were found, 1 appeared to be WHO prequalified. 37 test kits were found for HIV, 1 appeared to be WHO prequalified. **Conclusion and Significance:** These results show not only the availability but also the ease of purchasing RDTs that may have not been adequately tested. As a result, potentially less effective tests may be in use. In addition to causing patient harm through potential misdiagnosis, the purchase of tests that do not work properly are a waste of resources. Recommendations are made for greater awareness, research and centralised testing systems to address this important issue.

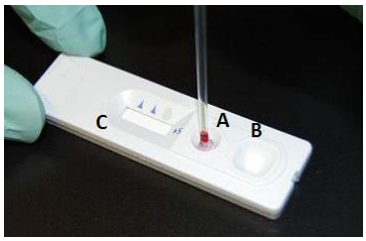


Image derived from https://www.flickr.com/photos/cdcglobal/8271756665

Figure 1: An example of a Rapid Diagnostic Test. A sample of blood is collected from the patient and applied to the sample pad on a test card (A) along with reagents that the blood will react with if a particular antigen is present. Buffer is added to another hole (B) to carry the blood along the length of the RDT. If antigen is detected then the test will show this result with the presence of a band in the test card window (C).

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BIOGRAPHY

Dr. Melissa Chowdhury is currently working as an HIV/GUM Registrar at the North Middlesex University Hospital, London. Her interest in the use of Rapid Diagnostic Tests developed when she saw first-hand how useful they can be in resource limited settings, when she undertook a voluntary placement in HIV clinics in Myanmar in 2017. Prior to that she developed an interest in HIV medicine and Infectious Disease during her work as an HIV/GUM Registrar at the Mortimer Market Centre and Bloomsbury Clinic, London. She completed her MBBS degree at University College London.

Email: melissachowdhury@gmail.com

NOTES/COMMENTS: