

Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021

APPROVED MINUTES
September 21, 2021
1:00 P.M. – 3:00 P.M.
Wisconsin State Laboratory of Hygiene
2601 Agriculture Drive
Madison, WI 53718

MEMBERS PRESENT: Chair James Morrison, Vice-Chair Greg Pils, Secretary Dr. James Schauer, Dr. German Gonzalez, Dr. Richard Moss, Greg Pils, Gil Kelley, Jeffery Kindrai, Jessica Blahnik, Gina Green-Harris

WSLH STAFF PRESENT: Kevin Karbowski, Allen Benson, Cynda DeMontigny, David Webb, Noel Stanton, Jan Klawitter, Dr. Errin Rider, James Sterk, Amy Miles, Dr. Heather Barkholtz, Dr. Kaitlin Sundling, Dr. Kelsey Florek, Noel Stanton, Kris Hansbery, Dr. Martin Shafer and Nathaniel Javid

DNR STAFF PRESENT: Zana Sijan, Steve Geis

GUESTS PRESENT: Dr. Ryan Westergaard, Paula Tran

Chair James Morrison made a motion to call the meeting to order at 1:00 P.M. Dr. Richard Moss seconded the motion. The meeting commenced at 1:00 P.M.

Item 1. ROLL CALL

Chair James Morrison initiated the roll call of the Board. Nathaniel Javid conducted the roll call of the Board members. All Board Member seats or their designated representatives were present except Dr. Bob Corliss. There were no attendees on the public telephone line.

Item 2. APPROVAL OF MINUTES

Approve the minutes of the June 22, 2021 Board Meeting as submitted. **Greg Pils** entertained a motion to approve the minutes. **Dr. Richard Moss** seconded the motion. The voice vote approving the minutes was unanimous.

Item 3. REORGANIZATION OF AGENDA

There was no request to reorganize the agenda.

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Item 4. PUBLIC APPEARANCES

None

Item 5. BOARD MEMBERS' MATTERS

Mr. Jim Morrison informed the Board that he has accepted a position as EHS Director for Bates College, a small college in the state of Maine, and where Mr. Morrison is presently located. Mr. Morrison is happy to stay on as long as the Governor's Office is on board and until a transitional strategy is devised. Mr. Morrison thanked everyone he has worked with on the board over the years.

Mr. Nathaniel Javid informed the Board that he has taken on a new position on campus at the UW Department of Family Medicine and Community Health, starting with them on Monday, October 4, 2021. He thanked everyone and said it had been an honor working with the board for the past 9 years. Mr. Morrison acknowledged that Mr. Javid had been central to keeping board meetings organized and thanked him for his long-term service to the board. Multiple Board Members individually thanked Mr. Javid.

Mr. Chuck Warzecha informed the Board that he will be retiring from State service. Mr. Warzecha briefly introduced Paula Tran, State Health Officer and Administrator for the Division of Public Health, as his replacement. He thanked the Board and was thanked by Mr. Morrison for his service to the State as well as the Board.

Dr. Schauer thanked Mr. Morrison, Mr. Warzecha and Mr. Javid for all of their contributions.

Dr. Schauer advised that a new hire would be coming on to assume Mr. Javid's role, and that they are excited to work with Ms. Tran. Dr. Schauer noted that Mr. Morrison will remain Chair, as his location is not of concern, and WSLH would work in conjunction with the Governor's office to find a replacement in March. Mr. Warzecha's replacement will be decided by the Secretary of DHS.

Dr. Schauer again thanked the departing members on behalf of the WSLH.

Item 6. INTRODUCTION OF New WSLH Board Member JESSICA BLAHNIK

Coroners and Medical Examiners Representative, Marathon County ME Jessica Blahnik, introduced herself to the board and was welcomed by various parties.

Item 7. LABORATORY IMPROVEMENT DIVISION PRESENTATION

- **Kristine Hansbery, Director of LID, Wisconsin State Laboratory of Hygiene**

- **Ann Hennings, Proficiency Testing Coordinator/Safety Officer, Wisconsin State Laboratory of Hygiene**

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Dr. Schauer provided an introduction for Kristine Hansbery who presented on Lab Improvement Division (LID)/WSLH Proficiency Testing (PT) Program.

Ms. Hansbery provided a brief history of LID's public health mission: As a public health lab, we have an advantage in our relationships with CDC and APHL. WSLH is a leader and are looked to by other agencies to provide proficiency testing programs that are needed and aren't available; we do this work for the US and globally. We are very agile in creating programs, as we did with the SARS-CoV-2 (COVID-19) PT program.

