Protocol-Driven Intensive Outpatient Management of Pregnant Patients With Symptomatic Coronavirus Disease 2019

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Background. Reports of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection have focused on pregnant women hospitalized due to moderate to severe coronavirus disease 2019 (COVID-19) or asymptomatic women diagnosed through universal screening at the time of obstetric admission. Many pregnant women who have symptomatic SARS-CoV-2 infection may not meet criteria for hospitalization; however, whether and how these women can be managed safely in outpatient setting is not well described.

Methods. We sought to describe the time to symptom and viral clearance and to identify predictors of hospitalization to better understand the safety of monitoring pregnant patients with symptomatic COVID-19 in the outpatient setting. We performed a retrospective cohort study of pregnant patients with symptomatic, confirmed COVID-19 illness at a large, academic medical center. Patients had systematic telehealth follow up by a clinician team to assess for symptoms, provide virtual prenatal care, and arrange in-person visits when appropriate in a dedicated outpatient center. Data were collected via chart abstraction.

Results. Of 180 pregnant patients presenting with symptoms and undergoing reverse-transcription polymerase chain reaction (RT-PCR) testing, 67 patients with confirmed COVID-19 infection were identified during the study period. Nineteen (28%) required acute care given worsening of COVID-19 symptoms, and 95% of these were directed to this acute care setting due to symptom severity telehealth evaluation. Nine women (13%) were admitted to the hospital given worsening symptoms, 3 required intensive care unit care, 2 required ventilatory support, and 2 required delivery. Women with the presenting symptoms of fever, cough, shortness of breath, chest pain, or nausea and vomiting were more likely to require admission. The median duration from initial positive test to RT-PCR viral clearance was 26 days. Disease progression, time to viral clearance, and duration of symptoms did not vary significantly by trimester of infection.

Conclusions. Management of the majority of pregnant women with symptomatic COVID-19 illness can be accomplished in the outpatient setting with intensive and protocol-driven monitoring for symptom progression.

Keywords. COVID-19; COVID-19 prenatal care; outpatient care; outpatient management; pregnancy.
MATERIALS AND METHODS

We performed a retrospective cohort study of all pregnant women receiving prenatal care at a large, academic medical center serving patients from multiple communities presenting with symptoms consistent with COVID-19 illness and confirmed to have SARS-CoV-2 infection by reverse-transcription polymerase chain reaction (RT-PCR) nasopharyngeal swabs from March 6 to May 22, 2020. Women receiving care at other institutions or who were transferred to our institution for inpatient management were excluded from this analysis.

The cohort was identified by the study staff through 2 primary mechanisms: (1) all patients who called the outpatient prenatal care office with symptoms concerning for COVID-19 illness who were subsequently tested for SARS-CoV-2 infection, and (2) all patients with prenatal care at our outpatient center who presented to the emergency room and/or labor and delivery triage with symptoms concerning for COVID-19 illness and subsequently underwent testing. All patients with confirmed intrauterine pregnancies who were treated in the emergency room or by other services and met criteria as described above were included in this analysis. Ascertainment was optimized by 2 methods: (1) all providers were asked to submit patients with COVID-19 evaluations to our clinical team, and (2) our clinical list was cross-referenced daily against a hospital-wide daily census of COVID-19-positive patients. As depicted in Figure 1, testing criteria in Massachusetts evolved throughout the study period, and thus not all patients with symptoms concerning for COVID-19 illness underwent testing. Those without testing data available were not included in the analysis. We did not include asymptomatic patients because the ascertainment of data would have been incomplete because the availability of and guidelines for testing asymptomatic patients changed over time.

Outpatient Tracking and Telehealth Care for Pregnant Women With Coronavirus 2019

Pregnant women with symptoms consistent with COVID-19 who were found to be positive for SARS-CoV-2 were followed on a patient tracking list. This list was kept via the Epic electronic health record system, which is a secure platform for the safeguarding of health information.

