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Houston We Have a Problem: Ground Zero for the US Coronavirus Outbreak

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Personal Narratives From Investigators

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Houston We Have a Problem: Ground Zero for the US Coronavirus Outbreak

Yuan-Po Tu

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Friday, February 28th, 2020, 4:15 PM—
Houston We Have a Problem

I looked at my messages and noticed I had missed a call from the county's health district epidemiologist. I wondered what she was calling about but wasn't too worried. As the contact person for infectious disease at our clinic, it was not unusual for me to receive communication from the health department. When she answered the phone, I jokingly asked her what she had to report late on a

Friday. What she said next changed our world: two days previously, a patient in our clinic had tested positive for coronavirus (COVID-19).

As I listened, gathering the details, I frantically looked up the case. I typed a message furiously to my chief medical officer:

Houston we have a problem.

One of our patients tested positive for COVID-19.

I am on the phone getting the details.

Press conference at 7:00 PM.

Reviewing the chart, I saw that the patient was a local high school student who had presented to one of our clinics two days earlier. He had a high fever and a rash. The patient had not traveled outside the country. In our electronic medical record (EMR) system, the screening algorithm identified the patient as potentially infectious. He had been appropriately triaged and placed in a room with a mask on. The providers taking care of him documented that they wore appropriate personal protective equipment. So far, so good.

Washington State—Ground Zero for the US Coronavirus Outbreak

Six weeks before I got this call, the first person hospitalized due to COVID-19 had occurred at a hospital in town. Now reacting to the first

community-acquired case of COVID-19, The Everett Clinic opened its command center at 6:30 AM on Saturday, February 29. As it was a weekend, the focus was on containment. Initial operations focused on developing an urgent care strategy, placing greeters at all clinic entrances, and supply chain assessment.

From our previous experience with the 2009 H1N1 pandemic, we knew that diagnostics and supply chain management would be challenging. Our immediate concern was our supply of N-95 respirator masks. I led the clinic's response during H1N1, so we had a plan. Post H1N1, in the after-action review, we created a disaster response depot in our warehouse. Included in this were plastic barrier gowns and N-95 respirators. The Director of Materials Management instructed her team to place orders for more N-95 respirators and surgical masks immediately. We hoped the orders placed over the weekend would be in the front of the queue before the distributors were inundated with orders on Monday. We were relieved after the Director and I drove to the warehouse, pulled three pallets, and located our stash of N-95 respirators. Our relief was short-lived.

Monday, March 2nd—the Command Center

I was seated next to the Director of Materials Management in the incident command center when she informed me that over 10,000 surgical masks had been issued over the weekend. At the current utilization (burn) rate, we would soon have a critical shortage. In the 12 months preceding the pandemic, the clinic used 360,000 surgical masks, at a burn rate of approximately 1,000 per day. We projected that we would need 100,000 surgical masks per month at a burn rate of 3,333 masks per day. This estimate was very accurate—we have used 1.5 million surgical masks in the 12 months since the beginning of the pandemic. Mask supplies were the tip of the iceberg—we faced multiple shortages throughout the pandemic.

The First Week's Response

The Everett Clinic was as well prepared to face the challenges of a pandemic as any organization. Our

leadership was stable. Many of us had been part of the H1N1 response. We had cultivated close relationships with the Washington Department of Health (DOH), participating in the influenza monitoring program and submitting influenza specimens to the DOH for years. After the first case of coronavirus was hospitalized in our town in January, we hosted pandemic table-top exercises in conjunction with the Snohomish Health District. During the first weekend, I fielded requests from the DOH epidemiologist to obtain samples from children for COVID-19 screening. We suspected that COVID-19 was circulating in our community as our urgent care clinics were facing huge demands for testing from patients with respiratory virus symptoms who were testing negative for influenza. At the time, for a specimen to be tested for SARS-CoV-2, the person had to have been in Wuhan, China. The extent of the virus's spread would soon become apparent as the pandemic made a dramatic and deadly appearance at a nursing home and hospital in a neighboring community in March.

Designing the Experiment

With the mask shortages and arrival of COVID-19 in our community, it became apparent that shortages of N-95 respirators, collection kits, nasopharyngeal swabs, viral transport media and testing would be an on-going issue. The focus quickly shifted as we felt the impact of COVID-19 on clinical operations. During the first ten days of the pandemic, only the State DOH lab was able to perform SARS-CoV-2 testing.

