Leaders

Near patient testing: is it here to stay?

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Introduction

Near patient testing, or "point-of-care" testing as it is widely called, is difficult to define well. Clearly, it refers to testing which is not performed in a central hospital laboratory but is performed close to the patient. A broad definition would include that testing which is performed in decentralised units such as a critical care unit, an emergency room or an operating room. A narrow definition would only include those tests which are done physically next to the patient or by the patients themselves. This article will mostly concentrate on the narrow definition. The types of testing will be defined and then the advantages and disadvantages will be discussed.

One of the first commercially available examples of near patient testing was the urine glucose dipstick, which was introduced several decades ago. This allowed a health care worker on the floor to test for the presence of glucose in a patient's urine. This was followed later by a dipstick which allowed testing for glucose, protein, bilirubin, haemoglobin, etc., in a patient's urine. The specific blood glucose test strip also allows diabetic patients to monitor their own glucose values at home (discussed later in this article).

Home testing

The shelves of supermarkets and chemist's shops are now stocked with do-it-yourself home test kits. These include tests for fertility, pregnancy, occult blood, glucose, and cholesterol, to name but a few. There is also an effort to make home testing for HIV-1 infection available. In the United States, the Food and Drug Administration (FDA) is studying whether to license diagnostic kits that require the patient to be the phlebotomist in testing for HIV antibodies. These kits would involve the person pricking their finger with a lancet provided with the kit. They would place the blood on filter paper and send it to a predesignated laboratory. The results would be given to the client over the telephone after punching in a unique identifying code number. If the result was positive, it would be given to the patient by a counsellor after the confirmatory test had been done. The whole process would be entirely anonymous. This approach is clearly less worrisome than having people actually doing the testing themselves without the benefit of medical advice. It

is also clear that many more people would be identified as HIV positive as in the United States; about 33% of people infected with HIV are not tested until the signs and symptoms of the acquired immunodeficiency syndrome (AIDS) appear. There is concern, however, that adolescents using such kits may not follow telephone advice, and HIV positive subjects would be a continued threat to society. This whole arena is clearly very controversial. There is an excellent article on this subject by Bayer and Stryker in the *New England Journal of Medicine*.¹

Another home-sampling kit called Drug Alert (Barringer Consumer Products Inc., New Providence, New Jersey, USA) has just been made available. The kits allow parents to gather particulate matter from clothes, desks or other belongings of adolescents to detect the presence of drugs of abuse. The swipe or collection device is used to wipe surfaces. The parent then seals the swipe in a plastic bag and sends it to Barringer Laboratories for analysis. The samples are tested by ion mobility spectrometry. One problem with this approach is that it does not definitely show ingestion or injection of a drug of abuse. With the traditional urine testing, the presence of the drug in the person's body is actually identified. False positive results could occur from contamination by innocent contact or from objects such as money.

Home pregnancy testing has become a widespread business and this is how most women nowadays check to see whether they are pregnant. Although these tests are easy to carry out, there are still pitfalls that can occur due to misreading or misinterpreting instructions. Hicks and Iosefsohn² in a study using lay persons demonstrated that about 9.5-12% of home pregnancy test results were incorrect, even among well-motivated subjects.

The use of glucose meters for diabetics at home has become standard practice in the United States and many other countries. This article will not deal with the benefits of this, but suffice it to say that this approach offers a great deal of convenience to the patient. Those meters which allow the physician to be sure that the patient is actually doing the monitoring are clearly the best. It is critical that the patient is extremely well instructed in the use of glucose meters and that their competency is checked from time to time. A new profession that has

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sprung up in recent years is that of the diabetic educator. This person spends much time teaching patients the correct use of glucose meters and when it is necessary to contact the physician.

Bedside testing

Technology using "dry testing" or advanced microchips has led to extremely precise and accurate results and great stability of equipment. This has hastened the introduction of bedside testing.

Bedside monitoring of whole blood glucose has been used for many years and yet it is still difficult to control the quality of this testing in the hospital setting, a problem which has been the subject of many recent papers.³⁻⁵ A consensus conference⁶ has recommended that a target for future glucose monitors should be no more than a 5% analytical error. Few, if any, current monitors can meet this standard.³ It has been shown⁴ that there is a higher variance of precision when multiple operators, controls and test strips are used. It was also noted that results for the same sample could vary by 33%. It is very important that each institution sets standards for acceptability of instrument performance and that evaluations should take place in the hands of those personnel who will be using them and not by laboratory personnel. Weiner⁶ points out the difficulty that there is a difference in the volume of red cells from one blood sample to another and that the results with some methods are affected by these differences. The question now arises as to whether biosensors for blood glucose will supplant the traditional approach.

