

Agenda

Clinical Laboratory COVID-19 Response Call

Monday, November 1, 2021 at 3:00 PM EDT

Agenda

- **Welcome**
 - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Successful Mitigation of SARS-CoV-2 Transmission at a Residential Secondary School**
 - Kevin Volpp and Bruce Kraut, University of Pennsylvania
- **SARS-CoV-2 Variants Update**
 - John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response

JASMINE CHAITRAM: Hello, everyone. Thank you for joining the Clinical Laboratory COVID-19 Response Call. I am Jasmine Chaitram. I am the Associate Director for Laboratory Preparedness in the CDC Division of Laboratory Systems. Glad you could be here today. Before we get into our first topic on today's agenda, I will go through my regular reminders and housekeeping things. So standby as I change slides.

OK. So just a reminder, the [Division of Laboratory Systems](#). Our role is to support clinical and public health laboratories, and we do that in a number of ways and a number of topic areas, including quality laboratory science, workforce and training, safety, biological safety, and accessible and usable data, informatics, as well as preparedness and response. And our role in the COVID-19 has been specifically around preparedness and response activities. We serve as the liaison to the CDC Emergency Operations Center. And that's how we are able to connect you to important topics and speakers and subject matter experts on a variety of issues related to the COVID-19 response.

I do want to remind you that we have a [CDC Preparedness Portal](#), and this is hosted by the Division of Laboratory Systems. It does have links to CDC's main pages on COVID-19 information. We also have here archives of all of our [Clinical Laboratory COVID-19 Response Calls](#). I know I get a lot of emails with people that have missed the call and I always direct them to this page, where we usually get the transcript, the slides, and any notes associated with the call up onto the webpage. Usually it takes us about seven to ten days, so just be patient if you do miss the call and just keep checking this website for updates.

We also have here an archive of our [Laboratory Outreach Communication System](#) emails that we've been sending since the beginning of the response starting in January 2020. So if you want to go back and see any of those emails, you can find that here. And other preparedness activities that our division is involved in can also be found here.

Our next call will be on Monday, November 15, from 3PM to 4PM, and we continue to have these calls every other week. We also want to hear about your training and workforce development needs, so please email those to labtrainingneeds@cdc.gov.

And a reminder about asking questions, please use the Q&A box in the Zoom webinar system. We want those questions submitted in the Q&A box, so we can track them and use them. If you submit your questions into the chat, we won't be able to get to them later. We also want you to submit your name and email address with your question in case we are not able to answer your question during the call.

We're sometimes not able to answer the questions because of the number of questions that we have and the time is short. Sometimes people ask questions where we don't have subject matter experts readily available to answer them on the call. And so we do try to either get those answered by email, or we try to bring experts to the next call to answer those questions. So if you want to have your question answered, please provide your name and email and use the Q&A box.

And if you're with the media, a reminder that you should use the media@cdc.gov in order to submit any questions that you have. And if you're a patient, you should refer to your health care provider. And then a quick reminder also on questions, that this is a laboratory-based call. The topics we have here are about laboratory and testing, so please try to limit your questions to those particular subjects. And for those presentations that you see here or on the archive, they may contain presentation material from panelists that are not affiliated with CDC, so these do not necessarily reflect CDC's official position.

And with that, I think we're ready for our first speaker today. We have two individuals joining us from the University of Pennsylvania. And this is another topic similar to ones that we've presented in the last two calls about testing and the usefulness of testing to mitigate transmission in schools.

And so with that, I'm going to turn it over to Kevin Volpp and Bruce Kraut. And I think Kevin is going to go first.

KEVIN VOLPP: Great. Well, thanks very much, Jasmine. And welcome, everybody. I'm joined by Bruce Kraut, who is the Medical Director at the Lawrenceville School. I also want to note, I'm an unpaid medical advisor and board member of the Lawrenceville School myself, even though I'm primarily a faculty member at Penn.

And let's go to the next slide. I want to bring us back to the publication of this [CDC MMWR](#) report last spring, and also thank our other two co-authors, Smita Ghosh and John Neatherlin from the CDC.