A team of obstetricians and obstetrical registered nurses followed these patients with 3 times weekly phone calls to (1) assess for COVID-19-related symptoms and screen for severity according to the ACOG guidelines [9], (2) provide telemedicine prenatal care and anticipatory guidance about pregnancy during the quarantine period, (3) arrange for repeat testing to confirm clearance of the infection and subsequent return to in-person prenatal care as per CDC recommendations at the time of the study, and (4) arrange in-person appointments and

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Figure 1. Pregnant patients with symptoms concerning for severe acute respiratory syndrome coronavirus 2 infection. COVID-19, coronavirus disease 2019.
ultrasounds in a hospital-wide COVID-19 ambulatory care center when prenatal care could not be deferred until clearance. Dedicated team members with Spanish language proficiency reached out to Spanish-speaking patients when appropriate. These calls were scripted using the template in Appendix A. All patients were instructed to present for repeat PCR testing as soon as possible by the dedicated staff as per CDC guidelines at the time of the study and irrespective of the patient’s gestational age (GA).

When in-person visits were required as determined by the modified prenatal care schedule (Appendix B), patients were seen with appropriate personal protective equipment (PPE) in a dedicated COVID-19-specific area, named the RACC (Routine Ambulatory Care for COVID-19 patients) (Figure 2). Based on hospital policies during this period, we defined viral clearance as 2 consecutive COVID-19 negative test results performed at least 24 hours apart after the resolution of symptoms. Once viral clearance was achieved, patients were removed from this close monitoring by the clinic staff and returned to the routine combination of in-person and virtual prenatal care visits [8].

Data Abstraction
Data for patients with suspected SARS-CoV-2 infection were collected prospectively in a password-protected REDCap database. Patient demographics including maternal age, self-reported ethnicity/race, insurance, and preferred language were abstracted from the electronic medical record by a trained clinical research coordinator. In addition, pregnancy-specific variables such as GA, parity, prepregnancy body mass index (BMI), and medical comorbidities were recorded. The COVID-19-specific information including initial symptoms, duration and severity of symptoms, need for emergency room visits, or hospitalization were also collected, as well as information regarding interruption of prenatal care, including delay of in-person visits and need for visits in the RACC. All SARS-CoV-2 testing data were collected and stratified by GA at diagnosis and at viral clearance. Additional laboratory evaluation for COVID-19 prognostic markers were not routinely collected and were therefore not included in this analysis. All data abstracted were verified by chart review when applicable and verified by the primary author. Any missing data were supplemented with chart review, and if these remained unknown, they were reflected in the denominator reported. This study was approved by the institutional review board and received a waiver of informed consent.

Data Analysis
Patient characteristics for the cohort of symptomatic, SARS-CoV-2-positive patients were summarized with descriptive statistics. The COVID-19-specific parameters, such as presenting symptoms, day of disease progression (calculated as days from date of symptom onset to date of presentation to the emergency department or hospital admission for COVID-19 symptom severity), any acute care presentation (visit to the emergency room or hospitalization), hospitalization-specific factors (intensive care unit [ICU] admission and ventilator use), time to symptom clearance (calculated as days from date of symptom onset to the date of symptom clearance), and time to viral clearance (calculated as days from date of positive test result to the date of second negative test result), were summarized with descriptive statistics. In addition, all charts were abstracted to determine location of visits (routine prenatal care or RACC) as well as delays in prenatal care based on our modified approach to prenatal care during this time. Time to SARS-CoV-2 RT-PCR clearance, time to symptom resolution, and symptom day of disease progression were compared by trimester at time of diagnosis using Student’s t test.

To examine demographic and COVID-19 disease course differences between patients who required hospitalization and patients who were managed as outpatients, χ² tests, Fisher’s exact test, Student’s t tests, or Mann-Whitney U tests were applied, as appropriate. Due to the small number of patients requiring hospitalization, further adjusted modeling could not be conducted. All statistical analyses were conducted in Stata 15.0. P < .05 was used to represent statistical significance.

RESULTS
Of the 232 symptomatic women identified, 180 women were tested and 67 women with outpatient care at our institution were found to be positive for SARS-CoV-2 by RT-PCR (Figure 2). All patients in this cohort were then closely monitored via telephone visits by a COVID-19 team of physicians and nurses, and no patients were lost to follow up. Among the cohort of 67 women with symptoms and confirmed SARS-CoV-2 infection, the average maternal age was 31 years, and 31% were nulliparous. Although Hispanic women make up 17% of our pregnancy population, 61% of women in this cohort were Hispanic by self-reported ethnicity. Table 1 summarizes demographic characteristics including underlying medical comorbidities. Of women in our cohort, 37% were in the second trimester and 49% were in the third (Table 1).

