Evaluation of an Automated Blood Pressure Measuring Device Intended for General Public Use

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Abstract: Responding to Chicago newspaper reports, measurements of blood pressure by a publicly available, automated coin-operated device were compared with those of human observers using the standard cuff and auscultatory technique. One machine was examined in the laboratory, and eight others at randomly selected sites. Analysis of readings made on 100 persons in the laboratory and 227 in the field led to the following conclusions: 1) On the average, the machines measured fifth phase diastolic blood pressure at nearly the same level as did human observers; 2) The machines were more variable measuring systolic blood pressure with four differing from the average human reading by 1mm Hg or less, but two differing by 8mm Hg or more; 3) The agreement between machine-human pairs of readings was not as good as between human-human pairs, but the differences in level of agreement—both in determining the actual value and in categorizing the values as normal, borderline, or high—were small and have little practical importance; 4) Linear regression analyses of the relationship between simultaneously determined machine and human readings indicated that the average human-machine difference was the same over the range of pressures tested. Publicly available blood pressure measuring devices should be labeled concerning their purposes, capabilities, and limitations. Rules and regulations governing their use in the City of Chicago are being prepared by this city's Legal Department. (Am. J. Public Health 69:473-479, 1979.)

Introduction

The past decade has witnessed major advances in the detection, treatment, and control of hypertension.[1-5] Large scale screening programs and mass education efforts for the public and medical profession have helped achieve this progress.[6,7] To aid in the screening programs, many paramedical and lay people have been trained to measure blood pressure accurately. In addition, automated devices for blood pressure measurement have been developed. Most of the early machines were found to be inadequate, mainly because of marked deviations of the readings from the standard mercury sphygmomanometer or serious operating difficulties.[8-11]

More recently a second generation of automated BP measurement devices, intended for general public use, have begun to appear. Coin-operated devices of this type introduced into the Chicago area in 1977 are now located in drug stores, supermarkets, shopping centers, and department stores. Late in 1977, an article appeared in a Chicago newspaper questioning the accuracy of these coin-operated devices. This report was followed by editorials urging the City to investigate these machines with an eye toward possible regulation. The Chicago Department of Health accordingly ordered an evaluation by its Heart Disease Control Program of the Vita Stat,* the major prototype machine in the Chicago area, to determine whether a City Ordinance was necessary to protect the public. The Department of Preventive Medicine of Rush-Presbyterian-St. Luke's Medical Center was consulted and planned the statistical design of the study. This report details the results of this investigation.

Methods

The Vita-Stat is an automatic, coin-operated device that measures both systolic and diastolic blood pressure. A microphone is mounted in a looped cuff so as to be near the brachial artery when the arm is inserted. The automatic operation and signal processing is controlled by a microprocessor. After a start button is pressed, the cuff inflates to 160mm Hg. If Korotkoff sounds are sensed at that pressure, inflation is continued in 20mm Hg. increments until Korotkoff sounds are no longer sensed or until a maximum pressure of 220mm Hg. is reached. The cuff then deflates in 4–6mm Hg. decrements. There is a brief pause after each decrement to determine the presence or absence of Korotkoff sounds. Systolic blood pressure is registered at the appearance of the Korotkoff sounds and diastolic blood pressure at their disappearance. Various techniques are used to reject readings due to artifacts.

Six human observers were used to test the machine un-

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der laboratory as well as field conditions. One observer was an internist, one a trained technician with the Chicago Heart Association, one a Public Health Administrator trained in blood pressure measurement, and three were trained hypertension technicians employed by the Chicago Department of Health in its blood pressure screening program. All technicians and the Public Health Administrator used a standard procedure recommended by the American Heart Association.**

One machine*** was compared with results obtained by six human observers in the laboratory, where each of 100 participants had his or her blood pressure measured twice by the machine and twice by each of two human observers. The order in which these determinations were taken was varied randomly from subject to subject so as to avoid confounding the effects of sequence with comparisons between human and machine determinations. Each human observer measured blood pressure without knowing the values obtained previously by the machine or by other observers.

In addition to these sequentially determined measurements, a human observer also measured blood pressure simultaneously with each machine determination—i.e., during the machine's inflation-deflation cycle—by listening for Korotkoff sounds through a stethoscope placed over the antecubital space distal to the machine's cuff and reading pressure from a mercury manometer connected to the machine's cuff.