Early in the pandemic, we saw a lot of requests for a SARS-CoV-2 (COVID-19) PT program. The FDA gave blanket approval to a lot of kits and different methodologies that came out and were fast-tracked into laboratories, because we needed something for testing. They didn't go through the rigors they normally would have before they hit the market, which made it even more important that a proficiency program be created. When accuracies in results were questioned, we needed to respond.

Ann Hennings was introduced by Ms. Hansbery.

Ms. Hennings presented a timelines of the discovery and emergence of COVID-19 and its impact both globally and in Wisconsin from December 2019 through present.

In the first week of March 2020, LID was approached by WSLH Communicable Disease Division (CDD) Director Dr. Allen Bateman in regard to a need for proficiency testing for COVID-19 because the public health labs were starting their testing, lots of manufacturers were in the process of developing tests and they started getting calls from laboratories requesting positive samples to validate these methods.

A manufacturer of COVID-19 assays contacted Ms. Hennings about a product they had developed and wanted to recommend once it had achieved FDA approval. Shortly thereafter, Ms. Hennings had sent inquiries to their four common molecular/PCR material manufacturers to see what stage they were at. She provided specifications and requested pricing quotes. A survey was sent to current customers on March 17 to gauge interest in a new program and received 215 responses back.

April 1, Ms. Hennings submitted her program proposal to LID/WSLH PT management for approval. At that time she had received quotes from 3 of the 4 vendors, but there still lots of decisions to be made. Samples were varied, from liquid to swab, and at that time they were targeting certain portions of the gene that mirrored the very first CDC assay. One vendor was very close to a whole virus/whole genome product. LID collaborated with CDD to determine that optimal sample point. An outreach flyer was sent out to customers on April 8th to announce the program plans for 2020. By April 23rd, the first purchase orders were sent to the sample vendor to purchase the sample material needed for future events that occurred in June and October.

In just a couple of months a program was created where normally, when there is time, it can take a year to two years, while determining whether a program is of interest and if it will have enough participants. WSLH was on par with two of their competitors in the PT world as far as program release.

Enrollment numbers of the program: In 2020 it was a 3-sample program which morphed into a 5-sample program and over 90 participants. Ms. Hennings stated she has never had a program

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

take off so rapidly, which made it difficult to predict how many samples to order. We offered one event of SARS serology for antibody testing, which has remained steady throughout, although it may start to decrease slightly, as there is less antibody testing performed.

In 2021, we expanded to offer two SARS molecular programs in different formats, with a 5-sample set and 3-sample set, and the numbers for samples requested doubled.

The FDA website has been Ms. Hennings guide and resource, with the molecular methods that are approved for emergency use authorization along with the antigen. There are over 250 methods to check for SARS. Labs involved with and reporting to the proficiency program for 2020 and 2021 utilize over 40 different methods. Laboratory professionals from types of laboratories we don't necessarily have a lot of contact with - commercial, environmental, toxicology, veterinary - helped shoulder the burden, so the testing could be done.

We offer a swab sample type for the SARS Molecular Programs which is derived from the whole genome sequence (the whole virus): The PT material is dried onto that swab and the sample elution buffer is the viral transport media, which is the dry swab that the labs are using for patient testing. We wanted the dry swab action as there are labs that don't use any liquid; they process those swabs directly and cannot use a liquid program. Additionally, everyone has run into supply issues along the way.

As far as performance, everything has gone very well. WSLH PT grades by consensus and it has always been greater than 95% consensus for all SARS molecular samples so far. The only method that had any issue was a Hologic Aptima, and troubleshooting was performed by WSLH PT, along with the sample vendor and Hologic themselves trying to do some validation. Together, they determined that a liquid sample would work best for that particular method and that will be offered over the next year.

The SARS-CoV-2 antigen program, found in pharmacies and take-home tests, is a swab sample type and targets the nucleo-protein. The liquid elution method is not provided with this type, as the rapid-antigen kits contain all the reagent necessary and there are no problems to date.

The SARS serology program is a liquid sample type. In addition to ITG and the total antibody, IGM reporting will occur over the next year.

The molecular program started in 2020 as a 3-sample program shipped twice a year. In 2021, it was joined by the 5-sample program which is shipped three times a year. In 2022, these options will be offered along with the molecular liquid program for Aptima users and other large analyzers.

SARS is not regulated by Medicare/Medicaid but laboratories like the program options for the ability to test more staff. New York State requires their laboratories to have a 5-sample program. It's in place should it become regulated in the future.

