Quality Assurance in Health Care: Missions, Goals, Activities

Russell J. Eilers

The most challenging mission of medical personnel today is quality assurance in health care. To meet this challenge, the essential elements of a six-phase system for total quality control for the medical laboratory are outlined under the headings of design control, incoming material control, process control, output control, reliability control, and special verification studies. Review of existing goals and activities of programs related to this mission indicates both problems and rich opportunities for individual laboratory professionals and their organizations. For effective implementation of this mission, the laboratory professionals will have to create the atmosphere of a collegium where all interested scientists communicate across disciplines to eliminate the systematic biases and improve the accuracy, precision, and specificity of clinical laboratory measuring systems, to assure medically meaningful and useful assay results for the broad spectrum of health care that is necessary for the well, the near-well, and the sick.

Why Quality Assurance Mission?

The greatest challenge to medical personnel today is quality assurance in health care. The impetus of consumerism demands that laboratory professionals as individuals—and collectively as organizations—reconsider the priorities for the usual general missions of their organizations. Service to the members, representing the profession, and strengthening the profession itself are definitely self-serving missions and have been the ones emphasized by most organizations. The time has come to give the quality-assurance mission top priority and emphasize the mission of service to the public by developing mechanisms of direct service.

For implementation, a mission plan must be outlined that defines major problems and opportunities involved, goals and objectives for specific activities, strategies necessary, and the various "yardsticks" to assure effective spending of resources for these activities.

From experiences gained in applying quality-control engineering in other industries have evolved the principles of quality control (1). In the past 20 years some of these principles have been popularized and applied to the medical laboratory by individual laboratorians, professional associations, or government regulations—popularized sometimes to the extent of overemphasizing one principle (e.g., quality-control charts) to the detriment of other essential principles for a good quality-control system. This provides the opportunity to define a total quality-control system for the medical laboratory.

The Mission Plan

The quality-assurance mission can be met by an effective plan for total quality control for the medical laboratory (Table 1). The plan should integrate the quality development, quality maintenance, and improvement effects of various individuals within a laboratory to enable the most economical production of services, to allow for the full satisfaction of the physician-consumer and the patient.

For this six-phase system, the term "quality" does not have to mean (as in the popular sense) "best", but could mean "best for certain patient conditions"; i.e., the actual end-use of the laboratory result by the physician to solve the health-care problem and its cost. Control means a management activity of setting quality standards, appraising conformance to the standards, taking action when the standards are not met, and planning for improvements in the standards.

Phase I

Design control means a proper laboratory-facility
design and staffing pattern (organizational chart), to handle efficiently the anticipated work load of the selected assay procedures for the mix of health-care problems to be served by that laboratory.

In selecting proper assay procedures, laboratorians must rely upon their basic science education and specialty training in various disciplines. Likewise, they must participate in continuing-education and clinical-research activities through the avenues offered by their professional societies and medical institutions. To serve their membership, professional organizations offer journals, scientific sessions, seminars, workshops, education programs on laboratory management training, and monograph series on laboratory planning and design, or standardized methods.

Most laboratorians, as is also true of clinicians, think of their services in terms of disease problems and do not clearly delineate their possible roles in health-maintenance education, promotion of the public health, or aiding in resolving problems of psycho-social illness (Figure 1). Neglect by health professionals of the broad spectrum of health-care problems of the public has led to the “health-care crisis,” and has moved the public to demand politically that their health-care needs be met at economical cost. The major causes of death have not changed in the last 30 years, even though millions have been spent on research for cancer and heart disease (2). Life expectancy at age 65 for adults has changed only from 13 to 15 years from 1900 to 1970. The preponderance (97%) of primary-care services delivered has shifted from major medical disease problems (now 3%) to minor problems and to chronic-disease problems that have a major psycho-social illness component (2).

Today, the “health-care problem” is simply whether a patient has organic illness or is unable to deal with his environment (family, friends, job, or society).

New laboratory procedures should be added only after full consultation of the medical staff. Medical staff have begun to recognize the need for agreement on plans for screening procedures for outpatients and inpatients so that, on abnormal findings, the laboratory staff proceeds immediately with available tests that may aid in elucidating the abnormal result or implicate a specific diagnosis. Such planned medical systems should stop the current ping-pong game in laboratory testing, lead to a shortened patient hospital stay, and expedite general health-care delivery. The laboratory staff must learn to eliminate old, insensitive, imprecise, and inaccurate procedures from the list of available laboratory tests and replace them with procedures that provide rapid, meaningful results that affect the differential diagnosis or treatment.

Laboratorians must accept the challenge to communicate directly to the public on health maintenance and promotion by laboratory means, and also to communicate with all members of the primary health-care team on the proper utilization of laboratory procedures to meet the entire spectrum of health-care problems (e.g., use of adequate drug-abuse screening methods).

