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PROGRAM PROFILE

Drive Through Point of Care International Normalized Ratio Testing During the COVID-19 Pandemic

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In order to help combat COVID-19 and provide consistent and safe care for the veterans at the West Palm Beach Veterans Affairs Medical Center (WPVAMC), a drive through Point of Care International Normalized Ratio (POC-INR) testing site was implemented. This drive through clinic allows veterans taking warfarin to safely obtain anticoagulation management while complying with social distancing guidelines.

Keywords: anticoagulation; warfarin; drive through; pandemic; INR; DOAC; telehealth

In order to help combat COVID-19 and provide consistent and safe care for the veterans at the West Palm Beach Veterans Affairs Medical Center (WPVAMC), a new process was implemented for the Anticoagulation clinic for those who cannot or do not want to be switched off of warfarin and at the same time require safe anticoagulation management via point of care International Normalized Ratio (POC-INR) testing. To comply with best practices for "social distancing," medical visits that are considered "routine care" or not urgent are either being rescheduled or being performed as telehealth visits. While warfarin management can be performed via telephone or other virtual modality, canceling the lab draw visits may result in a negative impact on a patient's health resulting in possible emergency room (ER) visits or hospitalization for life threatening bleeding or thrombosis. Thus, a drive through POC-INR clinic has been implemented since April 17, 2020 and will continue to run at least until the medical center is open at full capacity.

According to expert opinion, telemedicine, drive through INR clinics, or home INR checks can reduce the risk of exposure for both patients and healthcare providers during the COVID-19 pandemic. Additionally, active involvement of the health system with regards to the care of patients treated with anticoagulation is critical to achieving positive outcomes for both COVID-19 infected and uninfected patients (Bikdeli et al., 2020). The Veterans Integrated Service Networks (VISN) guidance on anticoagulation use and monitoring for VA anticoagulation programs during the COVID-19 pandemic agrees with the above, with additional recommendations to extend follow-up INR checks or switching patients to Direct Oral Anticoagulants (DOACs) when appropriate. INR follow up intervals could be extended to 12 weeks per the American Society of Hematology (ASH) and American College of Chest Physicians (CHEST) guidelines when patients have stable INR (defined as three consecutive therapeutic INRs obtained at sufficient intervals, e.g., 4 weeks) (Department of Veterans Affairs, internal document, 2020).

Prior to the COVID-19 pandemic, the WPVAMC Anticoagulation Clinic utilized POC-INR testing to monitor patients taking warfarin. Patients would come into the medical center for the POC-INR test and could leave and have a same day follow-up telephone visit with one of the anticoagulation pharmacists, if they did not have a critical INR that needed immediate face-to-face attention. This set up made implementing a drive through INR testing site at the facility a feasible option in order to comply with social distancing standards, help decrease outpatient visits, and thus decrease potential virus exposure.

While venipuncture INR testing is typically regarded as the "gold standard," POC-INR testing is widely used in outpatient anticoagulation clinics because it is convenient and efficient. There have been potential concerns for discrepancies between POC-INR results and venipuncture INRs. To contest this, the WPVAMC determined that a confirmatory venous INR should be drawn if the POC-INR results greater than 3.9. This was determined based off correlations ran by the WPVAMC laboratory. The FDA sets stringent correlation standards stating that ≥95% of POC INRs should correlate

within ±20% of venipuncture INR (Bikdeli et al., 2020; Food and Drug Administration, 2016; Johnson, 2017).

POC machine used at the WPVAMC is the CoaguCheck ® XS Pro System. The manufacturer of this system claims that their device is accurate up to an INR of 8.0. The WPVAMC laboratory relaxed the aforementioned cut-off for POC-INR results that would require venipuncture confirmation of 3.9 to 4.4 temporarily during the COVID-19 pandemic based off new correlations. Per the manufacturer of the CoaguCheck ® XS Pro System, the device is accurate from a temperature range of 59 °F to 90 °F and a humidity index of 10–85% at an altitude of 4,300 meters. The monitor should be operated on a leveled surface, free of vibrations to ensure accuracy. The test strips are accurate if used from a temperature range of 35.5 °F to 86 °F (Roche Diagnostics, 2020).

