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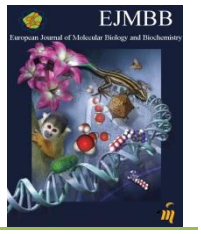

POINT OF CARE TESTING (POCT): A DIRECT INTERFACE OF THE LABORATORY AND THE PATIENT

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ABSTRACT
Point of care testing (POCT) offers a direct interface between the laboratory and the patient .The principle behind these tests is to generate a result quickly so that appropriate treatment can be implemented, leading to an improved clinical or economic outcome .POCT is usually performed by non-pathology health care professionals using devices ranging from a simple 'dip-stick' to highly sophisticated analytical instrumentation. POCT devices may include , Glucose meters, pregnancy strips /meters, Blood gas analysers, urine analysis, INR testing, Ketone meters, haemoglobin meters, HbA1c analysers, Drugs of abuse testing etc. Advancing technology has markedly expanded the potential for Point of Care Testing by increasing the range and reliability of devices and reducing the vulnerability to operator error. However, POCT carries additional risk and is generally more expensive than laboratory alternatives. It is therefore important to get the balance right and maximize the benefits that this exciting technology offers while ensuring that the quality of results and patient safety is not compromised.

INTRODUCTION

Historically, laboratory testing has been performed in a central laboratory by laboratorians. POCT is performed close to or at the patient's location-and often by non-laboratorians. This is clearly a different model from the historic central laboratory POCT tests are designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratories Classic example: bedside glucose testing in the hospital testing. The driving principle behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to be made.

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Common POCT includes

- Glucose
- Blood gas analysis/electrolytes
- Activated clotting time for high dose heparin
- Urine dipsticks, including pregnancy
- Occult blood
- Hemoglobin
- Rapid strep

The key objective of point of care testing is to generate a result quickly so that appropriate treatment can be implemented, leading to an improved clinical or economic outcome. The methods for measuring some biological compounds in blood and urine have become so robust and simple to use that measurements can be made away from the laboratory – by the patient's bedside, in the ward side room, at the OPD, at the Pharmacy or even in the home. Convenience and the desire to know results quickly, as well as expectation of commercial profit by the

manufacturers of the tests, have been the major stimuli for these developments. Experience has shown that motivated individuals, e.g. diabetic patients, frequently perform the tests as well as highly qualified professionals. The immediate availability of results at the point of care can enable the appropriate treatment to be instituted quickly and patients' fears can be allayed.

However, it is important to ensure that the limitations of any test and the significance of the results are appreciated by the tester to avoid inappropriate intervention or unnecessary anxiety.

Outside the laboratory

Table 1 shows what can be commonly measured in a blood sample outside the normal laboratory setting. The most common blood test outside the laboratory is the determination of glucose concentration, in a finger stab sample, at home or in the clinic. Diabetic patients who need to monitor their blood glucose on a regular basis can do so at home or at work using one of many commercially available pocket-sized instruments. There is a portable bench analyser. These analysers may be used to monitor various analytes in blood nd urine and are often used in outpatient clinics. Table 2 lists urine constituents that can be commonly measured away from the laboratory. Many are conveniently measured, semi-quantitatively, using test strips which are dipped briefly into a fresh urine sample. Any excess urine is removed, and the result assessed after a specified time by comparing a colour change with a code on the side of the test strip container. The information obtained from such tests is of variable value to the tester, whether patient or clinician. The tests commonly performed away from the laboratory can be categorized as follows:

A. Tests performed in medical or nursing settings. They clearly give valuable information and allow the practitioner to reassure the patient or family or initiate further investigations or treatment.

B. Tests performed in the home, or non-clinical setting. They can give valuable information when properly and appropriately used.

C. Alcohol tests. These are sometimes used to assess fitness to drive. In clinical practice alcohol measurements need to be carefully interpreted. In the Accident and Emergency setting, extreme caution must be taken before one can fully ascribe confusion in a patient with head injury to the effects of alcohol, a common complicating feature in such patients.