In order to maximize the accuracy of estimating relationships between the human and machine determinations, the two readings made by the machine and by each of the three human observers—two measuring sequentially and one simultaneously—were averaged to provide a single "best" estimate by the machine and by each of the three observers, and these mean values were used in the statistical analyses of the laboratory data reported below. Also, for some analyses, the four sequentially determined human readings were averaged to provide a single estimate of human measurement for that person.

Subjects in the laboratory tests were employees of the Chicago Department of Health; special effort was made to obtain similar numbers of males and females, blacks and whites, and young and older adults. Efforts were also made to insure a broad range of blood pressures by including many known hypertensives in the sample.

In addition to the work in the laboratory, eight machines at randomly chosen locations in Chicago were evaluated in comparison with the same two human observers, who traveled from location to location. At each site, 10 to 34 participants (N = 227 participants over all sites) were recruited to have blood pressure measured, twice by machine and once by each of the two observers. The sequence in which the machine and human readings were taken for each participant was randomly selected from a list of all possible sequences. As done in the laboratory, the human observers measured blood pressure without knowing the values obtained previously by the machine or the other human observer.

Some analyses used averages of the two machine readings and averages of the two human readings, but other analyses used the single measurements—for instance, first machine reading and first human reading—in order to estimate results that would occur when blood pressure was measured only once.

Analysis of these data was guided by three questions: On the average, did the machines tend to read blood pressure higher, lower, or the same as the human observers?; Did this average difference tend to be the same across all levels of blood pressure?; Was the agreement between machine and human in measuring blood pressure in the same person as good as the agreement between two humans? The analysis was done for the most part using the SPSS set of computer programs.[13] Agreement in categorizing participants as normal, borderline, or high with respect to blood pressure was assessed by kappa statistic, which can be considered as a percentage agreement adjusted for agreement expected by chance alone.[14] Homogeneity within sets of kappas was tested using the weighted least squares approach of Grizzle, Starmer, and Koch.[15] Homogeneity within sets of correlations was tested using a maximum likelihood procedure as suggested by Joreskog.[16]

Results

Difference in Mean Value between Machine and Human Readings

Table 1 shows the mean differences between the machine and human readings for systolic and diastolic blood pressures taken simultaneously and sequentially in the laboratory. Although statistically significant, the differences were small in magnitude. With respect to systolic pressures, the machine averaged 1.5 mm Hg. lower (P = 0.022) than simultaneously determined human readings, but 3.4 mm Hg. higher (P = 0.001) than sequentially determined human readings. With respect to diastolic blood pressure, the machine averaged 2.6 mm Hg. higher (P = 0.001) than simultaneously determined human readings, but 2.3 mm Hg. lower (P = 0.002) than sequentially determined human readings.

Table 2 shows the mean difference between machine and human readings of blood pressure at each of eight field sites. For systolic blood pressure, the mean differences var-

**First estimating systolic pressure by noting the pressure at which the radial pulse was obliterated, deflating the cuff entirely, reinflating to 20mm Hg. above the estimated systolic pressure, deflating at a rate of 2mm/sec. while listening for the appearance and disappearance of Korotkoff sounds through a stethoscope placed over the brachial artery at the antecubital space, and recording pressure to the closest even number. The internist's methods varied slightly.[12]

***The coin operating portion of the device tested in the laboratory was disconnected by the company prior to its delivery to the Department of Health for testing procedures, thereby obviating the necessity for coin usage during the laboratory analysis.

‡During the field testing, a representative of the Vita-Stat Company was notified the morning of the testing to meet the investigative team at the testing site to provide coins for operation of the machines. This representative took no part in the conduct of the field testing and no representative of the company was involved in any way with the data analysis.

TABLE 1—Differences in Mean Level of Blood Pressure Determined by the Machine and by Human Observers in the Laboratory

Variable (mm Hg)	Machine†		Human†		Difference			
	Mean	SD	Mean	SD	Mean	SD	N	95% confidence interval
Laboratory, Simultaneous Determinations								
Systolic BP	129.3	21.3	130.8	21.2	−1.5	6.5	100	−2.8 to −0.2
Diastolic BP	80.9	12.7	78.4	13.0	2.6	4.1	100	1.7 to 3.4
Laboratory, Sequential Determinations								
Systolic BP	129.3	21.3	125.9	19.2	3.4	10.1	100	1.4 to 5.4
Diastolic BP	80.9	12.7	83.2	10.7	−2.3	7.0	100	−3.7 to −0.9

†Each value entering these analyses was the mean of two machine determinations or the mean of two human determinations.
BP = blood pressure
N = number of observations
SD = standard deviation

ied from −5.7 mm Hg. (machine lower than human) to 12.9 mm Hg. (machine higher than human), while for diastolic pressure the mean differences varied from −3.5 to 3.0 mm Hg. Analysis of variance indicated that this sample of machines was homogeneous with respect to mean machine-human differences in reading diastolic pressure and, assuming a random effects model, the overall mean difference was 0.5 mm Hg. with 95 per cent confidence interval of −1.4 to 2.5 mm Hg. However, the sample of machines was not homogeneous with respect to mean machine-human difference in measuring systolic pressure; therefore, an overall mean difference was not calculated.

