NOVEMBER / DECEMBER '09

INSIGHTS

OCCURRENCE MANAGEMENT

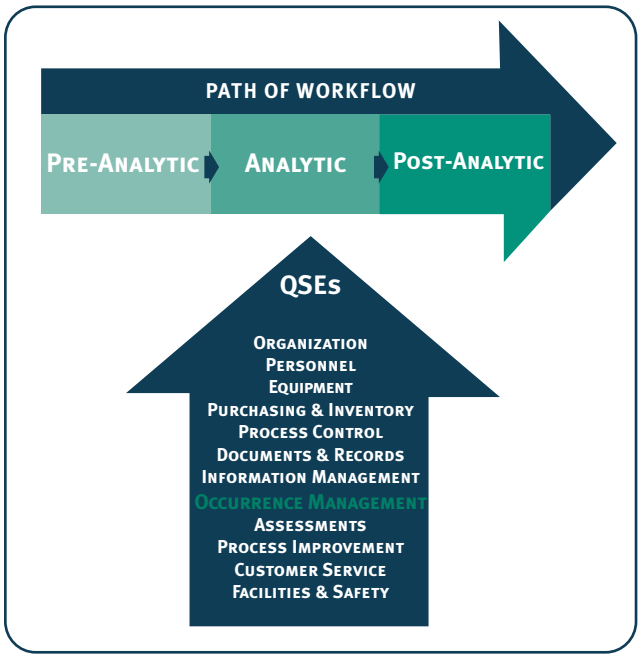
As a follow-up to a previous Insights article ("Don't Let History Repeat Itself: Manage and prevent occurrences promptly by following these steps" May/June '09), we are offering a more detailed three-part series. We will present specific examples to show you how to manage and prevent occurrences. See http://www.cola.org/resources.html?PDFCategoryID=4 to view previous Insights articles.

One goal of a laboratory should be to detect, correct and prevent problems.
One means of doing this is through Quality Assessment.
One way of looking at Quality Assessment is through the Quality Systems approach.

"Quality Systems" relies on the interaction of 12 Quality System Essentials (QSEs) that serve as the basic building blocks for a successful laboratory. The Quality Systems approach focuses on the processes we use to plan our business, to manage our resources and to measure, monitor and improve our performance. This enables us to create a consistent, quality product (laboratory results) and meet the needs of our customers.

The Quality System Essential "Assessments" includes development and implementation of a Quality Assessment Plan aimed at confirming that laboratory processes function as intended and deliver the appropriate outcomes.

When these assessments identify a problem or something that should not happen, it is considered an occurrence (also called a non-conforming event or NCE). The Quality System Essential "Occurrence Management" defines the processes a laboratory uses to investigate occurrences, control their impact and implement corrective actions to prevent their recurrence. This QSE is used to identify, report, investigate, track, trend and document occurrences that do not conform to our laboratory's established policies, processes and procedures and/or do not meet our customer's expectations.



Although staff should be trained on how to recognize and report them, occurrences can be detected and reported by anyone, including patients and their families. The reporting process should allow for open communication and must be non-punitive in nature. The focus of the investigation should be on understanding the issue, discovering why it happened and improving the process to prevent recurrence. The focus must not be on placing blame.

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Following Up

FROM THE CHAIR

Since COLA takes its responsibilities to its customers seriously, we want to address your comments, suggestions and concerns. This "Follow-up" issue of Insights does just that.

The Occurrence Management article is the first in a series. It was developed in response to a phone inquiry at COLA headquarters. The caller commented that a previous article would have been more helpful if it provided a practical application. The follow-up series will present not just one, but a total of three examples that span the path of workflow.

A speaker at our recent Orlando Symposium for Clinical Laboratories touched on an interesting topic in her presentation on Hemoglobin A1c. This sparked a follow-up article that we hope you find intriguing.

We are proud of your comments about the Symposium, and are sharing them in this issue. Your comments and suggestions are used to help plan future events, like our next Symposium, which will be held April 21 – 24, 2010, during National Medical Laboratory Professionals Week, at the Hilton Baltimore.

