A Survey of Quality Indicator Use in the Clinical Laboratory

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OBJECTIVE: A survey of clinical laboratories was conducted to capture information about quality indicators in use within the state of Arizona. This information was then used to determine which quality indicators are applicable across the spectrum of clinical laboratories making them suitable for benchmarking laboratory performance. The objectives of this study were also to heighten awareness of benchmarking practices for clinical laboratory managers and laboratory quality assurance personnel, to develop objective methods of quality monitoring for performance improvement, and to encourage collaboration between laboratories and accreditation agencies.

METHODS: A review of the current literature was conducted to assess the status of benchmarking within the clinical laboratory. Data were also obtained from the Centers for Medicare & Medicaid Services (CMS) about all licensed clinical laboratories in Arizona. A mail survey was then created and conducted to investigate the use of clinical laboratory quality indicators in Arizona.

SETTING AND PARTICIPANTS: A paper survey was mailed to a representative sample of clinical laboratory managers included in the CMS licensed laboratories listing for the state of Arizona.

MAIN OUTCOME MEASURES: The selected sample was surveyed by mail and validation testing of the survey was conducted using the *t*-test. The compiled survey data is also presented in the form of histograms.

RESULTS: Applying the *t-test* to the sample vs. population data proved that the sample was not a very good representation of the population and a better selection method should be used in future studies. Of the 319 of 3198 clinical laboratories randomly selected to receive the survey, 21 (6.58% of the sample or 0.66% of the population) responded with completed surveys. The information received from the respondents revealed a relationship between test volume and the number of indicators being monitored by clinical laboratories, the preference of indicators being monitored by those laboratories, the size of the laboratories where the majority of benchmarking is occurring, and a link between accrediting agencies and benchmarking activities.

CONCLUSION: The survey proved that quality indicators are used for quality improvement purposes within the clinical laboratory; although it also showed that the industry still does not have a standardized approach to the use of quality indicators for benchmarking performance against other laboratories.

ABBREVIATIONS: CAP = College of American Pathologists; CDC = US Centers for Disease Control and Prevention; CLIA = Clinical Laboratory Improvement Act of 1988; CMS = Centers for Medicare & Medicaid Services; JCAHO = Joint Commission on Accreditation of Healthcare Organizations; NQF = National Quality Forum; PPM = provider performed microscopy; TAT = turnaround time.

INDEX TERMS: clinical laboratory science; healthcare quality indicators; healthcare benchmarking.

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Very little has been written about the use of quality indicators within the clinical laboratory, although the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has worked hard to initiate quality processes in healthcare and use them as a basis for accreditation. To achieve this they have moved toward a holistic approach for their inspections by reviewing both patient outcomes and patient safety. A large part of their inspections also involves a process audit. In the case of a laboratory inspection, the inspector will review the laboratory testing that was ordered, what the results were, how the quality control testing performed at the time of patient testing, who performed the testing and their credentials, training and competency assessment, and finally the patient's outcome.

This approach is more in line with today's quality systems approach than any of the other accreditation organizations, but it fails to review other quality processes such as the use of quality monitors and other improvement activities. To ensure these areas are reviewed, JCAHO requires accredited laboratories to monitor certain National Patient Safety Goals[1,2] to:

- improve the accuracy of patient identification,
- improve the effectiveness of communication among caregivers,
- reduce the risk of healthcare-associated infections, and
- encourage the active involvement of patients and their families in the patient's care as a patient safety strategy.

Although JCAHO gives some guidelines of how these monitors are to be measured, such as "Comply with current US Centers for Disease Control and Prevention (CDC) hand hygiene guidelines" for the reduction of risk of healthcare-associated infections, they are not specific and therefore don't allow for accurate comparison. Since they are not laboratory specific they do not reflect the laboratories' testing abilities.

As opposed to JCAHO, the College of American Pathologists (CAP) is a laboratory-based organization and their accreditation process focuses solely on the laboratory. For this reason, their development of quality indicators are laboratory specific, and focused on the clinical laboratory testing processes, from order entry to result reporting.

