Title: A Novel Method of Assessing Clinical Preparedness for COVID-19 and Other Disasters

Running Title: Assessing COVID19 Preparedness

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A Novel Method of Assessing Clinical Preparedness for COVID-19 and Other Disasters

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**Quality Issue:** The emergence of COVID-19 highlights the necessity of rapidly identifying and isolating potentially infected individuals. Evaluating this preparedness requires an assessment of the full clinical system, from intake to isolation.

**Initial Assessment:** Unannounced Standardized Patients (USPs) present a nimble, sensitive methodology for assessing this readiness.

**Choice of solution:** Pilot the Unannounced Standardized Patient methodology, which employs an actor trained to present as a standardized, incognito potentially infected patient, to assess clinical readiness for potential COVID-19 patients at an urban, community safety-net clinic.

**Implementation:** The Unannounced Standardized Patient was trained to present at each team’s front desk with the complaint of feeling unwell (reporting a fever of 101 degrees Fahrenheit in the past 24 hours) and exposure to a roommate recently returned from Beijing. The Unannounced Standardized Patient was trained to complete a behaviorally-anchored assessment of the care she received from the clinical system.

**Evaluation:** There was clear variation in care Unannounced Standardized Patients received; some frontline clerical staff followed best practices; others did not. Signage and information on disease spread prevention publicly available was inconsistent. Qualitative comments shared by the Unannounced Standardized Patients and those gathered during group debrief reinforced the experiences of the Unannounced Standardized Patients and hospital leadership.

**Lessons Learned:** Unannounced Standardized Patients revealed significant variation in care practices within a clinical system. Utilization of this assessment methodology can provide just-in-time clinical information about readiness and safety practices, particularly during emerging outbreaks. Unannounced Standardized Patients will prove especially powerful as clinicians and systems return to outpatient visits while remaining vigilant about potentially infected individuals.

**Quality Issue**
The spread of novel Coronavirus disease 2019 (or COVID-19) globally has required the rapid
development and implementation of protocols to safely care for patients while protecting healthcare
teams.\textsuperscript{1,2} In previous outbreaks, hospital systems underprepared for Ebola, Severe Acute Respiratory
Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) inadvertently contributed to the
spread of infection.\textsuperscript{3} A high degree of system preparedness reduces multi-level risk, and practices
that enable prompt identification and isolation of contagious individuals are essential in mitigating the
spread of emergent diseases.\textsuperscript{4}

**Initial Assessment:**

While healthcare systems have checklists and toolkits to assess clinical preparedness, new
methodologies to assess clinical implementation of safety protocols that go beyond routine health and
safety assessment are needed. Unannounced Standardized Patients (USP) can provide a
comprehensive, just-in-time assessment of the care a clinical system provides\textsuperscript{5} and catalyze solutions
by providing evaluation and education to a health care system on response to specific patient safety
concerns.

**Choice of solution:**

Unannounced Standardized Patients are a nimble methodology that can be mobilized to quickly
assess the entire clinical system and provide just-in-time information on care related to emerging
crises. Unannounced Standardized Patients enable the introduction of a controlled, standardized
“stimulus” into healthcare settings (standardizing the patient characteristics, clinical symptoms,
medical history, etc.) and provide immediate information on the care they receive. This pilot
intervention introduced Unannounced Standardized Patients in February of 2020, a period when
COVID-19 was circulating undiagnosed in many regions. They presented with potential COVID-19
symptoms to an urban, community safety-net clinic to assess, or test staff and clinician readiness
when faced with a hazardous pathogen.
Implementation:

Clinicians with experience in medical education and simulation – at the request of an urban community outpatient clinic – developed an Unannounced Standardized Patient case to test preparedness for evaluation of an outpatient, potentially infected with COVID-19. The Unannounced Standardized Patient was trained to present at each team’s front desk as a 25-year-old female who is a registered patient in the system. The Unannounced Standardized Patient presented with the complaint of feeling unwell (reporting a fever of 101 degrees Fahrenheit in the past 24 hours) and having exposure to a roommate recently returned from Beijing.

