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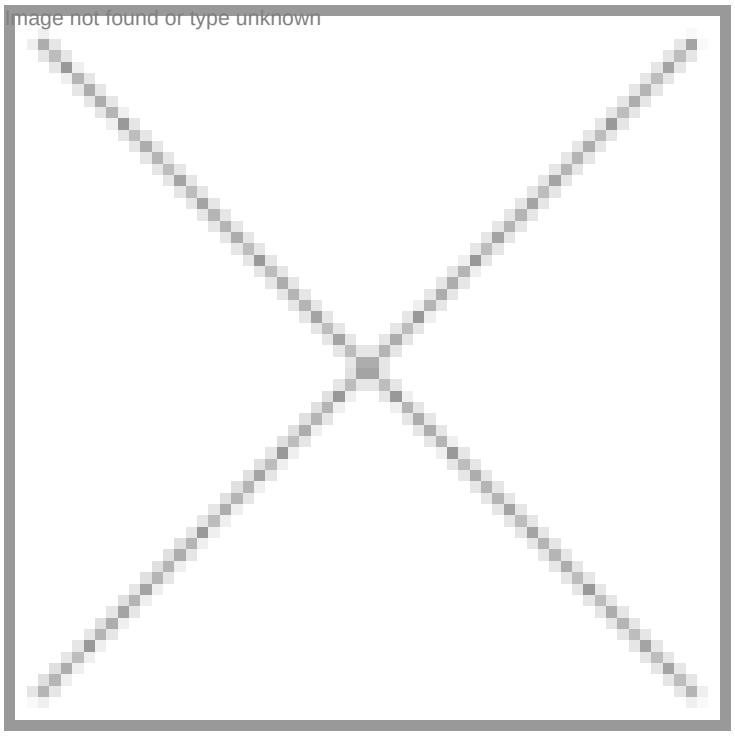
Different people but less differentiated drugs

06 November 2009 | News



Different people but less differentiated drugs

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Today half the medicines fail to produce the desired effect; only around half of all patients actually benefit from their drug treatment.
This situation particularly is unsatisfactory for patients or doctors because neither the desired effects nor the side effects can be clearly defined or reliably calculated; and it is unsatisfactory for health insurers too, as they will be pay for treatments whose quality leaves a lot to be desired in many cases.
This is where the concept of personalized healthcare steps in.

What is personalized healthcare?
Personalized healthcare (PHC) is about fitting treatment to patients to obtain better clinical outcomes. It is based on the concept that the treatment will be selected based on patient characteristics that become known through molecular diagnostic tests.
PHC recognizes that we are all individuals and that the ‘one-size- fits-all’ approach is not effective. While a drug can behighly effective for one patient, the same drug might not show the desired results when given to a second patient with the same diagnosis and even be harmful in a third one.
Based on the knowledge of disease biology, the mechanisms of actions of the drugs and the biological differences between

patients as well as the characteristics of their disease, we are now able to tailor treatments and diagnostic tests to the needs of specific patient populations. It is a treatment tailored to specific needs of individual groups with shared features (eg., genetic characteristics), who can be grouped together in such a way that treatments can be optimally tailored to their needs. The approach of PHC is to use new molecular insights and molecular diagnostic tests to better tailor medicine and better manage disease.

Potential of PHC

Conventional medicines have traditionally been prescribed on a 'one size-fits-all' 'trial-and-error' basis, that is effective about half the time. This approach results in a large number of adverse drug reactions and misdiagnoses—which are in part responsible for approximately 200,000 deaths every year in the US alone.

Today, response rates to treatments vary from 20-75 percent, depending on the drug and the disease. For that reason, patients and physicians are demanding better care and safer and more effective treatment.

A century ago, blood cancers were known simply as 'disease of the blood'. Today, cancers of the blood have beenseparated into 90 distinct leukemias and lymphomas, each with its own distinct therapy.

Oncology

Breast Cancer: One of the greatest advancement in the treatment of breast cancer is the drug, Herceptin, (trastuzumab) which targets HER2 positive breast cancer, a type of breast cancer that is known to be more aggressive. However, we know that not every patient responds to this treatment.Approximately 25 percent of breast cancer patients have HER2 gene over-expression. By measuring the presence of the growth factor, HER2, in breast cancer through a specific HER2 test can determine the HER2 positive beast cancer patients who will respond to Herceptin, therewith improving outcomes and reducing costs by treating only those patients who benefit.

