



# 2026 Clinical 2.0 Workshop

March 1- 3, 2026

Poll results

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**slido**

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## How many times have you attended the CL2.0 Workshop? (1/2)

0 5 5

- 2
- 2
- 5
- 0
- First time
- 2
- 4
- 1
- First timer
- Heath prediction strategy
- 4
- 0
- 0
- 3
- 2
- 2
- 5
- 2
- public policy
- 8
- First time
- 0
- 1
- 0
- 2
- 1
- 2
- 6



# How many times have you attended the CL2.0 Workshop? (2/2)

0 5 5

- 2
- 2
- 1
- 1
- 1
- 1
- 3
- 1
- 1
- 1
- 8
- first time
- 4
- 3
- 6
- 5
- 9
- 1
- 2
- 0
- 2
- Second
- 2
- 0
- 2
- 2
- 3
- 3



## What is the ideal level of control of systolic blood pressure for a patient with CKD, Diabetes and Hypertension?

0 2 3

< 120 mm Hg



< 130 mm Hg



< 140 mm Hg



I don't know for sure





**To what extent has your organization addressed the potential impact of quantum computing on your future priorities? ("Be honest now" as Austin Power would say.....)**

0 2 0

A lot

0 %

A bit (ha ha)

10 %

Not much

15 %

Zero

45 %

What the heck are you talking about?

30 %



0 1 7

## What percentage of your current business model is involved with direct value based purchasing contracting?

> 50 %



> 25%



> 10 %



< 5%



I am not sure.....





## How familiar are you with the Chicago Quantum Exchange Initiative?

0 1 6

Very familiar and actively involved

6 %

Very familiar and would like to get involved

6 %

Not very familiar but would like to definitely know more

19 %

I've never heard of this effort before now, how can I learn more?

69 %



## Five Options for Clinical Lab 2.0 Language – VOTE NOW!

0 4 3

VCWBs — Validated Continuous Wearable Biomarkers



RTWBs — Real-Time Wearable Biomarkers



LWBMs — Longitudinal Wearable Biomarker Metrics



CWBDs — Continuous Wearable Biomarker Data



In Situ Biomarkers (ISBs)





## Enter your comments and questions here for the panel

(1/2)

005

- Dr. Hanek, would you accept, as a practicing physician, every patient you see to be analysed by Dr. Balis' models and presented to you via your EMR?
- Perhaps Lab (CL 2.0) can work with vendor testing partners for direct to patient testing and connecting patients to care pathways within their health systems? Alternative to traditional 13 minute clinic visit? Peel some patients off of PCP's shoulders?
- In regards to AI and Longitudinal views of the patient journey, how do you see the models you're developing interacting with models industry partners are launching?
- It seems CPT payment systems are not only "misaligned" they are diametrically opposed to better data sets.
- Should Lab 2.0 be in direct contact with patients with care pathways where appropriate instead of PCPs to reduce the time and gap from patient result to initiating care?



## Enter your comments and questions here for the panel

(2/2)

005

- Dr. Hanak's comments about over-screening and over-treatment need more attention. Population health goals don't always jibe with individual goals. Predictive testing at the population level can have very low predictive value at the individual level (particularly for low prevalence diseases), and can subject large numbers of individuals to unnecessary follow-up, cost, anxiety, and disruption to quality of life.
  - What about treatment follow-up?  
Adding a medication Is
- a system perturbation. The response to treatment, in a data rich environment, should give key insights into the underlying condition and prognosis
- Is "early" detection of CKD early enough? How do genetic drivers for CKD play into your strategy?
  - How can your vendor testing partners help you achieve your goals?



