

MEETING AGENDA

FEVENT:	Testing Surge Workgroup	Date / Time:	July 10, 2020 @ 1130
Author:	Lindsay Garfinkel, EY	Approved:	August 21, 2020

Enter information below: (text box will automatically expand, numbering is automatic)

Required Attendees (X=Present):

	NCDHHS	<i>Sec. Mandy Cohen</i>	X	NCDHHS	<i>Dr. Betsey Tilson</i>
X	NCDHHS	<i>Dr. Scott Shone</i>	X	NCDHHS	<i>Dr. Cardra Burns</i>
X	NCDHHS	<i>Dr. Zack Moore</i>	X	NCDHHS	<i>Dr. Shannon Dowler</i>
	NCDHHS	<i>Jay Ludlam</i>	X	NCDHHS	<i>Azzie Conley</i>
	NCDHHS	<i>Amanda Fuller-Moore</i>	X	LabCorp	<i>Traci Butler and Clay Gibson</i>
X	Quest	<i>Natalie Jackson Betsey Swider</i>	X	Duke	<i>Dr. Michael Datto</i>
X	MAKO	<i>Josh Arant</i>	X	Atrium Health	<i>Dr. Gerald Capraro</i>
X	UNC Health	<i>Dr. Melissa Miller</i>	X	NC Medical Society	<i>Dr. Garrett Franklin</i>
X	Old North State Medical Society	<i>Dr. Charlene Green</i>	X	NCCHCA	<i>Chris Shank</i>
X	NCCHCA	<i>Dr. Mark Massing</i>	X	Mecklenburg Cty	<i>Dr. Meg Sullivan</i>
X	NC Board of Pharmacy	<i>Jay Campbell</i>	X	NC Healthcare Association	<i>Dr. John Fallon</i>
X	NCALHD	<i>Stacie Saunders</i>	X	NC Institute of Public Health	<i>Doug Urland</i>
	NC HIEA	<i>Christie Burris</i>		UNC Gillings School of Global Public Health	<i>Dr. Kauline Cipriani</i>
X	Manatt (in support of NC DHHS)	<i>Emily Carrier</i>	X	NCNG (in support of NC DHHS)	<i>Dale Cowan</i>
X	Ernst/Young (in support of NC DHHS)	<i>Lindsay Garfinkel, Kendall Ford, Lori Feller</i>		Guests:	<i>Rhonda Stephens, Jay Tildon</i>

Agenda:

- I. **Welcome and Roll Call**—Dr. Burns (5 min)
- II. **Opening Remarks**—Secretary Cohen, if available (5 min)
- III. **New Business**
 - a. **Test Trends and Hot Topics**—Dr. Shone (5 min)
 - b. **State Testing Standing Order**—Dr. Tilson (10 min)
 - c. **Update on new collection sites or testing partnerships**—Dr. Massing (10 min)
 - d. **Pooled Specimen Testing Discussion**—Drs. Datto and Capraro (15 min)

MEETING AGENDA

- e. **Collection and Testing Capacity and Barrier Survey Results** —Dr. Shone (15 min)
IV. **Due Outs Assigned and Closing**—Drs. Burns, Tilson or Moore, if available (5 min)

Tasks / Due Outs: (List the recommended lead responsible for each task)

Due Date	Organization POC	Task
7/17	Dr. Scott Shone and Dr. Gerald Capraro	Work on adding the research side and the implications of that discussion to the document, and recirculate the document next week to the Scientific Study Council and the Test Surge Workgroup and have a document to Secretary Cohen by EOW next week

Discussion by Major Topic: (Information not covered on slides or handouts)

- Dr. Burns welcomed the group and conducted roll-call.
- Dr. Tilson started us off with Test Trends and Hot Topics
 - NC continues to, “tick up” at the same velocity (NC is not surging, stable, or declining).
 - NC reported the highest hospitalizations in the past two days; ICU rate is stabilizing and decreasing, and NC still has capacity in the healthcare system
 - NC may have capacity issues in the future, but we are not there yet
 - Many neighboring states are surging, so NC, “looks good,” compared to other SE states; NC was hotspot a few weeks ago and is now a simmer spot in comparison to other states such as California and Arizona; NC is not where we want to be yet, but not surging
 - We are going to be hard pressed to continue to ease restrictions, but to learn lessons about easing restrictions from other states that eased restrictions and are seeing huge surges (e.g. Texas now and Florida soon)
- Dr. Tilson then briefed about the State Testing Standing Order
 - pushed out on Tuesday (7/7)
 - The following were highlights:
 - We heard that for HMP (those who are typically not as well connected into the medical health care system), there was a barrier around needing to have an order for diagnostic test (which was especially highlighted by community-based testing and SNF surveillance). We wanted to minimize this through this standing order
 - Standing order includes diagnostic COVID-19 test (used diagnostic to include more than molecular, such as antigen) – authorizes collection and submission to a lab for diagnostic testing for COVID-19; does not mandate or override but authorizes the submission of samples under this order
 - State Testing Standing Order includes items to be helpful, best practices, linking people to medical homes, and that the team developed a document on patient guidance for what to do in isolation and quarantine to hand out during sample collection.
 - State Testing Standing Order alludes to increased data requirements that the General Assembly passed requiring not just physicians, but other

