

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Newborn Screening Update

by Charleen Adams, DOH/PHL

Federal advisory boards and childhood advocacy groups recommend expanded newborn screening. In response, the Washington State Department of Health Newborn Screening (NBS) Program convened a series of Advisory Committee meetings. The committee discussed adding 16 conditions to the existing newborn screening panel. The committee held meetings from September 5, 2006 to December 10, 2007.

The Advisory Committee members consist of interested stakeholders. These include medical experts, parents, childhood advocacy groups, principle payers, and medical ethics and public health representatives. They evaluated the candidate conditions and made recommendations to the State Board of Health. The committee used five criteria to evaluate conditions:

- What is the condition's prevention potential and medical rationale?
- How good is the available treatment?
- What is the public health rationale?
- Is there available technology to effectively screen?
- Is there adequate cost-benefit justification?

One of the candidate conditions (3-methylcrotonyl CoA carboxylase deficiency) did not meet the criteria for prevention potential and medical rationale.

The Advisory Committee recommended that the State Board of Health add 15 metabolic conditions to the screening panel. These included disorders of fatty acid, amino

acid, and organic acid metabolism. The Board unanimously approved the recommendation on May 14, 2008.

The revised regulations for expanded screening became effective on July 17, 2008. They gave the Department until September to make the changes. The NBS Program began screening for 14 of the 15 conditions on July 21, 2008. Screening for the last condition, tyrosinemia type I, began September 22, 2008. The delay was due to building modifications needed to install safety equipment.

A brief description of the new conditions is found below. Our website at <http://www.doh.wa.gov/nbs> provides more information.

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

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The NBS Program now screens for 25 congenital conditions. Nineteen of the 25 conditions are detected via tandem mass spectrometry (MS/MS) from a single punch of a dried blood spot. The program helps prevent death and disability for babies in Washington State through early detection and intervention.

Amino acid disorders of metabolism are characterized either by the body's inability to process amino acids correctly or to process the ammonia released during the breakdown of amino acids. The accumulation of amino acids, ammonia, or other by-products may cause severe complications. These include mental retardation, coma, seizures, and possibly death. Early detection and treatment can prevent most or all of these:

- Argininosuccinic acidemia (ASA)
- Citrullinemia (CIT)
- Tyrosinemia type I (TYR-I)

Fatty acid oxidation disorders of metabolism are characterized by the body's inability to use fat efficiently to make energy. When the body needs extra energy, such as during prolonged fasting or acute illness, infants with these disorders can suffer dangerously low blood sugar and metabolic crises. The result can be serious damage

to the brain, liver, heart, eyes, and muscle. They can also cause death. Early detection and treatment can prevent most or all of these consequences:

- Carnitine uptake defect (CUD)
- Long-chain L-3-OH acyl-CoA dehydrogenase (LCHAD) deficiency
- Trifunctional protein deficiency (TFP)
- Very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency

Organic acid disorders of metabolism are characterized by the accumulation of non-amino organic acids and toxic intermediates. This may lead to metabolic crisis with increases in acid and ammonia in the blood. It can also cause dangerously low blood sugar levels that can result in severe nerve and physical damage and possibly death. Early detection and treatment can prevent most or all of these:

- 3-OH 3-CH₃ glutaric aciduria (HMG)
- Beta-Ketothiolase deficiency (BKT)
- Glutaric acidemia type I (GA-I)
- Isovaleric acidemia (IVA)
- Methylmalonic acidemia (CblA,B)
- Methylmalonic acidemia - mutase deficiency (MUT)
- Multiple carboxylase deficiency (MCD)
- Propionic acidemia (PROP)

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Secretary, DOH: Mary Selecky
Health Officer: Maxine Hayes, MD, MPH
Director, PHL: Romesh Gautam, PhD
Program Manager, LQA: Susan Walker
Editor: Leonard Kargacin (206) 418-5416
Circulation: Leonard Kargacin (206) 418-5416

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:

ELABORATIONS
Washington State Public Health Labs
1610 NE 150th Street
Shoreline, WA 98155

e-mail address: leonard.kargacin@doh.wa.gov

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Website addresses:

DOH home page: <http://www.doh.wa.gov>
LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page:
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

15th Annual Clinical Laboratory Conference

November 10, 2008
8:00 a.m. - 4:30 p.m.

Doubletree Hotel at SeaTac
International Airport

If you have not received a copy of the program, contact Leonard Kargacin:
phone: (206) 418-5416,
e-mail: leonard.kargacin@doh.wa.gov

The program is also available from the LQA website:
http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm.

Laboratory Chain of Custody Documentation

by Laura Kentala and Shelley Lankford, DOH/PHL

A Chain of Custody (COC) is the process used to maintain and document the chronological history of evidence and to ensure that the evidence collected at a scene is the same as that entered into a court of law. A COC is required when a specimen or sample is considered potential evidence. A detailed “paper trail” showing the seizure, custody, control, transfer, analysis, and disposition of the evidence must accompany the specimen throughout its journey.

