



EVENT:	Testing Surge Workgroup	Date / Time:	July 17, 2020 @ 1130
Author:	Lindsay Garfinkel, EY	Approved:	August 21, 2020

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

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

#### Agenda:

- Welcome and Roll Call—Dr. Burns (5 min)
- Opening Remarks—Secretary Cohen, if available (5 min) II.
- III. **New Business** 
  - a. Vacant Co-Chair position—Dr. Burns (5 min)
  - b. Resolve to Save Lives Introduction—Marina Smelyanskaya (5 min)
  - c. Test Trends and Hot Topics—Dr. Shone (5 min)
  - d. Pooled Specimen Testing Follow-up Discussion—Drs. Datto and Capraro (15 min)





- e. **Strategies to Address Testing Capacity Barriers Discussion**—Dr. Shone and all (15 min)
- f. Sub-Workgroup Report Outs (if, any) Drs. Green and Datto (10 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
-	EY	Coordinate and populate a table to explain the who, what, where, and when for testing methodologies and populations
COB 7/17	All	Provide any additional review/input to Dr. Capraro and Dr. Shone on the pooled testing document

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

- I. Welcome and Roll Call—Dr. Burns (5 min)
  - a. Dr. Burns skipped this section as there was a lot of new business to address.
- II. Opening Remarks—Secretary Cohen, if available (5 min)
  - a. Dr. Green was recognized as an addition to the Andrea Harris Social, Economic, Environmental, and Health Equity Task Force.
- III. New Business
  - a. *Vacant Co-Chair position*—Dr. Burns (5 min)
    - i. Dr. Burns informed the group that Dr. Massing stepped down from the association. Dr. Burns asked the group if they had any issues with Dr. Massing continuing to Co-Chair. No one in the group had any objections.
  - b. **Resolve to Save Lives Introduction**—Marina Smelyanskaya (5 min)
    - i. Marina Smelyanskaya provided a background on herself and Resolve to Save Lives. Marina joined Resolve recently. Resolve to Save Lives is run by Tom Friedland, former Director of the CDC. The goal of Resolve to Save Lives is to help jurisdictions with the epidemic. Marina's background is in community health and TB and HIV, but most recently in TB. Marina has done research in pooling and TB.
    - ii. Marina reported that the goal of her joining the call is to see if Resolve can support the state or some of the jurisdictions within the state with comms, EPI planning, or by sharing any learnings from other jurisdictions.
    - iii. Dr. Burns added that it will be important to get Marina's insight on things happening throughout the country and the interest in a pool solution and solutions to testing barriers, reagents, volume, etc., which is NC's current state right now.
  - c. Test Trends and Hot Topics—Dr. Shone (5 min)
    - i. Dr. Shone reported that yesterday, Secretary Cohen shared the data for the state. Dr. Shone reported the following for North Carolina:





- 1. Positive cases are generally trending up.
- 2. Percent positivity has dipped below 10% the last 3 days (which is good).
- 3. There is a need to discuss the immediate and long-term challenges of testing (TAT, reagents, etc.).
- 4. Testing numbers continue to increase (labs are meeting high bars that are thrown/set).
- 5. On Wednesday (7/15) and Thursday (7/16), the state went above 30,000 people tested (for the first time since testing began). Dr. Shone noted that this is a huge accomplishment/achievement considering where we were 1 month ago.
- 6. As of today (7/17), over 1.3 million tests have been performed.
- 7. Hospital numbers continue to trend up.
- 8. Cases in ICU beds is around the 350 mark.
- ii. Dr. Shone told the group the following message: testing is just one piece of the whole response. Prevention and the 3Ws have to be reinforced to break the cycle.
- iii. Dr. Shone turned to Dr. Moore to report more information. Dr. Moore had nothing else to report.
- iv. Dr. Shone shared the following hot topics:
  - 1. Exponential volume increases in commercial labs.
  - 2. Exponential decreases in reagents in all other labs.
  - 3. Lack of national guidance, testing strategies, and supply chain management that we need and are raising.
- d. Pooled Specimen Testing Follow-up Discussion—Drs. Datto and Capraro (15 min)
  - i. Dr. Shone shared that they presented a draft document in last week's meeting (7/10) and received major comments back around assuring reporting (a critical piece that we need to think about is how to report results and assure they get back to the public health system, especially with Dr. Tilson's standing order around reporting both positives and negatives there needs to be a mechanism for such reporting), and about research labs (CMS and FDA have spoken that research labs can do pooled testing as long as results aren't used for patient management and are not reported back in a personally identifiable way) any positives out of a research lab need to come back to a CAP or CLIA lab research labs need to have a coordinated process with a CLIA lab already.
  - ii. Dr. Shone shared that the strategy of pooling has a lot of potential benefits, but a lot of potential negatives as well. The document that Dr. Shone provided before the meeting addresses such. Dr. Shone shared that pooling has potential uses and the document identified potential populations that it could be used in, but this is dependent on building an infrastructure in labs to make sure that it's the most effective. Dr. Shone





