CLINICAL PHARMACY RESEARCH REPORT

Appointment attendance and patient perception of drive-up INR testing in a rural anticoagulation clinic during the COVID-19 pandemic

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Abstract

Introduction: The Anticoagulation Forum and Centers for Disease Control and Prevention (CDC) recommend drive-up international normalized ratio (INR) testing to combat INR non-adherence and increase safety during the coronavirus disease 2019 (COVID-19) pandemic. Patient perceptions and impact on attendance have not been studied.

Objective: To assess appointment volume and patient perception after initiation of drive-up INR testing in a rural pharmacist-managed anticoagulation clinic.

Methods: This cross-sectional cohort survey study offered each patient attending the anticoagulation clinic via drive-up or in-office visit a survey between May 27 and July 2, 2020. Patients testing off-site were excluded. Study end points included monthly patient volume, visit type preference, testing barriers, desired drive-up duration, and overall clinic satisfaction. Clinic appointment volume from October 2019 to June 2020 was collected retrospectively through a schedule review.

Results: Sixty-four (80%) of 80 surveys offered were completed: 46.6% of respondents preferred drive-up testing, 26.7% indifferent, and 26.7% preferred in-office visits; 38.7% of respondents indicated a greater likelihood of continuing routine INR monitoring via drive-up testing. Of the respondents completing the survey curbside, 46% and 27% of respondents identified reduced COVID-19 transmission risk and ease of transportation as benefits of drive-up INR testing, respectively. March and April clinic volumes were 19% and 22% below average, respectively, returning to baseline after drive-up testing was implemented. Clinic rating before and after drive-up testing remained high at 2.75 on a scale of 0-3. While infection risk was identified as the biggest barrier to care by 32.8% of respondents, 59.3% of all respondents wanted drive-up testing to continue indefinitely.

Conclusions: Drive-up INR testing improves patient attendance during the COVID-19 pandemic. Patient perception of drive-up testing is positive. About 46% of respondents preferred drive-up INR testing with telehealth follow-up and 59.3% of respondents want drive-up testing to continue indefinitely, which suggests this
It is well documented that routine international normalized ratio (INR) monitoring is a critical component of safe and effective warfarin management.\textsuperscript{1-3} Data from the IN-RANGE trial suggest that as many as 40% of patients have significant poor adherence, and that poor adherence is associated with double the rate of out-of-range INRs.\textsuperscript{4} The correlation of poor time in therapeutic range and poor outcomes is well established.\textsuperscript{1-3}

However, routine monitoring typically requires regular contact with the health system. During the coronavirus disease 2019 (COVID-19) pandemic, it has been documented that patients are avoiding health care in order to maintain social distancing and reduce potential virus exposure.\textsuperscript{5} The National Cardiac Societies, the Anticoagulation Forum, and the Centers for Disease Control and Prevention (CDC) recommend drive-up INR testing with telehealth assessment and follow-up as a method to continue routine monitoring with significantly less potential for virus exposure.\textsuperscript{6-8}

Several papers present broad strategies to employ telehealth and social distancing while continuing chronic care management, including anticoagulation management.\textsuperscript{9-11} Drawing inspiration from these sources, the clinic described in this paper altered its model of care to include an alternative option of drive-up INR testing. This model combines drive-up INR testing with phone-based anticoagulation management. At this clinic, patients may opt for this model or traditional, in-office visits based on personal preference.

As with many of our adaptions to the novel and ever-changing pandemic, evidence supporting drive-up INR testing is limited. The purpose of this study is to assess patient perceptions of drive-up INR testing with telehealth assessment and follow-up during the COVID-19 pandemic. Additional goals include determining impact of drive-up INR testing on warfarin monitoring adherence, assessing overall clinic satisfaction, and identifying the non-COVID-19 barriers addressed by drive-up testing.

1 | METHODS

1.1 | Study design and patient population

This cross-sectional cohort study describes a survey of patients at a rural anticoagulation clinic. All adult patients on warfarin therapy managed by the anticoagulation clinic were eligible for survey between the dates of May 26 and July 2, 2020. A six-week survey duration was expected to reach the majority of clinic patients and assess their perceptions of the newly initiated drive up service. Patients with home INR meters or other methods of off-site INR testing precluding in-office or drive-up visits were excluded. Additionally, initial visits to establish care were required to be in-person to complete anticoagulation education. Retrospective medical record analysis of appointment volume and individual patient volume was then collected from October 2019 through June 2020. Time in therapeutic range (TTR) was calculated quarterly retrospectively for the clinic from January 2020 through June 2020. This study was approved as exempt by the University of Illinois at Chicago Health Sciences Center at the Rockford Institutional Review Board (IRB).

