FINAL: Follow-Up Questions for Dr. Stack and Dr. Thoroughman

Program Review and Investigations Committee Meeting (9/10/2020)

September 1, 2020

COVID-19 Testing and Reporting Process Presentation (August 13, 2020)

Responses in RED.

1. COVID-19 Laboratory Reporting (Slide #10):

a. Estimated number of "pop-up" labs in the Commonwealth;

Unknown.

b. Estimated number of tests completed by "pop-up" labs for CY 2020;

Unknown.

c. Estimated number of "point-of-care" facilities in the Commonwealth;

Unknown.

d. Estimated number of rapid tests completed by "point-of-care" facilities since March 1,

2020;

Unknown.

e. Process by which "pop-up" labs and "point-of-care" facilities are identified; and

Multiple possible ways, some examples of which are:

1. Clinician orders and/or performs POC test. Result is positive. Clinician submits a PUI or EPID-200 form to local health department (LHD) and/or KDPH, but does not submit laboratory report. Clinician is in compliance with provider reporting obligation, but not in compliance with laboratory reporting obligation. Discrepancy noted by LHD and/or KDPH.
2. Patient informed of a positive test result. Patient contacts LHD and/or KDPH for guidance. Public Health record is created. No subsequent report received from provider and/or laboratory confirming patient self-reported result. Discrepancy noted by LHD and/or KDPH.

f. Process by which KDPH estimates the number of additional tests performed by "popup" labs and "point-of-care" facilities.

KDPH does not estimate this.

2. Reporting of Positives vs. ALL Test Results (Slide #11):

a. Process by which "pop-up" labs and "point-of-care" facilities are encouraged to report

testing results pursuant to 902 KAR 2:020;

KDPH provides public notice of reporting obligations via numerous channels including, but not limited to:

1. Publication on dedicated COVID-19 website
    a. Provider letter
    b. Laboratory letter
2. Distribution of provider and laboratory letters via numerous formal channels including, but not limited to:
    a. Kentucky Board of Medical Licensure
    b. Kentucky Board of Nursing
    c. Kentucky Board of Pharmacy
    d. Kentucky Cabinet for Health and Family Services
3. Public-private partnerships including, but not limited to:
    a. Kentucky Hospital Association
    b. Kentucky Medical Association
    c. Kentucky Health Department Association
4. Live and taped education on clinician webinars conducted by KDPH.
5. Periodic announcements at Governor press conferences.
6. Social media posts.

b. Process by which KDPH is following up with the Commissioner's mandate that all labs

"get onboarded" to the Kentucky Health Information Exchange (KHIE);

Direct outreach by KDPH staff to providers and/or laboratories found to be out of compliance.

c. Steps taken by KDPH to use and combine data from KHIE and secondary reporting

methods such as National Electronic Disease Surveillance System (NEDSS), Fax, and

Electronic file (spreadsheet) submission;

KDPH efforts related to this query include, but are not limited to:

1. Onboarding of laboratories into KHIE as outlined in 2.1.b above; this provides a stream of electronic laboratory reports that automatically populate within NEDSS.
2. Collecting data from providers and/or laboratories via web-based surveys.
3. Manually entering fax/e-fax reports into NEDSS and other data systems.
4. Receiving information verbally at LHDs and KDPH which is then entered into NEDSS and other data systems manually.
5. Creation and curation of topic-specific datasets using Microsoft Excel and other software applications to organize, analyze, and visualize data.

d. Process by which negative test results identified in KHIE and NEDSS are used to "determine positivity rate of testing"; and

This process is described in a guidance document available through the state COVID-19 website.

e. Are Kentucky's requirements for reporting test results consistent with the required data elements identified in the Coronavirus Aid, Relief, and Economic Security Act (CARES), Section 18115?

Note: While there is no Kentucky statute that requires reporting of negative test results, 902 KAR 2:020E (6) (2) requires both positive and negative test results for COVID-19 to be reported to the local health department within 24 hours.

It should also be noted that Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).

Generally speaking, yes.

3. Lab Testing Surveillance (Slide #13):

a. Describe the process by which the National Guard contingent assigned to KDPH in April 2020 created its Lab Survey; and

KDPH epidemiologists created the survey. The National Guardsmen/women contacted laboratories to ask the questions contained in the survey.

b. Provide a copy of the Lab Survey template currently used.

You may view the survey here.

4. Specific Testing Questions (Slide #14):

a. Describe how the United States Food and Drug Administration (FDA) updates KDPH on its quality assurance findings and recommendations regarding COVID-19 testing labs;

FDA regulates tests (i.e., assays). U.S. Health and Human Services regulates laboratories. Both agencies communicate via formally established notification processes. KDPH does not have a role in these processes.

b. Provide a list of the "few laboratories" where the State Lab provided assistance to the

FDA;

Assistance was provided directly to the laboratories, not the FDA, for assay validation. "State Lab" has assisted University of Louisville, University of Kentucky, Solaris Diagnostics, Lexington VA Hospital, Louisville Metro Public Health, Gravity Diagnostics, St. Elizabeth Healthcare, Baptist Health East Louisville, Pikeville Medical Center, Lexar Labs, Prescient Labs, Diatherix, Ethos Labs, Amazon IT lab**,** P & C Labs, Charleston Area Medical Center (CAMC).

c. Provide a list of the "unscrupulous testing operations" that have been brought to

KDPH's attention and the actions it took to investigate them; and

KDPH does not maintain such a list. If questionable practices are encountered, KDPH reports them to the government agency with relevant regulatory authority.

d. Provide a list of laboratories that have "false" results of 100%.