Colorectal Cancer: An excellent example of personalized healthcare at work is the KRAS mutation test.This test helps direct treatment for patients afflicted with metastatic colorectal cancer. Recently, scientists have developed more targeted therapies for colorectal cancer that look at limiting the growth of the cancerous cells. One such therapy is the epidermal growth factor receptor (EGFR) inhibitor (or anti-EGFR therapy), which prevents growth signals from entering the cells, thus stunting the growth of the tumor. Patients with a mutated KRAS gene (35 percent-45 percent of metastatic colorectal cancer patients) are unlikely to respond to EGFR inhibitors. With the TheraScreen KRAS mutation test, both doctors and patients will have a better idea on which treatment option to employ for greater effectiveness.

Lung Cancer: The TheraScreen EGFR 29 Test designed to enable detection of 29 of the most common somatic mutations in the EGFR gene and detects mutations not visible by sequencing. Recent studies in non-small cell lung cancer (NSCLC) have shown that some patients carry somatic mutations in the EGFR gene. These mutations may correlate with responsiveness to the EGFR tyrosine kinase inhibitors, a targeted therapy for NSCLC.

Virology

HIV: The way in which HIV patients regularly test their viral load is one of the earlier examples of personalized healthcare. A patient will have their viral load tested (along with a CD4 cell count) when they are first diagnosed with HIV – this acts as a baseline. They are then tested again two-six weeks after they begin their treatment to evaluate whether therapy is effective.

Subsequent tests are carried out every three to four months to monitor long-term therapy to ensure the patient has not developed a drug resistance. The advent of tests has helped HIV turn from being an acute short term disease, to a chronic disease.

HCV: Hepatitis is a viral infection that can go undetected in the body for years. Left untreated, it can lead to cirrhosis, liver failure and cancer. Detection and treatment are essential in the early stages when the likelihood of cure is relatively high. Tests that diagnose and monitor the virus in the blood and treatment with drug, Pegasys, have helped many of the people who have been infected. However, not all patients respond equally to this treatment. A HCV viral load test measures early response to therapy with drugs such as Pegasys, while a test that identifies Hepatitis C virus subtype provides information that helps to determine the correct duration of treatment with such medicines.

A shorter treatment duration with Pegasys/Copegus will provide patients with full benefits of therapy while reducing unnecessary drug exposure. The four-month treatment course will be for patients with particular strains of chronic Hepatitis C (genotype 2 or 3) who have low virus levels before starting treatment, and who show a rapid virological response by clearing the virus from the blood within the first four weeks of treatment. This is a new treatment concept in Hepatitis C, which seeks to customize regimens for patients based on how well they respond to treatment.

Metabolism

Diabetes: Diagnostics provides blood glucose tests to tailor insulin treatment to patients' needs. This is one of the first usesof personalized healthcare in modern medicine.

Osteoporosis: A broad range of tests are made available to assess bone integrity and to monitor the effects of anti-resorptive therapy with drugs such as Bonviva/Boniva. They show response much earlier than bone mineral density. Further simple

causes, such as Vitamin D deficiency is common in 60–70 percent of the Indian population.

Drug Metabolism

Now there is a pharmacogenetic test to analyze variations in two genes that play a major role in the metabolism of many widely prescribed drugs. This is the world's first commercial pharmacogenetic product for predicting individual drug response that implements gene chip technology. Examples include drugs such as Warfarin.

Transplantation

Mycophenolate mofetil is an immunosuppressant to prevent the body from rejecting a kidney, liver or heart transplant. The key metabolite is mycophenolic acid (MPA). An immunochemistry-based test measuring MPA, guides optimal patient dosing. This enables doctors to accurately tailor these dosages and to safely lower dosages of more toxic agents, thus further improving the outcome for patients.

Medical science continues to achieve rapid significant advances in treating patients. Understanding how patients aredifferent and respond differently to a medicine is fundamental to learning how to treat disease at the right time and with the right medicine.