Next year, there will be the ability to detect SARS, influenza, and RSV. Popular methods may detect 1, 2 or all 3, using one set of swabs. There are allocation issues and the price for the cartridges are high, so combining it into one will be a cost-savings for the laboratories.

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Ms. Hennings offered her thanks to all PT staff for supporting the addition of the new SARS programs, including the collaborative efforts of CDD.

Ms. Hansbery summarized the presentation overview of Rapid Response, some of the obstacles that LID faced, and how the programs were developed. Ms. Hennings did a great job of getting this one on the ground and running, rapidly. This one had to be done quickly and more SARS testing has been done than ever before.

Mr. Warzecha stated that the early months of the response was so important, particularly the ability to trust the program, while at the same time there was the undermining of scientific trust going on and that we also had to be skeptical of what was coming out from certain vendors. He thanked them for the science response WSLH was able to provide from Wisconsin and the work that was done.

Mr. Morrison echoed Mr. Warzecha's comments and thanked Ms. Hennings and Ms. Hansbery.

Item 8. STRATEGIC PLAN UPDATE

Dr. Schauer provided an introduction of the DEI (Diversity, Equity and Inclusion) initiative, Space, Human Biomonitoring activities.

**■ Erinn Rider, Associate Director, Wisconsin State Laboratory of Hygiene
and Director, Clinical Laboratory Services**

Dr. Rider is leading the DEI initiative. She summarized the DEI initiative, stating that, as an organization that serves the people of Wisconsin, WSLH has a responsibility to move forward on the DEI effort, to look within the laboratory and organization and insuring that WSLH is providing a culture of diversity, equity and inclusion for staff, as well as reflecting that outward to WSLH's partners and customers.

This is the first year of the initiative and the hope is to secure funding, providing resources to hire an outside DEI consultant for their expertise and professional experience. With a consultant, WSLH can examine needs assessment, and data analysis, such as staff and customer surveys, demographic data analysis, current practices assessment and training for our staff in needed areas. Goals are for WSLH leadership to participate in DEI development opportunities as well as obtaining partner and stakeholder input.

In years two and three, implementation and accountability as well as further development are the goals. This would include developing a DEI taskforce to hold us accountable, in practice and culture, and to create and implement changes when change is needed. WSLH would continue to participate in training and educational opportunities. Dr. Rider has reached out to campus resources as well and is trying to further identify resources for starting, developing and continuing the initiative.

Partner/Stakeholder input request: Board Members were invited to a future DEI Retreat along with the participation of leadership members of WSLH, envisioned as a 2 to 4 hour-long meeting of brainstorming and advice for WSLH. Board members could anticipate WSLH reaching out to them in the future regarding the DEI Retreat.

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Dr. Schauer advised that the retreat wasn't limited to the Board Members, so if they wanted to include members from their organization who may be better representatives regarding these interests, or complement them, WSLH is open to their participation. WSLH is interested in best practices, aspects in developing a future workforce, networking with groups around the state, and how WSLH can be more inclusive regarding those the organization serves.

**■ David Webb, Assistant Director, Wisconsin State Laboratory of Hygiene
and Director, Environmental Health Division**

Timeline for space and facilities –

Short-term Needs: Mr. Webb advised the needs for expansion and capacity are along the lines of PFAS (imminent needs), Newborn Screening (NBS) (short-term) and the Soils Lab. Mr. Webb advised we are trying to make best use of Stovall, which is not fully occupied - nor is it fully usable, based upon the age and the condition of the infrastructure.

Mid-Term – The interest is in building a wing onto Agriculture Drive location, requiring conversations on extramural funding, possibly at the federal level as there is strong interest in supporting public health laboratories. Walton Commons is a leased building so we will need to consider what that means for our IT Division.

Long-Term – Eventually exiting the 70-year-old Stovall Building and relocating is a project that will not happen immediately but needs to be looked at and planned out.

Hill Farms, a DOA building, is where the Soils Lab from Marshfield is going to be housed in a few months. Noel Stanton along with many others, has done a lot of work on that. DOA has been a great partner for getting into that building and this location may be helpful to us in terms of functionality, down the road.

Dr. Rider and Mr. Webb are in the process of working with colleagues at SMPH and campus and an external firm for an engineering study on Stovall to determine whether the building can tolerate a renewal or overhaul on the 3rd floor. If it can, it will be determined what kind and how much work can be done, along with the financial considerations. It would have to be determined what amount would justify 7-10 more years, but it will not be a large amount of money going into an old building with issues.

