

Written Testimony
House Committee on Science, Space, and Technology
Hearing on Fighting Flu, Saving Lives: Vaccine Science and Innovation
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Chair Johnson, Ranking Member Lucas, and other members of the committee, thank you for the privilege to appear before you today. I am Sharon Watkins, President of the Council of State and Territorial Epidemiologists (CSTE) and State Epidemiologist for the Pennsylvania Department of Health. Thank you for the opportunity to testify before the Committee regarding “Fighting Flu, Saving Lives: Vaccine Science and Innovation.” CSTE is an organization of 56 member states and territories representing applied public health epidemiology and serves as the professional home for 2,000 applied public health epidemiologists or “disease detectives” nationwide working tirelessly to respond to and protect the public’s health. In my over 20 years as a public health professional I have witnessed the devastating impact of seasonal influenza, the 2009 H1N1 pandemic, measles, pertussis, and many other vaccine preventable disease (VPD) in the communities I serve. Throughout influenza seasons, state, local, tribal, and territorial health departments partner with clinical stakeholders and the Centers for Disease Control and Prevention (CDC), to conduct disease surveillance and gain a comprehensive understanding of when and where influenza is circulating, any potential changes in the virus that may lead to health disparities, work to contain outbreaks and deliver life-saving vaccine.

Whether it’s influenza, measles, pertussis, Ebola, dengue, Zika, lead, hepatitis A, human papillomavirus (HPV), wildfires, tornados, or now the use of e-cigarettes, public health threats are persistent and constantly evolving here at home and overseas. Effective prevention and efficient, timely responses rely on an interactive network of governmental public health agencies

at the federal, state, local, tribal, and territorial levels working with health care providers and the public and private sector. Every day, this cooperative network saves lives by detecting and responding to influenza and other health threats, like *E. coli* contaminated lettuce, mumps, varicella, meningococcal meningitis, opioid overdoses, Zika, and more.

Unfortunately, this essential public health network is seriously disadvantaged by an antiquated public health data system that relies on obsolete information sharing methods including faxes and phone calls, and is in dire need of security upgrades. Lack of interoperability, reporting consistency, and data standards lead to errors in quality, completeness, timeliness, and communication. Sluggish, manual processes—paper records, phone calls, spreadsheets, and faxes requiring manual data entry—are *still in widespread use* and have important consequences, most notably delayed detection and response to influenza and public health threats of all types: chronic, emerging, and urgent. For reference, every week, the Pennsylvania Department of Health Bureau of Epidemiology that I direct receives over 250 faxed or paper case reports of disease requiring immediate review and processing before being sent on to the appropriate front line staff who contact impacted individuals to conduct interviews, implement control measures (like excluding children from daycares and schools to prevent others from becoming sick), identify risk factors for how they may have gotten sick, and compile and communicate the information to inform the public and policy makers. These 250 paper case reports are many pages long translating to 1000s of pages per week—critical test results including those for hepatitis A, STDs, HIV, childhood lead, and other diseases being communicated slowly and requiring multiple steps to process. Rapid advances in data science and evolving cybersecurity threats demand public health professionals stay up to date with current skills and tools to protect, defend privacy, and securely integrate health data.

In my experience on the front lines of public health emergency detection, prevention, and response as a public health epidemiologist in Florida during the 2009 H1N1 influenza pandemic, and now here in Pennsylvania, I have seen first-hand and heard from colleagues about the challenges and frustrations with the current data infrastructure to respond to influenza, VPDs, and other public health threats. I will share a few recent examples of those experiences with you.

Amid the outbreak of lung illness associated with e-cigarettes, distinguishing e-cigarette, or vaping, product use-associated lung injury (EVALI) cases from influenza infection as the virus begins to circulate widely is becoming increasingly challenging. Not to mention the added challenge of determining the impact of influenza co-infections among EVALI cases.