And if we go to the next slide, I'll take you back to where we were at the time in terms of why we wrote this paper. As you know, in the fall of 2020, schools nationally were struggling to stay open and stay open for in-person learning. There were a lot of concerns about uncontrolled transmission of SARS-CoV-2 in school settings. And what we wrote about was the approach we developed at the Lawrenceville School in

Lawrenceville, New Jersey, that was really a comprehensive approach to minimize risk of COVID transmission. And partly because we were doing testing twice a week of all the students, faculty, and staff, we found fairly quickly we had a lot of data that we could use to evaluate the success of our efforts. And we wrote this paper to share that information for wider adoption and potential dissemination with a broader audience.

So let's go to the next slide. So the bottom line was that in the fall of 2020, we achieved very successful containment. And I'm going to talk to you through a set of numbers here looking at testing data that was from the biweekly surveillance testing we did on faculty, staff, and students. So as you can see here, for a school that had 775 students and about 400 faculty and staff, we did a lot of testing. There were about 22 tests on average for faculty and staff members, and about 15 on average for students. And this had to do with the fact that faculty and staff arrived earlier, there's a lot of preparatory work, and the students had a somewhat staggered arrival based on quarantine periods and the like.

But then what we found over the course of the semester was we had 19 positive tests among faculty and staff and eight among students, so a total of 27. And we did a lot of contact tracing. We'll talk a little bit more about that in a moment. But both manual contact tracing and using electronic transmitters, which measure proximity. And interestingly enough, we only found two cases that could be linked to on-campus transmission. Two out of 27. Furthermore, we identified 31 people who were close contacts who needed to be quarantined, and of those 31, zero ended up testing positive.

And so what we feel that this really spoke to was the effectiveness of our protocols in minimizing transmission. It's unusual that there's this much testing that was being done that would enable us to come to this conclusion. But let me take you to the next slide and give you a flavor for how we set up this system. So before students arrived, the Lawrenceville School, by way of context, is a boarding school in Lawrenceville, New Jersey, that is about 2/3 boarding students and 1/3 day students. It's students grade 9 through 12.

We required everyone to do pre-arrival testing, and we also asked people to do a two-week quarantine. We, of course, had no way of monitoring that, but the hope, of course, was that people would take that seriously. To be on the safe side, we also, once people arrived on campus, did a 10-day modified quarantine, which required three negative tests, three days apart before people would be released from quarantine. And I say modified quarantine because the students were allowed out of their rooms to get some exercise. And there were various ways in which we tried to recognize that having students from around the world just be locked in their rooms for 10 days on arrival probably wasn't going to be entirely palatable.

We did require, throughout the semester, universal masking outside of dorm rooms. There were a lot of efforts made for physical distancing and de-densification. So the classrooms were all measured and the chairs were all set up so they were at least six feet apart. This meant that in many classes there weren't enough spaces for all the students to be there at all times. So in many classes, we had a hybrid learning

system where roughly 2/3, sometimes 3/4, sometimes 100% but not always, of students were in the classroom, and then some students were remotely and they would rotate.

We had upgraded ventilation in all the buildings, using HEPA filters in the classrooms, MERV-13 filters in the dormitories. All dining was take-out only, with meals eaten outdoors. As I mentioned, there was twice-weekly testing. We did a lot of manual and electronic contact tracing, and then isolation of new cases with quarantine. We had no athletic competitions with other schools, but we did have daily practices of the teams that was allowed to take place generally outdoors. And then one of the key elements of the system was what we called the Best for All Behavioral Compact, and this was a really fundamental underpinning which I think was really central to our success in terms of setting expectations for students, faculty, and staff and then having a system for monitoring that and really some teeth behind it.

And if we go to the next slide, Dr. Kraut is going to tell us a bit about the Best for All Agreement, which in some sense, was the heart of the system.

BRUCE KRAUT: Thanks, Kevin. So as Kevin mentioned, the Best for All Agreement-- and this phrase actually derives from the mission statement of the Lawrenceville School, which reads in part, "inspiring the best in each, to seek the best for all." And it served as a Behavioral Compact, as he said, between all members of the community, not just students, but also faculty, staff, and families. It emanated actually from our Dean of Students Office, and by signing it, our community members acknowledged their commitment to adhere to a broad set of preventive and mitigation measures that were largely within their control. And this served really, as Kevin has said, the cornerstone of our defensive strategy.