In Orlando, many of you previewed COLAcentral, our interactive web portal for COLA members. It provides many versatile options to help manage your laboratory, and is the latest way for you to make comments and provide feedback to us. Check it out at www.colacentral.com.

As this issue and COLAcentral show, we appreciate your feedback and strive to follow-up effectively.

Verlin K. Janzen, MD, FAAF
Chair, COLA Board of Directors

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The investigation should provide information to educate staff, to connect occurrences with their outcomes, to limit their impact, and to determine the true, or root, cause(s) of the errors. (Specific questions to ask during an investigation will be presented later in this article.) Root causes can be classified as *System Problems* (the process does not work properly or does not deliver the intended outcome), *Knowledge Problems* (ineffective, inadequate or insufficient training) or *Behavior Problems* (personnel exhibit reckless or at risk actions).

Tracking identified occurrences and monitoring processes over time help prevent the same problems from recurring. If a problem does recur, you should question whether the root cause was successfully identified. Another reason for recurrence is that the corrective action (see below) did not properly address the root cause.

Errors can occur anywhere along the Path of Workflow (POW). They can also be of a more general nature and have an effect on the entire process. **Table 1** lists examples of occurrences throughout the POW.

Regardless of what the occurrence is or where it happens, remedial and corrective actions need to be taken and documented. *Remedial actions* are steps taken to resolve the immediate problem. *Corrective actions* address the root cause(s) of the problem. Since corrective actions should provide a long-term solution that prevents recurrence, a time frame should be established for follow-up to verify that the actions taken were effective. *Preventive actions* are proactive measures to address potential occurrences before they actually happen. Examples to help clarify the differences between these actions are provided in **Table 2.**

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TABLE 1: EXAMPLES OF OCCURRENCES ALONG THE PATH OF WORKFLOW

Pre-Analytic
- Unacceptable Samples
  - Unlabeled or mislabeled specimens
  - Incorrect collection container
  - Incorrect collection timing
  - Improper transport conditions or timing
- Wrong Orders or Order Entry

Analytic
- Invalid Testing
  - Procedural controls or QC failure
  - Equipment or reagent failure
- Delays in turnaround time
- Failure to follow established procedures

Post-Analytic
- Reporting problems
  - Delay in reporting results
  - Incorrect results reported
  - Results reported on wrong patient
  - Report sent to wrong location
- Reprinted or redelivered reports
- Incorrectly archived samples

General
- Complaints from practitioners or patients
- Ineffective complaint resolution
- Manufacturer recalls
- Communication failures
- Events that could have caused harm ("near misses")
- Lawsuits

Documentation of an occurrence should always include a description of the problem, the date and time it happened, the date and time it was discovered, who was involved, and the remedial action taken. Pertinent information collected during the investigation also needs to be documented. Support documents, such as copies of maintenance and QC records or requisitions and reports, should be included when appropriate.

To conduct an investigation, several questions should be asked and answered:

- What?
  - What happened?
  - What actions led to the occurrence?
  - What part of the path of workflow is involved?
  - What QSEs are involved?
  - What was the outcome?
  - What impact did it have on patients and/or personnel?
  - What data would help to determine if this is an isolated event or a systemic problem?

TABLE 2: REMEDIAL, CORRECTIVE AND PREVENTIVE ACTIONS

Adapted from CLSI document GP-32A, Vol. 27 No. 2; Management of Nonconforming Laboratory Events

Remedial Action:
- Steps taken to rectify a recognized occurrence
  Example: Providing a new copy of a laboratory report to a practitioner who claims he or she did not receive the original report

Corrective Action:
- Steps taken to remove the root cause(s) of an occurrence
  Example: Providing courier delivery of laboratory reports directly to the practitioner's office instead of putting them in a hospital-based mailbox where they could be misdirected or inadvertently discarded

Preventive Action:
- Steps taken to eliminate the cause of a potential occurrence or other undesirable potential situation
  Example: Planned system improvements for delivery of laboratory reports directly to the practitioner's personal wireless device using web-based technology