Complicating the response around the country, is obtaining near-real time information about influenza vaccination status of suspected cases to further evaluate illness and impact of the vaccine among these now high-risk patients for influenza infection complications. Not only are our public health surveillance data systems not receiving information seamlessly from our immunization registries, but they are not operating in seamless interoperable ways with the healthcare community. Deciphering faxed reports and sifting through medical records to identify critical pieces of medical information like influenza vaccination status is time consuming.

Review of radiographic imaging to distinguish injury from flu infection and other critical information is even more time-consuming, and all of these steps are frequently done in a piecemeal approach as different bits of paper information arrive at different times and leads to lost opportunity and sometimes death. As evidence, I submit to you, and ask you to decipher as my disease detectives are doing daily, ADDENDUM 1, a typical sample four pages of an average 350-page medical record fax received by the Pennsylvania Department of Health on one of our EVALI cases.

Nationally, there is limited coverage and lack of full participation of emergency departments (ED) in public health syndromic surveillance systems, which inhibits our ability to rapidly identify changes in the severity of the influenza season. Unfortunately, approximately 40 percent of all ED visits are *not* submitted to public health departments and key information like pregnancy status is not systematically recorded or provided to public health; leaving public health professionals flat-footed in identifying and responding to severe influenza infections among high risk groups for influenza complications, including pregnant women—where despite the science, we see increased vaccine hesitancy. While the influenza vaccine isn't "perfect," it does significantly reduce severe complications—hospitalizations and deaths—especially among high risk groups like pregnant women, children, and the elderly. Hourly, real-time information about the number of people presenting to the ED for care as a result of an influenza infection can be powerful in communicating with the public to encourage vaccination. Additionally, key data sources like death data are not always electronically available to public health staff and are not available to be visualized in the national syndromic surveillance system alongside other data (e.g. ED data) further limiting the ability of public health to identify the severity of the season or outbreak early, even before final coding of death certificate data (which can take months). This gap in real-time ED data and limited use of advanced descriptive and predictive analytic tools, including artificial intelligence and machine learning to identify outbreaks early, as soon severe illnesses are occurring and well before thousands of deaths occur, is devastating, and demonstrates that the underlying obstruction to effective public health surveillance in magnitude and scope is not a technical limitation, rather it is a resource problem.

Death certificates were one of the first sources of public health surveillance data. When we look at influenza mortality data, every death certificate tells a story. Influenza mortality data

when viewed collectively, uncover health disparities, inform policy and funding decisions, and improve outbreak and disaster response efforts. Sadly, in some states, death certificates are still filed on paper, and nationally only 63 percent of all death certificates are submitted to CDC for national aggregation within 10 days (<https://www.cdc.gov/surveillance/pdfs/Tracking-Deaths-protects-healthh.pdf>); and while improved, 10 days is still too long, and it typically takes weeks to months to have final influenza season death estimates. Then, even after the data are received, it is fragmented and unconnected to vaccination information, leading to missed opportunities to understand and evaluate vaccine effectiveness. Tragically, each year, most pediatric influenza deaths occur in unvaccinated children, but it can take weeks to uncover and link the influenza death information with vaccination history (or medical examiner information which is not linked with death registration systems) in order to communicate meaningful information to policymakers, the media, the public, and providers who need answers to questions—where did the deaths occur and what populations are most vulnerable? What immediate steps can be taken to prevent more deaths based on today’s data? Unfortunately, because of the lag in paper-based data systems and lags caused by the non-integration of key public health data systems, public health officials are hampered to provide fast, high-quality answers the public wants, needs, and expects in our technologically capable world.

