

Clearing the Pathway for Molecular Diagnostic Tests

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People living with chronic conditions benefit from many medical advances developed over the past 20 years. Many diseases that were once fatal diagnoses are now managed utilizing various drug therapies.

However, far too often, treatments may work well for some people, while providing marginal benefits or causing significant harm to others.

One example is antidepressants. According to a study at the Tel Aviv University (TAU) Sackler School of Medicine, the most popular antidepressants only work for approximately 60% of the patients with depression. For the other 40% of the patients, it takes a trial-and-error approach to find the right treatment strategy. As David Gurwitz, PhD, at TAU stated, patients need a “best-fit, personalized regimen.”¹ For people with autoimmune diseases, it is even more difficult to create the right treatment plan.

Today, billions of dollars are spent annually on research, development, and clinical trials to create new healthcare products. How can we improve on this process so that patients can reap the full return on investment?

Molecular diagnostics can be an important element in the development of personalized medicine by determining the course of a disease and evaluating the patient’s response to a given therapy based on the individual’s genetic makeup. Such processes are already being tested as a prognostic indicator of congestive heart failure to better identify patients in need of more intensive forms of therapy.² Molecular diagnostics have also been applied in the detection and treatment of other disease categories.

The National Health Council (NHC) has engaged in conversations with various patient advocacy groups and other stakeholders to examine new methods to more accurately identify the benefits of therapies at the point of care, taking into consideration a patient’s individual genetic makeup.

Creating and utilizing molecular diagnostic tests could allow us to better target treatments to those who will benefit and reduce costs by more accurately determining safety and efficacy of related medicines. Janet Woodcock, MD, director of the Center for Drug Evaluation and Research at the US Food and Drug Administration, has pointed out

that targeting therapies to the likely-to-benefit patient groups—or to exclude those individuals with a low probability of a positive response—is a powerful method of increasing value in healthcare delivery.³ Such advances in science also hold promise for better health outcomes for patients with chronic diseases.

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PricewaterhouseCooper states in a 2009 report on diagnostics that there is “a growing imperative, both clinical and budgetary, to accompany therapies with diagnostic tools of increasing sensitivity and specificity to better enable the identification of those patients in the relevant disease subtype and most likely to benefit from the therapy.”⁴ The company predicts that the marketing model foreseen for most specialist therapies in 2020 will include a companion diagnostic as a key component.

However, should we wait 10 years while the needs of patients are left unmet? We need a system that ensures that advances in science are more quickly married to the needs of individual patients.

The NHC is proposing a public–private approach that would remove the barriers that impede progress in the development and use of molecular diagnostics.

Currently, there is ambiguity in the evidentiary standards for molecular diagnostic tests and the regulatory approval pathway. This lack of certainty discourages investment in the development of the new therapies utilizing such tests. What we need is better communication between government and industry and a goal-oriented approach to revising the regulatory process.

What we also need to do is a better job of explaining to the public that molecular diagnostic tests could ensure that individuals with different but related conditions receive targeted drug therapies that work for their specific disease subtype.

How we go about clarifying and creating a process to support greater use of molecular diagnostic testing is currently under debate. As Dr Woodcock has pointed out, "Given the huge stakes involved in reimbursement decisions and the variety of methodological approaches that could be used to compare interventions, an epistemological 'food fight' over evidentiary standards is likely in this emerging field."³

If we can get the appropriate stakeholders from the public and private sectors working together, we can come up with workable menu of action steps that will greatly benefit the patient community.

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REFERENCES

1. Nauert R. Matching medications to genes. <http://psychcentral.com/news/2009/10/28/matching-medications-to-genes/9182.html>. Accessed January 20, 2010.
2. BG Medicine acquires exclusive rights to biomarkers of congestive heart failure from ACS Biomarker. <http://www.bg-medicine.com/content/news-center/news/q/id/71>. Accessed January 20, 2010.
3. Woodcock J. Chutes and ladders on the critical path: comparative effectiveness, product value, and the use of biomarkers in drug development. <http://www.nature.com/clpt/journal/v86/n1/full/clpt200933a.html>. Accessed January 20, 2010.
4. Probst L, Kubitza L, McDougall G, Pillari T. Diagnostics 2009: moving toward personalised medicine. <http://www.pwc.com/gx/en/pharma-life-sciences/Diagnostics-2009/diagnostics-2009.jhtml>. Accessed January 20, 2010. 