KDPH does not have such a list.

5. COVID-19 Case Reporting (Slide #20):

a. Describe the process of removing daily duplicates; and

Each test report appears in a KDPH data system. KDPH staff reviews duplicate reports (e.g., same test result submitted more than once, same patient tested multiple times, etc.) and removes them.

b. Provide additional detail with respect to the statement "For COVID-19, we are

compressing about 2 weeks of work into a few hours each day".

A large team of epidemiology staff are collecting, curating, analyzing, and reporting data at a volume and pace that historically would have taken much longer, rather than less than a day.

6. Reporting Process to Governor (Slide #21):

a. Identify the primary data sources that the Division of Epidemiology uses to report the

following data points for the Governor's daily reports;

i. Case numbers/mortality,

ii. Lab testing numbers,

iii. Patient disposition counts,

iv. Race/Ethnicity distributions; and

v. Stats for new cases and deaths.

KHIE electronic lab reports, fax/efax lab reports, CDC PUI forms, Kentucky EPID-200 forms, NEDDS, online survey instruments, LHDs.

7. Mortality Tracking (Slide #22):

a. Describe the process and criteria by which the Death Review Committee (Committee)

receives, reviews, and rules on questionable COVID-19 death cases; and

For death certificates for which the cause of death is not clear as to the contribution of COVID-19 or appears to incorrectly include or exclude COVID-19 as contributory to the cause of death, the Committee reviews patient medical records, discusses the information available, and reaches consensus opinion on whether COVID-19 is appropriate for inclusion or exclusion.

b. Since its creation, how many questionable deaths has the Committee reviewed and

what percentage of those deaths were found to be "non-COVID-19-Related?"

41 and 41.5% (17 of 41) (as of 9/8/20).

8. Recovered Cases (Slide #24):

a. Identify the length of time that the National Guard Lab Survey tracked and collected

data on the number of "recovered" cases; and

The survey process for patient disposition began on April 5, 2020 and continued until August 1, 2020 when KDPH transitioned to using the Patient Disposition variable designation of "Symptoms Resolved" in NEDSS (National Electronic Disease Surveillance System).

b. Provide the cumulative data on "recovered" cases up to the point KDPH transitioned to

classifying such cases as "Symptom Resolution".

KDPH listed 7,481 patients as "Recovered" on 7/31/2020, the day before transitioning to the "Symptoms Resolved" designation in NEDSS. On August 1st, the number of cases designated as "Recovered" was 8,135.

9. Daily Reporting (Slide #25):

a. What specific steps does KDPH take to reconcile the inconsistencies between "daily

reporting" and "daily incidence of disease" with respect to delayed reporting, date of

onset of symptoms, and date of specimen collection?

KDPH aggregates, organizes, de-duplicates, categorizes, and analyzes raw data from many sources (see 2.c.1-5 above). Members of the epidemiology team reconcile discrepancies and convert raw data into more standardized form that addresses many of the inconsistencies encountered.

10. Status of Committee Member Requests from Meeting:

a. Total number of death reviews and the number that were determined to be questionable (Senator Carroll);

41 reviews as of 9/8/20. 17 (41.5%) determined not to be COVID-19-related deaths by the Committee.

b. Number of Kentucky children who have died from the flu and COVID-19 (Senator Carroll); and

Children defined as Kentuckians <18 years old at the time of death. Influenza (2019-2020 season) = 6. COVID-19 = 1.

c. Answers to several questions that Senator Westerfield emailed to KDPH prior to the August 13th meeting to determine whether the administration considered factors like child abuse referrals, drug overdoses, and academic performance related to school openings.

Questions submitted previously by Senator Westerfield; these responses were sent to him directly.

1. Which metric is more helpful in your decision-making? Incidence or positivity rate?

   Both metrics have value; both metrics have limitations; both metrics are just two of many different types of data used to inform decision-making. Folks continue trying to make this simpler than it is.

   Test positivity is a good indicator of presence of disease in a population if you can accurately define the populations included in the numerator (all positive results) and denominator (total # of tests, both positive and negative).

   Incidence is also a good indicator of disease activity when you know both the number of confirmed positive cases and the total number of people in a defined population.

   We use many other metrics, though, to provide a multi-dimensional view of the present situation. These additional metrics include the # of COVID-19 hospitalizations, COVID-19 ICU admissions, COVID-19 ventilator patients as well as total # of currently occupied and/or available inpatient beds, ICU beds, and ventilators. We also receive input from around the state and from the federal government regarding testing supply and PPE supply availability and/or shortages.

Which is more trustworthy based on the reliability and consistency of the data?