Phase II—Material Control

Incoming material control involves receiving or stocking, at the most economical levels of quality, only those materials and equipment meeting the laboratory’s specifications. A laboratory may meet this requirement by purchasing (e.g.) reagent-grade chemicals as defined by the American Chemical Society, the highly pure NBS Standard Reference Materials (SRM’s) as calibrators, industry-produced cyanmethemoglobin standards that meet the specifications of the International Committee for Standardization in Hematology (ICSH) as certified by the college of American Pathologists (CAP), and the CAP Clinical Standard Solutions or other working standard solutions that are linked to the NBS SRM’s in the laboratory. The laboratory may buy microbiological reagents and products labeled as being produced according to specifications outlined by the Center for Disease Control (CDC). It should utilize NBS certified physical standards to verify the absorbance and wavelength scales of instruments, temperature scales, or analytical weights. It may select industrial kits and

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**Table 1.**

**MEDICAL LABORATORY TOTAL QUALITY CONTROL**

| I. DESIGN CONTROL: FACILITY, STAFFING, AND ASSAYS FOR MIX OF HEALTH CARE PROBLEMS |
| II. RAW MATERIAL CONTROL: STANDARDS, CONTROLS, REAGENTS, INSTRUMENTS, GLASSWARE, SAMPLES, PERSONNEL |
| III. PROCESS CONTROL: INTERNAL TO CALIBRATE AND CONTROL PROCESS; EXTERNAL TO MONITOR AND REFINE PROFICIENCY |
| IV. OUTPUT CONTROL: EACH RESULT(S) IN MEDICAL SIGNIFICANCE FORMAT |
| V. RELIABILITY CONTROL: ASSAY UTILIZATION CORRELATES WITH HEALTH CARE NEEDS |
| VI. VERIFICATION CONTROL: INSPECTION AND ACCREDITATION; WORKLOAD AND MANHOUR RECORD; COST ANALYSIS |

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**Fig. 1. Spectrum of health problems and services**

reagent systems that have been verified by the CAP Product Evaluation Program. It should utilize assay methods that have an accuracy equivalent to the Clinical Reference Methods (CRM's) developed by the NBS or follow the methods published by the American Association of Clinical Chemists (AACC) as "Selected Methods".

Phase II—Standardization Activities

The above-recommended materials, methods, and products to implement Phase II reflect standardization activities by diverse organizations to aid laboratorians in their selective buying of products to effect the provision of quality laboratory services. The most common standardization activities of organizations have been in the area of standardization of materials, methods, and modes of practice. With time these standards have been incorporated into regulatory activities or organizations and governments to assure utilization of the standards by all parties involved in the delivery of particular services, thus defining a new second level of regulatory standards. Through the integration of regulatory and material and method standards with other requirements, value standards for society have evolved such as the Medicare Act, the Clinical Laboratory Improvement Act of 1967 (CLIA-67), the OSHA requirements, and Professional Standard Review Organizations (PSRO).

The problem is to coordinate the diverse standardization activities of individuals, government, and organizations, to avoid duplication of effort. To this end, the National Committee for Clinical Laboratory Standards (NCCLS) was formed in 1968 in response to a call issued by the CAP in 1967. This committee is a federation of all interested parties in the clinical laboratory field (professional, scientific, industrial, and governmental organizations). NCCLS serves as an open forum for discussion of proposed standards developed by the area committees of the NCCLS or submitted by member organizations. NCCLS provides the administrative mechanism to assure member consensus on proposed standards (Table 2).² NCCLS needs to establish a working relationship with other consensus standard-developing organizations in the U.S.A.—e.g., the American Society for Testing and Materials (ASTM) and the American National Standards Institute (ANSI)—to allow cross fertilization in meeting the need for standards within the health industry with that of other industries.

Similarly, on the international level there is need for a single agency to coordinate the standardization activities of the interested international groups. True, the IFCC coordinates their activities with IUPAC. ICHS coordinates standardization activities for the International Society of Hematology and the International Society of Blood Transfusions, and relates to the International Committee on Hemostasis and Thrombosis. Most microbiological and biological standards have been developed and coordinated through the World Health Organization (WHO). During the 1972 Pathology Congress, the Commission on World Standards of the World Association of Societies of Pathologists, IFCC, and ICHS met to resolve differences and coordinate their activities in regards to terminology for the implementation of metric units and quantities for laboratory medicine. The International Atomic Energy Commission is now active in the clinical nuclear medicine area. The International Standards Organization (ISO) is also beginning activity that relates to laboratory glassware and sample-collection containers. The World Health Congress of WHO has recognized the international need for coordination of standards for in vitro diagnostic kits and reagents. A conference was held on this in June 1973 at CDC, with final recommendation drafted for the May 1974 27th Health Congress. During this 27th Congress, WHO was directed to attempt to coordinate—internationally—all standardization activities in the clinical laboratory field under one permanent WHO panel of experts. Names of experts would be sought from the appropriate international organizations. Will this activity truly coordinate all interested parties from the professions, sciences, government, and the industry? Will this provide international consensus standards?