Dr. Moss responded that there is benefit to co-locating state lab R&D with other members of the university medical community and that going west and southeast of the campus may be something to consider. This was advised with no plan or promise to it, but as an informative premise to keep in mind.

Dr. Schauer discussed continuing participation with the campus master plan and pursuing the potential federal dollars.

**■ Noel Stanton Dr. Heather Barkholtz and Dr. Martin Shafer – Clinical
Biomonitoring – looking for chemicals, drugs, toxins and contaminants
in humans**

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Noel Stanton, Chemical Emergency Response Section

Testing typically blood based and urine with occasional alternate matrices. The matrix is very dependent on which substance is being sought.

This is a potential growth area for WSLH with our robust analytical and staff capabilities. We are very well-equipped by comparison with other bodies. We have strong partnerships with APHL and CDC, Center for Environmental Health, and DHS/DPH. We have extensive background in dealing with biological matrices from both an analytical and a process perspective.

There are two typical approaches: limited, well-defined cohort vs population-based surveillance is more complex, expensive, and difficult to implement. We're looking to seek out that work where we can.

The support is most typically grant and contract funding. Frequently where this is done well, there is legislative support for it as well as fee-for-service work.

Recently completed an investigation into PFAS exposure in Wisconsin. At this point, there are very few robust PFAS exposure data generated in Wisconsin. This was a broadly cooperative enterprise with UW SHOW program for specimens and DPH who will be a major partner interpreting the data. Hopefully this will represent a rough measurement of the Wisconsin population.

It is important to note that this is presently an investigative test, but our process was robust.

At this point, we captured 38 compounds. 605 serum specimens were tested from Wisconsin residents. We observed an average of 9 PFAS compounds in concentrations high enough to quantify.

30 of the 38 compounds we measured were observed in one or more samples. The most detected compound was PFOA. 4 compounds were observed in only a single sample. Only one sample was found with no detectable PFAS.

What we're seeing in Wisconsin is roughly similar to other studies, but Mr. Stanton is unable to comment on the biological half-lives. Dr. Martin Schafer noted a broad range has been found.

Dr. Heather Barkholtz - WSLH Forensic Toxicology and UW School of Pharmacy

Dr. Barkholtz joined UW-Madison in April.

Three distinct waves of opioid crises. Prescription based replaced by heroin replaced by fentanyl and now fentanyl analogs. This creates difficulties for analysis because the structure changes just enough to elicit new responses biologically and evade detection. This amounts to a legal grey area.

Increased incidence of polysubstance use depending on the main drug of choice make it more difficult to discuss exactly which substances a person was under the influence of when driving.

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Many opioid users are seeking medical attention due to very dangerous reactions to fentanyl usage. Opioid overdose incidence are not uniform across the state's populations.

The limitations of hospital-based detection can cause issues especially with the fentanyl analogs because the substance may not be detected in commonly used techniques.

Proposing a bio surveillance project using already existing urine samples from emergency patients who had a billing code implying an opioid event. We could work with de-identified specimens and subject them to additional testing to identify more information about what exactly was in the specimen related to polysubstance usage and how that impacted the event that brought the patient to seek treatment.

This could produce information of use to clinicians, first responders, and analytical toxicologists to help them make better-informed decisions about the population involved with opioid, polysubstance and emerging substances use. We are seeking Wisconsin partners for this project both in Northern Wisconsin and Milwaukee.

Dr Gonzalez asked a question regarding a table on a slide. The table comes from APHL's Bio surveillance task force document.

Dr Martin Shafer – Trace Element Research Group (Trace Element Clean Lab)

Activities:

- Measuring concentrations to assess exposure level or intensity using a variety of clinical matrices.

- The use of stabilized ratios of selected elements to help us understand the source of that element.

With magnetic sector inductively coupled plasma mass spectrometer, the lab can identify dozens of elements in a couple of minutes. This is a routine and long-standing capability of the Clean Lab. Coupled with an HPLC we can speciate elements where the toxic effect depends on the form of the element, as with arsenic and platinum.

Dr. Shafer mentioned the many partnerships across the country - some driven by cancer concerns.

Isotope ratio measurement is important to provide information on sourcing and environmental processing. We have an advanced instrument for about 8 years to perform this measurement at a very specific level. Partnering with DHS on lead exposures in Milwaukee and Racine to understand the source of the exposure to the child and have a paper in process for that. A project is also ongoing in Suriname.

We've done a lot of work with dried blood spots using them to quantify 23 or so elements using the tools mentioned above to produce much higher quality analysis than was available previously. A large proposal is out to UL (Underwriters Laboratory) to expand the work to organic and inorganic contaminants demonstrating the utility for dried blood spots in wider applications.