Nationally, there have already been dozens of influenza outbreaks in skilled nursing and long-term care facilities this influenza season already. Despite clear public health recommendations to vaccinate staff and residents in these facilities, when investigating outbreaks, unfortunately we consistently find under vaccination among residents, staff, and their family member visitors. In Pennsylvania, our population is aging, and we have over 80,000 citizens residing in over 700 nursing homes. In the 2018-19 flu season, we had 284 outbreaks

among these facilities impacting more than 3400 residents and staff and our data indicated that only 69 percent of staff and 78 percent of residents were vaccinated among those long-term care facilities (for which data were available). Much of the data related to these outbreaks required significant back and forth follow-up to obtain the data needed to understand the outbreak.

Making these investigations more challenging is the time needed to collect vaccination information from the facility—often provided on hand-written line-lists or paper records which may be faxed to public health or sent as pdfs, if at all, and the make recommendations. Obtaining and linking the vaccination information delays administration of life-saving vaccine given as prophylactic treatment following an outbreak. Time spent in finding records, review of paper records, and manual and duplicate entry of data is time that public health could be spending addressing recommendations to the facility, their residents, and visitors; and this is true across all outbreak types.

During the 2009 H1N1 influenza pandemic or any of the hundreds of influenza related outbreaks that occur each year in schools, assisted living or nursing facilities, samples must be collected for specialized testing at the state laboratories. Influenza viral strain surveillance is a key component of our public health surveillance and vaccine development approach to determine if key changes or mutations to the virus have occurred. These highly specialized laboratory tests are only able to be performed in state public health laboratories or at the CDC due to availability of necessary reagents and state of the art diagnostics. Unfortunately, the CDC and nearly all state public health laboratories have no data system to order a laboratory test electronically. Thus, when samples are sent for specialized testing, they are accompanied only by paper order forms – there is no electronic method to track the process: if the sample has been sent, for submitters or epidemiologists to know if the state or the CDC laboratories received it, the quality and viability

of the sample on arrival, where the sample is located prior to testing, or when testing and results are anticipated. And once results are available, there is no electronic process to rapidly communicate those results back to submitters.

- Laboratories are often not notified of incoming orders and samples. Laboratories cannot anticipate or plan for staffing capacity, surge, or what types of tests will need to be completed until the sample arrives. Staff are unaware when a specimen is lost or does not arrive.
- Thousands of samples come through a laboratory, and each must be manually accepted and entered by staff. During the 2018-19 moderate influenza season US public health laboratories collectively tested 80,993 specimens (<https://www.cdc.gov/mmwr/volumes/68/wr/mm6824a3.htm>). When data are missing, staff must contact submitters to complete or verify the information— which is time-consuming and error-prone.
- Order information is not linked to vaccine histories or epidemiologic surveillance systems, where risk factor information about persons under investigation is stored.

These processes and modes of data sharing are slow, cumbersome, and make it logistically impossible to respond effectively to the speed and intensity with which the influenza seasons or the 2009 H1N1 pandemic hit.

In August of this year, Pennsylvania experienced its 14th measles case of 2019 (<https://www.media.pa.gov/Pages/Health-Details.aspx?newsid=642>) with over 1250 measles cases reported nationally this year and the most since 1992 (<https://www.cdc.gov/measles/cases-outbreaks.html>). As of November, we have had 17 cases in Pennsylvania. In response to these

cases, we have identified 1,000s of close contacts and exposures, and for each contact or exposed person, needed to rapidly determine vaccination status in an unconnected world where health data is not shared or easily accessible to public health. Hundreds of exposures are common for each case and gathering vaccination history or rapidly testing for immune status, must all be done quickly, before prophylaxis is no longer possible and quarantine is considered. We collect and review detailed travel and location histories for cases (see timeline for potential exposure locations (<https://www.media.pa.gov/Pages/Health-Details.aspx?newsid=642>), and then collect and manually connect lists of hundreds of individuals potentially exposed by being at the same location or venue. Why? Because key electronic data systems storing health care visits, epidemiologic, laboratory and immunization data had no way to seamlessly share the information and speed the response. When vaccine status or immune status cannot be confirmed, or confirmed in time, quarantine occurs. Without rapid access and connectivity of health data, unnecessary testing and quarantine can occur, leading to strains on public health resources and budgets, potential lost wages for citizens, and lost productivity for the community and workplace.

