Quality Assurance for Blood Glucose Monitoring in Health-Care Facilities

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Objective: To describe the practice of quality assurance (QA) for capillary blood glucose monitoring (CBGM) in health-care facilities. Research Design and Methods: Descriptive survey data were collected from a purposive sample of 378 health-care providers, who use CBGM and direct CBGM QA programs, from acute- and chronic-care facilities in 47 states. Subjects completed a 36-item multiple-choice survey about QA practices for CBGM by providers. Results: Only 53.4% of respondents reported a multidisciplinary advisory group to assist in decision making for the CBGM program. Almost one-third reported no clinical laboratory involvement in their QA program. Over 70% of respondents reported inclusion of all clinical areas in the CBGM program. Comparison of results of the same patient sample by laboratory reference method and CBGM system was done routinely by only 43.6% of respondents. Scheduled proficiency testing was reported by 33.4%. Only 5.8% of respondents reported the coexistence of a CBGM advisory group, full participation of the laboratory, and quarterly proficiency testing. Over 50% of respondents reported a patient charge for CBGM. Conclusions: When survey results are compared with regulatory and accreditation standards, it is evident that a wide gap exists. Resources to bridge this gap may be scarce in many facilities. Further research is needed to determine minimal QA standards for CBGM that provide for optimal patient outcomes. *Diabetes Care* 14:1043–49, 1991

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Capillary blood glucose monitoring (CBGM) proliferated in health-care settings in the early 1980s, although the quality assurance (QA) guidelines for this new technology were less rapid in development (1–3). The purpose of CBGM was to provide a timely and accurate measurement of a patient's blood glucose so that appropriate therapy could be instituted by nursing and medical staff (4,5). Laboratory determinations of blood glucose were often delayed beyond a clinically reasonable time for treatment of acute complications of diabetes (2,6). Accuracy and precision of CBGM determinations have been studied in both laboratory and clinical situations (7–9). However, by 1986, both health-care professionals and clinical laboratory staff had voiced concerns regarding CBGM as an ancillary laboratory test (5). A major concept that emerged was that multidisciplinary support was necessary to promote a successful CBGM program (10,11).

Although there are various standards regarding QA for CBGM from regulatory and accrediting agencies at both the national and state levels (11–14), there is no consensus concerning minimal standards for accuracy of blood glucose test results that are of clinical significance to patient care. Although there have been reports of adverse outcomes to patients associated with the use of CBGM in health-care facilities (15–17), others suggest no grave consequences to patient outcomes (7,18).

Various types of training programs for health-care personnel performing CBGM and the frequency of reevaluation of their performance also have been studied for predictors of greater accuracy in test results (19–21). However, improvements in training programs remain under the time and cost constraints of each health-care facility.

In 1989, proposed guidelines for QA were formulated by the National Committee for Clinical Laboratory Stan-

dards (NCCLS) (11), and in 1990, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) published its revised standards for decentralized laboratory testing (12,13). Medicare-approved hospitals and skilled nursing facilities are subject to Health Care Financing Administration (HCFA) regulations for QA in CBGM (22). In general, there is little descriptive information available concerning the clinical practice of QA for CBGM. Thus, the purpose of this research was to describe the practice of QA for CBGM in a wide range of health-care facilities; including characteristics of QA program structure, the education/certification process for those who perform the procedure, and quality control (QC) test procedures. Additional data concerning infection-control practices, sources of blood samples, and reimbursement for the CBGM service were also collected.

RESEARCH DESIGN AND METHODS

Attendees at the 1989 national conference of the American Association of Diabetes Educators (AADE) were used as a purposive nonprobability sample to obtain data concerning QA practice. The survey and a cover letter that described the criteria for inclusion in the sample were placed inside registration packets. Approximately 1300 surveys were distributed. The two criteria for inclusion in the sample were that the person *1*) practiced in a health-care facility that used CBGM in the care of clients and *2*) was the director or coordinator of the CBGM program or shared this responsibility.