Test-positivity is more challenging to make precise due to variable timing of sample collection vs. test result reporting and due to longstanding limitations in test-reporting policies, processes, and technologies. However, when these limiting variables stay constant and data are averaged over a period of time, this metric is very helpful for trending purposes.

Incidence is also a valuable metric in different ways. As long as testing is available, people are willing to be tested, and epidemiologists can curate the data to eliminate duplicate test results then counting confirmed cases is a useful way to evaluate the presence of disease in residents of a particular geographic region.

2. Is there a local measure or metric available to better guide and fine tune decisions, particularly at the local-most level?

   See above in #1. Numerous metrics have utility and limitations.

3. What specifically should Kentucky state government do to be better prepared for the next one of these?

   Investment in public health overall, in public health infrastructure, including improving information systems and capacity to handle large amounts of data, and maintaining a larger, well-trained, public health workforce (epidemiologists, clinical, environmental, IT, and administrative-skilled individuals) to allow for more flexibility in responding and more surge capacity.

4. What is the threshold that would trigger the next shutdown in the unfortunate event we have another one of these?

   If an infectious disease is spreading rapidly enough to result in excess deaths and/or cause enough people to become ill and require hospital services in a short-enough period of time to strain or overwhelm healthcare capacity.

5. How long is contact tracing data kept? What information is gathered? Who has access to it? Is it being used for any purpose other than to trace contacts?

   Basic information is gathered; name, address, phone number, e-mail, etc. LHDs and KDPH epidemiologists, disease investigators and limited supervisory personnel have access to this. This data is not used for any other purpose other than to trace contacts. Privacy and data security standards are well established and maintained.

6. Is school data related to abuse/dependency/neglect referrals, substance use, behavioral health referrals weighed against COVID data when making the recommendations and orders related to schools?

These are all public health issues. Social-emotional status of students, food insecurity, drug overdoses, child abuse, etc. all weigh on the minds of public health. Balancing these issues with the effects of a deadly virus that spreads so rapidly presents challenges. However, death or long-term health impacts on individuals from this virus cannot be reversed. Currently, these unintended consequences of managing COVID-19 are not contemporaneously measureable as individuals diagnosed with COVID and any associated deaths. Data is being collected on abuse/neglect as well as for overdose deaths and other behavioral health impacts. The use of medication assisted therapy, telehealth and other tele-visitation put in place since the very early stages of COVID-19's entrance into Kentucky has been very helpful. The assessment of the full consequences of COVId-19 and impact of the measures taken to minimize the impact on individuals and the economy will be measured and studied for years to come.

11. Outside Factors (Page 3, Committee Minutes, 1st paragraph):

a. What type of training, guidance, or both does KDPH provide to testing labs to ensure that outside factors do not compromise test results? Outside factors may include the following:

i. Obtaining a good specimen at the beginning;

ii. Length of time it takes to get the specimen to the lab;

iii. Not cleaning equipment properly; and

iv. How well the specimens are preserved during shipment.

These responsibilities are not assigned to KDPH; other agencies regulate laboratories.

12. Suspect Cases (Page 3, Committee Minutes, 2nd paragraph):

a. What process does KDPH use to adjust data for the removal of "suspect cases" and other errors?

See other answers above.

13. Health Inequities (Page 5, Committee Minutes):

a. What specific steps does KDPH take to address health inequities in Black and minority communities related to COVID-19?

KDPH works in partnership with LHDs to provide targeted support for community-based COVID-19 testing, education, and other resources to address health inequities in Black and minority communities. Additionally, KDPH analyzes available data to better understand and mitigate the impact of COVID-19 in Black and minority communities.

KDPH is also developing focused strategies to build a bridge between healthcare/public health institutions and communities. We encourage partnership with local trusted grassroots organization to inform citizens in the Black and LatinX communities of their higher rates of disease and, in the Black community, the higher rates of death from COVID-19. Increasing testing and beginning plans for upcoming vaccinations are in development at both the state and local public health department levels.

More broadly, Governor Beshear has taken steps to extend Medicaid eligibility to Black, minority, and other underserved populations to reduce health inequities through expanded access to healthcare services.

14. Stockpiles of Personal Protective Equipment or PPE (Page 7, Committee Minutes, 1st paragraph):

a. What specific steps does KDPH take to ensure that at least 2-3 months available supplies for first responders and hospitals continues to be met?

1. Identify critical PPE items (e.g., N-95 respirators, surgical/procedural masks, gowns, and gloves);
2. Estimate aggregate demand for these items based on data submitted by Kentucky hospitals and first responders;
3. Require acute care hospitals to maintain a 2-week supply of critical PPE on-hand at all times;
4. Estimate normal supply chain will be able to fulfill 50% of demand; and
5. Procure quantities estimated to fulfill the unmet need.

15. How often does KDPH review 902 KAR 2:020 to address the following areas: 1) consistency with federal law and other criteria; 2) whether its mandates are helping to more accurately report test data; and 3) whether its mandates are adequately addressing public health issues?

KDPH makes ongoing use of 902 KAR 2:020 for reportable disease surveillance. Reviews are undertaken and amendments made as circumstances warrant.