Clear information about availability of influenza vaccine becomes paramount during flu season and especially during seasons of more severe activity or when supply chain issues impact delivery. In Pennsylvania and across public health we work vigorously to respond, activating our emergency operations center, conducting frequent calls with public health and the health care community, issuing health advisory notices to providers, and issuing press releases to keep the public informed about influenza disease occurrence, vaccine availability and uptake. It is confusing to the public about when and where to get vaccinated with differing options for convenience or coverage. Parents may delay getting children vaccinated due to the increased

challenge of scheduling a specific provider office visit, but our public health messaging, driven by science and data should provide clear messages and motivation. However, with disease data dragging, our fragmented public health surveillance system constricts our ability to implement timely life-saving interventions.

Finally, our focus today is on influenza and vaccination innovation, but as a public health professional who works across disciplines, I must reflect these public health data challenges are broad and systemic and hamper our public health responses beyond influenza and vaccine development to other critical but non-infectious disease threats. When I reflect upon some of the recent public health emergencies, such as Zika, the opioid epidemic, and now e-cigarettes and EVALI, one of the common critical stumbling blocks to rapid response has centered on data collection, data management, and data sharing. I fear that this will continue and worsen, unless investment in data infrastructure occurs across all of public health. To provide one such example, in Pennsylvania, we were working in concert with CDC and the Agency for Toxic Substances and Disease Registry (ATSDR), responding to a manufacturing plant that had released lead into the air in a community that understandably wants answers about their health: What are our blood levels? How many people and children have been tested? How do they compare to other communities? Does my child need to be tested? Unfortunately, those questions couldn't be quickly or adequately answered with today's data, because, like with influenza, while health care facilities have data stored in electronic medical records, data are sent on paper to the public health department and the stacks take time to enter and process. Included as ADDENDUM 2 are examples of the millions of hand-written, paper lead lab reports that I received while in Florida and now in Pennsylvania.

These modes of data sharing are slow and cumbersome. They are also vulnerable. With sophisticated cybersecurity threats, it is critical that public health systems are equipped to prevent and respond to cyberattacks. Health care providers are *required* to report diseases and conditions to public health departments. These health records contain sensitive personal information—required to be reported and protected by state laws—and they demand significant care in handling to protect the privacy and safety of patients, particularly since such systems are frequently the target of hackers.

The nation’s public health infrastructure is so fragmented and antiquated that health care providers who *already have the data stored and collected in electronic health records* cannot rapidly share these health data because public health departments cannot receive them electronically. This environment leads to an increased burden on providers to report—or delays and failures to report—and inefficiency and frustration on the part of patients, care providers and public health professionals. It leads to lost time, lost opportunities, and lost lives. In any outbreak, time matters—whether the issue is vaccine and prophylactic treatment following meningococcal exposure, which needs to be rapidly disseminated, or measles cases who need to be isolated to prevent others from becoming infected, or where vaccine effectiveness to prevent pertussis needs to be evaluated for both children and adults, or where influenza threatens the lives of pregnant mothers and their babies. Most importantly, data matters. I have stood before communities who are justifiably bewildered and angered that public health cannot access data or access it faster. “Why can I simply log into a portal and get my medical test results and history in a matter of minutes and you, who are charged with protecting public health, don’t seem to have access to or the systems to get today’s health data?”

Public health professionals, providers, policymakers, and the public will all agree that to halt influenza and foster vaccine development and innovation (be it Zika, dengue, malaria, Lyme or Ebola), we need more, better, faster, and secure data to protect the public’s health. To date, in the demand for better data, we have taken a piecemeal, fragmented approach to funding our public health data infrastructure. When a new disease emerges, such as 2009 H1N1, Congress has funded standalone data systems at CDC to support the response. But this funding approach is inconsistent and does not support an invested, sustainable enterprise approach in detection and prevention *before* an event occurs. While Congress’s support and funding during emergencies is critical to support a response, a well-planned, long-term, optimal data collection and data system management are necessary and cannot be approached as ‘one and done.’

