

Comparison of the use of four desktop analysers in six urban general practices

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SUMMARY. *There is little data on the advantages and disadvantages of using desktop analysers in general practice. This prospective trial compared four of the analysers available in the United Kingdom, in six urban general practices, over a six month period. Of the 2619 tests where the time was noted, 55.8% were performed outside the hours when routine transport to a hospital laboratory was possible (after 12.00 hours). Of the 3530 tests performed the commonest were measurements of cholesterol (14.4 tests per 5000 patients per 30 days), glucose (6.0 tests) and haemoglobin (5.6 tests). Less than 5% of the tests were performed as an emergency despite the speed at which results are available. The main reasons for requesting the tests were screening or case finding (56.9%), with the remainder for monitoring chronic disease, especially diabetes and hypercholesterolaemia. There was evidence that the use of the machines in the four practices reduced requests for hospital laboratory blood tests by 24–40% of pre-study levels. However, there was a considerable increase in testing for cholesterol (three fold) and haemoglobin (eight fold) on the desktop analysers, compared with the number of laboratory tests requested before the study. The cost per test of using such machines is closely related to the level of activity and probably does not compete favourably with hospital testing unless several tests are performed each day. Quality control tests were within the specified limits on at least 98% of occasions, however these tests also identified the need for laboratory back up where a problem was found.*

Keywords: *near patient testing, practice based diagnostic tests; desktop analysers; diagnostic techniques.*

Introduction

NUMEROUS test systems are now available for performing laboratory tests outside the hospital laboratory.¹⁻⁵ The systems fall into three main groups: simple dipsticks and other disposable devices requiring no instrumentation; small dedicated single test meters (usually employing dry reagent chemistry); and more complex desktop analysers. All can be used by non-laboratory staff and produce rapid results.

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Dipsticks and single test meters have been widely adopted by general practice. In contrast, multi-test desktop analysers are mainly used in small specialist medical units and by individual doctors, particularly in the United States of America. The main benefits claimed for testing in the practice are the time saved and the convenience for both the doctor and the patient. In some countries the test may earn a fee.⁶ For the general practitioner in the United Kingdom the main attraction is the ease and rapidity of obtaining test results, compared with the possible delays of a week or more in receiving a report from a hospital laboratory.⁷ However, desktop analysers are not widely used by British general practitioners, probably because the cost of the equipment and the running costs are not at present reimbursable. Indeed the main experience in the UK has been in lipid screening,^{8,9} using analysers loaned from pharmaceutical companies at no cost to the practices. However, with the advent of budget holding in April 1991,¹⁰ these machines may offer financial savings to budget holding practices who would previously have allocated funds to routine outpatient pathology testing. This may stimulate a new demand for desktop analysers among general practitioners in the UK.

Data are available that confirm the accuracy^{4,5} and ease of use¹¹⁻¹⁴ of such analysers in the laboratory, but there is little information on their use by non-laboratory staff in general practice. The aim of this study was therefore to evaluate the uptake of four widely available analysers (Table 1) in routine general practice, and to establish their advantages and limitations. The evaluation took place during separate technical studies for the Department of Health in 1990.¹⁵

Method

Six urban practices (A to F) in Birmingham participated in the study: A was an inner city group practice with three doctors, 1.3 full time equivalent nurses and 4800 patients; B was an inner city group practice with four doctors, one nurse and 7600 patients; C was a suburban group practice with four doctors, one nurse and 7000 patients; D was a suburban group practice with 4.5 full time equivalent doctors, 1.25 nurses and 10 700 patients; E was a suburban group practice with five doctors, 1.5 nurses and 8400 patients; F was an inner city group practice with four doctors, one nurse and 6000 patients. All were training practices with trainees in post. None had any previous experience with this type of instrumentation.

At least one doctor and one practice nurse from each practice were given three hours' training in the Wolfson Research Laboratories, Birmingham by a medical laboratory scientific officer on the machine they were to use. This tuition covered operation, daily and weekly maintenance of the instrument, the need for and techniques of quality control and the procedure for obtaining capillary blood samples.

Instruments were installed in each practice by staff from the Wolfson Research Laboratories, who also provided reagents and quality control sera as required. The physical requirements for testing in the practice were a flat stable surface about 4.0 feet (1.2 metres) wide, which was easily accessible during working hours with sufficient electrical power points (one to three) for the instrument and, if necessary, a centrifuge. Refrigerator space (one or two shelves in a domestic refrigerator) and a small

amount of freezer space were needed for storing reagents and a limited supply of quality control material.