Linear Association between the Human and Machine Readings

Linear regression analysis of human blood pressure readings on simultaneously determined machine readings was performed. Correlations of 0.95 for both systolic and diastolic pressures indicated a very good fit of these data to

TABLE 2—Mean Difference between Paired Machine and Human Blood Pressure Determinations at Each of Eight Field Sites

Site No.	Machine		Human		Difference			
	Mean	SD	Mean	SD	Mean	SD	N	95% confidence intervals
Systolic Blood Pressure, mm Hg								
1	136.1	18.1	136.3	19.5	−0.1	11.3	30	−4.3 to 4.1
2	143.5	21.0	142.5	19.3	1.0	9.6	33	−2.3 to 4.4
3	137.8	13.8	133.6	13.9	4.2	9.5	30	0.7 to 7.8
4	138.1	18.4	143.8	20.0	−5.7	6.5	29	−8.2 to 3.2
5	152.1	18.6	151.4	17.8	0.7	9.5	32	−2.8 to 4.1
6	158.4	35.5	145.5	28.7	12.9	10.0	10	5.8 to 20.0
7	134.2	18.0	126.2	17.2	8.0	7.2	29	5.2 to 10.8
8	147.1	22.2	147.9	27.6	−0.8	10.6	34	−4.4 to 2.9
All†								
Diastolic Blood Pressure, mm Hg								
1	79.9	13.1	83.4	9.6	−3.5	8.4	30	−6.6 to −0.3
2	90.4	10.5	87.4	9.8	3.0	7.0	33	0.5 to 5.5
3	91.7	10.1	89.6	8.3	2.1	5.4	30	0.1 to 4.1
4	87.3	11.2	89.3	11.4	−2.0	8.2	29	−5.1 to 1.1
5	86.8	11.1	84.8	10.3	2.0	7.0	32	−0.5 to 4.5
6	90.0	16.4	87.3	9.9	2.7	9.4	10	−4.0 to 9.4
7	82.4	14.4	81.9	10.9	0.5	6.6	29	−2.0 to 3.0
8	82.0	13.5	81.6	11.5	0.4	7.2	34	−2.1 to 2.9
All†					0.5	2.4	8	−1.4 to 2.5

†The standard deviations and 95 percent confidence intervals for mean differences over all eight sites have been calculated using a random effects model. An overall mean difference for systolic blood pressure was not calculated because statistical analysis revealed that the sample of machines was not homogeneous in mean machine-human difference.
N = number of observations
SD = standard deviation

the linear model. For systolic pressure, the slope was 0.950 with 95 per cent confidence interval of 0.89 to 1.01. The slope for diastolic blood pressue was 0.973 with 95 per cent confidence interval of 0.91 to 1.04. These observed values for the slopes were not significantly different from 1, and it is reasonable to conclude—for the simultaneous determinations, at least—that the average machine-human difference was the same over the range of pressures examined here.

Reliability of Categorizing Blood Pressure

The human and machine readings of blood pressure were analyzed for agreement in categorizing persons as normal, borderline or high with respect to systolic pressure only, diastolic pressure only, and both systolic and diastolic pressures considered jointly.‡‡

Results from the field studies are summarized in Table 3. With respect to systolic pressure only, two human observers agreed in classifying 77.5 per cent of 227 persons as normal, borderline, or high. After adjusting for agreement expected by chance, the value for kappa was 64.2. The agreement between pairs of machine determinations was somewhat lower (70.5 per cent, κ 54.3), and the machine-human level of agreement was slightly lower still (69.2 per cent, κ 52.7). However, a test for homogeneity indicated that the kappas did not differ significantly among themselves.

With respect to diastolic pressure only, machines in the field were somewhat more reliable than the two human observers. The values of kappa were 61.9 and 48.5 for the machine-machine and human-human comparisons, respectively, while kappa for the machine-human comparison was 44.7. These kappas did vary significantly among themselves; in particular, the machine-machine kappa was significantly higher than the human-human and machine-human kappas.