CSTE and our partners—the Association for Public Health Laboratories (APHL), the National Association for Public Health Statistics and Information System (NAPHSIS), and the Healthcare Information and Management Systems Society (HIMSS)—together with more than 90 other institutions representing patients and consumers, public health professionals, health care providers, and health systems believe the time has come to step up and take a coordinated, comprehensive, strategic approach to building a public health data super highway of the 21st Century to speed the seamless exchange of data for all diseases and conditions, to *predict* and *prevent* public health threats before they occur and to allow rapid response when they do occur. This interstate system of systems will seamlessly and securely collect sensitive data about diseases and conditions from health care providers and report it automatically to public health departments, link it to other key data—including birth and death records and immunization registries—and where required to be reported nationally, share that data seamlessly and securely with CDC.

And while our proposed *approach to funding* this IT modernization is new, what we're proposing isn't. The data systems that feed this public health information superhighway already exist, have demonstrated value, and are used to varying degrees in all state and local public health departments. What we need is to bring all jurisdictions online with all of these systems, and to modernize receiving, sharing, and connecting data that exists in silos. In addition, CDC needs its own secure data platform to receive data electronically from the states via the National Notifiable Disease Surveillance System. For further information about the need to modernize the public health data systems and workforce, please see CSTE's newly released a new report, "Driving Public Health in the Fast Lane: The Urgent Need for a 21st Century Data Superhighway" at <http://resources.cste.org/data-superhighway/mobile/index.html>.

To support this essential infrastructure and modernize public health data, several Congressional initiatives have been introduced. H.R.2741 the *Leading Infrastructure for Tomorrow's America Act*, includes Section 45001 on public health data system transformation. In the Senate, S. 1793, the *Saving Lives Through Better Data Act* and Section 405 of S. 1895 the *Lowering Health Care Costs Act* would give CDC the authority to expand and modernize public health data systems and allow for more, better, faster, secure data to track public health events like influenza outbreaks, vaccination rates, and e-cigarette illness. This modernization of CDC's data systems is essential for public health departments like mine to be able to share and report data in a timely and practical manor.

However, what we really need to make this happen are resources. This is why the proposed funding of \$100 million to support better data infrastructure at the CDC that was included in the House Labor, Health and Human Services Appropriations bill is urgently needed.

This is an essential first installment towards a more robust and effective data superhighway in the US.