1.2 | Objectives

The primary objective was to assess patient perceptions of drive-up INR testing with telehealth assessment and follow-up during the COVID-19 pandemic. Secondary objectives included determining if drive-up INR testing impacts patient attendance at routine INR monitoring appointments, measuring overall clinic satisfaction, and establishing data on barriers to care other than those associated with COVID-19.

1.3 | Program description

On May 4, 2020, the anticoagulation clinic altered its model of care to include drive-up INR testing with phone-based anticoagulation management. Prior to this date, 90% of clinic patients were seen in person for routine INR monitoring, assessment, and follow-up, and only 10% of patients utilized home INR meters or other methods of off-site testing (home health care or venous INR at a remote lab). In-person testing requires patients to travel from home to the hospital, park, interact with an employee to screen their temperature at the entrance, wait in line at registration, and navigate approximately 50 yards to the clinic office. Initially, the anticoagulation clinic offered extended interval INR testing in stable patients, but the duration of the COVID-19 pandemic and Illinois stay-at-home order necessitated a novel care model.

All patients were given the option to continue with traditional, in-office visits or opt for drive-up INR testing with telehealth assessment and follow-up. Drive-up patients were instructed to pull up to a conveniently located circle driveway under a weather-protected awning at their pre-specified appointment time. Efforts were made to schedule drive-up appointments within a 90-minute window of a 4-hour clinic session, but exceptions were made for patients unable to arrive in the 90-minute drive-up testing period. Anticoagulation clinic staff (pharmacist and/or 1-2 advanced pharmacy practice experience
(APPE) student[s]) met each patient curbside with an INR meter and associated supplies. The blood sample was collected from patients who remained in their cars and was analyzed immediately. Two INR machines were available to limit patient wait times and protect against machine malfunction. Patients with point-of-care INR results ≥4.9 were offered venous INR verification per clinic policy. Patients were provided written INR results on a warfarin dosing card and told to stay by their phones for further instruction. A formal patient assessment was not completed at this time to minimize person-to-person exposure, but patients often noted missed/extra doses, bleeding/bruising, etc., which was formally assessed upon a follow-up phone call. The entire interaction took an average of 3 minutes (plus survey time, if necessary). Once patients drove away, the anticoagulation clinic staff returned to the office where results were entered electronically and patients were telephoned within 3 hours of their appointment time for further data collection, clinical workup, assessment, and plan. Patients were provided dosing instructions and a follow-up appointment date and time on the phone.

1.4 | Data collection

Patients presenting to either traditional, in-office care or drive-up INR testing between the dates of May 26 and July 2, 2020 were provided a paper survey (Supporting Information). Patients were instructed to complete the survey prior to receiving INR testing. Results were collected anonymously. Demographic data, including age and sex, were collected via chart review immediately as each patient completed the survey. Once patients completed the survey, demographics were marked by clinic staff and the survey was placed in a folder without any unique identifiers to ensure survey and patient anonymity. On average, the survey took 2 to 3 minutes to complete. No guidance was provided to patients as to how to complete the survey. Patients were only surveyed once, even if they were seen in the clinic multiple times during the survey period. If a patient declined a survey, they were offered the survey again at subsequent visits. The survey addressed:

1. Preference of visit type.
2. Difficulties attending INR visits in the past.
3. Reason for currently using drive-up INR testing (if applicable).
4. Likelihood of attending each type of clinic visit (drive-up or in-person).
5. Length of time that drive-up services should be offered in the future.
6. Perception of the anticoagulation clinic before the COVID-19 pandemic (on a 0-3 scale).
7. Perception of the anticoagulation clinic at the time of care (on a 0-3 scale).
8. Avoidance of seeking medical care due to the COVID-19 pandemic.

The medical record was retrospectively analyzed to determine appointment volumes, unique patient volumes, and TTR to determine if compliance with routine monitoring was impacted by the COVID-19 pandemic and/or by drive-up INR testing. Individual appointments were counted to determine appointment volume and individual patients were counted to determine unique patient volume. Rates prior to the pandemic and during the survey period were compared.

1.5 | Statistical analysis

Frequency distributions were done for each of the study variables using IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, New York). Paired t-tests were used to determine differences between a survey respondent’s rating of the clinic before and after the start of drive-up testing. Due to non-normal distribution of values, Mann-Whitney nonparametric tests were used to assess the difference in clinic ratings between patients who were seen curbside compared with face-to-face appointments.

2 | RESULTS

2.1 | Baseline characteristics

During the survey period, there were 172 (134 curbside and 38 face-to-face) encounters with 80 individual patients at the anticoagulation clinic. Each individual patient was offered a survey. Sixty-four of 80 surveys offered were completed, representing an 80% response rate. Of those who completed surveys, 53 (82.8%) were seen curbside and 11 face-to-face. There was no difference in visit type distribution between those who completed the survey and all patients seen in the anticoagulation clinic during the survey period. There were also no differences in baseline characteristics of age and sex between those who were surveyed curbside and those surveyed face-to-face (Table 1).

