

A pragmatic approach to point-of-care testing

Ian Cowie has been involved with point-of-care testing for over 25 years. Here, he gives his views on how he believes point-of-care testing will continue to develop over the years ahead.

“The real benefits of POCT include the identification of conditions that can be treated at an earlier stage than would otherwise have been the case

guidelines will cover all POCT settings, which can include prisons, cruise liners, pharmacies and GP practices.

Quality counts

Over the years, I have learned that perhaps the most important issue affecting POCT results is the ability to obtain good-quality samples for testing. Even laboratories with full accreditation, the best available equipment, good-quality control procedures and the best available analysts will not obtain the correct results with poor-quality samples.

Fig 1. Abaxis Piccolo Xpress analyser, a true point-of-care system.



During the 1980s, the term ‘decentralised testing’ was used and this process was expected to have the benefit of producing rapid results in the presence of the patient, and could, in turn, help lead to earlier diagnosis and treatment compared to traditional diagnostic procedures. Today, the basic aim of point-of-care testing (POCT) is very much the same, but the development of POCT is being hindered for a number of reasons.

During the 1980s and early 1990s, the name evolved to near-patient testing and we saw the development of many new easy-to-use POCT technologies including the HemoCue haemoglobin analyser, blood gas analysers such as i-Stat and IRMA, blood glucose meters, CRP meters, HbA1c analysers, cholesterol meters, pregnancy tests, INR measuring devices, and so on. This technological advancement contributed to a rise in POCT but also contributed to some poor-quality results and in some cases results which could have led to misdiagnosis.

Over the next few years the name evolved to point-of-care testing and we also saw the development of several different sets of POCT guidelines from various organisations, which were designed to protect the patient.

So, when we examine the situation today, together with some of the more recent technological advancements, it would appear that we are approaching a possible divergence on POCT policy. On the one hand we have calls for complete regulation, but this could be very

difficult to manage due to the diversity of POCT sites. On the other hand we could embrace the continuing development of true POCT technologies that are easy to use and which are designed to eliminate poor-quality data.

So, how should we be approaching this POCT issue? The various current reviews (ie the Carter and Darzi reports) appear to be paving the way for significant future changes in diagnostic testing procedures. Current proposals should be developed and expanded further and should be treated as a new opportunity by all, particularly in the area of POCT.

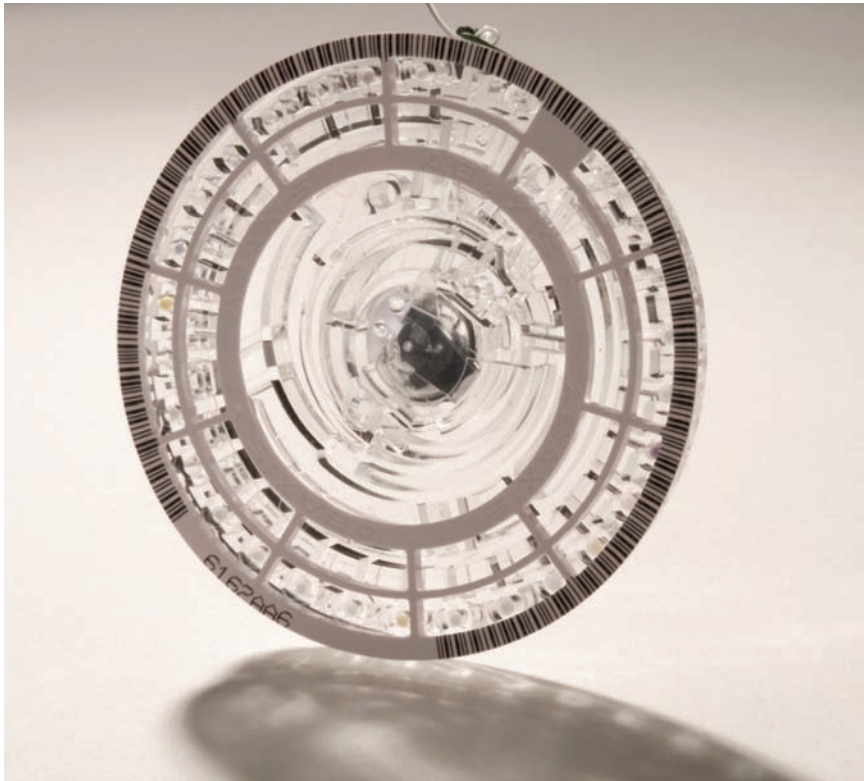
A matter of principle

I mentioned that the development of POCT was being hindered for a number of reasons and I believe that one of these reasons is the current POCT guidelines. I am not saying that POCT guidelines are not required, but why should we try to impose laboratory principles on the POCT setting? In many situations, the POCT setting is not a laboratory, and different POCT settings have different requirements. In fact, some new technologies such as the Abaxis Piccolo biochemistry analyser (Fig 1) embrace many of the quality requirements in the POCT guidelines. This analyser has an onboard ‘intelligent quality control’ system that includes internal calibration software. It also quantifies levels of haemolysis, lipaemia and icterus and suppresses results when these interferents’ limits are exceeded.

