In vitro diagnostics in the next 5 years - A personal look to the future

by Doris-Ann Williams

Having been invited to write on the future for *in vitro* diagnostic testing to commemorate the 25th Anniversary of Clinical Laboratory International, I am at a loss - could we really have anticipated the changes and advances we have seen in the last 25 years? I still remember when it took a week to run a routine radioimmunoassay from set-up to reporting the results with all the incumbent overnight incubations, not to mention plotting the standard curve by hand and reading each result from it individually. These same results can now be obtained within minutes on automated analysers!
Without the use of a crystal ball, I have tried to capture my own views and ideas for the future. Clearly there are many areas involving diagnostics which will be affected: the clinical laboratory, near patient testing and self testing. This does not take into account the undoubted effect pharmacogenomics and genetics will have on our healthcare in the future.

In secondary care within hospitals, the clinical laboratory has already shown signs of evolution to full automation where the requirement for human intervention will shift from biomedical scientists to support engineers for the instrumentation. High-tech clinical lab equipment now allows a barcode labelled whole blood sample to be automatically spun down and aliquotted before different portions of the sample are directed to the appropriate testing instruments for the required analyses. The results are then collated and reported via the laboratory computer system. The possibility for samples to have all information and test requirements spoken into a barcode labelling device so that each sample is coded when the sample is taken is only a small step further, and already many hospitals have samples whizzing through from the wards to the Pathology department by pneumatic tube delivery systems. How long will it be before the new monitor screens being made available now to individual bedsides within hospitals can also be used by attending medical staff to download and upload patient information including requests for results directly from the laboratory?

Near patient testing, or point-of-care testing (POCT) has been slower to kick in than many people would have predicted 5 years ago, but is now gathering momentum rapidly in both secondary care and primary care settings. POCT in secondary care is already available in accident & emergency units, on general wards, out-patient clinics and in operating theatres. For example, tests can now be run during thyroid surgery to ensure the right amount of thyroid tissue from an overactive gland is removed, thus eliminating the need for any further surgical intervention. As technology enables further miniaturisation of instrumentation, combined with ease of use, the number of applications for POCT within a hospital setting will increase dramatically. There will always be issues of training, maintenance and quality control to take into account, but these are already being addressed and I am confident they can be overcome.

The increased use of POCT in primary care will improve the delivery of healthcare by increasing the speed of results and therefore diagnosis, enabling treatment for many conditions to begin more quickly. It will also reduce the drain on resource at secondary care level, saving money for healthcare providers. Less time spent at outpatient clinics will benefit the patient, or should I say consumer. Many tests are already available in simple cassette format with easy to interpret colour change reactions to show the results, such as the test differentiating between fungal or bacterial vaginitis. By identifying the causative organism on the first visit, the patient can receive the right treatment immediately. Thus, the indirect costs of follow-up visits are avoided, with the added bonus that the patient does not suffer the symptoms of the infection any longer than necessary. These sorts of tests could be performed by anyone in the primary care arena from doctors to nurses to pharmacists.

Many of the POCT's which could be performed in primary care could equally be performed by individuals upon themselves or family members. In the case of blood glucose monitoring for diabetics and, more recently, monitoring anti-coagulation therapy, this is already being done. The public are already accustomed to pregnancy testing kits and these have been joined on the pharmacy shelves by other test kits such as ovulation predictors and those for cholesterol measurement. Led by consumer demand the number of tests will increase and, as long as quality is maintained and explicit instructions for use provided, these could augment the healthcare professionals by helping patients to make informed decisions for minor conditions - possibly after consultation with a pharmacist - on whether a medical appointment is required to obtain further advice and treatment. An example of this is a test to differentiate between a sore throat caused by a viral or bacterial infection. Legislation in Europe, which will come into force from December 2003, will ensure all test kits provided in OTC have been manufactured reliably and produce consistent results. Government bodies will monitor performance and ensure any product failures are investigated.

Finally, and here my imagination could really run riot, we have the areas of genetics and pharmacogenomics. It must be sensible to assume that the pharmaceutical industry will take the example of the drug Herceptin, currently only licensed for use in the USA when used in combination with a diagnostic test, to ensure many new drugs can be targeted to specific patients and/or used to monitor treatment of the patient by that drug. The increased knowledge of an individual's genetic make-up will enable drug therapy to be tailored to best suit that person's individual characteristics. Diagnostics will also play a major role in the development of novel pharmaceuticals and reduce the time required in bringing these to market, which should significantly reduce the final cost. Perhaps genetic testing will enable each child to have any pre-disposition to disease and illness mapped at birth, preventing or delaying onset of disease. Gene therapy may ensure congenital defects such as cystic fibrosis can be treated. However, the whole topic of gene tests and genetic testing is already raising contentious moral and ethical issues of how far we can go when interfering with nature, both in science and as human beings.

In summary, I am sure that the years to come will see healthcare progressing as rapidly as it has in the past 25 years. It is essential that the value of IVD diagnostics is seen by healthcare providers so that there is investment to ensure that any technology developed can be implemented to the advantage of both the system and the individual.

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