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- How?
  - How did the occurrence happen?
  - How was it identified?
  - How long has it been happening?
  - How many customers were affected?
- When?
  - When did the occurrence happen?
  - When was it discovered and reported?
  - When was it investigated?
- Who?
  - Are particular departments or functions involved or impacted?
  - Are specific people or groups involved or impacted?
  - Are resource or supplier issues contributing to this occurrence?
- Why?
  - More specifically, "Why did it happen?" Following each answer, ask why again, until you come to a point where there are no more answers. Look at the last response, then classify it as either a System, Knowledge or Behavior problem.
  - *System Problem:* Is there a process that defines what should happen and when? Is the process being followed? Does the process deliver the intended result?
  - *Knowledge Problem:* Do personnel know what they are supposed to do? Do they know how to perform required tasks? How do you know they are competent in the required tasks? Are education and training adequate, sufficient and effective?
  - *Behavior Problem:* Do personnel exhibit reckless or at-risk behaviors? Do personnel disregard the established process?

To manage the impact of an occurrence, ask the following questions: Does this have the potential to cause harm to patients or personnel (is it an "incident")? Should testing (service) be stopped until the occurrence is corrected? Who needs to be made aware of this (staff, management, physicians, etc.)? Is there a need to recall patients or retest specimens?

After the investigation is complete, the next step is to develop corrective actions. To do this, focus on the classification of the root cause. Brainstorm potential actions to address system, knowledge or behavior problems. History has shown that eighty to ninety percent of occurrences are system problems. This could mean that there is a not a defined process, that the process has not been implemented, or that it is ineffective. By focusing on the system, it is easy to avoid blaming an individual since the error would have occurred no matter who was performing the task.

Now, we will look at a specific occurrence and utilize the information just presented to manage and resolve it.

Pre-analytic Scenario: Our laboratory is located at the main site of a multi-specialty, multi-site practice. Each of the four offices performs waived testing as well as phlebotomies for the chemistry, hematology (CBC) and coagulation (PT) tests done at the main lab. The problem is a customer complaint; the patient is upset about having to return to a satellite location to have blood redrawn.

It seems that we had an unacceptable specimen and someone implemented a remedial action: have the patient return for a specimen redraw. The need to recollect a specimen became another problem that was detected and reported via the patient complaint. At first glance, we might suspect there is a phlebotomist who requires retraining or, at the very least, has to be reminded of the proper specimen collection and/or labeling procedures. Is that accurate? Could it be more than that? The occurrence needs to be investigated. Let's apply the Quality Systems approach and see what happens. Remember that we have to document all of our findings and provide supporting documentation when appropriate.

When things go wrong, we often make assumptions and react from our own experiences. It is difficult not to do this. Since we are just starting our investigation, any conclusions we draw are based on our own assumptions. Experience can be a valuable teacher, but may lead us astray if we don't confirm the facts, and at this point, we have

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very few. We don't know what specimen/test was collected. We don't know why the original specimen was unacceptable. We don't know why the patient is upset about coming back for a redraw. We don't know what site or staff were involved. We do know that we have to find out.

To begin our investigation, several questions come to mind. These may or may not prove to be significant to the issue at hand, but they need to be asked.

- What patient was involved?
- What site was involved?
- What specimen(s) and/or test(s) required recollection?
- When did this occur?
- When was the specimen identified as unacceptable and when was the patient notified?
- Was the patient informed of the reason for the redraw?
- Has anyone looked into this already?
- Are other patients and/or sites involved?
- Why did the sample(s) have to be recollected?
- Why was the patient complaining? (Inconvenience? Incompetent personnel? Lack of communication?)
- Does the patient have other complaints about this issue?
- Does the patient have complaints about other issues?
- Questions about the procedures involved:
  - What is the procedure for specimen collection and transport? Was it followed?
  - What is the redraw procedure? Was it followed?
  - What are the criteria for specimen rejection? Was rejection of this specimen appropriate?
- Who will you talk to about this complaint?
  - Patient
  - Phlebotomist who collected the original specimen
  - Phlebotomist who collected the second specimen
  - Person who determined the specimen was unacceptable
  - Person who contacted the patient

By answering these questions, our investigation showed that this specimen had an incomplete label, that this is only one of many samples that have been mislabeled, and that this is an issue at multiple sites. Personnel at the main laboratory confirm this information. So, our one patient complaint has suddenly become a major issue involving multiple sites and multiple employees.