The most common presenting symptoms were cough (72%), runny nose (57%), and myalgia (52%). Fever was reported in 42% of patients and shortness of breath in 39%. The least common

Figure 2. Routine ambulatory care for coronavirus disease 2019 (RACC (Routine Ambulatory Care for COVID-19 patients)).
The presenting symptom was nausea and vomiting, reported in 10% of patients (Table 2). In-person prenatal care visits that would have been planned based on our modified approach to prenatal care during this time were delayed due to COVID-19 in 23 patients, or 35% of the cohort. In addition, 17 patients (25%) required visits in the RACC given the inability to delay in-person care.

The median duration from initial positive test to viral clearance, as defined in Methods, was 26 days with a range of 10–56 days. Patients reported symptoms for an average of 17 days with a range of 3–45 days (Table 2). Day of disease progression, day of hospitalization (both as defined in Methods), time to viral clearance, and duration of symptoms did not vary by trimester of infection (Table 3).

Although the majority of pregnant women in this cohort were managed as outpatients, 19 (28%) required presentation to an acute care setting because of worsening symptoms of COVID-19 illness. The average day of acute care presentation was day 5.7, with a standard deviation of 4.5 days. Nine patients (13% of the total cohort) were admitted to the hospital. Among those 19 women with increased symptom severity necessitating an acute care visit, 18 (95%) had a telephone visit with a provider before their presentation in which their symptoms were assessed for severity, and they were advised to present for further evaluation. The single patient who presented to an outside emergency department without prompting by a telehealth provider had developed worsening symptoms between her 3 times weekly clinic follow-up calls. She was not admitted to the outside institution. None of the patients sent to the hospital were sent for obstetrical complaints.

Of the 9 women admitted to the hospital secondary to complications from COVID-19 illness, 3 women required ICU admission, 2 required ventilatory support, and 2 were delivered. To identify potential predictors of hospitalization, women requiring hospitalization were compared to the women who continued outpatient management (Table 4). Women hospitalized were more likely to present with initial symptoms of fever ($P = .019$), cough ($P = .042$), shortness of breath ($P = .01$), chest pain ($P = .041$), or nausea and vomiting ($P = .001$). As anticipated based on symptom severity, patients who required admission to the hospital reported persistence of symptoms for longer than women who were not admitted (24 vs 14 days, $P = .002$); however, time to viral clearance did not vary between the groups (18 vs 18 days, $P = .6$).

| Demographic | Confirmed COVID-19-Positive Cohort (N = 67) |
|-------------|---------------------------------|
| Age (mean ± SD) | 31 ± 6.2 |
| Parity (mean ± SD) | 1.3 ± 1.3 |
| Nulliparous | 21 (31%) |
| Hispanic | 41 (61%) |
| Race | |
| Black | 7 (10%) |
| White | 15 (22%) |
| Asian | 1 (1%) |
| Other/Unspecified | 44 (66%) |
| Primary language | |
| English | 34 (51%) |
| Spanish | 30 (45%) |
| Other/Unspecified | 3 (4%) |
| Prepregnancy BMI (mean ± SD) | 29 ± 4.4 |
| Insurance | |
| Public | 37 (55%) |
| Private | 26 (39%) |
| None | 1 (1%) |
| Unspecified | 3 (4%) |
| Medical Comorbidities | |
| Gestational DM | 9 (13%) |
| Pregestational DM | 1 (1%) |
| Chronic hypertension | 7 (10%) |
| Asthma | 8 (12%) |
| Chronic liver disease | 1 (1%) |
| Gestational age at first diagnostic sign, in weeks (mean ± SD) | 25.5 ± 9.7 |
| First trimester | 9 (13%) |
| Second trimester | 25 (37%) |
| Third trimester | 33 (49%) |