The College of American Pathologists' current list of suggested quality monitors is selected from data gathered during their performance of Q-Probes studies.[3] So as not to create a conflict of interest between their accreditation of a facility and their Q-Tracks program (which is a separate fee-for-service program), CAP only gives "Examples of key indicators [which] include, but are not limited to":[4]

- Patient/Specimen Identification
- Test Order Accuracy
- Stat Test Turnaround Time
- Critical Value Reporting
- Customer Satisfaction
- Specimen Acceptability
- Corrected Reports – General Laboratory
- Corrected Reports – Anatomic Pathology
- Surgical Pathology/Cytology Specimen Labeling
- Blood Product Wastage
- Blood Culture Contamination

The College of American Pathologists' Q-Probes studies were designed to study individual laboratories' current problems for potential improvement. The selection of areas of study was therefore based on laboratories notifying CAP of areas where problems were occurring and paying CAP to review these areas in a performance improvement format. CAP's subsequent development of Q-Tracks uses the information gathered from the Q-Probes studies in a benchmarking format to allow all laboratories that wish to participate a way of monitoring these selected indicators over time.

A review of the current literature of the Q-Tracks program indicates that the organizations that initially subscribed to Q-Probes and Q-Tracks were larger organizations. This assumption is based on the types of monitors selected being those that are applicable only to larger facilities; such as wristband monitoring for patient identification accuracy and blood culture contamination rates.[5,6] Smaller facilities such as acute care hospitals and outpatient clinics may have very few to no in-patients with wristbands, or the need for blood culturing, so data from such indicators would be unavailable or only available in such small quantities as to be unusable as a continuous monitor of statistical significance. CAP's use of data from larger facilities may be due to larger organizations having more funding available to subscribe to outside monitoring rather than having to rely solely on in-house methods.

To date Q-Tracks has monitors for:[7]

- Patient Identification Accuracy
- Blood Culture Contamination
- Laboratory Specimen Acceptability
- In-Date Blood Product Wastage
- Satisfaction with Outpatient Specimen Collection
- Stat Test Turnaround Time Outliers

- Morning Rounds Inpatient Test Availability
- Critical Values Reporting
- Type and Screen Completion for Scheduled Surgery
- Turnaround Time (TAT) of Troponin
- Gynecologic Cytology Outcomes: Biopsy Correlation Performance
- Physician Satisfaction with Surgical Pathology Reports

The only research studies published about clinical laboratory indicator use to date and their ability to improve performance are those associated with the Q-Probes and Q-Tracks programs.

The CDC is currently working with the National Quality Forum (NQF), a consortium of public and private members, to create clinical laboratory monitors that are nationally

Figure 1. Mail survey

A SURVEY OF QUALITY INDICATOR USE AND BENCHMARKING PRACTICES WITHIN THE STATE OF ARIZONA

Please take a few moments to complete this survey about the collection of clinical laboratory indicators data. The information collected will determine indicators currently in use and identify those that are applicable across the spectrum of clinical labs for benchmarking suitability. This survey is one part of a thesis presentation to the faculty of California State University Dominguez Hills. Please return the survey in the envelope provided within 30 days of receipt.

1. What is your laboratory's annual test volume?
   - ☐ <10,000
   - ☐ 10,001 – 50,000
   - ☐ 50,001 – 100,000
   - ☐ 100,001 – 1,000,000
   - ☐ >1,000,000

2. What services does your laboratory provide? Please check all that apply.
   - ☐ Phlebotomy
   - ☐ Chemistry
   - ☐ Microbiology
   - ☐ Hematology
   - ☐ Coagulation
   - ☐ Urinalysis
   - ☐ Blood Bank
   - ☐ Immunology
   - ☐ Molecular Biology
   - ☐ Virology
   - ☐ Toxicology
   - ☐ Histology/Cytology

3. Which of the following quality indicators does your laboratory routinely (monthly/quarterly) monitor?
   - ☐ Patient Specimen Identification Accuracy
   - ☐ Test Order Accuracy
   - ☐ Turnaround Time
     - ☐ STAT
     - ☐ All
   - ☐ Critical Value Reporting
   - ☐ Customer Satisfaction
     - ☐ Patient Satisfaction
     - ☐ Physician/Provider Satisfaction
     - ☐ Other_____
   - ☐ Specimen Acceptability
   - ☐ Corrected Reports
   - ☐ Blood Product Wastage
   - ☐ Blood Culture Contamination
   - ☐ Type and Screen Completion for Scheduled Surgery
   - ☐ Cytology/Biopsy Correlation
   - ☐ Point-of-Care Testing Accuracy
   - ☐ Workload/Full Time Employees
   - ☐ Reference Laboratory Expenses
   - ☐ Other_____
   - ☐ Other_____
   - ☐ Other_____
   - ☐ Other_____
   - ☐ Other_____
   - ☐ Other_____