So, before standard POCT guidelines are approved and published, all stakeholders should be included in discussions involving the practicalities of the POCT setting. Such stakeholders should include users of POCT products, laboratory advisors, budget-holders and the manufacturers of the products involved. It is also unlikely that one set of

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Fig 2. The Abaxis Piccolo reagent disc can be used to measure up to 13 different parameters and gives good-quality results in approximately 12 minutes from whole blood samples.



Towards the end of last year, a television programme followed a group of volunteers who were asked to carry out a range of diagnostic tests purchased from high-street pharmacies. Each volunteer was asked to carry out all of the tests, which involved taking several fingerprick blood samples.

Anyone with knowledge of POCT might see right away that the results obtained would likely be of little value and possibly also give bad press to the manufacturers of the tests, and this proved to be the case. However, no one, not even the manufacturers' representatives asked to defend their products, discussed the importance of obtaining good-quality samples.

It was stated later in the programme that this was not a properly planned and executed scientific study, which makes me question why this part of the programme was even shown in the first place.

Clear instructions

I believe that the second most important part of POCT is user training. Those without analytical skills are likely to get the wrong results, even with what we might perceive as the simplest of tests. For example, when a multi-pad urine test strip was used, I had the recent experience of seeing a GP reading the test strip about 15 minutes after removing it from the urine sample. He said he was just allowing it "to cook"! Such simple procedures may not require the operator to be trained, but are we really surprised that individuals are not carrying out simple procedures properly when we look at the product instructions insert from many similar products?

Instructions can extend to several thousand words in small print on two or three sides of A4 page size, try to cover almost every eventuality and are designed mainly for the purpose of avoiding possible litigation. What is really required in addition to these A4 pages for such products is a small card providing no more than five lines of clear, step-by-step instructions on how to carry out the test.

Workable guidelines

This brings us to the range of POCT guidelines that have been produced, mainly by laboratory workers. I believe strongly that those writing POCT guidelines should work with all stakeholders, including the manufacturers of the tests, so that workable guidelines for users of POCT products can be achieved. The guidelines should consider a programme such as the Clinical Laboratory Improvement Amendments (CLIA) system used in the USA. This system is designed to ensure the accuracy, reliability and timeliness of patient test results, irrespective of where the test is carried out. Waived tests are listed and these include such tests as urine dipsticks and faecal occult blood (FOB) tests, as

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these are regarded as simple procedures for which the possibility of erroneous results is negligible.

Under the current system, this waiver may be granted if a test meets statutory requirements (eg three steps or less) if the manufacturer provides scientifically valid data verifying that the waiver criteria have been met. This should divide tests into two categories: those that need to comply with full POCT guidelines and those that may be exempt from most of the guidelines. Such an approach could help with future regulation.

Several testing systems that are technically quite complex (eg glucose analysers [not meters]) are being used in the POCT setting. Users of these products really need to comply with appropriate POCT guidelines and ensure that they have been trained adequately and understand the processes involved. This should include record-keeping, product maintenance and quality control procedures. Simpler tests (eg rapid tests) are unlikely to require such a degree of control and should fall into a subcategory within the POCT guidelines.

Quality control

Running quality control (QC) samples in the POCT setting has always been a subject for debate. In the laboratory, procedures are well documented and compliance is high, but outside the laboratory the running of QC samples may be limited and in some situations non-existent. Quality control is important to ensure a testing system is producing accurate results. However, by applying laboratory criteria in POCT guidelines, are we trying to enforce a frequency of testing that may be inappropriate and counter-productive, particularly when the technology may only require a very small amount of QC testing? This issue needs to be discussed fully with all concerned so that a more practical approach can lead to a quality service.

Some newer technologies have been designed to overcome operator variability, eliminate calibration steps and reduce but not eliminate the requirement for QC samples. An example is the Abaxis Piccolo, which was developed originally by NASA for use in the Space Shuttle. This analyser can produce a relatively wide range of biochemistry test results (Fig 2), and accurate results can be obtained easily by non-technical or -scientific staff after a short training period. Of course, a good-quality blood sample is essential.