The survey was a 36-item multiple-choice instrument with an "other" choice in most items for individualized responses. Content and face validity were judged by a six-member panel of experts in CBGM. This survey was distributed with the assumption that only certain individuals would fit the criteria for the study.

The survey data were analyzed with descriptive statistics, including frequencies, percentages, and measures of central tendency where appropriate. Relationships between several items were evaluated with χ^2 and Spearman's ρ statistics (23).

RESULTS

Three hundred eighty-five surveys were either returned at the conference or mailed to the investigators within 8 wk. The 378 usable surveys became the nonprobability sample (Table 1). The sample represented CBGM programs in 47 states in the United States, with 5 respondents from Canada. Most were registered nurses, with 78.6% of the sample being certified diabetes educators. Most respondents were diabetes nurse educators working in hospital settings.

General characteristics of the QA programs. Regarding characteristics of the QA program, 19.8% (n = 75) of the facilities stated that they had no formal program for QA for CBGM. For the other 303 facilities, the mean ± SD length of time that the facility had a formal QA program was 3.2 ± 1.9 yr (range 0.5–10 yr). Three hundred facilities (79.4%) reported that there were written, facility-specific policies and procedures for their CBGM programs. Table 2 identifies the sources of guidelines followed in structuring a CBGM QA program. Most respondents (66.5%) structured their programs with a combination of standards and guidelines from national and state regulatory agencies, accrediting bodies (JCAHO, College of American Pathologists [CAP]), and consensus-development organizations (i.e., NCCLS).

Of those responding, 53.4% (n = 198) used multidisciplinary advisory groups to assist in the decision making for CBGM programs. The composition of such advisory groups included individuals from the following departments: nursing (included by 93.9% of those with advisory groups), laboratory (70.7%), medicine (64.1%), and QA (56%). Less frequently included were representatives from departments of pharmacy (28.7%), nutrition (4.5%), and staff education (3%).

TABLE 1
Characteristics of respondents/facilities

	*n**	%
Profession		
Registered nurse	360	95.2
Registered dietitian	12	3.2
Physician	1	0.3
Other (exercise physiologist, laboratory technologist)	5	1.3
Title of primary position in facility		
Diabetes nurse educator	260	69.0
Nutritionist	9	2.4
Other (clinical nurse specialist, nurse practitioner, endocrinologist, administrator)	108	28.6
Certified diabetes educator		
Yes	297	78.6
No	81	21.4
Health-care facility		
Hospital	262	69.3
Outpatient clinic only	44	11.6
Physician's private practice	21	5.6
Long-term–care facility	2	0.5
Other (combined inpatient and outpatient, home health care, private practice)	49	13.0
Beds in primarily inpatient facility (*n*)		
<100	20	5.4
100–300	118	31.6
301–500	93	24.9
>500	62	16.6
Not applicable	80	21.4
Total weekly patient volume in primarily outpatient facility		
<50	50	13.4
51–150	36	9.6
150–300	17	4.5
>300	28	7.5
Not applicable	243	65.0

*Missing values account for totals <378.

TABLE 2
Characteristics of quality assurance (QA) programs

	n*	%
Guidelines followed for QA program		
JCAHO	42	12.1
State	1	0.3
Manufacturer's	63	18.2
Combination	230	66.5
Other (none, hospital's, CAP)	10	2.9
Laboratory's participation or cooperation in QA program for CBGM		
Full	107	29.9
Limited	127	35.5
None	109	30.4
Other (e.g., resource for information, uncooperative)	15	4.2
Testing equipment used in CBGM program		
BG meters with test strips	240	64.2
Visually read BG test strips	6	1.6
Both	122	32.6
Other (lab BG analyzers, none)	6	1.6
>1 brand of BG meter used in facility		
Yes	111	29.6
No	258	68.8
No BG meter used	6	1.6
Are certain patient care areas excluded from CBGM program?		
No (any area may perform CBGM)	259	70.8
Yes	107	29.2

JCAHO, Joint Commission for Accreditation of Healthcare Organizations; CBGM, capillary blood glucose monitoring; CAP, College of American Pathologists; BG, blood glucose.
*Missing values account for totals <378.

