Labstand: A Computerized System for Reporting Clinical Laboratory Data in Standard Units

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A computerized system, Labstand, is described which was developed to simplify the presentation of laboratory data for the clinician. It converts data into standard units (su) on a scale of 0 to 100, identical for all tests. Conversions are based on both normal and abnormal ranges, determined from clinical experience, to allow both immediate recognition of abnormality and estimation of the degree of abnormality. This paper reports the findings of a study using this system which involved 1,412 abnormal laboratory results. Overall, both recognition and follow-up rates were higher when Labstand was used, but not to a statistically significant level. However, significantly higher follow-up rates were found when Labstand was used by residents with lower than average Internal Medicine National Board scores. In contrast, follow-up was higher when normal range laboratory reports were used by residents with higher than average scores. These findings seem consistent with the fact that use of Labstand requires minimal knowledge of ranges and biological measurement units and may indicate that the lower scoring residents have a greater need for such a new system than do the higher scoring residents.

The development of numerous diagnostic laboratory tests has had a significant impact upon clinical medicine. It is estimated that more than two billion such tests are performed in the United States each year.[1] Proper use of these tests for the benefit of patients presents both a challenge and a problem for clinicians. Several studies have indicated that clinicians do not recognize, or perhaps choose to ignore, many abnormal laboratory tests.[2-5] The reasons for this phenomenon are not clear, but efforts have been made in the past to develop systems which might simplify the presentation of laboratory data for the practitioner.[6-9] The present study reports the trial of a new system, called Labstand, in the ambulatory primary care setting.
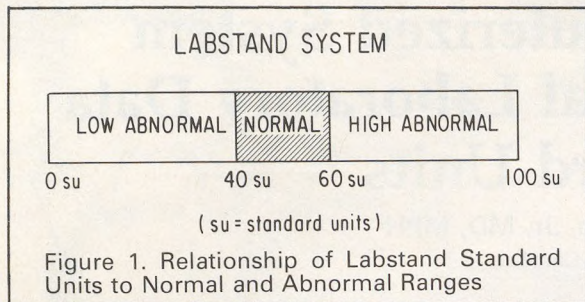
Methods

Description of the Labstand Standard Reference System

Labstand is a system that translates laboratory values into standard units, uniform for all tests, with the goal that brief inspection of any labora-

LABSTAND SYSTEM

| LOW ABNORMAL | NORMAL | HIGH ABNORMAL |

0 su   40 su   60 su   100 su

(su = standard units)

Figure 1. Relationship of Labstand Standard Units to Normal and Abnormal Ranges

tory report will reveal immediately whether the result is normal or abnormal, high or low, and to what degree. This process requires of the reader no knowledge of the normal or abnormal ranges for the laboratory tests.

Data are converted by computer into standard units (su) on a scale of 0-100 su, where 0-39.99 su always represents the *low abnormal range,* 40-59.99 su: the *normal range,* and 60-100 su: the *high abnormal range* (Figure 1). Zero represents the "lowest expected" abnormal value for a particular laboratory test in the clinical setting, and 100 su, the "highest expected" abnormal. These outer boundaries of abnormality are estimated from information on disease in the medical literature, and the normal ranges are those in use by the laboratory* performing all the tests during the present study. The ranges for these tests are shown in Table 1 and the literature sources used for estimation of abnormal ranges in Table 2.

The formula for converting conventional units to Labstand units is:

$$X = B + [(A-B)(y-b) \div (a-b)]$$

in which:

X = Labstand standard reference units (su)

y = conventional laboratory value to be converted

A = highest value in the appropriate standard unit range, namely: 39.99 su for a low abnormal, 59.99 su for normal, and 100 su for high abnormal.

B = lowest value in the appropriate standard

unit range, namely: 0 su for low abnormal, 40 su for normal, and 60 su for high abnormal.

a = highest value in the appropriate conventional value range for the particular laboratory test (Table 1)

b = lowest value in the appropriate convention value range for the particular laboratory test (Table 1)

Example: Convert the serum uric acid value of 11.3 mg/100 ml into Labstand standard units (su). Since the value lies within the high abnormal range (Table 1 shows the range to be 8.1-20.0 mg/100 ml), the high range values are used in the computation:

$$X = 60 + [(100-60)(11.3-8.1) \div (20.0-8.1)]$$
$$= 70.76 \text{ su}$$

Given this Labstand value of 70.76 su for uric acid, it is readily apparent that the result is abnormal, high, and approximately 25 percent as high as it could get, ie, 70.76 su lies at a point approximately 25 percent of the full range from 60 su to 100 su.