Methods

The drive through clinic required a multidisciplinary approach in order to be organized promptly and continue to run successfully. The team included members from the following departments: pharmacy, nursing, Medical Support Assistant (MAS), laboratory, VA police, and medical media. Over a 2-week period, a Standard Operating Procedure (SOP) document was created outlining the responsibilities for the MAS clerks, Anticoagulation Clinic Nurses, and Anticoagulation Clinic Pharmacists. Lab protocols, equipment needed, and additional measures to be taken during a patient's initial chart review are also outlined in the SOP. An excerpt from the original SOP detailing the previously mentioned protocols and responsibilities can be found the supplementary information. Additional measures outlined by the VISN guidance (i.e., follow up INR intervals and switching to DOACs when appropriate) are also incorporated in the SOP.

Data was recorded in real time to ensure that no patients were lost to follow-up and to recognize any systematic problems in order to allow for protocol changes to be made in a timely manner. The data collected is represented in **Tables 1** and **2**. The data was recorded in an Excel spreadsheet and saved onto the secure VA "S drive." Descriptive statistics were utilized to analyze the results. All data will remain confidential. This project has been approved by the Research and Development Committee at the West Palm Beach VA Medical Center and exempted from Institutional Review Board (IRB) approval.

Results

Over the course of about 7 weeks, 607 appointments were scheduled in the nursing clinic for an INR draw. As noted in **Figure 1**, there were 297 (48.9%) appointments where the patient was eligible and agreed to be scheduled for the drive through. Of the 297 appointments, 237 (79.8%) of the appointments were deemed successful. **Table 1** represents reasons why appointments were not scheduled into the drive through clinic. **Table 2** represents reasons why appointments that were scheduled were deemed "unsuccessful." Additionally, we compared our "no show" rate for

Table 1: Appointments not converted to drive through (n = 168).

Reason	N (%)
Other appointment	86 (27.7)
Other labs	24 (7.7)
Transportation	47 (15.2)
Refused	13 (4.2)
Could not reach	60 (19.3)
On a DOAC	18 (5.8)
Bridging	2 (0.6)
Unstable	6 (1.9)
New Consult	11 (3.5)
CBOC or HBPC patient	3 (1.0)
Stable, appointment extend	3 (1.0)
Inpatient	3 (1.0)
Employee of VA	3 (1.0)
DOM patient	2 (0.6)
No longer on warfarin	6 (1.9)
Unclear	21 (6.8)
Timing issue	2 (0.6)

Note: DOAC: Direct Oral Anticoagulant.
CBOC: Community Based Outpatient Clinics.

Table 2: Unsuccessful Drive Through Appointments (n = 38).

Reason	N (%)
No show	20 (33.3)
Unclear	13 (21.7)
Forgot	26 (43.3)
Patient could not find drive-through location	1 (1.7)

Note: HBPC: Home Based Primary Care.
DOM: Domiciliary.

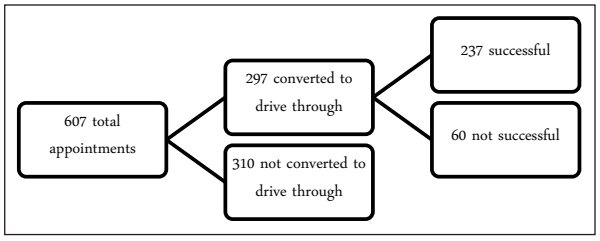

Figure 1: Appointments Converted to Drive Through Methods.

the entire anticoagulation clinic 1 month prior to implementing the drive through (3/17/2020–4/16/2020) versus 1 month with the drive through option (4/17/2020–5/17/2020) and about 2 months into the drive through (5/18/2020–5/28/2020). The rate decreased from 16.2% to 12.1% and then finally to 11.3%. The maximum number of appointments scheduled per day in the clinic was 13, the minimum was 3, and the median was 9.