At present there are no guidelines for what constitutes adequate quality assurance when using desktop analysers in general practice. In this study, a practice similar to that used in laboratories was advised: a quality control test was to be performed whenever a test was done for the first time that day, and if necessary after every 10th similar test done subsequently that day, or if problems arose.

Following installation, a short training review was arranged before the study started. Operators were given simple quality control tests, and when their results were judged reliable were awarded certificates of competence.¹⁶ The medical laboratory scientific officer visited each practice at weekly intervals, or when requested by telephone, to deal with any problems, to recalibrate instruments when necessary and to observe the operators to ensure that technical competence was maintained. There was no attempt to direct the frequency or selection of tests and all practices were free to use their normal hospital laboratory service as desired.

The six practices were divided into two groups. Group one (practices A–D) performed three months' evaluation on the Reflotron machine and three months on the Vision machine (two practices used the Vision machine first and two the Reflotron machine). Practices A, C and D recorded details on all blood pathology tests requested in the six weeks prior to the machine being installed. This recording of hospital blood tests continued for the three months of testing with each machine. In addition, all four practices recorded the following details on tests performed on the desktop analyser: time of test; who operated the machine; the type of test; urgency and reason for request; type of clinic (normal surgery or special clinic); patient diagnosis; whether a quality control test was performed; and any general comments. Three practices (A, C and D) collected data on turnaround times for hospital tests for six weeks prior to and six weeks during the study period. At the end of the first three months' evaluation, written records were collected and practice staff debriefed. The instruments were then exchanged, operators retained and a further three months' evaluation carried out.

Group two consisted of three practices (D from group one and practices E and F) who evaluated the Ektachem DT and Easy ST machines for three months each (practice F evaluated

the Ektachem DT only for three months).

When presenting the results of this study, analyser test rates of number of tests per 5000 patients per 30 days were calculated because the intervention took place over a six month period and the numbers would have become too small if rates of tests per 1000 patients per year were used. However, readers who wish to compare the findings presented here with test rates quoted elsewhere should multiply the rates by 2.43 to obtain number of tests per 1000 patients per year.

Results

Nurses performed most of the 3530 analyser tests carried out during the six month study period (69.9%) with the remainder done by doctors. Of the 2619 tests where the time of the test was noted, 44.2% were performed before noon (08.00–11.59 hours), 28.3% were done in the afternoon (12.00–15.59 hours) in special clinics and 27.5% during times of evening surgeries (16.00–20.00 hours).

The majority of tests for which there were complete records were classified as routine with only 4.2% performed as an emergency (Table 2). A total of 1499 tests (56.9%) were done to establish a diagnosis and the remainder for monitoring purposes. Most tests were carried out in a routine clinic (66.1%). Indeed, of the 1106 tests performed in group one practices (A–D), 78.6% were related to only four clinical areas: disease screening (24.1%), diabetes monitoring (22.8%), hypercholesterolaemia monitoring (18.9%) and checking haemoglobin levels (12.7%).

Of the 3530 tests performed the most common were for cholesterol (14.4 tests per 5000 patients per 30 days, range in practices 4.7–29.6 tests per 5000 patients per 30 days), glucose concentrations (6.0 tests, range 0–26.5 tests) and haemoglobin (5.6 tests, range 1.7–13.4 tests) (Table 3). These were the top three tests for the Vision and Reflotron machines but the concentration of triglycerides was the second most common test on the Easy ST and Ektachem DT machines.

Overall, 62.5% of all tests performed were for lipid analysis, haemoglobin or glucose concentration. The fourth most popular test was for triglycerides (8.6% of all tests, range in practices 4.2%–15.5%) and the fifth was urea (5.6%, range 0.9%–8.0%). The sixth and seventh most performed tests were potassium (4.8% of all tests, range in practices 0%–11.4%) and sodium

Table 1. Details of the four desktop analysers tested.

