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Will Diagnostics Return to Its Roots?

Diagnostic tests originated at patients' bedsides more than 3,000 years ago. However, over the past 200 years, diagnostics moved into laboratories as the tests became more complex. Now further technological advances are bringing these tests out of the laboratory and back to a near-patient environment. This change in procedure will save both lives and money.

Know Faster, Act Faster

Use of diagnostic tests principally falls into three categories. The first is long-term monitoring of chronic diseases (e.g., measuring glucose levels to control diabetes). The second is routine screening of a population for a particular condition; this can either provide a definitive diagnosis or indicate whether further, more expensive testing is advisable. The third is to provide definitive diagnoses when doctors believe that symptoms indicate a particular disease. A move from central laboratories toward point-of-care (PoC) testing will enable more diagnostic tests to shift from providing a diagnosis to providing routine screening, saving lives and money by catching diseases earlier.

Straddling the second and third categories falls the emerging field of *theranostics*, also known as *personalized medicine*. This is the use of a diagnostic test, usually based on a particular gene expression, to determine the likelihood that a patient will respond favorably to a particular medication, or to determine a person's predisposition to developing a particular condition. Theranostics is a newly emerging field, so it may be too early to consider in detail the benefits of a PoC setting over laboratory tests. However, it is intuitively clear that there could be advantages in PoC theranostics in emergency rooms or for mass population screening.

From Symptoms to Savings: Money and Lives

One example of a disease for which suitable PoC screening could save lives and money is lung cancer. Initial symptoms, such as fatigue and cough, are unspectacular and unlikely to lead a doctor immediately to the conclusion of cancer. At present, diagnosis is achieved through complicated procedures such as bronchoscopies, X-rays, and tomography scans. Such tests are not only distressing to patients but costly, and therefore are not routinely carried out. New tests are being developed that can detect tumor cells in mucus. They could provide the starting point for an inexpensive, doctor-based test that could be conducted as part of routine screening. Even if such a test were capable only of signaling a definitive "no" or a "move on to X-rays," this would still save lives.

Early detection of lung cancer offers the possibility of one-off surgery with a follow-up course of chemotherapy potentially leading to remission. Survival statistics for non–small-cell lung cancer caught at this early stage are as good as 80% (*Survival* in this case is defined as living for five years after diagnosis). However, because of current difficulties in diagnosing this type of cancer, most diagnoses occur when it is at an advanced stage, and survival rates drop to below 10%. Surgery is not an option for these patients, and treatment regimes consist of ongoing chemotherapy, radiotherapy, and potentially new drug treatments such as Tarceva, which alone can cost up to $60,000 a year.

The Future: Simple, Clear, and Inexpensive

Moving diagnostics in a PoC direction can be successfully achieved only through an integrated multidisciplinary approach. Taking the testing out of laboratories and putting it into the hands of unskilled users, for routine or long-term use, imposes very different requirements on these devices. They include ease of use, clarity of result, and a low cost per test.

For low-cost manufacturing, diagnostics companies face a significant challenge. Given their history, many such companies are primarily experienced in producing relatively small numbers of complicated laboratory test equipment for trained, skilled users. Moving diagnostics toward the PoC will increase production volumes, mandating the use of high-volume manufacturing and assembly techniques.

A number of diagnostic products have been successfully brought into the mass market, including glucose monitors and pregnancy tests. The most popular glucose meters currently sell in volumes of ~50 million per year. Manufacturers of these instruments leverage knowledge from traditionally high-volume sectors such as consumer electronics and the automotive industry.

Although diagnostics companies need to make fundamental changes in the way they design products, their core competency — analyte recognition chemistry — remains at the heart of every product. There is no point in developing a test that produces ambiguous results. Specificity of the signaling reagent is a vital step in producing a clear answer. This must be combined with suitable detection technologies (e.g., optical detection) as well as sophisticated signal processing techniques. Those methods will increase in importance as the concept of point-of-care diagnostics grows in scope. Each device will have to provide a self-calibrated interpretation of the optical signal for comparatively unskilled users.

The next few years promise to be pivotal in the growth of PoC technology, returning the diagnostics industry to its roots in a near-patient environment. PoC diagnostics could improve the quality of life for millions of people. If this new generation of products is to provide the tools doctors need to bring about a step-change in diagnostic methods, then the industry will need to embrace new principles in design and manufacturing. Otherwise, industry runs the risk of being left behind.

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