

Comparison of the use of a dry chemistry analyser in primary care in Norway and the United Kingdom

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SUMMARY. *The results of a quality assessment survey of the most commonly used dry chemistry instrument in primary care in Norway and the United Kingdom, the Reflotron® (Boehringer), are reported including an evaluation of some of the operational characteristics of the Reflotron users. The primary care users in Norway taking part in the study comprised 95 occupational health care departments and 89 general practices. In the UK, primary care users taking part were 95 occupational health care departments and 37 general practices. In terms of both accuracy and precision evaluation of concentrations of bilirubin, cholesterol, gamma-glutamyl transferase, glucose, triglycerides, urea and uric acid by primary care users was similar in the two countries, and to that of 60 Norwegian laboratories. Examination of operational characteristics revealed a lack of effective quality control measures in both countries, and some differences in the pattern of usage between primary care users in Norway and the UK, especially in general practice. The result of Reflotron tests were ready before the patient left in a considerably higher proportion of general practices in the UK than in Norway.*

It is concluded that the Reflotron is suitable for primary care use, but good, routine quality of analysis must be ensured through collaboration between primary care users and clinical chemists.

Keywords: *desktop analysers; dry chemistry; practice based diagnostic tests; diagnostic test results; quality control.*

Introduction

THE use of desk top analysers which employ carrier-bound reagents, so-called dry chemistry instruments, has become widespread during the last few years. The provision of dietary advice linked to 'on the spot' cholesterol assays has probably been a primary reason for this increase, but as the instruments are capable of analysing most blood constituents requested in primary care,^{1,2} wider use with regard to the number of constituents, operating conditions, and clinical applications might be expected. The Reflotron® (Boehringer) is the dry chemistry instrument most commonly used in primary care in Norway and

the United Kingdom and has been thoroughly evaluated in reference laboratories.³⁻⁹ However, some studies, generally involving only a few laboratories or assessing the use of cholesterol assays only, have been concerned with performance in primary care.^{8,10-16} Both Haukeland University Hospital in Norway and the Wolfson Research Laboratories in the UK have recently performed external quality assessment surveys of dry chemistry instruments in primary care: the Norwegian study¹² focused on a wide range of blood constituents analysed by 'innovative' primary care users whereas the UK study^{11,16} examined cholesterol performance in a scheme with regular distribution of quality control material.

Since in Norway general practices perform a considerable range of laboratory tests themselves¹⁷ whereas in the UK practices currently do few tests,^{18,19} a joint venture was considered appropriate. The aim of this study was to compare the quality of the results obtained using the Reflotron in primary care in Norway and the UK, and to compare the performance in primary care with that of laboratories in Norway. In addition, some operational characteristics of primary care users were evaluated.

Method

In Norway all primary care users of the Reflotron recorded on instrument dealers' mailing lists were recruited to the study. In the UK all participants in the Wolfson Research Laboratories' extra-laboratory cholesterol assessment scheme¹⁶ were asked to participate. In November 1989 all participants received a commercial stable liquid human quality control serum (Sero/Nycomed) by post and were asked to analyse it in duplicate, on two different working days, for all blood constituents that they would routinely assay using the Reflotron. An accompanying questionnaire was addressed to the practice/department with instructions that it was to be completed jointly by at least one of the operators of the instrument and one of the doctors. In general, closed questions were used, but respondents were also given the opportunity to volunteer other information or opinions. The questionnaire elicited information on the operation of the instrument and the practice setting. In addition, all Norwegian hospital laboratories received the same serum in a simultaneous quality control assessment conducted by the Norwegian external quality assessment scheme for clinical chemistry.

Target values, for assessment of performance, were determined separately for the Reflotron users and for the most commonly used hospital laboratory method owing to a matrix effect (the influence of the quality control material itself on the result of the measurement). Target values for the Reflotron users in Norway and the UK were also determined separately for practical reasons. Blood constituents analysed in duplicate by less than 12 respondents were omitted from the study. First, the median for the duplicate analyses in each group was calculated. The median for respondents with acceptable precision was then calculated; the difference tolerated, as a percentage of the median, was set to be double the acceptable coefficients of variation from the quality assessment scheme (Table 1). Finally, limits for acceptable accuracy by the scheme's standards (percentage deviation) were determined relative to the median for respondents

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with acceptable precision. The target values were calculated as the median for respondents with accurate and precise results.