What should we do now? Since the issue has changed, we have to gather more data. If we were performing a QA review we would monitor the procedures being performed by direct observation and gather information over a specific period of time. However, this is management of an occurrence, so we have to gather historic data. We need information to help us understand what has already happened. Let's start by looking for the number of unacceptable specimens, where they were collected and why they were rejected.

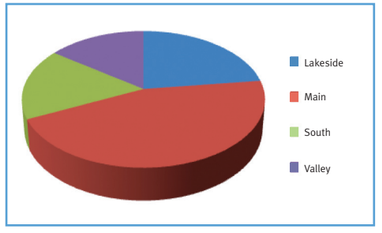

Figure 1 *Unacceptable Specimens by Site*

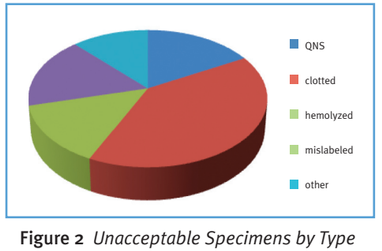

Figure 2 *Unacceptable Specimens by Type*

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Looking back over two months worth of data, we discovered that there were a total of 100 unacceptable specimens collected at all four locations. There were four main reasons for rejection including specimens that were clotted, hemolyzed and QNS in addition to the mislabeled specimens. The remainder of the unacceptable specimens were grouped in a general "other" category, which includes incorrect temperature, improper transport, unlabeled specimens and specimens collected in the wrong container.

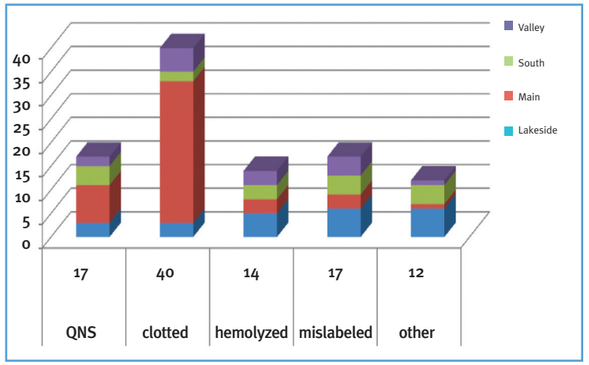

Figure 3 *Unacceptable Specimens by Site and Type*

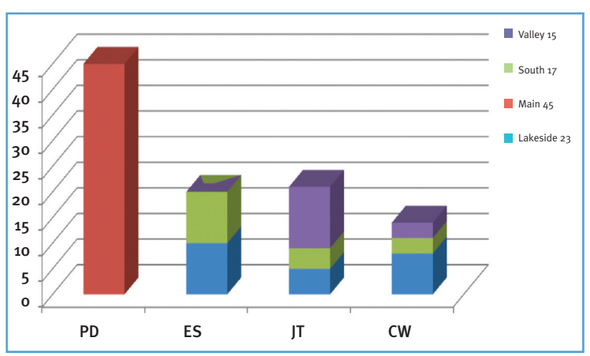

Figure 4 *Unacceptable Specimens by Phlebotomist*

When we look at the data (Chart 1), we find that mislabeled specimens were not our only issue and they were not our biggest issue. When we use pie charts (Figures 1 & 2) to display the data, we appear to have some significant information, especially about the Main site and clotted specimens. However, we still need more data to properly understand what is actually happening.

CHART 1

	Lakeside	Main	South	Valley	Total
QNS	3	8	4	2	17
Clotted	3	30	2	5	40
Hemolyzed	5	3	3	3	14
Mislabeled	6	3	4	4	17
Other	6	1	4	1	12
Total	**23**	**45**	**17**	**15**	**100**

For example, would it help to know which specimens were rejected at each site? Let's break out the data by site to see whether it is significant.

It may also help to know who collected which specimens. If one person collects more unacceptable specimens than the others, it may be due to that person's technique. If all phlebotomists are collecting the same amount of unacceptable specimens, the root cause may be a training issue. Figure 3 shows the breakdown of which specimens were collected at each site. It shows that there were more unacceptable specimens collected at the Main site than the other sites. It also appears that the main reason for rejection at Main is clotted specimens. Can you think of a reason to explain the abundance of clotted specimens?