4. Does your laboratory benchmark/compare quality data with other laboratories?
   - ☐ Yes
   - ☐ No

   If yes, who do you benchmark/compare quality data with?
   - ☐ Private Data Collection Agency
   - ☐ Governmental Agency
   - ☐ Accreditation Agency (CAP, COLA, JCAHO, etc.)
   - ☐ Clinical Laboratory Network (such as an
   - ☐ organization's internal network)
   - ☐ Private
   - ☐ Governmental
   - ☐ Other_____

5. Who accredits your laboratory?
   - ☐ CAP
   - ☐ CLIA
   - ☐ COLA
   - ☐ JCAHO
   - ☐ Other_____

applicable for benchmarking.[8] NQF's goal is to produce indicators that are both relevant to the laboratory (pre-analytic, analytic, and post-analytic monitors) and laboratory test monitors that monitor performance for the whole healthcare system (system monitors). The NQF's current list of possible monitors include:

- Diabetes Monitoring (system)
- Hyperlipidemia Screening (system)
- Test Order Accuracy (pre-analytic)
- Patient Identification (pre-analytic)
- Blood Culture Contamination (pre-analytic)
- Adequacy of Specimen Information (pre-analytic)
- Accuracy of Point-of-Care Testing (analytic)
- Cervical Cytology/Biopsy Correlation (analytic)
- Critical Value Reporting (post-analytic)
- Turnaround Time (analytic)
- Clinician Satisfaction (post-analytic)
- Clinician Follow-up (post-analytic)

This is a young program of study and clearly more work needs to be performed before a consensus and any form of standardization can be achieved for the measurement of quality indicators in the clinical laboratory. Progress appears to be occurring and this progress is necessary, not only to achieve and ensure better patient care but as Lusky states, "Some things aren't a matter of whether but of when. And national quality measures for [clinical] laboratories that can be linked to payment incentives or inspection penalties or both are likely to be one of them."[9]

The goal of this study was to survey clinical laboratories of all sizes and scopes within the state of Arizona to identify quality indicators currently being monitored. This would allow for a comparison of monitors recommended by CAP, JCAHO, and the NQF. It would also allow for the segmentation of monitors based on laboratory size and scope, to determine whether monitors for different facility types are necessary.

MATERIALS AND METHODS

To obtain data that may be generalized for any state throughout the United States an arbitrary single state, the state of Arizona, was selected as the survey sample.

Relevant data about all licensed clinical laboratories currently operating within the state of Arizona were obtained from the CMS of the Department of Health and Human Services.[8] These data included Clinical Laboratory Improvement Amendment (CLIA) Act licensure numbers, names of laboratories, laboratory addresses and contact information, the type of certificate of licensure held (compliance, waived, provider performed microscopy, or accredited), type of control (ownership), and facility type (ambulatory surgery center, community clinic, ancillary test site, etc.) The list contained 3198 licensed laboratories within the state of Arizona printed in order of licensure number; of this list, a sample of 319 (10%) laboratories were selected to receive a mailed survey. The sample selection was made using a systematic approach with a random number start, as described by Hayes.[10]

The survey (Figure 1) contained questions regarding laboratory demographics that were not available on the CMS list, such as the laboratory's annual test volume (an indicator of laboratory size), the services provided (an indicator of laboratory type), and the accrediting organization by which the laboratories were inspected (for comparison of indicator use and accreditation agency). The intention of the survey was to capture data about all clinical laboratory types and sizes, so that the information obtained was a fair representation of quality indicators in the clinical laboratory industry.

The actual sample size used for the final investigation was determined by the survey response rate.

RESULTS

The data collected from the list of laboratories obtained from the CMS, was used to calculate a possible correlation (r) between the population data and the sample, using t-tests (with a $p = 0.05$) as described by Crossley.[11] This was performed to determine whether the sample surveyed was representative of the Arizona laboratory population

Table 1. Correlation and t-test comparisons of surveyed sample vs. population

	r^2	r	t	t_{crit} ($p = 0.05$)
Type of certificate of licensure	0.991	0.995	18.07	3.18
Type of control	0.999	0.999	89.20	2.31
Facility type	0.907	0.952	15.61	2.06

r^2 = correlation coefficient squared; r = correlation coefficient; t = t-test result; t_{crit} = critical value that the t-test result must be less than for results to be comparable

(Table 1). Upon initial review, the data in Table 1 appear to indicate that the sample data correlate well with the population but when the *t*-test is applied, one can see that the two sets of data (population vs. sample) are not the same, indicating that the selected sample was not a very good representation of the population being surveyed. Even with this limitation, the survey results produced some important information that could provide a basis for future research.