To secure comparable groups of Reflotron users in the two countries, both for assessment of quality of analysis as well as for comparison of operational characteristics, only respondents from general practice or occupational health care departments were considered. These respondents were assessed individually with respect to accuracy and precision using criteria modified from the Norwegian quality assessment scheme (Table 1), that is, results were characterized as accurate/inaccurate and as precise/imprecise in the feedback report. Results were classified as accurate, or valid, if the mean did not deviate by more than the stated percentage from the target value; results were classified as precise, or reproducible, if the difference between duplicate results was within the given percentage of the target value.

Accuracy for the two primary care Reflotron groups and the laboratories is expressed as percentiles of results from individual respondents, and as percentages of respondents with accurate results. However, to avoid using dichotomous criteria, group differences were assessed statistically by transforming deviations from the target values so as to be relative to a target value of 100 for all blood constituents, using means of the duplicate results and absolute values for the deviations. Differences in the distribution of deviations for the Reflotron users and the hospital laboratories could then be tested by the non-parametric Mann Whitney *U* test. Significance was accepted at the 5% level, but owing to multiple comparisons, a modified Bonferroni's procedure was performed (adjusted $\alpha = 0.01$) to avoid statistical artifacts.

Group precision was assessed by calculating coefficients of variation for each group of respondents from the formula:

$$\frac{[\sum (\text{Result 1} - \text{result 2})^2 / 2n]^{1/2}}{\text{Mean of results} \times 100}$$

where n = number of respondents analysing the constituent in question, after exclusion of outlying values, that is differences exceeding three standard deviations from the mean difference. This was done in order to avoid the distorting effect of a few (one to four) grossly imprecise respondents. However, no results were excluded when calculating coefficients of variation for the few UK Reflotron users analysing bilirubin and uric acid. The coefficients of variation represent the mean precision of 'the respondent', that is the respondent's ability to achieve the same result from the same specimen; the lower the coefficient of variation, the better is the precision. Significant differences between coefficients of variation were calculated using the ratio of variances and the *F* distribution²⁰ (adjusted $\alpha = 0.01$).

Results

Reports were received from 95 Reflotron users in occupational health care in Norway and 95 occupational health care users in the UK. A total of 89 Norwegian and 37 UK general practices responded. In Norway, 45 (51%) of the general practices were group practices, whereas 28 (76%) of the UK practices were group practices. The Norwegian users represented 70% of Reflotron instruments operative in primary care; a comparable figure for the UK could not be determined. The control serum was analysed by all 60 Norwegian laboratories participating in the external quality assessment scheme. The numbers of respondents analysing each blood constituent are shown in Table 1.

Table 2 presents an overview of group accuracy. No significant differences were found between the two Reflotron groups, and both groups of users performed as well as hospital laboratories.

Table 3 shows the precision of the groups of respondents. Norwegian Reflotron users performed significantly better than UK users regarding the measurements gamma-glutamyl

Table 1. Blood constituents examined, criteria used to assess analytical quality, and number of respondents analysing each blood constituent.

Blood constituent	Measurement units	% accuracy ^a	% imprecision ^b	No. of respondents		
				Reflotron users in Norway	Reflotron users in UK	Laboratories in Norway
Bilirubin	$\mu\text{mol l}^{-1}$	10	20	61	12	50
Cholesterol	mmol l^{-1}	5	10	184	118	50
GGT	IU l^{-1}	10	14	127	39	37
Glucose	mmol l^{-1}	10	10	111	47	35
Triglycerides	mmol l^{-1}	10	20	98	47	—
Urea	mmol l^{-1}	10	16	42	25	41
Uric acid	$\mu\text{mol l}^{-1}$	10	10	84	14	44

^aGreatest allowable percentage deviation from the target value. ^bGreatest allowable difference between duplicate results, as a percentage of the target value. GGT = gamma-glutamyl transferase.

Table 2. Accuracy of respondents as percentiles of individual results and as percentages of respondents with accurate results.

Blood constituent	Reflotron users in Norway			Reflotron users in UK			Laboratories in Norway		
	Target value	10-90 percentile	% accurate	Target value	10-90 percentile	% accurate	Target value	10-90 percentile	% accurate
Bilirubin	119	102-127	80	117	108-126	100	107	100-118	92
Cholesterol	5.6	5.4-6.0	76	5.5	5.3-6.1	70	6.0	5.8-6.3	84
GGT	67	58-74	69	72	48-75	74	96	86-106	81
Glucose	10.8	10.1-11.5	90	10.6	10.1-11.1	94	10.4	9.9-11.1	100
Triglycerides	1.81	1.55-2.26	55	1.83	1.68-2.28	57	—	—	—
Urea	15.3	13.7-16.3	83	14.9	13.7-15.8	92	15.4	14.3-16.4	95
Uric acid	206	191-220	89	209	200-220	100	164	156-215	75

GGT = gamma-glutamyl transferase.