In January 2020, I had been awarded a clinical scholar fellowship by the Research and Development (R & D) arm of United HealthGroup. Using the Hierarchy of Controls, I began designing and planning a study to look at alternative ways to collect SARS-CoV-2 test samples that could potentially obviate the need for full PPE, thereby saving PPE and decreasing the aerosol exposure risk to health care workers. The virology lab at the nearby reference lab was just beginning to offer molecular testing for the diagnosis of COVID-19. Arrangements were made with the lab to perform the analytical testing for the proposed study.

The plan was to recruit 500 to 550 symptomatic patients presenting to our urgent care clinics. Each study patient would have four samples sent to the lab for analysis. We planned to capture essential elements of patients' clinical history and exam findings in the EMR. The study design was to compare health care worker-obtained nasopharyngeal (NP) samples with patient-collected samples. Each study patient would have a NP swab collected by a health care worker then patient self-collected bilateral mid turbinate, anterior nasal and tongue samples. I partnered with a reference virology lab to perform the SARS-CoV-2 assays. Working closely with the EMR team and the R & D team of UnitedHealth Group, we designed the experiment, obtained an expedited IRB approval, and programed the EMR in ten days.

Serendipity—Saturday, March 14, 2020

On Saturday afternoon, I received a call from the R & D team of UnitedHealth Group informing me that they heard rumors that the Gates Foundation was attempting to run a similar study. The Foundation was excited to hear about our plans as they had been trying to set up a similar study to test the same hypothesis. I invited them to join

our final Webex call before starting the study the next day.

The Saturday evening call was the final check-in before starting the study. Leadership, lead nurses, urgent care clinical staff, representatives from the lab, and the EMR programmers were on the call, with the R & D team of UnitedHealth Group and members of the Gates Foundation listening in. I was reviewing the protocol and going over the details of the study when my phone rang. The call was from the reference virology lab. In the past three days, the lab had received a larger than expected number of clinical samples and experienced longer turn-around times. The testing demand was not unique to the reference lab but was being seen throughout the United States. The lab director apologized and informed me that the lab could not keep its commitment to analyze the samples coming from our study. Without a lab to run the SARS-CoV-2 assays, the study was dead in the water.

What transpired during the next few hours on Saturday evening was amazing. After multiple contacts and calls, Quest Diagnostics agreed to perform the SARS-CoV-2 assays from our proposed study. We spent Sunday updating the institutional review board (IRB), rewriting the protocols and reprograming the EMR. There was only a day and

a half delay with the reference lab pulling out of the study. By Monday, we were rolling out the protocol and training the sites one by one.

500 Study Subjects in One Week

At the beginning of the pandemic, the demand for testing was high, but few labs had validated assays, so access to testing was limited. Since our study offered an option for COVID-19 testing, enrollment was robust.

Recruitment occurred in multiple urgent care clinics. The samples were shipped to California where the SARS-CoV-2 assays were performed. Slowly, results trickled in. There were four samples per subject and the samples were subject to the vagaries of shipping to California. Once received, the results of the SARS-CoV-2 assays were compiled in a spreadsheet. As soon as the data was validated, it was sent to the UnitedHealth Group R & D team in Minnesota for statistical analysis. It took only a week before we reached 30 positive subjects on March 22nd.

Sunday, March 23rd—Presenting to the FDA
The online meeting with the FDA was scheduled for Sunday evening. We worked on our presentation right up to the 7:30 PM PT start time. As the principal investigator, I represented the study site. There were also members from the R & D team and the Gates Foundation on the call. The presentation went smoothly, with only a few questions asking for clarification of our laboratory results. Many of the questions were regarding the patients' clinical appearance and findings. As Washington State was the center of the United States' initial COVID-19 outbreak, there was limited experience in the presentation of COVID-19 patients in the outpatient setting. I noted that influenza-like-illness was not entirely accurate description of patients presenting in the outpatient setting. I noted that in our experience, many patients did not have elevated temperatures when they presented to the clinic and that their symptoms were more diffuse and variable than the typical influenza patient.