| Table 1. Demographics |
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| Table 2. COVID-19-Specific Information |
|---------------------------------------|
| Clinical Characteristic | Confirmed Symptomatic Cohort (N = 67) |
| Initial Symptoms | |
| Fever | 28 (42%) |
| Cough | 48 (72%) |
| Shortness of breath | 26 (39%) |
| Chest pain | 13 (19%) |
| Myalgia | 35 (52%) |
| Runny nose | 38 (57%) |
| Sore throat | 22 (33%) |
| Anosmia | 23 (34%) |
| Nausea/vomiting | 7 (10%) |
| Duration of symptoms (days) (mean ± SD)$^a$ | 172 ± 9.7 |
| Time from positive test to clearance (days) (mean ± SD)$^b$ | 28.5 ± 11.9 |
| Presentation for acute care | 19 (28%) |
| Disease day of acute care presentation (mean ± SD) | 5.7 ± 4.5 |
| Called for severity$^c$ | 18 (95%) |
| Hospitalization for COVID-19 illness | 9 (13%) |
| Disease day of hospitalization (mean ± SD) | 6.2 ± 1.9 |
| ICU admission | 3 (33%)$^d$ |
| Ventilator use | 2 (22%)$^d$ |
| Delivery | 2 (22%)$^d$ |

Abbreviations: BMI, body mass index; COVID-19, coronavirus disease 2019; DM, diabetes mellitus; SD standard deviation.

$^a$N = 64 patients had complete data on symptom resolution at the time of this manuscript.

$^b$N = 45 patients had complete data on COVID-19 clearance at the time of this manuscript.

$^c$Denominator is patients with acute care presentations (n = 19).

$^d$Denominator is all those hospitalized (n = 9).
All 67 patients were contacted regularly with telephone visits documented in the medical record. Some patients were still being followed at the time that data analysis began and therefore information regarding symptom duration and viral clearance was not yet available. No patient was lost to follow up.

### DISCUSSION

In our cohort, we found that among 67 symptomatic pregnant patients with confirmed SARS-CoV-2 infection receiving outpatient care at our institution, the majority experienced mild symptoms and could undergo continued outpatient management for both of their COVID-19 symptoms and their routine prenatal care. Among our cohort, 19 (28%) required an acute level of care, only 9 (13%) required hospitalization for COVID-19 disease progression, and only 3 required ICU admission. The majority of patients were able to remain at home; however, of those requiring an acute care setting, progression of disease severity occurred on average on day 6 after symptom onset. In addition, among those requiring presentation to an acute care setting for COVID-19 illness, 95% had a telephone encounter with our team before their presentations, appropriately triaging these patients for further evaluation. We also identified that having initial symptoms of fever, cough, shortness of breath, chest pain, and nausea and vomiting were associated with higher rates of disease progression and hospitalization. We did not find an association between maternal ethnicity, race, BMI, age, or GA of infection and acute care needs.

These findings echo the findings by Breslin et al [4] who reported a 14% rate of hospitalization among 29 symptomatic women initially managed at home; however, this differs from the most recent findings published by the CDC identifying a 31% risk of hospitalization [10]. Although the CDC data are representative of a large group of patients, their data notably did not distinguish between hospitalizations for obstetrical indications and those for COVID-19 complications. Our data was able to differentiate by reason for hospitalization, perhaps making it more representative of the risk for COVID-19-related hospitalizations.

Although the majority of pregnant patients with COVID-19 illness experience mild disease [1, 3–6] similar to what has been reported for the general population [7], it is unknown whether pregnant patients experience symptoms similarly to nonpregnant individuals. In our cohort, the most common symptoms were cough, myalgia, fever, and shortness of breath, and the average duration of symptoms was 17 days with a range of 3 to 45 days. In addition, the CDC reports that progression to severe disease, should it occur, is a higher risk at day 7 after symptom onset [11]. Among our hospitalized patients, the average day after symptom onset at which women required acute care was day 6.

The pregnant population is a unique outpatient group because their ongoing care varies in frequency as the pregnancy progresses and may not be able to be safely deferred or performed via telemedicine given GA-specific screenings and testing [12]. Although ACOG has proposed safe changes to the prenatal care schedule for all patients during the time of the pandemic, the prenatal care schedule for patients with documented ongoing SARS-CoV-2 infection continues to be changed and adapted [13].