Phase II—Specimen Control

The specimen from the patient is a raw material that must also be controlled. A laboratory should define for its collection operation the relationship of time and meals to the specimen being drawn and the position of the patient during the collection because interpretation of some results are affected by the position of the patient. Shouldn't this information be included on the report form? The maximum tourniquet time must be well defined, to prevent effect upon certain constituents. And should a history not be taken about medications that the patient may be on and that may interfere with certain chemical assay techniques? Do laboratory manuals in the physician's office or nursing station indicate how long containers are to be used, especially if specimens are collected by nonlaboratory personnel and must be transported within the institution or over a distance?

² See "Special Report," this issue—Ed.

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**Table 2.**

<table>
<thead>
<tr>
<th>Working Guidelines for A</th>
</tr>
</thead>
<tbody>
<tr>
<td>S — Search in Science and Practice a Basis for a Standard</td>
</tr>
<tr>
<td>T — Test the Basis Within and Outside the Laboratory</td>
</tr>
<tr>
<td>A — Analyze the Results and Annotate a Set of Specifications</td>
</tr>
<tr>
<td>N — Narrate the Set of Specifications as a Proposed Standard</td>
</tr>
<tr>
<td>D — Discuss in Open Forum and Thru Written Communication</td>
</tr>
<tr>
<td>A — Analyze the Comments and Criticisms</td>
</tr>
<tr>
<td>R — Revise the Proposal and Retranslate as a Tentative Standard</td>
</tr>
<tr>
<td>D — Document the Tentative Standard by a Consensus Vote as a National Clinical Laboratory Standard</td>
</tr>
</tbody>
</table>
What enzymes and hematological constituents are stable if shipped over a great distance? Criteria must be defined for accepting or rejecting specimens upon their receipt in the laboratory; in any event, the time of arrival and the condition of the sample, if adverse to processing, should be recorded. Personnel should be instructed about the hazards of handling samples, especially the aerosol spray that may be formed as they open stoppered containers. Yes, there is a rich opportunity to recommend definite guidelines for clinical samples as a raw material.

Phase II—Personnel Control

Because quality work begins with qualified personnel, the human elements of laboratory staff need to be controlled. This means job descriptions should be written for all categories of laboratory personnel, including requirements of education and experience. Tasks and functions should be analyzed, so that duties and responsibilities will be properly assigned to each position in the organizational chart.

Phase III—Internal Control

Process control can be divided into internal and external quality-control mechanisms. The laboratory procedures manual should detail for each method the internal quality-control means of using known highly pure materials as standards in a known solvent to calibrate the method and the use of appropriate assay concentrations of control materials an appropriate number of times in each batch of determinations for a particular constituent, to assure that the overall process is in control. The limits for control should be defined by the director or supervisor. Large lots of control materials should be used, so that a laboratory can determine the limits for within-day variation of the process and compare this to the variation between days as well as months of the year, to document the temporal precision and stability of the assay procedure.

Regional groups of laboratories are now utilizing the same pools of control material so that they can intercompare their precision for a particular method and the instrumentation used in determining the same constituent. To aid regional study groups, the CAP offers a Quality Assurance Service (QAS)—a computer service—to perform the statistical analysis to determine within-laboratory variations and to provide interlaboratory comparisons. The monthly QAS report allows the laboratory staff to document the quality-control efforts within the laboratory, to observe the trends and stability of the precision of their methods over time, to compare their own laboratory's precision with that of peers utilizing the same measurement systems, and to detect bias of the laboratory measurement systems, in relation to selected comparison methods. The QAS provides the industry an opportunity to form national groups via their maintenance contracts, to study the performance of their assay systems during actual operating conditions in the field. Yes, to help ascertain the basis of the problem—is it the operator, the reagents, the calibrators, or the machine? Thus, the QAS program serves the needs of an internal quality program as well as an external program of regional study groups to refine the precision and accuracy of the process.

Phase III—Preventive Maintenance

Another important internal quality-control technique is a preventive maintenance program that requires a regularly scheduled examination of all equipment involved in assay procedures before they break down and assures that they are in proper functioning order (3). Adequate records of documentation should be kept on their performance and a record of repair of each instrument. The latter may allow trends of breakdown to be defined, especially for complex multichannel instruments.

Phase III—External Control

External quality-control in the United States started with the CAP Survey Program in 1949. The objectives were to define the basic profile of laboratory testing on the national level, stimulate interest in new and better standards in the clinical laboratory field, and diminish interlaboratory variability by defining overall areas of deficiencies, so that these could be corrected through education. With passage of the Medicare Law in 1966 and CLIA-67, the survey concept was converted to that of proficiency testing of individual laboratories. The laboratories receive unknown samples and report their results to a service agency of a professional group or government bureau, who grades and scores the results to define the laboratory's proficiency in determining particular constituents; thus a mechanism is established for government agencies to monitor the quality of the work of the laboratories involved.

Experience of the CAP Survey Programs as an interlaboratory testing scheme demonstrates many other benefits for participating laboratories beyond meeting the requirement of proficiency testing as provided in various laws and regulations.