All of our other defenses against contagion and spread were then implemented in a layered approach, following the so-called Swiss cheese model that was described back in 1990 by psychologist James Reason, where some slices of the cheese have perhaps more or larger holes than other slices, but as a block taken together, they keep any natural errors in human behavior, which are to be expected, after all, from causing an outbreak in this case, or a complete breakdown of our systems.

Kevin has mentioned some of these measures. They are of varying yield, so to speak. Students did self-temperature checks in the morning before leaving their rooms. Employees did self-temperature checks before coming to work. A symptom tracking app, that was actually developed by one of our science faculty and tied into our existing sentinel notification app, gave either a green or a red display that either allowed the student to proceed about campus or gave him or her instructions, depending on the combination of symptoms checked, on remaining in their room or at home until contacted by our dedicated telehealth nurse who was situated in the infirmary.

This nurse could then easily and safely triage the student so as to minimize the risk and streamline their evaluation at a specified appointment time in our infirmary. Students had to show the green pass also on their phone before being allowed to enter classroom or other buildings and other facilities on campus. We also had the proximity tracing devices that Kevin mentioned that were worn at all times on campus by the entire community, and this technology, as he said, did help support our regular gumshoe contact tracing,

which we performed in house-- that is, by members of our staff who had been trained on the New Jersey program. They reported to me and they had direct contacts with our local health department contact tracing system.

We also, as he mentioned, had distances in our buildings all across campus very carefully measured to promote proper distancing, whether in classrooms, dining facilities, or elsewhere. And engineering interventions were instituted in all the buildings to minimize the risk of spread from airborne and surface contact. Go to the next slide.

So those represent just a few of the many layers of our strategy, but we've always been mindful of the mental health toll that some restrictions can take, especially on students. So even while we strove last year to enforce physical distancing rigorously, for example, we tried equally hard not to promote social distancing or social isolation. So this is also why now this fall, we have a highly vaccinated community with greater than 95% of our community fully vaccinated.

We've been able to judiciously, deliberately, and gradually peel back some of those layers of defenses. As long as the results of our ongoing, twice-weekly testing, which is now a pooled saliva testing that's performed-- as long as that data continues to give us reassuring feedback. Which you can see from this slide, they currently do. This is our current dashboard as of a few days ago. And it's very reassuring, particularly when measured against viral prevalence in the surrounding region. Go to the next slide.

So we have been able to lift, for example, the daily self-temperature checks, the wearable proximity readers, the degree of masking and distancing outdoors and during athletics, the use of the symptom tracking app itself and the associated virtual nursing visit. Dining restrictions have been eased. Rooming assignments, that prior to this year had kept all students in single rooms, have also been liberalized to allow doubles and even triples in some circumstances.

But this doesn't mean, of course, that such measures were in any way, unnecessary last year, but rather that our adherence to the aforementioned Best for All Agreement and our currently highly vaccinated community status seems to have struck the right balance with our modified prevention and mitigation measures in the current viral climate.

And I'll turn it back to Kevin to close us out.

KEVIN VOLPP: Thanks, Bruce. So we believe that our data illustrate that it is possible to nearly eliminate on-campus transmission of SARS-CoV-2, both based on what we observed in the fall of 2020 and what we've observed this fall. This does require a comprehensive approach to universal masking, prompt isolation of identified cases, and some sort of behavioral compact like the Best for All Agreement that people adhered to.

We do think that the regular testing, as a way to identify cases and promptly isolate them, is an important component of this. We don't have a way of isolating the effect of upgraded ventilation. We believe that

was probably an important ingredient here, but don't have a good way, of course, to measure the incremental impact. One might think about this approach as being akin to the universal precautions that are used in clinical settings by health care providers, and it has stood us in good stead last fall, last spring, and this fall.