Table 3. Precision of respondents as coefficients of variation and as percentages of respondents with precise results.

Blood constituent	Reflotron users in Norway		Reflotron users in UK		Laboratories in Norway	
	CV	% precise	CV	% precise	CV	% precise
Bilirubin	5.8	95	3.2	100	2.8 ^a	100
Cholesterol	3.5	91	3.5	88	3.0	96
GGT	3.8 ^b	93	6.5	85	2.7 ^b	97
Glucose	3.0 ^b	95	5.1	91	3.1	94
Triglycerides	7.9	88	6.8	74	—	—
Urea	4.4	95	2.8	92	3.0	98
Uric acid	2.5 ^c	98	2.0 ^c	100	4.4	93

CV = coefficient of variation (standard deviation as a percentage of the mean). GGT = gamma-glutamyl transferase. ^aSignificantly better than Norwegian Reflotron users. ^bSignificantly better than UK users. ^cSignificantly better than laboratories.

transferase and glucose concentration. The laboratories also performed significantly better than UK Reflotron users with respect to gamma-glutamyl transferase concentrations, and better than Norwegian Reflotron users regarding bilirubin concentration. Both Norwegian and UK users performed significantly better than the laboratories regarding the measurement of uric acid concentration.

Table 4 shows some of the operational characteristics of the Reflotron users; not all of the respondents gave full details. In both countries, the instruments were operated by personnel with little or no laboratory training. In Norway, most Reflotron users did more than just cholesterol assays, used anticoagulated blood and performed relatively few internal quality controls. About half of the general practices in Norway did not use test results in conjunction with the consultation. In contrast, most UK Reflotron users could use test results 'on the spot', used mainly capillary blood, and carried out internal quality controls weekly. Many UK users focused on cholesterol assays. About 25% of all users replied that they had needed unscheduled assistance from the dealer for operational problems during the last six months; reasons for this were not asked for in the questionnaire.

Discussion

In 1990 about 54 000 Reflotron instruments were said to be operative worldwide. The Reflotron can perform assays for several blood constituents, and the test menu is expanding, but the range of tests offered is still smaller than that of laboratories. However, a number of commonly requested tests can be carried out 'near' the patient, and this possibility raises important questions of cost effectiveness;²¹ assuring quality of analysis is also an essential prerequisite of such use.²²

No important differences between Norwegian and UK Reflotron users regarding quality of analysis were found in this study even though testing traditions differ, and, overall, performance was good. It may be that the UK users represent a subgroup with especially good performance, as they were all participants in the UK external quality assessment scheme for cholesterol. However, this is not the case with the Norwegian group, and the data show that good quality of analysis can be achieved both in general practice and in occupational health care departments. The reason may be that the Reflotron is largely operator independent,²³ because it is precalibrated by the manufacturer and requires little technical skill to operate. The fact that most of the UK results are from occupational health care units does not invalidate this conclusion; implementation problems in the two settings should not be very different. It should, however, be borne in mind that the design of the study was open and educational, and did not prevent the participants choosing 'good' days for the analyses or analysing the specimen more than twice, thereby 'improving' precision. However, it is unlikely that this has seriously affected the results since poor

Table 4. Operational characteristics of the Reflotron users.

Operational characteristic	No. of Norwegian Reflotron users		No. of UK Reflotron users	
	Occupational health (n = 95)	General practice (n = 89)	Occupational health (n = 95)	General practice (n = 37)
<i>Operator of the instrument</i>				
Nurse	82	15	83	33
Medical secretary ^a	7	36	—	—
Laboratory technician	1	10	7	0
Doctor	1	5	3	1
Other	0	6	1	2
More than one operator	4	16	1	0
<i>Number of tests per week</i>				
<20	45	15	35	17
20–49	37	26	30	6
50–99	13	17	16	6
100+	0	24	2	2
<i>Type of test material(s)</i>				
Capillary blood	15	1	68	29
Heparinized/EDTA blood	34	29	5	1
Capillary and heparinized/EDTA blood	25	27	7	4
Serum	2	4	6	2
Serum and heparinized/EDTA blood	1	8	0	0
Capillary blood and serum	6	9	2	0
Other	12	9	3	1
<i>Use of internal quality control tests</i>				
Weekly	39	50	61	27
Sporadic	47	29	11	2
Never	8	4	17	6
<i>Miscellaneous</i>				
Results ready before patient leaves	84	41	86	31
Unscheduled assistance from dealer required during last six months	30	20	18	15
Cholesterol assays only	21	2	37	21

^aIn Norway only; shorter education than received by nurses, but the education includes some laboratory training, which nurses do not receive. EDTA = ethylene diaminetetra-acetic acid.

performance would not lead to any penalty, and UK users were accustomed to participation in a quality control scheme.

