Creating surveillance data infrastructure using laboratory analytics: Leveraging visuun and epic systems to support COVID-19 pandemic response

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\section*{ABSTRACT}

\textbf{Background:} Pandemics are unpredictable and can rapidly spread. Proper planning and preparation for managing the impact of outbreaks is only achievable through continuous and systematic collection and analysis of health-related data. We describe our experience on how to comply with required reporting and develop a robust platform for surveillance during an outbreak.

\textbf{Materials and methods:} At Mount Sinai Health System, New York City, we applied Visuun, a laboratory analytics dashboard, to support main response activities. Epic System Inc.’s SlicerDicer application was used to develop clinical and research reports. We followed World Health Organization (WHO); federal and state guidelines; departmental policies; and expert consultation to create the framework.

\textbf{Results:} The developed dashboard integrated data from scattered sources are used to seamlessly distribute reports to key stakeholders. The main report categories included federal, state, laboratory, clinical, and research. The first two groups were created to meet government and state reporting requirements. The laboratory group was the most comprehensive category and included operational reports such as performance metrics, technician performance assessment, and analyzer metrics. The close monitoring of testing volumes and lab operational efficiency was essential to manage increasing demands and provide timely and accurate results. The clinical data reports were valuable for proper managing of medical surge requirements, such as healthcare workforce and medical supplies. The reports included in the research category were highly variable and depended on healthcare setting, research priorities, and available funding. We share a few examples of queries that were included in the designed framework for research projects.

\textbf{Conclusion:} We reviewed here the key components of a conceptual surveillance framework required for a robust response to COVID-19 pandemics. We demonstrated leveraging a lab analytics dashboard, Visuun, combined with Epic reporting tools to function as a surveillance system. The framework could be used as a generic template for possible future outbreak events.

\section*{1. Background}

Novel coronavirus (COVID-19) disease emerged as a community-level outbreak in Wuhan city of China in December 2019 and was declared a global pandemic on March 11, 2020.\textsuperscript{1} In early March 2020, the number of cases increased 13-fold in only 2 weeks and the number of affected countries increased three-fold.\textsuperscript{2} Meanwhile, the United States emerged as the world epicenter and New York State, with a 57% prevalence rate, was recognized as the national epicenter.\textsuperscript{2} The New York state governor issued series of executive orders to establish the framework to control the spread of disease. These measures included a rapid increase in temporary surge testing centers, permitting nurse practitioners to order COVID-19 tests without a practice agreement and authorizing licensed pharmacists to order tests. In another unprecedented measure, the office of the U.S. President called on all public health officials and private and hospital laboratories to share daily updated COVID-19 testing data with federal agencies.\textsuperscript{4} Such testing data are crucial in tracking the spread of the pandemic and informing the government’s response. However, collecting laboratory data from scattered satellite locations and analyzing massive data in a short period of time is a labor-intensive task and requires scalable infrastructure and rapid access to resources.

Aside from the mandatory reporting requirements, the extensive analysis of different laboratory data points is necessary for better strategizing laboratory operations, monitoring patient outcomes, and identifying the

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most effective clinical intervention during outbreaks. The visualization of time-series laboratory data and the ability to adjust for relevant clinical and demographic factors (e.g., age, sex, and underlying conditions) are essential for researchers to identify the patterns of progression, illuminate underlying causes, and reveal treatment opportunities. Consistent and accurate data collection and integration from multiple laboratory resources and analysis of the data provide key information on monitoring disease burden and assessing the extent of outbreak.5

This paper describes the efforts of the laboratory team at Mount Sinai Health System (MSHS), New York City, to develop a reliable and efficient framework for COVID-19 surveillance using analytic platforms such as Visiun and Epic SlicerDicer reporting tool. The proposed reporting structure can be applied as a generic template for possible future outbreaks.

