

# NEAR PATIENT TESTING IN CLINICAL PATHOLOGY: BENEFITS AND IMPLICATIONS

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## INTRODUCTION

Since the eighteenth century, side room tests for urine sugar protein, and bile salts have been used by physicians for clinical diagnosis.<sup>1</sup> With the introduction of venepuncture, complicated blood tests requiring considerable laboratory skill were introduced gradually into clinical practice. This led to the establishment of centralised clinical pathology laboratory services. Further developments in automation pioneered by Skegg<sup>2</sup> enabled faster analysis of routine specimens and higher through-put of data. The result was a logarithmic increase in the laboratory workload which was further accentuated by increasing demand for newer and more tests.<sup>3,4,5</sup> The routine diagnostic laboratory, being so over-whelmed by these demands, was unable to provide clinically desirable rapid tests as expected by the clinicians. To meet the unsatiable quest of clinicians for more and newer tests, the clinical pathology laboratory services had to depend on regular acquisition of rapid and bigger analysers – an expensive exercise for both the health services and the patients with uncertain outcome.

In recent years the introduction of chemically impregnated solid phase (e.g. diagnostic strips), rapid chemistry, and miniaturised and sophisticated, but user-friendly instruments have opened up new vistas for near-patient and self testing. This development could provide a solution to the present unsatisfactory utilisation of the laboratory services. However, it could also cause significant changes in future laboratory and clinical practice.

Currently it is possible for a trained medical practitioner, with minimal interest in clinical laboratory methodology, to analyse quantitatively or semi-quantitatively blood glucose, haemoglobin, creatinine kinase, thyroxine, theophylline, blood gases, electrolytes, urine human chorionic gonadotrophic (HCG) and luteinising hormones (LH).<sup>6,7,8</sup> The repertoire of routine diagnostic tests available will increase gradually and extend to other disciplines of pathology in the near future. These side-room tests can be carried out easily and will make results available rapidly to the clinician for therapeutic monitoring in the intensive care unit, accident and emergency unit, metabolic and endocrine clinics, and wards. The clinical demand for instant tests and instant therapy can be met and this probably would help to decrease the workload of the overworked central laboratory.

Since the introduction of near-patient testing technology, facilitated by innovation and a vigorous marketing strategy, the professions are being increasingly pressurised to evaluate the indications, performance and robustness of these analytical systems. Several evaluations have been carried out globally.

The overall impression<sup>6,9</sup> was that it is possible to carry out the tests nearer the patients so as to give clinically acceptable results. However, a slightly poorer precision than routine laboratory tests is produced, provided the operator is trained and educated in the operation and interpretation of the test.<sup>10,11</sup> Some interfering factors in the new dry chemistry systems have also been uncovered during the process of evaluation.<sup>12</sup> Evaluation of a locally available dry and wet chemistry system designed for near-patient testing showed a within-batch coefficient of variation of less than 5.3 % for cholesterol values in the range of four to seven mmol/l ( $n=20$  determination for each system).<sup>13</sup> These were quite close to the desirable standard of performance.<sup>14</sup> However unorthodox modification of the operational instruction e.g. cutting the test strip into half, misalignment of the test strip while reading its colour changes (in dry chemistry system), lipaemia and haemolysis in whole blood (analysed by the wet chemistry system) could give rise to abnormally high or low results which could lead to wrong clinical decision. A falsely elevated serum creatinine value due to secondary hyperlipidaemia in a patient with chronic renal failure could cause drastic alteration of his dialysis regime.

## **POSSIBLE EFFECTS OF NEAR-PATIENT TESTING ON THE FUTURE ORGANISATION OF THE CLINICAL PATHOLOGY LABORATORY**

The introduction of near-patient testing into rural areas seems inevitable because of the following factors: 1) inadequate laboratory services to meet the increasing clinical demand for quality services 2) low capital cost of equipments (not necessarily cost per test 3) lack of effective legislative control over the side-room tests and 4) the marketing strategy of the laboratory industry. These developments in turn will certainly necessitate modification of the training of the pathologist and technical staff, and the rethinking of the future laboratory organisation. The medical profession should be prepared for these changes.

The pathologist trained in the traditional way may not be adequately prepared to cope with the expected laboratory revolution. His changing role and job responsibilities have to be redefined and emphasised. He will probably play a gradually increasing role in interpretation of laboratory data. He would need the help of computers and more versatile knowledge based software supported by data from analysis of clinical pathological changes in healthy subjects, for application to individual patients. With the assistance of his scientific and technical staff, he has to play a greater role in quality control, supervision of maintenance and back up of the side-room tests, clarification of test interferences, designing of investigation protocol, and development of new methods of multiple data interpretation. He also has to set up "difficult" tests e.g. analysis of amino acids, trace elements, and labile peptide hormones, immunocytochemical detection of tumour markers, DNA and chromosome analysis, and quantitative histological examination by computer-assisted imaging.