If a value of 70.76 su were reported for serum glucose, it would indicate the identical relative degree of clinical abnormality, but would have been derived from a conventional glucose value of 349.5 mg/100 ml using the following computation:

$$X = 60 + [(100-60)(349.5-110.1) \div (1000-110.1)] = 70.76 \text{ su}$$

Thus, comparable numerical values are produced for different tests having different conventional ranges.

Study Design

The study was conducted in the Duke-Watts Family Medicine Center during the first four months of 1976, at which time there were 6,196 registered patients and 7,066 patient encounters. Of these, only the adult patients (age 18 years or older) of resident physicians were studied. These physicians were 27 family medicine residents, 12 of whom were in their first year of training, 11 in their second, and 4 in their third. Of these, 25 were recent graduates of 20 different US medical schools and two were foreign medical graduates.

Laboratory reports on 30 frequently requested tests (23 blood chemistry tests and seven hematology tests listed in Table 1) were converted into computerized reports, half of which were displayed in normal ranges following the con-

*National Health Laboratories, Winston-Salem, North Carolina.

Table 1. Adult Normal and Abnormal Ranges for Frequently Requested Blood Tests
Abnormal ranges, from medical literature. See Table 2 for references.
Normal ranges, from National Health Laboratories, Winston-Salem, NC, 1976.

Laboratory Test	Units of Measurement	Low Abnormal Range Lowest Expected	Low Abnormal Range Upper Limit	Normal Range Lower Limit	Normal Range Upper Limit	High Abnormal Range Lower Limit	High Abnormal Range Highest Expected
1. Glucose	mg/100 ml	20.0	64.9	65.0	110.0	110.1	1000.0
2. Calcium	mg/100 ml	5.0	8.4	8.5	11.0	11.1	23.6
3. Phosphorus	mg/100 ml	1.4	2.4	2.5	4.5	4.6	12.0
4. Alkaline Phosphatase	mu/ml	0.0	29.9	30.0	115.0	115.1	2850.0
5. Cholesterol	mg/100 ml	20.0	149.9	150.0	300.0	300.1	2000.0
6. Triglycerides	mg/100 ml	0.0	29.9	30.0	200.0	200.1	10000.0
7. BUN	mg/100 ml	2.0	9.9	10.0	25.0	25.1	200.0
8. Creatinine	mg/100 ml	*	*	0.7	1.4	1.5	20.0
9. Uric Acid	mg/100 ml	0.2	2.4	2.5	8.0	8.1	20.0
10. Total Protein	gm/100 ml	3.0	5.9	6.0	8.0	8.1	10.0
11. Albumin	gm/100 ml	1.1	3.4	3.5	5.0	5.1	5.6
12. Globulin	gm/100 ml	1.9	2.4	2.5	3.2	3.3	9.0
13. A/G Ratio	—	0.12	0.8	0.9	1.9	2.0	2.07
14. Total Bilirubin	mg/100 ml	*	*	0.2	1.5	1.6	45.0
15. Direct Bilirubin	mg/100 ml	*	*	0.2	0.5	0.6	25.0
16. Indirect Bilirubin	mg/100 ml	*	*	0.2	1.0	1.1	45.0
17. SGOT	mu/ml	*	*	7.0	40.0	40.1	4000.0
18. SGPT	mu/ml	*	*	7.0	40.0	40.1	4000.0
19. LDH	mu/ml	*	*	100.0	225.0	225.1	4000.0
20. Sodium	mEq/liter	110.0	134.9	135.0	145.0	145.1	175.0
21. Potassium	mEq/liter	2.0	3.4	3.5	5.0	5.1	10.0
22. Chloride	mEq/liter	84.0	94.9	95.0	105.0	105.1	135.0
23. CO_2	mEq/liter	2.0	23.9	24.0	32.0	32.1	60.0
24. WBC	thou/cmm	0.05	4.7	4.8	10.8	10.9	500.0
25. RBC male	mil/cmm	0.5	4.3	4.4	6.0	6.1	12.0
female	mil/cmm	0.5	4.1	4.2	5.4	5.5	12.0
26. Hemoglobin male	gm/100 ml	2.0	12.9	13.0	17.0	17.1	24.0
female	gm/100 ml	2.0	11.9	12.0	16.0	16.1	24.0
27. Hematocrit male	%	5.0	40.9	41.0	51.0	51.1	92.0
female	%	5.0	36.9	37.0	47.0	47.1	92.0
28. MCV	cu	53.0	79.9	80.0	96.0	96.1	160.0
29. MCH	uug	14.0	26.9	27.9	31.0	31.1	56.0
30. MCHC	%	22.0	31.9	32.0	36.0	36.1	39.0

*Values below normal not expected clinically.