1.1. Operational environment

MSHS is a multisite health system with eight hospitals, a total of 3815 beds, and more than 410 ambulatory practice locations. The SARS-CoV-2 viral testing samples are only processed at CLIA-certified laboratories. Samples are collected at eight affiliated hospitals, physician offices, or facilities such as nursing homes. There are two clinical pathology lab information systems (CP-LIS) across our healthcare system for reporting the test results: Sunquest (v8.1, Tucson, AZ, USA) and SCC Soft (v4.5, Clearwater, FL, USA). All testing results were shared with patients electronically via an Epic patient portal. The viral testing is the PCR-based method run on seven analyzers (two Roche Cobas 6800 [Roche, Basel, Switzerland], two Diasorin Simplexa [Diasorin Molecular, Cypress, CA], one BioFire® FilmArray® Torch System [BioFire Diagnostics, Salt Lake City, UT], one Cepheid-Genexpert Infinity 48s [Cepheid, Synnyvale, CA], and one Genmark Eplex-Genmark ePlex System [GenMark Diagnostics, Carlsbad, CA]). The majority (approximately 97%) of viral testing is performed on the Roche Cobas 6800 platform. The current microbiology lab results 1000–1500 tests per day. Antibody testing is performed by enzyme-linked immunosorbent assay (ELISA) for measuring the highest dilution of SARS-CoV-2 IgA, IgG, and IgM antibodies. Approximately 45,000 antibody test results are reported per day using two BioTek (Winskovi, VT, USA) instruments. Fig. 1 (A) and (B) shows the designed order panel in Epic for viral testing and antibody for hospitalized and ED patients.

2. Materials and methods

Early in the pandemic, our IT team created the most essential reports by writing SQL scripts and Crystal Reports and using CP-LIS data. The list of reports was designed in collaboration with the IT department, laboratory informatics, and chemistry and microbiology divisions. As the pandemic persisted, the list of the required reports and the recipients across healthcare system was expanded. Visiun programmers developed the system (CP-LIS) across our healthcare system for reporting the test results: Sunquest (v8.1, Tucson, AZ, USA) and SCC Soft (v4.5, Clearwater, FL, USA). All testing results were shared with patients electronically via an Epic patient portal. The viral testing is the PCR-based method run on seven analyzers (two Roche Cobas 6800 [Roche, Basel, Switzerland], two Diasorin Simplexa [Diasorin Molecular, Cypress, CA], one BioFire® FilmArray® Torch System [BioFire Diagnostics, Salt Lake City, UT], one Cepheid-Genexpert Infinity 48s [Cepheid, Synnyvale, CA], and one Genmark Eplex-Genmark ePlex System [GenMark Diagnostics, Carlsbad, CA]). The majority (approximately 97%) of viral testing is performed on the Roche Cobas 6800 platform. The current microbiology lab results 1000–1500 tests per day. Antibody testing is performed by enzyme-linked immunosorbent assay (ELISA) for measuring the highest dilution of SARS-CoV-2 IgA, IgG, and IgM antibodies. Approximately 45,000 antibody test results are reported per day using two BioTek (Winskovi, VT, USA) instruments. Fig. 1 (A) and (B) shows the designed order panel in Epic for viral testing and antibody for hospitalized and ED patients.

2.1. Technical background

Visiun is a software vendor specializing in tools which run analytics on data from laboratory information systems (LIS). Visiun’s flagship product is called Performance Insight (PI). Visiun’s tools are LIS-agnostic, and they have processed data from all major laboratory information systems.

The Visiun dashboard comprises two components: (1) the software component or PI, an LIS-agnostic application that runs on desktop as a Microsoft Excel add-on. While it uses proprietary algorithms to analyze the data, it presents the end result using native Excel visualizations. When user’s run any of the 100+ prebuilt reports, PI queries the SQL Server database for the data and then presents the results in Excel. Users can elect to store several years of data from the LIS in the PI database. PI can run unattended so it can import data from the LIS and generate reports on a scheduled basis. When doing so, PI can distribute those reports via email (via Outlook or SMTP-direct). (2) Another key component is an SQL server database for LIS-extract files and storage of the reports. For optimal data transmission, network connectivity with at least 80 Mbit/s is required.

The data-flow diagram [Fig. 2] illustrates the main components of the information system and user interaction points with PI. The laboratory data are collected from two different CP-LIS (Sunquest and Soft lab) installed at multiple affiliated locations. Queries are run daily, and data can be extracted from the internal data repository in a range of standard prebuilt formats and stored on the network. PI can be set up to access the internal lab data repository on a regular basis and import new data into the PI SQL server database.