With respect to classification based on systolic and diastolic pressures jointly, the human-human kappa (61.0) was somewhat higher than either the machine-machine kappa (55.1) or the machine-human kappa (53.3). However, these kappas did not differ significantly among themselves.

Results from the laboratory, shown in Table 4, indicated that the machine-human agreement was less than the human-human agreement for systolic pressure alone and for diastolic pressure alone. However, when using both pressures jointly, the machine-human and human-human reliabilities did not differ significantly, although again the machine-human reliability tended to be somewhat lower than the human-human reliability.

Reliability of Blood Pressure Measurements

Table 5 shows the coefficients of correlation between pairs of pressures measured independently by two humans; by one of the two humans and the machine, and by the other human and the machine. The correlations for systolic pressure were all quite high. The correlations for diastolic pressure are generally somewhat lower, which probably reflects the greater difficulty in ascertaining the fifth Korotkoff phase as compared to the first. Each set of correlations was analyzed to test the hypothesis that differences among correlations within a set were due to sampling variation only, and this hypothesis of homogeneity was rejected ($P < 0.007$) for all four sets. Inspection of the correlations indicated that, in part, the heterogeneity occurred because the human-human

‡‡The criteria for normal, borderline, and high systolic pressure were <140mm Hg, 140-159mm Hg, and 160+ mm Hg, respectively; the corresponding criteria for diastolic pressure were <90mm Hg, 90-94mm Hg, and 95+ mm Hg. The joint criteria for normal were systolic<140mmHg *and* diastolic <90mm Hg; for high they were 160+ mm Hg *or* 95+ mm Hg; the remainder were considered borderline.

TABLE 3—Level of Agreement between Two Independent Human Determinations, between Two Machine Determinations, and between Machine and Human Determinations in Classifying Persons as Normal, Borderline, or High with Respect to Level of Systolic Blood Pressure Only, Diastolic Blood Pressure Only, and Both Pressures Jointly under Field Conditions

	Percentage Agreement			Kappa†		
Comparison	Systolic	Diastolic	Joint	Systolic	Diastolic	Joint
Human-Human	77.5	71.4	74.0	64.2	48.5	61.0
Machine-Machine	70.5	79.7	70.0	54.3	61.9	55.1
Machine-Human	69.2	68.7	69.2	52.7	44.7	53.3
Test for homogeneity of the kappas						
χ^2 (2 degrees of freedom)				4.93	11.37	2.18
P				0.08	<0.01	0.34
Differences between pairs of kappas						
Human-Human vs. Machine-Machine				9.9	−13.4*	5.9
Human-Human vs. Machine-Human				11.5	−3.4	7.7
Machine-Machine vs. Machine-Human				1.6	17.2*	1.8

†Kappa expresses the level of agreement after adjusting for agreement expected on the basis of chance alone
*$P < 0.05$
The systolic criteria for normal, borderline, and high were <140, 140–159, and 160+. The diastolic criteria were <90, 90–94, and 95+. The joint criteria for normal were diastolic <140 *and* diastolic <90; for high the criteria were systolic 160+ or diastolic 95+; the remainder were classified as borderline.

TABLE 4—Differences between Human-Human Reliability (Kappa) and Machine-Human Reliability in Categorizing Blood Pressure as Normal, Borderline, or High: Six Observers and One Machine in the Laboratory

Observer	Systolic Criteria†			Diastolic Criteria†			Joint Criteria†		
	κ with other Human	κ with Machine	Difference	κ with other Human	κ with Machine	Difference	κ with other Human	κ with Machine	Difference
A	55.4	62.2	−6.8	55.0	43.5	11.5*	60.4	49.7	10.7
B	66.8	43.1	23.7*	58.7	39.0	19.7*	53.9	42.9	11.0
C	60.0	48.8	11.2	73.1	73.6	−0.5	71.5	57.4	14.1
D	72.7	65.2	7.5	77.5	49.7	27.8*	69.1	74.5	−5.4
E	64.1	47.9	16.2*	61.8	64.9	−3.1	58.2	53.3	4.9
F	49.2	19.7	29.5*	59.8	58.6	1.2	50.3	56.1	−5.8
Test that the sample differences were drawn from a population with mean difference of zero.									
χ^2 (6 degrees of freedom)			34.32			18.60			9.37
P			<0.001			0.005			0.154

†The systolic criteria for normal, borderline, and high were <140, 140–159 and 160+. The diastolic criteria were <90, 90–94, and 95+. The joint criteria for normal were <140 *and* <90 and for high were 160+ or 95+; the remainder were classified as borderline.

