Editorials

Emerging diagnostic technologies in primary care:

what's on the horizon?

Apart from computers sitting in consulting rooms, most GPs' desks and doctor's bags include an array of fairly old-fashioned medical equipment such as stethoscopes, auroscopes, and peak flow meters. For instance, the Wright Peak Flow meter was first introduced in the 1970s, and it seems many of the technological advances of the 21st century have largely bypassed diagnostic testing in general practice.

GPs are often reminded of this after patients have been referred to hospital, where within a very short period of time, they receive numerous blood tests, imaging investigations, and rapid pathology. But GPs do have good access to almost all of the same blood tests that are available to hospital settings, indeed the numbers of blood tests performed in general practice has increased dramatically in recent years. Much of this increase is driven by guidelines to screen more patients and monitor them more frequently,[1] and additional factors include diagnostic uncertainty, patient anxiety, and litigation, among others.

This is not to downplay the key role that history and examination plays in directing further clinical assessment, but many symptoms and signs are insufficient to rule in or rule out particular diagnoses, or to monitor patients with chronic diseases.

Technological advances in diagnostic tests that are found in hospitals are now poised to appear in primary care. Many of these advances have occurred because of the speed, size and range of devices that can provide accurate measurements of a wide range of biochemical, microbiological, and haematological parameters.

Some technologies have already been realised in primary care practice. Glucometers transformed the speed and ease of obtaining accurate blood glucose levels, and urine dipsticks removed the need for microscopy in many patients. Advances in electronics have also made in-roads into general practice, with cheap and generally accurate blood pressure devices now widely available both in the practice and at home.[2]

Similarly point-of-care tests have now been developed for many common blood tests, such as lipid profiles, HbA1c, C-reactive protein, INR, and urine albumin-creatinine ratio.[3]

The medical technology industry is a major part of the UK economy with over 3000 companies with a combined turnover of £15 billion.[4] The UK is at present the 5th largest market in Europe for *in vitro* diagnostics. There are currently vast arrays of point-of-care tests and technologies on the market and new ones are being developed all the time. Manufacturers of diagnostic tests expect a steady growth in the adoption of point-of-care tests into primary care worldwide. With GPs and primary care commissioning groups taking a front seat in current NHS changes, it is timely to address the issue of which new point-of-care tests should be used, and why. Pressures are increasing to perform more tests, more rapidly, reducing referrals, keeping patients informed, and reducing the risk of diagnostic errors. Moreover, reductions in health service funding demand balancing these with improved cost effectiveness.

Evaluating the evidence behind new diagnostic tests is important to identify those that provide the best clinical and economic value for primary care. Since 2009, we have used a 'Horizon Scanning' approach to identify new and emerging diagnostic technologies relevant to primary care. Using intelligence drawn from published research and the diagnostics industry, we use a systematic approach to review the evidence behind new diagnostic technologies. These reports are independent; the Horizon Scanning is funded by the National Institute of Health Research, rather than industry, which allows unbiased assessments. The reports summarise the available research evidence, including technical accuracy (that is, the extent to which the test measures what it says it measures), clinical utility (that is, what difference the test result provides to patient outcomes), and cost-effectiveness. All of these are freely available at www.madox.org, and the *BJGP* publishes the most relevant ones to general practice in the Clinical Intelligence section. In a forthcoming issue of the *BJGP*, for example, we will review the evidence behind point-of-care testing for coeliac disease.

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Box 1. Key drivers of diagnostic technology innovation and adoption[5]

- Rapid and significant advances in test technologies and related bioinformatics and connectivity capabilities.
- Increases in numbers of tests performed.
- Pressure from patients, carers and clinicians for more accurate and rapid diagnoses and treatment selection.

Why is it necessary to use a structured assessment of the evidence behind new diagnostic tests? First, it is important to remember the 'bar' for approval of a new diagnostic test is not particularly high. Obtaining CE marking is relatively straightforward, and for diagnostic tests typically involves demonstrating technical accuracy in a laboratory setting. By the time a device is marketed in the UK, there may be limited evidence of evaluation in clinical populations, particularly primary care.

However, GPs not only need evidence that a test has been examined in a primary care setting, but also that the test has been shown to make a difference to patient outcomes. Some technologies have been adopted widely, at substantial cost, before research has later shown they are not as useful in all patients or cost effective as initially thought (for example, glucometers). Once new tests are introduced, and widely disseminated, it is much more difficult to withdraw them. So, finding comparative evidence that a new test actually provides better care for patients and is cost effective is essential.

For some of the 28 technologies we have looked at so far, we have found good evidence that they can provide better clinical outcomes than existing tests. For example, INR self-monitoring to adjust warfarin reduces the rate of thromboembolic events, and point-of-care testing for D-dimer in conjunction with the Wells criteria can rule out lower leg deep vein thrombosis in about half of patients presenting with suspected deep vein thrombosis in primary care. However, for other tests which we

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would anticipate strong demand in primary care (for example, point of-care-tests for lipids and HbA1c, pulse oximeters, non-invasive bilirubin meters), there is often little evidence of clinical utility in primary care. For most of the tests we have identified there is still a relative lack of appreciation of some of the regulatory and laboratory accreditation hurdles that need to be overcome before tests could be widely adopted in primary care.

There also seems to be a mismatch between the tests that are produced and what GPs and other practice staff (such as practice nurses, district nurses, and midwives) may actually want. It is not always clear whether the diagnostic test industry has thought carefully enough about which tests GPs would use most often, and which tests to prioritise for research and development.

However, there is now growing collaboration between the diagnostic test industry, the NICE Diagnostics Assessment Programme, the Technology Strategy Board, and primary care, which will hopefully improve communication between industry and front-line clinicians to inform prioritisation of research (see Box 1).[5] In order to further improve understanding as to which point-of-care tests GPs and commissioners should prioritise for adoption, we encourage *BJGP* readers to contact us with their views and suggestions for priority point-of-care tests and devices for primary care.

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