As I mentioned in response to a question in the Q&A, we did deliberately move to remote only last winter - December, January, February. It was thought, for a number of reasons, that was the only practical alternative. We have students from all over the United States, all over the world, and we would have had to quarantine them for two weeks after Thanksgiving break, before winter break, and then after winter break. That would have taken us into late January, and spring break starts late February. So it didn't make sense to bring everyone back for that for only four weeks of a normal semester given how cold it is in New Jersey in February. So we brought everyone back in March and everything went smoothly last spring and has gone smoothly this fall.

So let me stop there and happy to take any questions. There are some other questions in the Q&A we did not get to.

JASMINE CHAITRAM: Thank you both for presenting this information. It sounds like the mitigation strategies were working. Can you talk a little bit more about the testing? Was there a dedicated lab that was performing this testing, and how did you set up the testing?

KEVIN VOLPP: Bruce, did you want to take that one?

BRUCE KRAUT: Sure. So last year, we used the nasal swab testing from that was sent to the Broad Institute in Boston. Broad gave us a very quick turnaround. And of course, turnaround time was of quintessential importance to us. In terms of the efficacy of our testing, really everything depends upon, of course, accuracy, as well as turnaround time. So we stood up a very impressive and robust twice-a-week testing program, using the self-swab techniques provided by the Broad Institute and our staff in tents outdoors, except when the weather was too inclement for us or our students and community members to be outdoors, we performed them out there in the open.

And as far as confirmatory testing, in concurrence with guidelines from our local and state health officials, a positive test from Broad was treated as positive. In other words, we did not try to prove a false positive on any of those tests. We accepted them and acted accordingly. This year, we are-- actually as of last spring, when we found that prevalence of the virus was lower both in our region and indeed across the country, we switch to pooled saliva testing from Mirimus Lab, which gives quite a good turnaround time. The results take a couple of reflex tests to get us down to any individual positive case, but it suits our needs well and the ease of testing has increased both compliance and the resource needs. So that's the current testing program.

JASMINE CHAITRAM: Great. And there are a couple more questions popping up. A question about how did you fund the testing program.

KEVIN VOLPP: Well, the school had to spend a lot of money on this comprehensive program and so the testing program was something that was part of that. We just had to find the money to make it happen, recognizing that we didn't think we could safely run the school without doing it.

BRUCE KRAUT: A majority of positive cases-- to answer the question from Phoebe-- the majority of positive cases were asymptomatic screening results. We did do testing through the infirmary on symptomatic individuals who had reported symptoms on the symptom tracking app and could be brought in for specific testing through the infirmary. But there were actually very few positive cases collected through that.

JASMINE CHAITRAM: OK. And there's a question about a CLIA Certificate of Waiver, and whether or not you have to obtain one. If the testing was done at a lab offsite, then that lab most likely had the appropriate CLIA certifications. Your clinic that was doing testing most likely also had that, but can you just comment?

BRUCE KRAUT: So that's correct. So within our clinic, that is correct. We were not responsible for any additional waivers that the lab would be responsible for. We did use the Sofia Rapid Antigen testing in our lab last fall and somewhat into the spring. So we had a CLIA waiver for that. But we always backed up those antigen tests with send-out PCR nasal swabs to a local laboratory that performed those. Last spring, we also acquired the Cepheid Rapid PCR machine. We are currently using that for symptomatic testing instead of the rapid antigen test.

JASMINE CHAITRAM: Thank you. There's a follow up from Phoebe about the asymptomatic positive cases and did they go on to develop symptoms.

BRUCE KRAUT: Yes, in a few cases they did. Yes.

JASMINE CHAITRAM: Thank you. There is a long comment in the Q&A box. I'm just trying to read it really quickly. But I think it's about vaccinated students attending in-person-- sorry, hopefully you're seeing it, too.

BRUCE KRAUT: I am. Just reading it now.

JASMINE CHAITRAM: OK. Yeah, rather than me read the whole thing. But I guess they just want your feedback on how to maximize resources. So I think the question is-- I think the question could be something about not doing testing of vaccinated students or having just the unvaccinated students learn from home. And so that way, all of this testing is unnecessary. But what are your thoughts on that?

KEVIN VOLPP: Well, this is obviously-- it's an interesting question, but a complicated answer. We, as Dr. Kraut mentioned, we had a vaccine mandate this fall. We did allow medical and religious exemptions, and

we've discussed at length how stringent to be about exemptions and allowing exemptions, and what are the criteria for those.