Respondents were asked to describe the role of the clinical laboratory in the CBGM QA program. Although ~66% of the sample reported some degree of laboratory involvement, 30.4% reported no laboratory involvement (Table 2).

Concerning the specific type of CBGM equipment or materials utilized in health-care facilities, most respondents (64.2%) reported the use of blood glucose meters with reagent strips only, and 1.6% reported the use of visually read reagent strips only. Of those with meters, 68.8% reported using only one brand of blood glucose meter in their programs (Table 2).

Of those responding, 75.1% (n = 274) stated that all patient-care areas in the facility that provide CBGM also participate in the QA program. In 29.2% (n = 107) of respondents, however, certain patient-care areas were excluded from the CBGM program (i.e., the area may not use CBGM equipment). Of those reporting excluded areas, 28% excluded neonatal areas, 12% excluded the operating room, 8.4% excluded the emergency department, and 6.3% excluded critical care areas of their facility. Most frequently cited reasons for excluding certain patient-care areas from the CBGM program included: the area had patients with deviations from the normal range for hematocrit, which could affect the accuracy of the CBGM test result; nurses did not perform CBGM frequently enough to ensure proper technique; and the laboratory provided timely blood glucose test results.

Education/certification process. Descriptive information concerning eligibility and the "education/certification" (authorization) process for those who perform CBGM was elicited from respondents (Table 3). Fifty-three percent of the respondents reported that all licensed health-care professionals were eligible to perform CBGM. Among the 21.1% who responded "other," the following were specified: students, lab technicians, patients, "undefined," and "who knows?" Components of the initial education program for CBGM are described in Table 3. The "other" choices, which was 45.9% of the responses, included classroom instruction and return demonstration only (n = 108), self-study and video (n = 10), and one-to-one instruction (n = 15).

Some form of recertification for continued performance of CBGM was required in 61.2% of the responding programs. Under "other" for frequency of recertification, the specified responses included "during

TABLE 3
Education or certification programs for capillary blood glucose monitoring (CBGM)

	n*	%
Have an initial certification program for those who perform CBGM		
Yes	299	80.4
No	73	19.6
How often are personnel required to be recertified for continued performance of CBGM?		
Every 6 mo	17	4.6
Once/yr	186	50.8
Other ("as needed," every 2 yr)	21	5.7
Personnel not recertified	142	38.8
Personnel eligible to perform routine CBGM for patients		
All licensed health-care personnel	200	53.3
Licensed and unlicensed health-care personnel	55	14.7
Laboratory personnel only	7	1.9
Registered nurses only	34	9.1
Other (students, lab technicians)	79	21.1
Modality for personnel to learn information and techniques for CBGM		
During new employee orientation	214	58.8
Special class for certification	68	18.7
On the job	67	18.4
Other (unstructured, uncertain)	15	4.1
Components included in initial education or certification program for CBGM		
Classroom instruction only	24	6.7
Classroom instruction, return demonstration, written test	169	47.3
Other (classroom instruction and return demonstration only, one-to-one instruction)	164	45.9

*Missing values account for totals <378.

QC audits," "as needed," "every two years," "before research," and "with a new meter" (Table 3).

QC and proficiency testing. Items pertaining to QC testing of CBGM systems are reported in Table 4. Most of the sample indicated that QC tests are performed at least once per day. Of those responding in the "other" category, ~50% indicated infrequent or unscheduled QC testing, e.g., monthly, "when dirty," "varies."

In 81.9% of the respondents, QC aqueous glucose test solutions were purchased from the manufacturer of the meter and utilized with the manufacturer's printed range of acceptable values. For 6.4% of respondents, the manufacturer's QC test solutions were used, but the laboratory or the CBGM coordinator defined the range of acceptable values. Blood-based QC test solutions were used by 2.5% of the sample, with another 1.9% utilizing aqueous glucose solutions prepared by their clinical laboratories.