The next chart, Figure 4, shows the breakdown of who collected the unacceptable specimens at which site. It highlights the data, but does it add to our understanding? PD draws more unacceptable specimens than anyone and is the only one who draws unacceptable specimens at the Main site. So it appears that there may be an issue with PD's technique.

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Is this the only explanation? What if PD is the only full-time phlebotomist? Drawing more total specimens than the others could explain why PD has more unacceptable specimens. What if PD is the only phlebotomist scheduled to work at Main? This would explain why no one else draws unacceptable specimens there. Could there be another way to explain the unacceptable specimens at Main? As we continue to ask "Why?" we discover that the collection tubes in use at Main for the last two weeks were outdated. This would explain the high number of clotted specimens. It also shows that our assumption about PD's technique was incorrect. If the expired tubes were not discovered, the high incidence of clotted specimens would have continued regardless of who the phlebotomist was or how many times PD was retrained.

Is there anything else that stands out? Look at Figure 5 which shows the comparison of acceptable to unacceptable specimens per phlebotomist. Half of the specimens drawn by ES are unacceptable. Why would this happen? Again, continuing to ask "Why?" helps us determine the root cause. This is what our investigation revealed:

- ES is the newest employee.
- ES works one day each week, alternating between South and Lakeside.
- ES had the same number of unacceptable specimens at each location.

Are you rethinking hiring ES? Before you compose the termination letter, let's continue to ask "Why?" As it turns out, ES was going through training when another employee needed emergency medical leave. ES was called into service without completing training. This could be classified as a Knowledge Problem (insufficient training); however, a closer look reveals it is really a System Problem. Since we continued to ask "Why?" we discovered that there is no mechanism in place for documenting new employee training and ensuring its completion before the new employee works independently.

The last thing that our investigation revealed is that the phlebotomists were not aware of the unacceptable specimens. Each stated that they would have tried to address the issue if they had known about it.

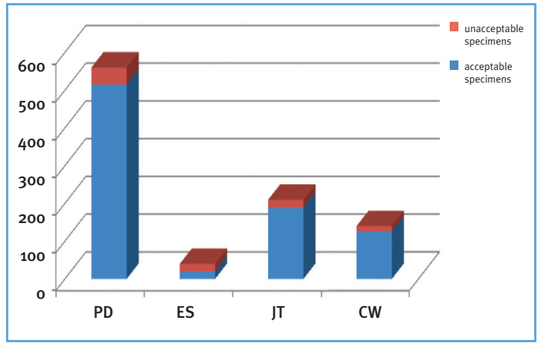

Figure 5 *Unacceptable/Acceptable Specimens by Phlebotomist*

In our example, it first seemed that a solution to the problem would be requiring that staff re-read the collection and labeling procedures. A follow-up on this corrective action would probably have shown little or no improvement. During our investigation, we discovered three root causes to be addressed. By tailoring the corrective actions to the root causes, we can show a decline in the number of unacceptable specimens. **Table 3,** on page 8, summarizes the results of the investigation and the corrective actions taken.

This is one example of how to put aside our assumptions, rely less on our past experiences and use the Quality Systems approach to address a pre-analytic occurrence. Through data collection and analysis, we can make our corrective actions meaningful and specific to the significant issues.

The next article in the series will highlight an Analytic Scenario.

Resources for these articles include:

- *CLSI document GP-32A, Vol. 27 No. 2; Management of Nonconforming Laboratory Events*
- *Two Continuing Education sessions presented at the Symposium for Clinical Laboratories, Sep 16 – 19, 2009, Orlando, FL:*
  - *"Quality Systems Approach to Quality Assessment", presented by Kathryn Connolly, CQA(ASQ), MT(ASCP); COLA Quality System Manager and Rebecca Kenner, MT(ASCP), DLM; COLA Surveyor*
  - *"Making Lemonade from Laboratory Nonconformances", presented by Lucia M. Berte, MA, MT(ASCP), SBB, DLM, CQA(ASQ), CQM/OE; President, Laboratories Made Better! P.C.*