And I think it's always, with every organization, it's a bit of a balancing act with wanting to respect individual freedoms and choices, but at the same time, recognizing the needs of the community. And clearly, if you have a school which is a residential community, there is an imperative to have as high a percentage of students, faculty, staff vaccinated as possible.

So a lot of efforts were made to try to convince individuals who are reluctant to get vaccinated to get vaccinated. And I think that's reflected in the fact that the vaccination rates are in the 98-99% range, which is pretty good. And maybe Bruce-- let me ask you to comment a bit on what students or faculty and staff had to do in terms of qualifying for a medical or religious exemption, and anything you can share about discussions the school had on the criteria that were used.

BRUCE KRAUT: Sure. Well, religious exemptions are permitted for vaccination, generally for students in the state of New Jersey. And so it was in alignment with that, that religious exemptions, in addition to obviously, medical exemptions, were part of our requirement. So for religious exemptions, some of our students who have claimed religious exemption have had religious exemptions in the past for other vaccines. Some of them are new. But I would say that we didn't talk a lot about the educational component of what we, and with Kevin's assistance, did for this community to bring the community along to get such a high rate of vaccination. And that was extraordinarily important.

There are fairness and equity issues that I think need to always be balanced, as Kevin has said. It's such a small percentage of students who have not been fully vaccinated on our campus, and of staff as well, that we feel very comfortable that we have created at least a ring immunity, if you will, of our vaccination strategy and in-person residential life on campus. Even if we have not technically achieved herd immunity in our region.

The only other thing I would say on it, is that transmission-- it is possible, obviously, for those who are vaccinated to still get the virus, potentially transmit the virus, and also potentially get rather ill with the virus. So we were not in any way going to let down our guard, especially in this close-packed residential community that we live in, in terms of testing any member of the community.

JASMINE CHAITRAM: OK. Well I'm not seeing any other questions for you at this time. I do want to thank both of you, Kevin and Bruce, for joining us and giving us this presentation and answering all of the questions that we did have. Really do appreciate your time.

BRUCE KRAUT: Thanks for having us.

KEVIN VOLPP: Thank you for having us.

JASMINE CHAITRAM: OK. And so we are going to move to our next agenda item, which is actually our last agenda item. We have a very short agenda today. We were supposed to have an update from the Laboratory and Testing Task Force on variants during our last call and ran out of time. But John Barnes was gracious enough to join us again today and he's going to do that update today instead.

And I'm actually going to stop sharing my screen so that John can show you information live from the CDC website, and hopefully this will all be easy to do. So let's see. John, are you on?

JOHN BARNES: I am. I am ready to go when you are.

JASMINE CHAITRAM: OK. And I'm going to stop sharing, and hopefully you can start sharing.

JOHN BARNES: All right. Can everybody see?

JASMINE CHAITRAM: I can see it. Looks good.

JOHN BARNES: All right, good. So for those not familiar, this is the [COVID Data Tracker web page](#) about variants and variant proportions. And we update this weekly as we get more and more data from our genomic surveillance efforts that CDC is doing. So we have two main areas of sequencing our input that we do for genomic surveillance.

One of them is our NS3, which states submit and jurisdictions submit sequences to CDC. And the second one is we have a number of labs in which we contract with to-- clinical labs that provide genetic data that actually go into some of this.

So this is what we call the Nowcast data. This is a model that estimates the more recent proportions of circulating viruses. So not sure how often you all click around on this particular website, but this is here and updated weekly as I said.

The data has pretty much been the same for the last couple of months, honestly. Where we're essentially looking at this huge wave of Delta, which is caused by this B1617.2. It's varying proportions of 99 point something percent per week-to-week at this point.

We're also looking at our two sublineages that we have, called AY.1 and AY.2, dedicated sublineages from the Pango lineage. These are what we call our Delta Plus mutations. These have additional spike mutations that are of concern because they have potential for issues with therapeutics that we may be having-- which we have right now. And so we watch these separately. And then we get some of these other lineages. These others-- a lot of this data is actually data that doesn't match full Pango thresholds and quality issues. And so these are a lot of other things in that category.