There was no current literature on the use of surveys to obtain information about quality indicator use within the medical field; therefore, the survey was constructed following the guideline of Hayes[10] for customer satisfaction surveys. A direct comparison (correlation analysis or *t*-test) could not be made between the respondents and the initially selected sample or population because the survey did not ask questions about type of licensure held, type of ownership, or facility type. This would have made a direct comparison and complete survey validity testing possible.

Of the 319 clinical laboratories selected to receive a survey, 21 responded with completed surveys. This represented 6.58% of the sample or 0.66% of the total population of licensed clinical laboratories within the state of Arizona.

The survey data collected was used to make a comparison between the laboratory's test volume and the average number of quality indicators monitored (Figure 2). Although the correlation coefficient of 0.6193 is not high, these data do indicate that larger sized laboratories are performing more indicator monitoring compared to smaller facilities. The low correlation coefficient may be due to the low sample size and could improve if the sample size were increased.

There are only three indicators that are required or suggested for monitoring by JCAHO, CAP, and NSF; these are patient specimen identification accuracy, critical value reporting, and physician/provider satisfaction (Table 2). Therefore, it is not surprising that these three indicators were monitored by more laboratories than most of the other indicators. Two other quality indicators that were monitored as much as the above-mentioned three were specimen acceptability (suggested by CAP) and test order accuracy (suggested by both CAP and NQF).

The two quality indicators that were monitored the least were type and screen completion for scheduled surgery and cytology/biopsy correlation, two indicators that are highly specific for specialized laboratories (blood banks and anatomic pathology laboratories, respectively).

Patient/specimen identification, critical value reporting, and patient satisfaction were also the only three indicators that were monitored by all laboratory sizes surveyed (<10,000; 10,001-50,000; 50,001-100,000; 100,001-1,000,000; >1,000,000) which may be an important factor when considering indicators that are applicable to most if not all clinical laboratories. STAT turnaround times, specimen acceptability, and blood culture contamination were only monitored by the larger facilities.

Most of the responding laboratories that had a test volume of >10,000 were performing some type of benchmarking activities (Figure 3). The smallest facilities, with a test volume of 0-10,000, seem least likely to perform benchmarking activities.

Of the facilities that were benchmarking quality indicator data, private data collection agencies and private clinical laboratory networks appeared to be the favored methods of quality data comparison. A few laboratories included private industry, such as reagent manufacturers, as a means for benchmarking quality assurance data. This response may be a misunderstanding of the dif-

Figure 2. Test volume vs. number of indicators monitored

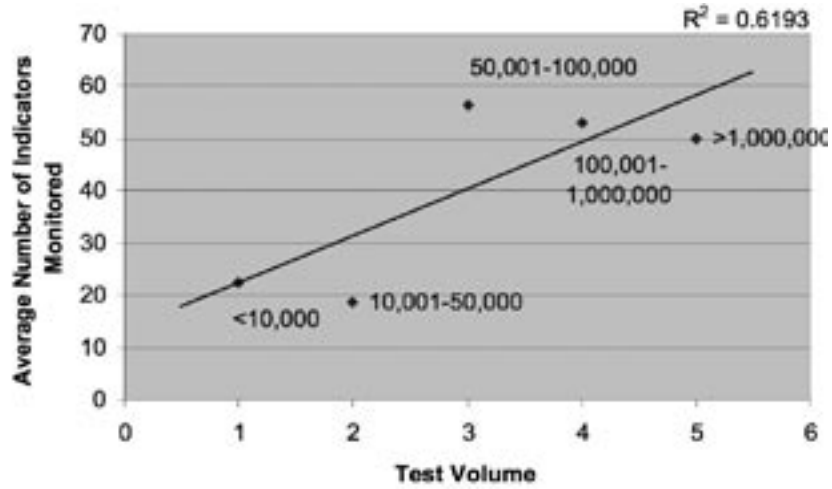


Table 2. List of monitors surveyed with associated accrediting organizations

Monitors surveyed	Accreditation/ quality organization	Percentage of laboratories monitoring
Patient Specimen Identification Accuracy	JCAHO/CAP/NQF	57
Test Order Accuracy	CAP/NQF	43
Turnaround Time – STAT	CAP	33
Turnaround Time – All	NQF	33
Critical Value Reporting	JCAHO/CAP/NQF	62
Patient Satisfaction	JCAHO/CAP	38
Physician/Provider Satisfaction	JCAHO/CAP/NQF	43
Specimen Acceptability	CAP	57
Corrected Reports	CAP	33
Blood Product Wastage	CAP	29
Blood Culture Contamination	CAP/NQF	29
Type and Screen Completion for Scheduled Surgery		0
Cytology/Biopsy Correlation	NQF	5
Point-of-Care Testing Accuracy	NQF	24
Workload/Full-time Employees		19
Reference Laboratory Expenses		24