Table 2. Derivation of Abnormal Ranges
Medical literature sources for outer limits of abnormal ranges,
with examples of diseases causing laboratory values at the high and low clinical extremes.

Laboratory Test	Diseases with Extreme Laboratory Values				
	With Lowest Expected Clinical Values	Reference No./Page		With Highest Expected Clinical Values	Reference No./Page
1. Glucose	Islet cell tumor	10	797	Diabetic ketoacidosis	10	380
2. Calcium	Hypoparathyroidism	11	324	Hyperparathyroidism	12	177
3. Phosphorus	Hyperparathyroidism	12	177	Hypoparathyroidism	11	324
4. Alkaline Phosphatase	Hypophosphatasia	11	325	Cirrhosis or amyloidosis	13	824*
5. Cholesterol	Abetalipoproteinemia	13	634	Hyperlipoproteinemia IV	13	627
6. Triglycerides	Abetalipoproteinemia	13	634	Hyperlipoproteinemia I, IV, V	13	627
7. BUN	Rehydration after dehydration	14	493	Renal failure	13	592
8. Creatinine	****	-	-	Renal failure	13	593
9. Uric Acid	Hereditary xanthinuria	15	744	Leukemia	22	1690
10. Total Protein	Intestinal lymphangiectasia	16	1645	Postnecrotic cirrhosis	13	814**
11. Albumin	Intestinal lymphangiectasia	16	1645	Dehydration	17	57
12. Globulin	Intestinal lymphangiectasia	16	1645	Postnecrotic cirrhosis	13	814
13. A/G Ratio	Postnecrotic cirrhosis	13	814***	Dehydration	17	57***
14. Total Bilirubin	****	-	-	Crigler-Najjar syndrome	11	190
15. Direct Bilirubin	****	-	-	Obstructive jaundice	18	130
16. Indirect Bilirubin	****	-	-	Crigler-Najjar syndrome	11	190
17. SGOT	****	-	-	Acute hepatic necrosis	13	826
18. SGPT	****	-	-	Acute hepatic necrosis	13	827
19. LDH	****	-	-	Megaloblastic anemia	13	852-853
20. Sodium	Water intoxication	19	1621	Osmotic diuresis	19	1624
21. Potassium	Acidosis	19	1625	Renal failure	19	1628
22. Chloride	Respiratory acidosis	20	195	Dehydration & renal failure	21	174
23. CO$_2$	Diabetic ketoacidosis	10	380	Zollinger-Ellison syndrome	19	1636
24. WBC	Agranulocytosis	22	1298	Leukemia	19	1542
25. RBC	Megaloblastic anemia	19	1468	Polycythemia vera	22	992
26. Hemoglobin	Aplastic anemia	23	259	Polycythemia vera	22	993
27. Hematocrit	Megaloblastic anemia	22	568	Polycythemia vera	22	992
28. MCV	Iron deficiency anemia	22	657	Megaloblastic anemia	22	568
29. MCH	Iron deficiency anemia	22	657	Megaloblastic anemia	22	568
30. MCHC	Iron deficiency anemia	22	657	Hereditary spherocytosis	22	753

*Estimated as follows: 100 Bodanski units x 28.5 (conversion factor furnished by National Health Laboratories) = 2850 mu/ml
**Estimated from highest globulin (9.0 gm) and lowest albumin (1.1 gm)
***Estimated from values of total protein, albumin and globulin
****Diseases with low values not identified

ventional laboratory values (Figure 2) and half in Labstand standard units following the conventional values (Figure 3). Residents were stratified according to year of training and randomly divided into two groups. While one group received laboratory reports showing normal ranges, the other received Labstand reports. Each group used each type of laboratory report half of the study period. The residents were aware that a study was being conducted to test the new system but otherwise had only minimum details.