As future laboratory and near-patient tests are extremely "user friendly", and supposedly non-operator dependent, the requirement for highly skilled laboratory staff will decline except in some research laboratories where specialised labour-intensive assays involving complicated extraction, and chromatography steps are carried out. The training of the technologist will have to change accordingly. The overall running cost of the laboratory may not decrease drastically. This is due to 1) requirement to maintain basic "back-up" services for side-room test, 2) a marginal decrease in the running cost (because of decrease in workload) of the relatively economic routine test carried out in the diagnostic laboratory, and 3) increased purchase of more sophisticated equipment for "difficult" tests. The medico-legal accountability of wrong test results carried out by near-patient testing will have to be redefined and preferably shared between the pathologist and the clinician whose close co-operation is essential for high quality services.

## **POSSIBLE EFFECT OF NEAR-PATIENT TESTING ON THE ORGANISATION OF CLINICS AND WARDS**

The introduction of near-patient testing into clinics is not synonymous with provision of rapid but poor quality services. On the contrary the system should be subjected to the same conventional stringent quality control program as applied to the clinical laboratory.<sup>15</sup> The teaching of undergraduate clinical pathology should be modified so that the qualified doctor is encouraged to become familiar with and interested in the clinical and scientific basis of the test and his overall responsibilities.<sup>16</sup> He should not hold the archaic attitude of letting only the technical staff look after the test. He should at least know the problem of transposition of specimen, biohazard of handling infectious biological specimen in between examining patients, and dispensing drugs.<sup>17</sup> He should also know the meaning and quality of the results (such as in-vivo and in-vitro interferences ) before making value judgements, and be responsible for referring the specimen to the routine laboratory in case of doubt for a second professional opinion.<sup>18,19,20,21</sup>

In the hospital, the traditional tussle between the clinician and the pathologist over excessive unnecessary investigation and poor, delayed, inaccurate laboratory results will probably decrease when the clinician becomes a self auditor of his own tests and budget. He has to justify all the near-patient tests carried out by him and his staff for clinical diagnosis. This may become an efficient way of monitoring unnecessary laboratory investigation.

In some central hospitals, mobile laboratories consisting of portable laboratory analysers which can be wheeled immediately to the intensive care or special care nursery units, clinics or wards, are required to provide additional support for near-patient testing.<sup>8</sup> In the private clinics and laboratories there may be a danger of over testing and excessive charging of patients. This could have an adverse effect on the future health insurance scheme in the private health services. The professional bodies working jointly with the Ministry of Health probably could help to curb this possible trend.

A properly carried out near-patient test could certainly shorten the waiting time for laboratory results and indirectly the duration of hospitalisation of the patients e.g. improved availability of "real time" cardiac enzyme data could contribute to the early discharge of patient from intensive care facilities.<sup>22</sup> Decentralised testing can also eliminate the cost of transportation, specimen preparation, and clerical handling of the requests. This could contribute to the efficiency of the health care system.

## **POSSIBLE EFFECTS ON THE PATIENTS**

Self-testing for monitoring diabetic control under the instruction of clinicians has been practised over the past five years. Some of the problems encountered are "superficial" hyperglycaemia, reporting of fabricated results of perfect diabetic control by the patient to please the clinician.<sup>23</sup> The new generation of glucose monitor with built-in memory chips for recording test results could overcome this problem of non-compliance. In this situation as the patients are carrying out the test under the instruction of the attending physician, it is the latter who should be responsible for ensuring the validity of the result.

In recent years several manufacturers have been marketing self-testing kits for pregnancy, which could be bought over the counter from the pharmacies.<sup>24</sup> There is a high probability that the test could be carried out without proper instruction, quality control, and assisted interpretation by trained laboratory personnel. With the increasing awareness of health education and interest in self-testing it is most likely that the enthusiasm for self-testing will grow. The situation will pose a number of problems: a) Should the patient interpret the result and practise self-medication and self-referral,<sup>25</sup> b) Who is accountable for the results.<sup>26</sup> In the absence of legislative control, interest in self-testing could encourage the growth of

“diagnostic kiosk” not unlike that of the local “eating stalls” where simple analysis such as for glucose, cholesterol, triglyceride, uric acid, and creatine kinase could be carried out for a few dollars in supermarkets by non-laboratory and non-medical staff with minimal capital investment. This will certainly have undesirable effects on the health care system of the country in the future.

At the present moment there is a need to define the method of delivering self-testing to the patients. Preferably self-testing should be supervised by the pathologist who works closely with the clinicians. He could provide the necessary technical training, quality assurance to the patients, assist in the interpretation and further selection of specialised tests to confirm the initial abnormal findings and advise the patients on further consultation with the appropriate clinicians. This could reduce the waiting time of the patients who need answer to certain specific clinical problems which can be readily solved by simple blood test e.g. HBsAg carrier, hypercholesterolaemia, and thyrotoxicosis. In this way self-testing could complement the medical services in places where there is a high patient to doctor ratio.

## CONCLUSION

Legislation is urgently needed at the moment<sup>15</sup> to define the quality, staffing, safety of laboratory practice and to protect the patient from unnecessary health risk. The professional bodies could certainly contribute positively to this and the maintenance of quality clinical and laboratory practice amongst their members.

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