ference between quality control and quality assurance on the part of the respondents, as quality control data, not quality assurance data, is regularly collected by reagent/instrument manufacturers for comparison. Eleven of the 21 respondents indicated that they "benchmark/compare quality data".

Thirteen of the 21 respondents also indicated that they were accredited through CLIA as opposed to other clinical laboratory accreditation agencies (Figure 4). CLIA usually accredits facilities that are performing waived and/or provider performed microscopy (PPM), whereas larger facilities performing more complex testing with higher regulatory requirements are usually accredited by CAP or JCAHO. Therefore, the survey findings were largely affected by the number of smaller facilities that responded to the survey and could be more accurate if each licensure group were surveyed separately. The data in Figure 4 also shows that less than half of the laboratories accredited through CLIA are benchmarking.

DISCUSSION

Clinical laboratories have collected quality indicator data to monitor performance and initiate improvement for approximately 10 to 20 years, but they may not fully recognize the value of using these data to perform comparisons (benchmarking) with other clinical laboratories on a large scale, and large-scale comparisons may provide a more objective picture of their laboratory's performance. Many laboratories have collected quality data based on their own laboratory's experiences and needs; this has led to the development of a variety of monitors that are hard to compare directly.

The two largest clinical laboratory accreditation agencies, CAP and

JCAHO, have studied the use of quality monitors within the clinical laboratory. Both agencies began by selecting monitors that were already in existence. CAP used the information it collected to develop a voluntary benchmarking tool called Q-Tracks, while JCAHO is progressing toward standardization of clinical laboratory quality monitors to encourage collaboration between clinical laboratories.

Before any form of collaborative comparisons can take place, clinical laboratory scientists must define the indicators that are needed to monitor performance and exactly how they should be monitored, a goal of the NQF. These monitors should be based on the size and/or scope of the laboratory.

This survey was conducted to capture information about the status of clinical laboratory quality monitoring, and benchmarking practices, with the expectation of identifying indicators that are comparable across a spectrum of laboratories.

A review of the literature failed to locate any previous clinical laboratory surveys conducted to collect information about the use of quality monitors. Therefore, the survey was created using guidelines from customer satisfaction surveys described by Hayes[10] and the lists of quality monitors described by CAP, JCAHO, and the NQF.[1,4,8]

Information obtained from on the CMS list was used to determine the validity of the selected sample by obtaining the *t* values for the population data vs. the sample data. Unfortunately, this data analysis showed that the surveyed sample was not a fair representation of the population and therefore weakens the validity of conclusions made regarding the data collected. Final survey validation would best be determined by performing comparisons of the population data vs. the survey respondent data. This survey did not capture the relevant information to perform these calculations, as it did not address questions about the facilities' certification, control, and type from the actual respondents.

Of the 319 laboratories initially surveyed, 21 laboratories responded, allowing some conclusions to be drawn from the information received.

Figure 3. Number of laboratories performing benchmarking activities by test volume