reported that therefore, pooling is not an immediate or short-term solution, and we would need to build forward as we go into the fall.

- iii. Dr. Shone handed it to Dr. Capraro to further report.
- iv. Dr. Capraro shared that we cannot just jump into pooling just because it sounds good. Dr. Capraro gave credit to Dr. Shone for the last page of the document on who should be and shouldn't be pooled. Dr. Capraro opened the discussion up to comments and criticisms.
- v. Marina Smelyanskaya shared that she has an interest in providing shared experiences. Marina shared Nebraska's experience with pooled testing that was reviewed in a paper; they conducted pooled testing when the percent positivity was <10% and the paper describes the process. Marina reported that she spoke with the author of the paper last week and he is assisting Maine's school system in setting up protocols and a way to return. Marina agreed that pool testing can be useful with low prevalence. Marine reported that they did it with the state public health labs and pooled 4,000 patients total.
- vi. Dr. Datto asked the group, "is it ok to have imperfect testing and know it? Are we going to pool because pool testing is, "just good enough"?
- vii. Dr. Shone shared that there are now discussions of us running out of plastics (a reality). Dr. Shone shared that there are similar discussions about reagents (Roche, Cepheid, Abbott say they don't have the supply). Dr. Shone shared that the demand is not dropping and unless we change our who (who gets tested, which we don't want to back down a lot), our testing strategy weighs in. Dr. Shone added that we have always said no test is better than a junk test because a junk test leads to poor outcomes, but we are now forced to have the conversation of is a not good test better than no test, which is a question for clinicians and those who follow up with results. Dr. Shone added that this paper answers what we think of a state (absent of federal guidance) and addresses if pooling is an option (a very limited option). Dr. Shone said that we need to think similarly for everything else and that we need clinical input (for example, antigen testing has a high false negative probability, but to reduce the burden of molecular tests since we have many antigen supplies, do we recommend doing antigen test to eliminate 5-10% of tests that we are outsourcing?) (for example, if you would have run a flu test, should you run a COVID rapid test?). Dr. Shone says that we need to answer these questions to get ahead and do the thinking.
- viii. Dr. Burns noted that the group should document these points and anything that we can proactively do now (e.g. bulk purchase of antigen tests, plastics, etc. now) on paper to get it to the Secretary.
  - ix. Dr. Datto said that Abbott ID now tests are looking good now. Dr. Datto asked the group in what setting, is 'good' good enough?
  - x. Dr. Burns shared that there are some labs with capacity. Dr. Burns offered that if community partners need help with finding a lab that we are aware of with capacity, to let her know. Dr. Burns shared that we assessing the





purchase of lab capacity based on the proposals we are getting (this is why we did the RFQ is to get a list of labs that say have capacity and can provide results in 48 hours or less).