Conventional laboratory values were entered into the computer through a cathode ray terminal in the Family Medicine Center by the medical technologist. In addition to computing Labstand values, the computer stored the laboratory data with demographic and other clinical data on each patient, selected the appropriate laboratory report format for each resident according to which type his group was receiving at the time, displayed the data on the laboratory report, and listed on computer printout all abnormal laboratory test results

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Laboratory Report - Family Medicine Center 04/20/76

John Doe   ID #01-125-48   By: Dr. Smith
Age: 55

Tests		Normal Range
GLU	158.0 MG/100 ML	65.0-100.0
CA	11.9 MG/100 ML	8.5-11.0
PHOS	3.3 MG/100 ML	2.5-4.5
ALK PHOS	43.3 MU/ML	30.0-115.0
CHOL	219.0 MG/100 ML	150.0-300.0
TRIG	115.0 MG/100 ML	30.0-200.0
BUN	71.0 MG/100 ML	10.0-25.0
CREAT	3.3 MG/100 ML	.7-1.4
URIC A.	11.3 MG/100 ML	2.5-8.0
T.P.	6.8 GM/100 ML	6.0-8.0
ALB	3.4 GM/100 ML	3.5-5.0
GLOB	3.4 GM/100 ML	2.5-3.2
A/G	1.0 -	.9-1.9
T BIL	.6 MG/100 ML	.2-1.5
D BIL	.2 MG/100 ML	.2-.5
I BIL	.4 MG/100 ML	.2-1.0
SGOT	25.0 MU/ML	7.0-40.0
SGPT	15.0 MU/ML	7.0-40.0
LDH	189.0 MU/ML	100.0-225.0
NA	131.0 MEQ/LITER	135.0-145.0
K	4.8 MEQ/LITER	3.5-5.0
CL	107.0 MEQ/LITER	95.0-105.0
CO_2	13.0 MEQ/LITER	24.0-32.0
WBC	9.0 THOU/CMM	4.8-10.8
RBC	4.18 MIL/CMM	4.4-6.0
HGB	10.5 GM/100 ML	13.0-17.0
HCT	32.5%	41.0-51.0
MCV	76.0 CU	80.0-96.0
MCH	24.7 UUG	27.0-31.0
MCHC	31.6%	32.0-36.0

Figure 2. Sample Laboratory Report Using Normal Ranges

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for use of those conducting the study.

Other data were collected from the medical records of those patients with abnormal values. This was facilitated by the problem-oriented records in use by all residents. All medical record reviews were conducted by the principal investigator. Most were done one to three months after the date of the laboratory test, with a minimum of one month, a maximum of six months, and a mean of 63 days.

Recognition and follow-up of abnormal laboratory tests were used to measure outcome. The criteria for each category were as follows:

A. *Both Recognition and Follow-up*
1. Repeat of the laboratory test.
2. Change in diagnostic and/or therapeutic plans as a result of the test.
3. Explanation in the progress notes as to why such steps (as 1 and 2 above) were not taken.

Laboratory Report - Family Medicine Center 04/20/76

John Doe   ID #01-125-48   By: Dr. Smith
Age: 55

Tests		Standard Units (su)
GLU	158.0 MG/100 ML	62.15 su
CA	11.9 MG/100 ML	62.56 su
PHOS	3.3 MG/100 ML	48.00 su
ALK PHOS	43.3 MU/ML	43.13 su
CHOL	219.0 MG/100 ML	49.20 su
TRIG	115.0 MG/100 ML	50.00 su
BUN	71.0 MG/ 100 ML	70.50 su
CREAT	3.3 MG/100 ML	63.89 su
URIC A.	11.3 MG/100 ML	70.76 su
T.P.	6.8 GM/100 ML	48.00 su
ALB	3.4 GM/100 ML	39.99 su
GLOB	3.4 GM/100 ML	60.70 su
A/G	1.0 -	42.00 su
T BIL	.6 MG/100 ML	46.15 su
D BIL	.2 MG/100 ML	40.00 su
I BIL	.4 MG/100 ML	45.00 su
SGOT	25.0 MU/ML	50.90 su
SGPT	15.0 MU/ML	44.85 su
LDH	189.0 MU/ML	54.23 su
NA	131.0 MEQ/LITER	33.73 su
K	4.8 MEQ/LITER	57.32 su
CL	107.0 MEQ/LITER	62.54 su
CO_2	13.0 MEQ/LITER	20.09 su
WBC	9.0 THOU/CMM	54.00 su
RBC	4.18 MIL/CMM	38.73 su
HGB	10.5 GM/100 ML	31.18 su
HCT	32.5%	30.63 su
MCV	76.0 CU	34.19 su
MCH	24.7 UUG	33.17 su
MCHC	31.6%	38.78 su

Explanatory Note: In the Labstand standard unit system:
0-39.99 su always represents the clinical LOW ABNORMAL RANGE,
40-59.99 su always represents the clinical NORMAL RANGE,
60-100 su always represents the clinical HIGH ABNORMAL RANGE, and
<0 or >100 su means the test value is outside the range of clinically expected values.

