Title: A framework for selecting analytical biomarkers: a first principles approach

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Biomarkers are objective indications of a medical state that can be measured accurately and reproducibly. Traditional biomarkers enable diagnosis of disease through detection of disease-specific molecular signatures or distinct physiological or anatomical signatures. Appropriate selection of biomarkers with innovative test design can transform patient care by providing earlier diagnosis, treatment monitoring, and ultimately reduced burden of disease. These results will be best achieved through collaborations between researchers, device designers, and clinicians to drive test development for addressing clinical questions.

We developed a framework for selecting biomarkers that are most likely to provide useful information about a patient's disease state. This framework describes the trade-offs between biomarkers' sensitivity/specificity for a disease-causing agent, the complexity of detection, and how this knowledge can be applied to the development of diagnostic tests. This report also details assessment criteria for successful tests.

Our framework aims to assist stakeholders from test developers to clinicians by focusing on validating biomarker selection for an explicit clinical question (e.g., direct correlation with pathogenesis) followed by test development expediency (e.g., ease of detection). There are few, if any, ideal biomarkers due to trade-offs based on performance, cost, and usability. Its important to consider how and where a test will be used in order to select an appropriate biomarker. Our framework is intended to help assess these trade-offs to design new systems and enhance those that are already available.

Biography

Samantha Byrnes completed a PhD in Bioengineering and an MPH in Global Health Metrics at the University of Washington, Seattle. She has lived and worked in developing settings which has included the testing of a nucleic acid purification and storage prototype in Nicaragua and helping develop an assessment framework for a vaccination campaign in Bangladesh. Currently, she works for Intellectual Ventures Laboraotry focusing on development of products for rapid disease diagnosis and biomarker selection.

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