Respondents were asked whether measurements of blood glucose from a split sample, defined as "a comparison of results from analyses of sample by laboratory reference method and blood glucose monitoring equipment," were a routine part of their QA program. More than half of respondents (56.4%) reported that this comparison testing was not a routine part of the QA program. Only 10.2% of the respondents reported that one split sample was performed each month per meter. The frequency of proficiency testing, defined on the survey as "portions of a test sample are analyzed at the same time by multiple blood glucose meters and by the laboratory reference method for comparision," is reported in Table 4.

TABLE 4
Quality control (QC) testing procedures

	*n**	%
Personnel who perform QC tests		
Nurse designated for each area	191	52.3
Each nurse before 1st BG test of that day	64	17.5
Laboratory personnel	19	5.2
No QC tests	21	5.8
Other ("unspecified," unit secretary, each unit decides)	70	19.2
Frequency that each meter is tested with QC test solutions		
Once/shift	80	21.7
Once/day	181	49.1
Only when problem occurs	35	9.5
QC test solutions not used	13	3.5
Other (weekly, monthly)	60	16.3
Type of QC test solutions used		
High control	16	4.4
Low control	19	5.3
Both for each test	267	74.0
Other (normal range solutions, alternate high and low solutions)	59	16.3
Is comparison of capillary blood glucose monitoring results with laboratory reference method (split samples) routine part of QA program?		
Yes	158	43.6
No	205	56.4
Frequency of proficiency testing		
Once/month	36	10.0
Once/3 mo	84	23.4
Not performed	168	46.8
Other ("random," "during research," "when problems")	71	19.8

*Missing values account for totals <378.

Maintenance and cleaning of instruments as a part of the total quality assurance program were reportedly done once each day by 26.2% (n = 96), once each week by 26%, and "only when appears dirty" by 29.2% of respondents. In the "other" category, the most frequent responses were that cleaning and/or maintenance was done "after each patient" (n = 6), "once each shift" (n = 8), and "with each new vial of strips" (n = 16).

Data were collected regarding actual sources of blood for testing, infection control, and patient charges for the blood glucose test. Responses to "What are the actual sources of patients' blood used for blood glucose monitoring?" were: fingertips only (49.5%) and fingertips, earlobes, heels (for neonates) (9.9%); 20.2% replied "all of the above" in addition to blood samples from venous and arterial lines.

In response to "Does your policy/procedure specify that protective gloves must be worn by personnel while performing CBGM?," 74.2% (n = 277) reported "yes." In 19.1% of respondents, it was reported that, to their knowledge, protective gloves were worn all of the time, 42.7% stated "most of the time", and 33.6% stated "infrequently." In 4.3% of the sample, protective gloves were "never" worn.

Patients were charged for the CBGM service in 55% (n = 205) of the respondent's institutions. When the survey data were analyzed by type of facility, 29.5% of those described as outpatient clinics reported that they had a patient charge for the blood glucose test compared to 60.3% of those from an inpatient setting reporting a patient charge.

Supplementary data analyses were done to assess relationships between characteristics of the CBGM programs. There was a significant χ^2 statistic (20.9, 4 df, $P < 0.0001$), indicating a relationship between the presence of a multidisciplinary advisory group and greater frequency of QC tests performed.

A Spearman's ρ statistic was used to assess the relationship between the degree of laboratory involvement in the QA program for CBGM and the number of years that a facility has had a QA program in effect. A significant ρ (-0.18, $P < 0.001$), suggested a relationship between greater involvement and greater length of QA program.

Finally, post hoc analysis assessed the number of facilities that reported the coexistence of all five of the following CBGM program characteristics: *1*) presence of a multidisciplinary advisory group, 2) full participation or cooperation of the laboratory in the QA program,

3) quarterly proficiency testing, 4) a CDE with at least coresponsibility for the program, and 5) an initial certification process for those performing CBGM. All five characteristics were reported by only 4.5% (n = 17) of the sample; the first three characteristics were reported in only 5.8% (n = 22) of the sample.