	Easy ST	Ektachem DT	Reflotron	Vision
Supplier	BDH	Kodak	Boehringer Mannheim UK	Abbott Diagnostics
List price (£) ^a	8000	10 000 ^b	3960	10 500
Reagent	Reagent cuvettes	Dry reagent slides	Dry reagent strips	Cassettes
Cost per test (£)				
Cholesterol	1.09	1.20	0.81	1.75
Haemoglobin	0.79	0.90	0.63	1.75
Glucose	0.50	0.68	0.62	1.75
Specimen ^c	70 µl plasma	10 µl plasma	32 µl whole blood or plasma	100 µl whole blood or plasma
Repertoire	48 tests	28 tests	15 tests	24 tests
Throughput	One test at a time, takes 1–5 min	Up to six tests at a time, one test takes 3 min	One test at a time, takes 5 min	Batches of up to 10 tests, takes 5–15 min per batch
Calibration	Required	Required	Precalibrated	Required

^a Prices (excluding VAT) quoted in December 1990 for the instrument and essential accessories, ready for use. ^b Price for all three modules; purchase of only one or two limits the test repertoire. ^c All measure haemoglobin in whole blood.

Table 2. Classification of tests performed for which there were complete records, according to urgency, reason for test and type of clinic.

	Number (%) of tests	
<i>Urgency</i>		
Routine	2561	(95.8)
Emergency	112	(4.2)
<i>Reason</i>		
Diagnostic	1499	(56.9)
Monitoring	1136	(43.1)
<i>Type of clinic</i>		
Special	894	(33.9)
Routine	1743	(66.1)

(4.4%, range 0%–10.6%) despite these only being available on the Ektachem DT machine. Wider variation occurred with the less commonly performed tests, namely gamma glutamyl transpeptidase at 3.6% (range 0%–8.0%), bilirubin at 2.7% (range 0.8%–4.3%), urates at 2.7% (range 2.4%–4.2%), aspartate aminotransferase at 2.6% (range 1.1%–3.8%) and alanine aminotransferase at 2.3% (range 0.2%–5.6%). A further 10 tests were variably performed and accounted for less than 9% of all tests.

Hospital tests

Practices A, C and D reduced their requests for hospital blood tests from 16.5 tests per 5000 patients per 30 days, to 9.9 during the period in which they used the Reflotron machine and 12.3 during the period in which they used the Vision machine (Table 4). The mean, turnaround times for hospital tests in this study for practices A, C and D were between 5.2 days for erythrocyte sedimentation rate and 6.9 days for concentration of thyroid stimulating hormone. The range of turnaround times was large: 25% of cholesterol concentration results were returned within three days but 75% were returned within nine days.

Costs of analyser testing

The ratio of tests to quality controls was low, ranging from 0.1 to 1.0 for albumin concentration to 1.6 to 1.0 for cholesterol concentration. This was because practices sometimes performed quality control tests without doing patient tests later in the day. The estimated cost of performing tests was related to the frequency of testing. Table 5 demonstrated that performing two tests for cholesterol concentration per week on a Reflotron machine would cost over £14.00 per test. The equivalent charge at a private clinic in Birmingham would be £10.00 (personal communication). Even if the practice were performing two cholesterol tests per day the cost would still be nearly £5.50 per test.

Table 3. Number of tests performed before and during the study.

	Number of tests per 5000 patients per 30 days					
	Sent to laboratory before study ^a	Reflotron	Vision	Ektachem	Easy ST	All four machines
Cholesterol	4.9	15.2	16.2	10.9	12.8	14.4
Glucose ^b	4.7	5.4	10.8	2.9	0.8	6.0
Haemoglobin	0.7	6.0	7.6	4.2	1.9	5.6
Triglycerides	1.4	1.4	2.9	4.4	6.0	3.2
Total for all tests	16.5	31.0	46.2	74.3	37.2	44.3

^a Practices A, C and D. ^b Excluding glucose meters.

Table 4. Number of blood tests sent to hospital laboratories for analysis before and during the study by practices A, C and D (total population 22 500 patients).

Test	Number of laboratory tests per 5000 patients per 30 days		
	Before study	Period in which Reflotron used	Period in which Vision used
Full blood count	5.5	3.2	3.7
Serum profile ^a	2.9	1.6	2.2
Erythrocyte sedimentation rate	2.5	1.5	1.6
Thyroid function	1.8	1.0	0.9
Concentration of electrolytes	0.5	0.2	0.6
Glycosylated haemoglobin/fructosamine	0.5	0.1	0.3
Presence of Epstein Barr virus	0.4	0.2	0.4
Liver function	0.3	0.3	0.3
Concentration of rheumatoid factors	0.2	0.3	0.4
Miscellaneous	1.9	1.5	1.9
Total	16.5	9.9	12.3

^a Concentration of urea, creatinine and electrolytes plus liver function tests.