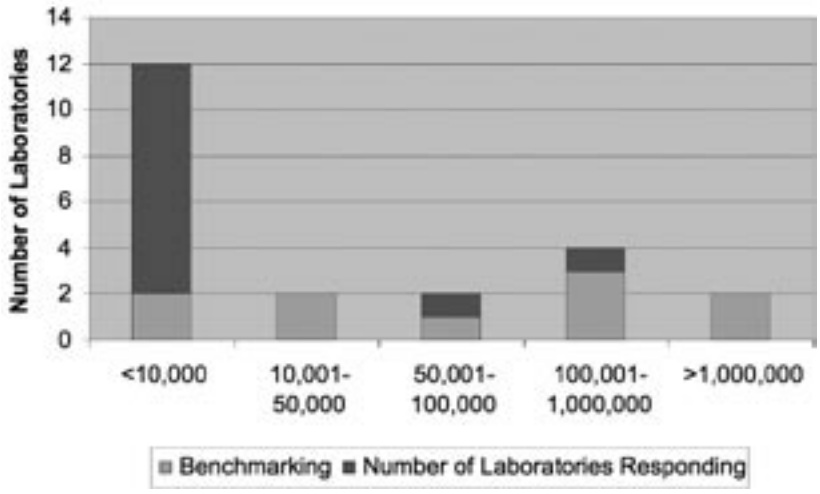
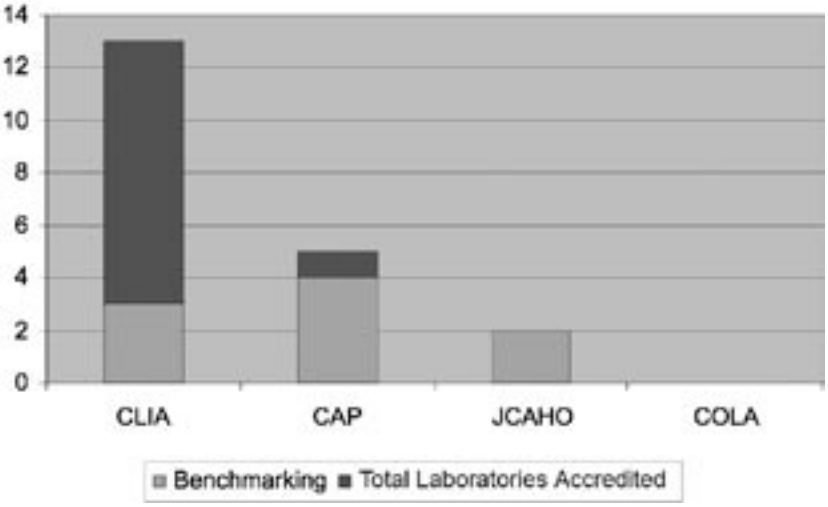


Figure 4. Who accredits the surveyed laboratories and how many perform benchmarking activities?



Larger facilities appear to be performing more quality indicator monitoring than smaller facilities. This is not surprising because larger facilities are the moderate to high complexity testing laboratories as defined by the CMS[12] that have more stringent regulatory requirements than smaller laboratories.

When laboratories do select quality indicators to monitor, they generally select monitors that represent the entire process for all laboratory testing. To do this, at least one monitor is usually selected to represent pre-analytical testing, analytical testing (the actual measuring phase), and post-analytical testing. The results of the survey indicate that the top six monitored indicators are:

- Critical Value Reporting (post-analytical)
- Patient Specimen Identification Accuracy (pre-analytical)
- Specimen Acceptability (pre-analytical)
- Test Order Accuracy (pre-analytical)
- Customer Satisfaction – Physician/Provider (system)
- Customer Satisfaction – Patient (system)

These monitors do appear to be a good representation of the entire process (as long as system monitors are considered equivalent to analytical monitors) and are applicable to most laboratory sizes and scopes. This would make them easily comparable and an attractive selection for benchmarking purposes.

Many laboratories monitor three to six quality indicators, which seems to be a reasonable amount for monthly monitoring. Benchmarking too many monitors may become prohibitive and probably counterproductive, especially when laboratories also have to address their own unique problems for monthly monitoring and performance improvement. Some larger facilities with more specialized testing may want to benchmark other monitors that are more specific to their needs, such as cytology/biopsy correlation accuracy or type and screen completion for scheduled surgery, so this option must also be available.

The data collected indicate that benchmarking is occurring at a high rate in the facilities that are performing >10,000 tests per year. This was a surprising finding and it may be due to survey self-exclusion by laboratories not performing any monitoring activities. One of the problems with using a voluntary survey to collect data is that facilities that may not feel comfortable with their performance (don't monitor quality indicators and/or benchmark) may decide not to answer the survey. This would skew the data, making it seem that there are more laboratories performing monitoring and benchmarking than actually are.

Further research needs to be performed in this area before successful benchmarking programs can be produced that will be applicable to most, if not all, clinical laboratories. If future surveys are performed, the support of at least one of the nationally recognized accreditation organizations would probably encourage a larger survey response. Another suggestion is to survey laboratories that hold different types of licensure separately, so that the information collected could be analyzed based on laboratory size/or scope. Additionally, construction of a survey that can directly compare sample and population data against response data would allow for the appropriate validity testing of the survey tool.

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