First, the state of the art in determining a specific constituent can be reflected by statistical analysis of the results obtained on the national level on the same pool of materials. Such statistics do reflect trends for improvement in the state of the art for some assay procedures (Table 3).

Second, the survey report returned to the laboratory allows the director to compare the laboratory's results to that of peer laboratories using the same assay measurement system, as well as to a selected comparison method.

A third benefit is that the relative value of a particular medical device for determining a constituent may be indicated, for example, determination of the relative density of urines. The inter-laboratory variability among laboratories that use the refractometer is far less than among those that use the urinometer float (Figure 2). In the Survey Programs, most labo-
ratories utilizing the refractometer can consistently come within ±0.002 units of the target mean value.

A fourth benefit is that the influence of an accepted standard or recommended method for a particular constituent assay may be shown. The best example for this is the improvement of hemoglobinometry in the United States with acceptance of the cyanmethemoglobin (HiCN) method and standard (Table 4). In the early 1960's, the interlaboratory coefficient of variation was 4 to 5%, but now in the early 1970's this has decreased to 3% for the manual techniques, and less than 2% for automated techniques. Belk and Sunderman observed in Pennsylvania in 1945 that less than half of the laboratories could come within 1 g of the true value (4). In the 1970's with 99% of the laboratories in the Survey Program utilizing the recommended HiCN method and the availability of certified HiCN standards, >95% of the laboratories come within 1 g of true values for the unknown sample. In fact, in the CAP Survey Program, grading and scoring has been on an arbitrary basis, i.e., ±0.4 g/dl as limits for good performance and ±0.8 g/dl for acceptable performance. For the >6000 laboratories enrolled in the Comprehensive and Basic Survey the individual sample mean values are now scattered around the ±0.4 g/dl line from the true value (Figure 3). In fact, the time has come to set the arbitrary performance limits for this determination at ±0.2 g/dl for good results and ±0.5 g/dl for acceptable results. This approaches the limits of the known accuracy and precision of this method as defined by VanKampen and Zilstra, i.e., ±0.1 to 0.4 g/dl, depending on the concentration of hemoglobin in the unknown sample (Table 5). Yes, the original mission goal of the National Research Council to improve the accuracy and precision in hemoglobinometry in the United States is being attained. Can such mission goals be defined for other constituent assays within the clinical laboratory field?
A five-part mission plan for a meaningful measurement system\(^3\) in clinical chemistry has been outlined by Cali of NBS (5) as follows:

1. A rational, self-consistent system of units of measurement, i.e., Système International d’Unités (SI).
2. Well-characterized standard reference materials (SRM’s).
4. Assessment of field methods via SRM’s and CRM’s.
5. Mechanisms to assure long-term integrity of the measurement system (interlaboratory trials or proficiency tests).

Part I involves the acceptance by all laboratory practitioners of the IFCC recommendations of units and quantities consistent with SI units (6). NBS has already released 18 well-characterized clinical SRM’s for use in practice as calibrators.\(^4\) Likewise, NBS has offered one CRM as a method of known accuracy for calcium (7) that is related to the NBS definitive method in which calcium is determined by isotope dilution–mass spectrometry.

Parts 4 and 5 depend on professional organizations of laboratorians to accomplish. Fortunately, these organizations have already been involved in the development and assessment of field methods through the research of their individual members. More importantly, involved by the criteria established by their editorial boards for publication of new or revised methods in their journals, the monograph series on standardized methods, and the interlaboratory testing surveys that provide mechanisms for laboratorians to evaluate field methods vs. selected comparison methods of accepted value. The CAP Survey programs and the CDC Proficiency Testing programs have been and are capable of meeting the essentials suggested by Cali for a sponsoring agency to assure the integrity of the measurement system:

1. Prepare stable test samples of normal, high, and low values for analytes.
2. Analyze samples to obtain values of known accuracy by use of available SRM’s and CRM’s (or preferably definitive methods) or other accepted mechanism.
3. Distribute test samples to participating laboratories.
4. Statistically analyze the reported data of the participants and provide agency reports informing the participants of
   a. Day-to-day precision within laboratory
   b. Accuracy of results vs. that of peers using the same measuring system
   c. Accuracy of results vs. those obtained by alternative method(s)
   d. Statement of acceptability of results