Common tests on blood performed away from the laboratory

Analyte Used when investigating

- Blood gases Acid–base status
- Glucose Diabetes mellitus
- Urea Renal disease
- Creatinine Renal disease
- Bilirubin Neonatal jaundice
- Therapeutic drugs Compliance or toxicity
- Salicylate Detection of poisoning
- Paracetamol Detection of poisoning
- Cholesterol Coronary heart disease risk
- Alcohol Fitness to drive/confusion, coma

Tests on urine performed away from the laboratory

Analyte Used when investigating

- Ketones Diabetic ketoacidosis
- Protein Renal disease
- Red cells/haemoglobin renal disease
- Bilirubin Liver disease and jaundice
- Urobilinogen Jaundice/haemolysis
- pH Renal tubular acidosis
- Glucose Diabetes mellitus
- Nitrites Urinary tract infection
- HCG Pregnancy test

MATERIALS AND METHODS

Methodology

It is a feature of many sideroom tests that their simplicity disguises the use of sophisticated methodology. One type of home pregnancy test method involves an elegant application of monoclonal antibody technology to detect the human chorionic gonadotrophin (HCG), which is produced by the developing embryo (Fig 4.2). The test is simple to carry out; a few drops of urine are placed in the sample window, and the result is shown within 5 minutes. The addition of the urine solubilizes a monoclonal antibody for HCG, which is covalently bound to tiny blue beads. A second monoclonal antibody specific for another region of the HCG molecule, is firmly attached in a line at the result window. If HCG is present in the sample it is bound by the first antibody, forming a blue bead–antibody–HCG complex. As the urine diffuses through the strip, any HCG present becomes bound at the second antibody site and this concentrates the blue bead complex in a line – a positive result. A third antibody recognizes the constant region of the first antibody and binds the excess, thus providing a control to show that sufficient urine had been added to the test strip,the most likely form of error

General problems

The obvious advantages in terms of time saving and convenience to both patient and clinician must be balanced by a number of possible problems in the use of these tests. They include:

Cost

Many of these tests are expensive alternatives to the traditional methods used in the laboratory. This additional expense must be justified, for example, on the basis of convenience or speed of obtaining the result

Analytical problems

Many problems under this heading will have little to do with the assay technology but will be due to operator errors. Tests designed for use outside the laboratory are robust but are by no means foolproof. Most operators will not be trained laboratory technicians but patients, nurses or clinicians. If an assay is to be performed well these individuals must be trained in its use. This may require the reading of a simple set of instructions (e.g. a home pregnancy test) or attending short training sessions (e.g. the ward-based blood gas analyser).

The most commonly encountered analytical errors arise because of failure to:

- calibrate an instrument
- clean an instrument
- use quality control materials
- store reagents or strips in appropriate conditions.

All of these problems can be readily overcome by following instructions carefully. Regular maintenance of the equipment may be necessary, and simple quality control checks should be performed. It should always be possible to arrange simple quality control cross checks with the main biochemistry laboratory.

Interpretive problems

Even when analytically correct results are obtained, there are other problems which must be overcome before the exercise can be considered a success. The general appropriateness of the test must be considered. If an assay is performed in an individual of inappropriate age, sex, or at the wrong time of day, or month, then the result may be clinically meaningless. Similarly, the nature of the sample collected for analysis should be considered when interpreting the result. Where the results seem at odds with the clinical situation, interference from contaminants (e.g. detergents in urine containers) should be considered as should cross reactivity of the assay with more than one analyte (e.g. haemoglobin and myoglobin).

Any biochemical assay takes all these potential problems into account. However,with extra-laboratory testing, correct interpretation of the result is no longer the laboratory's responsibility but that of the operator.

The future

There is no doubt that in the future, biochemical testing of patients at the point of care will become practical for many of the analytes currently measured in the laboratory. There is, however, likely to be much debate about costs and the clinical usefulness of such non laboratory- based analyses.

CASE HISTORY

At a village fete, a local charity group was fundraising by performing certain sideroom tests. An 11-year-old boy was found to have a blood glucose of 14.4 mmol/L. His family was concerned, and an hour later his cousin, a recently diagnosed diabetic, confirmed the hyperglycaemia with his home monitoring equipment, and found glycosuria +++.

Question What is the significance of these findings?