Figure 3. Sample Laboratory Report Using Labstand Standardized Units

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Table 3. Family Medicine Residents' Performance on Internal Medicine National Board Examination (Part II)
(Raw Score Figures, September 1975)

	Number of Candidates	Range of Scores	Median Score	Mean Score	Standard Deviation
Family Medicine Residents	23	360-670	505	500	84
Overall US Candidates	4,300	240-710	*	489	94

*Information not available.

(The emphasis here was on the decision of the resident as a result of the abnormal test, rather than the actual final outcome. For example, if a notation was made in the record that the patient was advised to return for further study, this was counted as positive follow-up, even if the patient never actually returned as instructed.)

B. *Recognition but No Follow-up*

1. Notation in the progress notes or on the problem list that the result was abnormal, but then no follow-up.
2. Circling or otherwise specially marking the abnormal result on the laboratory sheet, but then no follow-up.

C. *Neither Recognized Nor Followed Up*

No evidence in the medical record of acknowledgement of the abnormality, according to the criteria for A and B above.

For the analyses, recognition was defined as acknowledgement by the doctor on the medical record that the test result was abnormal. Therefore, it included both those values recognized and followed up, and those recognized and not followed up (categories A and B combined). Follow-up included only those abnormals both recognized and followed up (category A). Recognition and follow-up were not intented to be mutually exclusive and were analyzed separately.

The principal factor studied was "type of laboratory report," comparing the effect of the Labstand system with that of the normal range system. The hypothesis was that the Labstand report would be associated with higher rates of recognition and follow-up of abnormal laboratory values than the conventional normal range report.

Other factors studied for possible effect on the association between type of laboratory report and recognition and follow-up were:

1. *Degree of abnormality of the laboratory value:* Since the Labstand values are derived from abnormal ranges based on the range of clinical abnormality, they were used as the basis for determining two classes of degree of abnormality. Labstand values of 36.00 to 39.99 su in the low abnormal range and those of 60.01 to 64.00 su in the high abnormal range were classed as one to ten percent of maximum clinical abnormality. Values of 0.00 to 35.99 su in the low range and those of 64.01 to 100.00 su in the high range were classed as greater than ten percent abnormal.
2. *Indication for obtaining the laboratory test:* From information on the medical records, it was determined whether the test was obtained for health maintenance reasons only or whether a medical problem was the basis.
3. *Type of laboratory test:* Chemistry or hematology
4. *Resident's year of training:* First, second, or third year

5. *Resident's Internal Medicine National Board (Part II) Score:*
The 23 residents who took the examination were divided into a high score group (12 with scores above the average for the group) and a low score group (11 with scores below the average). Table 3 shows the comparison of their performance with that of all National Board candidates in September 1975. The residents'

mean is higher than the national average (500 vs 489), the variance is smaller (standard deviation of 84 vs 94), and the range is not as wide (360-670 vs 240-710). In spite of these differences, there is a remarkable similarity, particularly when considering the small size of the study group, indicating that the residents' scores are to a high degree representative of the entire candidate population.

Table 4. Reasons for Exclusion of Some Abnormal Laboratory Values from Analyses		
Reason for Exclusion		**Count**
1. Repeat laboratory tests for the same patient. (Only tests from the initial encounter were used.)		83
2. No verification that resident saw the laboratory report. (Verification was based on resident's initialing the report.)		27
3. False positive laboratory results given to the resident:		
a. Due to change in normal range by the laboratory during the study.		72
b. Due to inadvertent use of female normal ranges for males (RBC, HGB, HCT).		13
c. Due to faulty operation of the laboratory auto-analyzer.		56
d. Due to undetermined causes.		5
Subtotal	146	146
4. False negative laboratory results given to the resident. (All of these were due to change of normal range by the laboratory during the study.)		125
5. Missing Values (Information not obtained from medical record review.)		31
Total Itemized Exclusions		412
Subtract for tests having dual indication for exclusion		–8
Total Laboratory Values Excluded		404
Abnormal Laboratory Values Before Exclusions	1412	
Laboratory Values Excluded	–404 (28.6 percent)	
Laboratory Values Used in Analyses	1008	

Statistical Methods

All statistical evaluations of rate differences in this study were done using the Chi-square statistic.