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TABLE 3: RESULTS OF INVESTIGATION

Occurrence	Root Cause	Corrective Action
Over half of the specimens drawn by ES are unacceptable	System Problem: ES was only partially trained but had to cover for staff on emergency leave. Training was never completed.	Implement a documented New Employee Training Program. Create a checklist of specific duties that employees should know after training. The new employee, the trainer and the supervisor should sign when the trainee exhibits entry level competency. The trainee does not work independently until competency is exhibited for all duties on the list.
Clotted specimens (2/3 of unacceptable specimens at Main)	System Problem: Inventory control: EDTA tubes in phlebotomy room at Main were expired.	Designated personnel are to check the lot numbers and expiration dates of all supplies as part of the daily start-up procedure. Lot numbers and dates are recorded as supplies are placed in use. Personnel record their initials each day stating that they confirmed supplies have not outdated.
Large number of unacceptable specimens	Knowledge Problem: Phlebotomists unaware of unacceptable specimens	Supervisor to provide feedback to phlebotomists following monthly QA meetings. Sample collection data is already tracked and reported during the meetings, but is not communicated to phlebotomists.
		Supervisor to provide immediate inservice for all phlebotomists. Training to include proper collection and labeling techniques, criteria for acceptable specimens and the reasons behind the requirements. Inservice to be repeated annually if indicated by Annual Competency Reviews.

Corrective Actions are to be implemented at all locations to ensure uniformity of quality patient care.

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CAN THE HBA1C TEST BE USED TO DIAGNOSE DIABETES?[1]

Current practice is to utilize the HbA1c test to *monitor and manage* diabetes. This article reports on the recent recommendation of an International Expert Committee[2,3], that the test can also be used to *diagnose* diabetes.

The International Expert Committee consisted of members appointed by the American Diabetes Association[4], the European Association for the Study of Diabetes and the International Diabetes Federation, and was convened in 2008 to consider the current and future means of diagnosing diabetes in nonpregnant individuals[5]. Even though their findings were published in the summer of 2009, the sponsoring agencies are still considering the recommendation and have not yet adopted it.

According to the Centers for Disease Control and Prevention (CDC)[6], "Diabetes mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin production, insulin action, or both. Diabetes can be associated with serious complications and premature death." These serious complications are long-term and can affect the eyes, kidneys and nervous system. Diabetes also substantially increases the risk for cardiovascular disease since it affects blood vessels and the heart.

How is HbA1c related to diabetes?
There are several types of hemoglobin, the oxygen-carrying protein found inside red blood cells (RBCs), but the predominant form is hemoglobin A (HbA), of which hemoglobin A1 (HbA1) is a subcomponent. Glycated hemoglobin, or HbA1c, occurs when glucose circulating in the bloodstream spontaneously binds to hemoglobin. The higher the level of blood glucose, the more glycated hemoglobin is formed. The glucose remains bound throughout the life span of the RBC, which is normally around 120 days. HbA1c forms on a daily basis and is *slowly* cleared from circulation as older RBCs (with glycated hemoglobin) die and younger RBCs (with non-glycated hemoglobin) take their place[7]. Thus, HbA1c captures the degree of glucose exposure over time, making it a measurable marker of long-term blood sugar levels and its control.

*Note: Even though convention refers to this as "plasma" glucose, the reference includes serum and whole blood levels as well.

Currently, diabetes is diagnosed by measuring blood (or plasma or serum) glucose levels in one of two ways. A patient can undergo an oral glucose tolerance test, which begins when a measured amount of glucose is ingested. Glucose levels are then measured over time to ascertain the patient's glucose metabolism. Studies have shown that the 2 hour level (2HPG or 2 hour plasma* glucose) is the most significant measure. The second method of measuring blood glucose is to test a sample after the patient has undergone a specified period of fasting (FPG or fasting plasma* glucose).

Should HbA1c be used to diagnose diabetes?
In 1997, the American Diabetes Association (ADA) published a report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus which reexamined the then near 20 year traditional basis for diagnosing diabetes. Based on data from separate studies examining almost 5000 participants, this older committee recommended that diabetes should be diagnosed based on the relationship between glucose levels and the presence of long-term complications of chronic high blood sugar levels (hyperglycemia), such as retinopathy. A strong correlation between HbA1c levels and retinopathy has been demonstrated by several observational studies and by controlled clinical studies of type 1 and type 2 diabetes patients.