So this is the national data that you can see, and it's pretty boring. And then you can see the actual state and regional data here. And some features about this-- the pie graphs are really kind of ridiculous at this point, because they're all orange. Except there's a tiny, tiny sliver of Other every once in a while. In region

9, we actually do have a little bit of higher proportion of this AY.1 variant, as you can see. To show here where it's at, 0.4%. Right here, we've had something that we've been watching in Hawaii, where we've had a little bit more of the AY.1 variant in there and been working on keeping that under monitor.

So one of the additional features that came along a couple of weeks ago that I really wanted to highlight for you guys is the weighted proportions of variance by jurisdiction. So all of the states and territories have a line in this. And these are weighted proportions, whereas before we were only giving proportions from states that had over 300 sequences within the last four weeks. This has now allowed us to provide that data without that threshold. And now, we have these weighted proportions for all of our variants of concern and variants of interest.

Again, this has been fortified by another stream of data, which is actually state submission data for genomic surveillance or national surveillance. We're using tagged sequences from the states that are generated by the states, and pulling those out from our databases that we use to populate this. And combining it with our data in order to make these estimates. And that's been a really big help, particularly in Alaska. Alaska does quite a bit of sequencing. They've been doing a lot of-- it's been very helpful for their proportions. Hawaii has also been really, really good about it, too.

Not picking on anybody else that has because there are several other states that have been outstanding in this area. So wanted to point that out and show that these new little features that we have on our variant tracker page. And that's pretty much all we have, Jasmine. Happy to take any additional questions.

JASMINE CHAITRAM: Thank you. There were a couple of questions. The first one is, why are AY.1 and AY.2 being reported when a AY.3, AY.4 and AY.25 are much more prevalent sublineages?

JOHN BARNES: So that's a really great question. AY.1 and AY.2 actually have those additional mutation at spike 417, which is actually a variant. Gives us a little bit of difficulty with our antibody therapeutics in some cases. So that's one of the reasons.

JASMINE CHAITRAM: Great. And then a question about prevalence available on the tracker. Can you go over that?

JOHN BARNES: Prevalence of-- the specific prevalence of Delta? The prevalence, really at this point, you can see that in the proportions versus the total number of sequences that you have. So the prevalence is kind of done on that. Prevalence of actual positive cases is not done on this tracker.

JASMINE CHAITRAM: Right. I think that they could probably find that on the other COVID tracker.

JOHN BARNES: Right.

JASMINE CHAITRAM: We can maybe do a demo of that in a future call to help people find that information easier. OK. Next question is, does CDC have any info information about other influences-- I'm assuming variants from around the world-- that may be impacting the US in the near future?

JOHN BARNES: Yes. So we do an evaluation of what sequences we have coming from the globe. We do not actually put that into a website, but it is part of our normal day-to-day, is to look at those, do an evaluation and analysis of the variants that we see globally, and see if there's any risk to the national population. So that is part of what we're keeping track of. So yeah, we do that.

JASMINE CHAITRAM: OK, great. We had three questions pop in that were very similar and you just answered them about monitoring other countries. Let's see. OK. I think that's going to be it for you, John, for today. And thank you for joining us. Appreciate your time, as well. I know you're super busy.

JOHN BARNES: No worries. Glad to help.

JASMINE CHAITRAM: Thank you. OK. So then I see one other question here. Recommendations for using rapid NAATs to confirm discordant results. And I'll just mention that CDC does have a page about NAATs, nucleic acid amplification tests, and in that page, we do talk about laboratory-based NAATs being used to confirm discordant results.

I do think we say there that if you're in a scenario that requires you to use a rapid NAAT, so maybe you don't have access or you need to have the results faster than a lab-based test, that we do recommend that you check that specific rapid NAAT test to make sure that the results are not presumptive in nature. And that would be in the instructions for use that is issued with the authorization of the test from FDA.

And I think that's all that we can answer for today. And so it's a short call, as I mentioned. Do again appreciate you all joining us for these calls. And our next call will be on Monday, November 15. And we will see you then at 3PM on Monday, November 15. Thank you.