A biosensor is an analytical device that uses a bioreceptor such as an enzyme, antibody, microorganism, etc., to recognise the analyte directly without the need for specimen processing. Recently, technology has advanced to the stage that electrochemical biosensors for glucose can perform reliable measurements in undiluted whole blood. However, some problems remain in that the concentrations of glucose measured are often about 7% higher than traditional measurements due to the water content of the sample in diluted methods.

Perhaps one of the most innovative and exciting approaches to "point-of-care" testing is a hand-held instrument somewhat similar in size to a telephone hand piece. (i-STAT Corp., Princeton, New Jersey, USA). It includes a central data system that can communicate test results to the laboratory or hospital information system, thereby giving easy access to the results for interpretation by the pathologist or clinical biochemist. Two drops of blood are introduced into a single-use disposable cartridge which is inserted into the portable analyser. The analyser makes electrical contact with the cartridge and recognises the tests to be run. A calibrant solution is automatically sent over the sensor for measurement. After calibration, the blood sample is automatically positioned over the biosensors. The electrical signals produced are measured by the analyser. It then calculates, displays and stores the results. All of this takes

Figure 1 Comparison of PCO₂ values using the i-STAT and Corning blood gas analysers.

Figure 2 Comparison of pH values using the i-STAT and Corning blood gas analysers.

90 seconds at the bedside. Different panels of tests are available in different cartridges. Available tests include sodium, potassium, chloride, ionised calcium, urea nitrogen, glucose, pH, pCO₂, haematocrit, bicarbonate*, total carbon dioxide*, base excess*, anion gap*, and haemoglobin* (* = calculated).

One of the concerns about using such a device has been cost. If one compares reagent tests, the cartridges are more expensive than other traditional main laboratory methods. However, in this era of restructuring and patient consumer satisfaction, it is possible to reduce the cost of this approach. Our approach is to have such testing done by staff nurses and respiratory therapists, and to reduce the number of technologists in the laboratory. Currently, we have five full time equivalents engaged in doing blood gases in order to cover three shifts, seven days a week, 365 days a year. The average, fully loaded cost (labour, manpower, reagents, etc.) of performing blood gases is £4.07 (\$6.13) per test, and this becomes £3.64 (\$5.46) per test with the hand-held device. This represents an annual saving in our hospital of about £33 000 (\$50 000). More importantly, the labour savings in the laboratories are worth over £133 000 (\$200 000) a year and I believe that the cartridge costs will decrease significantly as more systems come into use. Turnaround time is also greatly decreased with this approach. The quality of the blood gas results is excellent, as can be seen from figs 1 and 2.

We have recently introduced the Triage System (Biosite Diagnostics, San Diego, Cali-

fornia, USA) for testing for drugs of abuse, which is ideal for screening in the Accident and Emergency department. This panel for drugs of abuse uses a rapid multiple immunoassay system. All positive results are confirmed by gas chromatography/mass spectrometry and so far, we have had very few false negative results.

The issue of specimen handling is not of concern except to ensure that a good flow of blood is initiated and the first drop discarded before the blood is collected. This avoids contamination by tissue fluid. In all bedside testing devices, the blood is introduced immediately and, therefore, evaporation of the specimen is less of a problem than using traditional instrumentation.

In order to set up a good bedside testing programme in a hospital, it is essential to have a "point-of-care" testing coordinator (generally a well qualified medical technologist) who reports to a designated laboratory director. This coordinator is responsible for selecting the test methodologies and making sure they agree with the main laboratory results. They should set reference and critical values in conjunction with the director. They are responsible for quality control, proficiency testing, troubleshooting, in-service training, and competency evaluation. When establishing costs, these must include supplies, reagents, labour, quality control, calibration, proficiency testing materials, maintenance and service, instrument depreciation, and specimen collection. A team of involved individuals (stakeholders) is essential for optimal operation of a bedside testing programme. Ideally, this should consist of one of the laboratory directors (probably the clinical biochemist or a pathologist), the "point-of-care" coordinator, a nursing representative, an information systems specialist, an educator/trainer, and a clinician, and possibly someone

from medical records. The clinical biochemist or a pathologist would still be responsible for review and interpretation of results as well as suggesting any necessary further testing. Discussion and good communication with clinical colleagues is essential.

The clear advantages of bedside testing are that more rapid results can be obtained and, if the nurse or other health care worker currently on the floor does the testing, there are fewer people interacting with the patient. Well defined studies need to be done to see whether stabilisation of the patient and clinical outcomes improve and also whether length of stay decreases and in turn, health care costs decrease. The question of accuracy seems to be moot as many studies including our own have shown the quality of results with today's technology is excellent. Control by the central laboratory is important and can be realised by being networked with the laboratory information system.

It is my belief that "point-of-care" testing in the hospital is here to stay and that by the end of the next decade, the majority of routine or screening tests will be done in this way. This is because it provides convenience for both the patient and the physician. The hospital laboratory of the future could well be the focus for esoteric and sophisticated testing and all other testing would be done at the bedside or in the physician's office, off site.

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