MEETING AGENDA

healthcare providers to report positives – they are now required to report negatives, so new data reporting now has positives and negatives; there is a temporary order requiring this data reporting and a guidance document on how to do this reporting and the specific data to be reported (including race and ethnicity).

- Many labs that are reporting, so if a provider orders a test and is sending it to a reporting lab, that provider does not have to report the negatives on their own as the lab would already be reporting this information (labs that fall into this category include LabCorp and Quest).
- Dr. Tilson told the group that she is open to any feedback.
 - Comment from Mecklenburg County (Dr. Meg Sullivan): the reporting of negatives has been causing confusion/concern among providers including how that works in their workflow and the extra burden. We need clarification on this.
 - Response from Dr. Tilson: this is in the guidance, but it may not be clear. We have heard this feedback. We will be pushing out an FAQ on the Standing Order and data reporting.
- Dr. Massing provided an update on new collection sites or testing partnerships
 - Dr. Burns shared that current barriers are high TAT and reagent concerns – need to brainstorm solutions to help providers that are building partnerships and trying to have collection sites.
 - Organization: Vidant Health (Reporter: Dr. John T. Fallon, MD, Director of Labs)
 - Sent a screen shot of their detailed dashboard.
 - Organization: Granville Vance Health Department (Reporter: Lisa Harrison)
 - We are working with local partners in Granville and Vance Counties to have an outreach testing event in community every month. We hosted our first one at a church in Vance County on June 24th and aim for a Granville County with the LatinX population as our focus on July 26th
 1. Granville Vance Public Health
 2. Church, Fair Grounds, Health Department, more to be determined locally based on date, time and target population ease-of-access
 3. 19 in-house
 4. Duke University and El Centro
- Dr. Shone moved on to the Collection and Testing Capacity and Barrier Survey results
 - Feels like March or April again in terms of the same problems that the country is facing (maxing capacity, reagent concerns, PPE strains)
 - Commercial partners are seeing high volumes

MEETING AGENDA

- Hospital systems are having reagent problems
- Dr. Shone noted that he is reminded of one of the first questions asked in one of the first meetings of this group from Dr. Datto around who we should be testing; Dr. Shone asked: how do we overcome barriers, maintain what we have built, and have a discussion starting today about how to respond to the challenges ahead to continue to support testing collection needs with the full recognition that testing is one piece of the response and that communities adhering to public health mitigation is necessary for prevention?
- There is a capacity survey distributed weekly and there is a dashboard to analyze and present the data;
 - There may be survey fatigue and we need to decide if the survey should be distributed biweekly now that we have baseline data and are seeing similar trends over the three weeks that it has been distributed and that we may be able to respond better if we change the cadence
 - Dr. Shone then shared his screen to show the dashboard and presented the following:
 - 72 responses in the past week (has gone down substantially over 3 weeks)
 - Collecting and processing: 54 organizations said that they are collecting, 36 said that they are testing, and 29 said that they are doing both – need to do QA
 - Dashboard can see what collection sites need (masks, face shields, swabs, gloves, staff, etc.)
 - Can look at reported capacity vs. what they did that week
 - Can breakdown by county to see highest capacity or testing
 - Can see comments/notes and look for keywords to pull out
 - Can click into processing sites and get more details on specific sites and their needs
 - Goal: someone submits that they need more swabs and that need would link to the distribution team to get them out – initially reactive and then to be proactive to push out supplies
 - Reagents: we are working with our federal partners to identify where more reagents could be allocated; Roche and Cepheid continue to be significant issues with allocations with no end in sight (Cepheid problems to get worse before better according to HHS – phasing out COVID cartridge in August) – we haven't solved the reagent supply chain issues
 - Dr. Shone opened the discussion up to questions/comments on the dashboard:
 - Question from Duke (Dr. Datto): is the dashboard available to all of us or just you?