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Project ongoing with Harvard's Beth Israel Deaconess Medical Center piloting the use of nasal strips to assess exposure to environmental contaminants and atmospheric aerosols. Completing the pilot before the pandemic, we developed all the analytic and supporting protocols, we were able to get our proposal funded by NIH and that proposal will be starting up in fall of this year.

Item 9. FINANCIAL REPORT

■ **Kevin Karbowski, Chief Financial Officer, Wisconsin State Laboratory of Hygiene**

Mr. Karbowski highlighted the variance between our actual status vs our budget. Our DHS revenue is 67% over based largely on COVID work. 32% negative in revenue on DNR revenue based on COVID causing much less activity than expected. 14.3% variance on UW System revenue due to less testing being done for UW Student Health Services during the period when the students were not in town. 27% reduced Occupational Health due to fewer samples for our OSHA activity. 50.1% variance in APHL revenue due to such a concentration of work on COVID that APHL had less non-COVID work for us to do.

Total support and revenue – 51M expected. Actual revenue was about 57M actual revenue number leaving us about 10% over on revenue for the last fiscal year.

On the expense side, we were 22% above expectations for supplies and services largely due to additional needs for COVID-related supplies, but offset by a reduced need for non-COVID supplies, resulting in a positive \$189,000 operating income.

Mr. Karbowski mentioned the previous discussion of requests for price increase. Given the uncertainty and the desire to break even on the budget, the request will not be made at this time.

Working capital (cash and accounts receivable) went down 1.5M, as the result of a lot of equipment purchases. Operating contingency (60 days of quick assets on hand) went up \$440,000, due to increased activity.

Item 10. CONTRACTS REPORT

■ **Kevin Karbowski, Chief Financial Officer, Wisconsin State Laboratory of Hygiene**

Contracts signed since the last Board Meeting. The total amount of contracts signed over the last three months is \$1.6M in additional work with the WI Department of Health Services.

Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021

Item 11. HR UPDATE

- **Cynda DeMontigny, HR Director, WSLH - June 12- Sept 10 –**

Recruitments –

DPD – 3
EHD – 5
OSHA - 0
Admin -2
CDD – 3
LID - 0

Staff turnaround –

Hires

DPD – 3
EHD – 6
LID – 0
CDD – 5
Admin – 2
OHD – 0

Resignations

DPD - 3
EHD - 5
LID - 0
CDD - 1
Admin - 0
OHD - 1

Retirements

DPD – 1
EHD - 2

Item 12. DIRECTOR'S REPORT

- **Dr. Jamie Schauer, Director, WSLH**

Dr. Kelsey Florek – Variant Dashboard

Displaying a publicly accessible Variant dashboard for COVID and details some of the functionality. It's open source allowing other labs to possibly use it and allowing us to use it as a base for future development. Data is automated and does not need human intervention.

At peak, we had 700-800 views daily with 400-500 people interacting.
Presently up to 150 views a day with many actually interacting with the data and plots.

Ms. Jan Klawitter mentioned the use of the dashboard by media sources around the state – noted WBAY daily referencing back to our dashboard.

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
December 21, 2021**

Dave Webb – Water Boil Notice

1 boil water notice – Door County

Jan Klawitter – Recent events

Amy Miles has accepted the APHL’s Co-Chair Bio surveillance task force

Cytogenetics and Molecular Genetics labs partnering with UW Center for Human Genomics and Precision Medicine – opening UW Undiagnosed Genetic Disease Clinic. Our labs will function as “specimen traffic controller.” We will be performing up front nucleic acid extraction and banking and coordinate distribution of specimens to secondary labs.

Publications

As part of a CDC-led study looking at the effectiveness in real-world conditions of the mRNA vaccines, we developed a quantitative RT-PCR test method that could measure viral loads for SAR-CoV-2 in a person’s body – NEJM June publication

Erin Mani – part of an APHL webinar on PFAS discussing our development of PFAS testing.

Martin Schafer- Central States Water Magazine published articles on wastewater monitoring for COVID

More publications in the Board Agenda

Mr. Chuck Warzecha – closing remarks and recognition of presenters and Dr. Schauer.

Mr. Jim Morrison made a motion to adjourn. Mr. Jeff Kindrai voted to adjourn and Mr. Chuck Warzecha seconded. The motion passed unanimously and the meeting was adjourned.



Respectfully submitted by:

James J. Schauer, PhD, P.E., M.B.A.
Secretary, Wisconsin State Laboratory of Hygiene
Board of Directors