CONCLUSIONS

Because this sample (n = 378) was drawn from the national AADE conference, most attendees were probably either specialists in diabetes or part of a team that provides care to persons with diabetes. Of those attending this meeting, we estimated that <50% would fit our stated criteria for completing the survey. This estimate was based on the diabetes team model; institutions may send more than one team member to this conference for diabetes educators. Thus, we feel confident that we obtained a response rate from eligible individuals of >50%. There is also reason to think that the QA data from the survey may be representative of the "best cases" of CBGM programs in health-care facilities because the sample was drawn from a specialty conference.

The results concerning which standards or guidelines are followed in structuring CBGM QA programs (Table 2) highlight a possible source of confusion for those responsible for the QA programs. There are numerous regulatory agencies (e.g., HCFA, state Departments of Health), accrediting bodies (e.g., JCAHO, CAP), and groups (NCCLS) that develop standards by consensus; each of these has a different degree of specificity in their standards, and some are more stringent than others. Also, there may be variable levels of enforcement of the HCFA-Medicare regulations for CBGM programs. We concluded that the confusion concerning the sources of the various standards and which standards must be followed may be a barrier to QA program development in health-care facilities.

The NCCLS guideline (11) proposes that a multidisciplinary committee be instituted in health-care facilities to advise those responsible for CBGM on issues related to the total QA program. Only 53.4% of those responding indicated the existence of such a multidisciplinary group, and within this group, the most frequently cited participating departments were nursing, laboratory, medicine, and quality assurance. For the 46.6% of facilities that do not have an advisory group, communication for problem solving may be difficult and thus a barrier to adherence with QA standards.

Neither the NCCLS guidelines (11) nor the JCAHO standards (12) require that the clinical laboratory in health-care facilities be involved in the QA program for CBGM; however, guidelines from the Canadian Association of Pathologists (24) and CAP (14) specify that the service must be under the supervision of the laboratory. Although the skills and knowledge required for a complete QA program are in the purview of a laboratorian's education (25), the skills and knowledge needed for precision, accuracy, linearity and proficiency studies and for analysis of QA data are not generally found in a nurse's basic or graduate education. Nevertheless, 30.4% of respondents reported no participation or cooperation from the lab, and another 35.5% reported only limited participation or cooperation from the lab. Note that there was a significant Spearman's ρ correlation between degree of laboratory involvement reported and number of years that the facility has had a structured program for QA in CBGM. Thus, it seems that many nursing departments or individuals have been asked to develop a program of QA for CBGM without the assistance of the very department that has the technical expertise for this endeavor.

Certain characteristics of CBGM programs are considered to enhance the accuracy of results by decreasing the complexity of the program. One characteristic recommended by the NCCLS is that each facility have only one brand of instrument for CBGM (11); however, almost one-third of the respondents reported the use of more than one brand of instrument for CBGM. A second characteristic recommended by the NCCLS guidelines is that each facility decide on and define the specific areas of use for CBGM (11). Of those responding, 70.5% reported that any area may perform CBGM; this may indicate simply the lack of a decision-making process for selecting appropriate areas of use within health-care facilities or a lack of awareness of the need to make such decisions.

Both NCCLS (11) and JCAHO (12) guidelines recommend that personnel have an education program to achieve competency in the test procedure. Most respondents (80.4%) stated that they provide an initial certification program for CBGM. Although 55.4% reported that recertification was required at least once per year, another 38.8% reported no recertification program (Table 3). Periodic reeducation increases both accuracy and precision in staff who use meters in health-care settings (20). JCAHO specifies quarterly checks for competency of staff performing CBGM (12). Meeting this requirement for quarterly checks of competency, given the present level of recertification in health-care facilities, may be a costly endeavor in terms of staff time and resources, unless it is simply a periodic assessment of accuracy data for operators.