3. Architecture

3.1. Data used for COVID-19 surveillance

To develop the data framework, we followed a multi-step process that involved reviewing WHO guidelines, federal and state policies, internal administrative guidelines, departmental policies, and expert consultation. Following the Coronavirus Aid, Relief, and Economic Security (CARES) Act, all detected COVID-19 results are reported to the Secretary of the Department of Health and Human Services (HHS)7 (Supplement 1).

To meet these requirements, an extensive training was provided and all personnel were instructed to make every reasonable effort to collect complete demographic data.

3.2. COVID-19-specific data elements7

The following questions are specific to COVID-19 disease:

1. The first test (Y/N/U)
2. Employed in healthcare? Y/N/U
3. Symptomatic as defined by CDC? Y/N/U; if yes, then Date of Symptom Onset mm/dd/yy
4. Hospitalized? Y/N/U
5. ICU? Y/N/U
6. Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other settings): (Y/N/U)
7. Pregnant? Y/N/U

These questions were included as required fields and part of “ask on order entry” (AOE) questions, except questions 4 and 5. As staff collecting the sample will specify their exact location when logging into Epic, repeating the same questions as AOE seems redundant.

3.3. Building ad-hoc queries

Users can create queries through an ad-hoc report setting panel including multiple filters such as test, patient and physician information, testing location, results, diagnosis-related group (DRG), days of the week, and hours of days. Each filter group contains relevant data fields that can be set by selecting available options from the dropdown list. Users could also set a custom filter by combining data fields from different test groups. For more advanced reporting, users could program complex filters to define the timing between targeted events. Fig. 3 illustrates the report setting for the SARS-CoV-2 antibody report. Reports will be emailed to different user groups based on the scheduled setting.
3.4. HIPAA consideration

The Office of Civil Rights (OCR), on February 2020, announced that covered entities might share patient information, without a patient’s authorization, for treatment, to public health authorities such as CDC or state or local health departments, and to persons at risk of contracting or spreading the disease. OCR, on March 24, 2020, issued detailed guidance on disclosure of the protected health information (PHI) of an individual who has been infected with, or exposed to, SARS-CoV-2 without HIPAA (Health Insurance Portability and Accountability Act) authorization with law enforcement, paramedics, other first responders. OCR withheld imposing penalties for HIPAA rule violations on covered entities and their business associates for public health emergency duration. However, these changes were temporary and not applicable to the implementation of our

Fig. 1. (A) Order panel for COVID-19 viral testing. (B) Order panel for COVID-19 antibody testing.
Fig. 2. The data flow of laboratory-based data and user interaction points with Visiun.

Fig. 3. Ad-hoc report setting.
dashboard. The data stays secure within the organization’s firewall. Only users who have access to the Mount Sinai network could use the application. Since managing access control can get quite complicated if done at the application level, Visiun controls access to the SQL server’s database. The audit trail is also set up and maintained at the SQL server level. Unlimited users could have access to the application and run ad-hoc reports using pre-built filters. However, only the vendor has access to and can modify the raw data, including editing master tables, developing complex queries, and saving new reports.

4. Results

Using a combination of multiple systems such as Epic, customized reports, and the Visiun application in our health system, we were able to aggregate and transmit key clinical and laboratory reports rapidly. Our reports, and the Visiun application in our health system, we were able to save new reports.

4.1 Performance metrics

The number of tested samples and percent positive for COVID-19 report and grouped by age along with the overall percentage of patient visits for influenza-like illness (ILI) are indicators used to examine the age distribution pattern of pandemic. Since age is considered a risk factor for severe COVID-19 disease, these data have significant clinical and public health implications. The daily percentage of positive tests was calculated as the number of positive SARS-CoV-2 test results divided by the total number of tested results. The overall percentage of patient visits for ILI is the number of ED visits with chief complaint symptoms such as fever, cough, shortness of breath, or difficulty breathing divided by total ED visits. The percentage age distributed was calculated by 10-year age increments.