Answer: As is common in these circumstances, the boy had consumed a large amount of refined carbohydrate – two cans of soft drinks, a jam doughnut and in excess of 200 g of assorted sweets over the preceding 2 hours. Thus, it is to be expected that the blood glucose would be high and a diagnosis of diabetes mellitus should not be made. A follow-up fasting glucose would, however, be appropriate if there were persisting worries about the diagnosis in this case.

RESULTS

Clinical outcomes

The effect of point of care testing can be assessed in terms of the benefit to the diagnostic or treatment strategy and thus overall health outcome.[5] The box gives some examples of clinical outcomes. Any test will be beneficial only if appropriate action is taken on the result. Thus, the rate limiting step in reducing length of ospital stay may not be delivery of a test result, but acknowledgement of the result (communication, appreciation, and action few formal studies have linked the use of point of care testing to outcomes. In some situations the natural course of the disease or an acute clinical episode suggests that rapid provision of the test result would be beneficial—that is, there is evidence of outcome by association. Two such examples are tests to measure blood gas and electrolyte concentrations in patients in intensive care and to measure blood paracetamol concentrations in patients with paracetamol poisoning

Some examples of improved clinical outcomes from using point of care testing

Outcome Example

Faster decision making Chest pain, drug, Starting treatment earlier, Drug overdose, Improved adherence to treatment Diabetes, Reduced incidence of complications Diabetes, Quicker optimization of treatment, Anticoagulation, Reduced reoperation or readmission rate, Parathyroidectomy, Patient satisfaction fewer journeys, Ownership of disease.

STUDIES ON POCT ON DIFFERENT CLINICAL SETUPS

Self-testing

Evidence from the Diabetes Control and Complications Trial and United Kingdom Prospective Diabetes Study makes an irrefutable case for point of care testing, although it has been argued that there is too much testing similarly, routine monitoring of blood glucose concentrations in women with gestational diabetes to minimise the complications to mother and baby requires point of care testing. There is also evidence that knowledge of patients' glycated haemoglobin concentration at the time

of their consultation can improve glycaemic control, probably through improved education and therefore adherence to treatment. Improving adherence to treatment could be one of the most valuable contributions of point of care testing, particularly when there are no other signs and symptoms to indicate the effectiveness of treatment. Sawicki showed an improvement in anticoagulation status and other patient outcome measures in patients receiving anticoagulants. A small study has also shown that point of care measurement of anticonvulsant drug concentrations leads to a more rapid achievement of optimal concentrations. Point of care testing may also be useful for osteoporotic patients who are taking drugs to improve bone mineral density and those with other diseases where adherence to treatment is poor.

Primary care

A systematic review by Hobbs et al found little evidence to support the use of point of care testing in primary care Most studies focused on technical performance of point of care testing devices rather than outcomes. One study comparing laboratory and point of care testing suggested that certain tests might be used to rule out the need for other tests—for example, in the case of suspected urinary tract infection. Fenwick et al argued that urine leucocyte esterase and nitrite tests can effectively rule out patients with suspected urinary tract infection, which could reduce the inappropriate use of antibiotics as well as laboratory workload. Similarly, point of care testing for *H pylori* infection may reduce the number of patients referred for endoscopy. Jones et al showed that such testing led to eradication therapy being started earlier and rationalised the treatment of other gastrointestinal disorders.

Point of care tests for C reactive protein in patients with bacterial infection also led to earlier treatment, although they did not change prescribing patterns. The authors concluded that although the test had some clinical benefits, the operational and economic benefits were greater.

The real challenge for point of care testing will come as the responsibility for ongoing care of chronic diseases is devolved to primary care, as has been suggested for patients with diabetes mellitus. The only way that doctors will be able to have patients' results available at the consultation will then be through point of care testing.

Accident and emergency (AER)

Point of care tests have great potential for facilitating faster decision making and therefore more effective patient triage in the accident and emergency department. The main studies in accident and emergency have been on tests for measuring blood gas and electrolyte concentrations. However, they found little clinical benefit compared with laboratory based testing. This may be because these tests are not the most appropriate for the patients who require rapid intervention or because provision of the test result is not the rate limiting step. Rapid analysis of cardiac markers may improve the recognition of patients who will benefit from early treatment as well as those who are at greatest risk of a later cardiac event. Similarly, point of care tests forD-dimer can help identify patients at risk of a pulmonary embolism or deep vein thrombosis, with improved outcomes. Recent evidence also suggests that early availability of serum protein Rs 200 (a marker of brain damage) results in patients with head injury improves clinical outcome.