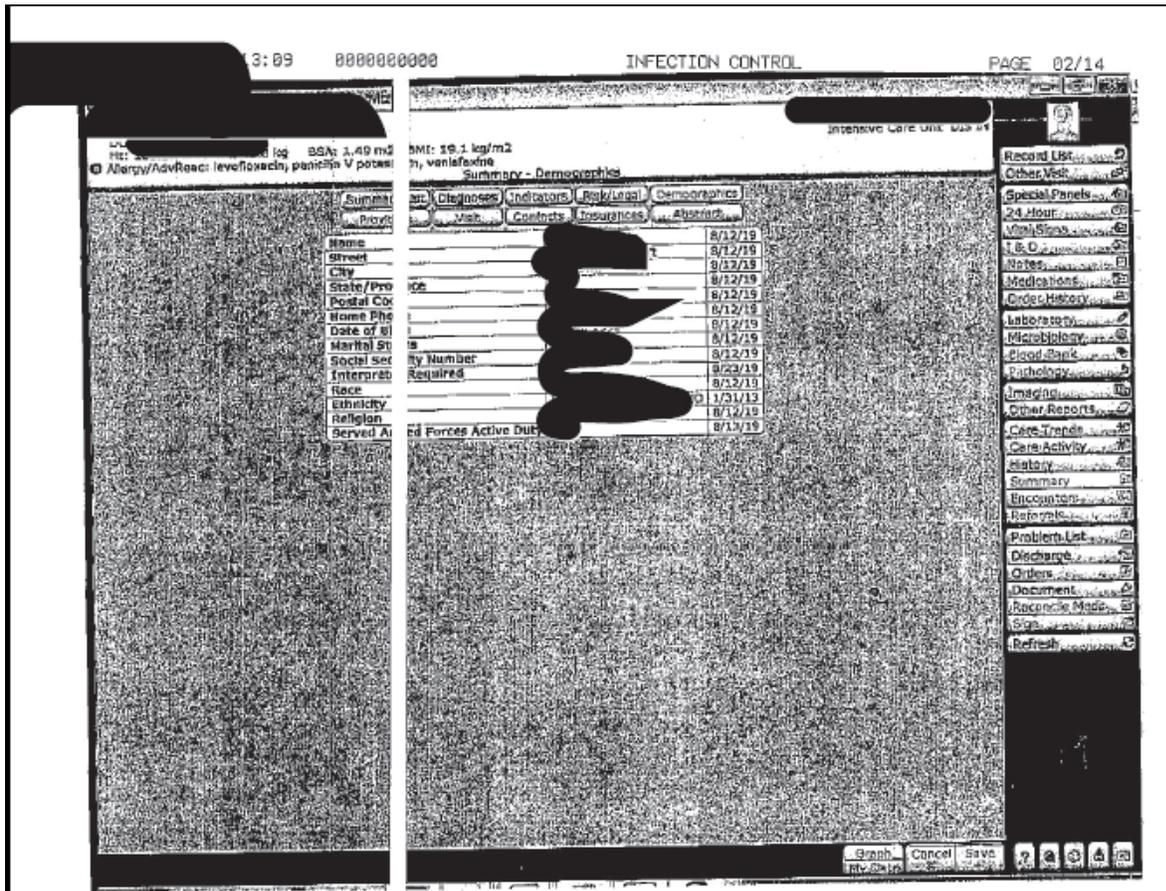
Our nation requires a modernized, electronic, interoperable, enterprise public health data system and a new generation of skilled public health data scientists. We strongly urge you to prioritize and support a public health surveillance enterprise that will speed the data collection and response for current and future public health threats.

In a world where travel across the globe can be accomplished within 36 hours, the demands for public health surveillance have changed dramatically over the past several decades and we need to ensure we are protecting the public's health in the way the public wants and needs to be protected. Diseases can have infectious and non-infectious consequences (Zika), old diseases re-emerge (measles), life threatening genetic changes or mutations (influenza), and common behaviors can have sudden and devastating impacts (EVALI) and public health must be able to rapidly respond. Aging data infrastructure is hampering our responses and it cannot be improved without widespread investment. CSTE hopes in your ongoing deliberations about fostering the critical science of vaccine development and use, you will consider the foundational need for a modernized, electronic, interoperable public health data system, a new generation of skilled public health data scientists, and their necessity to optimally evaluate one of public health's best prevention and control strategies (vaccination). We recognize this effort must be funded with *new* money, rather than cut already underfunded public health programs. Without federal support, public health surveillance modernization will remain unattainable and the health of the nation will suffer. The technology is available to develop the enterprise public health data superhighway, but new, consistent, reliable and sustained investments are needed to improve the health of the nation. A robust, sustained commitment to transform today's public health data

system will ultimately improve Americans' health. We look forward to working with the Committee in these endeavors and hope you will turn to the CSTE as a resource in the future.

Thank you very much for the opportunity to testify before you today.

ADDENDUM 1: Redacted Example of Typical 350-page Fax Received by PA Public Health Officials



Example faxes of medical records received by public health officials in Pennsylvania for individuals under investigation for severe lung illness associated with e cigarettes; these medical records are individually reviewed by public health disease detectives to determine if the ill individual is part of the outbreak associated with e cigarettes.