2.2 | Primary objective

Based on survey results, 46.6% of respondents preferred drive-up INR testing with telehealth follow-up, while 26.7% preferred face-to-face visits during the COVID-19 pandemic; 26.7% of respondents had no preference between the two visit types (Figure 1) and 8.1% of respondents indicated willingness to continue routine INR monitoring only with drive-up INR testing but not with face-to-face visits. Furthermore, 30.6% of respondents indicated that they were more likely

| TABLE 1 | Baseline characteristics |
|---------|-------------------------|
| Characteristic | Curbside (N = 53) | Face-to-face (N = 11) |
| Age, years, reported as median (interquartile range) | 74 (70-77) | 74 (69.75-79.25) |
| Male sex, N (%) | 31 (58.5) | 7 (63.6) |
to continue routine INR monitoring via drive-up INR testing than they would if face-to-face visits were the only option (Figure 2). Of the respondents who completed the survey curbside, 46% identified reduced coronavirus transmission risk as the biggest benefit of drive-up INR testing with telehealth follow-up. Figure 3 describes the other benefits of drive-up INR testing, ranked by first, second, and third largest benefit.

2.3 | Secondary objectives

2.3.1 | Patient attendance

The anticoagulation clinic had an average of 134 patient visits per month prior to the COVID-19 pandemic and saw an average of 90 unique patients per month. This fell to 109 visits (19% below average) and 76 unique patients (16% below average) in March, and to 105 visits (22% below average) and 69 unique patients (23% below average) in April. Upon initiation of drive-up INR testing and telehealth follow-up on May 4, the anticoagulation clinic had 132 clinic visits and 86 unique patients in May and 150 clinic visits and 100 unique patients in June. Average patient visits per month remained steady at 1.49, 1.48, and 1.52 during the pre-COVID, pre-drive up (March and April), and post-drive up (May and June) time periods (Table 2).

2.3.2 | Patient satisfaction

Overall, rating of the clinic both before and after drive-up INR testing was implemented remained high at 2.75 on a scale of 0 to 3. Specifically, no evidence of impact on perception of the clinic was found based on Mann-Whitney U testing ($P = .875$). No ratings of poor were reported. There was no statistically significant difference between clinic ratings when comparing respondents who had face-to-face appointments compared with drive-up appointments ($P = .83$). Additionally, TTR was 69.1% for the first quarter of the year (January through March) and 69.7% for the second quarter of the year (April through June), which encompassed the survey period. There was no statistically significant change in TTR between these two quarters.
follow-up required development and implementation of novel procedures and protocols. However, financial investment in this new model of care was minimal. The clinic already possessed appropriate equipment and staff that could be easily repurposed. The relatively low number of visits per month at this particular clinic, 132 in May and 150 in June, allowed staff to have the time necessary to implement these new procedures. Additionally, the location of the clinic was well suited for this transition, with a conveniently located circle driveway under a weather-protected awning nearby. Staff were required to simultaneously run two workflows, because all patients were given the option to continue with traditional, in-office visits or opt for drive-up INR testing with telehealth assessment and follow-up. However, the duration of the COVID-19 pandemic and Illinois stay-at-home order made implementation of these two simultaneous workflows necessary.

Patient perceptions of drive-up INR testing with telehealth assessment and follow-up during the COVID-19 pandemic were favorable. While not every respondent preferred this model of care, offering an alternative option to face-to-face visits helped ensure that more than a third of patients continued with essential routine INR testing when they indicated that they may not have otherwise. Of note, when given the option to be seen curbside or face-to-face, only 17.2% of patients opted to actually be seen in-person, however when surveyed, 26.7% of patients indicated a preference for face-to-face visits during the pandemic.

Patient attendance reflects the overall favorable perception of drive-up INR testing. The number of clinic visits and individual patients seen dropped significantly with the onset of the COVID-19 pandemic, and returned to baseline with the introduction of drive-up INR testing and telehealth assessment and follow-up. Number of visits per patient per month remained stable throughout the pre-COVID, pre-drive-up, and post-drive-up periods, indicating the change in appointment volume pre-drive-up was not because individual patients were being seen less frequently and the recovery in-clinic volume was not because individual patients were being seen more frequently.