The finding that, overall, Reflotron users as a group seem to perform as well as laboratories, is important for several reasons. First, test results should be of the same quality irrespective of

whether they are produced in primary care or by laboratories.²⁴ Secondly, since serious disease is relatively rare in primary care, and laboratory tests are often used to rule out disease,¹ good quality of analysis is crucial in avoiding false positive as well as false negative test results. Finally, since laboratory test results are often used interchangeably at different levels of care, the quality of results should be comparable.²⁵

Most cholesterol concentrations obtained by the Reflotron users in this study were of acceptable quality. However, about 25% of Reflotron users (Table 2) fail to achieve the present American standard for cholesterol accuracy of a maximum of 5% bias,²⁶ and the Norwegian laboratories in this study (Table 2) and American laboratories²⁶ fared no better. Regarding precision in determining cholesterol concentration, the Reflotron users in this study were well within the present requirement of a maximum coefficient of variation of 5%,²⁶ and the coefficients of variation for cholesterol concentration determined by Reflotron presented here, are consistent with those obtained by others.^{6,8,13,27,28} These results for cholesterol performance indicate that cholesterol screening, if it is agreed to be desirable, might be accurately and precisely done in primary care although studies have shown discrepancies between Reflotron users' and laboratories' results which would be of clinical importance; in some instances apparently as a result of poor technique and the use of outdated test strips.^{11,16,29,30} However, assuming that the prevalence of hypercholesterolemia is 25%, a positive predictive value of 0.92 and a negative predictive value of 0.93 have been demonstrated when using the Reflotron for screening purposes with a reference laboratory method as the 'gold standard'.³¹ These figures are much higher than those obtained in other initial screening tests.³¹

Analysis of glucose with traditional glucose meters has proved inaccurate and of variable precision in several studies.^{15,32-34} The Reflotron appears capable of providing high quality results for glucose concentration in primary care, which are particularly important when excluding the possibility of diabetes. However, it cannot be concluded from this data that Reflotron measurements can be used for diagnosing diabetes mellitus.

Many respondents in occupational health care and general practice in the UK reported that test results were ready before the patient left. The results could thus be used in the encounter, possibly enhancing clinical effectiveness. However, test results in many Norwegian general practices were not ready when the patient was still present. The advantage to both doctor and patient is then far less; if tests are not obtained sufficiently quickly as to be used in the consultation, then in most instances they could probably just as well be carried out by a laboratory.^{12,35} The question of what laboratory tests should be done in primary care should reflect clinical need more than ability to perform the tests, or whether the test earns a fee.^{21,35,36}

Many Reflotron users in this study performed internal quality control tests sporadically or not at all, especially in Norway. These users are therefore unable to demonstrate a stable, satisfactory quality of analysis, and this may well have medicolegal consequences.²² In addition, operational problems affecting the quality of analysis may not be detected. Ignorance concerning the importance of internal quality control tests, and the non-technical nature of performing tests, may lead users to rely solely on external quality assessment, or on occasionally sending serum for simultaneous testing in a laboratory; some of the users in this survey actually commented that this was the case. However, external quality assessment should be additional and complementary to internal quality control, in order to ensure accuracy.

As analytical quality is increasingly embodied in and determined by the technology, correct sampling technique is para-

mount. Determination of cholesterol concentration using a Reflotron has been shown to deteriorate when capillary blood specimens were collected by laymen.²⁷ Capillary blood is presumably the test material of choice when few constituents are assayed, as reflected in the responses from UK general practice, and in the relatively high combined use of both capillary blood and anticoagulated blood or serum in Norway. However, variability when obtaining capillary blood is likely to be greater than with conventional venous specimens,¹⁶ although the finding that most instruments are operated by one person probably improves the quality of results by reducing analytical imprecision. Thus, quality assurance in primary care must encompass the entire procedure, for example by certifying operators, and not just focus on quality control sample testing. Further, as the measurement of cholesterol concentration using a Reflotron has been studied extensively, it is known that some batches of reagent strips are less accurate than others.³⁷ It is not known if this batch variation also applies to other blood constituents, and this could not be evaluated in this study. However, quality assurance systems must be designed to detect this possibility.

In conclusion, the Reflotron seems suitable for use in primary care. Nevertheless, good routine quality of analysis must be ensured, primarily through collaboration between primary care users and clinical chemists. Guidelines for the proper use of these instruments should be established, thereby sending important signals both to instrument manufacturers and public health authorities.

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