The last report was built to collect data such as age, sex, and demographic information (e.g., race and ethnicity) of people who test positive for SARS-CoV-2 and are hospitalized within 14 days of the positive test. This report only shows the counts of the patients and could be used at the state level to calculate other data such as hospitalization rate and how many people are hospitalized with COVID-19 compared with the entire number of people residing in different regions of state, which is a more accurate indicator for surveillance.11

2. State reports

Below are the state-specific reports that were developed and shared with local and state officials:

2.1. Viral testing (positive, negative, total) by patient zip code/county. This report contains the number of confirmed cases or people with a positive molecular test per county or zip code. The data also query the number of people with negative test result and total number of performed testing per zip code. The result is reported as daily test rate, percent positive, and number of new cases in each zip code.12 The total number of testing is also used as a metric of adequacy of testing. A neighborhood is considered to have adequate testing when at least 260 residents per 100,000 have been tested in 1 week.13

2.2. Heat map [Fig. 4] illustrates the geographical distribution of patients with SARS-CoV-2-positive test result. The data will help the state determine the need for COVID-19 testing and treatment, social distancing policies, and required Medicaid expansion or private insurance plan changes.

These data serve as an early warning to identify clusters of cases, outbreak impact assessment and monitor the effectiveness of preventive measures, changes in health practices, and policies. A similar heat map was developed using Visiun to better study the geographical distribution of confirmed cases (positive molecular tests). However, there are few differences between our internal developed map and the state heat map. Our map demonstrates the total number of new confirmed cases in each day by zip code. The state map highlights the percent of people with positive molecular test by zip code in the past 7 days.14,15 As it is illustrated in Fig. 5, the state heat map is marked by density of color. However, our heat map [Fig. 4] is marked by size only; the bigger the circle is, the larger the number of confirmed cases is in the zip code.

3. Laboratory operational reports

The laboratory operational reports include three categories of reporting: performance metrics, technician performance assessment, and analyzer metrics. Using these reports, the key performance indicators (KPIs), case volumes, turn-around-time (TAT), and inform staffing changes could be monitored as needed.

This category was essential for managing the laboratory surge capacity during pandemic.

4.1. Performance metrics

These metrics were used to evaluate productivity and recognize how effective our operation is at meeting patients’ needs. The first two reports are cumulative charts showing the total number of received samples for viral and antibody testing. These charts are generated by adding all the collected samples from different affiliated hospitals and clinics each day. They provide a quick visual view of flow of productivity. The third report [Fig. 6]
is a comprehensive report summarizing several data related to the hourly throughput for viral testing and the TAT for reporting the results such as hourly average TAT and target TAT. This report also shows the number of outlier samples that do not meet the target TAT and the results are delayed. The most reporting delays occur at 2 pm. The increase in the number of outliers could be an indication of inefficiency and requires further analysis of the underlying causes. The last report is a combination of a bar and line diagram. The bar chart [Fig. 7] shows the number of resulted tests grouped by the average TAT. The cumulative percent line shows the percentage of resulted tests and the corresponding average TAT. As it is shown in this diagram, 80% of viral tests are resulted in less than 7 h.

4.2. Technician performance assessment

These reports helped in identifying bottlenecks and apportioning tasks to technicians while monitoring their performance.
The first report shows the number of the tests resulted by each technician during their shift. If the total number of finalized results by certain technician is significantly lower than other staff, the appropriate steps should be taken to find the cause. Some of the reasons could be the need for additional training, lack of access to proper tools, and disorganized work environment. The second report shows average number of the resulted tests per technician per hour compared with tests received per hour. This report demonstrates technician’s productivity rate. If the number of resulted tests remains relatively constant but the number of received tests increases, assigning additional technicians may be considered to avoid the delay in TAT.