* $P < 0.05$

correlations tended to be slightly larger than the human-machine correlations.

Discussion

The availability of an accurate, automated blood pressure measuring device would enhance mass screening for undetected hypertension, and serve as a convenient, relatively inexpensive way for hypertensive patients to monitor themselves. On the other hand, inaccurate measurement, overreliance on one determination, or a lack of appreciation of the true meaning of one or more blood pressure measurements, whether normal or abnormal, in the evaluation and treatment of hypertension could lead to serious consequences. Because of this potential for good and harm, adequate evaluation of new devices is essential for public protection.

Most of the accumulated knowledge of high blood pressure is based on the auscultatory measurement of blood pressure by a trained observer using a mercury sphygmomanometer and a stethoscope. Any assessment of automated devices, therefore, must compare the new procedure with this method.[9] Unfortunately, there is no blood pressure standard that can be measured by both automated device and observer in assessing accuracy. Therefore, all measurements must be on human beings, and since blood pressure may vary rapidly in man the assessment of accuracy of measurement is difficult.

Three principal questions were addressed in this evaluation of an automated device intended for general public use. The first was whether the machine's readings of blood pressure tended on the average to be higher, lower, or the same as readings made by skilled human observers using the standard procedure.

Our results indicate that when the machine and a trained observer measure blood pressure simultaneously, there is very good agreement. However, when blood pressure is measured in this manner it is measured according to the

TABLE 5—Correlations among Observer and Machine Readings of Blood Pressure

	Sequential Laboratory Determinations					
	1st Human Average with 2nd Human Average	1st Human Average with Machine Average	2nd Human Average with Machine Average	Average Correlation	χ^2 for Homogeneity	P
Systolic BP	0.919	0.883	0.860	0.887	9.96	0.007
Diastolic BP	0.891	0.806	0.810	0.836	14.36	<0.001
	Sequential Field Determinations					
	Observer E with Observer C	Observer E with Machine	Observer C with Machine	Average Correlation	χ^2 for Homogeneity	P
Systolic BP	0.859	0.823	0.865	0.848	7.23	0.003
Diastolic BP	0.799	0.715	0.695	0.723	14.44	<0.001

BP = blood pressure

technique of measurement incorporated in the machine—a technique which differs from the traditional cuff, auscultatory procedure. Because of this very important difference in technique of blood pressure measurement, it is essential that the machine perform well in sequential measurement with trained observers as well as in simultaneous measurement.

The results of sequential measurement showed little difference on the average between human and machine determinations of diastolic pressure. All nine mean differences (the laboratory sequential and the eight field mean differences) were less than 4.0 mm Hg. and eight were under 3.0 mm Hg. Statistical analysis revealed that the sample of eight machines tested in the field could be considered homogeneous with respect to average machine-human difference in determining diastolic pressure, results compatible with the idea that the machines on the average measured diastolic blood pressure at nearly the same level as skilled human observers. However, the average machine-human difference in measuring systolic pressure varied from −5.7 to 12 mm Hg., and statistical analysis indicated that the sample of machines was heterogeneous in this respect. These results suggest that some aspect of the machine's procedure for reading systolic blood pressure may be unduly sensitive to malfunction or maladjustment and indicates the need for meticulous calibration and recalibration of the machines by manufacturers and service organizations.

A second question was whether the average machine-human difference was the same for all levels of blood pressure. This was investigated by analyzing the linear association between the simultaneously determined human and machine readings of blood pressure. The slopes for systolic and diastolic blood pressures were very close to 1, indicating that for every unit change in the machine's reading the average human reading changed by a nearly equal amount. Therefore, the average machine-human difference would be the same over the range of pressures tested.

The third question concerned reliability of measurement and classification of persons as having normal, borderline, or high blood pressure, i.e., did the machine's determination and classification of blood pressure agree with a human's to the same extent as humans agreed with each other? Agreement in classifying blood pressure as normal, borderline, or high is particularly important in screening programs because it is usually this classification that determines whether or not screenees will be advised to consult a physician. Analysis of the sequentially determined laboratory determinations revealed that the machine-human agreement was somewhat lower than the human-human agreement. These differences were statistically significant, however, only for classifications based on systolic pressure alone or diastolic pressure alone; the difference was not statistically significant when the classification was based on systolic and diastolic pressures considered jointly. In the field, also, the machine-human agreement tended to be lower than the human-human agreement, although these differences were not statistically significant.*

Reliability was also evaluated by analyzing the correlations between pairs of measurements. In general the correlations were high, particularly for systolic pressure. There was a tendency for human-human correlations to be higher than machine-human correlations, but these differences were not large.