A fifth benefit of the survey program for participants has been the ranking of constituent assay methods by their precision. Table 6 is an example, it shows a ranking of the within-day precision of assay methods for calcium from the 1971 CAP Survey data. The survey data base also provides a sixth benefit: methods can be ranked for accuracy by utilizing a selected comparison method (e.g., for calcium, the atomic absorption field method or the NBS definitive method just mentioned). As a special project the NBS assayed vials from the pooled specimens used as unknowns in the 1971 CAP Survey Program by both the definitive method and the CRM atomic absorption method for calcium. In Table 7, note that four of the 1971 field methods for determination of calcium provided results within ±2% of the mean values obtained by the definitive method for these samples, the stated accuracy goal for the NBS calcium CRM. Further studies are needed to validate this relationship of field methods for calcium methodology. In the future this could be done for other constituents to provide meaningful measurements for clinical chemistry. Problem: with such information available, will laboratorians take action to select the better methods for accuracy and precision or will more forceful education be necessary? By proper selection of concentrations of constituents to be assayed in the Survey Program, the survey data can indicate the quantitative relationships among short-term (within-day laboratory precision), long-term (month-to-month precision within the laboratory), and interlaboratory variation. The data in Table 8 clearly demonstrate that most of the analytical error in clinical laboratories generally is caused by sources of error within the individual laboratory. Effort should be spent on improving the short- and long-term within-laboratory precision. The CAP Survey data in Table 9 demonstrate that the short-term precision being attained within laboratories for certain methods has improved. Laboratorians now have the opportunity to

\(^3\) A report by NBS Director Richard W. Roberts [Anal. Chem. 47, 648A (1975)] outlining NBS activities in this area will interest our readers.—Ed.

Table 6.
PRECISION OF CALCIUM METHODS
1971 SURVEY

<table>
<thead>
<tr>
<th>METHOD</th>
<th>STANDARD DEVIATION mg/dl</th>
<th>COEFFICIENT OF VARIATION %</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRESOLPHTHALEIN COMPLEX 12/30</td>
<td>0.14</td>
<td>1.5</td>
</tr>
<tr>
<td>CRESOLPHTHALEIN COMPLEX 12/60</td>
<td>0.20</td>
<td>2.2</td>
</tr>
<tr>
<td>ATOMIC ABSORPTION</td>
<td>0.22</td>
<td>2.4</td>
</tr>
<tr>
<td>AUTO ANALYZER</td>
<td>0.23</td>
<td>2.5</td>
</tr>
<tr>
<td>CALCEIN NON-FLUOROMETRIC</td>
<td>0.34</td>
<td>3.7</td>
</tr>
<tr>
<td>CALCEIN FLUOROMETRIC</td>
<td>0.35</td>
<td>3.8</td>
</tr>
<tr>
<td>EMISSION FLAME PHOTOMETER</td>
<td>0.35</td>
<td>3.8</td>
</tr>
<tr>
<td>CHLORANILATE PRECIPITATE</td>
<td>0.43</td>
<td>4.7</td>
</tr>
<tr>
<td>OXALATE PRECIPITATE</td>
<td>0.45</td>
<td>4.9</td>
</tr>
</tbody>
</table>

Table 7.
COMPARISON OF FIELD CALCIUM METHODS
WITH NBS REFERENCE METHODS (CRM & ID-MS)
(1971 SURVEY)

<table>
<thead>
<tr>
<th>CALCIUM METHOD</th>
<th>NO. OF LABS</th>
<th>% DEVIATION OF METHOD MEAN FROM ID-MS MEAN VALUE</th>
<th>AVERAGE</th>
<th>MAXIMUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXALATE PRECIPITATE</td>
<td>108</td>
<td>0.6</td>
<td>3.4</td>
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<tr>
<td>CHLORANILATE PRECIPITATE</td>
<td>550</td>
<td>-1.8</td>
<td>-4.1</td>
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<tr>
<td>EMISSION</td>
<td>665</td>
<td>2.8</td>
<td>5.1</td>
<td></td>
</tr>
<tr>
<td>CALCEIN NON-FLUOROMETRIC</td>
<td>206</td>
<td>-0.9</td>
<td>-1.7</td>
<td></td>
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<tr>
<td>CALCEIN FLUOROMETRIC</td>
<td>502</td>
<td>-2.3</td>
<td>-3.2</td>
<td></td>
</tr>
<tr>
<td>CRESOL COMPLEXONE A.A.</td>
<td>257</td>
<td>1.4</td>
<td>1.6</td>
<td></td>
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<tr>
<td>CRESOL COMPLEXONE SMA 12/30</td>
<td>139</td>
<td>0.0</td>
<td>-1.0</td>
<td></td>
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<tr>
<td>CRESOL COMPLEXONE SMA 12/60</td>
<td>704</td>
<td>-1.4</td>
<td>-2.1</td>
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<tr>
<td>ATOMIC ABSORPTION (PARTICIPANTS)</td>
<td>104</td>
<td>-0.4</td>
<td>-1.3</td>
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<tr>
<td>ATOMIC ABSORPTION (REFEREES)</td>
<td>10</td>
<td>-1.5</td>
<td>-2.3</td>
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<tr>
<td>ATOMIC ABSORPTION (NBS CRM)</td>
<td>1</td>
<td>0.7</td>
<td>1.4</td>
<td></td>
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</table>