At our institution, retesting pregnant women to confirm viral clearance was a clinical priority of the COVID-19 care team in anticipation of needed in-person visits and potential need for labor and delivery to occur during this time period. In this cohort, we identified a median of 26 days from initial positive test to clearance of the infection defined as 2 negative tests performed 24 hours apart. However, there was a large range of clearance from 10 to 56 days. This prolonged demonstration of RT-PCR-positive viral status may impact the prenatal care schedule differentially according to trimester. For women with infection during the early trimester, it would be reasonable to defer routine visits until patients have recovered fully from their COVID-19 illness. However, should patients require time-sensitive assessments such as fetal anatomical survey evaluation, glucose screening, antenatal testing, or group B streptococcus screening, it may not be possible to defer their visits until viral clearance has been demonstrated. In our center, we were able to care for all patients with documented SARS-CoV-2

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### Table 3. Clearance Days, Disease Progression, and Symptom Days by Trimester

| Clinical Characteristic | 1st (0–11.9 Weeks) (n = 9) | 2nd (12–27.9 Weeks) (n = 26) | 3rd (28–40 + Weeks) (n = 33) | Global P Value |
|-------------------------|-----------------------------|-------------------------------|-------------------------------|----------------|
| Time from RT-PCR positive test to RT-PCR clearance (days) | 38.3 ± 7.7 | 26.8 ± 10.8 | 273 ± 13.1 | .095 |
| Time from first symptom to symptom resolution (days) | 18 ± 9.0 | 17 ± 10.1 | 172 ± 9.8 | .97 |
| Disease day of acute care presentation | 3.5 ± 0.7 | 6.7 ± 6.0 | 5.4 ± 3.7 | .67 |
| Disease day of hospitalization | — | 5.6 (2.1) | 7 (1.6) | .31 |

Abbreviations: RT-PCR, reverse-transcription polymerase chain reaction.

a All data presented as mean ± standard deviation.

b For those who presented to acute care (total N = 19; 1st trimester N = 2; 2nd trimester N = 7; 3rd trimester N = 10).
forc For those who were admitted to the hospital for coronavirus disease 2019 (total N = 9; 1st trimester N = 0; 2nd trimester N = 5; 3rd trimester N = 4).
Although time to viral clearance has not previously been described in a pregnant population, prolonged positive RT-PCR test results have been reported in a nonpregnant cohort [14–16], and, more importantly, no viral transmission has been documented from infected individuals 9 days after symptom onset despite persistently positive RT-PCR testing [17, 18]. Given these findings, the CDC introduced the idea of time-based infection clearance that allows for resolution of COVID-19-enhanced precautions based on symptom resolution and time elapsed since the onset of symptoms [19]. These clinical recommendations were implemented after completion of this database, and therefore 2 consecutive negative RT-PCR tests were required for clearance during the study time period. Utilizing the time-based infection status resolution in future pregnant cohorts may improve the prenatal and hospital-based care of pregnant women with SARS-CoV-2 infection by avoiding the resource-heavy pursuit of 2 consecutive negative tests, which does not correlate with disease transmission. However, it is important to note that because our pregnant cohort was symptomatic for an average of 17 days, the CDC’s current time-based clearance of 10 days after symptom onset will allow for clearance of persistently symptomatic patients. Although transmission is thought to not occur at this time point, it will be important to educate patients and providers that women may continue to experience symptoms even when they are thought to be out of the window the risk for COVID-19 transmission. In addition, it is important to note that although this study used test-based clearance no longer recommended by the CDC, we were able to continue to care for all patients despite a longer time required for clearance. Current time-based guidelines may decrease the delay in routine prenatal care delivery, or they may decrease the need for designated clinical areas such as the RACC.

Although disease progression was not common in our cohort, when increased severity occurred in this population, it occurred at a similar time frame compared to the general population, namely, on day 6. Understanding the time course of disease progression in a pregnant population can aid providers caring for these patients in the outpatient setting to anticipate care needs, provide anticipatory guidance for patients, and plan closer contact during the time when the potential for additional care is highest.