The Unannounced Standardized Patient was trained for the case and to complete a behaviorally-anchored assessment of the care she received from the clinical system (11 items), including: 1) response to provided concern and safety protocols followed by front desk staff, 2) overall experience of clinical microsystem and of clinic navigation; and 3) the patient-centeredness of care provided by the team. Training of the Unannounced Standardized Patient took thirty minutes and consisted of patient storyline and overview of the system structure review. Following the visit and prior to completion of the checklist, the Unannounced Standardized Patient participated in a facilitated debrief with clinical staff and leadership. Each visit went undetected until the Unannounced Standardized Patient disclosed that they were an actor during debrief; clinical staff was asked during debrief if they had identified the patient as an actor; they had not. The intervention team also solicited qualitative commentary on the experience from clinical leadership.

Evaluation:
Unannounced Standardized Patient visits (n=4) were conducted over a one-month period. Visits revealed variation in degree of clinical preparedness when confronted with a possibly infectious patient; Unannounced Standardized Patients participated in clinical debriefs to provide feedback on best practices and missed opportunities.

In half of visits, frontline clerical staff who first encountered the patient followed best practices in immediately providing a mask and isolating the patient. In both instances, the clinical staff explained the process of isolation to the patient before it occurred. Upon isolation, the Unannounced Standardized Patient reported being visited by a provider for assessment, and further identified them as wearing full personal protective equipment (PPE) (including gloves, gown, respiratory and eye protection) for the duration of the visit. COVID testing swabs were not collected. In half of visits (medicine clinic, lab/radiology), the frontline staff told the Unannounced Standardized Patient to go to another floor or return to the waiting room until further notice without providing a mask or calling a nurse or other clinician to perform a clinical assessment.

Hospital signage for prevention of COVID-19 spread was present in two of the four waiting rooms, and hand sanitizer stations were available in all four waiting areas. Qualitative comments reinforced the experiences of the Unannounced Standardized Patient and hospital leadership (Table 1).

**Lessons Learned:**

This just-in-time pilot assessment of an urban community clinic’s preparedness for patients presenting with possible COVID-19 or similar emerging infectious diseases captured critical, behaviorally-specific information on team and system performance. Unannounced Standardized Patients gathered three essential pieces of information for hospital leadership including (1)
quantitative, behaviorally-anchored information on their experience (2) qualitative, experiential feedback and (3) information from an in-person debrief with the clinical team who cared for them.

Results of the study showed that while clinical systems had protocols in place to engage with patients of possible infectious risk, they were not uniformly implemented. In half of the visits, frontline staff either failed to recognize or solicit triggers that would have merited immediate isolation of the patient. In visits where the Unannounced Standardized Patient was isolated, medical assistants provided explanation of the process and providers utilized appropriate PPE. These results served as a needs assessment and enabled teams to conduct an immediate, post-visit training on the COVID-19 symptoms isolation protocol.

Previous studies have outlined the ease and cost-effectiveness of Unannounced Standardized Patients for clinical effectiveness assessment. The Unannounced Standardized Patient methodology also provides crucial insight into the communication skills and patient-centeredness of the care team or providers. In feedback, the Unannounced Standardized Patient noted that the demeanor of the care team had a powerful impact on their sense of well-being during isolation. In one visit, they wrote “a sign was hung on the door, but I couldn't make out what it said…the provider seemed anxious and from the chatter outside the room I felt anxious myself.” While in another, “[the provider] walked next to me instead of in front of me and made me feel very comfortable.” This information, on how the care made the Unannounced Standardized Patient feel provides nuanced information that cannot easily be collected in a traditional, standardized assessment of clinical preparedness and can help health systems to make small changes in clinician behaviors than can vastly impact the patient’s emotional state. Further, in debrief following visits, clinical leadership was able to unmask the objectives of the drill and provide specific feedback on improvement areas for future risk mitigation. After each encounter with the Unannounced Standardized Patient a staff debriefing was conducted, gathering staffs view of what they felt they needed to be better prepared. A “no blame” culture was employed to
allow the affected staff to express their fears and concerns in dealing with a [person under investigation]. Staff input informed necessary protocol changes for handling other persons under investigation during future encounters. The integrations of Unannounced Standardized Patient into our quality improvement program models how Unannounced Standardized Patients can enable productive, engaging debriefs to teach system gaps and create a responsive learning health.