Table 5. Cost of a cholesterol test performed using a Reflotron machine according to the number of tests performed in a week.

Number of tests per week	Cost per test (£) ^a			
	Capital ^b plus maintenance	Labour (nurse)	Consumables ^c	Total
2	11.02	1.47	1.81	14.20
10	2.20	1.47	1.81	5.48
20	1.10	1.47	1.81	4.38
30	0.73	1.47	1.81	4.01
40	0.55	1.47	1.81	3.83
50	0.44	1.47	1.81	3.72

^a Based on prices quoted in December 1990; includes VAT at 15%. ^b Spread over five years. No allowance is made for rent, fittings, overheads or profit for the practice. ^c Including quality controls.

Quality control

Observation of the practices during the study reassured the investigators that the technical competence in sample collection and appropriate, accurate use of quality controls (demonstrated at the start of the study) was maintained throughout.

On the few occasions that quality control materials gave results that were outside the defined limits (under 2% of occasions), this was generally due to inappropriate use of the material. The commonest problems were failure to mix the material adequately before use or blockage of pipettes. Most difficulties were due to the operator, but on five occasions the instrument required calibration or more detailed attention, and three reagent batches appeared faulty.

Views of practice staff

On debriefing, the tests which general practitioners said that they would most like to have available were erythrocyte sedimentation rate, mean corpuscular volume and full blood count (as adjuncts to haemoglobin measurements), concentration of electrolytes (for monitoring patients on diuretic drugs), glycosylated haemoglobin or fructosamine (to supplement glucose assays in diabetic patients), and concentration of thyroid stimulating hormone.

On a practical level the Reflotron was popular because of its small size (300 × 350 × 195 mm), portability (5.5 kg) and quiet operation. The doctors and nurses commented that although other instruments had larger repertoires and greater test capability, they were slower, noisier, took up more space (to avoid recalibration the machines were not moved), or required a centrifuge. These therefore might have to be sited outside the consulting or treatment room, but were amenable to batch testing after surgery, with patients telephoning later in the day for results and advice.

Discussion

Several studies have shown that desktop analysers are accurate when used in the laboratory^{4,5} and this study has demonstrated that they can be operated safely and reliably by non-laboratory staff in general practice provided they have been trained and receive continued laboratory support.

In this study no attempt was made to influence the use made of the machines. The practices were largely consistent in the main applications which were adopted for the analysers, namely screening for and monitoring of abnormal cholesterol, haemoglobin and glucose concentrations. This was despite the great variation in how the machines worked and what tests were available. The instruments stimulated an increase in testing in these clinical areas. This was especially true of cholesterol testing which increased from 4.9 tests per 5000 patients per 30 days before the study to between 10.9 and 16.2 depending on the machine used, and haemoglobin estimation which increased from 0.7 tests per 5000 patients per 30 days to between 1.9 and 7.6.

It was interesting to note that practices A, C and D reduced their requests for hospital blood tests during the period of the study. This was principally due to fewer requests for full blood counts (from 5.5 to 3.5 tests per 5000 patients per 30 days) and erythrocyte sedimentation rates (from 2.5 to 1.6 tests) and could suggest that a substantial proportion of blood counts are performed merely to estimate the haemoglobin concentration. Such a hypothesis is reinforced by the increase in haemoglobin testing discussed above. It is noteworthy that only five investigations accounted for 80% of all requests for hospital blood tests, namely full blood count, serum profile, concentration of electrolytes, thyroid function test and erythrocyte sedimentation rate.

Such findings reinforce the need to debate the level of usage of tests such as haemoglobin concentration and erythrocyte sedimentation rate in general practice. The sensitivity and specificity of such tests will be inextricably linked to the accuracy of signs or symptoms that prompt the doctor to order the

investigation. Professional consensus over what constitutes a reasonable trigger for investigation will encourage a greater confidence among doctors about their clinical acumen, as well as promoting cost efficiency.

This study confirms earlier findings^{7,17} that desktop analysers have a useful role in screening, either opportunistically or in well person clinics where the rapid results might have a greater impact on the advice that should follow. However, a practical problem noted by some doctors in this study was that there was not always time to follow up abnormal results with sufficient health education on the same occasion. This would not be such a problem in dedicated screening clinics where there is likely to be more time set aside for the patients, but could prolong regular surgeries where a worried patient might need a further extended discussion with the doctor or nurse.