4.3. Analyzer metrics

The U.S. pursued batch testing or sample pooling to be able to test larger portions of the population in shorter period of time. Most analyzers approved by the FDA use the same strategy. This way the samples could be combined and tested within a single batch. The reports in this category demonstrate the number of processed batches by each analyzer. They also show the number of loaded samples in each batch and the ratio of stat vs. routine samples. These reports were developed to compare the performance of each analyzer for viral testing. The laboratory manager could use the data to effectively divide the received volume among analyzers to

Fig. 6. This diagram shows COVID-19 viral testing TAT. The accepted TAT is set as <10 h (green line). The largest batches of samples (red dotted line) are received at 1 am, 2 pm, and 9 pm.

Fig. 7. The chart demonstrates the number of the resulted tests grouped by average TAT. About 50% of the viral tests are resulted in <5.5 h.
achieve an optimal TAT. Similar reports were designed to show the frequency of processed batches for antibody testing and the number of received sample in each batch.

4. Clinical reports

This category contains reports that are related to the plasma therapy to treat COVID-19 infection. The Infectious Disease Society of America guideline, published on April 27, 2020, recommended the use of convalescent plasma for management of patients with COVID-19 disease. A study conducted between March 24 and April 8, 2020, at Mount Sinai Hospital showed potential effectiveness of convalescent plasma with an SARS-CoV-2 anti-spike antibody titer of 1:320 against COVID-19. Convalescent plasma recipients had higher discharge and survival rates. They also had shorter period of symptoms and less frequent need for intubation when compared with the control group. The total number of antibody tests resulted each day list the antibody test results (positive and negative), and the titer of antibodies in positive tests was queried daily. Only patients with high-titer convalescence plasma who met all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) are qualified to donate plasma. The high titer is defined as a neutralizing antibody titer of ≥ 250 in the Broad Institute’s neutralizing antibody assay or an S/C cutoff of ≥ 12 in the Ortho VITROS IgG assay. Another report was developed to show the list of eligible donors based on established protocol for antibody treatment. The last report in this category shows the total number of completed daily transfusions of convalescent plasma units to infected patients.

5. Research reports

Research projects were incorporated into outbreak response activities to provide timely essential information about different characteristics of disease. Collecting relevant laboratory and clinical information to create a rich dataset to conduct current and future research studies was valuable. Studying different clinical symptoms of the disease, imaging findings, responding to different therapies, and various complications helped us strategize our response to control the disease during pandemics. Some of research queries are listed in Table 1.

Several reports highlighted that pregnant women are at increased risk of severe COVID-19 infection. The list of pregnant patients with positive viral test result is obtained using the SlicerDicer module in Epic.

Understanding the life cycle of SARS-2-CoV-2 virus and serology is essential in screening, diagnosis, and monitoring of patients. Additional research reports were developed to study the viral factors and serostatus level, seroconversion time, and titer [Figs 8 and 9].

5. Discussion

Pandemics are impossible to predict. They can begin at any time of the year, and the duration can vary from region to region. The clinical attack rate, hospitalization rate, mortality, and secondary complications differ widely among countries, states, and even health systems and clinics. The extensive data analysis and monitoring of routine reports are essential to identify any unusual event or anomalies that might suggest a shift in disease patterns or possible emergence of genetic changes in the virus. Such data can also be useful for early detection and monitoring pandemic waves’ progress and to inform prompt and proportional response plan. With this knowledge, communities can prepare the required workforce, collect necessary supplies such as personal protective equipment and pharmaceuticals, and deploy new laboratory capacity, including serology and molecular testing.

A key factor in pandemic response efficacy is the design of surveillance system that places the reporting, and the data contained in them, in the proper category. Our reporting framework improved timely internal dissemination of information. It established a reliable communication channel among leadership and different frontline respondents such as nursing, clinician, emergency, and ICU staff, so that they could make informed decisions for allocating various care resources. The framework made possible efficient required external reporting as well.