## What recommended actions do you have for the Business-Alternative Payment Model Committee?

006

(1/2)

- Is one your questions to Payers: "would you provide separate payment for services of this nature?"
- It's been almost 10 years, should we have already started the process of creating Clinical Lab 2.0 billing codes since fee for service is still hanging around?
- Include extended interpretive lab reports in the need for reimbursement structure
- You might need to develop a questionnaire for labs based on "who they are", eg independent lab, system lab, hospital lab before they approach payers.
- How do laboratorians take credit for their good work? We are always being scooped by other departments!
- Are you going to crowd source these surveys with current attendees? Will you "gather in" our own survey findings?
- How can Lab 2.0 clinical activities, including physician consultations,



## What recommended actions do you have for the Business-Alternative Payment Model Committee?

006

(2/2)

direct patient interactions, and participation in patient rounding, be reimbursed by payers? Without a defined reimbursement structure, sustained adoption and system level change will remain difficult.



## What recommended actions do you have for the Multi-Institutional Demonstration Projects Committee?

0 0 1

- How can a 2-year time frame be reduced?
- Can we (attendees) approach you (Demonstration Project Committee) with our own institutions, our own initiatives?



## What recommended actions do you have for the Pathology Informatics-Artificial Intelligence Committee?

005

- But if the demonstration project committee needs two years to wrangle the data to ground , what is needed for local datasets to be normalized, harmonized, deduplicated, validated?
- Should AI platforms be considered methods that should be validated (similar to lab tests, algorithms, etc) or agents that should be credentialed (like practitioners, med lab scientists, pathologists, etc)?
- Where are you sourcing the digital solutions to support these studies?
- Leading question: can we do what your committee is describing with our own local datasets? Or are massive centralized datasets needed?
- What do you see as to the role of FDA and/or CLIA in any oversight of these predictive or diagnostic models?
- Where are you publishing? Likely more impact if you get something peer reviewed



## What recommended actions do you have for the Education/Certification Committee?

004

- DCDCLS is very much part of the movement, and soon the manuscript will highlight collaboration and alignment among DCLS, pathology, and advanced-level MLS diagnostic health consultants. Make sure you. Khosrow
- Implementation science training could also be important.
- So can DCLS be both role models and leaders in this space?
- The DCLS profession is already established, and the educational pipeline is in place. Lab 2.0 is actively taught within DCLS programs, making this an opportunity to build on existing infrastructure rather than reinvent it.
- Will front line laboratory technologists also learn about how they are helping to build-the-cathedral (and not just chisel stone)?
- Last year (2025), Diagnostic Consultant was different from DLCS. Have you now merged them?



## Add your comment and questions here for the Committees

(1/3)

0 1 2

- Leveraging of available technologies and data through vendor relationships and health system partnerships
- Nursing also is aligned as a field under one professional organization. Laboratory is sometimes fragmented and not alignment in advocating lab efforts.
- Institutional clinical pathways that have been pre-vetted for validity can empower the front line decision-making. An example at my institution (spearheaded by Aya) was reflex adjustment of antibiotic dosing and drug change, by a Pharmacist, on the basis of Microbiology results, without needing a physician order.
- Takeaway: Instead of asking, what is my blood pressure (or insert any laboratory test result), ask, what is my risk for xyz disease or condition?
- I think that the continued roll out of VBC and changes



## Add your comment and questions here for the Committees

(2/3)

0 1 2

- to privacy and consent law will naturally lead to direct incentivization of patients for consent and adherence. I also think that consumer data will come to occupy a more and more important role
- Opportunity to remove barriers, navigate internal IT landscape and partner with digital vendors to build sustainable models.
  - Advancing laboratory medicine as SOP in team based care Role of consumerism
- I'm still fuzzy on how we are leveraging advanced analytics/ large language models
- Dr Zarbo discussed performance measures within the CIN. More standardized measures of appropriate use and impact eg More consistent tracking and shared decision-making of ASCVD risk reduction for patients.
  - Determine key pain points within the lab medicine and pathology industries to



## Add your comment and questions here for the Committees

0 1 2

(3/3)

support the transformative

laboratory medicine

framework discussed today as a  
health informatics vendor

- The current billing system doesn't provide the optimal incentives
- When we talk about the phlebotomist interacting with the patient and identifying opportunities to close gaps in care, how do you envision the patient being able to get those additional labs at that moment while they are already there for lab services?
- Intervention pathology and