Another benefit of desktop analysers is that tests can be carried out after the time when samples would normally have to be sent to the hospital, which for most practices would be from late mornings onwards. Indeed, some 56% of tests in this study were performed after midday. This factor could be especially useful in rural practices.

The estimated costs presented here do not show any credit for savings on transport of specimens. However, current analysers can perform only a proportion of biochemistry and haematology tests. The cost of using desktop analysers is the main factor which will determine their use. Leese and Hutton⁷ estimated the mean cost per test on a Reflotron as £2.32, but they assumed lower labour costs, assumed high usage and made no allowance for quality control. The machines do represent a considerable capital investment. In this analysis it was found that approximately half the consumable cost was due to the reagent strip, which varies between tests and machines. Most of the remainder was due to quality control tests. The frequency of assaying quality control material could be reduced but the procedure must not be abolished.¹⁸ Savings could be made by following advice and not performing quality controls to check that machines were working before patients arrived, since no testing might take place that day. Many quality control tests were done because practices need these as a check after any abnormal results. This was not strictly necessary, but might represent good practice and prove desirable on medico-legal grounds.

At present, the major limitation on the use of desktop analysers is that most of the tests available are not those most needed by the general practitioner. The exceptions are cholesterol, haemoglobin and glucose concentrations, all of which can be estimated on single test machines. Practices vary in the use they make of existing pathology services¹⁹ and will vary in the use made of desktop analysers.

General practices will still need hospital laboratories. Furthermore, laboratory staff need to be involved^{20,21} in the use of practice based analysers, for example in training, technical backup, calibration, supply of quality control materials and test reagents, and to provide advice on issues such as test selection or interpretation.²⁰ Reagents are often unstable and bulky to store in practice refrigerators. Since some of these need to be brought to room temperature prior to use, this can limit the repertoire of tests which can be kept ready for immediate use.

The importance of training should not be underestimated. Surveys of cholesterol assays in primary care^{22,23} have shown that most results are satisfactory, but clinically significant errors are not uncommon. These are usually operator dependent mistakes such as use of outdated or inappropriately stored reagents; poor sample collection technique (such as inclusion of air bubbles or excessively squeezing to obtain capillary blood samples); and lack of quality control. Poor quality results are

likely to lead to renewed demands for legislation,²¹ which would further discourage general practitioners from doing their own tests.

Fund holding practices or rural centres might be tempted to use one of these analysers. However, since in the urban practices studied here cholesterol and glucose concentrations represented over 40% of tests, single test glucose and cholesterol meters (or other single test systems) could be more appropriate. These are considerably cheaper, more portable and more compact. However, the range of tests available on desktop analysers is expanding and should they become more relevant to the needs of British general practices then greater uptake seems likely.

At present, even in fund holding practices there is apparently little sign that general practitioners in the UK are planning to do their own laboratory tests on desktop analysers, possibly because of the capital investment involved and uncertain profitability. In these circumstances it may be better to invest in improved computer data links with laboratories or fax transmissions for the majority of pathology tests, and to use single test machines where immediate results are required on significant numbers of patients.

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MRCGP EXAMINATION — 1992/93

The dates and venues of the next two examinations are as follows:

October/December 1992

Written papers: Tuesday 27 October 1992 at centres in London, Manchester, Edinburgh, Newcastle, Cardiff, Belfast, Dublin, Liverpool, Ripon, Birmingham, Bristol and Sennelager.

Oral examinations: In Edinburgh on Monday 7 and Tuesday 8 December and in London from Wednesday 9 to Saturday 12 December inclusive.

The closing date for the receipt of applications is Friday 4 September 1992.

May/July 1993

Written papers: Wednesday 5 May 1993 at those centres listed above.

Oral examinations: In Edinburgh from Monday 21 to Wednesday 23 June and in London from Thursday 24 June to Saturday 3 July inclusive.

The closing date for the receipt of applications is Friday 26 February 1993.

MRCGP is an additional registrable qualification and provides evidence of competence in child health surveillance for accreditation.

For further information and an application form please write to the Examination Department, Royal College of General Practitioners, 14 Princes Gate, London SW7 1PU. Telephone: 071-581 3232.