Further research is needed to identify predictors of disease progression that can guide the triage of pregnant women with COVID-19 to supportive care at home versus the acute care setting. In our center, in anticipation of a second wave, we plan to center telemedicine calls for COVID-19-affected patients at approximately day 6 and to provide enhanced anticipatory guidance for those presenting initially with more severe symptoms. In addition, future studies should aim to describe maternal, fetal, and neonatal outcomes by maternal disease severity and timing of maternal infection with SARS-CoV-2 according to

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### Table 4. Patient and COVID19 Factors by Hospitalization Status

| Demographic and/or Clinical Characteristic | Managed Outpatient (n = 58) | Hospitalized for COVID19 (n = 9) | P Value |
|-------------------------------------------|----------------------------|---------------------------------|---------|
| Age (median, IQR)                         | 30.5 (28–35)               | 31 (28–35)                      | .96     |
| Parity (median, IQR)                      | 1 (0–2)                    | 1 (0–1)                         | .22     |
| Nulliparous                               | 17 (29%)                   | 4 (44%)                         | .36     |
| Hispanic                                  | 36 (62%)                   | 5 (56%)                         | .71     |
| Race                                      |                            |                                 | .85     |
| Black                                     | 6 (10%)                    | 1 (11%)                         |         |
| White                                     | 12 (21%)                   | 3 (33%)                         |         |
| Asian                                     | 1 (2%)                     | 0 (0%)                          |         |
| Other/Unspecified                         | 39 (67%)                   | 5 (56%)                         |         |
| Primary Language                          |                            |                                 | .52     |
| English                                   | 28 (48%)                   | 6 (67%)                         |         |
| Spanish                                   | 27 (47%)                   | 3 (33%)                         |         |
| Other                                     | 3 (5%)                     | 0 (0%)                          |         |
| BMI (median, IQR)                         | 29.1 (25.2–31.2)           | 30.7 (29.8–34.7)                | .062    |
| Insurance                                 |                            |                                 | .59     |
| Public                                    | 33 (57%)                   | 4 (44%)                         |         |
| Private                                   | 21 (36%)                   | 5 (56%)                         |         |
| None                                      | 1 (2%)                     | 0 (0%)                          |         |
| Unknown                                   | 3 (5%)                     | 0 (0%)                          |         |
| Medical Comorbidities                     |                            |                                 |         |
| Gestational diabetes                      | 8 (14%)                    | 1 (11%)                         | .83     |
| Pregestational diabetes                   | 1 (2%)                     | 0 (0%)                          | .69     |
| Chronic hypertension                      | 5 (9%)                     | 2 (22%)                         | .21     |
| Asthma                                    | 6 (10%)                    | 2 (22%)                         | .31     |
| Chronic liver disease                     | 1 (2%)                     | 0 (0%)                          | .69     |
| Initial Symptoms                          |                            |                                 |         |
| Fever                                     | 21 (36%)                   | 7 (78%)                         | .019    |
| Cough                                     | 39 (67%)                   | 9 (100%)                        | .042    |
| Shortness of breath                       | 19 (33%)                   | 7 (78%)                         | .010    |
| Chest pain                                | 9 (16%)                    | 4 (44%)                         | .041    |
| Myalgia                                   | 28 (48%)                   | 7 (78%)                         | .099    |
| Runny nose                                | 33 (57%)                   | 5 (56%)                         | .94     |
| Sore throat                               | 18 (31%)                   | 4 (44%)                         | .43     |
| Anosmia                                   | 21 (36%)                   | 2 (22%)                         | .41     |
| Nausea/vomiting                           | 3 (5%)                     | 4 (44%)                         | .001    |
| Duration from positive test to clearance (days) (median, IQR) | 18 (14.5–21.5) | 18 (16–26) | .91 |
| Duration of symptoms (days) (median, IQR) | 14 (7–18) | 24 (18–31) | .002 |
| Gestational age at first diagnostic sign, in weeks (median, IQR) | 27.9 (176–32.4) | 25.7 (20.1–28.9) | .83 |
| First trimester                           | 9 (16%)                    | 0 (0%)                          | .31     |
| Second trimester                          | 20 (34%)                   | 5 (56%)                         |         |
| Third trimester                           | 29 (50%)                   | 4 (44%)                         |         |

Abbreviations: BMI, body mass index; COVID-19, coronavirus disease 2019; IQR, interquartile range.
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