Operating theatre (OT)

Rapid testing during surgery may reduce the length of an operation, which could reduce the clinical consequences of an extended operative period of time spent in a postoperative intensive care unit. For example, point of care tests for ionised calcium during the anhepatic phase of liver transplantation could reduce the adverse effects of the citrate load from transfused blood. Similarly, assessment of coagulation status by point of care testing during cardiopulmonary bypass surgery reduces the requirement for blood products, postoperative blood loss, and the time spent in postoperative high dependency care. Intraoperative measurement of parathyroid hormone concentration improved the success of reoperative parathyroidectomy from 76% to 94%. The test has also been shown to support the use of minimally invasive parathyroidectomy.

Economic outcomes

It is almost axiomatic that providing a more rapid result saves time and therefore money. However, there will be no saving unless the result is acknowledged and action taken. The economic benefit of point of care testing can be judged in terms of the short term gain from more effective use of resources in the immediate episode of care. For example, use of point of care testing to assess coagulation status and platelet function has been shown to reduce the requirement for blood products, with Despotis et al estimating that it could save over 1.7 crores of rupees a year in their institutions.

Some examples of economic outcomes from use of point of care testing

- Reduced number of clinic visits
- Reduced length of hospital stay
- Earlier discharge from hospital
- Fewer unnecessary hospital admissions
- Better optimized drug treatment
- Less inappropriate use of drugs
- Reduced use of blood products
- Reduced use of staff ,equipment and estate
- Improved quality of life

The long term gain is reflected in societal benefits, which have to be measured through quality of life indices—for example, prolonged life years or work years gained. Little formal data exist on quality of life, although

the finding that point of care testing in diabetes delays the onset of complications implies economic and wider societal benefit. Reduction in the length of hospital stay has been seen as one of the main advantages of point of care testing. The rapid availability of a result reduces the time to make decisions, thereby allowing more rapid triage, treatment, or discharge. In addition, point of care testing can be used to guide whether a patient needs admitting to hospital, as has been suggested for patients with chest pain.

Few studies have examined economic outcomes, although many studies have shown that point of care testing is more expensive than the laboratory equivalent. This is not unexpected because point of care testing loses the potential benefits of the economy of scale (automation, etc) in a central laboratory provision. Studies of economic outcomes are needed in which the results of tests are acted on quickly and the economics of the complete patient episode are built into the assessment. Point of care tests will become widely used only if the potential savings can be realized.

While waiting lists remain, movement of resources away from beds and staff seems unthinkable. However, in the short term, point of care testing can help to reduce the length of hospital stay. In the longer term, use of these tests to improve patient management and therefore reduce the disease burden will also benefit the healthcare system.

Another factor in determining use of point of care tests will be the rationalisation of pathology services. The creation of large core laboratories as the centrepiece of multitrust pathology consortiums will increase the demand for point of care testing unless transport of specimens and information technology facilities are radically improved.

CONCLUSION

So POCT can be tool for the provision of a test when the result will be used to make a decision and to take appropriate action, which will lead to an improved health outcome… the key objective of POCT is to produce a result more quickly. The technology now exists to enable a wide range of diagnostic tests to be provided at the point of care. The need for such testing clearly exists and will increase as the practice of medicine changes and individuals take greater responsibility for their health. Rapid provision of results can facilitate better clinical decision making, improved patient adherence, and greater patient satisfaction, all of which lead to improved clinical outcomes. Although the cost of producing a result at the point of care may be greater than for laboratory testing, point of care tests have wider patient, operational, economic, and societal benefits.

Take home messages

- Many biochemical tests are performed outside the normal laboratory setting, for the convenience of patient and clinician.
- Although apparently simple, such tests may yield erroneous results because of operator errors.
- It is important that advice be readily available to interpret each result in the clinical context
- Requires trained operators to ensure a good quality service
- Testing is effective only if action taken on the result
- Testing has been shown to reduce the hospital stay, improve adherence to treatment and reduce complications
- Although POCT is more expensive, it produces more widely economic benefits.

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