As mentioned above, there were 237 successful drive-through appointments. The appointments were analyzed in an Excel sheet, and duplicate patient names were removed; this left 159 individual patients that had a POC-INR drawn successfully via the drive through modality. We randomly selected 16 (10.1%) of these patients for a brief three question survey to determine patient satisfaction; the following three questions were asked:

1. On a scale of 1 to 5, how safe did you feel using the WPVAMC's drive through INR clinic?
   - 1- very unsafe, 2- unsafe, 3- neutral, 4- safe, 5- very safe
2. During the COVID-19 outbreak, did you prefer using the drive through clinic or coming into the medical center?
3. One a scale of 1 to 5, how satisfied were you with your experience at the WPVAMC's drive through INR clinic?
   - 1- very dissatisfied, 2- dissatisfied, 3- neutral, 4- satisfied, 5- very satisfied

All 16 patients scored the first question at a 5, indicated that they all felt "very safe" utilizing this drive through clinic. One patient (6.3%) preferred the coming into the medical center, whereas the other 15 (93.7%) preferred the drive-through clinic. Finally, the average score for question 3 was 4.8/5, indicating that the patients felt satisfied to very satisfied with this clinic.

One obstacle that occurred was that some patients would have their INR checked at the drive through clinic but not automatically be scheduled in the pharmacist's telephone clinic for follow up. This was recognized quickly, and a new order set was created so that the nurse taking the patient's INR lab could easily schedule them for a follow-up INR as well as a follow up pharmacist call all in one order on the electronic medical record.

Discussion and Conclusion

The Drive Through INR Clinic has been running efficiently since it's pilot week and will continue to be an available modality to the veterans followed by the Anticoagulation Clinic at the WPVAMC at least until the medical center is functioning at full capacity. At that point, the decision will be made to either continue offering this service or to terminate it. If the clinic is terminated, the SOP will be saved as a feasible option to implement if needed in the future. While there are other sites that have implemented similar clinics, to our knowledge, this is one of the first published articles on the matter.

The anticoagulation clinic's "no show" rates were tracked. The rates at the brink of the pandemic, prior to the implementation of the Drive Through INR clinic, appeared to be higher than usual. Additionally, a trend was noticed in which patients were calling to extend their appointments to later dates. Appointment extension was possibly due to the patients feeling uncomfortable coming into the medical center and being unnecessarily exposed to the COVID-19 virus. As seen in the results, the no-show rates declined steadily once this modality became an option. This is possibly explained by patients feeling safer utilizing the drive through method or because the staff called all patients and reminded them of their appointment when offering the drive through clinic option. Regardless, patients' overall satisfaction with the clinic was excellent and the nursing staff did not feel as if it was an extra burden on their workday.

There were some glitches that occurred during the initial phases of initiating this clinic. The most notable concern was that proper follow-up was not being scheduled on a consistent basis. To combat this, a new order set was created for return-to-clinic orders in the electronic medical record system. Additionally, our anticoagulation nurse did not have a laptop to enter the return to clinic orders, this was later provided. Since the clinic was being monitored in real time, the team was able to adjust the SOP in order to continue to provide a safe and effective clinic.

In conclusion, the Drive Through INR Clinic met its overall goal: to maximize safety for our veterans on warfarin who need routine INR monitoring and minimize exposure to COVID-19 for both patients and staff.

Implications for Clinical Practice

The Drive Through INR Clinic was deemed to be a "best practice" during the COVID-19 pandemic. Not only did the veterans appreciate this method for INR checks, but the staff did as well. So much so that there are plans for this drive through method to continue even once the pandemic subsides. The drive through clinic would have never been created if the COVID-19 pandemic did not occur. The team learned that this drive through method helps to decrease possible exposure to infections (i.e., COVID-19, the seasonal flu, etc.), decrease wait time for the patient, increase the utility of the clinic, decrease no show rates, and increase patient satisfaction. Aside from decreasing possible exposure to infection, the rest of the benefits of this clinic are independent of the COVID-19 pandemic. Therefore, it is always important to continuously question if current practices are truly the best practice, or if there is a better way to better care for veterans. If other VA Medical Centers already utilize the POC-INR machine as their standard of care for INR draws and have pharmacists call patients with INR results, then this clinic could be easily implemented at another facility by utilizing the SOP that is outlined in the Supplementary Materials and editing it to fit their respective facility's needs.

Additional File

The additional file for this article can be found as follows:

- **Supplementary Information.** Standard Operation Procedures (SOP). DOI: https://doi.org/10.21061/jvs.v6i2.205.s1

Competing Interests

The authors have no competing interests to declare.

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