It is recommended that all laboratories have a written procedure for handling patient specimens that may be considered as evidence. If you are a Sentinel Laboratory, a COC procedure is especially critical. Your procedure should provide directions on how to document the integrity of each specimen by tracking its handling and storage from the point of receipt at your laboratory to final disposition of the specimen.

Your laboratory must identify where legal specimens are stored and how control of the integrity of the specimen is maintained while it is in your custody. If you do not have the luxury of having a secured room, there are other options to provide security. Examples include using equipment that can be locked such as an incubator or refrigerator or a small transport box that can be locked or taped with evidence tape for sealing purposes. It is important to keep the specimen, all aliquots, culture tubes, and Petri dishes in the same secured area.

When does a COC process begin? The COC process begins with the collection of a specimen by a health care provider at the request of the local police, FBI, or other agency, and continues as it moves from site of collection to the laboratory. When there is a transfer of the specimen from your laboratory to another laboratory, the COC must be continued with each transfer. As the specimen moves through your lab and then possibly on to a reference laboratory, many different COC forms may be created along the way. All of these forms need to be collected, copied, and stored in a secure location in your facility.

The COC process requires three separate forms, each with a different function.

- The Receipt of Property Received/Returned (RPR/R) form
- The Chain of Custody (COC) form
- The Visitors Log (VL)
-

Receipt of Property Received/Returned (RPR/R) form: The collector of the specimen or sample generates the RPR/R. This form may contain information that the other COC forms do not. This information may include specific site of collection detail, type of specimen or samples, case number (usually given by the FBI for a bioterrorism or chemical terrorism event), and the reason for obtaining the sample.

If the specimen is transferred to a laboratory for testing, the initial RPR/R form must remain with the specimen at all times until the transfer is complete. Photo ID is required to verify identity for both the person delivering and receiving the specimen. The receiving laboratory person will sign the initial RPR/R form; make a copy to retain with the specimen, and give the original back to the delivery person. The person who receives the specimen becomes the custodian of the specimen while it is in the laboratory, and creates the laboratory chain of evidence forms (see below). This person remains the custodian of the specimen until it is transferred to another person.

Laboratory Protocol and Forms - The receiving laboratory should now have the following forms available:

- Copy of the original RPR/R form
- Laboratory RPR/R form: All pertinent information is transferred from the original RPR/R form to the laboratory RPR/R form
- COC form
- VL

The person who receives the specimen for the laboratory becomes the custodian of the specimen and creates a RPR/R form

Chain of Custody, continued from page 3

for the laboratory. This person remains the custodian until it is transferred to another person. Record all signatures, dates, and times of the transfer.

The Chain of Custody, or COC, form is initiated when the specimen arrives in the testing laboratory. It is necessary to sign and date the form every time custody is transferred within the laboratory. This includes initial receipt, storage, testing, result reporting, and final disposition of the specimen or transfer to a different laboratory for further testing. Keep the specimen and all associated forms in the predetermined secured/locked area controlled by the custodian. If the specimen is divided into aliquots to be tested by different areas in your laboratory, a duplicate set of COC forms must be established for each separate portion of the specimen. The person who is testing the aliquot becomes the custodian of that aliquot. They are accountable for the split specimen and all of the associated paperwork.

The Visitors Log (VL) is initiated after the specimen arrives in the laboratory and is secured. Maintain the VL in the immediate vicinity of the specimen within the restricted area (e.g., BSL-3 laboratory, refrigerator, freezer, etc.) where the specimen is analyzed and/or stored. The form documents all activities of all staff or visitors entering or leaving the secured area where the specimen is stored or tested. Record the name of the staff member or visitor, signature, and the date and time of entry in the VL.

Is a COC necessary for all specimens coming into your lab? No, but it must be started the minute a specimen becomes evidence. It may be initiated when the law enforcement agent collects a sample at an event site. It may be implemented as soon as a child is diagnosed with gonorrhea. It could begin six months after completing the testing on food for Salmonella. There is no specific set time when the COC must be initiated. The COC process is initiated on a case-by-case basis.

Maintaining proper documentation during the entire process is essential. The custodian is responsible for maintaining and collecting all COC documentation generated at your laboratory. The custodian guarantees integrity of each specimen by tracking its handling and storage from the point of receipt at your laboratory to final disposition of the specimen. Only the copies of the forms will accompany the specimen when it is transferred to another laboratory. The originals are only released when clear and written instructions are given to the custodian by a legal authority.

Storage of all the completed forms is very important. The room or file selected for this job must remain locked at all times and the key stored in a secure location. If a storage room is used, it must be very secure with solid walls and ceilings. No cubicles or soft ceilings are permissible.