Fast food to rapid results

We have seen critical reports where a 'burger van' in a car park has been used to offer a POCT testing service. So what! Have we the evidence to show that the results produced were incorrect? Should the testing system used perhaps have been 'CLIA' waived? Are laboratory-based guidelines really applicable to this testing service?

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Such alarmist stories should be avoided. There are various mobile testing units currently being used which are staffed by appropriately qualified personnel and which are following written procedures. So, why don't we get real evidence of any poor analytical practice so that we can help the operators offer an improved service? We should not be resisting entrepreneurs but working with them to bring an understanding of testing to the patient, particularly with the emergence of laboratory centralisation.

There are proponents of over-the-counter (OTC) tests as well as POCT diagnostic testing and screening services because the real benefits of such testing can give patients an early indication of conditions that can be treated at an earlier stage than would otherwise have been the case. Thus, POCT should be encouraged and improved, not resisted.

Point-of-care testing is not just about carrying out tests, it is also for the benefit of the patient. Some patients have long distances to travel to their local hospital to give a blood sample. They need to find a parking space when they arrive – often difficult – and there are also parking charges. They can be kept waiting for long periods of time to see a doctor or phlebotomist and they have probably had to take a day off work, too. So, let's start thinking of the benefits to the patient when considering POCT services. It is encouraging to note, however, that phlebotomists have already been sited at some Asda stores and at pharmacies. Perhaps these services could be extended to offer a limited analytical testing service (eg INR and cholesterol testing).

Reinventing the wheel

The cost of setting up POCT is often cited as a major reason for not proceeding with the service. I often hear that POCT costs are prohibitive when compared with laboratory tests. This may be true for some testing systems,

True costing analysis can often demonstrate the real advantage of POCT



Fig 3. HemoCue haemoglobin analyser.

All stakeholders should be included in discussions involving the practicalities of the point-of-care testing setting

particularly if POCT is carried out in a clinic in the same hospital as the laboratory, but how do we cost convenience and efficiency for both healthcare workers and for the patient? Where POCT is not undertaken in the vicinity of the laboratory it may prove to be cheaper, but due to the NHS budgetary system this is almost impossible to calculate, particularly when different process costs are spread over different departmental budgets. However, in the private healthcare sector, a true costing analysis is likely to be achieved more easily and this can often demonstrate the real overall cost advantage of POCT.

Why does almost everyone need to carry out a full evaluation for a new testing system? The manufacturers' specifications for products are available and the products will be CE marked and have FDA approval. When a suitable product with the required specification is selected, why is a short demonstration or trial not sufficient before deciding on which product to select? Do we always have to reinvent the wheel?

From time to time I hear complaints about specific pieces of POCT equipment. One such instance was about the HemoCue haemoglobin analyser (Fig 3) and I saw that the results obtained were somewhat inaccurate. However, I have had experience of using this HemoCue analyser and found it to be one of the best POCT systems available. From the results, I could only conclude that either sample quality was poor or that the operator may not have received adequate training, which reinforces the importance of these two points.

The future in question

Generally, high-street pharmacists are the most accessible healthcare professionals for the general public and on numerous occasions have tried to offer a POCT service for a variety of tests. This has not proved particularly successful for various reasons. The length of time taken to carry out a test and the subsequent discussion with the patient is a disadvantage, as is the fact that patients have to pay for tests that would be free if carried out by their GP. Currently, this has given very little benefit to the pharmacist and, without suitable funding, POCT in the pharmacy is unlikely to develop further.

Various questions will need to be addressed if POCT is to develop properly in the future. Where is POCT being carried out? What products should be included for processing under POCT guidelines? What products should be CLIA-waived? Who should be responsible for carrying out training? How can we ensure that quality samples are taken? How should a QC sample programme be set up without carrying out unnecessary testing? When are we going to involve all stakeholders? Are manufacturers going to include a simple instructions card? Do POCT systems need full connectivity? When are we going to stop trying to impose laboratory practices in non-laboratory settings?

Governance and regulation

In conclusion, we should consider a programme of clinical governance and appropriate regulation for POCT, but we have a lot of work to do first. We need to embrace the true benefits of POCT for both the analyst and the patient and also work to minimise any potential dangers. We need to recognise that new technologies are being developed constantly, some of which are true POCT systems and might fall into the CLIA-waiver category.

We should realise that many of the current POCT guidelines need to be reworked to include the specific needs of the POCT site, and ensure that all stakeholders are included in their development. We have a major opportunity ahead of us and a lot of work to do, but I believe that by all stakeholders working together we can develop a POCT system that is truly functional and a benefit to everyone in the future. □

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