While Unannounced Standardized Patients are an underutilized methodology, we are not the first to employ them for assessing readiness for infectious disease. A pilot study employing Unannounced Standardized Patients to assess infectious disease preparedness in an emergency department found that patients were isolated during 78% of visits and that assessing travel history was correlated with isolation. Our assessment findings were similar. In instances where our Unannounced Standardized Patient was asked travel-related history upfront, they were placed in isolation. Expanding the use and number of our novel methodology to include additional clinical sites in our health system will provide a more thorough understanding of preparedness and allow us to make immediate adjustments to the implementation of safety protocols. Preparing frontline hospitals for emerging infectious disease is critical for the future of patient safety and prevention. Introducing Unannounced Standardized Patients to gather clinical safety data is the first step in identifying the gaps that could lead to system-wide infection.

Deploying Unannounced Standardized Patients provided rapid, inexpensive feedback to the clinical system on its responsiveness to potentially infected individuals. In this quality improvement project, the same Unannounced Standardized Patient case received notably different care at each desk she visited; teams were then able to promptly debrief lessons learned and establish new, relevant protocols. This model can be easily adapted at academic medical institutions who likely have cohorts of standardized patients, who can be trained to present as unannounced. As COVID-19 spreads and
social distancing evolves, rapid, meaningful feedback on outpatient preparation will be necessary. Unannounced Standardized Patients are a relatively easy way to ensure that clinics remain able to rapidly identify and isolate these patients, not only as infectious diseases emerge, but even after peak infections have subsided. The scope of findings of this study is limited by the number of cases sent to the clinic and time of visits (weekday, daytime only). Future Unannounced Standardized Patient visits will seek to also assess evening and overnight staff within the hospital. The use of standardized cases and evaluation tools can assist clinical systems in assessing capabilities and gaps, especially in emerging crises, allowing for rapid quality improvement to address critical needs.

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Data Availability: Data will be held in RedCap by NYU Langone and can be shared in an anonymized fashion.
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Table 1. Location/ Timing of Visit and Unannounced Standardized Patient (USP) Reported Experience

| Location     | Timing of visit                                                                 | Quotes from USP                                                                 |
|--------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Medicine     | USP arrived at 1:10 PM, presented symptoms, was told to wait in waiting area until 3:40 PM | “[She/He/They] then told me they had an appointment at 3:40 PM. If I stayed, [she/he/they] could register me as a patient now, or I could come back and be registered. If I stayed in the waiting room [she/he/they] explained I might be see sooner….I would have infected countless people over the course of the next few hours [if I had waited in waiting room]” |
| Desk X       |                                                                                 |                                                                                |
| Medicine     | USP arrived at 1:20 PM, brought to isolation and began visit with provider at 1:31 PM | “Despite sensing that something serious was going on, I felt like I was in capable hands due to [her/his/their] direct nature and desire to get me to the nurses as quickly as possible” |
| Desk Y       |                                                                                 | “I was introduced to X, a nurse, who escorted me in and told me to wait. When I was first introduced to X, [she/he/they] was not wearing |
protective gear. I waited-outside the room I could hear general hubbub and it seemed like other people had been gathered to assist. A sign was hung on the door, but I couldn't make out what it said. There was a general air of chaos, unease, and confusion on what the proper protocol was.”

“The provider seemed anxious and from the chatter outside the room, I felt anxious myself. I didn’t know what was going on and that they didn’t even know if they could take my temperature led to my feeling like they did not have a plan for me”

| Eye and Vision Desk | USP arrived at 11:00 AM, brought to isolation and began visit with provider at 11:15 AM |
|---------------------|------------------------------------------------------------------------------------------|
|                     | “[the staff at front desk] was very kind but did not immediately ask me the travel question which led to my waiting at the desk for ten minutes as we sorted through logistical items.” |
|                     | “The supervisor introduced herself and led me to a room and told me to make myself comfortable.” |
| Location            | Event Description                                                                 | Patient Experience                                                                 |
|---------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Lab and Radiology Desk | USP arrived at 11:15 AM, presented symptoms, and was told to go to medicine floor | [She/He/They] was very kind and did not make me feel anxious in the least. [She/He/They] kept repeating that everything was going to be okay and they were going to take care of me. [She/He/They] walked next to me instead of in front of me and made me feel very comfortable. When we got to the isolation room [she/he/they] told me to make myself comfortable and that someone would be in shortly."

"[She/He/They] collected all my vitals and was very calm and did not seem worried about what was happening, which was a marked changed from my last visit and very welcome. I felt like I was in very capable hands."

"The clinic was calm and pleasant and the waiting room was well organized. The trouble was I was expected to take a number and I was there for other reasons so I did not."