It is impossible to predict when a routine laboratory specimen will have to be treated as evidence. For this reason, you must plan and develop policies and procedures for handling COC processes before you have a legal specimen. Your laboratory must identify where legal specimens are stored and how control of the integrity of the specimen is maintained while it is in your custody. Train your entire staff on your COC process including the proper use of the forms. Testifying in court is one of the most daunting tasks for laboratory professionals to face. Having an indisputable COC process in place will help.

Helpful websites:

<http://www.epa.gov/air/oaqps/eog/coc/>

<http://www.asm.org/Policy/index.asp?bid=6342>

<http://www.bt.cdc.gov/labissues/>

Washington's Laboratory Complaint Process

by Susan Walker, DOH/LQA

In 2006, the General Accounting Office (GAO) released a report on the federal CLIA program. One of GAO's recommendations was that all laboratorians be knowledgeable about how they can file complaints against laboratories. In 2008, the Centers for Medicare and Medicaid Services (CMS) asked that all accrediting organizations and CLIA-exempt states comply with this GAO recommendation. Since Washington is a CLIA-exempt state, we will comply with this recommendation by informing all our laboratories of the complaint process in our state through Elaborations Newsletter articles. In addition, over the next two-year inspection cycle, we will be providing information about filing complaints to personnel in all the laboratories that we inspect.

The Laboratory Quality Assurance (LQA) office investigates all relevant complaints concerning laboratories licensed under the Medical Test Site (MTS) law that relate specifically to this law. LQA does not investigate complaints about personnel issues, OSHA/WISHA concerns, billing fraud and abuse, etc. LQA itself does not investigate complaints about physicians, nurses, or any other health care professionals, but the complaint can be filed using the same contact information below. If you are unsure whether the complaint is against the facility or a person, please submit the complaint to us anyway, and we will route it to the appropriate office for review.

LQA requests that complaints be made in writing outlining the specific details of the issue that cannot or have not been able to be resolved internally by the laboratory administration. The identity of the complainant is not required; however, if the investigation results in legal action, LQA cannot guarantee the anonymity of the complainant in those proceedings. However, Washington State has a whistleblower law to protect employees who file complaints against their employer. If the complainant prefers anonymity, no name or identifying information will be recorded.

How to file a complaint: Use these contact options to file a complaint about a laboratory, hospital, pharmacy, other licensed facility, and licensed professionals.

Complaint Hotline:	1-800-633-6828, available 24 hours a day, 7 days a week
Phone:	(360) 236-2620
Fax:	(360) 236-4818
E-mail:	HSQAComplaintIntake@doh.wa.gov
Electronically:	http://www.doh.wa.gov/lqa.htm or http://www.doh.wa.gov

NOTE: There is a link to the Complaint Process on the LQA website (<http://www.doh.wa.gov/lqa.htm>) and from the Washington State Department of Health website (<http://www.doh.wa.gov>). Select the "Topics A-Z" option from the choices on the left side of the screen. Select the letter "C" and click on the following option:

- How to File a Complaint Against a Facility.

Leave your name and daytime phone number with area code.

You may also file a complaint by printing and completing the Complaint Form (found at the website <http://www.doh.wa.gov/hsqa/FSL/CompHome.htm>). Mail the completed form to:

Department of Health
PO Box 47857
Olympia, WA 98504-7857

What happens next? Once the initial complaint is processed, it is referred to the specific office responsible for inspecting that type of facility. An acknowledgement letter is sent to the person who filed the complaint. This letter contains a case number that should be used when communicating with our office about the complaint.

Every complaint is evaluated and prioritized by its potential impact on consumers, residents, or patient health and safety. Based on the priority of the complaint, we conduct an investigation that may include an on-site unscheduled visit, interviews, and records review. When the investigation is complete, a letter is sent to the person who filed the complaint. State regulations do not allow the release of the investigation findings until the investigation is complete.

Washington Laboratory Complaint Process

From the Washington State Department of Health website at <http://www.doh.wa.gov>

1. Select the "Topics A-Z" option from the choices on the left side of the screen.
2. Select the letter "C" and click on the following options:
 - How to file a complaint against a facility

Refer to the article on page 5 of this issue of Elaborations.

Calendar of Events

PHL Training Classes:
(<http://www.doh.wa.gov/ehsphl/phl/training/train.htm>)

Gram Stain Training: A Practical Approach
December 10 Shoreline

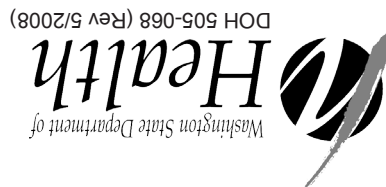
Northwest Medical Laboratory Symposium
October 15-18 Portland

15th Annual Clinical Laboratory Conference
November 10 SeaTac

2009 ASCLS-WA Spring Meeting
April 2009 Spokane

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD) 1-800-833-6388).



ELABORATIONS
 Washington State Department of Health
 1610 NE 150th Street
 Shoreline, WA 98155