Neither JCAHO (12) nor the NCCLS (11) recommended the level of personnel eligible to perform CBGM. The content of the training program recommended by NCCLS would seem to require the level of a licensed health-care professional (11). The data in Table 3 concerning eligibility to perform CBGM reflects the ambiguity on this issue. Although 53.3% reported that all licensed health-care personnel are eligible, other responses ranged from "RNs only" to "anyone" and "undefined." Standards that more clearly delineate the appropriate level of personnel for CBGM would be helpful to individuals responsible for these programs, especially in their staffing negotiations with administrators.

Concerning the data on QC testing procedures, there were wide discrepancies between the practice in health-care facilities and the standards for QA programs (Table 4). The NCCLS proposed that operators perform a QC test before their first patient test of each day (11). In contrast to that recommendation, the practice data revealed only 17.5% with such a pattern of QC testing. A practice pattern of QC tests performed at least once each day per meter was reported by 70.8%, but most respondents (52.3%) reported that QC tests were performed by only one nurse designated for each area. These QC tests do not assess the entire system or include assessment of each operator. The JCAHO standards on QC test frequency specify that QC tests are performed "on each procedure each day the procedure is performed" (PA.6.4.1.4). The terminology of this standard, especially the interpretation of "procedure," may contribute to confusion concerning QC testing.

Both JCAHO (12) and NCCLS (11) specify that proficiency testing be done according to state's or institution's requirements. However, 46.8% reported no proficiency testing as defined on this survey. Another 19.8% specified that it was done intermittently ("when problems occur," "in research"). Note that, as described in this survey item, proficiency tests may have been construed by respondents as only internal (institutional) rather than from an external agency. In any case, most programs may have to seek added resources to meet the minimal requirements, which may now require use of an approved proficiency testing agency.

Although universal precautions for infection control in the handling of body fluids are appropriate for CBGM (26), only 19.1% of the sample reported adherence by their staff "all of the time" to use of protective gloves during the procedure. The barrier to wearing protective gloves may be simply the inconvenience of putting them on. In light of reports of the transmission of hepatitis B virus from reuse of the platform for spring-loaded blood-sampling devices (27), the seriousness and vulnerability of patients and staff to cross-infection of blood-borne diseases must be stressed in education programs for CBGM.

We believe that certain CBGM program characteristics, although not minimal standards, may be indicative of a milieu conducive to accuracy in test results, adherence to policy and procedure by staff, and institutional support. From the practice data, only 4.5% of the sample reported the coexistence of all five of the previously stated characteristics. Only 5.8% of the sample reported the presence of at least the first three characteristics, which we believe reflect an institutional commitment to the success of the program. These small percentages are more striking considering the nature of our sample, which we consider to be representative of the more developed CBGM programs.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88; Public Law 578) will have important ramifications for CBGM in health-care facilities and other test sites (28). The final regulations from HCFA are pending, and there is uncertainty as to the test classification of CBGM with a meter. Federal regulatory requirements of CLIA '88 may supersede the QA standards from other accrediting agencies (22).

In conclusion, the importance of these practice data is to document the wide gap between clinical practice of QA for CBGM and the standards and guidelines. The effort to close this gap may require resources that the health-care delivery system is either unwilling or unable to expend to keep CBGM as an ancillary laboratory test. Responsibility for this increasingly complex program for QA often has been assumed by diabetes nurse educators who may not have adequate technical expertise for designing QA programs or the resources to carry them out. Although the diabetes educators' input in the CBGM program is essential, diverting great amounts of their time from patient education and care may be short sighted. It is of vital importance for both the success of CBGM programs and preservation of the education, counseling, and consultative roles of diabetes educators that multidisciplinary groups in health-care facilities assume collaborative responsibility for their CBGM programs. Further research is needed to determine the minimal standards for various components of the QA program so that a level of accuracy of clinical significance to patient outcomes is achieved within the constraints of health-care facility resources.

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