Our Clinic Was Built for This Moment

It was only the third week of the pandemic. I was immensely proud of our organization's accomplishment in proving that patients could self-collect a nasal sample. The method was much more comfortable for the patient, safer for health care workers, alleviated the shortage of nasopharyngeal swabs, and a faster way to collect specimens.

I am often asked how we accomplished this in the middle of a pandemic in such a short timeframe. In many ways, we were fortunate (and unfortunate) to be the site where the first COVID-19 patient was hospitalized, and the first outpatient community-acquired case of COVID-19 landed. Our clinic values people and has the right culture to respond to a situation as unique as a novel pandemic virus.

Our collaboration in 2009 with the Health District and other community health care entities led to an unified county-wide vaccination campaign, in which 29,000 H1N1 vaccinations were administered in a single day. In the H1N1 action report, we created a disaster supply depot storing PPE in our warehouse.

The clinic has fostered relationships with the public health department through which we conducted table-top exercises on a pandemic respiratory virus in January 2020. I served on the State of Washington Disaster Medical Advisory Board to the State of Washington Secretary of Health. The EMR systems and the degree of standardization of our urgent care facilities have allowed for programing the protocol so that every enrolled patient's information was recorded in a flowsheet and could be extracted electronically. It was fortuitous that I was a clinical research fellow of the United HealthGroup R & D division.

I cannot say enough positive things about our leadership. They understood that we were in the eye of the storm and recognized that this was indeed a pandemic before the WHO officially declared COVID-19 a pandemic on March 11th. Our urgent funding requests for supplies and personnel were rapidly approved outside of the standard review process. After the reference laboratory pulled out of the study at the 11th hour, Quest Diagnostics stepped in and generously performed thousands

of SARS-CoV-2 assays. The experimental plans were designed, executed and completed in a three short weeks in large part due to streamlined contracts, legal agreements, and expedited compliance oversight.

When I reflected on what we accomplished, I am filled with awe and gratitude for my clinic colleagues and their contributions. They are truly the heroes.

Related Works

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Caring for Others, but What About Us?

Francisco José Barbosa Camacho

Acknowledgement. I would like to thank all physicians, nurses, and health personnel who are fighting against COVID-19. A special thanks to the Biomedical Research Unit 02 and the Mexican Institute of Social Security staff for all their work and efforts to understand the impact of this pandemic on our hospital personnel. And to my love, who brought the best of me during the most difficult times.

The medical community often stands in a chaotic place. We are acclaimed by relieved patients or despised by their loved ones in cases where no effort was enough for saving their family member. A pandemic represents a similar situation. In some cases, it has brought us together as a species, taking care of each other and catching up with our relatives and friends; at the same time it has brought us apart when political or personal

quarrels arise in the light of misinformation and quarantine desperation. With new papers and data as a sword and personal protective equipment as a shield, hospital and medical personnel have been the front-line warriors against this invisible foe. We as researchers, since the beginning, have been fighting along them to provide updated and new information to tackle the situation at hand.

Personally, I have always thought that patient's mental and physical health is as important as the medical and hospital personnel's. Lately, research has been focused on finding new diagnoses or treatment options, often ignoring the mental baggage this period has accumulated in the medical community. Additional to the usual stressors suffered by the medical personnel—such as long-hour shifts and heavy workloads—the fear of contagion, aggression from the general population, and an even bigger workload in hospitals can contribute to elevated levels of burnout. We focused our efforts in exploring the impact on the mental health of our city's hospitals' staff, especially the intensity of fear and anxiety in the COVID-19 and non-COVID-19 exclusive hospitals, as those hospitals attend to the biggest part of our general population. As only a few studies have been made regarding our caretaker section of the population, we sought to find how our hospital personnel were coping through this difficult time. In our research, we found that the general population often showed higher fear levels than those found in hospital personnel. As expected, the nursing and medical staff presented higher levels of fear than other medical staff members. We hypothesized that this could be due to a better understanding of the disease in terms of contagion mechanisms. Also, when analyzing the anxiety produced by this new disease, we found that at least 10% of our sample presented dysfunctional levels of anxiety. Between the fear of being sick and the anxiety created due to treating COVID-19 patients, a mental health crisis is rising within the front-lines of attention.

Another under-studied area this year is the effect of the pandemic on the students' mental health and academic performance. We surveyed over six hundred university students to analyze the effects of the quarantine confinement and online classes on