Table 8.
SOURCES OF ANALYTICAL ERROR

<table>
<thead>
<tr>
<th>CONSTITUENT</th>
<th>2 S.D. CONFIDENCE LIMITS</th>
<th>% CONTRIBUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ALL METHODS</td>
<td>Short Term</td>
</tr>
<tr>
<td>Calcium mg/dl</td>
<td>± 0.73</td>
<td>± 1.06</td>
</tr>
<tr>
<td>Cholesterol mg/dl</td>
<td>±15.4</td>
<td>±22.0</td>
</tr>
<tr>
<td>Glucose mg/dl</td>
<td>±1.17</td>
<td>±12.3</td>
</tr>
<tr>
<td>Total Protein g/dl</td>
<td>±0.25</td>
<td>±0.35</td>
</tr>
<tr>
<td>Urea Nitrogen mg/dl</td>
<td>±1.92</td>
<td>±3.65</td>
</tr>
<tr>
<td>Uric Acid mg/dl</td>
<td>±0.44</td>
<td>±0.85</td>
</tr>
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</table>

Table 9.
PRECISION-SURVEYS 1971-1973
SHOWN AS C.V.

<table>
<thead>
<tr>
<th>CONSTITUENT</th>
<th>1971</th>
<th>1972</th>
<th>1973</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>3.8</td>
<td>3.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>4.9</td>
<td>4.0</td>
<td>3.6</td>
</tr>
<tr>
<td>Glucose</td>
<td>3.6</td>
<td>3.2</td>
<td>3.0</td>
</tr>
<tr>
<td>Urea Nitrogen</td>
<td>6.9</td>
<td>6.4</td>
<td>6.3</td>
</tr>
<tr>
<td>Total Protein</td>
<td>2.7</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>4.8</td>
<td>4.5</td>
<td>3.9</td>
</tr>
</tbody>
</table>

realistically define the necessary precision and accuracy goals for each constituent analysis and relate these goals to medical needs. Medical needs have been defined by Barnett based on the needs as defined by consumer physicians by interview (8). Cotlove et al. (at the NIH) have defined the tolerable limits for precision needed, based on the biological variation in a number of constituents, as observed in individuals over a period of time (9). Note in Table 10 that the limits defined by Cotlove are in some cases a bit narrower than those defined by Barnett, but they are not in serious disagreement. Already in the 1972 Surveys the short-term and long-term precision for some constituents met the medical needs as defined by Barnett or Cotlove et al., or both. This is particularly true for cholesterol, uric acid, and urea nitrogen, although further improvement is possible. Without too much further effort, the necessary precision can be obtained for glucose and total protein. Much more effort must be expended to meet the medical criteria for calcium. It is not unreasonable then to propose accuracy and precision goals for 1980 for all assay methods for common constituents needed for medical care. I offer the sample listing in Table 11 as reasonable goals that can be attained by clinical laboratories by using the best of current methods and technology.

In Phase III of this mission plan (Table 1), the
roles of federal agencies and those of laboratory professional organizations become linked. The federal agencies may provide reference points, may monitor laboratory quality by evaluation mechanisms, or may use the clout of law to make some laboratories improve; likewise, they may use the clout of law to force some manufacturers to improve the products they sell for use in the clinical laboratory field. The professional organizations have opportunities to maintain their independence by developing standards for reference materials, methods, and modes of practice; and through peer-evaluation programs of their organizations to monitor the attainment of goals for accuracy and precision and to set priorities for goals. The professional organizations have and should continue to be responsible for defining the necessary quality of personnel needed. Quality laboratory work begins with qualified personnel. Also, laboratorians should guide industry in its production of tools and technology that laboratories need and that can meet the regulations of the FDA and the following criteria for technology (10):

- Provides a service
- Meets defined needs and demands of the public and the physicians who are ordering the tests for them
- Affects large number of people and institutions
- Enhances efficiency of proven methods for treating, preventing or eliminating causes of disease.

Phase IV

For output control, the 12 guidelines for quality laboratory reports should be met (11). Most laboratory reports, today, do provide identification of the patient, his location and physician, and the date and time the sample was collected. Most laboratorians do assure that exceptionally low and high values have been rechecked for proper processing and calculated correctly, and that significant results are being flagged to bring them to the attention of the physician at the bed side. Most laboratorians are providing a compact form of reports that are easy to prepare and most do some grouping of results according to physiological significance, specific organ, or specific disease, thus aiding the physician in solving his patient-care problems.

But laboratories are not using a consistent terminology or format, or a common set of abbreviations and symbols. The time has come to use the IFCC recommendations for the quantities and units consistent with SI (6). Many laboratories do not define their own reference ranges for their particular constituent assay methods, but rely on normal values defined by others in the literature, even though they have been obtained by a modified or different assay method. Likewise, many laboratories are not clearly distinguishing abnormal and normal results. How can this be accomplished and still be related to the specific problems of individual patients?