- xi. Dr. Datto asked the group why suppliers can't do a better job of putting supplies where they're needed. Dr. Datto shared that if there are labs that can service our NC population, why we can't get the supplies redistributed to our labs in NC.
  - 1. Dr. Shone shared that it's a methodology issue. Dr. Shone said that the these are not labs that can do 1,000s of samples/day as whey are using semi-automated to manual methods to do a few hundred to a thousand per day. Dr. Shone said that these labs with capacity are small labs that are typically for genetics or urine toxicology and have dropped their instruments and turned their capacity to this. Dr. Shone said that plastics is the issue that affects everyone.
  - 2. Dr. Datto said that this is only an interim/limited solution because a lab will say that they have capacity and then everyone goes to use them.
- xii. Dr. Burns asked the group if the plastics that we need can be made by others (not HHS); Are there any other manufacturers that we could bring a plastic to and say to say this is what we need?
  - 1. Dr. Fallon shared that boat companies can made plastics.
  - 2. Dr. Miller shared an experience where there have been problems using generic substitutes instead of tecan tips and that the companies don't support this.
  - 3. Dr. Burns asked the group to think of anything that could be made and let her, and the team know so that we as a state can figure out how to find what we need on that end. Dr. Burns shared that they had reached out for the PPE need to get manufactures who are not normally producing PPE to supply some of those needs. Dr. Burns also shared that this is being done with swabs in other states (the states partnered with universities to do 3D swabs). Dr. Burns cautioned that we want to get ahead of this as much as possible.
- xiii. Dr. Burns brought up antigen testing and the need to know the, "who, what, when, where," for such.
  - Dr. Carpraro said that we need a document that takes into account the previous documents. Dr. Capraro shared that he envisioned a table that says for molecular, here is who we should and shouldn't test, and to do the same with antigen, antibody, etc.
    - a. Dr. Capraro shared that at point of care to use molecular (Roche's Liat will have EUA rather than Abbott ID now).
    - b. Dr. Capraro shared that antigen and Abbott ID now testing will work best in symptomatic patients within 4-5 days of symptom onset if we run out of the gold standard. Dr.





Capraro said that it's not worth using this testing if it's not with this population. Dr. Capraro shared that antigen tests on market that have received EUA received EUA because they've been done in symptomatic patients. Dr. Capraro said that the prevalence rate should not be less than 13% for antigen testing population.

- c. At the time of this meeting, Atrium was/is not using antigen testing. However, Atrium discussions regarding antigen testing included the issues stated here - namely, trying to identify a sub-population of specimens that are from symptomatic patients and have a high prevalence, in order to maximize the reliability of the testing platform.
- d. Dr. Capraro said that asymptomatic testing should occur (especially for exposed/at-risk individuals); however, these individuals should be tested with a molecular test, NOT an antigen test.
- Dr. Datto shared that the challenge around asymptomatic testing is that providers are not really willing to let that go even with PPE.
  Dr. Datto asked those in hospital settings from the group to speak to this.
- 3. Dr. Miller shared that they had been trying to categorize by risk, but so far, the surgeons want everyone tested. The issue with testing capacity is that they are about to have 45,000 students and faculty coming back in 2 weeks.
- 4. Dr. Datto said that there has also been a lot of interest at Duke about what they are doing with the kids for screening and surveillance.
  - a. Dr. Miller said she has also been asked about this. She was told Duke will test all of the students, but Duke has less students than UNC.
  - Dr. Datto said that they are not testing them themselves as they are sending to LabCorp for the initial student screening.
- 5. Dr. Tilson said that there are two conversations occurring:
  - a. First: the utility of testing in a healthcare setting if both the patient and provider are masked and in full PPE, more specifically around procedures, not just a healthcare encounter.
  - b. Second: if everyone was appropriately PPEd, but there was a known exposure, does a contact need to be tested.
    - i. Dr. Tilson said that we are thinking through and talking with the CDC about the second one. Dr. Tilson said that students are coming back and UNC says that they are not doing that pre-emptive testing of students coming back as people are in





and out of community, so it doesn't make sense. Dr. Tilson shared that they have a working group and UNC has been vocal that they will not be doing this.

- ii. Dr. Miller said that this is also because there is no one to do the testing.
- iii. Dr. Tilson shared that it also just doesn't make sense because they go into the community.
- iv. Dr. Datto said that people are proposing testing once a week, twice a week, using Abbotts, etc., but have no plan.
- v. Dr. Tilson shared that there is no way to do that. Dr. Tilson said that everyone wants schoolteachers, kids in pre-k, and basically the whole population to be tested every week.
- vi. Dr. Fallon shared that he represents ECU. Dr. Fallon shared his screen to show a dashboard screen capture that had data as of midnight last night (7/16). Dr. Fallon shared that they tested 606 student athletes to come back to ECU in Greenville (and tested some multiple times). Dr. Fallon said that they started testing in early June and the student athletes were negative until a week and a half ago when 1 student tested positive and then another and then there was an outbreak. Dr. Fallon said that the student athletes have been told to distance, wear masks, wash hands, to stick around and not go into community, and then even still, this is what happens (they had a chicken wings party and the positive activity has been the result of that). Dr. Fallon said that because they reached over 10% positivity rate, the ECU athletic department paused student athlete activity. Dr. Fallon said that this was random and symptomatic testing and that this is what's going to happen for others.
- vii. Dr. Datto asked Dr. Fallon if he would be willing to let the group share his anecdote with their institutions. Dr. Fallon said yes and that it has already been put in the press.
- viii. Dr. Fallon shared that ECU's TAT was less than 12 hours.
- xiv. Dr. Burns brought the conversation back to Dr. Capraro's suggestion to make a table with testing methodologies and include the who, what, and when. Dr. Burns shared that this is something that EY can coordinate and





populate with given information and that there should be something already to use as a start, but to work off of this and then circulate for feedback.