When analyzing patient perceptions of this alternative model of care, the rural nature of the population as well as the relatively low number of coronavirus cases within the county during the survey period must be considered. The clinic described is located in Lee County, Illinois. The Illinois department of public health confirmed COVID-19 cases and 1 death were reported within the same timeframe. This county is considered rural by the United States Census Bureau and the Office of Management and Budget definitions, with a population of 34 527 residents, 90.4% of which are white Caucasian, and has an estimated population density of 47.63 inhabitants per square mile. The rural nature of the county and the low caseload likely impacts patient perceptions of changes in usual procedures made to lower the risk of infection.

Risk of virus transmission was identified as the biggest barrier to routine care, while reduced infection risk was seen to be the biggest benefit of drive-up INR testing. However, this study identified other barriers to routine care that drive-up INR testing seemed to benefit, which is worth exploring. Difficulties walking or driving was identified as the largest difficulty with coming to

2.3.3 | Barriers to care

Coronavirus infection risk was identified as the largest difficulty with coming to the anticoagulation clinic during the COVID-19 pandemic by 32.8% of respondents. Difficulty with transportation (walking or driving) was identified as the largest difficulty with coming to the anticoagulation clinic by 20.3% of respondents. Issues with appointment times were identified as the largest difficulty with coming to the anticoagulation clinic by only 4.7% of respondents (Figure 4).

Patients surveyed were asked how long they would like to see drive-up INR testing with telehealth follow-up continue. Interestingly, 59.3% of respondents would like to see drive-up INR testing continued forever even after the pandemic resolves, 13.5% of respondents would like to see drive-up INR testing continue until an effective COVID-19 vaccine is developed, and 22% of respondents would be satisfied with drive-up INR testing lasting just through the stay-at-home order (Figure 5).

3 | CONCLUSIONS

The transition to drive-up INR testing with telehealth assessment and follow-up required development and implementation of novel procedures and protocols. However, financial investment in this new model of care was minimal. The clinic already possessed appropriate equipment and staff that could be easily repurposed. The relatively low number of visits per month at this particular clinic, 132 in May and 150 in June, allowed staff to have the time necessary to implement these new procedures. Additionally, the location of the clinic was well suited for this transition, with a conveniently located circle driveway under a weather-protected awning nearby. Staff were required to simultaneously run two workflows, because all patients were given the option to continue with traditional, in-office visits or opt for drive-up INR testing with telehealth assessment and follow-up. However, the duration of the COVID-19 pandemic and Illinois stay-at-home order made implementation of these two simultaneous workflows necessary.

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When analyzing patient perceptions of this alternative model of care, the rural nature of the population as well as the relatively low number of coronavirus cases within the county during the survey period must be considered. The clinic described is located in Lee County, Illinois. The Illinois department of public health confirmed 145 750 COVID-19 cases statewide, with 7005 deaths through July 2, 2020 at the end of the survey period. Within Lee County, 98 confirmed COVID-19 cases and 1 death were reported within the same timeframe. This county is considered rural by the United States Census Bureau and the Office of Management and Budget definitions, with a population of 34 527 residents, 90.4% of which are white Caucasian, and has an estimated population density of 47.63 inhabitants per square mile. The rural nature of the county and the low caseload likely impacts patient perceptions of changes in usual procedures made to lower the risk of infection.

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the anticoagulation clinic by 20.3% of respondents and was among the top three largest difficulties identified by 28.1% of respondents. While curbside services do not allay driving difficulties, they can reduce the burden of transport from car to clinic and back. Unfortunately, the survey question did not distinguish between walking and driving difficulties, and the survey size was not sufficient to statistically test whether patients who identified these difficulties indicated a preference for continuing curbside testing indefinitely. However, the fact that 59.3% of respondents would like to see drive-up INR testing continue forever, even after the pandemic resolves, seems to imply that a portion of patients find benefit in this alternative service beyond the scope of the pandemic. Investigating where exactly this benefit lies and why respondents would like to see this service continue may help us better meet the needs of patients in the future.

Other weaknesses of this cross-sectional cohort study include a small survey size and the single-centered nature of the study. Patients were not provided guidance as to how to complete the survey so as to not skew survey results; however this led to some patients not answering every question. That being said, there are very few studies to date examining how the adaptions to the COVID-19 pandemic that our health systems have undertaken across the country have affected patients. To our knowledge, this is the first study of its kind examining patient perceptions and patient attendance rates of drive-up INR testing with telehealth assessment and follow-up. This adaption to clinical care, recommended by the Anticoagulation Forum and the CDC, guided pharmacists across the country to shift their clinics to a curbside model. Now it is important that we study these adaptions to much further.

CONFLICT OF INTEREST
The authors declare no conflicts of interest.

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Zobeck B, Carson E, MacDowell M, Hunt A, Reeder A. Appointment attendance and patient perception of drive-up INR testing in a rural anticoagulation clinic during the COVID-19 pandemic. J Am Coll Clin Pharm. 2021;4:459–464. https://doi.org/10.1002/jac.5.1390