Results

Data were collected on 1,412 abnormal laboratory test results. Of these, 404 values were excluded, leaving 1,008 abnormal values from 296 patients for the analysis in this report. Reasons for exclusion are detailed in Table 4. Of these excluded tests, 197 were due to change in normal limits by the laboratory, which were unrecognized initially by the investigator. The range alterations accompanied the changeover to a new type of auto-analyzer. Another group of 56 exclusions resulted from faulty operation of the auto-analyzer.

Overall, both recognition and follow-up rates were higher when Labstand laboratory reports were used than when normal ranges were used, but these differences were not statistically significant. Recognition was 42.2 percent with Labstand, compared with 38.4 percent with normal ranges (.2<P<.3). Follow-up was 26.6 percent with Labstand, compared with 24.2 percent with normal ranges (.4<P<.5).

Statistically significant differences were found, however, when the abnormal laboratory values from patients of residents with higher than average National Board scores were analyzed separately from those of residents with lower than average scores. As shown in Figure 4, those with higher scores had a higher follow-up rate using normal range reports (35.6 percent) than when using Labstand reports (18.2 percent), while in contrast, the residents with lower scores had a higher rate using Labstand (32.2 percent) than when using normal ranges (21.5 percent). The P-value for the high score analysis was P<.0005, and for the low score, .005<P<.01.

The other factors studied had no significant effect on the association between type of laboratory report and recognition and follow-up rates.

Figure 4. Effect of Internal Medicine National Board Scores and Type of Laboratory Report On Follow-up of Abnormal Values
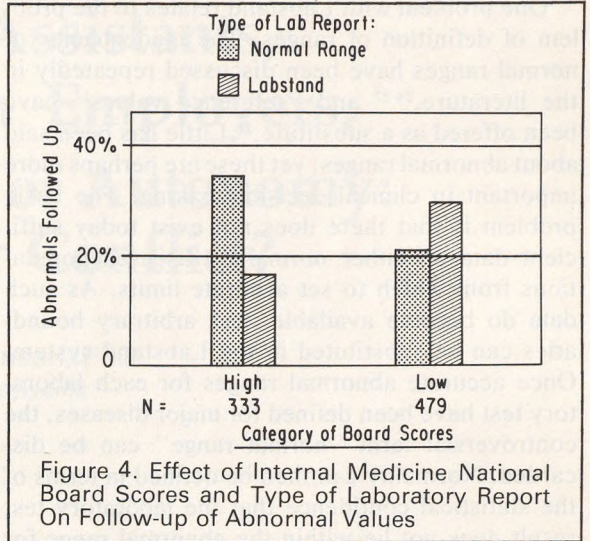
Discussion

Most of the findings from this study do not support, to a statistically significant level, the hypothesis that the Labstand standardized system is associated with higher recognition and follow-up than the conventional normal range system. However, the significant difference between follow-up rates of high scoring and low scoring residents is remarkable. One way to interpret these results, assuming that Board scores are indicative of cognitive skills related to management of medical problems, is that residents with higher than average scores do not need the additional help offered by Labstand in identifying abnormals and their degree of abnormality, as much as do those residents with lower scores. There is the further implication that Labstand may be of particular value to health-care professionals whose training may not include intensive exposure to clinical pathology. This could be important as more physician's associates, nurse practitioners, and medical technologists become actively involved in patient management.

One problem with Labstand relates to the problem of definition of ranges. The inadequacies of normal ranges have been discussed repeatedly in the literature,[24-27] and "reference values" have been offered as a substitute.[28] Little has been said about abnormal ranges; yet these are perhaps more important in clinical decision-making. The basic problem is that there does not exist today sufficient data on either normal or diseased populations from which to set accurate limits. As such data do become available, less arbitrary boundaries can be substituted in the Labstand system. Once accurate abnormal ranges for each laboratory test have been defined for major diseases, the controversial term "normal range" can be discarded. Normality can then be defined in terms of the statistical confidence that the laboratory test result does not lie within the abnormal range for any known disease.

One question concerning the present study is whether or not it represents an adequate trial of the standardized system. It probably does not, primarily because most of the 30 laboratory tests studied are so frequently obtained that their normal ranges are familiar to most residents. A trial is needed which includes less familiar tests, eg, serum magnesium or vitamin B-12 levels. Such a study, impossible in the primary care ambulatory setting because of the small numbers of such tests, would have to be conducted within the hospital.

Labstand represents only a beginning in development of a simplified reporting system to aid the clinician. It should be retested, revised, and refined because the number and complexity of laboratory tests will most certainly increase with the continued expansion of technology in medicine.

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