MEETING AGENDA

- i. Response from Dr. Shone: it is just internal but have had many requests from stakeholder groups who want to have insight into their partner organizations, so we are working to expand it. What you see now is different than what it was yesterday, and we are still making changes. We might be able to make more visible to you all over the next few weeks.
- Comment from Duke (Dr. Datto): if we shift to bi-weekly distribution, I will fill out the survey.
 - i. Response from Dr. Shone: I think bi-weekly makes sense. It allows us to be more visible in our response to the responses which will encourage participation.
- Question from Quest (Natalie Jackson): We have continued to add Walmart marketplace sites and added that to comments section of the survey, but we haven't been giving the details. Is there another location for us to provide that in?
 - i. Response from Dr. Shone: We are going through the comments now to see where is best to put that information before re-deploying the survey in a week and a half. We will have guidance before the next time that we deploy it.
- Comment from Quest (Natalie Jackson): We have a spreadsheet with actual data if you want that.
 - i. Response from Dr. Shone: We have had feedback that certain fields are not allowing certain values. We appreciate the survey responses.
- Question from Duke (Dr. Datto): Scott, you mentioned supply shortages with Roche, Abbott, Cepheid and that it's putting more pressure on large labs. If those large entities are seeing TAT increase, are their problems around supplies or around instruments, personnel, throughput, etc.?
 - i. Response from Quest (Natalie Jackson): we have been transparent in our media releases around surge and demand on a national basis and increasing the opportunity for testing. Last week, we shared that we are seeking vendors to help. Our goal is to be at 150,000 tests nationally by the end of the month.
- Question from Duke (Dr. Datto): is it a reagent supply issue or are there other bottlenecks?
 - i. Response from Quest (Natalie Jackson): I can't answer from a commercial standpoint but could

MEETING AGENDA

- check and connect offline. Demand continues to rise, and we are working to add more capacity.
 - ii. Response from LabCorp (Traci Butler): The problem has been that volume has doubled in last few weeks. We have been able to manage, but we are trying to keep up with volume and turnaround time and need to get the equipment.
 - iii. Response from Dr. Shone: there is a finite supply of reagents in US currently. Where that gets allocated to is a black box. Secretary Cohen said yesterday in press conference that it would help us if we knew where allocations were going from vendors. This is not a NC specific problem, it's a problem for all major hospital systems. People who need the most access to testing are taking the longest to get it back.
 - 1. Response from LabCorp (Traci Butler): If they can't get reagents at the hospital, that is then getting sent to us and using our capacity and we can't get the test out in timely manner. This is a viscous cycle.
 - iv. Question from Dr. Burns: are you all looking at diversifying your labs since volume is increasing to LabCorp, Quest, etc.?
 - 1. Response from Old North State Medical Society (Dr. Charlene Green): Mako is having shorter time.
 - v. Response from Dr. Shone: there are other smaller diagnostic labs with lower throughput platforms than hospital labs. They might have a capacity of 100, 200, 300 per day that might sustain HTP or mobile sites. If you need to identify labs, we can facilitate that.
- ***During Drs. Datto's and Capraro's Pooled Specimen Testing Discussion*** Dr. Shone opened with discussing antigen testing.
 - Had multiple calls with sites that are not using antigen testing appropriately (mass testing asymptomatic), which leads to faster inaccurate results.
 - Everyone is talking about pooled testing from Dr. Fauci down. The Scientific Study Council came together to discuss pooled testing. Dr. Shone thanked partners (hospital, labs, and universities) and said that they came up with the document that Dr. Shone sent out prior to the meeting.
 - Pooling is not the solution to the problems, but that it has a potential role
 - Dr. Capraro said that he hoped that everyone reviewed the drafts that have been circling around

MEETING AGENDA

- Dr. Capraro said that everyone has considered pooling because it seems reasonable at first, but then when you think about logistical issues, it seems to not be, “the silver bullet.” Dr. Capraro noted that many, “silver bullets,” turned out to be brass over the past few months. Dr. Capraro reported that he can agree that it would save on reagents, but that there are several issues outlined in the document and explained below:
 - Trying to determine the appropriate pool size – depends on a number of factors (prevalence, specimen collection volume, what asset is being used, regulatory, etc.).
 - Technique: do you pool specimens prior to extraction or after? This question would need to be addressed by each lab to determine optimal performance.
 - Logistics:
 - i. Atrium has an average of 2,000-3,000 specimen per day and cannot do that manually all in house and can look for automation, but there is a several month lead time to get a robot.
 - ii. Storage of specimen for pooling (where, how, what conditions do they need to be stored in so if we have to find the individual positive specimens from the pool and retest, we can). Dr. Capraro added that these are not trivial issues.
 - How do we report results of a pool? Is there a middleware to assign to a pool and then break it up into individual reports? This process might be manual, which is prone to error.
 - Which patients do we choose to pool? This depends on prevalence.
 - i. Symptomatic patients’ prevalence is 18% at Atrium (too high)
 - ii. Testing of HMP through mobile collection and testing prevalence is 24% (too high)
 - iii. Somewhere 8% or less or 5% or less is reasonable, but there are still the pre-analytic and post-analytic issues
 - Dr. Capraro closed his summary by saying that the group needs to tackle to above issues to address pooling with providers
- Dr. Capraro opened the discussion up to questions/comments:
 - Comment from Duke (Dr. Datto): I agree with everything that you said, and this is a nice document and summary. I want to emphasize that if you’re using system like Roche 6800 or 8800 or Abbott Alinity, pool testing does not make it easier. You may save on reagents but not on personnel time, labor, or logistics. Pooling makes it operationally much harder
 - Comment from Duke (Dr. Datto): Determining the right pool size is challenging. It is guess work to know how well it’s going to work
 - Response from Dr. Capraro: Agreed
 - Question from Dr. Burns: where do we go from here? Do we crisp up the draft with points from this group regarding pool testing?