- 1. Dr. Sullivan suggested that from a local perspective, they need strong recommendations around who should be tested, but also who is not recommended for testing (e.g. like there should not be a negative test required to return to work). Also, Dr. Sullivan said that these need to be strong statements so as not to be left too broad. Dr. Sullivan also brought up the Governor's announcement for school and asked, "how do we prioritize testing and who should not be prioritized?"
  - a. Dr. Shone appreciated the request to include who should not be tested. Dr. Shone said that the recommendations can go as far as to say testing is not appropriate at this point with this method.
  - b. Dr. Burns said that the including the who/who not, what test, why, situations where they should be/should not be tested helps us frame this table that EY can start now and opened it up to the group to start providing answers.
    - Dr. Capraro said that antigen testing, and Abbott ID now have enough overlap to use same populations. Dr. Capraro said that according to regulations, EUA is specific for symptomatic. Dr. Capraro said that the following should be tested using antigen testing: symptomatic patients within 4-5 days of symptom onset.
    - ii. Dr. Franklin said that on the hospital side, they are not distinguishing between yes test or no don't test by a day or time or how long symptoms have been there or if there is one symptom or more than one symptom.
    - iii. Dr. Sullivan said that we need to clarify who should be tested for antigen testing and to then clarify if those patients then PCR testing or not.
    - iv. Dr. Tilson said that she is nervous about strongly saying that we shouldn't be testing asymptomatic patients as 40% of positives are asymptomatic or mild. Dr. Tilson has been hearing from providers and patients who say that they can't get an asymptomatic test. Dr. Tilson that we already have guidance around HMP and that we need to listen to what we've been pushing out. Dr. Tilson is nervous about creating a hard line.
    - v. Dr. Datto said that in the hospital setting, if PPE is available they should assume that everyone that





they're treating has COVID-19 and not to waste testing if testing is in very short supply. Dr. Datto said that it's not that asymptomatic testing doesn't provide value, it does. It just doesn't provide significant added value if we are already using a face shield, PPE, N95, etc. Dr. Datto said thattesting is redundant in that setting. Dr. Datto said we should try to limit testing to areas where it can truly mitigate risk

- vi. Dr. Burns said that from the patient perspective, while it may not mean anything to the clinician, it brings a peace of mind to end user to know if they are positive or negative.
- e. **Strategies to Address Testing Capacity Barriers Discussion**—Dr. Shone and all (15 min)
  - i. The group did not get to this agenda item, but some strategies to address testing capacity barriers were discussed in the above agenda item.
- f. Sub-Workgroup Report Outs (if, any) Drs. Green and Datto (10 min)
  - i. The group did not get to this agenda item.
- IV. **Due Outs Assigned and Closing**—Drs. Burns, Tilson or Moore, if available (5 min)
  - a. Dr. Datto said that he regular conversations with Angela Wiles from the Senator's office and that it might be good for the Senator's office to hear what Governor Cooper's team is doing here. Dr. Datto asked Dr. Burns and Dr. Shone if we can extend an invite to her to sit in on these meetings as she's interested in knowing what's going on here.
    - i. Dr. Burns said that she would need to know more and would need to run it by the legislative team.
  - b. Dr. Burns recapped next steps below:
    - i. Approved the pooled testing document. Those who have not provided their input to give their review/input to Dr. Capraro or Dr. Scott by COB 7/17. The next step is to push this to get it to be a public document.
    - ii. Develop a matrix/chart to show the who, what, when, and where for testing. Dr. Burns said that we are not there yet to clearly say that we're not testing any asymptomatic with the percentages known spread. Dr. Burns said that this matrix will include next steps (if A doesn't work, go to B or C). Dr. Burns said that there is a document from April that the EY team can add to.
  - c. Dr. Green said that she was concerned about a comment earlier and that in the HMP and rural populations, ethnicity doesn't matter because they are tired of being sick and dying.
  - d. Dr. Sullivan added that requesting who should not be tested was focused on employers and those that are being re-tested.





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