An opportunity of high priority is to develop a feasible mechanism to allow each laboratory (regardless of size) to determine their own normal value reference system for their assay methods. The classical approach of averaging of normal subject results is too demanding and costly for the smaller laboratories but can be accomplished by most medium-sized and larger laboratories over a period of time. Institutions can and have attempted to use normal values extracted from the assay results in their patient population utilizing one of the three statistical methods (12-14a and b). This does provide normal value ranges with the laboratory assay method, but are they valid? This could be explored by QAS regional study groups as a planned activity. The ranges extracted by a group of laboratories utilizing the same measuring system could be statistically intercompared for consistency of the ranges. Such ranges could be compared to a normal value range defined by the classical method by one of the larger laboratories in the peer group or from a pool of data on normal individuals of defined characteristics contributed by all laboratories in the peer group. The ultimate, though, is to define normal value limits for individuals as reported by Williams et al. (15) by assaying duplicate samples from the same individual within the same day and repeat samples over a period of time. This could be done by a peer group of laboratories in a regional study group utilizing the same assay system, who pool their data to provide a population of individual ranges for comparison.

Of course, if the efforts of laboratory organizations and the FDA are successful, and only field methods of good precision and equivalent accuracy are to be used by all laboratories in the near future, only one common set of normal limits will be needed for all field methods for an analyte. Limits would have to vary for the essential characteristics of age, sex, or environment, and not be method dependent.

Phase V

Reliability control should assure that assay utilization does in fact correlate with health-care needs. Does the laboratory result help or confuse the physician in solving the patient-care problem for which it was ordered? Does the laboratory just provide results of qualitative and quantitative tests or does it provide, with these results, meaningful normal values with confidence limits that relate to the precision, accuracy, sensitivity, and specificity of the assay method and their interrelationships?

A first step to meet this obligation is a variety of communications by the laboratory staff. A laboratory manual should be provided, that outlines the proper instructions for collection of samples, assay method to be utilized, and expected normal values. A laboratory bulletin or newsletter should be utilized to report changes and revisions of the methods or new laboratory procedures being offered and their relationship to normal and pathophysiology. Laboratory rounds can be utilized to find the problems technolo-
gists are having within the laboratory with samples or methods, the problems of the nurse at the nursing station in obtaining either samples or results from the laboratory, and the physicians can be contacted directly concerning supposed laboratory-error problems. Likewise, the physician should be contacted directly at any time by the laboratory staff concerning unusual results that should be brought immediately to his attention. Remember, laboratory reports are usually a one-way communication. How does the laboratory staff assure that the results were received, the vagaries of sample collection and the effect of accuracy and precision of methods and confidence limits were understood, and proper physician response was elicited?

Laboratory personnel have been expected to be involved in the interpretation of cell patterns seen in blood smears, and the urinary sediment, and the patterns of protein electrophoresis. Has the time not come for the staff to be involved in the interpretation of batteries of laboratory procedures to aid diagnosis or health maintenance screening? To do the latter, the laboratory staff must assume the obligation to develop a laboratory data-analysis system.

Criteria for health-information systems require that the system must be parsimonious, problem-oriented, person-specific, yet population-based (10). Two tools are available to aid in meeting these criteria. First, the laboratory staff should work with the medical staff for the establishment and use of the problem-oriented medical chart within the institution. This recording method defines the patient-care problems from the patient’s data base (history, physical exam, and baseline laboratory data). Also, documents from the further administrative, clinical, laboratory, or therapeutic procedures utilized for each problem, their effect in providing clinical conclusions regarding diagnosis and patient outcome (16)—yes, the scientific-method approach to the patient’s problems, with documentation recorded in the medical chart. Laboratorians as basic scientists should be more than prepared to aid in the adoption of this approach to patient care. But a systematized nomenclature for these problems, procedures, and diagnoses would facilitate their intercorrelation.

Existing systems of classifying disease do not cover many normal physiological and pathophysiological problems or include all possible procedures, or are only a classification of disease entities based on anatomical diagnoses. Ideally, a computer-compatible nomenclature of medical language is needed. This opportunity can be met by the Systemized Nomenclature of Medicine (SNO-MED) being developed by the College of American Pathologists with other medical specialties, based on the Systemized Nomenclature of Pathology (SNOP) (17).

SNO-MED is a nomenclature with philosophically sound categories that cover anatomical location, morphological change, normal and abnormal physiology and psychology, etiological agents, and all administrative, diagnostic, and therapeutic procedures utilized by the health-care team in dealing with a patient’s problem. Another category provides the necessary semantic operators to flesh out the other categories, to provide the natural medical language as spoken and written by the health team—a computer-compatible nomenclature for current medical language, to facilitate the use of the problem-oriented chart within an institution. Together, these two tools will support the development of the four-phase process of the multivariate laboratory data-analysis system needed to synthesize and interpret multiple laboratory results to aid the physician as described by Grams et al. (18).

The initial process phase of analytical error limits effectively reduces the population normal range to a subject-specific range by screening each new assay result on a subject against previous results, to determine whether it is attributable to the analytical error of the assay technique or an actual change in the status of the subject (18b).

The second phase is an evaluation process of multivariate normality. The process takes cognizance of the limits of normal for a single test or sets of two or more tests (batteries) that may have physiological or pathological interrelationships in defining the abnormal results (18c).