Note records have been redacted here to protect patient confidentiality.

[REDACTED]

apprec ortho
"Addendum [REDACTED] on [REDACTED]"

EXAM: MR [REDACTED]

HISTORY: Weakness

TECHNIQUE: MRI of the [REDACTED] utilizing the following sequences: axial T2, coronal oblique T1, coronal oblique T2 with fat saturation, and sagittal T1 with fat saturation.

COMPARISON: Plain films date 08/2019

FINDINGS: No fracture or destructive bony lesion. No significant arthropathy of the glenohumeral joint with AC joint. There is a tubular T2 hyperintense finding measuring about 2.4 x 0.6 x 0.7 cm along the anterior supraspinatus myotendinous area. This is nonspecific however may reflect the sequela of myotendinous injury. More distally however no tearing of the rotator cuff tendon insertions or pathology otherwise is clearly identified. Long head of biceps appears to be in normal anatomical position. There is intraspinatus myotendinous area as outlined suspicious for the sequelae of a myotendinous injury noting the actual rotator cuff tendon insertions themselves appear to be within normal limits. There is no labral pathology is clearly suspected.

IMPRESSION:
Area of T2 hyperintensity in the supraspinatus myotendinous area as outlined suspicious for the sequelae of a myotendinous injury noting the actual rotator cuff tendon insertions themselves appear to be within normal limits.
Workstation ID : [REDACTED]

After review of MRI findings with [REDACTED] we make the following changes to our recommendations:

1. Continue with neurology consult as recommended previously.
2. No need for sling immobilization as there are no signs of [REDACTED] instability on MRI today. Recommend PT for the left shoulder while she remains inpatient and as an outpatient as well. Increase shoulder movement as tolerated.
3. Follow-up with us in 2-3 weeks after discharge for ongoing evaluation.

Please contact us with any questions or concerns. I did discuss this plan with [REDACTED] at [REDACTED] pm today. "

apprec ID
Impression and Plan

Problem List:

- (1) Hypoxemia
- (2) Multilobar lung infiltrate

Impression and Plan: clinically better, Ct neg for abscesses
Leucocytosis and thrombocytosis improving
Stable off of antibiotics, rash likely acneiform, as she says she gets them
Will sign off
Pl call us if we can help
Thank you

[REDACTED]

[REDACTED]

Encounter Date:

Order-Level Scanned Encounter Result(s) (continued)

[Redacted Patient Information]

Patient Name: [Redacted] Procedure Date: [Redacted]
MRN: [Redacted] Date of Birth: [Redacted]
Procedure Date No Time: [Redacted]

Procedure Name: Bronchoscopy
Indications/Preoperative Diagnosis: Atelectasis of the left upper lobe, Atelectasis of the left lower lobe, Atelectasis of the right middle lobe, Atelectasis of the right lower lobe, Bilateral atelectasis

Providers: [Redacted] (Doctor)
Referring MD:
Requesting Physician:
Complications: No immediate complications

Impression/Postoperative Diagnosis: Bilateral infiltrates, F/O
Recommendation: - Await BAL, biopsy, brushing, culture and cytology results.

Procedure: Pre-Anesthesia Assessment:
- The anesthesia plan was to use general anesthesia.
After obtaining informed consent, the Bronchoscope was introduced through the mouth, via laryngeal mask airway and advanced to the tracheobronchial tree of both lungs. The procedure was accomplished without difficulty. The patient tolerated the procedure well.

Findings:
Vocal cords appeared normal. Mucosa appeared normal without any cobblestoning or lesions. No endobronchial lesions, minimal clear secretions. BAL done in all lobes, Return was clear. Brushings done in RML and RLL. Transbronchial biopsies done in RML and RLL. No bleeding, patient tolerated procedure well
Estimated Blood Loss: Estimated blood loss: none.