The reports in the federal category are good examples to demonstrate the dynamic progress of pandemics and its impact on strategic policies at all levels. One of the reports in this category is the percentage age distribution of patients with positive viral testing calculated by 10-year age increments. At the beginning of pandemic, the COVID-19 incidence was the highest among older individuals. However, during June-August, the age trend shifted to the 20–29 age group. This transition in age distribution is important in mitigation of spread of virus for different reasons. First, younger adults, who usually have mild or no symptoms, are more likely to spread the virus in community. Secondly, this age group also compromised a large proportion of essential workers and implementation of prevention strategies such as quarantine can be more challenging or not possible. Thirdly, the increase in younger age groups usually precedes increase in older groups who are at risk of hospitalization and severe illness by 7–15 days. Thus, such reporting will help federal governments to manage the surge capacity and forecast and allocate medical supply requirements for a proportionate response. This report also has clinical
implications at the institutional level. These metrics will help an organization to forecast patient influx and strategize for allocation of healthcare resources. These data are also helpful in predicting the percentage of critically ill patients who may need advanced therapies such as mechanical ventilation, which will help with proper triaging of patients and planning for required services and procedures.

In addition, demographic data related to the patients with positive viral testing who are hospitalized were used to develop and/or adjust state-level forecasts of the number of new COVID-19 hospital admissions per day. The most important public health implication of this report is determining the most high-risk groups and subsequently helping with establishing the public health prevention strategies and monitoring the results in the target age group. There are also clinical implications such as determining the prognosis of admitted patients and helping clinicians to make informed decisions for the best outcome. Understanding the mortality risk factors will help clinicians to better triage patients at the time of admission. These data also help with forecasting and planning for required services and procedures for each risk group. High-risk patients may need advanced therapies such as mechanical ventilation and admission to ICU, which require planning for essential equipment and procedures.

Visuion supports several different visualization motifs such as spatial view of hotspots, multi-views, or combining different chart types. Another important feature of Visuion is the advanced graph association capability. Outbreak data analysis may demand to establish relationships among three different sets of data and visualize these types of data in the 3D surface graph [Fig. 10]. Visuion makes the visual comparison easier. Multiple studies have shown the application of the analytics dashboards developed by statisticians in studying the surveillance data.20–22

Fig. 9. The lag time between the first positive COVID-19 test and first negative result. The diagram shows that the COVID-19 viral test becomes negative in 3 weeks in approximately 50% of the patients.

Fig. 10. Time course of developing COVID-19 antibody. Seroconversion takes place within the first week in the majority of infected patients.
There are some drawbacks to the Visiun analytics platform. Visiun offers a familiar and known analytic paradigm, Excel, to laboratory directors to employ. However, all users do not have access to navigate the tables and data fields to develop new and complex reports. Therefore, they need to submit a request to the vendor’s data analysts to run such reports, which makes the process complicated and occasionally unsuccessful due to a lack of fluid bidirectional communication between clinicians and analysts.

Although Visiun deployment showed optimal performance in our pandemic surveillance and management, however, we recommend the following actions as improvements to enhance Visiun’s functionality.

1. **Enhancement of AOEs**
   - Only basic and routine testing information such as patient demographic and location and time of collection was electronically transferred to CP-LIS. The COVID-specific data such as the presence of clinical symptoms and pregnancy should be electronically captured and stored in laboratory information systems. Also, adding questions regarding congregate care setting status to the AOE list could help identify local outbreaks in care facilities and create a report category for monitoring disease behavior in such patients.

2. **Integration with AP-LIS data source**
   - Interfacing Visiun with anatomic pathology laboratory information systems will help us collect data regarding following biopsies or possible surgeries in SAR-CoV-2-positive patients and track the incidence rate of short- or long-term complications.

3. **Adding forecasting capability**
   - In the current design, the trend identification is usually made manually by users, which could only provide short-term forecasts. For the long-term prediction of underlying patterns, integration with a machine-learning algorithm, which could analyze large numbers of variables collected over a longer period, is required.

### 6. Conclusion

We used the Visiun application to support core activities required for COVID-19 pandemic preparedness and response. The Epic reporting tools were mainly applied to provide clinical and research queries. The designed information infrastructure has been used to study COVID-19 outbreak characteristics, strategize the response, track surveillance data, and identify effective preventive measures and treatment protocols. The designed generic framework consisting of major stakeholder groups, key report categories, and a generic template report setting could be adjusted and customized based on specific characteristics of possible future influenza-like outbreaks.

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Nil.

### Declaration of Competing Interest

There are no conflicts of interest.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.4103/jpi.jpi_54_21.