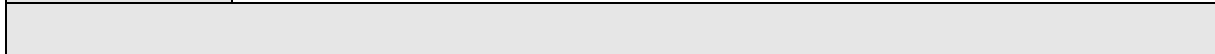
MEETING AGENDA

- Response from UNC Health (Dr. Melissa Miller): it is important to get something out because some labs don't realize that you need EUA for this and are being pressured. People see pooling as the solution. We need something out from the state to point to.
 - i. Question from Dr. Shone: do you think this document gets there? Do you think we need to more clearly define what pooling is and is not? Do we need to highlight the IT barriers? Can this doc be more refined or is it on the right path?
 1. Response from UNC Health (Dr. Melissa Miller): it is on right path. ASM and IDSA are working on guidance. The labs on the phone can handle this, but around knowing what to do for validation, other labs can't do this and can't do it safely. I echo Dr. Datto's point that what you are gaining in reagents would be lost in staff and labor costs. Pooling would increase errors and take a lot of staff. We would be doing pooling for a prevalence of 1% or less of procedure screens. We need to discuss with our surgeons whether low risk outpatient procedures need a screen. Getting this from state would be helpful for guidance. Right now, we test anyone for any procedure.
- Comment from NC Healthcare Association (Dr. Fallon): We are running a CLIA lab and it is unlikely that we will ever do pooling. One point is that if you're doing surveillance testing and want to do pooling, you don't need FDA approval or EUA. You can pool in a research lab as a surveillance and refer positive pool samples to a CLIA lab as clinical testing. If you are doing surveillance for large populations, you don't need to do it in a CLIA lab.
 - i. Response from Duke (Dr. Datto): each positive in the pool would be sent for testing. That is a slippery slope. This is a hairs edge away from clinical medicine and that lab would be making clinical decisions about who needs a follow up and who doesn't. Research labs are not clinical labs.
 - ii. Response from NC Healthcare Association (Dr. Fallon): I am not proposing this, but the FDA is saying there is a difference between surveillance and screening.
 - iii. Question from Duke (Dr. Datto): but then what do you do with it?

MEETING AGENDA

- iv. Response from NC Healthcare Association (Dr. Fallon): this is already happening for genetic testing and tumor testing.
 - v. Response from Dr. Moore: this is problematic for public health response. You either get a result that's not clear if it's actionable or don't get a result. And then we're telling people to get tested. This is too long of a time for intervention.
 - vi. Response from NC Healthcare Association (Dr. Fallon): agreed. We have been pushing back on surgeons as well.
 - vii. Response from Duke (Dr. Datto): I would strongly say a research lab cannot do surveillance testing on the pre-operative/pre-procedure population. I could see surveillance testing on all undergraduates at a school to identify a dorm or floor. Pre-op/pre-procedure testing can never be in a research setting.
 - viii. Response from NC Healthcare Association (Dr. Fallon): I agree.
 - ix. Response from Dr. Capraro: this would also be a barrier issue. If we start allowing the research space to do testing even in pool fashion, more sites will be competing for the limited resources of reagents and transport media.
 - x. Response from Dr. Shone: A piece to add to the document is the research side and the implications of that discussion. I will work with Gerry to work on this and recirculate next week to the Scientific Study Council and the Test Surge Workgroup and have a document to Secretary Cohen by EOW next week.
- Dr. Dowler reported that the CHAMP initiative for high throughput testing was kicked off; the zip codes in the beginning are in the eastern part of NC. She shared a summary attachment that is an external facing document to be shared broadly that includes contact information for the vendors; these vendors are bringing new lab capacity; the vendors are Vidant Health and Orig3n.
 - Dr. Burns closed the meeting with the following:
 - There is more work to do around mitigating barriers
 - We don't want to lose public trust around testing and cannot test our way out of a respiratory virus (need prevention – masks, social distancing, 3Ws)

Next Meeting:	17 July 2020, 1130-1230 Microsoft Teams Link ; Phone: 984-204-1487, Conference ID: 575 272 672#
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MEETING AGENDA