In assessing the validity of the Vita-Stat Machine as a blood pressure measuring device, one must determine its accuracy in comparison to human observers. All of our analyses indicate that although its performance is not quite as good as trained human observers, it does possess a high degree of accuracy and the differences between machine and human determinations, although at times reaching statistical significance, have little practical significance, particularly in terms of screening.

Previous studies found earlier automated blood pressure measuring devices intended for use in adults to be inaccurate and unsatisfactory.[9] The American Heart Association, as recently as December 1977, recommended against their use, at least until more adequate testing has been reported.[17] The National High Blood Pressure Coordinating Committee, which functions under the auspices of the National High Blood Pressure Education Program, has been more conciliatory suggesting that with proper safeguards we may achieve the benefits of publicly available blood pressure measuring devices while minimizing hazards of misinterpretation and misuse.[18] The Committee recommended that adequate supplies of informational material be available where automated devices are used, and that standards for performance, use, labeling, and maintenance of such devices be developed by the Food and Drug Administration under the authority of PL 94-295, the Medical Devices Amendments of 1976. Such standards to this date have not been developed.

The development of accurate, automated, self-administered blood pressure measuring devices will aid in screening large numbers of individuals for abnormalities of blood pressure and facilitate more frequent blood pressure determinations in persons under medical treatment. The hazards lie in possible misinterpretation of results, the establishment or lack of establishment of a diagnosis of hypertension without proper medical evaluation and possible changes in treatment or lack of treatment without medical supervision. Because of these hazards, all automated blood pressure measuring devices made available for public use should be required to present adequate information concerning their purposes, capabilities, and limitations. A guide indicating the meaning of blood pressure measurement and listing accepted standards of normal, borderline, and elevated levels of blood pressure should be included, and the following points should be communicated clearly: 1) These instruments are intended for screening purposes only; 2) They do not substitute for medical consultation; 3) Blood pressure varies over time and an elevation or lack of elevation on one or more occasions does

*It should be noted that for classifications based on diastolic pressure only, machine-machine agreement in the field was significantly better than either human-human or machine-human agreement. However, this analysis involved two readings by the same machine compared with two readings taken independently by two different human observers; the results might have been different if the analysis had involved two readings by two different machines.

not constitute a diagnosis of hypertension or normotension; 4) Self-diagnosis is hazardous, and blood pressure readings must be interpreted by a medically qualified person; 5) Self-adjustment of anti-hypertensive medication is hazardous without medical supervision; 6) The presence of the machine does not constitute an endorsement by a governmental or other health agency. Finally, all such devices should be tested by an appropriate agency for safety, and provisions made for periodic recalibration.

The results of this study and the conclusions presented above were submitted to the Chicago Commissioner of Health who appointed an expert Ad-Hoc Committee to evaluate the findings and recommend possible action for the City Council. After carefully reviewing the data, this Committee recommended that the Department of Health adopt the following Rules and Regulations governing the use of automated blood pressure machines in the City of Chicago: 1) An independent, scientific analysis attesting to the safety and accuracy of each manufacturer's machine prototype must be presented to the City for review prior to introduction of any machine; 2) Information is to be provided for the public, and shall be firmly attached to each machine indicating the six cautions noted above; 3) Machine distributors must perform calibration verification for each machine at least every two weeks, and maintain separate records for each machine to be available for review by City inspectors.

At the time this paper was written these regulations were in the process of being prepared by the Legal Department of the City for implementation. We believe that they are sufficient to protect and inform the public. Once the Food & Drug Administration formulates its requirements for such devices, they may replace or add to the currently proposed regulations. In the meantime, the current recommendations and the method of analysis described in this report may serve as a prototype for the study of other automated blood pressure measuring devices.

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EDITOR'S NOTE: It is not the policy of the Journal to publish studies that merely evaluate a medical device or drug. It is the responsibility of government agencies to protect the public and the professions from fraudulent claims and potentially harmful products. The foregoing report of Berkson, et al, however, illustrates the timely and constructive response of a local health department to a situation that other responsible agencies were *not* handling. It also provides a model which studies of this type would do well to emulate.