Since HbA1c measures chronic hyperglycemia and has been shown to correlate well with disease complications, the 1997 Expert Committee considered HbA1c as a means of diagnosing diabetes. They did not recommend it, however, partly due to the lack of assay standardization. A follow-up report in 2003 also stopped short of recommending HbA1c as a marker for diagnosing diabetes.

The more recent 2008 International Expert Committee now recommends the use of HbA1c as a diagnostic measure. This is based on their examination which shows that the accuracy and precision of HbA1c assays is at least equal to those of glucose assays, which is partly due to advances in instrumentation and standardization. Recent studies have shown that glucose measurements are actually less accurate than most practitioners realize. Problems include lack of instrument precision, instrument bias, pre-analytic errors (e.g., specimen handling) and in vitro glycolysis.

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In contrast, HbA1c levels are relatively stable after specimen collection, can be drawn at any time, require no patient preparation (fasting or pre-draw glucose loading) and are relatively unaffected by stress and disease state. Also, studies have shown that HbA1c levels vary less than glucose levels between samples drawn from the same patient on subsequent days (that is, they show little biologic variability). In addition, a recently introduced reference method to calibrate HbA1c instruments should further improve standardization in most of the world.

What should the criteria be for diagnosis?
The 2008 International Expert Committee recommends that diabetes should be diagnosed when HbA1c levels are ≥6.5%, when confirmed by repeat testing. Confirmation is not needed when patients are symptomatic and have plasma glucose levels >200 mg/dl (>11.1 mmol/L). If HbA1c testing is not possible, current diagnostic measures should be used. If either HbA1c, FPG or 2HPG are available, the practitioner should decide which method to use for diagnostic purposes, since it has been recommended to avoid using different methods.

The Committee also stated that "individuals with a HbA1c level ≥6.0% but <6.5% are likely at the highest risk for progression to diabetes, but this range should not be considered an absolute threshold at which preventative measures are initiated. When assessing risk, implementing prevention strategies, or initiating a population–based prevention program, other diabetes risk factors should be taken into account. In addition, the HbA1c level at which to begin preventative measures should reflect the resources available, the size of the population affected, and the anticipated degree of success of the intervention."

Why should HbA1c NOT be used to diagnose diabetes?
- *Cost* – In many parts of the world, the cost of performing the testing is prohibitive for making it a routine screening method.
- *Variant hemoglobin* – Some hemoglobin traits (i.e. HbS, HbC, HbF and HbE) can interfere with some HbA1c assays. However, some assays can correct for the presence of the most common variants.
- *RBC Turnover* – Any condition that changes red cell turnover (e.g., hemolytic anemia, chronic malaria, major blood loss or blood transfusions) will affect HbA1c values.
- *Pregnancy* – Changes in red cell turnover during pregnancy will affect HbA1c values.
- *Other reasons* – There is evidence that HbA1c levels increase with age and that there may be some difference in levels among different races. Neither of these are well studied nor well known enough to suggest adopting age-specific or race-specific diagnostic values.

If diabetes is suspected in any of these cases, glucose measurements (FPG and/or 2HPG) will still be required for diagnosis.

Controversy
In a Clinical Laboratory News article published in December 2008[8], the American College of Endocrinology (ACE) and the World Health Organization (WHO) believed it was premature to consider using HbA1c as a diagnostic test.

"The ACE task force on pre-diabetes consensus statement[9] on the diagnosis and management of pre-diabetes pointedly did not address the possibility of adopting HbA1c for such a purpose, and indeed, did not include further evaluation of HbA1c in its recommendations for further research needed."

"Aside from a concern about insufficient data in support of HbA1c's predictive value, WHO faces practical considerations in making any HbA1c-related recommendations. 'The consensus paper was written from the position of the U.S., which has resources, populations, and needs that are not quite the same as the WHO clientele,' noted Gojka Roglic, MD, medical officer for the WHO diabetes program. 'Many countries in sub-Saharan Africa don't have a lab infrastructure even to measure blood glucose, so practices there won't change as a result of any updated screening or diagnosis guidelines.' Nonetheless, WHO does intend to revisit diagnostic or screening criteria or possibly both, perhaps in late 2009."

