

The Cantest Framework: Evaluating Diagnostic Strategies for Early Cancer Detection

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Introduction

Early cancer detection is a public and policy goal, with primary care being the best place to do it. This has sparked a desire for better cancer early detection tests, preferably ones that can be used in primary care settings. The development of novel biomarkers and other tests, on the other hand, has mostly benefitted prognostication and surveillance of patients who have already been diagnosed with the disease. In contrast, enhancing the precision and timeliness of cancer diagnosis in cancer patients who arrive to primary care with symptoms has yielded modest advantages. A broader set of superior testing could be game-changing. This 'grand challenge' of improving early cancer diagnosis has been recognized by a wide range of stakeholders including policymakers, purchasers, health care providers and consumers, and industry.

While technological advancements are resulting in an increasing number of new diagnostics involving biomarkers, sensors, imaging devices, and artificial intelligence algorithms, the vast majority of seemingly promising cancer diagnostic tests in early development fail due to the so-called 'spectrum effect,' in which they do not perform adequately in the low prevalence populations in which they will eventually be used. When used in a population with a lower prevalence of disease (or at higher risk), a test designed in a group with a higher prevalence of disease (or at higher risk) will often have a lower sensitivity and higher specificity (or at lower risk). As a result, there are more false positive tests and more referrals to specialists, such as for symptomatic women with elevated CA125.

Alternatively, a test may be over-marketed and misused – a well-known example is the widespread use of Prostate Specific Antigen (PSA) testing before the results of screening trials were available. Thus, in evaluating testing for cancer and other low-prevalence disorders, potential over-investigation and over-diagnosis, deciding on the reference standards to be used in assessing test accuracy, and results significant to patients are all challenges.

New tests have been thoroughly evaluated in a variety of medical fields, including biochemistry, pathology, radiography, and

genomics, using frameworks defined by academic or policy groups at national and international levels. These frameworks are applicable at various stages of the diagnostic process, from concept to execution. They are intended to provide guidance to a wide range of stakeholders, including test creators, clinicians, researchers, and policymakers, on what evidence is required at each stage of a test's development, from bench to community.

Several common phases of test evaluation were recognized in the previous study of diagnostic test frameworks, published in 2009: technical efficacy, clinical accuracy, comparative accuracy, diagnostic and therapeutic effects, patient outcomes, and societal issues. Most frameworks simply defined sections of the diagnostic evaluation process, and many of them overlooked concerns unique to communities with low frequency of the ailment in question.

CanTest framework

Despite the fact that no framework completely satisfied our needs, the consensus committee felt that the Lin et al model was the most closely related to our objectives? It did, however, leave out important details like incorporating a test into a testing plan and using a test for triage. Furthermore, the majority of the frameworks were very simplistic, ignoring non-linearity in development, *i.e.* the necessity for iteration back and forth between research phases. Horvath et al's Assessment Framework, as well as Thompson et al's model's combining numerous test qualities, were among the first to recognize the iterative or cyclical nature of test evaluation, as well as the interaction between distinct phases of evaluation. The Safer Dx paradigm was the only one that addressed the interplay of test performance and provider interpretation in the context of the patient's diagnostic process, as well as interactions between various components of the diagnostic work system that were scattered in place and time. The test's significance in triaging patients for possible extra testing and specialized referral was also made clear by Safer Dx. Finally, Safer recognized the importance of coordinating the diagnostic process (which frequently involves performing and interpreting many tests at different times and locations) as well as ensuring fail-safe patient follow-up.

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Because no other framework met their needs, the consensus group created the CanTest Framework, which was informed by these major articles and fine-tuned by iterative discussion and consensus within the interdisciplinary group. We wanted to create a new comprehensive, methodological framework for test developers, including industry, research funders, and academia, that addressed the continuum from test development to

influence on diagnosis and patient outcomes in everyday practice. We wanted to include: a shift in focus from evaluating a single test to evaluating its integration into a diagnostic strategy; greater clarity around changes in test performance from highly selected populations to the final intended, lower prevalence population; and the iterative nature of test evaluation and development.