## Add your comments and questions for the Policy & Industry Committees

004

- Jack Glad you are here ! Part of the missed diagnosis biases including Anchoring Availability Closure
- Did they examine you? Abdominal exam?
- FDA Center for Devices and Radiologic Health (CDRH) evolving regulatory standards for Software as a Medical Device (SaaMD) to assess validity and risk of harm from CDSS apps.
- Clinical decision support
- What role can/does/will clinic decision support play in the CMS Access contract?
- Scope- of-practice has been lurking in the near background. Should there be policy consideration of how Lab (i.e. CL2.0 leadership) could empower a broader swath of the healthcare delivery team (nursing, PAs, Pharmacists, drug store mini clinics, etc.)?



## Outcomes Matter! Add your comments and questions for this session

(1/2)

005

- Is this model only for academic centers? How could community facilities do this?
- Ruth is identifying the fundamental components of the Laboratory 2.0 operation. Not just study, The scalability process is being assessed to evaluate the high prevalence conditions under which the health system is at risk.
- What are the expected averted transplants and deaths expected with a successful implementation of the program?
- Recommended an elf test for a surgical pt for mASH/mASLD during case conference. Surgeon said why elf when NIS4 is more sensitive and specific. How do you respond?
- If I remember correctly, ELF is approved by the FDA for patients with advanced liver disease (I.e. Elastography indicating advanced fibrosis). So the ADA guidelines are for off-label use of ELF. Will this study have relevance to FDA review of this test (for screening at an earlier stage of disease)?



## Outcomes Matter! Add your comments and questions for this session (2/2)

005

- Tracking and risk-stratifying disease is possible.
- Once these groups have collaborated, will the legal review be expedited for another study?



## What is needed to replicate a demonstration project at your site?

005

- Availability of resources (staff, IT infrastructure, etc) within an already overworked workforce.
- Someone in the position and with the bandwidth to lead
- Multi site IRB and compliance reviews
- Multi-site IRB and DUA (which take 8 months)
- Lab Desire, Clinician Alignment and IT Approval.
- Legal and office of research buy in.



**From Tests to Diagnosis - CL2.0 Pillar: Diagnostic Impact over Test Production**

0 1 3

## Which outcome best reflects success in a Clinical Lab 2.0 diagnostic model?

A) Consistent achievement of benchmark turnaround times across all assays

0 %

B) High analytical accuracy and low repeat-testing rates

8 %

C) Reliable translation of abnormal results into timely clinical action

85 %

D) Increased availability of advanced and esoteric testing

8 %



## When does laboratory data become most valuable for predicting patient risk?

0 1 6

A) When a single result crosses a critical threshold

6 %

B) When results are trended over time across care settings

94 %

C) When paired with rapid turnaround and automation

0 %

D) When interpreted strictly within reference ranges

0 %



The “People Matter” Theme: CL2.0 Pillar: People as the Enabler of Transformation

## What ultimately determines whether Clinical Lab 2.0 succeeds or fails?

0 1 6

A) Technology and automation maturity

0 %

B) Reimbursement and policy reform

31 %

C) Vendor innovation and interoperability

19 %

D) Workforce roles, training, and cultural alignment

50 %



**Education & Training for the Future State - CL2.0 Pillar: Education, Training, and Culture Change**

**What training gap most limits laboratories' ability to operate in the Clinical Lab 2.0 future state?**

006

A) Advanced analytical methodologies



B) Informatics and data visualization



C) Clinical communication and consultative skills



D) Regulatory and accreditation expertise





## PEOPLE MATTER: Comments or questions for this session?

003

- Given the recent Dept. of Education changes to the list of professional degrees and the federal loan limits that are proposed, I wonder if this could be a partnership opportunity between the education committee and the policy committee.
- During the clinical care rounds, can you give an example of input that a DCLS would provide?
- How does DCLS differ from PhDs in Micro or Chemistry except that they have broader oversight in leadership vs a narrower clinical focus?



## "Engineering Proactive Prediction": Comments and questions for this session

0 0 1

- Dr. Laufer's tool followed by Dr. Vijaykumar's commentary is impactful!