In phase three, by pattern recognition, the process of multivariate diagnosis evaluates the abnormal results from multivariate normality to establish a possible differential diagnosis (18d).

In phase four, the trend-analysis process evaluates the patterns of repeated assay results over time during the disease process, to confirm a diagnosis or to predict the course of a particular symptom complex or disease entity (18e).

New modes of practice requirements for physicians are evolving, all of which require peer review in some form (19, 20). The multivariate laboratory data-analysis system of Gram et al., used in conjunction with problem-oriented charts and SNO-MED, provides a rich opportunity for the laboratory staff to aid the physician staff in meeting the challenge of professional standard review organization (PSRO’s) by providing statistical expressions for “norms” as a “screen” mechanism to sift out exceptional performance of care by individual physicians for review. More importantly, it will provide a sound scientific basis upon which to recommend “standards” and “criteria” for proper utilization of laboratory procedures for quality health care, derived from the local medical care experience. Yes, this would be a health-term approach to guiding and effecting proper utilization of laboratory procedures for a maximum cost benefit to the patient.

Phase VI

Verification control involves special investigative studies to evaluate the total system of quality control. The ultimate overall view is an inspection and
accreditation program of the medical laboratory by a peer group of laboratori ans. The programs of the CAP and the American Association of Blood Banks (AABB) have defined broad standards as to the proper operation of the medical laboratory. Detailed check lists are used during the inspection process to verify and document the overall total quality control system of that medical laboratory. These general standards and checklists cover personnel, facility, methods, and instrumentation, internal and external quality control, record keeping, and personnel safety. The CAP program has now accredited 1200 general medical laboratories. All are accredited for multiple categories of laboratory service and represent all types and sizes of laboratories. The AABB has accredited 1,700 laboratories for immunohematology and blood banking. The Center for Disease Control, under the CLIA-67 Act, has licensed 700 laboratories for one or more categories of laboratory service. Under CLIA-67, the CAP program has been declared equivalent to that of the CDC and is annually reviewed by CDC to assure that it is equivalent. The recent regulations of the Secretary of H.E.W. have made the Medicare and CLIA-67 programs similar or equivalent in their standard requirements. This promotes the possibility of one set of standards for all medical laboratory work in the country. The only major group of laboratories not covered to date by these standards requirements is that of the physician's office laboratory. But already in some states these labs are being regulated under laboratory licensure laws. Also, various professional organizations offer the physician an office laboratory interlaboratory survey program, to help the physician evaluate his own laboratory.

Another special process study is the CAP Workload Recording Method for Clinical Laboratories (21). In Canada and the United States, the need for a uniform thesaurus to assist in the raw counting of clinical laboratory tests across the country became evident. Likewise, a realistic way to weight the raw count was needed, to reflect the productivity of the laboratory, especially as it is influenced by automated or semiautomated devices. Verification was needed that proposed changes in methodology and instrumentation technology would improve the productivity of the laboratory or reduce the laboratory cost to the patient. Thus, in North America through the cooperation of the Canadian Association of Pathologists and the College of American Pathologists, a workload-recording system has been developed based on time-engineered weight factors (unit values) determined for the most common procedures.

Ongoing studies in both countries are verifying the productivity of laboratories with regard to manual, semi-automated, and automated methods. A time engineering general study plan and special protocols have been developed that will define what the unit value should be for a new method or technology. This will allow the laboratory or an industry releasing a new measurement system to develop unit values and share them with their colleagues around the world. By means of this CAP workload-recording system, and a record of man hours worked within the laboratory, the laboratory director is rapidly approaching the ability to predict and justify the technical staff and space needs as indicated by their work-load figures. This becomes the beginning of a cost-analysis system, because technical labor is 50–70% of the total cost for procedures. Opportunity is at hand for a common set of guidelines to be developed for a chart of accounts for the laboratory, which will define the various cost centers for the allotment of expenses and income to allow the question of net cost or income to be evaluated.

Within this cost-analysis system though, one of the greatest challenges to the laboratory director will be to determine what percentage of the total cost of the laboratory operation is being applied for overall quality control. Quality-control engineers recommend that quality-control costs should not be more than 10% of the total cost to manufacture a particular product. Industry supplying materials and equipment for the laboratory field report quality-control costs ranging from 10% to as high as 25%. Preliminary studies in some medical laboratories indicate costs as high as 20 to 30% of the overall laboratory cost being devoted to quality control. Is this reasonable? Can it be reduced? There is a high priority opportunity, for the staff of each individual laboratory not only to develop a total quality-control system, but also to utilize this system to measure and optimize the cost of that quality-control system and how it may effect the cost of laboratory work for patient care.

In conclusion, this mission plan of total quality control for the medical laboratory can meet the challenge of quality assurance and points out problems and opportunities for each member of the laboratory to be aware of, to further his proper role in the quality control program for his laboratory. The laboratory professionals on the health care team must police themselves and their organizations, as they work for quality health care. Each laboratorian must ask himself, "Should not all laboratory professionals join together in the pursuit of excellence to provide quality health care?"

References