Even though some have suggested the use of HbA1c to diagnose diabetes, there is still not a broad based consensus that it should be used for this purpose.

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CAN THE HBA1C TEST BE USED TO DIAGNOSE DIABETES?
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[1]Toni Clinton, PhD(BCLD), MT(ASCP), "Hemoglobin A1c: New Opportunities in Diabetes Management", Continuing Education session, Symposium for Clinical Laboratories, September 16 – 19, 2009 in Orlando FL

Dr. Clinton is Vice President of Laboratory Operations at Sonic Healthcare and an Assistant Professor of Pathology and Clinical Laboratory Science at the University of Tennessee Health Science Center. In her session, she mentioned that a recent article published in Clinical Laboratory News (see #2) recommended that HbA1c be used to diagnose diabetes in addition to its current management indication. She also stated that the American Diabetes Association currently does not recommend using HbA1c as a means of diagnosing diabetes.
Referencing that article as well as additional research led to the creation of this article.

[2]http://www.aacc.org/publications/cln/2009/august/Pages/inside0809.aspx
Genna Rollins, *"Expert Committee Endorses HbA1c Test for Diagnosing Diabetes, ADA Considering Official Recommendation";* Clinical Laboratory News, August 2009; Volume 35, Number 8
[3]http://www.diabetesincontrol.com/index.php?option=com_content&view=article&id=6981
"*ADA - International Expert Committee Recommends A1c Test to Diagnose Diabetes*", DiabetesInControl.com News and Information for Medical Professionals, originally posted 08 June, 2009; Issue 472
[4]http://www.diabetes.org/ The American Diabetes Association (ADA)
[5]http://care.diabetesjournals.org/content/32/7/1327.full?sid=1c8cdc2a-2c23-420f-8d43-4a70dc1ce184
David M. Nathan, M.D., *"International Expert Committee Report on the Role of the A1C Assay in the Diagnosis of Diabetes"*, Diabetes Care, journal of the American Diabetes Association; Published online before print June 5, 2009, doi: 10.2337/dc09-9033 Diabetes Care July 2009 vol. 32 no. 7 1327-1334
[6]http://www.cdc.gov/diabetes/faq/index.htm
The Centers for Disease Control and Prevention; *Diabetes Program, Frequently Asked Questions*
[7]http://www.labtestsonline.org/understanding/analytes/a1c/glance.html Lab Tests Online; A1c and eAG
[8]http://www.aacc.org/publications/cln/2008/december/Pages/CovStory1Dec08.aspx
Gina Rollins, *"A New Role for Hemoglobin A1c"*, Clinical Laboratory News, December 2008; Volume 34, Number 12
[9]http://www.aace.com/meetings/consensus/prediabetes/index.php
"Diagnosis and Management of Prediabetes in the Continuum of Hyperglycemia—When Do the Risks of Diabetes *Begin?"* A Consensus Statement from the American College of Endocrinology and the American Association of Clinical Endocrinologists; Endocrine Practice, October 2008; vol. 14 No. 7 933-946

SYMPOSIUM FOR CLINICAL LABORATORIES
An interactive experience in Quality Systems

The COLA Symposium staff wanted to share some of the comments we received following our recent Orlando event. Thanks for the great feedback!

- A well put together and educational meeting. I would recommend to colleagues.
- I can't believe how much I missed by not attending before.
- As a physician new to the world of lab directorship, I was amazed at what I didn't know about the overall function and upkeep of the POL. I feel that a good foundation has been laid for my future as a Lab Director.
- I have been accredited for 16-18 years. I did not think any of the workshops or speakers would have anything for me, but I was surprised. I have a lot to take back for our staff, lab and director that will make things much easier for all. Thanks.
- I learned about QC & QA; being a physician, I had no idea of this aspect of the laboratory.
- This has been a great Symposium. It is so nice for us that you keep us small labs informed. We have to do it all too, maybe at a smaller scale, but still has to be done.

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