## DIAGNOSTIC MEDICINE CONSORTIUM: Please add your comments or questions here (1/3)

007

- Could you also use the model to identify what the level of confidence is in the prediction/ recommendation, and to flag what incremental information that's currently missing for the patient (eg which diagnostic test) would have the largest impact on improving model confidence?
- For cancer these outputs could easily be fed through current NCCN guidelines and vast and latest references for additional sense making for both clinicians and patients.
- How will you handle informed consent if the outputs are used for example on deciding which trials are available for any given patient?
- If I'm ever presented at tumor board, I hope Vincent is there!
- I'm not certain... no, I am certain... that I don't understand half the terms needed to give responses to the prompts.



## DIAGNOSTIC MEDICINE CONSORTIUM: Please add your comments or questions here (2/3)

007

How does one start learning this information to make the most use of these tools when our background is not computer based language or modeling?

- Are you applying any standard methods of Verification Validation and Uncertainty Quantification (VVUQ) for the inputs and outputs?
- I am not sure I would know how ask them.....
- I'm not sure I would know how to answer all of those questions.
- Dr Balis can we

assume you're able to bring in Imaging and biosensing data eg electrophysiologic and dynamic cardiac cath/functional MRI/echocardiography? Also interested in continous pulse wave amplitude and contour data.

- "Has the data extraction process been formally validated? If so, what validation methodology was used? Additionally, has any longitudinal tracking been conducted using Zeta Storm data with real patient populations?



**DIAGNOSTIC MEDICINE CONSORTIUM: Please add your comments or questions here**  
(3/3)

007

- Now we're talking!
- With earlier talk could consider contrasting kodak with fuji film which discovered how to utilize its extant camera chemicals to develop cosmetics. Japan conventionally viewed as very conservative culturally so was curious how such a shift was advocated for and achieved and thought could be good learning case.



## NAVIGATING GOVT AFFAIRS TOWN HALL: Please add your comments or questions here (1/3)

0 1 1

- We're seeing a shift in patient (consumer) behavior, and the DTC market is the only way to currently "bypass" the historic route of insurance approvals for testing. We're already seeing the patient journey change from their entry into owning their health journey from starting at the PCP to starting w the lab I.e. function/rhythm health. Patients will be the key to this policy shift and the payers getting on board
- ASCP has a Patient Champions program
- with personal stories on their website
- How do you get the pols to tell their own personal stories on how diagnostics impacted their lives or a loved one?
- We beed Khasrow and Dr. Morice to go on a podcast tour to talk about this... ones that average people listen to, not just ones that talk about science and policy reform
- Patient advocacy can be a powerful Adjunct if



## NAVIGATING GOVT AFFAIRS TOWN HALL: Please add your comments or questions here (2/3)

0 1 1

- done well. Personal stories get the pols attentions.
- Bring some patients who have benefited along w you to your discussions.....
  - Could rising measles and other vaccine associated disease outbreaks potentially serve a mini-covids to get us back upstairs? Rather they were not happening but have to use cards we're dealt
  - Modernizing CLIA has to be near the top of the list.
  - Like the Institute for Clinical and Economic Review (ICER)?
  - South Korea has a great medical system.
  - Is DMC prepared to develop/partner for cost effectiveness evaluations of its work?
  - Is there a better model outside the US we should contemplate?
  - How do we get the general population to start demanding things change? Do they even know we are trying to do this to keep them and their families well?
  - Vincent could build it



## NAVIGATING GOVT AFFAIRS TOWN HALL: Please add your comments or questions here (3/3)

0 1 1

- Healthcare is something all politicians run on... are any of them invested in changing payment structure?
- If fee for service incentivizes utilization rather than prevention, how should policymakers redesign reimbursement structures to compensate laboratories for reducing admissions, complications, and unnecessary downstream care?
- And nearly all capitations have incentives (or penalties) that are directly related to lab testing. So do Level 1 risk, negotiate for that incentive
- Capitation
- Would it be reasonable to replace fee for service to fee for cost avoidance and preemptive medicine. Would that even be possible?